

A Customized Algorithm to Evaluate the Quality and Reliability of Real-World Lab Data

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- Real-world data (RWD) data collected outside of clinical trials.
- The quality and reliability of RWD are for successful RWD studies.
- Lab tests essential part of RWD faced quality and reliability challenges.

FDA | CDER | Small Business and Industry Assistance **INDUSTRY NEWS**

CDER Establishes New Center for Real-World Evidence Innovation

Today, the U.S. Food and Drug Administration's [Center for Drug Evaluation and Research \(CDER\)](#) announced the new [CDER Center for Real-World Evidence Innovation \(CCRI\)](#) which aims to coordinate, advance, and promote the use of real-world data (RWD) and real-world evidence (RWE) in regulatory decision-making across CDER.

RWD relates to a patient's health status and/or the delivery of health care routinely collected from a variety of sources (e.g., electronic health records, medical claims, product and disease registries, and cutting-edge technologies). By using data from routine clinical practice, we can generate evidence (referred to as RWE) that provides valuable insights into the safety and effectiveness of medical products.

The volume and complexity of data available to support drug development have increased substantially over the past several decades. This increase—combined with enhanced computing power, emerging technologies, and advances in epidemiological and statistical methods—are transforming how drugs are developed, manufactured, and utilized.

The goal of CCRI will be to advance, coordinate, and promote consistency across RWD/RWE-related initiatives in CDER, including related uses of emerging technologies in both internal and external FDA

Opportunity



- FDA's Real-world Evidence (RWE) Program Leverages RWD for healthcare and regulatory decisions.
- Provides frameworks and guidance for using RWD/RWE in drug and biologic evaluations.
- Emphasizes data quality (DQ) and reliability as critical for decision-making.

A screenshot of the U.S. Food & Drug Administration (FDA) website showing a guidance document. The header is dark blue with the FDA logo and "U.S. FOOD & DRUG ADMINISTRATION" text. To the right are "Search" and "Menu" buttons. Below the header, a breadcrumb trail reads: "Home / Regulatory Information / Search for FDA Guidance Documents / Real-World Data: Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products". The main content area is white and features the title "Real-World Data: Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products" in a large, bold, black serif font. Above the title is the label "GUIDANCE DOCUMENT" in a smaller, black, sans-serif font. Below the title is the subtitle "Guidance for Industry" in an italicized, black, serif font. The date "JULY 2024" is centered below the subtitle. At the bottom of the page are two blue buttons: "Download the Final Guidance Document" and "Read the Federal Register Notice".

U.S. FOOD & DRUG ADMINISTRATION

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GUIDANCE DOCUMENT

Real-World Data: Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products

Guidance for Industry

JULY 2024

Download the Final Guidance Document Read the Federal Register Notice

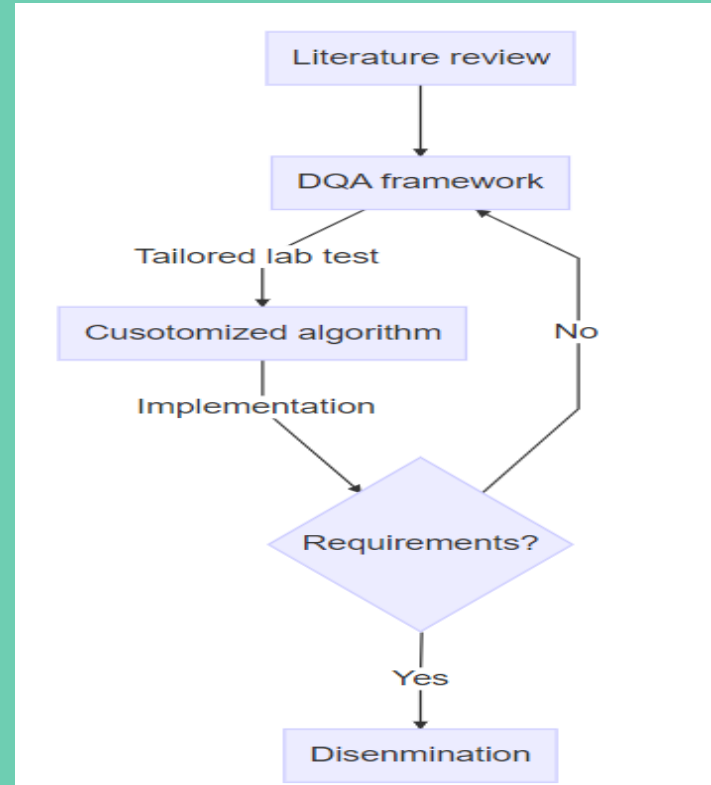
Real-world data Issues: incompleteness, inconsistency, and inaccuracy.

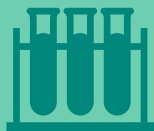
- Gaps in existing quality assessment frameworks.
- FDA emphasizes the importance of ensuring RWD is “fit-for-purpose” for reliable research and regulatory outcomes.

Customized Algorithm Process



1. Literature review.
2. Online resources lab DQ.
3. Build check for labs of interest.
4. Implementation.
5. Result analysis.
6. Dissemination.





Implementation of lab DQ checks based on OHDSI DQD framework.



Result analysis of customized DQD framework.



Customization of SQL queries for specific lab tests.



Query modification and lab codes expanding.

1. Technology: R language with HTML/JavaScript result display.
2. Framework: Uses CSV files and SQL scripts for DQ checks.
3. Extensible: Allows for additional DQ checks and customization.

Customization for Lab Data

Focus on Lab Data
(MEASUREMENT Table)

Contains lab test orders
and results

Numerical Values:
VALUE_AS_NUMBER

Categorical Values:
VALUE_AS_CONCEPT.



Oncology-related labs



Diabetes-related labs



Metabolic syndrome related labs



Liver panel/disease labs



General population labs

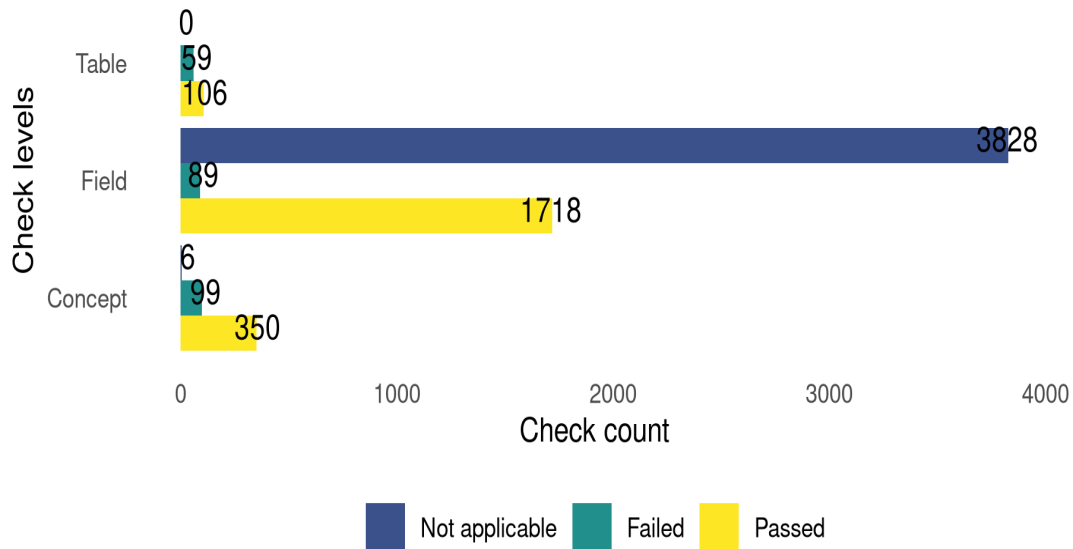
Results



Check results



- 2 Contexts
- 3 Check levels
- 3 Categories
- 6 Subcategories
- 104 Unique checks
- 6255 Total checks



Shiny Dashboard for DQ Checks



The screenshot shows a web application interface. On the left is a dark sidebar with a vertical list of navigation items: "Home" (with a house icon), "Overview" (with a document icon), "Results" (with a document icon), and "Meta" (with a document icon). The main content area has a light blue header. Below the header, there is a section titled "RWDEx lab data quality check" with a flask icon. The text in this section describes a tailored lab data quality assessment conducted within the OHDSI data quality dashboard framework. It states that results are accessible for five major databases on the Real World Data Exchange platform. It then instructs the user to choose a database in the Overview tab and navigate to other tabs for further details. Below this text is a "Notes:" section with a notepad icon, stating that quality results were updated on September 23, 2024, and that databases that have been refreshed will need to rerun the algorithm.

RWDEx lab data quality check

This tailored Lab data quality assessment was conducted within the OHDSI data quality dashboard framework.

Results of the assessments are accessible for five major databases on the Real World Data Exchange platform.

Please choose a database in the Overview tab and navigate to the other tabs for further details.

 **Notes:**

Quality results were updated on September 23, 2024.

Databases that have been refreshed will need to rerun the algorithm.



- Syntax errors: Syntax conversions from SQL Server to Redshift through SQL render.
- OMOP CDM compliance: Deviation of standards CDM.
- Failure to Meet Thresholds: A thorough resolution required collaborative analysis with independently verify and adjust the data queries.
- Screening Failed DQ Checks: Failed DQ checks often result from flawed SQL implementation, ETL process issues, or inherent problems with the data sources.

- Beyond SQL: Enhancements to the R package were essential to implement specific DQ checks.
- DQ Indicators: A more sophisticated DQ framework to advance beyond this basic indicator.
- Investigating ETL Processes: Addressing these problems is vital for enhancing the overall DQ.
- Source Data Verification: document known issues stemming directly from the initial data collection. Potential inaccuracies or anomalies in the data, guiding more informed analysis.

1. Some sophisticated assessments needs open-source languages such as Python and R.
2. SQL queries may require syntax conversion.
3. Comprehensive list of data quality constraints.
4. Implementation of the algorithm needs resources.

- Well-documented process and easily reproducible codes, exemplifies compliance with FDA guidance.
- Adaptable for other data elements quality check.
- Cost-efficient approach for assessing RWD usability.
- A compliant process for regulatory submissions involving RWD.

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THANK YOU!



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