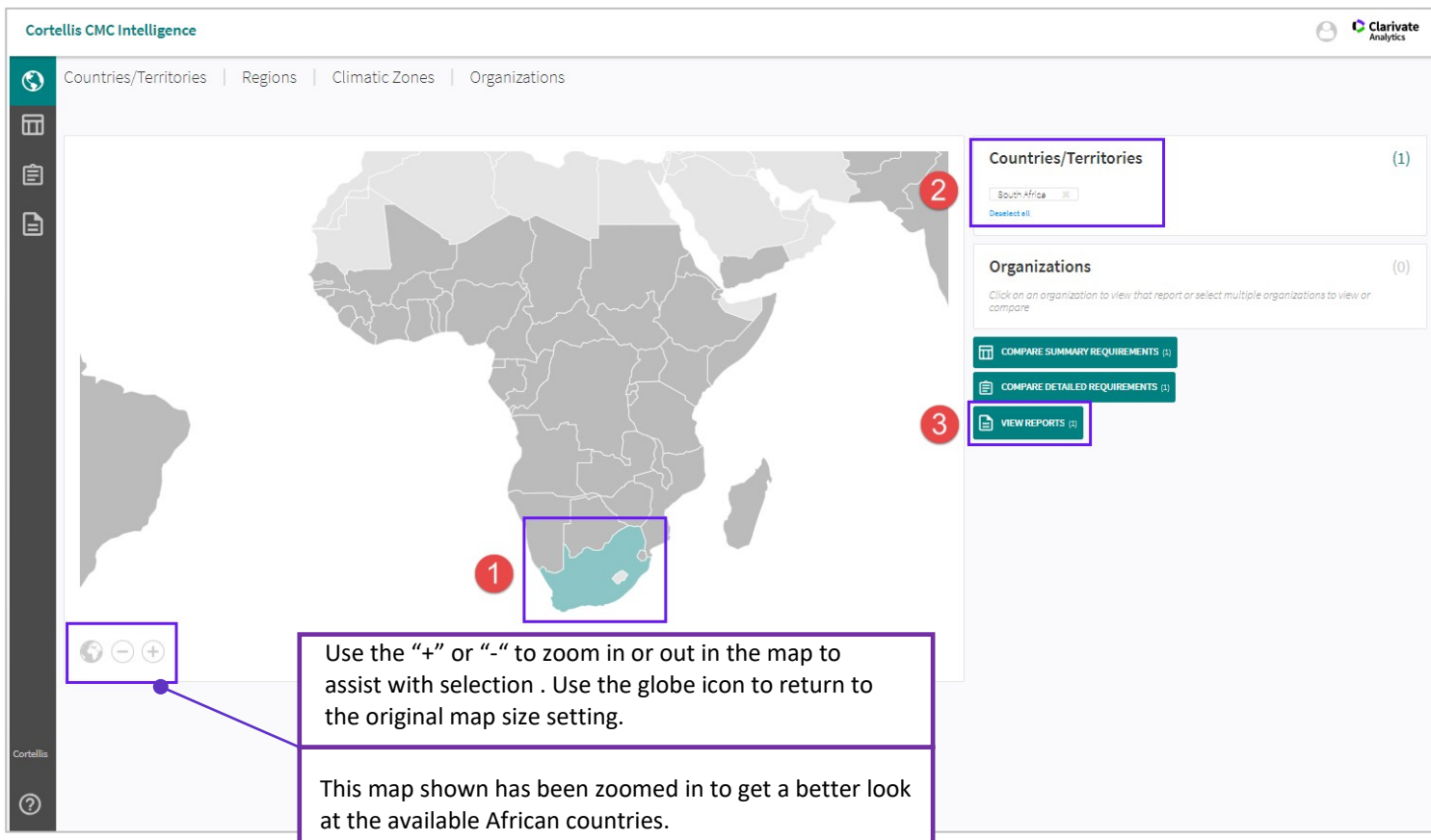


How do I ensure compliance for a single country?

Cortellis CMC Intelligence

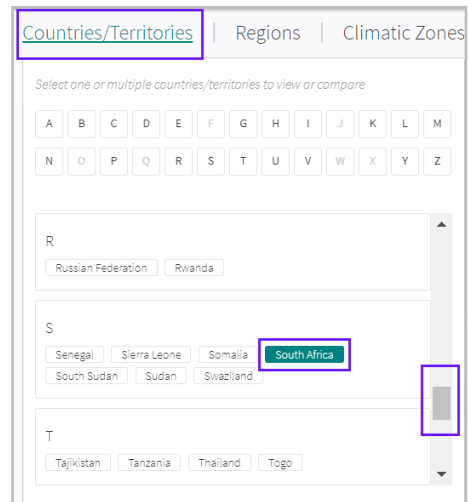
Example: Imagine that you have a dossier drawn up and already registered in one country, for example the US. You want to start spreading the dossier in Africa since some African countries are included in the collaborative agreement ZAZIBONA that provides a fast-track procedure of the revisions when already 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**.



The screenshot displays the Cortellis CMC Intelligence interface. The top navigation bar includes "Countries/Territories", "Regions", "Climatic Zones", and "Organizations". The main map shows Africa with South Africa highlighted in green. A red circle '1' is placed over South Africa. A red circle '2' is placed over the "Countries/Territories" panel on the right, which shows "South Africa" selected. A red circle '3' is placed over the "VIEW REPORTS (1)" button in the right-hand panel. A callout box points to the map's zoom controls, stating: "Use the '+' or '-' to zoom in or out in the map to assist with selection. Use the globe icon to return to the original map size setting." Another callout box below it states: "This map shown has been zoomed in to get a better look at the available African countries." The right-hand panel also shows "Organizations (0)" and buttons for "COMPARE SUMMARY REQUIREMENTS (1)", "COMPARE DETAILED REQUIREMENTS (2)", and "VIEW REPORTS (1)".

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

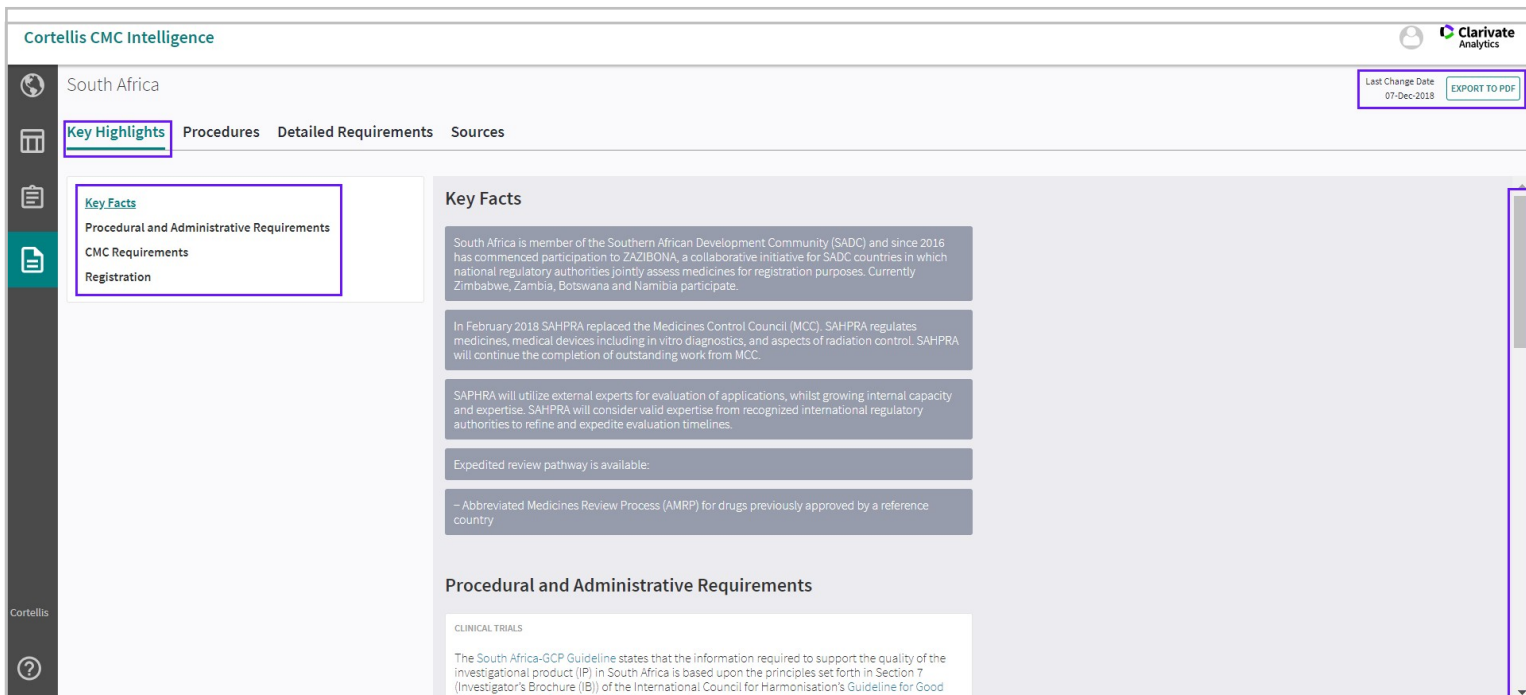


The **Key Highlights** section of the report is shown first. Click on **Procedures, Detailed Requirements or Sources** to navigate to those sections of the report.

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.

Cortellis CMC Intelligence Clarivate Analytics

South Africa EXPORT TO PDF

Key Highlights **Procedures** Detailed Requirements Sources

[Regulatory Submission Procedures](#)

EMA Article 58 Approved

WHO Prequalification

Stringent Regulatory Authority Approved

Regulatory Submission Procedures

EMA ARTICLE 58 APPROVED

SAHPRA participates at EMA art. 58 procedure depending on product type.

WHO PREQUALIFICATION

SAHPRA aligns itself with WHO PQ program for API.

STRINGENT REGULATORY AUTHORITY APPROVED

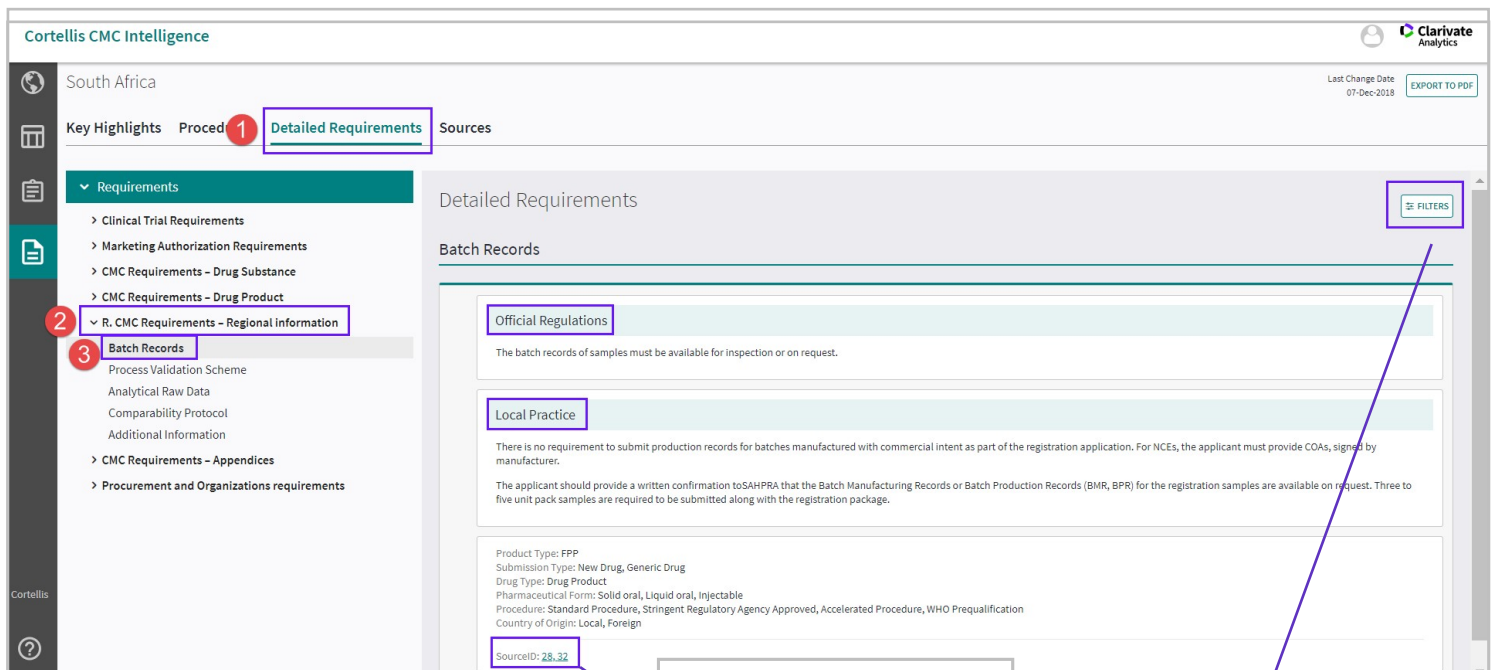
Abbreviated Medicines Review Process (AMRP) for INCEs previously approved by a reference country.

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.

12-Aug-2014
Guideline for registration of medicines -
Pharmaceutical and analytical CTD / eCTD
SAHPRA
IDRAC Number: 201341

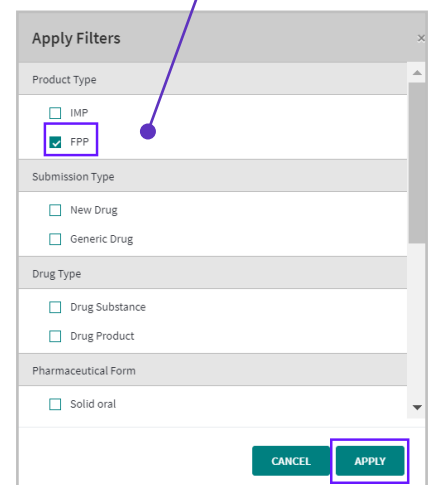
Filters allow you to narrow down the content of the report to just specific types of data.

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.

Cortellis CMC Intelligence

South Africa

Key Highlights Procedures Detailed Requirements **Sources**

30-Jun-2018
Tried Approach Limited, Nairobi, Kenya
Subject Matter Expert
SourceID: 32

01-Jun-2018
Application to conduct a clinical trial
SAHPRA **GET PDF**
SourceID: 674

12-Feb-2018
Press release: APPOINTMENT OF THE SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY (SAHPRA)
SAHPRA **GET PDF**
IDRAC Number: 269820
SourceID: 467

01-Dec-2017
SA Guide to Good Manufacturing Practices for medicines
SAHPRA **GET PDF**
IDRAC Number: 270362
SourceID: 30

25-Aug-2017
MEDICINES AND RELATED SUBSTANCES ACT, 1965 as amended in Aug 2017
SAHPRA **GET PDF**
IDRAC Number: 257804
SourceID: 39

01-Jun-2016
Communication to industry on ZA-CTD implementation
SAHPRA **GET PDF**
SourceID: 31

SAHPRA
South African
Health Products
Regulatory Authority

APPLICATION TO CONDUCT A CLINICAL TRIAL

| | |
|--|--|
| Study Title | |
| Protocol No. | |
| Version No. | |
| Study Medicine | |
| SAHPRA* Ref. no. (if applicable) | |
| SAHPRA* Ref number(s) of comparator medicine(s) (if applicable) | |
| SAHPRA* Ref number(s) of concomitant medicine(s) (if applicable) | |
| Date(s) SAHPRA approval or previous protocol(s) | |
| Sponsor: | |
| Applicant: | |
| Contact Person: | |
| Address: | |
| Telephone No.: | |
| Fax No.: | |
| Cell No.: | |
| E-mail address: | |
| Date of Application: | |

*Refers to registration number for registered medicines issued by MCC

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Help is available on every page. The question mark icon takes you to Customer Care, guides and recorded training.