Quick start guide

Cortellis CMC Intelligence

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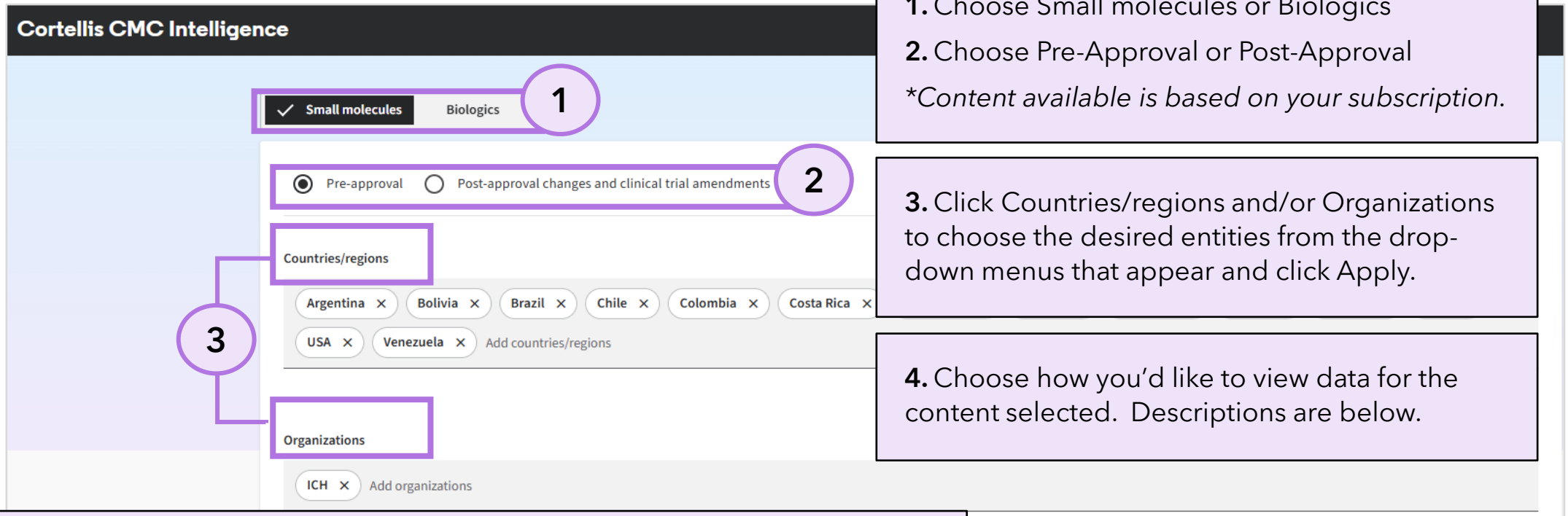
Home



1. Choose Small molecules or Biologics

2. Choose Pre-Approval or Post-Approval

**Content available is based on your subscription.*

3. Click Countries/regions and/or Organizations to choose the desired entities from the drop-down menus that appear and click Apply.

4. Choose how you'd like to view data for the content selected. Descriptions are below.

Summary: Compare and contrast core requirements for your selections to identify differences and similarities across countries

Detailed: Explore official regulatory requirements and local practices organized into eCTD structure efficiently linked to the source documents

Report: View a visualization of regulatory submission pathways, read key facts, procedures and requirements to gather understanding of the regulatory submission

Updates: The latest updates to the content for your selected country or organization to quickly identify and locate changes

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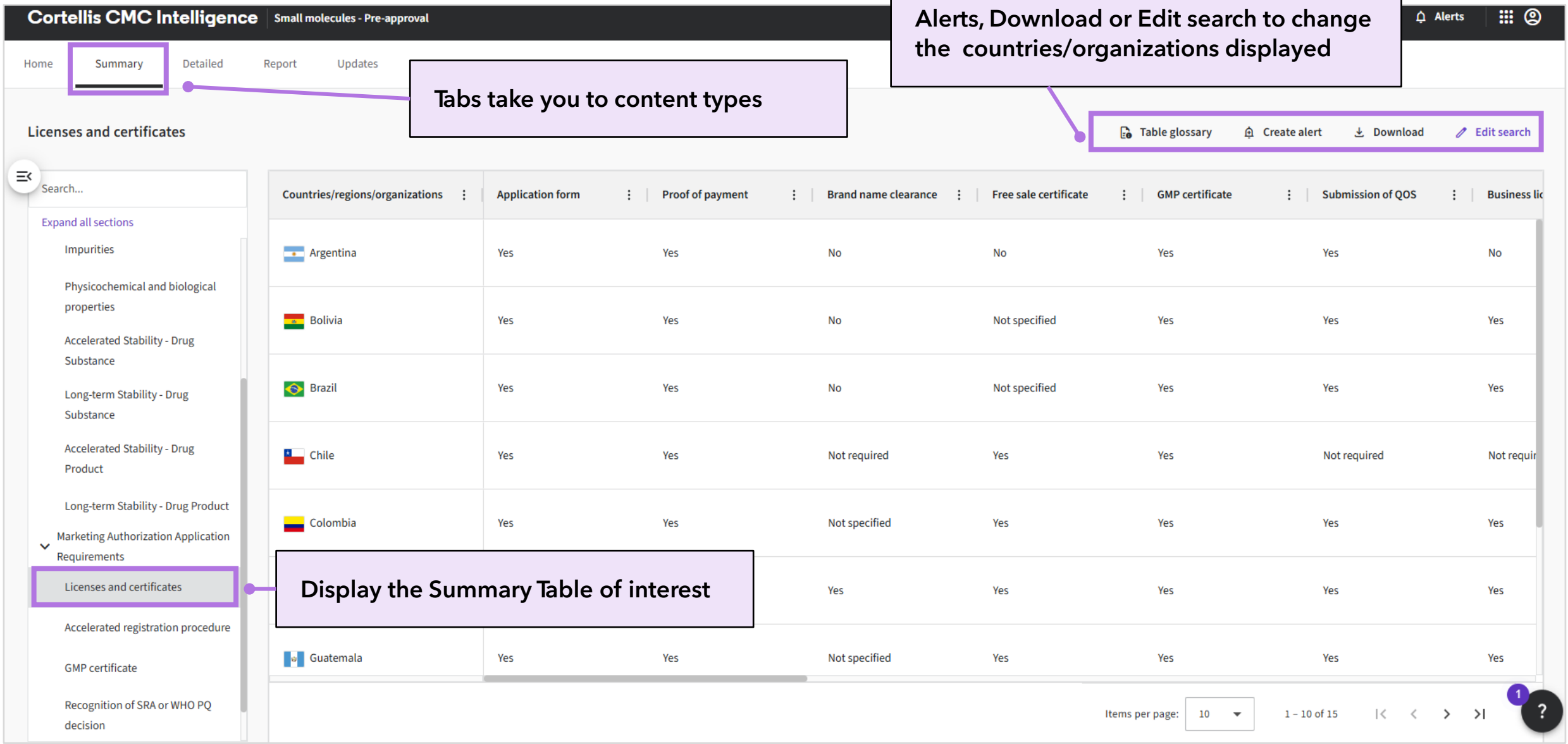
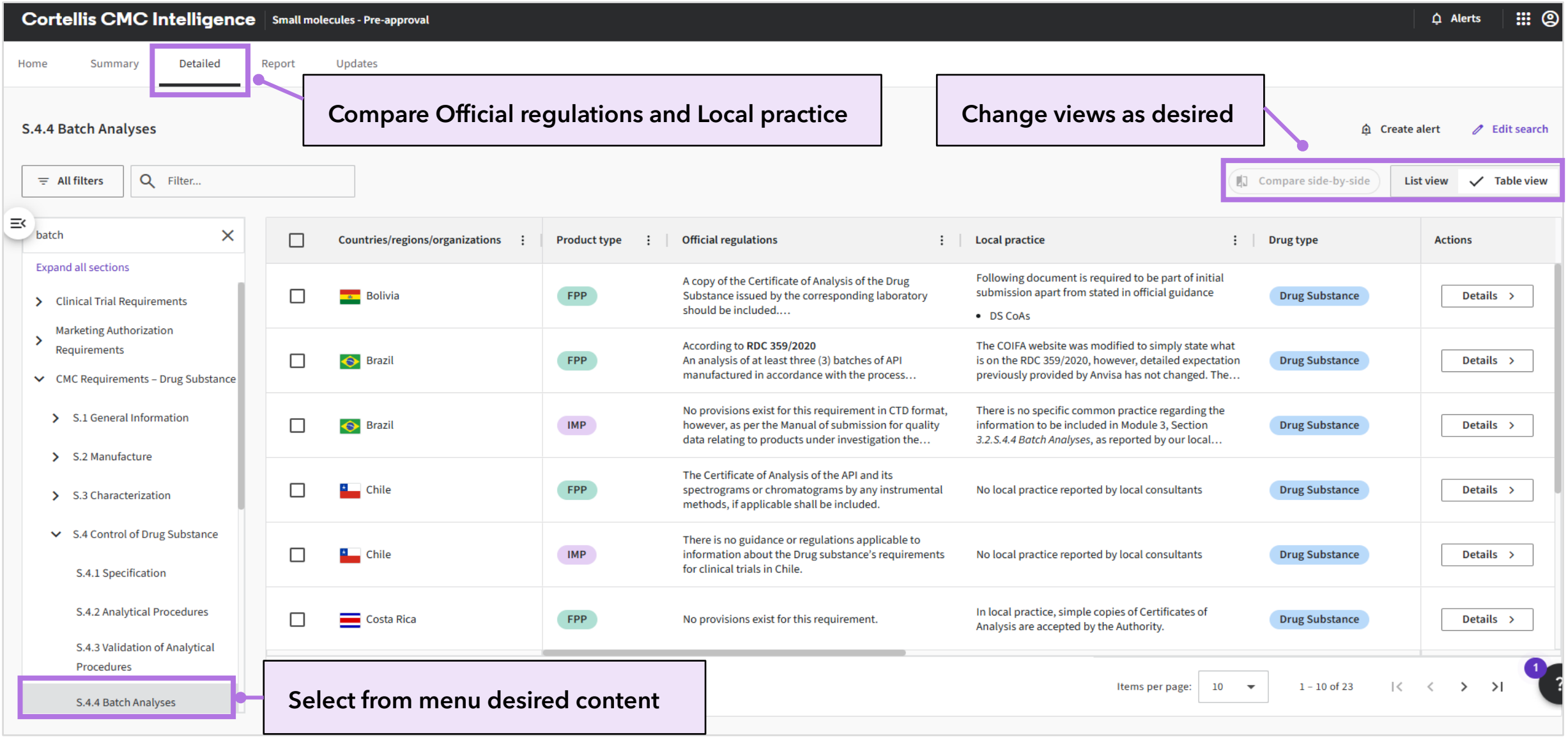
View Summary Reports

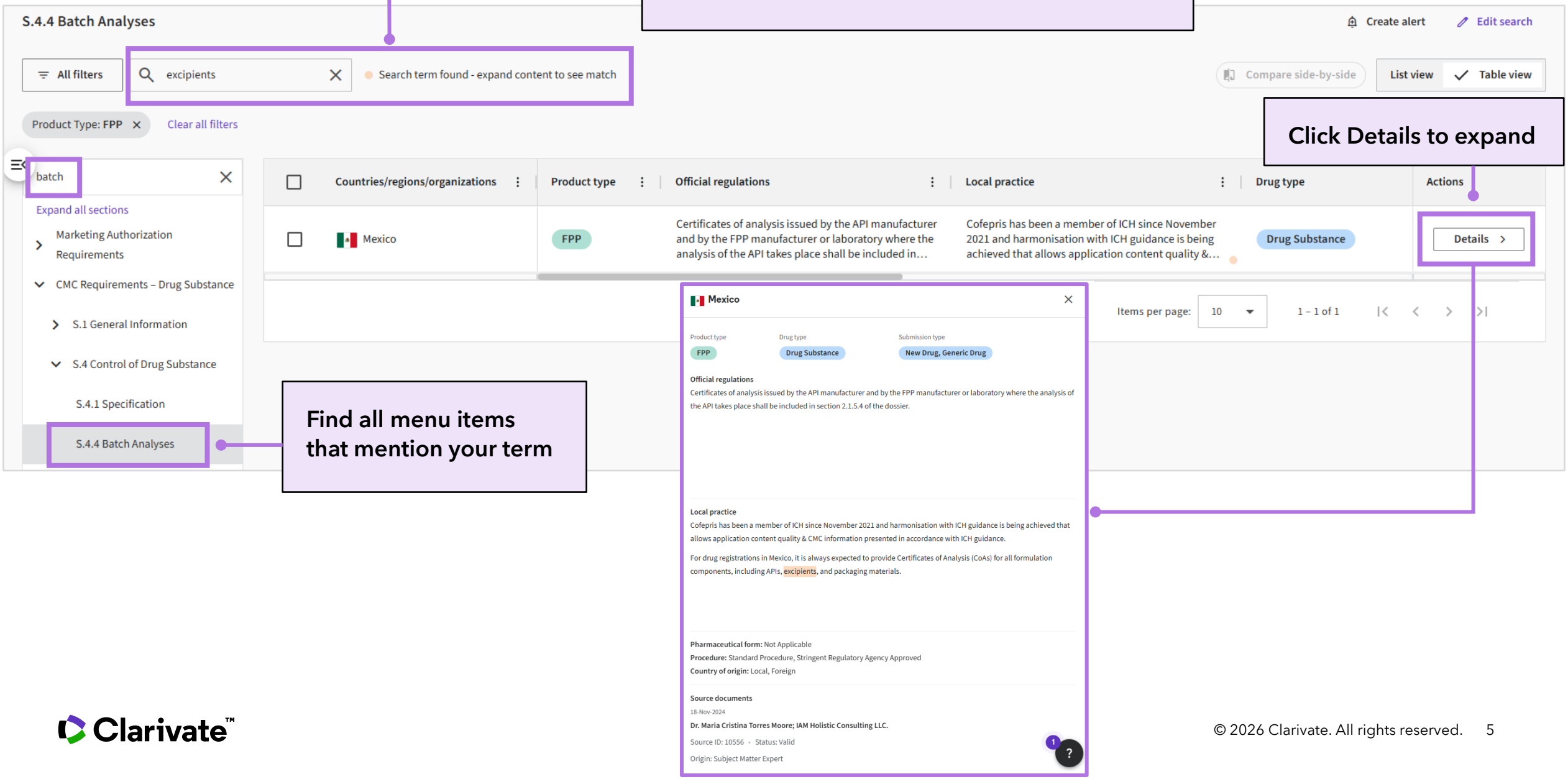


View Detailed Requirements



View Detailed Requirements

Find all report content that mentions your term

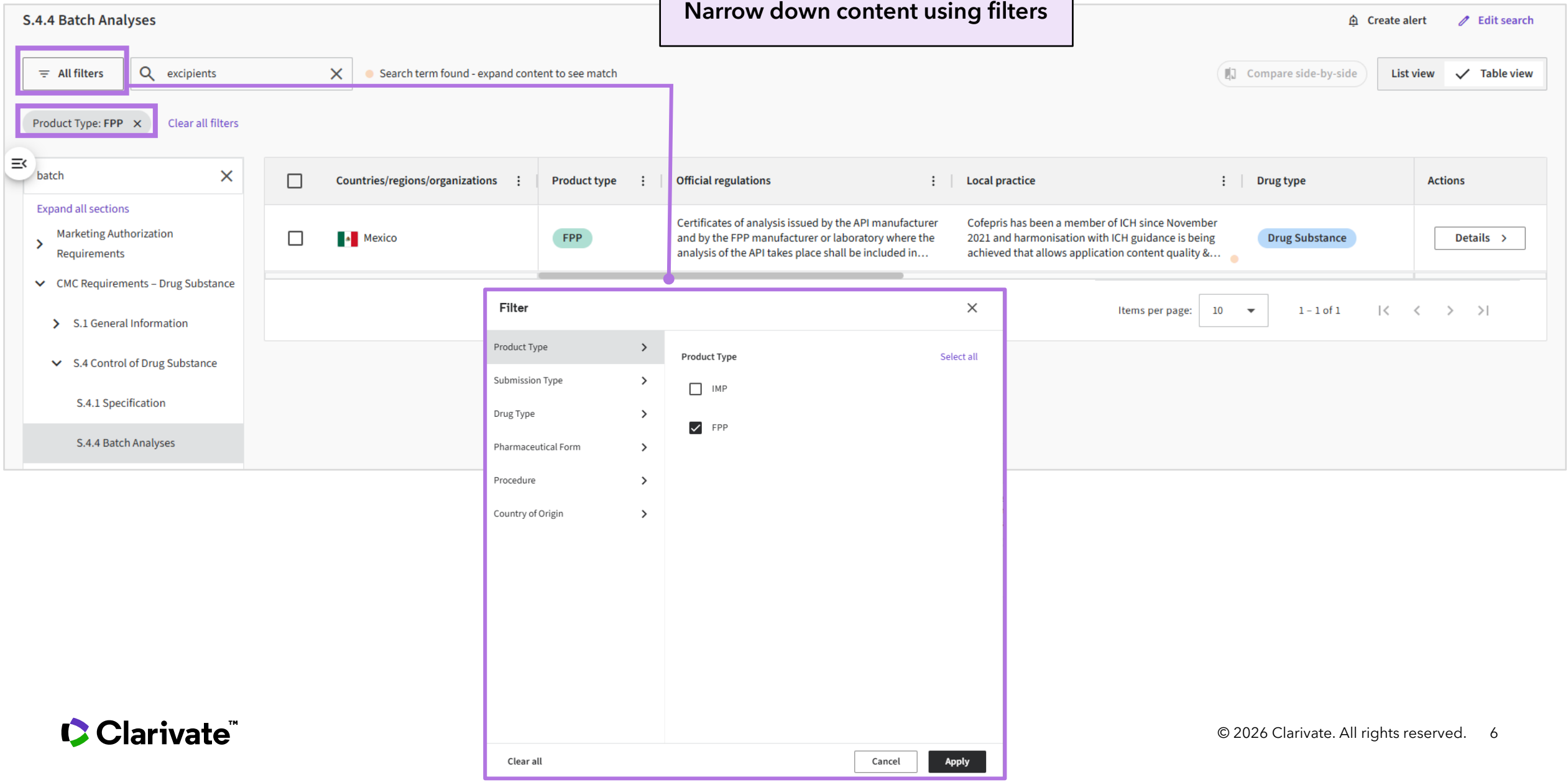


Click Details to expand

Find all menu items that mention your term

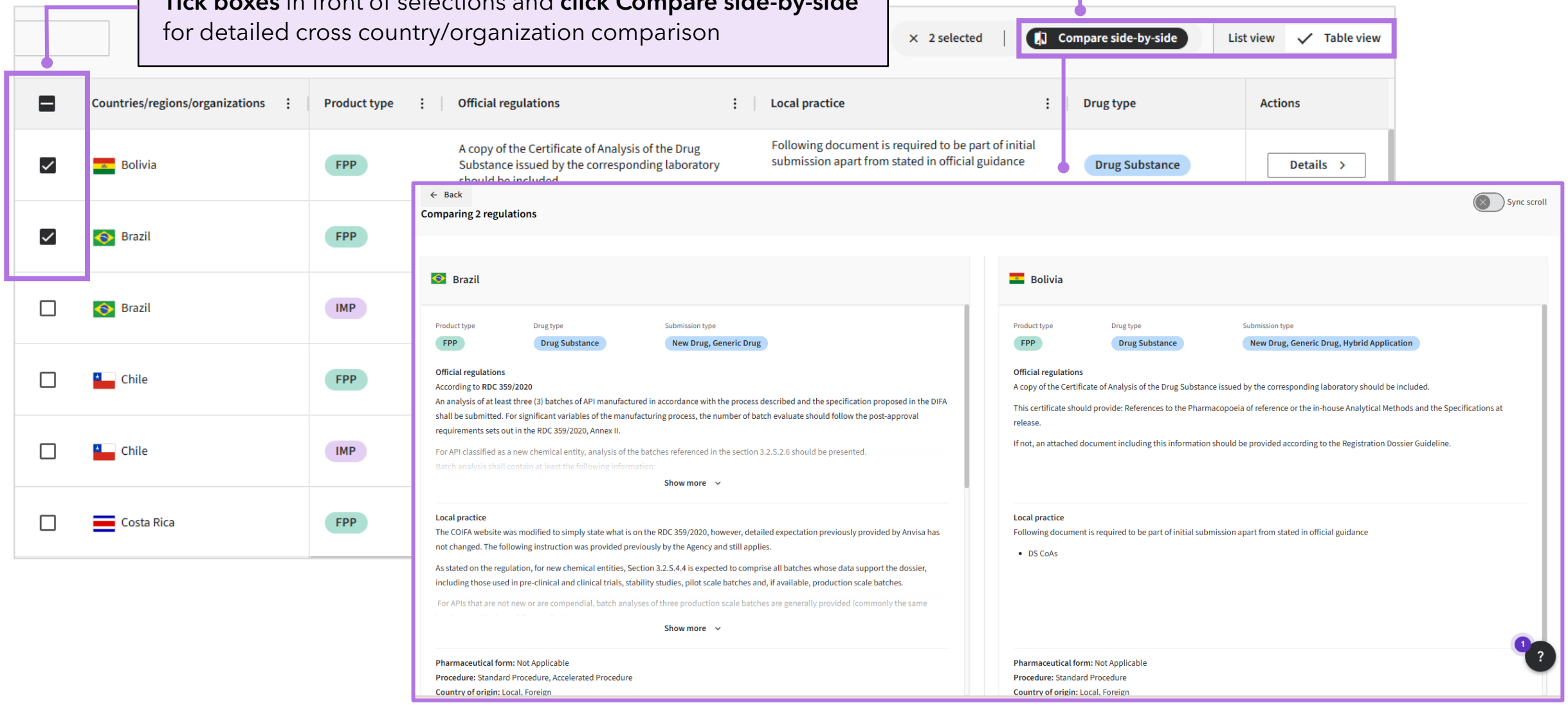
View Detailed Requirements

Narrow down content using filters



View Detailed Requirements

Tick boxes in front of selections and **click Compare side-by-side** for detailed cross country/organization comparison



View Reports

Cortellis CMC Intelligence | Small molecules - Pre-approval

Alerts

Home | Summary | Detailed | Report | Updates

Procedures

Create alert | Download | Edit search

USA

Use drop down to go to Report for selected countries

Search...

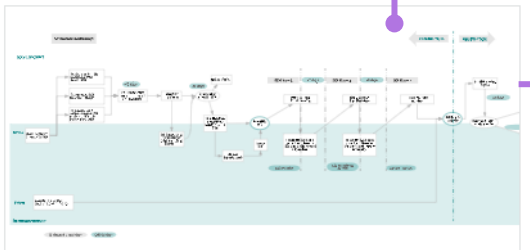
Expand all sections

- Key facts
- Key requirements
- Upcoming guidelines and drafts
- Procedures
- Detailed requirements
  - Clinical Trial Requirements
  - Marketing Authorization Requirements
  - CMC Requirements – Drug Substance
  - CMC Requirements – Drug Product
  - Product Interchangeability
  - CMC Requirements – Appendices

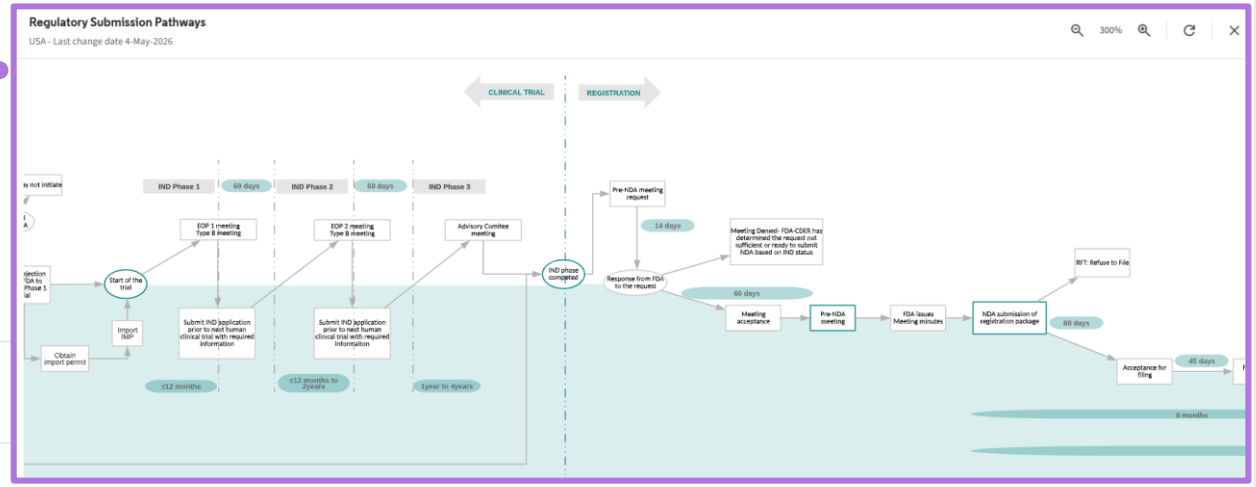
USA • Last change date 4-May-2026

Regulatory Submission Pathways

Click visual to expand



Select Report menu items to view



Stringent Regulatory Authority Approved

No specific pathway for SRA Approved Products.

WHO Prequalification

WHO lists the US FDA approved products with the reference "USFDA" have been added to the list of medicinal products prequalified by WHO, on the basis of assessments and inspections conducted by US FDA. Provision is made for the exchange of relevant information between the US FDA and WHO (under the terms of a corresponding confidentiality agreement).

No specific pathway for WHO PQ Products to gain approval in US; the usual approval procedure for assessment by FDA need to be followed prior to marketing drug in US.

Accelerated Procedure

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Set up Alerts

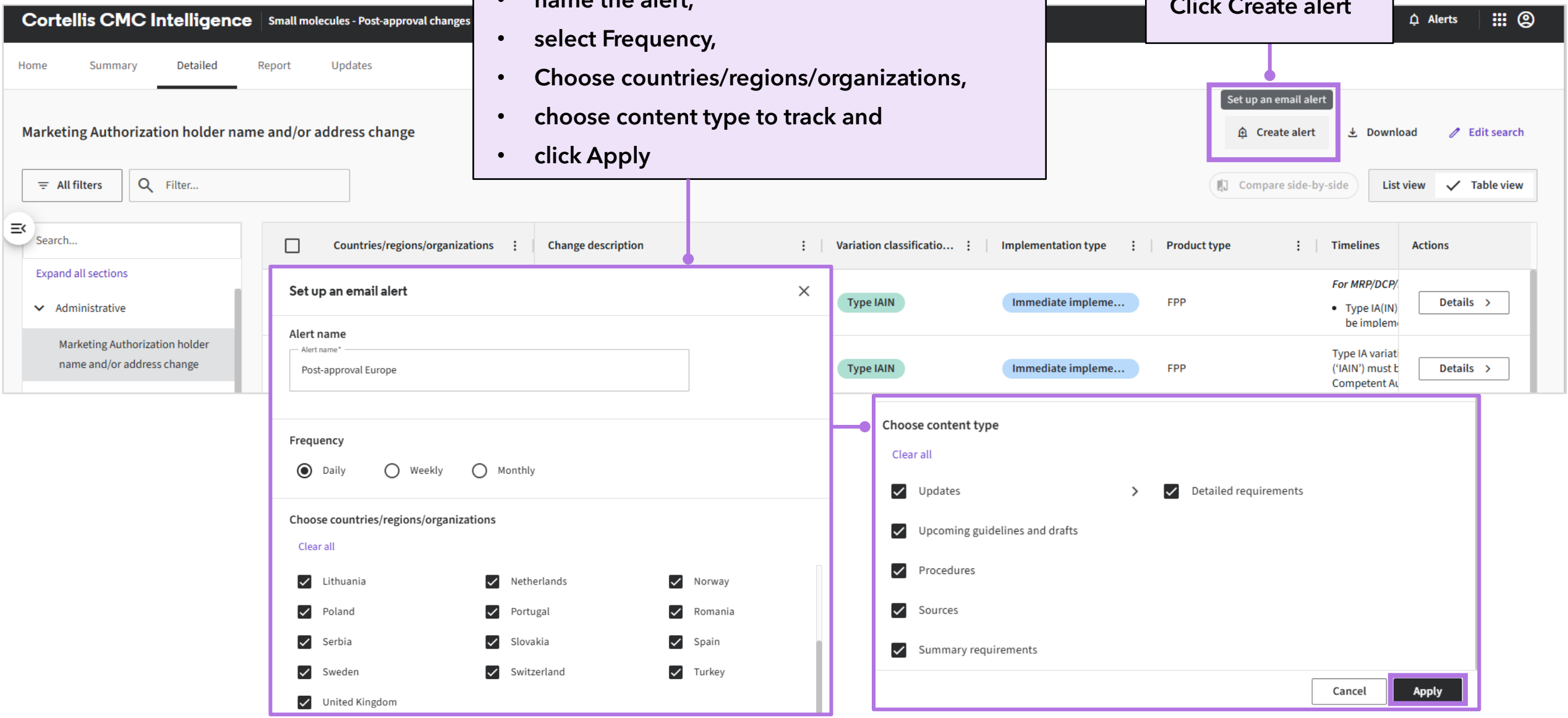
2

In the pop-up:

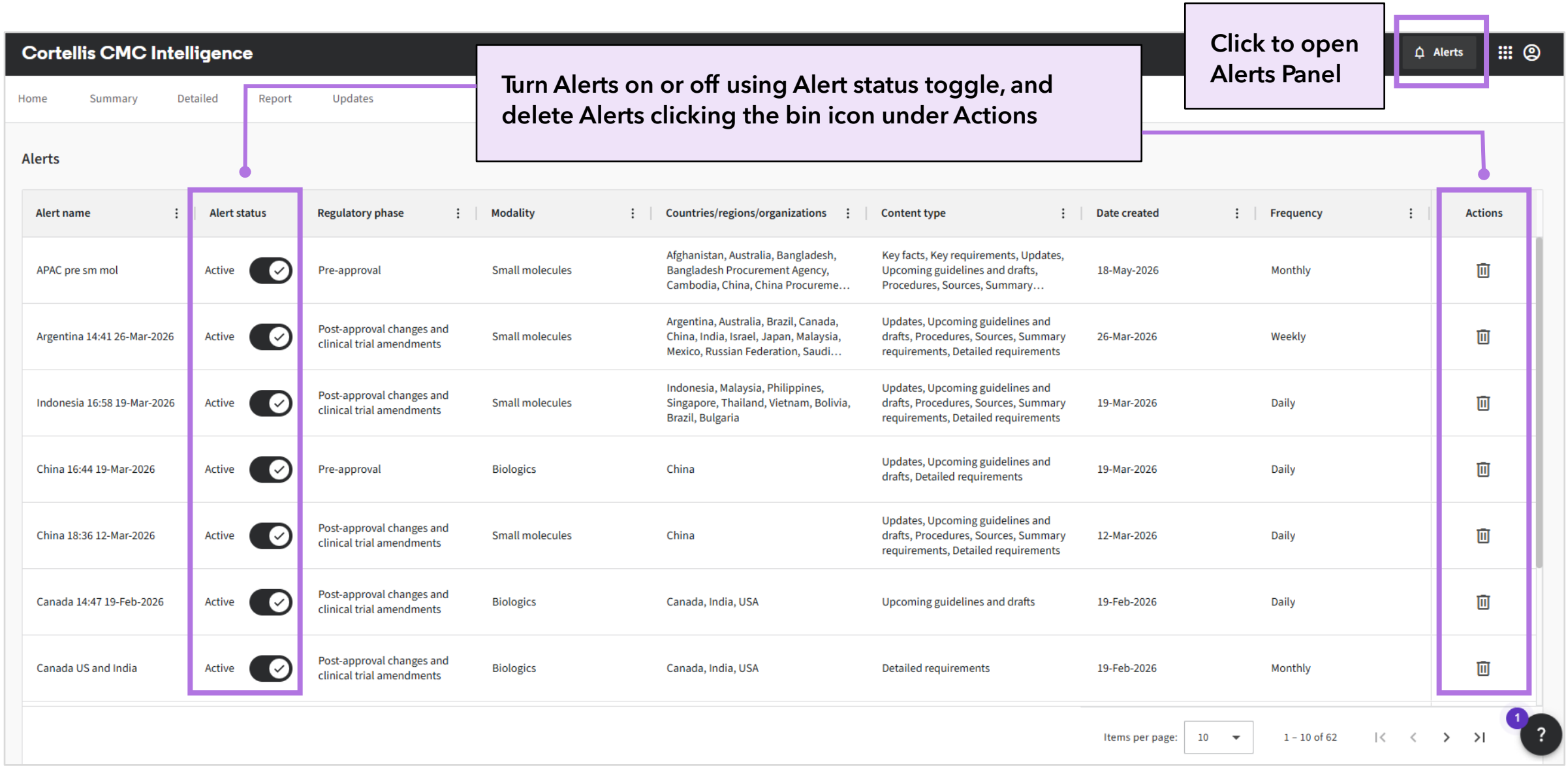
- name the alert,
- select Frequency,
- Choose countries/regions/organizations,
- choose content type to track and
- click Apply

1

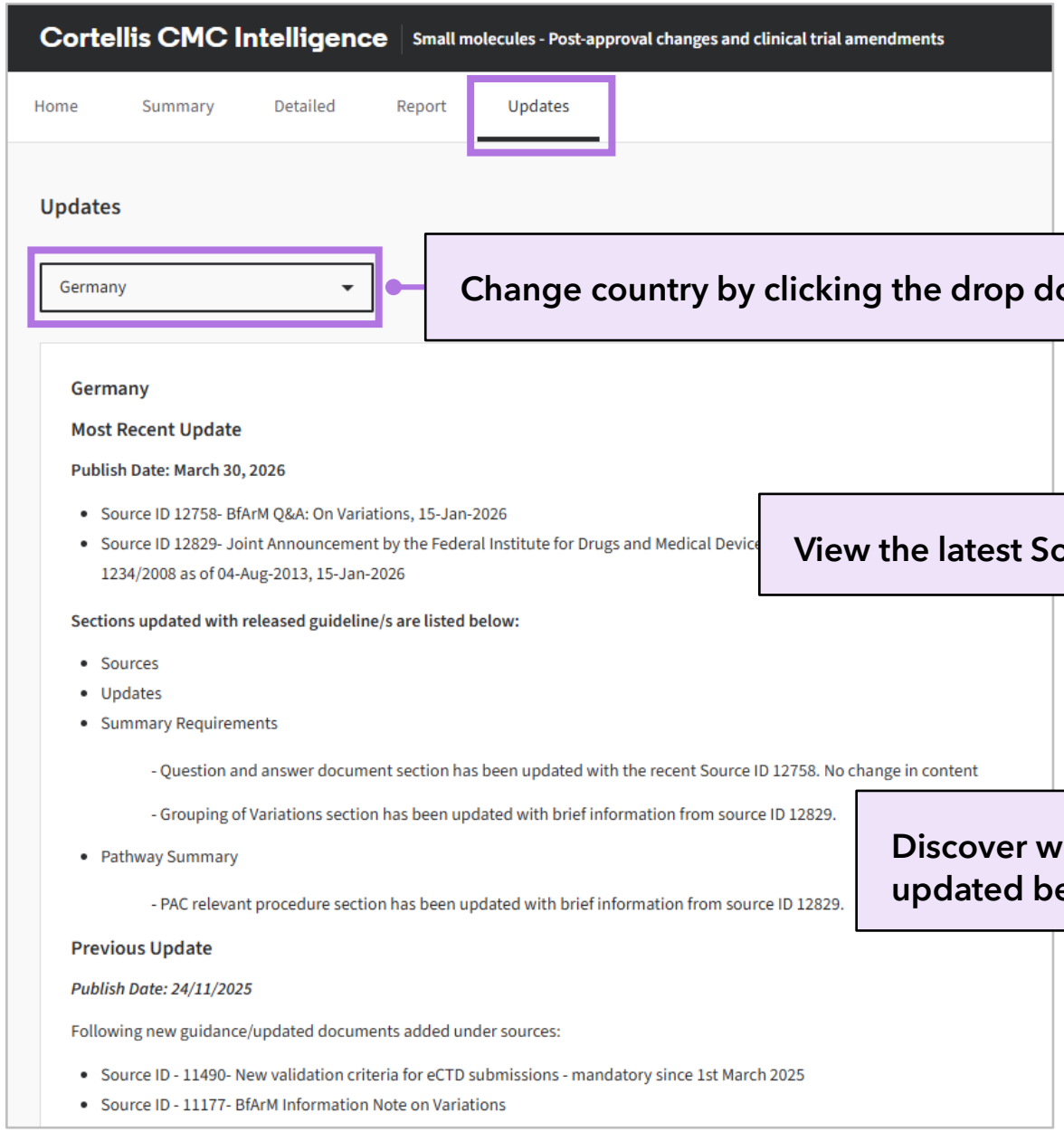
Click Create alert



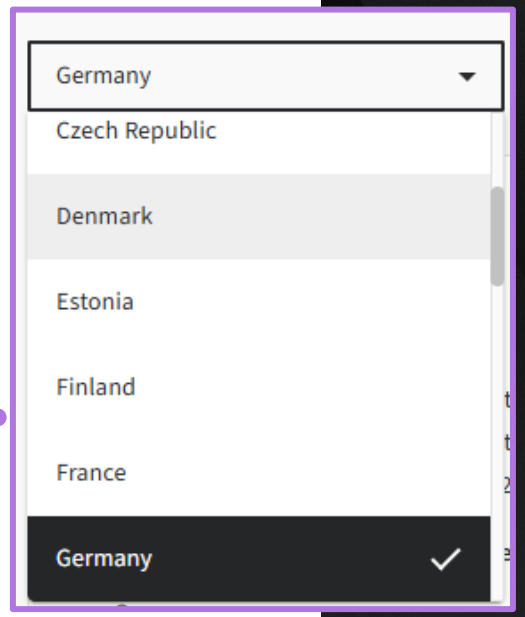
Manage Alerts



Updates



Change country by clicking the drop down



View the latest Source documents

Discover where in the country report was updated because of these new documents

If you have questions, please contact lsh.support@clarivate.com

