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Study Status

Reset All Filters

Choose Population:

All Patients

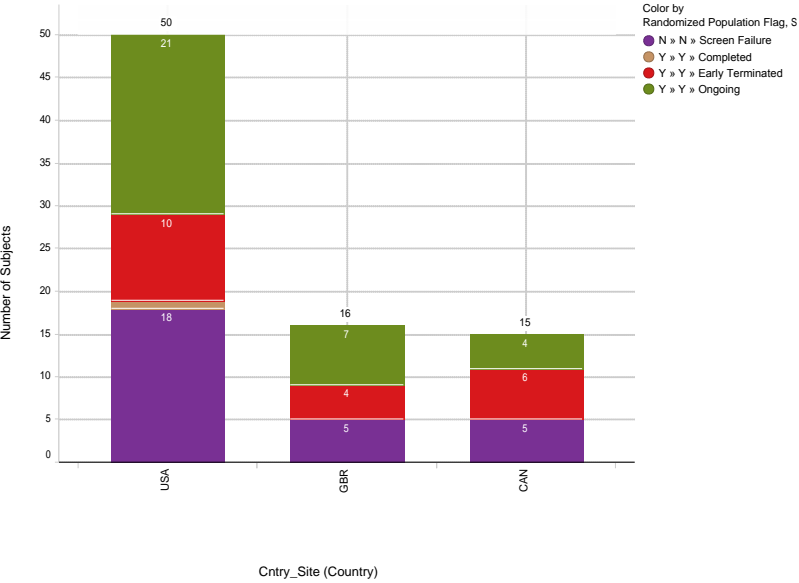
Mark to Patient Listing

Mark bars of interest then click to show only those subjects on the Patient Listing page.

Summary of Subjects Status

Random	Treated	Status	Sum	Percent
N	N	Screen Failure	28	34.6
Y	Y	Ongoing	32	39.5
		Early Terminated	20	24.7
		Completed	1	1.2
Grand total			81	100.0

Bar Chart of Patients Distribution by Site



Demographics

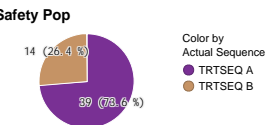
[Reset All Filters](#)

[Mark to Patient Listing](#)

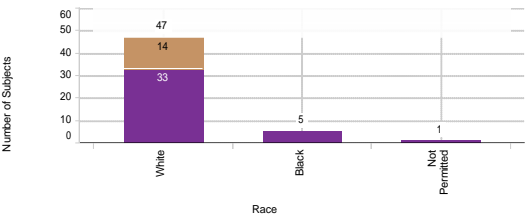
Mark bars of interest then click to show only those subjects on the Patient Listing page.

Safety Pop

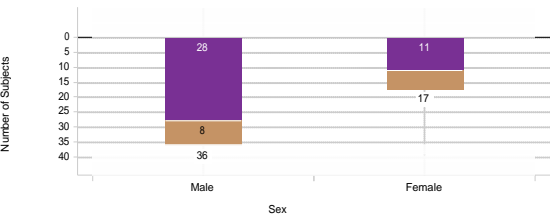
Treatment	# Subjects
TRTSEQ A	39
TRTSEQ B	14



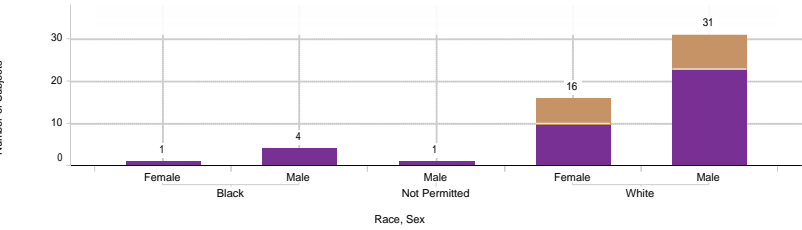
Number of Subjects by Race (Safety Population)



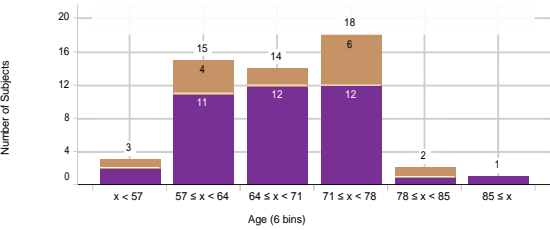
Number of Subjects by Sex (Safety Population)



Number of Subjects by Race/Sex (Safety Population)



Number of Subjects by Age Group(Safety Population)



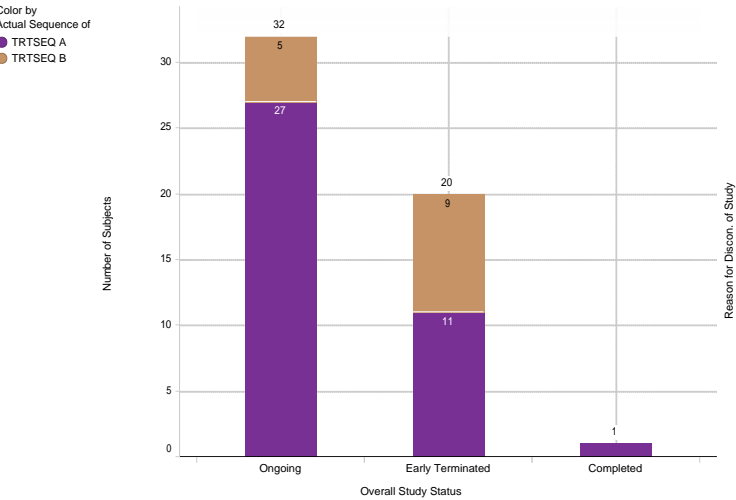
Disposition

[Reset All Filters](#)

[Mark to Patient Listing](#)

Mark bars of interest then click to show only those subjects on the Patient Listing page.

Summary of Disposition by Treatment Group (Safety Pop)



Reasons for Discontinuation of Study by Treatment Group

Mark Completed and/or Early Terminated group(s) in Summary of Disposition chart to view discontinuation reasons here.

Number of Subjects

Death (Summ to PP)

Reset All Filters

Mark to Patient Listing

Mark bars of interest then click above to show only those subjects on the Listing page.

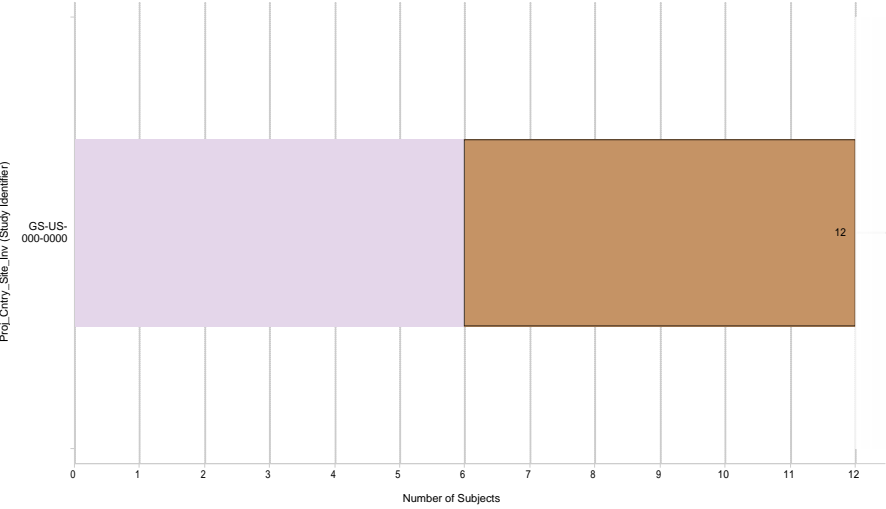
Mark to PP

Mark the interested subjects in the Patients Listing below and click "Mark to PP" button to see the details in Patient Profile(PP) page.

Patients

Subject Identifier
81002
81024
82001
82024
82032
84020

Summary of Death Counts



Summ Off-Study /Off-TRT

Reset All Filters

Summary of Overall Study Status

Study Identifier	Country	Actual Sequence of Treatment, Overall Study Status						Grand total
		TRTSEQ A			TRTSEQ B			
		Completed	Early Ter...	Ongoing	Early Ter...	Ongoing		
GS-US-000-...	CAN	---	4	3	2	1		10
	GBR	---	---	6	4	1		11
	USA	1	7	18	3	3		32
Grand total		1	11	27	9	5		53

Proj_Cntry_Site_Inv (Country)

Number of Subjects

Mark to Patient Listing

Mark bars of interest then click above to show only those subjects on the Listing page.

Summary of Overall Treatment Status

Study Identifier	Country	Actual Sequence of Treatment, Overall Study Treatment Status						Grand total
		TRTSEQ A			TRTSEQ B			
		Completed	Early Ter...	Ongoing	Early Ter...	Ongoing		
GS-US-000-...	USA	1	15	10	4	2		32
	GBR	---	2	4	4	1		11
	CAN	---	5	2	2	1		10
Grand total		1	22	16	10	4		53

Proj_Cntry_Site_Inv (Country)

Number of Subjects

Off-TRT

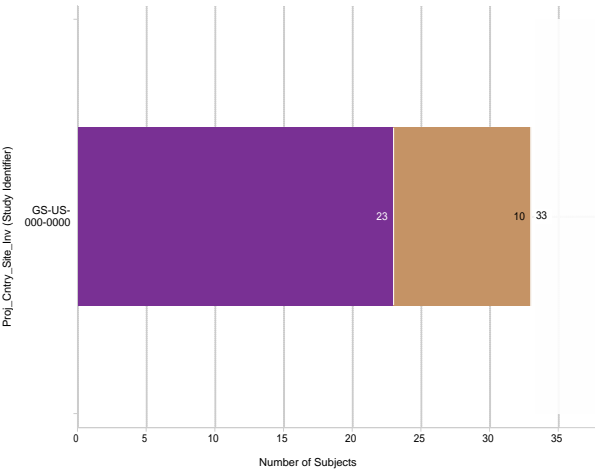
[Reset All Filters](#)

[Mark to Patient Listing](#)

Mark bars of interest then click above to show only those subjects on the Listing page.

Summary of Off-Treatment Subjects (Safety Population)

Color by
Actual Sequence of
● TRTSEQ A
● TRTSEQ B



Reason for Off Treatment



AE Listing

Reset All Filters

Last Mark Page

Return to previous marked page

Reset Listing

Display all Listing rows

AE Listing

Site Number	Subject Identifier	Reported AE Term	Dictionary-Derived Term	Primary System Organ Class	Start Date/Time of Adverse Event	End Date/Time of Adverse Event	Serious AE	AE Severity	AE Toxicity Grade	Ongoing	Related to study procedures	Related to Study Treatment	Related to Study Treatment 1	Relat ed to Stu...
9013	81002	BILATERL PEDAL OEDE...	Oedema peripheral	General disorder...	13 MAR 2015	24 APR 2015	N		GRADE 1	No			NOT RELATED	NO...
9013	81002	CHEST INFECTION	Lower respiratory tract infe...	Infections and inf...	24 JAN 2015	30 JAN 2015	N		GRADE 2	No			NOT RELATED	NO...
9013	81002	COUGH	Cough	Respiratory, thor...	31 JAN 2015	19 MAY 2015	N		GRADE 1	No			NOT RELATED	NO...
9013	81002	DIZZINESS	Dizziness	Nervous system...	05 OCT 2015	12 MAY 2016	N		GRADE 1	Yes			NOT RELATED	NO...
9013	81002	EARLY SATIETY	Early satiety	General disorder...	13 FEB 2015	12 MAY 2016	N		GRADE 1	No			NOT RELATED	NO...
9013	81002	FATIGUE	Fatigue	General disorder...	08 MAY 2015	12 MAY 2016	N		GRADE 1	No			NOT RELATED	NO...
9013	81002	HEPATOMEGALY	Hepatomegaly	Hepatobiliary dis...	30 JAN 2015	12 MAY 2016	N		GRADE 1	No			NOT RELATED	NO...
9013	81002	NIGHT SWEATS	Night sweats	Skin and subcut...	01 JAN 2015	30 JAN 2015	N		GRADE 1	No			NOT RELATED	NO...
9013	81002	RIGHT HEAL ULCER	Skin ulcer	Skin and subcut...	01 MAR 2015	02 MAY 2015	N		GRADE 2	No			NOT RELATED	NO...
9013	81002	SHORTNESS OF BREATH	Dyspnoea	Respiratory, thor...	20 MAR 2015	12 MAY 2016	N		GRADE 1	No			NOT RELATED	NO...
9013	81002	SWEATING NECK	Hyperhidrosis	Skin and subcut...	26 MAY 2015	12 MAY 2016	N		GRADE 1	No			NOT RELATED	NO...
9013	81002	THIAMINE DEFICIENCY	Vitamin B1 deficiency	Metabolism and...	UN JUL 2015	16 OCT 2015	N		GRADE 1	No			NOT RELATED	NO...
9013	81002	VITAMIN D DEFICIENCY	Vitamin D deficiency	Metabolism and...	UN APR 2015	12 MAY 2016	N		GRADE 1	No			NOT RELATED	NO...
9013	81002	WEIGHT LOSS	Weight decreased	Investigations	19 JUN 2015	12 MAY 2016	N		GRADE 2	Yes			NOT RELATED	RE...
5779	81003	GI BLEED (UPPER)	Upper gastrointestinal hae...	Gastrointestinal...	5 JUL 2015	10 JUL 2015	Y		GRADE 3	No			NOT RELATED	NO...
5779	81003	ACUTE GI BLEED	Gastrointestinal haemorrha...	Gastrointestinal...	29 AUG 2015	2 SEP 2015	Y		GRADE 3	No			NOT RELATED	NO...
5779	81003	BRUISING (HANDS)	Contusion	Injury, poisoning...	9 FEB 2015	18 MAR 2015	N		GRADE 1	No			NOT RELATED	NO...
5779	81003	CELLULITIS (LEFT LEG)	Cellulitis	Infections and inf...	24 SEP 2015	02 OCT 2015	Y		GRADE 3	No			NOT RELATED	NO...
5779	81003	CLOSTRIDIUM DIFFICIL...	Clostridium difficile infection	Infections and inf...	1 DEC 2015	5 DEC 2015	Y		GRADE 3	No			NOT RELATED	NO...
5779	81003	DIARRHEA	Diarrhoea	Gastrointestinal...	26 JAN 2015	13 MAR 2015	N		GRADE 1	No			NOT RELATED	NO...
5779	81003	DIARRHEA	Diarrhoea	Gastrointestinal...	1 SEP 2015		N		GRADE 1	Ongoing	No		NOT RELATED	NO...
5779	81003	EDEMA (LOWER EXTRE...	Oedema peripheral	General disorder...	06 SEP 2015		N		GRADE 1	Ongoing	No		NOT RELATED	NO...
5779	81003	FATIGUE	Fatigue	General disorder...	22 JUN 2015		N		GRADE 1	Ongoing	No		NOT RELATED	NO...
5779	81003	GI BLEED	Gastrointestinal haemorrha...	Gastrointestinal...	17 JUL 2015	20 JUL 2015	Y		GRADE 3	No			NOT RELATED	NO...
5779	81003	GI BLEED	Gastrointestinal haemorrha...	Gastrointestinal...	16 AUG 2015	18 AUG 2015	Y		GRADE 3	No			NOT RELATED	NO...
5779	81003	INTERMITTENT DRY CO...	Cough	Respiratory, thor...	02 FEB 2015	15 APR 2015	N		GRADE 1	No			NOT RELATED	NO...

Filter settings

pp
- Data Source Name: (01 EX, 02 SV, 052 LB-Hem, 053 LB-Uri, 054 LB-Oth)

AE by SOC and PT

Reset All Filters

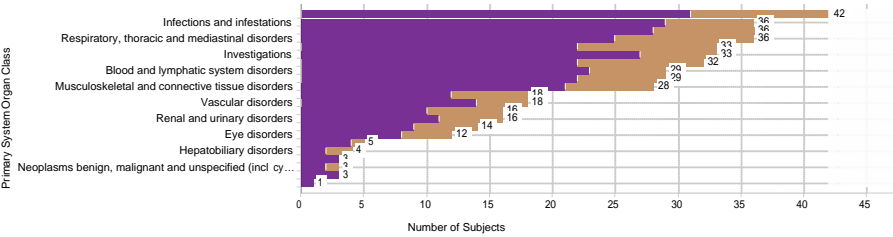
Mark to AE Listing

Mark bars of interest then click above to show only those subjects on the Listing page.

Mark to PP

Mark the interested subjects in the Patients Listing below and click "Mark to PP" button to see the details in Patient Profile(PP) page.

AE Summary by SOC



Color by
Actual Sequence of Treatment

- TRTSEQ A
- TRTSEQ B

AE Summary by Preferred Term

Color by
Actual Sequence of Treatment

Patients

Subject Identifier

Mark bar(s) of interest in AE Summary by SOC to view associated preferred terms here.

Dictionary-Derived Term

Number of Subjects

AE Preferred Term to PP

Reset All Filters

AE summary by preferred term:

All AEs

▼

Mark to AE Listing

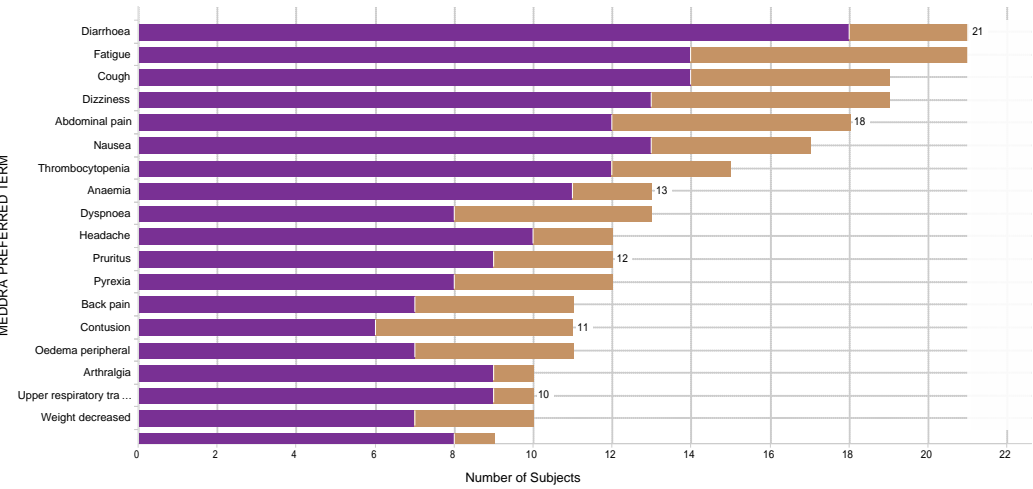
Mark bars of interest then click above to show only those subjects on the Listing page.

Mark to PP

Mark the interested subjects in the Patients Listing below and click "Mark to PP" button to see the details in Patient Profile(PP) page.

MEDDRA PREFERRED TERM

Patients
Subject Identifier



AE by Max Sev to PP

[Reset All Filters](#)

[Mark to AE Listing](#)

Mark bars of interest then click above to show only those subjects on the Listing page.

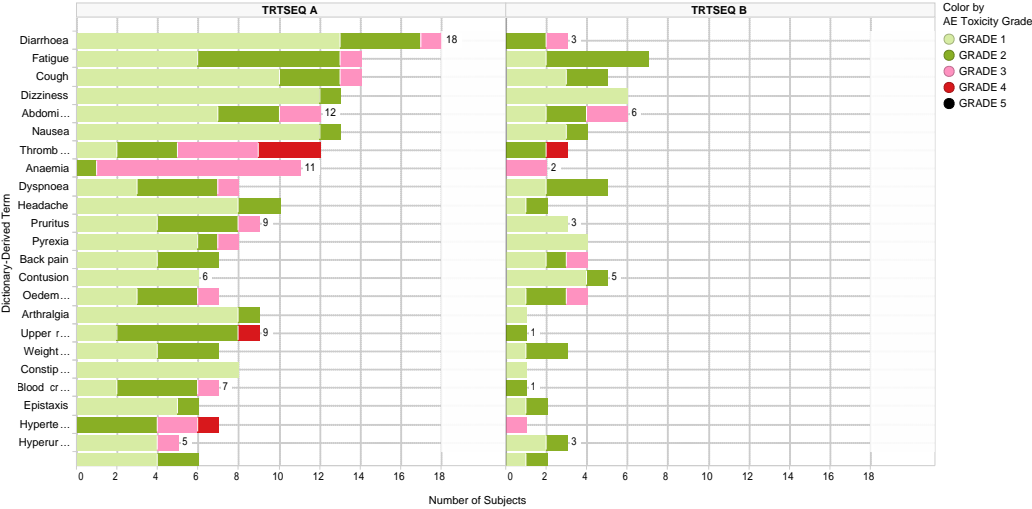
[Mark to PP](#)

Mark the interested subjects in the Patients Listing below and click "Mark to PP" button to see the details in Patient Profile (PP) page.

Patients

Subject Identifier

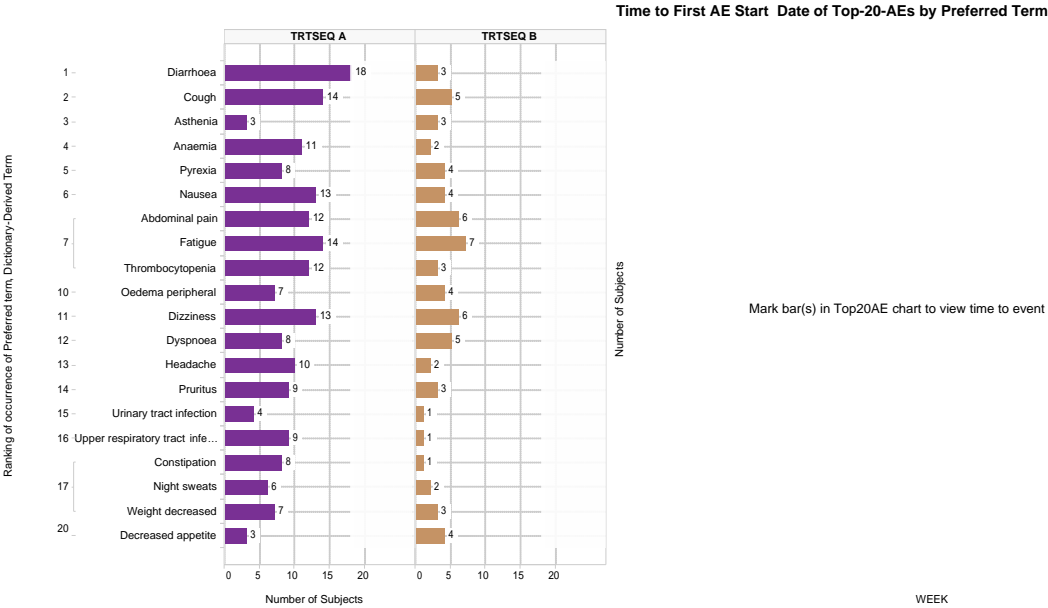
AE Summary by Maximal Severity



Time to Events - AE

Top20AE

Color by
Actual Sequence of Tre
● TRTSEQ A
● TRTSEQ B



AE Tox. to LB

Reset All Filters

AE Preferred Term

Type to search in list

(All) 314 values

Abdominal discomfort

Abdominal distension

Abdominal pain

Abdominal pain lower

Abdominal pain upper

Abdominal wall haematoma

Acute kidney injury

AE Severity/ Toxicity Grade

☒ GRADE 1

☒ GRADE 2

☒ GRADE 3

☒ GRADE 4

☒ GRADE 5

AE Listing										
Site Number	Subject Identifier	Reported AE Term	Dictionary-Derived Term	Primary System Organ Class	Start Date/Time of Adverse Event	End Date/Time of Adverse Event	Coding Dictionary and Version	Serious AE	AE Severity	A E T
9013	81002	BILATERL PED...	Oedema peripheral	General disorder...	13 MAR 2015	24 APR 2015	19	N		G
9013	81002	CHEST INFECTI...	Lower respirator...	Infections and inf...	24 JAN 2015	30 JAN 2015	19	N		G
9013	81002	COUGH	Cough	Respiratory, thor...	31 JAN 2015	19 MAY 2015	19	N		G
9013	81002	DIZZINESS	Dizziness	Nervous system...	05 OCT 2015	12 MAY 2016	19	N		G
9013	81002	EARLY SATIETY	Early satiety	General disorder...	13 FEB 2015	12 MAY 2016	19	N		G
9013	81002	FATIGUE	Fatigue	General disorder...	08 MAY 2015	12 MAY 2016	19	N		G
9013	81002	HEPATOMEGALY	Hepatomegaly	Hepatobiliary dis...	30 JAN 2015	12 MAY 2016	19	N		C
9013	81002	NIGHT SWEATS	Night sweats	Skin and subcut...	01 JAN 2015	30 JAN 2015	19	N		G
9013	81002	RIGHT HEAL UL...	Skin ulcer	Skin and subcut...	01 MAR 2015	02 MAY 2015	19	N		G
9013	81002	SHORTNESS O...	Dyspnoea	Respiratory, thor...	20 MAR 2015	12 MAY 2016	19	N		G
9013	81002	SWEATING NECK	Hyperhidrosis	Skin and subcut...	26 MAY 2015	12 MAY 2016	19	N		G
9013	81002	THIAMINE DEFL...	Vitamin B1 defici...	Metabolism and...	UN JUL 2015	16 OCT 2015	19	N		G
9013	81002	VITAMIN D DEFI...	Vitamin D deficie...	Metabolism and...	UN APR 2015	12 MAY 2016	19	N		G
9013	81002	WEIGHT LOSS	Weight decreased	Investigations	19 JUN 2015	12 MAY 2016	19	N		G

LB Listing

1) Mark AE(s) of interest in AE listing to view subject ID here.

2) Mark subject(s) of interest in subject listing to view lab listing here.

LB Tox. to AE

Reset All Filters

LB Test Name:

Type to search in list

(All) 10 values

Alkaline Phosphatase

ALT (SGPT)

AST (SGOT)

Cockcroft Gault Creat Clear

Hemoglobin

Lymphocytes

Tot ANC(seg,bnd,met,my,pr,bi)

LB Toxicity Grade:

☒ 0

☒ 1

☒ 2

☒ 3

☒ 4

☒ (Empty)

LB Listing												
Subject Identifier	Investigator ID	Lab Test Name	Visit Number	Visit Name	Visit Type	Date/Time of Specimen Collection	Study Day of Specimen	LB Alert Flag	Toxicity Grade	Reported Text Result	Reported Numeric Result	Reported Units
81002	09013	Alkaline Phosph...	-10.00	Screening	S	2014-12-19T11:...	-12	N	0	76	76.00	U/L
81002	09013	Alkaline Phosph...	2.00	RT Week 2	S	2015-01-09T09:...	10	N	0	73	73.00	U/L
81002	09013	Alkaline Phosph...	4.00	RT Week 4	S	2015-01-30T12:...	31	N	0	65	65.00	U/L
81002	09013	Alkaline Phosph...	8.00	RT Week 8	S	2015-02-27T11:...	59	N	0	65	65.00	U/L
81002	09013	Alkaline Phosph...	12.00	RT Week 12	S	2015-03-27T10:...	87	N	0	69	69.00	U/L
81002	09013	Alkaline Phosph...	16.00	RT Week 16	S	2015-04-24T11:...	115	N	0	66	66.00	U/L
81002	09013	Alkaline Phosph...	20.00	RT Week 20	S	2015-05-22T10:...	143	N	0	71	71.00	U/L
81002	09013	Alkaline Phosph...	24.00	RT Week 2...	S	2015-06-19T10:...	171	N	0	79	79.00	U/L
81002	09013	Alkaline Phosph...	104.00	ET Week 4	S	2015-07-24T10:...	206	N	0	74	74.00	U/L
81002	09013	Alkaline Phosph...	108.00	ET Week 8	S	2015-08-21T10:...	234	N	0	74	74.00	U/L
81002	09013	Alkaline Phosph...	112.00	ET Week 12	S	2015-09-18T11:...	262	N	0	79	79.00	U/L
81002	09013	Alkaline Phosph...	9000.00	End of Treat...	U	2015-10-16T10:...	290	N	0	83	83.00	U/L
81002	09013	Alkaline Phosph...	9030.00	Follow-Up 3...	U	2015-11-06T11:...	311	N	0	79	79.00	U/L
81002	09013	ALT (SGPT)	-10.00	Screening	S	2014-12-19T11:...	-12	N	0	30	30.00	U/L

AE Listing

1) Mark lab record(s) of interest in lab listing to view subject ID here.

2) Mark subject(s) of interest in subject listing to view AE listing here.

CM Listing

Reset All Filters

Last Mark Page

Return to previous marked page

Reset Listing

Display all Listing rows

CM Listing

Site Number	Subject Identifier	Reported Drug Name	Indication	Analysis Start date	Start Date/Time of Medication	End Date/Time of Medication	Ongoing?	Dose per Administration	Dose Description	Dose Units	Route of Administration	Dose Form	Dosing Frequency per In...
9013	81002	AMLODIPINE	HYPERTENSION	6/1/2010	UN JUN 2010	12 MAY 2016					Oral		
9013	81002	AMOXICILLIN	CHEST INFECTI...	1/24/2015	24 JAN 2015	13 FEB 2015					Oral		
9013	81002	APIXABAN	CRYOFIBRINO...	8/21/2015	21 AUG 2015	12 MAY 2016					Oral		
9013	81002	ASPRIN	ULCER RIGHT...	6/26/2015	26 JUN 2015	10 JUL 2015					Oral		
9013	81002	AZITHROMYCIN	LEG ULCER INF...	3/15/2015	15 MAR 2015	18 MAR 2015					Oral		
9013	81002	BIMATOPROST	CATARACTS	11/6/2015	06 NOV 2015	12 MAY 2016					Ophthalmic		
9013	81002	CHOLECALIFE...	VITAMIN D DEFI...	1/30/2015	30 JAN 2015	12 MAY 2016					Oral		
9013	81002	CO-AMOXICLAV	CHEST INFECTI...	3/10/2015	10 MAR 2015	15 MAR 2015					Oral		
9013	81002	DOXYCYCLINE	RESPIRATORY ...	12/12/2015	12 DEC 2015	UN DEC 2015					Oral		
9013	81002	FUROSEMIDE	FOR LEG AND...	3/13/2015	13 MAR 2015	24 APR 2015					Oral		
9013	81002	HYLO-FORTE	CATARACTS	11/6/2015	06 NOV 2015	12 MAY 2016					Ophthalmic		
9013	81002	PREDNISOLONE	LEG ULCERS	3/1/2012	UN MAR 2012	29 JAN 2015					Oral		
9013	81002	PREDNISOLONE	LEG ULCERS	1/30/2015	30 JAN 2015	12 MAY 2016					Oral		
9013	81002	RANITIDINE	GASTROESOP...	3/1/2012	UN MAR 2012	12 MAY 2016					Oral		
9013	81002	THIAMINE	THIAMINE DEFI...	7/10/2015	10 JUL 2015	16 OCT 2015					Oral		
9013	81002	TRAMADOL	LEG PAIN	3/1/2014	UN MAR 2014	UN FEB 2015					Oral		
9013	81002	WARFARIN	CRYOFIBRINO...	2/1/2013	UN FEB 2013	25 JUN 2015					Oral		
9013	81002	WARFARIN	ULCER RIGHT...	7/10/2015	10 JUL 2015	20 AUG 2015					Oral		
5779	81003	ACETAMINOPH...	LEFT ANKLE PA...	1/10/2014	10 JAN 2014		Ongoing				Oral		
5779	81003	ACYCLOVIR	PNEUMONIA	9/10/2015	10 SEP 2015	02 OCT 2015					Oral		
5779	81003	ALLOPURINOL	URIC ACID PRO...	4/1/2013	UN APR 2013		Ongoing				Oral		
5779	81003	ASPIRIN	CORONARY AR...	1/1/2001	UN UNK 2001	5 JUL 2015					Oral		
5779	81003	AZITHROMYCIN	PNEUMONIA	9/10/2015	10 SEP 2015	02 OCT 2015					Oral		
5779	81003	CALCIUM CARB...	SUPPLEMENTA...	10/7/2015	7 OCT 2015		Ongoing				Oral		
5779	81003	DOXYCYCLINE	PNEUMONIA P...	10/7/2015	7 OCT 2015		Ongoing				Oral		
5779	81003	EXJADE	IRON OVERLOAD	1/22/2014	22 JAN 2014		Ongoing				Oral		

CM by WHO Drug Name to PP

[Reset All Filters](#)

[Mark to CM Listing](#)

Mark bars of interest then click above to show only those subjects on the Listing page.

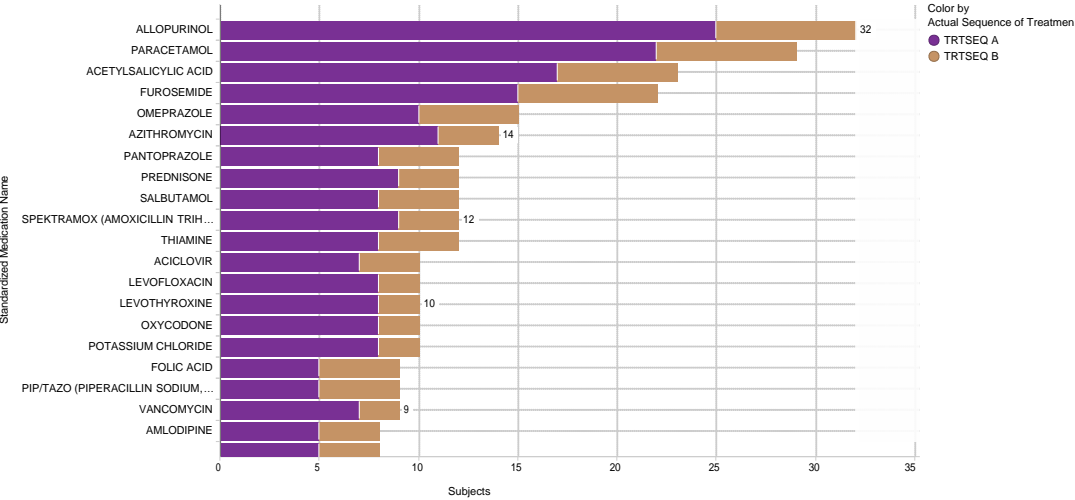
[Mark to PP](#)

Mark the interested subjects in the Patients Listing below and click "Mark to PP" button to see the details in Patient Profile (PP) page.

Patients

Subject Identifier

CM Summary by WHO Drug Name



EX Listing

Reset All Filters

EX Listing

Subject Identifier	Site Number	Treatment Name	Dose per Admi...	Dose Units	Dose Form	Dosing Frequen...	Route	Analysis Start...	Start Date/Time...	Analysis End D...	End Date/Time...	Ongoing?	Study D...
81002	9013	Momelotinib	200	mg		Daily	Oral	6/26/2015	26 JUN 2015	10/16/2015	16 OCT 2015		Perman...
81002	9013	Ruxolitinib	20	mg		Twice per day	Oral	1/31/2014	31 JAN 2014	5/8/2015	08 MAY 2015		
81002	9013	Ruxolitinib	15	mg		Twice per day	Oral	5/8/2015	08 MAY 2015	6/26/2015	26 JUN 2015		Perman...
81003	5779	Momelotinib	200	mg		Daily	Oral	1/26/2015	26 JAN 2015	7/5/2015	5 JUL 2015		
81003	5779	Momelotinib	150	mg		Daily	Oral	7/27/2015	27 JUL 2015	12/1/2015	1 DEC 2015		Perman...
81003	5779	Ruxolitinib	10	mg		Twice per day	Oral	5/15/2013	15 MAY 2013	1/25/2015	25 JAN 2015		Perman...
81004	9282	Momelotinib	200	mg		Daily	Oral	3/5/2015	05 MAR 2015	10/6/2016	06 OCT 2016		
81004	9282	Momelotinib	100	mg		Daily	Oral	10/7/2016	07 OCT 2016	10/13/2016	13 OCT 2016		Perman...
81006	8810	Momelotinib	200	mg		Daily	Oral	3/19/2015	19 MAR 2015	6/30/2016	30 JUN 2016		
81006	8810	Momelotinib	200	mg		Daily	Oral	7/8/2016	08 JUL 2016	7/22/2016	22 JUL 2016		Perman...
81007	8810	Momelotinib	200	mg		Daily	Oral	3/20/2015	20 MAR 2015			Ongoing	
81008	8810	Momelotinib	200	mg		Daily	Oral	3/27/2015	27 MAR 2015			Ongoing	
81010	10015	Momelotinib	200	mg		Daily	Oral	5/14/2015	14 MAY 2015	10/29/2015	29 OCT 2015		
81010	10015	Momelotinib	100	mg		Daily	Oral	10/30/2015	30 OCT 2015	11/5/2015	05 NOV 2015		Perman...
81010	10015	Ruxolitinib	10	mg		Twice per day	Oral	2/28/2013	28 FEB 2013	5/13/2015	13 MAY 2015		
81011	8810	Hydroxyurea	1	G		Other	Oral	5/5/2015	5 MAY 2015	7/24/2015	24 JUL 2015		Perman...
81011	8810	Momelotinib	200	mg		Daily	Oral	7/27/2015	27 JUL 2015	12/27/2015	27 DEC 2015		Perman...
81011	8810	Ruxolitinib	5	mg		Twice per day	Oral	5/23/2015	23 MAY 2015	7/5/2015	05 JUL 2015		Perman...
81012	9102	Momelotinib	200	mg		Daily	Oral	5/22/2015	22 MAY 2015			Ongoing	
81012	9102	Ruxolitinib	15	mg		Twice per day	Oral	4/15/2014	15 APR 2014	5/21/2015	21 MAY 2015		Perman...
81014	9282	Momelotinib	200	mg		Daily	Oral	6/11/2015	11 JUN 2015	2/1/2017	01 FEB 2017		
81014	9282	Momelotinib	100	mg		Daily	Oral	2/2/2017	02 FEB 2017	2/8/2017	08 FEB 2017		
81016	8808	Momelotinib	200	mg		Daily	Oral	6/30/2015	30 JUN 2015	7/29/2015	29 JUL 2015		
81016	8808	Momelotinib	150	mg		Daily	Oral	8/12/2015	12 AUG 2015			Ongoing	
81016	8808	Ruxolitinib	5	mg		Twice per day	Oral	6/25/2015	UN MAR 2015	6/29/2015	29 JUN 2015		Perman...
81019	5779	Momelotinib	200	mg		Daily	Oral	7/8/2015	8 JUL 2015	10/28/2015	28 OCT 2015		Perman...
81022	8810	Momelotinib	200	mg		Daily	Oral	7/16/2015	16 JUL 2015	4/7/2016	07 APR 2016		Perman...
81023	9887	Momelotinib	200	mg		Daily	Oral	7/17/2015	17 JUL 2015	7/29/2015	29 JUL 2015		

MH Listing

Reset All Filters

MH Listing

Study Identifier	Site Number	Unique Subject...	Subject Identifier	Sequence Num...	Reported Term...	Dictionary-Deri...	Body System or...	Coding Diction...	Analysis Start...	Start Date impu...	Start Date/Time...	End Date/Time...	Condiiti...
GS-US-000-0000	9013	GS-US-000-000...	81002	1	ANAEMIA	Anaemia		19	12/19/2014		19 DEC 2014	20 DEC 2014	
GS-US-000-0000	9013	GS-US-000-000...	81002	4	CRYOFIBRINO...	Cryofibrinogenae...		19	10/2/2012		02 OCT 2012		Ongoing
GS-US-000-0000	9013	GS-US-000-000...	81002	9	ELEVATED PSA	Prostatic specific...		19	9/13/2010		13 SEP 2010		Ongoing
GS-US-000-0000	9013	GS-US-000-000...	81002	5	GASTROESOP...	Gastrooesophag...		19	3/1/2012	Y	UN MAR 2012		Ongoing
GS-US-000-0000	9013	GS-US-000-000...	81002	6	HYPERTENSION	Hypertension		19	1/1/2010	Y	UN UNK 2010		Ongoing
GS-US-000-0000	9013	GS-US-000-000...	81002	7	LEG PAIN	Pain in extremity		19	3/1/2014	Y	UN MAR 2014		Ongoing
GS-US-000-0000	9013	GS-US-000-000...	81002	10	LEG ULCERS	Skin ulcer		19	3/1/2012	Y	UN MAR 2012		Ongoing
GS-US-000-0000	9013	GS-US-000-000...	81002	2	MODERATE AO...	Aortic stenosis		19	2/5/2014		05 FEB 2014	11 DEC 2015	
GS-US-000-0000	9013	GS-US-000-000...	81002	8	PRIMARY MYEL...	Primary myelofib...		19	4/1/2012	Y	UN APR 2012		Ongoing
GS-US-000-0000	9013	GS-US-000-000...	81002	3	RIGHT CATARA...	Cataract		19	9/3/2014		03 SEP 2014		Ongoing
GS-US-000-0000	5779	GS-US-000-000...	81003	1	ANEMIA	Anaemia		19	9/8/2010		08 SEP 2010		Ongoing
GS-US-000-0000	5779	GS-US-000-000...	81003	17	BILATERAL LE...	Oedema peripheral		19	5/29/2013		29 MAY 2013		Ongoing
GS-US-000-0000	5779	GS-US-000-000...	81003	22	BLURRED VISION	Vision blurred		19	1/26/2015	Y	UN JAN 2015		Ongoing
GS-US-000-0000	5779	GS-US-000-000...	81003	5	BUNDLE BRAN...	Bundle branch bl...		19	1/21/2015		21 JAN 2015		Ongoing
GS-US-000-0000	5779	GS-US-000-000...	81003	15	COLON POLYP...	Large intestinal p...		19	5/6/2013		06 MAY 2013	06 MAY 2013	
GS-US-000-0000	5779	GS-US-000-000...	81003	6	CORONARY AR...	Coronary artery...		19	1/1/2001	Y	UN UNK 2001	UN UNK 2001	
GS-US-000-0000	5779	GS-US-000-000...	81003	2	CORONARY AT...	Arteriosclerosis c...		19	5/1/2013		1 MAY 2013		Ongoing
GS-US-000-0000	5779	GS-US-000-000...	81003	7	DIVERTICULOSIS	Diverticulum		19	5/6/2013		6 MAY 2013		Ongoing
GS-US-000-0000	5779	GS-US-000-000...	81003	8	DYSPNEA	Dyspnoea		19	1/26/2015	Y	UN JAN 2015		Ongoing
GS-US-000-0000	5779	GS-US-000-000...	81003	11	HEARING IMPAI...	Hypoacusis		19	1/26/2015	Y	UN JAN 2015		Ongoing
GS-US-000-0000	5779	GS-US-000-000...	81003	12	HYPOTENSION	Hypotension		19	1/26/2015	Y	UN UNK 2015		Ongoing
GS-US-000-0000	5779	GS-US-000-000...	81003	13	HYPOTHYROIDI...	Hypothyroidism		19	4/1/2013	Y	UN APR 2013		Ongoing
GS-US-000-0000	5779	GS-US-000-000...	81003	9	INCREASED FA...	Fatigue		19	12/1/2012	Y	UN DEC 2012		Ongoing
GS-US-000-0000	5779	GS-US-000-000...	81003	10	INTERNAL HEM...	Haemorrhoids		19	5/6/2013		6 MAY 2013	6 MAY 2013	
GS-US-000-0000	5779	GS-US-000-000...	81003	14	IRON OVERLOAD	Iron overload		19	1/22/2014		22 JAN 2014		Ongoing
GS-US-000-0000	5779	GS-US-000-000...	81003	3	LEFT ANKLE PA...	Arthralgia		19	10/25/2013		25 OCT 2013		Ongoing
GS-US-000-0000	5779	GS-US-000-000...	81003	4	LEFT HIP PAIN	Arthralgia		19	8/1/2013	Y	UN AUG 2013		Ongoing
GS-US-000-0000	5779	GS-US-000-000...	81003	18	PNEUMONIA	Pneumonia		19	7/4/2010		04 JUL 2010	UN AUG 2010	
GS-US-000-0000	5779	GS-US-000-000...	81003	19	PRIMARY MYEL...	Primary myelofib...		19	4/1/2008	Y	UN APR 2008		Ongoing

LB Listing

Reset All Filters

Last Mark Page

Return to previous marked page

Reset Listing

Display all Listing rows

LB Listing

Subject Identifier	Visit Number	Visit Name	Visit Type	Category for Lab Test	Lab Test Name	Lab Test Code	LB Alert Flag	Toxicity Grade	Date/Time of Specimen Collection	Study Day of Specime...	Reported Text Result	Reported Numeric Result	Reported Units	Reported Reference Range Low	Reported Reference Range High	Conventi onal Text Result
81002	-10.00	Screening	S	CHEMISTRY	Alkaline Phosphatase	RCT1407	N	0	2014-12-19T11:19:00	-12	76	76.00	U/L	35	130	76
81002	2.00	RT Week 2	S	CHEMISTRY	Alkaline Phosphatase	RCT1407	N	0	2015-01-09T09:32:00	10	73	73.00	U/L	35	130	73
81002	4.00	RT Week 4	S	CHEMISTRY	Alkaline Phosphatase	RCT1407	N	0	2015-01-30T12:45:00	31	65	65.00	U/L	35	130	65
81002	8.00	RT Week 8	S	CHEMISTRY	Alkaline Phosphatase	RCT1407	N	0	2015-02-27T11:10:00	59	65	65.00	U/L	35	130	65
81002	12.00	RT Week 12	S	CHEMISTRY	Alkaline Phosphatase	RCT1407	N	0	2015-03-27T10:54:00	87	69	69.00	U/L	35	130	69
81002	16.00	RT Week 16	S	CHEMISTRY	Alkaline Phosphatase	RCT1407	N	0	2015-04-24T11:30:00	115	66	66.00	U/L	35	130	66
81002	20.00	RT Week 20	S	CHEMISTRY	Alkaline Phosphatase	RCT1407	N	0	2015-05-22T10:45:00	143	71	71.00	U/L	35	130	71
81002	24.00	RT Week 24/E...	S	CHEMISTRY	Alkaline Phosphatase	RCT1407	N	0	2015-06-19T10:50:00	171	79	79.00	U/L	35	130	79
81002	104.00	ET Week 4	S	CHEMISTRY	Alkaline Phosphatase	RCT1407	N	0	2015-07-24T10:00:00	206	74	74.00	U/L	35	130	74
81002	108.00	ET Week 8	S	CHEMISTRY	Alkaline Phosphatase	RCT1407	N	0	2015-08-21T10:10:00	234	74	74.00	U/L	35	130	74
81002	112.00	ET Week 12	S	CHEMISTRY	Alkaline Phosphatase	RCT1407	N	0	2015-09-18T11:55:00	262	79	79.00	U/L	35	130	79
81002	9000.00	End of Treatm...	U	CHEMISTRY	Alkaline Phosphatase	RCT1407	N	0	2015-10-16T10:55:00	290	83	83.00	U/L	35	130	83
81002	9030.00	Follow-Up 30...	U	CHEMISTRY	Alkaline Phosphatase	RCT1407	N	0	2015-11-06T11:15:00	311	79	79.00	U/L	35	130	79
81002	-10.00	Screening	S	CHEMISTRY	ALT (SGPT)	RCT4	N	0	2014-12-19T11:19:00	-12	30	30.00	U/L	6	35	30
81002	2.00	RT Week 2	S	CHEMISTRY	ALT (SGPT)	RCT4	N	0	2015-01-09T09:32:00	10	31	31.00	U/L	6	35	31
81002	4.00	RT Week 4	S	CHEMISTRY	ALT (SGPT)	RCT4	HN	1	2015-01-30T12:45:00	31	50	50.00	U/L	6	35	50
81002	8.00	RT Week 8	S	CHEMISTRY	ALT (SGPT)	RCT4	HN	1	2015-02-27T11:10:00	59	40	40.00	U/L	6	35	40
81002	12.00	RT Week 12	S	CHEMISTRY	ALT (SGPT)	RCT4	HN	1	2015-03-27T10:54:00	87	46	46.00	U/L	6	35	46
81002	16.00	RT Week 16	S	CHEMISTRY	ALT (SGPT)	RCT4	HN	1	2015-04-24T11:30:00	115	40	40.00	U/L	6	35	40
81002	20.00	RT Week 20	S	CHEMISTRY	ALT (SGPT)	RCT4	HN	1	2015-05-22T10:45:00	143	48	48.00	U/L	6	35	48
81002	24.00	RT Week 24/E...	S	CHEMISTRY	ALT (SGPT)	RCT4	N	0	2015-06-19T10:50:00	171	34	34.00	U/L	6	35	34
81002	104.00	ET Week 4	S	CHEMISTRY	ALT (SGPT)	RCT4	N	0	2015-07-24T10:00:00	206	23	23.00	U/L	6	35	23
81002	108.00	ET Week 8	S	CHEMISTRY	ALT (SGPT)	RCT4	N	0	2015-08-21T10:10:00	234	26	26.00	U/L	6	35	26
81002	112.00	ET Week 12	S	CHEMISTRY	ALT (SGPT)	RCT4	N	0	2015-09-18T11:55:00	262	19	19.00	U/L	6	35	19
81002	9000.00	End of Treatm...	U	CHEMISTRY	ALT (SGPT)	RCT4	HN	1	2015-10-16T10:55:00	290	37	37.00	U/L	6	35	37
81002	9030.00	Follow-Up 30...	U	CHEMISTRY	ALT (SGPT)	RCT4	HN	1	2015-11-06T11:15:00	311	39	39.00	U/L	6	35	39

LB Scatter Plot

Reset Filters

Select a LAB TEST NAME for X Axis:

Cockcroft Gault Creat Clear

Select a LAB TEST NAME for Y-axis:

ALT (SGPT)

Mark to LB Listing

Mark plots of interest then click above to show only those subjects on the Listing page.

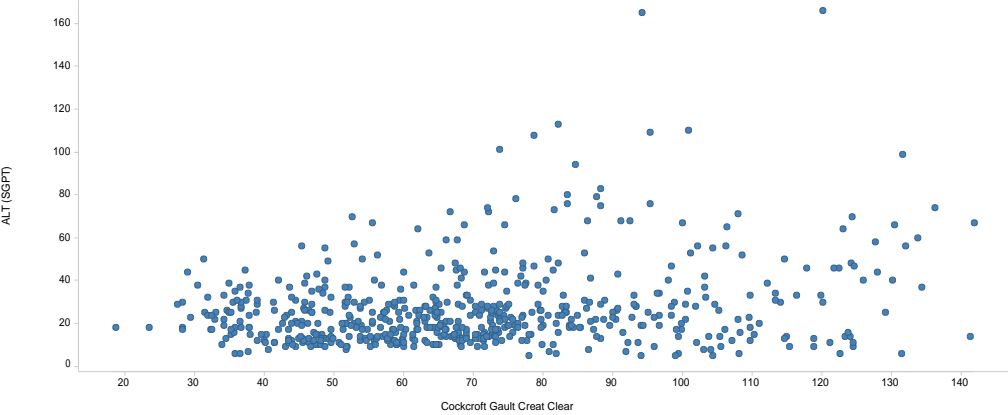
Mark to PP

Mark the interested subjects in the Patients Listing below and click "Mark to PP" button to see the details in Patient Profile(PP) page.

Patients

Subject Identifier

LB Tests Scatter Plot



LB Tox Grade Summ

Reset All Filters

Toxicity Grade:

☒ 0

☒ 1

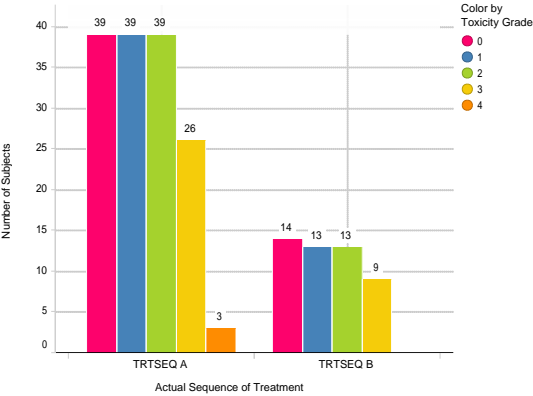
☒ 2

☒ 3

☒ 4

☐ (Empty)

Lab Toxicity Summary (Counts)



Filter settings

lb
- Toxicity Grade: (0, 1, 2, 3, 4)

Lab Toxicity Summary (Counts)

Toxicity Grade

Mark to LB Listing

Mark plots of interest then click above to show only those subjects on the Listing page.

Mark to PP

Mark the interested subjects in the Patients Listing below and click "Mark to PP" button to see the details in Patient Profile(PP) page.

Patients

Subject Identifier

Lab Test Name

Mark bar(s) of interest in Lab Toxicity Summary to view details here.

Number of Subjects

LB Spaghetti

[Reset Filters](#)

Select a LAB TEST NAME:
Alkaline Phosphatase

[Mark to LB Listing](#)

Mark plots of interest then click above to show only those subjects on the Listing page.

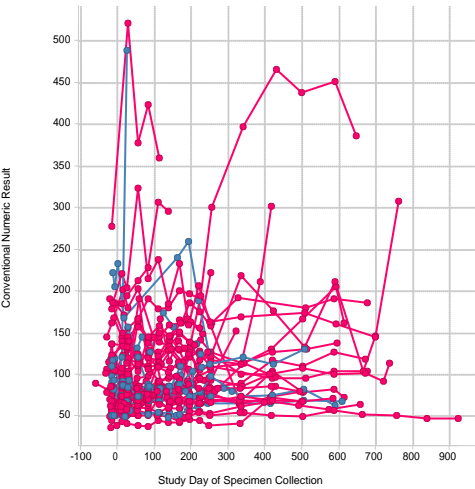
[Mark to PP](#)

Mark the interested subjects in the Patients Listing below and click "Mark to PP" button to see the details in Patient Profile (PP) page.

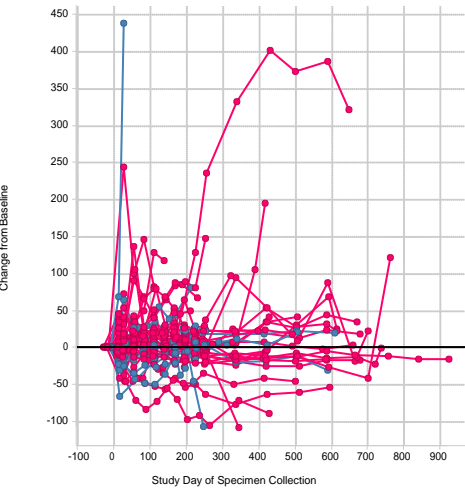
Patients

Subject Identifier

LB Results




LB Change from Baseline



LB Box Plot

[Reset All Filters](#)

Select a LAB TEST NAME:

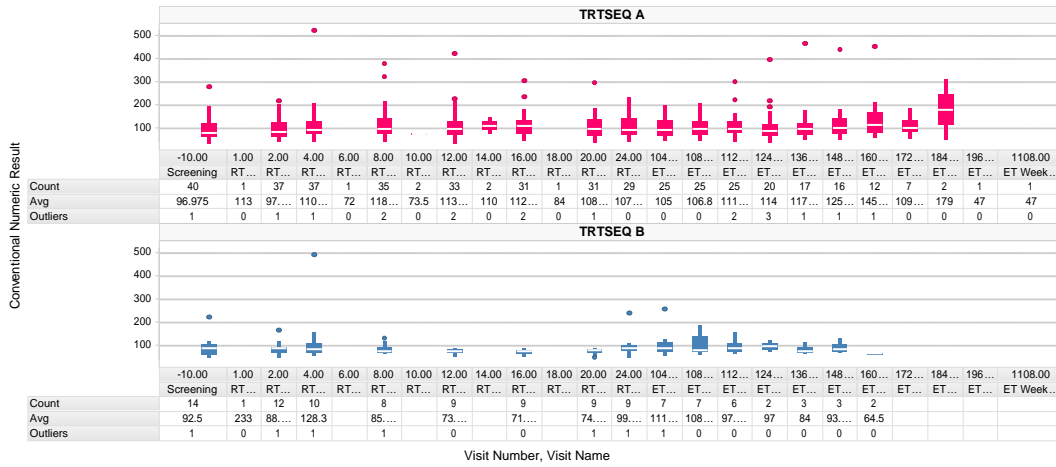
Alkaline Phosphatase [Mark to LB Listing](#)

Mark plots of interest then click above to show only those subjects on the Listing page.

Mark to PP

Mark the interested subjects in the Patients Listing below and click "Mark to PP" button to see the details in Patient Profile(PP) page.

Box Plot of LB Data by LB Test Name



Patients

Subject Identifier

DILI-Hy's Law

[Reset All Filters](#)

[Mark to LB Listing](#)

Mark plots of interest then click above to show only those subjects on the Listing page.

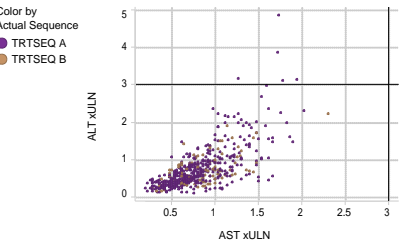
[Mark to PP](#)

Mark the interested subjects in the Patients Listing below and click "Mark to PP" button to see the details in Patient Profile(PP) page.

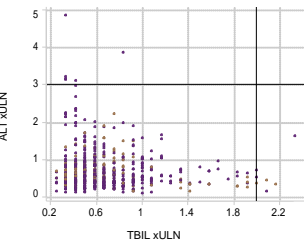
Patients

Subject Identifier

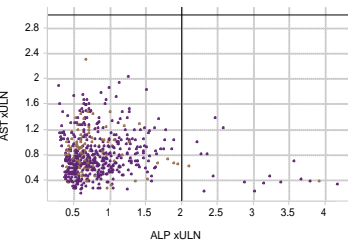
ALT xULN vs. AST xULN



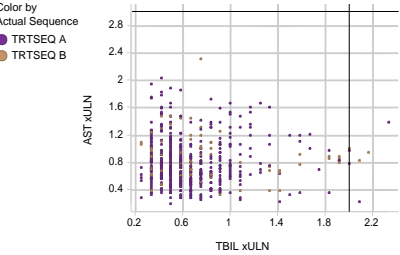
ALT xULN vs. TBIL xULN



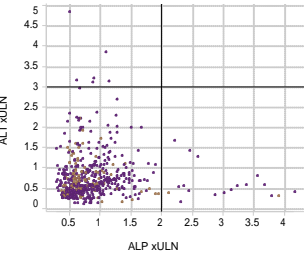
AST xULN vs. ALP xULN



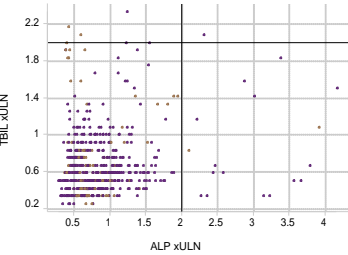
AST xULN vs. TBIL xULN



ALT xULN vs. ALP xULN



TBIL xULN vs. ALP xULN



Patient Profile

Click the 'Last Mark Page' button to go back to the last marked page you are

reviewing: [Last Mark Page](#)

Click the 'Reset Patients' button to reset the patient listing to show all safety

patients: [Reset Patients](#)

[Reset All Filters](#)

Select Filter for PP:

- ☒ 01 EX
- ☒ 02 SV
- ☒ 03 AE
- ☒ 04 CM
- ☒ 051 LB-Che
- ☒ 052 LB-Hem
- ☒ 053 LB-Uri
- ☒ 054 LB-Oth

Patients

Subject Identifier
81002
81024
82001
82024
82032
84020

Demographics

Mark subject(s) of interest in Patients Listing to view demographics details here.

Patient Profile

Mark subject(s) of interest in Patients Listing to view patient profile here.

DATANAME, CATEGORY

Color: ● Tox. Gr >=3 ● Dose Modify ● Dose Interruption

Shape: ✕ Terminated ▶ Start, ◀ End, ▷ Start(imputed), ◁ End(imputed)

Relative Day (imputed)

Patient Profile (LB)

Patients

Subject Identifier
81002
81003
81004
81006
81007
81008
81010
81011
81012
81014
81016
81019
81022
81023
81024
81026
81027
81032
81033
81035
81037
81044
81050
81051
82001
82002
82003
82012
82014
82019
82021

LB: Results vs. Study Day

Conventional Results

Mark subject(s) of interest in Patients Listing to view lab details here.

Study Day

LB: Change From Baseline vs. Study Day

Change from Baseline

Mark subject(s) of interest in Patients Listing to view lab details here.

Study Day

Patient Profile (listing)

Patients

Subject Identifier
81002
81003
81004
81006
81007
81008
81010
81011
81012
81014
81016
81019
81022
81023
81024
81026
81027
81032
81033
81035
81037
81044
81050
81051
82001
82002
82003
82012
82014
82019
82021

Demographics

Mark subject(s) of interest in Patients Listing to view DM details here.

Drug Exposure

Mark subject(s) of interest in Patients Listing to view EX details here.

AE Listing

Mark subject(s) of interest in Patients Listing to view AE details here.

CM Listing

Mark subject(s) of interest in Patients Listing to view CM details here.

Medical History

Mark subject(s) of interest in Patients Listing to view MH details here.

LB Listing

Mark subject(s) of interest in Patients Listing to view LB details here.