Mapping REDCap Data into SDTM: A Case Study of Healthy Volunteer Research Data

Presented by Susan Mutter, Director, Statistical Programming,
PROMETRIKA, LLC

Meet the Speaker

Susan Mutter

Title: Director, Statistical Programming

Organization: PROMETRIKA, LLC

Susan has more than 25 years of diverse experience in clinical database design and management, and statistical programming. She has shared her extensive knowledge of CDISC and SDTM at conferences and training programs in the US, Russia, Europe and Asia. Earlier in her career, Susan participated as a research associate and data analyst for several projects sponsored by the US Military and NASA. She has co-authored several journal articles on nutrition in military field situations. Susan received her Bachelor of Arts in Psychobiology from Mount Holyoke College and is a member of the CDISC Advisory Council Task Force.

Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author and do not necessarily reflect the official policy or position of CDISC.*

- *The author has no real or apparent conflicts of interest to report.*

Agenda

1. Introduction
2. What is REDCap and how is it related to CDISC?
3. Details on the Case Study
4. Mapping the Data
5. Conclusions

Introduction

Introduction

- Have you heard of REDCap?
- Have you used the REDCap interface?
- Have you worked with data from REDCap?

What is REDCap and how is it related to CDISC?

What is REDCap and how is it related to CDISC?

Research Electronic Data Capture (REDCap)

- Developed at Vanderbilt University (Nashville, Tennessee, USA)
- A free, user-friendly web-based interface which requires no background knowledge or technical experience to use
- Made available for use exclusively to non-profit institutions

As of April 2025, the REDCap Consortium consists of:

- 7760 institutions
- 160 countries
- 2.3 million projects
- 3.7 million users
- 45,300 citations
- Potential for a huge pool of data that pharma could tap into (e.g. Natural History)

What is REDCap and how is it related to CDISC? - 2

Googling for “REDCap to CDISC SDTM”, etc. doesn’t generate a lot of hits

- Challenges of Academia Using CDISC Standards*
  - Regardless of the human study research topic, many data points are easily standardized
  - Data points that are difficult to standardize are also the items where SDTM mapping is difficult and therefore advanced CDISC education is needed
  - Money and time budgets are needed for training
  - Many institutions have short term contracts (<5 years), so most personnel will be leaving/graduating, right when they become experts

*A use-case analysis of Clinical Data Interchange Standards Consortium/Study Data Tabulation Model in academia in an investigator-initiated clinical trial Nagoya J. Med. Sci. 84. 120–132, 2022

What is REDCap and how is it related to CDISC? - 3

- CDISC Real World Data Connect project recommendations*
  - Make CDISC standards easier to use in settings outside clinical research for regulatory submission
  - Take steps to support academic and public health researchers in the use of data coming from observational studies and registries
    - CDISC Translated metadata from 34 CDASH Foundational eCRFs and 20 CDASH Crohn's Disease eCRFs into REDCap eCRF metadata**
      - Searching for "CDASH", "CDISC", etc. in REDCap yields nothing
      - Possible to find the forms by searching for "REDCap" in the CDISC website and following several links to REDCap

*Use of Clinical Data Interchange Standards Consortium (CDISC) Standards for Real-world Data: Expert Perspectives From a Qualitative Delphi Survey

JMIR Med Inform 2022;10(1):e30363

**Making Clinical Data Acquisition Standards Harmonization (CDASH) Electronic Case Report Forms Available on the REDCap Shared Data Instrument Library

J Soc Clin Data Manag. 2022 ; 2(3): . doi:10.47912/jscdm.172

Details of the Case Study

Details of the Case Study

"Does an agent positively affect human physical performance during exercise under induced hypoxia?"

- Phase 1 healthy volunteer study
- Out of 96 total screened, 19 treated subjects were followed over 6 weeks
- Performed at a major clinic in the USA
- Potential applications for pilots, mountaineers, military, etc.

Site Investigator downloaded "free software" and proceeded to build a study

- The software was REDCap
- The investigator tried
- Data was ugly

PROMETRIKA enlisted to map the data into SDTM after the study finished

Mapping the Data

Mapping the Data: Methods/Tools for Mapping

- R package: REDcap2SDTM
  - Requires embedding domain name, variable name, and test code in the REDCap field annotation in the form
    - Not feasible for this study

- Import forms into other systems that can “export” into SDTM
  - Some data appeared to have been pulled directly from EHR, so no form
  - No budget to re-enter the data
  - Still would require post processing

- Manual mapping
  - Roll up sleeves and dive in

Mapping the Data: Exported Data File Structure

- Excel Spreadsheets
  - 2 tabs
    - Raw (raw values)
    - Labels (decoded values) – preferred
    - Variable names are different in each tab
    - Check both tabs for values
- Form level spreadsheets
  - Similar to datasets exported from other EDC systems
  - Lesson Learned: ignore these
    - Missing some data points from related form
    - Not all forms were represented

	A	B	C	D	E	F	G	H	I	J
1	record_id	redcap_event_name	redcap_repeat_instrument	redcap_repeat_instance	return_date	return_qty	return_recorderinitials	return_photo1	return_photo2	drug_return_complete
2	13	visit_4_arm_2			1/11/2023 8:00	1	signature_2023-03-23_1313.png	Front.jpg	Back.jpg	2
3	20	visit_4_arm_2			2/20/2023 20:00	1	signature_2023-02-21_0904.png	IMG_0032.jpg	IMG_0031.jpg	2
4	28	visit_4_arm_2			2/22/2023 8:00	1	signature_2023-03-23_1319.png	Front.jpg	back.jpg	2
5	39	visit_4_arm_2			6/7/2023 8:00	1	signature_2023-06-13_1311.png	Front.jpg	Back.jpg	2

Raw | Labels

	A	B	C	D	E	F	G	H	I	J
1	Record ID	Event Name	Repeat Instrument	Repeat Instance	Date Patient Returned Packaging:	Quantity Returned	Recorder's Initials:	Please attach photo of the front of the packaging	Please attach photo of the back of the packaging	Complete ?
2	13	Visit #4 (Arm 2: Phase 2)			1/11/2023 8:00	0	signature_2023-03-23_1313.png	Front.jpg	Back.jpg	Complete
3	20	Visit #4 (Arm 2: Phase 2)			2/20/2023 20:00	0	signature_2023-02-21_0904.png	IMG_0032.jpg	IMG_0031.jpg	Complete
4	28	Visit #4 (Arm 2: Phase 2)			2/22/2023 8:00	0	signature_2023-03-23_1319.png	Front.jpg	back.jpg	Complete
5	39	Visit #4 (Arm 2: Phase 2)			6/7/2023 8:00	0	signature_2023-06-13_1311.png	Front.jpg	Back.jpg	Complete

Raw | Labels

Mapping the Data: Exported Data File Structure - 2

- Excel Spreadsheets (cont.)
  - "ALL" spreadsheet contains all the data (640 columns x 519 rows for this study)
    - Lesson Learned: Use this file
      - Contains form data and pulls from EHR
      - Contains survey completion dates

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R
1	record_id	redcap_event_name	redcap_repeat_instrument	redcap_repeat_instance	redcap_survey_identifier	screening_form_timestamp	dob	age	gender	race___1	race___2	race___3	race___4	race___5	race___6	ethnicity	height_self reported	weight_self reported
2	5	screening_and_opti_arm_1				5/24/2022 15:23	6/7/1978		1	0	0	0	0	0	1	2	6'5"	215
3	5	visit_1_arm_1																
4	5	visit_3_arm_1																
5	5	screening_and_opti_arm_1	protocol_deviation_form	1														
6	5	visit_1_arm_1	vitals	1														
7	5	visit_1_arm_1	urine_pregnancy_test	1														

Raw | Labels

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R
1	Record ID	Event Name	Repeat Instrument	Repeat Instance	Survey Identifier	Survey Timestamp	Date of Birth:	Age	Gender:	Race (choice=American Indian)	Race (choice=Alaska Native)	Race (choice=Asian)	Race (choice=Black or African American)	Race (choice=Native Hawaiian or Other Pacific Islander)	Race (choice=White)	Ethnicity	Height: (self-reported)	Weight: (self-reported)
2	5	Screening and Optional Forms (Arm 1: Phase 1)				5/24/2022 15:23	6/7/1978		Male	Unchecked	Unchecked	Unchecked	Unchecked	Unchecked	Checked	Non Hispanic/Latino	6'5"	215
3	5	Visit #1 (Arm 1: Phase 1)																
4	5	Visit #3 (Arm 1: Phase 1)																
5	5	Screening and Optional Forms (Arm 1: Phase 1)	Protocol Deviation Form	1														
6	5	Visit #1 (Arm 1: Phase 1)	Vitals	1														
7	5	Visit #1 (Arm 1: Phase 1)	Urine Pregnancy Test	1														

Raw | Labels

Mapping the Data: SAS Data File Structure

- Challenging to reconcile Excel columns and SAS variables
  - Long variable names don't convert well
  - Hard to correlate variables with form questions
    - Solution: create Excel version of SAS Proc Contents and annotate

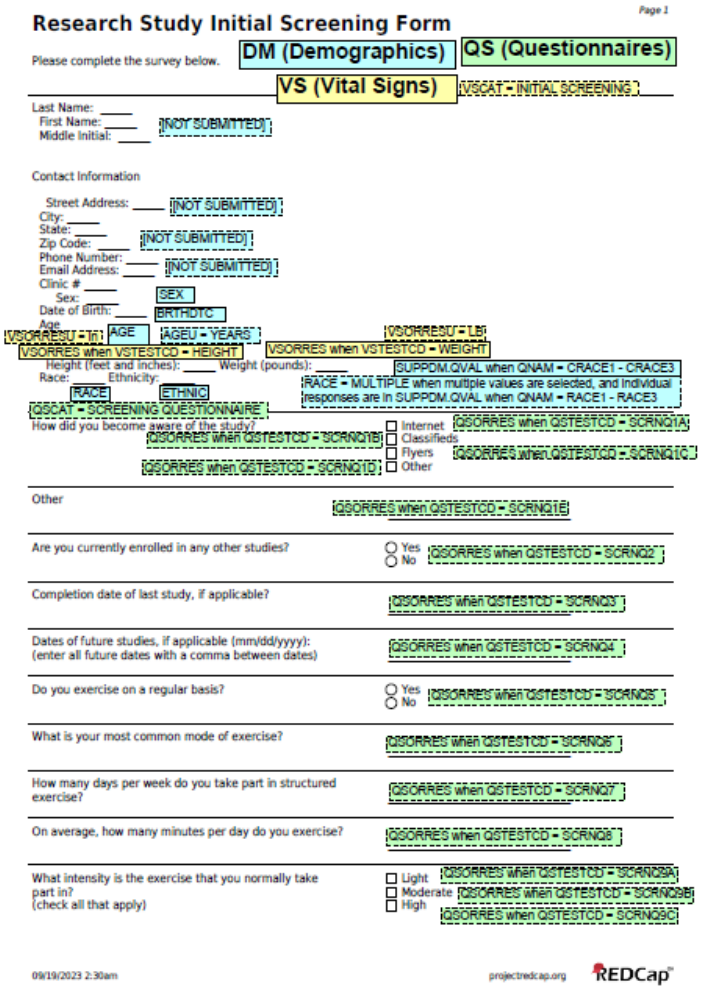
25	Variables in Creation Order								
26	#	Variable	Type	Len	Format	Informat	Label	Comments	
241								DOMAIN	TESTCD	TEST
242	215	ORDER_OF_EXERCISE_TRIALS_	Char	14	$14.00	$14.00	Order of Exercise Trials:	SUPPLB		
243	216	VAR216	Num	8	BEST.		Power Output @ RER = 1.0 (W):	SUPPLB		
244	217	VAR217	Num	8	BEST.		Baseline 2,3-DPG:	LB	DPG	2,3-Diphosphoglycerate
245	218	BASELINE_ATP_	Num	8	BEST.		Baseline ATP:	LB	ATP	Adenosine Triphosphate
246	219	VAR219	Num	8	BEST.		Normoxic Cycling #1 (non-pedaling):	LB	DPG	2,3-Diphosphoglycerate
247	220	VAR220	Num	8	BEST.		Normoxic Cycling #2 (Stage 1):	LB	DPG	2,3-Diphosphoglycerate
248	221	VAR221	Num	8	BEST.		Normoxic Cycling #3 (RER 1.0):	LB	DPG	2,3-Diphosphoglycerate
249	222	VAR222	Num	8	BEST.		Normoxic Cycling #4 (Max):	LB	DPG	2,3-Diphosphoglycerate
250	223	VAR223	Num	8	BEST.		Hypoxic Cycling #1 (non-pedaling):	LB	DPG	2,3-Diphosphoglycerate
251	224	VAR224	Num	8	BEST.		Hypoxic Cycling #2 (Stage 1):	LB	DPG	2,3-Diphosphoglycerate
252	225	VAR225	Num	8	BEST.		Hypoxic Cycling #3 (RER 1.0):	LB	DPG	2,3-Diphosphoglycerate
253	226	VAR226	Num	8	BEST.		Hypoxic Cycling #4 (Max):	LB	DPG	2,3-Diphosphoglycerate
254	227	VAR227	Num	8	BEST.		Normoxic Cycling #1 (non-pedaling):_1	LB	ATP	Adenosine Triphosphate
255	228	VAR228	Num	8	BEST.		Normoxic Cycling #2 (Stage 1):_1	LB	ATP	Adenosine Triphosphate
256	229	VAR229	Num	8	BEST.		Normoxic Cycling #3 (RER 1.0):_1	LB	ATP	Adenosine Triphosphate
257	230	VAR230	Num	8	BEST.		Normoxic Cycling #4 (Max):_1	LB	ATP	Adenosine Triphosphate
258	231	VAR231	Num	8	BEST.		Hypoxic Cycling #1 (non-pedaling):_1	LB	ATP	Adenosine Triphosphate
259	232	VAR232	Num	8	BEST.		Hypoxic Cycling #2 (Stage 1):_1	LB	ATP	Adenosine Triphosphate
260	233	VAR233	Num	8	BEST.		Hypoxic Cycling #3 (RER 1.0):_1	LB	ATP	Adenosine Triphosphate
261	234	VAR234	Num	8	BEST.		Hypoxic Cycling #4 (Max):_1	LB	ATP	Adenosine Triphosphate
262	235	COMPLETE__13	Char	10	$10.00	$10.00	Complete?_13			

Mapping the Data: SAS Data File Structure - 2

25	Variables in Creation Order								
26	#	Variable	Type	Len	Format	Informat	Label	Comments	
288								DOMAI	TESTCD	TEST
289	261	_21__O2__REST_FOREARM_BLOOD_FLOW	Num	8	BEST.		21% O2- Rest Forearm Blood Flow	CV	BLDFLRT	Blood Flow Rate
290	262	_15__O2__REST_FOREARM_BLOOD_FLOW	Num	8	BEST.		15% O2- Rest Forearm Blood Flow	CV	BLDFLRT	Blood Flow Rate
291	263	_10__O2__REST_FOREARM_BLOOD_FLOW	Num	8	BEST.		10% O2- Rest Forearm Blood Flow	CV	BLDFLRT	Blood Flow Rate
292	264	VAR264	Num	8	BEST.		21% O2- 10%MVC Forearm Blood Flow	CV	BLDFLRT	Blood Flow Rate
293	265	VAR265	Num	8	BEST.		15% O2- 10%MVC Forearm Blood Flow	CV	BLDFLRT	Blood Flow Rate
294	266	VAR266	Num	8	BEST.		10% O2- 10%MVC Forearm Blood Flow	CV	BLDFLRT	Blood Flow Rate
295	267	VAR267	Num	8	BEST.		21% O2- 20%MVC Forearm Blood Flow	CV	BLDFLRT	Blood Flow Rate
296	268	VAR268	Num	8	BEST.		15% O2- 20%MVC Forearm Blood Flow	CV	BLDFLRT	Blood Flow Rate
297	269	VAR269	Num	8	BEST.		10% O2- 20%MVC Forearm Blood Flow	CV	BLDFLRT	Blood Flow Rate
298	270	_21__O2__REST_BRACHIAL_ARTERY_DI	Num	8	BEST.		21% O2- Rest Brachial Artery Diameter	CV	DIAMETER	Diameter
299	271	_15__O2__REST_BRACHIAL_ARTERY_DI	Num	8	BEST.		15% O2- Rest Brachial Artery Diameter	CV	DIAMETER	Diameter
300	272	_10__O2__REST_BRACHIAL_ARTERY_DI	Num	8	BEST.		10% O2- Rest Brachial Artery Diameter	CV	DIAMETER	Diameter
301	273	VAR273	Num	8	BEST.		21% O2- 10%MVC Brachial Artery Diameter	CV	DIAMETER	Diameter
302	274	VAR274	Num	8	BEST.		15% O2- 10%MVC Brachial Artery Diameter	CV	DIAMETER	Diameter
303	275	VAR275	Num	8	BEST.		10% O2- 10%MVC Brachial Artery Diameter	CV	DIAMETER	Diameter
304	276	VAR276	Num	8	BEST.		21% O2- 20%MVC Brachial Artery Diameter	CV	DIAMETER	Diameter
305	277	VAR277	Num	8	BEST.		15% O2- 20%MVC Brachial Artery Diameter	CV	DIAMETER	Diameter
306	278	VAR278	Num	8	BEST.		10% O2- 20%MVC Brachial Artery Diameter	CV	DIAMETER	Diameter
307	279	_21__O2__REST_HEART_RATE	Num	8	BEST.		21% O2- Rest Heart Rate	VS	HR	Heart Rate
308	280	_15__O2__REST_HEART_RATE	Num	8	BEST.		15% O2- Rest Heart Rate	VS	HR	Heart Rate
309	281	_10__O2__REST_HEART_RATE	Num	8	BEST.		10% O2- Rest Heart Rate	VS	HR	Heart Rate
310	282	VAR282	Num	8	BEST.		21% O2- 10%MVC Heart Rate	VS	HR	Heart Rate
311	283	VAR283	Num	8	BEST.		15% O2- 10%MVC Heart Rate	VS	HR	Heart Rate

Mapping the Data: The aCRF

- Extremely dense 33 page CRF
- No CDASH type forms used
- Annotation challenges
  - Not much room for annotations
  - One page mapped to 7 domains
- Categorizing the data
  - Unexpected/Unusual domains
    - AG – CO administered to induce Hypoxia
    - CV – Blood Flow Rate, Cardiac Output, Diameter, Peak Envelope and Power Output
    - FA – Headache: frequency and types
    - FT – Left and right elbow range of motion tests
    - MB – Hepatitis, HIV and COVID
    - PR – Catheter and IV placement and blood donation
    - RE – Oxygen consumption
    - SC – Dominant hand


Page 1

Research Study Initial Screening Form

Please complete the survey below.

DM (Demographics)

QS (Questionnaires)

VS (Vital Signs)

[VSCAT = 'INITIAL SCREENING']

Last Name: ____
First Name: ____
Middle Initial: ____

[NOT SUBMITTED]

Contact Information

Street Address: ____ [NOT SUBMITTED]
City: ____
State: ____
Zip Code: ____ [NOT SUBMITTED]
Phone Number: ____
Email Address: ____ [NOT SUBMITTED]
Clinic # ____
Sex: ____ SEX
Date of Birth: ____ BRTHDTC
Age: ____ AGE [AGEU = 'YEARS']

[VSORRESU = 'in'] [VSORRESU = 'LB']
[VSORRES when VSTESTCD = 'HEIGHT'] [VSORRES when VSTESTCD = 'WEIGHT']
Height (feet and inches): ____ Weight (pounds): ____

Race: ____ Ethnicity: ____ RACE ETHNIC

[SUPPDM.QVAL when QNAM = 'CRACE1 - CRACE3']
[RACE = 'MULTIPLE when multiple values are selected, and individual responses are in SUPPDM.QVAL when QNAM = 'RACE1 - RACE3']

[QSCAT = 'SCREENING QUESTIONNAIRE']

How did you become aware of the study?
☐ Internet ☐ Classifieds ☐ Flyers ☐ Other
[QSORRES when QSTESTCD = 'SCRNQ1A'] [QSORRES when QSTESTCD = 'SCRNQ1B'] [QSORRES when QSTESTCD = 'SCRNQ1C'] [QSORRES when QSTESTCD = 'SCRNQ1D']

Other [QSORRES when QSTESTCD = 'SCRNQ1E']

Are you currently enrolled in any other studies? ○ Yes ○ No [QSORRES when QSTESTCD = 'SCRNQ2']

Completion date of last study, if applicable? [QSORRES when QSTESTCD = 'SCRNQ3']

Dates of future studies, if applicable (mm/dd/yyyy): (enter all future dates with a comma between dates) [QSORRES when QSTESTCD = 'SCRNQ4']

Do you exercise on a regular basis? ○ Yes ○ No [QSORRES when QSTESTCD = 'SCRNQ5']

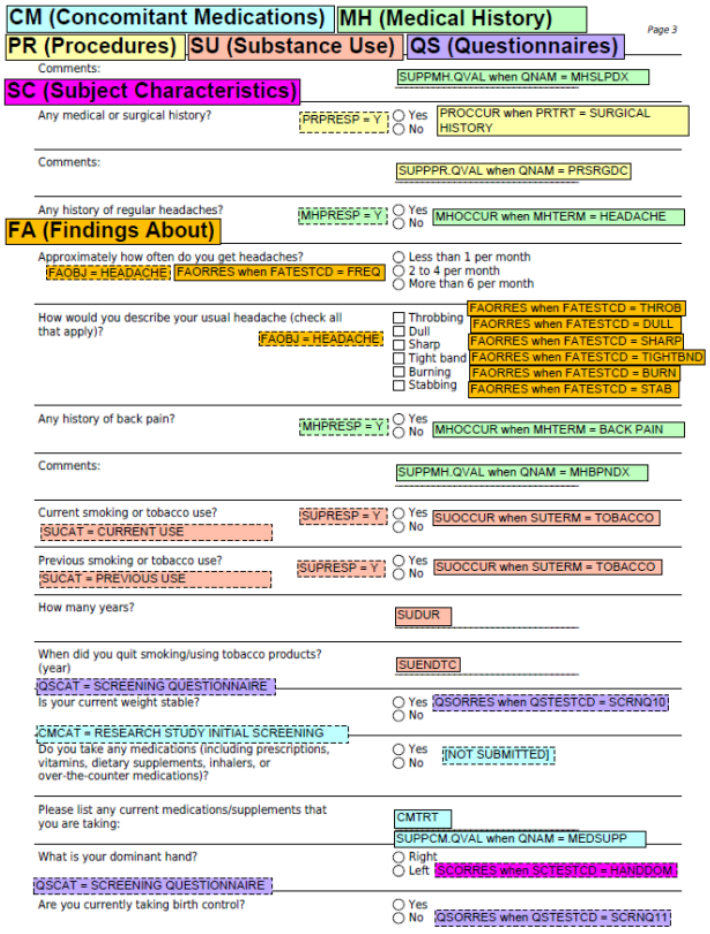
What is your most common mode of exercise? [QSORRES when QSTESTCD = 'SCRNQ6']

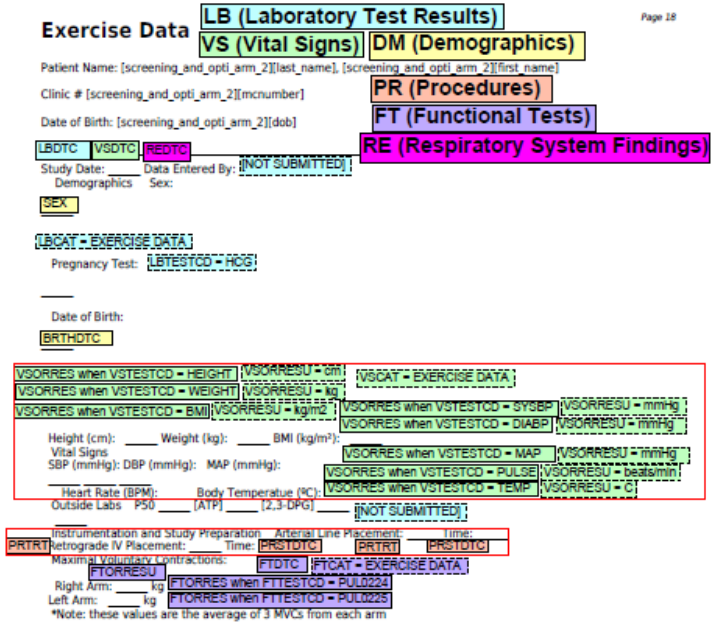
How many days per week do you take part in structured exercise? [QSORRES when QSTESTCD = 'SCRNQ7']

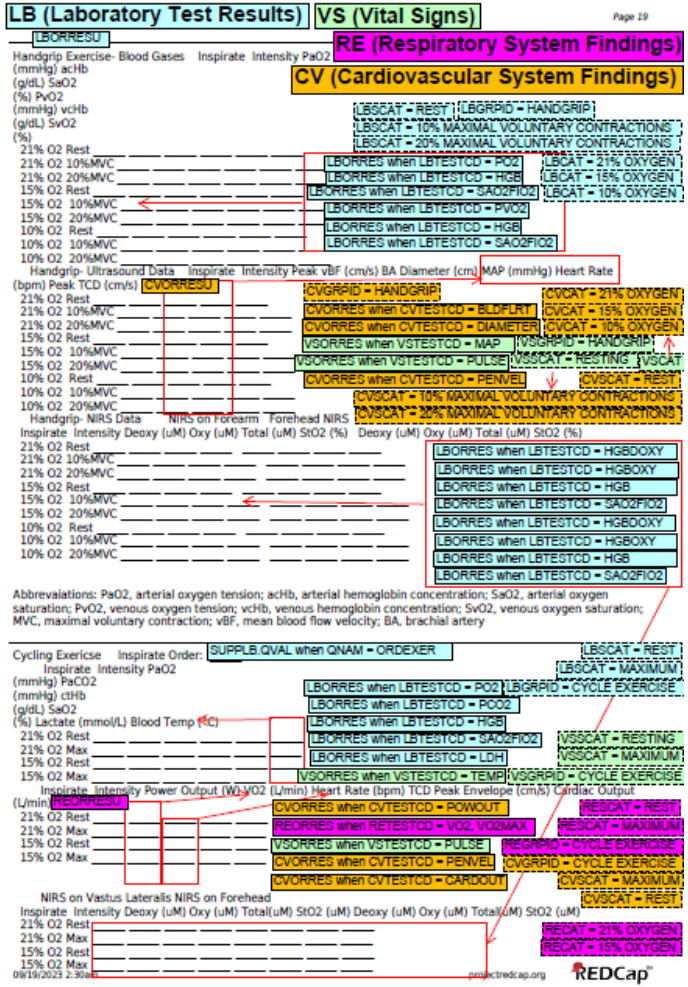
On average, how many minutes per day do you exercise? [QSORRES when QSTESTCD = 'SCRNQ8']

What intensity is the exercise that you normally take part in? (check all that apply) ☐ Light ☐ Moderate ☐ High
[QSORRES when QSTESTCD = 'SCRNQ9A'] [QSORRES when QSTESTCD = 'SCRNQ9B'] [QSORRES when QSTESTCD = 'SCRNQ9C']

09/19/2023 2:30am projectredcap.org REDCap


CM (Concomitant Medications)
MH (Medical History)
PR (Procedures)
SU (Substance Use)
QS (Questionnaires)
Page 3
Comments:
SUPPMH.QVAL when QNAM = MHSLPDX
SC (Subject Characteristics)
Any medical or surgical history?
PRPRESP = Y
Yes
No
PROCCUR when PRTRT = SURGICAL HISTORY
Comments:
SUPPPR.QVAL when QNAM = PRSRGDC
Any history of regular headaches?
MHPRESP = Y
Yes
No
MHOCCUR when MHTERM = HEADACHE
FA (Findings About)
Approximately how often do you get headaches?
FAOBJ = HEADACHE
FAORRES when FATESTCD = FREQ
Less than 1 per month
2 to 4 per month
More than 6 per month
How would you describe your usual headache (check all that apply)?
FAOBJ = HEADACHE
Throbbing
Dull
Sharp
Tight band
Burning
Stabbing
FAORRES when FATESTCD = THROB
FAORRES when FATESTCD = DULL
FAORRES when FATESTCD = SHARP
FAORRES when FATESTCD = TIGHTBND
FAORRES when FATESTCD = BURN
FAORRES when FATESTCD = STAB
Any history of back pain?
MHPRESP = Y
Yes
No
MHOCCUR when MHTERM = BACK PAIN
Comments:
SUPPMH.QVAL when QNAM = MHBPNDX
Current smoking or tobacco use?
SUCAT = CURRENT USE
SUPRESP = Y
Yes
No
SUOCCUR when SUTERM = TOBACCO
Previous smoking or tobacco use?
SUCAT = PREVIOUS USE
SUPRESP = Y
Yes
No
SUOCCUR when SUTERM = TOBACCO
How many years?
SUDUR
When did you quit smoking/using tobacco products? (year)
SUENDTC
QSCAT = SCREENING QUESTIONNAIRE
Is your current weight stable?
Yes
No
QSORRES when QSTESTCD = SCRNQ10
CMCAT = RESEARCH STUDY INITIAL SCREENING
Do you take any medications (including prescriptions, vitamins, dietary supplements, inhalers, or over-the-counter medications)?
Yes
No
[NOT SUBMITTED]
Please list any current medications/supplements that you are taking:
CMTRT
SUPPCM.QVAL when QNAM = MEDSUPP
What is your dominant hand?
Right
Left
SCORRES when SCTESTCD = HANDDOM
QSCAT = SCREENING QUESTIONNAIRE
Are you currently taking birth control?
Yes
No
QSORRES when QSTESTCD = SCRNQ11
09/19/2023 2:30am
projectredcap.org
REDCap


Exercise Data
LB (Laboratory Test Results)
VS (Vital Signs)
DM (Demographics)
PR (Procedures)
FT (Functional Tests)
RE (Respiratory System Findings)
Page 18
Patient Name: [screening_and_opti_arm_2][last_name], [screening_and_opti_arm_2][first_name]
Clinic # [screening_and_opti_arm_2][mcnumber]
Date of Birth: [screening_and_opti_arm_2][dob]
LBDTC
VSDTC
REDTC
Study Date:
Data Entered By:
[NOT SUBMITTED]
Demographics
Sex:
SEX
LBCAT = EXERCISE DATA
Pregnancy Test:
LBTESTCD = HCG
Date of Birth:
BRTHDTC
VSORRES when VSTESTCD = HEIGHT
VSORRESU = cm
VSCAT = EXERCISE DATA
VSORRES when VSTESTCD = WEIGHT
VSORRESU = kg
VSORRES when VSTESTCD = BMI
VSORRESU = kg/m2
VSORRES when VSTESTCD = SYSBP
VSORRESU = mmHg
VSORRES when VSTESTCD = DIABP
VSORRESU = mmHg
Height (cm):
Weight (kg):
BMI (kg/m²):
Vital Signs
SBP (mmHg):
DBP (mmHg):
MAP (mmHg):
VSORRES when VSTESTCD = MAP
VSORRESU = mmHg
VSORRES when VSTESTCD = PULSE
VSORRESU = beats/min
Heart Rate (BPM):
Body Temperatue (ºC):
VSORRES when VSTESTCD = TEMP
VSORRESU = C
Outside Labs
P50
[ATP]
[2,3-DPG]
[NOT SUBMITTED]
Instrumentation and Study Preparation
Arterial Line Placement:
Time:
PRTRT
Retrograde IV Placement:
Time:
PRSTDTC
PRTRT
PRSTDTC
Maximal Voluntary Contractions:
FTDTC
FTCAT = EXERCISE DATA
FTORRESU
Right Arm:
kg
FTORRES when FTTESTCD = PUL0224
Left Arm:
kg
FTORRES when FTTESTCD = PUL0225
*Note: these values are the average of 3 MVCs from each arm
09/19/2023 2:30am
projectredcap.org
REDCap


LB (Laboratory Test Results)
VS (Vital Signs)
Page 19
RE (Respiratory System Findings)
CV (Cardiovascular System Findings)
LBORRESU
Handgrip Exercise- Blood Gases Inspirate Intensity PaO2 (mmHg) acHb (g/dL) SaO2 (%) PvO2 (mmHg) vcHb (g/dL) SvO2 (%)
21% O2 Rest
21% O2 10%MVC
21% O2 20%MVC
15% O2 Rest
15% O2 10%MVC
15% O2 20%MVC
10% O2 Rest
10% O2 10%MVC
10% O2 20%MVC
LBSCAT = REST
LBGRPID = HANDGRIP
LBSCAT = 10% MAXIMAL VOLUNTARY CONTRACTIONS
LBSCAT = 20% MAXIMAL VOLUNTARY CONTRACTIONS
LBORRES when LBTESTCD = PO2
LBORRES when LBTESTCD = HGB
LBORRES when LBTESTCD = SAO2FIO2
LBORRES when LBTESTCD = PVO2
LBORRES when LBTESTCD = HGB
LBORRES when LBTESTCD = SAO2FIO2
LBCAT = 21% OXYGEN
LBCAT = 15% OXYGEN
LBCAT = 10% OXYGEN
Handgrip- Ultrasound Data Inspirate Intensity Peak vBF (cm/s) BA Diameter (cm) MAP (mmHg) Heart Rate (bpm) Peak TCD (cm/s)
CVORRESU
CVGRPID = HANDGRIP
CVORRES when CVTESTCD = BLDFLRT
CVORRES when CVTESTCD = DIAMETER
VSORRES when VSTESTCD = MAP
VSORRES when VSTESTCD = PULSE
CVORRES when CVTESTCD = PENVEL
CVCAT = 21% OXYGEN
CVCAT = 15% OXYGEN
CVCAT = 10% OXYGEN
VSGRPID = HANDGRIP
VSSCAT = RESTING
CVSCAT = REST
CVSCAT = 10% MAXIMAL VOLUNTARY CONTRACTIONS
CVSCAT = 20% MAXIMAL VOLUNTARY CONTRACTIONS
Handgrip- NIRS Data NIRS on Forearm Forehead NIRS Inspirate Intensity Deoxy (uM) Oxy (uM) Total (uM) StO2 (%) Deoxy (uM) Oxy (uM) Total (uM) StO2 (%)
LBORRES when LBTESTCD = HGBDOXY
LBORRES when LBTESTCD = HGBOXY
LBORRES when LBTESTCD = HGB
LBORRES when LBTESTCD = SAO2FIO2
LBORRES when LBTESTCD = HGBDOXY
LBORRES when LBTESTCD = HGBOXY
LBORRES when LBTESTCD = HGB
LBORRES when LBTESTCD = SAO2FIO2
Abbreviations: PaO2, arterial oxygen tension; acHb, arterial hemoglobin concentration; SaO2, arterial oxygen saturation; PvO2, venous oxygen tension; vcHb, venous hemoglobin concentration; SvO2, venous oxygen saturation; MVC, maximal voluntary contraction; vBF, mean blood flow velocity; BA, brachial artery
Cycling Exericse Inspirate Order:
SUPPLB.QVAL when QNAM = ORDEXER
Inspirate Intensity PaO2 (mmHg) PaCO2 (mmHg) ctHb (g/dL) SaO2 (%) Lactate (mmol/L) Blood Temp (°C)
21% O2 Rest
21% O2 Max
15% O2 Rest
15% O2 Max
LBSCAT = REST
LBSCAT = MAXIMUM
LBGRPID = CYCLE EXERCISE
LBORRES when LBTESTCD = PO2
LBORRES when LBTESTCD = PCO2
LBORRES when LBTESTCD = HGB
LBORRES when LBTESTCD = SAO2FIO2
LBORRES when LBTESTCD = LDH
VSORRES when VSTESTCD = TEMP
VSSCAT = RESTING
VSSCAT = MAXIMUM
VSGRPID = CYCLE EXERCISE
Inspirate Intensity Power Output (W) VO2 (L/min) Heart Rate (bpm) TCD Peak Envelope (cm/s) Cardiac Output (L/min)
REORRESU
21% O2 Rest
21% O2 Max
15% O2 Rest
15% O2 Max
CVORRES when CVTESTCD = POWOUT
REORRES when RETESTCD = VO2, VO2MAX
VSORRES when VSTESTCD = PULSE
CVORRES when CVTESTCD = PENVEL
CVORRES when CVTESTCD = CARDOUT
REGRPID = CYCLE EXERCISE
CVGRPID = CYCLE EXERCISE
RESCAT = REST
RESCAT = MAXIMUM
CVSCAT = MAXIMUM
CVSCAT = REST
NIRS on Vastus Lateralis NIRS on Forehead Inspirate Intensity Deoxy (uM) Oxy (uM) Total(uM) StO2 (uM) Deoxy (uM) Oxy (uM) Total(uM) StO2 (uM)
21% O2 Rest
21% O2 Max
15% O2 Rest
15% O2 Max
RECAT = 21% OXYGEN
RECAT = 15% OXYGEN
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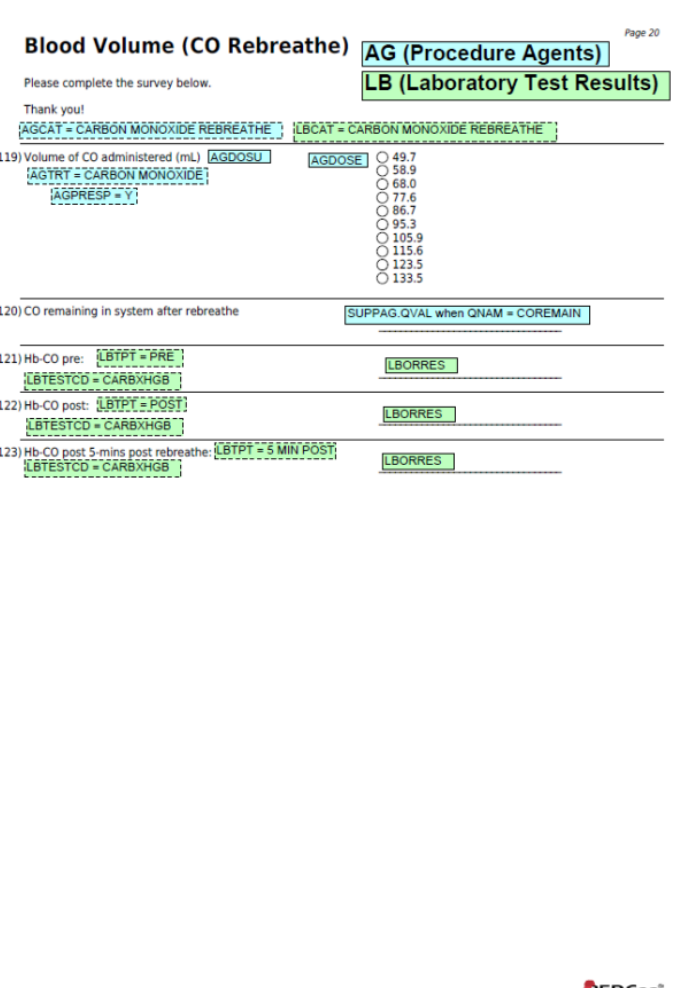
Blood Volume (CO Rebreathe)
Page 20
AG (Procedure Agents)
LB (Laboratory Test Results)
Please complete the survey below.
Thank you!
AGCAT = CARBON MONOXIDE REBREATHE
LBCAT = CARBON MONOXIDE REBREATHE
119) Volume of CO administered (mL) AGDOSU
AGTRT = CARBON MONOXIDE
AGPRESP = Y
AGDOSE
49.7
58.9
68.0
77.6
86.7
95.3
105.9
115.6
123.5
133.5
120) CO remaining in system after rebreathe
SUPPAG.QVAL when QNAM = COREMAIN
121) Hb-CO pre:
LBTPT = PRE
LBTESTCD = CARBXHGB
LBORRES
122) Hb-CO post:
LBTPT = POST
LBTESTCD = CARBXHGB
LBORRES
123) Hb-CO post 5-mins post rebreathe:
LBTPT = 5 MIN POST
LBTESTCD = CARBXHGB
LBORRES
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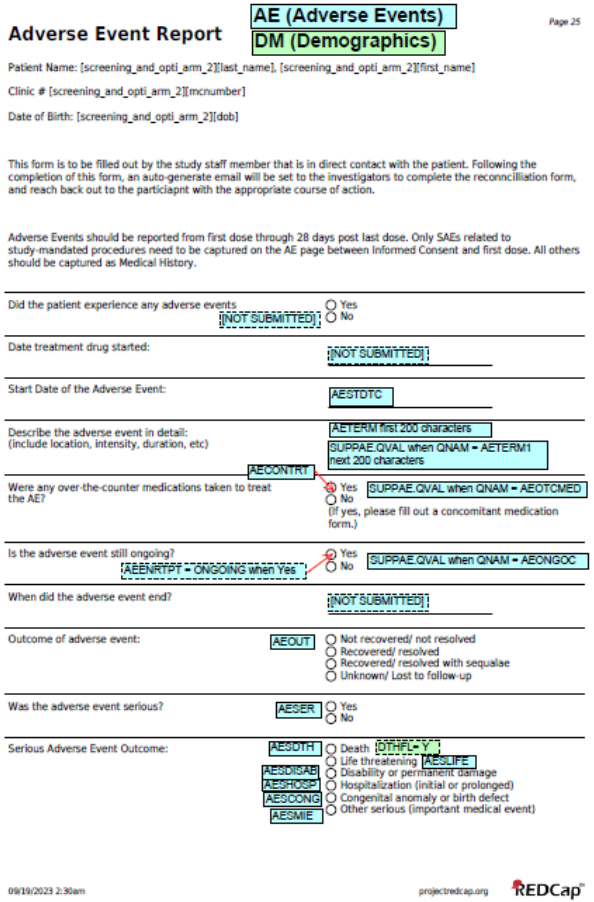
Mapping the Data: Specifications and Programming

- Mapping to Controlled Terminology (CT) challenges
  - Parsing out CM term, dose, unit, route, frequency and indication from comment style free text
  - Determining decodes of values required looking at both the Raw and Label tabs
- Data issues and challenges
  - Identifying the visit for a row sometimes had to be based on the data points that were present
  - Data was locked and final, so no corrections possible
    - A fair amount of existing data issues
    - Very helpful to only have to spec for the data that was present
    - Height data was sometimes converted to a partial date when exporting into Excel
      - Documented conversion correction in csdrg.pdf

Reported Height in EDC	Reported Height in Excel	Reported Height in SAS	Converted Height in SAS
5-9	9-May	45421	5’ 9”

Mapping the Data: Specifications and Programming - 2

- Data issues and challenges (cont.)
  - AE information collected in two different forms that needed to be merged together
    - Adverse Event Report
      - Date treatment drug started: incomplete
      - End date: all blank
    - Adverse Event Reconciliation
      - Diagnosis contained Preferred Term
      - Predominant Symptom: redundant
      - Resolution: only resolved or ongoing
      - Please specify: all blank



Adverse Event Report AE (Adverse Events) DM (Demographics) Page 25

Patient Name: [screening_and_opti_arm_2][last_name], [screening_and_opti_arm_2][first_name]

Clinic # [screening_and_opti_arm_2][mcnumber]

Date of Birth: [screening_and_opti_arm_2][dob]

This form is to be filled out by the study staff member that is in direct contact with the patient. Following the completion of this form, an auto-generate email will be set to the investigators to complete the reconnciliation form, and reach back out to the particiapnt with the appropriate course of action.

Adverse Events should be reported from first dose through 28 days post last dose. Only SAEs related to study-mandated procedures need to be captured on the AE page between Informed Consent and first dose. All others should be captured as Medical History.

Did the patient experience any adverse events [NOT SUBMITTED] ○ Yes ○ No

Date treatment drug started: [NOT SUBMITTED]

Start Date of the Adverse Event: AESTDTC

Describe the adverse event in detail: (include location, intensity, duration, etc) AETERM first 200 characters; SUPPAE.QVAL when QNAM = AETERM1 next 200 characters

Were any over-the-counter medications taken to treat the AE? AECONTRT ○ Yes SUPPAE.QVAL when QNAM = AEOTCMED ○ No (if yes, please fill out a concomitant medication form.)

Is the adverse event still ongoing? AEENRTPT = ONGOING when Yes ○ Yes ○ No SUPPAE.QVAL when QNAM = AEONGOC

When did the adverse event end? [NOT SUBMITTED]

Outcome of adverse event: AEOUT ○ Not recovered/ not resolved ○ Recovered/ resolved ○ Recovered/ resolved with sequalae ○ Unknown/ Lost to follow-up

Was the adverse event serious? AESER ○ Yes ○ No

Serious Adverse Event Outcome: AESDTH ○ Death DTHFL = 'Y'; AESLIFE ○ Life threatening; AESDISAB ○ Disability or permanent damage; AESHOSP ○ Hospitalization (initial or prolonged); AESCONG ○ Congenital anomaly or birth defect; AESMIE ○ Other serious (important medical event)

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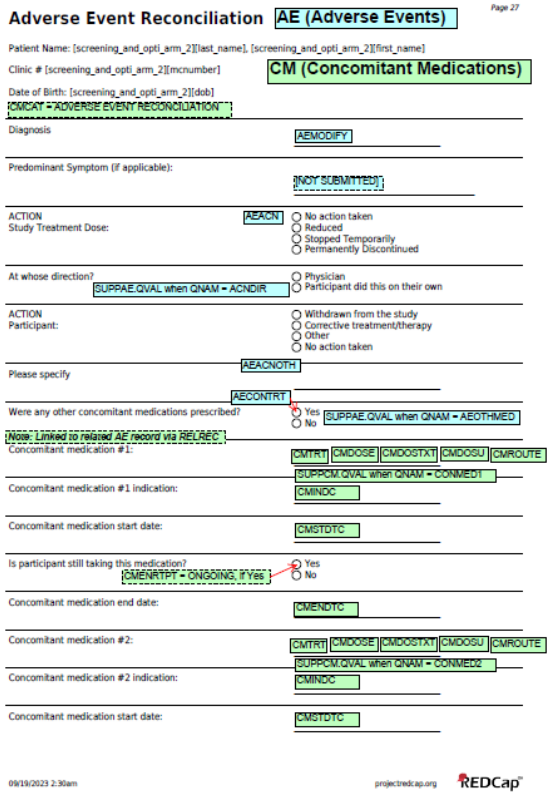
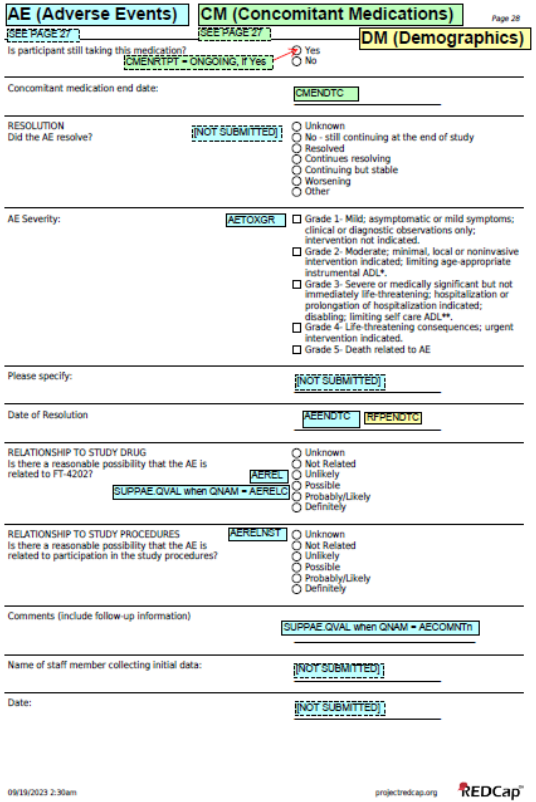
Mapping the Data: Specifications and Programming - 2

- AE information collected in two different forms that needed to be merged together (cont.)





Mapping the Data: Specifications and Programming - 3

- Additional data added later
  - Missing lab data was provided in a separate Excel spreadsheet
- Usual clinical trial data that was missing
  - Informed Consent Date not captured in REDCap for all subjects
    - Documented in csdrg.pdf
  - Actual date/time of first dose
    - Derived from date of last dose (which was assigned from a lab date)
  - Failed Inclusion/Exclusion Criteria (IE not created)
    - Detailed “Screening Questionnaire” instead
  - Most units and methods were not included in the data
    - Assigned from text in the form, variable label or protocol

Mapping the Data: Specifications and Programming - 4

- Usual clinical trial data that was missing (cont.)
  - Sex and Age for some subjects
  - Lab ranges were imbedded in a lengthy Word document
    - Added as an appendix to csdrg.pdf
  - Dates for when some events happened were not collected
    - The ALL file contained survey completion dates that could be leveraged, in some cases
      - PROMIS Questionnaire was filled out at the site by the subject (confirmed with the site)
  - Only the Preferred Term medical coding term for AEs and CMs was provided in the data
    - Versions of dictionaries used to code were not available
    - Request to “programmatically merge” the missing information from the dictionaries was not feasible
    - Used an external coding tool to completely code the terms

Mapping the Data: Specifications and Programming - 5

- Use of “look up” tabs to assist in programming
  - CMTERM from three different forms

medsupplementslist	group_	term_	dose_	units_	route_	freq_	indic_
Birth control	MED1	Birth control					
Claritin D	MED2	Claritin D					
Clobetasol propionate (topical steroid)	MED3	Clobetasol propionate (topical steroid)			TOPICAL		
Daily multi-vitamin	MED4	Multi-vitamin				QD	
Daily multi-vitamins, phexofenadine (seasonal alergies)	MED5	Multi-vitamin				QD	
Daily multi-vitamins, phexofenadine (seasonal alergies)	MED5	Phexofenadine					SEASONAL ALLERGIES

birthcontrol_type	term_	dose_	units_
Aviane 0.1mg/0.02mg	Aviane	0.1/0.02	mg
Estrogen progesterone pill	Estrogen progesterone		PILL
Ethinylestradiol + Gestodene (Gynera)	Ethinylestradiol and Gestodene (Gynera)		

concomitant_medication__1_	term_	dose_	units_	route_
human papillomavirus type 16, L1 capsid protein (residues 2-471) vaccine / human papillomavirus type 18, L1 capsid protein (residues 2-472) vaccine Injectable Product	human papillomavirus type 16, L1 capsid protein (residues 2-471) vaccine / human papillomavirus type 18, L1 capsid protein (residues 2-472) vaccine Injectable Product			
ibuprofen 200 MG Oral Tablet [Advil]	Advil	200	mg	Oral

Mapping the Data: Specifications and Programming - 6

- Use of “look up” tabs to assist in programming (cont.)
  - CVTEST

Source		Target							
Filename	Variable Name	CVCAT	CVSCAT	CVTESTCD	CVTEST	CVORRESU	CVMETHOD	CVLOC	CVGRPID
ALL_L	_21__O2__REST_TCD_PEAK_ENVELOPE	21% OXYGEN	REST	PENVEL	Peak Envelope	cm/s	TRANSCRANIAL DOPPLER ULTRASOUND	SKULL	HANDGRIP EXERCISE
ALL_L	VAR289	21% OXYGEN	10% MAXIMAL VOLUNTARY CONTRACTION	PENVEL	Peak Envelope	cm/s	TRANSCRANIAL DOPPLER ULTRASOUND	SKULL	HANDGRIP EXERCISE
ALL_L	VAR290	21% OXYGEN	20% MAXIMAL VOLUNTARY CONTRACTION	PENVEL	Peak Envelope	cm/s	TRANSCRANIAL DOPPLER ULTRASOUND	SKULL	HANDGRIP EXERCISE
ALL_L	_15__O2__REST_TCD_PEAK_ENVELOPE	15% OXYGEN	REST	PENVEL	Peak Envelope	cm/s	TRANSCRANIAL DOPPLER ULTRASOUND	SKULL	HANDGRIP EXERCISE
ALL_L	VAR292	15% OXYGEN	10% MAXIMAL VOLUNTARY CONTRACTION	PENVEL	Peak Envelope	cm/s	TRANSCRANIAL DOPPLER ULTRASOUND	SKULL	HANDGRIP EXERCISE
ALL_L	VAR293	15% OXYGEN	20% MAXIMAL VOLUNTARY CONTRACTION	PENVEL	Peak Envelope	cm/s	TRANSCRANIAL DOPPLER ULTRASOUND	SKULL	HANDGRIP EXERCISE
ALL_L	_10__O2__REST_TCD_PEAK_ENVELOPE	10% OXYGEN	REST	PENVEL	Peak Envelope	cm/s	TRANSCRANIAL DOPPLER ULTRASOUND	SKULL	HANDGRIP EXERCISE
ALL_L	VAR295	10% OXYGEN	10% MAXIMAL VOLUNTARY CONTRACTION	PENVEL	Peak Envelope	cm/s	TRANSCRANIAL DOPPLER ULTRASOUND	SKULL	HANDGRIP EXERCISE
ALL_L	VAR296	10% OXYGEN	20% MAXIMAL VOLUNTARY CONTRACTION	PENVEL	Peak Envelope	cm/s	TRANSCRANIAL DOPPLER ULTRASOUND	SKULL	HANDGRIP EXERCISE

- Clear, detailed specifications made the programming go relatively quickly
  - Used two SDTM SME’s with advanced SAS programming skills

Mapping the Data: Define and SDRG

- Define creation went smoothly, thanks to the clear specifications
- Data oddities and mapping issues were noted in the csdrg.pdf

> **3.4.11 EX – Exposure**
>
> The actual dates of exposure were not collected, so the EC domain was not created, since it would be exactly the same as the EX domain. The P50OXYGN lab test was collected on the same day that the last dose of study drug was taken, so that date is used as the last study drug dose date and then 6 days is subtracted from it to derive the first study drug dose date.
>
> **3.4.14 LB – Laboratory Test Results**
>
> Normal ranges were not captured in EDC but were made available within a separate document that is included here as Appendix II.

- Final mapping resulted in a relatively low number of Pinnacle 21 issues
  - Most were data value related
  - The mapping strategy worked!

Conclusions

Conclusions

- Data from REDCap can successfully be mapped into SDTM manually
  - Requires deep understanding of SDTM standards and the collected data (and patience)
  - May only be possible by a limited number of organizations
- Outreach is potentially needed to ensure that REDCap users are aware of:
  - The existence of CDASH forms and what they are
  - Standards in general to make the process easier
    - REDCap documentation could be updated to mention CDASH forms
    - Sponsors working with academic institutions could provide guidance through:
      - Standards leads
      - CDASH/SDTM SMEs
    - CDISC avenues for promoting
      - CAC member outreach
      - More press
      - More presentations at related conferences

Thank You:

For listening!

To my colleague Elena Prosekova for her expertise and good humor in helping complete this study mapping

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