

Advancing interactive CQM framework: Transforming innovation into implementation

Yash Ankurbhai Shah, Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach, Germany

Kavitha Allala, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, USA

Presenter: Hitoshi Yamauchi, Nippon Boehringer Ingelheim Co., Ltd.

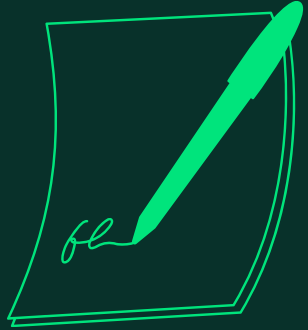
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Agenda

- 01 Setting the Stage**

- 02 From Static to Interactive: The CQM Journey**

- 03 Driving Adoption and Continuous Improvement**

- 04 Looking Ahead: Future Direction**

Setting the Stage

Open-source Landscape Overview



1. Rapid Growth

Expanding ecosystem
(pharmaverse, admiral, teal,
ramnog, pharmaRTF, DaVinci,
etc.)



2. Key Benefits

Cost efficiency, flexibility, and
interactive outputs



3. Adoption Challenges

Upskilling from SAS® to R, lack
of standardization



4. Industry Trends

Global collaboration, focus on
interactivity, and AI/LLM
integration

Introduction to Clinical Quality Monitoring (CQM)



- **What is CQM?**
 - A quarterly cross-functional review of aggregated clinical data (tables, listings, figures) to ensure data integrity and accuracy
 - Involves trial team members: Clinical leaders, study physicians, statisticians, data managers, programmers, and safety physicians
- **Why CQM Initiative?**
 - Current process relies on static PDF outputs generated in SAS®, often thousands of pages long
 - Review meetings are time-intensive (1–2 hours) and require manual querying via email for clarifications
- **Challenges in Current Process**
 - Static outputs: PDF files are difficult to navigate and review efficiently
 - Dependency: Reviewers rely heavily on programmers for filtering, sorting, and exporting data
 - Time Lapse: Queries and resolutions during the review process cause delays
- **Interactive CQM**
 - Improved efficiency in clinical data review
 - Enhanced reviewer autonomy with interactive tools
 - Reduced reliance on programmers for data queries and clarifications

From Static to Interactive: The CQM Journey

Interactive CQM Framework: Last Year's Progress



Challenges identified

- Static outputs (e.g., PDFs) were resource-intensive and lacked interactivity
- Reviewers relied heavily on programmers for filtering, sorting, and exporting data
- Time-consuming, iterative review process with delays in query resolution



Proposed solution

- Interactive CQM Framework leveraging open-source R packages:
 - Framework reduces dependency on programmers and speeds up review cycles



Workflow overview

- Programmer Develops Tables: Using {Tplyr} to create summary tables and listings
- Outputs can be integrated into Desired Platforms:
 - Shiny App: Fully interactive application for reviewing data
 - Quarto Shiny: Lightweight and customizable reporting
 - Internal Framework (DaVinci): Modular and scalable solution for clinical trial reporting
 - End results shared with users: Reviewers can sort, filter, export, and drill down into data

Workflow Overview

Programmer develops
tables



Programmers put them into
desired output (Shiny App,
Quarto Shiny, Internal framework)



See the end results and share with their
end users (custom shiny app, Quarto,
DaVinci framework)

```
tab2 <- Tplyr::tplyr_table(adae, TRTA) |>
  Tplyr::set_pop_data(adsl) |>
  Tplyr::set_pop_treat_var(TRT01A) |>
  Tplyr::add_layer(
    Tplyr::group_count("All subject") |>
    Tplyr::set_distinct_by(USUBJID) |>
    Tplyr::set_format_strings(Tplyr::f_str(
      "xx",
      distinct_total
    ))
  ) |>
  Tplyr::add_layer(
    Tplyr::group_count("Subjects with adverse events") |>
    Tplyr::set_distinct_by(USUBJID) |>
    Tplyr::set_format_strings(Tplyr::f_str(
      "xx (xx %)",
      distinct_n, distinct_pct
    ))
  ) |>
  Tplyr::add_layer(
    Tplyr::group_count(AESEV, by = "Adverse event severity") |>
    Tplyr::set_distinct_by(USUBJID) |>
    Tplyr::set_format_strings(Tplyr::f_str(
      "xx (xx %)",
      distinct_n, distinct_pct
    ))
  )
```

```
# Define UI for application
ui <- fluidPage(

  # Application title
  titlePanel("demo CQM app"),

  # Main panel with tabs
  mainPanel(
    tabsetPanel(

      tabPanel("Demographics",
        reactableUI("res1")),
      tabPanel("Adverse Events",
        reactableUI("res2")),
      tabPanel("Demographics",
        reactableUI("res3")),
      tabPanel("Demographics listing",
        customizedlistingUI("listing1")),

    )
  )
)
```

```
# Define server logic
server <- function(input, output) {

  customizedlistingServer("listing1", mock_adsl, "listthree.csv", showAllcols = TRUE)
  reactableServer("res1", results1, table1, "adslownloadfile.csv", showAllcols = TRUE)
  reactableServer("res2", results2, table2, "adaedownloadfile.csv", showAllcols = list("STUDYID"),
    minimumcolwidth = 50)
  reactableServer("res3", results1, table1, "adslownloadfile.csv", showAllcols = list("AGE", "EOSSTT"),
    minimumcolwidth = 1)

}

# Run the application
shinyApp(ui = ui, server = server)
```

Age (years)	Sex	Weight (kg)	Height (cm)	Ethnicity
66	M	70.0	170.0	White

Number of patients	Placebo	Xanomeline High Dose	Xanomeline Low Dose
1	1	1	1

Age (years)	Sex	Weight (kg)	Height (cm)	Ethnicity
66	M	70.0	170.0	White



Goal:

- Unified tool for efficient, interactive output reviews
- Focus on CQM requirements, not just SAS-to-R conversion
- Stakeholder needs drive implementation via DaVinci modules



Creation of Template Catalog:

- Standardized CQM templates for faster, consistent outputs across Therapeutic Areas(TAs)
- Templates can be requested or customized as needed



New Features:

- Data Review Tracking
- Bulk Editing
- Dynamic Titles
- Highlight data refresh for real-time updates
- Interactive tables with global filters for dynamic re-rendering



Impact

- **Faster:** Quicker reviews
- **Better:** More efficient decisions, fewer iterations
- **Easier:** Rapid app development for programmers

Evolution of the framework

Data Review Tracking

Da Vinci

Subject Level Filter
06 of 306 total entries selected
Add / Remove Filters
Clear All Filters

Click to see inputs Download Reset all filters Reset Row Order Review

Search:

	Latest Review	Latest Reviewer	Status	USUBJID [Unique Subject Identifier]	AESEV [Severity/Intensity]	RFXSTDTC [Date/Time of First Study Treatment]	RFSTDTC [Subject Reference Start Date/Time]	AETERM [Reported Term for the Adverse Event]	AEHLGT [High Level Group Term]	AEHLT [High Level Term]	AELLT [Lowest Level Term]	AEDECOD [Dictionary-Derived Term]	AESOC [System Class]
	All	All	All	All	All	All	All	All	All	All	All	All	All
1	Action required	SP	Conflict I can fix	01-701-1015	MILD	2014-01-02	2014-01-02	APPLICATION SITE ERYTHEMA	HLGT_0152	HLT_0617	APPLICATION SITE REDNESS	APPLICATION SITE ERYTHEMA	GE DISOR ADMIN SITE C
2	Resolved	SP	Conflict I can fix	01-701-1015	MILD	2014-01-02	2014-01-02	APPLICATION SITE PRURITUS	HLGT_0338	HLT_0317	APPLICATION SITE ITCHING	APPLICATION SITE PRURITUS	GE DISOR ADMIN SITE C
3	Action required	SP	Conflict I can fix	01-701-1015	MILD	2014-01-02	2014-01-02	DIARRHOEA	HLGT_0588	HLT_0148	DIARRHEA	DIARRHOEA	GASTRO DISO
4	Action required	TSTAT	Conflict	01-701-1023	MILD	2012-08-05	2012-08-05	ATRIOVENTRICULAR BLOCK SECOND DEGREE	HLGT_0086	HLT_0415	AV BLOCK SECOND DEGREE	ATRIOVENTRICULAR BLOCK SECOND DEGREE	CA DISO
5	Action required	TSTAT	OK	01-701-1023	MILD	2012-08-05	2012-08-05	ERYTHEMA	HLGT_0192	HLT_0284	ERYTHEMA	ERYTHEMA	SK SUBCL TISSUE
6	Resolved	TSTAT	OK	01-701-1023	MODERATE	2012-08-05	2012-08-05	ERYTHEMA	HLGT_0192	HLT_0284	LOCALIZED ERYTHEMA	ERYTHEMA	SK SUBCL TISSUE
7	Reviewed with no issues	TSTAT	OK	01-701-1023	MILD	2012-08-05	2012-08-05	ERYTHEMA	HLGT_0192	HLT_0284	ERYTHEMA	ERYTHEMA	SK SUBCL TISSUE
8	Pending		Pending	01-701-1028	MILD	2013-07-19	2013-07-19	APPLICATION SITE ERYTHEMA	HLGT_0152	HLT_0617	APPLICATION SITE ERYTHEMA	APPLICATION SITE ERYTHEMA	GE DISOR ADMIN SITE C
9	Pending		Pending	01-701-1028	MILD	2013-07-19	2013-07-19	APPLICATION SITE PRURITUS	HLGT_0338	HLT_0317	APPLICATION SITE ITCHING	APPLICATION SITE PRURITUS	GE DISOR ADMIN SITE C

9 records

Dataset name: CQM_AE_list Dataset date: 2025-Jan-22 (CET)

Bulk Edit

Content / CQM_demo

Da Vinci

Subject Level Filter

254 of 254 total entries selected

Add / Remove Filters

Clear All Filters

ManualListingPatient Profile

Click to see inputsDownloadReset all filtersReset Row OrderReview

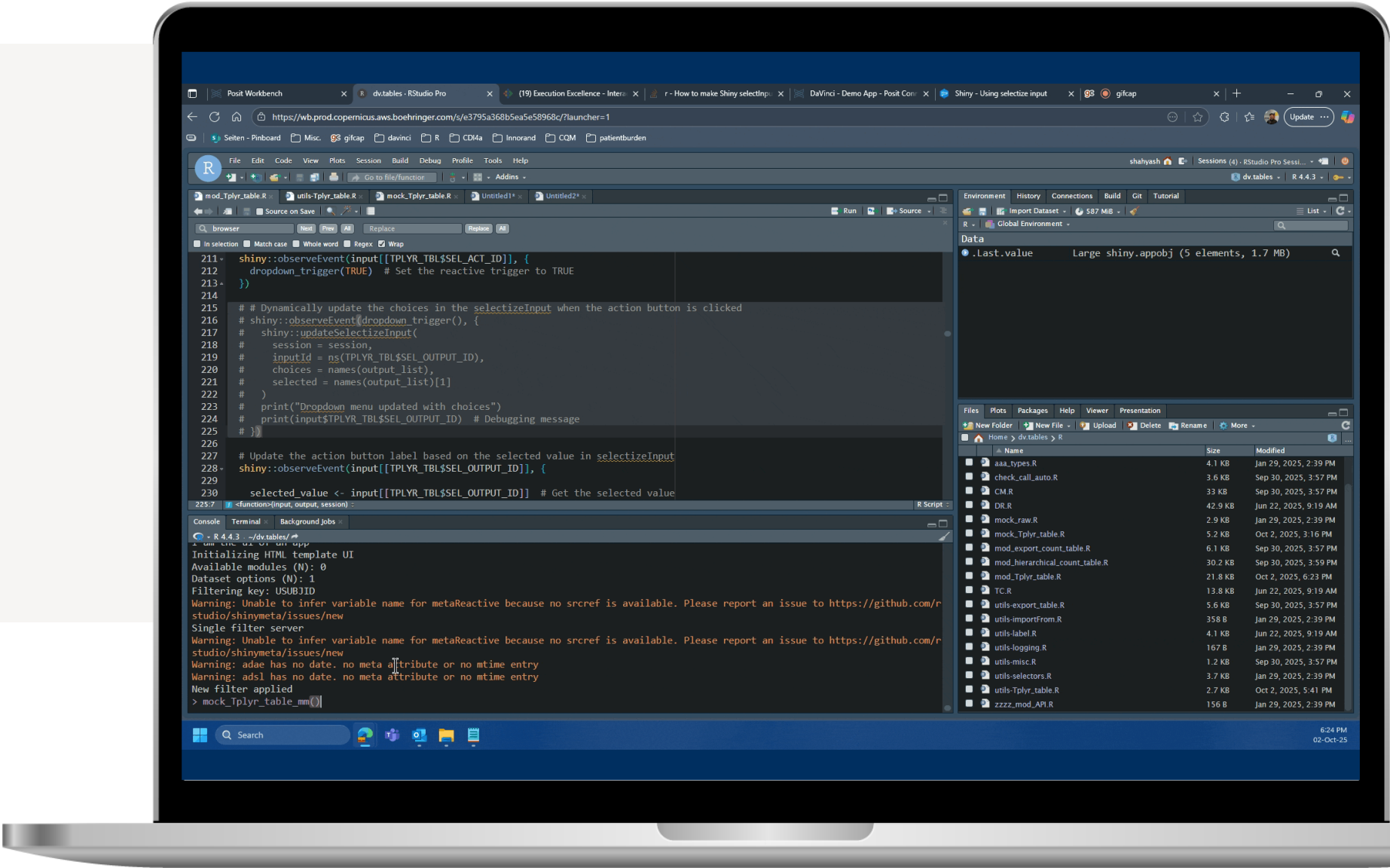
Search:

	USUBJID [Unique Subject Identifier]	AESEV [Severity/Intensity]	RFXSTDTC [Date/Time of First Study Treatment]	RFSTDTC [Subject Reference Start Date/Time]	AETERM [Reported Term for the Adverse Event]	AEHLGT [High Level Group Term]	AEHLT [High Level Term]	AELLT [Lowest Level Term]	AEDECOD [Dictionary- Derived Term]	AESOC [Primary System Organ Class]	AESTDTC [Start Date/Time of Adverse Event]	AEENDTC [End Date/Time of Adverse Event]	AEOU [Out- Adverse E
	All	All	All	All	All	All	All	All	All	All	All	All	All
1	01-701-1015	MILD	2014-01-02	2014-01-02	APPLICATION SITE ERYTHEMA	HLGT_0152	HLT_0617	APPLICATION SITE REDNESS	APPLICATION SITE ERYTHEMA	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2014-01-03		NOT RECOVI RESOL
2	01-701-1015	MILD	2014-01-02	2014-01-02	APPLICATION SITE PRURITUS	HLGT_0338	HLT_0317	APPLICATION SITE ITCHING	APPLICATION SITE PRURITUS	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2014-01-03		NOT RECOVI RESOL
3	01-701-1015	MILD	2014-01-02	2014-01-02	DIARRHOEA	HLGT_0588	HLT_0148	DIARRHEA	DIARRHOEA	GASTROINTESTINAL DISORDERS	2014-01-09	2014-01-11	RECOVERED/
4	01-701-1023	MILD	2012-08-05	2012-08-05	ATRIOVENTRICULAR BLOCK SECOND DEGREE	HLGT_0086	HLT_0415	AV BLOCK SECOND DEGREE	ATRIOVENTRICULAR BLOCK SECOND DEGREE	CARDIAC DISORDERS	2012-08-26		NOT RECOVI RESOL
5	01-701-1023	MILD	2012-08-05	2012-08-05	ERYTHEMA	HLGT_0192	HLT_0284	ERYTHEMA	ERYTHEMA	SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2012-08-07	2012-08-30	NOT RECOVI RESOL
6	01-701-1023	MODERATE	2012-08-05	2012-08-05	ERYTHEMA	HLGT_0192	HLT_0284	LOCALIZED ERYTHEMA	ERYTHEMA	SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2012-08-07		NOT RECOVI RESOL
7	01-701-1023	MILD	2012-08-05	2012-08-05	ERYTHEMA	HLGT_0192	HLT_0284	ERYTHEMA	ERYTHEMA	SKIN AND SUBCUTANEOUS	2012-08-07	2012-08-30	RECOVERED/

9 recordsDataset name: CQM_AE_listDataset date: 2025-Jan-22 (UTC)

Could not gain write access to folder

Dynamic Titles



Data Refresh Column Highlight

Pending

Apply selected

Latest Review	Latest Reviewer	Status	STUDYID [Study ID]	SUBJID [Subject ID]	USUBJID [Unique Subject ID]	v1_dt [V1 Date]	RFSTDTC [Randomization date]	AEEPOCH [Epoch]	AETERM [Reported term]	AESER [Serious (Y/N)]	AESLIFE [Seriousness criteria]	AESTDTC [AE Start Date]	AEEENDTC [AE End Date]
All	All	All	All	["2303200101"]	All	All	All	All	All	All	All	All	All
☐ Reviewed with no issues	TSTAT	OK	1305-0023	2303200101	1305-0023-2303200101	2023-06-27	2023-08-07T12:07	Missing	URINARY INFECTION	N		2023-09-19	2023-09-26
☐ Action required	TSTAT	OK	1305-0023	2303200101	1305-0023-2303200101	2023-06-27	2023-08-07T12:07	Missing	SUSPECTED ACUTE EXACERBATION OF DISEASE	Y	N	2024-01-01	2024-02-25

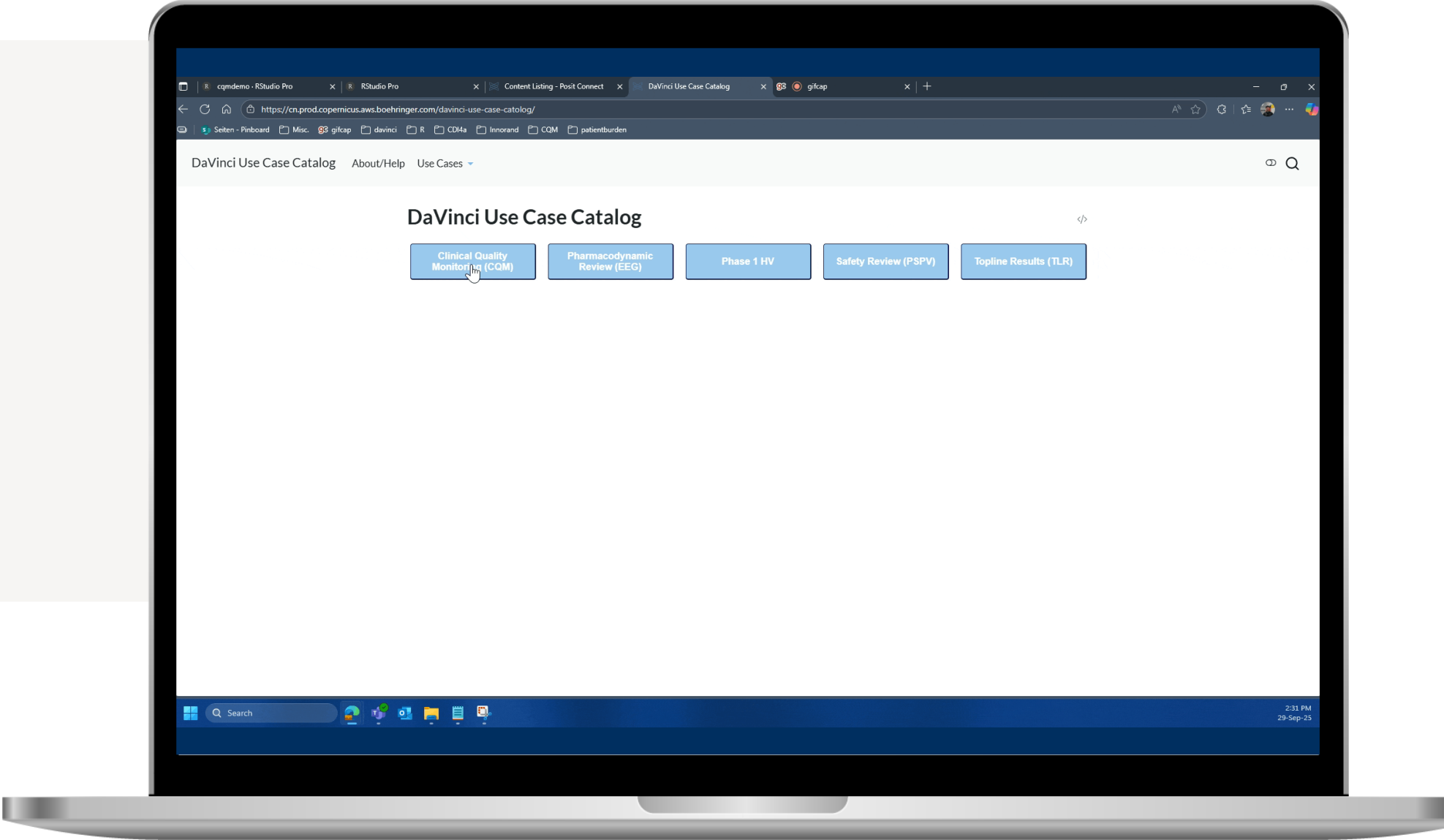
Latest Review	Latest Reviewer	Status	STUDYID [Study ID]	SUBJID [Subject ID]	USUBJID [Unique Subject ID]	v1_dt [V1 Date]	RFSTDTC [Randomization date]	AEEPOCH [No label]	AETERM [No label]	AESER [No label]	AESLIFE [Seriousness criteria]	AESTDTC [AE Start Date]	AEEENDTC [AE End Date]
All	All	All	All	All	All	All	All	All	All	All	All	All	All
1 ☐ Reviewed with no issues	TSTAT	Latest Outdated	1305-0023	2303200101	1305-0023-2303200101	2023-06-27	2023-08-07T12:07	Modified Term	Modified Term	Y		2023-09-19	2023-09-26
2 ☐ Action required	TSTAT	OK	1305-0023	2303200101	1305-0023-2303200101	2023-06-27	2023-08-07T12:07	Modified Term	Modified Term	Y	N	2024-01-01	2024-02-25
3 ☐ Resolved	TSTAT	OK	1305-0023	2303200102	1305-0023-2303200102	2023-06-28	2023-08-14T11:40	Missing	ELEVATED GLUCOSE	N		2023-06-28T10:50	

CQM Template Catalog

- **Standardized Templates:**
Serve as references for interactive outputs, with minor adjustments for specific needs.
- **Developer Efficiency:**
Enable quick creation of R Shiny apps using DaVinci modules—no need to start from scratch.
- **Stakeholder Collaboration:**
Templates requested and refined with input from various teams; finalized versions support consistent use across TAs.



CQM Template Catalog



Driving Adoption and Continuous Improvement

Outcome and Results



DaVinci Modules

Implemented features like review tracking, bulk review, data refresh, and interactive tables



Template Catalog

Expanded with standard and TA-specific templates, refined through team feedback



Continuous Improvement

Ongoing updates based on user and stakeholders' input



Adoption

Trial teams began using the interactive CQM from Q3 2025; training and resources support adoption



Future Expansion:

More trial teams expected to join, fostering collaboration and learning

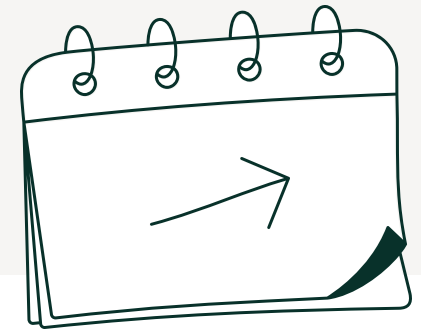
Anticipated Outcomes

- **Roadmap:** Clearer timelines and processes for template creation and review
- **Technical Challenges:** Debugging in R, learning DaVinci R package
- **Transition:** Adapting to new TAs, SAS®-to-R conversion not always direct
- **Efficiency:** Faster CQM reviews
- **Collaboration:** Improved cross-functional teamwork and knowledge sharing across TAs



Looking Ahead: Future Directions

What's Next?



CQM Adoption



- **Focus on training and onboarding through:**
 - **Pilot studies:** Work with trial teams to implement and refine the framework
 - **End-user engagement:** Regular feature presentations and stakeholder feedback sessions
 - **Training resources:** Short training videos to support adoption

Future Steps



- Development of **interactive CQM figure outputs** to complement listings and tables
- **Reduce the number of listing and table outputs** by providing more visual and intuitive insights via figures
- Expand the **Template Catalog** to include advanced features and support diverse needs
- Explore **LLM (Large Language Models) integration** for automation and decision support

Our Open Source Commitment

- After several years of in-house user research and development, DaVinci is now open-source and available on GitHub!



- DaVinci homepage:
[DaVinci - Dynamic Visualization for Clinical Insights – DaVinci](#)
- DaVinci repositories:
[Boehringer-Ingelheim repositories](#)

- Benefits of open-sourcing DaVinci



- Makes our packages accessible to others
- Encourages enhancements and direct contributions from the community

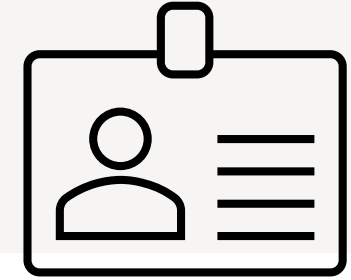


Homepage



Repositories

Contact Details



- Yash Ankurbhai Shah yash_ankurbhai.shah@boehringer-ingelheim.com
- Kavitha Allala kavitha.allala@boehringer-ingelheim.com
- Hitoshi Yamauchi hitoshi.yamauchi@boehringer-ingelheim.com