Version Number	Release Date	Comments/Major Updates Compared to Prior Version
1.0		- Based on ADS plan template: 001-MCG-160_RD-12_1 0 - Adapted for Define-XML v2.0 - Adapted for project centric approach - Added ADAEPL and associated controlled terminology - Moving Sheets CT, EXTCT, Document Links after Datasets - Minor improvements - Added Analysis Results Metadata (ARM) - Added ADAE and associated controlled terminology - Added ADCM and associated controlled terminology - Added ADMH and associated controlled terminology - Added CLINSITE and associated controlled terminology - Adapted column header comments to include rules specific to CLINSITE
2.0		- Marked ADAEPL as temporary interim solution. The preferred structure is ADAE. - Added variable COUNTRY to all ADSs sheets, except for ADTTRAN and ADGTRT - Updated to ADaM IG 1.1 - included ADOCCDS template - added derivations for ADGTRT
2.1		- minor fixes

StudyName	StudyDescription	ProtocolName	Standard Name	Standard Version	CDISC CT File References	UniqueIdentifier	AsOfDateTime
2012_0103	A phase 3 Study to Evaluate the Efficacy and Safety of Induction and Maintenance Regimens of Brodalumab Compared With Placebo and Ustekinumab in Subjects With Moderate to Severe Plaque Psoriasis (AMAGINE-2)	2012.103	ADaM-IG		ct-sdtm-ncievs-odm-2014-09.xml; ct-adam-ncievs-odm-2014-09.xml		

Dataset Name	Used by Study	Dataset Description	Dataset Structure	Key Variables of Dataset	Class of Dataset	Dataset Location	Comment	Documentation (define.xml)	External Document References	External Document Page Numbers	Sort
ADSL	2012_0103	Subject-Level Analysis Dataset	One record per study identifier per subject identifier	USUBJID,STUDYID	SUBJECT LEVEL ANALYSIS DATASET						1
ADPA	2012_0103	Efficacy Analysis Dataset	One record per study identifier per subject identifier per parameter code (per analysis visit)	USUBJID,STUDYID,PARAMCD, AVISITN	BASIC DATA STRUCTURE						2

Used by Study	Document	Document	Document Filename
2012_0103	DataGuide	Analysis Data Reviewers Guide	

CT Name	Used by Study	NCI/CDISC CT Name	Type	Sort	Code	Decode
$NYC	2012_0103	No Yes Response	text	1	N	No
$NYC	2012_0103	No Yes Response	text	2	Y	Yes
$NYC	2012_0103	No Yes Response	text	3	U	Unknown
$NYC	2012_0103	No Yes Response	text	4	NA	Not Applicable
NYC	2012_0103		integer	1	0	No
NYC	2012_0103		integer	2	1	Yes
NYC	2012_0103		integer	3	2	Unknown
NYC	2012_0103		integer	4	3	Not Applicable
$NYT	2012_0103		text	1	N	No
$NYT	2012_0103		text	2	Y	Yes
NYT	2012_0103		integer	1	0	No
NYT	2012_0103		integer	2	1	Yes
$SEXC	2012_0103	Sex	text	1	M	Male
$SEXC	2012_0103	Sex	text	2	F	Female
$SEXC	2012_0103	Sex	text	3	U	Unknown
$AGEUC	2012_0103	Age Unit	text	1	DAYS	
$AGEUC	2012_0103	Age Unit	text	2	HOURS	
$AGEUC	2012_0103	Age Unit	text	3	MONTHS	
$AGEUC	2012_0103	Age Unit	text	4	WEEKS	
$AGEUC	2012_0103	Age Unit	text	5	YEARS	
SEXC	2012_0103		integer	1	1	Male
SEXC	2012_0103		integer	2	2	Female
SEXC	2012_0103		integer	3	3	Unknown
PACD	2012_0103		integer	1	10	PASI
PACD	2012_0103		integer	2	20	sPGA
$PAC	2012_0103		integer	1	PASI	Psoriasis Area and Severity Index
$PAC	2012_0103		integer	2	sPGA	Static Physician's Global Assessment

CT Name	CT Descriptive Name	Used by Study	External Dictionary	External Dictionary Version	Type

Dataset Name	Context (Where condition)	Used by Study	Key Sequence	Variable Name	Variable Label	Variable Type	Variable Length
ADSL	*ALL*	2012_0103		STUDYID	Study Identifier	text	9
ADSL	*ALL*	2012_0103		USUBJID	Unique Subject Identifier	text	20
ADSL	*ALL*	2012_0103		SUBJID	Subject Identifier for the Study	text	10
ADSL	*ALL*	2012_0103		AGE	Age	integer	8
ADSL	*ALL*	2012_0103		AGEU	Age Units	text	6
ADSL	*ALL*	2012_0103		SEX	Sex	text	1
ADSL	*ALL*	2012_0103		SEXN	Sex (N)	integer	8
ADSL	*ALL*	2012_0103		WEIGHT	Weight (kg)	float	8
ADSL	*ALL*	2012_0103		PASI	Baseline PASI	integer	8
ADSL	*ALL*	2012_0103		sPGA	Baseline sPGS	integer	8
ADSL	*ALL*	2012_0103		AGEGR1N	Age Group 1 (N)	integer	8
ADSL	*ALL*	2012_0103		AGEGR1	Age Group 1	text	20
ADSL	*ALL*	2012_0103		ENRLFL	Enrolled Population Flag	text	1
ADSL	*ALL*	2012_0103		RANDFL	Randomized Population Flag	text	1
ADSL	*ALL*	2012_0103		TRTFL	Treated Population Flag	text	1

Dataset Name	Context (Where condition)	Used by Study	Key Sequence	Variable Name	Variable Label	Variable Type	Variable Length

ADSL	*ALL*	2012_0103		ARM	Description of Planned Arm	text	60
ADSL	*ALL*	2012_0103		ARMCD	Planned Arm Code	text	15
ADSL	*ALL*	2012_0103		ARMN	Planned Arm (N)	integer	8
ADSL	*ALL*	2012_0103		ARMSL	Planned Arm Short Label	text	20
ADSL	*ALL*	2012_0103		ACTARM	Actual Arm	text	60
ADSL	*ALL*	2012_0103		ACTARMCD	Actual Arm Code	text	15
ADSL	*ALL*	2012_0103		ACTARMN	Actual Arm (N)	integer	8
ADSL	*ALL*	2012_0103		ACTARMSL	Actual Arm Short Label	text	20
ADSL	*ALL*	2012_0103		TRT01P	Planned Treatment for Period 01	text	60
ADSL	*ALL*	2012_0103		TRT01PN	Planned Treatment for Period 01 (N)	integer	8
ADSL	*ALL*	2012_0103		TRT01A	Actual Treatment for Period 01	text	60
ADSL	*ALL*	2012_0103		TRT01AN	Actual Treatment for Period 01 (N)	integer	8

Variable Format	CT Name	Origin	Source / Derivation	External Document References
$9.		Predecessor	DM.STUDYID	
$20.		Predecessor	DM.USUBJID	
$10.		Predecessor	DM.SUBJID	
8.		Predecessor	DM.AGE	
$6.	$AGEUC	Predecessor	DM.AGEU	
$1.	$SEXC	Predecessor	DM.SEX	
8.	SEXC	Assigned	Numeric version of SEX variable based on Controlled Terminology	
5.1		Derived	VS.VSSTRESN, where VSTESTCD = 'WEIGHT'	
8.		Derived	QS.QSSTRESN where QS.QSTESTCD = "PASI" at VISIT 2	
8.		Derived	QS.QSSTRESN where QS.QSTESTCD = "sPGA" at VISIT 2	
8.		Derived	if . < AGE < 20 then 1 else if 20 <= AGE < 40 then 2 else if 40 <= AGE < 60 then 3 else if 60 <= AGE < 80 then 4 else if 80 <= AGE then 5	
$20.		Derived	if AGEGR1N = 1 then '< 20' else if AGEGR1N = 2 then '>= 20 - < 40' else if AGEGR1N = 3 then '>= 40 - < 60' else if AGEGR1N = 4 then '>= 60 - < 80' else if AGEGR1N = 5 then '>= 80'	
$1.	$NYT	Derived	Indicator flag whether the subject has enrolled into the study. For subjects with DM.RFICDTC is not missing it is Y else N.	
$1.	$NYT	Derived	Indicator flag whether the subject has entered or randomized into the study. For subjects with DM.ARMCD is not missing and not SCRNFAIL it is Y else N.	
$1.	$NYT	Derived	Subjects who were randomized and documented to have taken at least one dose of investigational treatment. For subjects with RANDFL=Y and non missing SE.SESTDTC where (SE.ETCD='TREAT' or SE.EPOCH='TREATMENT') it is Y else N	

$60.		Predecessor	DM.ARM	
$15.		Predecessor	DM.ARMCD	
8.		Assigned	Numeric version of ARM	
$20.		Assigned	Short Label for ARM	
$60.		Predecessor	DM.ACTARM	
$15.		Predecessor	DM.ACTARMCD	
8.		Assigned	Numeric version of ACTARM	
$20.		Assigned	Short Label for ACTARM	
$60.		Derived	One to One mapping of DM.ARM	
8.		Assigned	Numeric version of DM.ARM	
$60.		Derived	One to One mapping of DM.ACTARM	
8.		Assigned	Numeric version of DM.ACTARM	

External Document Page Numbers	Comment	SAS Programming Statements	Variable Order	CDISC Core	BI Core
			1	Req	Req
			2	Req	Req
			3	Req	Req
			4	Req	Req
			5	Req	Req
			6	Req	Req
			7	Req	Req
			8	Perm	Perm
			9		
			10		
			12		
			11		
			13	Cond	Cond
			14	Cond	Cond
	If ARM is not loaded, set to N for TRTFL		15		Cond

			16	Req	Req
			17	Req	Req
			18	Req	Req
			19	Req	Req
			20	Req	Req
			21	Req	Req
			22	Req	Req
			23	Req	Req
			24	Req	Req
			25	Perm	Perm
			26	Cond	Cond
			27	Perm	Perm

	A	B	C	D	E	J	K	L	M
1	*Dataset Name*	*Context (Where condition)*	*Used by Study*	*Key Sequence*	*Variable Name*	*CT Name*	*Origin*	*Source / Derivation*	*External Document References*
2	ADPA	*ALL*	2012_0103	1	USUBJID		Predecessor	ADSL.USUBJID	
3	ADPA	*ALL*	2012_0103	2	STUDYID		Predecessor	ADSL.STUDYID	
4	ADPA	*ALL*	2012_0103		SUBJID		Predecessor	ADSL.SUBJID	
5	ADPA	*ALL*	2012_0103		TRTP		Derived	ADSL.TRT01P	
6	ADPA	*ALL*	2012_0103		TRTPN		Derived	ADSL.TRT01PN	
7	ADPA	*ALL*	2012_0103		TRTA		Derived	ADSL.TRT01A	
8	ADPA	*ALL*	2012_0103		TRTAN		Derived	ADSL.TRT01AN	
9	ADPA	*ALL*	2012_0103		TRTFL		Predecessor	ADSL.TRTFL	
10	ADPA	*ALL*	2012_0103		AVISIT		Derived	QS.VISIT (VISIT 2 or VISIT 6)	
11	ADPA	*ALL*	2012_0103	3	AVISITN		Assigned	If AVISIT = "VISIT 2", then assign to 2; if AVISIT="VISIT 6" then assign to 6	
12	ADPA	*ALL*	2012_0103		PARAMCD	$PAC	Derived	QS.QSTESTCD ("PASI" or "sPGA")	
13	ADPA	*ALL*	2012_0103		PARAMN	PACD	Assigned	when PARAMCD = "PASI", PARAMN = 10; when PARAMCD = "sPGA", PARAMN = 20	
14	ADPA	*ALL*	2012_0103		PARAM		Assigned	when PARAMCD = "PASI", PARAM = "Psoriasis Area and Severity Index"; when PARAMCD = "sPGA", PARAM = "Static Physician's Global Assessment"	
15	ADPA	*ALL*	2012_0103		ABLFL		Derived	assign to "Y" for avisit = "VISIT 2"	
16	ADPA	*ALL*	2012_0103		AVAL		Derived	QS.QSSTRESN where QS.QSTESTCD contains ("PASI" or "sPGA")	
17	ADPA	*ALL*	2012_0103		BASE		Derived	AVAL when AVISITN= 2	
18	ADPA	*ALL*	2012_0103		CHG		Derived	base-aval for records of baseline and after, else set to missing	
19	ADPA	*ALL*	2012_0103		PCHG		Derived	See below	
20	ADPA	PARAMCD EQ "PASI"	2012_0103		PCHG		Derived	CHG/BASE *100% for records of baseline and after, else set to missing	
21	ADPA	PARAMCD EQ "sPGA"	2012_0103		PCHG		Derived	set to missing	
22	ADPA	*ALL*	2012_0103		PCHGCAT1		Derived	See below	
23	ADPA	PARAMCD EQ "PASI"	2012_0103		PCHGCAT1		Derived	For PARAMCD = PASI only, if PCHG>=75, then ">=75%", else if .<PCHG <75 then '75%'	

	N	O	P	Q	R	S
1	*External Document Page Numbers*	Comment	SAS Programming Statements	*Variable Order*	CDISC Core	BI Core
2				1		
3				2		
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6				5		
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9				8		
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	A	B	C	D	E	J	K	L	M
1	*Dataset Name*	*Context (Where condition)*	*Used by Study*	*Key Sequence*	*Variable Name*	*CT Name*	*Origin*	*Source / Derivation*	*External Document References*
24	ADPA	PARAMCD EQ "sPGA"	2012_0103		PCHGCAT1		Derived	set to missing	
25	ADPA	*ALL*	2012_0103		PCHGCA1N		Assigned	See below	
26	ADPA	PARAMCD EQ "PASI"	2012_0103		PCHGCA1N		Assigned	Numeric version of PCHGCAT2, if PCHG>=75, then "1", else if .<PCHG <75 then " 0 "	
27	ADPA	PARAMCD EQ "sPGA"	2012_0103		PCHGCA1N		Assigned	set to missing	
28	ADPA	*ALL*	2012_0103		PCHGCAT2		Derived	See below	
29	ADPA	PARAMCD EQ "PASI"	2012_0103		PCHGCAT2		Derived	For PARAMCD = PASI only, if PCHG>=100, then "100%", else if .<PCHG <100 then '100%'	
30	ADPA	PARAMCD EQ "sPGA"	2012_0103		PCHGCAT2		Derived	set to missing	
31	ADPA	*ALL*	2012_0103		PCHGCA2N		Assigned	See below	
32	ADPA	PARAMCD EQ "PASI"	2012_0103		PCHGCA2N		Assigned	Numeric version of PCHGCAT1, if PCHG>=100, then "1", else if .<PCHG <100 then " 0 "	
33	ADPA	PARAMCD EQ "sPGA"	2012_0103		PCHGCA2N		Assigned	set to missing	
34	ADPA	*ALL*	2012_0103		AVALCAT1		Derived		
35	ADPA	PARAMCD EQ "sPGA"	2012_0103		AVALCAT1		Derived	For PARAMCD = sPGA only, if sPGA at visit 6 = 0 , then "sPGA score of 0 ", else "sPGA score >0"	
36	ADPA	PARAMCD EQ "PASI"	2012_0103		AVALCAT1		Derived	set to missing	
37	ADPA	*ALL*	2012_0103		AVALCA1N		Assigned		
38	ADPA	PARAMCD EQ "sPGA"	2012_0103		AVALCA1N		Assigned	Numeric version of AVALCAT1, if "sPGA score of 0 ", then 1, else 0	
39	ADPA	PARAMCD EQ "PASI"	2012_0103		AVALCA1N		Assigned	set to missing	
40	ADPA	*ALL*	2012_0103		AVALCAT2		Derived	See below	
41	ADPA	PARAMCD EQ "sPGA"	2012_0103		AVALCAT2		Derived	For PARAMCD = sPGA only, if sPGA at visit 6 = 0 or 1 , then "sPGA score of 0 or 1 ", else "sPGA score >1"	
42	ADPA	PARAMCD EQ "PASI"	2012_0103		AVALCAT2		Derived	set to missing	
43	ADPA	*ALL*	2012_0103		AVALCA2N		Assigned	See below	
44	ADPA	PARAMCD EQ "sPGA"	2012_0103		AVALCA2N		Assigned	Numeric version of AVALCAT1, if "sPGA score of 0 or 1 ", then 1, else 0	
45	ADPA	PARAMCD EQ "PASI"	2012_0103		AVALCA2N		Assigned	set to missing	
46	ADPA	*ALL*	2012_0103		ANL01FL		Derived	set to "Y"	
47	ADPA	*ALL*	2012_0103		ANL01FN		Derived	Set to 1 if ANL01FL = 'Y' else set to missing	

	N	O	P	Q	R	S
1	*External Document Page Numbers*	Comment	SAS Programming Statements	*Variable Order*	CDISC Core	BI Core
24				23		
25				24		
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Dataset Name	Variable Label
USUBJID	subject ID
AESEQ	sequence number of AE for a subject
AESTDY	AE start date relative to the study start date
AEENDY	AE start date relative to the study start date
AETERM	AE term
AEDECOD	Decode of AE
AEBODSYS	Body System organ class
AESER	AE serious or not
AESEV	AE severity
AEREL	Investigator's assessment of whether AE is related to the treatment or not
AEOUT	AE outcome
ARM	Treatment arm
ARMCD	Treatment arm decode
SBJTSTAT	Subject status
SAFFL	Flag if the subject is in safety analysis dataset
SAFFN	Flag if the subject is in safety analysis dataset in numeric format