

WITH STANDARDS – UNLOCK THE POWER OF DATA

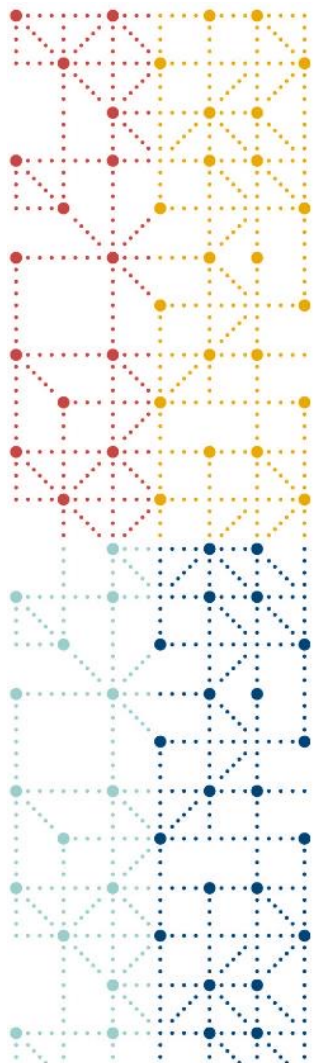


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**"Thinking Ahead: Using CDISC standards helps get the most out of your eCOA data"**

Presented by Monali Khanna  
Director, Data Science & Consulting, YPrime



## Meet the Speaker

Monali Khanna

**Title:** Director, Data Science & Consulting

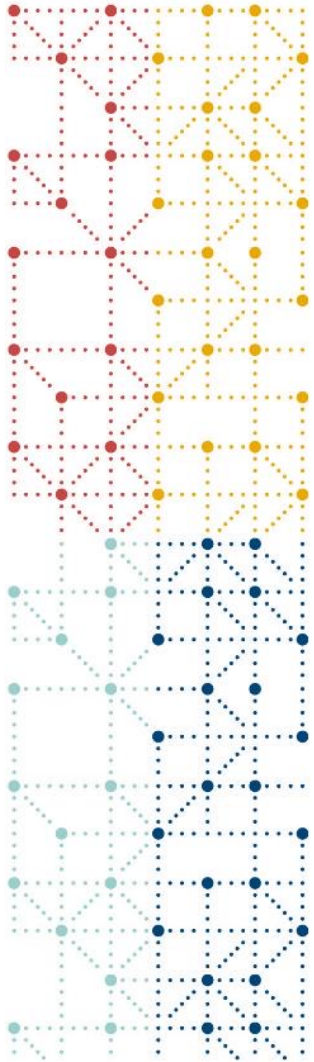
**Organization:** YPrime

Monali has strong experience in cross-functional team leadership, people, portfolio, and budget management within the clinical research industry. She has provided leadership and operational excellence to execute all Data and Statistical Science deliverables successfully. She and her team encourage and assist clinical research sponsors in adopting data standards and strategies from data collection to submissions to regulatory agencies. In her previous roles, she has led multiple projects for creating statistical analysis and programming in various therapeutic areas. She is an enthusiastic learner and supports initiatives for training and process improvements



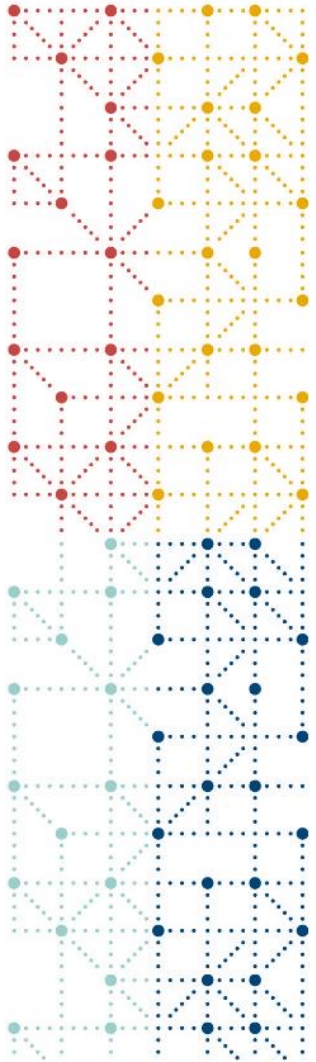
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## Agenda

1. Clinical Outcome Assessments and Rise of eCOA data
2. Varied expectations
3. What to think ahead of time
4. Creating efficiencies by adopting CDISC Data Standards
5. Use of standards in Questionnaire Library; Annotated Screen Reports; Global Data Transfer Agreement



## **Clinical Outcome Assessments and Rise of eCOA (electronic Clinical Outcome Assessments) Data**



# Clinical Outcome Assessments (COA)

A measure that describes or reflects how a patient feels, function or survives.



## PRO

### Patient Reported Outcome

Based on a report that comes directly from the patient, about the status of a patient's health condition without amendment or interpretation



## ObsRO

### Observer Reported Outcome

Based on a report of observable signs, events or behaviors related to a patient's health condition by someone other than the patient or a healthcare professional.



## ClinRO

### Clinician Reported Outcome

Based on a report that comes from a trained health-care professional after observation of a patient's health condition



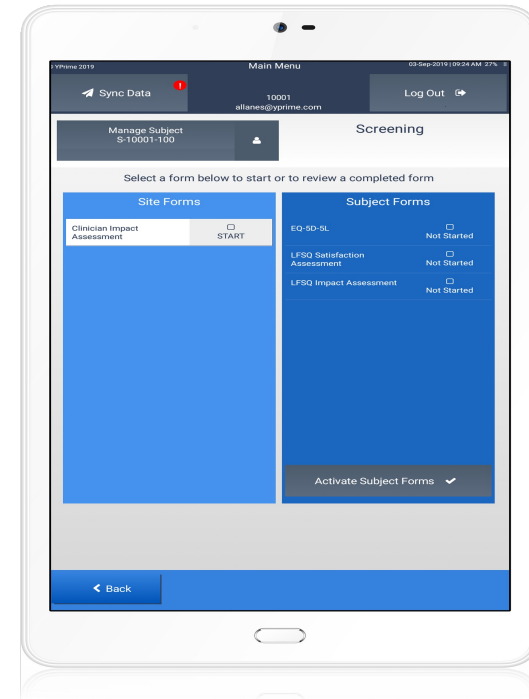
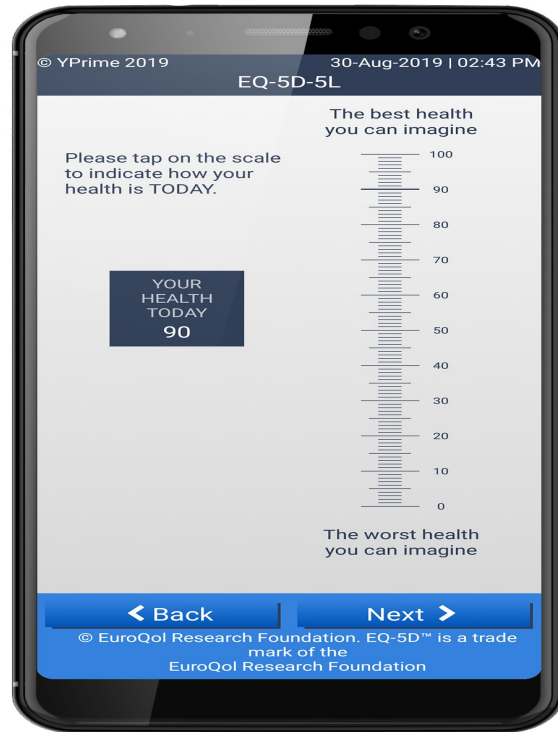
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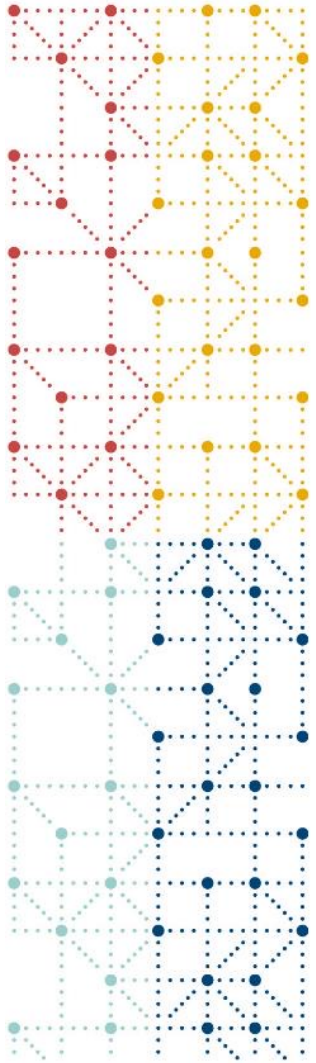
### Performance Outcome

Based on standardized task(s) actively undertaken by a patient according to a set of instructions.



# Rise of electronic Clinical Outcome Assessment Data

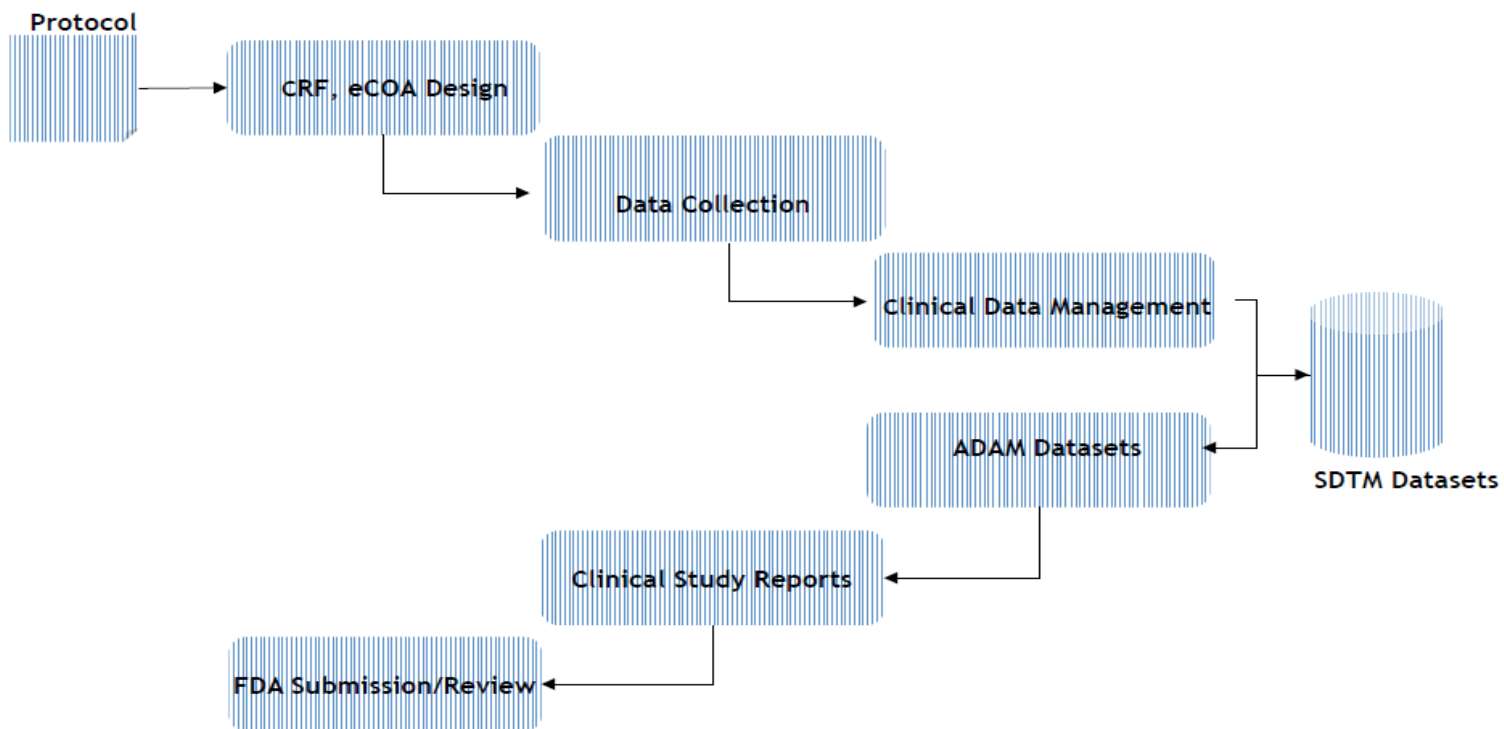


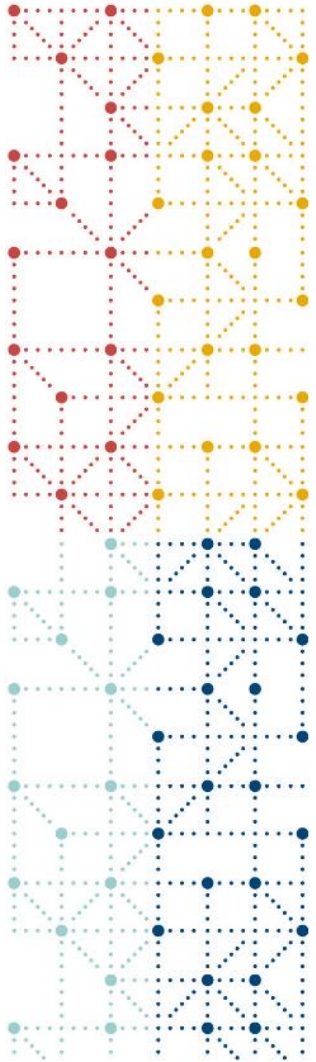


## Varied Expectations



# Different Stages and Varied Expectations





## How To Gain Overall Efficiencies Across The eCOA Data Life Cycle By Adopting CDISC Standards

## Involve All Stakeholders Early

- Include team members from cross functional teams
  - Therapeutic experts, outcomes research subject matter experts, clinical operations, biostatistics, data management, data science, subject matter experts on eCOA design and best practices
  - Understand workflows, milestones, timelines of each team/functional unit
    - Example, communicate the needs of analysis teams; study design should include understanding data collection and data transfer



# Discuss Right Instruments, Interfaces, and Users

- Device

- Performance; Security; Lifecycle, Supply Chain; data quality

- Instrument Design

- eCOA design; user interface; type of questionnaires; Logic, business rules, training

- Users

- Training for users including caregivers, plan for missed/unscheduled visits

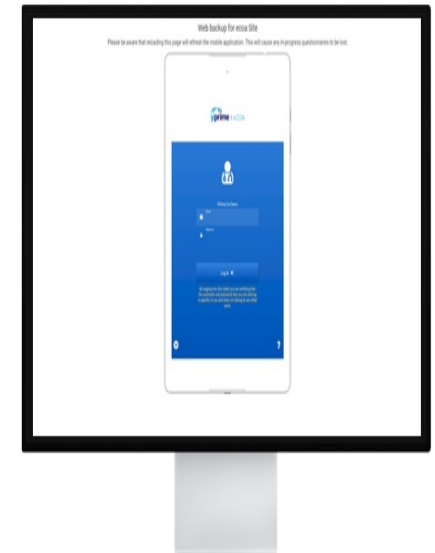
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Tablet



Web Backup





## Use Both CDASH and SDTM

- Ensures you're asking the same question and using the same answer lists from collection through analysis
- Optimizes the site's data requirements and structure for transmission, analysis, review and reuse
- Supports traceability back through data collection
- Minimizes programming and validation resources and increases quality when transferring data from capture to tabulation
- Helps to "future-proof" the data for warehousing and other uses beyond the initial study



## Include Questionnaire Library

### What is a Questionnaire Library?

- A stored approved version of a frequently used questionnaire with all configuration, languages, customization, and data standardization already attached. Ready to be taken off the shelf and dropped into a study with limited start up time

### How does a Questionnaire Library help?

- Allows for decreased startup time
- Allows for easier analysis across studies
- Aids standardization
- Fuels automation
- Reduces data post processing needs



# Create Annotated Screen Reports

## EQ-5D-5L eCOA Screen Report

**MOBILITY**

I have no problems in walking about

I have slight problems in walking about

I have moderate problems in walking about

I have severe problems in walking about

I am unable to walk about

## EQ-5D-5L eCOA Annotated Screen Report

**yprime** **QSEVINTX= TODAY**

**QS=Questionnaires** **QSCAT=EQ-5D-5L**

2.

Subject: 799-11112 EQ-5D-5L

**QSTESTCD=EQ5D0201**

Please select the ONE box that best describes your health TODAY.

**MOBILITY**

I have no problems in walking about **QSSTRESC/ QSSTRRESN=1**

I have slight problems in walking about **QSSTRESC/ QSSTRRESN=2**

I have moderate problems in walking about **QSSTRESC/ QSSTRRESN=3**

I have severe problems in walking about **QSSTRESC/ QSSTRRESN=4**

I am unable to walk about **QSSTRESC/ QSSTRRESN=5**

**QSORES where QSTESTCD=EQ5D0201**

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EQ-5D-5L, enGB,  
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## Annotated Screen Reports with Data Mapping

- Figure illustrates the same aSR (from previous slide) from the EQ-5D-5L with the addition of the unique vendor record identifiers (Yellow) and how these data may flow into a sponsor data warehouse (Gray)
- Improved granularity especially helpful to data management teams trying to reconcile databases

Annotations on the screenshot include:

- QSEVINTX= TODAY
- QSOAT=EQ-5D-5L
- QTESTCD=EQ5D0201
- QSSSTRESQ/QSSSTRESN=1
- QSSSTRESQ/QSSSTRESN=2
- QSSSTRESQ/QSSSTRESN=3
- QSSSTRESQ/QSSSTRESN=4
- QSSSTRESQ/QSSSTRESN=5
- YSORRES where QTESTCD=EQ5D0201
- YPrime ChoiceID= A24D86D3-6210-4595-C682-08D87963DC56
- YPrime ChoiceID= 22164048-C17F-4E3A-C683-08D87963DC56
- YPrime ChoiceID= 8CCA74EA-EDCD-435D-C684-08D87963DC56
- YPrime ChoiceID= F308CD91-0CB1-4C24-C685-08D87963DC56
- YPrime ChoiceID= 8936E692-4998-40EE-C686-08D87963DC56





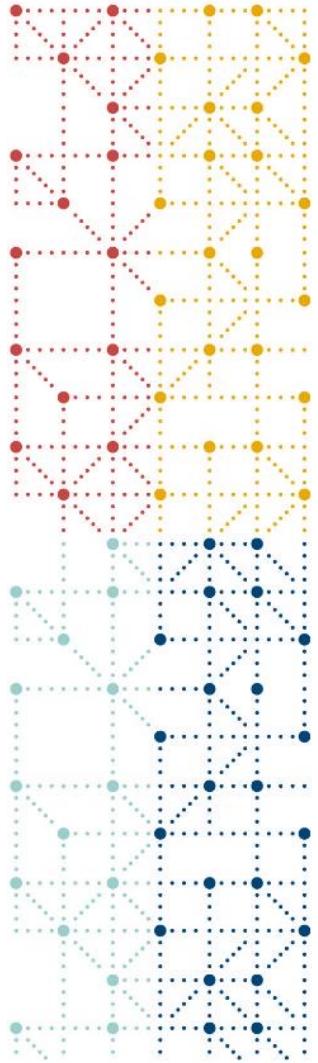
# Author Global Data Transfer Agreements

- Data Transfer Agreements or Specifications are documents that provide clear expectations for data exchange.
  - Should be started early (study design)
  - Should have input from multiple stakeholders and cross functional teams
    - Discuss how collected data will be used for analysis
    - Clear guidance on any value mapping
    - Are there strict conformance standards or guidelines
  - Should include file delivery details
    - File format, Field Definitions, Cumulative data or incremental, periodic or transactional exchanges, Frequency, destination, encryption, mode of transfer

## Global Data Transfer Agreement

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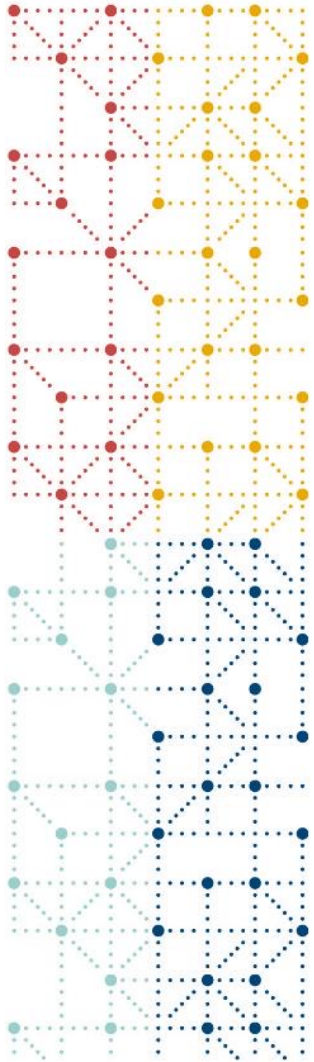
# Summary



## The Big Take Away

- Involve All Stakeholders Early
- Plan Ahead: Instruments, Usage, Training Needs
- Create Efficiencies by using Data Standards
- Provide Transparency from data collection to Submission
- THINK AHEAD, and use STANDARDS





**Thank You!**

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**cdisc**