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INTERCHANGE

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Getting More Efficiency from your Instruments Using CDISC

Frank Menius, Data Scientist II, YPrime
Monali Khanna, Director Data Science and Consulting, YPrime



Meet the Speaker

Frank Menius

Title: Data Scientist II

Organization: YPrime

Frank Menius is a graduate of The University of North Carolina and holds a graduate certificate in Applied Statistics and Data Management from NC State University. Mr. Menius is a former police officer, having served the City of Raleigh 12 years prior to transitioning into programming and data science. Mr. Menius specializes in clinical trial submission standards, has extensive experience in define.xml creation and is actively working to bring CDISC data standards to the eCOA and IRT environments. Frank is also a volunteer with the CDISC ADaM sub team working to build ADaM QRS supplement standards.



Disclaimer and Disclosures

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



Agenda

1. Introduction
2. Current way eCOA are collected
3. Using CDISC standards to gain efficiency
4. Challenges
5. Questions



Introduction

What do we want? EFFICIENCY! How do we get it? LIBRARIES!

Like LEGO, code libraries allow standardized code “Bricks” to be dropped into programming

- Whole instruments can be taken “off the shelf”
- Faster study start up
- Faster enrollment
- Cost and effort savings
- Standardization



But one Brick is missing!



But one Brick is missing!





Current way eCOA are collected

How are Electron Clinical Outcome Assessments (eCOA) collected?

Current data collection doesn't go much beyond paper source.

- Instrument (Questionnaire)
- Item (Question)
- Value (Answer)
- Date

Subject: 789-11112

EQ-5D-5L

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

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

INSTRUMENT	ITEM	VALUE	DATE
EQ-5D-5L	Please tap the ONE box that best describes your health TODAY. MOBILITY	I have no problems walking	19-Sep-23

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Back Next

Programming is needed to convert data for analysis and submission

QSTESTCD

QSCAT

QSORRES

INSTRUMENT	ITEM	VALUE	DATE
EQ-5D-5L	Please tap the ONE box that best describes your health TODAY. MOBILITY	I have no problems walking	19-Sep-23

QSSTRESN

QSSCAT

QSEVILNT

QS...

This programming is a loss of efficiency

DOCUMENT	ITEM	VALUE	DATE
-5D-5L	to the ONE box that describes your health ... MOBILITY	I have no problems walking	19-Sep-23



Using CDISC standards to gain efficiency

CDISC has a growing library QRS supplements



New to CDISC

Standards

Education

Resources

Events

Membership

Foundational

BRIDG

PRM

SEND

CDASH

SDTM

SDTMIG

ADaM

QRS

Medical Devices

Genomics

Data Exchange

CTR-XML

Dataset-JSON

Dataset-XML

Define-XML

LAB

ODM

RDF

SDM-XML

Terminology

Glossary

Controlled Terminology

NSV Registry

Therapeutic Areas

Alphabetical

By Disease Area

Published User Guides

Standards

Standards Roadmap

Publications

In Development

Public Reviews

Standards in Development

CDISC 360

CORE

CDISC Biomedical Concepts

Digital Data Flow

CDISC Library

CDISC Library

Real World Data

FHIR-CDISC

Vaccine Administration



Applying those supplements to eCOA

QSEVINTX=TODAY

Under each heading, please check the ONE box that best describes your health TODAY

- MOBILITY** **QSORRES when QSTESTCD=EQ5D0201**
- I have no problems walking **QSSTRESC/QSSTRESN=1**
 - I have slight problems walking **QSSTRESC/QSSTRESN=2**
 - I have moderate problems walking **QSSTRESC/QSSTRESN=3**
 - I have severe problems walking **QSSTRESC/QSSTRESN=4**
 - I am unable to walk **QSSTRESC/QSSTRESN=5**

SELF-CARE **QSORRES when QSTESTCD=EQ5D0202**

- I have no problems washing or dressing myself
- I have slight problems washing or dressing myself
- I have moderate problems washing or dressing myself
- I have severe problems washing or dressing myself
- I am unable to wash or dress myself

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities) **QSORRES when QSTESTCD=EQ5D0203**

- I have no problems doing my usual activities
- I have slight problems doing my usual activities
- I have moderate problems doing my usual activities
- I have severe problems doing my usual activities
- I am unable to do my usual activities

PAIN / DISCOMFORT **QSORRES when QSTESTCD=EQ5D0204**

- I have no pain or discomfort
- I have slight pain or discomfort
- I have moderate pain or discomfort
- I have severe pain or discomfort
- I have extreme pain or discomfort

ANXIETY / DEPRESSION **QSORRES when QSTESTCD=EQ5D0205**

- I am not anxious or depressed
- I am slightly anxious or depressed
- I am moderately anxious or depressed
- I am severely anxious or depressed
- I am extremely anxious or depressed



QSEVINTX=TODAY

QS=Questionnaires

QSCAT=EQ-5D-5L

2.

© Yprime 2021 10-Mar-2021 11:24:58 AM
Subject:789-11112

QSTESTCD=EQ5D0201 EQ-5D-5L

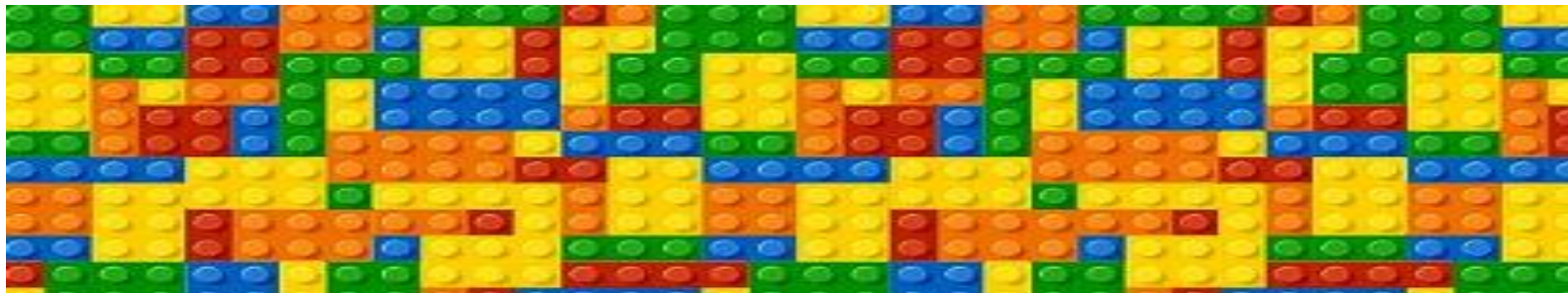
Please select the ONE box that best describes your health TODAY.

MOBILITY

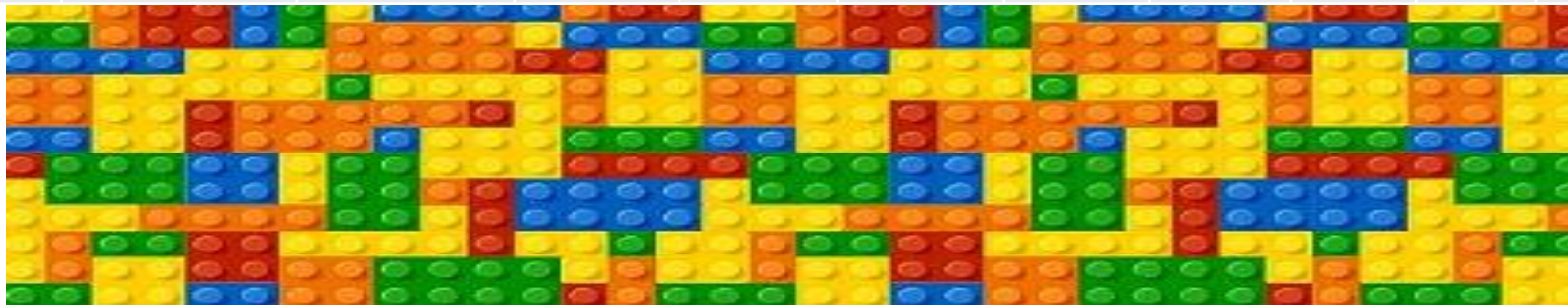
- I have no problems in walking about **QSSTRESC/QSSTRESN=1**
- I have slight problems in walking about **QSSTRESC/QSSTRESN=2**
- I have moderate problems in walking about **QSSTRESC/QSSTRESN=3**
- I have severe problems in walking about **QSSTRESC/QSSTRESN=4**
- I am unable to walk about **QSSTRESC/QSSTRESN=5**

QSORRES where QSTESTCD=EQ5D0201

Applying those supplements to eCOA



INSTRUMENT	ITEM	VALUE	DATE	QSTESTCD	QSTEST	QSCAT	QSEVINTX	QSORRES	QSSTRESC	QSSTRESN
EQ-5D-5L	Please tap the ONE box that best describes your health TODAY . MOBILITY	I have no problems walking	19-Sep-23	EQ5D0201	EQ5D02-Mobility	EQ-5D-5L	TODAY	I HAVE NO PROBLEMS WALKING	1	1





Challenges

Challenges

- Programming cost and effort moved to eCOA vendor development
- Customization at cost of efficiency
- CDISC supplement library is large and growing but not exhaustive
- Lack of consistent standards adoption by sponsors





Questions?



Thank You!



Frank Menius

Data Scientist II

frankmenius@yprime.com

<https://www.linkedin.com/in/frank-menius/>

Monali Khanna

Director, Data Science and Consulting

mkhanna@yprime.com

<https://www.linkedin.com/in/monali-k-a259a5178/>