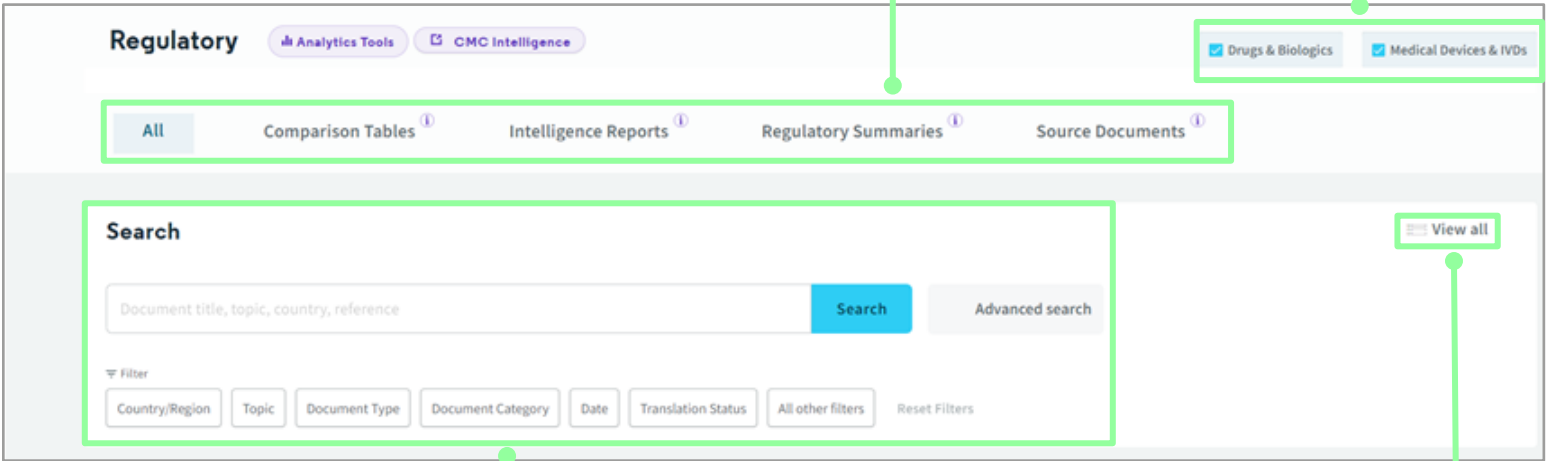


# Getting started with Cortellis Regulatory Intelligence

**Cortellis Regulatory Intelligence is a single, comprehensive source for global regulatory information, allowing you to monitor regulatory changes, understand submission routes and local practices, compare regulatory requirements across countries, and conduct pre-and post-marketing surveillance. Cortellis helps you increase regulatory compliance and keeps you up to speed with the ever-changing global regulatory environment.**

This quick guide covers how to run a search, navigate a results page and how to browse available topics/reports, as well as how to download the companion Cortellis Regulatory Alerts Mobile App.

## Regulatory Intelligence homepage



**Quick Access** – select a tab to browse or search within all or specific content.

**Quick Selection** – select your content by product.

**Search** – allows you to search on key words and/or apply filters.

**View all** – takes you to a results page listing every document in Cortellis, where you can apply filters to narrow down your results.

The screenshot shows the homepage layout with the following elements:

- Header:** "Regulatory" tab, "Analytics Tools" and "CMC Intelligence" buttons.
- Product Selection:** "Drugs & Biologics" and "Medical Devices & IVDs" checkboxes.
- Navigation Tabs:** "All", "Comparison Tables", "Intelligence Reports", "Regulatory Summaries", "Source Documents".
- Search Section:**
  - Search input field: "Document title, topic, country, reference"
  - Search button
  - Advanced search button
  - Filter section with dropdown and buttons: "Country/Region", "Topic", "Document Type", "Document Category", "Date", "Translation Status", "All other filters", "Reset Filters"
- View all button:** Located at the top right of the search results area.

## Search Regulatory Intelligence

**Example:** Find clinical research guidelines for the EU

1. Select the **Source Documents** tab at the top of the page.
2. Under **Filter** click on **Document Type**, select **Guideline** and click **Apply**.
3. Click on **Country/Region**, select **European Union** and click **Apply**.
4. Click on **Topic**, select **Clinical Research** and click **Apply**.
5. Then click the blue **Search** button.

### Search

Filter

Document Type

Country/Region

Topic

Date

Translation Status

Medical Devices Specialty

All other filters

Reset Filters

Regulatory Procedures (1203)

Clinical Research (1165)

Authorities and Organizations (1040)

Pharmacovigilance Technovigilance Risk Ma

Dossier Format and Submission (664)

Manufacturing and Control (655)

Packaging and Labelling (561)

Compliance and Inspection (523)

Non Clinical Studies (402)

Generics and Biosimilars (383)

Active Pharmaceutical Ingredient (290)

Other Topic (204)

Pediatrics (175)

Cancel

Apply

The **results** page is displayed.

Go back to the Regulatory Intelligence homepage or any specific content tab.

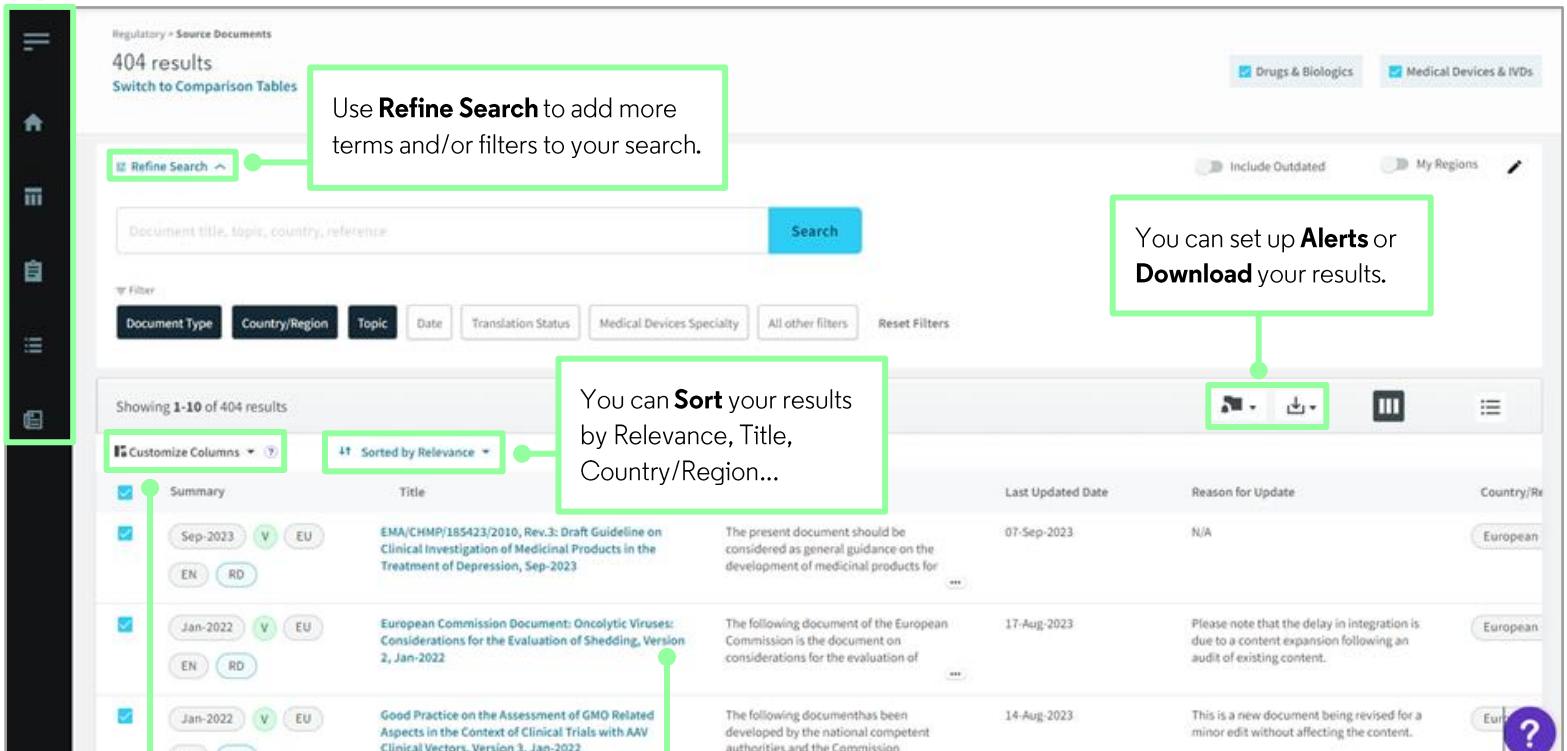
Use **Refine Search** to add more terms and/or filters to your search.

You can set up **Alerts** or **Download** your results.

You can **Sort** your results by Relevance, Title, Country/Region...

Use **Customize Columns** to add/remove data from the results page.

Open any document by clicking on the **hyperlinked title**.



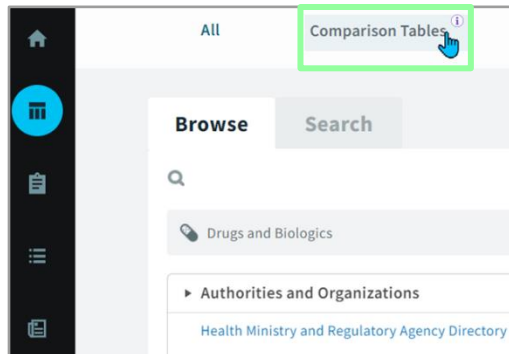
The screenshot shows the 'Regulatory > Source Documents' results page with 404 results. The interface includes a sidebar with navigation icons, a search bar, and various filters. Annotations point to specific features: the sidebar, the 'Refine Search' button, the 'Customize Columns' dropdown, the 'Sorted by Relevance' dropdown, the 'Alerts' and 'Download' icons, and the document titles in the results table.

Summary	Title	Last Updated Date	Reason for Update	Country/Region
Sep-2023 V EU EN RD	<a href="#">EMA/CHMP/185423/2010, Rev.3: Draft Guideline on Clinical Investigation of Medicinal Products in the Treatment of Depression, Sep-2023</a>	07-Sep-2023	N/A	European
Jan-2022 V EU EN RD	<a href="#">European Commission Document: Oncolytic Viruses: Considerations for the Evaluation of Shedding, Version 2, Jan-2022</a>	17-Aug-2023	Please note that the delay in integration is due to a content expansion following an audit of existing content.	European
Jan-2022 V EU EN RD	<a href="#">Good Practice on the Assessment of GMO Related Aspects in the Context of Clinical Trials with AAV Clinical Vectors, Version 3, Jan-2022</a>	14-Aug-2023	This is a new document being revised for a minor edit without affecting the content.	European

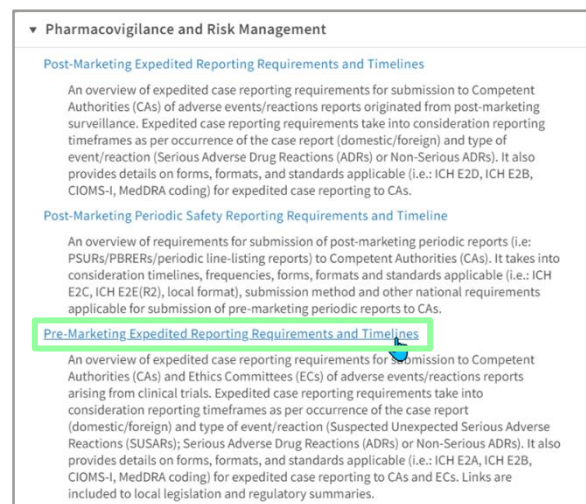
## Browse Regulatory Intelligence

From the Regulatory Intelligence homepage use the tabs at the top of the page to browse the list of topics and reports available for Comparison Tables, Intelligence Reports and Regulatory Summaries.

**Example:** Find the pre-marketing expedited reporting table for pharmacovigilance



1. Select the **Comparisons Table** tab at the top of the page.



2. Scroll down to Pharmacovigilance and Risk Management.
3. Click on Pre-Marketing Expedited Reporting Requirements and Timelines to open the comparison table.

## Cortellis Regulatory Alerts Mobile App



Get notified of regulatory changes daily on your mobile device. Download the app now - Apple: <https://apple.co/2MeV2iC> Android: <http://bit.ly/2YIOv7e>

After download, tap the Cortellis app icon. You will see a splash screen as the app loads, then a button appears stating, "I have a Cortellis account". Tap the button and sign in with your Cortellis username and password. If you sign in with Single Sign On (SSO), tap the Sign in with SSO link, enter your company name and tap Go. Then enter your corporate credentials. Once entered the log in process will be complete.

You'll then go through a series of screens asking you for your preferences. This makes it easier to set up alerts later. Alerts created on the App will translate to the desktop version of Cortellis and vice versa. You can also create a mobile library of all your favorite documents – printable from your phone – by saving them to your "favorites" plus you can share document links to your colleagues right from the app.

For more information contact Customer Service at **LS Product Support**.