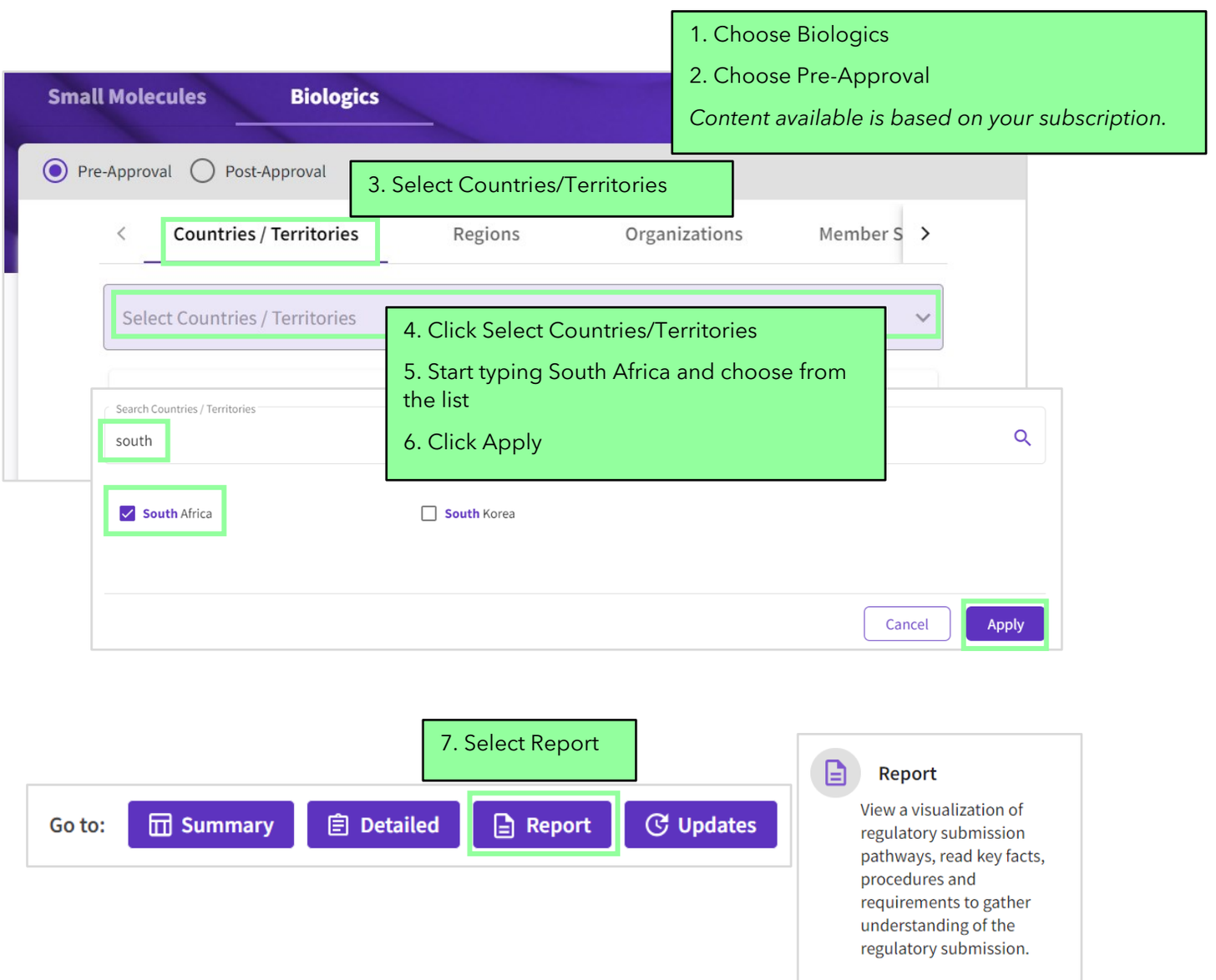
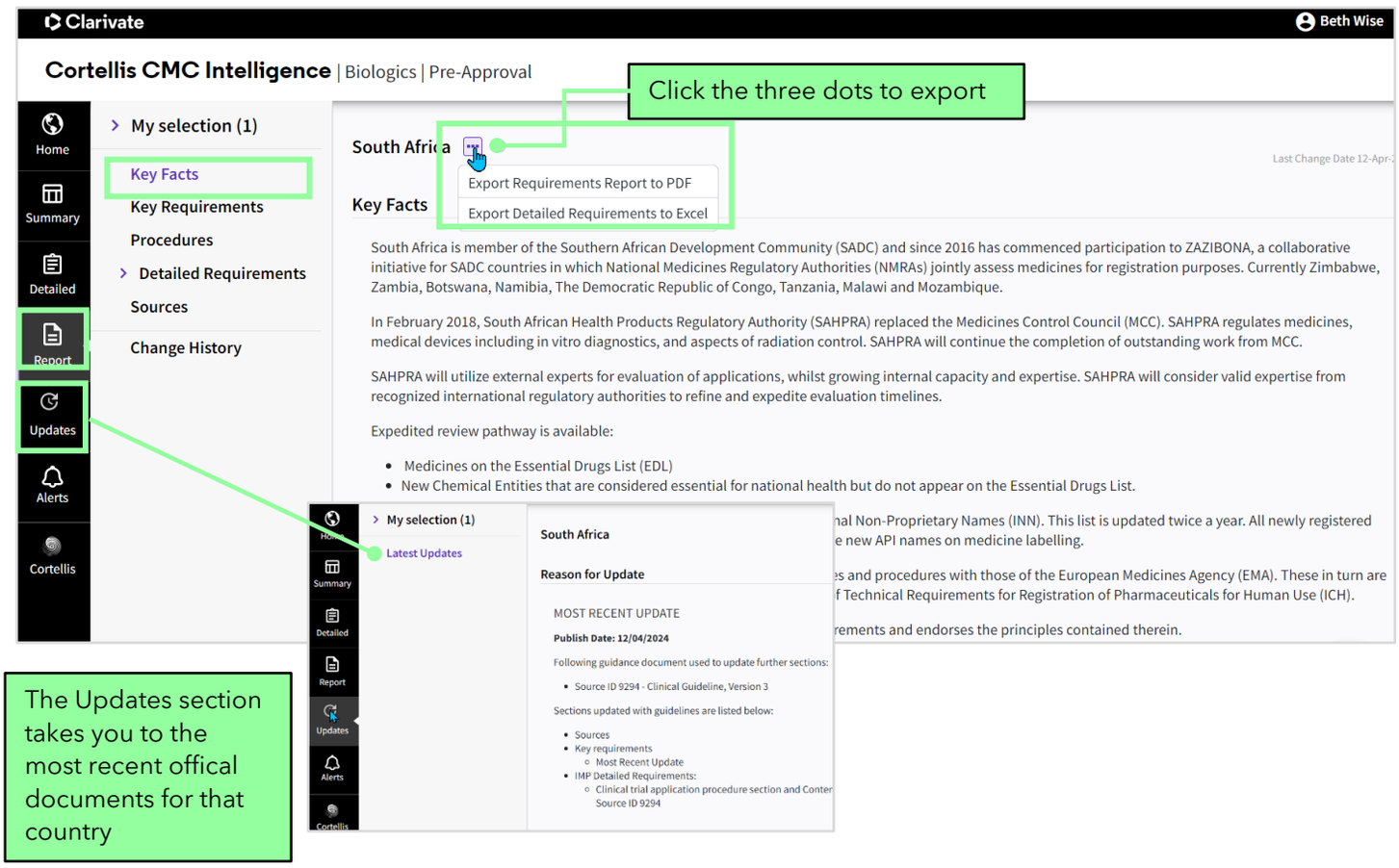
Ensure compliance for a single country

Example: *You have a dossier drawn up for a biologic and already registered in one country, for example the USA. You want to start spreading the dossier throughout Africa since some African countries are included in the collaborative agreement ZAZIBONA that provides a fast-track procedure of the revisions when already approved in one of the member states. You decide to register the product in South Africa to expedite this process.*

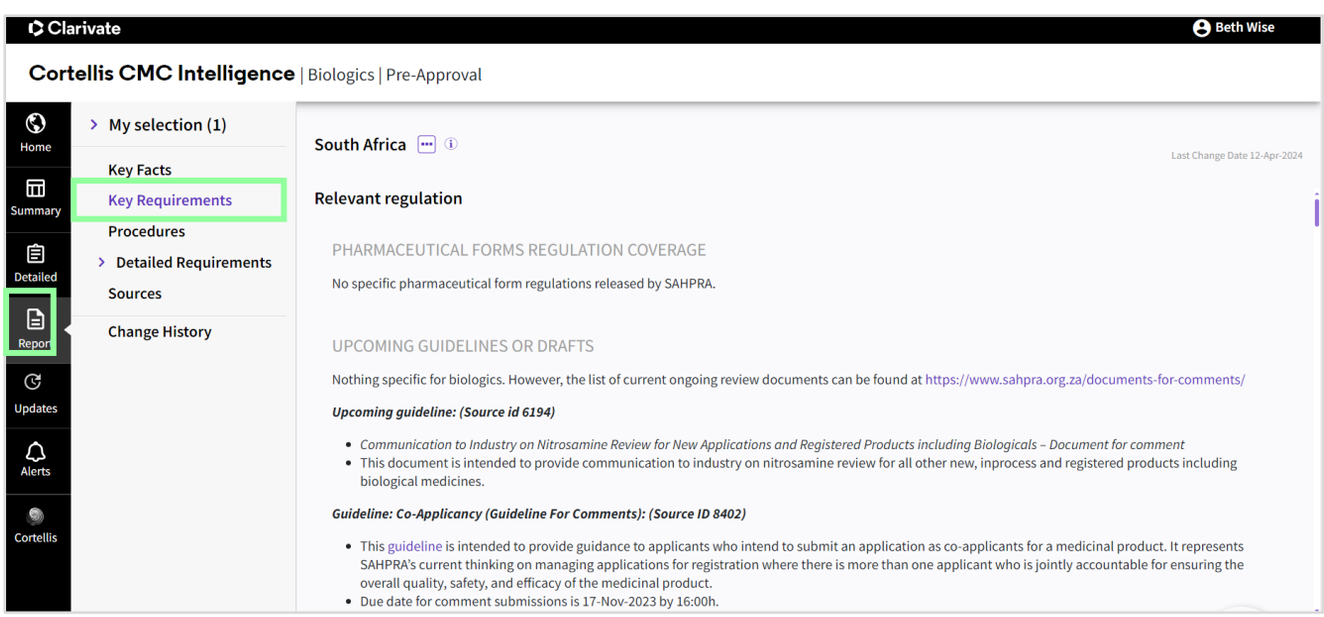


The **Key Facts** section opens. The basics about the Regulatory procedures are explained. Click on **Key Requirements, Procedures, Detailed Requirements, Sources or Change History** in the left-hand menu to navigate to those sections.

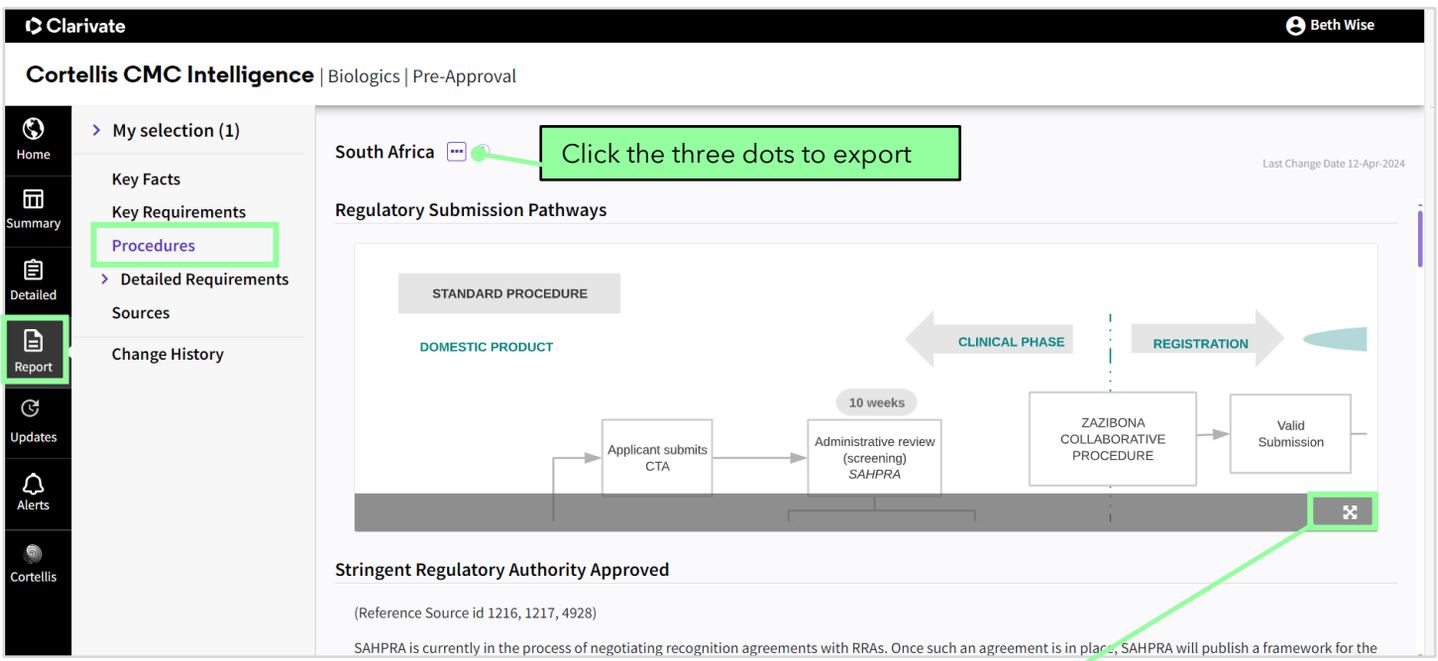


The Updates section takes you to the most recent offical documents for that country

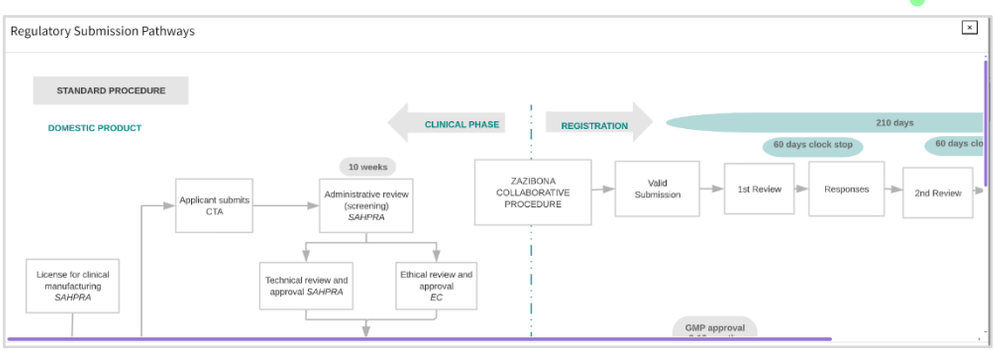
The **Key Requirements** section provides a quick review of regulations and procedures for that country, including upcoming guidelines or drafts, regulations, and other types of documents of note, Import/Export, Format and content of applications, Inspections and more.



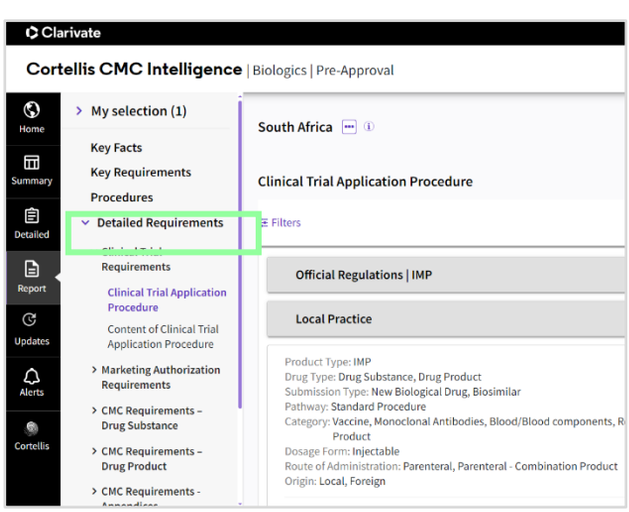
Procedures provides an overview of approval procedures including WHO Prequalification, Collaborative Agreements, Accelerated and priority pathways and more.

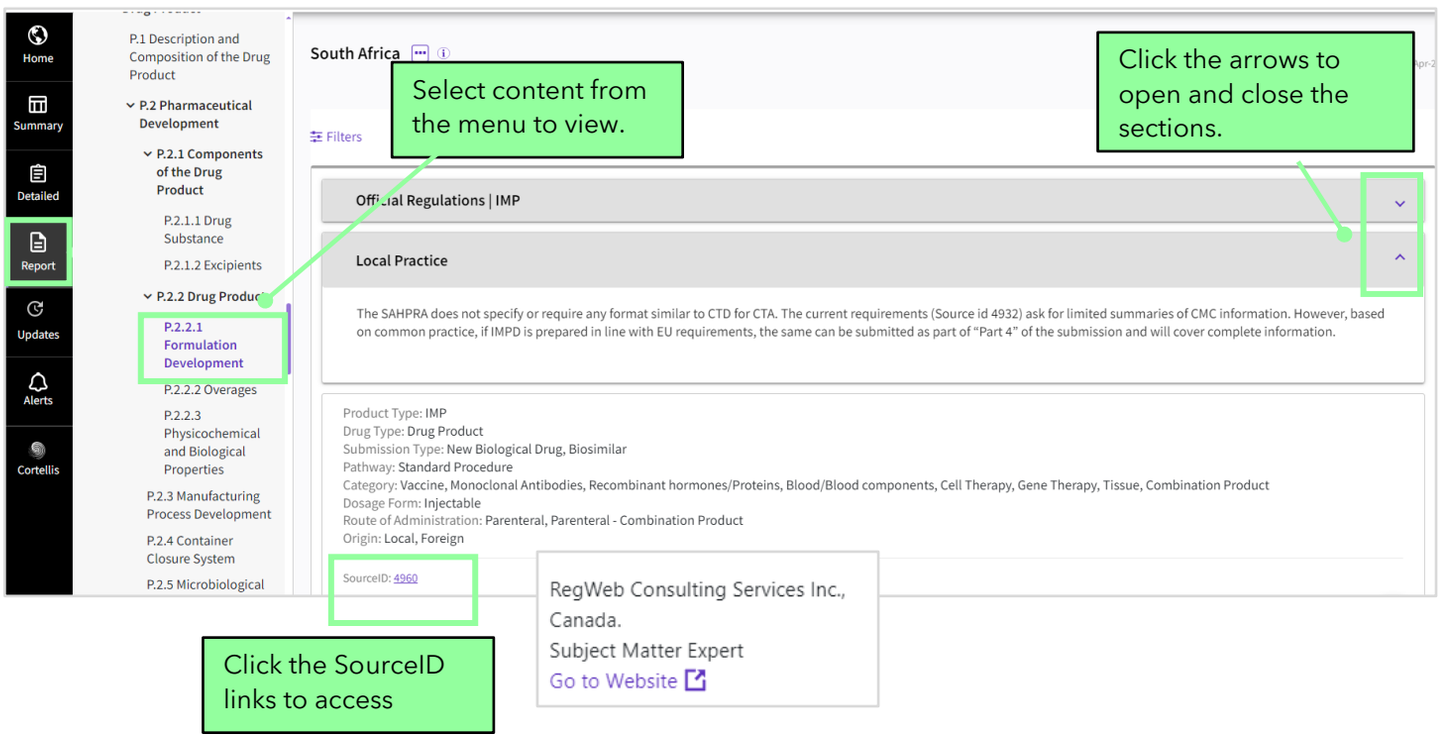


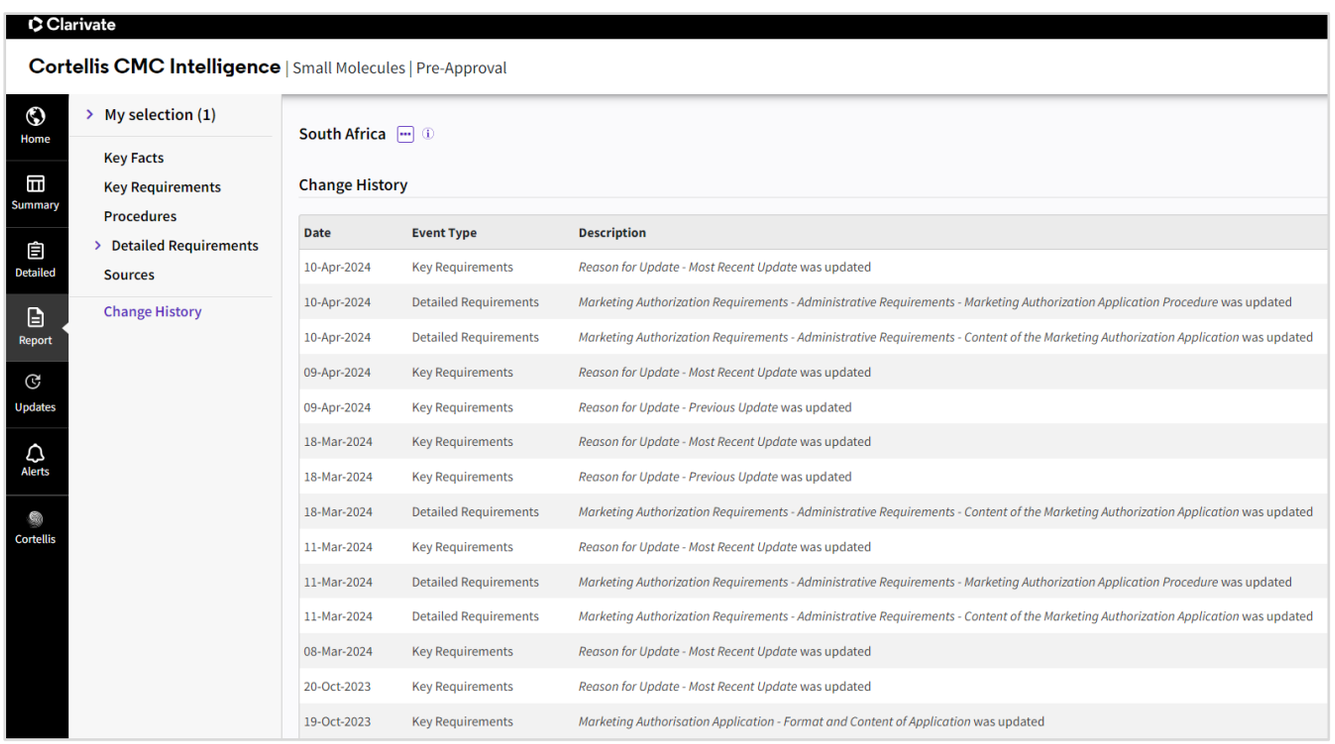
Click the icon to open the Regulatory Submission Pathways flowchart to fortify your strategies. Visual overviews of Estimated actual procedure times and Official times for Clinical Phase and Registration are provided.



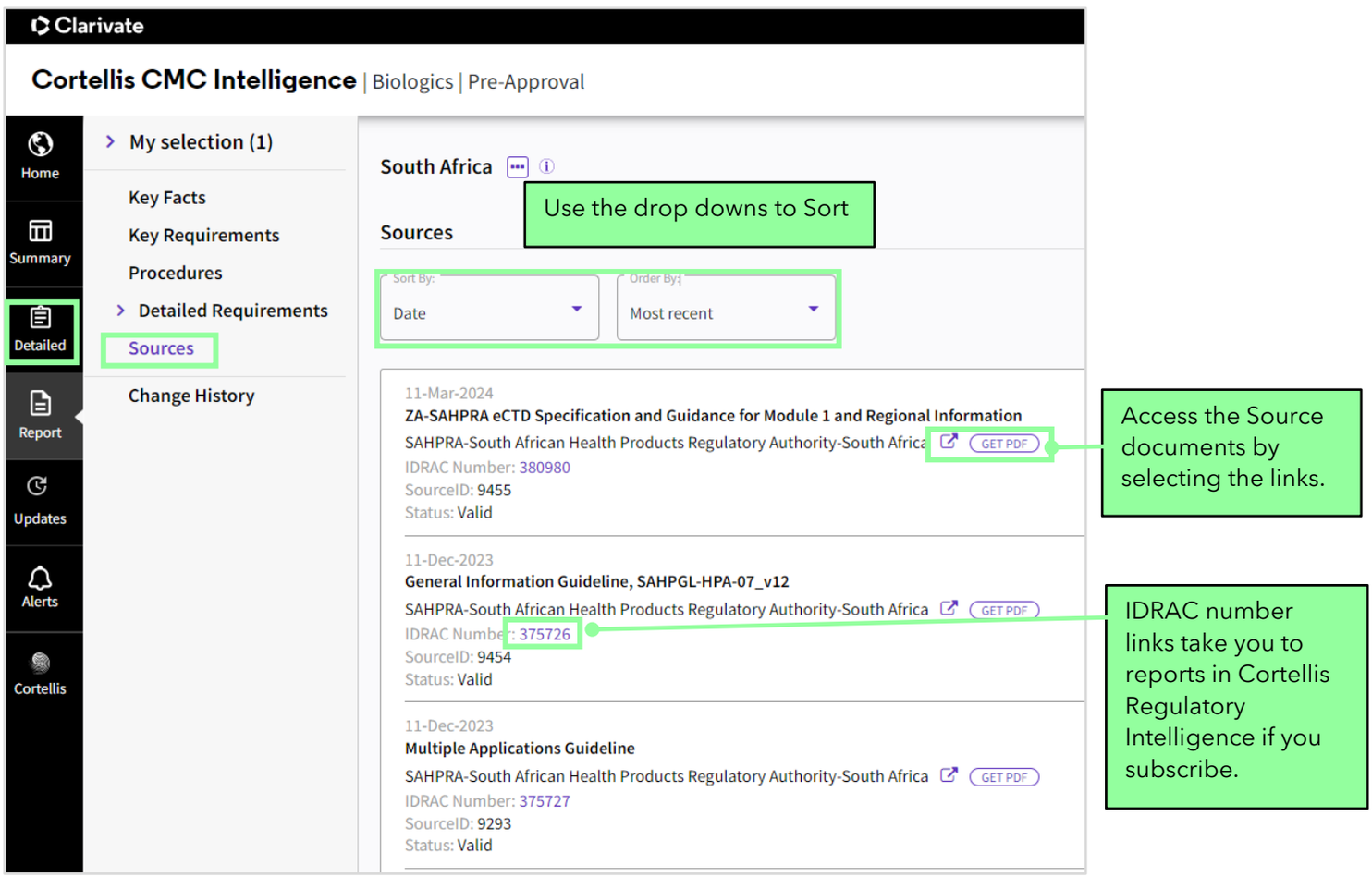
Detailed Requirements provides Official Regulation and Local Practice guidance on Clinical Trial, Marketing Authorization, and eCTD Module 3 requirements.





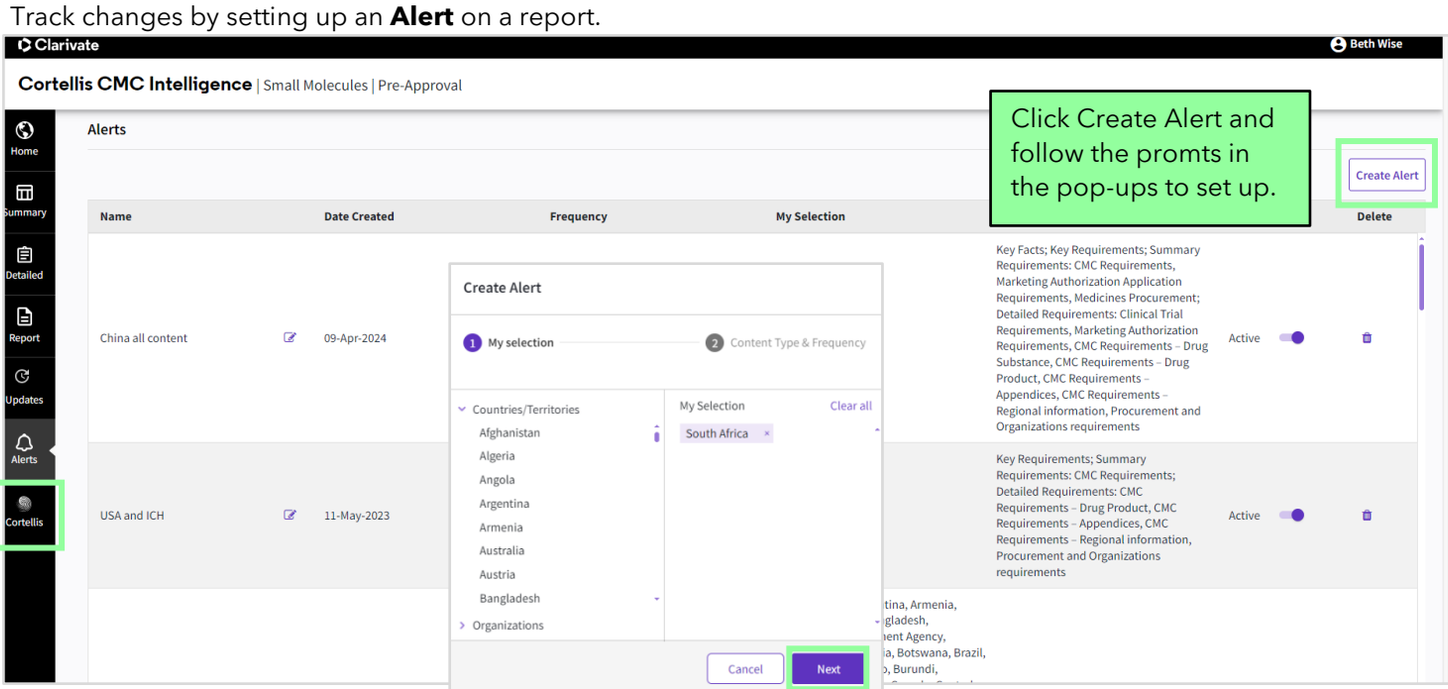


Sources allows you to view and access source documents from the Authorities used to create and update the Reports.



Change History details what's changed in the Report and when.

Track changes by setting up an **Alert** on a report.



For more information contact Customer Service at **LS Product Support**.