

# MEDRIO

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# Background

- Women's Health Clinical Research Center
- Investigator Initiated Trials (incontinence, hot flashes, pelvic pain, fibroids)
- Prior EDC Approach
  - Epi/Biostat DMG
  - RedCap
- Pain points
  - Form Flexibility
  - Data Quality
  - Data Product
- Options out there: either free, or very expensive
- Moderate solution?

# Outline

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- Overview
- Form Features: Forms, Relational Structure
- Data Quality: Queries, Form Rules, Visit Schedules
- Workflows: Data Coder, Data Monitor, Data Manager, Developer
- Other: Mobile, Security, Support
- Questions

# Medrio Overview

- eClinical
  - Electronic Data Capture
  - Direct Data Capture
  - ePRO
  - eConsent
- Cloud based
- Founded 2006, San Francisco
- WHCRC since 2014

# Medrio Overview

- Home Page Summary

The screenshot displays the Medrio Home Page Summary dashboard. The top navigation bar is blue with the LILA logo on the left and user information (mschembri) and links (Help, Logout) on the right. Below the navigation bar is a secondary bar with a menu (HOME, ENTER DATA, MANAGE, CODING, ANALYSIS, DASHBOARD) and a search bar labeled 'Quick Links' with the placeholder 'Subject ID'. The main content area is divided into three columns. The first column, 'STUDY ENROLLMENT', shows a count of 79 and a list of subject IDs from 80005 to 80131. The second column, 'OPEN QUERIES', shows a count of 138 and a list of queries such as '80005 - 36-Week Post-Intervention - Visit Status - svdat'. The third column, 'JANUARY 16, 2020 Thursday', shows a date and a list of events like '80062 - Baseline Visit - 3 Day Voiding Diary Data Entry'. Each list has a 'More' button at the top right.

**STUDY ENROLLMENT**  
79

**Subjects** [Add](#) [More](#)

- 80005
- 80007
- 80009
- 80056
- 80082
- 80087
- 80092
- 80094
- 80095
- 80096
- 80103
- 80106
- 80107
- 80111
- 80112
- 80121
- 80122
- 80124
- 80126
- 80129
- 80131

**OPEN QUERIES**  
138

**Queries** [More](#)

- 80005 - 36-Week Post-Intervention - Visit Status - svdat
- 80005 - 36-Week Post-Intervention - Visit Status - visitstatus
- 80007 - 36-Week Post-Intervention - Visit Status - svdat
- 80007 - 36-Week Post-Intervention - Visit Status - visitstatus
- 80009 - 36-Week Post-Intervention - Visit Status - svdat
- 80009 - 36-Week Post-Intervention - Visit Status - visitstatus
- 80056 - 36-Week Post-Intervention - Visit Status - svdat
- 80056 - 36-Week Post-Intervention - Visit Status - visitstatus
- 80150 - Telephone Screening - Eligibility and Randomization - lieranddat
- 80151 - Telephone Screening - Eligibility and Randomization - lieranddat
- 80152 - Telephone Screening - Eligibility and Randomization - lieranddat
- 82052 - 6-Week Clinic Visit - 3 Day Voiding Diary Data Entry - vddrecleak
- 82052 - 6-Week Clinic Visit - 3 Day Voiding Diary Data Entry - vddrecleak
- 82052 - 6-Week Clinic Visit - 3 Day Voiding Diary Data Entry - vddrecleak
- 82038 - 6-Week Clinic Visit - 3 Day Voiding Diary Data Entry - vddurday
- 82060 - 6-Week Clinic Visit - 3 Day Voiding Diary Data Entry - vddurday
- 82051 - 6-Week Clinic Visit - 3 Day Voiding Diary Data Entry - vddrecleak
- 80094 - 12-Week Clinic Visit - Height and Weight - abcircum1
- 80094 - 12-Week Clinic Visit - Height and Weight - abcircum2
- 80005 - 12-Week Clinic Visit - 3 Day Voiding Diary Data Entry - vddbed
- 82060 - 12-Week Clinic Visit - 3 Day Voiding Diary Data Entry - vddbed

**JANUARY 16, 2020**  
**Thursday**

**Approval** [More](#)

- 80062 - Baseline Visit - 3 Day Voiding Diary Data Entry
- 80056 - Baseline Visit - 3 Day Voiding Diary Data Entry
- 82004 - Baseline Visit - 3 Day Voiding Diary Data Entry
- 82004 - Baseline Visit - Sleep Diary Data
- 80067 - Baseline Visit - 3 Day Voiding Diary Data Entry
- 82009 - Baseline Visit - 3 Day Voiding Diary Data Entry
- 82009 - Baseline Visit - Sleep Diary Data
- 80055 - Baseline Visit - 3 Day Voiding Diary Data Entry
- 82025 - Baseline Visit - 3 Day Voiding Diary Data Entry
- 82025 - Baseline Visit - Sleep Diary Data
- 82003 - Baseline Visit - 3 Day Voiding Diary Data Entry
- 82003 - Baseline Visit - Sleep Diary Data
- 80061 - Baseline Visit - 3 Day Voiding Diary Data Entry
- 80029 - Baseline Visit - 3 Day Voiding Diary Data Entry
- 80059 - Baseline Visit - 3 Day Voiding Diary Data Entry
- 80041 - Baseline Visit - 3 Day Voiding Diary Data Entry
- 80035 - Baseline Visit - 3 Day Voiding Diary Data Entry
- 80057 - Baseline Visit - 3 Day Voiding Diary Data Entry
- 82020 - Baseline Visit - 3 Day Voiding Diary Data Entry
- 82020 - Baseline Visit - Sleep Diary Data
- 82030 - Baseline Visit - 3 Day Voiding Diary Data Entry

# Medrio Overview

- Participant Summary

LILA

LILAmschembriHelpLogout

HOMEENTER DATAMANAGECODINGANALYSISDASHBOARD

Quick LinksSubject ID

Subject: 82061 Site: Stanford Status: Enrolled LogSubject InfoView: Tabular

Manage Subject ProgressCancelUpdate

Forms	Data Entered	Open Queries	Status	Diary Review	ePRO	Locked
Telephone Screening						
Screening Visit						
Baseline Visit						
Randomization						
Visit Status	✓		Complete	N/A		
Assessment of Credibility/Expectations of Tx	✓		Complete	N/A		
Practice Adherence Self-Efficacy (PASE)	✓		Complete	N/A		
2-Week Telephone Call						
Visit Status	✓		Complete	N/A		
Health Update	✓		Complete	N/A		
6-Week Clinic Visit						
Visit Status	✓		Complete	N/A		
Medication Inventory	✓		Complete	N/A		
Physical Performance Testing Form	✓		Complete	N/A		
Pittsburgh Sleep Quality Index (PSQI)01H00M	✓	▲ 1	Not Complete	N/A		
Incontinence Impact Questionnaire (IIQ)01H00M	✓		Complete	N/A		
Urogenital Distress Inventory-6 (UDI-6)01H00M	✓		Complete	N/A		
Patient Perception of Bladder Cond (PPBC)01H00M	✓		Complete	N/A		
Pelvic Organ Prolapse/UI Sexual Q (PISQ-IR)01H00M	✓		Complete	N/A		
Fluid Intake and Behavior01H00M	✓		Complete	N/A		
Center for Epidemiologic Studies Depression (CESD)01H00M	✓		Complete	N/A		
Spielberger State Trait Anxiety Inv (STAI)01H00M	✓		Complete	N/A		
Hospital Anxiety Depression Scale (HADS)01H00M	✓		Complete	N/A		
Physical Function (PROMIS-8)01H00M	✓		Complete	N/A		

# Form Features Overview

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- Form Basics
- Form Format
- Form Layout
- Relational Structure

# Form Basics

- Form Sources
  - Templates: CDASH Library(CDISC\*)
  - Import Forms
  - Custom
- Field Types
  - Text
  - Categorical: Drop down, radio vertical/horizontal, select all
  - Dates/Times
    - Partial Dates
  - VAS (vertical or horizontal) (approved by EQ5D)
  - Calculated Fields (updated on save, or manually)
  - File uploads
- Skip Patterns (visible or hidden)



# Form Format

- Formatting controls
  - Rich Text Formatting
  - Label
  - Position (above, left)
  - Justification
  - Width
- Field Width
- Radio vertical/horizontal

Tobacco Use

Participant Acrostic:

Visit Date:   
15-Feb-2019

Staff ID:

1. Have you smoked 100 cigarettes or more in your entire life?  
(Interviewer note: 100 cigarettes are equal to 5 packs.)

☒ Yes

☐ No --> Questionnaire completed.

☐ Don't Know --> Questionnaire Completed

☐ Refused --> Questionnaire Completed

1a. How many years total have you smoked cigarettes?

1b. On average, of the entire time you have smoked, how many cigarettes did you usually smoke per day?

cigarettes per day

2. Do you smoke cigarettes now?

☒ Yes

☐ No --> Questionnaire Completed

☐ Refused --> Questionnaire Completed

2a. On average, how many cigarettes do you usually smoke per day now?

cigarettes per day

6. For 12-Week Visit only: Did you practice yoga or physical conditioning last night?

☐ Yes --> Go to 6a

☐ No --> Go to 7

6a. What time did you practice?

7. Was Heart Rate Variability measured?

☐ Yes

☐ No --> Explain below

If no, why:

8. Was Pre-ejection Period measured?

☐ Yes

☐ No --> Explain below

If no, why:

Subject: 70001 Visit: Screening Visit Status: Excluded Before Enrollment [Subject Info](#)

Physical Function (Promis8)

Form Tools

Please respond to each question or statement by marking one circle per row.

	Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do	
1. Are you able to do chores such as vacuuming or yard work?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
2. Are you able to go up and down stairs at a normal pace?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
3. Are you able to go for a walk of at least 15 minutes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
4. Are you able to run errands and shop?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

# Form Layout

- Tables
  - Place variable next to each other
- Meet standardized questionnaire structure
- Layout reflects nature of data
- Guideline Documents

Subject: 10001 Visit: Screening Visit Status: Screening [Subject Info](#)

Menopause-specific Quality Of Life (MENQoL)

For each of the following items, indicate whether you have experienced the problem in the PAST MONTH. If you have, rate how much you have been bothered by the problem. (Scale of 0-6 with 0 being "Not at all" and 6 being "Extremely")

Hot flushes or flashes <input type="radio"/> Yes <input type="radio"/> No	How much have you been bothered by hot flushes or flashes? <input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6
Night sweats <input type="radio"/> Yes <input type="radio"/> No	How much have you been bothered by night sweats? <input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6
Sweating <input type="radio"/> Yes <input type="radio"/> No	How much have you been bothered by sweating? <input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6
Being dissatisfied with my personal life <input type="radio"/> Yes <input type="radio"/> No	How much have you been bothered by being dissatisfied with your personal life? <input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6

Subject: 10002 Visit: Screening Visit Status: Enrolled [Log](#) [Subject Info](#)

Vital Signs Guideline Document

**Resting Vital Signs**

Before Vital Signs are taken, have participant lie down in a supine position for 5 minutes. After about 5 minutes, take 2 measurements of blood pressure and pulse in the supine position.

Cuff Size: ☒ Regular (9"-13") ☐ Large (13"-17") ☐ Adjustable (9"-17") [Q](#)

Arm Used: ☒ Left Arm ☐ Right Arm [Q](#)

<b>Measurement 1 (Supine)</b>	Systolic: <input type="text" value="120"/> <a href="#">Q</a>	Diastolic: <input type="text" value="65"/> <a href="#">Q</a>	Radial Pulse (beats per minute): <input type="text" value="60"/> <a href="#">Q</a>
<b>Measurement 2 (Supine)</b>	Systolic: <input type="text" value="122"/> <a href="#">Q</a>	Diastolic: <input type="text" value="60"/> <a href="#">Q</a>	Radial Pulse (beats per minute): <input type="text" value="60"/> <a href="#">Q</a>

If resting systolic blood pressure is >160 or <100 mmHg (both measurements), or resting diastolic blood pressure is >100 or <60 mmHg (both measurements), **check the Physical Exam Measurements operations manual chapter** to determine next steps. These measurements may result in exclusion of the participant, require urgent follow-up steps such as paging in the principal investigator during the visit, and/or require you to give the participant a standardized letter to take to her regular healthcare provider.

**ALERT:**  [Q](#)  
[Update Value](#)

# Forms

- Form Headers
  - Display data fields from other forms
- Visit Specific Fields
  - Appear only for selected visits

Subject: 20001 Visit: Screening Visit Status: Enrolled Log [Subject Info](#)

### Medication Inventory

Participant Acrostic:

Visit Date:   
12-Nov-2018

1. Does the participant have any medications to record? ☒ Yes ☐ No

2. Medications List

Row Tools	Medication or Therapy:
1	<input type="text" value="Asprin"/>
2	<input type="text" value="Antihistamine"/>
3	<input type="text"/>
4	<input type="text"/>
5	<input type="text"/>

More rows: [1](#) [5](#) [10](#)

**SCREENING VISIT:**

3. Is the participant taking any exclusionary medications requiring washout? ☐ Yes -> Go to 3a ☒ No

3a. Is participant willing to washout prior to randomization? ☐ Yes ☐ No --> Ineligible  
(if No, the participant is Ineligible)

# Relational Data Structure

- Repeated records
  - e.g. Medications, AE's, Pregnancies, Medication Adherence, Diaries
- Can combined non-repeated and repeated on same form
- Fixed Row Example

Subject: 10003 Visit: Baseline Visit Status: Early Termination Log [Subject Info](#)

3 Day Voiding Diary Data Entry

Date of Day 1: 9/4/2018 04-Sep-2018

Row Tools	Day of Diary	Time Awake:	Time to Bed:	Leakages were recorded:	Daytime Urinations in Toilet	Nighttime Urinations in Toilet	Daytime Urine Leakages
1	Day 1	07:30 AM	10:30 PM	<input type="radio"/> All of the time <input checked="" type="radio"/> Most of the time <input type="radio"/> Some of the time <input type="radio"/> None of the time	2	3	4
2	Day 2	07:30 AM	10:30 PM	<input type="radio"/> All of the time <input checked="" type="radio"/> Most of the time <input type="radio"/> Some of the time <input type="radio"/> None of the time	1	2	3
3	Day 3	07:57 AM	12:00 AM	<input type="radio"/> All of the time <input type="radio"/> Most of the time <input type="radio"/> Some of the time <input checked="" type="radio"/> None of the time	3	4	5











# Relational Data Structure

- Infinite Row Example
- Form is a functional tool, used to monitor entire AE history:
  - Update status of ongoing AE's (assign end date)
  - Identify when new reports are continuation from previously reported AE's

Subject: 10003 Visit: Continuous Forms Status: Early Termination Log Subject Info Forms: Adverse Event SAE - CDASH

Adverse Event SAE - CDASH Form Tools Save Save & Next

Participant Acrostic: SAKE

Row/Tools	Visit	AE #	Adverse Event	Other AE, please specify or enter diagnosis for SAE	Date Onset	Ongoing	Date Resolved
1  	Week 2	1	Increased fatigue/tiredness		9/18/2018 18-Sep-2018	<input checked="" type="radio"/> Yes <input type="radio"/> No	9/25/2018 25-Sep-2018
2  	Week 6	2	Other	Ankle sprain	10/30/2018 30-Oct-2018	<input checked="" type="radio"/> Yes <input type="radio"/> No	MM/dd/yyyy
3  	Week 6	3	Cold/flu		10/25/2018 25-Oct-2018	<input checked="" type="radio"/> Yes <input type="radio"/> No	11/20/2018 20-Nov-2018
4  					MM/dd/yyyy	<input type="radio"/> Yes <input checked="" type="radio"/> No	MM/dd/yyyy
5  					MM/dd/yyyy	<input type="radio"/> Yes <input checked="" type="radio"/> No	MM/dd/yyyy

More rows: 1 5 10

# Relational Data Structure

- Repeated Forms
  - Pre-specified or editable form labels
- Repeated Visits
  - Allow flexible follow-up
  - Pre-specified or editable visit labels

Subject: 1001 Site: Site A Status: Enrolled [Subject Info](#)

Manage Subject Progress

Forms	Data Entered
Month 1	
Visit Status	✓
Health Update	✓
Adverse Event SAE - CDASH	
Repeatable Vital Stats-1	✓
Repeatable Vital Stats-2	✓
Repeatable Vital Stats Last Measure	✓

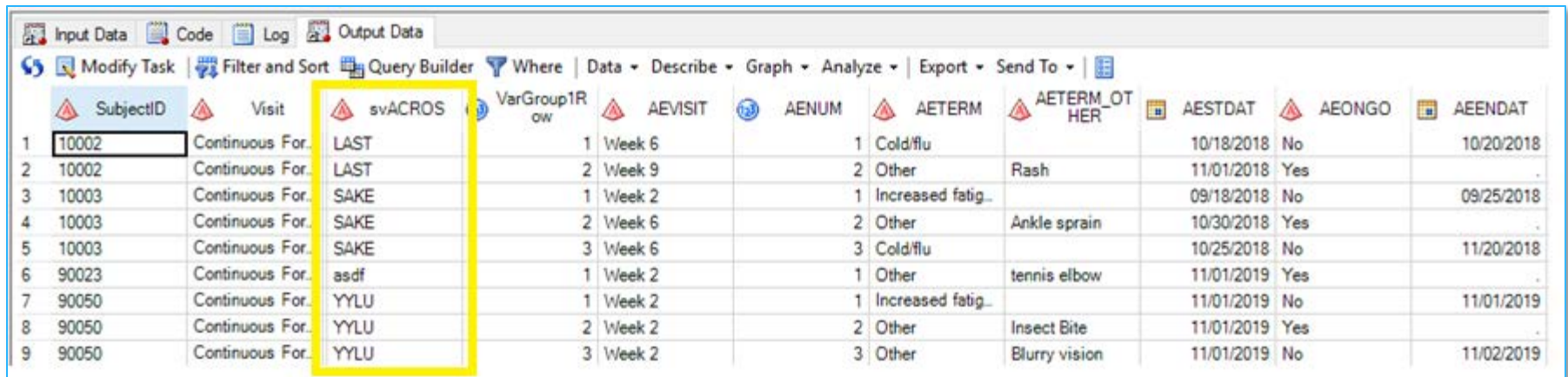
Subject: 1001 Site: Site A Status: Enrolled [Subject Info](#)

Manage Subject Progress

Forms	Data Entered	Open Queries	Status
Month 1			
Month 3			
Followup Repeat-1 (Add repeating Visit)			
Health Update Short	✓		Complete
Daily Headache Log	✓		Complete
Followup Repeat-2			
Health Update Short	✓		Complete
Daily Headache Log			Not Complete
Unscheduled			
Visit Status (Add new form)			
Visit Status (Jul-22-2016 10:33 AM)	✓		Complete

# Relational Data Structure

- One table per form
- Underlying data contains one record per row
- Non-row variables are repeated (optional)




The screenshot shows a software interface with a menu bar (Input Data, Code, Log, Output Data) and a toolbar (Modify Task, Filter and Sort, Query Builder, Where, Data, Describe, Graph, Analyze, Export, Send To). Below the toolbar is a table with 11 columns: SubjectID, Visit, svACROS, VarGroup1R, AEVISIT, AENUM, AETERM, AETERM\_OT, AESTDAT, AEONGO, and AEENDAT. The svACROS column is highlighted with a yellow box. The table contains 9 rows of data.

	SubjectID	Visit	svACROS	VarGroup1R	AEVISIT	AENUM	AETERM	AETERM_OT	AESTDAT	AEONGO	AEENDAT
1	10002	Continuous For...	LAST	1	Week 6		1 Cold/flu		10/18/2018	No	10/20/2018
2	10002	Continuous For...	LAST	2	Week 9		2 Other	Rash	11/01/2018	Yes	.
3	10003	Continuous For...	SAKE	1	Week 2		1 Increased fatig...		09/18/2018	No	09/25/2018
4	10003	Continuous For...	SAKE	2	Week 6		2 Other	Ankle sprain	10/30/2018	Yes	.
5	10003	Continuous For...	SAKE	3	Week 6		3 Cold/flu		10/25/2018	No	11/20/2018
6	90023	Continuous For...	asdf	1	Week 2		1 Other	tennis elbow	11/01/2019	Yes	.
7	90050	Continuous For...	YYLU	1	Week 2		1 Increased fatig...		11/01/2019	No	11/01/2019
8	90050	Continuous For...	YYLU	2	Week 2		2 Other	Insect Bite	11/01/2019	Yes	.
9	90050	Continuous For...	YYLU	3	Week 2		3 Other	Blurry vision	11/01/2019	No	11/02/2019

# Data Quality Overview

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- Visits: Visit Schedule and Report
  - Forms: Form Rules and Report
  - Data Points: Data Query System
- 
- Core Data Quality
- Other Reports
  - Data Monitors (following)



# DQ: Visit Schedule

- Visit Schedule
- Scheduled Visits Report
  - Overdue
  - Due
  - Scheduled

### Define Visit Schedules

Enrollment Date
 

IStartDat

 at
 

Telephone Screening

Visit	Schedule	Visit Window
Telephone Screening	0 days after enrollment	May occur 100 days before to 0 days after scheduled date
Screening Visit	0 days after enrollment	May occur 100 days before to 0 days after scheduled date
Baseline Visit	0 days after enrollment	May occur 50 days before to 0 days after scheduled date
Randomization	0 days after enrollment	May occur 14 days before to 0 days after scheduled date
2-Week Telephone Call	14 days after enrollment	May occur 6 days before to 6 days after scheduled date
6-Week Clinic Visit	42 days after enrollment	May occur 6 days before to 6 days after scheduled date
9-Week Telephone Call	63 days after enrollment	May occur 6 days before to 6 days after scheduled date
12-Week Clinic Visit	84 days after enrollment	May occur 6 days before to 6 days after scheduled date

Scheduled Visits Report

Report: Scheduled Visits

Show scheduled Visits for:

Report Date\*: 01/07/2020

Report Window: 14 Days

Site: All Sites

Update

07-Jan-2020

Download to Excel

Site	Group	Subject ID	Visit	Due Date*	Visit Window	Status	Days Past Due
Fremont - Clinical Research Unit	Post Menopausal	90378	4-Week Post-Discontinuation Phone Call	Jan-14-2020	Jan-07-2020 to Jan-21-2020	DUE	
	Post Menopausal	90384	Continuous Forms	Jan-16-2020	Oct-24-2019 to Jan-16-2020	3 FORMS COLLECTED	
	Post Menopausal	90384	12-Week Clinic Visit	Jan-16-2020	Jan-10-2020 to Jan-22-2020	SCHEDULED	
	Post Menopausal	90401	8-Week Phone Call	Jan-09-2020	Jan-03-2020 to Jan-15-2020	DUE	
	Post Menopausal	90403	8-Week Phone Call	Jan-21-2020	Jan-15-2020 to Jan-27-2020	SCHEDULED	
	Late Menopausal Transition	90406	2-Week Clinic Visit	Dec-10-2019	Dec-07-2019 to Dec-13-2019	OVERDUE	28
	Late Menopausal Transition	90406	3-Week Phone Call (if 0.6 mg/hr only)	Dec-17-2019	Dec-14-2019 to Dec-20-2019	OVERDUE	21
	Late Menopausal Transition	90406	5-Week Clinic Visit	Dec-31-2019	Dec-25-2019 to Jan-06-2020	OVERDUE	7
	Late Menopausal Transition	90406	8-Week Phone Call	Jan-21-2020	Jan-15-2020 to Jan-27-2020	SCHEDULED	

# DQ: Form Rules

- Accurate inventory of all required forms
- Special rules for optional/conditional forms

- Automatically updated Form Status:

- Not Expected
- Not Complete
- Complete

- Missing Forms Report

Subject: 30002 Site: Fremont - Clinical Research Unit Status: Enrolled Log [Subject Info](#)

Manage Subject Progress

Forms	Data Entered	Double Data Entered	Open Queries	Status
<b>Baseline/Randomization Visit</b>				
Visit Status	✓			Complete ▼
Health Update	✓			Complete ▼
Vital Signs	✓			Complete ▼
Run-In Compliance	✓			Complete ▼
Hot Flash Diary Data Summary				Not Complete ▼
Pregnancy Test				Not Expected
Final Inclusion Exclusion Checklist	✓			Complete ▼
Sleep Diary Data				Not Complete ▼
<b>1-Week Clinic Visit</b>				
Visit Status				Not Complete ▼
Health Update				Not Expected
Vital Signs				Not Expected
Dose Adjustment Form (Week 1 and 2)				Not Expected
Pregnancy Test				Not Expected

Missing Forms Report (forms not yet collected) Report: Missing Forms (forms not yet collected) ▼

Show missing forms for:

Sites: All Fremont - Clinical Research Unit Oakland - Clinical Research Unit San Francisco - Clinical Research Unit

Groups: All Late Menopausal Transition Post Menopausal

Visits: All Telephone Screening Screening Visit Baseline/Randomization Visit

Forms: All Visit Status Eligibility and Randomization Demographics

Sort by: Site Subject Visit Form

[Update](#)

[Download to Excel](#)

Subject ID	Site	Visit	Form	Scheduled Date	Days Past Scheduled	Days Late
10002	Fremont - Clinical Research Unit	Screening Visit	ECG	Oct-28-2019	74	74
10002	Fremont - Clinical Research Unit	Baseline/Randomization Visit	Sleep Diary Data	Oct-28-2019	74	74
10002	Fremont - Clinical Research Unit	2-Week Clinic Visit	Visit Status	Nov-11-2019	60	57
30002	Fremont - Clinical Research Unit	Baseline/Randomization Visit	Hot Flash Diary Data Summary	Nov-17-2019	54	54
30002	Fremont - Clinical Research Unit	Baseline/Randomization Visit	Sleep Diary Data	Nov-17-2019	54	54
30002	Fremont - Clinical Research Unit	1-Week Clinic Visit	Visit Status	Nov-24-2019	47	44

# DQ: Form Rules

- Form Rules: Define condition under which form is required

Define Form Rule

Describe

Name:

Description:

Show Skipped Forms: ☒

Define

Subject Properties

Visit Status

Eligibility and Randomization

Demographics

Health History

Enable selected forms when **all (AND)** of the following conditions are true:

xaeterm\_pregnancytest

at 1-Week Clinic Visit

=

Yes --> Complete Pregnancy Test Form

No --> Form Complete

or

Drag a variable here.

Drag a variable or condition here.

Health History Form

7a. Coordinator say to participant:  
"As a part of this study we ask that you try to avoid becoming pregnant while using the study medication, either by refraining from sexual activity or by consistently using non-hormonal contraceptive methods such as condoms, diaphragms, sponges, or an I.U. If you've had sexual activity that could lead to pregnancy since your last visit, we ask that you have a repeat a pregnancy test.  
Do you think a pregnancy test is appropriate at this visit?"  
☐ Yes --> Complete Pregnancy Test Form  
☐ No --> Form Complete

Final Inclusion Exclusion Checklist

Sleep Diary Data

☒ 1-Week Clinic Visit

Visit Status

Health Update

Vital Signs

Dose Adjustment Form (Week 1 and 2)

☒ Pregnancy Test

☒ 2-Week Clinic Visit

Visit Status

Health Update

# DQ: Data Queries

- Push data quality checks up into the EDC system
- Address data issues in real time, while the data is fresh
- Have a system to manage data checks
- Get a data product already vetted for data quality and internal consistency

*SCDM\* Best Practices:  
“Ensure adequate edit check  
procedures and query management  
tools are built into EDC software.”*

# DQ: Data Queries

- Query = Data Check
- Standard Queries
  - Missing data
  - Soft range checks
- Custom Queries
  - Date order/range
    - Study events after enrollment, visits occur in order
  - Eligibility checks
    - Randomized ppts meet individual criteria
  - Dosage used per protocol
- Cross-form and cross-visit checks
- Other uses
  - Flag Alert values (e.g. unexpected lab results)
  - Flag Protocol Deviation
  - Flag for follow-up (Ongoing AE's)
- Manual Queries

The screenshot displays a clinical trial data entry interface. At the top, a header bar shows 'Subject: 20001', 'Visit: Screening Visit', 'Status: Enrolled', and a 'Log' button. Below this is a 'Subject Info' button. The main section is titled 'Demographics'. It contains several fields: 'Participant Acoustic' with the value 'abaz', 'Date of Visit' with '06/08/2017' and a 'Now' button, and three numbered questions. Question 1 asks for gender, with 'Female' selected. Question 2 asks for birth date, with '06/08/1983' entered. Question 3 asks for marital status, with 'Annulled' selected. A query alert box is open on the right, stating 'The following open query exists: Variable: xbrthdat @ Screening Visit, Description: Extreme value (outside 1955-1981), Assigned To: Unassigned'. At the bottom, there is a field for 'If Other, please specify:'.

Subject: 20001 Visit: Screening Visit Status: Enrolled Log Subject Info

Demographics

Participant Acoustic: abaz [Q] [▲] [▶]

Date of Visit: 06/08/2017 [Q] [▲] [▶] Now [Q] [▲] [▶]

1. What is your gender—for example, would you describe yourself as female, male, or transgender or other? ☒ Female ☐ Male, transgendered, or other

2. Birth Date 06/08/1983 [Q] [▲] [▶] 08-Jun-1983

3. Marital Status ☒ Annulled ☐ Divorced ☐ Interlocutory ☐ Legally Separated ☐ Married ☐ Never Married ☐ Widowed ☐ Polygamous ☐ Domestic Partner ☐ Other [Q] [▲] [▶]

If Other, please specify: [Q] [▲] [▶]

The following open query exists:

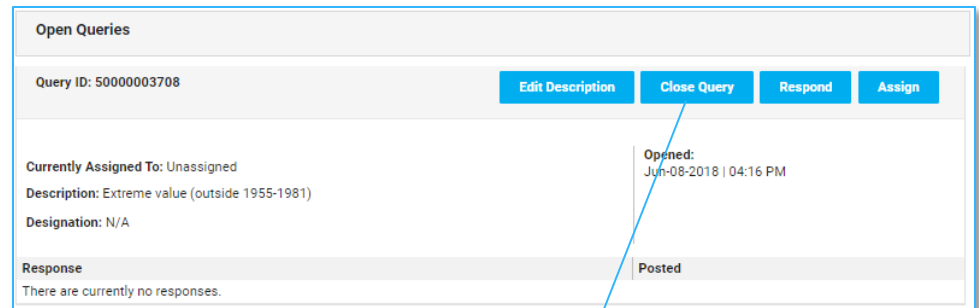
Variable: xbrthdat @ Screening Visit

Description: Extreme value (outside 1955-1981)

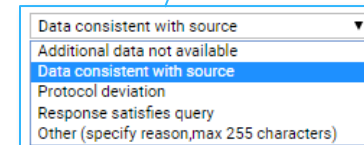
Assigned To: Unassigned

# DQ: Data Query Responses

- Respond
  - Start a dialogue
- Close Query
  - Document reason for data exception
- Assign
  - Redirect to another team member
- Auto close
  - Queries automatically disappear when condition is no longer met (the data are corrected)



The screenshot shows a web interface titled "Open Queries". It displays a specific query with ID "50000003708". At the top right of the query details are four buttons: "Edit Description", "Close Query", "Respond", and "Assign". Below the query ID, the "Currently Assigned To" is "Unassigned". The "Description" is "Extreme value (outside 1955-1981)" and the "Designation" is "N/A". On the right side, the "Opened" date and time are "Jun-08-2018 | 04:16 PM". At the bottom, there is a "Response" section with the text "There are currently no responses." and a "Posted" status.



A dropdown menu is shown, listing several options for data exceptions. The options are: "Data consistent with source", "Additional data not available", "Data consistent with source" (highlighted in blue), "Protocol deviation", "Response satisfies query", and "Other (specify reason,max 255 characters)".

# DQ: Data Query Management

- Form List Indicator
- Home Panel Summary
- Query Report
  - Filters
  - Bulk Response

Subject: 20001 Site: Oakland - Clinical Research Unit Status: Screening Log [Subject Info](#)

Manage Subject Progress

+	Forms	Data Entered	Double Data Entered	Open Queries	Status
-	Telephone Screening				
	Visit Status	✓			Complete
	Eligibility and Randomization	✓		▲ 4	Not Complete
-	Screening Visit				
	Visit Status	✓			Complete
	Demographics	✓		▲ 3	Not Complete
	Alcohol Use				Not Complete
	Tobacco Use	✓			Complete

LILA

HOME ENTER DATA MANAGE CODING ANALYSIS DASHBOARD

STUDY ENROLLMENT 76 OPEN QUERIES 155

Subjects [Add](#) [More](#)

80005  
80007  
80009  
80056  
80082

Queries [More](#)

80005 - 36-Week Post-Intervention - Visit Status - svdat  
80005 - 36-Week Post-Intervention - Visit Status - visitstatus  
80007 - 36-Week Post-Intervention - Visit Status - svdat  
80007 - 36-Week Post-Intervention - Visit Status - visitstatus  
80009 - 36-Week Post-Intervention - Visit Status - svdat

Query Listing

\* Please note that there may be a short delay after defining queries or entering data before the results are available on this page.

Query Type: [All Queries](#) Query Status: [All Open Queries](#) Site: [All Sites](#) Subject Status: [Enrolled](#) Forms: [All Forms](#) Field Status: [All Statuses](#) Assigned To: [All](#)

Custom query definition: [Type custom query definition name](#) Subject ID:  Query ID:  Sort by: [\[v\]](#)

[Apply](#)

[Export queries in Excel](#)

[Save](#)

1 of 2

Query Icon	Query ID	Name	Site	Subject ID	Visit	Form	Row Number	Days Open	Last Update	Close	Reason For Closing	Designation	Assigned To	Field Status
▲	80061266796	abcircum1: Missing Data	San Francisco	80094	12-Week Clinic Visit	Height and Weight		20	12/18/2019 2:06 PM	<input type="checkbox"/>	Select One	--	Unassigned	Missing
▲	80061266797	abcircum2: Missing Data	San Francisco	80094	12-Week Clinic Visit	Height and Weight		20	12/18/2019 2:06 PM	<input type="checkbox"/>	Select One	--	Unassigned	Missing
▲	80061274324	AEExpected: Missing Data	San Francisco	80087	Continuous Forms	Adverse Event SAE - CDASH	1	19	12/19/2019 10:28 AM	<input type="checkbox"/>	Select One	--	Unassigned	Missing
▲	80061274325	AEExpected: Missing Data	San Francisco	80087	Continuous Forms	Adverse Event SAE - CDASH	2	19	12/19/2019 10:28 AM	<input type="checkbox"/>	Select One	--	Unassigned	Missing
▲	80061274326	aefabs: Missing Data	San Francisco	80087	Continuous Forms	Adverse Event SAE - CDASH	1	19	12/19/2019 10:28 AM	<input type="checkbox"/>	Select One	--	Unassigned	Missing

Page Size: 50

# DQ:

## Notifications

- Triggered Email notifications
- Same mechanism as queries
- Create augmented process forms
- Example: ECG
  - Data fields
  - Process fields—control notifications to team members:
    - ECG uploaded (CC)
    - Ppt excluded (PI)
    - Letter required (PI)

Subject: 90024 Visit: Screening Visit Status: Complete Log [Subject Info](#)

ECG

**PART I: COORDINATOR SECTION**

Staff ID:  [Q](#)

Was a readable ECG tracing obtained? ☒ Yes --> Sign and date the ECG, upload the image into Medrio, and store the paper copy in the chart [Q](#) ☐ No --> ECG required for eligibility

Upload ECG File here: [File Attached](#) [Download](#) | [Clear File](#) [Q](#)

Does the preliminary ECG tracing include any of the following potentially significant alerts that require paging or calling the principal or co-investigator directly during the study visit?

Atrial fibrillation? ☒ No ☐ Yes --> Page or call PI [Q](#)

Atrial flutter? ☒ No ☐ Yes --> Page or call PI [Q](#)

Third-degree atrioventricular block? ☒ No ☐ Yes --> Page or call PI [Q](#)

Injury or ischemia characterized as acute or marked? ☒ No ☐ Yes --> Page or call PI [Q](#)

Does the ECG indicate a paced rhythm (pacemaker)? ☒ No ☐ Yes --> Confirm no pre-existing coronary artery disease, which would make them Ineligible. [Q](#)

**Note: Every participant must have an ECG, and that ECG must be reviewed by the PI (Alison Huang) or by a Co-I (Peter Ganz) before randomization, even if the preliminary machine reading is normal.**

**PART II: INVESTIGATOR SECTION**

Has the ECG image been reviewed by the principal or co-investigator? ☒ No [Q](#) ☐ Yes

Has the principal or co-investigator recommended exclusion of the participant based on ECG findings? ☒ No [Q](#) ☐ Yes - email sent to notify coordinator of exclusion

What was the ECG finding that prompted exclusion?  [Q](#)

Does the investigator recommend that the participant be given a standardized letter to take to her regular healthcare provider to obtain repeat ECG testing in the clinical setting, because of a significant abnormality detected on this FRAN ECG?? ☒ No - no significant abnormality was detected [Q](#) ☐ Yes - coordinator will be alerted by email to send letter

If yes, what abnormality on the FRAN ECG makes it advisable to send a standardized letter?  [Q](#)

**PART III: COORDINATOR FOLLOW UP**

Coordinator - was letter given to participant? ☒ No - specify reason why the required letter was not sent [Q](#) ☐ Yes

Reason letter was not sent:  [Q](#)



# DQ: Building Queries

- Sophisticated query builder
- Handles nested equations
- Drag-and-drop
- Timing choices
  - Across Visits
  - At Same Visit
  - Any Time
- Example
  - Nested And-Or

Create New Query Definition

Action(s)  
Fire Query:  Send Email:   
Query Designation:

Name:  Variable:   
Description (Optional):   
Embed value in description:  ☒ Do not show system-generated description

**Left Panel:**  
▶ Dipstick Urinalysis  
▶ Pregnancy Form  
▶ International Physical Activity  
▶ Healthy Days Core Module (C)  
hrqol1  
hrqol2  
hrqol2a  
hrqol3

Create a query when  of the following conditions are true:

hrqol2a at Screening Visit =  Don't Know/Not Sure Refused or Drag a variable here. [x]

hrqol3a at Screening Visit =  Don't Know/Not Sure Refused or Drag a variable here. [x]

When  of the following conditions are true:

hrqol4 at Screening Visit is not missing a value [x]  
hrqol4a at Screening Visit is not missing a value [x]  
Drag a variable or condition here.  
Drag a variable or condition here.

# Other Reports: Browse Data

- Data Listing
- Export
- Save & Share

**Browse Data Report**Report: Browse Data

Visits: At Any Visit

Variables:

xvsloc

xvsorres\_sysbp\_1

xvsorres\_diabp\_1

xvsorres\_pulse\_1

xvsorres\_sysbp\_2

xvsorres\_diabp\_2

xvsorres\_pulse\_2

BPALETRVALUE

xvsorres\_sysbp\_3

xvsorres\_diabp\_3

xvsorres\_pulse\_3

Subjects: All Enrolled Subjects (add Subgroup to this dropdown list)

Monitoring Status: All

Update Save

[Download in Excel](#)

1 of 1

Page Size: 50

Site	Group	Subject ID	Visit	Form	xvsorres_sysbp_1	xvsorres_diabp_1	xvsorres_pulse_1	xvsorres_sysbp_2	xvsorres_diabp_2	xvsorres_pulse_2
Oakland - Clinical Research Unit	Late Menopausal Transition	30001	1-Week Clinic Visit	Vital Signs	140	80	70	135	89	70
Oakland - Clinical Research Unit	Late Menopausal Transition	70001	Screening Visit	Vital Signs	130	80	70	120	75	60
Fremont - Clinical Research Unit	Late Menopausal Transition	10002	1-Week Clinic Visit	Vital Signs	125	68	60	120	65	60
Oakland - Clinical Research Unit	Late Menopausal Transition	30001	Screening Visit	Vital Signs	122	71	60	128	65	68
Oakland - Clinical Research Unit	Late Menopausal Transition	20001	Screening Visit	Vital Signs	121	55		122	60	68

# Other Reporting:

## Study Data Summary Report

- Site Level
- Filters
- Download

Study Data Summary Report

Last updated 01/12/2020 12:59 AM (Pacific Time)

Total export rows: 3

Site	Enrollment Goal	Enrollment Actual	Forms Expected	Forms Complete	Forms Not Complete	Forms Not Expected	Forms Done %	Queries Total	Queries Manual	Queries Open	Queries Responded	Queries Closed	Protocol Deviations	Locked	Locked %
Fremont - Clinical Research Unit	70	2	62	44	18	86	71%	88	2	11	0	77	1	0	0%
Oakland - Clinical Research Unit	70	17	1275	302	973	1468	24%	2607	0	2086	0	521	0	0	0%
San Francisco - Clinical Research Unit	70	2	142	38	104	376	27%	59	0	43	0	16	0	0	0%
Summary	210	21	1479	384	1095	1930	26%	2754	2	2140	0	614	1	0	0%

Form Monitored				
Required	Done	To Do	Done %	
Fremont - Clinical Research Unit	1	0	1	0%
Oakland - Clinical Research Unit	22	0	22	0%
San Francisco - Clinical Research Unit	1	0	1	0%

- Subject Level: Site Data Summary Report
- Form Level: Subject Data Summary Report

# Other Reports:

## BYO Clinical Data Report

- Long form table for Data Managers
- Access to full field (and form) level metadata

Long Form Data Update by									
Last updated 01/09/2020 12:50 AM (Pacific Time)									
Total export rows: 5,069									
<< < Page 1 of 102 > >>									
Rows Per Page 50									
Subject ID ↑	Visit	Form	Variable	Value	Row Number	Entered By	Last Updated	Last Updated By	Date entered / collection date
10001	Continuous Forms	Comments	Commentstext	asdfasd asldjf alsdj f,alskdj f,laskdj f,laskdj f,alksdjf,alksdj	1	Mike Schembri (mschembri)	05/31/2019 11:12 AM	Mike Schembri (mschembri)	05/31/2019 11:12 AM
10001	Baseline Visit	Incontinence Impact Questionnaire (IIQ)01H00M	iiq20	Not At All		Mike Schembri (mschembri)	03/11/2019 11:01 AM	Mike Schembri (mschembri)	03/11/2019 11:01 AM
10001	Baseline Visit	Pittsburgh Sleep Quality Index (PSQI)01H00M	psq3	08:40 AM		Mike Schembri (mschembri)	03/11/2019 11:01 AM	Mike Schembri (mschembri)	03/11/2019 11:01 AM
10001	Baseline Visit	Perceived Stress Scale (PSS-10)01H00M	pss1	Almost Never		Mike Schembri (mschembri)	03/11/2019 11:01 AM	Mike Schembri (mschembri)	03/11/2019 11:01 AM
10001	Baseline Visit	Perceived Stress Scale (PSS-10)01H00M	pss4	Almost Never		Mike Schembri (mschembri)	03/11/2019 11:01 AM	Mike Schembri (mschembri)	03/11/2019 11:01 AM
10001	Telephone Screening	Eligibility and Randomization	lierandomized	Eligible, participant randomized		Mike Schembri (mschembri)	03/11/2019 10:16 AM	Mike Schembri (mschembri)	03/11/2019 10:16 AM
10001	Baseline Visit	Perceived Stress Scale (PSS-10)01H00M	pss3	Almost Never		Mike Schembri (mschembri)	03/11/2019 11:01 AM	Mike Schembri (mschembri)	03/11/2019 11:01 AM
10001	Baseline Visit	Physical Function (PROMIS-8)01H00M	pfa11	With a little difficulty		Mike Schembri (mschembri)	03/11/2019 11:01 AM	Mike Schembri (mschembri)	03/11/2019 11:01 AM
10001	Baseline Visit	Spielberger State Trait Anxiety Inv (STAI)01H00M	stai4	Moderately So		Mike Schembri (mschembri)	03/11/2019 11:01 AM	Mike Schembri (mschembri)	03/11/2019 11:01 AM
10001	Baseline Visit	Spielberger State Trait Anxiety Inv (STAI)01H00M	stai36	Sometimes		Mike Schembri (mschembri)	03/11/2019 11:01 AM	Mike Schembri (mschembri)	03/11/2019 11:01 AM
10001	Baseline Visit	Spielberger State Trait Anxiety Inv (STAI)01H00M	stai37	Almost Never		Mike Schembri (mschembri)	03/11/2019 11:01 AM	Mike Schembri (mschembri)	03/11/2019 11:01 AM

# Other Reports:

## BYO Subject Data Trend

- Transposed by visit
- Build Your Own reports are customizable
- Schedule & Distribute (to email list)
  - BYO and/or Standard Reports

PSQI Time to Bed

Last updated 01/16/2020 02:39 AM (Pacific Time)Total export rows: 17

<< < Page 1 of 1 > >>Rows Per Page 50

		12-Week Clinic Visit	6-Week Clinic Visit	Baseline Visit
Subject ID	Subject Status	psqi1 (Pittsburgh Sleep Quality Index (PSQI)01H00M) ↓	psqi1 (Pittsburgh Sleep Quality Index (PSQI)01H00M)	psqi1 (Pittsburgh Sleep Quality Index (PSQI)01H00M)
90023	Enrolled	12:21 AM		09:00 PM
10002	Enrolled	11:50 PM	10:35 PM	08:20 PM
10001	Enrolled	10:00 AM	09:50 PM	10:40 PM
90025	Enrolled	04:50 PM	07:40 PM	08:30 PM

Schedule: PSQI Time to Bed

Schedule Weekly

Every 1 week(s)

☐ Sunday☒ Monday☐ Tuesday☐ Wednesday☐ Thursday☐ Friday☐ Saturday

Start Time 9:00 AMTimezone PDT (GMT-7:00)

Recipients (separate by commas)  
michael.schembri@ucsf.edu

Note that reports are generated and distributed using your permissions access. Ensure that reports are constructed and scheduled such that recipients are permitted to access the data they are receiving.

☒ Include report as e-mail attachment

CancelSchedule

# Other Reports

- Linked data report
- Data audit log
- Double data entry report
- Field status report
- Missing data report
- Unblinding subjects report
- Unblind log
- Query aging report
- Subgroup counts
- Weekly enrollment
- Dashboard

# Workflow Facilitation Overview

---

- (Clinical Coordinator)
- Data Coder
- Data Monitor
- Data Manager
- Developer

# Data Coder: Text Recodes

- Write-in fields
  - Assign codes online
  - Get second variable containing coded values

**Data Coding**

Coding variable: cmtrt

Unique Value For This Variable	Coded Value
Acetaminophen	Acetaminophen
ACETAMINOPHEN	Acetaminophen
ACETAMINOPHEN WITH CODEINE	Opioid
ACETYL L CARTININE	NA
Zinc	NA
ZINC	NA
ZOLOFT	Antidepressant
Zyrtec	Antihistamine

>> Bulk Code

Coding method description: [?]

Diabetes

HTN

Vitamin/Supplement/OTC/ other

Asthma

NSAIDS/pain medication

Cancel

Update



# Data Coder: Dictionary coding

- Types

- MedDRA<sup>1</sup> system organ class—Adverse events
- WHO<sup>2</sup> drug information—Medications

- Interface

- Coder role (PI)
- Automatic coding
  - Exact Match
  - Defined Synonyms
  - DM applies, PI verifies
- Can assign multiple codes

- Data Product

- All MedDRA hierarchies

- Coding Panel & Report

Form : Adverse Event SAE - CDASH at Continuous Forms Subject : 80080 MedDRA 22.0 (Hierarchy)

Search the dictionary with:  
☐ Contains ☐ Starts With ☐ Exact Match

Verbatim Term: ( View and Create Queries )  
sciatica flare-up

Dictionary Search:  
sciatica

LLT Code	LLT	PT	HLT	HLGT	SOC
<input type="checkbox"/> 10039674	Sciatica	(PT) 10039674 Sciatica	(HLT) 10052772 Lumbar spinal cord and nerve root disorders	(HLGT) 10041543 Spinal cord and nerve root disorders	(SOC) 1C disorder:
<input type="checkbox"/> 10039675	Sciatica (excl lumbar disc lesion)	(PT) 10039674 Sciatica	(HLT) 10052772 Lumbar spinal cord and nerve root disorders	(HLGT) 10041543 Spinal cord and nerve root disorders	(SOC) 1C disorder:
<input checked="" type="checkbox"/> 10039676	Sciatica aggravated	(PT) 10039674 Sciatica	(HLT) 10052772 Lumbar spinal cord and nerve root disorders	(HLGT) 10041543 Spinal cord and nerve root disorders	(SOC) 1C disorder:

Selected Terms:

LLT Code	LLT	PT	HLT	HLGT	SOC
<input checked="" type="checkbox"/> 10039676	Sciatica aggravated	(PT) 10039674 Sciatica	(HLT) 10052772 Lumbar spinal cord and nerve root disorders	(HLGT) 10041543 Spinal cord and nerve root disorders	(SOC) 10029205 Nervous system disorders

Remove Selected Terms Save as Synonym and Apply to Selected Verbatims

<sup>1</sup> Medical Dictionary for Regulatory Activities

<sup>2</sup> World Health Organization

# Data Monitor

- Monitors sign off on forms after review
- Create controlled multi-stage monitoring workflows
- Monitor entire forms or selected variables

Subject: 0001 Site: Detroit Status: Enrolled Log Subject Info								View: Tabula
Manage Subject Progress								
+ Forms	Data Entered	Open Queries	Status	Form Monitored	DM Review	Form Signed	Locked	
- Screening								
Inclusion Exclusion	✓		Complete Final	✓ <sub>M</sub>	✓ <sub>DM</sub>	✓ <sub>S</sub>	✓	
- Baseline Visit								
Randomization	✓		Complete Final	✓ <sub>M</sub>	✓ <sub>DM</sub>	✓ <sub>S</sub>	✓	
Enrollment	✓		Complete Final	✓ <sub>M</sub>	✓ <sub>DM</sub>	✓ <sub>S</sub>	✓	
Scoring	✓		Complete Final	✓ <sub>M</sub>	✓ <sub>DM</sub>	✓ <sub>S</sub>	✓	
Office Visits	✓		Complete Final	✓ <sub>M</sub>	✓ <sub>DM</sub>	✓ <sub>S</sub>	✓	
Labs			Not Expected	N/A			✓	
Metabolic Panel			Not Expected	N/A			✓	
- Visit 1								
Office Visits	✓		Complete Final	✓ <sub>M</sub>	✓ <sub>DM</sub>	✓ <sub>S</sub>	✓	
Labs			Not Expected	N/A			✓	
ECG Results			Not Expected	N/A			✓	
Physical Examination			Not Expected	N/A			✓	
Impact on Patient Lifestyle			Not Complete				✓	

# Data Manager: Subject Status

- Subject Status Categories

- Screening

- Excluded

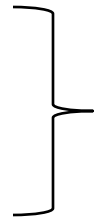
- Enrolled

- Completed

- Early Termination

- Other

- *Custom*



“Enrolled” for reporting purposes

- Rule based automatic updates

- Manual Override

- Subject status can be used in queries

- Reports focus on enrolled participants

# Data Manager: Field Properties

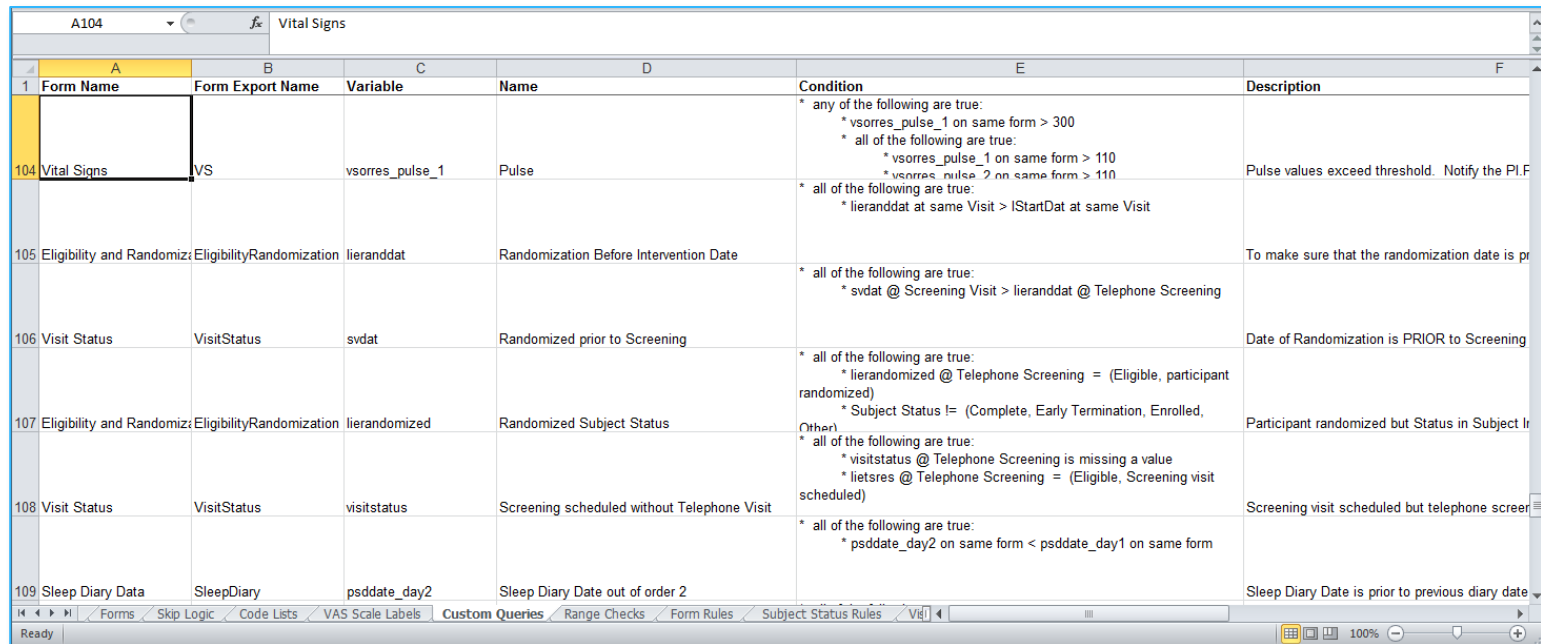
- Field Properties
  - SAS Label
  - Export Name
  - Flags:
    - PHI
    - SDTM (CDISC)
    - Required
  - Numeric length and precision
  - Coded Values
    - Character or Numeric
  - Include on Find Form
    - Search for subjects by field values

The screenshot shows the 'Field Properties' dialog for the variable 'vsorres\_sysbp\_1'. The dialog is organized into several sections:

- Variable Name [Required]:** vsorres\_sysbp\_1
- SAS Label Export [Required]:** Systolic Blood Pressure
- Description:** (Empty text box)
- Export Name [Required]:** VSORRES\_SYSBP\_1
- SDTM:** ☒
- Label Text on Form:** Systolic: (Rich text editor)
- Label Position:** Above
- Label Text Alignment:** Left
- Label Width:** (Empty text box) px
- External ID:** VSORRES\_SYSBP\_1
- Data Type:** Number (continuous)
- Display As:** Text Box
- Units:** (Empty text box)
- Form Display Length:** 6
- Tab Order:** (Empty text box)
- Enforce Length and Precision:** [No format selected] to [ ] digits and up to [ ] decimal places
- Display Precision:** 0
- Integer:** ☐
- Protected Health Information (PHI):** Baseline variable: ☐ \*Required: ☐ Analysis Variable: ☐ Coded Value Type: ☐ Include on Find Form: ☐ Read Only: ☐
- Entered Value:** ☐ **Coded Value:** ☐
- Coded Value Type:** Numeric
- Ranges:** Ranges are used in analysis, e.g. in a Baseline Table. There are currently no ranges defined for this Variable.
- Create a New Range:** Add a new Range to this Variable named [ ] which will include all values starting with [ ] and ending with [ ]. [Add Range](#)
- Buttons:** [Define Skip Logic](#), [Delete Variable](#), [Save and Close](#)

# Data Manager: Documentation

- Detailed Data Dictionary
  - Forms, fields, codes
  - Configuration details
  - **Includes:** General, Sites, Groups, Forms, Skip Logic, Coded Lists, VAS Scale Labels, Custom Queries, Range Checks, Form Rules, Subject Status Rules, Visits, Visit schedule, Monitoring, ePRO Configuration, ePRO Schedule, Roles & Permissions



	A	B	C	D	E	F
	Form Name	Form Export Name	Variable	Name	Condition	Description
104	Vital Signs	VS	vsorres_pulse_1	Pulse	* any of the following are true: * vsorres_pulse_1 on same form > 300 * all of the following are true: * vsorres_pulse_1 on same form > 110 * vsorres_pulse_2 on same form > 110	Pulse values exceed threshold. Notify the PI.
105	Eligibility and Randomization	EligibilityRandomization	lieranddat	Randomization Before Intervention Date	* all of the following are true: * svsdat @ Screening Visit > lieranddat @ Telephone Screening	To make sure that the randomization date is prior to screening
106	Visit Status	VisitStatus	svsdat	Randomized prior to Screening	* all of the following are true: * lierandomized @ Telephone Screening = (Eligible, participant randomized) * Subject Status != (Complete, Early Termination, Enrolled, Other)	Date of Randomization is PRIOR to Screening
107	Eligibility and Randomization	EligibilityRandomization	lierandomized	Randomized Subject Status	* all of the following are true: * visitstatus @ Telephone Screening is missing a value * lietsres @ Telephone Screening = (Eligible, Screening visit scheduled)	Participant randomized but Status in Subject Information is not randomized
108	Visit Status	VisitStatus	visitstatus	Screening scheduled without Telephone Visit	* all of the following are true: * psddate_day2 on same form < psddate_day1 on same form	Screening visit scheduled but telephone screening visit not scheduled
109	Sleep Diary Data	SleepDiary	psddate_day2	Sleep Diary Date out of order 2		Sleep Diary Date is prior to previous diary date

# Data Manager: Documentation

- Blank Annotated CRFs
  - Short
  - Long

FRAN\_\_Dev\_2  
Demographics

Participant Acrostic:  [Demog.DMACROS, TXT, 4000]

Date of Visit:  Now [Demog.DMDATE, DAT, 10]

1. What is your gender—for example, would you describe yourself as female, male, or transgender or other? ☐ Female [Demog.SEX, CNOM, 42]  
☐ Male, transgendered, or other (INELIGIBLE)

2. Birth Date  [Demog.brthdat, DAT, 10]

3. Marital Status ☐ Annulled [Demog.maristat, CNOM, 17]  
☐ Divorced  
☐ Interlocutory  
☐ Legally Separated  
☐ Married  
☐ Never Married  
☐ Widowed  
☐ Polygamous  
☐ Domestic Partner  
☐ Other

If Other, please specify:  [Demog.maristatother, TXT, 4000]

5. Race ☐ American Indian or Alaska Native [Demog.RACE, CMUL, 41]  
☐ Asian  
☐ Black or African American  
☐ Native Hawaiian or Other Pacific Islander  
☐ White or Caucasian  
☐ Other

If Other, please specify  [Demog.RACEOTHER, TXT, 4000]

4. Ethnicity ☐ Not Hispanic or Latina [Demog.ETHNIC, CNOM, 22]  
☐ Hispanic or Latina  
☐ Not Reported  
☐ Unknown

	Name	Export Name	Type	Max length	Categories
[1]	Participant Acrostic:	DMACROS	Text or Any Value	4000	
[2]	Date of Visit:	DMDATE	Date	10	
[3]	1. What is your gender—for example, would you describe yourself as female, male, or transgender or other?	SEX	Categorical select one (nominal)	42	
[4]	2. Birth Date	brthdat	Date	10	
[5]	3. Marital Status	maristat	Categorical select one (nominal)	17	
[6]	If Other, please specify:	maristatother	Text or Any Value	4000	
[7]	5. Race	RACE	Categorical select multiple	41	
[8]	If Other, please specify	RACEOTHER	Text or Any Value	4000	
[9]	4. Ethnicity	ETHNIC	Categorical select one (nominal)	22	
[10]	6. What is the highest level of education that you have completed?	SCORRES_EDUCATION	Categorical select one (nominal)	50	
[11]	Transcribed from paper?	sourcedoc_demog	Categorical select multiple	3	

# Data Manager: Documentation

- Completed CRF PDFs

Subject Identifier: 10002	Site: Fremont - Clinical Research Unit Visit: Screening Visit	Group: Late Menopausal Transition Form: Demographics
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Participant Acrostic:	<input type="text" value="AMAM"/>
Date of Visit:	<input type="text" value="10/25/2019"/> <a href="#">Now</a> 25-Oct-2019
1. What is your gender—for example, would you describe yourself as female, male, or transgender or other?"	<input checked="" type="radio"/> Female <input type="radio"/> Male, transgendered, or other (INELIGIBLE)
2. Birth Date	<input type="text" value="05/02/1970"/> <a href="#">31</a> 02-May-1970
3. Marital Status	<input type="radio"/> Annulled <input type="radio"/> Divorced <input type="radio"/> Interlocutory <input checked="" type="radio"/> Legally Separated <input type="radio"/> Married <input type="radio"/> Never Married <input type="radio"/> Widowed <input type="radio"/> Polygamous <input type="radio"/> Domestic Partner <input type="radio"/> Other
If Other, please specify:	<input type="text"/>
5. Race	<input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input checked="" type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> White or Caucasian <input type="checkbox"/> Other
If Other, please specify	<input type="text"/>
4. Ethnicity	<input checked="" type="radio"/> Not Hispanic or Latina <input type="radio"/> Hispanic or Latina <input type="radio"/> Not Reported <input type="radio"/> Unknown

01/13/2020 11:00 (Pacific Standard Time)	FRAN - Test	1
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# Data Manager: Data products

- Data product
  - Relational—1 table per form
  - SAS, SPSS, Stata, Tab-delimited
  - Two variables: Formatted Value, Coded Value
- API Access
- ODM CDISC data model
  - XML containing both study data and study configuration

WORK.DEMOG ▾												
Filter and Sort Query Builder Where Data Describe Graph Analyze Export Send To												
	SubjectID	Visit	DMACROS	DMACROS_CODED	DMDATE	DMDATE_CODED	SEX	SEX_CODED	brthdat	brthdat_CODED	SCORRES_EDUCATION	SCORRES_EDUCATION_CODED
1	10010	Screening Visit		.	11/27/2017	.	Female	F	.	.	High school	12
2	30001	Screening Visit	Abab	.	04/09/2018	.	Female	F	12/29/1973	.	Master's Degre...	18
3	30011	Screening Visit	abcd	.	10/12/2018	.	Female	F	.	.	College gradua...	16
4	20001	Screening Visit	abaz	.	10/12/2016	.	Female	F	06/08/1983	.	High school	12
5	40006	Screening Visit	ABAB	.	09/13/2019	.	Male, transgen...	NotFemale	.	.	Some college/...	14
6	30002	Screening Visit	BPRO	.	10/12/2019	.	Female	F	04/05/1970	.	College gradua...	16
7	30016	Screening Visit	JOAM	.	11/01/2016	.	Female	F	11/01/1980	.	Some college/...	14
8	40007	Screening Visit	ASAS	.	01/15/2017	.	Female	F	.	.	High school	12
9	30009	Screening Visit	ABCD	.	04/13/2017	.	Female	F	05/26/1959	.	No formal educ...	00
10	40009	Screening Visit	AABB	.	11/26/2018	.	Female	F	11/15/1970	.	Some college/...	14
11	70002	Screening Visit	abab	.	01/10/2019	.	Female	F	01/01/1960	.	Some college/...	14
12	10002	Screening Visit	AMAM	.	10/25/2019	.	Female	F	05/02/1970	.	Master's Degre...	18

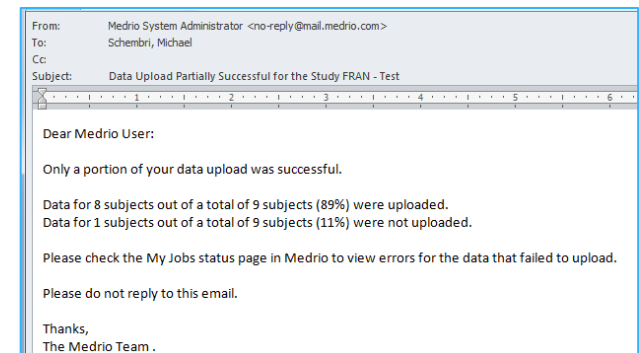


# Data Manager: Offline Entry

- Offline entry
  - Download formatted XL sheet templates

</

- Upload edited sheet
- Form and variable logic is checked
- Emailed upload status report



# Data Manager: Bulk Upload

- Bulk uploads
  - Create Map of Excel columns to any form fields
    - Map Field Names
    - Map Coded Values

The screenshot displays the 'Bulk Upload/Data Mapping' interface. At the top, the title 'Bulk Upload/Data Mapping' is shown. Below it, the 'Create or Edit Map Definition' section contains fields for 'Map Name' (FSH2), 'Map Description (Optional)', 'Form Name' (FSH Lab Result), 'Grid Name' (N/A), and 'File Name' (FSH2.xlsx). The main section, 'Map Columns to Fields', includes a 'Drag items from the File list to the Mapping List. View Mapping Activity Log' instruction. It features two columns: 'Form (Field) Name' and 'File (Column) Name'. The 'Form (Field) Name' column lists fields like 'Visit', 'Participant Acrostic (Text)', 'Collection Date: (Date)', 'Does the Screenshot meet any of (Multi)', '2. Was FSH sample collected fr (Self)', 'If No, please specify why not (Text)', and '3. FSH Level (mU/mL): (Num)'. The 'File (Column) Name' column lists corresponding file columns like 'SubjectID', 'Visit', 'Acrostic', 'LBDAT', 'Reason Done', 'Done', and 'FSHResult'. A 'Provide at Upload' button is visible at the top of the file column list.

Form (Field) Name	Mapping	File (Column) Name
Visit	Visit	SubjectID
Participant Acrostic: (Text)	Acrostic	Visit
Collection Date: (Date)	LBDAT	Acrostic
Does the Screenshot meet any of (Multi)		LBDAT
2. Was FSH sample collected fr (Self)		Reason Done
If No, please specify why not (Text)		Done
3. FSH Level (mU/mL): (Num)	FSHResult	FSHResult

- Upload sheet (CSV or Excel)
- Form and variable logic rules are checked (Ppt ID must already exist)
- Emailed upload status report

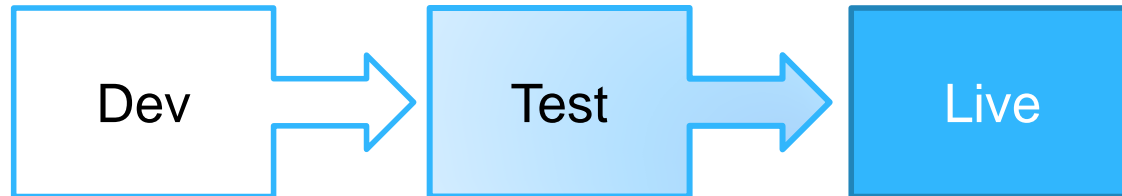
# Developer:

## Special Forms: Randomization, Labs

- Blinded randomization
  - Upload randomization scheme
  - Controlled randomization assignment
  - Blinded intervention group
- Lab reference ranges
  - Incorporate reference ranges into the form
  - Alters for out of range values
  - Ranges are specific to each:
    - Laboratory
    - Ppt characteristic (optional)
  - Bulk upload lab results

# Developer: Controlled Deployment

- Isolated duplicate environments
  - Dev
  - Test (testing, training)
  - Live
- Easy deployment
  - Activity monitoring
- Versioning documentation automated
- Deploy to select sites independently



# Other topics

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- Mobile
- Security
- Support

# Mobile

- DDC: Direct Data Capture
  - Coordinator facing
  - Tablet data collection (replace paper forms)
- ePRO: Patient Reported Outcomes
  - Tablet (in clinic)
    - Secure PRO—participant lock out
  - Email Survey Link
    - Create activation windows
    - Invitations sent automatically
    - Custom Study Login Portal: <https://lila.filloutyourform.com/>
- eConsent
  - Interactive: Video, quizzes
  - Versioning
    - Tracked
    - Supports re-consenting (requiring re-consent with updated consent form)
    - Automatically push updates to sites
  - In clinic (tablet)
  - Remotely (coming soon)

# Security & Regulation

- 21 CFR Part 11
- HIPAA compliant
- GDPR (European privacy regulations)
- Audit trails
  - Data: data edits, reason for change, queries, devices source
  - Development: monitoring, lab reference ranges, un-blinding events, deployment
- Data Redundancy: cloud based redundancy, recovery, access
- Google Cloud
  - SOC 1, 2, 3 Reports, ISO 27001, ISO 27017, ISO 27018, Cloud Security Alliance, PCI Compliance, HIPAA, CJIS, EU Model Clauses, and Privacy Shield compliance
  - Encrypted—AES 256-bit SSL and 2048 bit RSA public keys
  - Customers own the data on our servers
- Validated Software
  - Installation (IQ) and Functional Testing (OQ) with each release
  - Test environments available for new releases (to test study impacts pre-release)
  - Opt in or Opt out of new features
- Annual UCSF Risk Assessment
- UC BAA Agreement

# Support

- Online Manuals
- Training videos
- Knowledge based articles
- Online Community platform
  - Post questions, bugs, feature requests
- 24-hour support
- Annual conferences



# Questions

Thank you!

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