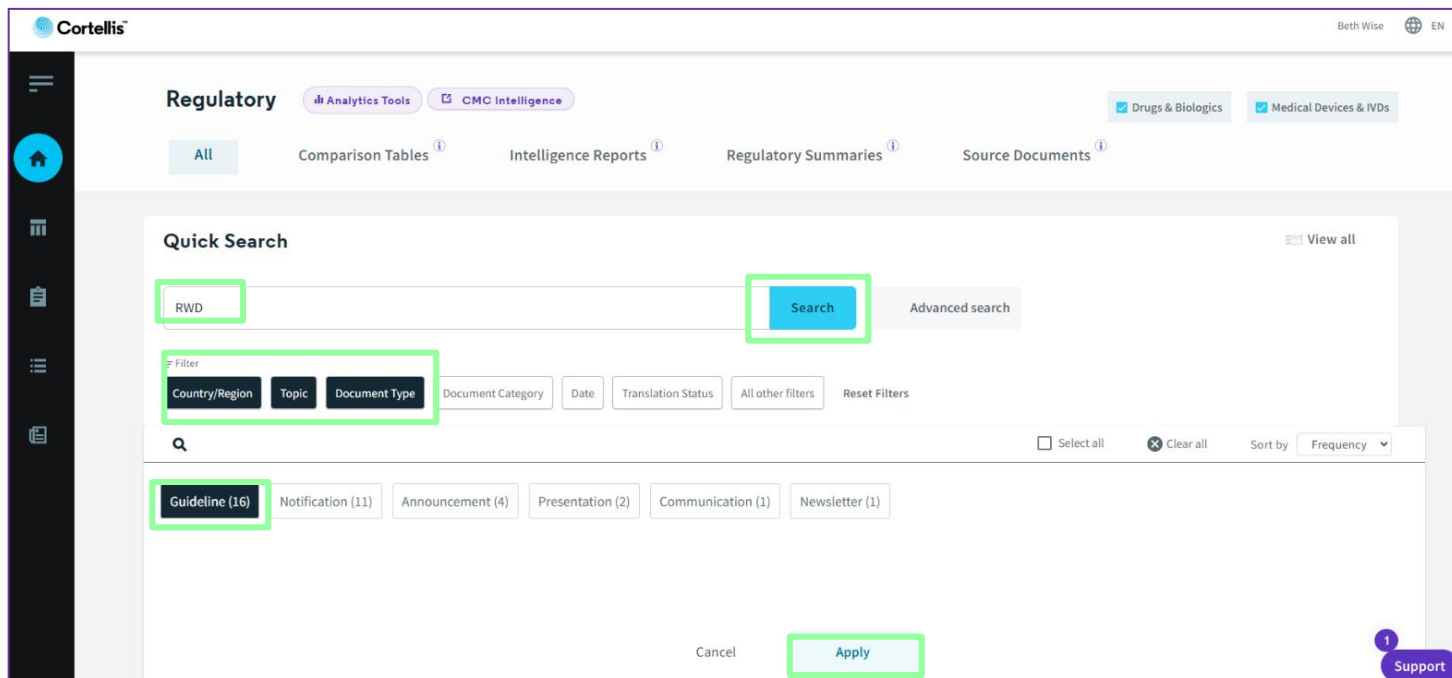


Searching Source Documents

Locate the Source or Reference documents you need, for example guidelines, regulations, approval documents and more, by using Quick Search on the Regulatory Home Page or Search on the Source Documents Page.

Example: Quickly locate all clinical research guidelines for China and Japan with a focus on real world evidence.

1. Use Quick Search on the Home Page
2. Ensure desired content is selected: Drugs & Biologics or Medical Devices & IVDs or both*
3. Type keyword RWD into the search field. ***This searches key fields in the reports only providing more targeted results***
4. Open the Country/Region filters and select Japan and China and click Apply
5. Open the Topic filter and select Clinical Research and click Apply
6. Open the Document Type filter and select Guideline and click Apply
7. Click Search



The screenshot shows the Cortellis Regulatory Intelligence interface. At the top, there's a navigation bar with 'Regulatory' and tabs for 'Analytics Tools' and 'CMC Intelligence'. Below this, there are tabs for 'All', 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents'. The 'Quick Search' section is prominent, with a search bar containing 'RWD' and a blue 'Search' button. Below the search bar, there's a 'Filter' section with buttons for 'Country/Region', 'Topic', and 'Document Type'. The 'Document Type' filter is expanded, showing a list of document types: 'Guideline (16)', 'Notification (11)', 'Announcement (4)', 'Presentation (2)', 'Communication (1)', and 'Newsletter (1)'. The 'Guideline (16)' option is highlighted. At the bottom right, there's a blue 'Support' button and a green 'Apply' button.

Filters turn black once criteria is applied.

Default includes only valid results. Toggle on to include outdated results in your list

10 results for 'RWD'

Switch to Comparison Tables

Refine Search

RWD

Search

Filter

Country/Region Topic Document Type Document C

Side by Side Viewer

Showing 1-10 of 10 results

Customize Columns

Sorted by Authority Acceptance Date

Summary	Title	Abstract	Last Updated Date	Reason for Update	Country/Region	Language
24-Nov-2023 V CN ZH RD	CDE Notification: Soliciting Public Comments on Technical Guidelines for the Application of Real-world Data Based on Disease Registries (Draft), 24-N	To promote and standardize real-world data applications based on disease registries, the Center for Drug Evaluation has drafted	27-Nov-2023	N/A	China	Chinese
28-Sep-2023 V CN ZH RD	CMDE Notification: Soliciting Public Comment on Technical Guidelines for Registration Review of Real-World Study Design and Statistical Analysis of M	According to the relevant requirements of the National Medical Products Administration's 2023 Medical Device			China	Chinese
		order to promote and regulate the search on the natural history of rare diseases, the Technical Guidelines for the			China	Chinese
		order to guide sponsors to scientifically and rationally design real-world research	12-Apr-2023	This update added a Cortellis exclusive English translation.	China	Chinese

Include Outdated

My Regions

Set Alerts and Export results

Cortellis finds results across Acronyms & Synonyms*

*Check Acronym & Synonym Guide to understand when Acronyms and Synonyms are being searched and when they are not

Example: Find US Approval documents that contain the term “abdominal pain”.

1. Select Source Documents. **This searches the entire document PDF**
2. Enter “abdominal pain” into the search bar. **Keywords can be searched in English or in local language**
3. Select the Country/Region filter and select USA and click Apply
4. Select Topic filter and Product Assessment and click Apply followed by Search

Regulatory

All Comparison Tables Intelligence Reports Regulatory Summaries Source Documents

Search

"abdominal pain"

Search

Advanced search

Filter

Document Type Country/Region Topic Date Translation Status Medical Devices Specialty All other filters Reset Filters

Product Assessment (58785) Authorities and Organizations (21876) Compliance and Inspection (17543) Generics and Biosimilars (8874) Clinical Research (8776) Dossier Format and Submission (7707)

Pharmacovigilance Technovigilance Risk Management (7505) Legislative Framework (5181) Manufacturing and Control (4440) Packaging and Labelling (2702) Regulatory Procedures (2653) Pediatrics (2617)

eHealth (2530) Prescription Requirements (2286) Distribution (2067) Other Topic (1315) Advertising and Promotion (1243) GXP (1100) Fees (992) Device Classification (863)

Cancel Apply

Summary	Title	Alt	Last Updated Date
<input checked="" type="checkbox"/> <div> <div>13-Dec-2023</div> <div>V</div> <div>US</div> </div> <div> <div>EN</div> <div>RD</div> </div>	New Drug Application (supplemental NDA) 211855/016: VUMERITY (diroximel fumarate) Capsule - Approval Package, 13-Dec-2023	This supplemental new drug application, NDA 211855/016, provided for revisions to the labeling consistent with new safety	15-Dec-2023
<input checked="" type="checkbox"/> <div> <div>13-Dec-2023</div> <div>V</div> <div>US</div> </div> <div> <div>EN</div> <div>RD</div> </div>	New Drug Application (supplemental NDA) 205382/013: INCRUSE ELLIPTA (umeclidinium bromide) Powder for Inhalation - Approval Package,	This supplemental new drug application, NDA 205382/013, provided for revisions to the 6 Adverse Reactions/6.2 Postmarketing	15-Dec-2023
<input checked="" type="checkbox"/> <div> <div>13-Dec-2023</div> <div>V</div> <div>US</div> </div> <div> <div>EN</div> <div>RD</div> </div>	New Drug Application (supplemental NDA) 204063/032: TECFIDERA (dimethyl fumarate) Capsule - Approval Package, 13-Dec-2023	This supplemental new drug application, NDA 204063/032, provided for revisions to the labeling consistent with new safety	15-Dec-2023
<input checked="" type="checkbox"/> <div> <div>12-Dec-2023</div> <div>V</div> <div>US</div> </div>	New Drug Application (supplemental NDA) 21468/024 & 204734/006: FOSRENOL (lanthanum carbonate) Tablet, 12-Dec-2023	These supplemental new drug applications, NDA 21468/024 & 204734/006, provided for	14-Dec-2023

5 of 26
Automatic Zoom

abdominal pain

Highlight all
Match case
Whole words
1 of 8 matches

▼ Evaluation/Decision

▼ File 1

▼ Original file

▼ APPROVAL LETTER

APPROVAL & LABELING

CONTENT OF LABELING

PROMOTION MATERIALS

PATENT LIST REQUIREMENTS

REPORTING REQUIREMENTS

▼ Product Information

▼ File 1

▼ Original file

▼ LABELING

HIGHLIGHTS OF PRESCRIBING INFORMATION

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

2 DOSAGE ADMINISTRATION

2.1 Blood Tests Prior to Initiation of VUMERITY

2.2 Dosing Information

2.3 Administration Instructions

2.4 Blood Tests to Assess Safety After Initiation of VUMERITY

2.5 Patients With Renal Impairment

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

5.1 Anaphylaxis and Angioedema

5.2 Progressive Multifocal Leukoencephalopathy

5.3 Herpes Zoster and Other Serious Opportunistic Infections

5.4 Lymphopenia

5.5 Liver Injury

5.6 Flushing

5.7 Serious Gastrointestinal Reactions

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

6.2 Postmarketing Experience

7 DRUG INTERACTIONS

Search within the document to find where search terms are found. Here we find search term “abdominal pain” under Adverse Reactions.

ADVERSE REACTIONS

Most common adverse reactions (incidence for dimethyl fumarate [which has the same active methoxy group as VUMERITY] ≥10% and ≥2% more than placebo) were flushing, abdominal pain, diarrhea, and nausea. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Biogen at 1-800-456-2255 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS

Use fetal harm. (8.1)

Patients with moderate or severe renal impairment should be monitored closely. (8.2)

CLINICAL PHARMACOLOGY

DESCRIPTION

CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

12.2 Pharmacodynamics

12.3 Pharmacokinetics

NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

13.2 Animal Toxicology and/or Pharmacology

CLINICAL STUDIES

HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

16.2 Storage and Handling

PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed.

For more information contact Customer Service at [LS Product Support](#).