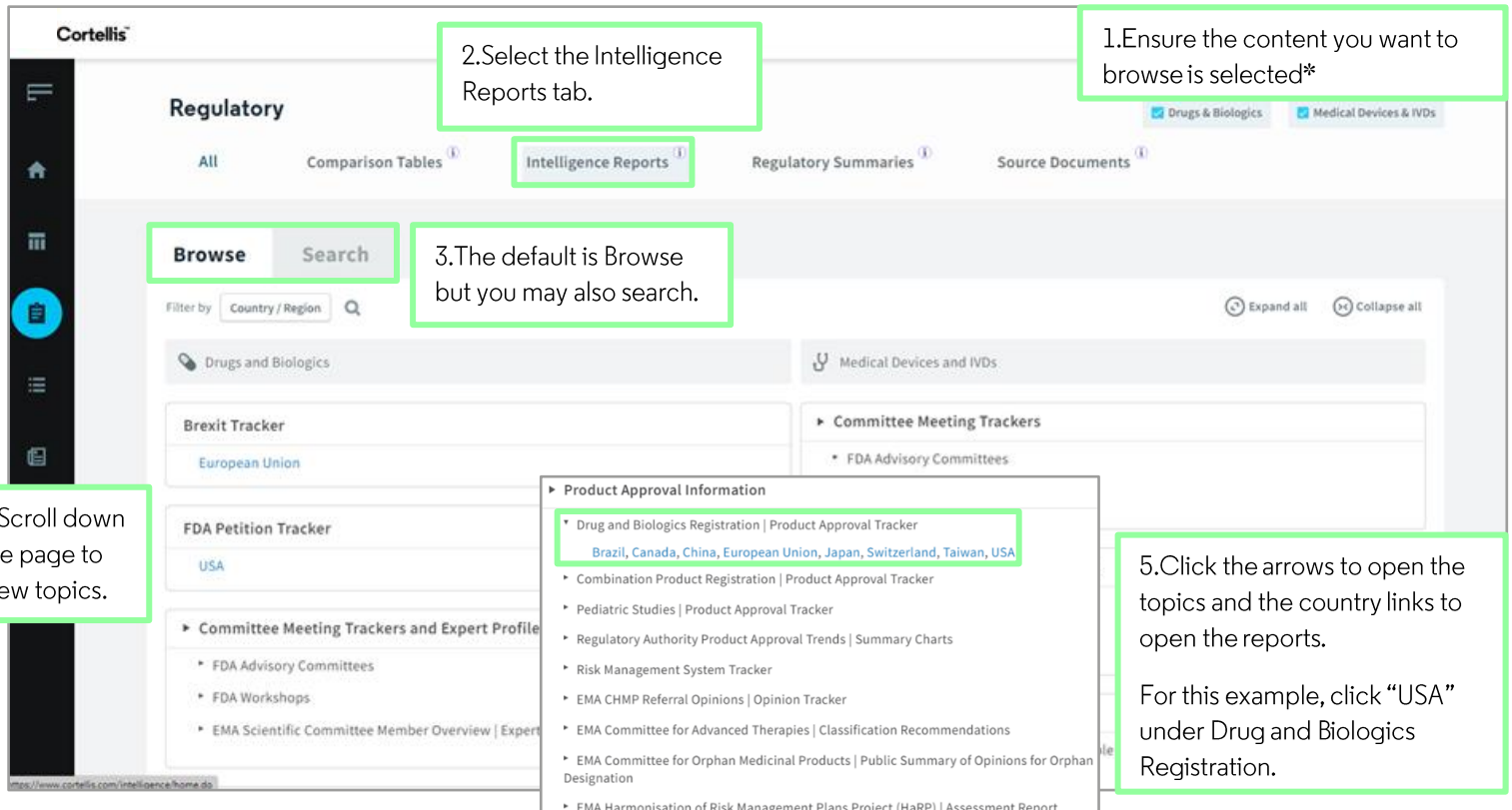
Value-Add Reports - Regulatory Intelligence Reports

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.

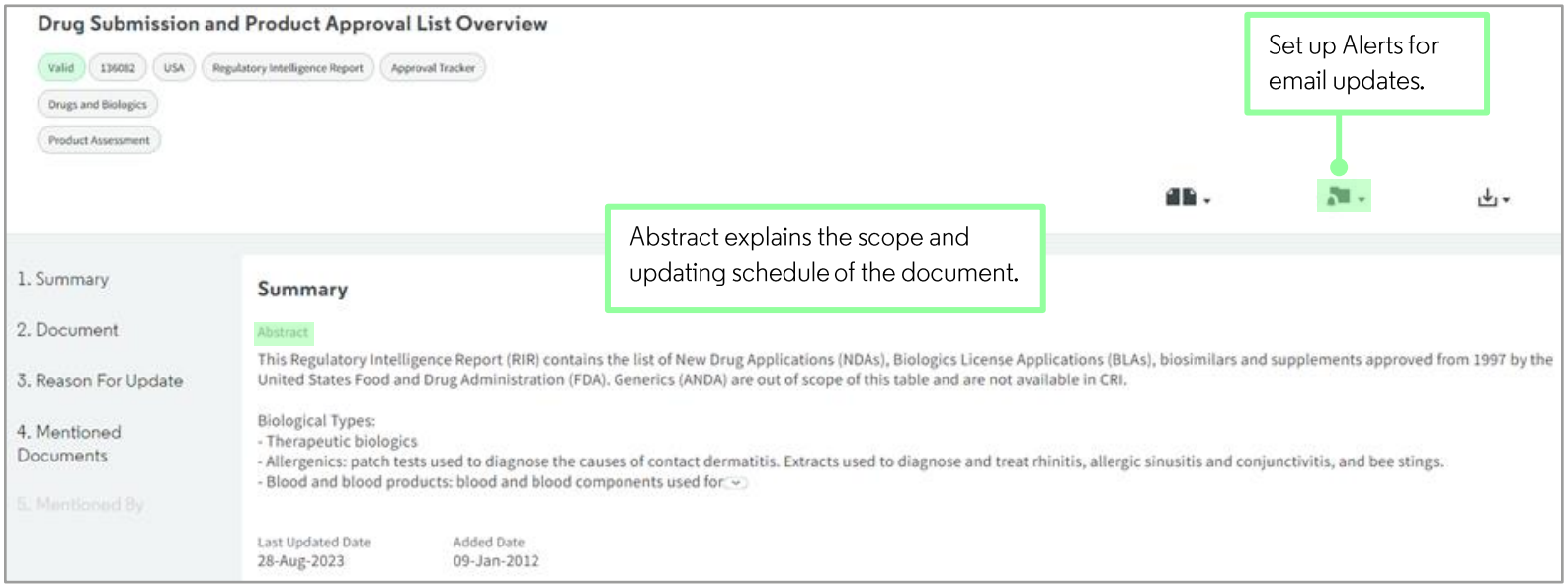
Accessing the Regulatory Intelligence Reports

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

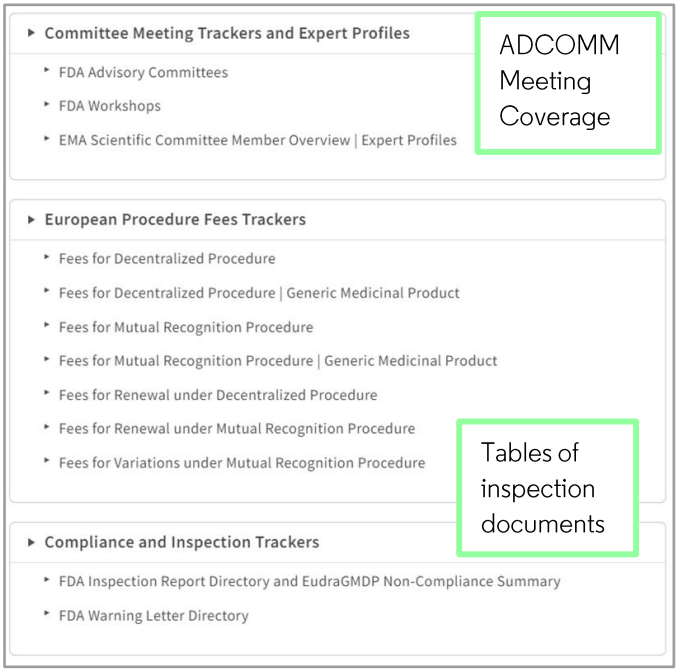


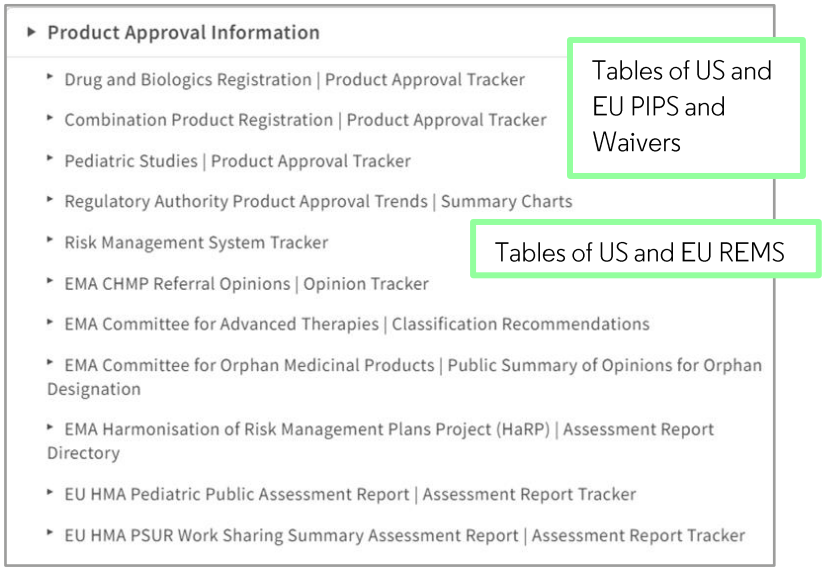
Name	Active Ingredient(s)	Application/Submission Type	Application Number	Active Substance Status	FDA Biological Type	FDA Chemical Type	Product Type	Dosage Form	Route of Administration	Therapeutic Area	Indication(s)	Company
ODOMZO	sonidegib	sNDA	205266/009	New active substance	Not applicable	New molecular entity (NME)	Drugs & Biologics	Capsule	Oral	Cancer	For the treatment of adult patients with locally advanced basal cell carcinoma (BCC) that has recurred following surgery	Sun Pharmace
FEMRING	estradiol acetate	sNDA	21367/020	New active substance	Not applicable	New active ingredient	Drugs & Biologics ; Medical Devices & IVDs	Ring	Vaginal	Disorders of sexual function, breast and reproduction	FEMRING is indicated: - For the treatment of moderate to severe vasomotor symptoms due to menopause.	Millicent Hold
ADYNOVATE	antihemophilic factor (recombinant) PEGylated	sBLA	125566/866	Known active substance	Blood and blood product	Not applicable	Drugs & Biologics	Solution	Intravenous	Hematologic diseases	in children and adults with hemophilia A (congenital factor VIII deficiency) for: - On-demand treatment and control of	Takeda Pharm
COMETRIQ	cabozantinib	sNDA	203756/011	New active substance	Not applicable	New molecular entity (NME)	Drugs & Biologics	Capsule	Oral	Cancer	For the treatment of patients with progressive, metastatic medullary thyroid cancer (MTC).	Exelixis Inc.
VEKLURY	remdesivir	sNDA	214787/024	New active substance	Not applicable	New molecular entity (NME)	Drugs & Biologics	Powder ; Solution	Intravenous	Infections	For the treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric patients (28 days of age and older and	Gilead Science
TRINTELLIX	vortioxetine	sNDA	204447/026	New active substance	Not applicable	New molecular entity (NME)	Drugs & Biologics	Tablet	Oral	Psychiatric disorders	For the treatment of major depressive disorder (MDD) in adults.	Takeda Pharm
ABRYSVO	respiratory syncytial virus vaccine	sBLA	125769/026	Known active substance	Vaccine	Not applicable	Drugs & Biologics ; Medical Devices & IVDs	Solution	Intramuscular	Respiratory disorders	ABRYSVO is indicated: - For active immunization of pregnant individuals at 32 through 36 weeks	Pfizer Inc.
PROQUAD	measles, mumps, rubella and varicella vaccine live	sBLA	125108/1209	Known active substance	Vaccine	Not applicable	Drugs & Biologics	Suspension	Intramuscular ; Subcutaneous	Infections	For active immunization for the prevention of measles, mumps, rubella, and varicella in children 12 months	Merck Sharp &

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 Warnir	Medication Guide	REMS	Pediatric Us	FDA Supplement Ty	FDA Supplement Rationale	Link to Product Approval Document
Oncology products	Yes	Yes	No	No	Non-efficacy supplement	Provided for updating the ODOMZO (sonidegib) Prescribing Information (PI) including revisions in section 13	370273
Post-Marketing Activities I	Yes	No	No	No	Non-efficacy supplement	Provided for changes to the excursions permitted in the storage conditions in the Prescribing Information, Patient	370269
Clinical Evaluation Hematology	No	No	No	Yes	Non-efficacy supplement	Provided to revise the US Prescribing Information (USPI) warning statement related to anaphylaxis, addition of	370265
Oncology products	No	No	No	No	Non-efficacy supplement	Provided for updates based on safety updates Core Safety Information (CCSI), comparative analysis in CCSI, and post-	370232
Antiviral products	No	No	No	Yes	Non-efficacy supplement	Provided to update the Prescribing Information that no dosage adjustment of VEKLURY is recommended for the	370226
Psychiatry products	Yes	Yes	No	No	Efficacy-labeling change with clinical data	Provided for revisions to subsection 8.4 Pediatric Use of the Prescribing Information (PI) to include information	370219
Viral Products	No	No	No	Yes	Non-efficacy supplement	Provided to include a revised Lot Release Protocol and Package Insert consistent with those reviewed and approved under	370205
Viral Products	No	No	No	Yes	Non-efficacy supplement	Provided to include the use of Sterile Diluent prefilled syringes, manufactured and located for reconstitution of	370172
Gastroenterology products	No	No	No	Yes	Original approval	Original approval	370171

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.**