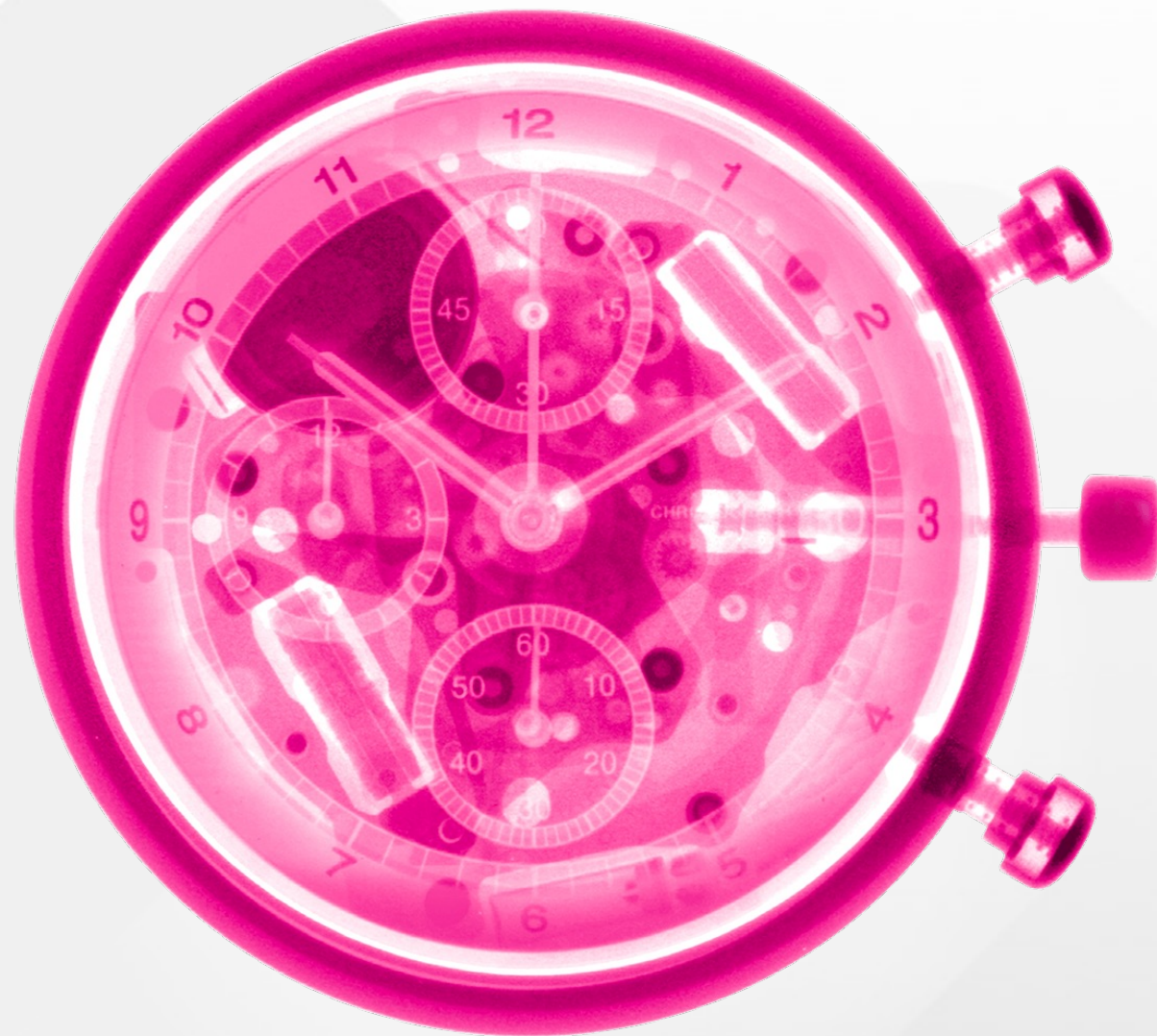




Getting More Efficiency from your Instruments Using CDISC



The Clinical Data
Science Conference

US 2024

25-28 February
Bethesda North Marriott Hotel
& Conference Center



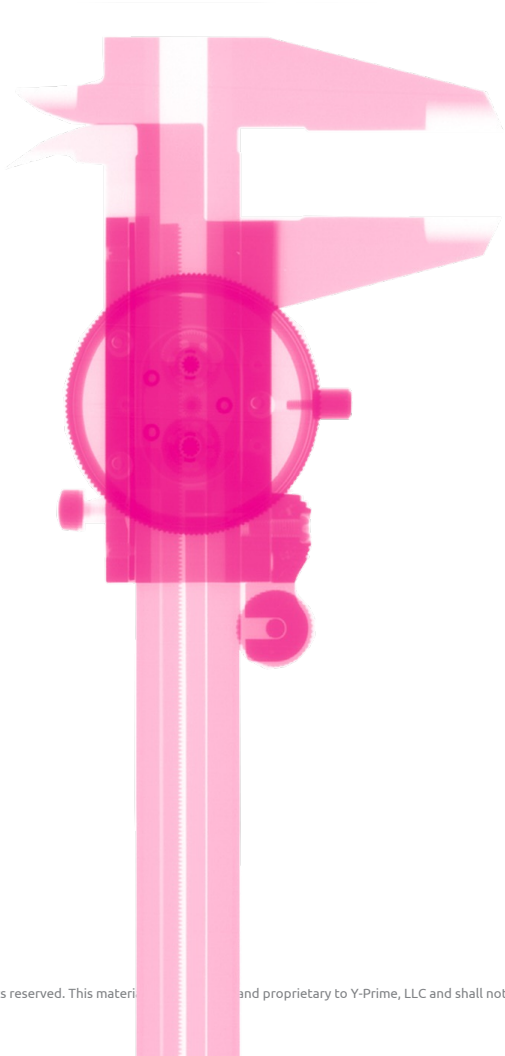
Walter Reed National
Military Medical Center

Introducing the Speaker



Frank Menius
Data Scientist II

Frank Menius is Data Science and Data Standards expert leveraging experience in project management, regulatory submissions, data standardization, process improvement, statistical programming, and training. Frank 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 brings additional extensive experience in problem solving, crisis management, and training honed from a previous career as a law enforcement officer. Frank is currently the Senior Data Scientist at YPrime where he is working to bring CDISC data standards to the eCOA, IRT, and decentralized clinical trial environments. Frank is a volunteer with the CDISC ADaM sub-team working to build ADaM QRS supplement standards. His team most recently published the NEWS2 ADaM QRS supplement. Frank Menius also has extensive experience in thought leadership with over 15 publications and presentations at industry events.



Agenda

- Introduction
- The current way eCOA are collected
- Using CDISC standard to gain efficiency
- Challenges
- Questions, Answers, and Discussion

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



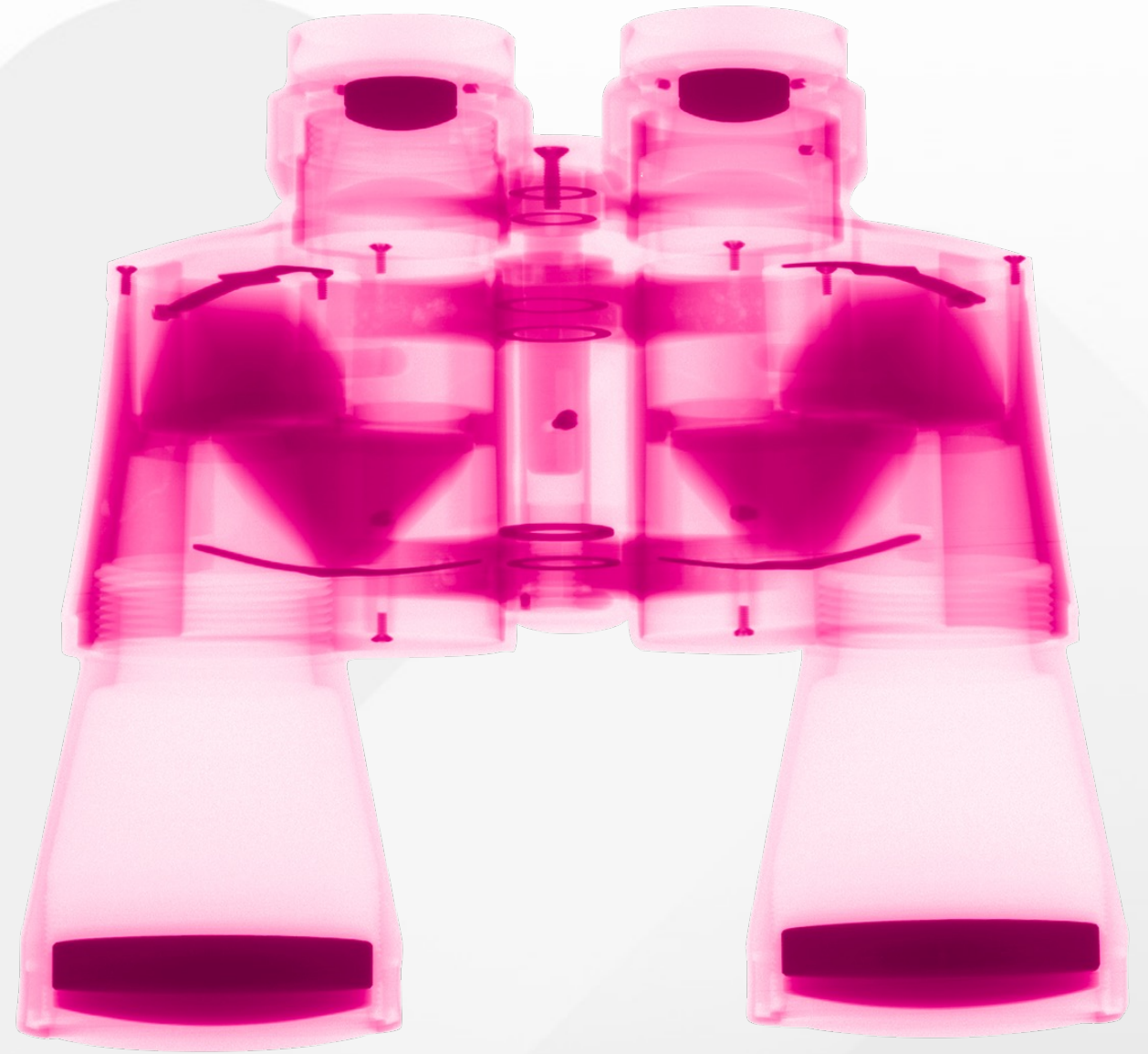
**But One Brick is
Missing!**





UP NEXT

The current way eCOA are collected



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

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

INSTRUMENT	ITEM	VALUE	DATE
EQ-5D-5L	Please tap the ONE box that best describes your health TODAY. MOBILITY	I have no problems walking	2023-09-19T15:32:33

© YPrime 202118-Mar-2021 | 12:49 93%

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

Back

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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	2023-09-19T15:32:33

QSTRESN



QSSCAT



QSEVILNT



QS...



UP NEXT

Using CDISC standards to gain efficiency



CDISC has a growing library of QRS Supplements for SDTM and ADaM

<https://www.cdisc.org/standards/foundational/qrs>



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 CDISC QRS 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 ☐

Y Prime

QSEVINTX=TODAY

QS=Questionnaires

QSCAT=EQ-5D-5L

2.

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

< Back

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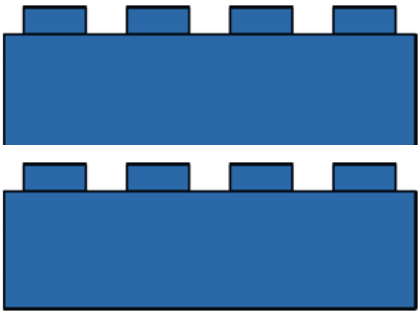
Next >

Sponsor ABC 999-ABC-1234

EQ-5D-5L, enGB,
Version 1.0

Applying CDISC QRS Supplements to eCOA

INSTRUMENT	ITEM	VALUE	DATE
EQ-5D-5L	Please tap the ONE box that best describes your health TODAY. MOBILITY	I have no problems walking	2023-09-19T15:32:33



DOMAIN	QSDTC	QSCAT	QSTESTCD	QSTEST	QSORRES	QSSTRESC	QSSTRESN	QSEVINTX	QSEVAL
QS	2023-09-19T15:32:33	EQ-5D-5L	EQ5D0201	EQ5D02-MOBILITY	I have no problems walking	1	1	TODAY	STUDY SUBJECT

CHALLENGES



The programming and development costs moves upstream to the vendor

Mitigation: Each Subsequent use of a programmed instrument increases overall efficiency



Study-specific customization nullifies any efficiency gained

Mitigation: Study teams may need to prioritize time and cost over customization



CDISC QRS supplement library is large and growing but not exhaustive

Mitigation: Use of basic SDTM processes on instruments that do not exists in QRS or with no controlled terminology

Mitigation: Assist CDISC in developing QRS supplements or controlled terminology for the instrument



Lack of consistent standard adoption by sponsors

Mitigation: Push sponsors to adopt CDISC standards for the entire life cycle of the trial.

Mitigation: The availability of faster and more cost-effective pre-programmed standardized instruments may encourage sponsors to adopt CDISC standards and gain overall efficiencies

Let's Get Building

Questions, Answers, Discussion

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LinkedIn



YPrime

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