

Cortellis Regulatory Intelligence

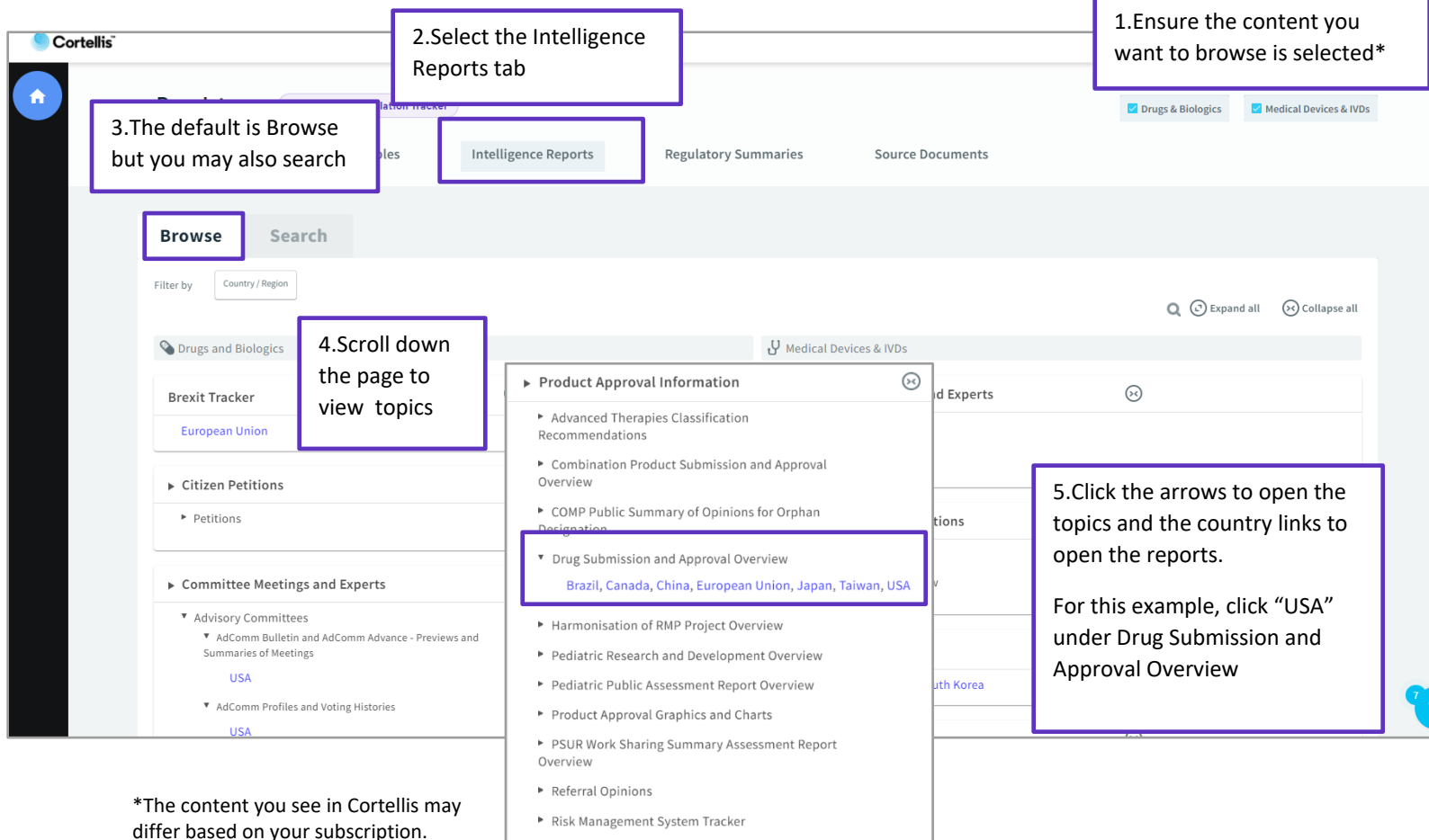
Value-Add Reports - Regulatory Intelligence Reports

The Regulatory Intelligence Reports are time-saving value-add reports created by Cortellis editors and consultants that help with common regulatory tasks, for example, **monitoring approvals, REMS, PIPs and Waivers, guidelines and more.**

You can also use them to prepare for inspections and get ready for ADCOMM meetings. **Regulatory Intelligence Reports take the form of bulletins, tracker spreadsheets and even graphs.** This guide shows how to browse and open the reports and begin benefitting from their enormous value.

Accessing the Regulatory Intelligence Reports

Example: Find US NDAs, BLAs and supplemental approvals in a trackable table that allows filtering by type of molecule, therapy area, approval date, regulatory designations and more. Plus link to the approvals.



The screenshot shows the Cortellis web interface. At the top, there are navigation tabs: 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents'. The 'Intelligence Reports' tab is selected. Below the tabs, there are filter options for 'Drugs & Biologics' and 'Medical Devices & IVDs'. A 'Browse' button is highlighted, and a search bar is visible. The main content area shows a list of topics under 'Drug Submission and Approval Overview', with 'USA' highlighted under the 'Drug Submission and Approval Overview' section. A dropdown menu is open, showing a list of topics including 'Product Approval Information', 'Advanced Therapies Classification Recommendations', 'Combination Product Submission and Approval Overview', 'COMP Public Summary of Opinions for Orphan Designation', 'Drug Submission and Approval Overview' (with sub-links for 'Brazil, Canada, China, European Union, Japan, Taiwan, USA'), 'Harmonisation of RMP Project Overview', 'Pediatric Research and Development Overview', 'Pediatric Public Assessment Report Overview', 'Product Approval Graphics and Charts', 'PSUR Work Sharing Summary Assessment Report Overview', 'Referral Opinions', and 'Risk Management System Tracker'.

1. Ensure the content you want to browse is selected*

2. Select the Intelligence Reports tab

3. The default is Browse but you may also search

4. Scroll down the page to view topics

5. Click the arrows to open the topics and the country links to open the reports.

For this example, click "USA" under Drug Submission and Approval Overview

*The content you see in Cortellis may differ based on your subscription.

Navigating the Regulatory Intelligence Reports

Drug Submission and Product Approval List Overview

Valid 136082 USA Regulatory Intelligence Report Approval Tracker

Drugs and Biologics Product Assessment

Set up Alerts for email updates

Abstract explains the scope and updating schedule of the document

1. Summary
2. Document
3. Mentioned By

Summary

Abstract

This Regulatory Intelligence Report (RIR) contains the list of New Drug Applications (NDAs), Biologics License Applications (BLAs), biosimilars and supplements approved from 1997 by the United States Food and Drug Administration (FDA). Generics (ANDA) are out of scope of this table and are not available in CRI.

Biological Types:

- Therapeutic biologics
- Allergens: patch tests used to diagnose the causes of contact dermatitis. Extracts used to diagnose and treat rhinitis, allergic sinusitis and conjunctivitis, and bee stings.
- Blood and blood products: blood and blood components used for transfusion, such as red blood cells, plasma, and platelets. Pharmaceutical products made from blood, such as clotting factors and immunoglobulins.
- Devices: medical devices and tests used to safeguard blood components, and cellular products from HIV, hepatitis, syphilis, and other infectious agents. Reagents used to type blood. Machines and related software used to collect blood and blood components.
- Gene therapy: gene therapy products that replace a person's faulty or missing genetic material.
- Human tissues and cellular products: human tissues for transplantation, such as skin, tendons, ligaments, and cartilage. Cellular products, such as human stem cells and pancreatic islets.
- Vaccines: vaccines used for prevention of infectious diseases. Vaccines to treat or prevent non-infectious conditions.
- Xenotransplantation products: live animal cells, tissues, or organs.

Date
01-Apr-2021

1. Summary
2. Document
3. Mentioned By

Document

None English

Download tables to Excel

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1 of 1 Automatic Zoom

Name	Active Ingredient(s)	Application/Submissio	Application Number	Active Substance Statu	FDA Biological Type	FDA Chemical Type	Product Type
DITROPAN XL	oxybutynin chloride	sNDA	20897/038	Known active substance	Not applicable	New dosage form	Drugs & Biologics
MYRBETRIQ	mirabegron	sNDA	202611/017	New active substance	Not applicable	New molecular entity (NME)	Drugs & Biologics
VYXEOS	cytarabine ; daunorubicin	sNDA	209401/006	Known active substance	Not applicable	New combination	Drugs & Biologics
NEOPROFEN	ibuprofen lysine	sNDA	21903/012	New active substance	Not applicable	New active ingredient	Drugs & Biologics
VASOSTRICT	vasopressin	sNDA	204485/011	Known active substance	Not applicable	Drug already marketed without an approved NDA	Drugs & Biologics
MYRBETRIQ GRANULES	mirabegron	NDA	213801	Known active substance	Not applicable	New dosage form	Drugs & Biologics
VITRAKVI	larotrectinib	sNDA	210861/006	New active substance	Not applicable	New molecular entity (NME)	Drugs & Biologics
DIASTAT ACUDIAL ; DIASTAT	diazepam	sNDA	20648/022	Known active substance	Not applicable	New dosage form	Drugs & Biologics ; Me Devices & IVDs
PEGASYS	peginterferon alfa-2a	sBLA	103964/5275	New active substance	Therapeutic biologic	Not applicable	Drugs & Biologics

Tables compile key data on the product approvals into an easy-to-sort format. Find products similar to yours, then link to the NDAs, BLAs and their supplements.

Review Category/Division	Boxed Warning	Medication Guide	REM	Pediatric Us	FDA Supplement Type	FDA Supplement Ratio	Link to Product Approval
Urology, Obstetrics, and Gynecology	No	No	No	Yes	Non-efficacy supplement	Provided for update to the labeling in compliance	327890
Urology, Obstetrics, and Gynecology	No	No	No	Yes	Efficacy-new indication	Provided a new indication for the treatment of	327883
Hematologic Malignancies 1	Yes	No	No	Yes	Efficacy-new indication	New indication to include the treatment of newly-	327881
Cardiology and Nephrology	No	No	No	Yes	Non-efficacy supplement	Provided for revisions to the approved label to add	327872
Cardiology and Nephrology	No	No	No	No	Non-efficacy supplement	Provided for revisions to labeling in accordance	327814
Urology, Obstetrics, and Gynecology	No	No	No	Yes	Original approval	Original approval	327813
Oncology products	No	No	No	Yes	Non-efficacy supplement	Provided for updates to the labeling and	327792
Neurology products	Yes	No	No	Yes	Non-efficacy supplement	Provided for updated Pharmacist Instruction	327775
Antiviral products	Yes	Yes	No	Yes	Non-efficacy supplement	Provided for updates to the 2.7 Preparation and	327773

Explore all that the Regulatory Intelligence Reports have to offer by using the Browse function and reading the Abstracts to understand what value the documents bring. Some highlights are below.

The screenshot shows a navigation menu on the left and a main content area on the right. Callouts point to specific features:

- ADCOMM Meeting Coverage**: Points to the 'Committee Meetings and Experts' section.
- Tables of US and EU inspection documents**: Points to the 'Compliance and Inspections' section.
- Tables of US and EU Guidelines**: Points to the 'Guidelines' section.
- Tables of US and EU PIPS and Waivers**: Points to the 'Pediatric Research and Development Overview' item in the 'Product Approval Information' list.
- Tables of US and EU REMS**: Points to the 'Risk Management System Tracker' item in the 'Product Approval Information' list.

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