

# 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. At the top left is the 'LILA' logo. The top right navigation bar includes 'LILA', a user profile icon for 'mechembri', 'Help', and 'Logout'. Below this is a secondary navigation bar with icons for 'HOME', 'ENTER DATA', 'MANAGE', 'CODING', 'ANALYSIS', and 'DASHBOARD'. A 'Quick Links' section on the right contains a search box with 'Subject ID' and a magnifying glass icon.

The main content area is divided into three columns:

- STUDY ENROLLMENT 79**: A list of 15 subject IDs (80005 to 80131) with 'Add' and 'More' buttons.
- OPEN QUERIES 138**: A list of 18 query titles (e.g., '80005 - 36-Week Post-Intervention - Visit Status - svdat') with 'Add' and 'More' buttons.
- JANUARY 16, 2020 Thursday**: A list of 18 approval entries (e.g., '80062 - Baseline Visit - 3 Day Voiding Diary Data Entry') with a 'More' button.

# Medrio Overview

- Participant Summary

LILA | mschembri | Help | Logout

HOME - ENTER DATA - MANAGE - CODING - ANALYSIS - DASHBOARD

Quick Links - Subject ID

Subject: 82061 Site: Stanford Status: Enrolled Log Subject Info View: Tabular

### Manage Subject Progress

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**

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 type="button" value="Q"/> ▶
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 type="button" value="Q"/> ▶
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 type="button" value="Q"/> ▶
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 type="button" value="Q"/> ▶

# 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:

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

2. Medications List

Row Tools	Medication or Therapy:
1 <input type="checkbox"/>	<input type="text" value="Asprin"/>
2 <input type="checkbox"/>	<input type="text" value="Antihistamine"/>
3 <input type="checkbox"/>	<input type="text"/>
4 <input type="checkbox"/>	<input type="text"/>
5 <input type="checkbox"/>	<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?  
(if No, the participant is Ineligible)  Yes  
 No --> 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:      
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 <input type="button" value="Q"/>	Day 1 <input type="button" value="Q"/>	07:30 AM <input type="button" value="Q"/>	10:30 PM <input type="button" value="Q"/>	<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	<input type="button" value="Q"/> 2 <input type="button" value="Q"/>	<input type="button" value="Q"/> 3 <input type="button" value="Q"/>	<input type="button" value="Q"/> 4 <input type="button" value="Q"/>
2 <input type="button" value="Q"/>	Day 2 <input type="button" value="Q"/>	07:30 AM <input type="button" value="Q"/>	10:30 PM <input type="button" value="Q"/>	<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	<input type="button" value="Q"/> 1 <input type="button" value="Q"/>	<input type="button" value="Q"/> 2 <input type="button" value="Q"/>	<input type="button" value="Q"/> 3 <input type="button" value="Q"/>
3 <input type="button" value="Q"/>	Day 3 <input type="button" value="Q"/>	07:57 AM <input type="button" value="Q"/>	12:00 AM <input type="button" value="Q"/>	<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	<input type="button" value="Q"/> 3 <input type="button" value="Q"/>	<input type="button" value="Q"/> 4 <input type="button" value="Q"/>	<input type="button" value="Q"/> 5 <input type="button" value="Q"/>

# 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 type="radio"/> Yes <input checked="" type="radio"/> No	9/25/2018 25-Sep-2018
2		Week 6	2	Other	Ankle sprain	10/30/2018 30-Oct-2018	<input type="radio"/> Yes <input checked="" type="radio"/> No	MM/dd/yyyy
3		Week 6	3	Cold/flu		10/25/2018 25-Oct-2018	<input type="radio"/> Yes <input checked="" 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	✓

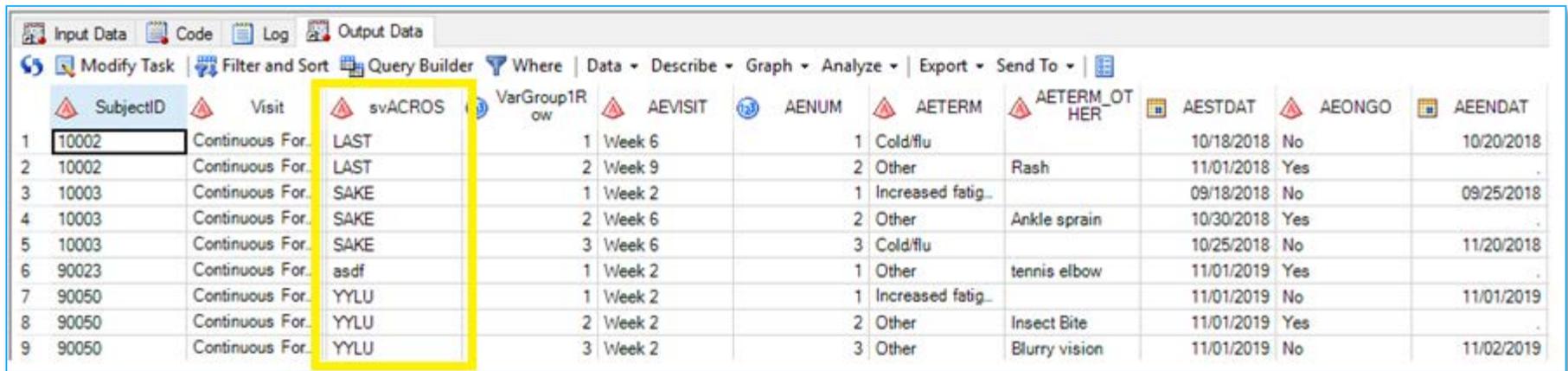
Subject: 1001 Site: Site A Status: Enrolled [Subject Info](#)

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 displays a data management interface with a table of records. The table has the following columns: SubjectID, Visit, svACROS, VarGroup1R, AEVISIT, AENUM, AETERM, AETERM\_OT, AESTDAT, AEONGO, and AEENDAT. The svACROS column is highlighted with a yellow box. The data is as follows:

	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
  
- Other Reports
- Data Monitors (following)



Core Data Quality

# 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
-	Baseline/Randomization Visit				
	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 ▾
-	1-Week Clinic Visit				
	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:  Groups:  Visits:  Forms:

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

All  
 Late Menopausal Transition  
 Post Menopausal

All  
 Telephone Screening  
 Screening Visit  
 Baseline/Randomization Visit

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	<a href="#">Sleep Diary Data</a>	Oct-28-2019	74	74
10002	Fremont - Clinical Research Unit	2-Week Clinic Visit	<a href="#">Visit Status</a>	Nov-11-2019	60	57
30002	Fremont - Clinical Research Unit	Baseline/Randomization Visit	<a href="#">Hot Flash Diary Data Summary</a>	Nov-17-2019	54	54
30002	Fremont - Clinical Research Unit	Baseline/Randomization Visit	<a href="#">Sleep Diary Data</a>	Nov-17-2019	54	54
30002	Fremont - Clinical Research Unit	1-Week Clinic Visit	<a href="#">Visit Status</a>	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:

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#### Define

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

at  =  or

**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 for a subject named '20001' during a 'Screening Visit'. The subject's status is 'Enrolled'. The 'Demographics' section is active, showing fields for 'Participant Acrostic' (abaz), 'Date of Visit' (06/08/2017), and 'Birth Date' (06/08/1983). A data query alert is triggered for the 'Birth Date' field, indicating an 'Extreme value (outside 1955-1981)'. The alert box provides details: Variable: xbrthdat @ Screening Visit, Description: Extreme value (outside 1955-1981), and Assigned To: Unassigned. The 'Marital Status' field is also visible with radio button options: Annulled, Divorced, Interlocutory, Legally Separated, Married, Never Married, Widowed, Polygamous, Domestic Partner, and Other.

# 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)

Open Queries

Query ID: 50000003708

Edit Description Close Query Respond Assign

Currently Assigned To: Unassigned  
Description: Extreme value (outside 1955-1981)  
Designation: N/A

Opened: Jun-08-2018 | 04:16 PM

Response  
There are currently no responses.

Posted

Data consistent with source

Additional data not available

Data consistent with source

Protocol deviation

Response satisfies query

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
<b>Telephone Screening</b>				
Visit Status	✓			Complete
Eligibility and Randomization	✓		▲ 4	Not Complete
<b>Screening Visit</b>				
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
80009 - 36-Week Post-Intervention - Visit Status - visitstatus

**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 Eligibility and Randomization Visit Status Demographics Field Status: All Statuses Assigned To: All

Custom query definition:  Subject ID:  Query ID:  Sort by:

[Apply](#) [Export queries in Excel](#) [Save](#)

1 of 2 Page Size: 50

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

# 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

The screenshot displays the 'Create New Query Definition' interface. At the top, there are fields for 'Action(s)', 'Fire Query:' (set to 'Yes'), 'Send Email:' (set to 'None'), and 'Query Designation:'. Below this, the 'Name:' field contains 'Missing Q4 Values Using Q2 and Q3', and the 'Variable:' field is set to 'hrqol2a at Screening Visit'. The 'Description (Optional):' field contains the text 'Q4 should not be entered (since both 2 and 3 are None)'. There is a checkbox for 'Do not show system-generated description' which is checked. On the left, a tree view shows a hierarchy of categories: 'Dipstick Urinalysis', 'Pregnancy Form', 'International Physical Activity', and 'Healthy Days Core Module (CT)'. Under 'Healthy Days Core Module (CT)', there are four items: 'hrqol1', 'hrqol2', 'hrqol2a', and 'hrqol3'. The main area is titled 'Create a query when all (AND) of the following conditions are true:'. It contains two rows of conditions, each with a variable, an equals sign, and a dropdown menu. The first row is 'hrqol2a at Screening Visit = None Don't Know/Not Sure Refused'. The second row is 'hrqol3a at Screening Visit = None Don't Know/Not Sure Refused'. Below these, there is a section titled 'When any (OR) of the following conditions are true:'. It contains two rows of conditions: 'hrqol4 at Screening Visit is not missing a value' and 'hrqol4a at Screening Visit is not missing a value'. There are also two empty dashed boxes for additional conditions.

# 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
- BPALERTVALUE
- 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%
<b>Summary</b>	<b>210</b>	<b>21</b>	<b>1479</b>	<b>384</b>	<b>1095</b>	<b>1930</b>	<b>26%</b>	<b>2754</b>	<b>2</b>	<b>2140</b>	<b>0</b>	<b>614</b>	<b>1</b>	<b>0</b>	<b>0%</b>

	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,alskdj f,askdj f,alksdj f,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	psqj3	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 AM ⌚ Timezone: 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

Cancel Schedule

# 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	>> Bulk Code
Acetaminophen	<input type="text" value="Acetaminophen"/>	
ACETAMINOPHEN	<input type="text" value="Acetaminophen"/>	
ACETAMINOPHEN WITH CODEINE	<input type="text" value="Opioid"/>	
ACETYL L CARTININE	<input type="text" value="NA"/>	
Zinc	<input type="text" value="NA"/>	
ZINC	<input type="text" value="NA"/>	
ZOLOFT	<input type="text" value="Antidepressant"/>	
Zyrtec	<input type="text" value="Antihistamine"/>	

Coding method description: [?]

Diabetes  
HTN  
Vitamin/Supplement/OTC/ other  
Asthma  
NSAIDS/pain medication

# 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: Tabular

### Manage Subject Progress

Forms	Data Entered	Open Queries	Status	Form Monitored	DM Review	Form Signed	Locked
<b>[-] Screening</b>							
Inclusion Exclusion	✓		Complete Final				
<b>[-] Baseline Visit</b>							
Randomization	✓		Complete Final				
Enrollment	✓		Complete Final				
Scoring	✓		Complete Final				
Office Visits	✓		Complete Final				
Labs			Not Expected	N/A			
Metabolic Panel			Not Expected	N/A			
<b>[-] Visit 1</b>							
Office Visits	✓		Complete Final				
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

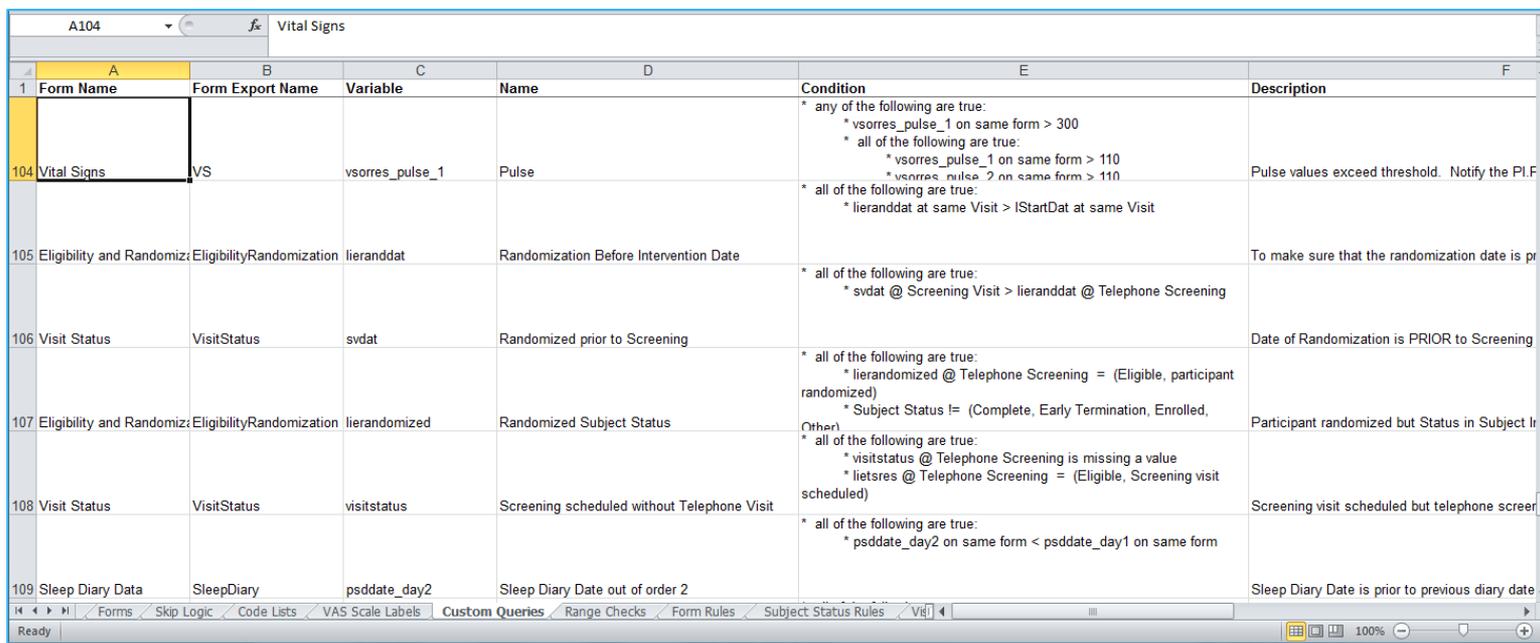
- Field Properties
  - SAS Label
  - Export Name
  - Flags:
    - PHI
    - SDTM (CDISC)
    - Required
  - Numeric length and precision
  - Coded Values
    - Character or Numeric
  - Include on Find Form
    - Search for subjects by field values

The screenshot shows the 'Field Properties' dialog box for the variable 'vsorres\_sysbp\_1'. The dialog is titled 'vsorres\_sysbp\_1' and has a 'Save and Close' button in the top right corner. The main content area is divided into several sections:

- Variable Name [Required]:** vsorres\_sysbp\_1
- Label Text on Form:** Systolic
- SAS Label Export [Required]:** Systolic Blood Pressure
- Description:** (Empty text area)
- Export Name [Required]:** VSORRES\_SYSBP\_1
- SDTM:**
- Label Position:** Above
- Label Text Alignment:** Left
- Label Width:** (Empty) px
- External ID:** VSORRES\_SYSBP\_1
- Data Type:** Number (continuous)
- Display As:** Text Box
- Units:** (Empty)
- Form Display Length:** 6
- Tab Order:** (Empty)
- Enforce Length and Precision:** [No format selected]
- Display Precision:** 0
- Protected Health Information (PHI):** Baseline variable:  \*Required:  Analysis Variable:  Coded Value Type:  Entered Value:  Coded Value:
- 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 (bottom left), Delete Variable (bottom right)

# 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



The screenshot displays a software interface window titled 'Vital Signs' with a table of configuration rules. The table has six columns: Form Name, Form Export Name, Variable, Name, Condition, and Description. The first row is highlighted in yellow and contains the following data:

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 P.I.F.
105 Eligibility and Randomiz	EligibilityRandomization	lieranddat	Randomization Before Intervention Date	* all of the following are true: * lieranddat at same Visit > IStartDat at same Visit	To make sure that the randomization date is pr
106 Visit Status	VisitStatus	svdat	Randomized prior to Screening	* all of the following are true: * svdat @ Screening Visit > lieranddat @ Telephone Screening	Date of Randomization is PRIOR to Screening
107 Eligibility and Randomiz	EligibilityRandomization	lierandomized	Randomized Subject Status	* all of the following are true: * lierandomized @ Telephone Screening = (Eligible, participant randomized) * Subject Status != (Complete, Early Termination, Enrolled, Other)	Participant randomized but Status in Subject I
108 Visit Status	VisitStatus	visitstatus	Screening scheduled without Telephone Visit	* all of the following are true: * visitstatus @ Telephone Screening is missing a value * lietsres @ Telephone Screening = (Eligible, Screening visit scheduled)	Screening visit scheduled but telephone screen
109 Sleep Diary Data	SleepDiary	psddate_day2	Sleep Diary Date out of order 2	* all of the following are true: * psddate_day2 on same form < psddate_day1 on same form	Sleep Diary Date is prior to previous diary date

The interface includes a navigation bar at the bottom with tabs for 'Forms', 'Skip Logic', 'Code Lists', 'VAS Scale Labels', 'Custom Queries', 'Range Checks', 'Form Rules', and 'Subject Status Rules'. The 'Custom Queries' tab is currently selected. The status bar at the bottom left shows 'Ready' and the bottom right shows a zoom level of 100%.

# 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

Participant Acrostic:

Date of Visit:  [Now](#)  
25-Oct-2019

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

2. Birth Date   
02-May-1970

3. Marital Status  Annulled  
 Divorced  
 Interlocutory  
 Legally Separated  
 Married  
 Never Married  
 Widowed  
 Polygamous  
 Domestic Partner  
 Other

If Other, please specify:

5. Race  American Indian or Alaska Native  
 Asian  
 Black or African American  
 Native Hawaiian or Other Pacific Islander  
 White or Caucasian  
 Other

If Other, please specify

4. Ethnicity  Not Hispanic or Latina  
 Hispanic or Latina  
 Not Reported  
 Unknown

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

# 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 ▾

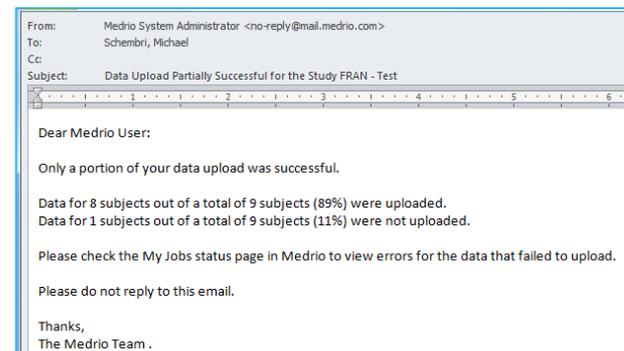
	SubjectID	Visit	DMACROS	DMACROS_CODED	DMDATE	DMDATE_CODED	SEX	SEX_CODE_D	brthdat	brthdat_CODED	SCORRES_EDUCATION	SCORRES_EDUCATION_CODED
1	10010	Screening Visit		.	11/27/2017	.	Female	F	.	.	High school	12
2	30001	Screening Visit	Abab	.	04/09/2018	.	Female	F	12/29/1973	.	Master's Degre...	18
3	30011	Screening 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

Subject Information		Demographics							
Subject ID	Site	Group	xdmacros	xdmdate	xsex	xbrthdat	xmaristat	xmaristatother	xrace
20009	Oakland - Clinic	Late Menopausal Transition							
40004	Oakland - Clinic	Late Menopausal Transition							
40006	Oakland - Clinic	Late Menopausal Transition	ABAB	9/13/2019	Male, transgendered, or other (INELIGIBLE)	6/2/1965	Divorced		American Indian or Alaska Native
30002	Fremont - Clinic	Late Menopausal Transition	BPRO	10/12/2019	Female	4/5/1970	Legally Separated		Asian
60606	Oakland - Clinic	Late Menopausal Transition							
70001	Oakland - Clinic	Late Menopausal Transition							
54321	San Francisco -	Late Menopausal Transition							
10002	Fremont - Clinic	Late Menopausal Transition	AMAM	10/25/2019	Female	5/2/1970	Legally Separated		Black or African American
20006	San Francisco -	Late Menopausal Transition	DAMD	12/1/2019	Female	12/18/1958	Never Married		

- 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. It includes a 'Create or Edit Map Definition' section with fields for 'Map Name' (FSH2), 'Map Description (Optional)', 'Form Name' (FSH Lab Result), 'Grid Name' (N/A), and 'File Name' (FSH2.xlsx). Below this is the 'Map Columns to Fields' section, which contains a table for mapping form fields to file columns. The table has two columns: 'Form (Field) Name' and 'Mapping'. The 'Form (Field) Name' column lists various form fields, and the 'Mapping' column shows the corresponding file column names. A 'File (Column) Name' list on the right shows the available columns from the file, including 'SubjectID', 'Visit', 'Acroscopic', 'LBDAT', 'Reason Done', 'Done', and 'FSHResult'. A double arrow button is positioned between the table and the file list.

Form (Field) Name	Mapping
Visit	Visit
Participant Acroscopic: (Text)	Acroscopic
Collection Date: (Date)	LBDAT
Does the Sreenee meet any of (Multi)	
2. Was FSH sample collected fr (Sel1)	
If No, please specify why not (Text)	
3. FSH Level (mU/mL): (Num)	FSHResult

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

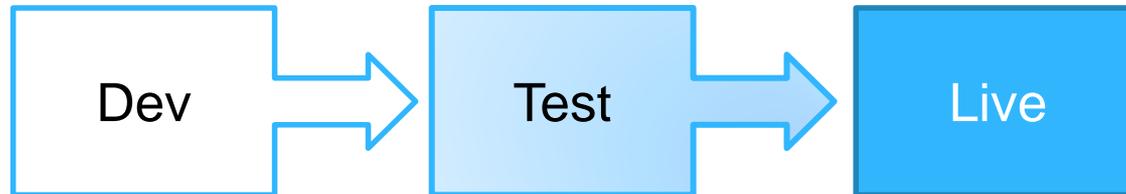
# Developer:

## 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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