



SDTM COMPLIANT DATA, HOW TO GET THERE EFFECTIVELY?

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Agenda

- Short introduction to PRA
- Set up Clinical Database
- Programming SDTM datasets
- Conclusions
- Questions



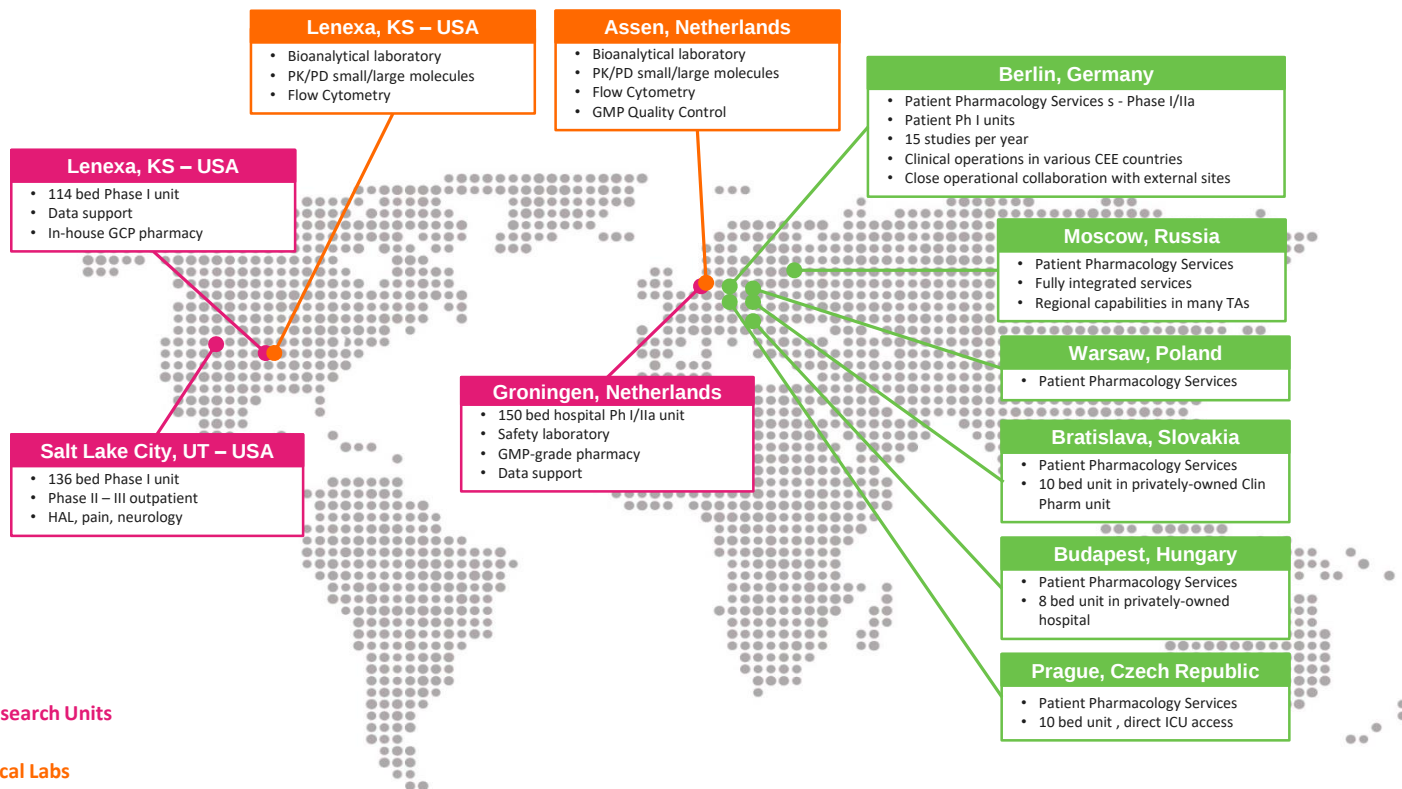
- Supporting Full Clinical Development Cycle



- Full-Service Leading CRO
 - Clinical development: Phase I – IV
 - Bioanalytical support: Non-clinical – Phase IV
 - GMP Pharmaceutical support (NL, US under development)
- 16,500 employees across > 85 countries



PRA Introduction - EDS



PRA Clinical Research Units

PRA Bioanalytical Labs

PRA Patient Pharmacology Services → (PRA owned units: Slovakia, Hungary, Czech Republic)



Overview of The Clinic

- 150 beds, all hospital based
- 52 beds Intensive Pharmacology Unit
- 24/7 ICU support
- GMP Pharmacy
- Fully automated in-house Central Lab
- AME / Microdose Facility
- Surgical Room
- PRA Bioanalytical Laboratory in Assen, NL

Martini Hospital



Types of Studies

- Biologics: MAbs, Biosimilars, higher risk FIH
- Pain Models, Neuro, Infectious Disease (HCV), Healthy Volunteers
- FIH SAD/MAD, DDI, FE, TQT, PK/PD, BA/BE
- AME, Microdose

Recruitment & Subject Population

- >33,000 Volunteers in database
- Integrated screening area
- Dedicated Recruitment Team for each study
- Satellite screening center Utrecht

Specialty Capabilities

- Cardiac/QTc, radiolabeled AME / microdosing, CSF sampling, pain models
- Imaging & Diagnostics: e.g. PET, SPECT, (f)MRI
- Mortara Surveyor Telemetry

Regulatory Environment

- Fastest timelines in EU
- 2 weeks IEC/CTA approval





Data Manager

- eCRF
- Definition of edit checks
- Validation and query resolution
- Data Transfer Agreement for external Data (e.g. safety lab, pk, ecg data)
- Coding
- Communication with client
- Timelines (incl SDTM deliverables)

Database Programmer

- Design/build eCRF/database incl QC (UAT)
- Program and QC edit checks (UAT)
- Provide input for Data Transfer Agreement
- Reconciliation of external data
- SDTM programming (incl define.xml, aCRF and cSDRG)
- Advise Data Manager on “technical” aspects



- Data Management System: Oracle Clinical
- Implemented in 1998
- Since 2006 direct Data Entry by Clinic Staff via RDC module
- Fully compliant 21 CFR Part 11

ORACLE Health Sciences



- Fast timelines
 - Final protocol to first screening assessment 2 to 3 weeks.
 - Quick delivery of SDTM compliant datasets after completion study
- Easily to adapt design
 - Several designs in one study protocol (e.g. SAD, MAD, FE part, DDI and Proof of Concept part with patients)
 - Phase I studies are subject to change
- Client wishes
 - eCRF specifications
 - SDTM specifications
- eCRF pages easy to complete
 - eCRF services as an eSource system. Direct Entry by Clinic Staff



- DCMs: Data Collection Modules

OPA (Regine De_Gier - OPSSRGIER at OLSPRD on 11-MAR-2019)

Action Move Clear Data Query Special Help Window

Maintain Study DCMs (Study:)

Data Collection Modules

Get Qualifying Question Character Layout Graphic Layout

DCM Name	Subset	Layout	Name	Domain	Status	Short Name	Type	Description
ADVERSE_EVENT	1	1	AE	UCB294EC_172945	A	AE	EVENTS	Adverse Events
ALCOHOL_BREATH	1	1	ALCO	UCB294EC_172945	A	AL	FINDINGS	Alcohol Breath Test
BLOOD_SAMPLING	1	1	BLD1_IR	UCB294EC_172945	A	BS	FINDINGS	Blood Sample Collection - Day
CARBON_MONOXIDI	1	1	CARB	UCB294EC_172945	A	CA	FINDINGS	Carbon Monoxide Test
CHILDBEAR_POT	1	1	METHOD	UCB294EC_172945	A	SC	FINDINGS	Childbearing Potential - Method
COMPLETION	1	1	COMPL	UCB294EC_172945	A	DS	EVENTS	Study Completion or Early Term
CONCO_MEDICATIO	1	1	PREVMED	UCB294EC_172945	A	CM	INTERVENTIONS	Previous Medications
CSSRS	1	1	BASE	UCB294EC_172945	A	CSSR	FINDINGS	C-SSRS - Baseline (Without P
DEMOGRAPHICS	1	1	DEMO	UCB294EC_172945	A	DM	SPECIAL_PURPOSE	Demography
ECG	1	1	ECG	UCB294EC_172945	A	EG	FINDINGS	ECG
HABITS	1	1	HABITS	UCB294EC_172945	A	HAB	SCREENING	Tobacco / Alcohol Consumption
INCL_EXCL	1	1	IE_IN	UCB294EC_172945	A	IE	FINDINGS	Eligibility Checklist Inclusion - v

Exit Save Change Study DCM Question Groups

Type DCM is key for structure raw datasets extracted



- DCM Questions (example ECG)

Question Name	SAS Name	SAS Label	Validation Failure Type	Help Text	Default Response
TIM	TIM	Time of Collection	NORMAL		
ORRES_PR_	PR	PR Interval, Aggregate	NORMAL	PRAG	
ORRES_QRSDUR_	QRSDUR	QRS Duration, Aggregate	NORMAL	QRSAG	
ORRES_QT_	QT	QT Interval, Aggregate	NORMAL	QTAG	
ORRES_QTCF_	QTCF	QTcF Interval, Aggregate	NORMAL	QTCFAG	
ORRESU_PR_	PRU	PR Interval Unit	NORMAL		msec
ORRESU_QRSDUR_	QRSDURU	QRS Duration Unit	NORMAL		msec
ORRESU_QT_	QTU	QT Interval Unit	NORMAL		msec
ORRESU_QTCF_	QTCFU	QTcF Interval, Aggregate	NORMAL		msec
ORRES_INTP_	INTP	Interpretation	NORMAL		
POS_	POS	ECG Position of subject	NORMAL		
METHOD_	METHOD	Method of ECG Test	NORMAL		12 LEAD STANDARD

- Per ECG parameter a question
- At the end of each question an underscore has been used. This will lead to starting SAS variables with the subset name of the DCM.
- Help text: EGTESTCD from Controlled Terminology and SAS label EGTEST from Controlled term



PRAHEALTHSCIENCES

PRA code:

Subject number: X8

Title (short):

Sponsor name:

Page Name: ECG_SCR

Sponsor code

Visit date:

Visit Name: SCREENING

ECG - 12 LEAD

Actual Time (hhmm)

Position

SUPINE

Not Done

☐

If not done, specify reason

Heart Rate (bpm)

PR Interval (msec)

QRS Duration (msec)

QT Interval (msec)

QTc Fridericia (msec)

ECG evaluation

☐ Normal

☐ Abnormal, not clinically significant

☐ Abnormal, clinically significant

If abnormal, specify

Comments



Running extraction macro result: 80% SDTM compliant raw datasets

	STUDYID	DOMAIN	USUBJID	EGGRPID	EGTESTCD	EGTEST	EGPOS	EGORRES	EGORRESU	EGSTRESC	EGSTRESN	EGSTRESU
1	ABC	EG	ABC-001-11301	1	EGHRMN	ECG Mean Heart Rate	SUPINE	52	beats/min	52	52	beats/min
2	ABC	EG	ABC-001-11301	1	INTP	Interpretation	SUPINE	NORMAL		NORMAL		
3	ABC	EG	ABC-001-11301	1	PRAG	PR Interval, Aggregate	SUPINE	212	msec	212	212	msec
4	ABC	EG	ABC-001-11301	1	QRSAG	QRS Duration, Aggregate	SUPINE	94	msec	94	94	msec
5	ABC	EG	ABC-001-11301	1	QTAG	QT Interval, Aggregate	SUPINE	404	msec	404	404	msec
6	ABC	EG	ABC-001-11301	1	QTCFAG	QTcF Interval, Aggregate	SUPINE	385	msec	385	385	msec
7	ABC	EG	ABC-001-11301	2	EGHRMN	ECG Mean Heart Rate	SUPINE	66	beats/min	66	66	beats/min
8	ABC	EG	ABC-001-11301	2	INTP	Interpretation	SUPINE	NORMAL		NORMAL		
9	ABC	EG	ABC-001-11301	2	PRAG	PR Interval, Aggregate	SUPINE	194	msec	194	194	msec
10	ABC	EG	ABC-001-11301	2	QRSAG	QRS Duration, Aggregate	SUPINE	88	msec	88	88	msec
11	ABC	EG	ABC-001-11301	2	QTAG	QT Interval, Aggregate	SUPINE	377	msec	377	377	msec
12	ABC	EG	ABC-001-11301	2	QTCFAG	QTcF Interval, Aggregate	SUPINE	389	msec	389	389	msec

	STUDYID	DOMAIN	USUBJID	EGGRPID	EGTESTCD	EGSTAT	EGREASND	EGMETHOD	EGBLFL	EGDRVFL	VISITNUM	VISIT	EGDTC	EGDY	COM	EGSPECIFY1
1	ABC	EG	ABC-001-11301	1	EGHRMN			12 LEAD STAND...			1	SCREENING	2018-04-16T09:33	-11		
2	ABC	EG	ABC-001-11301	1	INTP			12 LEAD STAND...			1	SCREENING	2018-04-16T09:33	-11		
3	ABC	EG	ABC-001-11301	1	PRAG			12 LEAD STAND...			1	SCREENING	2018-04-16T09:33	-11		
4	ABC	EG	ABC-001-11301	1	QRSAG			12 LEAD STAND...			1	SCREENING	2018-04-16T09:33	-11		
5	ABC	EG	ABC-001-11301	1	QTAG			12 LEAD STAND...			1	SCREENING	2018-04-16T09:33	-11		
6	ABC	EG	ABC-001-11301	1	QTCFAG			12 LEAD STAND...			1	SCREENING	2018-04-16T09:33	-11		
7	ABC	EG	ABC-001-11301	2	EGHRMN			12 LEAD STAND...			998	FINAL DISCHAR...	2018-07-09T09:19	74		
8	ABC	EG	ABC-001-11301	2	INTP			12 LEAD STAND...			998	FINAL DISCHAR...	2018-07-09T09:19	74		
9	ABC	EG	ABC-001-11301	2	PRAG			12 LEAD STAND...			998	FINAL DISCHAR...	2018-07-09T09:19	74		
10	ABC	EG	ABC-001-11301	2	QRSAG			12 LEAD STAND...			998	FINAL DISCHAR...	2018-07-09T09:19	74		
11	ABC	EG	ABC-001-11301	2	QTAG			12 LEAD STAND...			998	FINAL DISCHAR...	2018-07-09T09:19	74		
12	ABC	EG	ABC-001-11301	2	QTCFAG			12 LEAD STAND...			998	FINAL DISCHAR...	2018-07-09T09:19	74		

- Variables and sequence of variables according to SDTM IG
- Contents as much as possible SDTM compliant



Set up Oracle Clinical versus –Raw dataset

Question Name	SAS Name	SAS Label	Failure Type	Help Text
TIM	TIM	Time of Collection	NORMAL	
ORRES_PR_	PR	PR Interval, Aggregate	NORMAL	PRAG
ORRES_QRS DUR_	QRS DUR	QRS Duration, Aggregate	NORMAL	QRSAG
ORRES_QT_	QT	QT Interval, Aggregate	NORMAL	QTAG
ORRES_QTcF_	QTcF	QTcF Interval, Aggregate	NORMAL	QTcFAG
ORRESU_PR_	PRU	PR Interval Unit	NORMAL	
ORRESU_QRS DUR_	QRS DURU	QRS Duration Unit	NORMAL	
ORRESU_QT_	QTU	QT Interval Unit	NORMAL	
ORRESU_QTcF_	QTcFU	QTcF Interval, Aggregate	NORMAL	
ORRES_INTP_	INTP	Interpretation	NORMAL	
POS_	POS	ECG Position of subject	NORMAL	
METHOD_	METHOD	Method of ECG Test	NORMAL	

Helptext in OC → EGTESTCD
SAS label in OC → EGTEST

EGTESTCD	EGTEST
EGHRMN	ECG Mean Heart Rate
INTP	Interpretation
PRAG	PR Interval, Aggregate
QRSAG	QRS Duration, Aggregate
QTAG	QT Interval, Aggregate
QTcFAG	QTcF Interval, Aggregate
EGHRMN	ECG Mean Heart Rate
INTP	Interpretation
PRAG	PR Interval, Aggregate
QRSAG	QRS Duration, Aggregate
QTAG	QT Interval, Aggregate
QTcFAG	QTcF Interval, Aggregate



- Program: Kinship EXACT



- Developed by PRA
- Used for creation of tabulation deliverables including tabulation dataset, metadata specifications and define.xml following the CDISC SDTM model
- Based on SAS
- Easily reuse metadata from previous studies or template study
- Mapping tool
- Version history programs



SDTM Conversion –Variable Level Metadata 1

Domain Name	Variable Order	Variable Name	Variable Data Type	Variable Label	Key	Variable Core	Variable Role
EG	1	STUDYID	Character	Study Identifier	1	Required	Identifier
EG	2	DOMAIN	Character	Domain Abbreviation		Required	Identifier
EG	3	USUBJID	Character	Unique Subject Identifier	2	Required	Identifier
EG	4	EGSEQ	Numeric	Sequence Number		Required	Identifier
EG	5	EGGRPID	Character	Group ID		Permissible	Identifier
EG	6	EGREFID	Character	ECG Reference ID		Permissible	Identifier
EG	7	EGSPID	Character	Sponsor-Defined Identifier		Permissible	Identifier
EG	8	EGTESTCD	Character	ECG Test or Examination Short Name	5	Required	Topic
EG	9	EGTEST	Character	ECG Test or Examination Name		Required	Synonym Qualifier
EG	10	EGCAT	Character	Category for ECG	4	Permissible	Grouping Qualifier
EG	11	EGSCAT	Character	Subcategory for ECG		Permissible	Grouping Qualifier
EG	12	EGPOS	Character	ECG Position of Subject		Permissible	Record Qualifier
EG	13	EGORRES	Character	Result or Finding in Original Units		Expected	Result Qualifier
EG	14	EGORRESU	Character	Original Units		Permissible	Variable Qualifier
EG	15	EGSTRESC	Character	Character Result/Finding in Std Format		Expected	Result Qualifier
EG	16	EGSTRESN	Numeric	Numeric Result/Finding in Standard Units		Permissible	Result Qualifier
EG	17	EGSTRESU	Character	Standard Units		Permissible	Variable Qualifier
EG	18	EGSTAT	Character	Completion Status		Permissible	Record Qualifier
EG	19	EGREASND	Character	Reason ECG Not Performed		Permissible	Record Qualifier

- Reuse contents from template or previous study
- Key definition



SDTM Conversion –Variable Level Metadata 2

Domain Name	Variable Order	Variable Name	Variable Data Type	ODM Data Type	Significant Digits	Variable Origin	CRF Bookmarks	Named Destination	Computation OID	Code List	Code List Name
EG	1	STUDYID	Character	text		Protocol		☐		Select	
EG	2	DOMAIN	Character	text		Assigned		☐		Select	
EG	3	USUBJID	Character	text		Derived		☐	USUBJID	Select	
EG	4	EGSEQ	Numeric	integer		Derived		☐	SEQ	Select	
EG	5	EGGRPID	Character	text		Assigned		☐		Select	
EG	6	EGREFID	Character	text		eDT		☐		Select	
EG	7	EGSPID	Character	text		CRF Page	M5, M20, M28, M29, M42, M49	☒		Select	
EG	8	EGTESTCD	Character	text		Assigned		☐		Sponsor	EGTESTCD
EG	9	EGTEST	Character	text		Assigned		☐		Sponsor	EGTEST
EG	10	EGCAT	Character	text		Assigned		☐		Select	
EG	11	EGSCAT	Character	text				☐		Select	
EG	12	EGPOS	Character	text		Protocol		☐		Sponsor	EGPOS
EG	13	EGORRES	Character	text		CRF Page	M5, M20, M28, M29, M42, M49	☒		Select	
EG	14	EGORRESU	Character	text		Assigned		☐		Sponsor	EGRESU
EG	15	EGSTRESC	Character	text		Derived		☐	STRESC	Select	
EG	16	EGSTRESN	Numeric	integer		Derived		☐	STRESN	Select	
EG	17	EGSTRESU	Character	text		Derived		☐	STRESU	Sponsor	EGRESU
EG	18	EGSTAT	Character	text		CRF Page	M5, M20, M28, M29, M42, M49	☒		Sponsor	ND
EG	19	EGREASND	Character	text		CRF Page	M5, M20, M28, M29, M42, M49	☒		Select	

- Variable origin defining incl bookmarks
- Defining computation methods
- Select Code List



SDTM Conversion –Variable Level Metadata 3

Domain Name	Variable Order	Variable Name	Variable Data Type	Comment (define.xml)	Comment OID
EG	23	EGMETHOD	Character	Defaults to 12 LEAD STANDARD for ECG	
EG	24	EGBLFL	Character	Measurement of EGTPPTNUM = 0	
EG	25	EGDRVFL	Character	Y when value is derived, otherwise blank	
EG	26	EGEVAL	Character		
EG	27	VISITNUM	Numeric		COM_VISITNUM_U
EG	28	VISIT	Character		COM_VISIT_U

- Defining comment for Define.xml per variable or via a general comment



Exact – Derivation program

Kinship EXACT

File Edit View Study Manager Tools Reports Help

CDISC SDTM

Study Level Metadata Variable Level Metadata Domain Level Metadata Data Derivation

Program Name Maintained

AE_DER	Yes
CM_DER	Yes
COMPARE	Yes
DM_DER	Yes
DS_DER	Yes
EG_DER	Yes
EX_DER	Yes
FA_DER	Yes
IE_DER	Yes
LB_DER	Yes
MH_DER	Yes
PC_DER	Yes
PE_DER	Yes
PR_DER	Yes
QS_DER	Yes
SC_DER	Yes
SE_DER	Yes
SU_DER	Yes
SV_DER	Yes
TA_DER	Yes
TE_DER	Yes
TI_DER	Yes
TS_DER	Yes
TV_DER	Yes
VS_DER	Yes
XF_DER	Yes

Interactive Mode Connect SAS Server

Program Log Results Files Program Info Data Definition Table Data Transpose Data Transformation Dataset Columns

Program Name EG_DER SAS Log Debug Mode Normal Generate Excel

Save Run (F3) - I

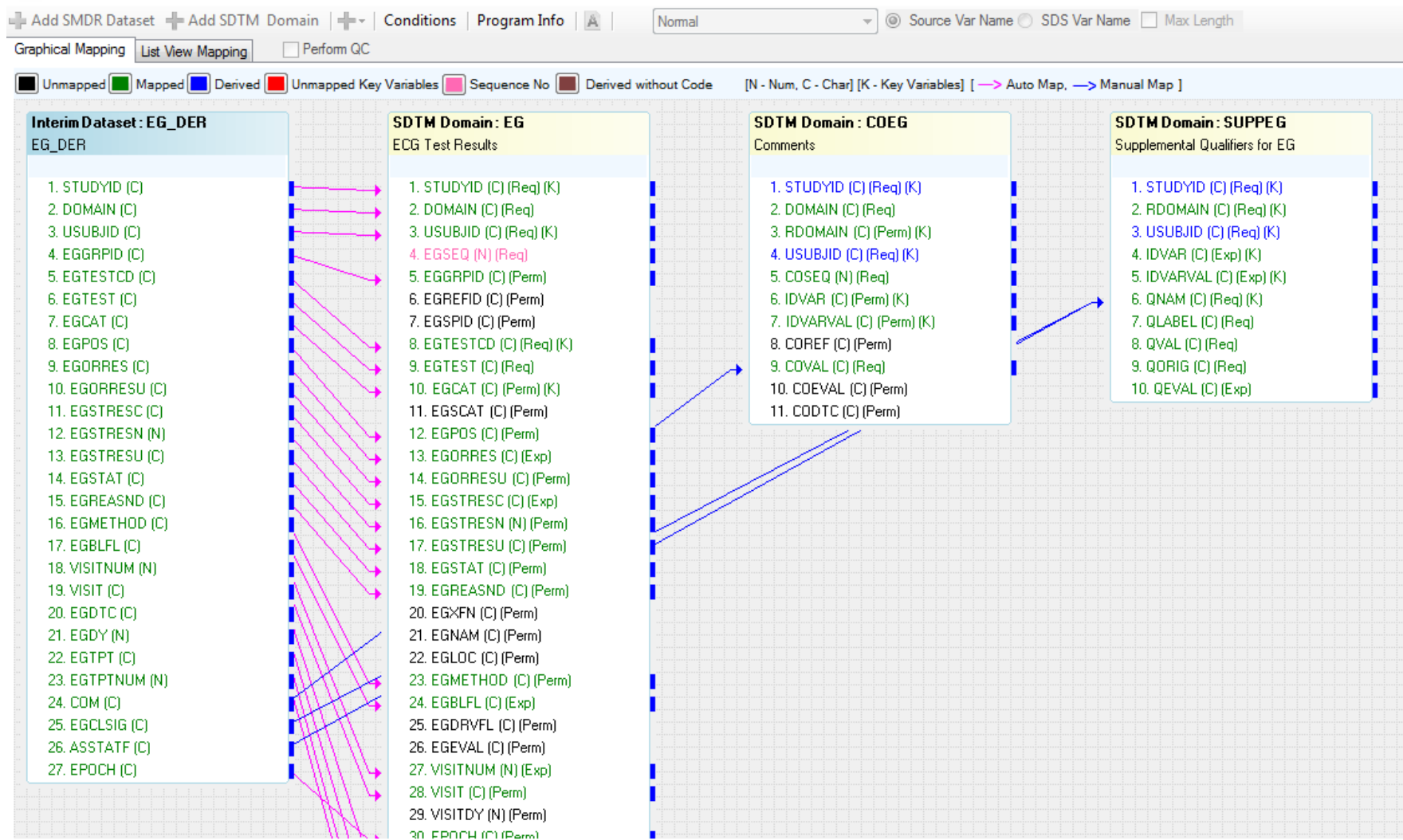
```
67
68
69 data eg02 uns;
70     set eg01;
71     length egclsig $1;
72     label egclsig = Clinically Significant;
73
74     ** All repeats get visit UNSCHEDULED, visitnum 888 and empty tptnum and tpt;
75     if visit=:'UNSCHE' then do;
76         *visitnum=visitnum+0.1;
77         *visit='UNSCCHEDULED' ||STRIP(PUT(visitnum,BEST.));
78         egtptnum=.;
79         egtpt='';
80     end;
81
82     ** Screening, early term visit and follow-up have empty tptnum and tpt;
83     if visit IN ('SCREENING','FINAL DISCHARGE') then
84         do;
85             egtptnum=.;
86             egtpt='';
87         end;
88
89     ** When no original result then also no units and no refranges;
90     if egorres='' then egorresu='';
91
92     ** When no standard result then also no units and no refranges;
93     if egstresc='' and egstresn = . then egstresu='';
94
95     ** Correct evaluation;
96     if egtested='INTP' and egorres='ABNORMAL, NOT CLINICALLY SIGNIFICANT' then do;
97         egorres = 'ABNORMAL';
98         egstresc='ABNORMAL';
99         egclsig='N';
```



- For each domain a derivation program will be created
- As a result an interim dataset will be created including variables which should go into the CO domain or SUPP– domain
- The interim domain will be mapped to the Value Level Meta Data.



Exact Mapping





Exact Mapping 2

CO domain

13. EGSTRESN (N)
14. EGSTRESU (C)
15. EGSTAT (C)
16. EGREASND (C)
17. EGMETHOD (C)
18. EGBLFL (C)
19. EGDRVFL (C)
20. VISITNUM (N)
21. VISIT (C)
22. EPOCH (C)
23. EGDTC (C)
24. EGDY (N)
25. EGTPT (C)
26. EGTPTNUM (N)
27. COM (C)
28. EGCLSIG (C)

SDTM Domain : COEG

Comments

1. STUDYID (C) (Req) (K)
2. DOMAIN (C) (Req)
3. RDOMAIN (C) (Perm) (K)
4. USUBJID (C) (Req) (K)
5. COSEQ (N) (Req)
6. IDVAR (C) (Perm) (K)
7. IDVARVAL (C) (Perm) (K)
8. COREF (C) (Perm)
9. COVAL (C) (Req)
10. COEVAL (C) (Perm)
11. CODTC (C) (Perm)

Add Map Details

Mapping Details

Source Variable Name: COM CO Variable Name: COVAL

Source Variable Label: General Comment CO Variable Label: Comment

Related Domain Abbreviation (RDOMAIN) Required? No

Identifying Variable (IDVAR) Select

Format / Date Conversion

☒ Format Select 

☐ Date Conversion

Convert Text Select

Variable Derivation

Derivation Code

Length 200

- RDOMAIN required YES/NO
- Define Identifying Variable (IDVAR), e.g. EGSPID, EGGRPID



Exact Mapping 3

Supplemental domain

16. EGREASND (C)
17. EGMETHOD (C)
18. EGBLFL (C)
19. EGDRVFL (C)
20. VISITNUM (N)
21. VISIT (C)
22. EPOCH (C)
23. EGDTC (C)
24. EGDY (N)
25. EGTPT (C)
26. EGTPTNUM (N)
27. COM (C)
28. EGCLSIG (C)

SDTM Domain: SUPPEG Supplemental Qualifiers for EG

1. STUDYID (C) (Req) (K)
2. RDOMAIN (C) (Req) (K)
3. USUBJID (C) (Req) (K)
4. IDVAR (C) (Exp) (K)
5. IDVARVAL (C) (Exp) (K)
6. QNAM (C) (Req) (K)
7. QLABEL (C) (Req)
8. QVAL (C) (Req)
9. QORIG (C) (Req)
10. QEVAL (C) (Exp)

Add Map Details

Mapping Details

Source Variable Name	EGCLSIG	Qualifier Variable Name	QNAM
Source Variable Label	Clinical Significance	Qualifier Variable Label	Qualifier Variable Name
		QLABEL	Clinical Significance

Qualifier Variable Name (QNAM)

Identifying Variable (IDVAR)

Origin (QORIG) ☐ CRF ☐ Derived ☐ CRF Page

Format / Date Conversion
☒ Format

☐ Date Conversion

Convert Text

Variable Derivation
Derivation Code

- RDOMAIN required YES/NO
- Define QNAM, QLABEL, QEVAL
- Assign Origin
- Assign Identifying Variable (IDVAR), e.g. EGSPID, EGGRPID



Batch SDTM run

CDISC Conversion Group Name Conversion Type ☐ Export to Excel

Conversion Output

☐ Dataset ☒ Dataset and XPT ☐ Export ODM file
☐ define.xml ☐ define.xml, Dataset and XPT ☐ Include printable PDF generation (define_printable.pdf)

☐ Delete missing observations for required variables ☒ SUPPQUAL is required as separate dataset for each domain
☐ Delete missing observations for QVAL ☐ Include RELREC

Available Domains	Description	Status
IE	Inclusion/Exclusion...	Fully
SUPPLB	Supplemental Qual...	Fully

Selected Domains	Description	Status
SE	Subject Elements	Fully
SV	Subject Visits	Fully
TA	Trial Arms	Fully
TE	Trial Elements	Fully
TI	Trial Inclusion/Exclu...	Fully
TV	Trial Visits	Fully
DM	Demographics	Partially
AE	Adverse Events	Partially
SUPPAE	Supplemental Qualifi...	Partially
CM	Concomitant Medica...	Partially
DS	Disposition	Fully
EG	ECG Test Results	Partially
COEG	Comments	Partially
SUPPEG	Supplemental Qualifi...	Partially
EX	Exposure	Fully
SUPPEX	Supplemental Qualifi...	Fully
COEX	Comments	Fully
LB	Laboratory Test Res...	Fully
COLB	Comments	Fully
MH	Medical History	Fully
SUPPMH	Supplemental Qualifi...	Fully
ML	Meal	Fully
SUPPML	Supplemental Qualifi...	Fully
PE	Physical Examination	Fully
COPE	Comments	Fully
PC	Pharmacokinetic Co...	Fully
COPC	Comments	Fully
QS	Questionnaires	Partially
VS	Vital Signs	Partially
COVS	Comments	Partially
SUPPVS	Supplemental Qualifi...	Partially
TS	Trial Summary	Fully

- Select programs to run in batch
- Order of programs
- SAS datasets, xpt files and/or excel files



Define.xml Value Level Metadata

Domain Name	Variable Order	Variable Name	Variable Data Type	ODM Data Type	Significant Digits	Variable Origin	CRF Bookmarks	Named Destination	Computation OID	Code List	Code List Name
EG	1	STUDYID	Character	text		Protocol		☐		Select	
EG	2	DOMAIN	Character	text		Assigned		☐		Select	
EG	3	USUBJID	Character	text		Derived		☐	USUBJID	Select	
EG	4	EGSEQ	Numeric	integer		Derived		☐	SEQ	Select	
EG	5	EGGRPID	Character	text		Assigned		☐		Select	
EG	6	EGREFID	Character	text		eDT		☐		Select	
EG	7	EGSPID	Character	text		CRF Page	M5, M20, M28, M29, M32, M40	☒		Select	
EG	8	EGTESTCD	Character	text		Assigned		☐		Sponsor	EGTESTCD
EG	9	EGTEST	Character	text		Assigned		☐		Sponsor	EGTEST
EG	10	EGCAT	Character	text		Assigned		☐		Select	
EG	11	EGSCAT	Character	text				☐		Select	
EG	12	EGPOS	Character	text		Protocol		☐		Sponsor	EGPOS
EG	13	EGORRES	Character	text		CRF Page	M5, M20, M28, M29, M32, M40	☒		Select	
EG	14	EGORRESU	Character	text		Assigned		☐		Sponsor	EGRESU
EG	15	EGSTRESC	Character	text		Derived		☐	STRESC	Select	
EG	16	EGSTRESN	Numeric	integer		Derived		☐	STRESN	Select	
EG	17	EGSTRESU	Character	text		Derived		☐	STRESU	Sponsor	EGRESU
EG	18	EGSTAT	Character	text		CRF Page	M5, M20, M28, M29, M32, M40	☒		Sponsor	ND
Domain Name	Variable Order	Variable Name	Variable Data Type	Comment (define.xml)				Comment OID			
EG	23	EGMETHOD	Character	Defaults to 12 LEAD STANDARD for ECG							
EG	24	EGBLFL	Character	Measurement of EGTPNUM = 0							
EG	25	EGDRVFL	Character	Y when value is derived, otherwise blank							
EG	26	EGEVAL	Character								
EG	27	VISITNUM	Numeric					COM_VISITNUM_U			
EG	28	VISIT	Character					COM_VISIT_U			



Overview Defined Computation Methods

Study Level Metadata		Computation Methods	Comments	Code Lists	Common Variables	Desired Case
						
Computation OID	Description					
 TPT	Value from CRF or created from xxTPTNUM preceded by (H), e.g. if xxTPTNUM is 12.75 then xxTPT is (H 12.75). Empty for SCREEN...					
 TSSEQ	Sequential number identifying records within each TSPARM in the domain					
 USUBJID	Concatenation of STUDYID - DM.SITEID - DM.SUBJID					
 VISIT(NUM)	Derived from visit-based subject-level domains					

Edit window:

Sponsor Defined

☐ Computation ☒ User Defined

Type

Computation OID

Description



- Value Level Metadata can be extracted from Exact
- Extracted excel sheet is input for derivation program
- Derivation program created to define the hyperlinks

*%let hyperlink1 = EG ~ EG ~ EGORRES ~ Y ~ EGCAT ~
EGTESTCD/EGTEST;*

This means EGORRES will be hyperlinked with the combination EGCAT and EGTESTCD

- The macro also assigns the same variable origins and page numbers from the domain variable to the nested levels and it determines if a value has type text, integer or float with the length and (only for float) the number of significant digits.



- If needed in the program per nested level origin, page number, computation method, comment and codelist can be assigned.

```
if domain='EG' and vari='EGCAT' and name= 'INTP' then do;  
  codelist_type='Sponsor';  
  codelist_name='NORMABNM';  
end;
```

- In the end an excel sheet will be created and will be imported in Exact



- Codelist can be defined manually or can be loaded via a SAS program for data driven codelists

Order	Code	Code List Value	Code List Text	CDISC Submission Value	CDISC Preferred Term	CDISC Synonym(s)
1	C25401	ABNORMAL	ABNORMAL	ABNORMAL		
2	C14165	NORMAL	NORMAL	NORMAL		

Normal Abnormal Response [CL.NORMABNM, C101834]

Permitted Value (Code)

ABNORMAL [C25401]

NORMAL [C14165]



- After all these steps the define can be created.

SDTM-IG 3.2

Annotated Case Report Form
 Reviewers Guide
 Tabulation Datasets
 Value Level Metadata
 Controlled Terminology
 Computational Algorithms
 Comments

ECG Test Results (EG) [Location: [eg.xpt](#)]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	12		Protocol	
DOMAIN	Domain Abbreviation		text	2		Assigned	Two-character abbreviation for the domain
USUBJID	Unique Subject Identifier	2	text	19		Derived	Concatenation of STUDYID - DM.SITEID - DM.SUBJID
EGSEQ	Sequence Number		integer	8		Derived	Sequential number identifying records within each USUBJID and generated using the key sequence of the domain
EGGRPID	Group ID		text	1		Assigned	Used to group all records of a single ECG measurement, numbers sequentially over trial
EGTESTCD	ECG Test or Examination Short Name	5	text	6	ECG Test Code	Assigned	Abbreviation of EGTEST
EGTEST	ECG Test or Examination Name		text	24	ECG Test Name	Protocol	ECG parameter
EGCAT	Category for ECG	4	text	11		Assigned	Either MEASUREMENT (EGTESTCD=EGHRMN) or INTERVAL (EGTESTCD=PRAG, QTAG, QTCFAG, QRSAG) or FINDING (EGTEST=EGABN) or empty (EGTEST=INTP)
EGPOS	ECG Position of Subject		text	6	["SUPINE"] <Position>	Protocol	
EGORRES	Result or Finding in Original Units		text	46		CRF Pages 5 UNS1	

Value Level Metadata - EG [EGORRES]

Variable	Where	Type	Length / Display Format	Controlled Terms or Format	Origin	Derivation/Comment
EGORRES	EGTESTCD = "EGABN1" (ECG Abnormality 1)	text	46	ECG Result	CRF Pages 5 UNS1	
EGORRES	EGTESTCD = "EGABN2" (ECG Abnormality 2)	text	46	ECG Result	CRF Pages 5 UNS1	
EGORRES	EGTESTCD = "EGABN3" (ECG Abnormality 3)	text	26	ECG Result	CRF Pages 5 UNS1	
EGORRES	EGTESTCD = "EGHRMN" (ECG Mean Heart Rate)	integer	2		CRF Pages 5 UNS1	
EGORRES	EGTESTCD = "INTP" (Interpretation)	text	8	["ABNORMAL", "NORMAL"] <Normal Abnormal Response>	CRF Pages 5 UNS1	
EGORRES	EGTESTCD = "PRAG" (PR Interval, Aggregate)	integer	3		CRF Pages 5 UNS1	
EGORRES	EGTESTCD = "QRSAG" (QRS Duration, Aggregate)	integer	3		CRF Pages 5 UNS1	
EGORRES	EGTESTCD = "QTAG" (QT Interval, Aggregate)	integer	3		CRF Pages 5 UNS1	
EGORRES	EGTESTCD = "QTCFAG" (QTcF Interval, Aggregate)	integer	3		CRF Pages 5 UNS1	



- Knowledge of SDTM datasets is very useful by set up eCRF / Database
- Datasets extracted from Clinical Data Management System are for 80 % SDTM compliant
- Standardized Database setup in Data Management System will save a lot of time during SDTM conversion
- SDTM programmers are familiar with the structure of the raw datasets
- Standardization will improve the quality and lets you focus on the items that are not standard.



Questions



WE ARE DEDICATED
TO THE FUTURE OF
CLINICAL DEVELOPMENT
AND TO EVERY
LIFE IT IMPROVES.



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