

# *An R based Tool to Build Questionnaires, Ratings, and Scales (QRS) in EDC for Clinical Trials*

*Cilantro*

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**Presentation# SI03, PHUSE US Connect**

**Jun 14 - 18, 2021**

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# Agenda



1. **Introduction – What are Questionnaires, Ratings, and Scales (QRS)**
2. **Why we need this app**
3. **Roche Global Data Standards**
4. **Roche MDR**
5. **Cilantro App Technical details**
6. **Take away message**

## **Introduction – What are Questionnaires, Ratings, and Scales (QRS) ?**

# Questionnaire, Ratings and Scales (QRS)



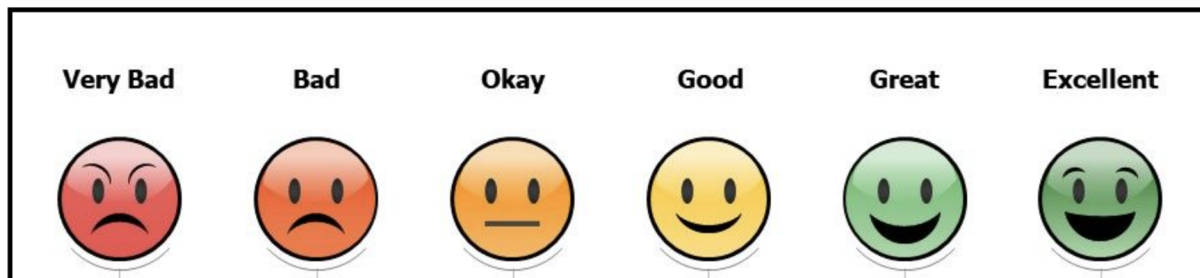
A QRS instrument is a series of questions, tasks, or assessments used in clinical research to provide a qualitative or quantitative assessment of a clinical concept or task-based observation.

CDISC provides conventions for QRS on how to structure the data in a standard format for both public domain and copyright-approved instruments.

Examples:

| Quality of Life Questionnaire |                                                                             |            |          |             |           |
|-------------------------------|-----------------------------------------------------------------------------|------------|----------|-------------|-----------|
| During the past week:         |                                                                             | Not at All | A Little | Quite a Bit | Very Much |
| 6.                            | Were you limited in doing either your work or other daily activities?       | 1          | 2        | 3           | 4         |
| 7.                            | Were you limited in pursuing your hobbies or other leisure time activities? | 1          | 2        | 3           | 4         |

## Rating Scale



## Abnormal Involuntary Movement Scale

### Trunk Movements

7. Neck, shoulders, hips, e.g., rocking, twisting, squirming, pelvic gyrations. Include diaphragmatic movements.  
0 1 2 3 4

### Global Judgments

8. Severity of abnormal movements.  
0 1 2 3 4

**Why do we need this app?**

# Challenges from the study teams



Study Teams

## Data Collection/Study Data Manager

- What QRS do I need to collect in EDC for my Study?
- How do I create the Forms and Fields in EDC using the QRS Metadata stored in the MDR?
- How much time will it take to manually build the Forms and Fields for EDC collection?

## Data Tabulation/Analysis

- How do I ensure the QRS Data are correctly implemented for Tabulation & Analysis in my study?
- If I collect QRS incorrectly in EDC, what is the downstream Data Tabulation and Analysis impact?



## Data Standards Team

- How can we facilitate implementation of QRS Forms and Fields (ALS) in EDC without discrepancies?
- How do we ensure the QRS will be collected and mapped to SDTM properly?
- How can we maximize the use of QRS data in clinical studies and significantly reduce the time it takes to manually build Forms and Fields in EDC?



There is no easy way to do this!!

## Underlying Problem - Collecting QRS in EDC is Manual Set-Up

The key underlying problem is the QRS metadata stored in the MDR is not in a format usable by EDC

- The QRS metadata is adopted from CDISC (when available), or developed following CDISC conventions for industry and sponsor defined Questionnaires.
- This QRS metadata is not in a readily consumable format for EDC system to design an eCRF.
- Collecting the standard metadata as eCRFs is not straightforward and in the process, the information may not be transcribed accurately.
- Tedious manual effort is required to collect as eCRFs in EDC



Cilantro helps the study teams to overcome these challenges and maximize the collection of QRS in clinical studies.

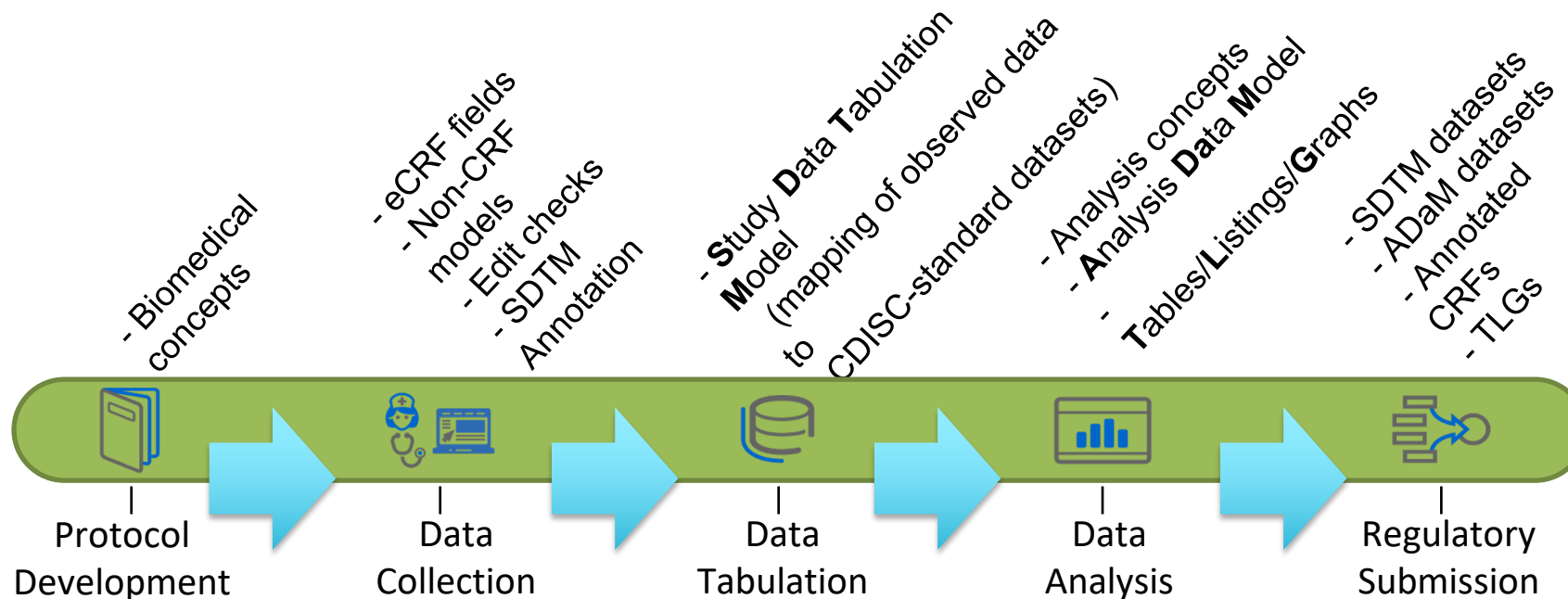
Driven by the Metadata and latest technologies, the app uses the standard metadata and creates all the attributes needed to automate the creation of the Forms, Fields, Codelists in EDC. This tool saves CDM Hours of tedious transcription of QRS metadata.

# **Roche Global Data Standards**

# Roche Global Data Standards

## What are they?

- Define how Roche clinical trial data should be collected, tabulated, analyzed, and submitted to regulatory authorities.
- Include all the 'layers' required, from biomedical concepts, metadata, and controlled terminology.
- Fully aligned with CDISC submission data standards (SDTM & ADaM), extended to ensure consistency across Roche clinical trials.
- Commonly used QRS are defined following CDISC Conventions and are part of our data standards



# Roche's MDR

## Data Standards in the GDSR (Roche MDR)

- All of Roche's Clinical Data standards are available in the GDSR to study teams (eCRFs, SDTM Mapping, Analysis)
- The GDSR is Roche and Genentech's MDR and is **the single source of truth for clinical data standards**, storing and making them available to users globally in the most business useful format.
- The data standards are **stored in semantic graphs** and the technology behind the GDSR is based on RDF, ontologies, and linked data principles aligned with Semantic Web (W3C) standards.
- The QRS metadata, is defined and stored following CDISC conventions. The format of these standards is in usable format primarily for Non-CRF collection, therefore creating a manual process for collection when collected via EDC.

### REST API

The GDSR makes content available through **a public REST API**. Users can programmatically access the data standards, catalog, publication information, and the archives, making automation of previously manual tasks possible.

### PUBLICATION VERSIONING

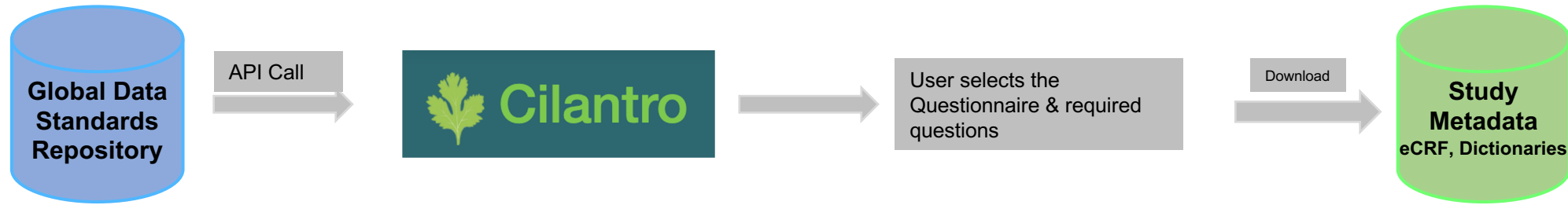
The GDSR uses **publication versioning** which allows users to access the archives of previous data standards versions. New, updated, and retired data standards are made available to users in a publication cycle and the previous publication is moved to an accessible archive.

## Cilantro App Technical details

## R Package & R-shiny Module

- To enable faster processing, the core logic of the app resides in the R-shiny packages and the user interface is built in R shiny.
- rCilantro is a Roche in-house developed R packages to support Cilantro App.
- The App can access different versions of the Questionnaire standards and prepare the metadata required to create the eCRF in the EDC.
- The App also harmonizes the standard naming conventions that further enable automation downstream in mapping them to SDTM datasets and create the controlled terminology for questionnaires.
- The R-shiny Module enables the pick & choose the questionnaires & questions required for a study.

# Cilantro App





## Questionnaire

Search:

| submission_term                                                               |
|-------------------------------------------------------------------------------|
| 1 Functional Activities Questionnaire Clinical Classification                 |
| 2 Cornell Scale For Depression in Dementia                                    |
| 3 Impact of Visual Impairment Scale Questionnaire                             |
| 4 Urticaria Control Test                                                      |
| 5 Work Productivity and Activity Impairment General Health V2.0 Questionnaire |
| 6 Abnormal Involuntary Movement Scale Clinical Classification                 |
| 7 Timed Up and Go Functional Test                                             |
| 8 European Quality of Life Five Dimension Five Level Scale Questionnaire      |
| 9 Fatigue Severity Scale                                                      |
| 10 Brief Pain Inventory Short Form Questionnaire                              |

Showing 1 to 10 of 363 entries

Previous **1** 2 3 4 5 ... 37 Next

## Questions

☐ Select/Deselect all

Show **10** entries

Search:

| question | internal_label                                                     |
|----------|--------------------------------------------------------------------|
| Q00101   | Writing checks, paying bills, balancing checkbook                  |
| Q00102   | Assembling tax records, business affairs, or papers                |
| Q00103   | Shopping alone for clothes, household necessities, or groceries    |
| Q00104   | Playing a game of skill, working on a hobby                        |
| Q00105   | Heating water, making a cup of coffee, turning off stove after use |
| Q00106   | Preparing a balanced meal                                          |
| Q00107   | Keeping track of current events                                    |
| Q00108   | Paying attention to, understanding, discussing TV, book, magazine  |
| Q00109   | Remembering appointments, family occasions, holidays, medications  |
| Q00110   | Traveling out of neighborhood, driving, arranging to take buses    |

Showing 1 to 10 of 11 entries

Previous **1** 2 Next

## Selected Questions

[Download ALS](#)

**Q001**

1 ✖

2 ✖

3 ✖

# How the study teams use it?

The study teams use the app to

- Create the CRF metadata for questionnaire by choosing the required ones.
- Using the app helps the study teams to adhere to the Roche design principles.
- **Review and resolve the discrepancies** in questionnaires before the study goes LIVE.
- Get the **SDTM annotations of the standard questionnaires in the study** and use it to create SDTM aCRF and mapping specifications. In future, the app will enable further automation of e-Submission deliverables.

The versioning in GDSR lets user to choose the version of standards (questionnaires) used for study design to produce accurate results.

**Take away message**

# Take away message



- Following FAIR principles and a Metadata driven approach has helped us create a solution that enables use of same Questionnaires, Ratings, and Scales (QRS) metadata for eCRF & non-eCRF data ensuring consistency in the data collected .
- Having the right infrastructure, well defined data standards, a MDR and efficient use of technology is key to the success.
- This idea could be extended to any EDC and MDR.

# References



- [www.cdisc.org](http://www.cdisc.org)
- GDSR – Data Standards in the GDSR (Global Data Standards Repository)
- <https://www.lexjansen.com/phuse/2019/pp/PP06.pdf> - Huw Mason, F Hoffmann - La Roche, Basel, Switzerland
- R packages by Hadley Wickham
- Shiny Dashboard <https://rstudio.github.io/shinydashboard/index.html>

***Doing now what patients need  
next***