

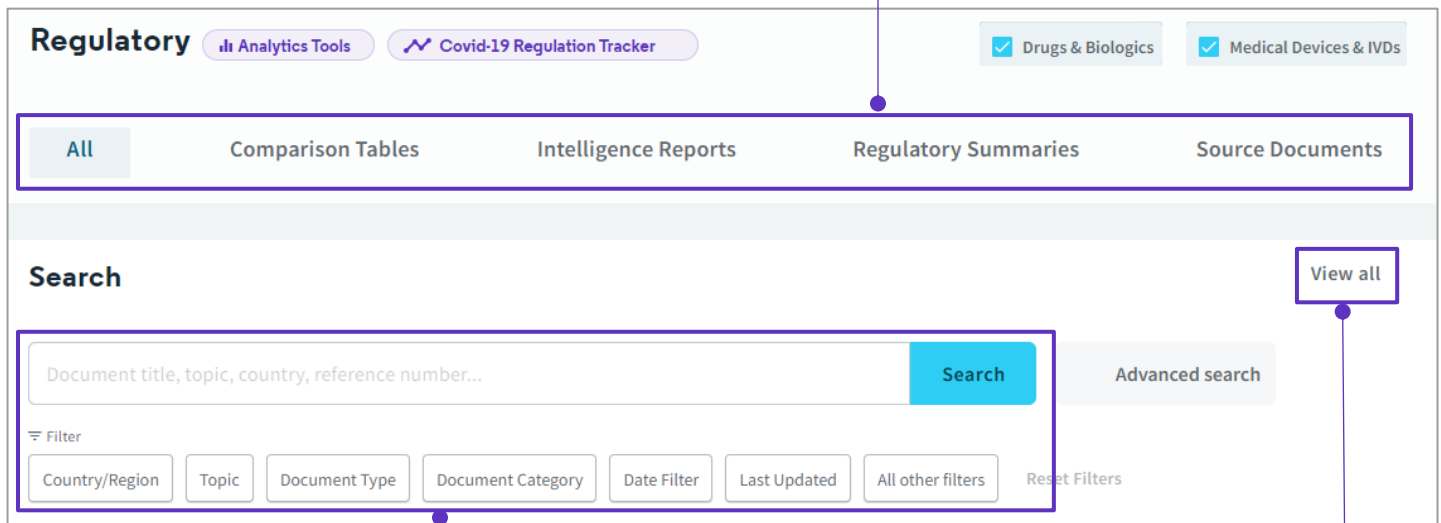
Getting started with Cortellis Regulatory Intelligence

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

Report Types – select a tab to browse or search within all or specific report types



The screenshot shows the Cortellis Regulatory Intelligence homepage. At the top, there is a navigation bar with the word "Regulatory" and two tabs: "Analytics Tools" and "Covid-19 Regulation Tracker". To the right, there are two checked checkboxes for "Drugs & Biologics" and "Medical Devices & IVDs". Below this is a horizontal menu with five tabs: "All", "Comparison Tables", "Intelligence Reports", "Regulatory Summaries", and "Source Documents". The "All" tab is currently selected. Below the menu is a search section with the heading "Search". It features a search input field with the placeholder text "Document title, topic, country, reference number...", a blue "Search" button, and an "Advanced search" link. Below the search field is a "Filter" section with several filter buttons: "Country/Region", "Topic", "Document Type", "Document Category", "Date Filter", "Last Updated", and "All other filters". There is also a "Reset Filters" link. A "View all" button is located to the right of the search section.

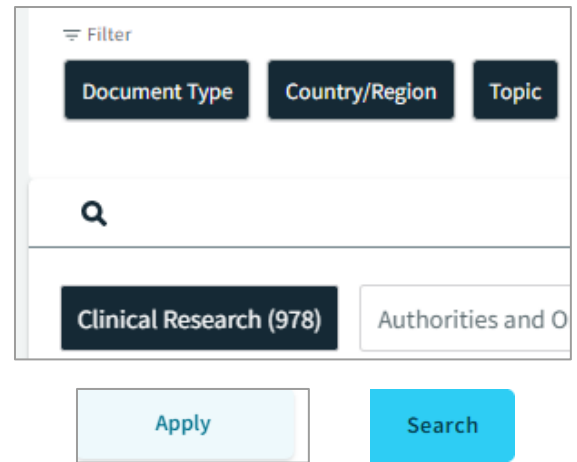
Search – allows you to search on key words and/or apply filters

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

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



The **results page** is displayed.

Go back to the Regulatory Intelligence **homepage**

Regulatory > Source Documents
323 results
Switch to Comparison Tables

Drugs & Biologics Medical Devices & IVDs

Include Outdated My Regions

Showing 1-10 of 323 results

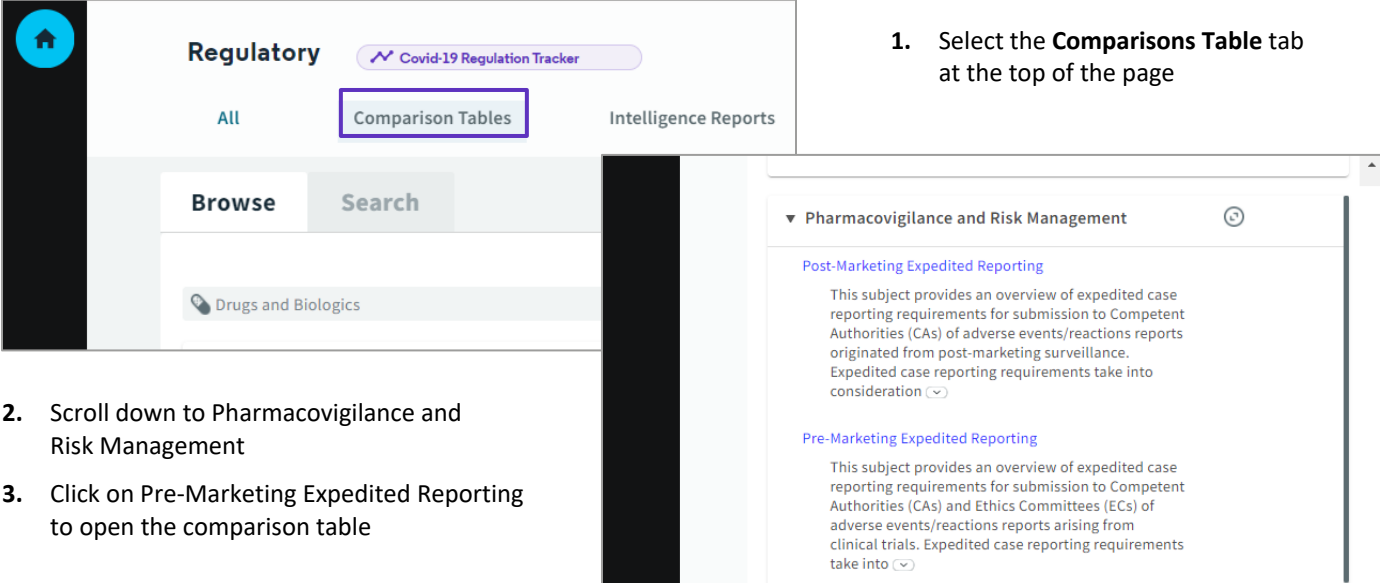
Customize Columns Sorted by Relevance

Summary	Title	Abstract	Country/Region
22-Oct-2009 V EU	98391 - EMEA/CHMP/CPWP/83508/2009: Guideline on Xenogeneic Cell-Based Medicinal Products - 22-Oct-2009	This Guideline addresses the scientific requirements for xenogeneic cell-based medicinal products for human use.	European Un
22-Oct-2009 V EU	98370 - EMEA/CHMP/EWP/356954/2008: Guideline on the Clinical Investigations of Medicinal Products for the Treatment of Pulmonary Arterial Hypertensio	Pulmonary hypertension is a group of diseases characterized by a progressive increase of pulmonary vascular resistance	European Un
22-Oct-2009 V EU EN RD	97347 - EMEA/CHMP/GTWP/60436/2007: CHMP Guideline on Follow-Up of Patients Administered with Gene Therapy Medicinal Products - 22-Oct-2009	This guideline is describing recommendations for clinical monitoring and addresses specific aspects of the active	European Un
22-Oct-2009 V EU EN RD	97312 - EMEA/CHMP/EWP/692702/2008: Reflection Paper on the Extrapolation of Results from Clinical Studies Conducted outside Europe to the EU-Populati	ange on 19-Mar-2020: Last minor edit to metadata. 2019: This final version	European Un
Sep-2009 V EU	95881 - PIM Guidance for Applicants (Centralised	The Product Information Management (PIM) N/A	Europe

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



The screenshot shows the 'Regulatory' homepage with a navigation bar containing 'All', 'Comparison Tables', and 'Intelligence Reports'. The 'Comparison Tables' tab is highlighted with a red box. Below the navigation bar are 'Browse' and 'Search' buttons, and a search bar with 'Drugs and Biologics' entered. On the right side, a dropdown menu is open for 'Pharmacovigilance and Risk Management', showing two entries: 'Post-Marketing Expedited Reporting' and 'Pre-Marketing Expedited Reporting'. The 'Pre-Marketing Expedited Reporting' entry is selected, and its content is displayed in a scrollable view.

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 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/2MeV2jC> 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.

Contact us: [Cortellis Training](#)