AstraZeneca training: Cortellis Regulatory Intelligence essentials and enhancements

Claudia Haas | February 2024

Agenda

- What is Cortellis and how to access it?
- Live demo
- Cortellis Regulatory Intelligence enhancements
- Feedback, wrap up, Q&A

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What is Cortellis Regulatory Intelligence?

Global regulatory information, across all functions and responsibilities

290K+ official documents

9.5K Value-add regulatory reports, analyses and global comparisons

Exclusive English translations

81 countries and regions Drugs & Biologic and 75 Medical Devices & IVDs

Updated daily

Regulatory experts & local consultants

What you will learn today:

1. How to subscribe to the Weekly Newsletter and set up your own alerts to keep track of changes
2. How to easily compare key requirements across countries & regions
3. Where to find up-to-date English language information on the legislation & guidelines you need to follow
4. Take advantage of recent enhancements, including machine translations and multiple search improvements.

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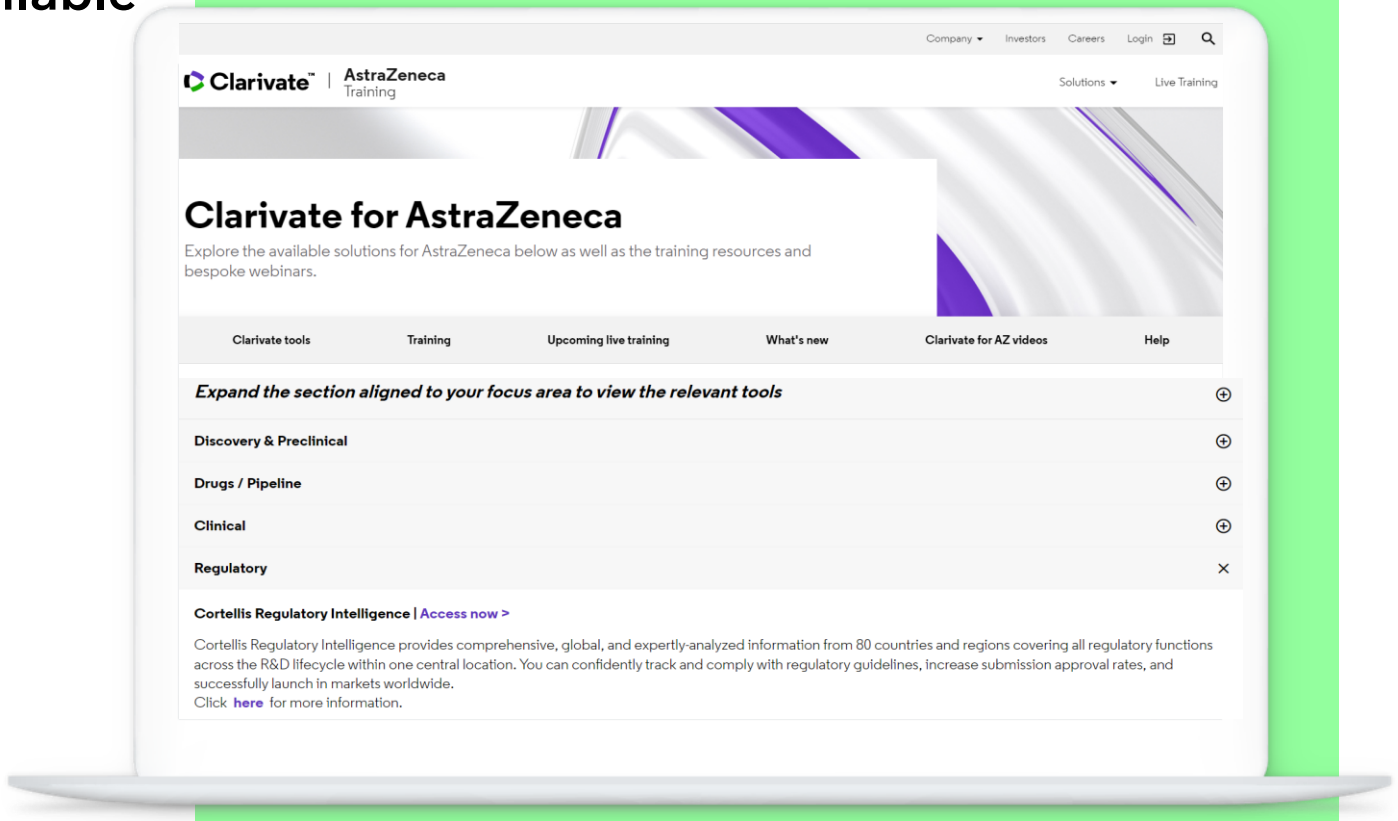
Clarivate for AstraZeneca Resource Page

Quick links to all Clarivate resources available to you

- ✓ Easy access to all platforms **including Cortellis access**
- ✓ Upcoming live sessions
- ✓ Recorded videos
- ✓ What's new
- ✓ Contact support



ACCESS HERE

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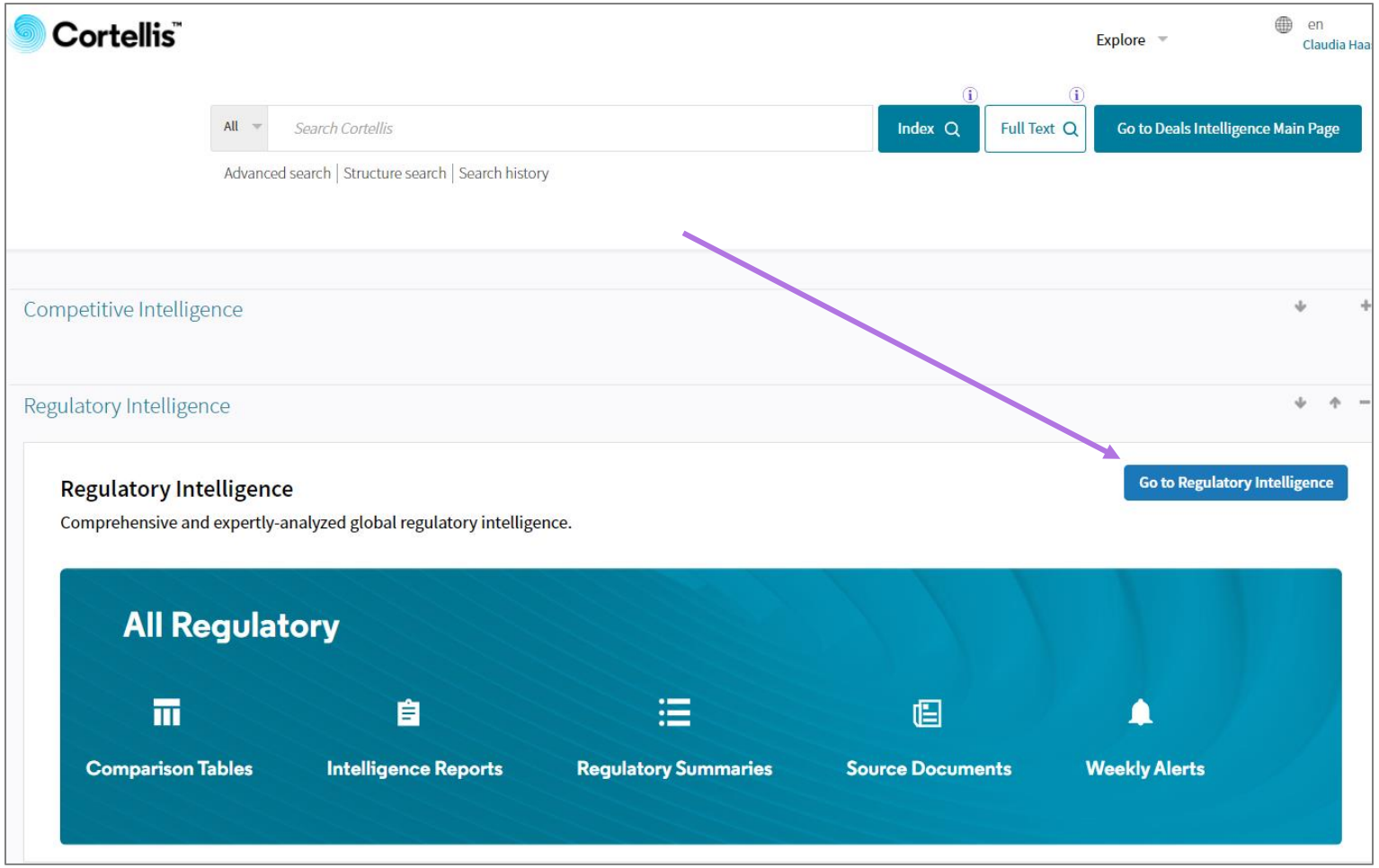
Handout

Cortellis Landing Page

Click the "**Go to**…" button to access Cortellis Regulatory Intelligence



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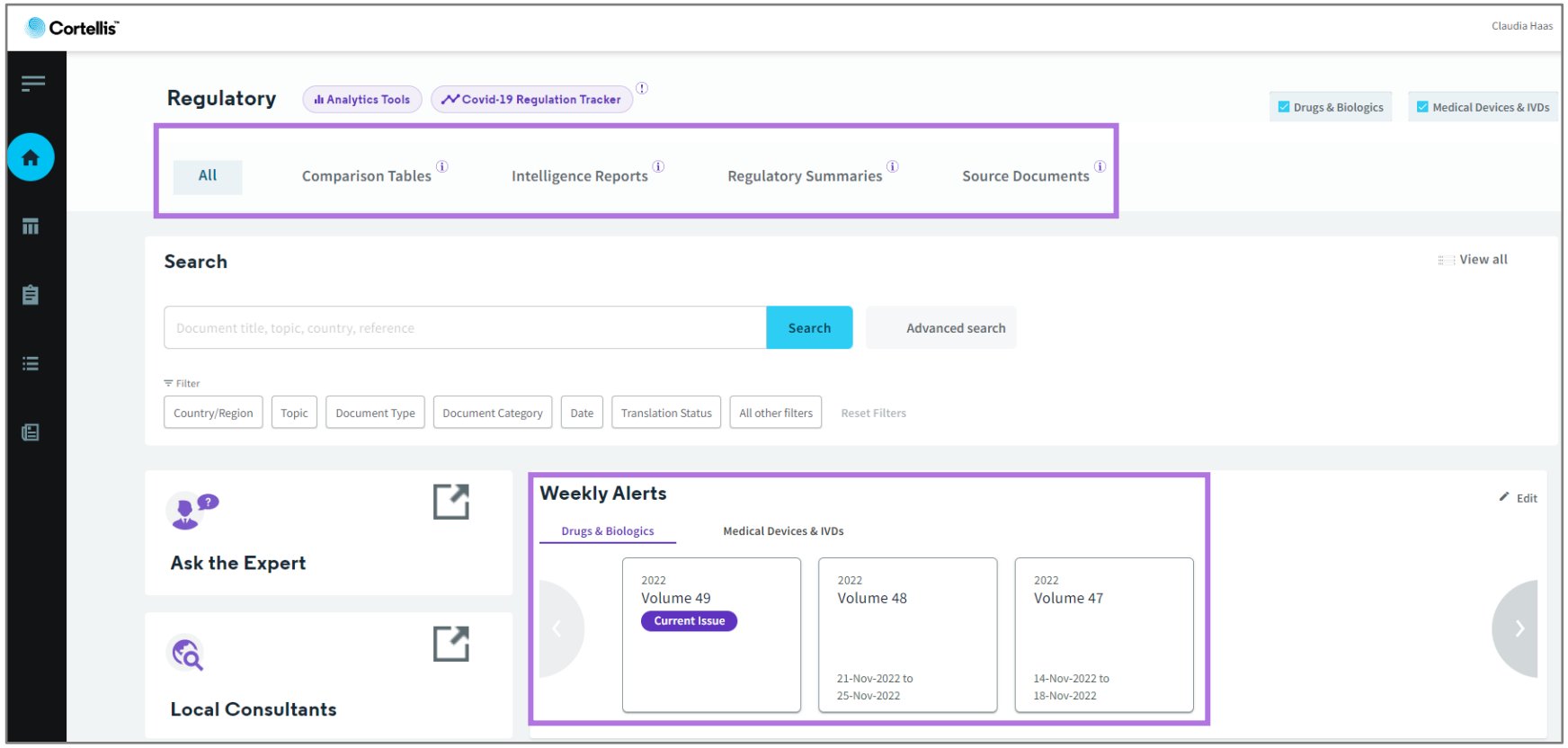
Cortellis Regulatory Homepage

Start searching through all documents, click the tabs to browse value-add tables, reports and summaries or access the Cortellis Weekly Alerts newsletter.



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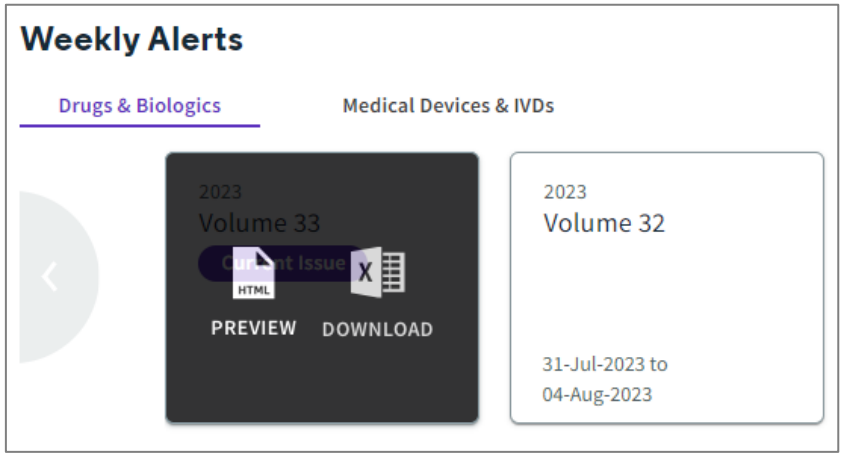
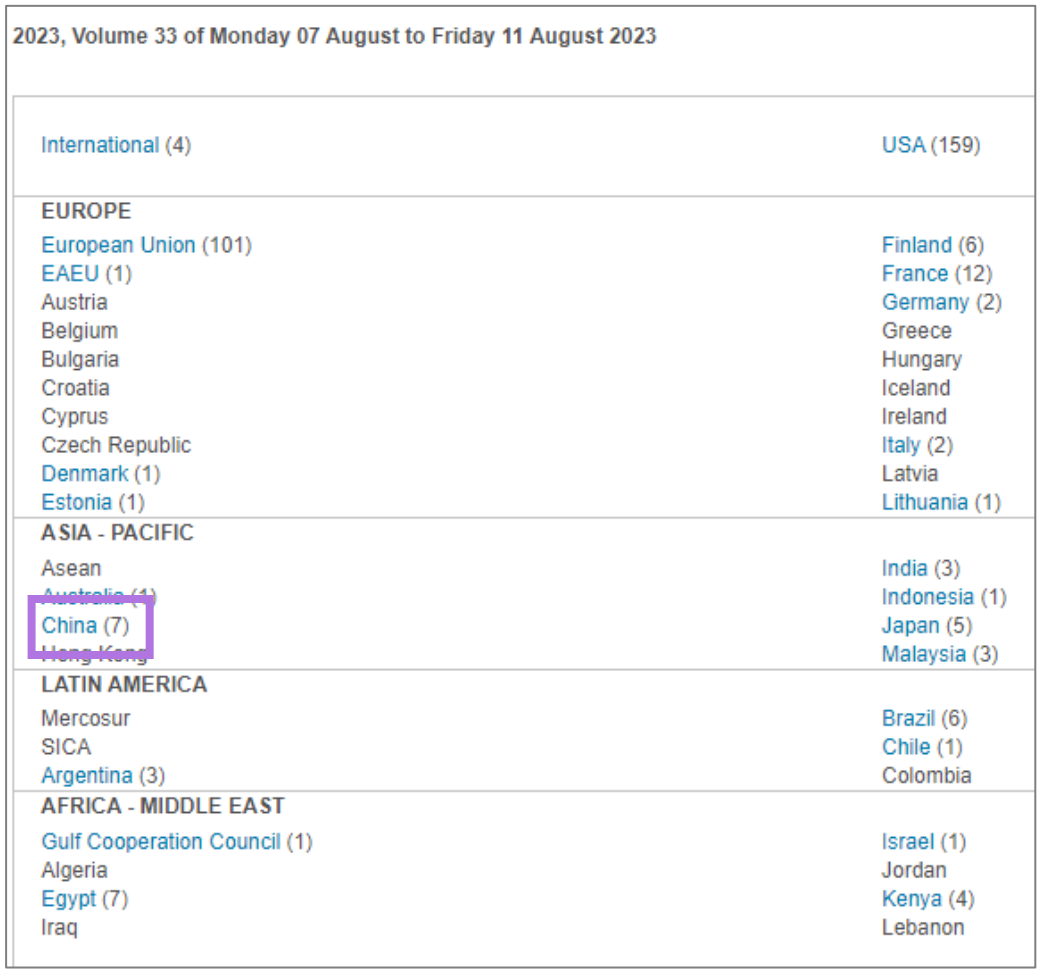
Cortellis Weekly Alert

Monday newsletter containing new and updated documents for all countries & regions of the previous week: Available in html format or Excel.





2023, Volume 33 of Monday 07 August to Friday 11 August 2023

International (4)	USA (159)
EUROPE	
European Union (101)	Finland (6)
EAEU (1)	France (12)
Austria	Germany (2)
Belgium	Greece
Bulgaria	Hungary
Croatia	Iceland
Cyprus	Ireland
Czech Republic	Italy (2)
Denmark (1)	Latvia
Estonia (1)	Lithuania (1)
ASIA - PACIFIC	
Asean	India (3)
Australia (1)	Indonesia (1)
China (7)	Japan (5)
Hong Kong	Malaysia (3)
LATIN AMERICA	
Mercosur	Brazil (6)
SICA	Chile (1)
Argentina (3)	Colombia
AFRICA - MIDDLE EAST	
Gulf Cooperation Council (1)	Israel (1)
Algeria	Jordan
Egypt (7)	Kenya (4)
Iraq	Lebanon

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Cortellis Weekly Alert

Monday newsletter containing new and updated documents for all countries & regions of the previous week: Available in html format or Excel.

	A	B	C	D	E	G
1	Country/Region	Title	Abstract	Link to full document	Authority Acceptan	Type
2	Argentina	Authorities / Organizations: Argentine Medicines Regulat	This document describes the structure, organization and r	Full report (IDRAC 26936)	9-Aug-23	Expert Report
3	Argentina	How to Market Herbal Products	This Regulatory Summary relates to plant based medicina	Full report (IDRAC 26808)	9-Aug-23	Expert Report
4	Argentina	Decree 405/2023: Approves the Regulation of Law 27.669 (	This Decree approves the regulation of Law 27.669 (IDRAC	Full report (IDRAC 369145)	4-Aug-23	Decree
5	Australia	Public Comments Tracker	This Regulatory Intelligence Report provides the Consulta	Full report (IDRAC 56646)	11-Aug-23	Public Comment
6	Brazil	Public Comments Tracker	This Regulatory Intelligence Report provides the Consulta	Full report (IDRAC 205712)	11-Aug-23	Public Comment
7	Brazil	Guide: Submission of Import Application through the LPC	ANVISA has created this guide aiming to explain the Impo	Full report (IDRAC 369219)	4-Aug-23	Guideline
8	Brazil	Public Consultation 1.188: Proposes a Resolution on the A	This Draft is a Resolution that proposes to amend Resolut	Full report (IDRAC 369244)	3-Aug-23	Resolution
9	Brazil	Resolution RDC 768: Establishes the Rules for the Labeling	This resolution aims at improving the format and content	Full report (IDRAC 369363)	4-Aug-23	Resolution
10	Brazil	Resolution RDC 807: Importation of Goods and Products S	This Resolution provides for the criteria and procedures f	Full report (IDRAC 369354)	4-Aug-23	Resolution
11	Canada	Legal Definitions and Marketing Requirements	This document provides the definition of medicinal produ	Full report (IDRAC 91648)	9-Aug-23	Expert Report
12	Canada	Marketing Authorization Procedures: Procedure for Apply	This document provides general information on the proce	Full report (IDRAC 130705)	10-Aug-23	Expert Report
13	Canada	Marketing Authorization Procedures: Withdrawal / Suspe	This document provides information about the Procedure	Full report (IDRAC 24054)	8-Aug-23	Expert Report
14	Canada	Combination Products Regulatory Framework	This regulatory summary is related to Combination Produ	Full report (IDRAC 48210)	7-Aug-23	Expert Report
15	Canada	Announcement: Exceptional Importation and Sale of Drug	This announcement informs about exceptional importatio	Full report (IDRAC 309645)	9-Aug-23	Announcement
16	Canada	Announcement: Health Product Advertising Incidents Rel	The health and safety of all Canadians is Health Canada's	Full report (IDRAC 310589)	10-Aug-23	Announcement
17	Canada	Notice: Drug and Vaccine Authorizations for COVID-19, 04	This notice provides information about Health Canada eva	Full report (IDRAC 318331)	4-Aug-23	Announcement
18	Canada	Patented Medicines (Notice of Compliance) Regulations (	Please note that this consolidated version include the las	Full report (IDRAC 24640)	25-Jul-23	Announcement
19	Canada	Access to Information Act, Consolidated Version as of 25-	This Act provides the legislation under which Canadians c	Full report (IDRAC 24622)	25-Jul-23	Law

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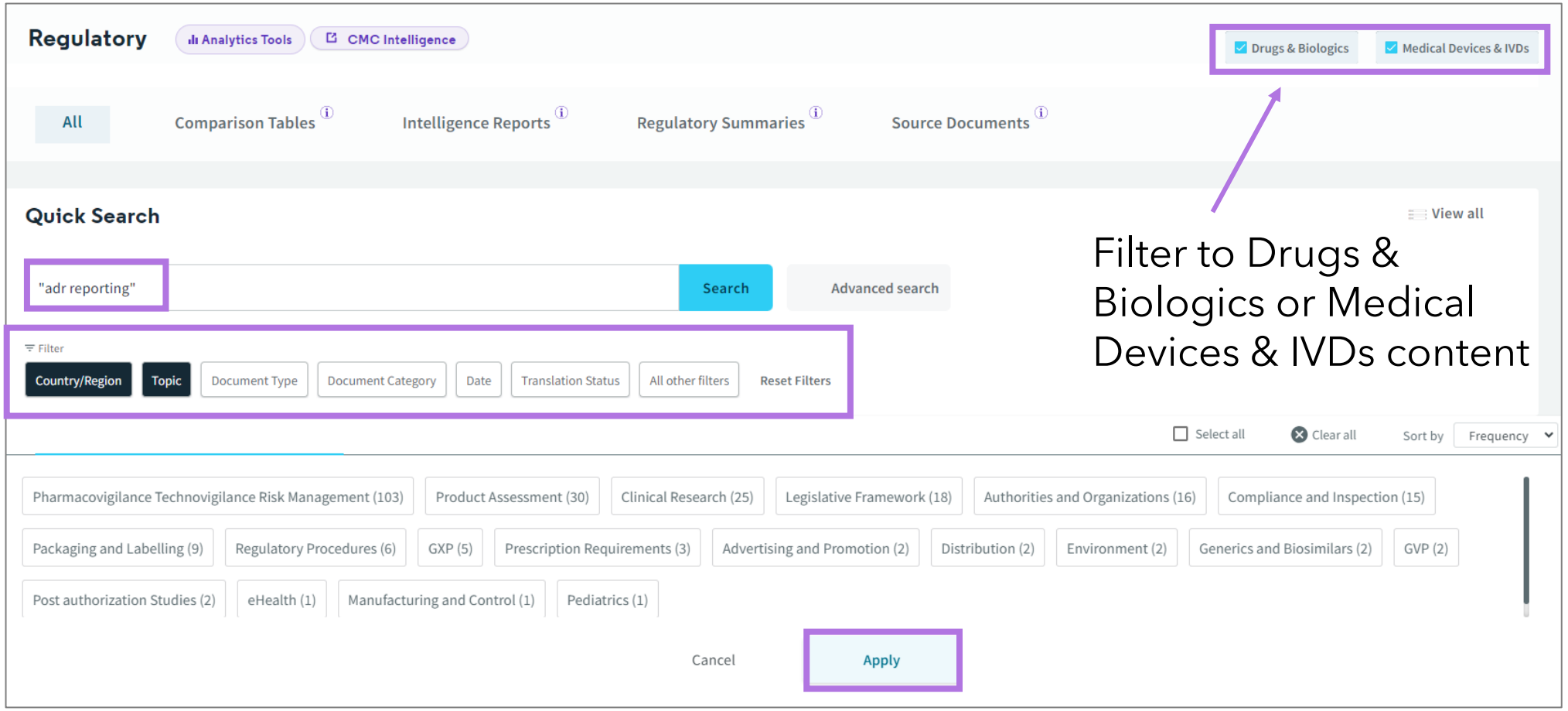
Search

Enter keywords and use dynamic filters to narrow down your search.



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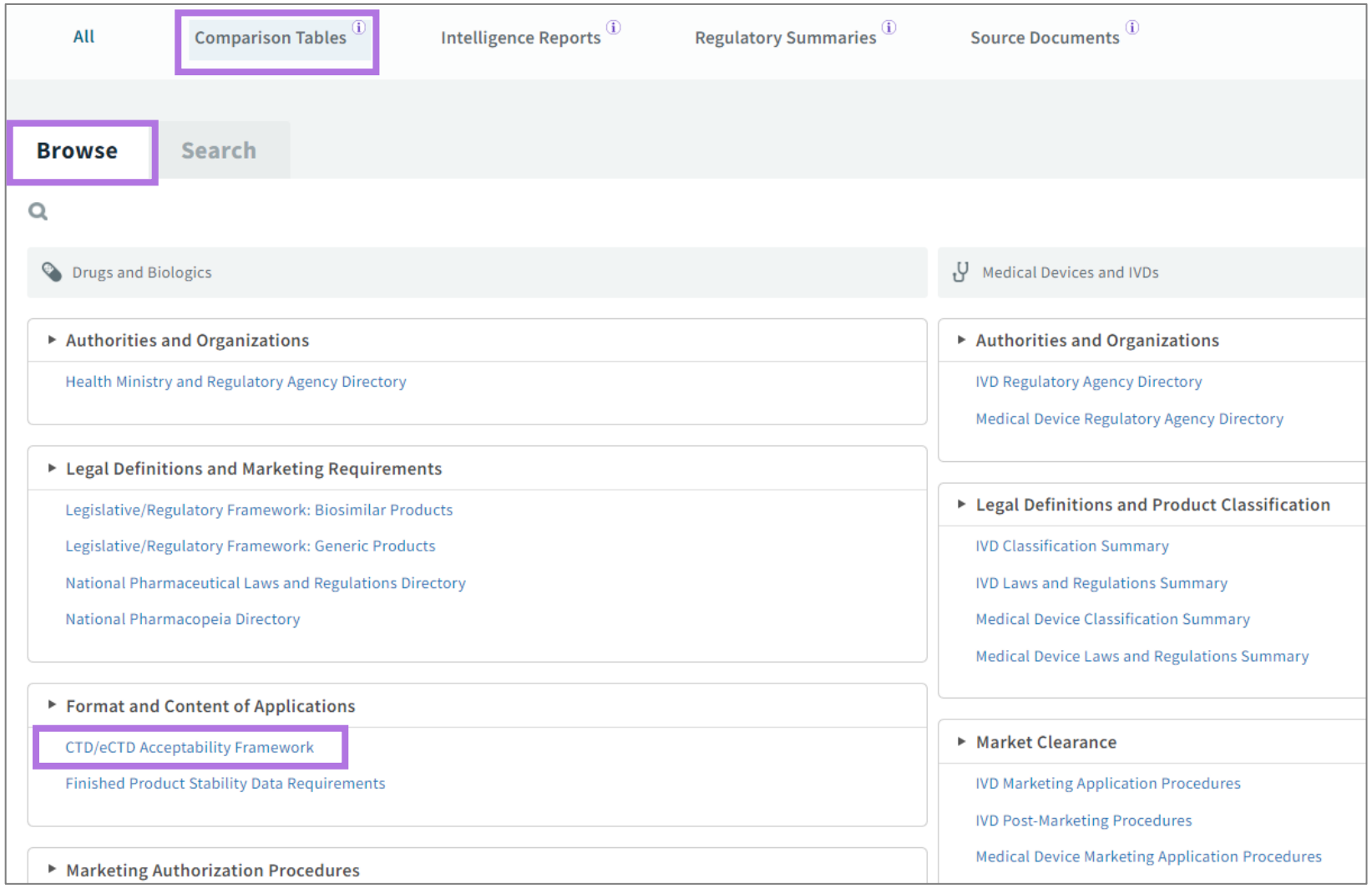
Browse Comparison Tables

Quickly browse Comparison Tables and click a topic of interest to open them.



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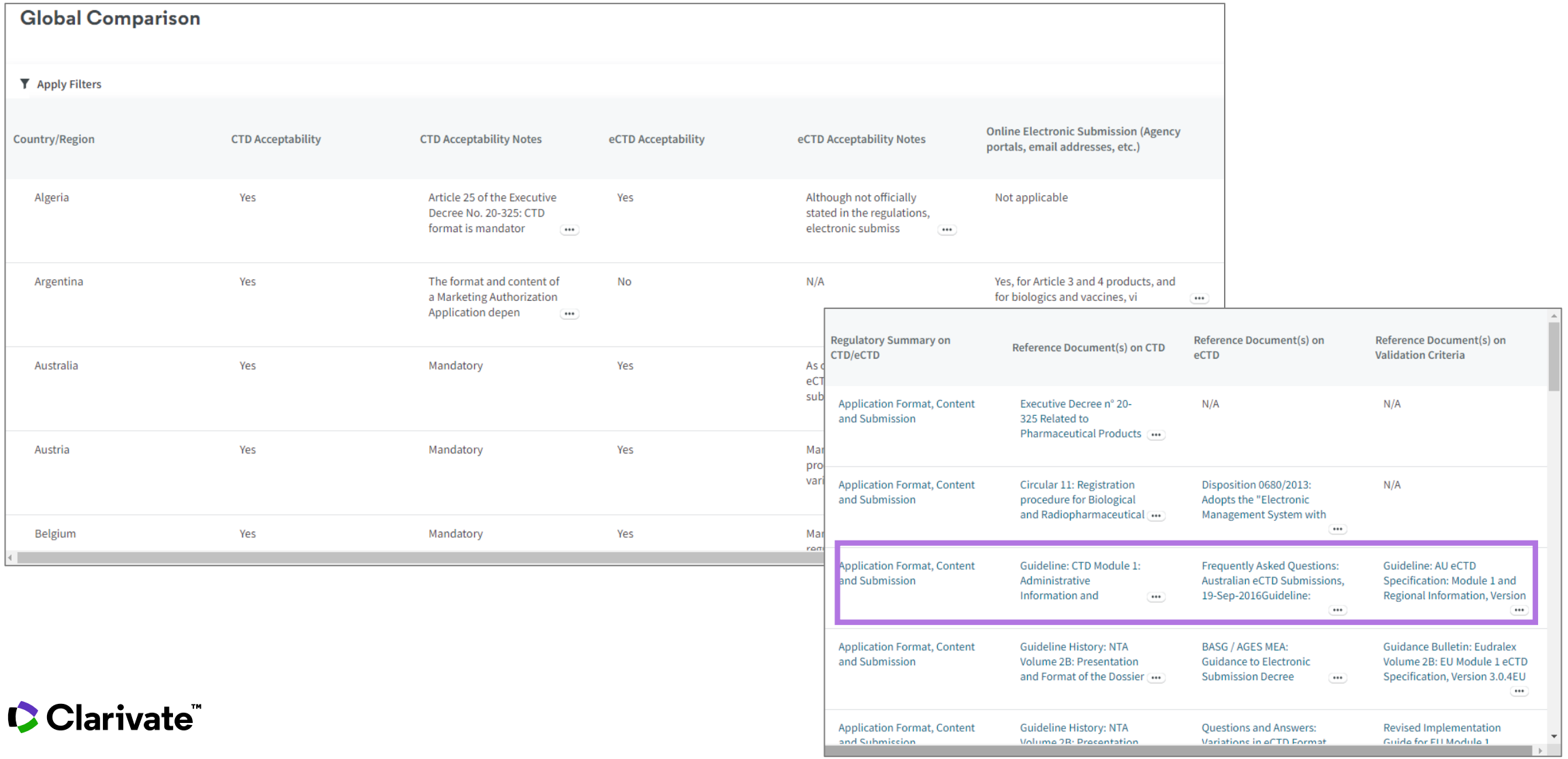
Comparison Tables - Example

Compare key requirements across countries & regions in one single place.
Link out to connected documents to learn more.



Global Comparison

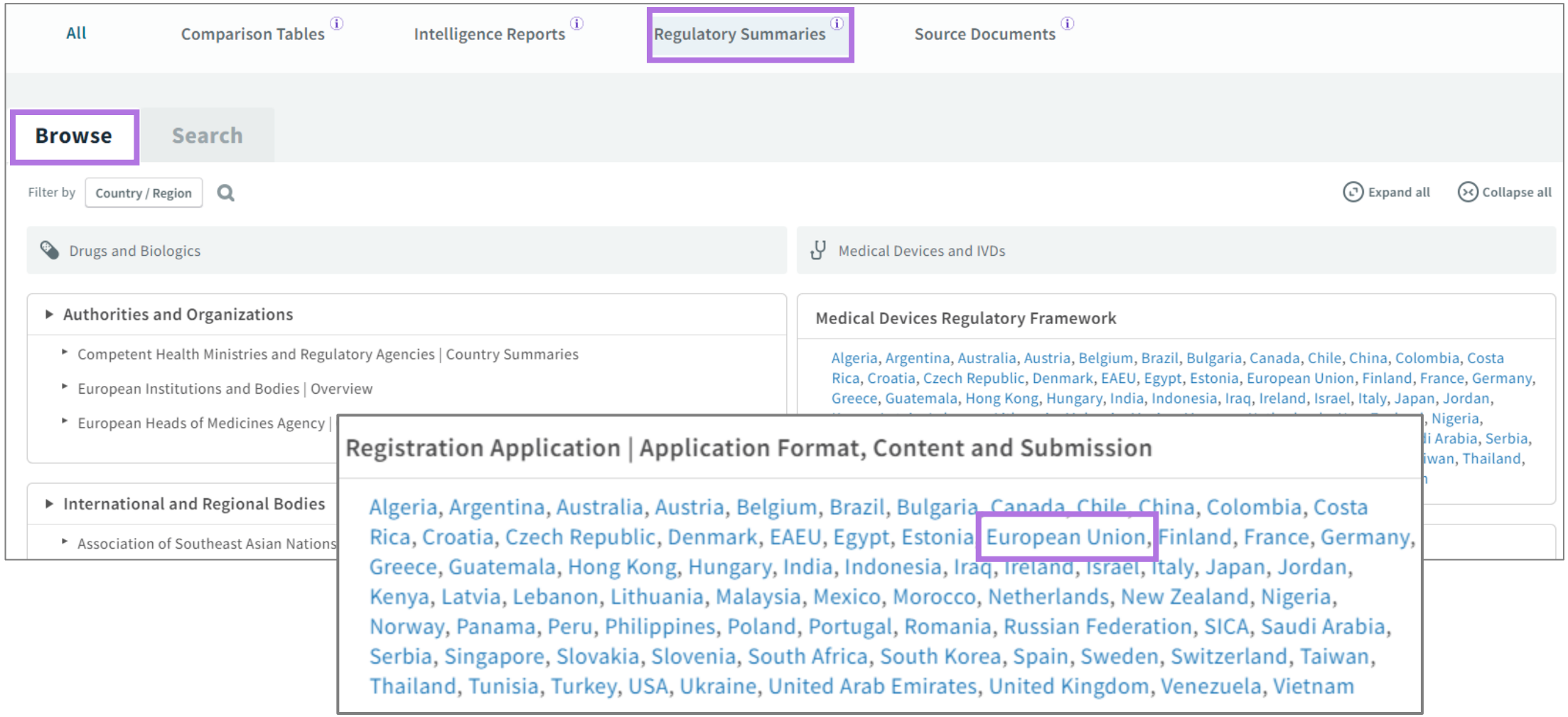
Apply Filters

Country/Region	CTD Acceptability	CTD Acceptability Notes	eCTD Acceptability	eCTD Acceptability Notes	Online Electronic Submission (Agency portals, email addresses, etc.)
Algeria	Yes	Article 25 of the Executive Decree No. 20-325: CTD format is mandator	Yes	Although not officially stated in the regulations, electronic submiss	Not applicable
Argentina	Yes	The format and content of a Marketing Authorization Application depen	No	N/A	Yes, for Article 3 and 4 products, and for biologics and vaccines, vi
Australia	Yes	Mandatory	Yes	As	
Austria	Yes	Mandatory	Yes	Mar	
Belgium	Yes	Mandatory	Yes	Mar	

Regulatory Summary on CTD/eCTD	Reference Document(s) on CTD	Reference Document(s) on eCTD	Reference Document(s) on Validation Criteria
Application Format, Content and Submission	Executive Decree n° 20-325 Related to Pharmaceutical Products	N/A	N/A
Application Format, Content and Submission	Circular 11: Registration procedure for Biological and Radiopharmaceutical	Disposition 0680/2013: Adopts the "Electronic Management System with	N/A
Application Format, Content and Submission	Guideline: CTD Module 1: Administrative Information and	Frequently Asked Questions: Australian eCTD Submissions, 19-Sep-2016Guideline:	Guideline: AU eCTD Specification: Module 1 and Regional Information, Version
Application Format, Content and Submission	Guideline History: NTA Volume 2B: Presentation and Format of the Dossier	BASG / AGES MEA: Guidance to Electronic Submission Decree	Guidance Bulletin: Eudralex Volume 2B: EU Module 1 eCTD Specification, Version 3.0.4EU
Application Format, Content and Submission	Guideline History: NTA Volume 2B: Presentation	Questions and Answers: Variations in eCTD Format	Revised Implementation Guide for EU Module 1

Browse Regulatory Summaries

Easily browse Regulatory Summaries and click a country of interest to open them.



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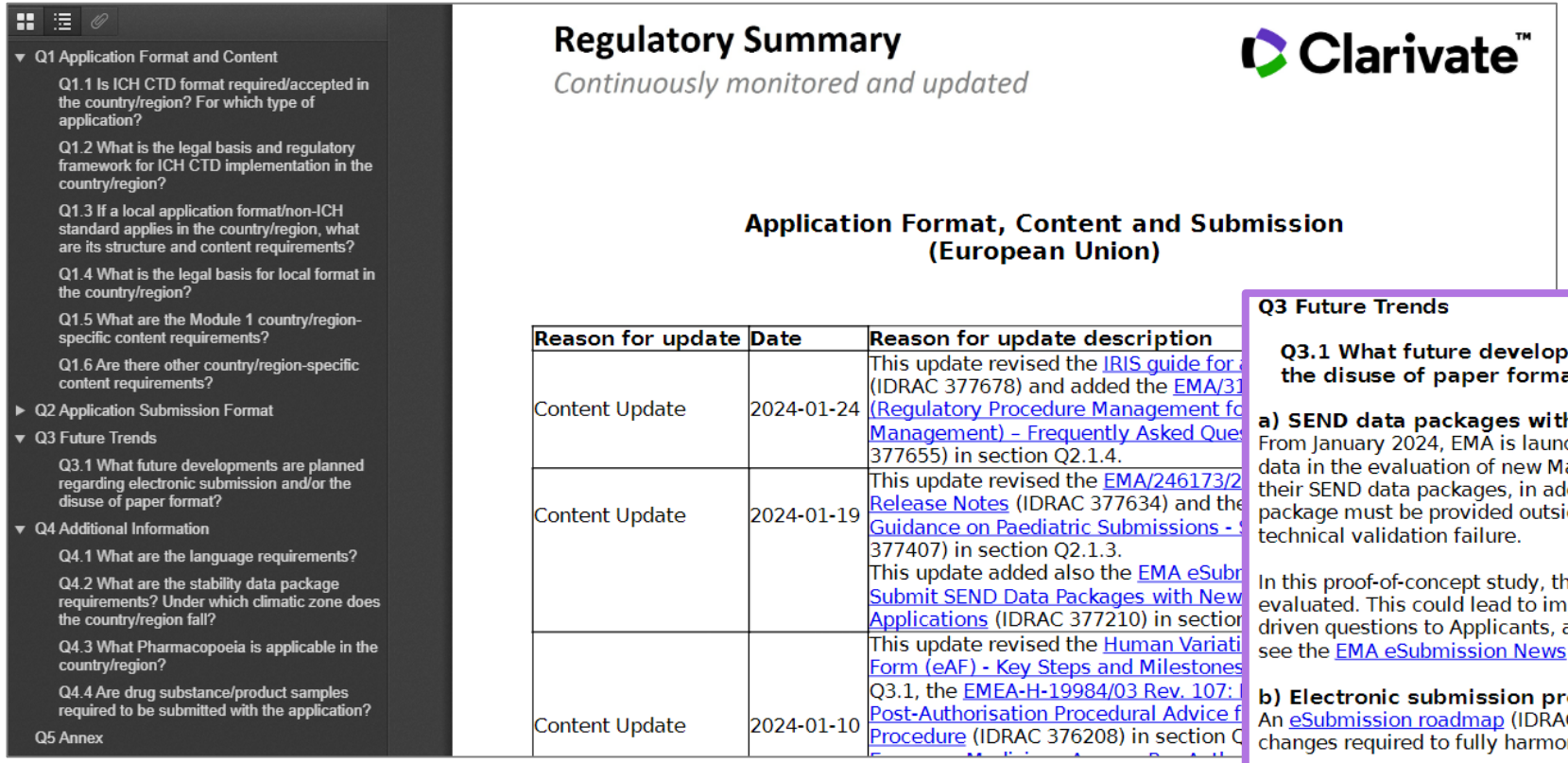
Regulatory Summary - Example

Topic's key questions answered at-a-glance



- Q1 Application Format and Content
  - Q1.1 Is ICH CTD format required/accepted in the country/region? For which type of application?
  - Q1.2 What is the legal basis and regulatory framework for ICH CTD implementation in the country/region?
  - Q1.3 If a local application format/non-ICH standard applies in the country/region, what are its structure and content requirements?
  - Q1.4 What is the legal basis for local format in the country/region?
  - Q1.5 What are the Module 1 country/region-specific content requirements?
  - Q1.6 Are there other country/region-specific content requirements?
- Q2 Application Submission Format
- Q3 Future Trends
  - Q3.1 What future developments are planned regarding electronic submission and/or the disuse of paper format?
- Q4 Additional Information
  - Q4.1 What are the language requirements?
  - Q4.2 What are the stability data package requirements? Under which climatic zone does the country/region fall?
  - Q4.3 What Pharmacopoeia is applicable in the country/region?
  - Q4.4 Are drug substance/product samples required to be submitted with the application?
- Q5 Annex

Regulatory Summary

Continuously monitored and updated

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Application Format, Content and Submission (European Union)

Reason for update	Date	Reason for update description
Content Update	2024-01-24	This update revised the IRIS guide for … (IDRAC 377678) and added the EMA/31… (Regulatory Procedure Management fo… Management) – Frequently Asked Que… 377655) in section Q2.1.4.
Content Update	2024-01-19	This update revised the EMA/246173/2… Release Notes (IDRAC 377634) and the… Guidance on Paediatric Submissions - … 377407) in section Q2.1.3. This update added also the EMA eSubm… Submit SEND Data Packages with New… Applications (IDRAC 377210) in section…
Content Update	2024-01-10	This update revised the Human Variati… Form (eAF) - Key Steps and Milestones… Q3.1, the EMEA-H-19984/03 Rev. 107: … Post-Authorisation Procedural Advice f… Procedure (IDRAC 376208) in section C…

Q3 Future Trends

Q3.1 What future developments are planned regarding electronic submission and/or the disuse of paper format?

a) SEND data packages with new Market Authorisation Applications
From January 2024, EMA is launching a proof-of-concept study to evaluate the added value of using SEND data in the evaluation of new Marketing Authorisation Applications. Applicants are encouraged to submit their SEND data packages, in addition to the eCDT format, as part of their MAA submission. The SEND package must be provided outside the eCTD, inside the working documents folder to avoid eCTD technical validation failure.

In this proof-of-concept study, the use of SEND data in the assessment of the non-clinical dossier will be evaluated. This could lead to improved and more consistent quality of assessments, to more science-driven questions to Applicants, and to faster completion of the non-clinical dossier assessment. Please see the EMA eSubmission News (IDRAC 377210).

b) Electronic submission processes in Europe
An eSubmission roadmap (IDRAC 296554) (Note) describes the issues that need to be addressed and changes required to fully harmonise electronic submission processes in Europe.

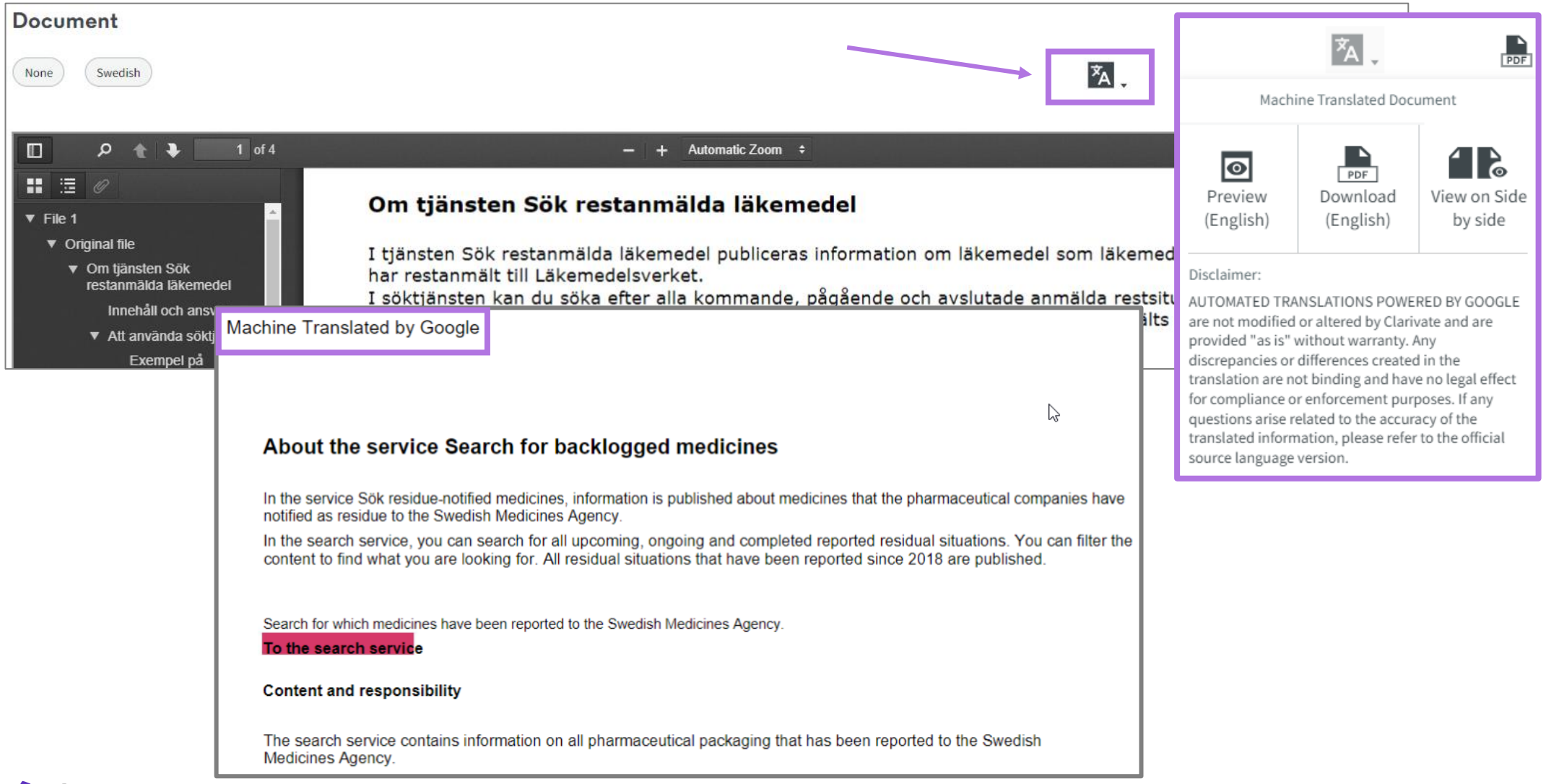
Note: European Medicines Regulatory Network: eSubmission roadmap (IDRAC 296554) , Jun-2019. See also visual representation of the timelines (IDRAC 296558) :

- Annex 1 (IDRAC 278589) : Implementation of eCTD v.4.0, Jun-2018
- Annex 2 (IDRAC 301677) : implementation of mandatory use of eCTD format for regulatory submission, Nov-2018
- Annex 4 (IDRAC 278590) : Replacement of the current PDF electronic application forms (eAFs) with the CESP Application Dataset Management Module (CESP Dataset Module), Jun-2018
- Annex 5 (IDRAC 278592) : Mandatory use of the Common Repository for EMA led procedures, Jun-2018

What’s new

NEW: English Machine translations (>34.000 added to Cortellis as of today)

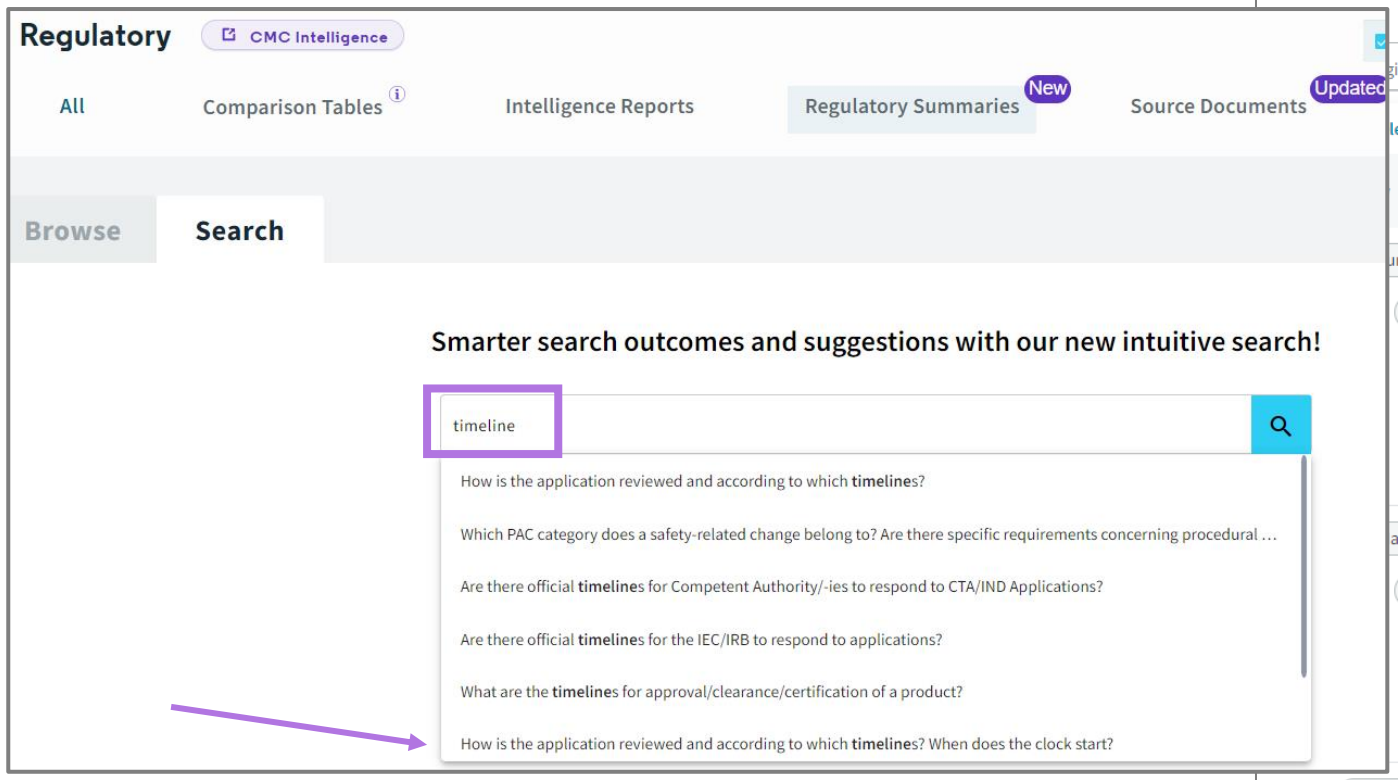
Easily access, search and download documents machine translated by Google*

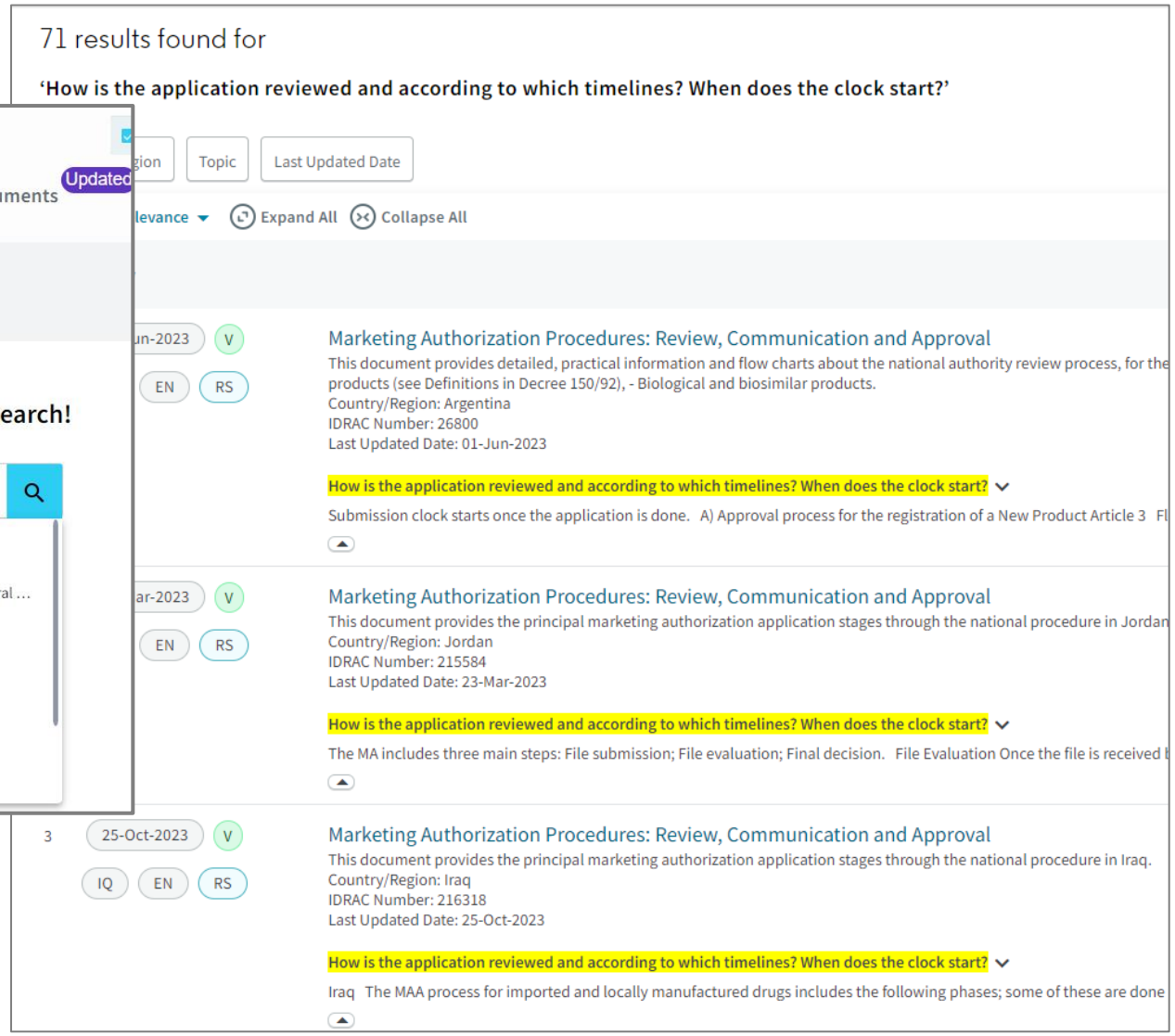


*added to all regulatory valid status documents in Cortellis without a human translation

NEW: Intuitive Search for Regulatory Summaries and Intelligence Reports

Get better results with autosuggestions and easily compare





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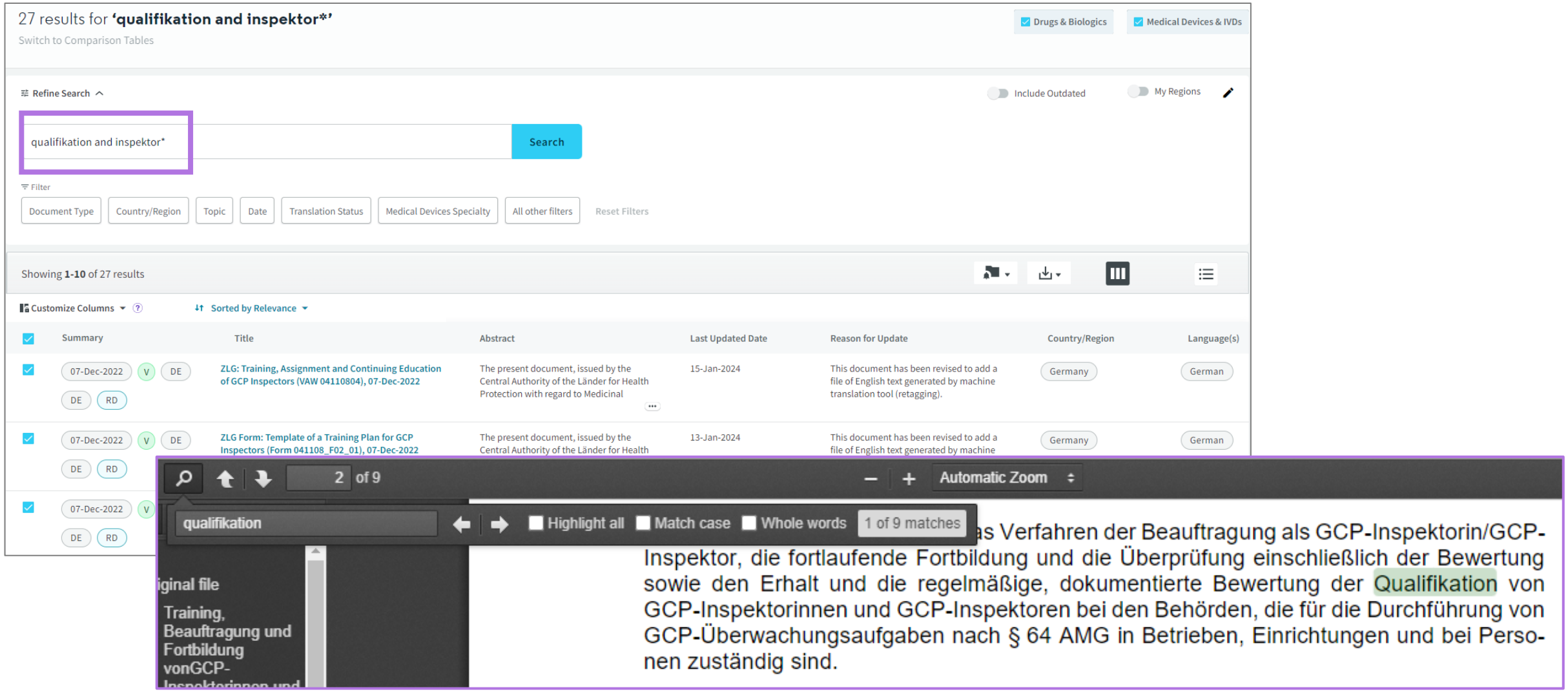
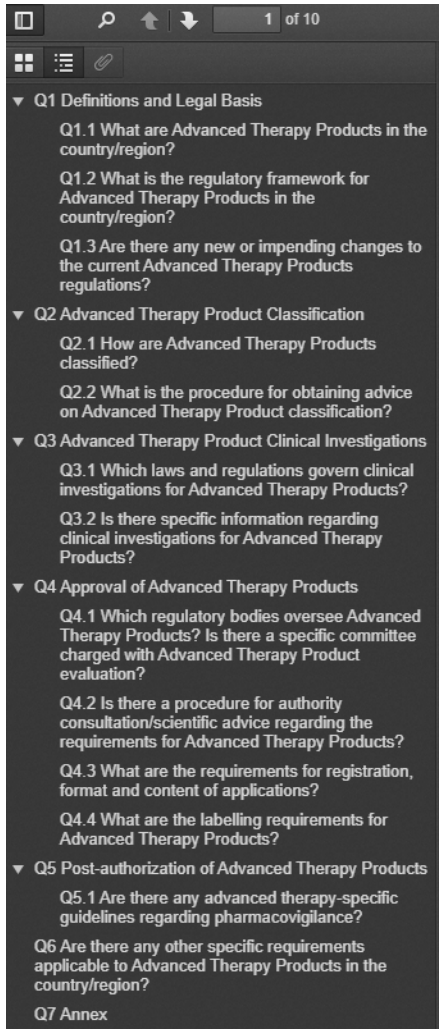
UPGRADED: Source Document Search

Search all source documents including the pdf full text using English or local language keywords



EXTENDED: How to market Advanced Therapy Medicinal Products (ATMP)

Regulatory Summaries available for 72 territories with new Q&A structure providing more insights



Regulatory Summary

Continuously monitored and updated

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How to Market Advanced Therapy Products (Taiwan)

Reason for update	Date	Reason for update description
Content Update	2024-02-02	This update added the procedure of Cell Therapy Technology Fee-based Consultation in section Q4.2.
New	2024-01-19	

Q1 Definitions and Legal Basis

Q1.1 What are Advanced Therapy Products in the country

In Taiwan, "Advanced therapy products" are regulated as "Regenerati

According to the draft version of Provisions on Regenerative Medicina 377018), "Regenerative medicines" use cells, genes, and derivatives body structures or functions, or for treatment or prevention of human "Regenerative medical technique" and "Regenerative medical prepar

"Regenerative medical technique", is regulated by the Medical Care A Governing the Application of Specific Medical Technique and Medical the following:

- Specific medical technique (Cell therapy technique, Specific ope Other specific medical technique)
- Specific examination, laboratory testing, and medical devices

(B) Regenerative medical preparations

For "Regenerative medical preparations", the clinical investigations shall follow the requirements of Pharmaceutical Affairs Act (PAA) (IDRAC 253489) and Regulations for Good Clinical Practice (GCP), 28-Aug-2020 (IDRAC 317460).

For Cell Therapy Medicinal Product

According to MOHW Announcement No. 1051413931: Revising Clinical Trials Plan Application Procedures for Human Cell Therapy Products, 17-Jan-2017 (IDRAC 239002), the Ministry of Health and Welfare established a provisional dual track system for the clinical trial protocol application for human cells therapy products. An applicant for a clinical trial protocol for a human cell therapy product may either choose the option of a consultation procedure prior to document submission or may choose to forego said consultation procedure and proceed directly to submission of the application for a clinical trial protocol for a human cell therapy product to the Food and Drug Administration under the Ministry of Health and Welfare. The document submissions for applications for clinical trial protocols for human cell therapy products are required to comply with requirements of MOHW Announcement No.1091401592 & MOHW Letter No.1091401633: Clinical Trials Guidelines for Human Cell Therapy Products (Revised Version), 01-May-2020 (IDRAC 311518) and MOHW Announcement No.1091401041: Checklist of Technical Documents for Human Cell Therapy Clinical Trials Applications, 12-Feb-2020 (IDRAC 306315).

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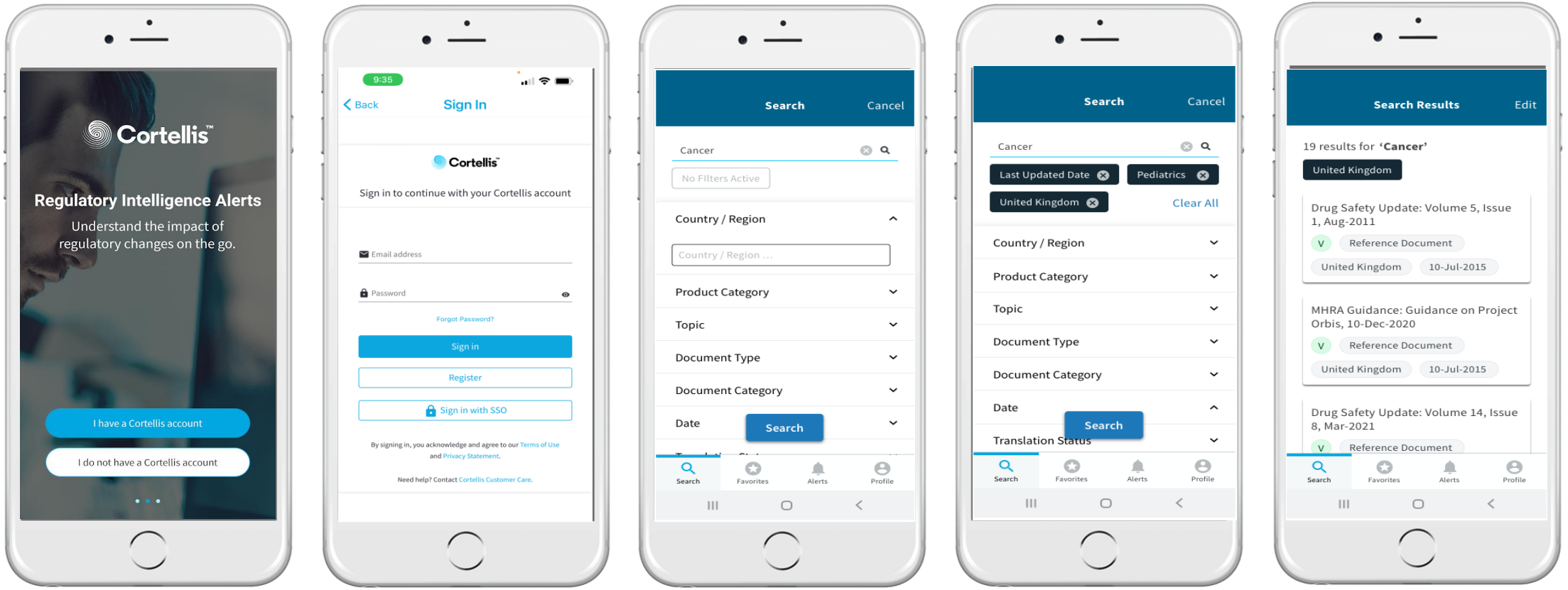

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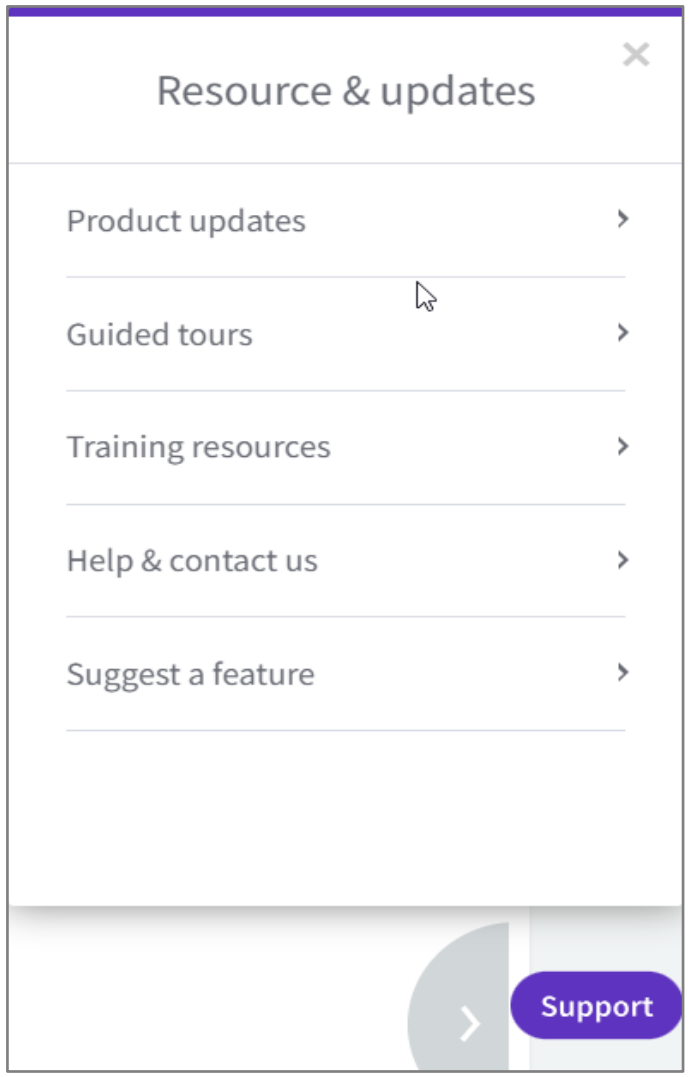

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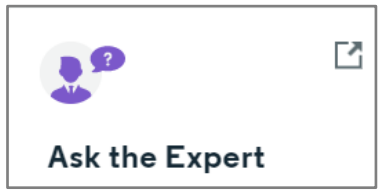

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“Research shows that an average learner forgets 70% of what they learned within 24 hours… ”

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