Navigating evolving pharmacovigilance requirements with Cortellis Regulatory Intelligence
30 minutes + Q&A

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Customer Education Team

July 2025

Agenda

- Cortellis Regulatory Intelligence
- Use case questions
- Live demo
- Coming soon: Cortellis AI Regulatory Assistant
- Feedback, wrap up, Q&A

Cortellis: Unlock hidden insights and bring life to science

Make data-driven decisions with speed and certainty

Supporting your needs across the drug/device development lifecycle

Discovery & Preclinical Development

Clinical Development & Regulatory

Portfolio Strategy & Business Development

Generics Strategy & Development

<<<<< Data | Insights | Consulting | Services >>>>>

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What is Cortellis Regulatory Intelligence?

Global regulatory information, across all functions and responsibilities

300K+ official documents

8K Value-add regulatory reports, analyses and global comparisons

All documents have English translations

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

Updated daily

Regulatory experts & local consultants

What will we cover today?

Use Case 1 (Slides 8-11):

Compare pre- and post-marketing PV reporting and surveillance requirements across multiple countries.

Use Case 2 (Slides 12-13):

Access and interpret key policy documents translated into English.

Use Case 3 (Slides 14-15):

Monitor Risk Management Plans (RMPs) for products in the European Union and the United States.

Use Case 4 (Slides 16-17):

Set up customized alerts to stay informed of regulatory changes.

Coming soon: Cortellis AI Regulatory Assistant (Slides 18-27)

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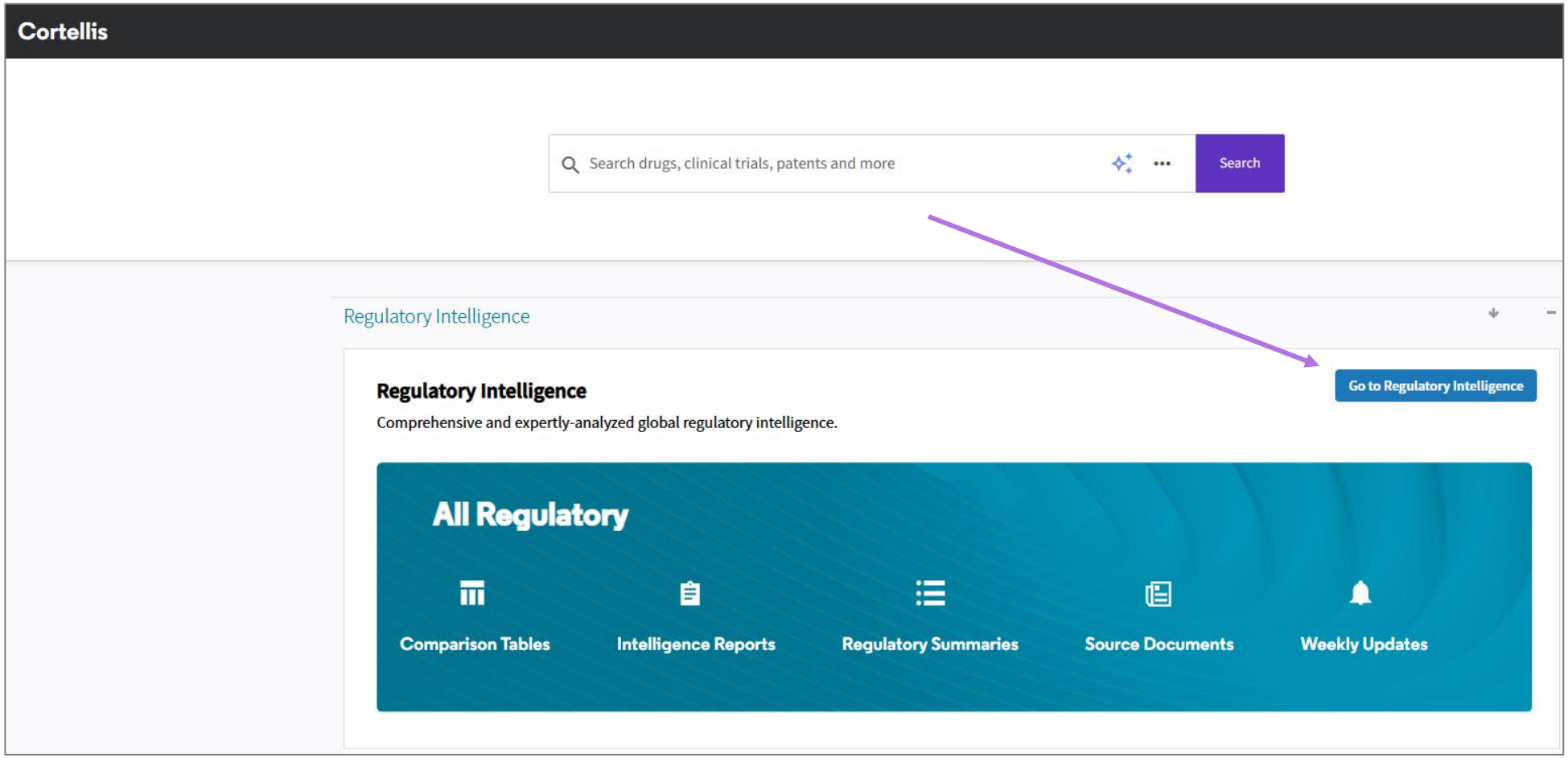
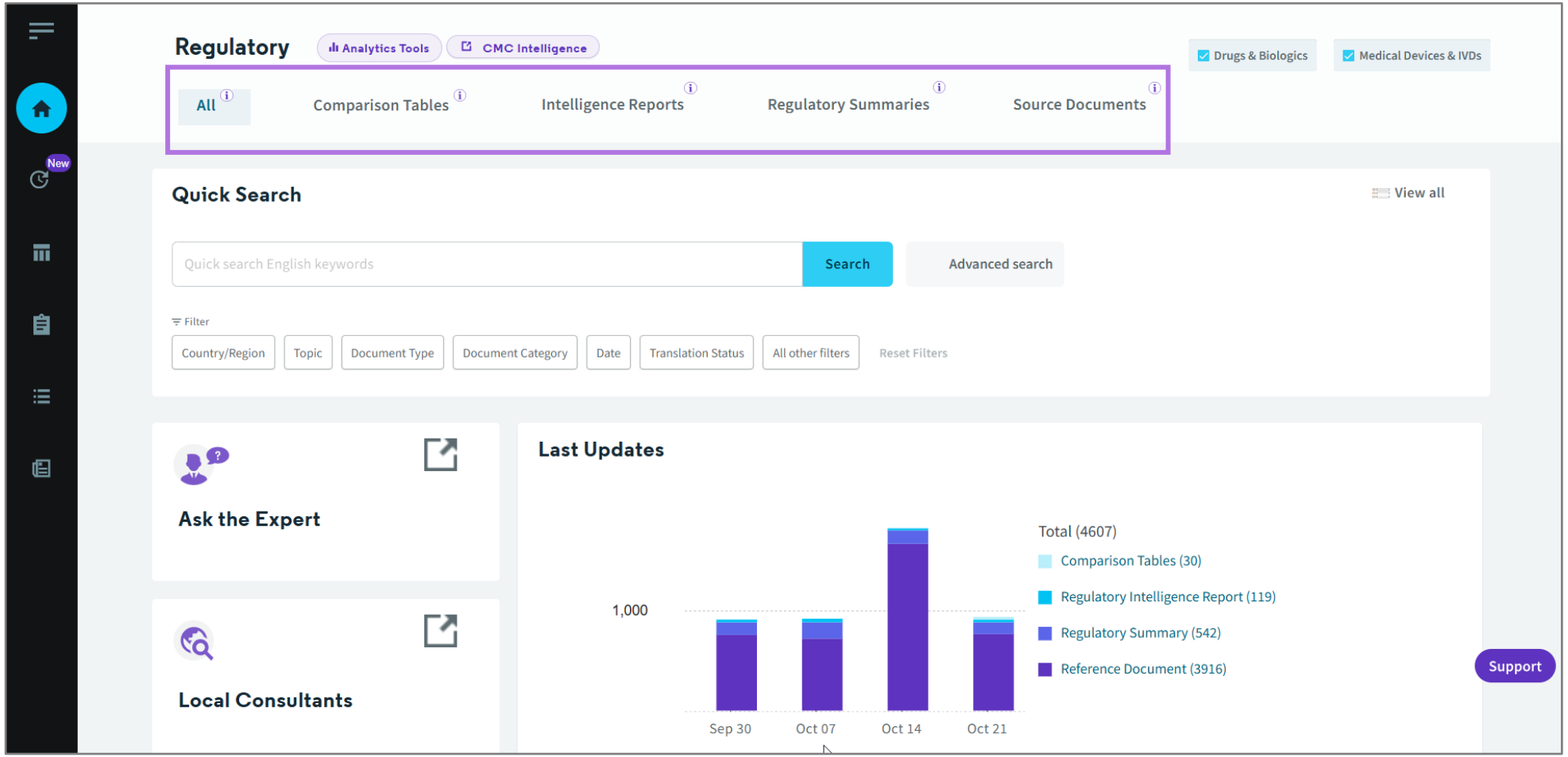
Cortellis Landing Page

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



Cortellis Regulatory Homepage

Click the tabs to browse value-add reports (Comparison tables, Intelligence Reports, Regulatory Summaries) or start searching with Quick Search or Source Documents Search.



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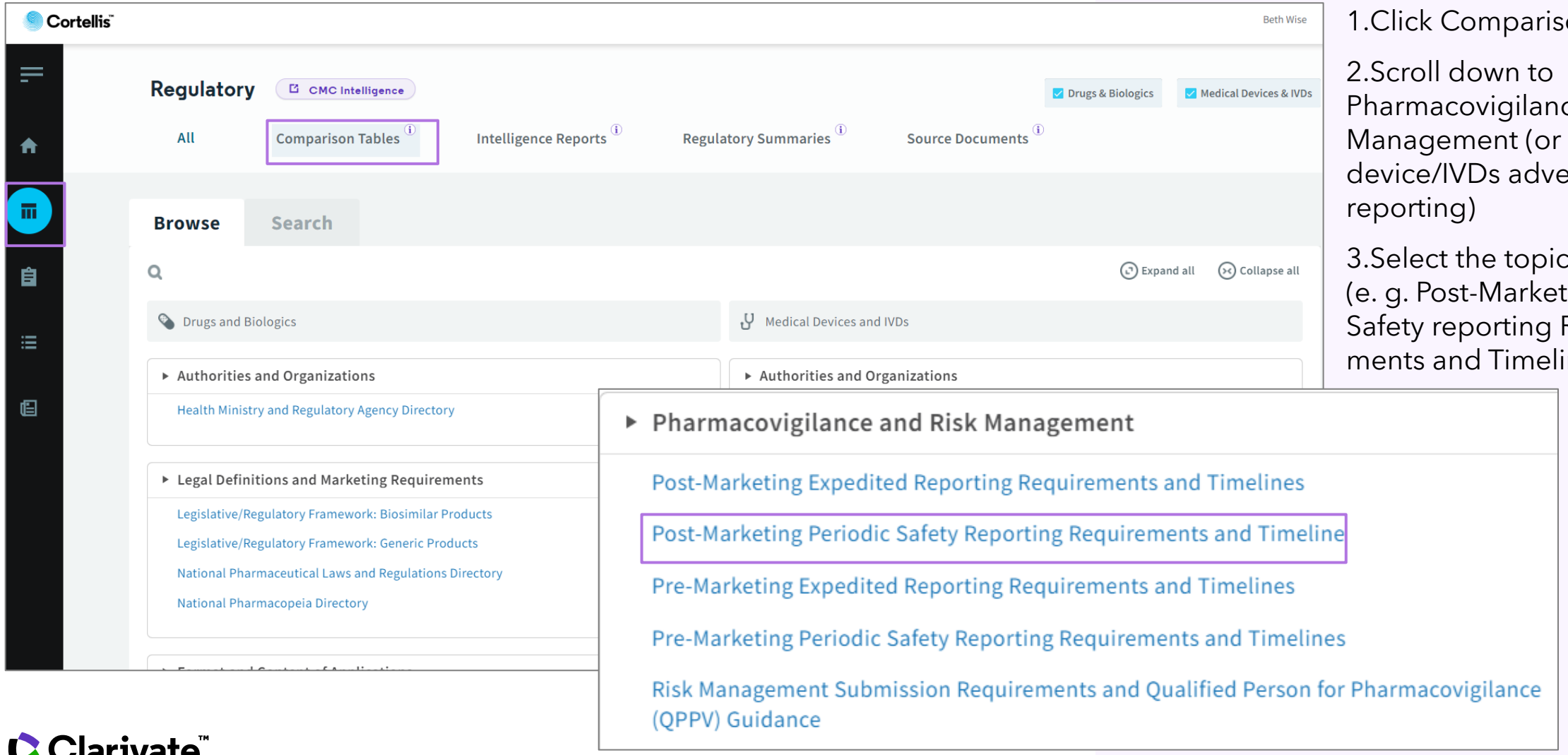
Compare incidents/adr reporting requirements across countries and regions

Comparison Tables



1.Click Comparison tables

2.Scroll down to Pharmacovigilance and Risk Management (or Medical device/IVDs adverse incident reporting)

3.Select the topic of interest (e. g. Post-Marketing Periodic Safety reporting Require-ments and Timelines

Compare incidents/adr reporting requirements across countries and regions

Comparison Tables

1.Compare data

2.Apply Filters

3.Scroll to the right to reveal more data

4.Link to official documents and Regulatory Summaries

Last Updated Date
11-Apr-2024

Global Comparison

Apply Filters

Country/Region	Requirements for submission of post-marketing periodic reports to CAs	Format/standards applicable to post-marketing periodic reports to CAs	Timelines/frequencies for submission of post-marketing periodic reports to CAs	Submission method for post-marketing periodic reports to CAs	Other requirements applicable to post-marketing periodic reports, if applicable	Regulatory Summary	Reference Document(s)
Algeria	For all medicinal products marketed in Algeria. Generics: PBRER not r	PBRER as described in Section 10-D of the Algerian PV Guidelines	Within 90 calendar days from the data lock point. PBRERs submission a	Electronic copy on a CD/DVD to: Centre National de Pharmacovigilance	Post autorisation safety study (PASS) might be requested by CNPM. En	Pharmacovigilance and Risk Management	Algerian Guidelines on Pharmacovigilance, Mar-2020
Argentina	All medicinal products marketed	Local format ICH E2C and E2C(R2) are accepted	DLP n regula during	Electronic: depto.snfvg@anmat.gob.ar OR Paper: ANMAT Av. de Mayo 869,	Not applicable	Pharmacovigilance and Risk Management	Disposition 5358/2012: Approves the Good Pharmacovigilance
Australia	Only required for medicines for which conditions have been	ICH E2C	Annua years after t	Submit electronic file to the Pharmacovigilance and Special Access Br	Not applicable	Pharmacovigilance and Risk Management	Guideline: Pharmacovigilance Responsibilities of
Austria	In compliance with EU	In compliance with EU	In cor	In compliance with EU	Not applicable	Pharmacovigilance and Risk Management	Law 153/2005: Amending the Austrian Drug Law, the Law on Prescription Obligation, the

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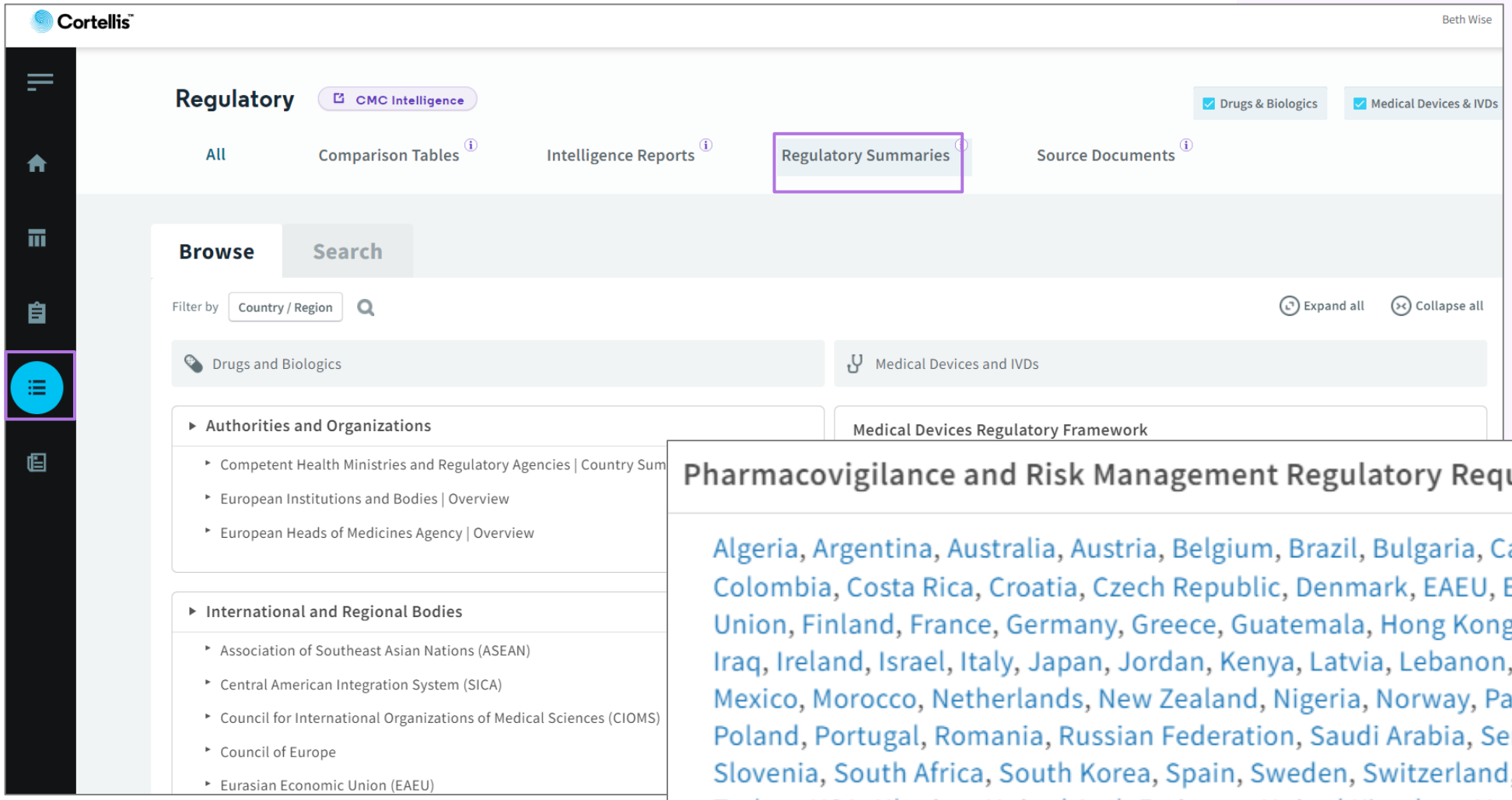
Dive Deep into PV requirements for a single country

Regulatory Summaries



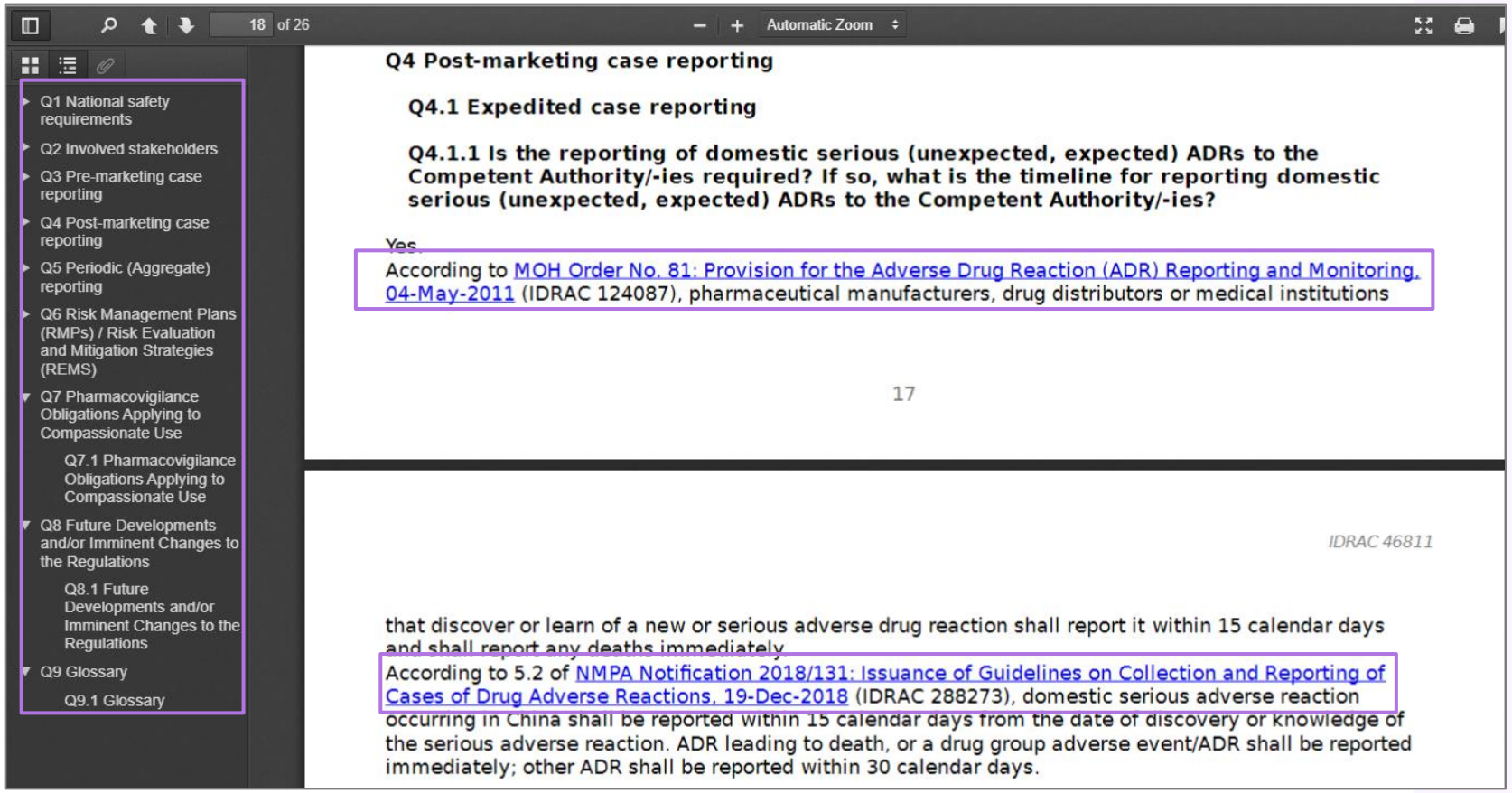
1.Click Regulatory Summaries

2.Scroll down to Pharmacovigilance and Risk Management Regulatory Requirements

3.Click China

Dive Deep into PV requirements for a single country

Regulatory Summaries

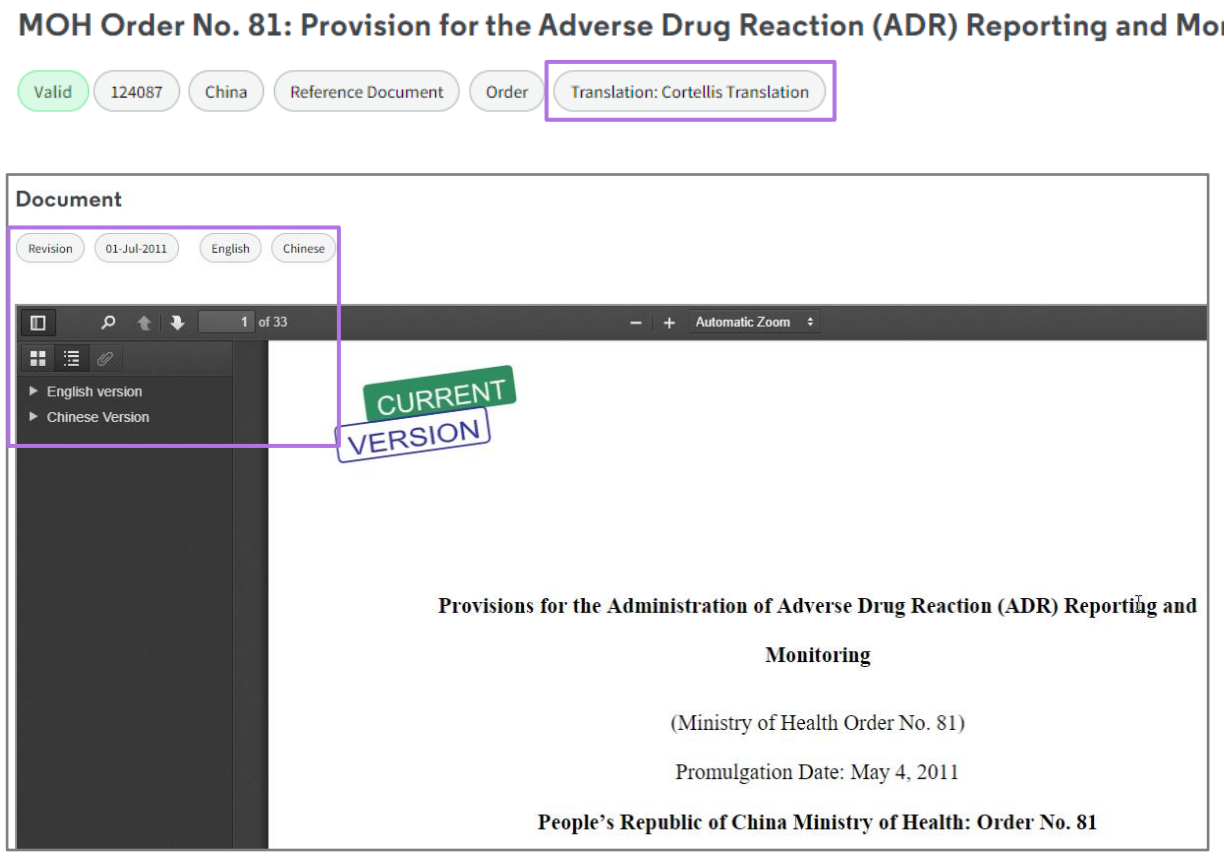


1.Consistent Q&A format across all countries/regions provides expert guidance

2.Link to official documents

Consult English translations – Cortellis translation

Source Documents



1. All non-English official local documents (valid versions) have an English translation:

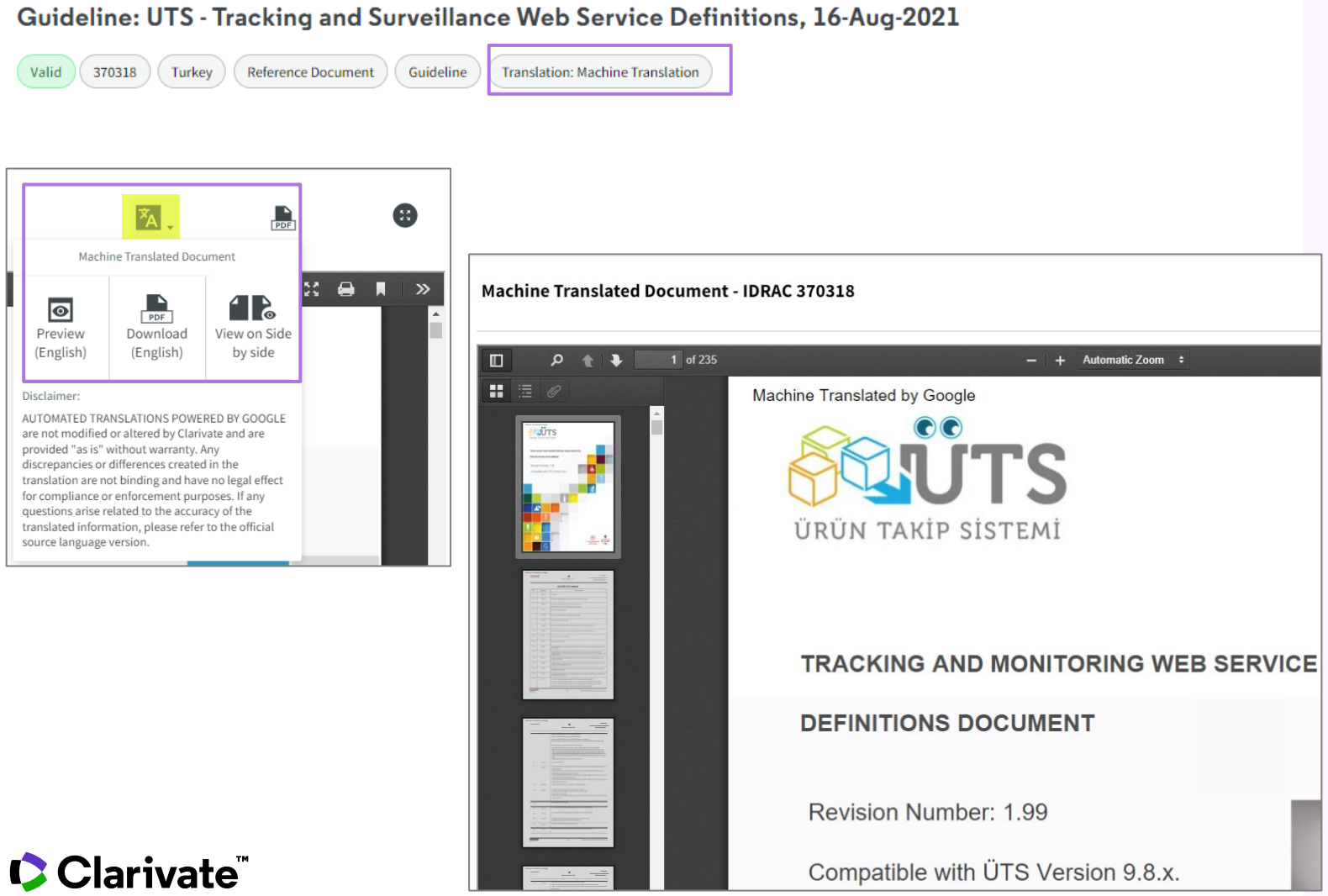
   -Either Machine translation
   -or Cortellis translation
   -or Authority translation (official or unofficial)

2. You can easily identify the type of translation with the label below the document title.

3. Cortellis and Authority translations are provided at the top of the pdf documents, local version(s) underneath.

Consult English translations – Machine translation

Source Documents



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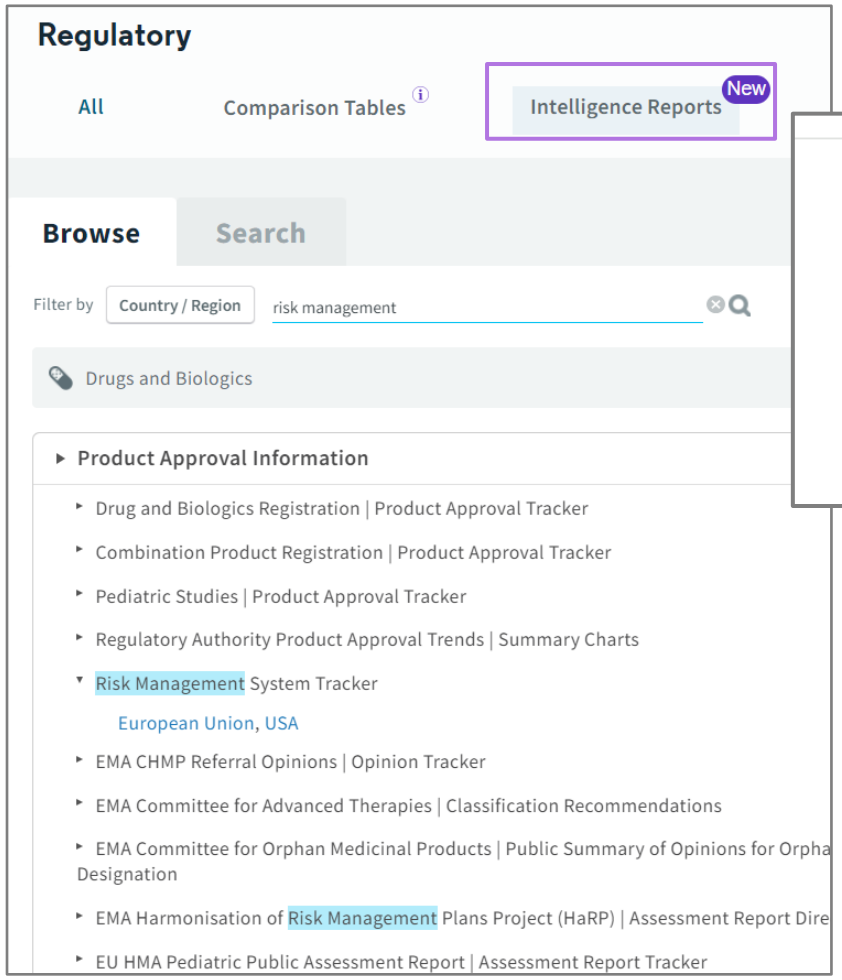
   -Either Machine translation
   -or Cortellis translation
   -or Authority translation (official or unofficial)

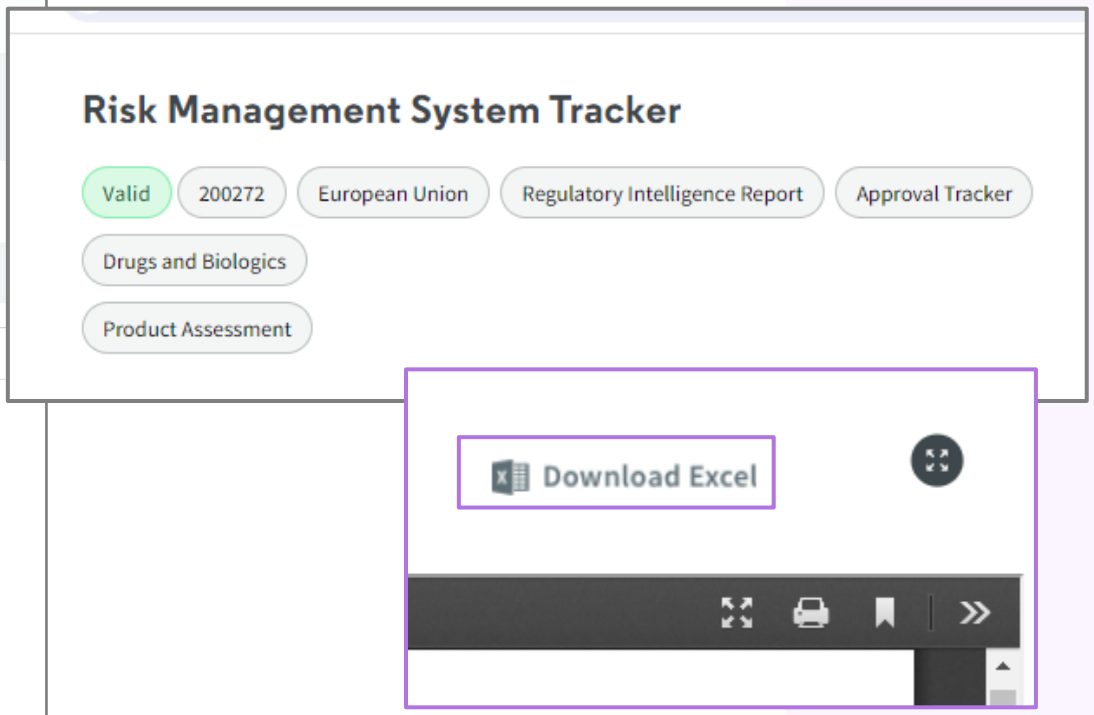
2. You can easily identify the type of translation with the label below the document title.

3. Machine translations have an extra button above the local version pdf to open or download the machine translation.

Track Risk Management Plans of products in the EU and US

Intelligence Reports





1.Click Intelligence Reports

2.Scroll down to Product Approval Information and click on Risk Management System Tracker

Alternatively enter risk management in the search field at the top (next to country/region filter)

3.Click European Union or USA

4.In the Tracker click Download Excel

Track Risk Management Plans of products in the EU and US

Intelligence Reports (Excel spreadsheet – European Union)

	A	B	C	D	E	F
1	Link to Product Approval Docume	Active Ingredient(s	Name	Application Number	Dosage Form	Route of Administration
2	382718	ramucirumab	CYRAMZA	EMEA/H/C/002829 Rev. 17	Solution	Intravenous
3	382717	tilmanocept	LYMPHOSEEK	EMEA/H/C/002085 Rev. 8	Kit for radiopharmaceutical preparation	Intradermal ; Intratumoral ; Peritumoral ; Subcutaneous
4	382716	abiraterone acetate	ABIRATERONE ACCORD	EMEA/H/C/005408 Rev. 2	Tablet	Oral
5	382715	tislelizumab	TEVIMBRA	EMEA/H/C/005919 Rev. 2	Solution	Intravenous
6	382662	hydrochlorothiazide ; telmisartan	KINZALKOMB	EMEA/H/C/000415 Rev. 40	Tablet	Oral
	382661	bevacizumab	ALYMSYS	EMEA/H/C/005286 Rev. 8	Solution	Intravenous

1.Explore the product and risk management related data in the spreadsheet

2.Filter columns as desired

3.Link out to connected product approval documents and PRAC meetings

	Q	R	S	T	U	
	Reason(s) on list of additional monitoring (	PRAC meeting	Identified Risk	Potential Risk	Risk Missing Information	RMiM
	Not applicable	356344	- Arterial thromboembolic events - Gastrointestinal perforation - Serious haemorrhagic events - Liver failure/liver injury (including hepatic encephalopathy in patients with HCC)	- Serious infection secondary to neutropenia - Posterior reversible encephalopathy syndrome - Severe clinical outcomes of venous thromboembolic events - Reproductive and developmental toxicity	Not Applicable	No
	Not applicable	377391	None	Failure to detect the sentinel lymph node due to medication errors	Use in Patients receiving more than one dose	No
	Not applicable	318661	None	None	None	No
	New active substance ; New biological	370415	Immune-mediated adverse reactions	Reproductive and developmental toxicity	None	Yes
	Not applicable	377391	Not Applicable	Not Applicable	Not Applicable	No
	New biological	353479	None	None	None	No

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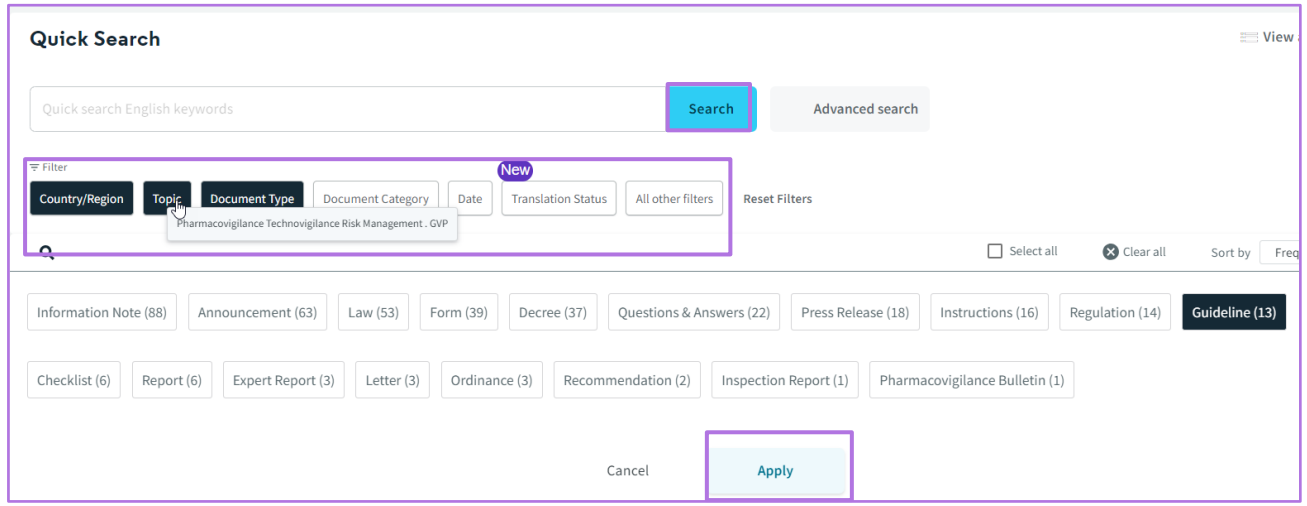
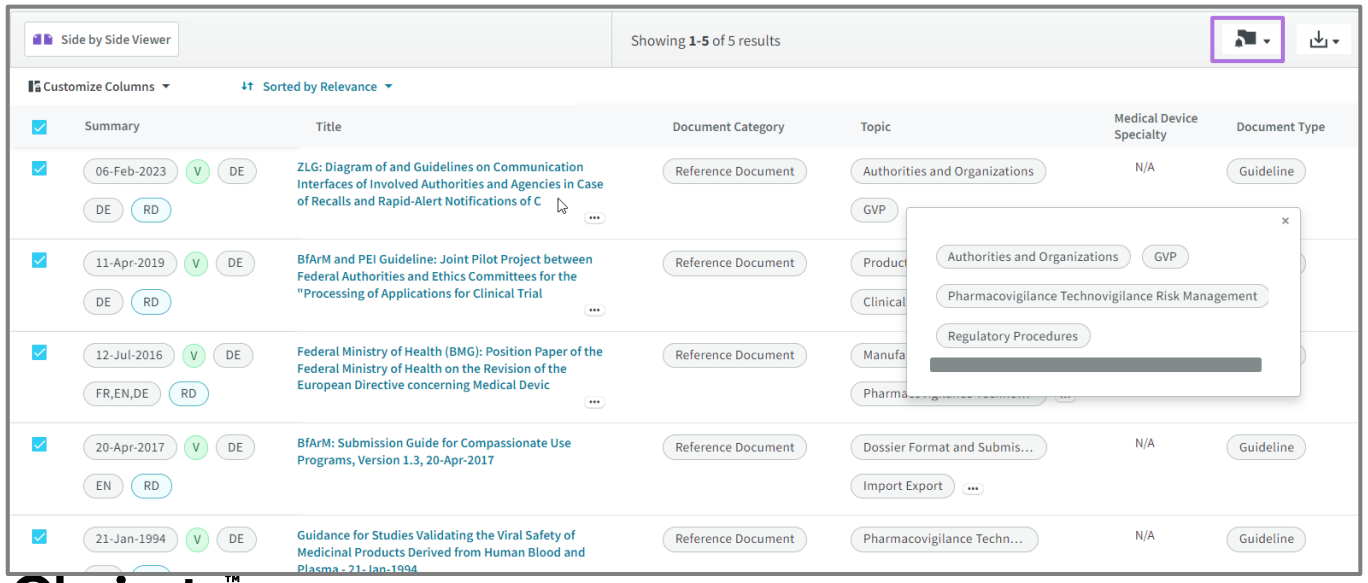
Identifying and monitoring official documents

Using Quick Search* and setting up Alerts

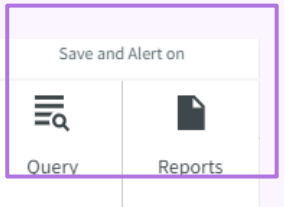


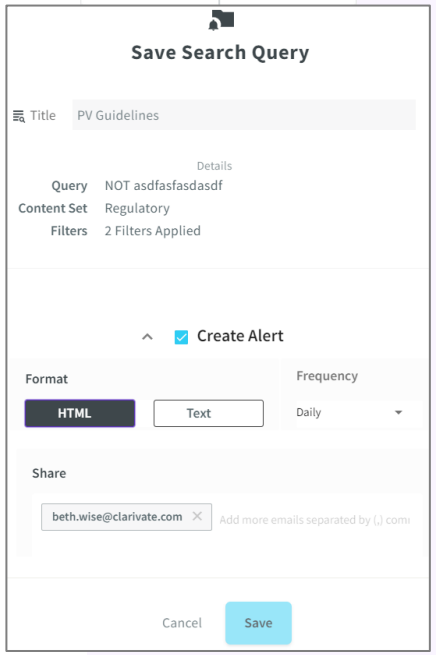


1.Run search by selecting terms (country, topic, document types etc.) from filters as desired. Click Apply after selecting a filter.

2.Click Search

*Quick Search supports English keywords only
•Searches through all Cortellis regulatory documents (including Regulatory Summaries and Intelligence Reports)
•Searches the title, abstract, reason for update and indexing fields (all provided in English)



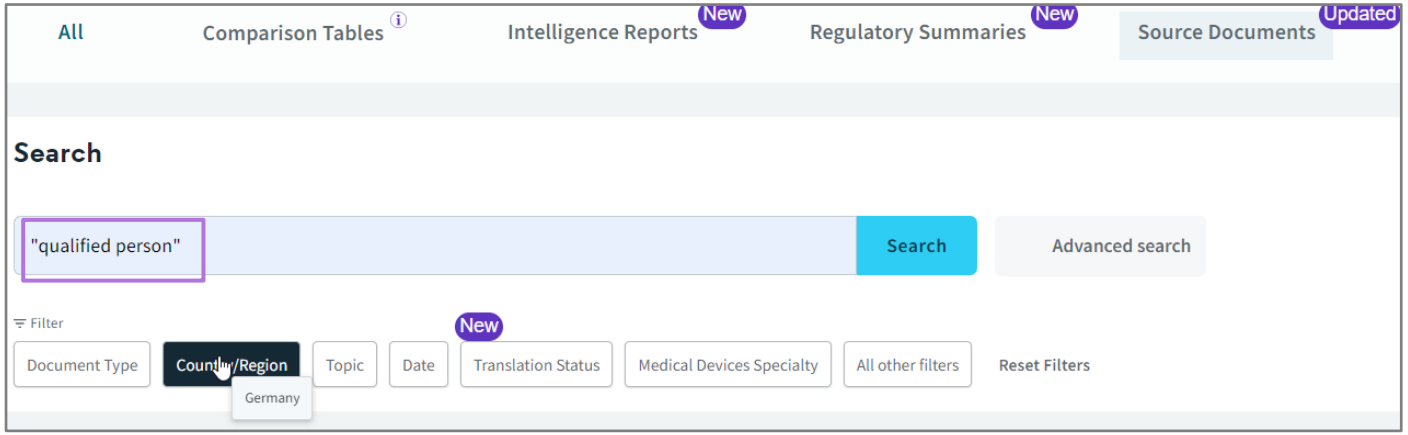


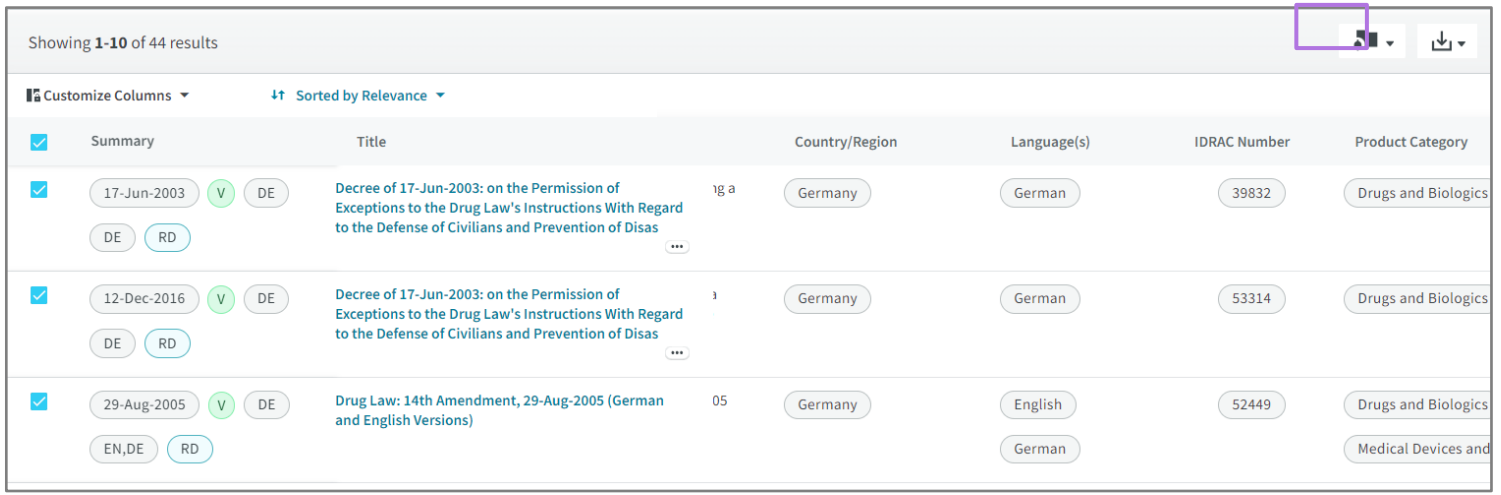
3.To set up Alerts click the Alert icon and select

4.Follow the prompts in Alert pop-up as it and click Save

Identifying and monitoring official documents

Using Source Documents Search* and setting up Alerts

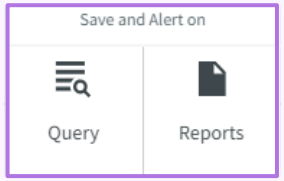


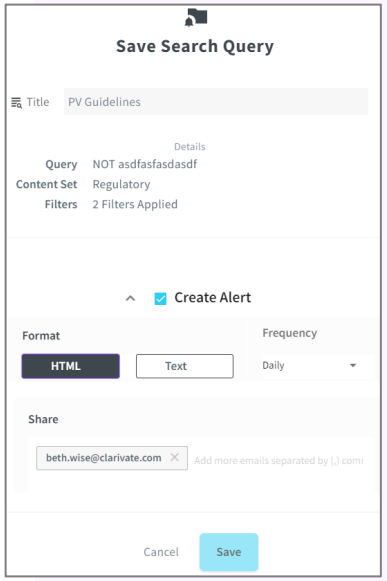


1. Enter your search term(s)
2. Add filters as desired
3. Click Search

*Source Documents Search supports English and local language keywords

- Searches localsource/reference documents only
- Searches entire documents including pdf full text („Search in any language anywhere")

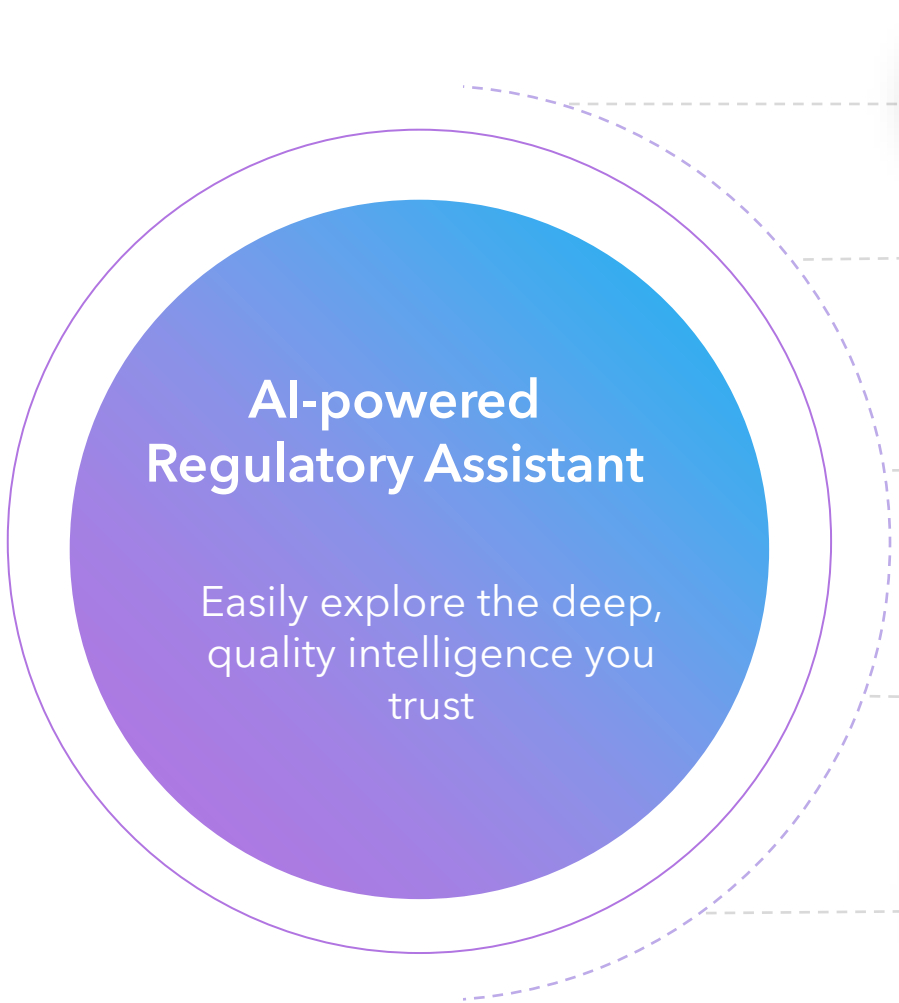




3. To set up Alerts click the Alert icon and select Query
4. Follow the prompts in the Alert pop-up as it appears and click Save

Coming soon:
Cortellis AI Regulatory Assistant

An AI assistant to simplify your access to regulatory information



Search intuitively, using **natural language** to find what you need – **Q2 2025 (Beta)**

Enriched experience with **narrated answers** – **Q2 2025 (Beta)**

References and links to relevant sections to facilitate further explorations - **Q2&Q3 2025**

Powered by Clarivate AI platform

User-driven transformation through our **Collaborative Partners Program**

Release dates are estimates only. Clarivate reserves the right to change its product plans or roadmap based on business priorities and market conditions.

A transformative AI partner you can trust

Proven and trusted AI rolled out across Clarivate industry-leading solutions (including Web of Science), used by:

- 3,050+ institutions and life sciences companies
- 1.85M+ queries submitted

“We particularly appreciated the obvious care, time and caution in which Clarivate went about developing its AI products.”

The Information Advisors Guide to Internet Research, Vol. 36, 2024

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Regulatory AI assistant to simplify your access to regulatory information

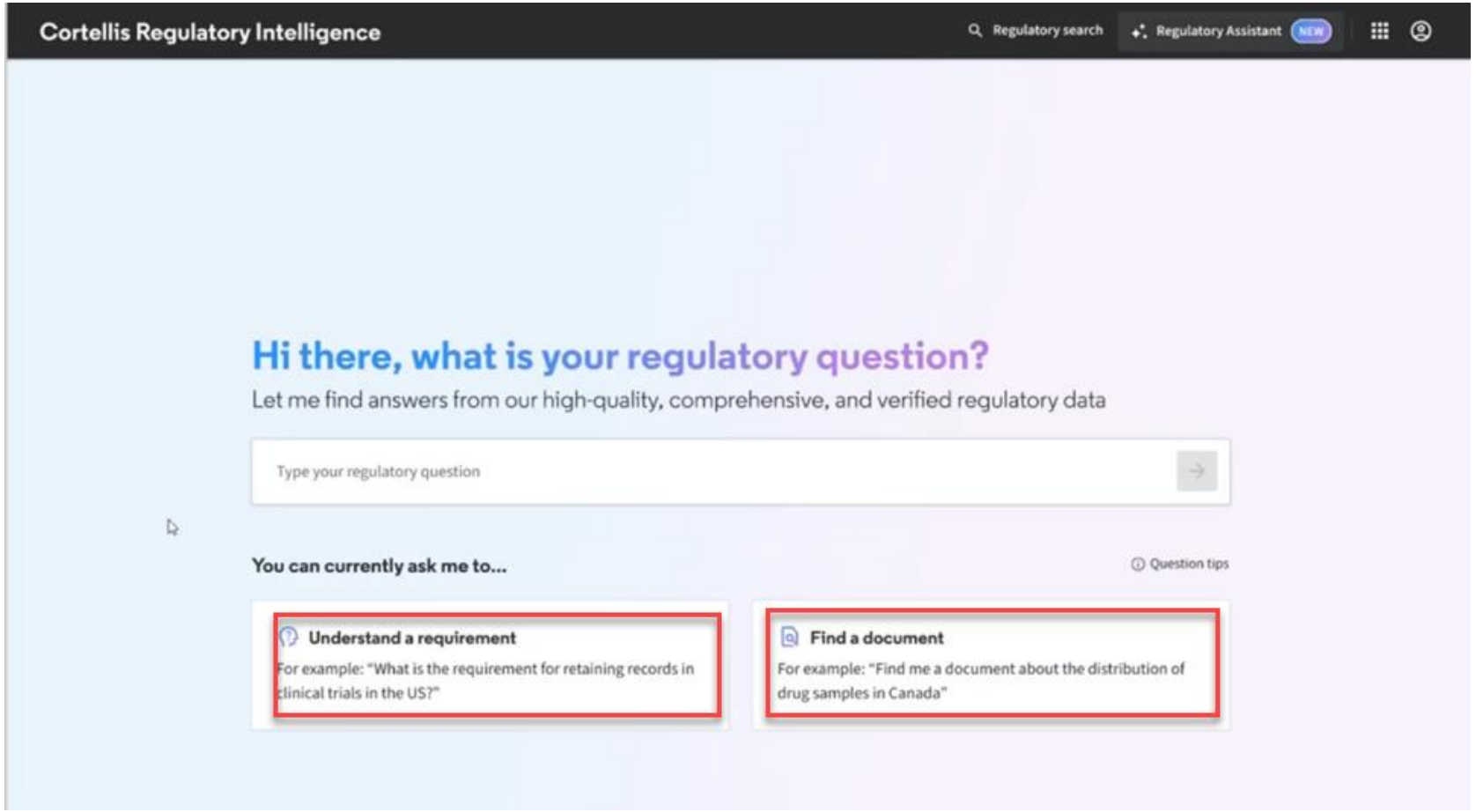
Two use cases available at launch Sept 2025:

Understand a requirement

"What is the requirement for retaining records in clinical trials in the US?"

Find a document

"Find me a document about the distribution of drug samples in Canada"



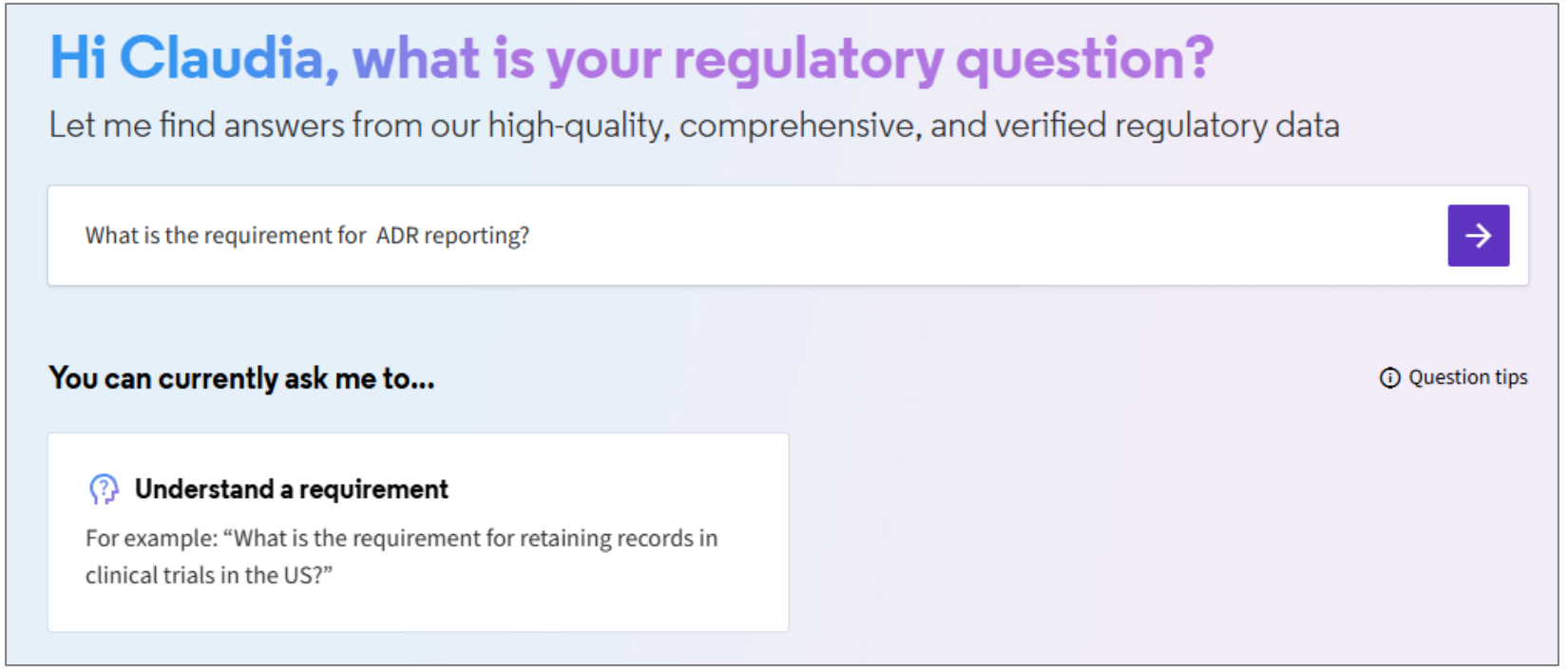
Disclaimer: conceptual mock-ups for illustrative purposes only; final designs and functionality subject to change

Regulatory AI assistant to simplify your access to regulatory information

Beta test example

Understand a requirement:

What is the requirement for ADR Reporting (in Mexico)?



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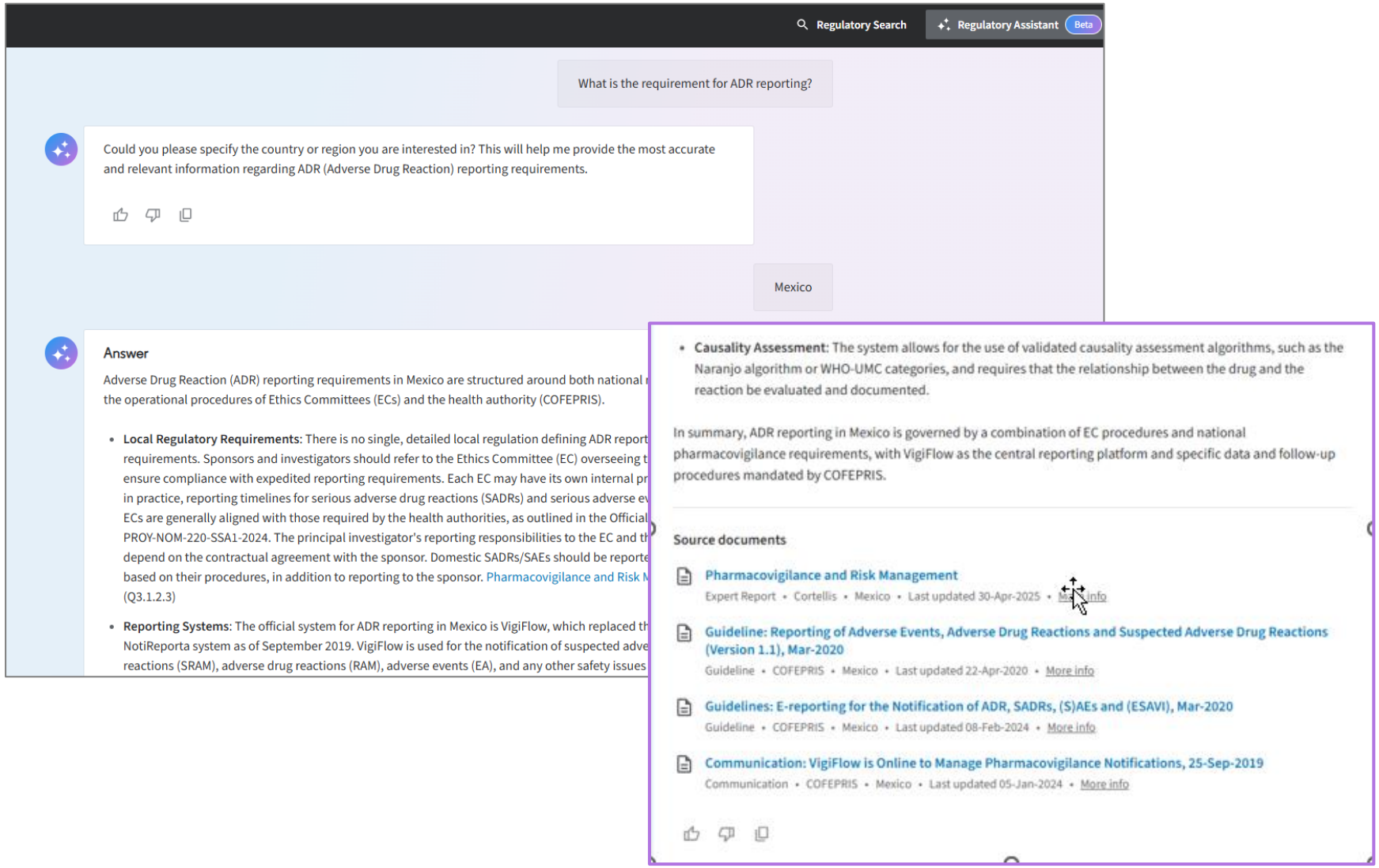
Regulatory AI assistant to simplify your access to regulatory information

- Answers provided in text format
- Includes inks to Source Documents
- Feedback rating – thumbs up or down or add more detail via free text



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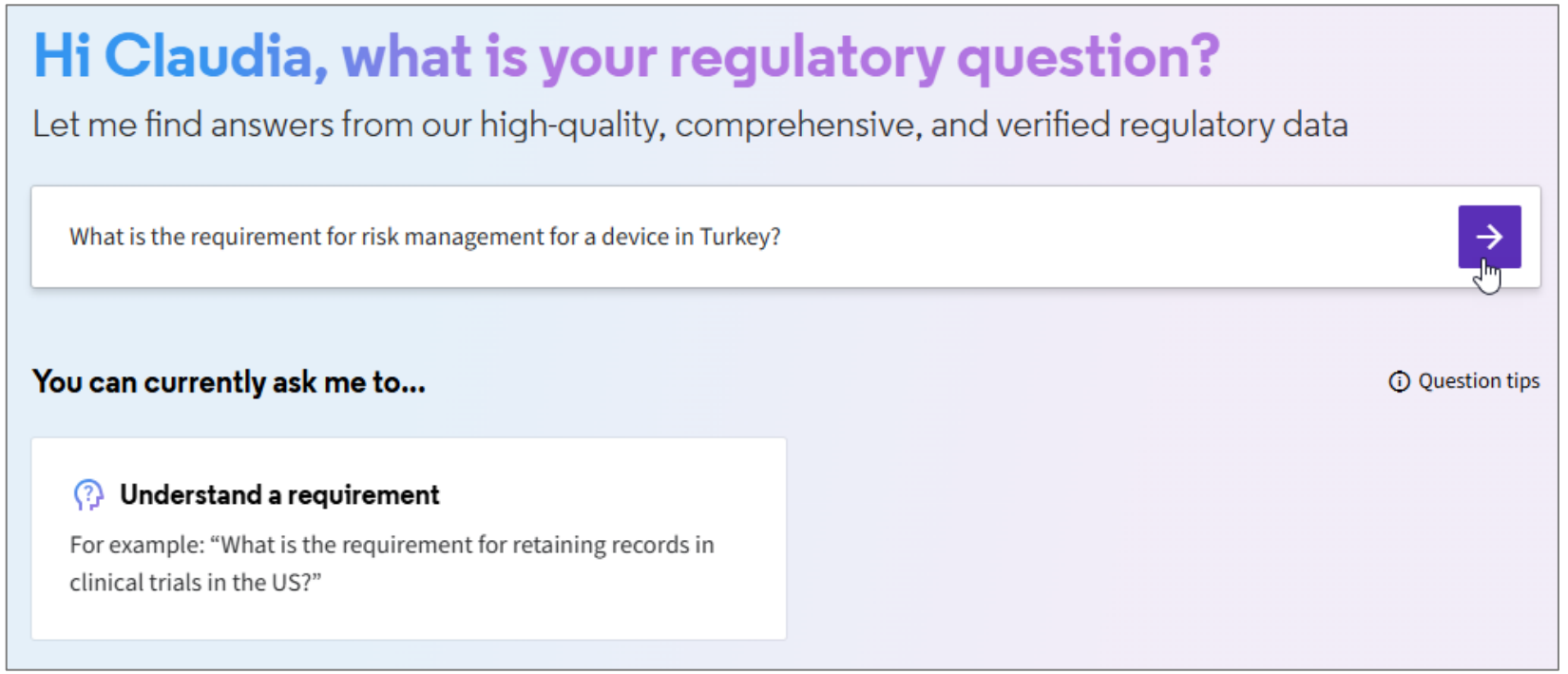
Regulatory AI assistant to simplify your access to regulatory information

Beta test example

Understand a requirement:

What is the requirement for risk management for a device in Turkey?



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Regulatory AI assistant to simplify your access to regulatory information

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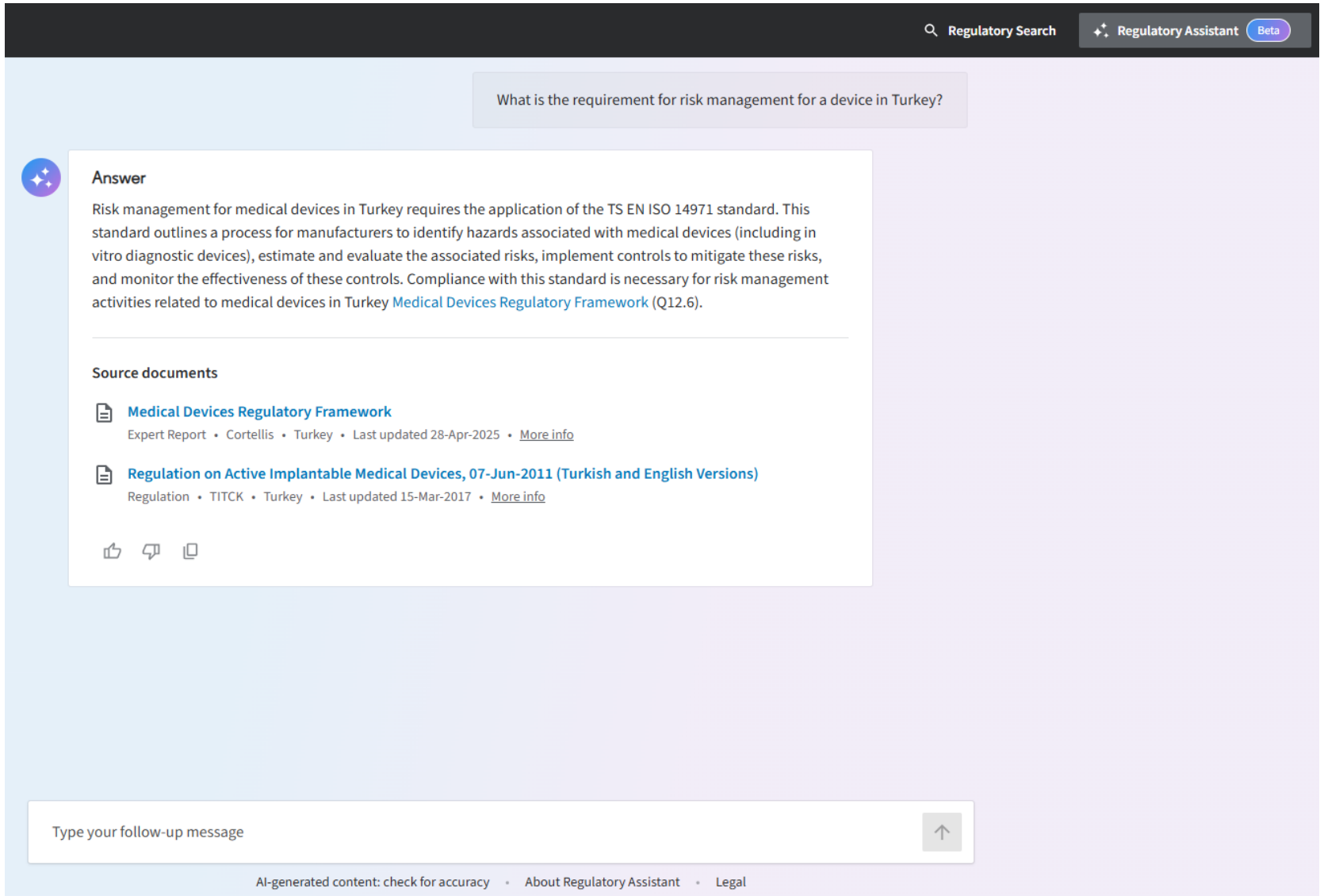

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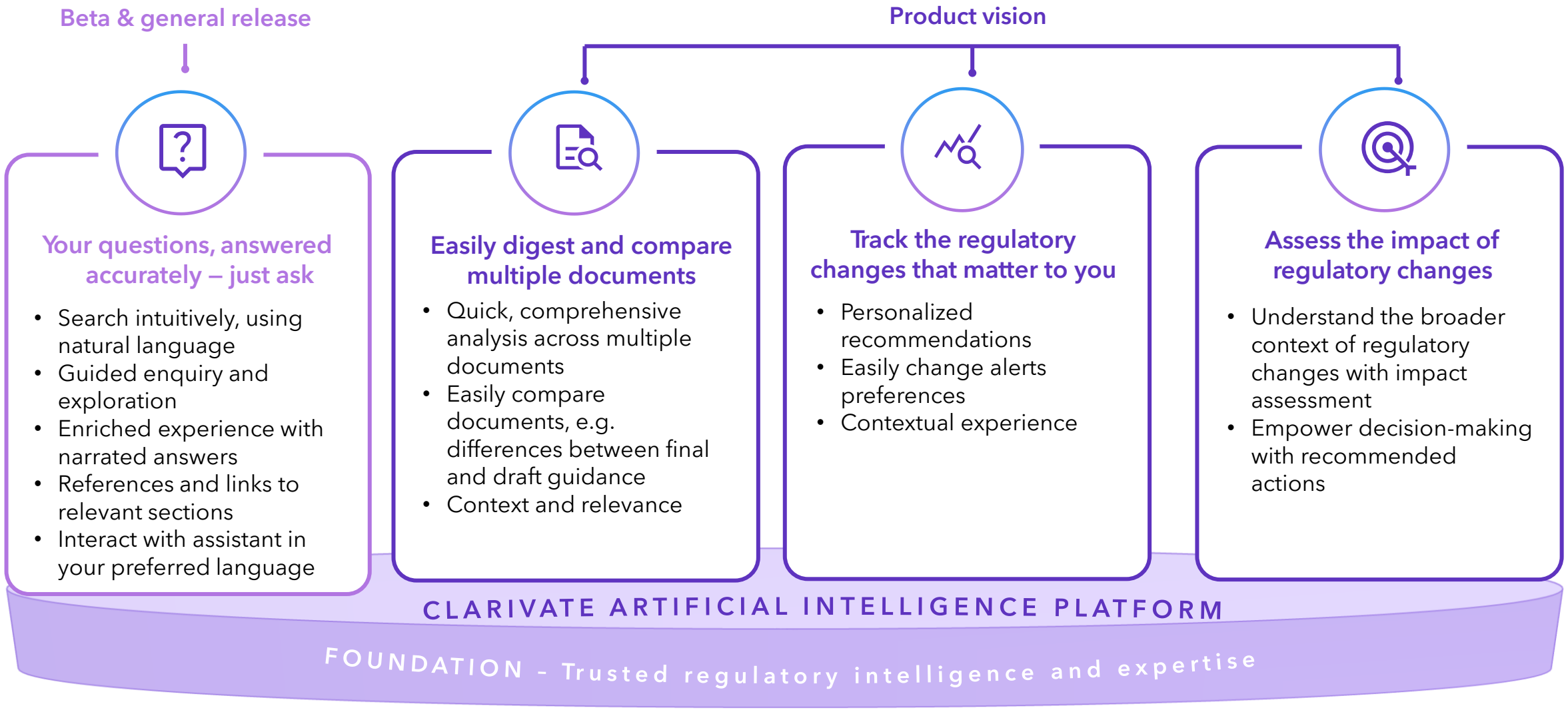
Vision and roadmap

Harnessing generative AI to fuel your regulatory strategy and compliance



Release dates are estimates only. Clarivate reserves the right to change its product plans or roadmap based on business priorities and market conditions.

How does the Regulatory Assistant work?

Understand user intent & context

↓

Plan path to execution

↓

Collect data from sources

↓

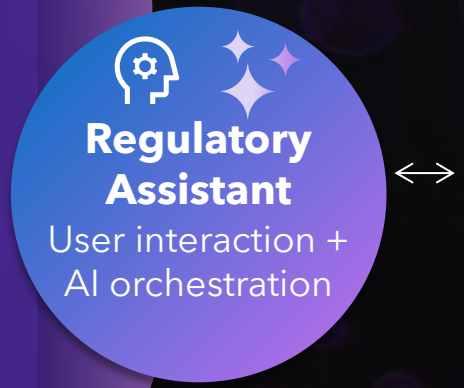
Execute

↓

Validate & enhance outputs

↓

Iterate & refine



Trusted Cortellis human curated content & original sources

Clarivate expert regulatory knowledge

Clarivate AI platform expertise

Fast, accurate and hassle-free:

- Full conversational experience
- Smooth entry point to Cortellis Regulatory Intelligence
- Search support for non-frequent users
- Ability to answer questions based on trusted sources – and refer back to them

Wrap-Up and Feedback

What did you learn about today that will have a great impact on your work?

- Compare pre- and post-marketing PV and Med Dev incidence reporting requirements across multiple countries.
- Monitor Risk Management Plans for products in the European Union and the United States.
- The new AI Regulatory Assistant once launched.

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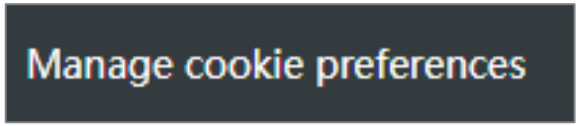
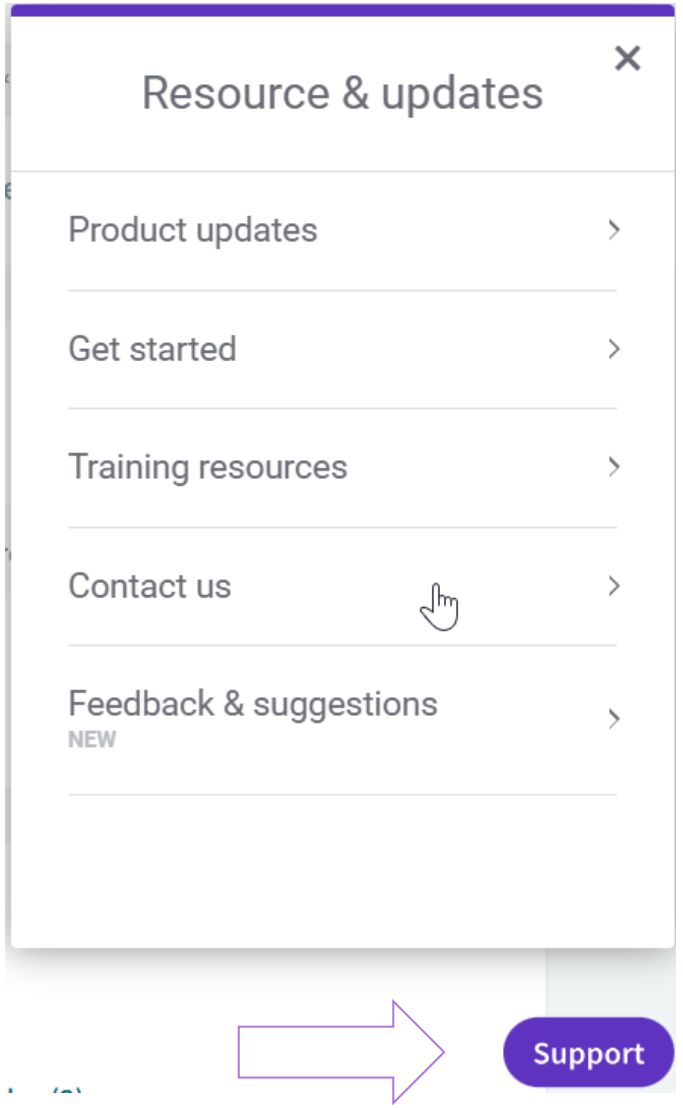
Get assistance with Cortellis

In-product guidance to assist you with your questions

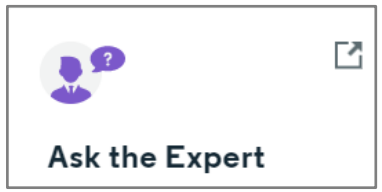
- Click at the Support Center button at the bottom of the screen

If not visible, please enable functional cookies under "Manage cookie preferences".





- Help & contact us – contact Customer Care
- Guided tours – walk through the Cortellis platform
- Training resources – recorded trainings, Quick guides and short videos
- Ask the Expert (on Regulatory homepage)



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About Clarivate

Clarivate is the leading global information services provider. We connect people and organizations to intelligence they can trust to transform their perspective, their work and our world. Our subscription and technology-based solutions are coupled with deep domain expertise and cover the areas of Academia & Government, Life Sciences & Healthcare and Intellectual Property. For more information, please visit clarivate.com