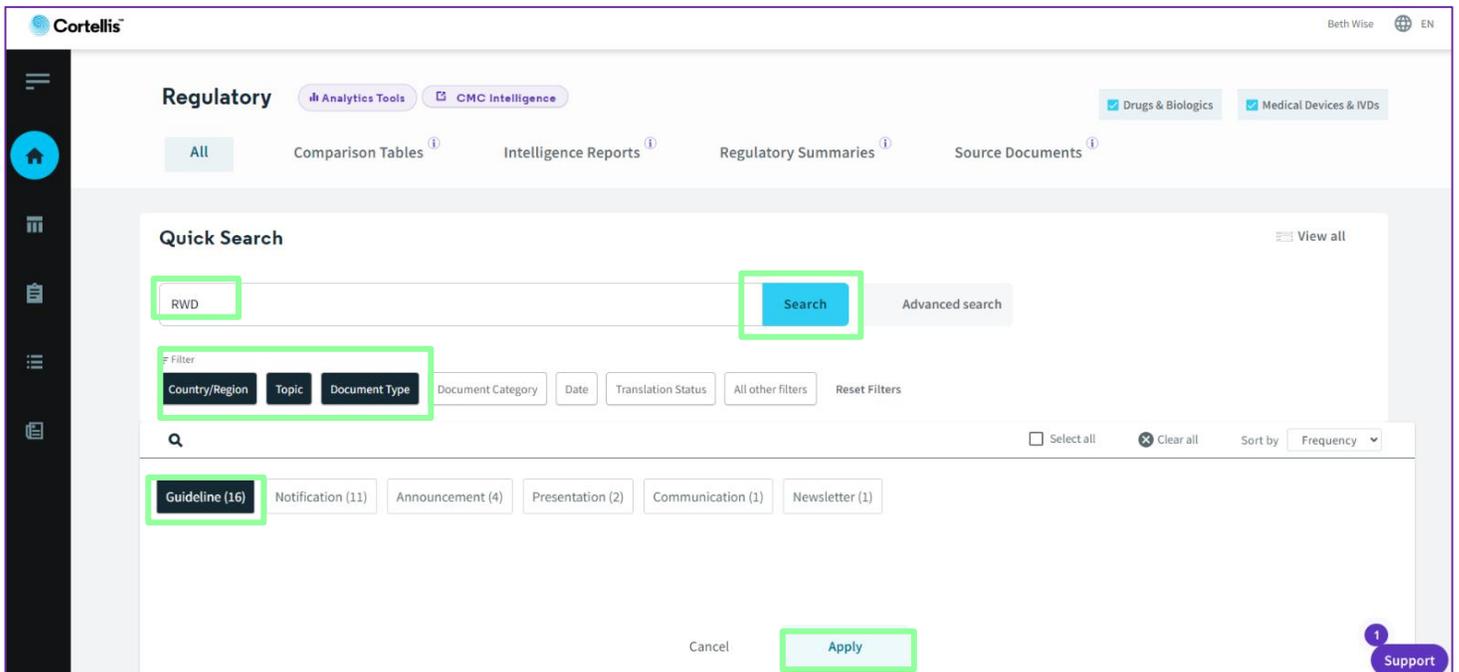


Searching Source Documents

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 that, there are tabs for 'All', 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents'. The 'Quick Search' section is prominent, with a search input field containing 'RWD' and a blue 'Search' button. Below the search field, there's a 'Filter' section with several filter categories: 'Country/Region', 'Topic', 'Document Type', 'Document Category', 'Date', 'Translation Status', and 'All other filters'. The 'Document Type' filter is expanded, showing 'Guideline (16)', 'Notification (11)', 'Announcement (4)', 'Presentation (2)', 'Communication (1)', and 'Newsletter (1)'. The 'Guideline (16)' filter is highlighted in black. 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 Toggle on to include outdated results in your list

Change how results are sorted, for example by Authority Acceptance Date

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

Customize Columns ? Sorted by Authority Acceptance Date

Summary	Title	Approval	Last Updated Date
<input checked="" type="checkbox"/> 13-Dec-2023 V US EN RD	New Drug Application (supplemental NDA) 211855/016: VUMERITY (dioximel 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"/> 13-Dec-2023 V US EN RD	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"/> 13-Dec-2023 V US EN RD	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"/> 12-Dec-2023 V US	New Drug Application (supplemental NDA) 21468/024 & 204734/006: FOSRENOL (lanthanum carbonate)	These supplemental new drug applications, NDA 21468/024 & 204734/006, provided for	14-Dec-2023

Click links to open documents

New Drug Application (supplemental NDA) 211855/016: VUMERITY (dioximel fumarate) Capsule - Approval Package, 13-Dec-2023

abdominal pain

1 of 8 matches

ADVERSE REACTIONS

Most common adverse reactions (incidence for dimethyl fumarate [which has the same active metabolite 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

8.1 Pregnancy

8.2 Lactation

8.4 Pediatric Use

8.5 Geriatric Use

8.6 Renal Impairment

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

12.2 Pharmacodynamics

12.3 Pharmacokinetics

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

13.2 Animal Toxicology and/or Pharmacology

14 CLINICAL STUDIES

16 HOW SUPPLIED/ STORAGE AND HANDLING

16.1 How Supplied

16.2 Storage and Handling

17 PATIENT COUNSELING INFORMATION

Revised: 12/2023

SEARCH WITHIN THE DOCUMENT TO FIND WHERE SEARCH TERMS ARE FOUND. HERE WE FIND SEARCH TERM "ABDOMINAL PAIN" UNDER ADVERSE REACTIONS.

FULL PRESCRIBING INFORMATION: CONTENTS*

- INDICATIONS AND USAGE
- DOSAGE AND ADMINISTRATION
 - Blood Tests Prior to Initiation of VUMERITY
 - Dosing Information
 - Administration Instructions
 - Blood Tests to Assess Safety After Initiation of VUMERITY
 - Patients With Renal Impairment
- DOSAGE FORMS AND STRENGTHS
- CONTRAINDICATIONS
- WARNINGS AND PRECAUTIONS
 - Anaphylaxis and Angioedema
 - Progressive Multifocal Leukoencephalopathy
 - Herpes Zoster and Other Serious Opportunistic Infections
 - Lymphopenia
 - Liver Injury
 - Flushing
 - Serious Gastrointestinal Reactions
- ADVERSE REACTIONS
 - Clinical Trials Experience
 - Postmarketing Experience
- DRUG INTERACTIONS

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

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