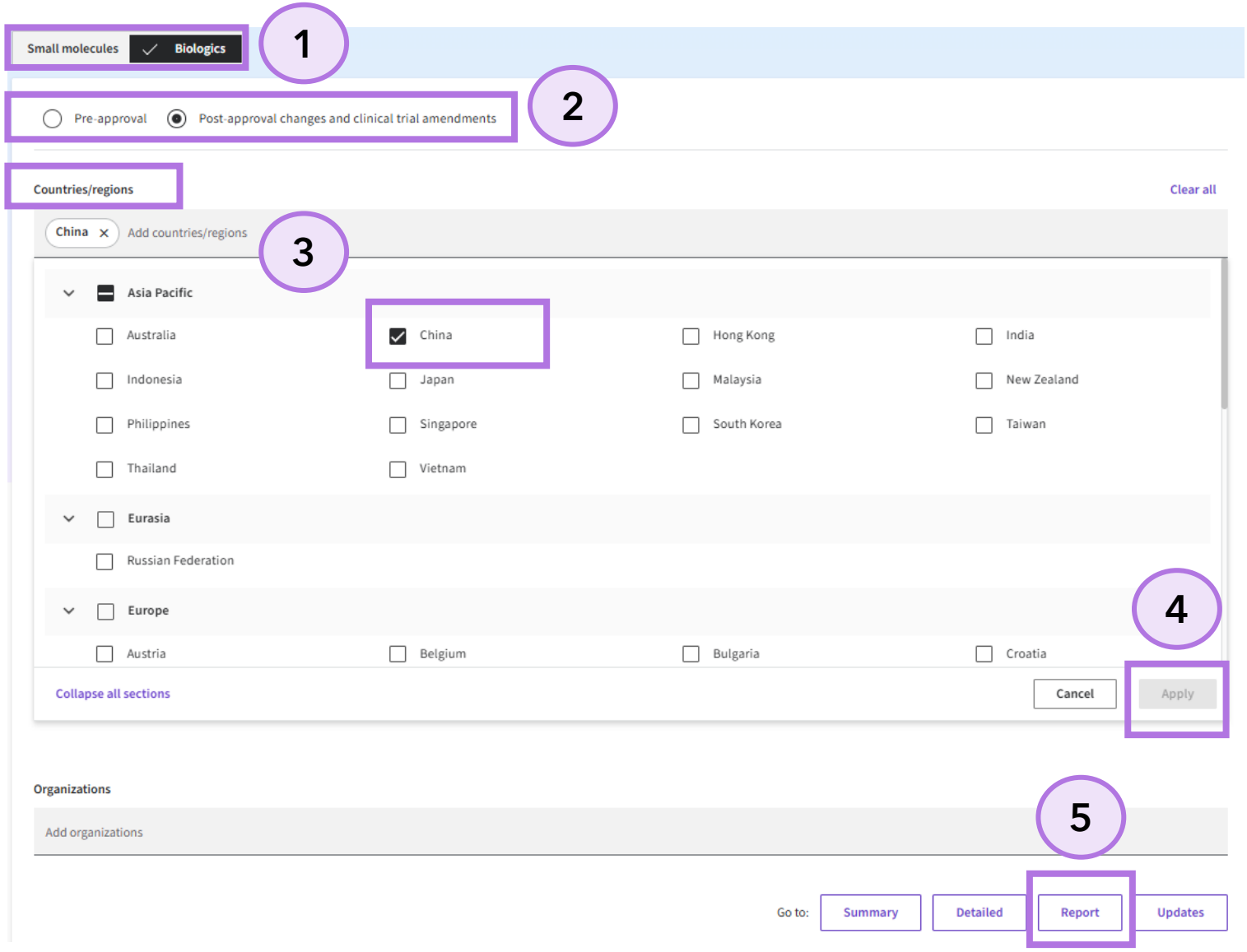
Ensure compliance for a single country

Cortellis CMC Intelligence

Clarivate™

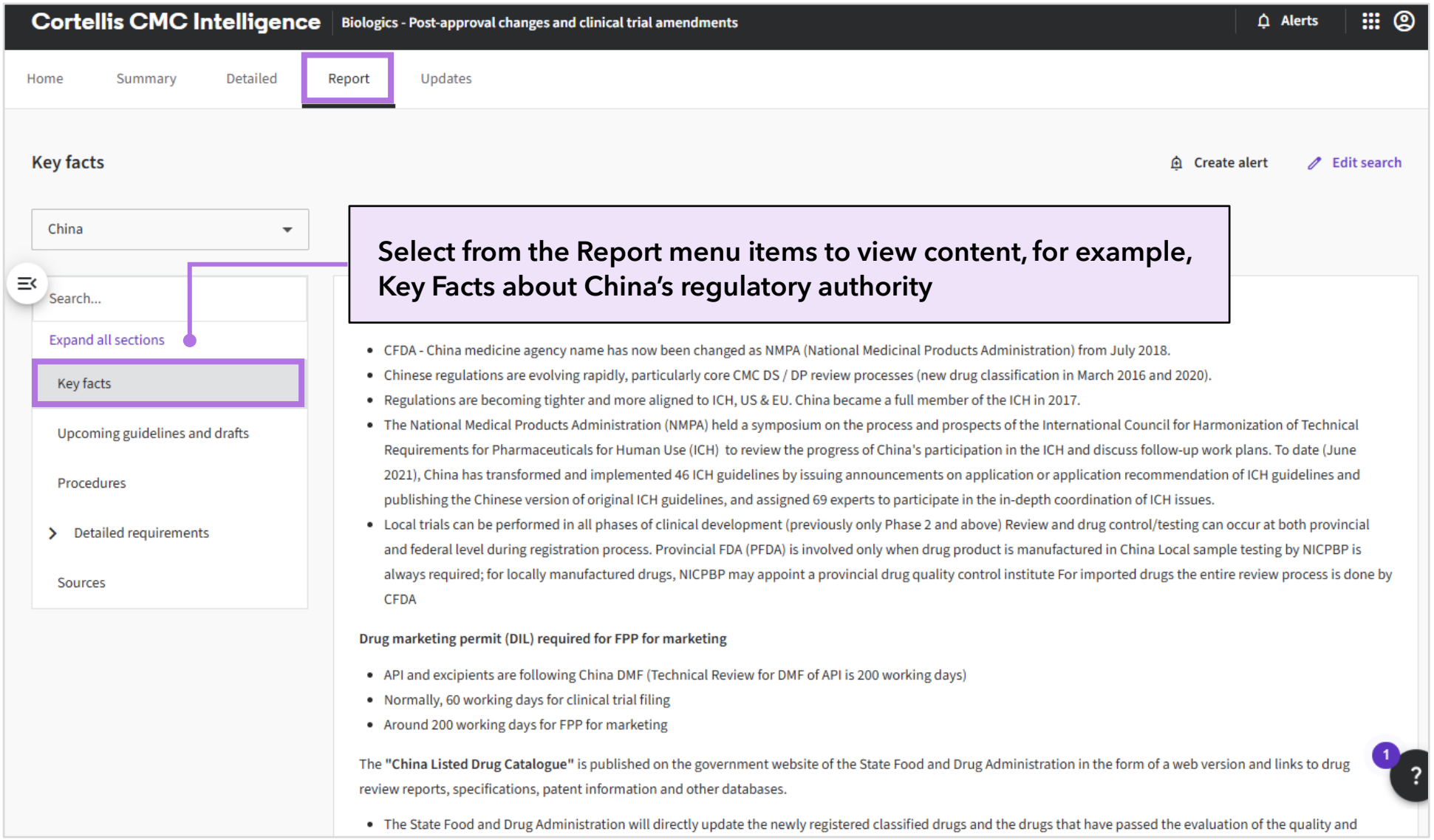
Example: Explore Pre- or Post-Marketing reports for a country to ensure compliance



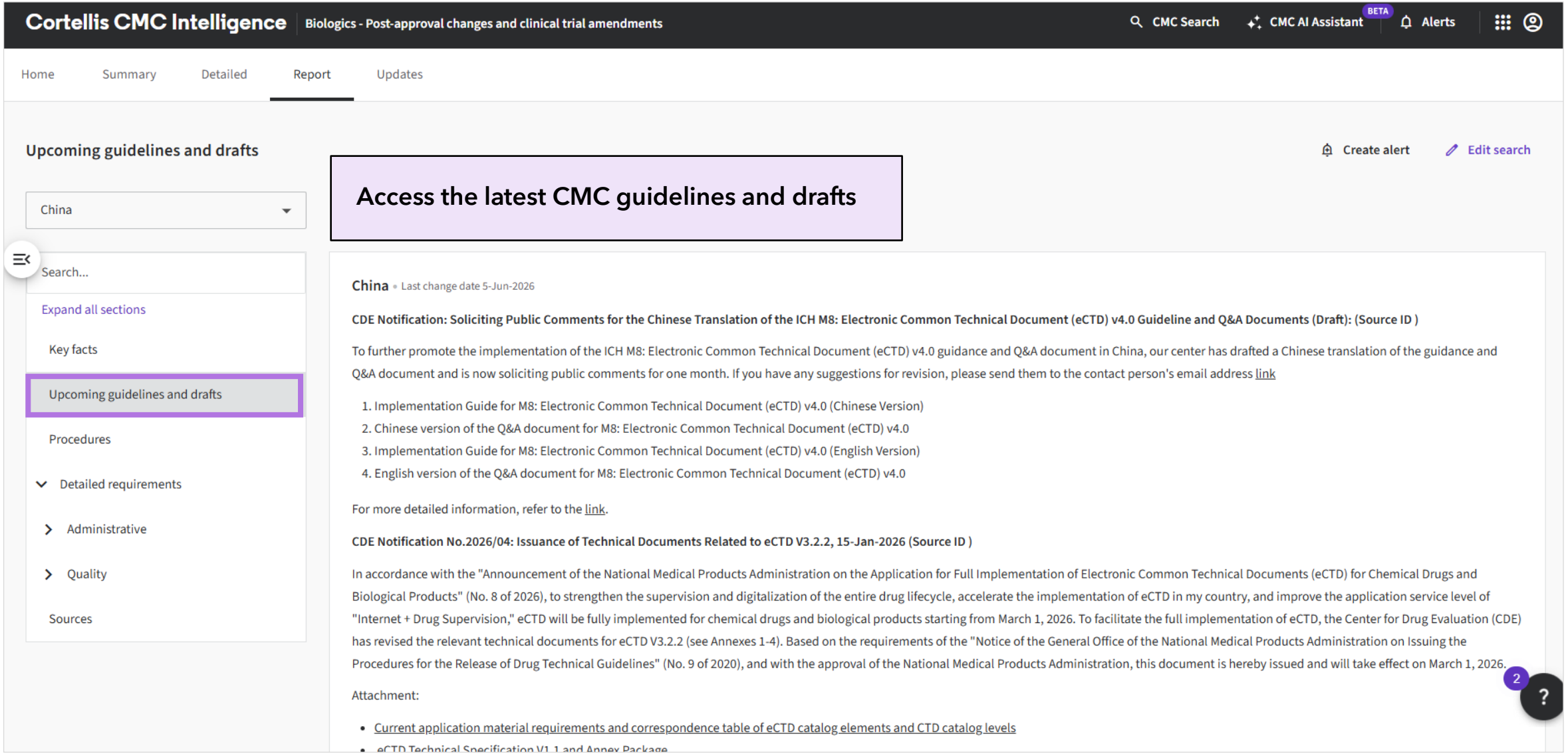
1. Choose Small molecules or Biologics
2. Choose Pre-Approval or Post-approval changes and clinical trial amendments
3. Click Countries/regions and/or Organizations to choose the desired entities from the drop-down menus that appear. For this example, let's select Biologics, Post Approval and China
4. Click Apply
5. Select Report

NOTE: Content available is based on your subscription. Regardless of the module/content selected the procedure for finding and navigating the Country reports is the same.

View Reports – use the menu bar to select content



Upcoming guidelines and drafts



View Reports – Submission Procedures

Procedures

Create alert Edit search

China

Select Procedures to view Submission Pathways

Search...

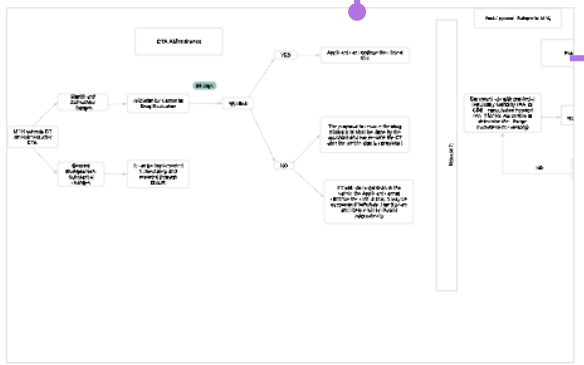
Expand all sections

- Key facts
- Upcoming guidelines and drafts
- Procedures
- Detailed requirements
  - Administrative
  - Quality
    - Manufacture
    - Control of Starting material/Active substances/Reagent/Intermediat
    - Container closure system
    - Stability
    - Design space and post approval management

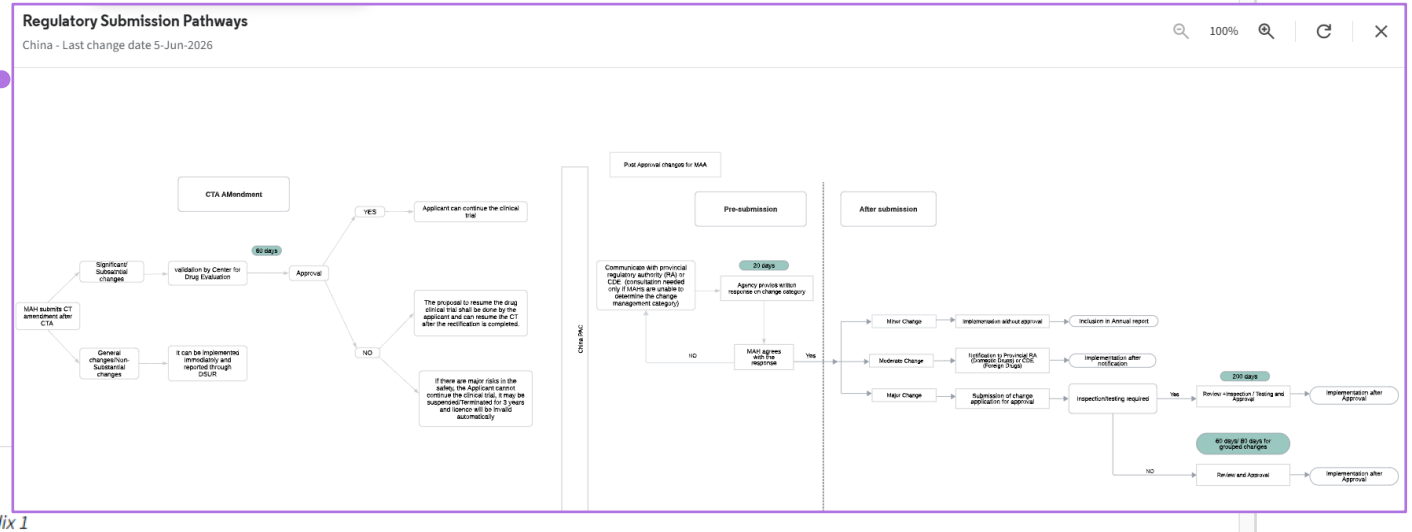
China • Last change date 5-Jun-2026

Regulatory Submission Pathways

Click visual to expand



CTA amendment & PAC Procedure



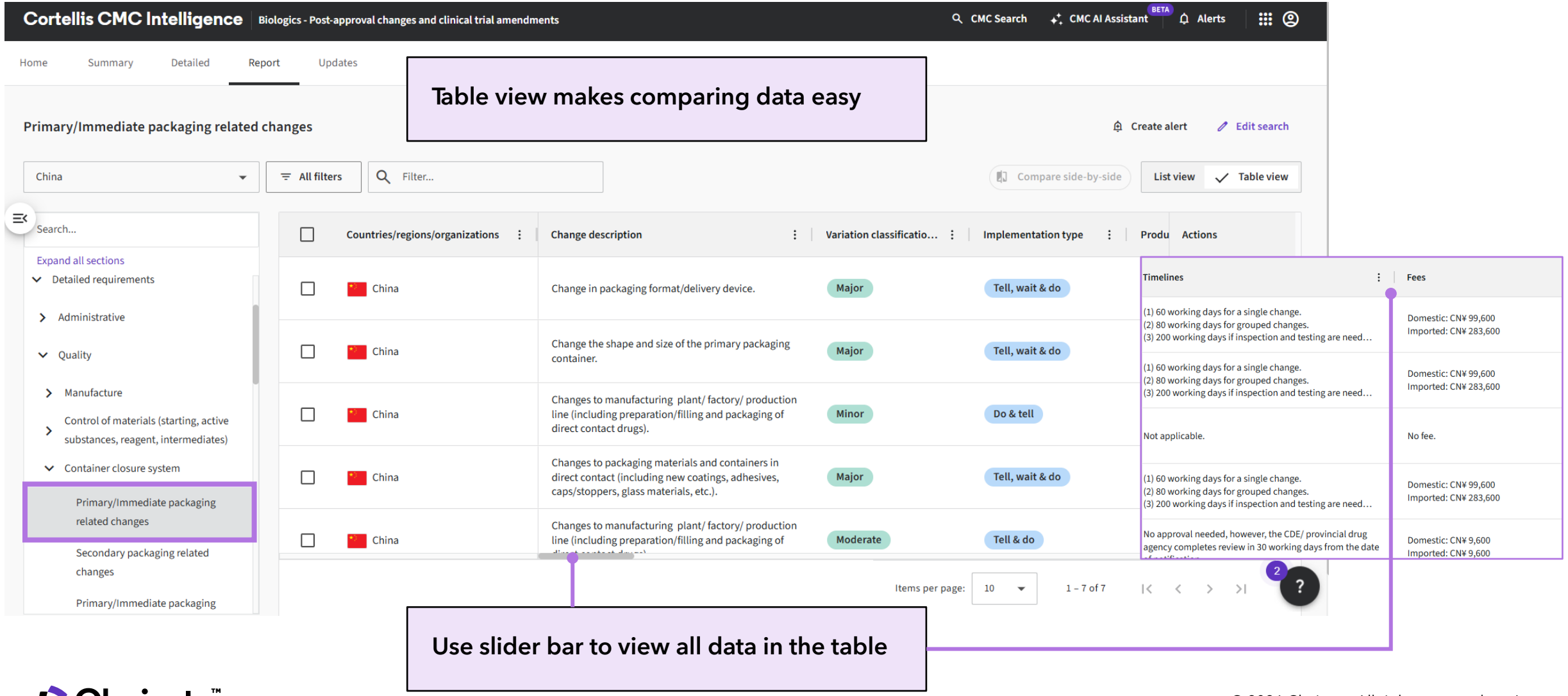
PAC Relevant Procedure

Provisions for Post-approval Changes of Drugs (Trial) Source ID 8367 *-Appendix 1*

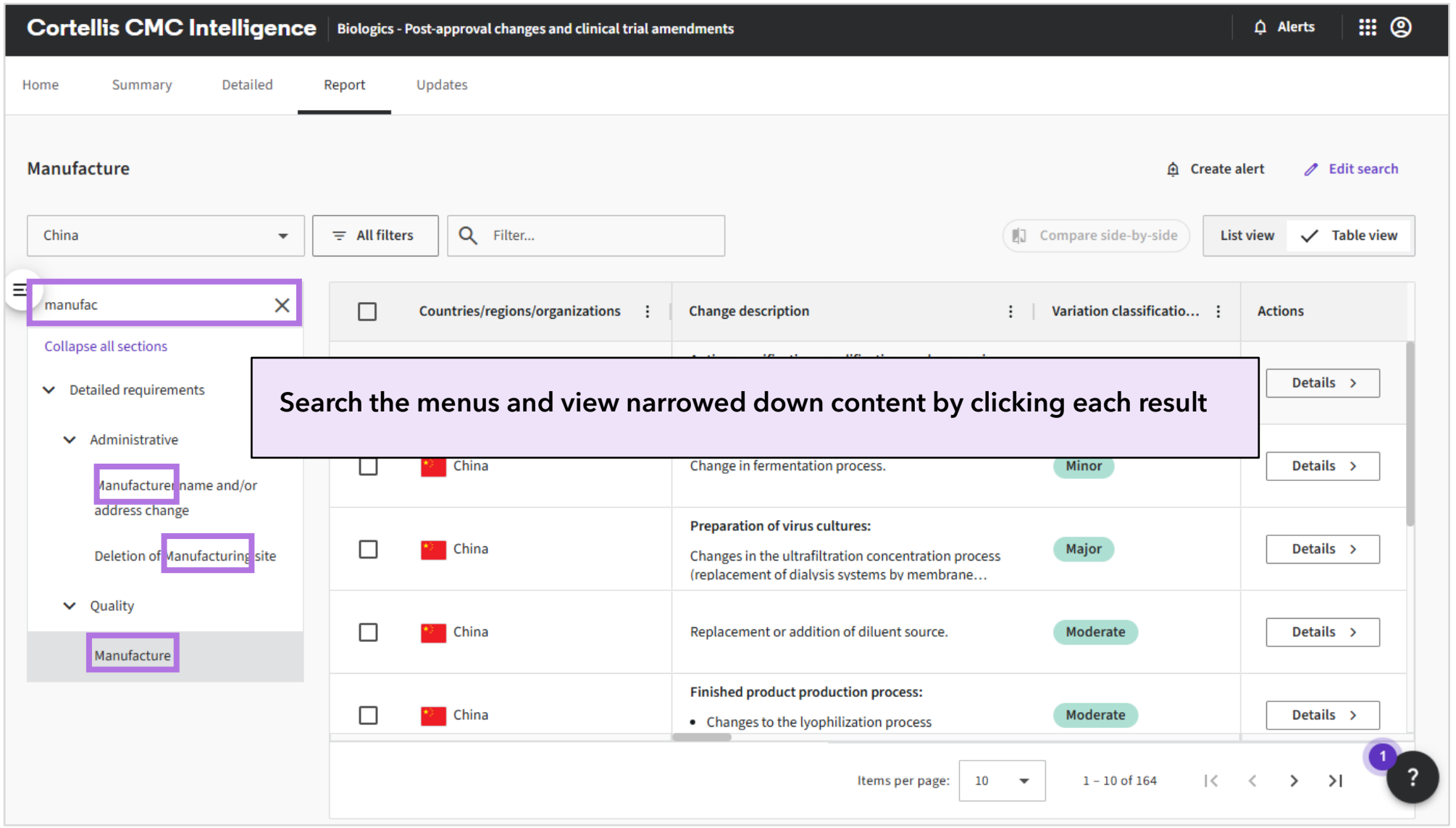
General Provisions

- Marketing authorization holders (hereinafter referred to as holders) for post-marketing changes in drugs, and strengthen the connection between drug registration and production supervision and management of drug regulatory authorities, according to the "Drug Administration Law" " The Vaccine Administration Law, the Measures for the Administration of Drug Registration (Order No. 27 of the State Administration for Market Regulation), and the Measures for the Supervision and Administration of Drug Production (Order No. 28 of the State Administration for Market Regulation) formulate these measures.
- The holder should take the initiative to carry out post-marketing research of drugs to realize the full life cycle management of drugs. Encourage holders to use new production technologies, new methods, new equipment , and new scientific and technological achievements to continuously improve and optimize production processes, continuously improve drug quality, and improve drug safety, effectiveness, and quality controllability.
- The holder is the main body responsible for the post-marketing change management of drugs, and should establish a post-marketing change control system in accordance with relevant requirements of drug regulatory

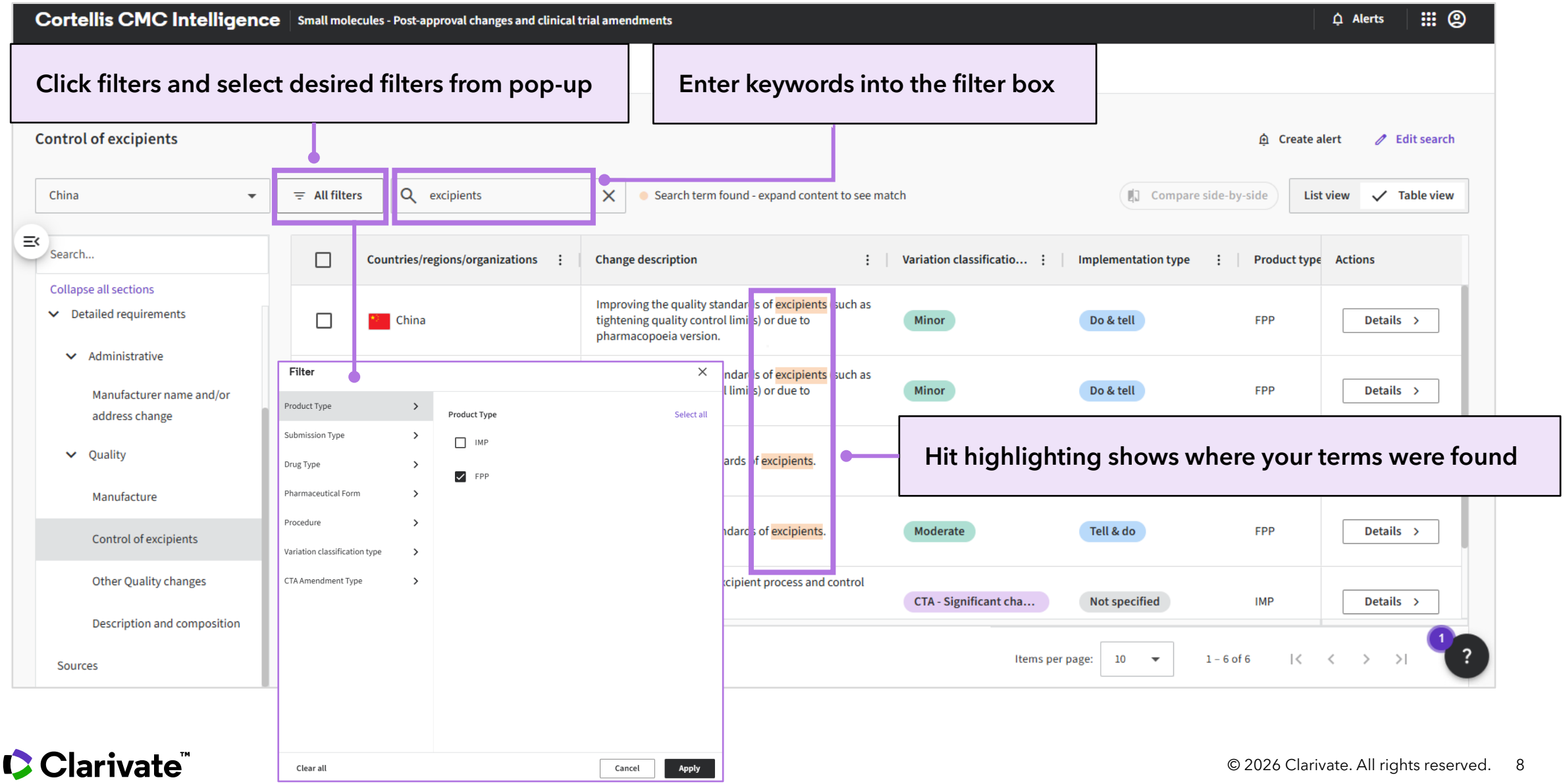
View Reports – Detailed requirements – Module 3 for Pre-approval and Changes for Post-approval changes and clinical trial amendments



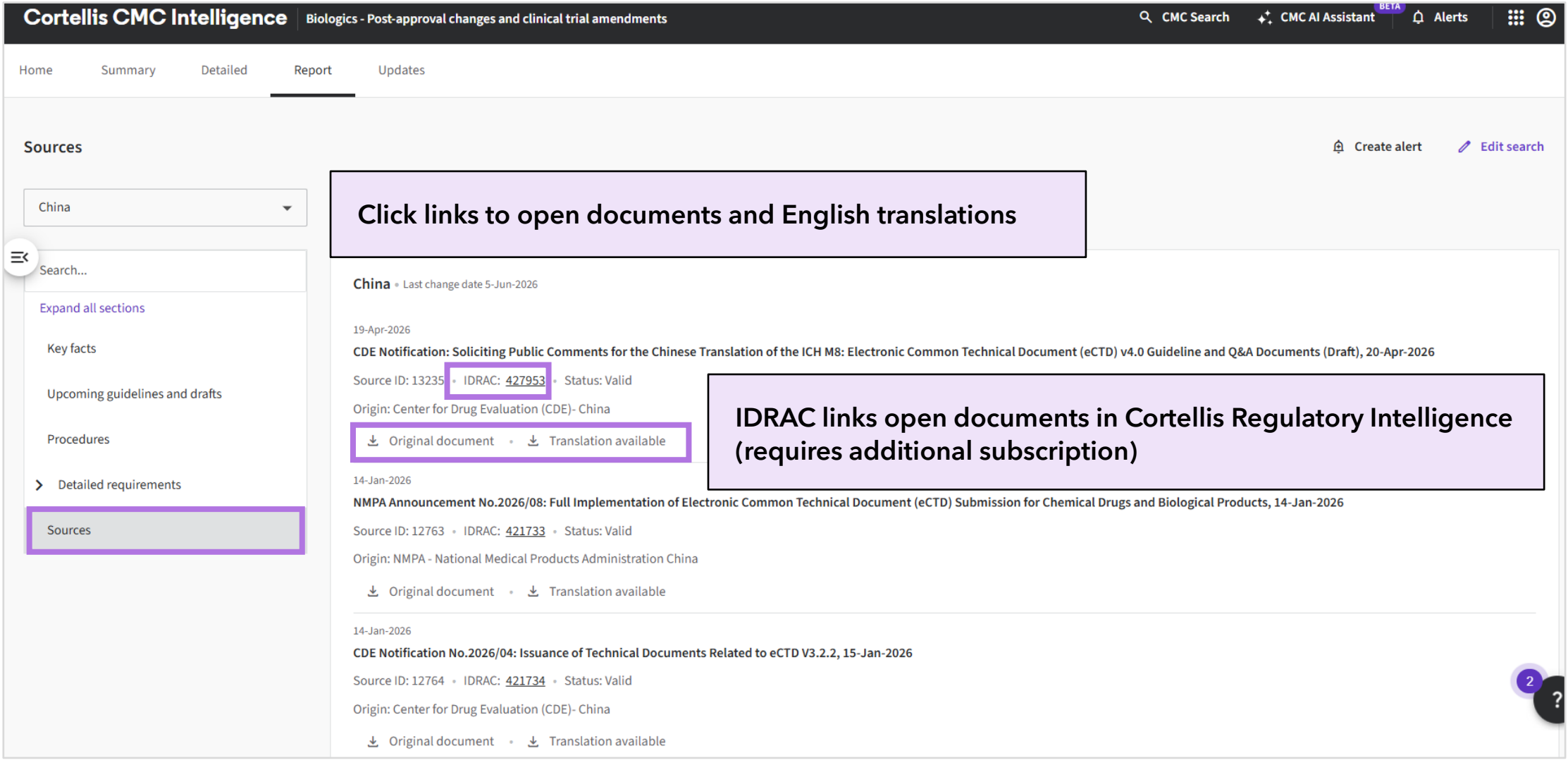
Filtering the Menu Bar



Filtering Report content



Accessing Source documents



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