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What's new in Cortellis Regulatory Intelligence
Claudia Haas & Beth Wise | February 2024

Quick quiz

- **What types of English translations does Cortellis Regulatory Intelligence provide?**
  - Machine translations
  - Cortellis translations
  - Authority translations

- **TRUE or FALSE: You can search across all source documents including the pdf full text using local language.**

- **Does Cortellis provide structured Summaries that help you bring Advanced Therapy Products (ATMPs) into more markets?**

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Quick quiz - answers

- **What types of English translations does Cortellis Regulatory Intelligence provide?**
  - Machine translations
  - Cortellis translations
  - Authority translations
  - All of the above

- **TRUE or FALSE: You can search across all source documents including the pdf full text using local language.**
  - TRUE: The upgraded Source Document Search enables you to search the pdf full text using keywords in English or foreign language.

- **Does Cortellis provide structured Summaries that help you bring Advanced Therapy Products (ATMPs) into more markets?**
  - Yes. “How to market ATMPs” Regulatory Summary expanded to 72 territories with new question structure providing more insights.

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Agenda

- Cortellis Regulatory Intelligence enhancements
- Live demo
- 2024 Outlook
- Feedback, Wrap-up and 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

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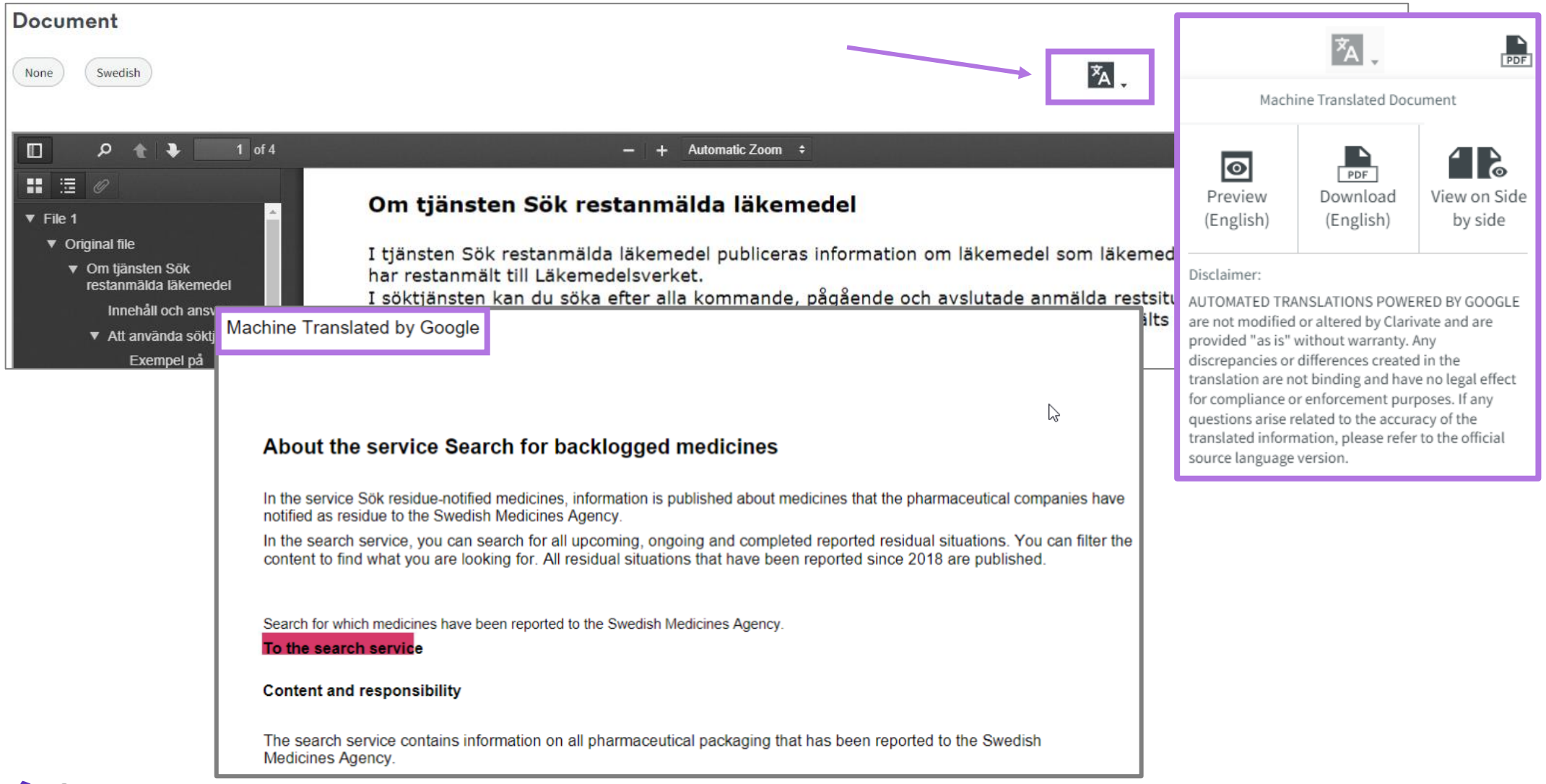
What's New

NEW: English Machine translations

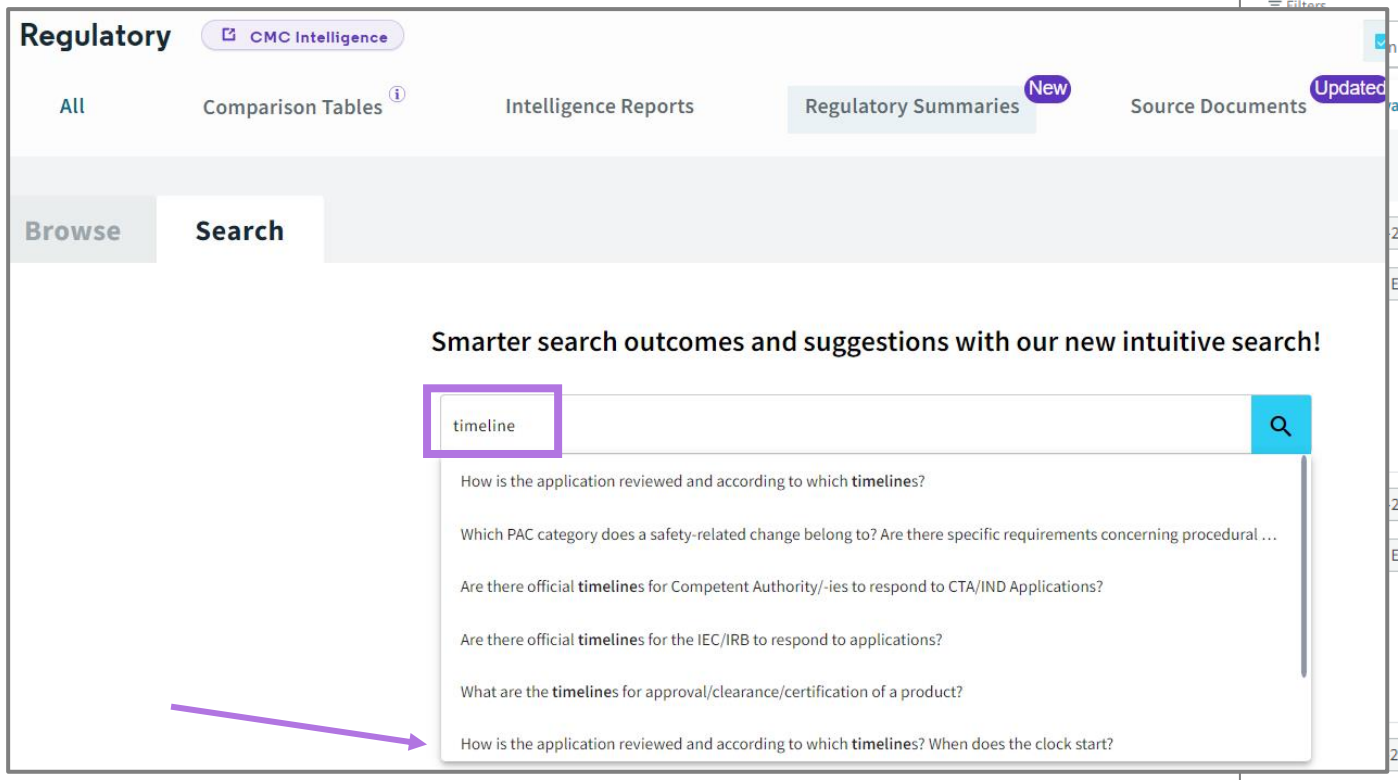
Easily access, search and download documents machine translated by Google*

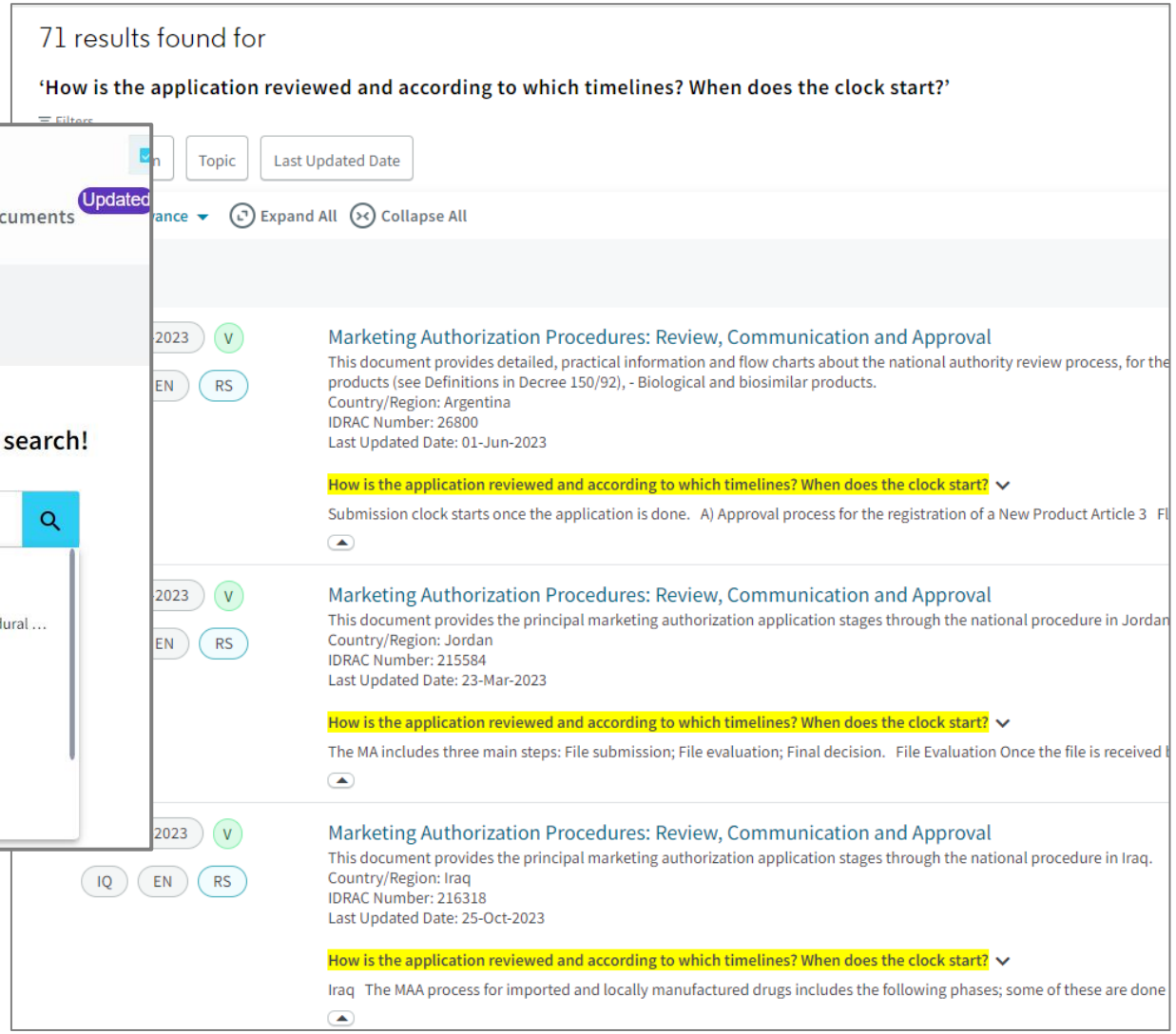


*added to all regulatory valid status documents in Cortellis without a human translation

NEW: Intuitive Search for Regulatory Summaries and Intelligence Reports

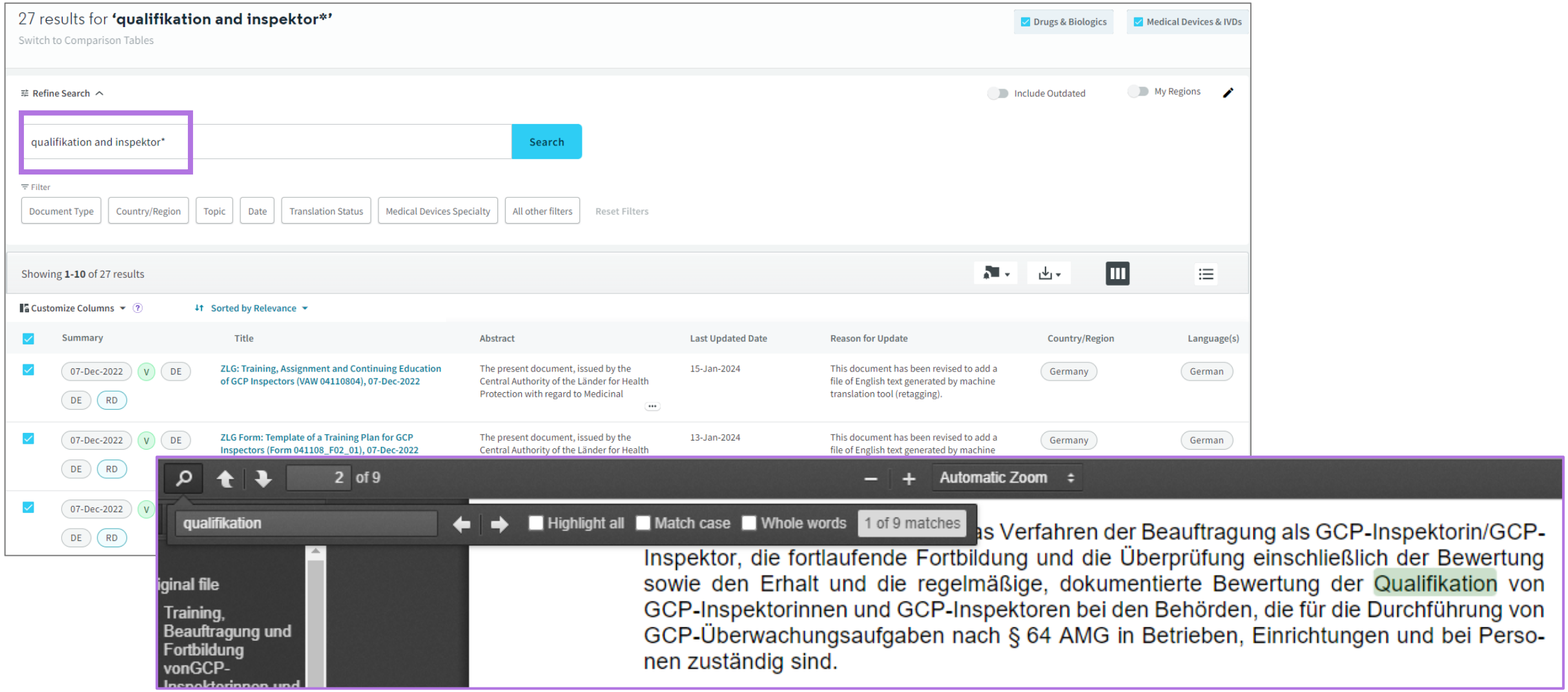
Get better results with autosuggestions and easily compare across countries





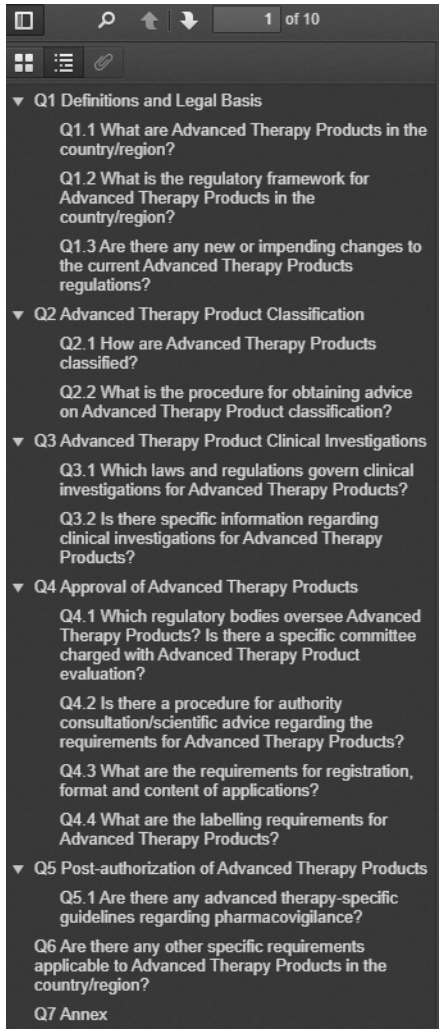
UPGRADED: Source Document Search

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



EXPANDED: How to market Advanced Therapy Medicinal Products (ATMPs)*

Regulatory Summaries 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).

*depending on your company's subscription

2024 Cortellis Regulatory Intelligence outlook

	2023 highlights	H1 2024	H2 2024	*Future*
Connected Data & Insights	**Enhanced Search** • Intuitively surface deeper insights from complex data **Content Expansion** • New European Public Assessment Reports (EPARs) data expansion streamlines your research process and make more informed decisions	**Machine Translations** • Top requested feature, expediting translations of non-English language content **New Weekly Updates** • New version with more user-friendly layout **Content Expansion** • Expand *RS: How to market Advanced Therapy Medicinal Products* to all available countries	**Cortellis Redesign** • Updating core components to improve performance, UeX and expedite future enhancements to the Cortellis platform	***Contextualized intelligence*** Continued investment in customer centric feature (such as highlighting changes), and content & country expansion
Advanced Analytics & GenAI	**FDA Analytics tools** • New data visualization to facilitate your preparation for FDA inspections or committee meetings for drugs & biologics	**FDA Analytics Tools *** • Content enhancements and new workflow to enable faster updates	**Gen AI Enhanced Search** • **Integrated** Drug Discovery, Regulatory and Drug Class Safety data	***Unlock value with more data Visualization & GenAI solutions*** • More in-depth analysis charts • Transform structured raw data to user friendly format • Continued investment in GenAI

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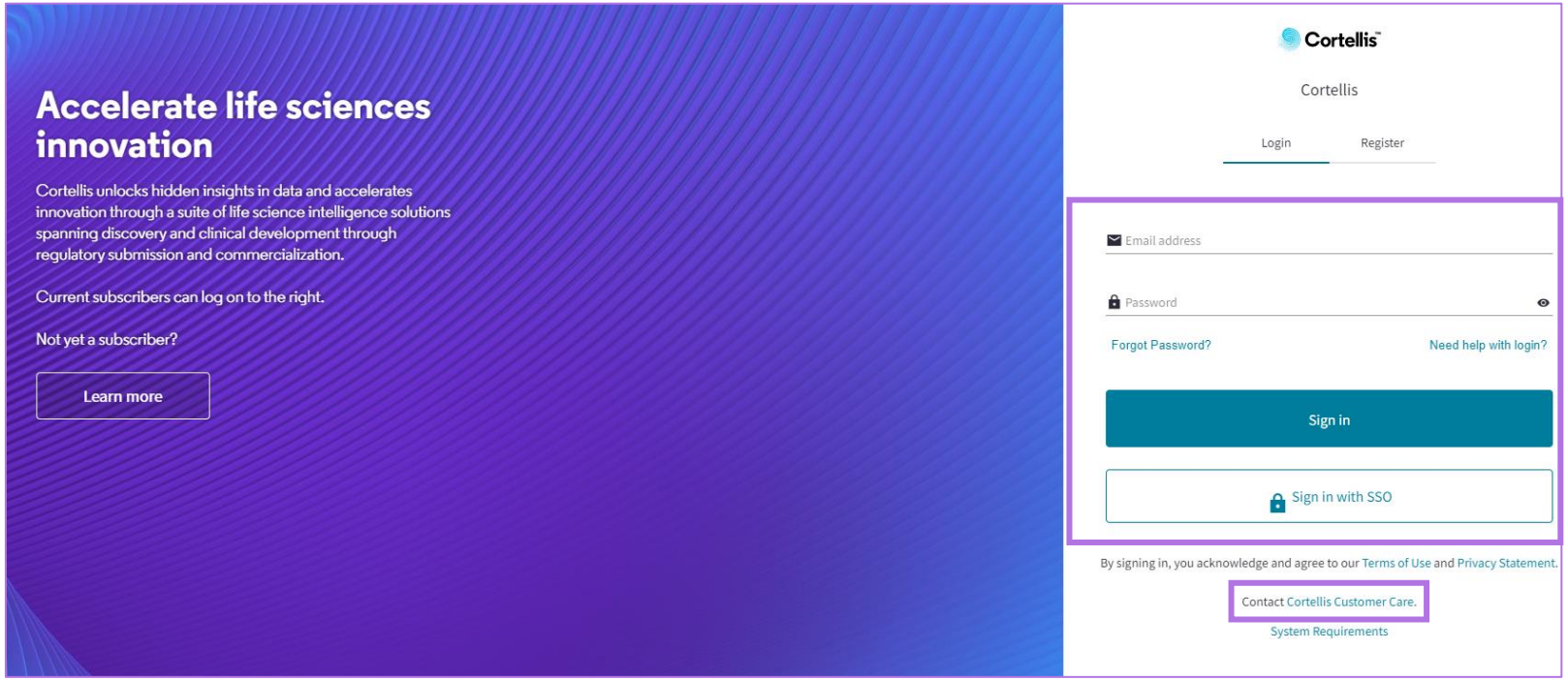
Release dates are estimates only. Clarivate reserves the right to change its product plans or roadmap based on business priorities and market conditions.

*Cortellis Regulatory Intelligence add-on modules

Handout

How do I access Cortellis?



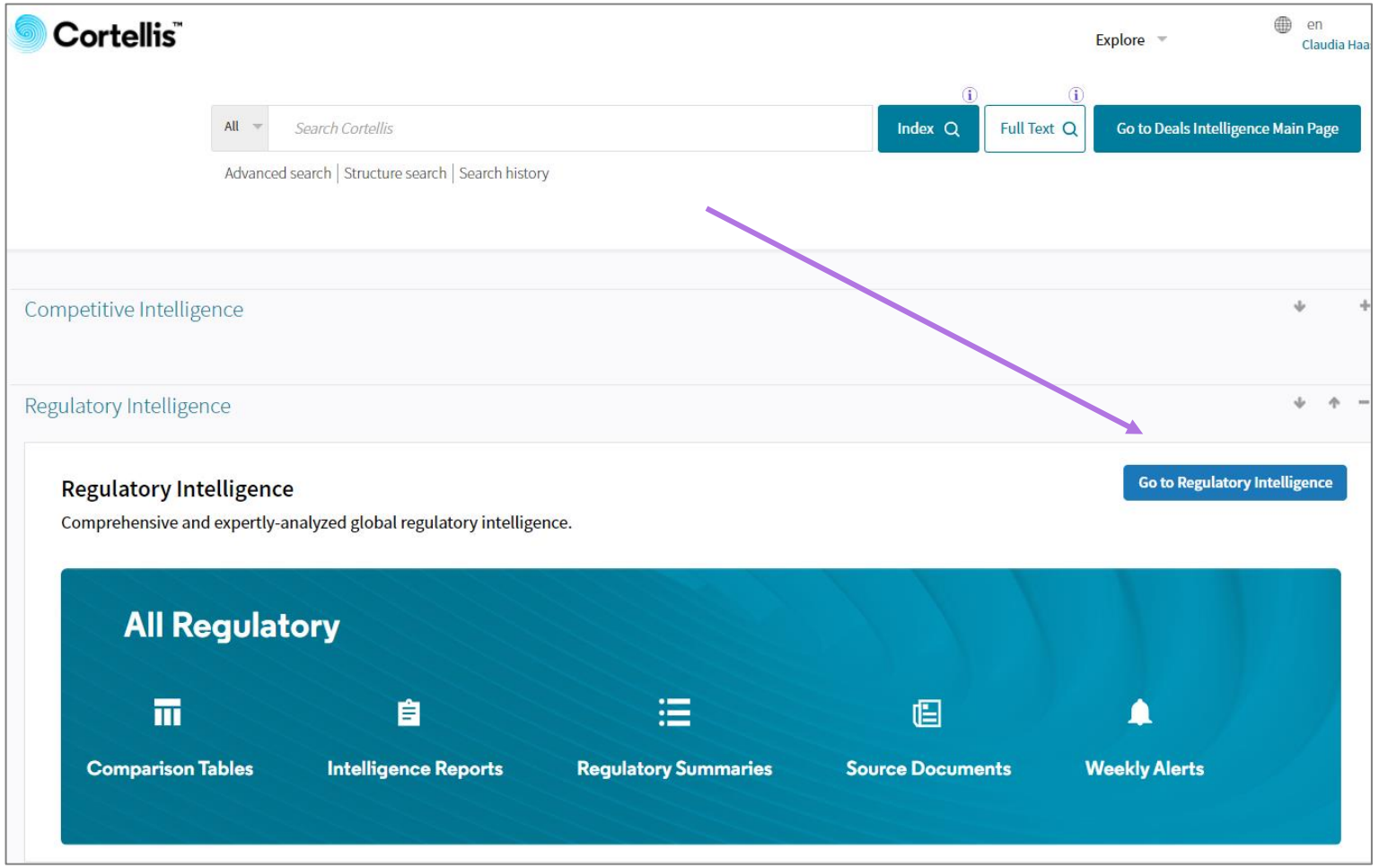
Go to this URL

Cortellis.com

- Username/password access: Enter your email address
- If you can't find the Clarivate email with your password, click Forgot Password to reset
- If you are a Single Sign On user, click the Sign in with SSO button and enter your company name
- Contact Customer Care from this link if you need help

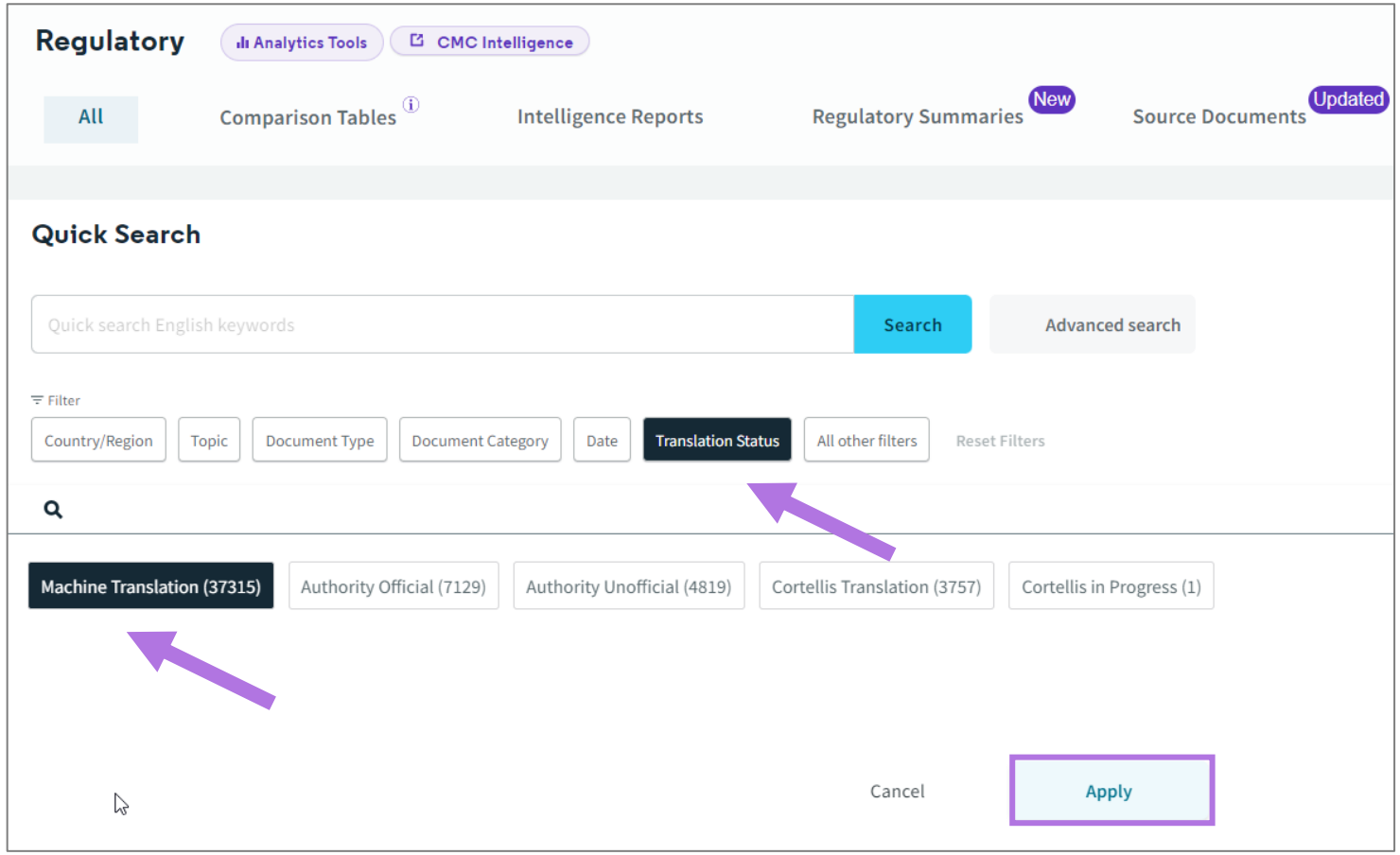
Cortellis Landing Page

If you subscribe to other Cortellis content, click the "**Go to**…" button to access Cortellis Regulatory Intelligence



Cortellis Regulatory Homepage: Quick Search

Easily find new English machine translations in Cortellis



1. Click the Translation Status filter

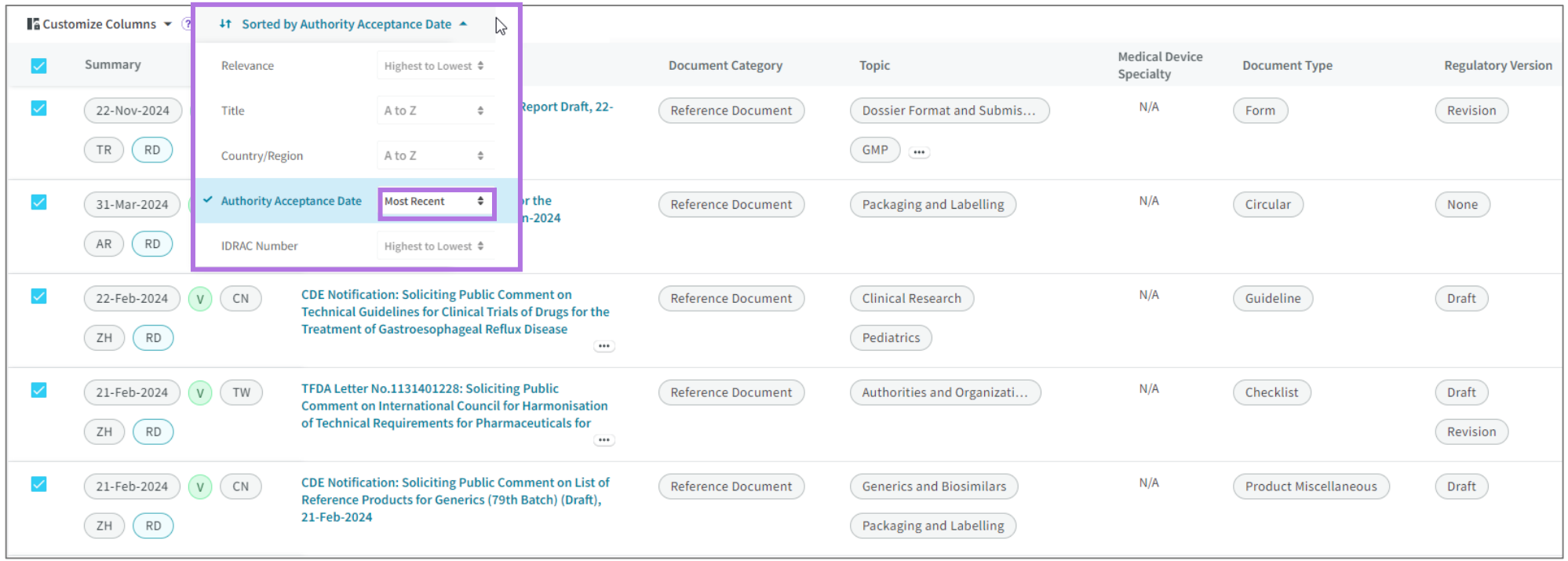
2. Select Machine Translation

3. Click Apply

4. Click the blue Search button

Cortellis results page

Easily find new English machine translations in Cortellis

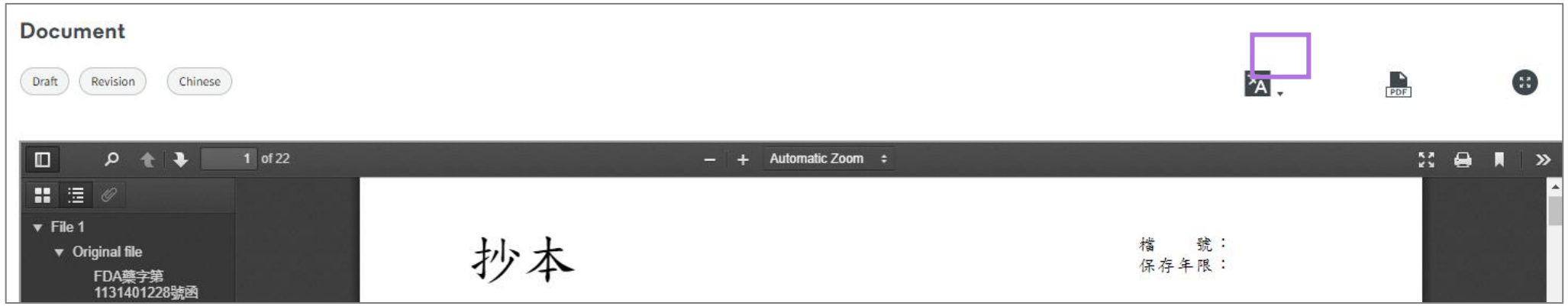


5. On the results page sort by acceptance date most recent
   - this brings the newest added documents to the top

6. Click the title to open a document of interest (e. g. a draft)

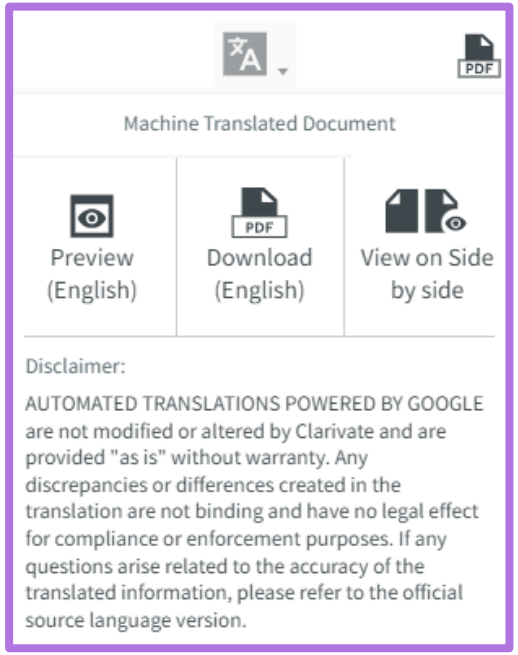
Cortellis document page

Easily find new English machine translations in Cortellis



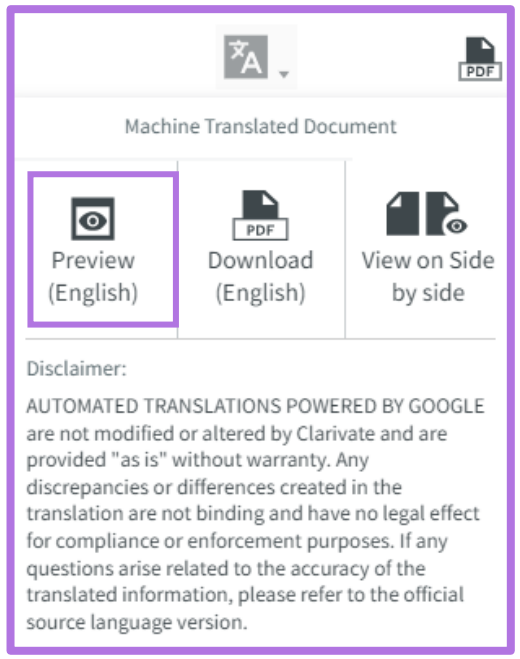
7. Click the new Machine Translation button

A pop-up appears giving you the options to view or download the machine translation or open it in the Side-by-Side viewer

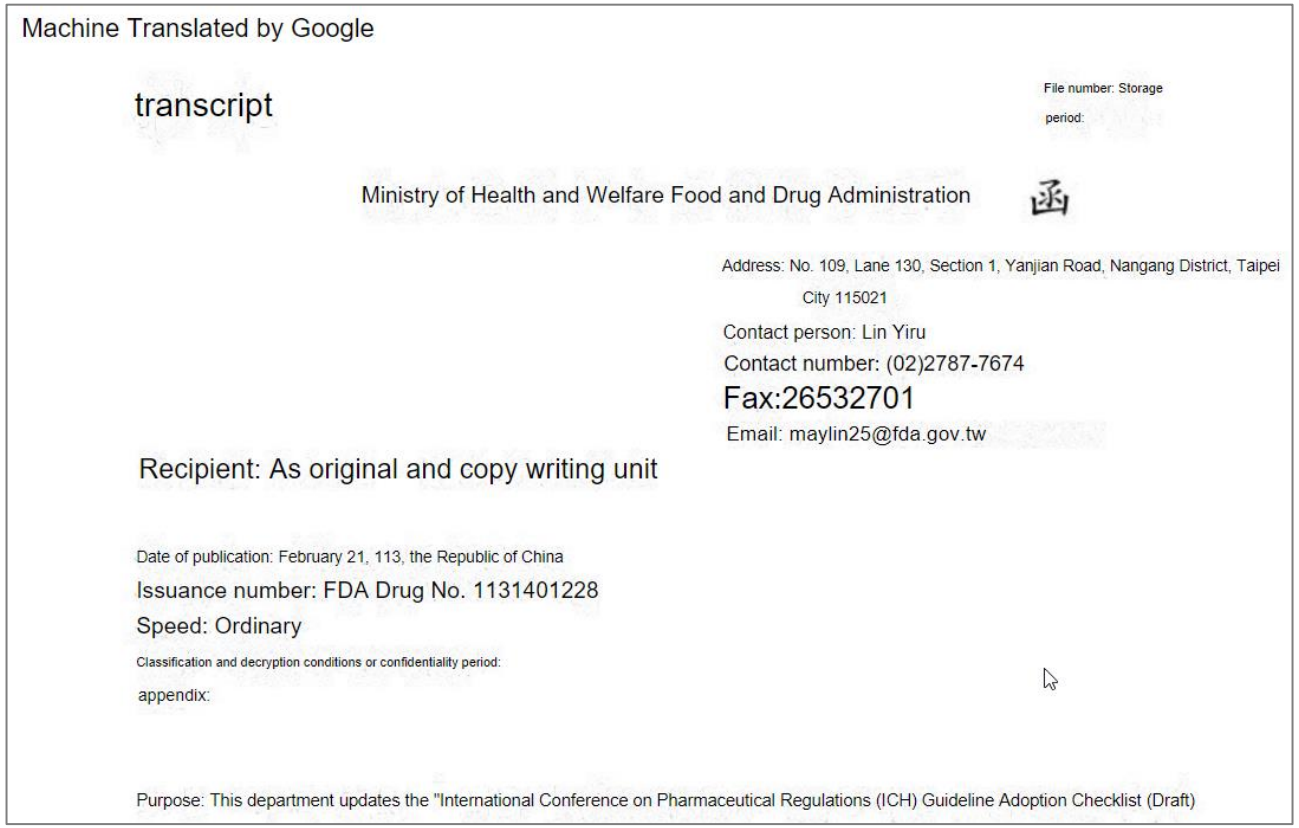


Cortellis document page

Easily find new English machine translations in Cortellis

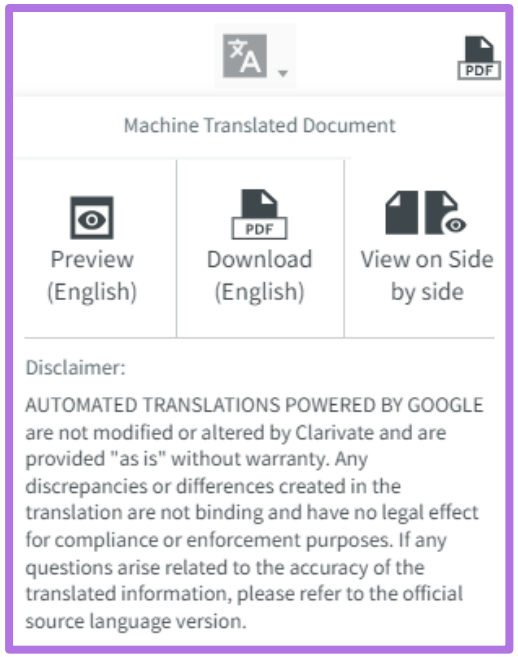


8. Click Preview to open the machine translation in its own pdf window



Cortellis document page

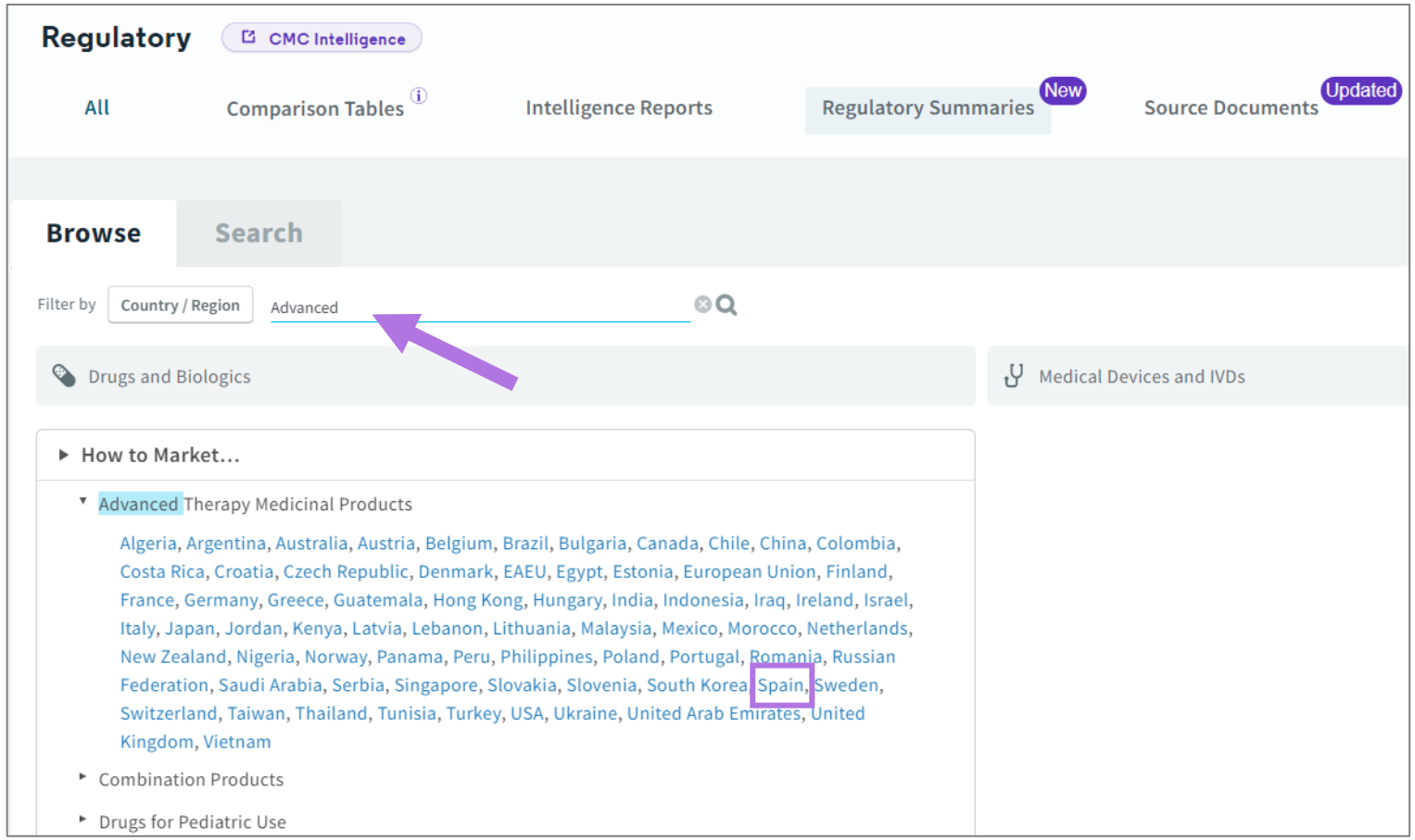
Easily find new English machine translations in Cortellis



9. Click View on Side by Side to open and compare the local version and the machine translation side by side

Cortellis Regulatory Summaries

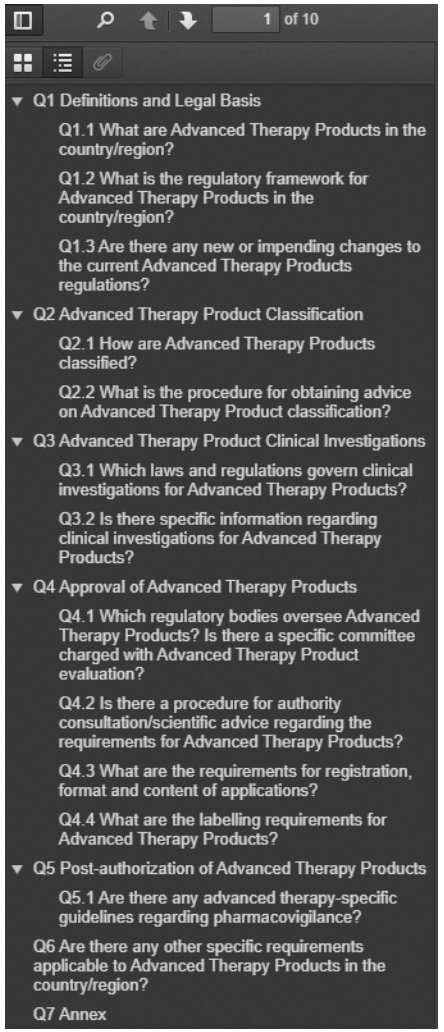
Explore the new content for Advanced Therapy Products



1. Click Regulatory Summaries
2. Click the magnifying glass and enter Advanced in the filtering search field near the top to quickly identify Summaries by title
3. In the How to Market section click Advanced Therapy Medicinal Products to see all available countries & regions
4. Click the country of interest to open the Summary

Cortellis Regulatory Summaries

Explore the new content for Advanced Therapy Products



Regulatory Summary

Continuously monitored and updated

Clarivate™

How to Market Advanced Therapy Products (Spain)

Reason for update	Date	Reason for update description
Formatting Change	2024-02-19	This document has been revised to update the following links: • EMEA/149995/2008 rev.1 (IDRAC 268785): Draft Guideline on Safety and Efficacy Follow-Up and Risk Management of Advanced Therapy Medicinal Products, 25-Jan 2018; • Regulation (EU) No 536/2014 (IDRAC 346051) of the European Parliament and of the Council on Clinical Trials on Medicinal Products for Human Use, and R... 16-Apr-2014 (as Last Amended ... Council Directive (EU) 2022/223 • NTA Volume 2C Rev 14.6 (IDRA... Packaging Information of Medic... Authorised by the Union, Apr-20... • EMA/CAT/852602/2018 (IDRAC 2... Quality, Non-Clinical and Clinica... Investigational Advanced Thera... Clinical Trials, 31-Jan-2019.
New	2024-01-19	New

Q6 Are there any other specific requirements applicable to Advanced Therapy Products in the country/region?

Fees

According to Royal Legislative Decree 1/2015 (IDRAC 292665) : Services and activities related to advanced therapy products not intended for marketing and being carried out by public entities integrated into the National Health System, will be exempt from payment of the corresponding rate, as well as scientific advisory services and clinical studies that are not going to be used to carry out for profit activities.

Hospitals

The AEMPS has developed a service on its website in order to bring the regulatory world closer to hospital entities for applications related to non-industrial manufacturing medicinal products (MFNI) to the Agency for evaluation. More information can be found at AEMPS Information Note MUH 21/2023 (IDRAC 373941) .

Compassionate Use

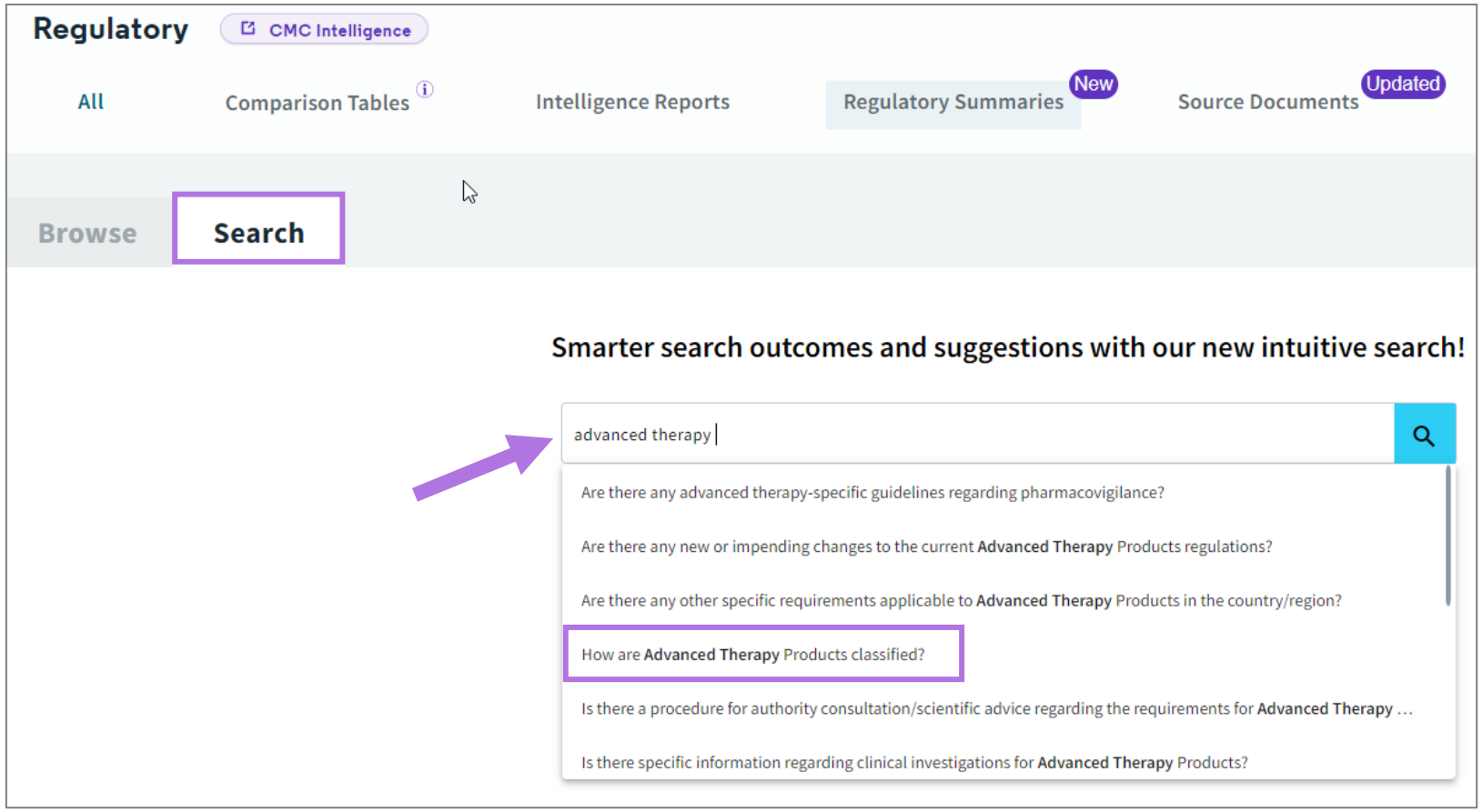
The authorization procedures for conducting clinical trials and compassionate use are the same for all advanced therapy medicinal products and are not affected by these exclusions. Where it is considered that an Advanced Therapy Medicinal Product may qualify for any of these exclusions, a consultation should be made to the AEMPS's Innovation and knowledge of medicinal products/ Innovation Office (innov_spain@aemps.es).

5. Use the bookmarks to jump to the sections and questions for interest

6. Click the hyperlinks to consult associated documents to learn more

New Intuitive Search for Regulatory Summaries

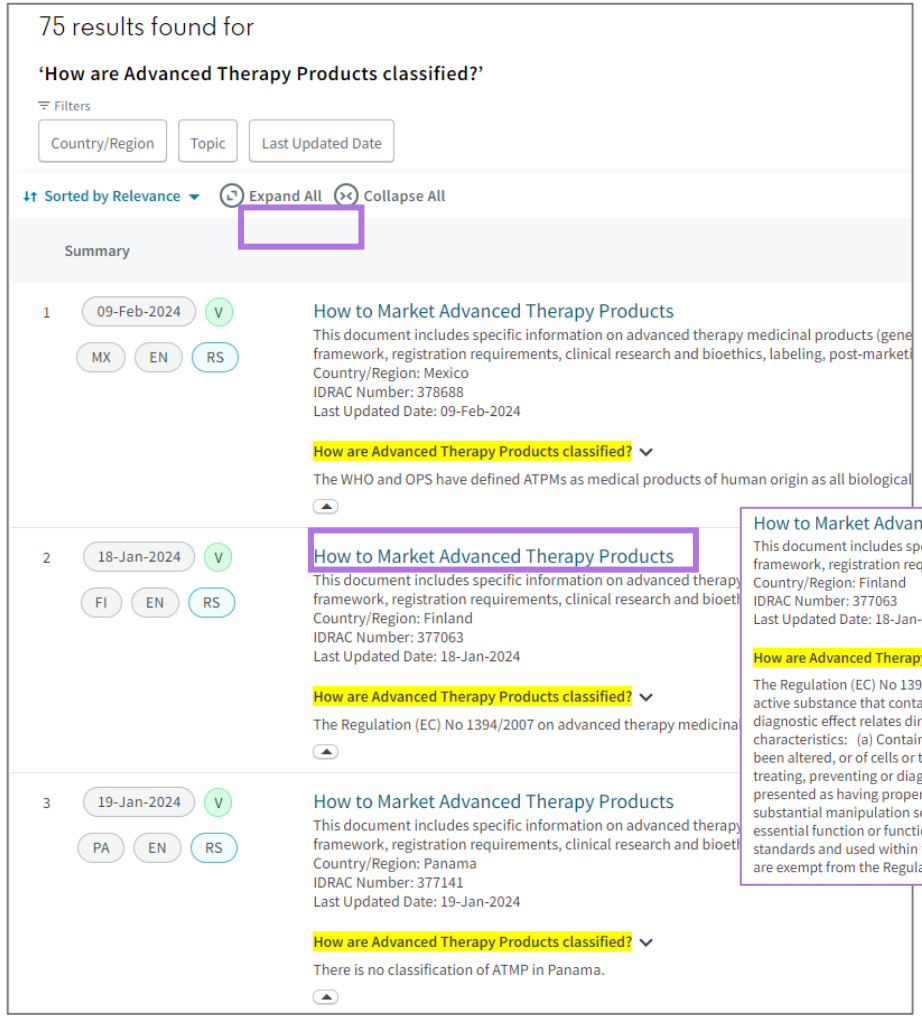
Get better results with autosuggestions and easily compare answers country by country

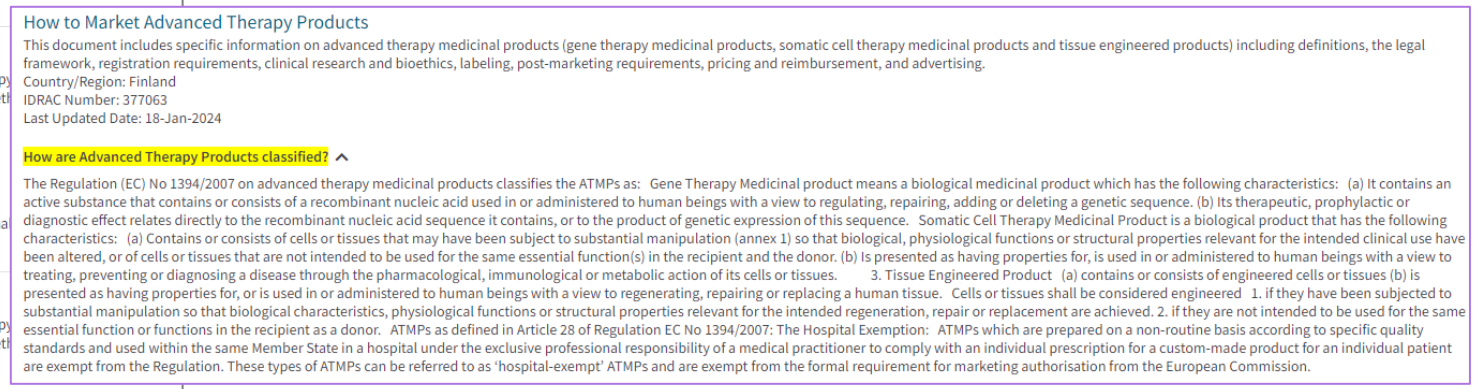


1. On the Regulatory Summaries page click Search
2. Enter keywords or a question in English
3. Select a question from the list of suggestions

New Intuitive Search for Regulatory Summaries

Get better results with autosuggestions and easily compare answers country by country





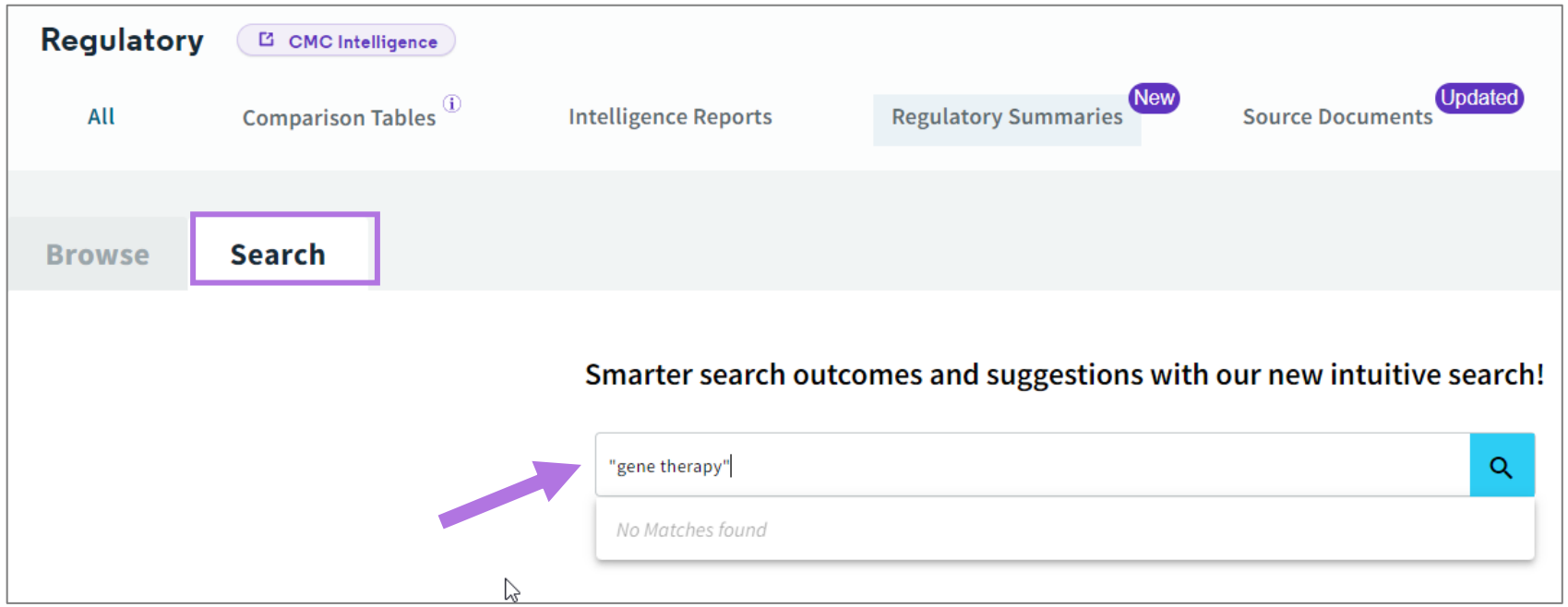
Relevant answers appear on the same page

4. Click Expand All to compare full answers across countries directly on the screen

5. If desired: Click a blue hyperlink to open a Regulatory Summary for more details

New Intuitive Search for Regulatory Summaries

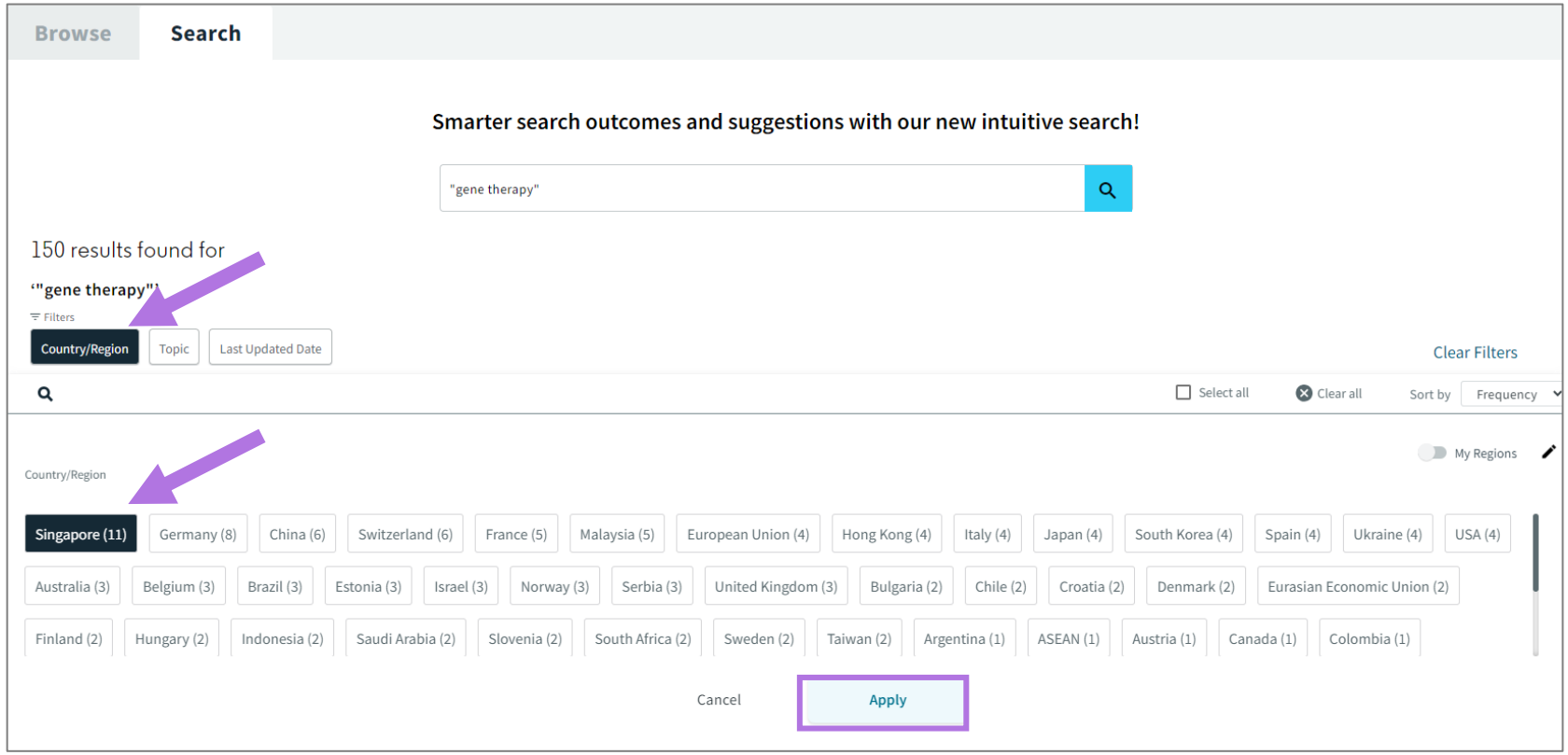
Quickly find out which Summaries talk about a topic for a country or region



1. On the Regulatory Summaries page click Search
2. Enter keywords or a question in English. For phrases use quotation marks
3. Click the blue Search button even if there were no suggestions

New Intuitive Search for Regulatory Summaries

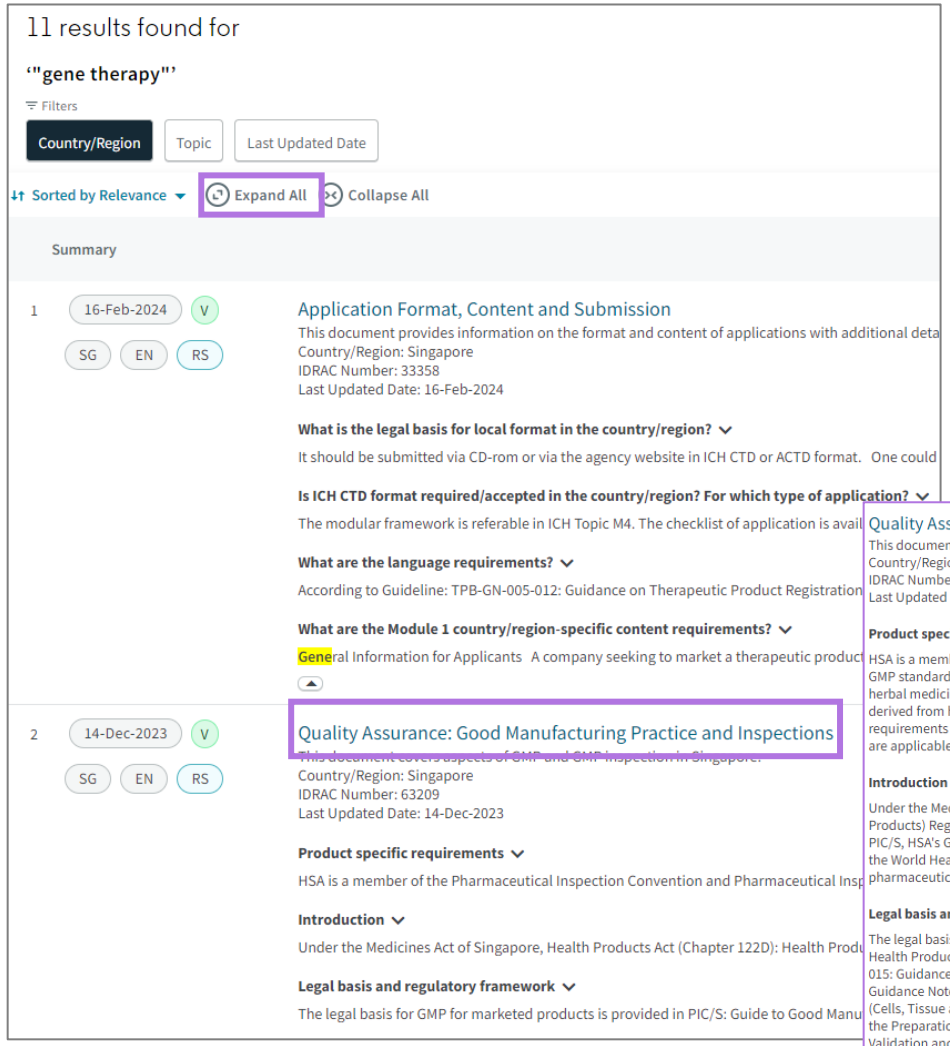
Quickly find out which Summaries talk about a topic for a country or region



4. Click the Country/Region filter
5. Select the country of interest
6. Click Apply
7. Optional: click the Topic filter, select the topic(s) of interest and Click Apply
8. Click the blue Search button to filter your search

New Intuitive Search for Regulatory Summaries

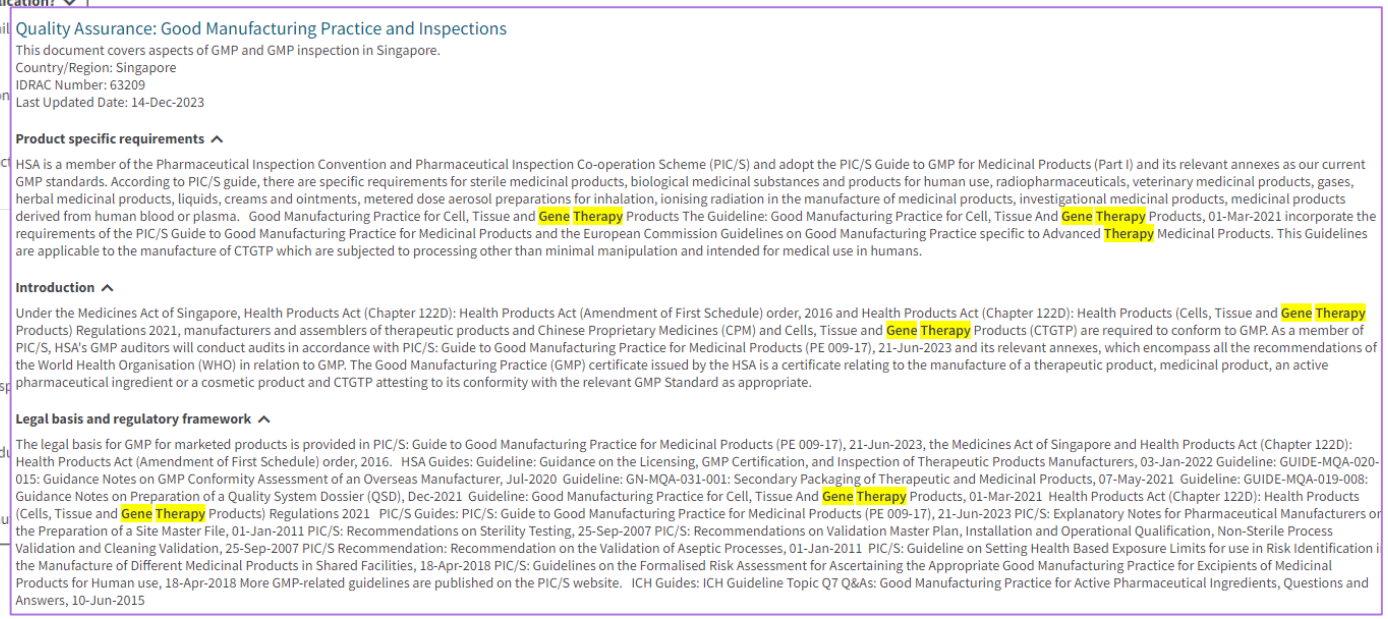
Quickly find out which Summaries talk about a topic for a country or region



This gives you the Summaries for the country talking about your topic or keyword(s) (including synonyms).

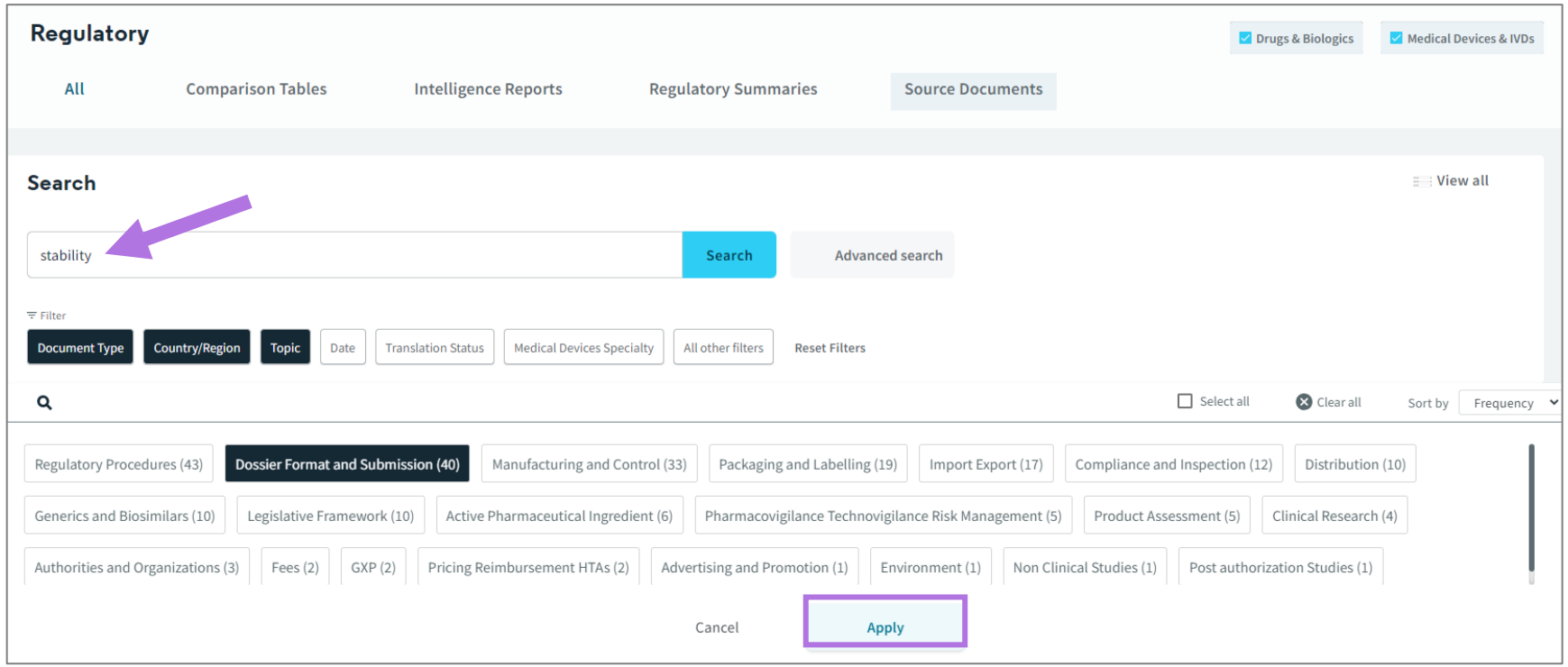
9. Click Expand All to see the context

10. If desired: Click a blue hyperlink to open a Regulatory Summary for more details



Upgraded Source Document Search

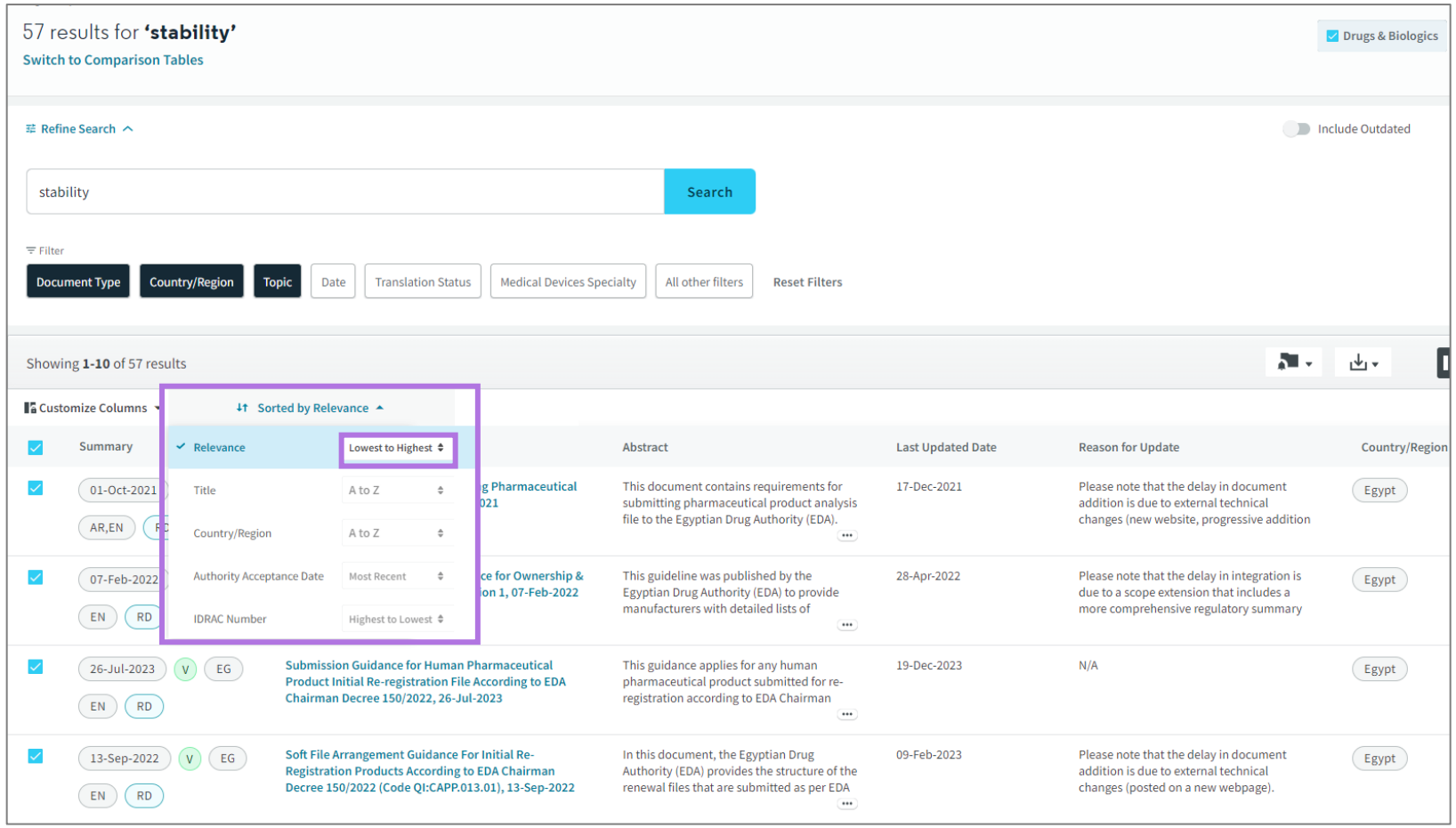
Search all source documents including the pdf full text using English or local language keywords



1. Click Source Documents
2. Enter your English or local language keyword(s) in the search bar
3. Optional: select filters and apply as desired, e.g.
   -Document Type: Guideline
   -Country/Region: Egypt
   -Topic: Dossier Format and Submission
4. Click the blue Search button

Upgraded Source Document Search

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



Results retrieved by relevancy highest to lowest as default, will mostly include your English keywords in the title and/or abstract.

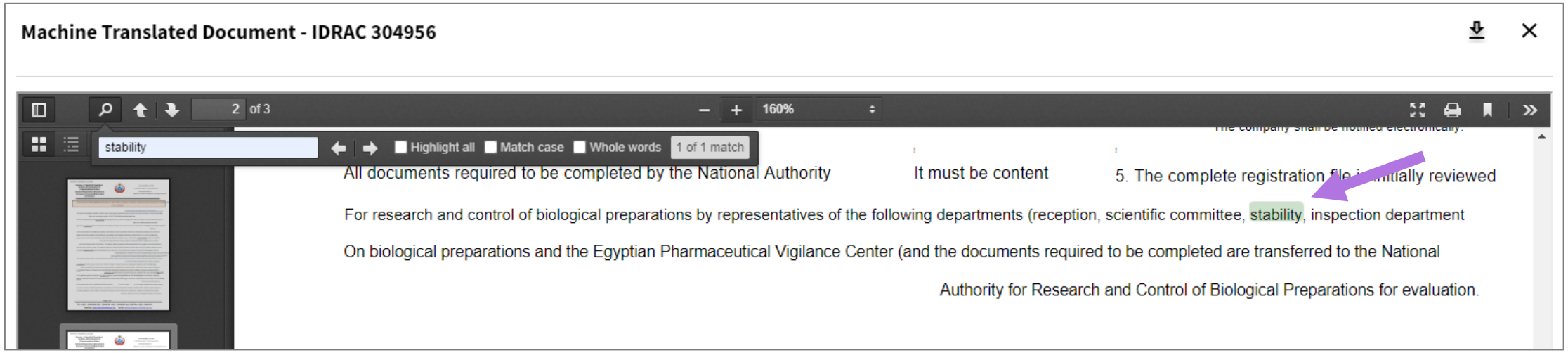
5. Optional: Change the relevance sorting to lowest to highest, to retrieve documents that may not mention your keyword in title or abstract

6. Click the hyperlinked title to open a document of interest

Upgraded Source Document Search

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

7. Use the Find in Document tool to jump to the relevant section(s) talking about your keyword(s).



Source Document Search and Quick Search Comparison

Different ways of searching depending on your queries and needs

Source Document Search

- Supports English and local language keywords
- Searches local source/reference documents only
- Searches entire documents including pdf full text („Search in any language anywhere“)
- More comprehensive results: usually retrieves more results than Quick Search
- Stability example showcased (Slides XX) retrieved 57 results as of Feb 22nd, 2024

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)
- More target results (keywords being always mentioned in title and/or abstract and/or other key fields)
- Stability example run with Quick Search retrieved 19 results as of Feb 22nd, 2024

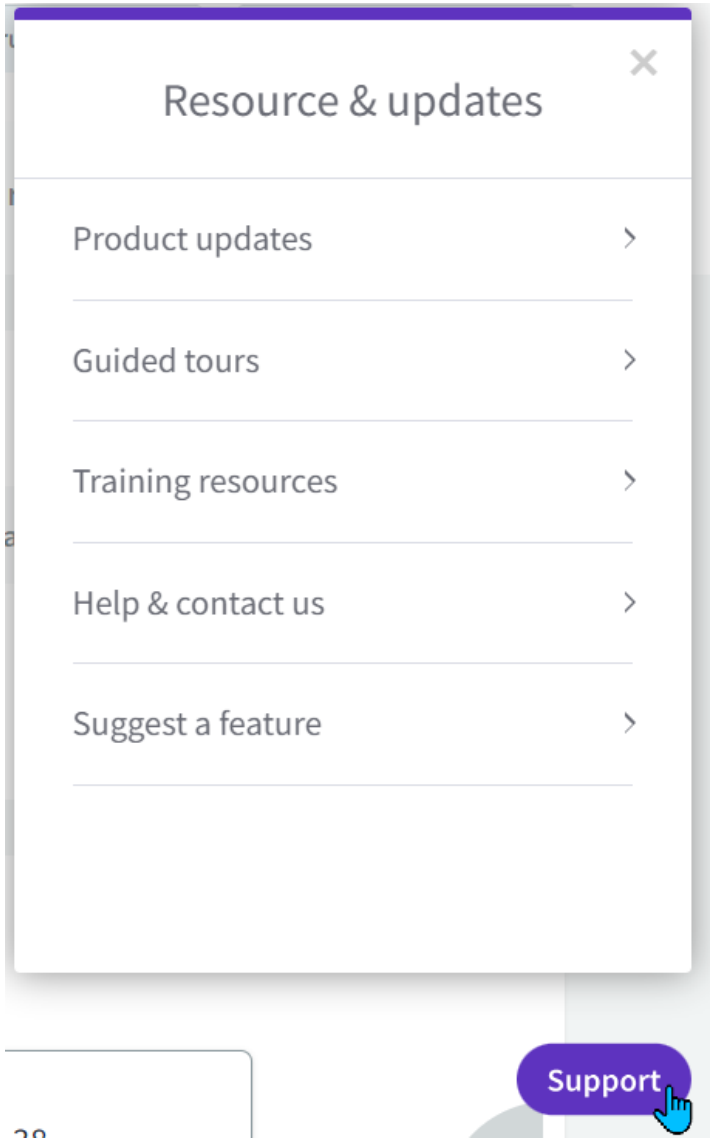
Get assistance with Cortellis

In-product guidance to assist you with your questions

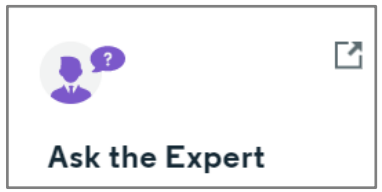
- Click at the Support button at the bottom of the screen

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

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

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