

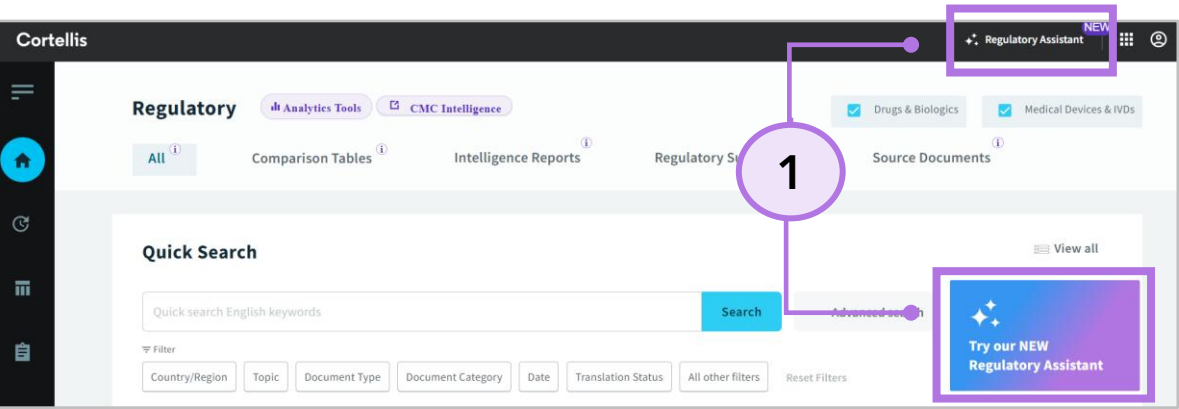
Summarize an authority document

Cortellis Regulatory Intelligence



Obtain a summary of authority documents in Cortellis, for example guidelines and legislation, from several entry points in Cortellis.

Example: Provide a brief summary of: **EMA/503781/2024: Data Quality Framework for EU Medicines Regulation Application to Real-World Data, 27-Mar-2026**



- 1. Access the **Regulatory Assistant** on the Home screen next to Quick Search OR from any Cortellis Regulatory Intelligence screen via the black ribbon at the top.
- 2. Select the **"Summarize a document"** task tile.
- 3. Type the **document name, title or IDRAC number** into the search box.

Hi Beth, what is your regulatory question?

Let me find answers from our high-quality, comprehensive, and verified regulatory data

Briefly summarize EMA/503781/2024: Data Quality Framework for EU Medicines Regulation Application to Real-World Data, 27-Mar-2026

➔

You can currently ask me to...

Understand a requirement

For example: "What is the requirement for retaining records in clinical trials in the US?"

Find a document

For example: "Find me a document about the distribution of drug samples in Canada"

Summarize a document

For example: "Briefly summarize the FDA's press release announcing completion of the first AI-assisted scientific review"

Compare versions

For example: "What changed between the latest EU Guideline on the Chemistry of Active Substances and the previous version?"

NOTE: The **IDRAC number** is a specific identifier number associated with each document in Cortellis Regulatory Intelligence. Searching the IDRAC number ensures you find the exact document you are looking for. Find the IDRAC number in the upper left-hand corner of the Cortellis document.



Briefly summarize EMA/503781/2024: Data Quality Framework for EU Medicines Regulation Application to Real-World Data, 27-Mar-2026



Answer

How was this generated? ▾

I have found the following documents that match your description. Please select which document you would like summarized:

- EMA/326985/2023: Data Quality Framework for EU Medicines Regulation, 30-Oct-2023
- EMA/503781/2024: Data Quality Framework for EU Medicines Regulation Application to Real-World Data, 27-Mar-2026
- EMA Workshop: Data Quality Framework for Medicines Regulation Held on 07-Apr-2022

Source documents ▴

- 1 [EMA/326985/2023: Data Quality Framework for EU Medicines Regulation, 30-Oct-2023](#)
Guideline • EMA • European Union • Last updated 05-Jun-2026 • More info • Summarize Version comparison
- 2 [EMA/503781/2024: Data Quality Framework for EU Medicines Regulation Application to Real-World Data, 27-Mar-2026](#)
Guideline • EMA • European Union • Last updated 07-Apr-2026 • Summarize Version comparison
- 3 [EMA Workshop: Data Quality Framework for Medicines Regulation Held on 07-Apr-2022](#)
Meeting • EMA • European Union • Last updated 30-Jun-2022 • More info • Summarize

Type your follow-up message

4. On the next page you may see your summary right away, or a list of several documents. If you see a list, choose the document you want summarized by **selecting that document's Summarize button**. **Your summary will appear.**

5. Ask for more detail on one section of the summary, or the whole summary by asking via the follow-up box.



Answer

Here is a brief summary of the "Data Quality Framework for EU medicines regulation: application to Real-World Data (RW-DQF)" (EMA/503781/2024):

- **Main Subject:** This draft document, developed by the European Medicines Agency (EMA) and the Committee for Human Medicinal Products (CHMP), provides a framework for assessing the quality of Real-World Data (RWD) used in EU medicines regulation. It extends the existing EMRN Data Quality Framework (DQF) to address the specific challenges of RWD.
- **Purpose:** The RW-DQF offers actionable recommendations for evaluating RWD quality, supporting regulatory submissions, and facilitating the use of Real-World Evidence (RWE) in regulatory decision-making.
- **Actionable Items:**
 - Stakeholders are encouraged to use the RW-DQF as a tool for assessing RWD quality.
 - The framework includes checklists, maturity models, and templates for RWD assessment.
 - It does not set fixed thresholds but promotes a continuous improvement approach.
- **Impact on Stakeholders:**
 - Applies to regulators, pharmaceutical companies, and other entities involved in regulatory processes using RWD.
- **Key Dates/Deadlines:**
 - Public consultation runs from 29 November 2024 to 29 January 2025.
 - Final adoption by CHMP occurred on 16 March 2025.

Relationships:

- This document is an extension of the EMRN DQF and should be read alongside related EMA and ICH guidelines.

Would you like a more detailed version of this summary?

Source documents ▴

- 1 [EMA/503781/2024: Data Quality Framework for EU Medicines Regulation Application to Real-World Data, 27-Mar-2026](#)
Guideline • EMA • European Union • Last updated 07-Apr-2026 • More info • Summarize Version comparison



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Please provide a more detailed summary



Source documents

6

- 1 [Pharmacovigilance and Risk Management](#)
Expert Report • Cortellis • China • Last updated 27-Feb-2026 • [More info](#)
- 2 [MOH Order No. 81: Provision for the Adverse Drug Reaction \(ADR\) Reporting and Monitoring, 04-May-2011](#)
Order • NMPA • China • Last updated 14-Aug-2025 • [More info](#) • [Summarize](#) • [Version comparison](#)
- 3 [NMPA Announcement No. 2018/66: Direct Reporting of Adverse Reactions by Marketing Authorization Holders of Drug Products, 29-Sep-2018 \(English and Chinese versions\)](#)
Announcement • NMPA • China • Last updated 15-Aug-2025 • [More info](#) • [Summarize](#) • [Version comparison](#)
- 4 [NMPA Notification 2018/131: Issuance of Guidelines on Collection and Reporting of Cases of Drug Adverse Reactions, 19-Dec-2018 \(English and Chinese Versions\)](#)
Notification • NMPA • China • Last updated 15-Aug-2025 • [More info](#) • [Summarize](#) • [Version comparison](#)

For more information contact Customer Care
at LSH.support@clarivate.com

6. You can request a summary of any Reference document from the Sources shown with a Regulatory Assistant answer – not only when you specifically ask for a summary.

7. Reference documents in Cortellis now include a Summarize button, so you can create a summary directly from the document. Simply click the AI Summary button.

The screenshot shows the Cortellis web interface. At the top, the header includes the Cortellis logo, a 'Regulatory Assistant' button with a 'NEW' badge, and user profile icons. A left sidebar contains navigation icons. The main content area displays a document titled 'CNIL Deliberation No. 2026-050 of 19-Mar-2026 approving a Reference Methodology relating to the Processing of Personal Data Implemented in the Context of Health Research requiring the Consent of the Person concerned for Participation in the Research (MR-001) and repealing Deliberation No. 2018-153'. Below the title are several filter tags: 'Valid', '430544', 'France', 'Reference Document', 'Legislation', 'Translation: Machine Translation', 'Drugs and Biologics', 'Medical Devices and IVDs', 'No specific Specialty', 'Clinical Research', and 'Regulatory Procedures'. On the right side of the document, there is a row of action buttons: 'AI summary' (highlighted with a purple circle and the number 7), 'Version Comparison', 'Side by side', 'Save & alert', and 'Download'. On the left, a table of contents lists: '1. Summary', '2. Document', '3. Reason For Update', '4. Mentioned Documents', and '5. Mentioned By'. The 'Summary' section is expanded, showing an 'Abstract' that states: 'This CNIL's deliberation updates and adopts the MR-001 reference methodology governing personal data processing in health research requiring participant consent, replacing Deliberation No. 2018-153 to reflect legal, technological, and security developments. It allows controllers to rely on a declaration of compliance instead of prior'. Below the abstract, there is a 'Previous version' section with a link to 'CNIL Deliberation 2018-153 on the Approval of a Reference Methodology Relating to Personal Data Processing, Implemented in the Healthcare Research Context with the Consent of the Data Subject (MR-001) - Repealing Decision No. 2016-262 of 21-Jul-2016, 03-May-2018'. A 'Support' button is visible in the bottom right corner.