

## Cortellis CMC Intelligence: how do I ensure compliance for a single country?

*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.*

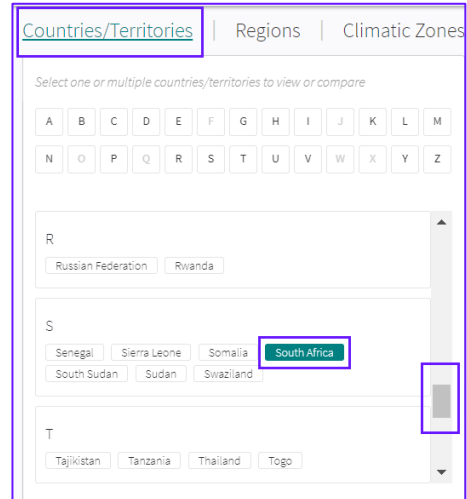
1. Click on “South Africa” on the map. All countries in dark grey on the map have available content. Selected countries turn green.
2. The selected country will appear in the upper right showing it has been selected. Click the “x” marks to the right of each selected country to deselect or click **Deselect all** to start over with the selection process.
3. Click on **View Reports**.

The screenshot displays the Cortellis CMC Intelligence interface. At the top, the title 'Cortellis CMC Intelligence' is visible, along with the Clarivate Analytics logo. Below the title, there are navigation tabs: 'Countries/Territories', 'Regions', 'Climatic Zones', and 'Organizations'. The main area features a map of Africa, where South Africa is highlighted in green, indicating it is selected. A red circle with the number '1' points to South Africa on the map. A red circle with the number '2' points to the 'Countries/Territories' panel on the right, which shows 'South Africa' selected and a 'Deselect all' button. A red circle with the number '3' points to the 'VIEW REPORTS (1)' button in the right-hand panel. A callout box with a blue border and an arrow pointing to the map's zoom controls (globe, minus, plus) contains the following text:

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.

This map shown has been zoomed in to get a better look at the available African countries.

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

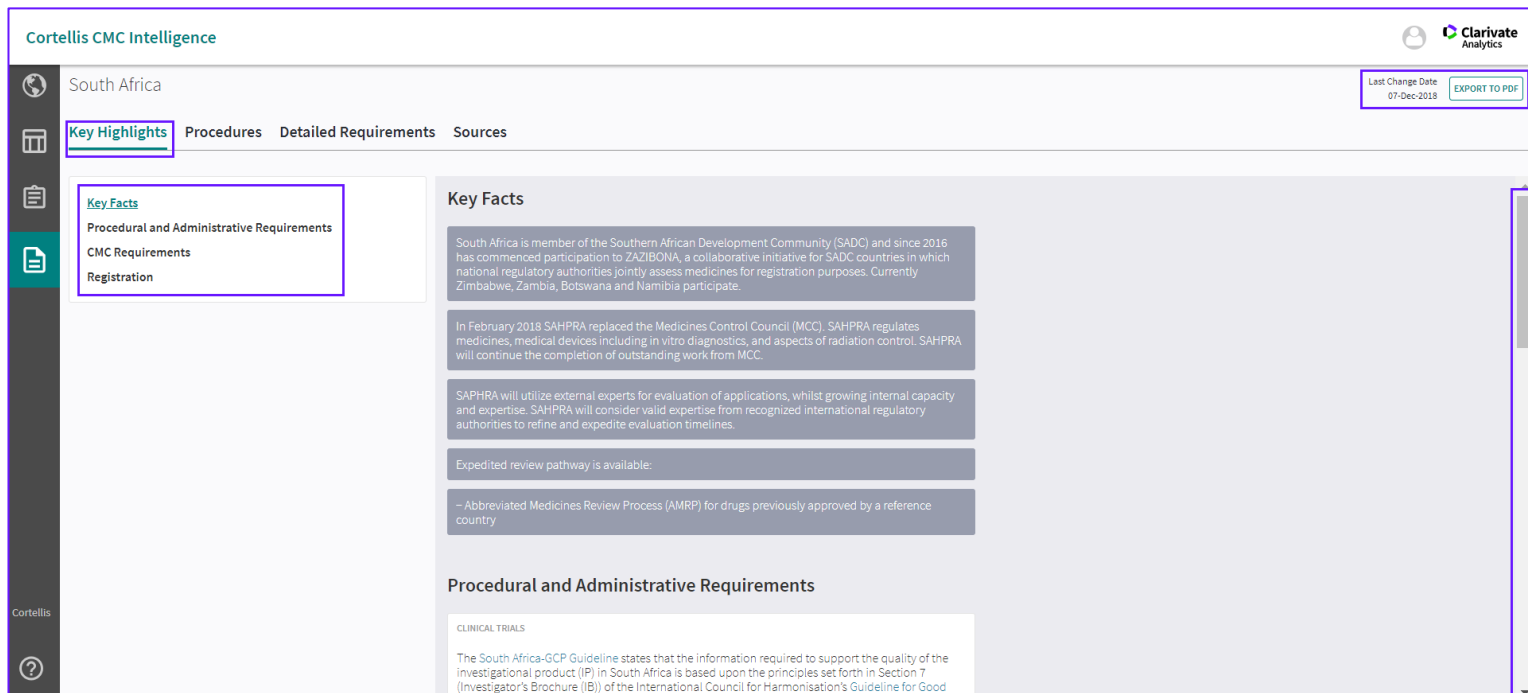


The **Key Highlights** section of the report is shown first. Click on **Procedures**, **Detailed Requirements** or **Sources** to navigate to those sections of the report.

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 screenshot displays the Cortellis CMC Intelligence interface for South Africa. The top navigation bar includes 'South Africa' and 'EXPORT TO PDF'. Below this, there are tabs for 'Key Highlights', 'Procedures', 'Detailed Requirements', and 'Sources'. The 'Procedures' tab is active, showing a list of regulatory submission procedures: 'Regulatory Submission Procedures', 'EMA Article 58 Approved', 'WHO Prequalification', and 'Stringent Regulatory Authority Approved'. The main content area is titled 'Regulatory Submission Procedures' and features a flow chart. The flow chart is divided into 'STANDARD PROCEDURES' and 'REGISTRATION'. The 'STANDARD PROCEDURES' section includes 'DOMESTIC PRODUCT' and 'TO BE REVIEWED'. The 'REGISTRATION' section includes 'REGISTRATION'. Below the flow chart, there are three text boxes: 'EMA/ARTICLE 58 APPROVED', 'WHO PREQUALIFICATION', and 'STRINGENT REGULATORY AUTHORITY APPROVED'. An 'X' icon in the bottom right corner of the flow chart area indicates that the chart can be expanded.

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**.

Cortellis CMC Intelligence

South Africa

Key Highlights **1** Detailed Requirements Sources

Requirements

- Clinical Trial Requirements
- Marketing Authorization Requirements
- CMC Requirements – Drug Substance
- CMC Requirements – Drug Product
- 2** **3** R. CMC Requirements – Regional information
- Batch Records
- Process Validation Scheme
- Analytical Raw Data
- Comparability Protocol
- Additional Information
- CMC Requirements – Appendices
- Procurement and Organizations requirements

Detailed Requirements

Batch Records

Official Regulations

The batch records of samples must be available for inspection or on request.

Local Practice

There is no requirement to submit production records for batches manufactured with commercial intent as part of the registration application. For NCEs, the applicant must provide COAs, signed by manufacturer.

The applicant should provide a written confirmation to SAHPRA that the Batch Manufacturing Records or Batch Production Records (BMR, BPR) for the registration samples are available on request. Three to five unit pack samples are required to be submitted along with the registration package.

Product Type: FPP  
Submission Type: New Drug, Generic Drug  
Drug Type: Drug Product  
Pharmaceutical Form: Solid oral, Liquid oral, Injectable  
Procedure: Standard Procedure, Stringent Regulatory Agency Approved, Accelerated Procedure, WHO Prequalification  
Country of Origin: Local, Foreign

SourceID: 28\_32

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

EXPORT TO PDF

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**.

Apply Filters

Product Type

- IMP
- FPP

Submission Type

- New Drug
- Generic Drug

Drug Type

- Drug Substance
- Drug Product

Pharmaceutical Form

- Solid oral

CANCEL APPLY

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

The screenshot displays the Cortellis CMC Intelligence interface for South Africa. The 'Sources' tab is active, showing a list of regulatory updates. A callout box highlights a 'GET PDF' link for the source 'Application to conduct a clinical trial' dated 01-Jun-2018. Another callout box shows a preview of the 'Clinical Trial Application Form' from SAHPRA (South African Health Products Regulatory Authority), which includes fields for study title, protocol number, version, sponsor, and applicant information. A third callout box points to a question mark icon in the bottom left corner of the interface.

**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

**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.

If you have any questions or would like further training, please contact us at: [cortellislearningcenter@clarivate.com](mailto:cortellislearningcenter@clarivate.com)