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THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

Building a Standardized eCOA Mapping Pipeline: From Vendor Data to SDTM

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Vanessa Sarrechia, Data Standards Lead – Data Acquisition, argenx

Speakers

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Agenda

Near Real-Time Data Flow

The eCOA Standardization Challenge

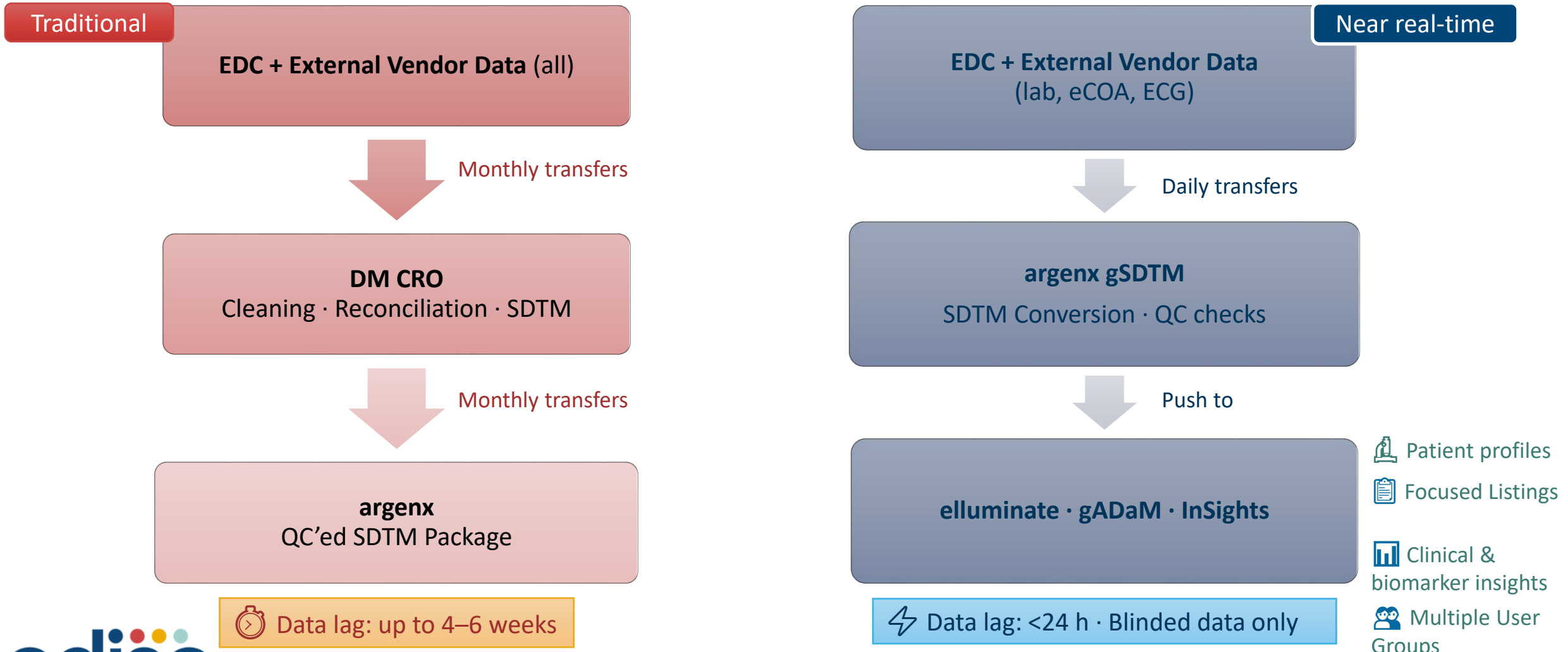
Designing a Standardized Mapping Pipeline

Lessons Learned & What's Next

Near Real-Time Data Flow

From monthly batch transfers to daily automated gSDTM delivery

Two Parallel Data Pathways



Standardization to enable near real-time data

NRT-ready

Standardized input = automated overnight conversion with minimal manual input

Scalable

Reusable templates & concept dictionaries

Aligned with DM CRO

gSDTM stays close to SDTM from DM CRO

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The eCOA Standardization Challenge

Why one questionnaire can become multiple mapping problems

Why vendor variability slows SDTM delivery

Inconsistent vendor outputs

Each vendor uses a different file structure and format — no shared standard for raw data delivery

Controlled Terminology complexity

QRS CT requires careful curation per instrument: --TEST, --ORRES, --STRESC, domain routing (QS/FT/RS) must all be managed consistently

Instrument variability

Same questionnaire (e.g., PGI) used in different versions across studies — different items, scales, coding

SDTM mapping variability

Different DM CROs implement SDTM mapping differently — inconsistent output even for the same instrument

Missing CDISC supplements

Most argenx questionnaires are not in the CDISC QRS supplement list — or are study-specific instruments

Why one questionnaire can become multiple mapping problems: PHQ-9 example

VENDOR	VENDOR_FORM	VENDOR_ITEM	VENDOR_LABEL	VENDOR_ANSWER	VENDOR_ANSWER_NUI
Vendor 1	PHQ-9	PHQ01	Q1 Thoughts Be Better Off Dead	Not at all	0
Vendor 1	PHQ-9	PHQ01	Q1 Thoughts Be Better Off Dead	Several days	1
Vendor 1	PHQ-9	PHQ01	Q1 Thoughts Be Better Off Dead	More than half the days	2
Vendor 1	PHQ-9	PHQ01	Q1 Thoughts Be Better Off Dead	Nearly every day	3
Vendor 2	PHQ9	DEDHRT1L	9. Thoughts that you would be better off dead or of hurting yourself in some way (DEDHRT1L)	Not at all	0
Vendor 2	PHQ9	DEDHRT1L	9. Thoughts that you would be better off dead or of hurting yourself in some way (DEDHRT1L)	Several days	1
Vendor 2	PHQ9	DEDHRT1L	9. Thoughts that you would be better off dead or of hurting yourself in some way (DEDHRT1L)	More than half the days	2
Vendor 2	PHQ9	DEDHRT1L	9. Thoughts that you would be better off dead or of hurting yourself in some way (DEDHRT1L)	Nearly every day	3

Designing the Standardized Mapping Pipeline

Three building blocks: DTA templates · QRS concept dictionaries · LSAF mapping engine

Three building blocks for reusable SDTM outputs

DTA Templates

Data-stream-specific Excel templates with fixed structure, naming conventions, and format requirements – same across all vendors

QRS Concept Dictionaries

Instrument-level concept dictionaries from QS, FT, and RS controlled terminology - vendor raw values mapped to SDTM codelist terms

LSAF Mapping Engine

SAS LSAF automated transformation: raw eCOA data into SDTM (QS, FT, RS) overnight, with embedded basic quality checks and QC outputs

DTA Minimal Requirements

Transfer variable name	Transfer variable label	Format	Anticipated maximum length	Allowed values	Test Identifiers Section	Codelists Section	Visit and/or Timepoint Identifiers Section	Description of variable use	Populate for all records	Unblinding Parameters	Results file Completion
STUDYID	Study Identifier	text	200	*Specify trial identifier as used in the clinical database*				*<Specify trial identifier as used in the Clario*	X		X
DOMAIN	Domain Abbreviation	text	200	"QRS"					X		X
SUBJID	Subect Identifier	text	200					*<Specify subject identifier as used in the Clar*	X		X
FILENAME	External File Name	text	200					e.g., ARGXxxxxxx_CLARIO_QRS_yyyymmdd	X		X
FORM	Vendor Form	text	200		X				X		X
ITEM	Vendor Field/Item	text	200		X				X		X
LABEL	Vendor Label	text	500		X				X		X
ANS_NUM	Vendor Numeric Answer	num	10		X					*< specify B or null >*	*< specify X or B>*
ANSWER	Vendor Answer	text	200		X					*< specify B or null >*	*< specify X or B>*
UNIT	Vendor Unit	text	10		X					*< specify B or null >*	*< specify X or B>*
LOG_SKIP	Logically Skipped item	text	1	"Y" or blank				*<Specify whether applicable or not>*		*< specify B or null >*	*< specify X or B>*
DATETIME	Form Save Time	Datetime	19					Date/Time in ISO8601 format e.g., 2022-11-	X		X
VISIT	Visit Name	text	200				V		X		X
EVAL	Evaluator	text	200		X					*< specify B or null >*	*< specify X or B>*

Machine-readable Excel format

Fixed column structure

Naming convention

File format specification

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QRS Concept Dictionary – EQ-5D-5L

Vendor-specific raw values

Standardized SDTM terms

VENDOR_FORM	VENDOR_ITEM	VENDOR_LABEL	VENDOR_ANSWER	VENDOR_ANSWER_NUI	DOMAIN	--TESTCD	--TEST	--CAT	--SCAT	--ORRES	--ORRESU	--STRESC
EQ-5D-5L	EQ5D5L01	Q1 Mobility	I have no problems walking	1	QS	EQ5D0201	EQ5D02-Mobility	EQ-5D-5L		I have no problems walking		1
EQ-5D-5L	EQ5D5L01	Q1 Mobility	I have slight problems walking	2	QS	EQ5D0201	EQ5D02-Mobility	EQ-5D-5L		I have slight problems walking		2
EQ-5D-5L	EQ5D5L01	Q1 Mobility	I have moderate problems walki	3	QS	EQ5D0201	EQ5D02-Mobility	EQ-5D-5L		I have moderate problems walking		3
EQ-5D-5L	EQ5D5L01	Q1 Mobility	I have severe problems walking	4	QS	EQ5D0201	EQ5D02-Mobility	EQ-5D-5L		I have severe problems walking		4
EQ-5D-5L	EQ5D5L01	Q1 Mobility	I am unable to walk	5	QS	EQ5D0201	EQ5D02-Mobility	EQ-5D-5L		I am unable to walk		5
EQ-5D-5L	EQ5D5L02	Q2 Self Care	I have no problems washing or d	1	QS	EQ5D0202	EQ5D02-Self-Care	EQ-5D-5L		I have no problems washing or dressing myself		1
EQ-5D-5L	EQ5D5L02	Q2 Self Care	I have slight problems washing c	2	QS	EQ5D0202	EQ5D02-Self-Care	EQ-5D-5L		I have slight problems washing or dressing myself		2
EQ-5D-5L	EQ5D5L02	Q2 Self Care	I have moderate problems wash	3	QS	EQ5D0202	EQ5D02-Self-Care	EQ-5D-5L		I have moderate problems washing or dressing myself		3
EQ-5D-5L	EQ5D5L02	Q2 Self Care	I have severe problems washing	4	QS	EQ5D0202	EQ5D02-Self-Care	EQ-5D-5L		I have severe problems washing or dressing myself		4
EQ-5D-5L	EQ5D5L02	Q2 Self Care	I am unable to wash or dress my	5	QS	EQ5D0202	EQ5D02-Self-Care	EQ-5D-5L		I am unable to wash or dress myself		5
EQ-5D-5L	EQ5D5L03	Q3 Usual Activities	I have no problems doing my usu	1	QS	EQ5D0203	EQ5D02-Usual Activities	EQ-5D-5L		I have no problems doing my usual activities		1
EQ-5D-5L	EQ5D5L03	Q3 Usual Activities	I have slight problems doing my	2	QS	EQ5D0203	EQ5D02-Usual Activities	EQ-5D-5L		I have slight problems doing my usual activities		2
EQ-5D-5L	EQ5D5L03	Q3 Usual Activities	I have moderate problems doing	3	QS	EQ5D0203	EQ5D02-Usual Activities	EQ-5D-5L		I have moderate problems doing my usual activities		3
EQ-5D-5L	EQ5D5L03	Q3 Usual Activities	I have severe problems doing my	4	QS	EQ5D0203	EQ5D02-Usual Activities	EQ-5D-5L		I have severe problems doing my usual activities		4
EQ-5D-5L	EQ5D5L03	Q3 Usual Activities	I am unable to do my usual activ	5	QS	EQ5D0203	EQ5D02-Usual Activities	EQ-5D-5L		I am unable to do my usual activities		5
EQ-5D-5L	EQ5D5L04	Q4 Pain Discomfort	I have no pain or discomfort	1	QS	EQ5D0204	EQ5D02-Pain/Discomfort	EQ-5D-5L		I have no pain or discomfort		1
EQ-5D-5L	EQ5D5L04	Q4 Pain Discomfort	I have slight pain or discomfort	2	QS	EQ5D0204	EQ5D02-Pain/Discomfort	EQ-5D-5L		I have slight pain or discomfort		2
EQ-5D-5L	EQ5D5L04	Q4 Pain Discomfort	I have moderate pain or discomf	3	QS	EQ5D0204	EQ5D02-Pain/Discomfort	EQ-5D-5L		I have moderate pain or discomfort		3
EQ-5D-5L	EQ5D5L04	Q4 Pain Discomfort	I have severe pain or discomfort	4	QS	EQ5D0204	EQ5D02-Pain/Discomfort	EQ-5D-5L		I have severe pain or discomfort		4
EQ-5D-5L	EQ5D5L04	Q4 Pain Discomfort	I have extreme pain or discomfo	5	QS	EQ5D0204	EQ5D02-Pain/Discomfort	EQ-5D-5L		I have extreme pain or discomfort		5
EQ-5D-5L	EQ5D5L05	Q5 Anxiety Depression	I am not anxious or depressed	1	QS	EQ5D0205	EQ5D02-Anxiety/Depression	EQ-5D-5L		I am not anxious or depressed		1
EQ-5D-5L	EQ5D5L05	Q5 Anxiety Depression	I am slightly anxious or depresse	2	QS	EQ5D0205	EQ5D02-Anxiety/Depression	EQ-5D-5L		I am slightly anxious or depressed		2
EQ-5D-5L	EQ5D5L05	Q5 Anxiety Depression	I am moderately anxious or depr	3	QS	EQ5D0205	EQ5D02-Anxiety/Depression	EQ-5D-5L		I am moderately anxious or depressed		3
EQ-5D-5L	EQ5D5L05	Q5 Anxiety Depression	I am severely anxious or depress	4	QS	EQ5D0205	EQ5D02-Anxiety/Depression	EQ-5D-5L		I am severely anxious or depressed		4
EQ-5D-5L	EQ5D5L05	Q5 Anxiety Depression	I am extremely anxious or depre	5	QS	EQ5D0205	EQ5D02-Anxiety/Depression	EQ-5D-5L		I am extremely anxious or depressed		5
EQ-5D-5L	EQ5D5LSCORE	Q6 Health State	<0 - 100>	<0 - 100>	QS	EQ5D0206	EQ5D02-EQ VAS Score	EQ-5D-5L		<0-100>		<0-100>

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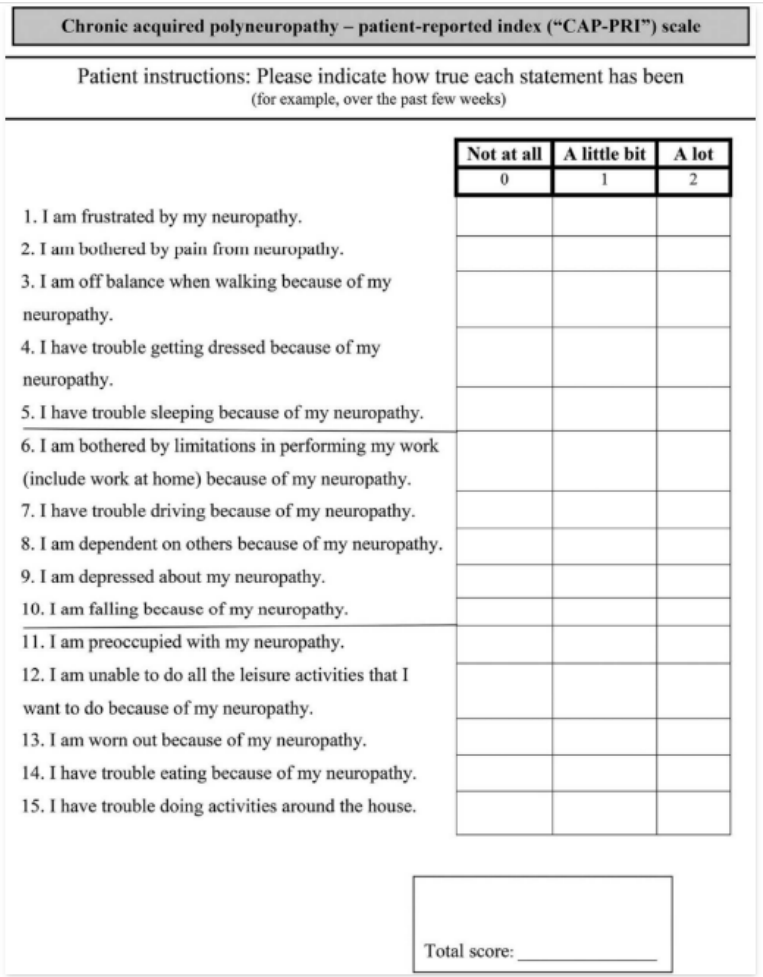
How do we get there?

Original forms from the eCOA vendor + signed DTA → CDISC QRS Supplements → CDISC CT → QRS Naming and Business Rules → Create a new mapping → Review by programming team



Chronic acquired polyneuropathy – patient-reported index ("CAP-PRI") scale

Patient instructions: Please indicate how true each statement has been
(for example, over the past few weeks)

	Not at all 0	A little bit 1	A lot 2
1. I am frustrated by my neuropathy.			
2. I am bothered by pain from neuropathy.			
3. I am off balance when walking because of my neuropathy.			
4. I have trouble getting dressed because of my neuropathy.			
5. I have trouble sleeping because of my neuropathy.			
6. I am bothered by limitations in performing my work (include work at home) because of my neuropathy.			
7. I have trouble driving because of my neuropathy.			
8. I am dependent on others because of my neuropathy.			
9. I am depressed about my neuropathy.			
10. I am falling because of my neuropathy.			
11. I am preoccupied with my neuropathy.			
12. I am unable to do all the leisure activities that I want to do because of my neuropathy.			
13. I am worn out because of my neuropathy.			
14. I have trouble eating because of my neuropathy.			
15. I have trouble doing activities around the house.			

Total score: _____

CAP-PRI	CAPPRI01	Q1 Frustrated		
CAP-PRI	CAPPRI02	Q2 Bothered		
CAP-PRI	CAPPRI03	Q3 Off Balance		
CAP-PRI	CAPPRI04	Q4 Trouble Getting Dressed		
CAP-PRI	CAPPRI05	Q5 Trouble Sleeping		
CAP-PRI	CAPPRI06	Q6 Bothered By Limitations		
CAP-PRI	CAPPRI07	Q7 Trouble Driving	0	Not at all
CAP-PRI	CAPPRI08	Q8 Dependent On Others	1	A little bit
CAP-PRI	CAPPRI09	Q9 Depressed	2	A lot
CAP-PRI	CAPPRI10	Q10 Falling		
CAP-PRI	CAPPRI11	Q11 Preoccupied		
CAP-PRI	CAPPRI12	Q12 Leisure Activities		
CAP-PRI	CAPPRI13	Q13 Worn Out		
CAP-PRI	CAPPRI14	Q14 Trouble Eating		
CAP-PRI	CAPPRI15	Q15 Trouble Doing Activities		
CAP-PRI	CAPPRISCORE	Total Score	0 - 30	--

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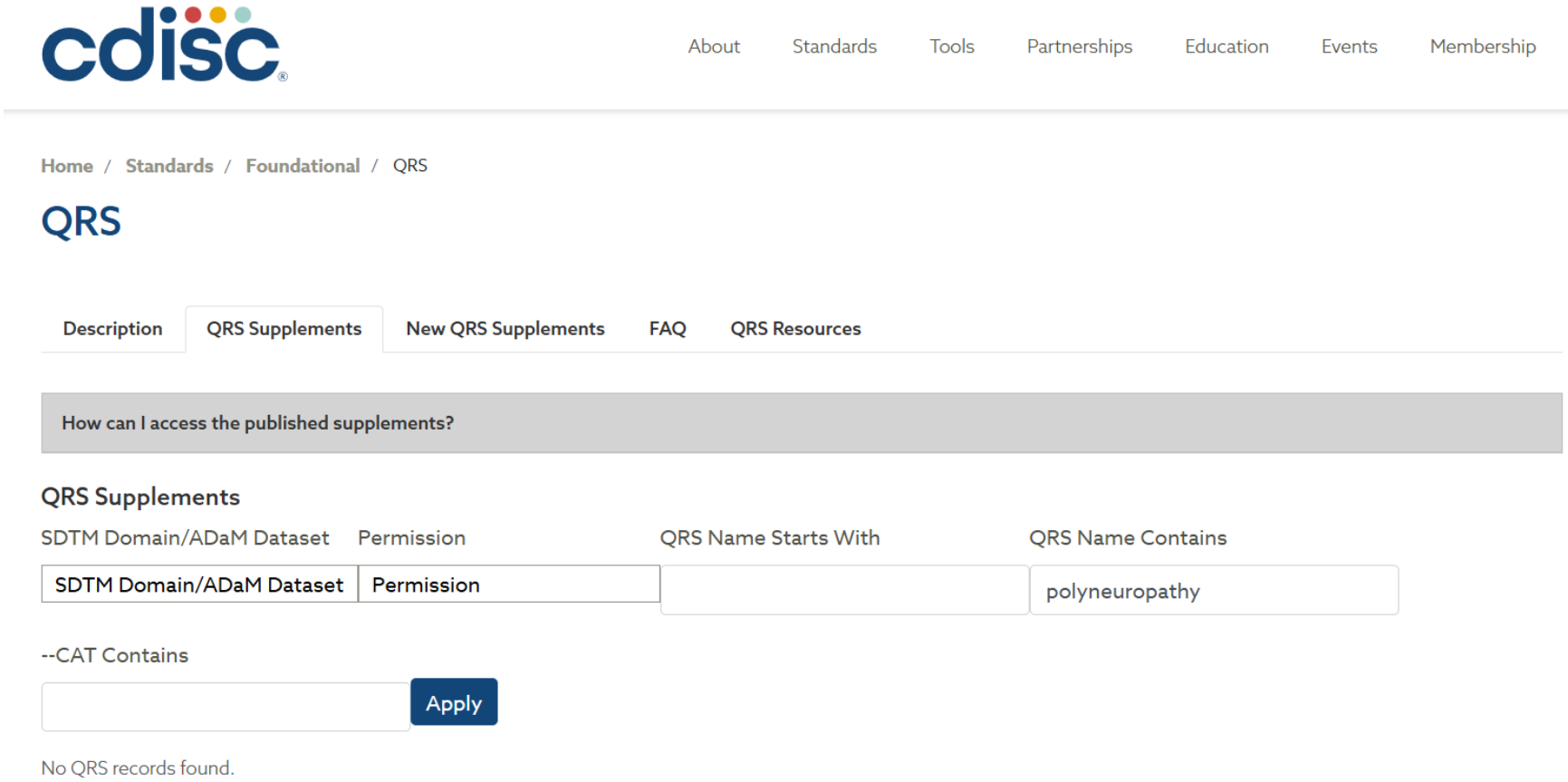
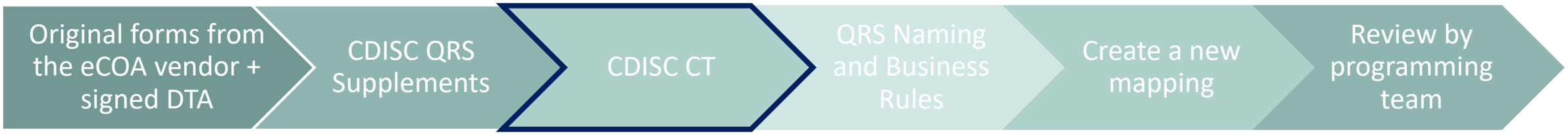


How do we get there?



Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C141657		No	10-Meter Walk/Run Functional Test Test Code	TENMW1TC	10-Meter Walk/Run Functional Test Test Code	10-Meter Walk/Run test code.	CDISC Functional Test 10-Meter Walk/Run Test Code Terminology
C174106	C141657		10-Meter Walk/Run Functional Test Test Code	TENMW101	TENMW1-Was Walk/Run Performed	10-Meter Walk/Run - Was the 10-meter walk/run performed?	10-Meter Walk/Run - Was Walk/Run Performed
C141700	C141657		10-Meter Walk/Run Functional Test Test Code	TENMW102	TENMW1-Time to Walk/Run 10 Meters	10-Meter Walk/Run - If yes, time to walk or run 10 meters.	10-Meter Walk/Run - Time to Walk/Run 10 Meters
C147592	C141657		10-Meter Walk/Run Functional Test Test Code	TENMW103	TENMW1-Wear Orthoses	10-Meter Walk/Run - If yes, did subject wear orthoses?	10-Meter Walk/Run - Wear Orthoses
C141701	C141657		10-Meter Walk/Run Functional Test Test Code	TENMW104	TENMW1-Test Grade	10-Meter Walk/Run - Test grade.	10-Meter Walk/Run - Test Grade
C141656		No	10-Meter Walk/Run Functional Test Test Name	TENMW1TN	10-Meter Walk/Run Functional Test Test Name	10-Meter Walk/Run test name.	CDISC Functional Test 10-Meter Walk/Run Test Name Terminology
C141701	C141656		10-Meter Walk/Run Functional Test Test Name	TENMW1-Test Grade	TENMW1-Test Grade	10-Meter Walk/Run - Test grade.	10-Meter Walk/Run - Test Grade
C141700	C141656		10-Meter Walk/Run Functional Test Test Name	TENMW1-Time to Walk/Run 10 Meters	TENMW1-Time to Walk/Run 10 Meters	10-Meter Walk/Run - If yes, time to walk or run 10 meters.	10-Meter Walk/Run - Time to Walk/Run 10 Meters
C174106	C141656		10-Meter Walk/Run Functional Test Test Name	TENMW1-Was Walk/Run Performed	TENMW1-Was Walk/Run Performed	10-Meter Walk/Run - Was the 10-meter walk/run performed?	10-Meter Walk/Run - Was Walk/Run Performed
C147592	C141656		10-Meter Walk/Run Functional Test Test Name	TENMW1-Wear Orthoses	TENMW1-Wear Orthoses	10-Meter Walk/Run - If yes, did subject wear orthoses?	10-Meter Walk/Run - Wear Orthoses

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***Rules that apply to all QS, FT, and CC/RS TEST-CD and Response Terminology**

1. US English is the strongly preferred language for QRS terminology.
 - For example, a questionnaire has tests and responses that are published in both American English and UK English translations (there may be other flavors of English from other countries). While some word(s) may be different between the the words are the same. Therefore the UK English version will NOT be treated as a separate version, and controlled terminology will only be developed for the US English version. For Example, in the KBILD questionnaire, the US Version has this response: A good bit of the time.

2. If US English version is available, always use US English version to code an instrument, unless:
- The instrument explicitly uses both English spellings of a term. For example, if an item on the instrument shows: Diarrhea/Diarrhoea. In this case, TEST NAME and CDISC Definition should include both English spellings of the term.
QSTEST = XXXX01-Diarrhea/Diarrhoea Frequency (if it fits in the 40 character limit)
QS Definition = XXXXXX Instrument – Diarrhea/Diarrhoea frequency.

3. If an instrument has no US English version at the time of request and CT development, but has other English versions, the QRS Controlled Terminology Team reserves the right to review and develop terminology on a case by case basis.
- For example, when HADS was developed there was only the UK English version available, therefore the UK version was used to develop controlled terminology.

4. Users should consider creating sponsor-specific, custom QSCAT synonyms when controlled terminology (CT) is not available and/or when the sponsor CRF has somewhat different wording from the CDISC annonated CRF. For example FACT/FACIT instruments. CDISC QSCAT synonyms for FACT/FACIT have the following naming convention: FACXXX (e.g. FAC100, FAC071, FAC005, etc.).

For FACT/FACIT instruments whose terminology has not been published by CDISC, users may create sponsor-defined terminology that is CDISC-compliant, and custom QSCAT synonyms. For instance, a custom QSCAT synonym may lo meant to be implemented, sponsors should create custom --CATs as they see fit):

Instrument name: Sponsor Specific FACT 1 – Lung
QSCAT synonym = FCTX01 (note: QSCAT synonym should contain 6 characters or less in order to leave enough space to build QSTESTCDs. See the "CC_FT_QS CAT Rules" tab for detail)
Question item 1: QSTESTCD = FCTX0101
Question item 2: QSTESTCD = FCTX0102

Instrument name: Sponsor Specific FACT 2 – Lung
QSCAT synonym = FCTX02
Question item 1: QSTESTCD = FCTX0201
Question item 2: QSTESTCD = FCTX0202

As another example, a sponsor has a version of a questionnaire different from the CDISC annotated CRF for which CDISC Controlled Terminology has been developed. The sponsor would then create a custom QSCAT and QSCAT synonyr

QSCAT synonym = ZPN01
Question item 1A: QSTESTCD = ZPN0101A
Question item 1B: QSTESTCD = ZPN0101B
Question item 2: QSTESTCD = ZPN0102, etc.

If CDISC Controlled Terminology has been developed, then sponsor test names would be based on existing CDISC Controlled Terminology. Naming rules on the other tabs of this document would still need to be followed.

General QRS Business Rules | CC_FT_QS CAT Rules | CC_FT_QS TEST-CD Rules | QRS Response Codelist Rules | QRS Response ORRES Rules | QRS Response STRESC Rules

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VENDOR_FORM	VENDOR_ITEM	VENDOR_LABEL	VENDOR_ANSWER	VENDOR_ANSWER_NUM	DOMAIN	--TESTC	--TEST	--CAT	--SCAT	--ORRES	--ORRE	--STRE
CAP-PRI	CAPPRI01	Q1 Frustrated	Not at all	0	QS	CAPR0101	CAPR01-Frustrated by Neuropathy	CAP-PRI		Not at all		0
CAP-PRI	CAPPRI01	Q1 Frustrated	A little bit	1	QS	CAPR0101	CAPR01-Frustrated by Neuropathy	CAP-PRI		A little bit		1
CAP-PRI	CAPPRI01	Q1 Frustrated	A lot	2	QS	CAPR0101	CAPR01-Frustrated by Neuropathy	CAP-PRI		A lot		2
CAP-PRI	CAPPRI02	Q2 Bothered	Not at all	0	QS	CAPR0102	CAPR01-Bothered by Pain	CAP-PRI		Not at all		0
CAP-PRI	CAPPRI02	Q2 Bothered	A little bit	1	QS	CAPR0102	CAPR01-Bothered by Pain	CAP-PRI		A little bit		1
CAP-PRI	CAPPRI02	Q2 Bothered	A lot	2	QS	CAPR0102	CAPR01-Bothered by Pain	CAP-PRI		A lot		2
CAP-PRI	CAPPRI03	Q3 Off Balance	Not at all	0	QS	CAPR0103	CAPR01-Off Balance When Walking	CAP-PRI		Not at all		0
CAP-PRI	CAPPRI03	Q3 Off Balance	A little bit	1	QS	CAPR0103	CAPR01-Off Balance When Walking	CAP-PRI		A little bit		1
CAP-PRI	CAPPRI03	Q3 Off Balance	A lot	2	QS	CAPR0103	CAPR01-Off Balance When Walking	CAP-PRI		A lot		2
CAP-PRI	CAPPRI04	Q4 Trouble Getting Dressed	Not at all	0	QS	CAPR0104	CAPR01-Trouble Getting Dressed	CAP-PRI		Not at all		0
CAP-PRI	CAPPRI04	Q4 Trouble Getting Dressed	A little bit	1	QS	CAPR0104	CAPR01-Trouble Getting Dressed	CAP-PRI		A little bit		1
CAP-PRI	CAPPRI04	Q4 Trouble Getting Dressed	A lot	2	QS	CAPR0104	CAPR01-Trouble Getting Dressed	CAP-PRI		A lot		2
CAP-PRI	CAPPRI05	Q5 Trouble Sleeping	Not at all	0	QS	CAPR0105	CAPR01-Trouble Sleeping	CAP-PRI		Not at all		0
CAP-PRI	CAPPRI05	Q5 Trouble Sleeping	A little bit	1	QS	CAPR0105	CAPR01-Trouble Sleeping	CAP-PRI		A little bit		1
CAP-PRI	CAPPRI05	Q5 Trouble Sleeping	A lot	2	QS	CAPR0105	CAPR01-Trouble Sleeping	CAP-PRI		A lot		2
CAP-PRI	CAPPRI06	Q6 Bothered By Limitations	Not at all	0	QS	CAPR0106	CAPR01-Bothered by Limitations	CAP-PRI		Not at all		0
CAP-PRI	CAPPRI06	Q6 Bothered By Limitations	A little bit	1	QS	CAPR0106	CAPR01-Bothered by Limitations	CAP-PRI		A little bit		1
CAP-PRI	CAPPRI06	Q6 Bothered By Limitations	A lot	2	QS	CAPR0106	CAPR01-Bothered by Limitations	CAP-PRI		A lot		2
CAP-PRI	CAPPRI07	Q7 Trouble Driving	Not at all	0	QS	CAPR0107	CAPR01-Trouble Driving	CAP-PRI		Not at all		0
CAP-PRI	CAPPRI07	Q7 Trouble Driving	A little bit	1	QS	CAPR0107	CAPR01-Trouble Driving	CAP-PRI		A little bit		1
CAP-PRI	CAPPRI07	Q7 Trouble Driving	A lot	2	QS	CAPR0107	CAPR01-Trouble Driving	CAP-PRI		A lot		2
CAP-PRI	CAPPRI08	Q8 Dependent On Others	Not at all	0	QS	CAPR0108	CAPR01-Dependent on Others	CAP-PRI		Not at all		0
CAP-PRI	CAPPRI08	Q8 Dependent On Others	A little bit	1	QS	CAPR0108	CAPR01-Dependent on Others	CAP-PRI		A little bit		1
CAP-PRI	CAPPRI08	Q8 Dependent On Others	A lot	2	QS	CAPR0108	CAPR01-Dependent on Others	CAP-PRI		A lot		2
CAP-PRI	CAPPRI09	Q9 Depressed	Not at all	0	QS	CAPR0109	CAPR01-Depressed	CAP-PRI		Not at all		0
CAP-PRI	CAPPRI09	Q9 Depressed	A little bit	1	QS	CAPR0109	CAPR01-Depressed	CAP-PRI		A little bit		1
CAP-PRI	CAPPRI09	Q9 Depressed	A lot	2	QS	CAPR0109	CAPR01-Depressed	CAP-PRI		A lot		2

How do we get there?

Original forms from the eCOA vendor + signed DTA → CDISC QRS Supplements → CDISC CT → QRS Naming and Business Rules → Create a new mapping → Review by programming team

Lessons Learned & What's Next

Key takeaways and the path toward 360i-style automation

Lessons learned

- Standards x Programming collaboration is essential
- Invest in concept dictionaries upfront
- DTA requirements need early vendor alignment
- QC logic must evolve with new instruments

Path toward 360i-Style Automation

CDISC 360i Vision	argenx eCOA process
Machine-readable, executable metadata	Structured DTA templates in an Excel (table) format
Standards-driven automation	Automated transformation from eCOA data to SDTM (QS, FT, RS)
Built-in end-to-end traceability	Traceability to source preserved through mappings
Metadata-driven change propagation	Reusable mappings across instruments, studies, and CROs
Human-in-the-loop validation	Embedded quality checks during automated processing

From today's pipeline to the next step

Now

Standardized eCOA method:

- Standardized DTA templates
- Reusable instrument mappings
- Source traceability preserved
- Automated eCOA-to-SDTM transformation

(Near) Future

USDM and 360i:

- Machine-readable metadata
- Automation of DTA creation
- Biomedical Concepts as reusable building blocks for USDM
- Broader lifecycle automation beyond the eCOA-to-SDTM step

Thank You!

Questions?