

Subject Case Report Forms

Rave.11.0_PRD_Annotation - Form Matrix

Signature Prompt: I confirm that all data in this case report form is correct.

Rave.11.0_PRD_Annotation: Form Matrix
Form: Subject Enrollment
Generated On: 23 Apr 2019 20:11:55

Global Subject ID		①
Enroll Date		②
Enrolled By		③
Contacts Log Line Record		④

Rave.11.0_PRD_Annotation: Form Matrix
Form: Subject Enrollment
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
①	SUBID	\$6	Subject Identifier		
②	ENRLDATE	dd MMM yyyy HH:nn			
③	ENRLBY	\$100			
④	LINENUM	2			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Subject Status
Generated On: 23 Apr 2019 20:11:55

Subject Status

- Active (future follow-up expected at a CARRA Registry Site) ☐ ①
- Inactive (future follow-up not expected at a CARRA Registry site, but subject still participating in Registry) ☐
- Discontinuation (alive but no longer participating in registry) ☐
- Deceased ☐

Date of last subject contact: _____

②

Reason subject inactive:

- Referred elsewhere for ongoing care: Specify name and location: ☐ ③
- Subject moved to a non-CARRA registry pediatric rheumatologist ☐
- Transitioned to adult rheumatology ☐
- Disease remission ☐
- Lost to follow-up ☐

Discontinuation Date _____

④

Reason for Discontinuation

- Subject withdrew consent ☐ ⑤
- Site decision ☐
- Other: specify: ☐

Date of Death _____

⑥

Cause of death: _____

⑦

Rave.11.0_PRD_Annotation: Form Matrix

Form: Subject Status

Generated On: 23 Apr 2019 20:11:55

Was death related to rheumatic disease?

Yes ☒ 8
No ☐
Unknown ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Subject Status
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① SUBJSTAT	1	Subject Status		1 = Active (future follow-up expected at a CARRA Registry Site) 2 = Inactive (future follow-up not expected at a CARRA Registry site, but subject still participating in Registry) 3 = Discontinuation (alive but no longer participating in registry) 4 = Deceased
② LSTCNTDT	dd- MMM- yyyy	Date of last subject contact		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Subject Status
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
③	RSNINACT	1	Reason subject inactive		1 = Referred elsewhere for ongoing care: Specify name and location: 2 = Subject moved to a non-CARRA registry pediatric rheumatolo gist 3 = Transitione d to adult rheumatolo gy 5 = Disease remission 4 = Lost to follow-up
④	DISCONDT	dd- MMM- yyyy	Discontinua tion Date		
⑤	RSNDISCN	1	Reason for Discontinua tion		1 = Subject withdrew consent 2 = Site decision 3 = Other: specify:

Rave.11.0_PRD_Annotation: Form Matrix
Form: Subject Status
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
⑥	DEATHDTC	dd- MMM- yyyy	Date of Death		
⑦	DTHCAUSE	\$100	Cause of death		
⑧	DTHRELAT	2	Death related to rheumatic disease		1 = Yes 0 = No 99 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix
Form: Stop JIA Status
Generated On: 23 Apr 2019 20:11:55

Stop JIA Baseline Date	<input type="text"/>	①
Stop JIA Subject Status	<div>Active <input checked="" type="radio"/></div> <div>Withdraw from Stop JIA <input type="radio"/> (continue in CARRA Registry)</div> <div>Complete (will continue in CARRA Registry) <input type="radio"/></div>	②
Date of Withdrawal	<input type="text"/>	③
Reason for withdrawal	<input type="text"/>	④

Rave.11.0_PRD_Annotation: Form Matrix
Form: Stop JIA Status
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
①	STOPBDTC	dd MMM YYYY			
②	STOPSTS	2			1 = Active 0 = Withdraw from Stop JIA (continue in CARRA Registry) 2 = Complete (will continue in CARRA Registry)
③	STOPDTC	dd MMM YYYY			
④	STOPWDR	\$100			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Frost Status
Generated On: 23 Apr 2019 20:11:55

Frost Baseline Date	<input type="text"/>	①
Frost Subject Status	<div>Active <input checked="" type="radio"/></div> <div>Withdrawn from FROST (remains in main CARRA Registry) <input type="radio"/></div> <div>Complete (will continue in CARRA Registry) <input type="radio"/></div>	②
Date of Withdrawal	<input type="text"/>	③
Reason for withdrawal	<input type="text"/>	④
Subject will not complete Home PROs	<input type="checkbox"/>	⑤
Date Subject Stopped Home PROs	<input type="text"/>	⑥

Rave.11.0_PRD_Annotation: Form Matrix
Form: Frost Status
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① FROSTBDT	dd MMM YYYY			
② FROSTSTS	1			1 = Active 0 = Withdrawn from FROST (remains in main CARRA Registry) 2 = Complete (will continue in CARRA Registry)
③ FROSTDTC	dd- MMM- YYYY			
④ FROSTWDR	\$100			
⑤ NOHOMPRO	1			
⑥ HOMEPRDT	dd- MMM- YYYY			

Rave.11.0_PRD_Annotation: Form Matrix
Form: PROMOTE Status
Generated On: 23 Apr 2019 20:11:55

PROMOTE Baseline Date

①

PROMOTE Subject Status

Active

☐ ②

Withdraw from PROMOTE
(continue in CARRA
Registry)

☐

Complete (will continue in
CARRA Registry)

☐

PROMOTE Date of Withdrawal

③

Rave.11.0_PRD_Annotation: Form Matrix
Form: PROMOTE Status
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① PROMBDTC	dd MMM YYYY			
② PROMOSTS	1			1 = Active 2 = Withdraw from PROMOTE (continue in CARRA Registry) 3 = Complete (will continue in CARRA Registry)
③ PROWTDTC	dd MMM YYYY			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Recapture JIA Status
Generated On: 23 Apr 2019 20:11:55

Recapture JIA Baseline Date _____ ①

Recapture JIA Subject Status

Active ☐ ②

Withdraw from Recapture JIA (continue in CARRA Registry) ☐

Complete (will continue in CARRA Registry) ☐

Recapture JIA Date of Withdrawal _____ ③

Approximate start date of episode of inactive disease preceding current flare (per treating physician's opinion): _____ ④

Rave.11.0_PRD_Annotation: Form Matrix
Form: Recapture JIA Status
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
①	RECAPBDT	dd MMM YYYY			
②	RCAPSTAT	1			1 = Active 2 = Withdraw from Recapture JIA (continue in CARRA Registry) 3 = Complete (will continue in CARRA Registry)
③	RECPWTD	dd MMM YYYY			
④	EPISTRDT	dd- MMM YYYY			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Consent Forms
Generated On: 23 Apr 2019 20:11:55

CONFIDENTIAL This form contains protected health information (PHI) that must be restricted from unauthorized distribution.

Original Registry Consent date _____ ②

Most recent re-consent date, if applicable _____ ③

Biorepository Sample consented Yes ☐ ④
No ☐

Consent Date _____ ⑤

Subject consented to the following samples: Blood ☐ ⑥

Urine ☐ ⑦

DNA and RNA ☐ ⑧

Cheek Swab (for DNA) ☐ ⑨

Stool Samples ☐ ⑩

Joint Fluid (joint injection/aspiration) ☐ ⑪

Extra tissue (tissue biopsy) ☐ ⑫

Lymph Node ☐ ⑬
Brain ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Consent Forms
Generated On: 23 Apr 2019 20:11:55

Lung ☐
Muscle ☐
Skin ☐
Other ☐

Biorepository Sample consent withdrawn

Fixed Unit: Yes **14**
☐

Withdrawal Date

15

Did subject request that samples be destroyed

Yes ☐ **16**
No ☐

Comment:

17

Rave.11.0_PRD_Annotation: Form Matrix
Form: Consent Forms
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
②	RGCNSDTC	dd MMM yyyy	Original Registry Consent date		
③	RECNSDTC	dd MMM yyyy	Most recent re-consent date		
④	BIOSAMCN	1	Biorepositor y Sample consented		1 = Yes 0 = No
⑤	BIOCONDT	dd MMM yyyy	Biosample Consent Date		
⑥	BIOSAMP1	1	Biosample consent: Blood		
⑦	BIOSAMP2	1	Biosample consent: Urine		
⑧	BIOSAMP7	1	Biosample consent: DNA and RNA		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Consent Forms
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
9	BIOSAMP3	1	Biosample consent: Cheek Swab (for DNA)		
10	BIOSAMP4	1	Biosample consent: Stool Samples		
11	BIOSAMP5	1	Biosample consent: Joint Fluid		
12	BIOSAMP6	1	Biosample consent: Extra tissue		
13	BIOSMP6A	2			1 = Lymph Node 2 = Brain 3 = Lung 4 = Muscle 5 = Skin 98 = Other
14	BIOCNWTD	1	Biorepository Sample consent withdrawn		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Consent Forms
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
15	BIOWTHDT	dd MMM yyyy	Biosample consent:Wit hdrawal Date		
16	SAMPDEST	1	Biosample consent: Samples be destroyed		1 = Yes 0 = No
17	BIOWTHCM	\$100	Biosample consent: withdrawn Comment		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Demographics A
Generated On: 23 Apr 2019 20:11:55

Date of Birth _____ ①

Race (check all that apply)

Asian ☐ ③

Black, African American, African, or Afro-Caribbean ☐ ④

Hispanic, Latino, or Spanish origin ☐ ⑤

Middle Eastern/North African ☐ ⑥

Native American, American Indian or Alaskan Native ☐ ⑦

Native Hawaiian or Other Pacific Islander ☐ ⑧

White ☐ ⑨

Prefer not to answer ☐ ⑩

Other ☐ ⑪

Other: specify _____ ⑫

Sex

Male ☐ ⑬

Female ☐

Other ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Demographics A
Generated On: 23 Apr 2019 20:11:55

Country of primary residence at onset of disease symptoms

- United States ☒ 14
- Canada ☐
- Other country ☐
- Unknown or do not wish to provide ☐

Zip Code/Postal Code:

_____ 15

Household income (annual gross)

- <25,000 ☒ 16
- 25-49,999 ☐
- 50-74,999 ☐
- 75-99,999 ☐
- 100,000-150,000 ☐
- above 150,000 ☐
- Unknown ☐
- Prefer not to answer ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Demographics A
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
①	BIRTHDAT	dd MMM yyyy	Date of Birth		
③	ASIAN	1	Asian		
④	BLACK	1	Black, Afro-Am, African, or Afro-Caribbean		
⑤	HISPANIC	1	Hispanic, Latino, or Spanish origin		
⑥	MIDEAST	1	Middle Eastern/Nor th African		
⑦	AMERIND	1	Native American, Am Indian or Alaskan Nat		
⑧	NATHWN	1	Native Hawaiian or Other Pacific Islander		
⑨	WHITE	1	White		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Demographics A
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
10 NOANSWER	1	Race: Prefer not to answer		
11 OTHRACE	1	Race: Other		
12 OTHRACSP	\$50	Race: Other: specify		
13 SEX	2	Gender		1 = Male 2 = Female 98 = Other
14 RESIDENC	2	Country of residence symptom onset		1 = United States 2 = Canada 98 = Other country 99 = Unknown or do not wish to provide
15 ZIPCODE	\$10	Zip Code/Postal Code:		
16 INCOME	2	Household income (annual gross)	1 = USD 2 = CAD 3 = UNK	1 = <25,000 2 = 25-49,999 3 = 50-74,999

Rave.11.0_PRD_Annotation: Form Matrix
Form: Demographics A
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				4 = 75-99,999 5 = 100,000-15 0,000 6 = above 150,000 99 = Unknown 7 = Prefer not to answer

Rave.11.0_PRD_Annotation: Form Matrix
Form: Demographics B
Generated On: 23 Apr 2019 20:11:55

Gender

Male ☒ ①
Female ☐
Other ☐

Highest level of parent/guardian education completed

Elementary/middle school (grade 1 -8) ☒ ②
Some high school (grade 9-11) ☐
Graduated high school (grade 12 or GED) ☐
College (1-4 year college, junior college or technical school) ☐
Graduate school (e.g., Masters, Doctorate, or professional degree) ☐
Prefer not to answer ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Demographics B
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① GENDER	2			1 = Male 2 = Female 98 = Other
② EDUCATE	1			1 = Elementary/ middle school (grade 1 -8) 2 = Some high school (grade 9-11) 3 = Graduated high school (grade 12 or GED) 4 = College (1-4 year college, junior college or technical school) 5 = Graduate school (e.g., Masters, Doctorate, or professional degree)

Rave.11.0_PRD_Annotation: Form Matrix
Form: Demographics B
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				6 = Prefer not to answer

Female subjects only: onset of menses (menarche) Yes ☐ ①
No ☐

Approximate date: _____ ②

Rave.11.0_PRD_Annotation: Form Matrix**Form: Menses****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
<hr/>				
① ONSTMENS 2		Onset of menses (menarche)		1 = Yes 0 = No
<hr/>				
② MENSOND	dd- MMM- yyyy	Onset of menarche date		
<hr/>				

Rave.11.0_PRD_Annotation: Form Matrix
Form: Comorbid Conditions
Generated On: 23 Apr 2019 20:11:55

Does subject have any secondary rheumatological diseases?

Yes ☐ ①
No ☐

Does subject have any other medical conditions?

Yes ☐ ②
No ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Comorbid Conditions
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① SECRHEUM	2	Any secondary rheumatolo gical diseases		1 = Yes 0 = No
② PREXCOND	2	Any other medical conditions		1 = Yes 0 = No

Rave.11.0_PRD_Annotation: Form Matrix
Form: Secondary Rheumatological Diseases
Generated On: 23 Apr 2019 20:11:55

Auto-inflammatory disease (including fever syndromes,
Chronic recurrent multifocal osteomyelitis) ☐ ①

Date of onset: _____ ②

Antiphospholipid Syndrome ☐ ③

Date of onset: _____ ④

Primary ☐ ⑤
Secondary ☐

Chronic Vasculitis (excluding Kawasaki and
Henoch-Schonlein purpura) ☐ ⑥

Date of onset: _____ ⑦

Idiopathic uveitis (not associated with other
rheumatologic disease) ☐ ⑧

Date of onset: _____ ⑨

Juvenile dermatomyositis ☐ ⑩

Date of onset: _____ ⑪

Juvenile idiopathic arthritis ☐ ⑫

Date of onset: _____ ⑬

Rave.11.0_PRD_Annotation: Form Matrix
Form: Secondary Rheumatological Diseases
Generated On: 23 Apr 2019 20:11:55

Juvenile fibromyalgia ☐ 14

Date of onset: _____ 15

Localized scleroderma ☐ 16

Date of onset: _____ 17

Macrophage Activation Syndrome ☐ 18

Date of onset: _____ 19

Mixed connective tissue disease ☐ 20

Date of onset: _____ 21

Primary Sjogrens disease ☐ 22

Date of onset: _____ 23

Sarcoidosis ☐ 24

Date of onset: _____ 25

Systemic lupus erythematosus ☐ 26

Date of onset: _____ 27

Systemic sclerosis



28

Date of onset:

29

Rave.11.0_PRD_Annotation: Form Matrix
Form: Secondary Rheumatological Diseases
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
①	AUTOINFL	1	Auto-inflam matory disease		
②	ORONSDT1	dd- MMM- yyyy	Auto-inflam matory disease: Date onset		
③	ANTIPHOS	1			
④	OROSDT13	dd- MMM- yyyy			
⑤	ANTIPRSC	1			1 = Primary 2 = Secondary
⑥	CHROVASC	1	Chronic Vasculitis		
⑦	ORONSDT2	dd- MMM- yyyy	Chronic Vasculitis: Date of onset		
⑧	IDIOPUVE	1	Idiopathic uveitis		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Secondary Rheumatological Diseases
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	Field Name	Data Type	SAS Label	Units	Values
9	ORONSDT3	dd- MMM- yyyy	Idiopathic uveitis: Date of onset		
10	JUVDERMA	1	Juvenile dermatomy ositis		
11	ORONSDT4	dd- MMM- yyyy	Juvenile dermatomy ositis: Date of onset		
12	JUVIDIOP	1	Juvenile idiopathic arthritis		
13	ORONSDT5	dd- MMM- yyyy	Juvenile idiopathic arthritis: Date of onset		
14	JUVFIBRO	1	Juvenile primary fibromyalgia		
15	ORONSDT6	dd- MMM- yyyy	JPFS: Date onset		
16	LOCLSCLR	1	Localized scleroderma		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Secondary Rheumatological Diseases
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	Field Name	Data Type	SAS Label	Units	Values
17	ORONSDT7	dd- MMM- yyyy	Localized scleroderma : Date of onset		
18	OROMAS	1			
19	OROSDT14	dd- MMM- yyyy			
20	MXCNNTIS	1	Mixed connective tissue disease		
21	ORONSDT8	dd- MMM- yyyy	MCTD: Date of onset		
22	PSJOGREN	1	Primary Sjogrens disease		
23	ORONSDT9	dd- MMM- yyyy	Primary Sjogrens disease: Date of onset		
24	SARCOID	1	Sarcoid		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Secondary Rheumatological Diseases
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	Field Name	Data Type	SAS Label	Units	Values
25	OROSDT10	dd- MMM- yyyy	Sarcoid: Date of onset		
26	SYSTLUPU	1	Systemic lupus erythemato sus		
27	OROSDT11	dd- MMM- yyyy	Systemic lupus erythemato sus: Date onset		
28	SYSTSCLR	1	Systemic sclerosis		
29	OROSDT12	dd- MMM- yyyy	Systemic sclerosis: Date of onset		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Other Medical Conditions
Generated On: 23 Apr 2019 20:11:55

Auto-immune hepatitis ☐ ①

Date of onset: _____ ②

Auto-immune thyroid disease ☐ ③

Date of onset: _____ ④

Psoriasis ☐ ⑤

Date of onset: _____ ⑥

Other autoimmune disease ☐ ⑦

Specify: _____ ⑧

Date of onset: _____ ⑨

Primary immunodeficiency syndrome(s) ☐ ⑩

Specify: _____ ⑪

Date of onset: _____ ⑫

Asthma ☐ ⑬

Date of onset: _____ ⑭

Rave.11.0_PRD_Annotation: Form Matrix
Form: Other Medical Conditions
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Avascular necrosis ☐ 15

Date of onset: _____ 16

Demyelinating disease ☐ 17

Date of onset: _____ 18

Diabetes - Type 1 ☐ 19

Date of onset: _____ 20

Diabetes - Type 2 ☐ 21

Date of onset: _____ 22

Cardiovascular Disease ☐ 23

Date of onset: _____ 24

Celiac disease ☐ 25

Date of onset: _____ 26

Cerebral palsy ☐ 27

Date of onset: _____ 28

Rave.11.0_PRD_Annotation: Form Matrix
Form: Other Medical Conditions
Generated On: 23 Apr 2019 20:11:55

Chronic renal insufficiency ☐ 29

Date of onset: _____ 30

Congenital heart disease ☐ 31

Cystic fibrosis ☐ 32

Hepatitis/Chronic Liver Disease ☐ 33

Date of onset: _____ 34

Hypercholesterolemia ☐ 35

Date of onset: _____ 36

Inflammatory bowel disease ☐ 37

Date of onset: _____ 38

Interstitial lung disease ☐ 39

Date of onset: _____ 40

Lipoid pneumonia ☐ 41

Date of onset: _____ 42

Rave.11.0_PRD_Annotation: Form Matrix
Form: Other Medical Conditions
Generated On: 23 Apr 2019 20:11:55

Malignancy ☐ 43

Date of onset: _____ 44

Pulmonary alveolar proteinosis ☐ 45

Date of onset: _____ 46

Pulmonary hypertension ☐ 47

Date of onset: _____ 48

Neuromyelitis Optica (NMO) ☐ 49

Date of onset: _____ 50

Trisomy-21 ☐ 51

Tuberculosis (Latent) ☐ 52

Date of onset: _____ 53

Is treatment completed? Yes ☐ 54
No ☐

Date treatment completed: _____ 55

Rave.11.0_PRD_Annotation: Form Matrix
Form: Other Medical Conditions
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Tuberculosis (Active) ☐ 56

Date of onset: _____ 57

Vitamin D Deficiency ☐ 58

Date of onset: _____ 59

Other major congenital or acquired disease/condition ☐ 60

Specify: _____ 61

Date of onset: _____ 62

Rave.11.0_PRD_Annotation: Form Matrix
Form: Other Medical Conditions
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
①	AUTHEPAT	1	Auto-immune hepatitis		
②	PREXDT01	dd- MMM- yyyy	Auto-immune hepatitis: Date of onset		
③	AUTOITHY	1	Auto-immune thyroid disease		
④	PREXDT02	dd- MMM- yyyy	Auto-immune thyroid disease: Date onset		
⑤	PSORIA	1	Psoriasis		
⑥	PREXDT03	dd- MMM- yyyy	Psoriasis: Date of onset		
⑦	OTAUTDIS	1	Other autoimmune disease		
⑧	OAUTOSPY	\$100	Other autoimmune disease: Specify		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Other Medical Conditions
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	Field Name	Data Type	SAS Label	Units	Values
9	PREXDT04	dd- MMM- yyyy	Other autoimmun e disease: Date of onset		
10	PRIMSYND	1	Primary immunodefi ciency syndrome(s)		
11	PIMSYNSP	\$100	Primary imm syndrome: Specify		
12	PREXDT05	dd- MMM- yyyy	Primary imm synd: Date of onset:		
13	ASTHMA	1	Asthma		
14	PREXDT06	dd- MMM- yyyy	Asthma: Date of onset		
15	AVASNECR	1			
16	PREXDT21	dd- MMM- yyyy			

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Form: Other Medical Conditions
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	Field Name	Data Type	SAS Label	Units	Values
17	DEMYEDIS	1	Demyelinati ng disease		
18	PREXDT07	dd- MMM- yyyy	Demyelinati ng disease: Date of onset		
19	DIATYPE1	1	Diabetes - Type 1		
20	PREXDT08	dd- MMM- yyyy	Diabetes - Type 1: Date of onset		
21	DIATYPE2	1	Diabetes - Type 2		
22	PREXDT09	dd- MMM- yyyy	Diabetes - Type 2: Date of onset		
23	CARDIODS	1	Cardiovascu lar Disease		
24	PREXDT10	dd- MMM- yyyy	Cardiovascu lar Disease: Date of onset		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Other Medical Conditions
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	Field Name	Data Type	SAS Label	Units	Values
25	CELIACDS	1	Celiac disease		
26	PREXDT11	dd- MMM- yyyy	Celiac disease: Date of onset		
27	CEREBRAL	1	Cerebral palsy		
28	PREXDT12	dd- MMM- yyyy	Cerebral palsy: Date of onset		
29	CHRRRENAL	1	Chronic renal insufficiency		
30	PREXDT13	dd- MMM- yyyy	Chronic renal insufficiency : Date onset		
31	CONHEART	1	Congenital heart disease		
32	CYSTICFB	1	Cystic fibrosis		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Other Medical Conditions
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
33	HEPATIIT	1	Hepatitis/C hronic Liver Disease		
34	PREXDT14	dd- MMM- yyyy	Hepatitis/C hron Liver Dis:Date onset		
35	HYPERCHO	1	Hypercholes terolemia		
36	PREXDT15	dd- MMM- yyyy	Hypercholes terolemia: Date of onset		
37	INFLBOWL	1	Inflammato ry bowel disease		
38	PREXDT16	dd- MMM- yyyy	Inflammato ry bowel disease: Date onset:		
39	ITLUNDIS	1	Interstitial lung disease		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Other Medical Conditions
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	Field Name	Data Type	SAS Label	Units	Values
40	PREXDT24	dd- MMM- yyyy	Inflammato ry bowel disease: Date onset:		
41	LIPOIDPN	1	Inflammato ry bowel disease		
42	PREXDT25	dd- MMM- yyyy	Inflammato ry bowel disease: Date onset:		
43	MALIGNAN	1	Malignancy		
44	PREXDT26	dd- MMM- yyyy	Malignancy: Date of onset:		
45	PULALVPR	1	Malignancy		
46	PREXDT27	dd- MMM- yyyy	Malignancy: Date of onset:		
47	PULMHYPO	1	Malignancy		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Other Medical Conditions
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
48	PREXDT17	dd- MMM- yyyy	Malignancy: Date of onset:		
49	NMO	1			
50	PREXDT22	dd- MMM- yyyy			
51	TRSOMY21	1	Trisomy-21		
52	TUBRLATE	1	Tuberculosi s (Latent)		
53	PREXDT18	dd- MMM- yyyy	Tuberculosi s (Latent): Date of onset		
54	TUBERTRT	2	Tuberculosi s (Latent): treat complete		1 = Yes 0 = No
55	TUBRTRDT	dd- MMM- yyyy	Tuberculosi s (Latent): Date treat comp		
56	TUBRACTV	1	Tuberculosi s (Active)		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Other Medical Conditions
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
57	PREXDT19	dd- MMM- yyyy	Tuberculosi s (Active): Date of onset:		
58	VITAMND	1			
59	PREXDT23	dd- MMM- yyyy			
60	OTHMAJDS	1	Other condition		
61	OTHJDISP	\$100	Other condition: Specify		
62	PREXDT20	dd- MMM- yyyy	Other condition: Date of onset		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Family Medical History
Generated On: 23 Apr 2019 20:11:55

Does the biologic mother, father or any sibling have any history of the following diseases?

Yes ☐ ①
No ☐
Unknown ☐
Refused ☐

If yes: check all that apply

Ankylosing spondylitis ☐ ③

Anti-phospholipid Antibody Syndrome ☐ ④

Autoimmune thyroiditis (including Graves' and Hashimoto's) ☐ ⑤

Cardiovascular disease ☐ ⑥

Celiac disease ☐ ⑦

Diabetes Type 1 ☐ ⑧

Dyslipidemia ☐ ⑨

Fibromyalgia ☐ ⑩

Hypercholesterolemia ☐ ⑪

Inflammatory bowel disease ☐ ⑫

Rave.11.0_PRD_Annotation: Form Matrix
Form: Family Medical History
Generated On: 23 Apr 2019 20:11:55

Juvenile idiopathic arthritis/juvenile rheumatoid arthritis	<input type="checkbox"/> 13
Malignancy	<input type="checkbox"/> 14
Mixed Connective Tissue Disease	<input type="checkbox"/> 15
Multiple sclerosis	<input type="checkbox"/> 16
Neuromyelitis Optica (NMO)	<input type="checkbox"/> 17
Psoriasis	<input type="checkbox"/> 18
Psoriatic arthritis	<input type="checkbox"/> 19
Reactive arthritis	<input type="checkbox"/> 20
Rheumatoid arthritis	<input type="checkbox"/> 21
Sjogren's Syndrome	<input type="checkbox"/> 22
Spondyloarthopathy/Enthesitis-related arthritis	<input type="checkbox"/> 23
Systemic lupus erythematosus	<input type="checkbox"/> 24
Other autoimmune disease	<input type="checkbox"/> 25

Rave.11.0_PRD_Annotation: Form Matrix
Form: Family Medical History
Generated On: 23 Apr 2019 20:11:55

Uveitis	<input type="checkbox"/>	26
Spontaneous abortions >2	<input type="checkbox"/>	27
Thrombosis	<input type="checkbox"/>	28
	Arterial <input type="checkbox"/>	29
	Venous (including DVT) <input type="checkbox"/>	

Rave.11.0_PRD_Annotation: Form Matrix
Form: Family Medical History
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① FAMHX	2	Biologic mother, father or sibling history of diseases		1 = Yes 0 = No 99 = Unknown 2 = Refused
③ ANKSPOND	1	Fam Hx: Ankylosing spondylitis		
④ ANTIPHOP	1			
⑤ AUTTHYRO	1	Fam Hx: Autoimmune thyroiditis		
⑥ CARDDISE	1	Fam Hx: Cardiovascular disease		
⑦ CELIAC	1	Fam Hx: Celiac disease		
⑧ DIABETES	1	Fam Hx: Diabetes Type 1		
⑨ DYSLIP	1	Fam Hx: Dyslipidemia		


Rave.11.0_PRD_Annotation: Form Matrix
Form: Family Medical History
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
10 FIBRO	1	Fam Hx: Fibromyalgia		
11 HYPCHOL	1	Fam Hx: Hypercholesterolemia		
12 IFBD	1	Fam Hx: Inflammatory bowel disease		
13 JUVARTH	1	Fam Hx: JIA/JRA		
14 MALIG	1	Fam Hx: Malignancy		
15 MIXCONTS	1			
16 MS	1	Fam Hx: Multiple sclerosis		
17 NEROMY	1			
18 PSORIASI	1	Fam Hx: Psoriasis		
19 PSORARTH	1			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Family Medical History
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
20 REACARTH	1			
21 RHUMARTH	1	Fam Hx: Rheumatoid arthritis		
22 SJOGREN	1			
23 SPONDY	1	Fam Hx: Spondyloart hopathy		
24 SYSLUPUS	1	Fam Hx: Systemic lupus erythemato sus		
25 OAUTODS	1	Fam Hx: Other autoimmun e disease		
26 ACUANUVE	1	Fam Hx: Uveitis		
27 SPONABOR	1			
28 THROMBOS	1			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Family Medical History
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
 THROTYPE	1			1 = Arterial 2 = Venous (including DVT)

Rave.11.0_PRD_Annotation: Form Matrix
Form: Diagnostic Tests
Generated On: 23 Apr 2019 20:11:55

ANA

Positive ☐ ①
Negative ☐
Not Done ☐
Unknown ☐

Date of first positive test: _____

②

Anti-CCP

Positive ☐ ③
Negative ☐
Not Done ☐
Unknown ☐

Date of first positive test: _____

④

IgM RF initial

Positive ☐ ⑤
Negative ☐
Not Done ☐
Unknown ☐

Date of first positive test: _____

⑥

IgM RF confirmatory

Positive ☐ ⑦
Negative ☐
Not Done ☐
Unknown ☐

Date of first confirmatory test: _____

⑧

HLAB27

Positive ☐ ⑨

Rave.11.0_PRD_Annotation: Form Matrix
Form: Diagnostic Tests
Generated On: 23 Apr 2019 20:11:55

Negative ☐
Not Done ☐
Unknown ☐

Date of first positive test: _____ 10

Anti-dsDNA antibodies Positive ☐ 11
Negative ☐
Not Done ☐
Unknown ☐

Date of first positive test: _____ 12

Anti-Sm antibody Positive ☐ 13
Negative ☐
Not Done ☐
Unknown ☐

Date of first positive test: _____ 14

Anti-ribonuclear protein (RNP)/Anti U1RNP antibody Positive ☐ 15
Negative ☐
Not Done ☐
Unknown ☐

Date of first positive test: _____ 16

Anti-Ro (SSA) antibodies Positive ☐ 17
Negative ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Diagnostic Tests
Generated On: 23 Apr 2019 20:11:55

Not Done ☐
Unknown ☐

Date of first positive test: _____ **18**

Anti-La (SSB) antibodies Positive ☐ **19**
Negative ☐
Not Done ☐
Unknown ☐

Date of first positive test: _____ **20**

Anticardiolipin antibodies – IgG Positive ☐ **21**
Negative ☐
Not Done ☐
Unknown ☐

Date of first positive test: _____ **22**

Anticardiolipin antibodies – IgA Positive ☐ **23**
Negative ☐
Not Done ☐
Unknown ☐

Date of first positive test: _____ **24**

Anticardiolipin antibodies – IgM Positive ☐ **25**
Negative ☐
Not Done ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Diagnostic Tests
Generated On: 23 Apr 2019 20:11:55

Unknown ☐

Date of first positive test:

26

Anti-B2 glycoprotein I – IgG

Positive ☐ **27**
Negative ☐
Not Done ☐
Unknown ☐

Date of first positive test:

28

Anti-B2 glycoprotein I – IgA

Positive ☐ **29**
Negative ☐
Not Done ☐
Unknown ☐

Date of first positive test:

30

Anti-B2 glycoprotein I – IgM

Positive ☐ **31**
Negative ☐
Not Done ☐
Unknown ☐

Date of first positive test:

32

Lupus anticoagulant

Positive ☐ **33**
Negative ☐
Not Done ☐
Unknown ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Diagnostic Tests
Generated On: 23 Apr 2019 20:11:55

<hr/>	
Date of first positive test:	<hr/>
<hr/>	
Coomb's test	Positive <input type="checkbox"/> 35 Negative <input type="checkbox"/> Not Done <input type="checkbox"/> Unknown <input type="checkbox"/>
<hr/>	
Date of first positive test:	<hr/>
<hr/>	
False-positive test for syphilis (RPR)	Positive <input type="checkbox"/> 37 Negative <input type="checkbox"/> Not Done <input type="checkbox"/> Unknown <input type="checkbox"/>
<hr/>	
Date of first positive test:	<hr/>
<hr/>	
anti p155/140/TIFF1-gamma	Positive <input type="checkbox"/> 39 Negative <input type="checkbox"/> Not Done <input type="checkbox"/> Unknown <input type="checkbox"/>
<hr/>	
Date of first positive test:	<hr/>
<hr/>	
Location Tested:	OMRF <input type="checkbox"/> 41 Other <input type="checkbox"/>
<hr/>	
anti MJ/NXP-2	Positive <input type="checkbox"/> 42 Negative <input type="checkbox"/> Not Done <input type="checkbox"/>
<hr/>	

Rave.11.0_PRD_Annotation: Form Matrix
Form: Diagnostic Tests
Generated On: 23 Apr 2019 20:11:55

Unknown ☐

Date of first positive test: _____

43

Location Tested:

OMRF ☐

44

Other ☐

anti MDA5

Positive ☐

45

Negative ☐

Not Done ☐

Unknown ☐

Date of first positive test: _____

46

Location Tested:

OMRF ☐

47

Other ☐

anti Jo1

Positive ☐

48

Negative ☐

Not Done ☐

Unknown ☐

Date of first positive test: _____

49

Location Tested:

OMRF ☐

50

Other ☐

Other anti-tRNA synthase:

Positive ☐

51

Rave.11.0_PRD_Annotation: Form Matrix
Form: Diagnostic Tests
Generated On: 23 Apr 2019 20:11:55

		Negative <input type="checkbox"/>	
		Not Done <input type="checkbox"/>	
		Unknown <input type="checkbox"/>	
Specify			52
Date of first positive test:			53
Location Tested:		OMRF <input type="checkbox"/>	54
		Other <input type="checkbox"/>	
anti Mi2		Positive <input type="checkbox"/>	55
		Negative <input type="checkbox"/>	
		Not Done <input type="checkbox"/>	
		Unknown <input type="checkbox"/>	
Date of first positive test:			56
Location Tested:		OMRF <input type="checkbox"/>	57
		Other <input type="checkbox"/>	
anti SRP		Positive <input type="checkbox"/>	58
		Negative <input type="checkbox"/>	
		Not Done <input type="checkbox"/>	
		Unknown <input type="checkbox"/>	
Date of first positive test:			59
Location Tested:		OMRF <input type="checkbox"/>	60

Rave.11.0_PRD_Annotation: Form Matrix
Form: Diagnostic Tests
Generated On: 23 Apr 2019 20:11:55

	Other	<input type="checkbox"/>
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anti HMGCR	Positive	<input type="checkbox"/>	61
	Negative	<input type="checkbox"/>	
	Not Done	<input type="checkbox"/>	
	Unknown	<input type="checkbox"/>	

Date of first positive test:			62
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Location Tested:	OMRF	<input type="checkbox"/>	63
	Other	<input type="checkbox"/>	

Other Myositis Specific Autoantibody	Positive	<input type="checkbox"/>	64
	Negative	<input type="checkbox"/>	
	Not Done	<input type="checkbox"/>	
	Unknown	<input type="checkbox"/>	

Specify			65
---------	--	--	----

Date of first positive test:			66
------------------------------	--	--	----

Location Tested:	OMRF	<input type="checkbox"/>	67
	Other	<input type="checkbox"/>	

anti-Ro	Positive	<input type="checkbox"/>	68
	Negative	<input type="checkbox"/>	
	Not Done	<input type="checkbox"/>	
	Unknown	<input type="checkbox"/>	

Rave.11.0_PRD_Annotation: Form Matrix
Form: Diagnostic Tests
Generated On: 23 Apr 2019 20:11:55

Date of first positive test:

69

anti-La

Positive ☐ 70
Negative ☐
Not Done ☐
Unknown ☐

Date of first positive test:

71

anti-Sm

Positive ☐ 72
Negative ☐
Not Done ☐
Unknown ☐

Date of first positive test:

73

anti-Ku

Positive ☐ 74
Negative ☐
Not Done ☐
Unknown ☐

Date of first positive test:

75

anti-PM-Scl

Positive ☐ 76
Negative ☐
Not Done ☐
Unknown ☐

Date of first positive test:

77

Rave.11.0_PRD_Annotation: Form Matrix
Form: Diagnostic Tests
Generated On: 23 Apr 2019 20:11:55

anti-topoisomerase	Positive	<input type="checkbox"/>	78
	Negative	<input type="checkbox"/>	
	Not Done	<input type="checkbox"/>	
	Unknown	<input type="checkbox"/>	

Date of first positive test:	_____	79
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anti-U1RNP	Positive	<input type="checkbox"/>	80
	Negative	<input type="checkbox"/>	
	Not Done	<input type="checkbox"/>	
	Unknown	<input type="checkbox"/>	

Date of first positive test:	_____	81
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any other URNP	Positive	<input type="checkbox"/>	82
	Negative	<input type="checkbox"/>	
	Not Done	<input type="checkbox"/>	
	Unknown	<input type="checkbox"/>	

Date of first positive test:	_____	83
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Other Myositis Associated Autoantibody	Positive	<input type="checkbox"/>	84
	Negative	<input type="checkbox"/>	
	Not Done	<input type="checkbox"/>	
	Unknown	<input type="checkbox"/>	

Specify	_____	85
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Date of first positive test:	_____	86
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Rave.11.0_PRD_Annotation: Form Matrix
Form: Diagnostic Tests
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① ANA	2	ANA		1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
② ANADTC	dd- MMM- yyyy	ANA: Date of first positive test		
③ ANTICCP	2	Anti-CCP		1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
④ ANTICDTC	dd- MMM- yyyy	Anti-CCP: Date of first positive test		
⑤ IGMRFINT	2	IgM RF initial		1 = Positive 2 = Negative 97 = Not Done 99 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix
Form: Diagnostic Tests
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
⑥	IGMRFDTC	dd- MMM- yyyy	IgM RF initial: Date first positive test		
⑦	IGMRFCN	2	IgM RF confirmator y		1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
⑧	IGMRCDTC	dd- MMM- yyyy	IgM RF: Date of first confirmator y test		
⑨	HLAB27	2	HLAB27		1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
⑩	HLAB2DTC	dd- MMM- yyyy	HLAB27: Date of first positive test:		
⑪	DSDNA	2			1 = Positive 2 = Negative

Rave.11.0_PRD_Annotation: Form Matrix
Form: Diagnostic Tests
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				97 = Not Done 99 = Unknown
12 DSDNADTC	dd- MMM- YYYY			
13 ANTISM	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
14 ANTISMDTC	dd- MMM- YYYY			
15 RNP	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
16 RNPDTCT	dd- MMM- YYYY			
17 SSA	2			1 = Positive 2 = Negative

Rave.11.0_PRD_Annotation: Form Matrix
Form: Diagnostic Tests
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				97 = Not Done 99 = Unknown
18 SSADTC	dd- MMM- YYYY			
19 SSB	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
20 SSB DTC	dd- MMM- YYYY			
21 ANTICARG	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
22 ACARGDTC	dd- MMM- YYYY			
23 ANTICARA	2			1 = Positive 2 = Negative

Rave.11.0_PRD_Annotation: Form Matrix
Form: Diagnostic Tests
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				97 = Not Done 99 = Unknown
24 ACARADTC	dd- MMM- YYYY			
25 ANTICARM	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
26 ACARMDTC	dd- MMM- YYYY			
27 ANTIB2G	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
28 ANB2GDTC	dd- MMM- YYYY			
29 ANTIB2A	2			1 = Positive 2 = Negative

Rave.11.0_PRD_Annotation: Form Matrix
Form: Diagnostic Tests
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				97 = Not Done 99 = Unknown
30 ANB2ADTC	dd- MMM- YYYY			
31 ANTIB2M	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
32 ANB2MDTC	dd- MMM- YYYY			
33 LUPSACOG	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
34 LUPACDTC	dd- MMM- YYYY			
35 COOMBS	2			1 = Positive 2 = Negative

Rave.11.0_PRD_Annotation: Form Matrix
Form: Diagnostic Tests
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				97 = Not Done 99 = Unknown
36 COOMBDTC	dd- MMM- YYYY			
37 RPR	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
38 RPRDTC	dd- MMM- YYYY			
39 ANTIP155	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
40 ANTIPDTC	dd- MMM- YYYY			
41 ANTIPLOC	2			1 = OMRF 98 = Other

Rave.11.0_PRD_Annotation: Form Matrix
Form: Diagnostic Tests
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
42 ANTIMMJ	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
43 ANTIMDTC	dd- MMM- YYYY			
44 ANTIMLOC	2			1 = OMRF 98 = Other
45 ANTIMDA5	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
46 ANTIMDDT	dd- MMM- YYYY			
47 ANTMDLOC	2			1 = OMRF 98 = Other
48 ANTIJO1	2			1 = Positive 2 = Negative 97 = Not Done

Rave.11.0_PRD_Annotation: Form Matrix
Form: Diagnostic Tests
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				99 = Unknown
49 ANTIJODT	dd- MMM- YYYY			
50 ANTJOLOC	2			1 = OMRF 98 = Other
51 OTHANTRN	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
52 OTHANSPF	\$50			
53 OTHANTDT	dd- MMM- YYYY			
54 OTHANLOC	2			1 = OMRF 98 = Other
55 ANTIMI2	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix
Form: Diagnostic Tests
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
56 ANTMI2DT	dd- MMM- YYYY			
57 ANTM2LOC	2			1 = OMRF 98 = Other
58 ANTISRP	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
59 ANTISRDT	dd- MMM- YYYY			
60 ANTSRLOC	2			1 = OMRF 98 = Other
61 HMGCR	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
62 HMGCRDT	dd- MMM- YYYY			
63 HMGCRLOC	2			1 = OMRF 98 = Other

Rave.11.0_PRD_Annotation: Form Matrix
Form: Diagnostic Tests
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
64 OTHERMSA	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
65 OTHERSPF	\$50			
66 OTHER1DT	dd- MMM- YYYY			
67 OTHR1LOC	2			1 = OMRF 98 = Other
68 ANTIRO	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
69 ANTIRODT	dd- MMM- YYYY			
70 ANTILA	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix
Form: Diagnostic Tests
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
71 ANTILADT	dd- MMM- YYYY			
72 ANTSM	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
73 ANTISMDT	dd- MMM- YYYY			
74 ANTIKU	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
75 ANTIKU DT	dd- MMM- YYYY			
76 ANPMSCL	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix
Form: Diagnostic Tests
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
77 ANPMSCDT	dd- MMM- YYYY			
78 ANTOPO	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
79 ANTOPODT	dd- MMM- YYYY			
80 ANU1RNP	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
81 ANU1RNDT	dd- MMM- YYYY			
82 ANOURNP	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix
Form: Diagnostic Tests
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
83 ANOURNDT	dd- MMM- YYYY			
84 OTHMAA	2			1 = Positive 2 = Negative 97 = Not Done 99 = Unknown
85 OTHMASPF	\$50			
86 OTHMAADT	dd- MMM- YYYY			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Insurance Log
Generated On: 23 Apr 2019 20:11:55

Insurance type (check all that apply)

Date of information _____ ②

Private Health Insurance ☐ ③

Medicare ☐ ④

Medicaid ☐ ⑤

Military Health Care ☐ ⑥

State-specific Plan (non-Medicaid) ☐ ⑦

Indian Health Services ☐ ⑧

Non-US Insurance ☐ ⑨

Other ☐ ⑩


None ☐ ⑪

Name of Insurance: _____ ⑫

Rave.11.0_PRD_Annotation: Form Matrix
Form: Insurance Log
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
②	INSURDTC	dd MMM yyyy	Insurance: Date of information		
③	PRHLTINS	1	Private Health Insurance		
④	MEDICARE	1	Medicare		
⑤	MEDICAID	1	Medicaid		
⑥	MILHLTCR	1	Military Health Care		
⑦	STATEPLN	1	State-specif ic Plan (non-Medic aid)		
⑧	INDHLTSR	1	Indian Health Services		
⑨	NONUSINS	1	Non-US Insurance		
⑩	OTHINSUR	1	Other		
⑪	NONEINSR	1	None		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Insurance Log
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
 INSUNAME	\$200	Name of Insurance:		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Disease Manifestations Form
Generated On: 23 Apr 2019 20:11:55

None ☐ ①

MRI Evidence of Active Sacroiliitis ☐ ②

Date of 1st Positive MRI: _____ ③

Active TMJ Arthritis Diagnosis ☐ ④

Date of Diagnosis: _____ ⑤

Rave.11.0_PRD_Annotation: Form Matrix
Form: Disease Manifestations Form
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① DISNONE	1			
② ACTSACRL	1			
③ POSMRIDT	dd- MMM- YYYY			
④ ACTTMJAR	1			
⑤ TMJDIGDT	dd- MMM- YYYY			

Rave.11.0_PRD_Annotation: Form Matrix
Form: ACR Classification Criteria Score
Generated On: 23 Apr 2019 20:11:55

TOTAL Number of Categories with Criteria Met

1

Rave.11.0_PRD_Annotation: Form Matrix
Form: ACR Classification Criteria Score
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
<hr/>				
① ACRSCORE	2			

Rave.11.0_PRD_Annotation: Form Matrix
Form: SLICC Classification Criteria Score
Generated On: 23 Apr 2019 20:11:55

TOTAL Number of Categories with Criteria Met

1

Rave.11.0_PRD_Annotation: Form Matrix
Form: SLICC Classification Criteria Score
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
<hr/>				
① SLICCSCR	3			

Rave.11.0_PRD_Annotation: Form Matrix
Form: SLICC Damage Index Form
Generated On: 23 Apr 2019 20:11:55

Date of Information _____

①

Damage occurring since diagnosis of lupus, ascertained by clinical assessment and present for at least 6 months unless otherwise stated. Repeat episodes mean at least 6 months apart to score 2. The same lesion cannot be scored twice.

No Damage

☐ ③

Ocular (either eye, by clinical assessment)

Any cataract ever

☐ ⑤

Retinal change OR optic atrophy

☐ ⑥

Neuropsychiatric

Cognitive impairment (e.g. memory deficit, difficulty with calculation, poor concentration, difficulty in spoken or written language, impaired performance level) OR major psychosis

☐ ⑧

Seizures requiring therapy for 6 months

☐ ⑨

Cerebral vascular accident ever

☐ ⑩

Enter number of CVAs, at least 6 months apart _____

⑪

Cranial or peripheral neuropathy (excluding optic)

☐ ⑫

Rave.11.0_PRD_Annotation: Form Matrix
Form: SLICC Damage Index Form
Generated On: 23 Apr 2019 20:11:55

Transverse myelitis	<input type="checkbox"/> 13
Renal	
Estimated or measured GFR <50%	<input type="checkbox"/> 15
Proteinuria 24h, \geq 3.5g	<input type="checkbox"/> 16
End-stage renal disease (regardless of dialysis or transplantation)	<input type="checkbox"/> 17
Pulmonary	
Pulmonary hypertension (right ventricular prominence, or loud P2)	<input type="checkbox"/> 19
Pulmonary fibrosis (physical and X-ray)	<input type="checkbox"/> 20
Shrinking lung (X-ray)	<input type="checkbox"/> 21
Pleural fibrosis (X-ray)	<input type="checkbox"/> 22
Pulmonary infarction (X-ray)	<input type="checkbox"/> 23
Cardiovascular	
Angina OR coronary artery bypass	<input type="checkbox"/> 25

Rave.11.0_PRD_Annotation: Form Matrix
Form: SLICC Damage Index Form
Generated On: 23 Apr 2019 20:11:55

Myocardial infarction ever	<input type="checkbox"/>	26
Enter number of MIs, at least 6 months apart		27
Cardiomyopathy (ventricular dysfunction)	<input type="checkbox"/>	28
Valvular disease (diastolic murmur, or systolic murmur > 3/6)	<input type="checkbox"/>	29
Pericarditis x6 months OR pericardiectomy	<input type="checkbox"/>	30
Peripheral Vascular		
Claudication x6 months	<input type="checkbox"/>	32
Minor tissue loss (pulp space)	<input type="checkbox"/>	33
Significant tissue loss ever (e.g. loss of digit or limb, resection)	<input type="checkbox"/>	34
Enter number of episodes of significant tissue loss, at least 6 months apart		35
Venous thrombosis with swelling, ulceration, OR venous stasis	<input type="checkbox"/>	36
Gastrointestinal		
Infarction or resection of bowel (below duodenum), spleen, liver, or gallbladder ever	<input type="checkbox"/>	38

Rave.11.0_PRD_Annotation: Form Matrix
Form: SLICC Damage Index Form
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Enter number of infarctions/resections, at least 6 months apart	<input type="text"/>	<input type="checkbox"/> 39
Mesenteric insufficiency	<input type="checkbox"/>	40
Chronic peritonitis	<input type="checkbox"/>	41
Stricture OR upper gastrointestinal tract surgery ever	<input type="checkbox"/>	42
Pancreatic insufficiency requiring enzyme replacement or with pseudocyst	<input type="checkbox"/>	43
Musculoskeletal		
Atrophy or weakness	<input type="checkbox"/>	45
Deforming or erosive arthritis (including reducible deformities, excluding avascular necrosis)	<input type="checkbox"/>	46
Osteoporosis with fracture OR vertebral collapse (excluding avascular necrosis)	<input type="checkbox"/>	47
Avascular necrosis	<input type="checkbox"/>	48
Enter number of locations of AVN, at least 6 months apart	<input type="text"/>	49
Osteomyelitis	<input type="checkbox"/>	50

Rave.11.0_PRD_Annotation: Form Matrix
Form: SLICC Damage Index Form
Generated On: 23 Apr 2019 20:11:55

Ruptured tendons	<input type="checkbox"/>	51
<hr/>		
Skin		
<hr/>		
Alopecia	<input type="checkbox"/>	52
<hr/>		
Extensive scarring or panniculum other than scalp and pulp space	<input type="checkbox"/>	54
<hr/>		
Premature Gonadal Failure		
<hr/>		
Yes	<input type="checkbox"/>	56
<hr/>		
Diabetes (regardless of treatment)		
<hr/>		
Yes	<input type="checkbox"/>	58
<hr/>		
Malignancy (exclude dysplasia)		
<hr/>		
Yes	<input type="checkbox"/>	60
<hr/>		
	1 site <input type="checkbox"/>	61
	> 1 site <input type="checkbox"/>	
	0 site <input type="checkbox"/>	
<hr/>		
<hr/>		
TOTAL of Criteria Selected		63
<hr/>		
<hr/>		

Rave.11.0_PRD_Annotation: Form Matrix
Form: SLICC Damage Index Form
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
①	SLICCDTC	dd- MMM- YYYY			
③	NODAMAGE	1			
⑤	CRTEVER	1			
⑥	RETOPATR	1			
⑧	COGIMP	1			
⑨	SEZTHPY	1			
⑩	CBVASACC	1			
⑪	CBVASNUM	2			
⑫	CRPRNEUR	1			
⑬	TRANMYEL	1			
⑮	GFR	1			
⑯	PROTENUR	1			
⑰	ESRENAL	1			

Rave.11.0_PRD_Annotation: Form Matrix
Form: SLICC Damage Index Form
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
16	PULHT	1			
20	PULFIBRO	1			
21	SRNKLUNG	1			
22	PLEURFIB	1			
23	PULNFARC	1			
25	ANGCABG	1			
26	MI	1			
27	MINUM	2			
28	CARDMYO	1			
29	VALVDIS	1			
30	PERCARD	1			
32	CLAUD	1			
33	TISSLOSS	1			
34	SIGTISSL	1			

Rave.11.0_PRD_Annotation: Form Matrix
Form: SLICC Damage Index Form
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
35 SIGTINUM	2			
36 VNTHROMB	1			
38 INFRCRE	1			
39 INFRCNM	2			
40 MESINSUF	1			
41 CPERITON	1			
42 GITRSRG	1			
43 PNCINS	1			
45 ATROWEAK	1			
46 ARTHRITS	1			
47 OSTEOPOR	1			
48 AVSNECRO	1			
49 AVSNENUM	2			
50 OSTEOMYE	1			

Rave.11.0_PRD_Annotation: Form Matrix
Form: SLICC Damage Index Form
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
51 RUPTENDN	1			
53 ALOPECIA	1			
54 SCARPANN	1			
56 PREGONAF	1			
58 DIABETS	1			
60 MALIGNAC	1			
61 MALIGNA	1			1 = 1 site 2 = > 1 site 0 = 0 site
63 DISCORE	3			

Rave.11.0_PRD_Annotation: Form Matrix**Form: Medications****Generated On: 23 Apr 2019 20:11:55**

Record all medications taken for treatment of study disease except for Steroids (recorded on a separate form). For medication taken more than a year prior to Baseline, please complete as much information as possible, including best estimate of at least the year of start and stop. Please complete a new log line each time a dose is changed.

Has the subject ever taken medications for treatment of study disease except for Steroids? Yes ☐ ②
No ☐

Medication _____ ③

Start Date _____ ④

Indication _____ ⑤
Active MAS ☐
Active Uveitis ☐
Primary disease treatment ☐
Hypertension ☐
Treatment for Calcinosis ☐
Treatment for TMJ Arthritis ☐
Unknown ☐

Dose _____ ⑥

Unit _____ ⑦
mg ☐
g ☐
mcg ☐
Other, specify ☐

Frequency _____ ⑧
Daily ☐
2x/day ☐
3x/day ☐

Rave.11.0_PRD_Annotation: Form Matrix

Form: Medications

Generated On: 23 Apr 2019 20:11:55

	4x/day	<input type="checkbox"/>
	Every other day	<input type="checkbox"/>
	2x / wk	<input type="checkbox"/>
	Weekly	<input type="checkbox"/>
	Every other week	<input type="checkbox"/>
	Every month	<input type="checkbox"/>
	As needed	<input type="checkbox"/>
	One time	<input type="checkbox"/>
	3 consecutive daily doses/month	<input type="checkbox"/>
	Other, Specify:	<input type="checkbox"/>

Route	Oral	<input checked="" type="checkbox"/> 9
	Intravenous	<input type="checkbox"/>
	Topical	<input type="checkbox"/>
	Intradermal	<input type="checkbox"/>
	Subcutaneous	<input type="checkbox"/>
	Intra-articular	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Inhaled	<input type="checkbox"/>
	Other, specify	<input type="checkbox"/>

If this medication has been stopped or the dose changed (other than a brief period (14 days)), please provide the last dose date, otherwise indicate it is Ongoing	Ongoing	<input checked="" type="checkbox"/> 10
	Stop date (last dose given)	<input type="checkbox"/>

Stop Date		<input checked="" type="checkbox"/> 11
-----------	--	--

Reason dose stopped	Medication has been discontinued	<input checked="" type="checkbox"/> 12
	Dosage is to be changed (add a new record with new dose information)	<input type="checkbox"/>

Rave.11.0_PRD_Annotation: Form Matrix
Form: Medications
Generated On: 23 Apr 2019 20:11:55

Reason for discontinuation or dose change



Rave.11.0_PRD_Annotation: Form Matrix
Form: Medications
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
②	ONMEDS	1	Subject on medications		1 = Yes 0 = No
③	MEDCATON	2	Medication		Medication
④	MEDSTRDT	dd- MMM- YYYY	Start Date		
⑤	INDICATN	2	Indication		1 = Active MAS 2 = Active Uveitis 3 = Primary disease treatment 4 = Hypertensio n 5 = Treatment for Calcinosis 6 = Treatment for TMJ Arthritis 99 = Unknown
⑥	DOSE	9.3	Dose		
⑦	MUNIT	2	Unit		1 = mg 2 = g 3 = mcg

Rave.11.0_PRD_Annotation: Form Matrix
Form: Medications
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				98 = Other, specify
8 FREQUENCY	2	Frequency		1 = Daily 2 = 2x/day 3 = 3x/day 4 = 4x/day 5 = Every other day 6 = 2x / wk 7 = Weekly 8 = Every other week 9 = Every month 10 = As needed 11 = One time 12 = 3 consecutive daily doses/mont h 98 = Other, Specify:
9 ROUTE	2	Route		1 = Oral 2 = Intravenous 3 = Topical 4 = Intradermal 5 = Subcutaneo us

Rave.11.0_PRD_Annotation: Form Matrix
Form: Medications
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				6 = Intra-articular 7 = Intraocular 8 = Inhaled 98 = Other, specify
10 STPDTRAD	1	Stop header		2 = Ongoing 1 = Stop date (last dose given)
11 MEDSTPDT	dd- MMM- YYYY	Stop Date		
12 MEDSTOP	1	Reason dose stopped		1 = Medication has been discontinued 2 = Dosage is to be changed (add a new record with new dose information)
13 STOPREAS	2	Reason discontinuation or dose change		MedicationReasonStop

Rave.11.0_PRD_Annotation: Form Matrix

Form: Visit

Generated On: 23 Apr 2019 20:11:55

Visit date _____ ①

Visit Status Completed ☐ ②
Missed ☐

Reason visit was missed CTP visit during routine follow-up interval ☐ ③
No clinic visit during routine follow-up interval ☐

Reason for unscheduled visit. New drug initiated ☐ ④
Sub-study enrollment: ☐
(specify)
Sub-study follow-up: ☐
(specify)
Other, specify ☐

Assessments

Questionnaires completed at this visit Yes ☐ ⑥
No ☐

Reason questionnaires not done Subject/parent refused ☐ ⑦
Site oversight ☐

Were biological sample drawn at this visit Yes ☐ ⑧
No ☐
Unknown ☐

Were any diagnostic test performed at this visit Yes ☐ ⑨
No ☐

Rave.11.0_PRD_Annotation: Form Matrix

Form: Visit

Generated On: 23 Apr 2019 20:11:55

Unknown ☐

Were any laboratory test performed at this visit

Yes ☒ 10
No ☐
Unknown ☐

Has the subject had any exposure [ever - baseline / since last visit - Followup] to glucocorticoids (steroids) for the treatment of rheumatologic disease (including oral, intra-articular, high-dose pulse IV; excluding eye drops or inhaled)

Yes ☒ 11
No ☐

Other Studies

Is the subject currently enrolled in any interventional studies?

Yes ☒ 12
No ☐
Unknown ☐

Is subject being treated for Lupus Nephritis?

Yes ☒ 14
No ☐

Is subject being treated according to CARRA Consensus Treatment Plan (CTP) for induction treatment of Lupus Nephritis?

Yes ☒ 15
No ☐

➞If Yes:

Which immunosuppressive regimen is being used for the CTP for induction treatment of lupus nephritis?

Mycophenolate ☒ 16
mofetil/mycophenolic acid
Intravenous ☐
cyclophosphamide

Which steroid regimen is being used for the CTP for induction treatment of lupus nephritis?

Primarily Oral ☒ 17

Rave.11.0_PRD_Annotation: Form Matrix

Form: Visit

Generated On: 23 Apr 2019 20:11:55

Oral and IV ☐

Primarily IV ☐

Is subject being treated according to CARRA Consensus
Treatment Plan (CTP) for JDM?

Yes ☐ 18

No ☐

➞If Yes, which one:

Moderate JDM ☐ 19

Skin Predominant JDM ☐

JDM with Persistent Skin
Disease ☐

select one:

Plan A: IV and PO steroids ☐ 20
+ methotrexate

Plan B: IV and PO steroids ☐
+ methotrexate + IVIG

Plan C: PO steroids only + ☐
methotrexate

select one:

Plan A: ☐ 21

Hydroxychloroquine
monotherapy

Plan B: Hydroxychloroquine ☐
+ methotrexate

Plan C: Hydroxychloroquine ☐
+ methotrexate + PO
steroids

select one:

Plan A: Addition of IVIG to ☐ 22
prior regimen

Plan B: Addition of MMF to ☐
prior regimen

Plan C: Addition of ☐
Cyclosporine to prior
regimen

Rave.11.0_PRD_Annotation: Form Matrix
Form: Visit
Generated On: 23 Apr 2019 20:11:55

Next followup

Is subject expected to return to site for a Follow-up
Registry visit?

Yes ☒ 24
No ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Visit
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
①	VISITDTC	dd MMM YYYY	Visit date		
②	VISREASN	1	Visit status		2 = Completed 3 = Missed
③	VISMISS	1			1 = CTP visit during routine follow-up interval 0 = No clinic visit during routine follow-up interval
④	UNSCRESN	2	Reason for unschedule d visit		1 = New drug initiated 2 = Sub-study enrollment: (specify) 3 = Sub-study follow-up: (specify) 98 = Other, specify
⑥	SUBJQUEST	1	Questionnai res completed		1 = Yes 0 = No

Rave.11.0_PRD_Annotation: Form Matrix
Form: Visit
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
⑦ QUSTRESN	1	Reason questionnai res not done		1 = Subject/par ent refused 2 = Site oversight
⑧ SAMPDRAW	2	Biological sample drawn		1 = Yes 0 = No 99 = Unknown
⑨ DIAGTEST	2	Diagnostic test performed		1 = Yes 0 = No 99 = Unknown
⑩ LABSDRAW	2	Laboratory test performed at this visit		1 = Yes 0 = No 99 = Unknown
⑪ STRODUSE	1	Exposure [ever - baseline / since last visit - Followup] to glucocortico ids		1 = Yes 0 = No
⑫ OTHSTUDY	2	Enrolled in any intervention al studies		1 = Yes 0 = No 99 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix
Form: Visit
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
14 LUPUSNEP	1			1 = Yes 0 = No
15 LUPUSCTP	1			1 = Yes 0 = No
16 IMMUREGI	1			1 = Mycophenol ate mofetil/myc ophenolic acid 2 = Intravenous cyclophosph amide
17 STERREGI	1			1 = Primarily Oral 2 = Oral and IV 3 = Primarily IV
18 CTPJDM	1			1 = Yes 0 = No
19 JDMYES	1			1 = Moderate JDM 2 = Skin Predominan t JDM

Rave.11.0_PRD_Annotation: Form Matrix
Form: Visit
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				3 = JDM with Persistent Skin Disease
20 MODJDM	1			1 = Plan A: IV and PO steroids + methotrexate 2 = Plan B: IV and PO steroids + methotrexate + IVIG 3 = Plan C: PO steroids only + methotrexate
21 SKNPRED	1			1 = Plan A: Hydroxychloroquine monotherapy 2 = Plan B: Hydroxychloroquine + methotrexate 3 = Plan C: Hydroxychloroquine + methotrexate + PO steroids

Rave.11.0_PRD_Annotation: Form Matrix
Form: Visit
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
22 PERSSKIN	1			1 = Plan A: Addition of IVIG to prior regimen 2 = Plan B: Addition of MMF to prior regimen 3 = Plan C: Addition of Cyclosporin e to prior regimen
24 CONTSTDY	1	Subject continuing in study		1 = Yes 0 = No

Rave.11.0_PRD_Annotation: Form Matrix
Form: Unscheduled Visit
Generated On: 23 Apr 2019 20:11:55

Visit date _____ ①

Reason for unscheduled visit.

New drug initiated ☐ ②

Sub-study enrollment: ☐
(specify)

Sub-study follow-up: ☐
(specify)

Other, specify ☐

Assessments

Questionnaires completed at this visit

Yes ☐ ④

No ☐

Reason questionnaires not done

Subject/parent refused ☐ ⑤

Site oversight ☐

Were biological sample drawn at this visit

Yes ☐ ⑥

No ☐

Unknown ☐

Were any diagnostic test performed at this visit

Yes ☐ ⑦

No ☐

Unknown ☐

Were any laboratory test performed at this visit

Yes ☐ ⑧

No ☐

Unknown ☐

Rave.11.0_PRD_Annotation: Form Matrix

Form: Unscheduled Visit

Generated On: 23 Apr 2019 20:11:55

Has the subject had any exposure since last visit to glucocorticoids (steroids) for the treatment of rheumatologic disease (including oral, intra-articular, high-dose pulse IV; excluding eye drops or inhaled)

Yes ☐ 9
No ☐

Other Studies

Is the subject currently enrolled in any interventional studies?

Yes ☐ 11
No ☐
Unknown ☐

Is subject being treated for Lupus Nephritis?

Yes ☐ 12
No ☐

Is subject being treated according to CARRA Consensus Treatment Plan (CTP) for induction treatment of Lupus Nephritis?

Yes ☐ 13
No ☐

➞If Yes:
Which immunosuppressive regimen is being used for the CTP for induction treatment of lupus nephritis?

Mycophenolate ☐ 14
mofetil/mycophenolic acid
Intravenous ☐
cyclophosphamide

Which steroid regimen is being used for the CTP for induction treatment of lupus nephritis?

Primarily Oral ☐ 15
Oral and IV ☐
Primarily IV ☐

Is subject being treated according to CARRA Consensus Treatment Plan (CTP) for JDM?

Yes ☐ 16
No ☐

➞If Yes, which one:

Moderate JDM ☐ 17

Rave.11.0_PRD_Annotation: Form Matrix
Form: Unscheduled Visit
Generated On: 23 Apr 2019 20:11:55

Skin Predominant JDM ☐

JDM with Persistent Skin Disease ☐

select one:

Plan A: IV and PO steroids + methotrexate ☐ 18

Plan B: IV and PO steroids + methotrexate + IVIG ☐

Plan C: PO steroids only + methotrexate ☐

select one:

Plan A: Hydroxychloroquine monotherapy ☐ 19

Plan B: Hydroxychloroquine + methotrexate ☐

Plan C: Hydroxychloroquine + methotrexate + PO steroids ☐

select one:

Plan A: Addition of IVIG to prior regimen ☐ 20

Plan B: Addition of MMF to prior regimen ☐

Plan C: Addition of Cyclosporine to prior regimen ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Unscheduled Visit
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
①	VISITDTC	dd MMM YYYY	Visit date		
②	UNSCRESN	2	Reason for unschedule d visit		1 = New drug initiated 2 = Sub-study enrollment: (specify) 3 = Sub-study follow-up: (specify) 98 = Other, specify
④	SUBJQUEST	1	Questionnai res completed		1 = Yes 0 = No
⑤	QUESTRESN	1	Reason questionnai res not done		1 = Subject/par ent refused 2 = Site oversight
⑥	SAMPDRAW	2	Biological sample drawn		1 = Yes 0 = No 99 = Unknown
⑦	DIAGTEST	2	Diagnostic test performed		1 = Yes 0 = No

Rave.11.0_PRD_Annotation: Form Matrix
Form: Unscheduled Visit
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				99 = Unknown
8 LABSDRAW	2	Laboratory test performed at this visit		1 = Yes 0 = No 99 = Unknown
9 STRODUSE	1	Exposure since last visit to glucocortico ids		1 = Yes 0 = No
11 OTHSTUDY	2	Enrolled in any intervention al studies		1 = Yes 0 = No 99 = Unknown
12 LUPUSNEU	1			1 = Yes 0 = No
13 LUPUSCTU	1			1 = Yes 0 = No
14 IMMUREGU	1			1 = Mycophenol ate mofetil/myc ophenolic acid

Rave.11.0_PRD_Annotation: Form Matrix
Form: Unscheduled Visit
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				2 = Intravenous cyclophosph amide
15 STERREGU	1			1 = Primarily Oral 2 = Oral and IV 3 = Primarily IV
16 CTPJDMU	1			1 = Yes 0 = No
17 JDMYESU	1			1 = Moderate JDM 2 = Skin Predominan t JDM 3 = JDM with Persistent Skin Disease
18 MODJDMU	1			1 = Plan A: IV and PO steroids + methotrexate

Rave.11.0_PRD_Annotation: Form Matrix
Form: Unscheduled Visit
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				2 = Plan B: IV and PO steroids + methotrexate + IVIG 3 = Plan C: PO steroids only + methotrexate
19 SKNPREDU	1			1 = Plan A: Hydroxychloroquine monotherapy 2 = Plan B: Hydroxychloroquine + methotrexate 3 = Plan C: Hydroxychloroquine + methotrexate + PO steroids
20 PERSSKIU	1			1 = Plan A: Addition of IVIG to prior regimen 2 = Plan B: Addition of MMF to prior regimen

Rave.11.0_PRD_Annotation: Form Matrix
Form: Unscheduled Visit
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				3 = Plan C: Addition of Cyclosporin e to prior regimen

Rave.11.0_PRD_Annotation: Form Matrix
Form: Physical Exam
Generated On: 23 Apr 2019 20:11:55

Height	cm <input type="checkbox"/> ①
	in <input type="checkbox"/>
	ND <input type="checkbox"/>

Weight	kg <input type="checkbox"/> ②
	lb <input type="checkbox"/>
	ND <input type="checkbox"/>

BMI (calculated)	<input type="text"/>	③
------------------	----------------------	---

Current Menses	Yes <input type="checkbox"/> ④
	No <input type="checkbox"/>

Systolic Blood Pressure	<input type="text"/>	Fixed Unit: mm Hg ⑤
-------------------------	----------------------	---------------------

Diastolic Blood Pressure	<input type="text"/>	Fixed Unit: mm Hg ⑥
--------------------------	----------------------	---------------------

PHYSICIAN assessments

Physician global assessment	<input type="text"/>	Fixed Unit: score ⑧
-----------------------------	----------------------	---------------------

Physician Pain Assessment:	Yes <input type="checkbox"/> ⑨
Does the patient have widespread pain? (Defined as	No <input type="checkbox"/>
pain in the left and right sides of the body, as well as	Not Done <input type="checkbox"/>
pain above and below the waist. This describes pain that	Not Collected <input type="checkbox"/>
is not directly attributed to the patient's rheumatic	
condition)	

Rave.11.0_PRD_Annotation: Form Matrix

Form: Physical Exam

Generated On: 23 Apr 2019 20:11:55

Physician Assessment of Interim Disease Activity
In the treating physician's opinion, has the patient's JIA
been in a state of inactive disease continuously since the
last CARRA Registry visit (Follow-up only)?

Yes ☐ **10**
No ☐
Unknown ☐

Physician Global Muscle Disease Activity _____ **11**

Physician Global Skin Disease Activity _____ **12**

Physician Global Extramuscular Disease Activity
(Excluding Skin Disease) _____ **13**

Patient/Parent Global

0 ☐ **14**
1 ☐
2 ☐
3 ☐
4 ☐
5 ☐
6 ☐
7 ☐
8 ☐
9 ☐
10 ☐
ND ☐

Events

Since the last visit, has the subject had any Serious
Adverse events or events of special interest?

Yes ☐ **16**
No ☐

Rave.11.0_PRD_Annotation: Form Matrix

Form: Physical Exam

Generated On: 23 Apr 2019 20:11:55

Has the subject had any of the following scenarios (not recorded as SAEs or ESIs) related to DMARDS taken since last visit:

Yes ☐ 17
No ☐
Unknown ☐

Check all that apply and provide brief description
Dispensing errors / Medication errors

☐ 18

Specify

19

Drug abuse and misuse

☐ 20

Specify

21

Drug exposure during pregnancy

☐ 22

Specify

23

Drug maladministration or accidental exposure

☐ 24

Specify

25

Drug use during lactation or breast-feeding

☐ 26

Specify

27

Drug-drug or food-drug interaction

☐ 28

Specify

29

Rave.11.0_PRD_Annotation: Form Matrix
Form: Physical Exam
Generated On: 23 Apr 2019 20:11:55

Lack of effectiveness	<input type="checkbox"/>	30
-----------------------	--------------------------	----

Specify		31
---------	--	----

Off-label use (provide description below)	<input type="checkbox"/>	32
---	--------------------------	----

Specify		33
---------	--	----

Overdose	<input type="checkbox"/>	34
----------	--------------------------	----

Specify		35
---------	--	----

Withdrawal or rebound symptoms (provide description below)	<input type="checkbox"/>	36
--	--------------------------	----

Specify		37
---------	--	----

Rave.11.0_PRD_Annotation: Form Matrix
Form: Physical Exam
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① HTORRES	6.2	Height	1 = cm 2 = in 97 = ND	
② WTORRES	6.2	Weight	1 = kg 2 = lb 97 = ND	
③ BMI	4.1	BMI (calculated)		
④ CURMENSE	1			1 = Yes 0 = No
⑤ SYSBP	3	Systolic Blood Pressure		
⑥ DIABP	3	Diastolic Blood Pressure		
⑧ PHYSCORE	\$4	Physician global assessment		
⑨ PHYPAIN	2			1 = Yes 0 = No 97 = Not Done 95 = Not Collected

Rave.11.0_PRD_Annotation: Form Matrix
Form: Physical Exam
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
10 INTDSACT	2			1 = Yes 0 = No 99 = Unknown
11 PHYGBMUS	\$4			Disease Activity
12 PHYGSKIN	\$4			Disease Activity
13 PHYGEXTR	\$4			Disease Activity
14 RHEURATE	2			0 = 0 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 97 = ND
16 HADSAE	1	SAE or ESI since last visit?		1 = Yes 0 = No

Rave.11.0_PRD_Annotation: Form Matrix
Form: Physical Exam
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
17	DMARDS	2	Special scenarios related to DMARDS		1 = Yes 0 = No 99 = Unknown
18	DMARDS7	1	Dispensing errors / Medication errors		
19	DMARDS7S	\$100			
20	DMARDS5	1	Drug abuse and misuse		
21	DMARDS5S	\$100			
22	DMARDS2	1	Drug exposure during pregnancy		
23	DMARDS2S	\$100			
24	DMARDS6	1	Drug maladministration or accidental exposure		
25	DMARDS6S	\$100			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Physical Exam
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	Field Name	Data Type	SAS Label	Units	Values
26	DMARDS3	1	Drug use during lactation or breast-feeding		
27	DMARDS3S	\$100			
28	DMARDS1	1	Drug-drug or food-drug interaction		
29	DMARDS1S	\$100			
30	DMARLACK	1	Lack of effectiveness		
31	DMARLACS	\$100			
32	DMARDS8	1	Off-label use (provide description below)		
33	DMARDS8S	\$100			
34	DMARDS4	1	Overdose		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Physical Exam
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Field Name	Data Type	SAS Label	Units	Values
35 DMARDS4S	\$100			
36 DMARDS9	1	Withdrawal or rebound symptoms		
37 DESCDMAR	\$200	Other scenario: describe		

Rave.11.0_PRD_Annotation: Form Matrix

Form: Primary Disease

Generated On: 23 Apr 2019 20:11:55

What is subject's primary rheumatological disease diagnosis

- Juvenile idiopathic arthritis ☐ ①
- Systemic Lupus Erythematosus (SLE) and Related Conditions ☐
- Juvenile Dermatomyositis (JDM)/Juvenile Polymyositis (JPM) ☐
- Other, specify ☐

Onset of symptoms (record UNK for unknown day or month, make best estimate of year)

②

Date first seen by pediatric rheumatologist (record UNK for unknown day or month, make best estimate of year)

③

Date of diagnosis:

④

Rave.11.0_PRD_Annotation: Form Matrix
Form: Primary Disease
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① PRRHEUMA	2	Primary rheumatolo gical disease		1 = Juvenile idiopathic arthritis 2 = Systemic Lupus Erythemato sus (SLE) and Related Conditions 3 = Juvenile Dermatomy ositis (JDM)/Juve nile Polymyositi s (JPM) 98 = Other, specify
② SYMPONDT	dd- MMM- yyyy	Onset of disease symptoms		
③ FSTSEEDT	dd- MMM- yyyy	Date first seen by ped rheumatolo gist		
④ DXDT	dd- MMM- yyyy	Date of disease diagnosis		

Rave.11.0_PRD_Annotation: Form Matrix

Form: Systemic Lupus Erythematosus (SLE) and Related Conditions

Generated On: 23 Apr 2019 20:11:55

Please select Primary Systemic Lupus Erythematosus (SLE) or Related Conditions

- Systemic Lupus Erythematosus (SLE) ☒ ①
- Acute Cutaneous Lupus (isolated) ☐
- Chronic Cutaneous Lupus (including DLE, isolated) ☐
- Sjogren's Syndrome ☐
- Mixed Connective Tissue Disease ☐
- Anti-Phospholipid Syndrome (Primary) ☐
- Probable SLE (at least 3 SLICC Criteria in the last 24 months) ☐

For all of the Lupus manifestations listed below, check the box that corresponds to correct frequency.

Fever >38°C

- Never (Baseline); Not Present Since Last Visit (Follow-up) ☒ ③
- Manifestation Now or Within 30 Days Prior to Visit ☐
- Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) ☐

Month/ Year that Manifestation was 1st observed _____

④

Skin and Mucous Membranes

Acute Cutaneous Lupus

Malar Rash

⑦

Rave.11.0_PRD_Annotation: Form Matrix

Form: Systemic Lupus Erythematosus (SLE) and Related Conditions

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	Never (Baseline); Not Present Since Last Visit (Follow-up)	<input type="checkbox"/>
	Manifestation Now or Within 30 Days Prior to Visit	<input type="checkbox"/>
	Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)	<input type="checkbox"/>
Month/ Year that Manifestation was 1st observed		8
Bullous Lupus	Never (Baseline); Not Present Since Last Visit (Follow-up)	<input type="checkbox"/> 9
	Manifestation Now or Within 30 Days Prior to Visit	<input type="checkbox"/>
	Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)	<input type="checkbox"/>
Month/ Year that Manifestation was 1st observed		10
Toxic Epidermal Necrolysis variant of SLE	Never (Baseline); Not Present Since Last Visit (Follow-up)	<input type="checkbox"/> 11
	Manifestation Now or Within 30 Days Prior to Visit	<input type="checkbox"/>
	Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)	<input type="checkbox"/>
Month/ Year that Manifestation was 1st observed		12

Rave.11.0_PRD_Annotation: Form Matrix

Form: Systemic Lupus Erythematosus (SLE) and Related Conditions

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Maculopapular Rash	Never (Baseline); Not Present Since Last Visit (Follow-up) <input type="checkbox"/> 13 Manifestation Now or Within 30 Days Prior to Visit <input type="checkbox"/> Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="checkbox"/>
Month/ Year that Manifestation was 1st observed	_____ 14
Photosensitive Lupus Rash	Never (Baseline); Not Present Since Last Visit (Follow-up) <input type="checkbox"/> 15 Manifestation Now or Within 30 Days Prior to Visit <input type="checkbox"/> Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="checkbox"/>
Month/ Year that Manifestation was 1st observed	_____ 16
Subacute Cutaneous Lupus	Never (Baseline); Not Present Since Last Visit (Follow-up) <input type="checkbox"/> 17 Manifestation Now or Within 30 Days Prior to Visit <input type="checkbox"/> Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="checkbox"/>
Month/ Year that Manifestation was 1st observed	_____ 18

Rave.11.0_PRD_Annotation: Form Matrix

Form: Systemic Lupus Erythematosus (SLE) and Related Conditions

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Chronic Cutaneous Lupus

Classical Discoid rash
→Localized (above neck)

Yes ☐ 20
No ☐

Never (Baseline); Not ☐ 21
Present Since Last Visit
(Follow-up)
Manifestation Now or ☐
Within 30 Days Prior to
Visit
Manifestation > 30 Days ☐
Prior to Visit (Baseline);
>30 Days Prior to Visit but
Since Last Visit (Follow-up)

Month/ Year that Manifestation was 1st observed

22

→Generalized

Yes ☐ 23
No ☐

Never (Baseline); Not ☐ 24
Present Since Last Visit
(Follow-up)
Manifestation Now or ☐
Within 30 Days Prior to
Visit
Manifestation > 30 Days ☐
Prior to Visit (Baseline);
>30 Days Prior to Visit but
Since Last Visit (Follow-up)

Month/ Year that Manifestation was 1st observed

25

Rave.11.0_PRD_Annotation: Form Matrix

Form: Systemic Lupus Erythematosus (SLE) and Related Conditions

Generated On: 23 Apr 2019 20:11:55

Hypertrophic (Verrucous) Lupus	Never (Baseline); Not Present Since Last Visit (Follow-up) <input type="checkbox"/> 26
	Manifestation Now or Within 30 Days Prior to Visit <input type="checkbox"/>
	Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="checkbox"/>
Month/ Year that Manifestation was 1st observed	_____ 27
Lupus Panniculitis (Profundus)	Never (Baseline); Not Present Since Last Visit (Follow-up) <input type="checkbox"/> 28
	Manifestation Now or Within 30 Days Prior to Visit <input type="checkbox"/>
	Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="checkbox"/>
Month/ Year that Manifestation was 1st observed	_____ 29
Mucosal Lupus	Never (Baseline); Not Present Since Last Visit (Follow-up) <input type="checkbox"/> 30
	Manifestation Now or Within 30 Days Prior to Visit <input type="checkbox"/>
	Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="checkbox"/>
Month/ Year that Manifestation was 1st observed	_____ 31

Rave.11.0_PRD_Annotation: Form Matrix

Form: Systemic Lupus Erythematosus (SLE) and Related Conditions

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Lupus Erythematosus Tumidus	Never (Baseline); Not Present Since Last Visit (Follow-up) <input type="radio"/> 32
	Manifestation Now or Within 30 Days Prior to Visit <input type="radio"/>
	Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="radio"/>
Month/ Year that Manifestation was 1st observed	<input type="text"/> 33
Chilblains Lupus	Never (Baseline); Not Present Since Last Visit (Follow-up) <input type="radio"/> 34
	Manifestation Now or Within 30 Days Prior to Visit <input type="radio"/>
	Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="radio"/>
Month/ Year that Manifestation was 1st observed	<input type="text"/> 35
Discoid Lupus/Lichens Planus Overlap	Never (Baseline); Not Present Since Last Visit (Follow-up) <input type="radio"/> 36
	Manifestation Now or Within 30 Days Prior to Visit <input type="radio"/>
	Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="radio"/>
Month/ Year that Manifestation was 1st observed	<input type="text"/> 37

Rave.11.0_PRD_Annotation: Form Matrix

Form: Systemic Lupus Erythematosus (SLE) and Related Conditions

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Oral Ulcers

Palate

Never (Baseline); Not Present Since Last Visit (Follow-up) ☐ **39**
Manifestation Now or Within 30 Days Prior to Visit ☐
Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) ☐

Month/ Year that Manifestation was 1st observed _____

40

Buccal

Never (Baseline); Not Present Since Last Visit (Follow-up) ☐ **41**
Manifestation Now or Within 30 Days Prior to Visit ☐
Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) ☐

Month/ Year that Manifestation was 1st observed _____

42

Tongue

Never (Baseline); Not Present Since Last Visit (Follow-up) ☐ **43**
Manifestation Now or Within 30 Days Prior to Visit ☐
Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) ☐

Rave.11.0_PRD_Annotation: Form Matrix

Form: Systemic Lupus Erythematosus (SLE) and Related Conditions

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Month/ Year that Manifestation was 1st observed _____ **44**

Nasal Ulcers

Never (Baseline); Not Present Since Last Visit (Follow-up) **45**
☐
Manifestation Now or Within 30 Days Prior to Visit ☐
Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) ☐

Month/ Year that Manifestation was 1st observed _____ **46**

Non-scarring alopecia

Never (Baseline); Not Present Since Last Visit (Follow-up) **47**
☐
Manifestation Now or Within 30 Days Prior to Visit ☐
Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) ☐

Month/ Year that Manifestation was 1st observed _____ **48**

Hematology

Hemolytic Anemia (Coomb's Positive)

Never (Baseline); Not Present Since Last Visit (Follow-up) **50**
☐
Manifestation Now or Within 30 Days Prior to Visit ☐

Rave.11.0_PRD_Annotation: Form Matrix

Form: Systemic Lupus Erythematosus (SLE) and Related Conditions

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	Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)	<input type="checkbox"/>
Month/ Year that Manifestation was 1st observed		<input checked="" type="radio"/> 51
Other anemia	Never (Baseline); Not Present Since Last Visit (Follow-up)	<input checked="" type="radio"/> 52
	Manifestation Now or Within 30 Days Prior to Visit	<input type="checkbox"/>
	Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)	<input type="checkbox"/>
Month/ Year that Manifestation was 1st observed		<input checked="" type="radio"/> 53
Thrombocytopenia (<100,000)	Never (Baseline); Not Present Since Last Visit (Follow-up)	<input checked="" type="radio"/> 54
	Manifestation Now or Within 30 Days Prior to Visit	<input type="checkbox"/>
	Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)	<input type="checkbox"/>
Month/ Year that Manifestation was 1st observed		<input checked="" type="radio"/> 55
Leukopenia	Never (Baseline); Not Present Since Last Visit (Follow-up)	<input checked="" type="radio"/> 56

Rave.11.0_PRD_Annotation: Form Matrix

Form: Systemic Lupus Erythematosus (SLE) and Related Conditions

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	Manifestation Now or Within 30 Days Prior to Visit <input type="checkbox"/>
	Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="checkbox"/>

Month/ Year that Manifestation was 1st observed _____ **57**

Anti-dsDNA antibodies	Never (Baseline); Not Present Since Last Visit (Follow-up) <input type="checkbox"/> 58
	Manifestation Now or Within 30 Days Prior to Visit <input type="checkbox"/>
	Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="checkbox"/>

Month/ Year that Manifestation was 1st observed _____ **59**

Musculoskeletal

Arthritis (2 or more joints affected)	Never (Baseline); Not Present Since Last Visit (Follow-up) <input type="checkbox"/> 61
	Manifestation Now or Within 30 Days Prior to Visit <input type="checkbox"/>
	Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="checkbox"/>

Month/ Year that Manifestation was 1st observed _____ **62**

Rave.11.0_PRD_Annotation: Form Matrix

Form: Systemic Lupus Erythematosus (SLE) and Related Conditions

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Myositis

Never (Baseline); Not Present Since Last Visit (Follow-up) ☐ 63
Manifestation Now or Within 30 Days Prior to Visit ☐
Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) ☐

Month/ Year that Manifestation was 1st observed _____

64

Cardiopulmonary

Pulmonary Hemorrhage

Never (Baseline); Not Present Since Last Visit (Follow-up) ☐ 66
Manifestation Now or Within 30 Days Prior to Visit ☐
Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) ☐

Month/ Year that Manifestation was 1st observed _____

67

Pneumonitis

Never (Baseline); Not Present Since Last Visit (Follow-up) ☐ 68
Manifestation Now or Within 30 Days Prior to Visit ☐
Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) ☐

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Month/ Year that Manifestation was 1st observed _____		69
Pleural Effusion	Never (Baseline); Not Present Since Last Visit (Follow-up) <input type="checkbox"/> Manifestation Now or Within 30 Days Prior to Visit <input type="checkbox"/> Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="checkbox"/>	70
Month/ Year that Manifestation was 1st observed _____		71
Pleuritis	Never (Baseline); Not Present Since Last Visit (Follow-up) <input type="checkbox"/> Manifestation Now or Within 30 Days Prior to Visit <input type="checkbox"/> Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="checkbox"/>	72
Month/ Year that Manifestation was 1st observed _____		73
Pericarditis by EKG	Never (Baseline); Not Present Since Last Visit (Follow-up) <input type="checkbox"/> Manifestation Now or Within 30 Days Prior to Visit <input type="checkbox"/> Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="checkbox"/>	74

Rave.11.0_PRD_Annotation: Form Matrix

Form: Systemic Lupus Erythematosus (SLE) and Related Conditions

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Month/ Year that Manifestation was 1st observed _____		75
Typical pericardial pain for > 1 day	Never (Baseline); Not Present Since Last Visit (Follow-up) <input type="checkbox"/> Manifestation Now or Within 30 Days Prior to Visit <input type="checkbox"/> Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="checkbox"/>	76
Month/ Year that Manifestation was 1st observed _____		77
Pericardial Rub	Never (Baseline); Not Present Since Last Visit (Follow-up) <input type="checkbox"/> Manifestation Now or Within 30 Days Prior to Visit <input type="checkbox"/> Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="checkbox"/>	78
Month/ Year that Manifestation was 1st observed _____		79
Myocarditis	Never (Baseline); Not Present Since Last Visit (Follow-up) <input type="checkbox"/> Manifestation Now or Within 30 Days Prior to Visit <input type="checkbox"/> Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="checkbox"/>	80

Rave.11.0_PRD_Annotation: Form Matrix

Form: Systemic Lupus Erythematosus (SLE) and Related Conditions

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Month/ Year that Manifestation was 1st observed _____

81

Neuro/Psychiatric

Cranial Neuropathy

Never (Baseline); Not Present Since Last Visit (Follow-up) ☐ 83
Manifestation Now or Within 30 Days Prior to Visit ☐
Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) ☐

Month/ Year that Manifestation was 1st observed _____

84

Peripheral neuropathy

Never (Baseline); Not Present Since Last Visit (Follow-up) ☐ 85
Manifestation Now or Within 30 Days Prior to Visit ☐
Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) ☐

Month/ Year that Manifestation was 1st observed _____

86

Seizures

Never (Baseline); Not Present Since Last Visit (Follow-up) ☐ 87
Manifestation Now or Within 30 Days Prior to Visit ☐

Rave.11.0_PRD_Annotation: Form Matrix

Form: Systemic Lupus Erythematosus (SLE) and Related Conditions

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	Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)	<input type="checkbox"/>
Month/ Year that Manifestation was 1st observed		88
Organic Brain Syndrome	Never (Baseline); Not Present Since Last Visit (Follow-up) Manifestation Now or Within 30 Days Prior to Visit Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Month/ Year that Manifestation was 1st observed		89
Cognitive impairment	Never (Baseline); Not Present Since Last Visit (Follow-up) Manifestation Now or Within 30 Days Prior to Visit Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Month/ Year that Manifestation was 1st observed		90
Psychosis	Never (Baseline); Not Present Since Last Visit (Follow-up)	<input type="checkbox"/>

Rave.11.0_PRD_Annotation: Form Matrix
Form: Systemic Lupus Erythematosus (SLE) and Related Conditions
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		Manifestation Now or Within 30 Days Prior to Visit <input type="checkbox"/>
		Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="checkbox"/>
<hr/>		
Month/ Year that Manifestation was 1st observed	_____	94
<hr/>		
Headache (only if not relieved by narcotics)	Never (Baseline); Not Present Since Last Visit (Follow-up) <input type="checkbox"/>	95
	Manifestation Now or Within 30 Days Prior to Visit <input type="checkbox"/>	
	Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="checkbox"/>	
<hr/>		
Month/ Year that Manifestation was 1st observed	_____	96
<hr/>		
Transverse Myelitis	Never (Baseline); Not Present Since Last Visit (Follow-up) <input type="checkbox"/>	97
	Manifestation Now or Within 30 Days Prior to Visit <input type="checkbox"/>	
	Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="checkbox"/>	
<hr/>		
Month/ Year that Manifestation was 1st observed	_____	98
<hr/>		

Rave.11.0_PRD_Annotation: Form Matrix

Form: Systemic Lupus Erythematosus (SLE) and Related Conditions

Generated On: 23 Apr 2019 20:11:55

Cerebrovascular Accident/Stroke	Never (Baseline); Not Present Since Last Visit (Follow-up) <input type="checkbox"/> 99
	Manifestation Now or Within 30 Days Prior to Visit <input type="checkbox"/>
	Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="checkbox"/>
Month/ Year that Manifestation was 1st observed	_____ 100
Visual Disturbance (including retinal vasculitis)	Never (Baseline); Not Present Since Last Visit (Follow-up) <input type="checkbox"/> 101
	Manifestation Now or Within 30 Days Prior to Visit <input type="checkbox"/>
	Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="checkbox"/>
Month/ Year that Manifestation was 1st observed	_____ 102
Mononeuritis Multiplex	Never (Baseline); Not Present Since Last Visit (Follow-up) <input type="checkbox"/> 103
	Manifestation Now or Within 30 Days Prior to Visit <input type="checkbox"/>
	Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="checkbox"/>
Month/ Year that Manifestation was 1st observed	_____ 104

Rave.11.0_PRD_Annotation: Form Matrix

Form: Systemic Lupus Erythematosus (SLE) and Related Conditions

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Gastrointestinal

Pancreatitis

Never (Baseline); Not Present Since Last Visit (Follow-up) ☐ 106
Manifestation Now or Within 30 Days Prior to Visit ☐
Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) ☐

Month/ Year that Manifestation was 1st observed _____

107

Serositis

Never (Baseline); Not Present Since Last Visit (Follow-up) ☐ 108
Manifestation Now or Within 30 Days Prior to Visit ☐
Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) ☐

Month/ Year that Manifestation was 1st observed _____

109

Esophageal Dysmotility

Never (Baseline); Not Present Since Last Visit (Follow-up) ☐ 110
Manifestation Now or Within 30 Days Prior to Visit ☐
Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) ☐

Rave.11.0_PRD_Annotation: Form Matrix

Form: Systemic Lupus Erythematosus (SLE) and Related Conditions

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Not Collected ☐

Month/ Year that Manifestation was 1st observed _____

111

Vasculitis

Other organ (eg GI, skin with ulcerations)

Never (Baseline); Not Present Since Last Visit (Follow-up) ☐ 113

Manifestation Now or Within 30 Days Prior to Visit ☐

Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) ☐

Month/ Year that Manifestation was 1st observed _____

114

Extremity manifestations

Raynaud's

Never (Baseline); Not Present Since Last Visit (Follow-up) ☐ 116

Manifestation Now or Within 30 Days Prior to Visit ☐

Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) ☐

Month/ Year that Manifestation was 1st observed _____

117

Rave.11.0_PRD_Annotation: Form Matrix

Form: Systemic Lupus Erythematosus (SLE) and Related Conditions

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Digital ulcers	Never (Baseline); Not Present Since Last Visit (Follow-up) <input type="checkbox"/> 118
	Manifestation Now or Within 30 Days Prior to Visit <input type="checkbox"/>
	Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="checkbox"/>
	Not Collected <input type="checkbox"/>

Month/ Year that Manifestation was 1st observed	_____ 119
---	-----------

Acrosclerosis	Never (Baseline); Not Present Since Last Visit (Follow-up) <input type="checkbox"/> 120
	Manifestation Now or Within 30 Days Prior to Visit <input type="checkbox"/>
	Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="checkbox"/>
	Not Collected <input type="checkbox"/>

Month/ Year that Manifestation was 1st observed	_____ 121
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Sclerodactyly	Never (Baseline); Not Present Since Last Visit (Follow-up) <input type="checkbox"/> 122
	Manifestation Now or Within 30 Days Prior to Visit <input type="checkbox"/>
	Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) <input type="checkbox"/>

Rave.11.0_PRD_Annotation: Form Matrix

Form: Systemic Lupus Erythematosus (SLE) and Related Conditions

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Not Collected ☐

Month/ Year that Manifestation was 1st observed _____ **123**

Sjogren's manifestations

Parotid gland, submandibular gland, or lacrimal gland swelling

Chronic (persistent swelling) ☐ **125**

Recurrent (periods of swelling followed by periods without swelling) ☐

Never ☐

Unknown/ Not Done ☐

Month/ Year that Manifestation was 1st observed _____ **126**

Recurrent and/or extensive dental caries (ever)

Yes ☐ **127**

No ☐

Unknown/ Not Done ☐

Month/ Year that Manifestation was 1st observed _____ **128**

Dry eyes (for more than 4 months)

Yes ☐ **129**

No ☐

Unknown/ Not Done ☐

Month/ Year that Manifestation was 1st observed _____ **130**

Dry mouth (for more than 4 months)

Yes ☐ **131**

No ☐

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	Unknown/ Not Done	<input type="checkbox"/>	
Month/ Year that Manifestation was 1st observed			132
Ophthalmology assessment for dry eyes (Schirmer test, ocular surface staining)	Normal	<input type="checkbox"/>	133
	Abnormal	<input type="checkbox"/>	
	Unknown/ Not Done	<input type="checkbox"/>	
Month/ Year that Manifestation was 1st observed			134
Salivary gland imaging	Normal	<input type="checkbox"/>	135
	Abnormal	<input type="checkbox"/>	
	Unknown/ Not Done	<input type="checkbox"/>	
Month/ Year that Manifestation was 1st observed			136
IF Abnormal, select imaging modality used (check all that apply):			
MRI		<input type="checkbox"/>	138
Ultrasound		<input type="checkbox"/>	139
Scintigraphy		<input type="checkbox"/>	140
Sialography		<input type="checkbox"/>	141
Unknown/ Not Done		<input type="checkbox"/>	142

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Not Collected

☐ 143

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
① PRIMSLE	1			1 = Systemic Lupus Erythemato sus (SLE) 2 = Acute Cutaneous Lupus (isolated) 3 = Chronic Cutaneous Lupus (including DLE, isolated) 4 = Sjogren's Syndrome 5 = Mixed Connective Tissue Disease 6 = Anti-Phosph olipid Syndrome (Primary) 7 = Probable SLE (at least 3 SLICC Criteria in the last 24 months)




Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
③ FEVERB	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
④ FVRBDTC	MMM- yyyy			
⑦ MALRRAS1	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit




Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
				2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
8 MALR1DTC	MMM-	yyyy		
9 BOLLUPUS	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)



Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
 BOLLDTC	MMM- yyyy			
 TOXEPIDR	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
 TOXEDDTC	MMM- yyyy			

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
 MACURSH	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
 MACURDTC	MMM- yyyy			
 PHOTORSH	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit

Rave.11.0_PRD_Annotation: Form Matrix
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Field Name	Data Type	SAS Label	Units	Values
				2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
 PHOTODTC	MMM-	yyyy		
 SUBCLUP	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)

Rave.11.0_PRD_Annotation: Form Matrix
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Field Name	Data Type	SAS Label	Units	Values
18 SUBCLDTC	MMM- yyyy			
20 LOCALIZE	1			1 = Yes 0 = No
21 DISCOIDR	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
22 DISCODTC	MMM- yyyy			
23 GENERAL	1			1 = Yes 0 = No

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Field Name	Data Type	SAS Label	Units	Values
24 DISCOIDG	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
25 DISCGDTC	MMM- yyyy			
26 HYPLUPUS	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
				2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
27	HYPLUDTC	MMM- yyyy		
28	LUPUPANN	1		0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
29 LUPUPDTC	MMM- yyyy			
30 MUCLUPUS	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
31 MUCLUDTC	MMM- yyyy			

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
32 LUERYTUM	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
33 LUERYDTC	MMM- yyyy			
34 CHILLUPU	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
				2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
35 CHILLDTC	MMM-	yyyy		
36 DILICPLN	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
37 DILICDTC	MMM- yyyy			
39 PALATE	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
40 PALATDTC	MMM- yyyy			

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions**

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Field Name	Data Type	SAS Label	Units	Values
41 BUCCAL	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
42 BUCCADTC	MMM- yyyy			
43 TONGUE	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
				2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
44	TONGUDTC	MMM- yyyy		
45	NASULCER	1		0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
46 NASULDTC	MMM- yyyy			
47 NSCRALOP	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
48 NSCRADTC	MMM- yyyy			

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
50 HEMANEMI	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
51 HEMANDTC	MMM- yyyy			
52 OTHANEMI	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
				2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
53	OTHANDTC	MMM- yyyy		
54	THRMBOCY	1		0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)

Rave.11.0_PRD_Annotation: Form Matrix

Form: Systemic Lupus Erythematosus (SLE) and Related Conditions

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Field Name	Data Type	SAS Label	Units	Values
55 THRMBDTC	MMM- yyyy			
56 LEUKOPEN	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
57 LEUKODTC	MMM- yyyy			

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
58 ANTIDNA	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
59 ANTIDDTCTC	MMM- yyyy			
61 ARTHRITB	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
				2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
62 ARTHRDTC	MMM-	yyyy		
63 MYOSITIB	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)

Rave.11.0_PRD_Annotation: Form Matrix
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Field Name	Data Type	SAS Label	Units	Values
64 MYOSIDTC	MMM- yyyy			
66 PULHEMOR	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
67 PULHEDTC	MMM- yyyy			

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions**

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Field Name	Data Type	SAS Label	Units	Values
68 PNEUMONI	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
69 PNEUMDTC	MMM- yyyy			
70 PLEUREFF	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
				2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
71 PLEURDTC	MMM-	yyyy		
72 PLEURITS	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
73 PLUREDTC	MMM- yyyy			
74 PERIEKG	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
75 PERICDTC	MMM- yyyy			

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
76 TYPERPAN	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
77 TYPERDTC	MMM- yyyy			
78 PERIRUB	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
				2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
79 PERIRDTC	MMM- yyyy			
80 MYOCARDI	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
81 MYOCADTC	MMM- yyyy			
83 CRANNEUR	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
84 CRANNDTC	MMM- yyyy			

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions**

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Field Name	Data Type	SAS Label	Units	Values
85 PERINEUR	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
86 PERINDTC	MMM- yyyy			
87 SEIZURES	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit




Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
				2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
88 SEIZUDTC	MMM- yyyy			
89 ORGBRNSY	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
90 ORGBRDTC	MMM- yyyy			
91 COGNIMPR	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
92 COGNIDTC	MMM- yyyy			

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
 PSYCHOSI	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
 PSYCHDTC	MMM- yyyy			
 HEADACHB	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
				2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
96 HEADADTC	MMM- yyyy			
97 TRANSMYL	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
98 TRANSDTC	MMM- yyyy			
99 CERACCST	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
100 CERACDTC	MMM- yyyy			

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions**

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Field Name	Data Type	SAS Label	Units	Values
101 VISDISTU	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
102 VISDIDTC	MMM- yyyy			
103 MONOMULT	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit

Rave.11.0_PRD_Annotation: Form Matrix
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Field Name	Data Type	SAS Label	Units	Values
				2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
104	MONOMDTCMMM-	yyyy		
106	PANCREAT	1		0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
107PANCRTDC	MMM- yyyy			
108SEROSITI	1			0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
109SEROSDTC	MMM- yyyy			

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
110 ESOPHDYS 2				0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up) 95 = Not Collected
111 ESOPHDTC MMM- yyyy				

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions**

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Field Name	Data Type	SAS Label	Units	Values
113OTHROGRN 1				0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
114OTHRODTC MMM- yyyy				
115RAYNAUDS 1				0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
				2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)
117	RAYNADTC	MMM- yyyy		
118	DIGULCER	2		0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestatio n Now or Within 30 Days Prior to Visit 2 = Manifestatio n > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
				95 = Not Collected
119	DIGULDTC	MMM- yyyy		
120	ACROSCLR	2		0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestation Now or Within 30 Days Prior to Visit 2 = Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
				95 = Not Collected
121	ACROSDTC	MMM- yyyy		
122	SCLERODT	2		0 = Never (Baseline); Not Present Since Last Visit (Follow-up) 1 = Manifestation Now or Within 30 Days Prior to Visit 2 = Manifestation > 30 Days Prior to Visit (Baseline); >30 Days Prior to Visit but Since Last Visit (Follow-up)

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
				95 = Not Collected
125 SCLERDTC	MMM- yyyy			
125 PAROTID	1			1 = Chronic (persistent swelling) 2 = Recurrent (periods of swelling followed by periods without swelling) 3 = Never 4 = Unknown/ Not Done
126 PAROTDTC	MMM- yyyy			
127 RECDENTL	2			1 = Yes 0 = No 99 = Unknown/ Not Done
128 RECDDEDTC	MMM- yyyy			
129 DRYEYES	2			1 = Yes 0 = No

Rave.11.0_PRD_Annotation: Form Matrix**Form: Systemic Lupus Erythematosus (SLE) and Related Conditions**

Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				99 = Unknown/ Not Done
130	DRYEYDTC	MMM- yyyy		
131	DRYMOUTH	2		1 = Yes 0 = No 99 = Unknown/ Not Done
132	DRYMODTC	MMM- yyyy		
133	OPHTHALB	2		1 = Normal 2 = Abnormal 99 = Unknown/ Not Done
134	OPHTHDTC	MMM- yyyy		
135	SALIVARY	2		1 = Normal 2 = Abnormal 99 = Unknown/ Not Done
136	SALIVDTC	MMM- yyyy		

Rave.11.0_PRD_Annotation: Form Matrix

Form: Systemic Lupus Erythematosus (SLE) and Related Conditions

Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
138 SALMRI	1			
139 SALULTRA	1			
140 SALSCINT	1			
141 SALSIALO	1			
142 SALUNKND	1			
143 SALNC	1			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Sjogren's Form
Generated On: 23 Apr 2019 20:11:55

Sjogren's Specific Biopsy Results

Has the subject [ever: baseline/since last visit:
follow-up] had a non-renal biopsy?

Yes ☐ ②
No ☐
Unknown ☐

IF YES, describe the findings:

Consistent with Sjogren's ☐ ③
Normal/No focal
inflammation ☐
Other/Unclear ☐

Was a focus score used?

Yes ☐ ④
No ☐
Unknown ☐

Topical Ocular Meds (select all that the subject is currently taking):

Cyclosporine 0.1% ☐ ⑥

Dexamethasone eye drops ☐ ⑦

Lifitegrast ☐ ⑧

Unknown/Not Done ☐ ⑨


Other: ☐ ⑩

(free text box) _____ ⑪

Rave.11.0_PRD_Annotation: Form Matrix
Form: Sjogren's Form
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
② NONRENAL	2			1 = Yes 0 = No 99 = Unknown
③ NONFINDG	1			1 = Consistent with Sjogren's 2 = Normal/No focal inflammatio n 3 = Other/Uncle ar
④ FOCUSORE	2			1 = Yes 0 = No 99 = Unknown
⑥ CYCLOSP0	1			
⑦ DEXAMETH	1			
⑧ LIFITEGR	1			
⑨ TOPOCUNK	1			
⑩ OCULAROT	1			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Sjogren's Form
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
<hr/>				
 OCULARSP	\$50			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Idiopathic Arthritis
Generated On: 23 Apr 2019 20:11:55

Total number of joints ever affected with arthritis

< 5 joints ☐ ①
>= 5 joints ☐
Not done ☐
Unknown ☐

JIA category of subject

Systemic arthritis ☐ ②
Oligoarthritis ☐
Polyarthritis (Rheumatoid factor negative) ☐
Polyarthritis (Rheumatoid factor positive) ☐
Psoriatic arthritis ☐
Enthesitis related arthritis ☐
Undifferentiated arthritis ☐

Arthritis in one or more joints

☐ ③

Daily fever

☐ ④

Evanescent (non-fixed) erythematous rash

☐ ⑤

Generalized lymphadenopathy

☐ ⑥

Hepatomegaly

☐ ⑦

Splenomegaly

☐ ⑧

Serositis

☐ ⑨

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Idiopathic Arthritis
Generated On: 23 Apr 2019 20:11:55

Arthritis in one to 4 joints during the first six months of disease	<input type="checkbox"/> 10
Persistent: affecting no more than 4 joints throughout the disease course	<input type="checkbox"/> 11
Extended: affecting a total of more than 4 after the first 6 months of the disease	<input type="checkbox"/>
Unknown at this time	<input type="checkbox"/>
Arthritis affecting 5 or more joints during the first six months of disease	<input type="checkbox"/> 12
Test for RF is negative	<input type="checkbox"/> 13
Arthritis affecting 5 or more joints during the first six months of disease	<input type="checkbox"/> 14
Test for RF is positive	<input type="checkbox"/> 15
Arthritis	<input type="checkbox"/> 16
Psoriasis	<input type="checkbox"/> 17
Dactylitis	<input type="checkbox"/> 18
Nail pitting or onycholysis	<input type="checkbox"/> 19

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Idiopathic Arthritis
Generated On: 23 Apr 2019 20:11:55

Psoriasis in a first-degree relative	<input type="checkbox"/>	20
Arthritis	<input type="checkbox"/>	21
Enthesitis	<input type="checkbox"/>	22
Sacroiliac joint tenderness and/or inflammatory lumbosacral pain	<input type="checkbox"/>	23
Positive HLA-B27 antigen	<input type="checkbox"/>	24
Actute (symptomatic) anterior uveitis	<input type="checkbox"/>	25
History of ankylosing spondylitis, enthesitis related arthritis, sacroilitis with inflammatory bowel disease, Reiter's syndrome, or acute anterior uveitis in a first degree relative	<input type="checkbox"/>	26
Arthritis that fulfills criteria in no category (e.g. because of the presence of exclusion criteria)	<input type="checkbox"/>	27
Arthritis that fulfills criteria in 2 or more categories	<input type="checkbox"/>	28
Was subject newly started on Methotrexate and/or a biologic at this visit?	Yes <input type="checkbox"/> No <input type="checkbox"/>	29
Has subject ever had Uveitis (Baseline) or has the subject had new onset, or previously reported Uveitis (Followup)?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	30

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Idiopathic Arthritis
Generated On: 23 Apr 2019 20:11:55

Has subject had an eye exam for Uveitis (follow-up:
since the last visit)?

Yes ☐ **31**
No ☐
Unknown ☐

Disease manifestations within the last 2 weeks

Fever attributable to JIA

Yes ☐ **32**
No ☐
Unknown ☐

Evanescant rash attributable to JIA

Yes ☐ **34**
No ☐
Unknown ☐

Generalized lymphadenopathy attributable to JIA

Yes ☐ **35**
No ☐
Unknown ☐

Hepatomegaly attributable to JIA

Yes ☐ **36**
No ☐
Unknown ☐

Splenomegaly attributable to JIA

Yes ☐ **37**
No ☐
Unknown ☐

Serositis attributable to JIA

Yes ☐ **38**
No ☐
Unknown ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Idiopathic Arthritis
Generated On: 23 Apr 2019 20:11:55

Psoriasis (active skin lesions) Yes ☐ 39
No ☐
Unknown ☐

Inflammatory back pain: Has the subject had symptoms suggestive of active inflammatory back pain, such as pain that improves with activity, worsens with rest, is associated with stiffness, and responds to NSAIDs? Yes ☐ 40
No ☐
Unknown ☐
Not Collected ☐

Total number of active joints (current assessment) _____ 41

Total number of joints with limited range of motion (current assessment) _____ 42

Active Enthesitis Yes ☐ 43
No ☐
Not Assessed ☐

Tender entheses count: _____ 44

Clinically active sacroilitis None ☐ 45
Right ☐
Left ☐
Bi-lateral ☐
Not Assessed ☐

Morning stiffness None ☐ 46
<= 15 Minutes ☐
16-60 Minutes ☐
>60 Minutes ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Idiopathic Arthritis
Generated On: 23 Apr 2019 20:11:55

Unknown ☐

Modified Schobers Test

Fixed Unit: cm **47**

Temporomandibular Joint Arthritis (TMJ):

Has the temporomandibular joint (TMJ) ever been imaged (Baseline) or has the TMJ been imaged since last visit (Follow-up)?

Yes ☐ **49**

No ☐

Unknown ☐

Not Collected ☐

IF Yes, how was the TMJ imaged? (select all that apply):

MRI with contrast ☐ **51**

MRI without contrast ☐ **52**

Ultrasound ☐ **53**

CBCT (Cone Beam CT Scan) ☐ **54**

X-ray ☐ **55**

Other: ☐ **56**

(specify) ☐ **57**

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Idiopathic Arthritis
Generated On: 23 Apr 2019 20:11:55

Maximal Mouth Opening Assessment (at this visit)	Greater than Three Fingers (normal) <input type="checkbox"/> 58
	Less than Three Fingers (abnormal) <input type="checkbox"/>
	Total incisal distance <input type="checkbox"/>
	Not Done <input type="checkbox"/>
	Not Collected <input type="checkbox"/>

Total incisional distance

Fixed Unit: mm **59**

Has subject been diagnosed as having active TMJ arthritis?	Yes <input type="checkbox"/> 60
	No <input type="checkbox"/>
	Unknown <input type="checkbox"/>
	Not Collected <input type="checkbox"/>

Has subject ever received intra-articular TMJ therapy (Baseline) or has subject received intra-articular TMJ therapy since last visit (Follow-up)?	Yes <input type="checkbox"/> 61
	No <input type="checkbox"/>
	Unknown <input type="checkbox"/>
	Not Collected <input type="checkbox"/>

IF Yes, treatment:

Intra articular glucocorticoid injection	<input type="checkbox"/> 62
Arthrocentesis and lavage and glucocorticoids	<input type="checkbox"/>
Arthrocentesis and lavage	<input type="checkbox"/>
Iontophoresis	<input type="checkbox"/>
Other: (specify)	<input type="checkbox"/>

Were systemic treatment changes made at this visit (or since last visit) based on TMJ arthritis?	Yes <input type="checkbox"/> 63
	No <input type="checkbox"/>
	Unknown <input type="checkbox"/>

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Idiopathic Arthritis
Generated On: 23 Apr 2019 20:11:55

Not Collected ☐

Imaging Results:

Radiographic evidence of damage of joints

Yes ☒ 65
No ☐
Not done ☐
Unknown ☐

Imaging evidence of SI damage (sclerosis, joint space narrowing, ankyloses) by X-ray, MRI or CT

Yes ☒ 66
No ☐
Not done ☐
Unknown ☐

Imaging evidence of active SI arthritis (synovitis, bone marrow edema) by MRI or CT

Yes ☒ 67
No ☐
Not done ☐
Unknown ☐

Did the subject ever have an MRI (Baseline) or has the subject had an MRI since last visit (Follow-up) of the sacroiliac joints?

Yes ☒ 68
No ☐
Unknown ☐
Not Collected ☐

IF Yes Date of most recent MRI:

69

Did the MRI show signs of active SI arthritis (e.g., bone marrow edema, gadolinium contrast enhancement)?

Yes ☒ 70
No ☐
Unknown ☐

Rave.11.0_PRD_Annotation: Form Matrix

Form: Juvenile Idiopathic Arthritis

Generated On: 23 Apr 2019 20:11:55

Did the MRI show signs of chronic SI damage (e.g., sclerosis, erosions, fusion/ankyloses, joint space narrowing, joint space widening)?

Yes ☒ 71
No ☐
Unknown ☐

Did the subject ever have an x-ray (Baseline) or has the subject had an x-ray since last visit (Follow-up) of the sacroiliac joints?

Yes ☒ 72
No ☐
Unknown ☐
Not Collected ☐

IF Yes Date of most recent XR: _____

73

Was the x-ray consistent with SI arthritis (e.g., sclerosis, erosions, fusion, joint space narrowing, joint space widening)?

Yes ☒ 74
No ☐
Unknown ☐




Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Idiopathic Arthritis
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① TOTJOINT	2	Total number of joints ever affected		1 = < 5 joints 2 = >= 5 joints 97 = Not done 99 = Unknown
② JIACAT	1	JIA category		1 = Systemic arthritis 2 = Oligoarthritis 3 = Polyarthritis (Rheumatoid factor negative) 4 = Polyarthritis (Rheumatoid factor positive) 5 = Psoriatic arthritis 6 = Enthesitis related arthritis 7 = Undifferentiated arthritis

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Idiopathic Arthritis
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
3	SYSART1	1	SJIA: Arthritis in one or more joints		
4	SYSART2	1	SJIA: Daily fever		
5	SYSART3	1	SJIA: Evanescent erythemato sus rash		
6	SYSART4	1	SJIA: Generalized lymphadeno pathy		
7	SYSART5	1	SJIA: Hepatomeg aly		
8	SYSART6	1	SJIA: Splenomeg aly		
9	SYSART7	1	SJIA: Serositis		
10	ARTHRIT4	1	Oligo: Arthritis 1-4 joints 1st 6 months		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Idiopathic Arthritis
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
 ART4AFCT	2	Oligo: type		1 = Persistent: affecting no more than 4 joints throughout the disease course 2 = Extended: affecting a total of more than 4 after the first 6 months of the disease 99 = Unknown at this time
 RHUMNEG1	1	Poly neg: Arthritis affecting 5 or more joints during the first six months of disease		
 RHUMNEG2	1	Poly neg: Test for RF is negative		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Idiopathic Arthritis
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
14 RHUMPOS1	1	Poly pos: Arthritis affecting 5 or more joints during the first six months of disease		
15 RHUMPOS2	1	Poly pos: Test for RF is positive		
16 PSORIAT1	1	Psoriatis: Arthritis		
17 PSORIAT2	1	Psoriatis: Psoriasis		
18 PSORIAT3	1	Psoriatis: Dactylitis		
19 PSORIAT4	1	Psoriatis: Nail pitting or onycholysis		
20 PSORIAT5	1	Psoriatis: Psoriasis in relative		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Idiopathic Arthritis
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
21	ENTHES1	1	Enthesitis: Arthritis		
22	ENTHES2	1	Enthesitis: Enthesitis		
23	ENTHES3	1	Enthesitis:S acroiliac joint tenderness		
24	ENTHES4	1	Enthesitis: Positive HLA-B27 antigen		
25	ENTHES5	1	Enthesitis: Actute anterior uveitis		
26	ENTHES6	1	Enthesitis: HX of ankyl spond relative		
27	UNARTHR1	1	Undiff: Arthritis that fulfills criteria in no category		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Idiopathic Arthritis
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
28 UNARTHR2	1	Undiff: Arthritis that fulfills criteria in 2 or more categories		
29 NEWMED	1	Newly started on Methotrexat e and/or a biologic at this visit		1 = Yes 0 = No
30 NEWUVEIT	2	Ever had Uveitis (Baseline) or new onset Uveitis (Followup)		1 = Yes 0 = No 99 = Unknown
31 FUEYEEXM	2	Eye exam for Uveitis		1 = Yes 0 = No 99 = Unknown
32 FEVER	2	Fever attributable to JIA		1 = Yes 0 = No 99 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Idiopathic Arthritis
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
34 EVANRASH	2	Evanescant rash attributable to JIA		1 = Yes 0 = No 99 = Unknown
35 GENLYMPH	2	Generalized lymphadeno pathy		1 = Yes 0 = No 99 = Unknown
36 HEPATOMG	2	Hepatomeg aly		1 = Yes 0 = No 99 = Unknown
37 SPLENOMG	2	Splenomeg aly		1 = Yes 0 = No 99 = Unknown
38 SEROSITS	2	Serositis		1 = Yes 0 = No 99 = Unknown
39 PSORIAS	2	Psoriasis (active skin lesions)		1 = Yes 0 = No 99 = Unknown
40 INFLBKPN	2			1 = Yes 0 = No 99 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Idiopathic Arthritis
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				95 = Not Collected
41 ACTJONUM	\$2	Total number of active joints		
42 LRMJONUM	\$2			
43 ACTENTHE	1	Active Enthesitis		1 = Yes 0 = No 2 = Not Assessed
44 TNDRECNT	2	Tender entheses count:		
45 ACTSACRO	1	Clinically active sacroilitis		1 = None 2 = Right 3 = Left 4 = Bi-lateral 9 = Not Assessed
46 MORSTIFF	2	Morning stiffness		1 = None 2 = <= 15 Minutes 3 = 16-60 Minutes 4 = >60 Minutes

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Idiopathic Arthritis
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				99 = Unknown
47 SCHOBERS	5.2	Modified Schobers Test		
49 TMJ	2			1 = Yes 0 = No 99 = Unknown 95 = Not Collected
51 MRICONTR	1			
52 MRIWCONT	1			
53 TMJULTRA	1			
54 CBCT	1			
55 TMJXRAY	1			
56 TMJOTHR	1			
57 TMJSPY	\$50			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Idiopathic Arthritis
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
58 MMOA	2			1 = Greater than Three Fingers (normal) 2 = Less than Three Fingers (abnormal) 3 = Total incisal distance 97 = Not Done 95 = Not Collected
59 MAXMOUTH2				
60 DIAGTMJ	2			1 = Yes 0 = No 99 = Unknown 95 = Not Collected
61 INTTMJTY	2			1 = Yes 0 = No 99 = Unknown 95 = Not Collected

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Idiopathic Arthritis
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
62 TMJTREAT	2			1 = Intra articular glucocortico id injection 2 = Arthrocente sis and lavage and glucocortico ids 3 = Arthrocente sis and lavage 4 = Iontophores is 98 = Other: (specify)
63 SYSTRTMJ	2			1 = Yes 0 = No 99 = Unknown 95 = Not Collected
65 RADIDAMG	2	Radiographi c evidence of joint damage		1 = Yes 0 = No 97 = Not done 99 = Unknown
66 SIDAMAGE	2	Imaging evidence of SI damage		1 = Yes 0 = No

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Idiopathic Arthritis
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				97 = Not done 99 = Unknown
67 SIARTHRI	2	Imaging evidence of active SI arthritis by MRI or CT		1 = Yes 0 = No 97 = Not done 99 = Unknown
68 MRI	2			1 = Yes 0 = No 99 = Unknown 95 = Not Collected
69 MRIDT	dd MMM YYYY			
70 MRISI	2			1 = Yes 0 = No 99 = Unknown
71 MRICSI	2			1 = Yes 0 = No 99 = Unknown
72 XRAYJIA	2			1 = Yes 0 = No

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Idiopathic Arthritis
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				99 = Unknown 95 = Not Collected
73 XRDT	dd MMM YYYY			
74 XRSI	2			1 = Yes 0 = No 99 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis (JDM) Form Part I.
Generated On: 23 Apr 2019 20:11:55

Please select Juvenile Dermatomyositis (JDM)/Juvenile Polymyositis (JPM)

Juvenile Dermatomyositis (JDM) ☐ ①
Juvenile Polymyositis ☐

If JDM, does patient have amyopathic/hypomyopathic/skin predominant disease?

Yes ☐ ②
No ☐
Unknown ☐

Myositis Diagnostic Features

History of symmetric proximal muscle weakness present?

Yes ☐ ④
No ☐
Unknown ☐

History of rash consistent with JDM present (Gottron's papules/sign and/or heliotrope rash)?

Yes ☐ ⑤
No ☐
Unknown ☐

Was an EMG performed?

Yes ☐ ⑥
No ☐
Unknown ☐

If yes,

Consistent with myositis ☐ ⑦
Abnormal but not consistent with myositis ☐
Normal ☐
Unknown ☐

Was a muscle biopsy performed?

Yes ☐ ⑧
No ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis (JDM) Form Part I.
Generated On: 23 Apr 2019 20:11:55

Unknown ☐

If yes,

Consistent with myositis ☐ **9**
Abnormal but not
consistent with myositis ☐
Normal ☐
Unknown ☐

Are elevated muscle enzymes present (now or
previously)?

Yes ☐ **10**
No ☐
Unknown ☐

Was an MRI performed?

Yes ☐ **11**
No ☐
Unknown ☐

If yes,

Consistent with myositis ☐ **12**
Abnormal but not
consistent with myositis ☐
Normal ☐
Unknown ☐

Previous treatment with DMARD, biologic or IVIG (i.e.
prior to registry enrollment)?

Yes ☐ **13**
No ☐
Unknown ☐

For the following lab tests, indicate the highest value prior to registry enrollment (and
since presumed disease onset)

Highest CK

Available ☐ **15**

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis (JDM) Form Part I.
Generated On: 23 Apr 2019 20:11:55

	Not Available	<input type="checkbox"/>
	Fixed Unit: U/L	<input checked="" type="checkbox"/> 16
	Fixed Unit: ULN	<input checked="" type="checkbox"/> 17
Highest ALT	Available	<input type="checkbox"/> 18
	Not Available	<input type="checkbox"/>
	Fixed Unit: U/L	<input checked="" type="checkbox"/> 19
	Fixed Unit: ULN	<input checked="" type="checkbox"/> 20
Highest AST	Available	<input type="checkbox"/> 21
	Not Available	<input type="checkbox"/>
	Fixed Unit: U/L	<input checked="" type="checkbox"/> 22
	Fixed Unit: ULN	<input checked="" type="checkbox"/> 23
Highest LDH	Available	<input type="checkbox"/> 24
	Not Available	<input type="checkbox"/>

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis (JDM) Form Part I.
Generated On: 23 Apr 2019 20:11:55

Fixed Unit: U/L **25**

Fixed Unit: ULN **26**

Highest Aldolase

Available ☐ **27**

Not Available ☐

Fixed Unit: U/L **28**

Fixed Unit: ULN **29**

Extramuscular Disease Activity (in the previous 4 weeks):

A. Constitutional Disease

Fever (>38.5°C) due to myositis

Present ☐ **32**

Absent ☐

Unknown ☐

Weight loss (>5%) due to myositis

Present ☐ **33**

Absent ☐

Unknown ☐

Fatigue due to myositis

Present ☐ **34**

Absent ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis (JDM) Form Part I.
Generated On: 23 Apr 2019 20:11:55

Unknown ☐

Global VAS for Constitutional Disease

Fixed Unit: Score **35**

B. Skeletal Disease

Arthritis

Present ☐ **37**

Absent ☐

Unknown ☐

Global VAS for Skeletal Disease

Fixed Unit: Score **38**

C. Gastrointestinal Disease

Dysphagia due to myositis

Present ☐ **40**

Absent ☐

Unknown ☐

Abdominal pain due to myositis

Present ☐ **41**

Absent ☐

Unknown ☐

Gastrointestinal ulceration (not oral ulcers) due to myositis

Present ☐ **42**

Absent ☐

Unknown ☐

Global VAS for Gastrointestinal Disease

Fixed Unit: Score **43**

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis (JDM) Form Part I.
Generated On: 23 Apr 2019 20:11:55

D. Pulmonary Disease

Pulmonary involvement (respiratory muscle weakness) Present ☐ 45
Absent ☐
Unknown ☐

Pulmonary involvement (interstitial lung disease) Present ☐ 46
Absent ☐
Unknown ☐

Dysphonia due to myositis Present ☐ 47
Absent ☐
Unknown ☐

Global VAS for Pulmonary Disease Fixed Unit: Score 48

E. Cardiovascular Disease

Cardiovascular involvement due to myositis (pericarditis, myocarditis, arrhythmia) Present ☐ 50
Absent ☐
Unknown ☐

Global VAS for Cardiovascular Disease Fixed Unit: Score 51

F. Other Extramuscular Disease Activity (excluding skin and muscle)? Yes ☐ 52
No ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis (JDM) Form Part I.
Generated On: 23 Apr 2019 20:11:55

If yes, in what organ system?

53

Global VAS for this organ system:

Fixed Unit: Score 54

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis (JDM) Form Part I.
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① PRIMJDM	1			1 = Juvenile Dermatomyositis (JDM) 2 = Juvenile Polymyositis
② IFJDM	2			1 = Yes 0 = No 99 = Unknown
④ HXSYPMPRO	2			1 = Yes 0 = No 99 = Unknown
⑤ HXRASH	2			1 = Yes 0 = No 99 = Unknown
⑥ EMG	2			1 = Yes 0 = No 99 = Unknown
⑦ EMGYES	2			1 = Consistent with myositis

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis (JDM) Form Part I.
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				2 = Abnormal but not consistent with myositis 3 = Normal 99 = Unknown
8 MUSBIOP	2			1 = Yes 0 = No 99 = Unknown
9 MUSBPYES	2			1 = Consistent with myositis 2 = Abnormal but not consistent with myositis 3 = Normal 99 = Unknown
10 ELMUSENZ	2			1 = Yes 0 = No 99 = Unknown
11 MRIPERF	2			1 = Yes 0 = No

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis (JDM) Form Part I.
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				99 = Unknown
12 MRIYES	2			1 = Consistent with myositis 2 = Abnormal but not consistent with myositis 3 = Normal 99 = Unknown
13 PRVDMARD	2			1 = Yes 0 = No 99 = Unknown
15 HIGHCK	1			1 = Available 0 = Not Available
16 CKUL	8.3			
17 CKULN	8.3			
18 HIGHALT	1			1 = Available

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis (JDM) Form Part I.
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				0 = Not Available
19 ALTUL	8.3			
20 HALTULN	8.3			
21 HIGHAST	1			1 = Available 0 = Not Available
22 HASTUL	8.3			
23 HASTULN	8.3			
24 HIGHLDH	1			1 = Available 0 = Not Available
25 HLDHUL	8.3			
26 HHLDULN	8.3			
27 HIGHALDO	1			1 = Available 0 = Not Available

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis (JDM) Form Part I.
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
28 HALDOUL	8.3			
29 HALDOULN	8.3			
32 FEVERMY	2			1 = Present 0 = Absent 97 = Unknown
33 WEIGHTLO	2			1 = Present 0 = Absent 97 = Unknown
34 FATIGMYT	2			1 = Present 0 = Absent 97 = Unknown
35 GLBVASA	\$4			Disease Activity
37 JARTHRIT	2			1 = Present 0 = Absent 97 = Unknown
38 GBLVASB	\$4			Disease Activity
40 DYSPHAGI	2			1 = Present 0 = Absent

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis (JDM) Form Part I.
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				97 = Unknown
41 ABDOMPAN	2			1 = Present 0 = Absent 97 = Unknown
42 GASULCMY	2			1 = Present 0 = Absent 97 = Unknown
43 GBLVASC	\$4			Disease Activity
45 PULRESPW	2			1 = Present 0 = Absent 97 = Unknown
46 PULINTLU	2			1 = Present 0 = Absent 97 = Unknown
47 DYSPHONA	2			1 = Present 0 = Absent 97 = Unknown
48 GBLVASD	\$4			Disease Activity

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis (JDM) Form Part I.
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
50 CARDMYTO	2			1 = Present 0 = Absent 97 = Unknown
51 GBLVASE	\$4			Disease Activity
52 EXTRADIS	2			1 = Yes 0 = No
53 ORGANSYS	\$50			
54 GBLVASF	\$4			Disease Activity

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis (JDM) Form Part II.
Generated On: 23 Apr 2019 20:11:55

Skin Disease Activity (Cutaneous Activity Tool); Skin Lesions Present at Time of Assessment:

1. - Gottron's papules or Gottron's sign Present ☐ ②
Absent ☐
Unknown ☐

2. - Heliotrope rash Present ☐ ③
Absent ☐
Unknown ☐

3. - Malar or facial erythema Present ☐ ④
Absent ☐
Unknown ☐

4. - Linear extensor erythema Present ☐ ⑤
Absent ☐
Unknown ☐

5. - 'V' sign Present ☐ ⑥
Absent ☐
Unknown ☐

6. - Shawl sign Present ☐ ⑦
Absent ☐
Unknown ☐

7. - Non-sun exposed erythema Present ☐ ⑧
Absent ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis (JDM) Form Part II.
Generated On: 23 Apr 2019 20:11:55

	Unknown	<input type="checkbox"/>
<hr/>		
8. - Extensive cutaneous erythema	Present	<input type="checkbox"/> 9
	Absent	<input type="checkbox"/>
	Unknown	<input type="checkbox"/>
<hr/>		
9. - Livedo reticularis	Present	<input type="checkbox"/> 10
	Absent	<input type="checkbox"/>
	Unknown	<input type="checkbox"/>
<hr/>		
10. - Cutaneous ulceration	Present	<input type="checkbox"/> 11
	Absent	<input type="checkbox"/>
	Unknown	<input type="checkbox"/>
<hr/>		
11. - Mucus membrane lesions	Present	<input type="checkbox"/> 12
	Absent	<input type="checkbox"/>
	Unknown	<input type="checkbox"/>
<hr/>		
12. - Periungual capillary loop changes	Present	<input type="checkbox"/> 13
	Absent	<input type="checkbox"/>
	Unknown	<input type="checkbox"/>
<hr/>		
13. - Mechanic's hands	Present	<input type="checkbox"/> 14
	Absent	<input type="checkbox"/>
	Unknown	<input type="checkbox"/>
<hr/>		
14. - Cuticular overgrowth	Present	<input type="checkbox"/> 15
	Absent	<input type="checkbox"/>
	Unknown	<input type="checkbox"/>

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis (JDM) Form Part II.
Generated On: 23 Apr 2019 20:11:55

15. - Subcutaneous oedema

Present ☐ 16
Absent ☐
Unknown ☐

16. - Panniculitis

Present ☐ 17
Absent ☐
Unknown ☐

17. - Alopecia (non-scarring)

Present ☐ 18
Absent ☐
Unknown ☐

Cutaneous Activity Tool Score

Fixed Unit: (auto-calculate) 19

Calcinosis Assessment

Calcinosis Ever

Yes ☐ 21
No ☐
Unknown ☐

If yes, calcinosis onset:

22

Calcinosis phenotype

☐ 23

Superficial plaques or nodules

Deep tumorous nodules or masses

☐ 24

Fascial plane

☐ 25

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis (JDM) Form Part II.
Generated On: 23 Apr 2019 20:11:55

Exoskeleton	<input type="checkbox"/>	26
<hr/>		
Calcinosis severity	Fixed Unit: Score	27
<hr/>		
Calcinosis diagnosed by Clinical exam	<input type="checkbox"/>	28
<hr/>		
X-ray	<input type="checkbox"/>	29
<hr/>		
CT Scan	<input type="checkbox"/>	30
<hr/>		
Other:	<input type="checkbox"/>	31
<hr/>		
Specify		32
<hr/>		
Calcinosis current	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	33
<hr/>		
How much pain have you had IN THE PAST WEEK due to your CALCINOSIS only?		34
<hr/>		
How much physical limitation have you had IN THE PAST WEEK due to your CALCINOSIS only?		35
<hr/>		
Overlap Features		
<hr/>		
Raynaud's (ever [baseline], since last visit [follow-up])	Yes <input type="checkbox"/>	37
<hr/>		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis (JDM) Form Part II.
Generated On: 23 Apr 2019 20:11:55

No ☐
Unknown ☐

If yes, Requiring Treatment?

Yes ☒ 38
No ☐
Unknown ☐

Sclerodactyly (ever [baseline], since last visit
[follow-up])

Yes ☒ 39
No ☐
Unknown ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis (JDM) Form Part II.
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
② GOTTRON	2			1 = Present 0 = Absent 97 = Unknown
③ HELIOTRO	2			1 = Present 0 = Absent 97 = Unknown
④ MALARERY	2			1 = Present 0 = Absent 97 = Unknown
⑤ LINERYTH	2			1 = Present 0 = Absent 97 = Unknown
⑥ VSIGN	2			1 = Present 0 = Absent 97 = Unknown
⑦ SHAWLSIG	2			1 = Present 0 = Absent 97 = Unknown
⑧ NSUNERYT	2			1 = Present 0 = Absent 97 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis (JDM) Form Part II.
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
9 EXTCUTER	2			1 = Present 0 = Absent 97 = Unknown
10 LIVEDO	2			1 = Present 0 = Absent 97 = Unknown
11 CUTULCER	2			1 = Present 0 = Absent 97 = Unknown
12 MUMEMLES	2			1 = Present 0 = Absent 97 = Unknown
13 PERCAPLO	2			1 = Present 0 = Absent 97 = Unknown
14 MECHANIC	2			1 = Present 0 = Absent 97 = Unknown
15 CUTOVRGR	2			1 = Present 0 = Absent 97 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis (JDM) Form Part II.
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
16 SUBCUOED	2			1 = Present 0 = Absent 97 = Unknown
17 PANNICUL	2			1 = Present 0 = Absent 97 = Unknown
18 JALOPECI	2			1 = Present 0 = Absent 97 = Unknown
19 CUTANSCR	2			
21 CALCIEVR	2			1 = Yes 0 = No 99 = Unknown
22 CALCINDT	MMM yyyy			
23 SUPPLAQU	1			
24 DPTUMOR	1			
25 FASCIALP	1			
26 EXOSKEL	1			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis (JDM) Form Part II.
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
27 CALCINSV	\$4			Disease Activity
28 CLINEXAM	1			
29 XRAY	1			
30 CTSCAN	1			
31 CALCINOT	1			
32 CALOTSPF	\$50			
33 CALCINCR	2			1 = Yes 0 = No 99 = Unknown
34 CALCIPAN	\$4			Disease Activity
35 CALCIPHY	\$4			Disease Activity
37 RAYNADS	2			1 = Yes 0 = No 99 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis (JDM) Form Part II.
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
38 REQTREAT	2			1 = Yes 0 = No 99 = Unknown
39 SCLERODA	2			1 = Yes 0 = No 99 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis Form Part I.
Generated On: 23 Apr 2019 20:11:55

Please select Juvenile Dermatomyositis (JDM)/Juvenile Polymyositis (JPM)

Juvenile Dermatomyositis (JDM) ☐ ①
Juvenile Polymyositis ☐

If JDM, does patient have amyopathic/hypomyopathic/skin predominant disease?

Yes ☐ ②
No ☐
Unknown ☐

Myositis Diagnostic Features

History of symmetric proximal muscle weakness present?

Yes ☐ ④
No ☐
Unknown ☐

History of rash consistent with JDM present (Gottron's papules/sign and/or heliotrope rash)?

Yes ☐ ⑤
No ☐
Unknown ☐

Was an EMG performed?

Yes ☐ ⑥
No ☐
Unknown ☐

If yes,

Consistent with myositis ☐ ⑦
Abnormal but not consistent with myositis ☐
Normal ☐
Unknown ☐

Was a muscle biopsy performed?

Yes ☐ ⑧
No ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis Form Part I.
Generated On: 23 Apr 2019 20:11:55

Unknown ☐

If yes,

Consistent with myositis ☐ **9**
Abnormal but not
consistent with myositis ☐
Normal ☐
Unknown ☐

Are elevated muscle enzymes present (now or
previously)?

Yes ☐ **10**
No ☐
Unknown ☐

Was an MRI performed?

Yes ☐ **11**
No ☐
Unknown ☐

If yes,

Consistent with myositis ☐ **12**
Abnormal but not
consistent with myositis ☐
Normal ☐
Unknown ☐

Previous treatment with DMARD,biologic or IVIG (i.e.
since last visit)?

Yes ☐ **13**
No ☐
Unknown ☐

Extramuscular Disease Activity (in the previous 4 weeks):

A. Constitutional Disease

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis Form Part I.
Generated On: 23 Apr 2019 20:11:55

Fever (>38.5°C) due to myositis

Present ☐ 16
Absent ☐
Unknown ☐

Weight loss (>5%) due to myositis

Present ☐ 17
Absent ☐
Unknown ☐

Fatigue due to myositis

Present ☐ 18
Absent ☐
Unknown ☐

Global VAS for Constitutional Disease

Fixed Unit: Score 19

B. Skeletal Disease

Arthritis

Present ☐ 21
Absent ☐
Unknown ☐

Global VAS for Skeletal Disease

Fixed Unit: Score 22

C. Gastrointestinal Disease

Dysphagia due to myositis

Present ☐ 24
Absent ☐
Unknown ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis Form Part I.
Generated On: 23 Apr 2019 20:11:55

Abdominal pain due to myositis	Present	<input type="checkbox"/>	25
	Absent	<input type="checkbox"/>	
	Unknown	<input type="checkbox"/>	

Gastrointestinal ulceration (not oral ulcers) due to myositis	Present	<input type="checkbox"/>	26
	Absent	<input type="checkbox"/>	
	Unknown	<input type="checkbox"/>	

Global VAS for Gastrointestinal Disease	Fixed Unit: Score	27
---	-------------------	----

D. Pulmonary Disease

Pulmonary involvement (respiratory muscle weakness)	Present	<input type="checkbox"/>	29
	Absent	<input type="checkbox"/>	
	Unknown	<input type="checkbox"/>	

Pulmonary involvement (interstitial lung disease)	Present	<input type="checkbox"/>	30
	Absent	<input type="checkbox"/>	
	Unknown	<input type="checkbox"/>	

Dysphonia due to myositis	Present	<input type="checkbox"/>	31
	Absent	<input type="checkbox"/>	
	Unknown	<input type="checkbox"/>	

Global VAS for Pulmonary Disease	Fixed Unit: Score	32
----------------------------------	-------------------	----

E. Cardiovascular Disease

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis Form Part I.
Generated On: 23 Apr 2019 20:11:55

Cardiovascular involvement due to myositis (pericarditis, myocarditis, arrhythmia)

Present ☐ **34**
Absent ☐
Unknown ☐

Global VAS for Cardiovascular Disease

Fixed Unit: Score **35**

F. Other Extramuscular Disease Activity (excluding skin and muscle)?

Yes ☐ **36**
No ☐

If yes, in what organ system?

37

Global VAS for this organ system:

Fixed Unit: Score **38**






Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis Form Part I.
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① PRIMJDMF	1			1 = Juvenile Dermatomyositis (JDM) 2 = Juvenile Polymyositis
② IFJDMF	2			1 = Yes 0 = No 99 = Unknown
④ HXSYPMPF	2			1 = Yes 0 = No 99 = Unknown
⑤ HXRASHF	2			1 = Yes 0 = No 99 = Unknown
⑥ EMGF	2			1 = Yes 0 = No 99 = Unknown
⑦ EMGYESF	2			1 = Consistent with myositis

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis Form Part I.
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				2 = Abnormal but not consistent with myositis 3 = Normal 99 = Unknown
⑧ MUSBIOPF	2			1 = Yes 0 = No 99 = Unknown
⑨ MUSBPYSF	2			1 = Consistent with myositis 2 = Abnormal but not consistent with myositis 3 = Normal 99 = Unknown
⑩ ELMUSENF	2			1 = Yes 0 = No 99 = Unknown
⑪ MRIPERFF	2			1 = Yes 0 = No

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis Form Part I.
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				99 = Unknown
 MRIYESF	2			1 = Consistent with myositis 2 = Abnormal but not consistent with myositis 3 = Normal 99 = Unknown
 PRVDMARF	2			1 = Yes 0 = No 99 = Unknown
 FEVERMYF	2			1 = Present 0 = Absent 97 = Unknown
 WEIGHTLF	2			1 = Present 0 = Absent 97 = Unknown
 FATIGMYF	2			1 = Present 0 = Absent

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis Form Part I.
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				97 = Unknown
19 GLBVASAF	\$4			Disease Activity
21 JARTHRIF	2			1 = Present 0 = Absent 97 = Unknown
22 GLBVASBF	\$4			Disease Activity
24 DYSPHAGF	2			1 = Present 0 = Absent 97 = Unknown
25 ABDOMPAF	2			1 = Present 0 = Absent 97 = Unknown
26 GASULCMF	2			1 = Present 0 = Absent 97 = Unknown
27 GLBVASCF	\$4			Disease Activity

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis Form Part I.
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
29 PULRESPF	2			1 = Present 0 = Absent 97 = Unknown
30 PULINTLF	2			1 = Present 0 = Absent 97 = Unknown
31 DYSPHONF	2			1 = Present 0 = Absent 97 = Unknown
32 GBLVASDF	\$4			Disease Activity
33 CARDMYTF	2			1 = Present 0 = Absent 97 = Unknown
35 GBLVASEF	\$4			Disease Activity
36 EXTRADIF	2			1 = Yes 0 = No
37 ORGANSYF	\$50			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis Form Part I.
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
38 GBLVASFF	\$4			Disease Activity

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis Form Part II.
Generated On: 23 Apr 2019 20:11:55

Skin Disease Activity (Cutaneous Activity Tool); Skin Lesions Present at Time of Assessment:

1. - Gottron's papules or Gottron's sign Present ☐ ②
Absent ☐
Unknown ☐

2. - Heliotrope rash Present ☐ ③
Absent ☐
Unknown ☐

3. - Malar or facial erythema Present ☐ ④
Absent ☐
Unknown ☐

4. - Linear extensor erythema Present ☐ ⑤
Absent ☐
Unknown ☐

5. - 'V' sign Present ☐ ⑥
Absent ☐
Unknown ☐

6. - Shawl sign Present ☐ ⑦
Absent ☐
Unknown ☐

7. - Non-sun exposed erythema Present ☐ ⑧
Absent ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis Form Part II.
Generated On: 23 Apr 2019 20:11:55

	Unknown	<input type="checkbox"/>
<hr/>		
8. - Extensive cutaneous erythema	Present	<input type="checkbox"/> 9
	Absent	<input type="checkbox"/>
	Unknown	<input type="checkbox"/>
<hr/>		
9. - Livedo reticularis	Present	<input type="checkbox"/> 10
	Absent	<input type="checkbox"/>
	Unknown	<input type="checkbox"/>
<hr/>		
10. - Cutaneous ulceration	Present	<input type="checkbox"/> 11
	Absent	<input type="checkbox"/>
	Unknown	<input type="checkbox"/>
<hr/>		
11. - Mucus membrane lesions	Present	<input type="checkbox"/> 12
	Absent	<input type="checkbox"/>
	Unknown	<input type="checkbox"/>
<hr/>		
12. - Periungual capillary loop changes	Present	<input type="checkbox"/> 13
	Absent	<input type="checkbox"/>
	Unknown	<input type="checkbox"/>
<hr/>		
13. - Mechanic's hands	Present	<input type="checkbox"/> 14
	Absent	<input type="checkbox"/>
	Unknown	<input type="checkbox"/>
<hr/>		
14. - Cuticular overgrowth	Present	<input type="checkbox"/> 15
	Absent	<input type="checkbox"/>
	Unknown	<input type="checkbox"/>

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis Form Part II.
Generated On: 23 Apr 2019 20:11:55

15. - Subcutaneous oedema Present ☐ 16
Absent ☐
Unknown ☐

16. - Panniculitis Present ☐ 17
Absent ☐
Unknown ☐

17. - Alopecia (non-scarring) Present ☐ 18
Absent ☐
Unknown ☐

Cutaneous Activity Tool Score Fixed Unit: (auto-calculate) 19

Calcinosis Assessment

Calcinosis Ever Yes ☐ 21
No ☐
Unknown ☐

If yes, calcinosis onset: 22

Calcinosis phenotype ☐ 23
Superficial plaques or nodules

Deep tumorous nodules or masses ☐ 24

Fascial plane ☐ 25

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis Form Part II.
Generated On: 23 Apr 2019 20:11:55

<hr/>	
Exoskeleton	<input type="checkbox"/> 26
<hr/>	
Calcinosis severity	Fixed Unit: Score 27
<hr/>	
Calcinosis diagnosed by Clinical exam	<input type="checkbox"/> 28
<hr/>	
X-ray	<input type="checkbox"/> 29
<hr/>	
CT Scan	<input type="checkbox"/> 30
<hr/>	
Other:	<input type="checkbox"/> 31
<hr/>	
Specify	_____ 32
<hr/>	
Calcinosis current	Yes <input type="checkbox"/> 33 No <input type="checkbox"/> Unknown <input type="checkbox"/>
<hr/>	
How much pain have you had IN THE PAST WEEK due to your CALCINOSIS only?	_____ 34
<hr/>	
How much physical limitation have you had IN THE PAST WEEK due to your CALCINOSIS only?	_____ 35
<hr/>	
Overlap Features	
<hr/>	
Raynaud's (ever [baseline], since last visit [follow-up])	Yes <input type="checkbox"/> 37
<hr/>	

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis Form Part II.
Generated On: 23 Apr 2019 20:11:55

No ☐
Unknown ☐

If yes, Requiring Treatment?

Yes ☒ 38
No ☐
Unknown ☐

Sclerodactyly (ever [baseline], since last visit
[follow-up])

Yes ☒ 39
No ☐
Unknown ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis Form Part II.
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
② GOTTRONF	2			1 = Present 0 = Absent 97 = Unknown
③ HELIOTRF	2			1 = Present 0 = Absent 97 = Unknown
④ MALARERF	2			1 = Present 0 = Absent 97 = Unknown
⑤ LINERYTF	2			1 = Present 0 = Absent 97 = Unknown
⑥ VSIGNF	2			1 = Present 0 = Absent 97 = Unknown
⑦ SHAWLSIF	2			1 = Present 0 = Absent 97 = Unknown
⑧ NSUNERYF	2			1 = Present 0 = Absent 97 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis Form Part II.
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
9 EXTCUTEF	2			1 = Present 0 = Absent 97 = Unknown
10 LIVEDOF	2			1 = Present 0 = Absent 97 = Unknown
11 CUTULCEF	2			1 = Present 0 = Absent 97 = Unknown
12 MUMEMLEF	2			1 = Present 0 = Absent 97 = Unknown
13 PERCAPLF	2			1 = Present 0 = Absent 97 = Unknown
14 MECHANIF	2			1 = Present 0 = Absent 97 = Unknown
15 CUTOVRGF	2			1 = Present 0 = Absent 97 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis Form Part II.
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
16 SUBCUOEF	2			1 = Present 0 = Absent 97 = Unknown
17 PANNICUF	2			1 = Present 0 = Absent 97 = Unknown
18 JALOPECF	2			1 = Present 0 = Absent 97 = Unknown
19 CUTANSCF	2			
21 CALCIEVF	2			1 = Yes 0 = No 99 = Unknown
22 CALCIFDT	MMM yyyy			
23 SUPPLAQF	1			
24 DPTUMORF	1			
25 FASCIALF	1			
26 EXOSKELF	1			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis Form Part II.
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
27 CALCINSF	\$4			Disease Activity
28 CLINEXAF	1			
29 XRAYF	1			
30 CTSCANF	1			
31 CALCINOF	1			
32 CALOFSPF	\$50			
33 CALCINCF	2			1 = Yes 0 = No 99 = Unknown
34 CALCIPAF	\$4			Disease Activity
35 CALCIPHF	\$4			Disease Activity
37 RAYNADSF	2			1 = Yes 0 = No 99 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix
Form: Juvenile Dermatomyositis Form Part II.
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
38 REQTREAF	2			1 = Yes 0 = No 99 = Unknown
39 SCLERODF	2			1 = Yes 0 = No 99 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix
Form: Myositis Damage Index
Generated On: 23 Apr 2019 20:11:55

Date of Information: _____

①

MUSCLE DAMAGE

Muscle atrophy (clinical)

Yes ☐

③

No ☐

Unknown ☐

Muscle weakness not attributable to active muscle disease

Yes ☐

④

No ☐

Unknown ☐

Muscle dysfunction: decrease in aerobic capacity

Yes ☐

⑤

No ☐

Unknown ☐

VAS for muscle damage

Fixed Unit: Score

⑥

SKELETAL DAMAGE

Joint contractures (due to myositis)

Yes ☐

⑧

No ☐

Unknown ☐

Osteoporosis with fracture or vertebral collapse (excluding avascular necrosis)

Yes ☐

⑨

No ☐

Unknown ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Myositis Damage Index
Generated On: 23 Apr 2019 20:11:55

Avascular necrosis

Yes ☐ 10
No ☐
Unknown ☐

Deforming arthropathy

Yes ☐ 11
No ☐
Unknown ☐

VAS for skeletal damage

Fixed Unit: Score 12

CUTANEOUS DAMAGE

Depressed scar/cutaneous atrophy

Yes ☐ 14
No ☐
Unknown ☐

Poikiloderma

Yes ☐ 15
No ☐
Unknown ☐

Lipoatrophy/lipodystrophy

Yes ☐ 16
No ☐
Unknown ☐

Alopecia (scarring)

Yes ☐ 17
No ☐
Unknown ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Myositis Damage Index
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Calcinosis (persistent)	Yes	<input type="checkbox"/>	18
	No	<input type="checkbox"/>	
	Unknown	<input type="checkbox"/>	

Sclerodactyly	Yes	<input type="checkbox"/>	19
	No	<input type="checkbox"/>	
	Unknown	<input type="checkbox"/>	

VAS for cutaneous damage	Fixed Unit: Score	20
--------------------------	-------------------	----

GASTROINTESTINAL DAMAGE

Persistent dysphagia	Yes	<input type="checkbox"/>	22
	No	<input type="checkbox"/>	
	Unknown	<input type="checkbox"/>	

Gastrointestinal dysmotility, constipation, diarrhea, or abdominal pain	Yes	<input type="checkbox"/>	23
	No	<input type="checkbox"/>	
	Unknown	<input type="checkbox"/>	

Infarction or resection of bowel or other gastrointestinal organs	Yes	<input type="checkbox"/>	24
	No	<input type="checkbox"/>	
	Unknown	<input type="checkbox"/>	

VAS for gastrointestinal damage	Fixed Unit: Score	25
---------------------------------	-------------------	----

PULMONARY DAMAGE

Rave.11.0_PRD_Annotation: Form Matrix
Form: Myositis Damage Index
Generated On: 23 Apr 2019 20:11:55

Impaired lung function due to respiratory muscle damage

Yes ☐ 27
No ☐
Unknown ☐

Dysphonia (persistent)

Yes ☐ 28
No ☐
Unknown ☐

Pulmonary fibrosis

Yes ☐ 29
No ☐
Unknown ☐

Pulmonary hypertension

Yes ☐ 30
No ☐
Unknown ☐

VAS for pulmonary damage

Fixed Unit: Score 31

CARDIOVASCULAR DAMAGE

Ventricular dysfunction

Yes ☐ 33
No ☐
Unknown ☐

Hypertension requiring treatment for >6 months

Yes ☐ 34
No ☐
Unknown ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Myositis Damage Index
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Angina or coronary artery bypass

Yes ☐ 35
No ☐
Unknown ☐

Myocardial infarction

Yes ☐ 36
No ☐
Unknown ☐

VAS for cardiovascular disease

Fixed Unit: Score 37

VASCULAR DAMAGE

Tissue or pulp space loss

Yes ☐ 39
No ☐
Unknown ☐

Digit or limb loss or resection

Yes ☐ 40
No ☐
Unknown ☐

Venous or arterial thrombosis with swelling, ulceration,
venous stasis

Yes ☐ 41
No ☐
Unknown ☐

VAS for peripheral vascular damage

Fixed Unit: Score 42

ENDOCRINE DAMAGE

Rave.11.0_PRD_Annotation: Form Matrix
Form: Myositis Damage Index
Generated On: 23 Apr 2019 20:11:55

Growth failure

Yes ☐ 44

No ☐

Unknown ☐

Not Applicable ☐

Diabetes mellitus

Yes ☐ 45

No ☐

Unknown ☐

Delay in development of secondary sexual characteristics

Yes ☐ 46

No ☐

Unknown ☐

Not Applicable ☐

Hirsutism or hypertrichosis

Yes ☐ 47

No ☐

Unknown ☐

Irregular menses

Yes ☐ 48

No ☐

Unknown ☐

Not Applicable ☐

Primary or secondary amenorrhea

Yes ☐ 49

No ☐

Unknown ☐

Not Applicable ☐

Infertility (male or female)

Yes ☐ 50

Rave.11.0_PRD_Annotation: Form Matrix
Form: Myositis Damage Index
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No ☐
Unknown ☐
Not Applicable ☐

Sexual dysfunction

Yes ☐ 51
No ☐
Unknown ☐
Not Applicable ☐

VAS for endocrine damage

Fixed Unit: Score 52

OCULAR DAMAGE

Cataract resulting in visual loss

Yes ☐ 54
No ☐
Unknown ☐

Visual loss, other, not secondary to cataract

Yes ☐ 55
No ☐
Unknown ☐

VAS for ocular damage

Fixed Unit: Score 56

INFECTION

Chronic infection

Yes ☐ 58
No ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Myositis Damage Index
Generated On: 23 Apr 2019 20:11:55

Unknown ☐

Multiple infections

Yes ☐ **59**

No ☐

Unknown ☐

VAS for infection

Fixed Unit: Score **60**

GLOBAL DAMAGE

Presence of malignancy

Yes ☐ **62**

No ☐

Unknown ☐

Death due to myositis

Yes ☐ **63**

No ☐

Unknown ☐

Physician VAS of global damage

Fixed Unit: Score **64**

Rave.11.0_PRD_Annotation: Form Matrix
Form: Myositis Damage Index
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① INFODT	dd MMM YYYY			
③ MUSATRO	2			1 = Yes 0 = No 99 = Unknown
④ MUSWEAK	2			1 = Yes 0 = No 99 = Unknown
⑤ MUSDYSF	2			1 = Yes 0 = No 99 = Unknown
⑥ VASMUSDM	\$4			Disease Activity
⑧ JOINTCON	2			1 = Yes 0 = No 99 = Unknown
⑨ OSTEOP	2			1 = Yes 0 = No 99 = Unknown
⑩ AVASCUL	2			1 = Yes 0 = No

Rave.11.0_PRD_Annotation: Form Matrix
Form: Myositis Damage Index
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				99 = Unknown
11 DEFARTH	2			1 = Yes 0 = No 99 = Unknown
12 VASSKEDM	\$4			Disease Activity
14 DEPRSCAR	2			1 = Yes 0 = No 99 = Unknown
15 POIKILO	2			1 = Yes 0 = No 99 = Unknown
16 LIPOATRO	2			1 = Yes 0 = No 99 = Unknown
17 ALOPSCAR	2			1 = Yes 0 = No 99 = Unknown
18 CALCINPR	2			1 = Yes 0 = No

Rave.11.0_PRD_Annotation: Form Matrix
Form: Myositis Damage Index
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				99 = Unknown
19 SCLERODC	2			1 = Yes 0 = No 99 = Unknown
20 VASCUTDM	\$4			Disease Activity
22 PERDYSPH	2			1 = Yes 0 = No 99 = Unknown
23 GASDYSMO	2			1 = Yes 0 = No 99 = Unknown
24 INFARBOW	2			1 = Yes 0 = No 99 = Unknown
25 VASGASDM	\$4			Disease Activity
27 IMPRLUNG	2			1 = Yes 0 = No 99 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix
Form: Myositis Damage Index
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
28 DYSPHON	2			1 = Yes 0 = No 99 = Unknown
29 PULMFIBR	2			1 = Yes 0 = No 99 = Unknown
30 PULMHYPR	2			1 = Yes 0 = No 99 = Unknown
31 VASPULDM	\$4			Disease Activity
32 VENTDYSF	2			1 = Yes 0 = No 99 = Unknown
33 HYPRTEN	2			1 = Yes 0 = No 99 = Unknown
34 ANGINABY	2			1 = Yes 0 = No 99 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix
Form: Myositis Damage Index
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
36 MYOINFA	2			1 = Yes 0 = No 99 = Unknown
37 VASCRDDM	\$4			Disease Activity
39 TISSPULP	2			1 = Yes 0 = No 99 = Unknown
40 DIGITLOS	2			1 = Yes 0 = No 99 = Unknown
41 VENOUS	2			1 = Yes 0 = No 99 = Unknown
42 VASVASDM	\$4			Disease Activity
44 GROWFAIL	2			1 = Yes 0 = No 99 = Unknown 96 = Not Applicable

Rave.11.0_PRD_Annotation: Form Matrix
Form: Myositis Damage Index
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
45 DIABMELL	2			1 = Yes 0 = No 99 = Unknown
46 SECSEXCR	2			1 = Yes 0 = No 99 = Unknown 96 = Not Applicable
47 HIRSUITI	2			1 = Yes 0 = No 99 = Unknown
48 IRRMENSE	2			1 = Yes 0 = No 99 = Unknown 96 = Not Applicable
49 AMENORRH	2			1 = Yes 0 = No 99 = Unknown 96 = Not Applicable
50 INFERTIL	2			1 = Yes 0 = No 99 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix
Form: Myositis Damage Index
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				96 = Not Applicable
51 SEXDYSFU	2			1 = Yes 0 = No 99 = Unknown 96 = Not Applicable
52 VASENDDM	\$4			Disease Activity
54 CATARACT	2			1 = Yes 0 = No 99 = Unknown
55 VISUALLO	2			1 = Yes 0 = No 99 = Unknown
56 VASOCUDM	\$4			Disease Activity
58 CHRINFEC	2			1 = Yes 0 = No 99 = Unknown
59 MULTINFE	2			1 = Yes 0 = No

Rave.11.0_PRD_Annotation: Form Matrix
Form: Myositis Damage Index
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				99 = Unknown
60 VASINFDM	\$4			Disease Activity
62 PREMALIG	2			1 = Yes 0 = No 99 = Unknown
63 DTHMYOS	2			1 = Yes 0 = No 99 = Unknown
64 VASGBLDM	\$4			Disease Activity

Rave.11.0_PRD_Annotation: Form Matrix

Form: Uveitis

Generated On: 23 Apr 2019 20:11:55

Date of diagnosis (new onset only) _____ ①

Date of most recent eye exam _____ ②

Uveitis type _____ ③

Chronic ☐

Acute ☐

Unknown ☐

Not Collected ☐

Which eye(s) has uveitis affected (check all that apply)?

Right ☐ ⑤

Left ☐ ⑥

Unknown ☐ ⑦

Current best corrected vision - right eye _____ ⑧

Normal (20/40 or better) ☐

Abnormal (worse than 20/40 but better than 20/400) ☐

Blind (worse than 20/400) ☐

Unknown ☐

Current best corrected vision - left eye _____ ⑨

Normal (20/40 or better) ☐

Abnormal (worse than 20/40 but better than 20/400) ☐

Blind (worse than 20/400) ☐

Unknown ☐

Rave.11.0_PRD_Annotation: Form Matrix

Form: Uveitis

Generated On: 23 Apr 2019 20:11:55

Has subject [ever - baseline / since last visit - Followup] used topical steroid drops? Yes ☐ **10**
No ☐
Unknown ☐

Is subject currently using topical steroid drops? Yes ☐ **11**
No ☐
Unknown ☐

What is the current frequency? Less than once daily ☐ **12**
1-2 times daily ☐
3 or more times daily ☐
Unknown ☐

Has subject [ever - baseline / since last visit - Followup] had intra-ocular or sub-tenon glucocorticoid injections? Yes ☐ **13**
No ☐
Unknown ☐

At the most recent eye exam, did the subject have any cells in the anterior chamber? Yes ☐ **14**
No ☐
Unknown ☐

How long have there been cells present? <3 months ☐ **15**
>=3 months ☐
Unknown ☐

Has the subject [ever - baseline / since last visit - Followup] had eye complications from uveitis (e.g. band keratopathy, significant glaucoma or cataracts)? Yes ☐ **16**
No ☐
Unknown ☐

Rave.11.0_PRD_Annotation: Form Matrix

Form: Uveitis

Generated On: 23 Apr 2019 20:11:55

Has the subject [ever - baseline / since last visit -
Followup] had eye surgery (other than sub-tenon or
intraocular injections) due to complications of uveitis or
its treatment?

Yes ☐ 17
No ☐
Unknown ☐






Rave.11.0_PRD_Annotation: Form Matrix**Form: Uveitis****Generated On: 23 Apr 2019 20:11:55**

	Field Name	Data Type	SAS Label	Units	Values
①	DIAXDTC	dd- MMM- yyyy	Uveitis Date of diagnosis		
②	EXAMDTC	dd- MMM- yyyy	Date of most recent eye exam		
③	UVEITYP	2			1 = Chronic 2 = Acute 99 = Unknown 95 = Not Collected
⑤	RIGHTYE	1	Eye Uveitis affected: Right		
⑥	LEFTYE	1	Eye Uveitis affected: Left		
⑦	UNKEYE	1	Eye Uveitis affected: Unknown		
⑧	CORVISRT	2	Current best corrected vision - right		1 = Normal (20/40 or better)

Rave.11.0_PRD_Annotation: Form Matrix**Form: Uveitis****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
				2 = Abnormal (worse than 20/40 but better than 20/400) 3 = Blind (worse than 20/400) 99 = Unknown
9 CORVISLT	2	Current best corrected vision - left		1 = Normal (20/40 or better) 2 = Abnormal (worse than 20/40 but better than 20/400) 3 = Blind (worse than 20/400) 99 = Unknown
10 EYEDROP	2	Topical steroid drops (ever/since last fu)		1 = Yes 0 = No 99 = Unknown
11 CRNTDROP	2	Currently topical steroid drops		1 = Yes 0 = No 99 = Unknown


Rave.11.0_PRD_Annotation: Form Matrix
Form: Uveitis
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
 CRNTFREQ	2	Current eye drop frequency		0 = Less than once daily 1 = 1-2 times daily 2 = 3 or more times daily 99 = Unknown
 EYEINJCT	2	Intra-ocular or sub-tenon glucocorticoid injections (ever/since last fu)		1 = Yes 0 = No 99 = Unknown
 CELLCHAM	2	Cells in the anterior chamber		1 = Yes 0 = No 99 = Unknown
 CELLPRST	2	How long have there been cells present		1 = <3 months 2 = >=3 months 99 = Unknown
 EYECOMPL	2	Eye complications		1 = Yes 0 = No 99 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix

Form: Uveitis

Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
 EYESURGY	2	Eye surgery		1 = Yes 0 = No 99 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix
Form: Laboratory Results
Generated On: 23 Apr 2019 20:11:55

Date of collection _____ ①

AST _____ Fixed Unit: U/L ②

Upper Limit of Normal _____ Fixed Unit: U/L ③

ALT _____ Fixed Unit: U/L ④

Upper Limit of Normal _____ Fixed Unit: U/L ⑤

C-Reactive Protein _____ mg/dL ⑥
mg/L
ND

Upper Limit of Normal _____ mg/dL ⑦
mg/L
ND

If Abnormal, is elevation due to rheumatic disease Yes ⑧
No
Unknown

Creatinine (serum) _____ mg/dL ⑨
mmol/L
ND

Rave.11.0_PRD_Annotation: Form Matrix
Form: Laboratory Results
Generated On: 23 Apr 2019 20:11:55

C3 (in last 30 days)	Normal/ High <input type="checkbox"/> 10
	Low <input type="checkbox"/>
	Not Done <input type="checkbox"/>

C4 (in last 30 days)	Normal/ High <input type="checkbox"/> 11
	Low <input type="checkbox"/>
	Not Done <input type="checkbox"/>

CH50 (in last 30 days)	Normal/ High <input type="checkbox"/> 12
	Low <input type="checkbox"/>
	Not Done <input type="checkbox"/>

Estimated GFR (eGFR)	Fixed Unit: mL/min 1.73m ² 13
----------------------	--

ESR	Fixed Unit: mm/hr 14
-----	----------------------

Upper Limit of Normal	Fixed Unit: mm/hr 15
-----------------------	----------------------

If Abnormal, is elevation due to rheumatic disease	Yes <input type="checkbox"/> 16
	No <input type="checkbox"/>
	Unknown <input type="checkbox"/>

Ferritin	Fixed Unit: ng/mL 17
----------	----------------------

Hemoglobin	g/dL <input type="checkbox"/> 18
------------	----------------------------------

Rave.11.0_PRD_Annotation: Form Matrix
Form: Laboratory Results
Generated On: 23 Apr 2019 20:11:55

g/L ☐
mmol/L ☐
ND ☐

Platelets **109/L or 103/mm3** ☐ **19**
/mm3 ☐

Or Platelets Not Done Fixed Unit: Not Done **20**
☐

Total cholesterol **mg/dL** ☐ **21**
mmol/L ☐
ND ☐

Triglycerides **mg/dL** ☐ **22**
mmol/L ☐
ND ☐

WBC **109/L or 103/mm3** ☐ **23**
/mm3 ☐

Or WBC Not Done Fixed Unit: Not Done **24**
☐

Neutrophils Fixed Unit: % **25**

Lymphocytes **cells/L** ☐ **26**

Rave.11.0_PRD_Annotation: Form Matrix
Form: Laboratory Results
Generated On: 23 Apr 2019 20:11:55

	cells/mm3	<input type="checkbox"/>
Or Lymphocytes Not Done	Fixed Unit: Not Done	<input type="checkbox"/>
CK	Fixed Unit: U/L	
Upper Limit of Normal	Fixed Unit: U/L	
LDH	Fixed Unit: U/L	
Upper Limit of Normal	Fixed Unit: U/L	
Aldolase	Fixed Unit: U/L	
Upper Limit of Normal	Fixed Unit: U/L	
Total IgG	Fixed Unit: mg/dL	
Or Total IgG Not Done	Fixed Unit: Not Done	<input type="checkbox"/>

Rave.11.0_PRD_Annotation: Form Matrix
Form: Laboratory Results
Generated On: 23 Apr 2019 20:11:55








Fixed Unit: Not Collected **36**



Rave.11.0_PRD_Annotation: Form Matrix
Form: Laboratory Results
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
①	LABDTC	dd- MMM- yyyy	Date of lab collection		
②	ASORRES	8.2	AST		
③	ASORRULN	8.2	AST: Upper Limit of Normal		
④	ALORRES	8.2	ALT		
⑤	ALORRULN	8.2	ALT: Upper Limit of Normal		
⑥	CREAPROT	8.2	C-Reactive Protein	1 = mg/dL 2 = mg/L 97 = ND	
⑦	CREAPULN	8.2	CRP: Upper Limit of Normal	1 = mg/dL 2 = mg/L 97 = ND	
⑧	CREAPABN	2	CRP Abnormal: due to rheumatic disease	1 = Yes 0 = No 99 = Unknown	
⑨	CREATVAL	8.2		1 = mg/dL 2 = mmol/L 97 = ND	

Rave.11.0_PRD_Annotation: Form Matrix
Form: Laboratory Results
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
 C3VAL	2			1 = Normal/ High 2 = Low 97 = Not Done
 C4VAL	2			1 = Normal/ High 2 = Low 97 = Not Done
 CH50VAL	2			1 = Normal/ High 2 = Low 97 = Not Done
 EGFRVAL	8.2			
 ESRRES	8.2	ESR		
 ESRULN	8.2	ESR: Upper Limit of Normal		
 ESRABN	2	ESR Abnormal, due to rheumatic disease		1 = Yes 0 = No 99 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix
Form: Laboratory Results
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
17	FERRTRES	8.2	Ferritin		
18	HGORRES	8.2	Hemoglobin	1 = g/dL 2 = g/L 3 = mmol/L 97 = ND	
19	PLORES	8.2	Platelets	1 = 109/L or 103/mm3 2 = /mm3	
20	PLATND	1			
21	TCORRES	8.2	Total cholesterol	1 = mg/dL 2 = mmol/L 97 = ND	
22	TRORES	8.2	Triglycerides	1 = mg/dL 2 = mmol/L 97 = ND	
23	WBORRES	8.2	WBC	1 = 109/L or 103/mm3 2 = /mm3	
24	WBCND	1			
25	NEORRES	8.2	Neutrophils		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Laboratory Results
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
26	LYMPHVAL	8.2		1 = cells/L 2 = cells/mm3	
27	LYMPND	1			
28	CK	8.2			
29	CKUPLN	8.2			
30	LDH	8.2			
31	LDHULN	8.2			
32	ALDOLASE	8.2			
33	ALDOULN	8.2			
34	TOTALIGG	8.2			
35	IGGND	1			
36	IGGNC	1			

Rave.11.0_PRD_Annotation: Form Matrix
Form: CMAS Form
Generated On: 23 Apr 2019 20:11:55

CMAS STATUS

Done ☐ ①
Not Done ☐

Head Lift

0 = Unable ☐ ②
1 = 1-9 sec ☐
2 = 10-29 sec ☐
3 = 30-59 sec ☐
4 = 60-119 sec ☐
5 = > = 120 sec ☐
Not Done ☐

Fixed Unit: # of sec ③

Leg Raise/Touch Object

0 ☐ ④
1 ☐
2 ☐
Not Done ☐

Straight Leg Lift/Duration

0 = Unable ☐ ⑤
1 = 1-9 sec ☐
2 = 10-29 sec ☐
3 = 30-59 sec ☐
4 = 60-119 sec ☐
5 = > = 120 sec ☐
Not Done ☐

Fixed Unit: # of sec ⑥

Rave.11.0_PRD_Annotation: Form Matrix
Form: CMAS Form
Generated On: 23 Apr 2019 20:11:55

Supine to Prone	0	<input type="checkbox"/>	7
	1	<input type="checkbox"/>	
	2	<input type="checkbox"/>	
	3	<input type="checkbox"/>	
	Not Done	<input type="checkbox"/>	

Sit-Ups

Hands on thighs, with counterbalance	0 = Unable or	<input type="checkbox"/>	9
	1 = Able	<input type="checkbox"/>	
	Not Done	<input type="checkbox"/>	

Hands across chest, with counterbalance	0 = Unable or	<input type="checkbox"/>	10
	1 = Able	<input type="checkbox"/>	
	Not Done	<input type="checkbox"/>	

Hands behind head, with counterbalance	0 = Unable or	<input type="checkbox"/>	11
	1 = Able	<input type="checkbox"/>	
	Not Done	<input type="checkbox"/>	

Hands on thighs, without counterbalance	0 = Unable or	<input type="checkbox"/>	12
	1 = Able	<input type="checkbox"/>	
	Not Done	<input type="checkbox"/>	

Hands across chest, without counterbalance	0 = Unable or	<input type="checkbox"/>	13
	1 = Able	<input type="checkbox"/>	
	Not Done	<input type="checkbox"/>	

Hands behind head, without counterbalance	0 = Unable or	<input type="checkbox"/>	14
---	---------------	--------------------------	----

Rave.11.0_PRD_Annotation: Form Matrix
Form: CMAS Form
Generated On: 23 Apr 2019 20:11:55

1 = Able ☐
Not Done ☐

TOTAL Sit-Up Score:

Fixed Unit: (auto-calculate) **15**

Supine to Sit

0 ☐ **17**
1 ☐
2 ☐
3 ☐
Not Done ☐

Arm Raise/ Straighten

0 ☐ **18**
1 ☐
2 ☐
3 ☐
Not Done ☐

Arm Raise/ Duration

0 = Unable ☐ **19**
1 = 1-9 sec ☐
2 = 10-29 sec ☐
3 = 30-59 sec ☐
4 = > = 60 sec ☐
Not Done ☐

Fixed Unit: # of sec **20**

Rave.11.0_PRD_Annotation: Form Matrix
Form: CMAS Form
Generated On: 23 Apr 2019 20:11:55

Floor Sit

0 ☐ 21

1 ☐

2 ☐

3 ☐

Not Done ☐

All Fours Maneuver

0 ☐ 22

1 ☐

2 ☐

3 ☐

4 ☐

Not Done ☐

Floor Rise

0 ☐ 23

1 ☐

2 ☐

3 ☐

4 ☐

Not Done ☐

Chair Rise

0 ☐ 24

1 ☐

2 ☐

3 ☐

4 ☐

Not Done ☐

Stool Step

0 ☐ 25

1 ☐

2 ☐

3☐

Not Done☐

Pick-Up

0☐

1☐

2☐

3☐

Not Done☐

26

Total CMAS Score

Fixed Unit: (auto-calculate)

27

Rave.11.0_PRD_Annotation: Form Matrix
Form: CMAS Form
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① CMASSTAT	2			1 = Done 97 = Not Done
② HEADLIFT	2			0 = 0 = Unable 1 = 1 = 1-9 sec 2 = 2 = 10-29 sec 3 = 3 = 30-59 sec 4 = 4 = 60-119 sec 5 = 5 = > 120 sec 97 = Not Done
③ HDLFSEC	3			
④ LEGRAISE	2			0 = 0 1 = 1 2 = 2 97 = Not Done
⑤ STRLEGLF	2			0 = 0 = Unable 1 = 1 = 1-9 sec 2 = 2 = 10-29 sec 3 = 3 = 30-59 sec

Rave.11.0_PRD_Annotation: Form Matrix
Form: CMAS Form
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				4 = 4 = 60-119 sec 5 = 5 = > = 120 sec 97 = Not Done
⑥ STLEGSEC	3			
⑦ SUPIPRON	2			0 = 0 1 = 1 2 = 2 3 = 3 97 = Not Done
⑨ HNDTHIG1	2			0 = 0 = Unable or 1 = 1 = Able 97 = Not Done
⑩ HNDCHST1	2			0 = 0 = Unable or 1 = 1 = Able 97 = Not Done
⑪ HNDHEAD1	2			0 = 0 = Unable or 1 = 1 = Able

Rave.11.0_PRD_Annotation: Form Matrix
Form: CMAS Form
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				97 = Not Done
12 HNDTHIG2	2			0 = 0 = Unable or 1 = 1 = Able 97 = Not Done
13 HNDCHST2	2			0 = 0 = Unable or 1 = 1 = Able 97 = Not Done
14 HNDHEAD2	2			0 = 0 = Unable or 1 = 1 = Able 97 = Not Done
15 SITUPSCR	1			
17 SUPINSIT	2			0 = 0 1 = 1 2 = 2 3 = 3 97 = Not Done

Rave.11.0_PRD_Annotation: Form Matrix
Form: CMAS Form
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
18 ARMRAISE	2			0 = 0 1 = 1 2 = 2 3 = 3 97 = Not Done
19 ARMRSDUR	2			0 = 0 = Unable 1 = 1 = 1-9 sec 2 = 2 = 10-29 sec 3 = 3 = 30-59 sec 4 = 4 = > = 60 sec 97 = Not Done
20 ARMDRSEC	3			
21 FLOORSIT	2			0 = 0 1 = 1 2 = 2 3 = 3 97 = Not Done
22 FOURMAN	2			0 = 0 1 = 1 2 = 2 3 = 3 4 = 4 97 = Not Done

Rave.11.0_PRD_Annotation: Form Matrix
Form: CMAS Form
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
23 FLOORISE	2			0 = 0 1 = 1 2 = 2 3 = 3 4 = 4 97 = Not Done
24 CHAIRISE	2			0 = 0 1 = 1 2 = 2 3 = 3 4 = 4 97 = Not Done
25 STOLSTEP	2			0 = 0 1 = 1 2 = 2 3 = 3 97 = Not Done
26 PICKUP	2			0 = 0 1 = 1 2 = 2 3 = 3 97 = Not Done
27 CMASSCOR	2			

Rave.11.0_PRD_Annotation: Form Matrix
Form: MMT8 Form
Generated On: 23 Apr 2019 20:11:55

MMT8 STATUS

Done ☐ ①
Not Done ☐

Tested unilaterally (dominant side)

Shoulder abductors

Fixed Unit: Score ③

0 ☐
1 ☐
2 ☐
3 ☐
4 ☐
5 ☐
6 ☐
7 ☐
8 ☐
9 ☐
10 ☐
ND ☐

Elbow flexors

Fixed Unit: Score ④

0 ☐
1 ☐
2 ☐
3 ☐
4 ☐
5 ☐
6 ☐
7 ☐
8 ☐
9 ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: MMT8 Form
Generated On: 23 Apr 2019 20:11:55

10 ☐
ND ☐

Wrist extensors

Fixed Unit: Score ⑤

0 ☐
1 ☐
2 ☐
3 ☐
4 ☐
5 ☐
6 ☐
7 ☐
8 ☐
9 ☐
10 ☐
ND ☐

Knee extensors

Fixed Unit: Score ⑥

0 ☐
1 ☐
2 ☐
3 ☐
4 ☐
5 ☐
6 ☐
7 ☐
8 ☐
9 ☐
10 ☐
ND ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: MMT8 Form
Generated On: 23 Apr 2019 20:11:55

Ankle dorsiflexors

Fixed Unit: Score **7**

- 0 ☐
- 1 ☐
- 2 ☐
- 3 ☐
- 4 ☐
- 5 ☐
- 6 ☐
- 7 ☐
- 8 ☐
- 9 ☐
- 10 ☐
- ND ☐

Neck flexors

Fixed Unit: Score **8**

- 0 ☐
- 1 ☐
- 2 ☐
- 3 ☐
- 4 ☐
- 5 ☐
- 6 ☐
- 7 ☐
- 8 ☐
- 9 ☐
- 10 ☐
- ND ☐

Hip abductors

Fixed Unit: Score **9**

- 0 ☐

- 1 ☐
- 2 ☐
- 3 ☐
- 4 ☐
- 5 ☐
- 6 ☐
- 7 ☐
- 8 ☐
- 9 ☐
- 10 ☐
- ND ☐

Hip extensors

Fixed Unit: Score **10**

- 0 ☐
- 1 ☐
- 2 ☐
- 3 ☐
- 4 ☐
- 5 ☐
- 6 ☐
- 7 ☐
- 8 ☐
- 9 ☐
- 10 ☐
- ND ☐

Total MMT8 Score

Fixed Unit: (auto-calculate) **11**

Rave.11.0_PRD_Annotation: Form Matrix
Form: MMT8 Form
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① MMT8STAT	2			1 = Done 97 = Not Done
③ SHDABDUT	2			0 = 0 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 97 = ND
④ ELBOWFLX	2			0 = 0 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 97 = ND
⑤ WRISTEXT	2			0 = 0 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6

Rave.11.0_PRD_Annotation: Form Matrix
Form: MMT8 Form
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				7 = 7 8 = 8 9 = 9 10 = 10 97 = ND
⑥ KNEEEXT	2			0 = 0 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 97 = ND
⑦ ANKLDORS	2			0 = 0 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 97 = ND
⑧ NECKFLEX	2			0 = 0 1 = 1 2 = 2 3 = 3 4 = 4

Rave.11.0_PRD_Annotation: Form Matrix
Form: MMT8 Form
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 97 = ND
9 HIPABDUT	2			0 = 0 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 97 = ND
10 HIPEXTEN	2			0 = 0 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 97 = ND
11 MMT8SCOR	2			

Total Activity Score		①
Total Damage Score		②

Rave.11.0_PRD_Annotation: Form Matrix
Form: CDASI Form
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
<hr/>				
① TOACTSCR	3			
<hr/>				
② TODAMSCR	2			
<hr/>				

Rave.11.0_PRD_Annotation: Form Matrix

Form: Urine

Generated On: 23 Apr 2019 20:11:55

Date of collection _____ ①

Specific gravity _____ ②

Urine protein to creatinine ratio (UPC) in last 30 days
< 0.5 mg/mg ☐ ③
> = 0.5 mg/mg ☐
Not Done ☐

Ratio: _____ ④

Fixed Unit: Ratio Not Collected ⑤
☐

mg/mg ☐ ⑥
mg/mmol ☐
Not Collected ☐

Random ☐ ⑦
First am void ☐
Timed: ☐

24hr ☐ ⑧
Other ☐

Due to active SLE? Yes ☐ ⑨
No ☐
Unknown ☐

Rave.11.0_PRD_Annotation: Form Matrix

Form: Urine

Generated On: 23 Apr 2019 20:11:55

Proteinuria in last 30 days < / = 0.5 g/24 hours ☐ 10
> 0.5 g/24hours ☐
Not Done ☐

Due to active SLE? Yes ☐ 11
No ☐
Unknown ☐

Dipstick: Protein None/trace ☐ 12
1+ ☐
2+ ☐
3+ more ☐
Not Done ☐

Urinary WBCs in last 30 days < 5 WBC/hfp ☐ 13
> / = 5 WBC/hpf ☐
Not Done ☐

Due to active SLE? Yes ☐ 14
No ☐
Unknown ☐

Urinary RBCs in last 30 days < 5 RBC/hpf ☐ 15
> / = 5 RBC/hfp ☐
Not Done ☐

Due to active SLE? Yes ☐ 16
No ☐
Unknown ☐

Casts in last 30 days

White cell casts	<input type="checkbox"/>	17
Red cell casts	<input type="checkbox"/>	
Hyaline casts	<input type="checkbox"/>	
Not Done	<input type="checkbox"/>	





Rave.11.0_PRD_Annotation: Form Matrix**Form: Urine****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
① URINEDTC	dd- MMM- YYYY			
② SPECGRAV	8.3			
③ SPOTURIN	2			1 = < 0.5 mg/mg 2 = > = 0.5 mg/mg 97 = Not Done
④ URINRATO	8.3			
⑤ RATIONC	1			
⑥ RATIOUNT	2			1 = mg/mg 2 = mg/mmol 95 = Not Collected
⑦ SPOTURAN	1			1 = Random 2 = First am void 3 = Timed:
⑧ SPOTUTIM	2			1 = 24hr 98 = Other

Rave.11.0_PRD_Annotation: Form Matrix**Form: Urine****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
9 SPOTSLE	2			1 = Yes 0 = No 99 = Unknown
10 PROT30	2			1 = < / = 0.5 g/24 hours 2 = > 0.5 g/24hours 97 = Not Done
11 PRO30SLE	2			1 = Yes 0 = No 99 = Unknown
12 DIPSTICK	2			0 = None/trace 1 = 1+ 2 = 2+ 3 = 3+ more 97 = Not Done
13 URINWBC	2			1 = < 5 WBC/hfp 2 = > / = 5 WBC/hpf 97 = Not Done

Rave.11.0_PRD_Annotation: Form Matrix**Form: Urine****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
 URWBCSLE	2			1 = Yes 0 = No 99 = Unknown
 URINRBC	2			1 = < 5 RBC/hpf 2 = > / = 5 RBC/hfp 97 = Not Done
 URRBCSLE	2			1 = Yes 0 = No 99 = Unknown
 CASTS	2			1 = White cell casts 2 = Red cell casts 3 = Hyaline casts 97 = Not Done

Rave.11.0_PRD_Annotation: Form Matrix

Form: Biopsy Form

Generated On: 23 Apr 2019 20:11:55

Date of Collection

①

Has the subject [ever - baseline / since last visit - Followup] had any non-renal biopsies consistent with disease diagnosis?

Yes ☐ ②

No ☐

Unknown ☐

IF YES: Check all that apply:

Skin

☐ ④

Lacrimal Gland

☐ ⑤

Conjunctiva

☐ ⑥

Liver

☐ ⑦

Lung

☐ ⑧

Parotid Gland

☐ ⑨

Minor Salivary Gland

☐ ⑩

Other

☐ ⑪

Has the subject [ever - baseline / since last visit - Followup] had one or more renal biopsies?

Yes ☐ ⑫

No ☐

Unknown ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Biopsy Form
Generated On: 23 Apr 2019 20:11:55

IF YES, answer question below

Biopsy Date: _____ 14

WHO Class I ☐ 15

WHO Class II ☐ 16

WHO Class III ☐ 17

WHO Class IV ☐ 18

WHO Class V ☐ 19

WHO Class VI ☐ 20

WHO Class Unknown ☐ 21

WHO Class Not Done ☐ 22

ISN/RSP Class I ☐ 23

ISN/RPS Class II ☐ 24

ISN/RPS Class III ☐ 25

Rave.11.0_PRD_Annotation: Form Matrix
Form: Biopsy Form
Generated On: 23 Apr 2019 20:11:55

Check one:

Active ☐ 26
Active/chronic ☐
Chronic ☐
Unknown ☐

ISN/RPS Class IV

☐ 27

Check one:

Segmented (active) ☐ 28
Segmented
(active/chronic) ☐
Global (chronic) ☐
Global (active) ☐
Segmented (chronic) ☐
Unknown ☐

ISN/RPS Class V

☐ 29

ISN/RPS Class VI

☐ 30

ISN/RPS Class Unknown

☐ 31

ISN/RPS Class Not Done

☐ 32

Rave.11.0_PRD_Annotation: Form Matrix
Form: Biopsy Form
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
①	BIOPDTC	dd- MMM- YYYY			
②	NONRBIOP	2			1 = Yes 0 = No 99 = Unknown
④	SKIN	1			
⑤	LACGLAND	1			
⑥	CONJUNCT	1			
⑦	LIVER1	1			
⑧	LUNG	1			
⑨	PAROTIDG	1			
⑩	MINSALGL	1			
⑪	OTHER	1			
⑫	RENLBIOP	2			1 = Yes 0 = No 99 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix
Form: Biopsy Form
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
14	BIOPSDTC	MMM- yyyy			
15	WHO1	1			
16	WHO2	1			
17	WHO3	1			
18	WHO4	1			
19	WHO5	1			
20	WHO6	1			
21	WHOUNK	1			
22	WHOND	1			
23	ISNRPS1	1			
24	ISNRPS2	1			
25	ISNRPS3	1			
26	ACTCHRO1	2			1 = Active 2 = Active/chro nic

Rave.11.0_PRD_Annotation: Form Matrix
Form: Biopsy Form
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				3 = Chronic 99 = Unknown
27 ISNRPS4	1			
28 SEGGLOB1	2			1 = Segmented (active) 2 = Segmented (active/chronic) 3 = Global (chronic) 4 = Global (active) 5 = Segmented (chronic) 99 = Unknown
29 ISNRPS5	1			
30 ISNRPS6	1			
31 ISNRPSUK	1			
32 ISNRPSND	1			

Rave.11.0_PRD_Annotation: Form Matrix

Form: SLEDAI Form

Generated On: 23 Apr 2019 20:11:55

Has the subject had any of the following disease manifestations at the time of visit or within the preceding 30 days?

Seizure Yes ☐ ②
No ☐

Psychosis Yes ☐ ③
No ☐

Organic Brain Syndrome Yes ☐ ④
No ☐

Visual Disturbance Yes ☐ ⑤
No ☐

Cranial Nerve Disorder Yes ☐ ⑥
No ☐

Lupus Headache Yes ☐ ⑦
No ☐

CVA Yes ☐ ⑧
No ☐

Vasculitis Yes ☐ ⑨
No ☐

Arthritis Yes ☐ ⑩

Rave.11.0_PRD_Annotation: Form Matrix
Form: SLEDAI Form
Generated On: 23 Apr 2019 20:11:55

	No <input type="checkbox"/>
Myositis	Yes <input type="checkbox"/> 11 No <input type="checkbox"/>
Urinary Casts	Yes <input type="checkbox"/> 12 No <input type="checkbox"/>
Hematuria	Yes <input type="checkbox"/> 13 No <input type="checkbox"/>
Proteinuria	Yes <input type="checkbox"/> 14 No <input type="checkbox"/>
Pyuria	Yes <input type="checkbox"/> 15 No <input type="checkbox"/>
Rash	Yes <input type="checkbox"/> 16 No <input type="checkbox"/>
Alopecia	Yes <input type="checkbox"/> 17 No <input type="checkbox"/>
Mucosal Ulcers	Yes <input type="checkbox"/> 18 No <input type="checkbox"/>
Pleurisy	Yes <input type="checkbox"/> 19 No <input type="checkbox"/>

Rave.11.0_PRD_Annotation: Form Matrix
Form: SLEDAI Form
Generated On: 23 Apr 2019 20:11:55

Pericarditis	Yes <input type="checkbox"/> 20
	No <input type="checkbox"/>
Low Complement	Yes <input type="checkbox"/> 21
	No <input type="checkbox"/>
Increased dsDNA Binding	Yes <input type="checkbox"/> 22
	No <input type="checkbox"/>
Fever	Yes <input type="checkbox"/> 23
	No <input type="checkbox"/>
Thrombocytopenia	Yes <input type="checkbox"/> 24
	No <input type="checkbox"/>
Leukopenia	Yes <input type="checkbox"/> 25
	No <input type="checkbox"/>
TOTAL SCORE (SUM)	<input type="text"/> 26

Rave.11.0_PRD_Annotation: Form Matrix
Form: SLEDAI Form
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
② SEIZUREB	1			8 = Yes 0 = No
③ PSYCHOB	1			8 = Yes 0 = No
④ OBS	1			8 = Yes 0 = No
⑤ VISDIST	1			8 = Yes 0 = No
⑥ CRANNERV	1			8 = Yes 0 = No
⑦ LUPHEAD	1			8 = Yes 0 = No
⑧ CVA	1			8 = Yes 0 = No
⑨ VASCULIT	1			8 = Yes 0 = No
⑩ ARTHRIT1	1			4 = Yes 0 = No
⑪ MYOSITIS	1			4 = Yes 0 = No

Rave.11.0_PRD_Annotation: Form Matrix
Form: SLEDAI Form
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
12 URINCAST	1			4 = Yes 0 = No
13 HEMATURI	1			4 = Yes 0 = No
14 PROTEINU	1			4 = Yes 0 = No
15 PYURIA	1			4 = Yes 0 = No
16 RASH	1			2 = Yes 0 = No
17 ALOPECIB	1			2 = Yes 0 = No
18 MUCULCER	1			2 = Yes 0 = No
19 PLEURISY	1			2 = Yes 0 = No
20 PERICARD	1			2 = Yes 0 = No
21 LOWCOMP	1			2 = Yes 0 = No

Rave.11.0_PRD_Annotation: Form Matrix
Form: SLEDAI Form
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
22 INCDNA	1			2 = Yes 0 = No
23 FEVERB1	1			1 = Yes 0 = No
24 THROMB1	1			1 = Yes 0 = No
25 LEUKOPB	1			1 = Yes 0 = No
26 SLEDAISC	3			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Biological Samples
Generated On: 23 Apr 2019 20:11:55

Sample collected: _____ ①

Specify tissue type

Lymph Node ☐ ②

Brain ☐

Lung ☐

Muscle ☐

Skin ☐

Other ☐

Date of sample collection _____ ③

Was the patient treated at the time of sample collection? Yes ☐ ④

No ☐

Status as of the above date:

Stored at site/Frozen -80 ☐ ⑤

degrees C

Stored at site/Frozen -20 ☐

degrees C

Shipped to Lab another ☐

facility

Shipping destination

Cincinnati (U.S. samples) ☐ ⑥

Toronto (Canadian ☐

samples)

Other, specify ☐

Date shipped: _____ ⑦

Rave.11.0_PRD_Annotation: Form Matrix
Form: Biological Samples
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
①	TYPAMPL	2	Type of sample		SampleType
②	TISSTYPE	2			1 = Lymph Node 2 = Brain 3 = Lung 4 = Muscle 5 = Skin 98 = Other
③	SMPCLDTC	dd- MMM- yyyy	Date of sample collection		
④	PRETREAT	2			1 = Yes 0 = No
⑤	SAMPSTAT	2	Status as of collection date		1 = Stored at site/Frozen -80 degrees C 2 = Stored at site/Frozen -20 degrees C 3 = Shipped to Lab another facility

Rave.11.0_PRD_Annotation: Form Matrix
Form: Biological Samples
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
⑥	SHIPDEST	2	Shipping destination		1 = Cincinnati (U.S. samples) 2 = Toronto (Canadian samples) 98 = Other, specify
⑦	SHIPDTC	dd- MMM- yyyy	Date shipped		

Rave.11.0_PRD_Annotation: Form Matrix

Form: Steroids

Generated On: 23 Apr 2019 20:11:55

Has the subject [ever: baseline/since last visit:
follow-up] taken glucocorticoids (steroids) for the
treatment of rheumatologic disease?

Yes ☐ ①
No ☐
Unknown ☐

➝IF Yes, has the subject previously taken
glucocorticoids in the past 12 months (if baseline) or
since last visit (if follow-up) but are not currently taking
at this visit?

Yes ☐ ②
No ☐
Unknown ☐

➝IF Yes, Number of Courses: _____

③

➝IF Yes, Start Date of Most Recent Course: _____

④

➝IF Yes, End Date of Most Recent Course: _____

⑤

➝IF Yes, Route:

PO ☐ ⑥
IV ☐
Both ☐

➝IF Yes, Maximum Daily Dose: _____

Fixed Unit: mg ⑦

➝IF Yes, Select Medication:

Methylprednisolone ☐ ⑧
Prednisolone ☐
Prednisone ☐
Other, specify ☐

Is the subject currently taking a glucocorticoid (steroid)
for the treatment of rheumatologic disease (NOT IV
pulse doses)?

Yes ☐ ⑨
No ☐
Unknown ☐

Rave.11.0_PRD_Annotation: Form Matrix

Form: Steroids

Generated On: 23 Apr 2019 20:11:55

<hr/>	
#10141;IF Yes, Start date	<hr/>
<hr/>	
OR	Fixed Unit: Ongoing since last visit
	<input type="checkbox"/>
<hr/>	
#10141;IF Yes, Select medication:	Methylprednisolone <input type="checkbox"/>
	Prednisolone <input type="checkbox"/>
	Prednisone <input type="checkbox"/>
	Other, specify <input type="checkbox"/>
<hr/>	
#10141;IF Yes, Route:	PO <input type="checkbox"/>
	IV <input type="checkbox"/>
<hr/>	
#10141;IF Yes, Dose:	Fixed Unit: mg
	<hr/>
<hr/>	
#10141;IF Yes, Frequency	Daily <input type="checkbox"/>
	2x/day <input type="checkbox"/>
	3x/day <input type="checkbox"/>
	4x/day <input type="checkbox"/>
	Every other day <input type="checkbox"/>
	Other, Specify: <input type="checkbox"/>
<hr/>	
Has subject [ever-baseline/since last visit-follow-up] received intra- articular glucocorticoid (steroid) injections?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
	Unknown <input type="checkbox"/>
<hr/>	
#10141;IF Yes, How many?	<hr/>
	<hr/>
<hr/>	

Rave.11.0_PRD_Annotation: Form Matrix

Form: Steroids

Generated On: 23 Apr 2019 20:11:55

Did the subject receive intra- articular glucocorticoid injections at this visit?

Yes ☐ 18
No ☐
Unknown ☐

➝IF Yes, How many?

19

Has the subject [ever-baseline/since last visit-follow-up] received high- dose "pulse" IV glucocorticoids?(e.g., 30mg/kg of methylprednisolone)

Yes ☐ 20
No ☐
Unknown ☐

➝IF Yes, has the subject received "pulse" IV glucocorticoids in the past 12 months if baseline; since last visit if follow-up?

Yes ☐ 21
No ☐
Unknown ☐

➝IF Yes, Start date

22

➝IF Yes, End Date:

23

OR

Fixed Unit: Ongoing

24

☐

➝IF Ongoing, Frequency

Daily ☐ 25
2x/day ☐
3x/day ☐
4x/day ☐
Every other day ☐
2x / wk ☐
Weekly ☐
Every other week ☐

Rave.11.0_PRD_Annotation: Form Matrix

Form: Steroids

Generated On: 23 Apr 2019 20:11:55

	Every month	<input type="checkbox"/>
	As needed	<input type="checkbox"/>
	One time	<input type="checkbox"/>
	3 consecutive daily	<input type="checkbox"/>
	doses/month	
	Other, Specify:	<input type="checkbox"/>

➝IF Yes, Number of Pulse Doses in [in last 12 months-baseline/since last visit-follow-up]:

26

➝IF Yes, Total Daily Dose:

Fixed Unit: mg

27

Rave.11.0_PRD_Annotation: Form Matrix
Form: Steroids
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① STEROID	2	Oral glucocorticoids		1 = Yes 0 = No 99 = Unknown
② ONSTEROI	2			1 = Yes 0 = No 99 = Unknown
③ NUMCOURS	3			
④ RECCOUDT	dd- MMM-YYYY			
⑤ ENCOURDT	dd- MMM-YYYY			
⑥ STEROUTE	1			1 = PO 2 = IV 3 = Both
⑦ MAXDLDOS	6.2			
⑧ STERMEDS	2			1 = Methylprednisolone 2 = Prednisolone 3 = Prednisone

Rave.11.0_PRD_Annotation: Form Matrix**Form: Steroids****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
				98 = Other, specify
9 TAKESTER	2	Currently taking an oral glucocortico ids		1 = Yes 0 = No 99 = Unknown
10 STERODTC	dd- MMM- yyyy	Oral glucocortico ids: Start date		
11 STEROONG	1	Oral glucocortico ids: Ongoing since last visit		
12 CURNTMED	2	Oral steroids:Cur rent Medication		1 = Methylpred nisolone 2 = Prednisolon e 3 = Prednisone 98 = Other, specify
13 CUROUTE	1			1 = PO 2 = IV

Rave.11.0_PRD_Annotation: Form Matrix
Form: Steroids
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
14 CURNTDOS	6.2	Oral steroids: Current Dose		
15 CURTFREQ	2	Oral steroids: Current Frequency		1 = Daily 2 = 2x/day 3 = 3x/day 4 = 4x/day 5 = Every other day 98 = Other, Specify:
16 INJECTON	2	I-A steroids injections		1 = Yes 0 = No 99 = Unknown
17 INJTMANY	3	I-A gsteroids injections: number		
18 INTRAVIS	2	I-A steroids injections at this visit		1 = Yes 0 = No 99 = Unknown
19 INTRAMNY	2	I-Ar glucocortico ids injections at this visit: number		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Steroids
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
20	HIDOSPLS	2	High-dose pulse IV steroids		1 = Yes 0 = No 99 = Unknown
21	CRNTHIPL	2	High-dose pulse IV steroids current		1 = Yes 0 = No 99 = Unknown
22	HIPLSDTC	dd- MMM- yyyy	High-dose pulse IV steroids: Start date		
23	HIPLIEDTC	dd- MMM- yyyy			
24	HIPLSONG	1	High-dose pulse IV steroids Ongoing		
25	HIPLSFRQ	2	High-dose pulse IV glucocortico ids: Freq		1 = Daily 2 = 2x/day 3 = 3x/day 4 = 4x/day 5 = Every other day 6 = 2x / wk 7 = Weekly 8 = Every other week 9 = Every month

Rave.11.0_PRD_Annotation: Form Matrix
Form: Steroids
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				10 = As needed 11 = One time 12 = 3 consecutive daily doses/mont h 98 = Other, Specify:
26 NUMPLSDO	3			
27 HIPLSDOS	6.2	High-dose pulse IV glucocortico ids: Dose		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Questionnaires
Generated On: 23 Apr 2019 20:11:55

Tanner breast stage (female only) _____ ①

Tanner pubic hair (female) _____ ②

Tanner pubic hair (male) _____ ③

Tanner genital stage (male only) _____ ④

Faces Pain Scale _____ ⑤

CHAQ disability Index _____ ⑥

Person completing Quality of Life questionnaires
Parent/Proxy (subject <8 years old or subject unable) ☐ ⑦
Subject (8 years or older) ☐

Qualtrics PROs Completed Yes ☐ ⑧
No ☐
Not Collected ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Questionnaires
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
①	TANRBRST	2	Tanner breast stage (female only)		
②	TANRHAIR	2	Tanner pubic hair (female)		
③	TANRHARM	2.0	Tanner pubic hair (male)		
④	TANRGENT	2	Tanner genital stage (male only)		
⑤	FACPNSCL	2	Faces Pain Scale score		
⑥	CHAQINDX	4.3	CHAQ disability Index score		
⑦	PERSNCMP	2	Person completing questionnaires		1 = Parent/Proxy (subject <8 years old or subject unable)

Rave.11.0_PRD_Annotation: Form Matrix
Form: Questionnaires
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				2 = Subject (8 years or older)
⑧ QUALTRIC	2			1 = Yes 0 = No 95 = Not Collected

Rave.11.0_PRD_Annotation: Form Matrix
Form: STOP-JIA CTP Baseline
Generated On: 23 Apr 2019 20:11:55

Consensus Treatment Plan

Has the subject had past or current treatment with any of the following medications for poly-JIA?
(Chronic (not PRN) NSAIDs, Intra-articular, topical or intra-ocular steroids, Hydroxychloroquine)

Yes ☐ ②
No ☐

Chronic (not PRN) NSAIDs

☐ ③

Intra-articular, topical or intra-ocular steroids

☐ ④

Hydroxychloroquine

☐ ⑤

Select the appropriate CTP as designated by the treating physician:

Plan A: Step up CTP ☐ ⑥
(Disease modifying anti-rheumatic drug (DMARD) monotherapy now, stepping up to add a biologic medication later if needed)
Plan B: Early Combination CTP (DMARD plus biologic medication started within one month of starting treatment) ☐
Plan C: Biologic First CTP (Biologic medication monotherapy at start of treatment) ☐

Enter the start date of the CTP:

_____ ⑦

Indicate the reason why the above CTP plan was selected for this subject: (Check all that apply)

Rave.11.0_PRD_Annotation: Form Matrix
Form: STOP-JIA CTP Baseline
Generated On: 23 Apr 2019 20:11:55

Patient/family preference	<input type="checkbox"/> 9
	<input type="checkbox"/> 10 Prefers method of medication administration
	<input type="checkbox"/> Concern about side effects of DMARDs
	<input type="checkbox"/> Concern about side effects of biologics
	<input type="checkbox"/> Concern about safety of treatment
	<input type="checkbox"/> Other
Physician preference	<input type="checkbox"/> 11
	<input type="checkbox"/> 12 Site always uses this treatment approach
	<input type="checkbox"/> Most comfortable with this treatment
	<input type="checkbox"/> This treatment works best
	<input type="checkbox"/> This treatment is safest
	<input type="checkbox"/> This treatment is best tolerated
	<input type="checkbox"/> Other
Concern about adherence	<input type="checkbox"/> 13
	<input type="checkbox"/> 14 Concern about adherence with oral medications
	<input type="checkbox"/> Concern about adherence with self-injected medications
	<input type="checkbox"/> Previous non compliance
	<input type="checkbox"/> Other

Rave.11.0_PRD_Annotation: Form Matrix
Form: STOP-JIA CTP Baseline
Generated On: 23 Apr 2019 20:11:55

Cost or insurance issues	<input type="checkbox"/>	15
--------------------------	--------------------------	-----------

Other	<input type="checkbox"/>	16
-------	--------------------------	-----------

JADAS score		17
-------------	--	-----------

Is the subject starting prednisone at this visit?	Yes <input type="checkbox"/>	18
	No <input type="checkbox"/>	

<p>If YES, indicate which prednisone dosing and tapering plan will be used (see Glucocorticoid Tapering tables):</p>	<table border="0" style="width: 100%;"><tr><td style="width: 80%;">Option 1 LOW DOSE PREDNISONE: Starting dose 0.2 mg/kg with 2 week taper</td><td style="width: 10%; text-align: right;"><input type="checkbox"/></td><td style="width: 10%; text-align: right;">19</td></tr><tr><td>Option 2 MEDIUM DOSE PREDNISONE: Starting dose 0.5 mg/kg with one month taper</td><td style="text-align: right;"><input type="checkbox"/></td><td></td></tr><tr><td>Option 3 HIGH DOSE PREDNISONE FAST TAPER: Starting dose 1 mg/kg with 1 month taper</td><td style="text-align: right;"><input type="checkbox"/></td><td></td></tr><tr><td>Option 4 HIGH DOSE PREDNISONE SLOW TAPER: Starting dose 1mg/kg with 3 Month taper</td><td style="text-align: right;"><input type="checkbox"/></td><td></td></tr><tr><td>Other</td><td style="text-align: right;"><input type="checkbox"/></td><td></td></tr></table>	Option 1 LOW DOSE PREDNISONE: Starting dose 0.2 mg/kg with 2 week taper	<input type="checkbox"/>	19	Option 2 MEDIUM DOSE PREDNISONE: Starting dose 0.5 mg/kg with one month taper	<input type="checkbox"/>		Option 3 HIGH DOSE PREDNISONE FAST TAPER: Starting dose 1 mg/kg with 1 month taper	<input type="checkbox"/>		Option 4 HIGH DOSE PREDNISONE SLOW TAPER: Starting dose 1mg/kg with 3 Month taper	<input type="checkbox"/>		Other	<input type="checkbox"/>	
Option 1 LOW DOSE PREDNISONE: Starting dose 0.2 mg/kg with 2 week taper	<input type="checkbox"/>	19														
Option 2 MEDIUM DOSE PREDNISONE: Starting dose 0.5 mg/kg with one month taper	<input type="checkbox"/>															
Option 3 HIGH DOSE PREDNISONE FAST TAPER: Starting dose 1 mg/kg with 1 month taper	<input type="checkbox"/>															
Option 4 HIGH DOSE PREDNISONE SLOW TAPER: Starting dose 1mg/kg with 3 Month taper	<input type="checkbox"/>															
Other	<input type="checkbox"/>															



Rave.11.0_PRD_Annotation: Form Matrix
Form: STOP-JIA CTP Baseline
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
② POLYJIA	1	Past/current treatment with following meds		1 = Yes 0 = No
③ CRONSAID	1	Chronic (not PRN) NSAIDs		
④ STEROIDS	1	Intra-articular, topical/intra-ocular steroids		
⑤ HYDRCHLO	1	Hydroxychloroquine		
⑥ CTP	1	CTP designated by treating physician		1 = Plan A: Step up CTP (Disease modifying anti-rheumatic drug (DMARD) monotherapy now, stepping up to add a biologic medication later if needed)





Rave.11.0_PRD_Annotation: Form Matrix
Form: STOP-JIA CTP Baseline
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				2 = Plan B: Early Combination CTP (DMARD plus biologic medication started within one month of starting treatment) 3 = Plan C: Biologic First CTP (Biologic medication monotherapy at start of treatment)
⑦ CTPSTDAT	dd- MM- yyyy	CTP start date		
⑨ PTPREFER	1	Patient/fami ly preference		
⑩ PTPREFSP	2	Patient/fami ly preference (choose one)		1 = Prefers method of medication administrati on

Rave.11.0_PRD_Annotation: Form Matrix
Form: STOP-JIA CTP Baseline
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				2 = Concern about side effects of DMARDs 3 = Concern about side effects of biologics 4 = Concern about safety of treatment 98 = Other
 PHYPPREF	1	Physician preference		
 PHYPPRESP	2	Physician preference (choose one)		1 = Site always uses this treatment approach 2 = Most comfortable with this treatment 3 = This treatment works best 4 = This treatment is safest

Rave.11.0_PRD_Annotation: Form Matrix
Form: STOP-JIA CTP Baseline
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				5 = This treatment is best tolerated 98 = Other
 ADHERENC	1	Concern about adherence		
 ADHERESP	2	Concern about adherence specify		1 = Concern about adherence with oral medications 2 = Concern about adherence with self-injected medications 3 = Previous non compliance 98 = Other
 COVERED	1	Cost or insurance issues		
 OTPHYRES	1	Other		

Rave.11.0_PRD_Annotation: Form Matrix
Form: STOP-JIA CTP Baseline
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
17	JADASBSE	\$4	JADAS score		
18	STPREDNS	2	Subject starting prednisone at this visit		1 = Yes 0 = No
19	STPREDY	2	Prednisone dosing and tapering plan		1 = Option 1 LOW DOSE PREDNISON E: Starting dose 0.2 mg/kg with 2 week taper 2 = Option 2 MEDIUM DOSE PREDNISON E: Starting dose 0.5 mg/kg with one month taper 3 = Option 3 HIGH DOSE PREDNISON E FAST TAPER: Starting dose 1 mg/kg with 1 month taper

Rave.11.0_PRD_Annotation: Form Matrix
Form: STOP-JIA CTP Baseline
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				4 = Option 4 HIGH DOSE PREDNISON E SLOW TAPER: Starting dose 1mg/kg with 3 Month taper 98 = Other

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST CTP Baseline
Generated On: 23 Apr 2019 20:11:55

ELIGIBILITY

Has the subject had past or current treatment with GC?

Yes ☐ ②
No ☐

CONSENSUS TREATMENT PLAN CHOICE

Select the appropriate CTP as designated by the treating physician:

Plan A: GC CTP ☐ ④
Plan B: Methotrexate CTP ☐
Plan C: IL-1 inhibitor CTP ☐
Plan D: IL-6 inhibitor CTP ☐

Enter the start date of the CTP: _____

⑤

The CTP choice was primarily based upon the following considerations (check all that apply):

Likelihood of effectiveness for ARTHRITIS ☐ ⑦

Likelihood of effectiveness for SYSTEMIC FEATURES ☐ ⑧

Likelihood of effectiveness for MACROPHAGE ACTIVATION SYNDROME ☐ ⑨

Minimization of systemic glucocorticoids ☐ ⑩

Method of administration (either convenience or adherence concerns) ☐ ⑪

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST CTP Baseline
Generated On: 23 Apr 2019 20:11:55

Safety profile	<input type="checkbox"/>	12
Cost or cost-effectiveness	<input type="checkbox"/>	13
Patient/family preference	<input type="checkbox"/>	14
Third party payer restrictions	<input type="checkbox"/>	15
Other	<input type="checkbox"/>	16
Other (with free text)	<input type="text"/>	
In the opinion of the treating physician, how often does he/she initiate a biologic agent at the time of diagnosis for the typical patient with SJIA of moderate severity?	<input type="checkbox"/> <10%	18
	<input type="checkbox"/> 25%	
	<input type="checkbox"/> 50%	
	<input type="checkbox"/> 75%	
	<input type="checkbox"/> >90%	
Systemic JIA Features		
1. - Date of onset of SJIA fever:	<input type="text"/>	
Number of days of fever in the past two weeks:	Fixed Unit: days	21
	<input type="checkbox"/> 0	
	<input type="checkbox"/> 1	
	<input type="checkbox"/> 2	
	<input type="checkbox"/> 3	
	<input type="checkbox"/> 4	

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST CTP Baseline
Generated On: 23 Apr 2019 20:11:55

5 ☐
6 ☐
7 ☐
8 ☐
9 ☐
10 ☐
11 ☐
12 ☐
13 ☐
14 ☐

2. - Date of onset of arthritis: _____ **22**

3. - Date of onset of sJIA rash: _____ **23**

OR Fixed Unit: Not applicable **24**
☐

MAS Assessment

4. - Has the subject ever had any MAS episodes? Yes ☐ **26**
No ☐

Glucocorticoid (GC) Dosing and Tapering

Will the subject be taking GC? Yes ☐ **28**
No ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST CTP Baseline
Generated On: 23 Apr 2019 20:11:55

If YES, indicate which prednisone dosing and tapering plan will be used (see Glucocorticoid Tapering tables):

- Option 1 PULSE STEROID ONLY ☒ 29
- Option 2 MODERATE DOSE PREDNISONE RAPID TAPER: Starting dose 1 mg/kg with one month taper ☐
- Option 3 MODERATE DOSE PREDNISONE FAST TAPER: Starting dose 1 mg/kg with 3 month taper ☐
- Option 4 MODERATE DOSE PREDNISONE SLOW TAPER: Starting dose 1mg/kg with 6 Month taper ☐
- Option 5 HIGH DOSE PREDNISONE FAST TAPER: Starting dose 2mg/kg with 3 Month taper ☐
- Option 6 HIGH DOSE PREDNISONE SLOW TAPER: Starting dose 2mg/kg with 6 Month taper ☐
- Other dosing ☐

specify

Fixed Unit: mg/kg 30

with

Fixed Unit: month taper 31

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST CTP Baseline
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
② TREATGC	1			1 = Yes 0 = No
④ CTPBASE	1			1 = Plan A: GC CTP 2 = Plan B: Methotrexate CTP 3 = Plan C: IL-1 inhibitor CTP 4 = Plan D: IL-6 inhibitor CTP
⑤ CTPSRBDT	dd- MMM- YYYY			
⑦ ARTHRITI	1			
⑧ SYSTFEAT	1			
⑨ MAS	1			
⑩ SYSTGLUC	1			
⑪ ADMINIS	1			
⑫ SAFEPRO	1			

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST CTP Baseline
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
13 COSTEFF	1			
14 PTFAMPRF	1			
15 THRDPRTY	1			
16 OTHCHOIC	1			
17 CHOICSPY	\$50			
18 INITBIOL	1			1 = <10% 2 = 25% 3 = 50% 4 = 75% 5 = >90%
20 FEVERDT	dd- MMM- YYYY			
21 DAYSFEVR	2			0 = 0 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 11 = 11 12 = 12 13 = 13

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST CTP Baseline
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				14 = 14
22 ARTHRIDT	dd- MMM- YYYY			
23 RASHDT	dd- MMM- YYYY			
24 RASHNA	1			
26 EVERMAS	1			1 = Yes 0 = No
28 TAKINGGC	1			1 = Yes 0 = No
29 PREDDOSE	1			1 = Option 1 PULSE STEROID ONLY 2 = Option 2 MODERATE DOSE PREDNISON E RAPID TAPER: Starting dose 1 mg/kg with one month taper

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST CTP Baseline
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				3 = Option 3 MODERATE DOSE PREDNISON E FAST TAPER: Starting dose 1 mg/kg with 3 month taper 4 = Option 4 MODERATE DOSE PREDNISON E SLOW TAPER: Starting dose 1mg/kg with 6 Month taper 5 = Option 5 HIGH DOSE PREDNISON E FAST TAPER: Starting dose 2mg/kg with 3 Month taper

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST CTP Baseline
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				6 = Option 6 HIGH DOSE PREDNISON E SLOW TAPER: Starting dose 2mg/kg with 6 Month taper 7 = Other dosing
30 DOSESPF	5.2			
31 MONTHTAP	2			

Rave.11.0_PRD_Annotation: Form Matrix
Form: STOP-JIA CRF Follow-Up
Generated On: 23 Apr 2019 20:11:55

Consensus Treatment Plan

Since last visit, is the subject following the same CTP at this visit?

Yes ☐ ②
No ☐

→IF NO, Is the subject following a new CTP?

Yes ☐ ③
No ☐

→IF YES, Select the appropriate CTP as designated by the treating physician:

Plan A: Step up CTP ☐ ④
(Disease modifying anti-rheumatic drug (DMARD) monotherapy now, stepping up to add a biologic medication later if needed)
Plan B: Early Combination CTP (DMARD plus biologic medication started within one month of starting treatment) ☐
Plan C: Biologic First CTP (Biologic medication monotherapy at start of treatment) ☐

Indicate the reason why the CTP plan was changed for this subject: (Check all that apply)

☐ ⑤

Patient/family preference

Method of medication administration ☐ ⑥
Side effects of DMARDs ☐
Side effects of biologics ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: STOP-JIA CRF Follow-Up
Generated On: 23 Apr 2019 20:11:55

	Concern about safety of treatment	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
Physician preference		<input type="checkbox"/> 7
<hr/>		
	Site always uses this treatment approach	<input type="checkbox"/> 8
	Most comfortable using this treatment	<input type="checkbox"/>
	This treatment works best	<input type="checkbox"/>
	This treatment is safest	<input type="checkbox"/>
	This treatment is best tolerated	<input type="checkbox"/>
	Adjustment due to intolerance or adherence	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
Cost or insurance issues		<input type="checkbox"/> 9
<hr/>		
Adherence issues		<input type="checkbox"/> 10
<hr/>		
	Concern about adherence with oral medications	<input type="checkbox"/> 11
	Concern about adherence with self-injected medications	<input type="checkbox"/>
	Concern about dosing frequency	<input type="checkbox"/>
	Documented non-compliance	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
Side effect or other adverse event (complete AE form)		<input type="checkbox"/> 12

Rave.11.0_PRD_Annotation: Form Matrix
Form: STOP-JIA CRF Follow-Up
Generated On: 23 Apr 2019 20:11:55

Inadequate response or disease flare	<input type="checkbox"/>	13
Other	<input type="checkbox"/>	14
Enter the start date of the new CTP:	<input type="text"/>	15
JADAS score (RAVE will automatically calculate this score)*:	<input type="text"/>	16
Is the subject taking prednisone?	Yes <input type="checkbox"/> No <input type="checkbox"/>	17
<hr/>		
→If YES, indicate which prednisone dosing and tapering plan will be used (see Glucocorticoid Tapering tables):	Option 1 LOW DOSE PREDNISONE: Starting dose 0.2 mg/kg with 2 week taper <input type="checkbox"/> Option 2 MEDIUM DOSE PREDNISONE: Starting dose 0.5 mg/kg with one month taper <input type="checkbox"/> Option 3 HIGH DOSE PREDNISONE FAST TAPER: Starting dose 1 mg/kg with 1 month taper <input type="checkbox"/> Option 4 HIGH DOSE PREDNISONE SLOW TAPER: Starting dose 1mg/kg with 3 Month taper <input type="checkbox"/> Other <input type="checkbox"/>	18

Rave.11.0_PRD_Annotation: Form Matrix
Form: STOP-JIA CRF Follow-Up
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
②	CURTREAT	1	Same CTP at this visit		1 = Yes 0 = No
③	NEWCTP	1	Subject is following new CTP		1 = Yes 0 = No
④	PLANNOW	1	CTP as designated by treating physician		1 = Plan A: Step up CTP (Disease modifying anti-rheum atic drug (DMARD) monotherap y now, stepping up to add a biologic medication later if needed)

Rave.11.0_PRD_Annotation: Form Matrix
Form: STOP-JIA CRF Follow-Up
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				2 = Plan B: Early Combinatio n CTP (DMARD plus biologic medication started within one month of starting treatment) 3 = Plan C: Biologic First CTP (Biologic medication monotherap y at start of treatment)
⑤ FPTPREFE	1	Reason CTP was changed for this subject		
⑥ FPTPRES	2	Pt/Family preference specify		1 = Method of medication administrati on 2 = Side effects of DMARDs 3 = Side effects of biologics

Rave.11.0_PRD_Annotation: Form Matrix
Form: STOP-JIA CRF Follow-Up
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				4 = Concern about safety of treatment 98 = Other
⑦ FPHYPREF	1	Physician preference		
⑧ FPHYPRSP	2	Physician preference specify		1 = Site always uses this treatment approach 2 = Most comfortable using this treatment 3 = This treatment works best 4 = This treatment is safest 5 = This treatment is best tolerated 6 = Adjustment due to intolerance or adherence

Rave.11.0_PRD_Annotation: Form Matrix
Form: STOP-JIA CRF Follow-Up
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				98 = Other
9 FCOST	1	Cost/insurance issues		
10 FADNEREN	1	Adherence issues		
11 FADNERSP	2	Adherence issues specify		1 = Concern about adherence with oral medications 2 = Concern about adherence with self-injected medications 3 = Concern about dosing frequency 4 = Documented non-compliance 98 = Other
12 SIDEFFET	1	Side effect/other AE		

Rave.11.0_PRD_Annotation: Form Matrix
Form: STOP-JIA CRF Follow-Up
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
13	INADEQUT	1	Inadequate response/disease flare		
14	FOTHPHYR	1	Other physician reason		
15	SNCTPDAT	dd- MMM-yyyy	Start date of new CTP		
16	JADASFU	\$4	JADAS score		
17	FPREDNIS	1	Subject taking prednisone		1 = Yes 0 = No
18	FPREDDOS	2	Prednisone dosing and tapering plan		1 = Option 1 LOW DOSE PREDNISON E: Starting dose 0.2 mg/kg with 2 week taper

Rave.11.0_PRD_Annotation: Form Matrix
Form: STOP-JIA CRF Follow-Up
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				2 = Option 2 MEDIUM DOSE PREDNISON E: Starting dose 0.5 mg/kg with one month taper 3 = Option 3 HIGH DOSE PREDNISON E FAST TAPER: Starting dose 1 mg/kg with 1 month taper 4 = Option 4 HIGH DOSE PREDNISON E SLOW TAPER: Starting dose 1mg/kg with 3 Month taper

Rave.11.0_PRD_Annotation: Form Matrix
Form: STOP-JIA CRF Follow-Up
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				98 = Other

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST CTP Follow-Up
Generated On: 23 Apr 2019 20:11:55

Systemic JIA Features

Number of days of fever in the past two weeks:

0	<input checked="" type="radio"/>	2
1	<input type="radio"/>	
2	<input type="radio"/>	
3	<input type="radio"/>	
4	<input type="radio"/>	
5	<input type="radio"/>	
6	<input type="radio"/>	
7	<input type="radio"/>	
8	<input type="radio"/>	
9	<input type="radio"/>	
10	<input type="radio"/>	
11	<input type="radio"/>	
12	<input type="radio"/>	
13	<input type="radio"/>	
14	<input type="radio"/>	

MAS Assessment

Has the subject had any MAS episodes since the last visit?

Yes	<input checked="" type="radio"/>	4
No	<input type="radio"/>	

Glucocorticoid (GC) Dosing and Tapering

Are GC being continued at this visit?

Yes	<input checked="" type="radio"/>	6
No	<input type="radio"/>	

If YES, indicate which prednisone dosing and tapering plan will be used (see Glucocorticoid Tapering tables):

Option 1 PULSE STEROID ONLY ☒ 7

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST CTP Follow-Up
Generated On: 23 Apr 2019 20:11:55

- Option 2 MODERATE DOSE ☐
PREDNISONONE RAPID
TAPER: Starting dose 1
mg/kg with one month
taper
- Option 3 MODERATE DOSE ☐
PREDNISONONE FAST TAPER:
Starting dose 1 mg/kg with
3 month taper
- Option 4 MODERATE DOSE ☐
PREDNISONONE SLOW
TAPER: Starting dose
1mg/kg with 6 Month taper
- Option 5 HIGH DOSE ☐
PREDNISONONE FAST TAPER:
Starting dose 2mg/kg with
3 Month taper
- Option 6 HIGH DOSE ☐
PREDNISONONE SLOW
TAPER: Starting dose
2mg/kg with 6 Month taper
- Other dosing ☐

specify

Fixed Unit: mg/kg **8**

with

Fixed Unit: month taper **9**

Are GC being started at this visit?

Yes ☐ **10**
No ☐

If YES, indicate which prednisone dosing and tapering
plan will be used (see Glucocorticoid Tapering tables):

Option 1 PULSE STEROID ☐ **11**
ONLY

- Option 2 MODERATE DOSE ☐
PREDNISONE RAPID
TAPER: Starting dose 1
mg/kg with one month
taper
- Option 3 MODERATE DOSE ☐
PREDNISONE FAST TAPER:
Starting dose 1 mg/kg with
3 month taper
- Option 4 MODERATE DOSE ☐
PREDNISONE SLOW
TAPER: Starting dose
1mg/kg with 6 Month taper
- Option 5 HIGH DOSE ☐
PREDNISONE FAST TAPER:
Starting dose 2mg/kg with
3 Month taper
- Option 6 HIGH DOSE ☐
PREDNISONE SLOW
TAPER: Starting dose
2mg/kg with 6 Month taper
- Other dosing ☐

specify

Fixed Unit: mg/kg

12

with

Fixed Unit: month taper

13

PHYSICIAN'S ASSESSMENT OF SUBJECT'S STATUS SJIA CTP FOLLOW-UP

What is the physician's assessment of subject's disease
status compared to the prior study visit?

- Improved ☐ 15
- Somewhat Improved ☐
- Unchanged ☐
- Somewhat Worsened ☐
- Worsened ☐

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Form: FROST CTP Follow-Up
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CONSENSUS TREATMENT PLAN CHOICE

Is or will the subject be following a different CTP than the one that was started at the last visit?

Yes ☒ 17
No ☐

IF YES, Select the appropriate CTP as designated by the treating physician:

Plan A: GC CTP ☒ 18
Plan B: Methotrexate CTP ☐
Plan C: IL-1 inhibitor CTP ☐
Plan D: IL-6 inhibitor CTP ☐

IF YES, Enter start date of the CTP

19

IF YES, The decision to change the CTP was based primarily on the following considerations: (Check all that apply)
Inefficacy of prior CTP for ARTHRITIS

☐ 20

Inefficacy of prior CTP for SYSTEMIC FEATURES

☐ 21

Inefficacy of prior CTP for MACROPHAGE ACTIVATION SYNDROME

☐ 22

Inability to wean systemic glucocorticoids

☐ 23

Poor tolerance of the method/route of administration of the prior CTP

☐ 24

Safety concerns (in the absence of a specific adverse event)

☐ 25

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Cost or cost-effectiveness	<input type="checkbox"/>	26
Patient/family preference	<input type="checkbox"/>	27
Third party payer restrictions	<input type="checkbox"/>	28
Poor adherence with prior CTP	<input type="checkbox"/>	29
Adverse safety event with prior CTP	<input type="checkbox"/>	30
Other	<input type="checkbox"/>	31
(with free text)		32

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST CTP Follow-Up
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Field Name	Data Type	SAS Label	Units	Values
② FEVERFUP	2			0 = 0 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 11 = 11 12 = 12 13 = 13 14 = 14
④ MASFUP	1			1 = Yes 0 = No
⑥ GCPFUP	1			1 = Yes 0 = No
⑦ PRDTAPCN	1			1 = Option 1 PULSE STEROID ONLY

Rave.11.0_PRD_Annotation: Form Matrix
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Field Name	Data Type	SAS Label	Units	Values
				2 = Option 2 MODERATE DOSE PREDNISON E RAPID TAPER: Starting dose 1 mg/kg with one month taper 3 = Option 3 MODERATE DOSE PREDNISON E FAST TAPER: Starting dose 1 mg/kg with 3 month taper 4 = Option 4 MODERATE DOSE PREDNISON E SLOW TAPER: Starting dose 1mg/kg with 6 Month taper




Rave.11.0_PRD_Annotation: Form Matrix
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Field Name	Data Type	SAS Label	Units	Values
				5 = Option 5 HIGH DOSE PREDNISON E FAST TAPER: Starting dose 2mg/kg with 3 Month taper 6 = Option 6 HIGH DOSE PREDNISON E SLOW TAPER: Starting dose 2mg/kg with 6 Month taper 7 = Other dosing
8 PRDTAPSP	5.2			
9 PRDTAPM	2			
10 GCSTRNOW	1			1 = Yes 0 = No

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST CTP Follow-Up
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Field Name	Data Type	SAS Label	Units	Values
11 GCPRDTPN	1			1 = Option 1 PULSE STEROID ONLY 2 = Option 2 MODERATE DOSE PREDNISON E RAPID TAPER: Starting dose 1 mg/kg with one month taper 3 = Option 3 MODERATE DOSE PREDNISON E FAST TAPER: Starting dose 1 mg/kg with 3 month taper 4 = Option 4 MODERATE DOSE PREDNISON E SLOW TAPER: Starting dose 1mg/kg with 6 Month taper

Rave.11.0_PRD_Annotation: Form Matrix
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Field Name	Data Type	SAS Label	Units	Values
				5 = Option 5 HIGH DOSE PREDNISON E FAST TAPER: Starting dose 2mg/kg with 3 Month taper 6 = Option 6 HIGH DOSE PREDNISON E SLOW TAPER: Starting dose 2mg/kg with 6 Month taper 7 = Other dosing
 GCPTSPF	5.2			
 GCPTMNT	2			
 PHYASSME	1			1 = Improved 2 = Somewhat Improved 3 = Unchanged

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST CTP Follow-Up
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Field Name	Data Type	SAS Label	Units	Values
				4 = Somewhat Worsened 5 = Worsened
17 DIFFRCTP	1			1 = Yes 0 = No
18 CTPFUP	1			1 = Plan A: GC CTP 2 = Plan B: Methotrexat e CTP 3 = Plan C: IL-1 inhibitor CTP 4 = Plan D: IL-6 inhibitor CTP
19 CTPFUPDT	dd- MMM- YYYY			
20 INEFARTH	1			
21 INEFSYSF	1			
22 INEFMAS	1			
23 WEANGLUC	1			

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST CTP Follow-Up
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Field Name	Data Type	SAS Label	Units	Values
24 POORTOLR	1			
25 SAFETYCN	1			
26 COSTS	1			
27 PATFMPRF	1			
28 THRDPAYR	1			
29 POORADHR	1			
30 ASECTP	1			
31 CHNGOTH	1			
32 CHNGOSPF	\$50			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Serious Adverse Events or Event of Special Interest
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If AE needs to be deleted, please choose yes from the dropdown and provide the reason for deletion.

Yes, delete the AE for this reason ☐ ①

Event Number (non-enterable field) _____

②

Event _____

③

④

Secondary Event Term _____

⑤

Infection Type: _____

⑥

Event onset date _____

⑦

Imputed onset date _____

⑧

Event Severity at onset (CTCAE level)

Grade 1 - Mild ☐ ⑨

Grade 2 - Moderate ☐

Grade 3 - Severe but not immediately

life-threatening

Grade 4 - Life-threatening consequences ☐

Grade 5 - Death related to AE ☐

Event Severity most extreme (CTCAE level)

Grade 1 - Mild ☐ ⑩

Grade 2 - Moderate ☐

Grade 3 - Severe but not immediately

life-threatening

Rave.11.0_PRD_Annotation: Form Matrix
Form: Serious Adverse Events or Event of Special Interest
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	Grade 4 - Life-threatening consequences	<input type="checkbox"/>
	Grade 5 - Death related to AE	<input type="checkbox"/>

Was this event serious? (If Yes, check all that apply)	Yes	<input type="checkbox"/> 11
	No	<input type="checkbox"/>

Death	<input type="checkbox"/> 12
-------	-----------------------------

Life-threatening	<input type="checkbox"/> 13
------------------	-----------------------------

Require inpatient hospitalization or prolongation of existing hospitalization	<input type="checkbox"/> 14
---	-----------------------------

Persistent or significant disability/incapacity	<input type="checkbox"/> 15
---	-----------------------------

Congenital anomaly or birth defect	<input type="checkbox"/> 16
------------------------------------	-----------------------------

Important medical event	<input type="checkbox"/> 17
-------------------------	-----------------------------

Event Outcome	Recovered/Resolved	<input type="checkbox"/> 18
	Recovering/Resolving	<input type="checkbox"/>
	Not recovered/Not resolved	<input type="checkbox"/>
	Recovered/Resolved with sequelae	<input type="checkbox"/>
	Fatal	<input type="checkbox"/>
	Unknown	<input type="checkbox"/>

Has Event stopped?	Stopped	<input type="checkbox"/> 19
--------------------	---------	-----------------------------

Rave.11.0_PRD_Annotation: Form Matrix
Form: Serious Adverse Events or Event of Special Interest
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Ongoing ☐

Event stop date

☒ 20

Subject's height closest available to onset of event

cm ☒ 21
in ☐
ND ☐

Subject's weight closest available to onset of event

kg ☒ 22
lb ☐
ND ☐

Was the subject on any immunomodulatory medications
at or within 30 days prior to event onset?

Yes ☒ 23
No ☐

Event Summary

☒ 24

Provide a summary, in chronological order, of the clinical
course of this event from onset through resolution. 1.
Presenting signs and symptoms; 2. Treatments and
response to treatments 3. Subject's status at time of
report and/or final outcome, as applicable; 4. Treating
hospitals and physicians

Relevant Laboratory and Diagnostic Tests

Were there any relevant laboratory or diagnostic tests
for this event? If yes record in the SAE Lab form.

Yes ☒ 26
No ☐

Concomitant Medications

Rave.11.0_PRD_Annotation: Form Matrix
Form: Serious Adverse Events or Event of Special Interest
Generated On: 23 Apr 2019 20:11:55

Was the subject on any concomitant medications within 30 days prior to onset of this event (other than immunomodulatory medications recorded on the Immunomodulatory medications form)? This includes steroids. If yes record on the SAE Concomitant Medication form

Yes ☒ 28
No ☐

Investigator Verification

I verify that this Event report form accurately displays the results of the examination, tests, evaluations and treatments noted within.

☐ 30

Evaluation date and time (electronic verification non-enterable system generated)

31

Sponsor Review Complete

☐ 32


Date Sponsor Review Completed

33

Rave.11.0_PRD_Annotation: Form Matrix
Form: Serious Adverse Events or Event of Special Interest
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
①	INACTVAE	1	AE delete		1 = Yes, delete the AE for this reason
②	AESPID	\$20	Event Number (non-entera ble field		
③	EVNTSPEC	\$100	Event		EventOfSpe cialIntrest
④	EVENTERM	\$200	Event term		
⑤	EVNTSPE2	\$100			
⑥	INFECTYP	\$100			
⑦	AESTDTC	dd- MMM yyyy	Event onset date		
⑧	IMPEVODT	dd MMM YYYY			
⑨	AESEV	2	Event Sev onset (CTCAE level)		1 = Grade 1 - Mild 2 = Grade 2 - Moderate

Rave.11.0_PRD_Annotation: Form Matrix
Form: Serious Adverse Events or Event of Special Interest
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Field Name	Data Type	SAS Label	Units	Values
				3 = Grade 3 - Severe but not immediately life-threatening ing 4 = Grade 4 - Life-threatening consequences es 5 = Grade 5 - Death related to AE
 SEVREXTR	2	Event Sev most extreme (CTCAE level)		1 = Grade 1 - Mild 2 = Grade 2 - Moderate 3 = Grade 3 - Severe but not immediately life-threatening ing 4 = Grade 4 - Life-threatening consequences es 5 = Grade 5 - Death related to AE

Rave.11.0_PRD_Annotation: Form Matrix
Form: Serious Adverse Events or Event of Special Interest
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
11	AESER	2	Event serious		1 = Yes 0 = No
12	AESDTH	1	Death		
13	AESLIFE	1	Life-threatening		
14	AESHOSP	1	Require inpatient hospitalization or prolongation of existing hospitalization		
15	AESDISAB	1	Persistent or significant disability/in capacity		
16	AESCONG	1	Congenital anomaly or birth defect		
17	AESMIE	1	Important medical event		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Serious Adverse Events or Event of Special Interest
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Field Name	Data Type	SAS Label	Units	Values
18 AEOUT	2	Event Outcome		1 = Recovered/Resolved 2 = Recovering/Resolving 3 = Not recovered/Not resolved 4 = Recovered/Resolved with sequelae 5 = Fatal 99 = Unknown
19 AEONGO	2	Event stopped		0 = Stopped 1 = Ongoing
20 AEENDTC	dd- MMM yyyy	Event stop date and time		
21 AEHEIGHT	6.2	Height	1 = cm 2 = in 97 = ND	
22 AEWEIGHT	6.2	Weight	1 = kg 2 = lb 97 = ND	

Rave.11.0_PRD_Annotation: Form Matrix
Form: Serious Adverse Events or Event of Special Interest
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
23 IMMUMEDS	2	Immunomodulatory med within 30 days		1 = Yes 0 = No
24 NARSYMPT	\$200	Narrative		
26 SAELABYN	2	Relevant laboratory or diagnostic tests		1 = Yes 0 = No
28 SAECMYN	2	Con med within 30 days of onset of event		1 = Yes 0 = No
30 PISIG	1	Investigator verification		
31 PIDTC	dd- MMM- yyyy	Investigator Evaluation date and time		
32 SPNREVIW	1			
33 SPREVDTC	dd MMM yyyy			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Immunomodulatory medications
Generated On: 23 Apr 2019 20:11:55

Medication _____ ①

Relationship of event to medication

Not related ☐ ②

Unlikely related ☐

Possibly related ☐

Probably related ☐

Definitely related ☐

Rationale for relationship with medication (only provide if relationship is possibly, probably or definitely related) _____ ③

Date of last administration prior to onset of event _____ ④

Action taken regarding medication

Dose not changed ☐ ⑤

Dose reduced ☐

Dose increased ☐

Drug Interrupted ☐

Drug discontinued ☐

Unknown ☐

Not applicable ☐

If medication was interrupted, is this adverse event the primary reason for the interruption? Yes ☐ ⑥

No ☐

NA ☐

If medication was discontinued, is this adverse event the primary reason for discontinuation? Yes ☐ ⑦

No ☐

NA ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Immunomodulatory medications
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If medication was discontinued, interrupted, or reduced
(dechallenged), did AE diminish/abate?

Yes ☐ 8
No ☐
NA ☐

If medication was restarted (Rechallenge), did AE
recur?

Yes ☐ 9
No ☐
NA ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Immunomodulatory medications
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
①	IMMED	2	SAE Immun Medication		Medication
②	AEREL	2	Relationship of event to medication		1 = Not related 2 = Unlikely related 3 = Possibly related 4 = Probably related 5 = Definitely related
③	AERELST	\$100	Rationale for relationship with medi		
④	ADMINDTC	dd- MMM- yyyy	Date last dose prior to onset of event		
⑤	AEACN	2	Action taken regarding medication		1 = Dose not changed 2 = Dose reduced 3 = Dose increased 4 = Drug Interrupted

Rave.11.0_PRD_Annotation: Form Matrix
Form: Immunomodulatory medications
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				5 = Drug discontinued 99 = Unknown 96 = Not applicable
⑥ AEDINRD	2	AEt primary reason for interruption		1 = Yes 0 = No 96 = NA
⑦ AEDIS	2	AE primary reason for discontinuation		1 = Yes 0 = No 96 = NA
⑧ AEDIMTD	2	AE diminish/abate		1 = Yes 0 = No 96 = NA
⑨ AERAPR	2	AE recur		1 = Yes 0 = No 96 = NA

Date and time		①
Test		②
Result		③
Unit (applicable for labs only)		④
Normal range or value		⑤

Rave.11.0_PRD_Annotation: Form Matrix**Form: SAE Labs****Generated On: 23 Apr 2019 20:11:55**

	Field Name	Data Type	SAS Label	Units	Values
①	DRAWDTC	dd- MMM- yyyy HH:nn	SAE lab draw date/time		
②	TESTNAM	\$200	Test		
③	TESTRST	\$200	Result		
④	TESTUNT	\$200	Unit		
⑤	NRANGE	\$200	Normal range or value		

Rave.11.0_PRD_Annotation: Form Matrix
Form: SAE Conmeds
Generated On: 23 Apr 2019 20:11:55

Medication Name	<input type="text"/>	①
Medication Start Date	<input type="text"/>	②
Medication Stopped	Stopped <input type="checkbox"/> Ongoing <input type="checkbox"/>	③
Medication Stop Date	<input type="text"/>	④
Medication Total Daily Dose	<input type="text"/>	⑤
Medication Unit	<input type="text"/>	⑥
Medication Indication	<input type="text"/>	⑦

Rave.11.0_PRD_Annotation: Form Matrix
Form: SAE Conmeds
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
①	MEDNAM	\$200	SAE Con Medication Name		
②	MEDSTDTC	dd- MMM- yyyy	Con Medication Start Date		
③	MEDONGO	\$10	Con Medication Stopped		0 = Stopped 1 = Ongoing
④	MEDSPDTC	dd- MMM- yyyy	Con Medication Stop Date		
⑤	MEDDOS	\$200	Con Medication Total Daily Dose		
⑥	MEDUNIT	\$200	Con Medication Unit		
⑦	MEDIND	\$200	Con Medication Indication		

Rave.11.0_PRD_Annotation: Form Matrix
Form: Event of Special Interest: MAS
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Lab Results

WBC (lowest value) Fixed Unit: $\times 10^9/\text{L}$ or $10^3/\text{mm}^3$ ②

Hemoglobin (lowest value) Fixed Unit: g/dl ③

Platelets (lowest value) Fixed Unit: $\times 10^9/\text{L}$ or $10^3/\text{mm}^3$ ④

ESR (lowest value) Fixed Unit: mm/hr ⑤

ESR ULN ⑥

CRP (highest value) mg/dL ☐ ⑦
mg/L ☐
ND ☐

CRP ULN ⑧

AST (highest value) Fixed Unit: U/L ⑨

AST ULN ⑩

ALT (highest value) Fixed Unit: U/L ⑪

Rave.11.0_PRD_Annotation: Form Matrix
Form: Event of Special Interest: MAS
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ALT ULN _____ 12

Triglycerides (highest value) _____ Fixed Unit: mg/dL 13

Ferritin (highest value) _____ Fixed Unit: ng/mL 14

Fibrinogen (lowest value) _____ Fixed Unit: mg/dL 15

Was hemophagocytosis confirmed by tissue biopsy performed during this MAS episode? Yes ☐ 16
No ☐

If Yes, what tissue was biopsied? ☐ 17
bone marrow

lymph node ☐ 18

liver ☐ 19

spleen ☐ 20

other ☐ 21

(specify) _____ 22

Clinical Information

Rave.11.0_PRD_Annotation: Form Matrix
Form: Event of Special Interest: MAS
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Fever Yes ☐ 24
No ☐

Hemorrhage/Abnormal bleeding Yes ☐ 25
No ☐

If Yes, specify ☐ 26
Purpura

Easy bruising ☐ 27

Mucosal bleeding ☐ 28

Other ☐ 29

(specify): _____ 30

Hepatomegaly Yes ☐ 31
No ☐

Splenomegaly Yes ☐ 32
No ☐

CNS Dysfunction Yes ☐ 33
No ☐

If Yes, specify: ☐ 34
Irritability

Rave.11.0_PRD_Annotation: Form Matrix
Form: Event of Special Interest: MAS
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Disorientation	<input type="checkbox"/>	35
Lethargy	<input type="checkbox"/>	36
Headache	<input type="checkbox"/>	37
Seizure	<input type="checkbox"/>	38
Coma	<input type="checkbox"/>	39
Other	<input type="checkbox"/>	40
(specify):		41
Other Organ Dysfunction	Yes <input type="checkbox"/> No <input type="checkbox"/>	42
If Yes, specify: Kidney	<input type="checkbox"/>	43
Severe? (serum Creatinine > 2X ULN)	<input type="checkbox"/>	44
Respiratory	<input type="checkbox"/>	45
Severe? (required intubation)	<input type="checkbox"/>	46
Cardiovascular	<input type="checkbox"/>	47

Rave.11.0_PRD_Annotation: Form Matrix
Form: Event of Special Interest: MAS
Generated On: 23 Apr 2019 20:11:55

Severe? (received inotropes/vasopressors)	<input type="checkbox"/>	48
---	--------------------------	----

Liver	<input type="checkbox"/>	49
-------	--------------------------	----

Severe? (coagulopathy plus encephalopathy)	<input type="checkbox"/>	50
--	--------------------------	----

Other	<input type="checkbox"/>	51
-------	--------------------------	----

(specify):		52
------------	--	----

Was patient admitted to hospital ICU?	Yes <input type="checkbox"/>	53
	No <input type="checkbox"/>	

Was an infectious trigger for this MAS event identified or presumed?	Yes <input type="checkbox"/>	54
	No <input type="checkbox"/>	

Rave.11.0_PRD_Annotation: Form Matrix
Form: Event of Special Interest: MAS
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
②	WBC	4.2			
③	HEMA	4.2			
④	PLATELET	5.2			
⑤	ESR	3			
⑥	ESRLULN	3			
⑦	CRP	5.2		1 = mg/dL 2 = mg/L 97 = ND	
⑧	CRPUL	5.2			
⑨	AST	4			
⑩	ASTULN	4			
⑪	ALT	4			
⑫	ALTULN	4			
⑬	TRIGLY	4			
⑭	FERRITIN	6			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Event of Special Interest: MAS
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
15 FIBRINO	4			
16 HEMOPHAG	1			1 = Yes 0 = No
17 BONEMARR	1			
18 LYMPHNOD	1			
19 LIVER	1			
20 SPLEEN	1			
21 TISSOTH	1			
22 TISSOSP	\$50			
24 FEVER1	1			1 = Yes 0 = No
25 HEMORRAG	1			1 = Yes 0 = No
26 PURPURA	1			
27 EASYBRUS	1			
28 MUCOSAL	1			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Event of Special Interest: MAS
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
29 HEMOROTH	1			
30 HEMOROSP	\$50			
31 HEPATOME	1			1 = Yes 0 = No
32 SPLENOME	1			1 = Yes 0 = No
33 CNSDYSFU	1			1 = Yes 0 = No
34 IRRITABL	1			
35 DISORIEN	1			
36 LETHARGY	1			
37 HEADACHE	1			
38 SEIZURE	1			
39 COMA	1			
40 CNSOTHER	1			
41 CNSOTHSP	\$50			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Event of Special Interest: MAS
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
42 OTHORGAN	1			1 = Yes 0 = No
43 KIDNEY	1			
44 KIDNSEVR	1			
45 RESPIRAT	1			
46 RESPSEVR	1			
47 CARDIOVA	1			
48 CARDSEVR	1			
49 LIVER2	1			
50 LIVERSEV	1			
51 OTHORGOT	1			
52 OTHORGSP	\$50			
53 ADMITICU	1			1 = Yes 0 = No
54 INFCTRIG	1			1 = Yes 0 = No

Date of Longterm Visit	<hr/>	①
------------------------	-------	---

Rave.11.0_PRD_Annotation: Form Matrix
Form: Longterm Visit
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① LONGTDTC	dd MMM YYYY			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Longterm Follow-up
Generated On: 23 Apr 2019 20:11:55

Who is completing this visit?

Patient (8 years or older) ☐ ①
Parent (Patient < 8 years or
patient unable) ☐

Date of Visit:

_____ ②

Are you/your child currently under the care of a
physician?

Yes ☐ ③
No ☐

IF Yes, What type of doctor(s) did you see?
Adult Rheumatologist

☐ ④

What was the date of your last pediatric visit?

_____ ⑤

Or

Fixed Unit: Don't Know ☐ ⑥

Pediatric Rheumatologist

☐ ⑦

What is your doctor's name?

_____ ⑧

Where is your doctor located?

Fixed Unit: (city) _____ ⑨

Fixed Unit: (state) _____ ⑩

Primary Care Physician

☐ ⑪

Rave.11.0_PRD_Annotation: Form Matrix
Form: Longterm Follow-up
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Cardiologist	<input type="checkbox"/>	12
--------------	--------------------------	----

Nephrologist	<input type="checkbox"/>	13
--------------	--------------------------	----

Ophthalmologist	<input type="checkbox"/>	14
-----------------	--------------------------	----

Don't know	<input type="checkbox"/>	15
------------	--------------------------	----

Other:	<input type="checkbox"/>	16
--------	--------------------------	----

Specify		17
---------	--	----

IF Yes, When was your most recent visit?		18
--	--	----

IF Yes, On a scale of 0-10, how prepared did you feel in transferring your care?	0 Not at all Prepared	19
	1	<input type="checkbox"/>
	2	<input type="checkbox"/>
	3	<input type="checkbox"/>
	4	<input type="checkbox"/>
	5	<input type="checkbox"/>
	6	<input type="checkbox"/>
	7	<input type="checkbox"/>
	8	<input type="checkbox"/>
	9	<input type="checkbox"/>
	10 Extremely prepared	<input type="checkbox"/>

Do you/your child have health insurance?	Yes	20
	No	<input type="checkbox"/>
	Don't Know	<input type="checkbox"/>

Rave.11.0_PRD_Annotation: Form Matrix
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IF Yes, What type of insurance? Private Health Insurance	<input type="checkbox"/>	21
Medicare	<input type="checkbox"/>	22
Medicaid	<input type="checkbox"/>	23
Military Health Care	<input type="checkbox"/>	24
State-Specific Plan (non-Medicaid)	<input type="checkbox"/>	25
Indian Health Services	<input type="checkbox"/>	26
Non-US Insurance	<input type="checkbox"/>	27
Other,	<input type="checkbox"/>	28
Specify:		29
None	<input type="checkbox"/>	30
Prefer not to answer	<input type="checkbox"/>	31
IF Yes, Name of insurance		32
Or	Fixed Unit: Don't Know	33
	<input type="checkbox"/>	

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Or

Fixed Unit: Prefer not to answer

34

☐

Are you/your child currently receiving disability benefits/SSI?

Yes ☐

35

No ☐

Don't Know ☐

What is your/your child's current living situation?

Living with parent(s)/Legal guardian ☐

36

Living with roommate ☐

Living with significant other ☐

Live alone ☐

Other, specify: ☐

I prefer not to answer ☐

What is your/your child's current marital status?

Married (living as married) ☐

37

Divorced/Separated ☐

Widowed ☐

Never Married ☐

I prefer not to answer ☐

What is your/your child's current employment status?

Employed full-time ☐

38

Employed part-time ☐

Full time student ☐

Part time student ☐

Homemaker ☐

Retired ☐

Disabled ☐

Not currently working ☐

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I prefer not to answer ☐

IF Employed full-time/part-time: What kind of work did
you do for pay in the past six months/since we last
spoke
Exec/Managerial

☐ 39

Tech/Sales/Clerical

☐ 40

Service

☐ 41

Farm/Forestry

☐ 42

Prod/Prec/Repair

☐ 43

Operator/Laborer

☐ 44

Don't Know

☐ 45

IF Not currently working, When did you stop working: _____ 46

What is your/your child's highest grade or year of school
completed?

Elementary/middle school ☐ 47

(grade 1 -8)

Some high school (grade ☐

9-11)

Graduated high school ☐

(grade 12 or GED)

College (1-4 year college, ☐
junior college or technical
school)

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Graduate school (e.g.,
Masters, Doctorate, or
professional degree) ☐
I prefer not to answer ☐

In general, how do your/your child's finances usually
work out at the end of the month?

Some money left over ☒ 48
Just enough to make ends
meet ☐
Not enough to make ends
meet ☐

Are you/your child currently taking steroids(by mouth or
IV – not creams or ointments)?

Yes ☒ 49
No ☐
Don't Know ☐

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Field Name	Data Type	SAS Label	Units	Values
① LNGFUWHO	1			1 = Patient (8 years or older) 2 = Parent (Patient<8 years or patient unable)
② LNGTRDTC	dd- MMM- YYYY			
③ CURRPHYS	1			1 = Yes 0 = No
④ ADULTRHE	1			
⑤ PEDIADTC	dd- MMM- YYYY			
⑥ PEDDTCDK	1			
⑦ PEDRHEU	1			
⑧ PEDNAME	\$50			
⑨ PEDLOC	\$50			
⑩ PEDSTATE	\$50			

Rave.11.0_PRD_Annotation: Form Matrix
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Field Name	Data Type	SAS Label	Units	Values
11 PRIMCARE	1			
12 CARDIOLO	1			
13 NEPHROLO	1			
14 OPHTHALM	1			
15 DONTKNO W	1			
16 PHYSOTH	1			
17 PHYSPF	\$50			
18 LNGVISDT	dd- MMM- YYYY			
19 TRANSSCL	2			0 = 0 Not at all Prepared 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9

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Field Name	Data Type	SAS Label	Units	Values
				10 = 10 Extremely prepared
20 HLTINSU	2			1 = Yes 0 = No 99 = Don't Know
21 PRIVATE	1			
22 MEDICAR	1			
23 MEDICAD	1			
24 MILTHTL	1			
25 STATESPF	1			
26 INDIANHL	1			
27 NONUSHTL	1			
28 OTHRHLT	1			
29 SPFYHTL	\$50			
30 NONEHTL	1			

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Field Name	Data Type	SAS Label	Units	Values
31 PRENOANS	1			
32 INSNAME	\$50			
33 NAMEDK	1			
34 NAMEANS	1			
35 DISABIL	2			1 = Yes 0 = No 99 = Don't Know
36 LIVSITU	2			1 = Living with parent(s)/Legal guardian 2 = Living with roommate 3 = Living with significant other 4 = Live alone 98 = Other, specify: 99 = I prefer not to answer

Rave.11.0_PRD_Annotation: Form Matrix
Form: Longterm Follow-up
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Field Name	Data Type	SAS Label	Units	Values
37 MARITAL	2			1 = Married (living as married) 2 = Divorced/Se parated 3 = Widowed 4 = Never Married 99 = I prefer not to answer
38 EMPLOY	2			1 = Employed full-time 2 = Employed part-time 3 = Full time student 4 = Part time student 5 = Homemaker 6 = Retired 7 = Disabled 8 = Not currently working 99 = I prefer not to answer

Rave.11.0_PRD_Annotation: Form Matrix
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	Field Name	Data Type	SAS Label	Units	Values
39	EXEC	1			
40	TECH	1			
41	SERVICE	1			
42	FARM	1			
43	PRODPREC	1			
44	OPERLABO	1			
45	DKNOEMP	1			
46	STPWRKDT	dd- MMM- YYYY			
47	SCHOOL	2			1 = Elementary/ middle school (grade 1 -8) 2 = Some high school (grade 9-11) 3 = Graduated high school (grade 12 or GED)

Rave.11.0_PRD_Annotation: Form Matrix
Form: Longterm Follow-up
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Field Name	Data Type	SAS Label	Units	Values
				4 = College (1-4 year college, junior college or technical school) 5 = Graduate school (e.g., Masters, Doctorate, or professional degree) 99 = I prefer not to answer
48 FINANCES	1			1 = Some money left over 2 = Just enough to make ends meet 3 = Not enough to make ends meet
49 LNGSTROD	2			1 = Yes 0 = No 99 = Don't Know

Rave.11.0_PRD_Annotation: Form Matrix

Form: Disease Status

Generated On: 23 Apr 2019 20:11:55

What is the subject's primary rheumatic disease diagnosis?

Juvenile idiopathic arthritis ☐ ①

Systemic Lupus
Erythematosus (SLE) and
Related Conditions

Juvenile
Dermatomyositis/Juvenile

Polymyositis

Other, Specify: ☐

Don't Know ☐

If Other, Indicate date of diagnosis:

_____ ②

Rave.11.0_PRD_Annotation: Form Matrix
Form: Disease Status
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① PRMDISEL	2			1 = Juvenile idiopathic arthritis 2 = Systemic Lupus Erythemato sus (SLE) and Related Conditions 3 = Juvenile Dermatomy ositis/Juveni le Polymyositi s 98 = Other, Specify: 99 = Don't Know
② DIAGNLDT	dd- MMM- YYYY			

Rave.11.0_PRD_Annotation: Form Matrix

Form: JDM/JPM

Generated On: 23 Apr 2019 20:11:55

Since we last spoke/In the past 6 months have you experienced weakness related to your JDM/JPM?

Yes ☐ ①
No ☐
Don't Know ☐

IF YES, please rank your weakness on a scale of 0-10 where 0 is very mild and 10 is very severe

②

Since we last spoke/In the past 6 months do you have active skin rash related to your JDM/JPM (not scarring or calcinosis)?

Yes ☐ ③
No ☐
Don't Know ☐

IF YES, how much of a problem is your JDM rash on a scale of 0-10 where 0 is no problem and 10 is significant problem.

④

Do you have calcinosis?

Yes ☐ ⑤
No ☐
Don't Know ☐

IF YES, did it first develop since we last spoke/in the past 6 months?

Yes ☐ ⑥
No ☐
Don't Know ☐

Yes: date of onset:

⑦

On a scale of 0-10 , how much pain have you had IN THE PAST WEEK due to your calcinosis only?

⑧

On a scale of 0-10 , how much physical limitation have you had IN THE PAST WEEK due to your calcinosis only?

⑨

Rave.11.0_PRD_Annotation: Form Matrix
Form: JDM/JPM
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① WEAKNESS	2			1 = Yes 0 = No 99 = Don't Know
② WEAKRANK	\$4			Disease Activity
③ SKINRASH	2			1 = Yes 0 = No 99 = Don't Know
④ SKINRANK	\$4			Disease Activity
⑤ CALCINOS	2			1 = Yes 0 = No 99 = Don't Know
⑥ CALCDEVL	2			1 = Yes 0 = No 99 = Don't Know
⑦ CALDEVDT	dd MMM YYYY			
⑧ CALCPAIN	\$4			Disease Activity

Rave.11.0_PRD_Annotation: Form Matrix
Form: JDM/JPM
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units		Values
9 CALCLIMT	\$4				Disease Activity

Rave.11.0_PRD_Annotation: Form Matrix

Form: JIA

Generated On: 23 Apr 2019 20:11:55

Since we last spoke/In the past 6 months have you/your child had a rash or fever due to JIA?

Yes ☐ ①
No ☐
Don't Know ☐

Have you/your child had any joint pain or swelling due to JIA?

Yes ☐ ②
No ☐
Don't Know ☐

IF Yes, Please indicate if today you/your child is feeling pain or has swelling in any of the joints listed below:

Neck

Fixed Unit: Presence of pain or swelling ⑧

☐

Lower back

Fixed Unit: Presence of pain or swelling ⑨

☐

Have you/your child had joint stiffness upon waking up over the past week?

Yes ☐ ⑩
No ☐

<15 minutes ☐ ⑪
15-30 minutes ☐
30 minutes to 1 hour ☐
1 to 2 hours ☐
More than 2 hours ☐

Rave.11.0_PRD_Annotation: Form Matrix

Form: JIA

Generated On: 23 Apr 2019 20:11:55

LEFT SIDE

Fingers ☒ ④

Wrist ☐

Elbow ☐

Shoulder ☐

Hip ☐

Knee ☐

Ankle ☐

Toes ☐

Presence of pain or swelling

☐ ⑤

RIGHT SIDE

Fingers ☒ ⑥

Wrist ☐

Elbow ☐

Shoulder ☐

Hip ☐

Knee ☐

Ankle ☐

Toes ☐

Presence of pain or swelling

☐ ⑦

LEFT SIDE

Fingers ☐ ④

Wrist ☒

Elbow ☐

Shoulder ☐

Hip ☐

Knee ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: JIA
Generated On: 23 Apr 2019 20:11:55

Ankle ☐

Toes ☐

Presence of pain or swelling ☐ ⑤

RIGHT SIDE

Fingers ☐ ⑥

Wrist ☒

Elbow ☐

Shoulder ☐

Hip ☐

Knee ☐

Ankle ☐

Toes ☐

Presence of pain or swelling ☐ ⑦

LEFT SIDE

Fingers ☐ ④

Wrist ☐

Elbow ☒

Shoulder ☐

Hip ☐

Knee ☐

Ankle ☐

Toes ☐

Presence of pain or swelling ☐ ⑤

RIGHT SIDE

Fingers ☐ ⑥

Rave.11.0_PRD_Annotation: Form Matrix

Form: JIA

Generated On: 23 Apr 2019 20:11:55

Wrist ☐
Elbow ☒
Shoulder ☐
Hip ☐
Knee ☐
Ankle ☐
Toes ☐

Presence of pain or swelling

☐ 7

LEFT SIDE

Fingers ☐ 4
Wrist ☐
Elbow ☐
Shoulder ☒
Hip ☐
Knee ☐
Ankle ☐
Toes ☐

Presence of pain or swelling

☐ 5

RIGHT SIDE

Fingers ☐ 6
Wrist ☐
Elbow ☐
Shoulder ☒
Hip ☐
Knee ☐
Ankle ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: JIA
Generated On: 23 Apr 2019 20:11:55

Toes ☐

Presence of pain or swelling ☐ ⑦

LEFT SIDE

Fingers ☐ ④
Wrist ☐
Elbow ☐
Shoulder ☐
Hip ☒
Knee ☐
Ankle ☐
Toes ☐

Presence of pain or swelling ☐ ⑤

RIGHT SIDE

Fingers ☐ ⑥
Wrist ☐
Elbow ☐
Shoulder ☐
Hip ☒
Knee ☐
Ankle ☐
Toes ☐

Presence of pain or swelling ☐ ⑦

Rave.11.0_PRD_Annotation: Form Matrix

Form: JIA

Generated On: 23 Apr 2019 20:11:55

LEFT SIDE

Fingers ☐ ④
Wrist ☐
Elbow ☐
Shoulder ☐
Hip ☐
Knee ☒
Ankle ☐
Toes ☐

Presence of pain or swelling

☐ ⑤

RIGHT SIDE

Fingers ☐ ⑥
Wrist ☐
Elbow ☐
Shoulder ☐
Hip ☐
Knee ☒
Ankle ☐
Toes ☐

Presence of pain or swelling

☐ ⑦

LEFT SIDE

Fingers ☐ ④
Wrist ☐
Elbow ☐
Shoulder ☐
Hip ☐
Knee ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: JIA
Generated On: 23 Apr 2019 20:11:55

Ankle ☒

Toes ☐

Presence of pain or swelling ☐ ⑤

RIGHT SIDE

Fingers ☐ ⑥

Wrist ☐

Elbow ☐

Shoulder ☐

Hip ☐

Knee ☐

Ankle ☒

Toes ☐

Presence of pain or swelling ☐ ⑦

LEFT SIDE

Fingers ☐ ④

Wrist ☐

Elbow ☐

Shoulder ☐

Hip ☐

Knee ☐

Ankle ☐

Toes ☒

Presence of pain or swelling ☐ ⑤

RIGHT SIDE

Fingers ☐ ⑥

- Wrist☐
- Elbow☐
- Shoulder☐
- Hip☐
- Knee☐
- Ankle☐
- Toes☒

Presence of pain or swelling ☐ 7

Rave.11.0_PRD_Annotation: Form Matrix
Form: JIA
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① RASHFEVL	2			1 = Yes 0 = No 99 = Don't Know
② SWELLINL	2			1 = Yes 0 = No 99 = Don't Know
④ LEFTSIDL	1			1 = Fingers 2 = Wrist 3 = Elbow 4 = Shoulder 5 = Hip 6 = Knee 7 = Ankle 8 = Toes
⑤ PAINSWLT	1			
⑥ RIGHTSIL	1			1 = Fingers 2 = Wrist 3 = Elbow 4 = Shoulder 5 = Hip 6 = Knee 7 = Ankle 8 = Toes
⑦ PAINSELT	1			

Rave.11.0_PRD_Annotation: Form Matrix
Form: JIA
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
8 NECKPAIL	1			
9 LOWRBACL	1			
10 JOINTSTL	1			1 = Yes 0 = No
11 TIMESTIL	1			1 = <15 minutes 2 = 15-30 minutes 3 = 30 minutes to 1 hour 4 = 1 to 2 hours 5 = More than 2 hours

Rave.11.0_PRD_Annotation: Form Matrix

Form: SLE

Generated On: 23 Apr 2019 20:11:55

Brief Index of Lupus Damage (BILD) Questionnaire

This survey collects information about symptoms you may have experienced related to your lupus. It takes most people about 10 minutes to go through the questionnaire. Please remember that if you are not comfortable answering any question, you can skip the question

OCULAR

1. Has an eye doctor ever told you that you had something wrong with the retina of your eye because of your lupus (the retina is the back of your eye) Yes ☐ **4**
No ☐
Don't Know ☐

Has a doctor ever told you that you had any of the following conditions or symptoms?

2. A cataract in your eye? Yes ☐ **6**
No ☐
Don't Know ☐

NEUROPSYCHIATRIC

3. A psychotic episode? Yes ☐ **8**
No ☐
Don't Know ☐

4. Seizures? Yes ☐ **9**
No ☐
Don't Know ☐

Rave.11.0_PRD_Annotation: Form Matrix

Form: SLE

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If yes: Did you ever have to take medication for seizures for at least 6 months?

Yes ☐ 10

No ☐

Don't Know/ Not Applicable ☐

5. Stroke?

Yes ☐ 11

No ☐

Don't Know ☐

If yes: Did you ever have more than 1 stroke at least 6 months apart?

Yes ☐ 12

No ☐

Don't Know/ Not Applicable ☐

6. Paralysis in your arms or legs that was so severe that you needed to be hospitalized?

Yes ☐ 13

No ☐

Don't Know ☐

If yes: Was the paralysis from a stroke or multiple sclerosis?

Yes ☐ 14

No ☐

Don't Know/ Not Applicable ☐

RENAL

7. Have you ever had a kidney transplant?

Yes ☐ 16

No ☐

Don't Know ☐

8. Have you ever been on dialysis?

Yes ☐ 17

No ☐

Don't Know ☐

Rave.11.0_PRD_Annotation: Form Matrix

Form: SLE

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Has a doctor ever told you that you had any of the following conditions or symptoms?

9. Pulmonary hypertension, which is high blood pressure in the lungs? (this is different from regular hypertension or high blood pressure)

Yes ☐ 19
No ☐
Don't Know ☐

10. A serious condition of your lungs, such as fibrosis or interstitial lung disease? (this does NOT include pneumonia, asthma, emphysema, pleurisy, COPD, or bronchitis)

Yes ☐ 20
No ☐
Don't Know ☐

CARDIOVASCULAR

11. Have you ever had coronary or heart bypass surgery?

Yes ☐ 22
No ☐
Don't Know ☐

Has a doctor ever told you that you had any of the following conditions or symptoms?

12. Heart disease, including angina or congestive heart failure?

Yes ☐ 24
No ☐
Don't Know ☐

13. Heart attack?

Yes ☐ 25
No ☐
Don't Know ☐

If yes: Did you ever have more than 1 heart attack at least 6 months apart?

Yes ☐ 26
No ☐
Don't Know/ Not Applicable ☐

Rave.11.0_PRD_Annotation: Form Matrix

Form: SLE

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14. An episode of pericarditis, which is an inflammation in the sack around the heart, that lasted 6 months or longer?

Yes ☐ 27
No ☐
Don't Know ☐

PERIPHERAL VASCULAR

15. Loss of flesh or thinning on the ends of your fingers?

Yes ☐ 29
No ☐
Don't Know ☐

16. Loss of a finger, toe, or part of an arm or leg? (note: not due to an accident)

Yes ☐ 30
No ☐
Don't Know ☐

17. Deep vein thrombosis (DVT) – or a blood clot in your arm or leg?

Yes ☐ 31
No ☐
Don't Know ☐

GASTROINTESTINAL

18. Have you ever had abdominal surgery because of your lupus?

Yes ☐ 33
No ☐
Don't Know ☐

If yes: What part of your abdomen was operated on (select all that apply):

Esophagus

☐ 35

Rave.11.0_PRD_Annotation: Form Matrix

Form: SLE

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Stomach	<input type="checkbox"/>	36
Small Intestine	<input type="checkbox"/>	37
Large Intestine/Colon	<input type="checkbox"/>	38
Spleen	<input type="checkbox"/>	39
Liver	<input type="checkbox"/>	40
Pancreas	<input type="checkbox"/>	41
Gall Bladder	<input type="checkbox"/>	42
Other (e.g. kidney, appendix, reproductive organs)	<input type="checkbox"/>	43

Has a doctor ever told you that you had any of the following conditions or symptoms?

19. Peritonitis, which is an inflammation of the lining of your abdomen?	Yes	<input type="checkbox"/>	45
	No	<input type="checkbox"/>	
	Don't Know	<input type="checkbox"/>	

MUSCULOSKELETAL

20. Deformities of your hand due to lupus? (note: this could be from ligaments in the hand becoming lax, or from rheumatoid arthritis, but NOT [osteo]arthritis, which can also cause deformities)	Yes	<input type="checkbox"/>	47
	No	<input type="checkbox"/>	
	Don't Know	<input type="checkbox"/>	

Rave.11.0_PRD_Annotation: Form Matrix

Form: SLE

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21. Osteoporosis, or thin bones, that resulted in a fracture?

Yes ☐ 48
No ☐
Don't Know ☐

22. Avascular necrosis? (this is when part of a bone dies)

Yes ☐ 49
No ☐
Don't Know ☐

23. Osteomyelitis? (this is an infection in a bone)

Yes ☐ 50
No ☐
Don't Know ☐

SKIN

24. Permanent scarring of your skin due to your lupus?
(note: This is most commonly due to discoid lupus rash,
also from fat inflammation or panniculitis)

Yes ☐ 52
No ☐
Don't Know ☐

25. A skin ulcer, which is an open sore on your skin, that
lasted 6 months or longer? (note: this is not an oral ulcer
or a 'cold sore')

Yes ☐ 53
No ☐
Don't Know ☐

PREMATURE GONADAL FAILURE (WOMEN ONLY)

26. (Age 40+): Did your menstrual periods stop before
you turned 40? (note: if due to hysterectomy, mark
"don't know")

Yes ☐ 55
No ☐
Don't Know ☐

Rave.11.0_PRD_Annotation: Form Matrix

Form: SLE

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(Age < 40): Do you still get your menstrual periods?
(note: if pregnant or nursing, mark "yes")

Yes ☒ 56
No ☐
Don't Know ☐

Has a doctor ever told you that you had any of the following conditions or symptoms?

DIABETES

27. Diabetes?

Yes ☒ 59
No ☐
Don't Know ☐

MALIGNANCY

28. Cancer?

Yes ☒ 61
No ☐
Don't Know ☐

If yes: What kind of cancer? (list all)

62

Systemic Lupus Activity Questionnaire (SLAQ)

IN THE PAST THREE MONTHS, have you had a lupus
flare? (A lupus flare is when your lupus gets worse)
Which of the following best describes you?

No, no flare ☒ 64
Yes, mild flare ☐
Yes, moderate flare ☐
Yes, severe flare ☐

I'm going to read you a list of lupus symptoms. IN THE LAST THREE MONTHS, how
bad has each of these symptoms been?

Rave.11.0_PRD_Annotation: Form Matrix

Form: SLE

Generated On: 23 Apr 2019 20:11:55

Please rate the disease activity of your lupus DURING
THE PAST 3 MONTHS on a scale of 0-10 where 0 is no
activity and 10 is the most activity

0 ☒ 65

1 ☐

2 ☐

3 ☐

4 ☐

5 ☐

6 ☐

7 ☐

8 ☐

9 ☐

10 ☐

ND ☐

Symptom

a. Lost weight without ☒ 66
trying

Where

67

How bad

Mild ☒ 68

Moderate ☐

Severe ☐

No Problem ☐

Symptom

b. Fatigue ☒ 66

Where

67

Rave.11.0_PRD_Annotation: Form Matrix

Form: SLE

Generated On: 23 Apr 2019 20:11:55

How bad

Mild ☒ 68
Moderate ☐
Severe ☐
No Problem ☐

Symptom

c. Fevers (>101 F, 38.5 C) ☒ 66
taken by thermometer

Where

67

How bad

Mild ☒ 68
Moderate ☐
Severe ☐
No Problem ☐

Symptom

d. Sores in the mouth or ☒ 66
nose

Where

67

How bad

Mild ☒ 68
Moderate ☐
Severe ☐
No Problem ☐


Symptom

66

Rave.11.0_PRD_Annotation: Form Matrix

Form: SLE

Generated On: 23 Apr 2019 20:11:55

e. Rash on cheeks (shaped  like a butterfly)

Where **67**

How bad Mild ☐ **68**
Moderate ☐
Severe ☐
No Problem ☐

Symptom f. Other rash (where:)  **66**

Where **67**

How bad Mild ☐ **68**
Moderate ☐
Severe ☐
No Problem ☐

Symptom g. Dark blue or purple  spots you could feel on **66**
your skin

Where **67**

How bad Mild ☐ **68**
Moderate ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: SLE
Generated On: 23 Apr 2019 20:11:55

		Severe	<input type="checkbox"/>
		No Problem	<input type="checkbox"/>
Symptom	h. Rash or feeling sick after going out in the sun		<input checked="" type="checkbox"/> 66
Where			67
How bad	Mild		<input checked="" type="checkbox"/> 68
	Moderate		<input type="checkbox"/>
	Severe		<input type="checkbox"/>
	No Problem		<input type="checkbox"/>
Symptom	i. Bald patches on the scalp, or clumps of hair on pillow		<input checked="" type="checkbox"/> 66
Where			67
How bad	Mild		<input checked="" type="checkbox"/> 68
	Moderate		<input type="checkbox"/>
	Severe		<input type="checkbox"/>
	No Problem		<input type="checkbox"/>
Symptom	j. Swollen glands (nodes) in the neck		<input checked="" type="checkbox"/> 66

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Where _____ **67**

How bad Mild ☒ **68**
Moderate ☐
Severe ☐
No Problem ☐

Symptom k. Shortness of breath ☒ **66**

Where _____ **67**

How bad Mild ☒ **68**
Moderate ☐
Severe ☐
No Problem ☐

Symptom l. Chest pain with a deep ☒ **66**
breath

Where _____ **67**

How bad Mild ☒ **68**
Moderate ☐
Severe ☐
No Problem ☐

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Symptom	m. Fingers or toes turning dead white or very pale in the cold (Raynaud's)	<input checked="" type="radio"/> 66
---------	--	-------------------------------------

Where	<hr/>	67
-------	-------	----

How bad	Mild <input checked="" type="radio"/> 68
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	No Problem <input type="radio"/>

Symptom	n. Stomach or belly pain	<input checked="" type="radio"/> 66
---------	--------------------------	-------------------------------------

Where	<hr/>	67
-------	-------	----

How bad	Mild <input checked="" type="radio"/> 68
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	No Problem <input type="radio"/>

Symptom	o. Persistent numbness or tingling in your arms or legs	<input checked="" type="radio"/> 66
---------	---	-------------------------------------

Where	<hr/>	67
-------	-------	----

How bad	Mild <input checked="" type="radio"/> 68
---------	--

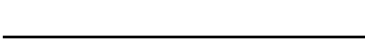
Rave.11.0_PRD_Annotation: Form Matrix

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Moderate ☐
Severe ☐
No Problem ☐

Symptom p. Seizures  66

Where  67

How bad Mild ☐ 68
Moderate ☐
Severe ☐
No Problem ☐

Symptom q. Stroke  66

Where  67

How bad Mild ☐ 68
Moderate ☐
Severe ☐
No Problem ☐

Symptom r. Forgetfulness  66

Where  67

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How bad

Mild ☒ 68
Moderate ☐
Severe ☐
No Problem ☐

Symptom

s. Feeling depressed ☒ 66

Where

67

How bad

Mild ☒ 68
Moderate ☐
Severe ☐
No Problem ☐

Symptom

t. Unusual headaches ☒ 66

Where

67

How bad

Mild ☒ 68
Moderate ☐
Severe ☐
No Problem ☐

Symptom

u. Muscle pain ☒ 66

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Where _____ **67**

How bad Mild ☒ **68**
Moderate ☐
Severe ☐
No Problem ☐

Symptom v. Muscle weakness ☒ **66**

Where _____ **67**

How bad Mild ☒ **68**
Moderate ☐
Severe ☐
No Problem ☐

Symptom w. Pain or stiffness in joints ☒ **66**

Where _____ **67**

How bad Mild ☒ **68**
Moderate ☐
Severe ☐
No Problem ☐

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Symptom

x. Swelling in joints

☒ 66

Where

67

How bad

Mild

☒ 68

Moderate

☐

Severe

☐

No Problem

☐

Rave.11.0_PRD_Annotation: Form Matrix**Form: SLE****Generated On: 23 Apr 2019 20:11:55**

Field Name	Data Type	SAS Label	Units	Values
④ SLEDS1	2			1 = Yes 0 = No 99 = Don't Know
⑥ SLEDS2	2			1 = Yes 0 = No 99 = Don't Know
⑧ SLEDS3	2			1 = Yes 0 = No 99 = Don't Know
⑨ SLEDS4	2			1 = Yes 0 = No 99 = Don't Know
⑩ SLEDS4Y	2			1 = Yes 0 = No 97 = Don't Know/ Not Applicable
⑪ SLEDS5	2			1 = Yes 0 = No 99 = Don't Know
⑫ SLEDS5Y	2			1 = Yes 0 = No

Rave.11.0_PRD_Annotation: Form Matrix
Form: SLE
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Field Name	Data Type	SAS Label	Units	Values
				97 = Don't Know/ Not Applicable
13 SLEDS6	2			1 = Yes 0 = No 99 = Don't Know
14 SLEDS6Y	2			1 = Yes 0 = No 97 = Don't Know/ Not Applicable
16 SLEDS7	2			1 = Yes 0 = No 99 = Don't Know
17 SLEDS8	2			1 = Yes 0 = No 99 = Don't Know
19 SLEDS9	2			1 = Yes 0 = No 99 = Don't Know
20 SLEDS10	2			1 = Yes 0 = No 99 = Don't Know

Rave.11.0_PRD_Annotation: Form Matrix
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Field Name	Data Type	SAS Label	Units	Values
22 SLEDS11	2			1 = Yes 0 = No 99 = Don't Know
24 SLEDS12	2			1 = Yes 0 = No 99 = Don't Know
25 SLEDS13	2			1 = Yes 0 = No 99 = Don't Know
26 SLEDS13Y	2			1 = Yes 0 = No 97 = Don't Know/ Not Applicable
27 SLEDS14	2			1 = Yes 0 = No 99 = Don't Know
28 SLEDS15	2			1 = Yes 0 = No 99 = Don't Know
30 SLEDS16	2			1 = Yes 0 = No

Rave.11.0_PRD_Annotation: Form Matrix
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Field Name	Data Type	SAS Label	Units	Values
				99 = Don't Know
31 SLEDS17	2			1 = Yes 0 = No 99 = Don't Know
33 SLEDS18	2			1 = Yes 0 = No 99 = Don't Know
35 SLEDS18A	1			
36 SLEDS18B	1			
37 SLEDS18C	1			
38 SLEDS18D	1			
39 SLEDS18E	1			
40 SLEDS18F	1			
41 SLEDS18G	1			
42 SLEDS18H	1			

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Field Name	Data Type	SAS Label	Units	Values
43 SLEDS18I	1			
45 SLEDS19	2			1 = Yes 0 = No 99 = Don't Know
47 SLEDS20	2			1 = Yes 0 = No 99 = Don't Know
48 SLEDS21	2			1 = Yes 0 = No 99 = Don't Know
49 SLEDS22	2			1 = Yes 0 = No 99 = Don't Know
50 SLEDS23	2			1 = Yes 0 = No 99 = Don't Know
52 SLEDS24	2			1 = Yes 0 = No 99 = Don't Know

Rave.11.0_PRD_Annotation: Form Matrix
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Field Name	Data Type	SAS Label	Units	Values
53 SLEDS25	2			1 = Yes 0 = No 99 = Don't Know
55 SLEDS26A	2			1 = Yes 0 = No 99 = Don't Know
56 SLEDS26B	2			1 = Yes 0 = No 99 = Don't Know
59 SLEDS27	2			1 = Yes 0 = No 99 = Don't Know
61 SLEDS28	2			1 = Yes 0 = No 99 = Don't Know
62 SLEDS28Y	\$100			
64 SLEDS29	1			0 = No, no flare 1 = Yes, mild flare 2 = Yes, moderate flare

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Field Name	Data Type	SAS Label	Units	Values
				3 = Yes, severe flare
66 SLEDS30A	\$1			Lupus Symptoms
67 SLED30AF	\$50			
68 SLEDS30B	1			1 = Mild 2 = Moderate 3 = Severe 0 = No Problem
69 SLEDS31	2			0 = 0 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 97 = ND

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Since we last spoke/In the past 6 months have you/your child had any of the following new medical events/conditions?

Aplastic anemia

Yes ☐ ②
No ☐
Don't Know ☐

IF Yes,Event Description:

③

IF Yes, when did this event/condition start?

④

IF Yes, did this event/condition require going to the hospital?

Yes ☐ ⑤
No ☐

Cardiovascular event:

Yes ☐ ⑥
No ☐
Don't Know ☐

IF Yes,Event Description:

⑦

IF Yes, when did this event/condition start?

⑧

IF Yes, did this event/condition require going to the hospital?

Yes ☐ ⑨
No ☐

Demyelinating disease

Yes ☐ ⑩
No ☐
Don't Know ☐

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IF Yes,Event Description:	<hr/>	11
IF Yes, when did this event/condition start?	<hr/>	12
IF Yes, did this event/condition require going to the hospital?	Yes <input type="checkbox"/> No <input type="checkbox"/>	13
Gastrointestinal perforation:	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/>	14
IF Yes,Event Description:	<hr/>	15
IF Yes, when did this event/condition start?	<hr/>	16
IF Yes, did this event/condition require going to the hospital?	Yes <input type="checkbox"/> No <input type="checkbox"/>	17
Infections treated with IV anti- infectives	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/>	18
IF Yes,Event Description:	<hr/>	19
IF Yes, when did this event/condition start?	<hr/>	20
IF Yes, did this event/condition require going to the hospital?	Yes <input type="checkbox"/> No <input type="checkbox"/>	21

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Infertility

Yes ☐ 22

No ☐

Don't Know ☐

IF Yes,Event Description: _____ 23

IF Yes, when did this event/condition start? _____ 24

IF Yes, did this event/condition require going to the hospital?

Yes ☐ 25

No ☐

Inflammatory bowel disease:

Yes ☐ 26

No ☐

Don't Know ☐

IF Yes,Event Description: _____ 27

IF Yes, when did this event/condition start? _____ 28

IF Yes, did this event/condition require going to the hospital?

Yes ☐ 29

No ☐

Lung disease

Yes ☐ 30

No ☐

Don't Know ☐

IF Yes,Event Description: _____ 31

IF Yes, when did this event/condition start? _____ 32

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IF Yes, did this event/condition require going to the hospital?	Yes <input type="checkbox"/> 33 No <input type="checkbox"/>
Macrophage activation syndrome	Yes <input type="checkbox"/> 34 No <input type="checkbox"/> Don't Know <input type="checkbox"/>
IF Yes,Event Description:	<input type="text"/> 35
IF Yes, when did this event/condition start?	<input type="text"/> 36
IF Yes, did this event/condition require going to the hospital?	Yes <input type="checkbox"/> 37 No <input type="checkbox"/>
Malignancy	Yes <input type="checkbox"/> 38 No <input type="checkbox"/> Don't Know <input type="checkbox"/>
IF Yes,Event Description:	<input type="text"/> 39
IF Yes, when did this event/condition start?	<input type="text"/> 40
IF Yes, did this event/condition require going to the hospital?	Yes <input type="checkbox"/> 41 No <input type="checkbox"/>
Mycobacterium tuberculosis infection:	Yes <input type="checkbox"/> 42 No <input type="checkbox"/> Don't Know <input type="checkbox"/>

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IF Yes,Event Description:	<input type="text"/>	43
IF Yes, when did this event/condition start?	<input type="text"/>	44
IF Yes, did this event/condition require going to the hospital?	Yes <input type="checkbox"/> No <input type="checkbox"/>	45
New autoimmune disease:	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/>	46
IF Yes,Event Description:	<input type="text"/>	47
IF Yes, when did this event/condition start?	<input type="text"/>	48
IF Yes, did this event/condition require going to the hospital?	Yes <input type="checkbox"/> No <input type="checkbox"/>	49
Optic neuritis	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/>	50
IF Yes,Event Description:	<input type="text"/>	51
IF Yes, when did this event/condition start?	<input type="text"/>	52
IF Yes, did this event/condition require going to the hospital?	Yes <input type="checkbox"/> No <input type="checkbox"/>	53

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Osteoporosis

Yes ☐ 54
No ☐
Don't Know ☐

IF Yes,Event Description:

55

IF Yes, when did this event/condition start?

56

IF Yes, did this event/condition require going to the hospital?

Yes ☐ 57
No ☐

Other opportunistic infections:

Yes ☐ 58
No ☐
Don't Know ☐

IF Yes,Event Description:

59

IF Yes, when did this event/condition start?

60

IF Yes, did this event/condition require going to the hospital?

Yes ☐ 61
No ☐

Pregnancy and pregnancy outcomes

Yes ☐ 62
No ☐
Don't Know ☐

IF Yes,
Are you currently pregnant?

Yes ☐ 63
No ☐

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IF Yes,
How many weeks along are you?

Fixed Unit: weeks

64

IF Not Currently Pregnant,
What was the outcome of the pregnancy?

Baby born ☐
Termination/abortion for
medical or non-medical
reasons ☐
Miscarriage ☐
Still birth ☐

IF Baby Born,
Were you diagnosed with preeclampsia?

Yes ☐
No ☐
Don't Know ☐

When did you deliver?

=<28 weeks (<7 months) ☐
29-33 weeks (7-8 months) ☐
34-36 weeks (8.5-9
months) ☐
=>37 weeks (>9 months) ☐

How much did your baby weigh at birth?

<3lbs 5oz ☐
3lbs 5oz - 5lbs 8oz ☐
5lbs 9oz - 8lbs 13oz ☐
>8lbs 13oz ☐

How long did your baby stay in the hospital from birth
to discharge home?

Fixed Unit: days OR

Fixed Unit: weeks

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IF Yes,Event Description:	<hr/>	71
IF Yes, when did this event/condition start?	<hr/>	72
IF Yes, did this event/condition require going to the hospital?	Yes <input type="checkbox"/> No <input type="checkbox"/>	73
Progressive multifocal leukoencephalopathy	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/>	74
IF Yes,Event Description:	<hr/>	75
IF Yes, when did this event/condition start?	<hr/>	76
IF Yes, did this event/condition require going to the hospital?	Yes <input type="checkbox"/> No <input type="checkbox"/>	77
Psoriasis	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/>	78
IF Yes,Event Description:	<hr/>	79
IF Yes, when did this event/condition start?	<hr/>	80
IF Yes, did this event/condition require going to the hospital?	Yes <input type="checkbox"/> No <input type="checkbox"/>	81

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Pulmonary hypertension

Yes ☐ 82
No ☐
Don't Know ☐

IF Yes,Event Description:

83

IF Yes, when did this event/condition start?

84

IF Yes, did this event/condition require going to the hospital?

Yes ☐ 85
No ☐

Uveitis (new onset):

Yes ☐ 86
No ☐
Don't Know ☐

IF Yes, Which eye(s) has uveitis affected?
Right

☐ 87

Left

☐ 88

Don't Know

☐ 89

IF Yes, Are you/your child currently using topical steroid eye drops?

Yes ☐ 90
No ☐
Don't Know ☐

IF Yes, How often to you/your child use topical steroid eye drops?

1-2 times daily ☐ 91
3 or more times daily ☐
Unknown ☐

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IF Yes,Event Description:	_____	92
---------------------------	-------	----

IF Yes, when did this event/condition start?	_____	93
--	-------	----

IF Yes, did this event/condition require going to the hospital?	Yes <input type="checkbox"/> No <input type="checkbox"/>	94
---	--	----

Since we last spoke/In the past 6 months, have you/your child gone to a hospital as a patient for any other reason?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Not Collected <input type="checkbox"/>	95
---	--	----

Event:	_____	96
--------	-------	----

Admission Date:	_____	97
-----------------	-------	----

Discharge Date:	_____	98
-----------------	-------	----

Type of hospital visit:	Scheduled/Planned <input type="checkbox"/> Admitted to hospital (unplanned, more than 23hrs) <input type="checkbox"/> ER visit only <input type="checkbox"/> Can't remember <input type="checkbox"/> Other, specify: <input type="checkbox"/>	99
-------------------------	---	----

Describe why you went to the hospital	_____	100
---------------------------------------	-------	-----

Was your hospitalization related to your rheumatic condition?	Yes <input type="checkbox"/> No <input type="checkbox"/>	101
---	--	-----

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Unknown ☐
Not Collected ☐

Hospital Name: _____ 102

Address: _____ 103

City: _____ 104

State: _____ 105

Since we last spoke/In the past 6 months, have you/your child gone to a hospital as a patient for any other reason Yes ☐ 106
No ☐

Admission Date: _____ 107

Discharge Date: _____ 108

Type of hospital visit: Scheduled/Planned ☐ 109
Admitted to hospital
(unplanned, more than
23hrs) ☐
ER visit only ☐
Can't remember ☐
Other, specify: ☐

Why were you hospitalized? _____ 110

Was your hospitalization related to your rheumatic condition? Yes ☐ 111

		No <input type="checkbox"/>
		Don't Know <input type="checkbox"/>
Where were you hospitalized?		112
Hospital Name:		
Address:		113
City:		114
State:		115

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Field Name	Data Type	SAS Label	Units	Values
② MEDEVT01	2			1 = Yes 0 = No 99 = Don't Know
③ EVTSPF01	\$50			
④ EVT01SDT	dd- MMM- YYYY			
⑤ REQHOS01	1			1 = Yes 0 = No
⑥ MEDEVT02	2			1 = Yes 0 = No 99 = Don't Know
⑦ EVTSPF02	\$50			
⑧ EVT02SDT	dd- MMM- YYYY			
⑨ REQHOS02	1			1 = Yes 0 = No
⑩ MEDEVT03	2			1 = Yes 0 = No 99 = Don't Know

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Field Name	Data Type	SAS Label	Units	Values
11 EVTSPF03	\$50			
12 EVT03SDT	dd- MMM- YYYY			
13 REQHOS03	1			1 = Yes 0 = No
14 MEDEVT04	2			1 = Yes 0 = No 99 = Don't Know
15 EVTSPF04	\$50			
16 EVT04SDT	dd- MMM- YYYY			
17 REQHOS04	1			1 = Yes 0 = No
18 MEDEVT05	2			1 = Yes 0 = No 99 = Don't Know
19 EVTSPF05	\$50			
20 EVT05SDT	dd- MMM- YYYY			

Rave.11.0_PRD_Annotation: Form Matrix
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Field Name	Data Type	SAS Label	Units	Values
21 REQHOS05	1			1 = Yes 0 = No
22 MEDEVT06	2			1 = Yes 0 = No 99 = Don't Know
23 EVTSPF06	\$50			
24 EVT06SDT	dd- MMM- YYYY			
25 REQHOS06	1			1 = Yes 0 = No
26 MEDEVT07	2			1 = Yes 0 = No 99 = Don't Know
27 EVTSPF07	\$50			
28 EVT07SDT	dd- MMM- YYYY			
29 REQHOS07	1			1 = Yes 0 = No
30 MEDEVT08	2			1 = Yes 0 = No

Rave.11.0_PRD_Annotation: Form Matrix
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Field Name	Data Type	SAS Label	Units	Values
				99 = Don't Know
31 EVTSPF08	\$50			
32 EVT08SDT	dd- MMM- YYYY			
33 REQHOS08	1			1 = Yes 0 = No
34 MEDEVT09	2			1 = Yes 0 = No 99 = Don't Know
35 EVTSPF09	\$50			
36 EVT09SDT	dd- MMM- YYYY			
37 REQHOS09	1			1 = Yes 0 = No
38 MEDEVT10	2			1 = Yes 0 = No 99 = Don't Know
39 EVTSPF10	\$50			

Rave.11.0_PRD_Annotation: Form Matrix
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Field Name	Data Type	SAS Label	Units	Values
40 EVT10SDT	dd- MMM- YYYY			
41 REQHOS10	1			1 = Yes 0 = No
42 MEDEVT11	2			1 = Yes 0 = No 99 = Don't Know
43 EVTSPF11	\$50			
44 EVT11SDT	dd- MMM- YYYY			
45 REQHOS11	1			1 = Yes 0 = No
46 MEDEVT12	2			1 = Yes 0 = No 99 = Don't Know
47 EVTSPF12	\$50			
48 EVT12SDT	dd- MMM- YYYY			
49 REQHOS12	1			1 = Yes 0 = No

Rave.11.0_PRD_Annotation: Form Matrix
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Field Name	Data Type	SAS Label	Units	Values
50 MEDEVT13	2			1 = Yes 0 = No 99 = Don't Know
51 EVTSPF13	\$50			
52 EVT13SDT	dd- MMM- YYYY			
53 REQHOS13	1			1 = Yes 0 = No
54 MEDEVT14	2			1 = Yes 0 = No 99 = Don't Know
55 EVTSPF14	\$50			
56 EVT14SDT	dd- MMM- YYYY			
57 REQHOS14	1			1 = Yes 0 = No
58 MEDEVT15	2			1 = Yes 0 = No 99 = Don't Know

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Field Name	Data Type	SAS Label	Units	Values
59 EVTSPF15	\$50			
60 EVT15SDT	dd- MMM- YYYY			
61 REQHOS15	1			1 = Yes 0 = No
62 MEDEVT16	2			1 = Yes 0 = No 99 = Don't Know
63 EVT16YES	1			1 = Yes 0 = No
64 EVT16YSW	2			
65 EVT16YNO	1			1 = Baby born 2 = Termination /abortion for medical or non-medica l reasons 3 = Miscarriage 4 = Still birth

Rave.11.0_PRD_Annotation: Form Matrix
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Field Name	Data Type	SAS Label	Units	Values
66 BABYBORN	2			1 = Yes 0 = No 99 = Don't Know
67 DELIVER	1			1 = =<28 weeks (<7 months) 2 = 29-33 weeks (7-8 months) 3 = 34-36 weeks (8.5-9 months) 4 = =>37 weeks (>9 months)
68 BABYWEIG	1			1 = <3lbs 5oz 2 = 3lbs 5oz - 5lbs 8oz 3 = 5lbs 9oz - 8lbs 13oz 4 = >8lbs 13oz
69 BABYHSDY	3			
70 BABYHSWK	2			
71 EVTSPF16	\$50			

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Field Name	Data Type	SAS Label	Units	Values
72 EVT16SDT	dd- MMM- YYYY			
73 REQHOS16	1			1 = Yes 0 = No
74 MEDEVT17	2			1 = Yes 0 = No 99 = Don't Know
75 EVTSPF17	\$50			
76 EVT17SDT	dd- MMM- YYYY			
77 REQHOS17	1			1 = Yes 0 = No
78 MEDEVT19	2			1 = Yes 0 = No 99 = Don't Know
79 EVTSPF19	\$50			
80 EVT19SDT	dd- MMM- YYYY			
81 REQHOS19	1			1 = Yes 0 = No

Rave.11.0_PRD_Annotation: Form Matrix
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Field Name	Data Type	SAS Label	Units	Values
82 MEDEVT20	2			1 = Yes 0 = No 99 = Don't Know
83 EVTSPF20	\$50			
84 EVT20SDT	dd- MMM- YYYY			
85 REQHOS20	1			1 = Yes 0 = No
86 LNGUVE	2			1 = Yes 0 = No 99 = Don't Know
87 UVERGHT	1			
88 UVELFT	1			
89 UVEDKN	1			
90 TOPSTROD	2			1 = Yes 0 = No 99 = Don't Know

Rave.11.0_PRD_Annotation: Form Matrix
Form: Medical Events/ Conditions
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
91 OFTDROP	2			1 = 1-2 times daily 2 = 3 or more times daily 99 = Unknown
92 EVTSPF21	\$50			
93 EVT21SDT	dd- MMM- YYYY			
94 REQHOS21	1			1 = Yes 0 = No
95 MEDEVNT	2			1 = Yes 0 = No 99 = Unknown 95 = Not Collected
96 MEDEVT	2			MedicalEven tConditions
97 ADMNDT	dd- MMM- YYYY			
98 DISCDT	dd- MMM- YYYY			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Medical Events/ Conditions
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
99 TYPEHP	2			1 = Scheduled/ Planned 2 = Admitted to hospital (unplanned, more than 23hrs) 3 = ER visit only 5 = Can't remember 98 = Other, specify:
100 WHYHOSPB	\$100			
101 RELTRHEB	2			1 = Yes 0 = No 99 = Unknown 95 = Not Collected
102 HOSPNM	\$50			
103 HOSPAD	\$50			
104 HOSPCT	\$50			
105 HOSPST	\$50			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Medical Events/ Conditions
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
106 OTHRHOSP	1			1 = Yes 0 = No
107 OTHADMDT	dd- MMM- YYYY			
108 OTHDISDT	dd- MMM- YYYY			
109 OTHTYPHS	2			1 = Scheduled/ Planned 2 = Admitted to hospital (unplanned, more than 23hrs) 3 = ER visit only 5 = Can't remember 98 = Other, specify:
110 WHYHOSP	\$100			
111 RELTRHEU	2			1 = Yes 0 = No 99 = Don't Know
112 OTHHPNAM	\$50			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Medical Events/ Conditions
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
113 OTHHPADD	\$50			
114 OTHHPCTY	\$50			
115 OTHHPSAT	\$50			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Rheumatic Condition Questions
Generated On: 23 Apr 2019 20:11:55

Considering all the ways that your rheumatic condition affects you, rate how you are doing:

0 Very Well ☒ ①

1 ☐

2 ☐

3 ☐

4 ☐

5 ☐

6 ☐

7 ☐

8 ☐

9 ☐

10 Very Poor ☐

Prefer Not to Answer ☐

We are also interested in learning whether or not you have been affected by pain because of your rheumatic condition.
How much pain do you think you had because of your rheumatic condition in the past week?

0 No Pain ☒ ②

1 ☐

2 ☐

3 ☐

4 ☐

5 ☐

6 ☐

7 ☐

8 ☐

9 ☐

10 Very Severe Pain ☐

Prefer Not to Answer ☐

Considering all the ways that your child's rheumatic condition affects your child, rate how your child is doing:

0 Very Well ☒ ③

1 ☐

2 ☐

3 ☐

4 ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Rheumatic Condition Questions
Generated On: 23 Apr 2019 20:11:55

5 ☐
6 ☐
7 ☐
8 ☐
9 ☐
10 Very Poor ☐
Prefer Not to Answer ☐

We are also interested in learning whether or not your child has been affected by pain because of his/her rheumatic condition.
How much pain do you think your child had because of his/her rheumatic condition in the past week?

0 No Pain ☒ 4
1 ☐
2 ☐
3 ☐
4 ☐
5 ☐
6 ☐
7 ☐
8 ☐
9 ☐
10 Very Severe Pain ☐
Prefer Not to Answer ☐

Who Completed (mapped from Longterm Followup)

Patient (8 years or older) ☒ 5
Parent (Patient < 8 years or patient unable) ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Rheumatic Condition Questions
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① HOWDOSU B	2			0 = 0 Very Well 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 Very Poor 99 = Prefer Not to Answer
② PAINSUB	2			0 = 0 No Pain 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 Very Severe Pain 99 = Prefer Not to Answer
③ HOWDOPRT2				0 = 0 Very Well

Rave.11.0_PRD_Annotation: Form Matrix
Form: Rheumatic Condition Questions
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 Very Poor 99 = Prefer Not to Answer
④ PAINPRT	2			0 = 0 No Pain 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 Very Severe Pain 99 = Prefer Not to Answer
⑤ LONGWHO11				1 = Patient (8 years or older)

Rave.11.0_PRD_Annotation: Form Matrix
Form: Rheumatic Condition Questions
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				2 = Parent (Patient<8 years or patient unable)

Rave.11.0_PRD_Annotation: Form Matrix
Form: Disease Activity Assessment Questions
Generated On: 23 Apr 2019 20:11:55

How do you rate your disease activity over the past week?

0 Very Well ☒ ①

1 ☐

2 ☐

3 ☐

4 ☐

5 ☐

6 ☐

7 ☐

8 ☐

9 ☐

10 Very Poor ☐

Prefer Not to Answer ☐

How do you rate your child's disease activity over the past week?

0 Very Well ☒ ②

1 ☐

2 ☐

3 ☐

4 ☐

5 ☐

6 ☐

7 ☐

8 ☐

9 ☐

10 Very Poor ☐

Prefer Not to Answer ☐

Who Completed mapped from Longterm Followup

Patient (8 years or older) ☒ ③

Parent (Patient < 8 years or patient unable) ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Disease Activity Assessment Questions
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① ACTIVSUB	2			0 = 0 Very Well 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 Very Poor 99 = Prefer Not to Answer
② ACTIVPAR	2			0 = 0 Very Well 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 Very Poor 99 = Prefer Not to Answer

Rave.11.0_PRD_Annotation: Form Matrix
Form: Disease Activity Assessment Questions
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
③ LONGWHO21				1 = Patient (8 years or older) 2 = Parent (Patient<8 years or patient unable)

Rave.11.0_PRD_Annotation: Form Matrix
Form: Pediatric Global Health Assessment
Generated On: 23 Apr 2019 20:11:55

In general, would you say your health is:

- Excellent ☒ ①
Very Good ☐
Good ☐
Fair ☐
Poor ☐
Prefer Not to Answer ☐
-

In general, would you say your quality of life is:

- Excellent ☒ ②
Very Good ☐
Good ☐
Fair ☐
Poor ☐
Prefer Not to Answer ☐
-

In general, how would you rate your physical health?

- Excellent ☒ ③
Very Good ☐
Good ☐
Fair ☐
Poor ☐
Prefer Not to Answer ☐
-

In general, how would you rate your mental health,
including your mood and your ability to think?

- Excellent ☒ ④
Very Good ☐
Good ☐
Fair ☐
Poor ☐
Prefer Not to Answer ☐
-

How often do you feel really sad?

- Never ☒ ⑤
Rarely ☐
-

Rave.11.0_PRD_Annotation: Form Matrix
Form: Pediatric Global Health Assessment
Generated On: 23 Apr 2019 20:11:55

Sometimes ☐
Often ☐
Always ☐
Prefer Not to Answer ☐

How often do you have fun with friends?

Never ☒ 6
Rarely ☐
Sometimes ☐
Often ☐
Always ☐
Prefer Not to Answer ☐

How often do your parents listen to your ideas?

Never ☒ 7
Rarely ☐
Sometimes ☐
Often ☐
Always ☐
Prefer Not to Answer ☐

In general, would you say your child's health is:

Excellent ☒ 8
Very Good ☐
Good ☐
Fair ☐
Poor ☐
Prefer Not to Answer ☐

In general, would you say your child's quality of life is:

Excellent ☒ 9
Very Good ☐
Good ☐
Fair ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Pediatric Global Health Assessment
Generated On: 23 Apr 2019 20:11:55

Poor ☐
Prefer Not to Answer ☐

In general, how would you rate your child's physical health?

Excellent ☒ 10
Very Good ☐
Good ☐
Fair ☐
Poor ☐
Prefer Not to Answer ☐

In general, how would you rate your child's mental health, including mood and ability to think?

Excellent ☒ 11
Very Good ☐
Good ☐
Fair ☐
Poor ☐
Prefer Not to Answer ☐

How often does your child feel really sad?

Never ☒ 12
Rarely ☐
Sometimes ☐
Often ☐
Always ☐
Prefer Not to Answer ☐

How often does your child have fun with friends?

Never ☒ 13
Rarely ☐
Sometimes ☐
Often ☐
Always ☐
Prefer Not to Answer ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: Pediatric Global Health Assessment
Generated On: 23 Apr 2019 20:11:55

How often does your child feel that you listen to his or her ideas?

- Never ☒ 14
- Rarely ☐
- Sometimes ☐
- Often ☐
- Always ☐
- Prefer Not to Answer ☐
-

Who complete mapped from Longterm Followup

- Patient (8 years or older) ☒ 15
- Parent (Patient<8 years or patient unable) ☐
-

Rave.11.0_PRD_Annotation: Form Matrix
Form: Pediatric Global Health Assessment
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① HELTHSUB	2			1 = Excellent 2 = Very Good 3 = Good 4 = Fair 5 = Poor 99 = Prefer Not to Answer
② LIFESUB	2			1 = Excellent 2 = Very Good 3 = Good 4 = Fair 5 = Poor 99 = Prefer Not to Answer
③ PHYSSUB	2			1 = Excellent 2 = Very Good 3 = Good 4 = Fair 5 = Poor 99 = Prefer Not to Answer
④ MENTLSUB	2			1 = Excellent 2 = Very Good

Rave.11.0_PRD_Annotation: Form Matrix
Form: Pediatric Global Health Assessment
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				3 = Good 4 = Fair 5 = Poor 99 = Prefer Not to Answer
⑤ SADSUB	2			1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always 99 = Prefer Not to Answer
⑥ FUNSUB	2			1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always 99 = Prefer Not to Answer
⑦ LISTNSUB	2			1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always 99 = Prefer Not to Answer


Rave.11.0_PRD_Annotation: Form Matrix
Form: Pediatric Global Health Assessment
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
8 HELTHPAR	2			1 = Excellent 2 = Very Good 3 = Good 4 = Fair 5 = Poor 99 = Prefer Not to Answer
9 LIFEPAR	2			1 = Excellent 2 = Very Good 3 = Good 4 = Fair 5 = Poor 99 = Prefer Not to Answer
10 PHYSPAR	2			1 = Excellent 2 = Very Good 3 = Good 4 = Fair 5 = Poor 99 = Prefer Not to Answer
11 MENTLPAR	2			1 = Excellent 2 = Very Good

Rave.11.0_PRD_Annotation: Form Matrix
Form: Pediatric Global Health Assessment
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				3 = Good 4 = Fair 5 = Poor 99 = Prefer Not to Answer
12 SADPAR	2			1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always 99 = Prefer Not to Answer
13 FUNPAR	2			1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always 99 = Prefer Not to Answer
14 LISTNPAR	2			1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always 99 = Prefer Not to Answer

Rave.11.0_PRD_Annotation: Form Matrix
Form: Pediatric Global Health Assessment
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
 LONGWHO31				1 = Patient (8 years or older) 2 = Parent (Patient<8 years or patient unable)

Rave.11.0_PRD_Annotation: Form Matrix

Form: Health Today

Generated On: 23 Apr 2019 20:11:55

Under each heading, please tick the ONE that best describes your/your child's health TODAY.

MOBILITY

- I have no problems in walking about ☒ ②
- I have slight problems in walking about ☐
- I have moderate problems in walking about ☐
- I have severe problems in walking about ☐
- I am unable to walk about ☐
- Prefer Not to Answer ☐
-

SELF-CARE

- I have no problems washing or dressing myself ☒ ③
- I have slight problems washing or dressing myself ☐
- I have moderate problems washing or dressing myself ☐
- I have severe problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐
- Prefer Not to Answer ☐
-

USUAL ACTIVITIES (e.g., work, study, housework, family or leisure activities)

- I have no problems doing my usual activities ☒ ④
- I have slight problems doing my usual activities ☐
- I have moderate problems doing my usual activities ☐
- I have severe problems doing my usual activities ☐
- I am unable to do my usual activities ☐
- Prefer Not to Answer ☐
-

Rave.11.0_PRD_Annotation: Form Matrix
Form: Health Today
Generated On: 23 Apr 2019 20:11:55

PAIN/ DISCOMFORT

- I have no pain or discomfort ☐ 5
- I have slight pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have severe pain or discomfort ☐
- I have extreme pain or discomfort ☐
- Prefer Not to Answer ☐
-

ANXIETY/ DEPRESSION

- I am not anxious or depressed ☐ 6
- I am slightly anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am very anxious or depressed ☐
- I am extremely anxious or depressed ☐
- Prefer Not to Answer ☐
-

We like to know how is your/your child's health today.
On a scale from 0 to 100.
100 means the best health you/your child can imagine.
0 means the worst health you/your child can imagine.
Using the scale, please indicate how is your/your child's health today.

7

Rave.11.0_PRD_Annotation: Form Matrix
Form: Health Today
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
② MOBILITY	2			1 = I have no problems in walking about 2 = I have slight problems in walking about 3 = I have moderate problems in walking about 4 = I have severe problems in walking about 5 = I am unable to walk about 99 = Prefer Not to Answer
③ SELFCARE	2			1 = I have no problems washing or dressing myself 2 = I have slight problems washing or dressing myself

Rave.11.0_PRD_Annotation: Form Matrix
Form: Health Today
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				3 = I have moderate problems washing or dressing myself 4 = I have severe problems washing or dressing myself 5 = I am unable to wash or dress myself 99 = Prefer Not to Answer
④ USUALACT	2			1 = I have no problems doing my usual activities 2 = I have slight problems doing my usual activities 3 = I have moderate problems doing my usual activities

Rave.11.0_PRD_Annotation: Form Matrix
Form: Health Today
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				4 = I have severe problems doing my usual activities 5 = I am unable to do my usual activities 99 = Prefer Not to Answer
⑤ PAINDISC	2			1 = I have no pain or discomfort 2 = I have slight pain or discomfort 3 = I have moderate pain or discomfort 4 = I have severe pain or discomfort 5 = I have extreme pain or discomfort 99 = Prefer Not to Answer

Rave.11.0_PRD_Annotation: Form Matrix
Form: Health Today
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
⑥ ANXIETY	2			1 = I am not anxious or depressed 2 = I am slightly anxious or depressed 3 = I am moderately anxious or depressed 4 = I am very anxious or depressed 5 = I am extremely anxious or depressed 99 = Prefer Not to Answer
⑦ HELTODAY	3			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Call Center Summary
Generated On: 23 Apr 2019 20:11:55

Date of Questionnaire: _____ ①

Questionnaire Status: Complete ☐ ②
Incomplete ☐
Not Done ☐

Reason for Incomplete or Not Done Patient Died: ☐ ③
Withdrawn ☐
Patient too ill ☐
Patient deaf ☐
Patient unreliable ☐
Language barrier ☐
Situation not conducive for ☐
phone call
Patient refused ☐
Patient incarcerated ☐
Unable to locate/ contact ☐
patient
Other ☐

Date of Death _____ ④

Was the patient hospitalized at time of death? Yes ☐ ⑤
No ☐

No valid contacts (patient or alternates) ☐ ⑥

Multiple attempts to valid contacts ☐ ⑦

Date last contact alive: _____ ⑧

Rave.11.0_PRD_Annotation: Form Matrix
Form: Call Center Summary
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① QUETDTC	dd- MMM- YYYY			
② QXSTATUS	1			1 = Complete 2 = Incomplete 3 = Not Done
③ RESNINCM	2			1 = Patient Died: 2 = Withdrawn 3 = Patient too ill 4 = Patient deaf 5 = Patient unreliable 6 = Language barrier 7 = Situation not conductive for phone call 8 = Patient refused 9 = Patient incarcerate d

Rave.11.0_PRD_Annotation: Form Matrix
Form: Call Center Summary
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				10 = Unable to locate/ contact patient 11 = Other
④ DETHDTC	dd- MMM- YYYY			
⑤ HOSPDTH	1			1 = Yes 0 = No
⑥ NOCONTAC	1			
⑦ MULTATTP	1			
⑧ LSTCONDT	dd- MMM- YYYY			

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST HOME PRO
Generated On: 23 Apr 2019 20:11:55

Who is answering these questions?

Patient (8 years or older) ☐ ①
Parent (Patient < 8 years or
patient unable) ☐

Have you/your child had FEVER (temperature above
100.4°F or 38°C) due to systemic JIA since your last
diary entry?

Yes ☐ ②
No ☐
Don't Know/ Prefer Not to
Answer ☐

How many days?

_____ ③

When was the most recent day with fever?

_____ ④

Have you/your child had a RASH due to systemic JIA
since your last diary entry?

Yes ☐ ⑤
No ☐
Don't Know/ Prefer Not to
Answer ☐

How many days?

_____ ⑥

When was the most recent day with rash?

_____ ⑦

How much pain due to systemic JIA have you/your child
had today?

_____ ⑧

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST HOME PRO
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① HOMEWHO 3	1			1 = Patient (8 years or older) 2 = Parent (Patient<8 years or patient unable)
② HADFEVE3	1			1 = Yes 0 = No 2 = Don't Know/ Prefer Not to Answer
③ FEVERDA3	2			
④ FEVR3DTC	dd MMM YYYY			
⑤ HADRASH3	1			1 = Yes 0 = No 2 = Don't Know/ Prefer Not to Answer
⑥ RASHDAY3	2			
⑦ RASH3DTC	dd MMM YYYY			

Rave.11.0_PRD_Annotation: Form Matrix

Form: FROST HOME PRO

Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
<hr/>				
⑧ MUCHPAI3	2			

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST HOME PROs
Generated On: 23 Apr 2019 20:11:55

Who is answering these questions?

Patient (8 years or older) ☐ ①
Parent (Patient < 8 years or
patient unable) ☐

Have you/your child had FEVER (temperature above
100.4°F or 38°C) due to systemic JIA since your last
diary entry?

Yes ☐ ②
No ☐
Don't Know/ Prefer Not to
Answer ☐

How many days? _____

③

When was the most recent day with fever _____

④

Have you/your child had a RASH due to systemic JIA
since your last diary entry?

Yes ☐ ⑤
No ☐
Don't Know/ Prefer Not to
Answer ☐

How many days? _____

⑥

When was the most recent day with rash? _____

⑦

How much pain due to systemic JIA have you/your child
had today? _____

⑧

Are you/your child taking a steroid by mouth
(prednisone/prednisolone)?

Yes ☐ ⑨
No ☐
Don't Know/ Prefer Not to
Answer ☐

How often do you take it? _____

1 time per day ☐ ⑩

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST HOME PROs
Generated On: 23 Apr 2019 20:11:55

2 times per day ☐
3 times per day ☐
Every other day ☐
Other ☐

Other, specify: _____ 11

Did you take your steroid today? Yes ☐ 12
No ☐

Do you take pills or liquid? Pills ☐ 13
Liquid ☐

What is the total number of mg you took for the whole day? _____ 14

What is the strength listed on your bottle? 15mg in 5ml ☐ 15
Other: ____mg in ____ml ☐
Unknown ☐

(ex. 10mg in 20ml) _____ 16

(ex. 10mg in 20ml) _____ 17

How much liquid (ml) did you take today? (total you took for the whole day, if you took it more than once a day) _____ 18

Did you take your steroid today or yesterday? Yes ☐ 19
No ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST HOME PROs
Generated On: 23 Apr 2019 20:11:55

Do you take pills or liquid?

Pills ☐ 20
Liquid ☐

What is the total number of mg you took for the whole day?

21

What is the strength listed on your bottle?

15mg in 5ml ☐ 22
Other: ___mg in ___ml ☐
Unknown ☐

(ex. 10mg in 20ml)

23

(ex. 10mg in 20ml)

24

How much liquid (ml) did you take today or yesterday?
(total you took for the whole day, if you took it more
than once a day)

25

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST HOME PROs
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① HOMEWHO 1 1				1 = Patient (8 years or older) 2 = Parent (Patient<8 years or patient unable)
② HADFEVR1 1				1 = Yes 0 = No 2 = Don't Know/ Prefer Not to Answer
③ FEVRDAY1 2				
④ FEVR1DTC	dd MMM YYYY			
⑤ HADRASH1 1				1 = Yes 0 = No 2 = Don't Know/ Prefer Not to Answer
⑥ RASHDAY1 2				
⑦ RASH1DTC	dd MMM YYYY			

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST HOME PROs
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
8 MUCHPAN1	2			
9 STERIOD1	1			1 = Yes 0 = No 2 = Don't Know/ Prefer Not to Answer
10 STERTAK1	2			1 = 1 time per day 2 = 2 times per day 3 = 3 times per day 4 = Every other day 98 = Other
11 STEROTH1	\$50			
12 STERTOD1	1			1 = Yes 0 = No
13 PILLIQ1	1			1 = Pills 2 = Liquid
14 STERPIL1	5.2			
15 STERLIQ1	2			1 = 15mg in 5ml


Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST HOME PROs
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
				98 = Other:___m g in ___ml 99 = Unknown
16 STRODMG1	5.2			
17 STRODML1	5.2			
18 LIQTODA1	5.2			
19 STERYES1	1			1 = Yes 0 = No
20 PILLI1	1			1 = Pills 2 = Liquid
21 STERPI1	5.2			
22 STERLI1	2			1 = 15mg in 5ml 98 = Other:___m g in ___ml 99 = Unknown
23 STRDMG1	5.2			
24 STRDML1	5.2			

Rave.11.0_PRD_Annotation: Form Matrix

Form: FROST HOME PROs

Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
<hr/>				
 LIQYEST1	5.2			

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST HOME ePRO
Generated On: 23 Apr 2019 20:11:55

Who is answering these questions?

Patient (8 years or older) ☐ ①
Parent (Patient<8 years or
patient unable) ☐

Are you/your child taking a steroid by mouth
(prednisone/prednisolone)?

Yes ☐ ②
No ☐
Don't Know/ Prefer Not to
Answer ☐

How often do you take it?

1 time per day ☐ ③
2 times per day ☐
3 times per day ☐
Every other day ☐
Other ☐

Other, specify: _____ ④

Did you take your steroid today?

Yes ☐ ⑤
No ☐

Do you take pills or liquid?

Pills ☐ ⑥
Liquid ☐

What is the total number of mg you took for the whole
day? _____ ⑦

What is the strength listed on your bottle?

15mg in 5ml ☐ ⑧
Other: ____mg in ____ml ☐
Unknown ☐

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST HOME ePRO
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(ex. **10mg** in 20ml) _____ **9**

(ex. 10mg in **20ml**) _____ **10**

How much liquid (ml) did you take today? (total you took for the whole day, if you took it more than once a day) _____ **11**

Did you take your steroid today or yesterday? Yes ☐ **12**
No ☐

Do you take pills or liquid? Pills ☐ **13**
Liquid ☐

What is the total number of mg you took for the whole day? _____ **14**

What is the strength listed on your bottle? 15mg in 5ml ☐ **15**
Other: ____mg in ____ml ☐
Unknown ☐

(ex. **10mg** in 20ml) _____ **16**

(ex. 10mg in **20ml**) _____ **17**

How much liquid (ml) did you take today or yesterday? (total you took for the whole day, if you took it more than once a day) _____ **18**

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST HOME ePRO
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Field Name	Data Type	SAS Label	Units	Values
① HOMEWHO 1 2				1 = Patient (8 years or older) 2 = Parent (Patient<8 years or patient unable)
② STEROID2 1				1 = Yes 0 = No 2 = Don't Know/ Prefer Not to Answer
③ STERTAK2 2				1 = 1 time per day 2 = 2 times per day 3 = 3 times per day 4 = Every other day 98 = Other
④ STROTHER2 \$50				
⑤ STERTOD2 1				1 = Yes 0 = No
⑥ PILLLIQ2 1				1 = Pills 2 = Liquid

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST HOME ePRO
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
⑦ STERPIL2	5.2			
⑧ STERLIQ2	2			1 = 15mg in 5ml 98 = Other: ____m g in ____ml 99 = Unknown
⑨ STRODMG2	5.2			
⑩ STRODML2	5.2			
⑪ LIQTODA2	5.2			
⑫ STERYES2	1			1 = Yes 0 = No
⑬ PILLI2	1			1 = Pills 2 = Liquid
⑭ STERPI2	5.2			
⑮ STERLI2	2			1 = 15mg in 5ml 98 = Other: ____m g in ____ml 99 = Unknown

Rave.11.0_PRD_Annotation: Form Matrix
Form: FROST HOME ePRO
Generated On: 23 Apr 2019 20:11:55

	Field Name	Data Type	SAS Label	Units	Values
16	STRDMG2	5.2			
17	STRDML2	5.2			
18	LIQYEST2	5.2			

Rave.11.0_PRD_Annotation: Form Matrix
Form: Site Transfers
Generated On: 23 Apr 2019 20:11:55

Has this subject ever transferred sites?		Yes <input type="checkbox"/> ①
		No <input type="checkbox"/>
Current Site	<input type="text"/>	②
PI Name at Current Site	<input type="text"/>	③
Transfer Site	<input type="text"/>	④
PI at Transfer Site	<input type="text"/>	⑤
Site Transfer Date	<input type="text"/>	⑥

Rave.11.0_PRD_Annotation: Form Matrix
Form: Site Transfers
Generated On: 23 Apr 2019 20:11:55

Field Name	Data Type	SAS Label	Units	Values
① TRANSFER	1			1 = Yes 0 = No
② CURRSITE	\$100			
③ PINAMECU	\$100			
④ TRANSITE	\$100			
⑤ PITRNSIT	\$100			
⑥ TRANSDT	dd MMM YYYY			