Cortellis Regulatory Intelligence

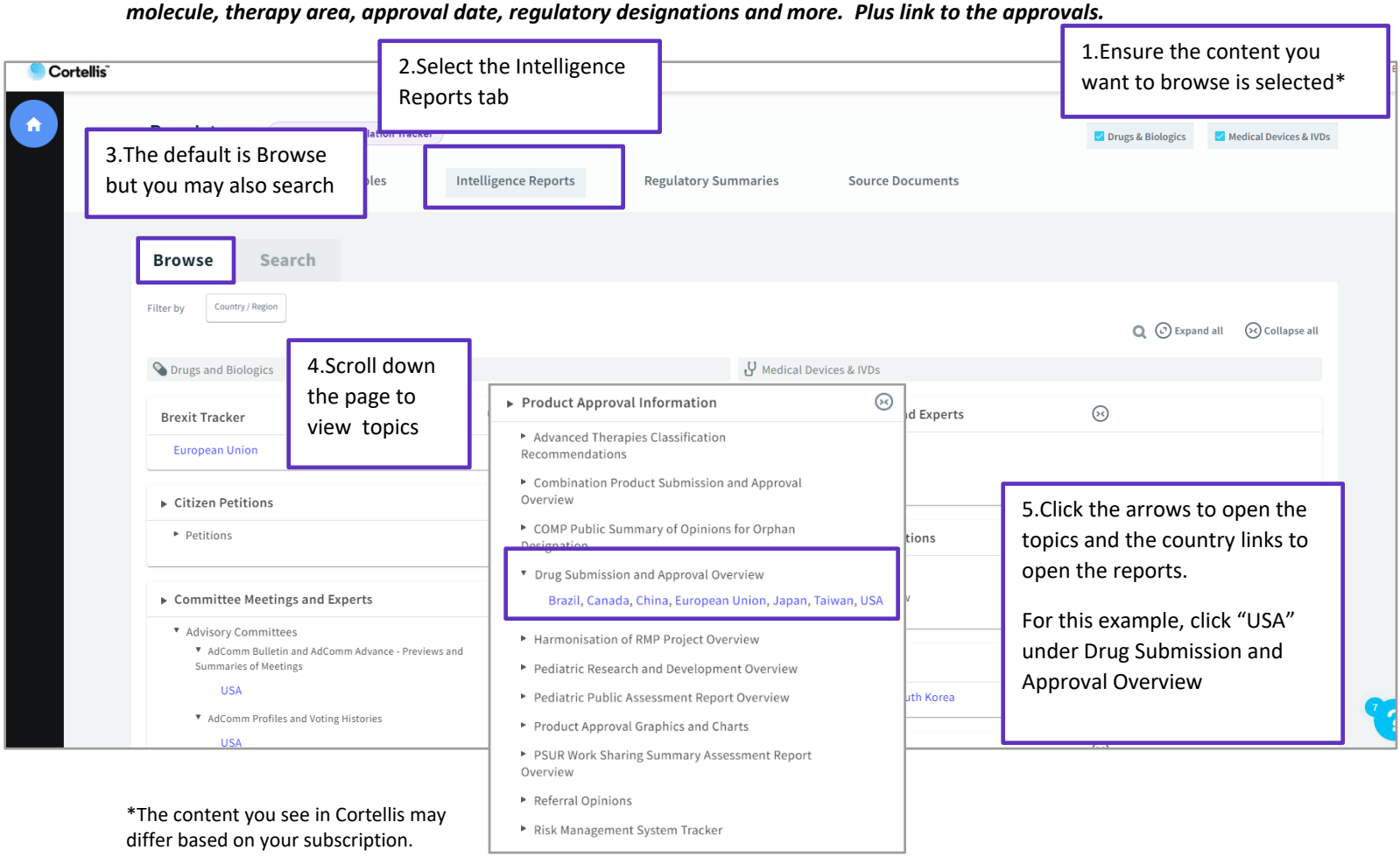
Value-Add Reports - Regulatory Intelligence Reports

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.

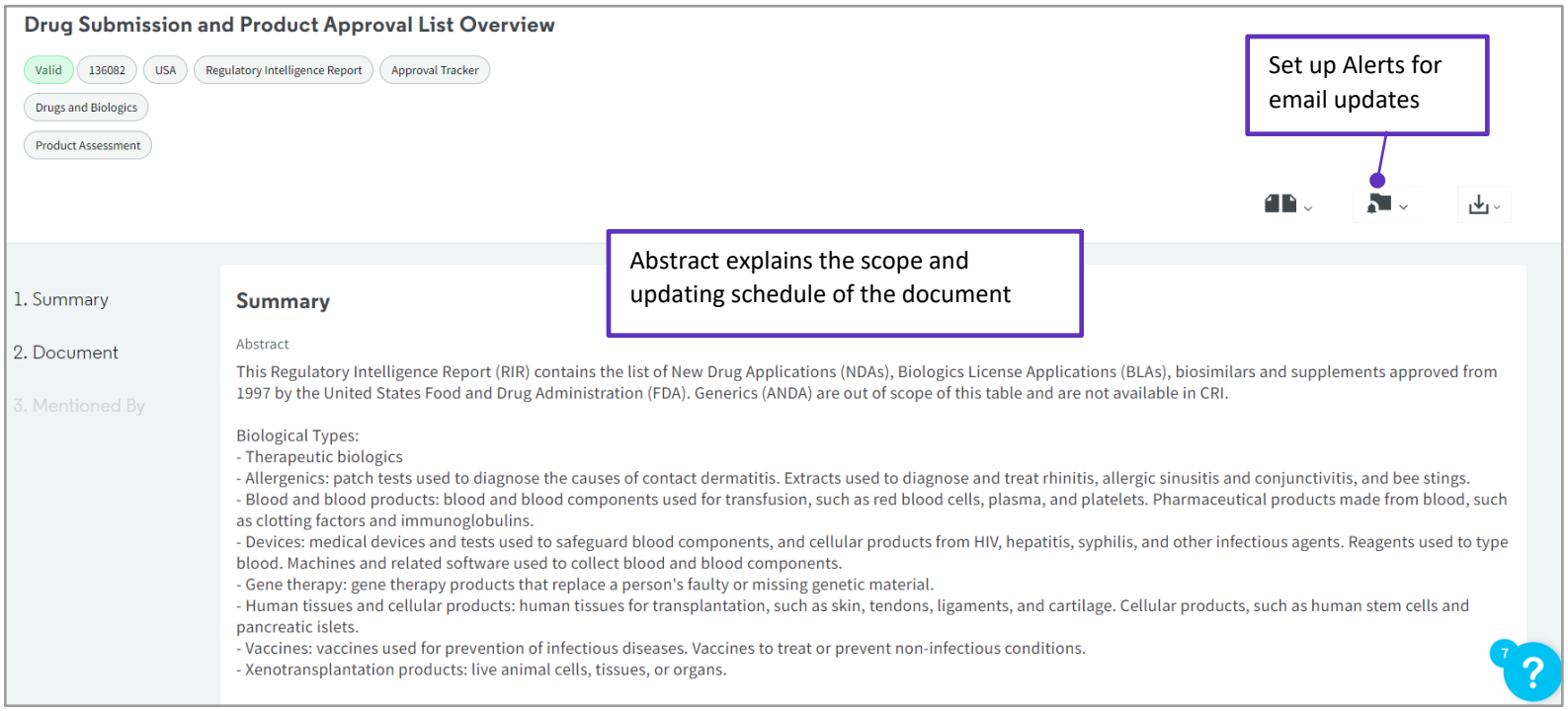
Accessing the Regulatory Intelligence Reports

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

Navigating the Regulatory Intelligence Reports



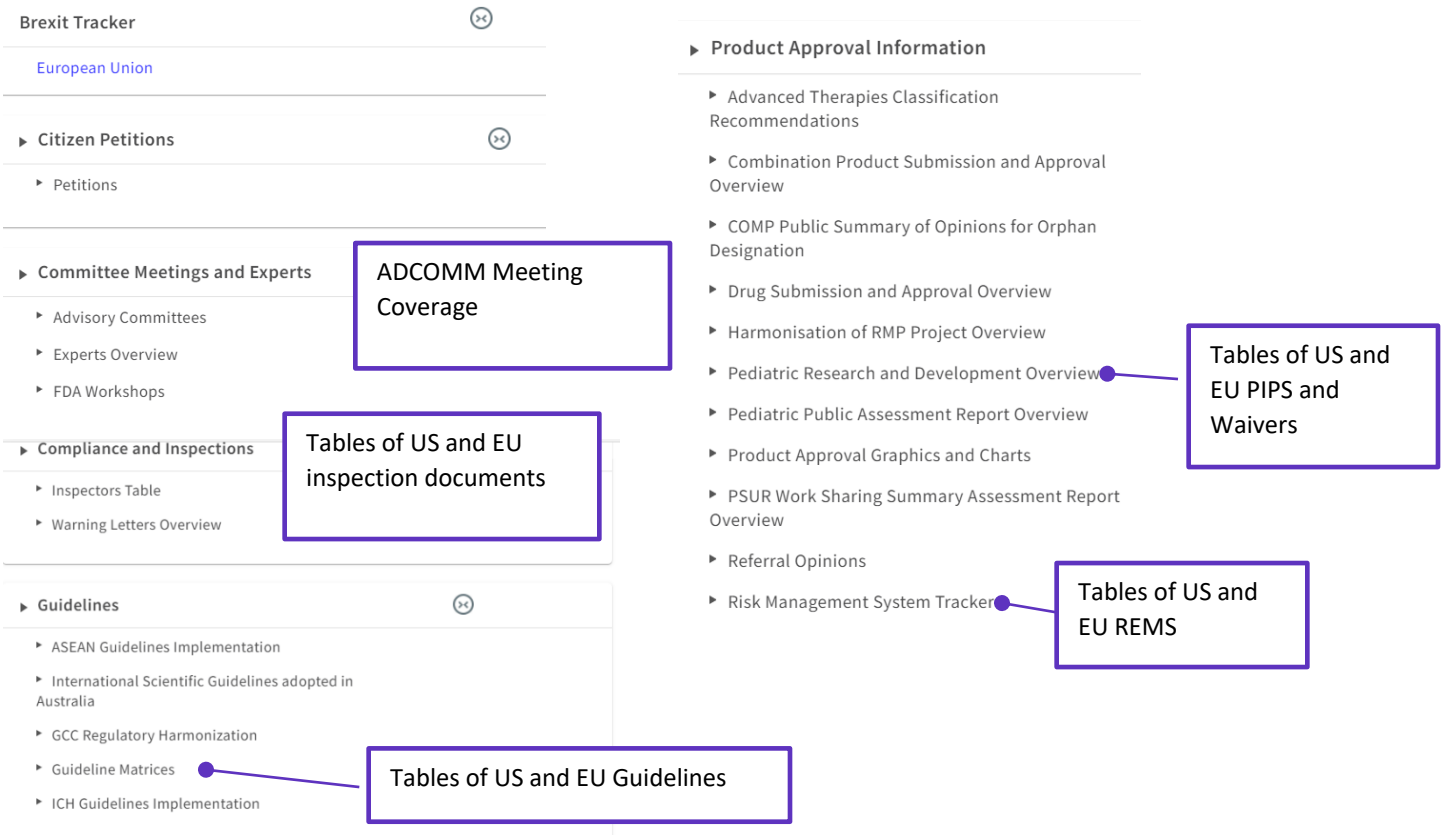
Name	Active Ingredient(s)	Application/Submissio	Application Number	Active Substance Statu	FDA Biological Type	FDA Chemical Type	Product Type
DITROPAN XL	oxybutynin chloride	sNDA	20897/038	Known active substance	Not applicable	New dosage form	Drugs & Biologics
MYRBETRIQ	mirabegron	sNDA	202611/017	New 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

Clarivate™

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/Divisi	Boxed Warnir	Medication Guide	REM	Pediatric Us	FDA Supplement Type	FDA Supplement Ratio	Link to Product Approv
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.



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