CDM Tools:

make your daily work easier

A SAS programming approach

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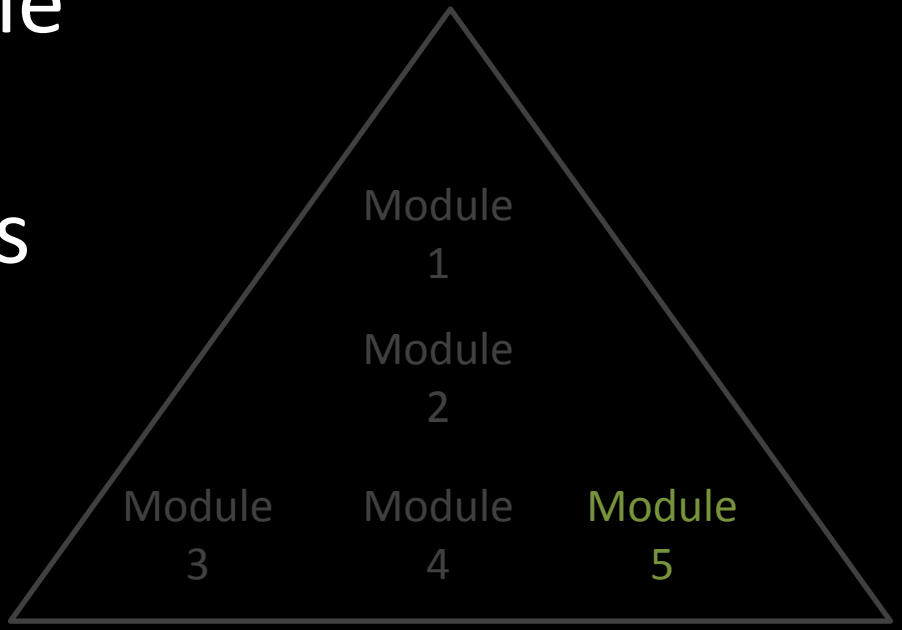
Quality Work for Quality World

Outline

Tool for SDTM Transformation

Tool for Patient Profile

Tool for CDM Reports



Tool for SDTM Transformation

Background

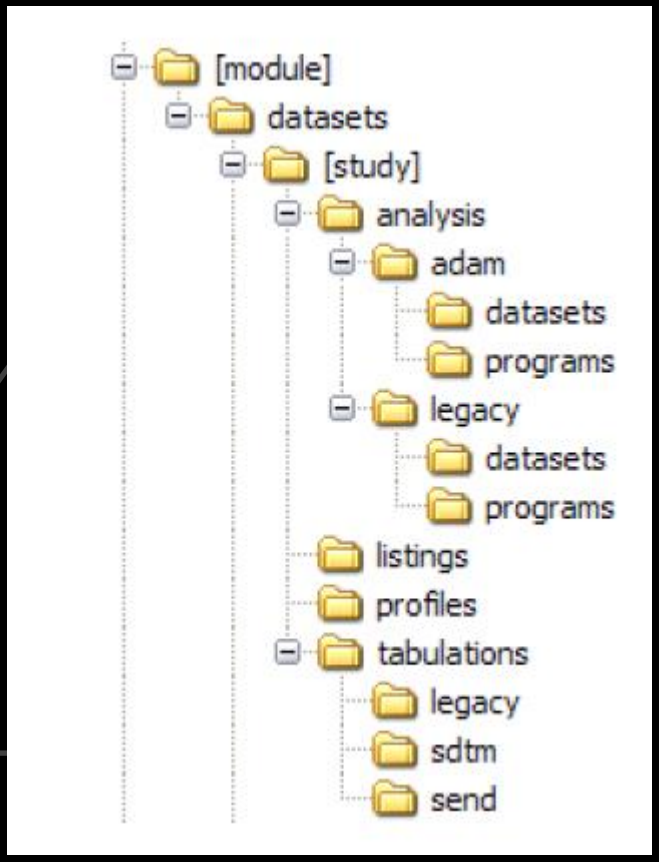
- Required by regulatory
- Consistence among CRF, programs, SDTM data, define.xml
- Easy to use

Design

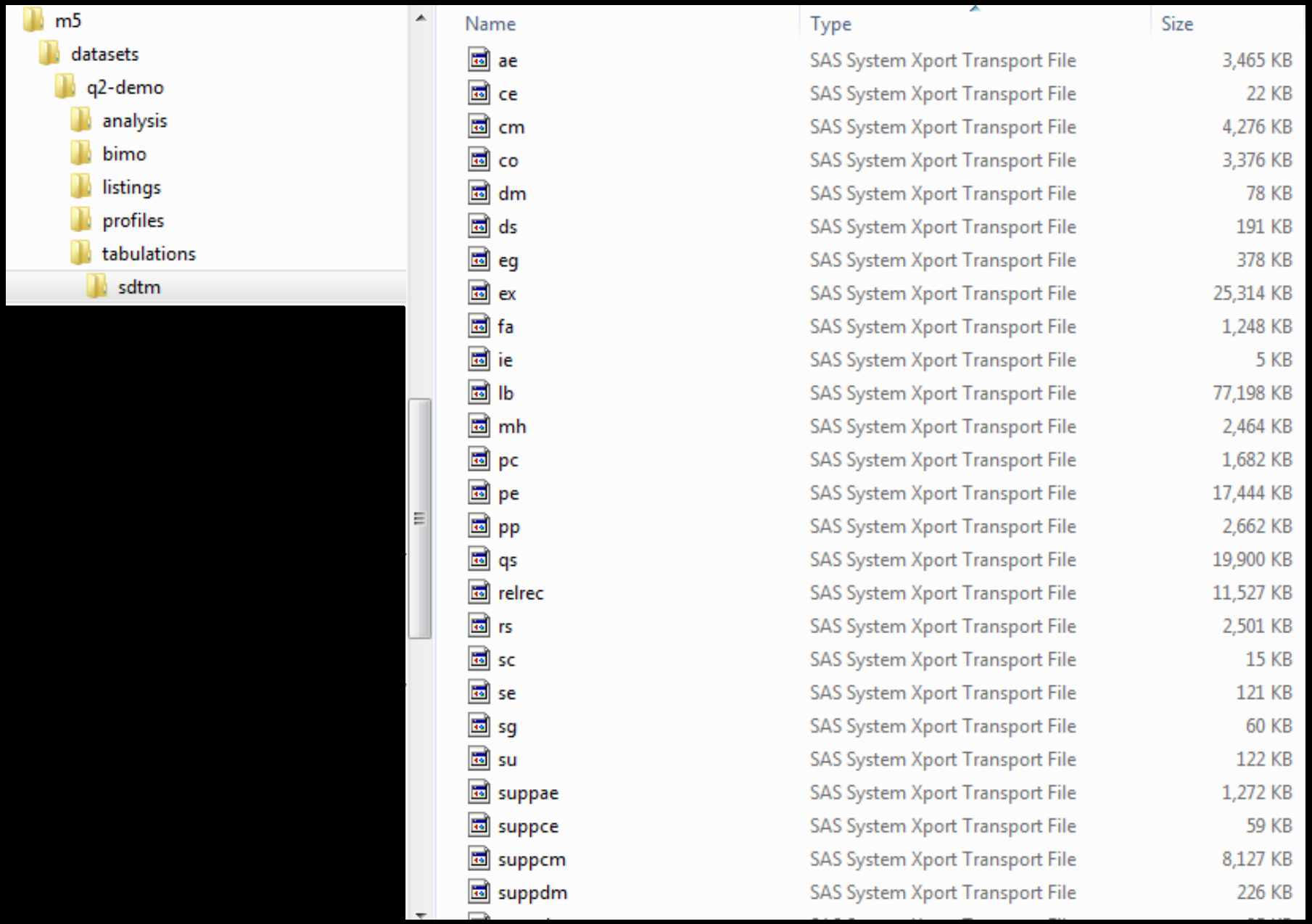
- aCRF → Specification → program → SDTM → define

Benefits

- Quality
- Reduce programming time and cost
- No SAS programming skill required



Example of SDTM datasets folder



Example of SDTM define.xml

- Annotated Case Report Form
- SDTM Tabulation Guide
- Datasets
  - Trial Arms (TA)
  - Trial Elements (TE)
  - Trial Inclusion/Exclusion Criteria (TI)
  - Trial Summary (TS)
  - Trial Visits (TV)
  - Comments (CO)
  - Demographics (DM)
  - Subject Elements (SE)
  - Subject Visits (SV)
  - Concomitant Medications (CM)
  - Exposure (EX)
  - Surgery (SG)
  - Substance Use (SU)
  - Adverse Events (AE)
  - Clinical Events (CE)
  - Disposition (DS)
  - Medical History (MH)
  - ECG Test Results (EG)
  - Findings About Events or Interventions (FA)
  - Inclusion/Exclusion Exceptions (IE)
  - Laboratory Test Results (LB)
  - Pharmacokinetic Concentrations (PC)
  - Physical Examination (PE)
  - Pharmacokinetic Parameters (PP)
  - Questionnaires (QS)
  - Response (RS)
  - Subject Characteristics (SC)
  - Tumor Results (TR)
  - Tumor Identification (TU)
  - Vital Signs (VS)

Datasets for Study Q2-DEMO

Dataset	Description	Class	Structure	Purpose	Keys	Location
TA	Trial Arms	Trial Design	One record per planned Element per Arm	Tabulation	STUDYID, ARMCD, TAETORD	ta.xpt
TE	Trial Elements	Trial Design	One record per planned Element	Tabulation	STUDYID, ETCD	te.xpt
TI	Trial Inclusion/Exclusion Criteria	Trial Design	One record per I/E criterion	Tabulation	STUDYID, IETESTCD	ti.xpt
TS	Trial Summary	Trial Design	One record per trial summary parameter value	Tabulation	STUDYID, TSPARMCD, TSVAL	ts.xpt
TV	Trial Visits	Trial Design	One record per planned Visit per Arm	Tabulation	STUDYID, VISITNUM, ARMCD	tv.xpt
CO	Comments	Special-Purpose	One record per related domain per IDVAR per IDVARVAL per comment reference per comment per subject	Tabulation	STUDYID, USUBJID, RDOMAIN, IDVAR, IDVARVAL, COREF	co.xpt
DM	Demographics	Special-Purpose	One record per subject	Tabulation	STUDYID, USUBJID	dm.xpt
SE	Subject Elements	Special-Purpose	One record per start data per end date per actual Element per subject	Tabulation	STUDYID, USUBJID, SESTDTC, SEENDTC, ELEMENT	se.xpt
SV	Subject Visits	Special-Purpose	One record per actual visit per start date per end date per description of unplanned visit per subject	Tabulation	STUDYID, USUBJID, VISITNUM, SVSTDTC, SVENDTC, SVUPDES	sv.xpt
CM	Concomitant Medications	Interventions	One record per category per subcategory per group ID per sponsor ID per recorded	Tabulation	STUDYID, USUBJID, CMCAT, CMSCAT,	cm.xpt

Example of SDTM Tabulations Data

Guide to SDTM Tabulations Data

Pharmacyclics Study Q2-1104-CA is titled "Multicenter, phase 2 study of Bruton's tyrosine kinase (Btk) inhibitor, PCI-32765, in relapsed or refractory mantle cell lymphoma"

This document provides an introduction to SDTM domain datasets that benefit from additional explanation beyond what is available in the Data Definitions (define.xml) document.

Contents

Tool for Patient Profile

Background

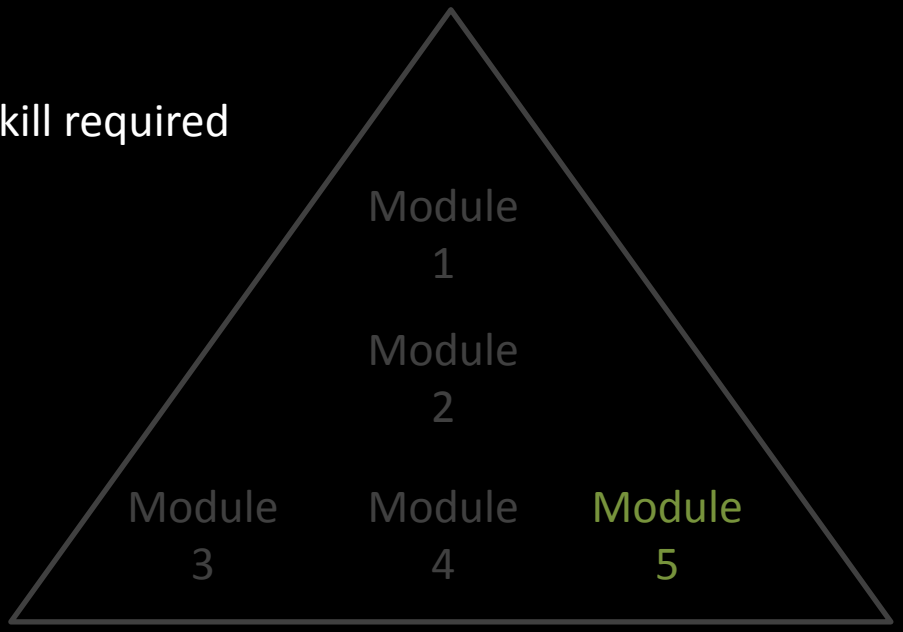
- Required by CDM or ClinOps, a M5 deliverable
- CDM data review, safety and / or efficacy review
- Easy to use

Design

- Scope → Target data → Configure spec → draft & final patient profile

Benefits

- Easy to generate, no SAS programming skill required
- Linked and color coded patient profile
- Graph enabled ppv
- Reduce time and cost



Tool for Patient Profile

Clinical Laboratory Tests: Chemistry, Part 1

Visit[1]	Visit Date	Form Status[2]	Sample Collection	Sodium <mmol/L>	Potassium <mmol/L>	Chloride <mmol/L>	CO2 <mmol/L>	Calcium <mg/dL>	Total Protein <g/dL>	Albumin <g/dL>	Phosphate <mg/dL>
Screening Visit (V1A)	23-Jul-12	MR	23-Jul-12	139	5.4	103	28	9.7	6.5	4.0 gm/dl	4.2
Post-Op Day 1 (V2)	27-Jul-12	MR	27-Jul-12	138	4.0	106	26	8.7	5.1	3.2 gm/dl	2.7
Post-Op Day 2 (V3)	28-Jul-12	MR	28-Jul-12	137	3.8	103	28	8.5	5.2	3.0 gm/dl	2.6
Post-Op Day 4 (V5)	30-Jul-12	M	30-Jul-12	138	6.5	106	24	8.1	4.2	2.2gm/dl	3.4
Post-Op Day 5 (V6)	31-Jul-12	MR	NOT REQUIRED PER PROTOCOL								
Outpatient/14 Day FU	15-Aug-12	MR	15-Aug-12	137	5.0	103	28	9.5	6.5	4.0 gm/dl	3.2
Unscheduled	30-Jul-12	M	30-Jul-12	138	3.9	106	28	8.5			

Clinical Laboratory Tests: Chemistry, Part 2

Visit[1]	AST (SGOT) <U/L>	Alkaline Phosphatase <U/L>	ALT (SGPT) <U/L>	Total Bilirubin <mg/dL>	Direct Bilirubin <mg/dL>	BUN <mg/dL>	Creatinine <mg/dL>	Glucose <mg/dL>	Creatine Kinase (CK or CPK) <U/L>
Screening Visit (V1A)	25	43	19	0.5	0.1	19	1.2	90	55
Post-Op Day 1 (V2)	25	28	17	0.5	0.1	9	1.0	146	146
Post-Op Day 2 (V3)	21	26	16	0.4	0.1	8	1.0	110	224
Post-Op Day 4 (V5)	15	26	11	0.2	0.1	8	0.8	575	82
Post-Op Day 5 (V6)									
Outpatient/14 Day FU	22	43	19	0.4	0.0	17	1.1	140	39
Unscheduled						10	0.9	132	

[1]: See Appendix 1
[2]: MR=Monitored Reviewed, M=Monitored, CR=Complete Reviewed, C=Complete, I=Incomplete, PM=Partial Monitored
[3]: Age is calculated as (Informed Consent Date- Birthday + 1)/365.25.

NOTE:Number in red: Above normal range; Number in blue: Lower than normal range; Number in green: Without lower and upper limit; Number with underline has hyperlink to comments; CS: Clinical Significant, NCS: Not Clinical Significant

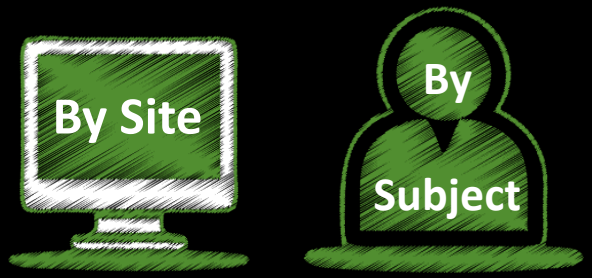
Modified Record

New Record

Generated on 2013-05-21T21:43:47

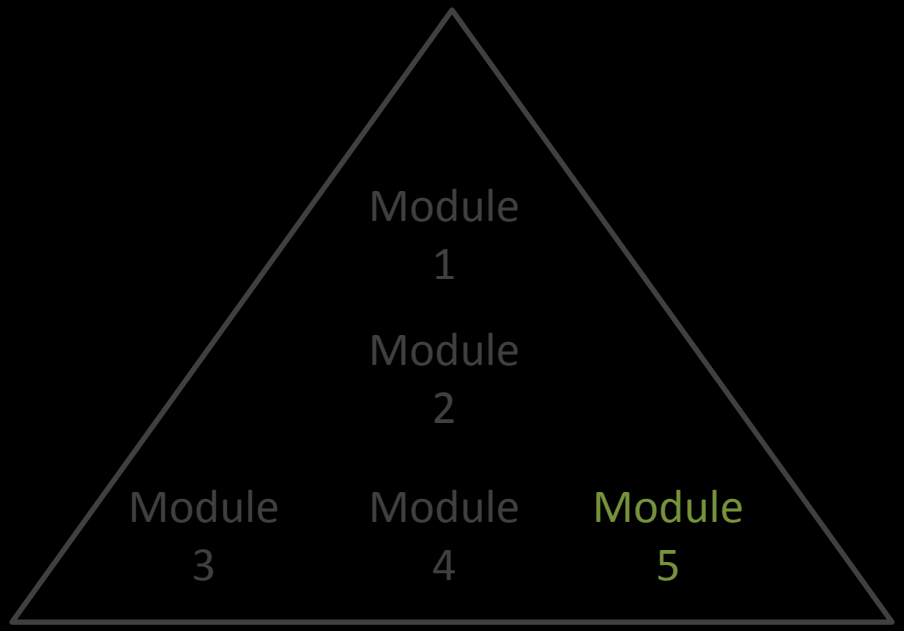
Tool for CDM Reports

Monitor Report ---- CRF status



Consistency Reports

Exception Report

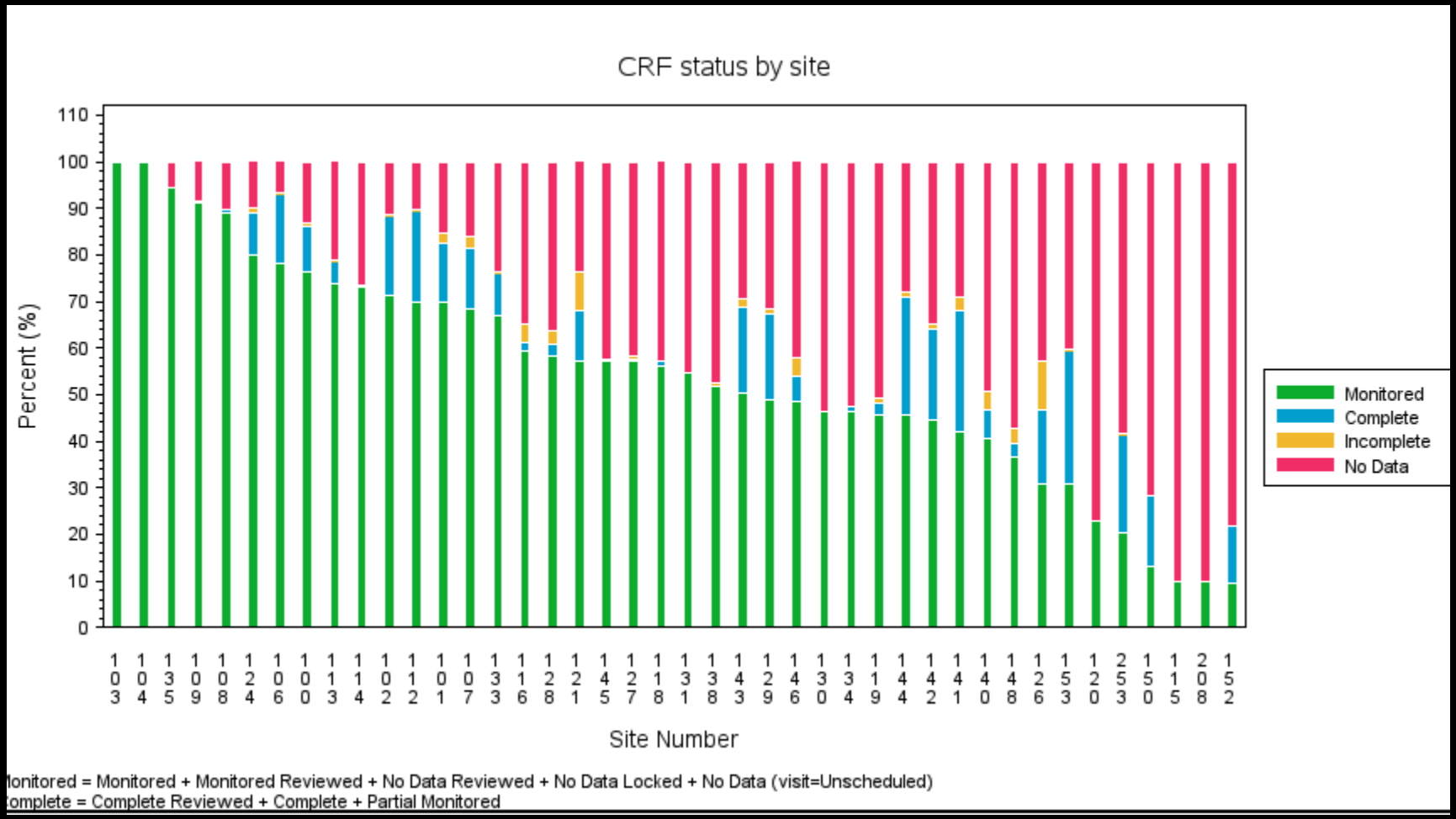


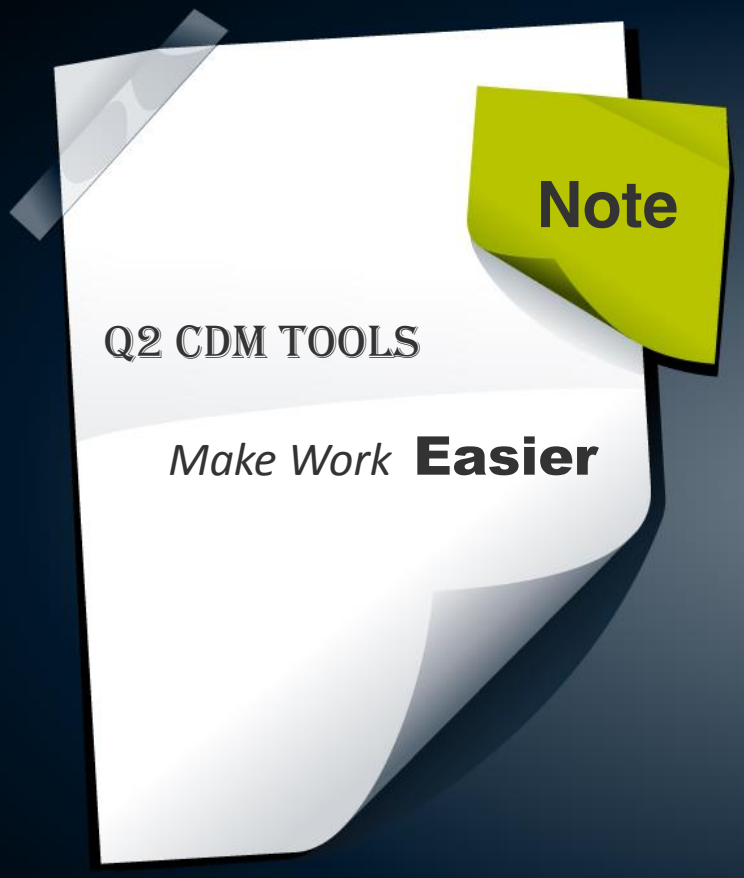
Tool for CDM Reports

AE vs CM

1	*Adverse Event & Concomitant Medications*									
2										
3	**Subject ID**	**Adverse Event**	**AE Start Date**	**AE End Date**	**Outcome**	**Medication Taken?**	**Concomitant Medications**	**Reason for Use**	**CM Start Date**	**CM End Date**
1969	900-201	Diarrhoea	2012-09-09	2012-09-09	Recovered, Date Stopped	Yes	Immodium (Gastro-Stop)	Diarrhoea	2012-11-14	2012-11-14
1970		Dizziness	2012-09-09	2012-09-09	Recovered, Date Stopped	Yes	Diabex	Diabetes	1990-06	
1971		low magnesium	2012-09-09	2012-10-09	Recovered, Date Stopped	Yes	Lantus	IDDM	1990-06	2012-11-12
1972		Worsening left knee pain due to osteoarthritis	2012-09-19		Ongoing	Yes	Novorapid	IDDM	1990-06	
1973		Hypercalcaemia	2012-09-28	2012-10-09	Recovered, Date Stopped	Yes	Pamidronate	Hypercalcaemia	2012-10-03	2012-10-03
1974							Pamidronate	hypercalcaemia	2012-11-06	2012-11-06
1975		Worsening left hip pain	2012-10-22		Ongoing	Yes	Rosuvastatin	High cholestrol	2007-09	
1976		left heel ulcer becoming necrotic	2012-11-02	2012-12-03	Recovered, Date Stopped	Yes	Astrix	Ischaemic Heart Disease	2007-09	2012-11-05
1977		diarrhoea	2012-11-14	2012-11-14	Recovered, Date Stopped	Yes	Immodium (Gastro-Stop)	Diarrhoea	2012-11-14	2012-11-14
1978		Hypotension	2012-12-08		Ongoing	Yes	Normal Saline	Hypotension	2012-12-08	
1979		Chest infection	2012-12-13		Ongoing	Yes	Panadol Osteo	Osteo arthritic pain	2011	
1980		Possibility of graft infection	2012-12-15		Ongoing	Yes	Spiriva	Congestive Heart Disease	2011-05	
1981		Possible Osteomyelitis left leg	2012-12-15		Ongoing	Yes	Bicor	CCF	2011-09-06	

Tool for CDM Reports
CRF Status by Site





Thank you