How do I ensure compliance for a single country?

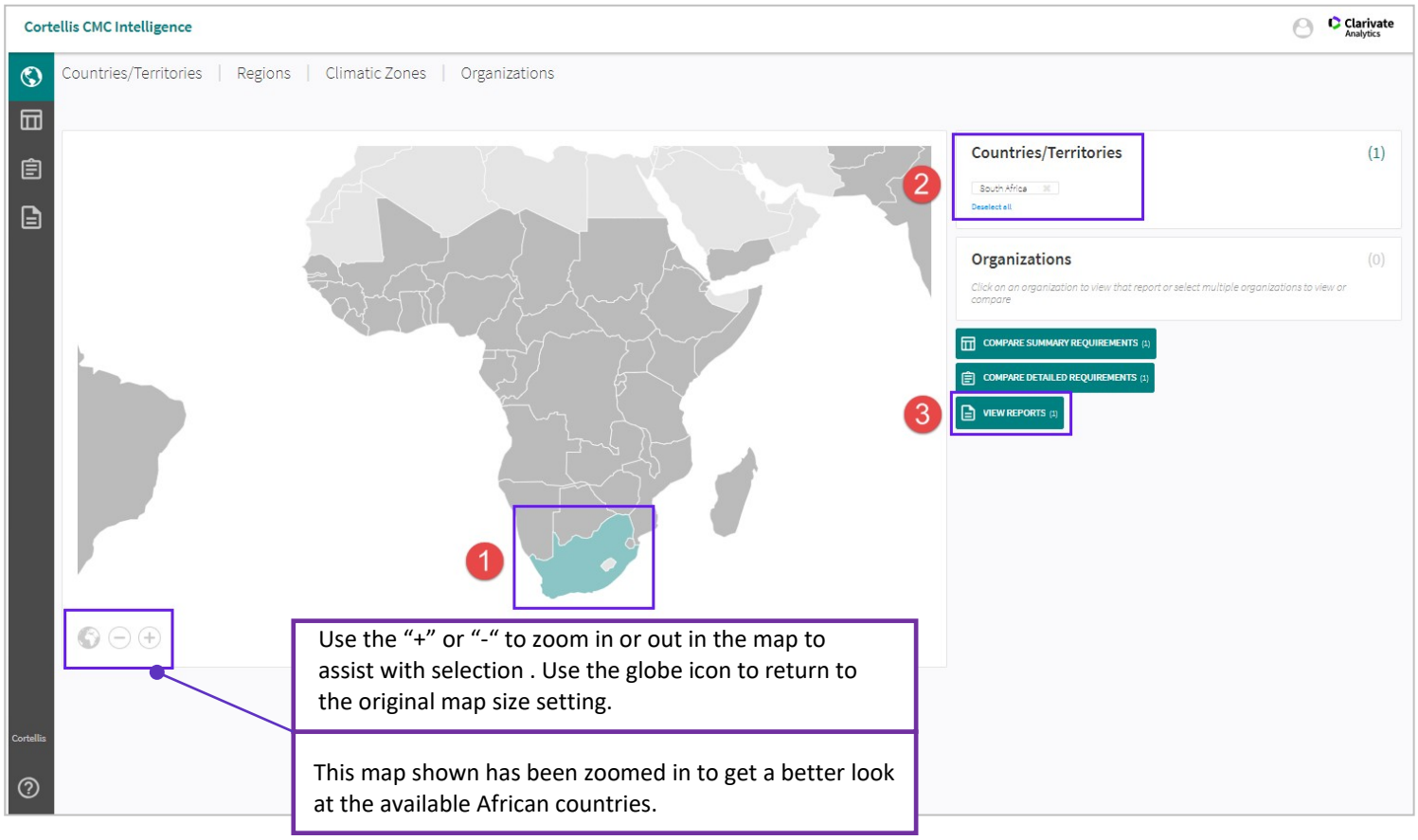
Cortellis CMC Intelligence

Example: Imagine that you have a dossier drawn up and already registered in one country, for example the US. You want to start spreading the dossier in 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 drug product first in South Africa to expedite this process.

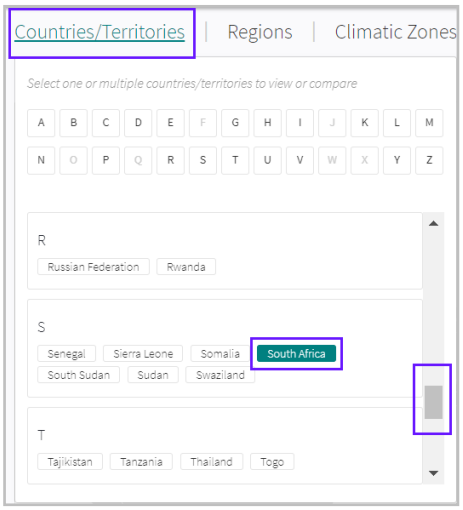
1. Click on“South Africa” on the map. All countries in dark grey on the map have available content. Selected countries turn green.

2. The selected country will appear in the upper right showing it has been selected. Click the “x” marks to the right of each selected country to deselect or click **Deselect all** to start over with the selection process.

3. Click on **View Reports**.



For countries you can't easily locate on the map, click on **Countries/Territories** and select the countries from the drop down that appears.

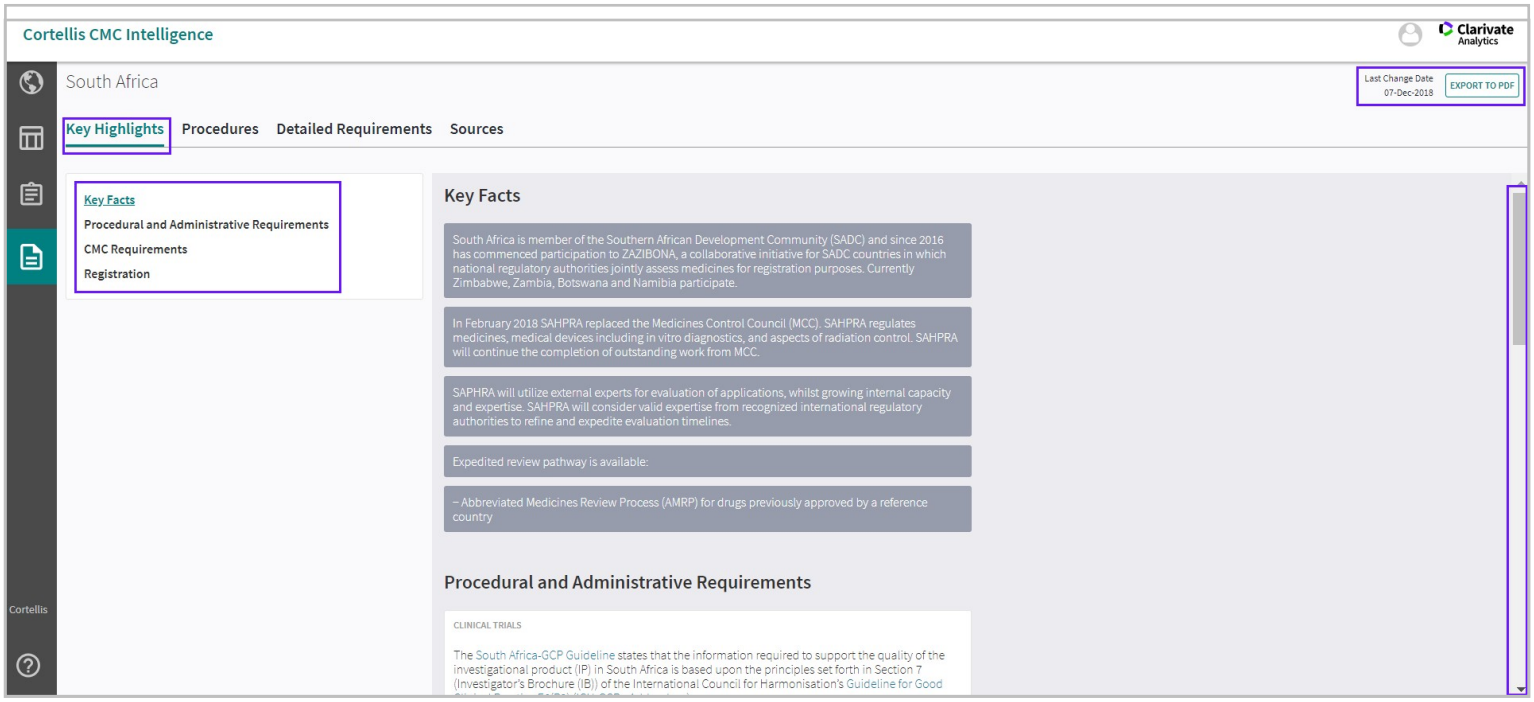


The **Key Highlights** section of the report is shown first. Click on **Procedures**, **Detailed Requirements** or **Sources** to navigate to those sections of the report.

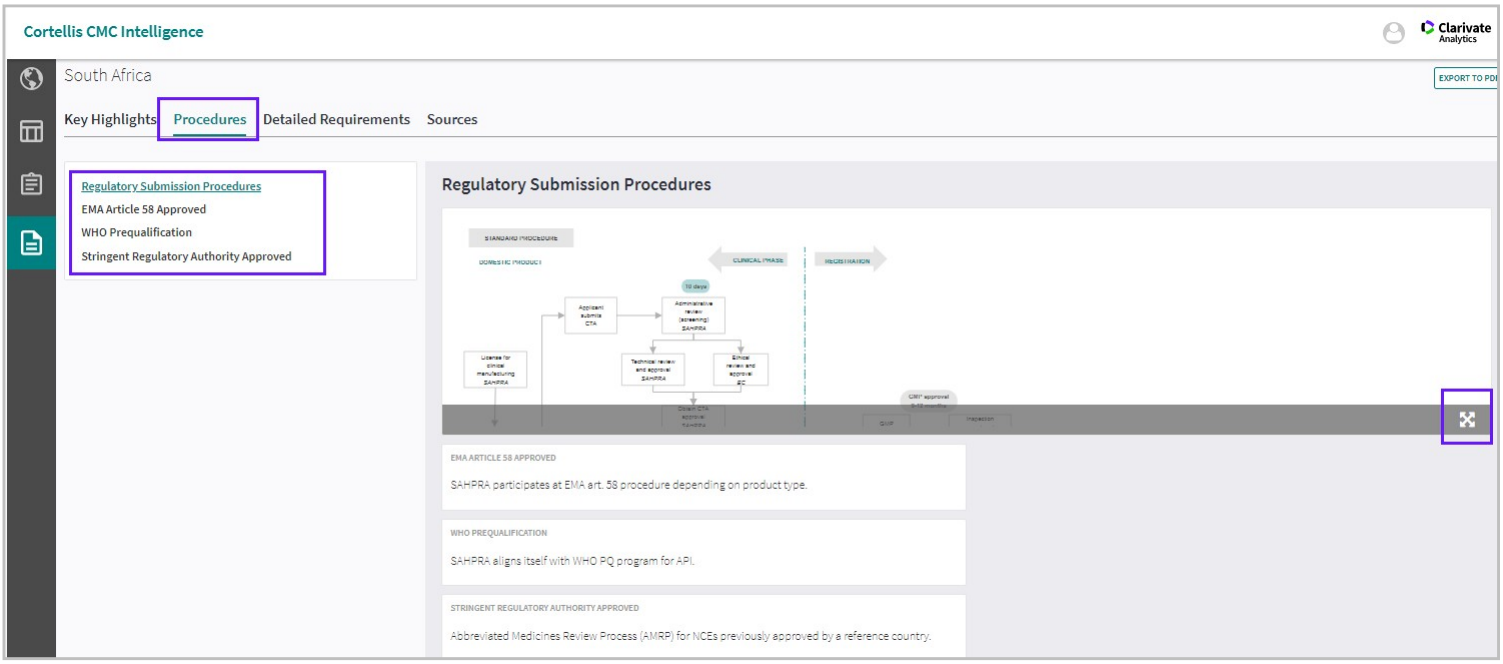
Click the titles on the left under **Key Facts** to jump to information down the page, or use the scroll bar.

Last Change Date shows when the report was last updated.

Export to PDF option is also available by clicking the button in the top right, to export country-specific Detailed Requirements and Summary Requirements content.



Procedures shows an expandable Regulatory Submissions Procedures flow chart as well as other data. Click the "**X**" icon in the lower right to expand the chart.

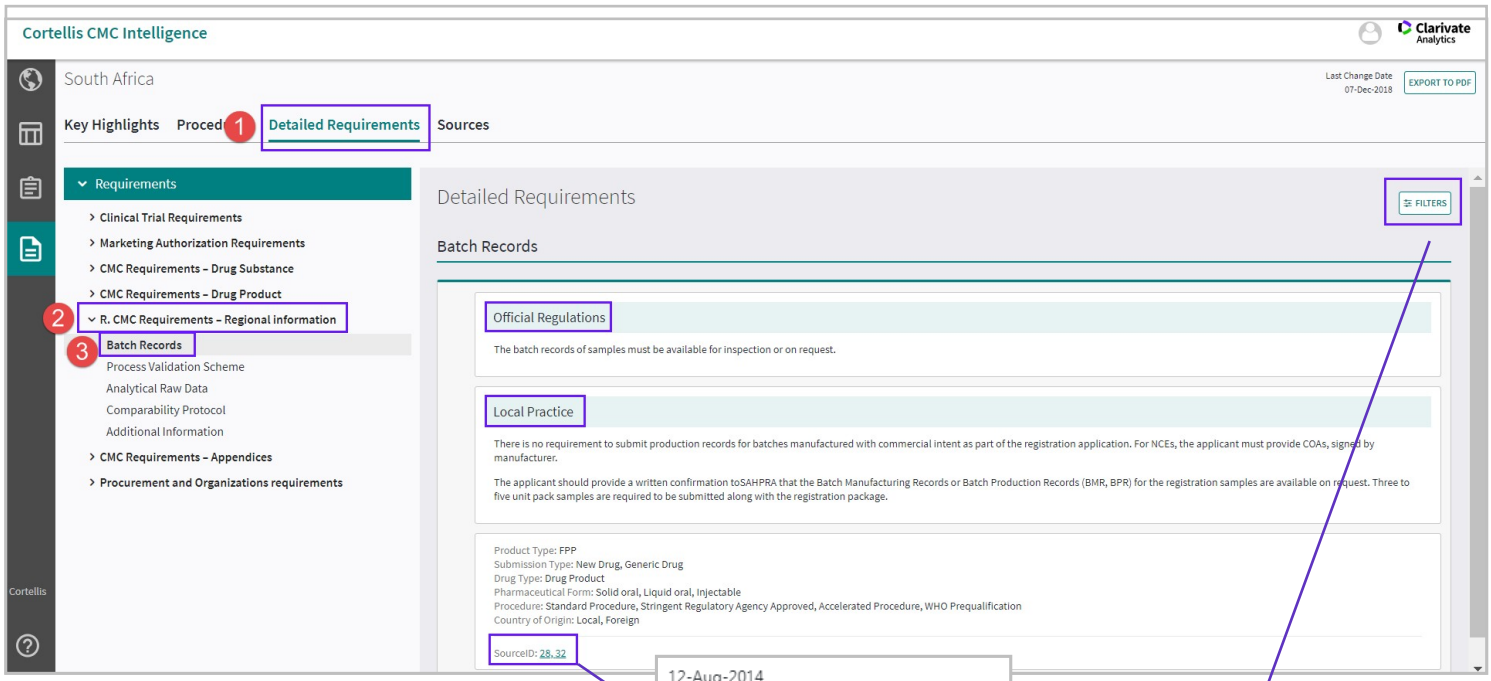


The **Detailed Requirements** section allows you to choose detailed data to view.

Example: You want to see if "Batch Records" is required for South Africa for FPPs (Finished Pharmaceutical Products).

1. Click **Detailed Requirements**
2. Select **CMC Requirements – Regional Information** to expand the menu
3. Select **Batch Records** and **Analytical Raw Data**

Official Regulations are the requirements from the regulatory authority and additional guidance from local consultants is provided in **Local Practice**.



Hover over the **SourceID** number at the bottom of the record to view the source.

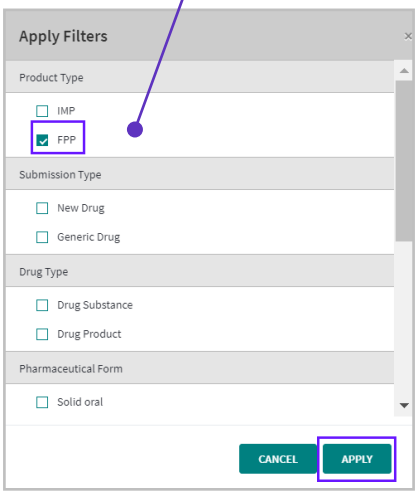
Filters allow you to narrow down the content of the report to just specific types of data.

For example, focus on just the FPP (Finished Pharmaceutical Product).

Click **Filters** in the upper right hand corner of the screen

Tick the boxes in front of the filters you'd like to apply in the pop-up

Click **Apply**.



The **Sources** tab shows the sources used to create the reports. Click the **Get PDF** links to open PDFs.