Portfolio Feasibility Report



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Revision Log

Date	Changed By	Summary of Changes
11 Mar 2019	Jennifer Gross	Initial draft of Instructions – transferred from PowerPoint

Instructions

1. What is the Portfolio Feasibility Report about?

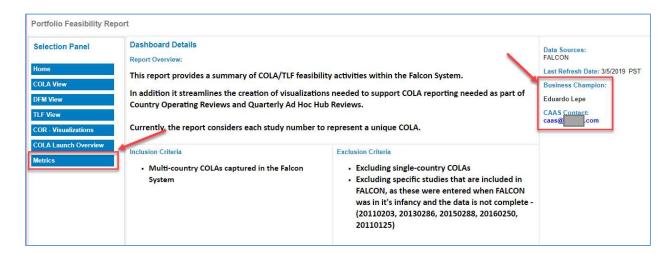
The "Portfolio Feasibility Report", or PFR, was developed to provide visibility to the status of ongoing feasibility efforts (COLAs and TLFs) tracked within the FALCON system and provide visualizations to support feasibility reporting needs related to Country Operating Reviews and Quarterly Hub Reviews. The tool is built using Spotfire and leverages data exported from FALCON to DevODS as well as other study data on DevODS.

2. Where can I find the Portfolio Feasibility Report?

- Here is a Link to the Portfolio Feasibility Report: Link
- FSP teammates should use their FSP Portal to access the report

3. Who can help me if I have an issue with the Portfolio Feasibility Report?

- On the right side of the Home page you will find information on the source of data, when it last refreshed and personnel responsible for this report.
- In addition, on the bottom left there is a link to the Metrics section which has information about how values are calculated within the report
- Please contact the CAAS mailbox should you have any specific questions about the report that are not addressed in any of these resources.



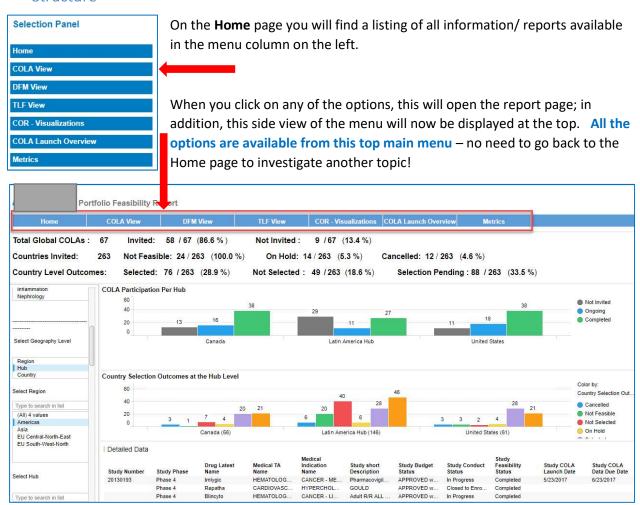
4. How does the Portfolio Feasibility Report Work? – Data Sources

- FALCON is the primary source for data.
 - Ensure that FALCON is up to date
- DevODS FALCON data is ported to DevODS daily
 - Any changes made to FALCON Study level information prior to 9 AM Pacific will be available in DevODS and therefore the Portfolio Feasibility Report by 10:30 PM the following evening.
 - Any changes made to FALCON Study-Country level information prior to Noon Pacific will be available in DevODS and therefore the Portfolio Feasibility Report by 10:30 PM the following evening.

 Other DevODS sources are updated on varying schedules from other operational systems.

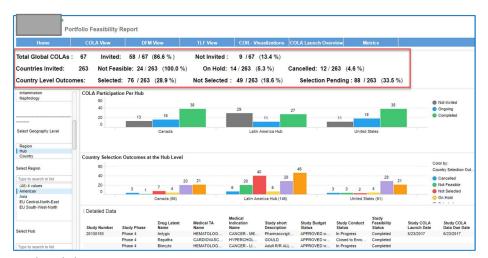
• Risks & Issues

- Country level data that is deleted from FALCON is preserved in DevODS. We currently conduct a monthly review to remove those records from DevODS. There will be instances where the Portfolio Feasibility Report contains country level information which is not present in FALCON.
- There may also be instances where country level data appears to be duplicated.
 This is the result of data being deleted in FALCON, preserved in DevODS and then the country is added back to FALCON for the same study and we wind up with multiple county level records in DevODS for a single feasibility effort.
- 5. How does the Portfolio Feasibility Report work? Home Page and General Tool Structure

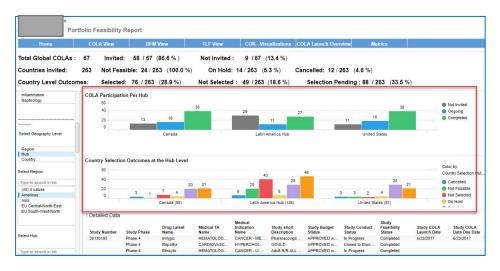


Most of the reports available share the same structure:

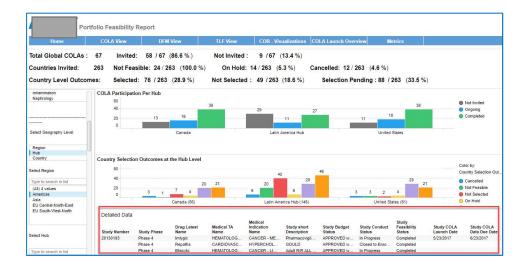
Metrics at the top of the screen



• Graphical data – to allow visualization of the topic and provide a means to take screenshots for presentations

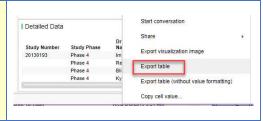


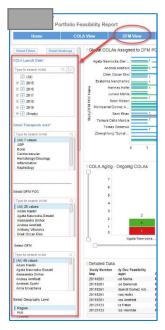
• Table view - which can be exported to Excel





To **EXPORT** table view information to **EXCEL** in any of the topics, right-click on any table cell and choose **Export table** from the menu window!



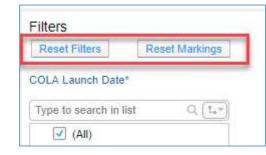


For each of the reports on the menu, several **filter options** are available on the left side. The filters available will depend on the information provided for that specific report.

Making the best use of the filters will optimize your experience with the PFR!

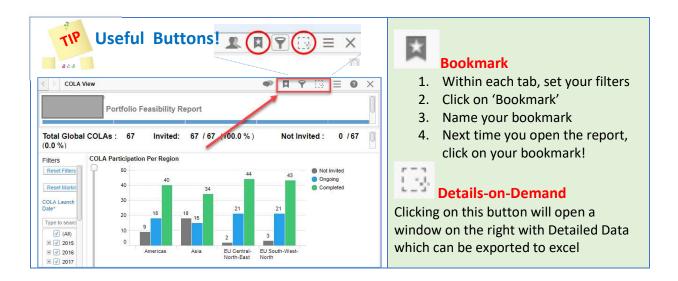


At the top of the left side filter options panel on most of the reports you will find two buttons, one to **Reset Filters**, the other to **Reset Markings**. Use these buttons to clear all of the filters or markings.





On the graphical views, you can move the buttons next to the x-axis and y-axis to modify the scale and improve the graphic visualization.



6. What information is available? – Reports/dashboards

The main menu offers the following options:

- COLA View
- DMF View
- TLF View
- COR Visualizations
- COLA Launch Overview
- Metrics

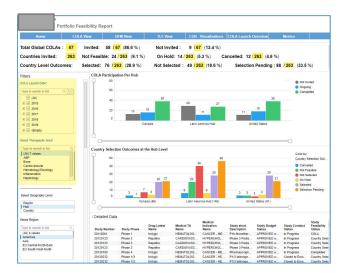
Let's go over each in detail.

7. COLA View

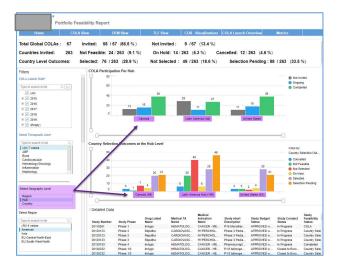


• Filtering: It is important to understand how the filtering works for this view as the metrics are designed to compare the selected Hub, Region or Country against the total Global COLAs for the time period and Therapeutic Area(s) specified.

The two top filters, **COLA Launch Date** and **Therapeutic Area** control the denominators of the metrics at the top of the page. Be sure to select the proper **period of interest** for your analysis.



• Grouping: The **Geographic Level** controls the **grouping** of the charts. In this example we are grouping by Hub:



The remaining filters give you the ability to restrict the visualizations and metrics to specific Countries, Hubs, Regions, etc. In the examples above the data is filtered for Region = Americas.

• Metrics: Let's look at the metrics at the top of the page in detail:

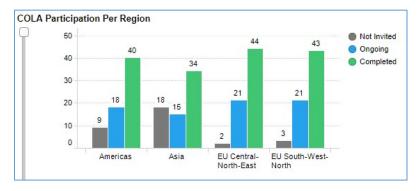
```
Total Global COLAs: 67 Invited: 58 / 67 (86.6 %) Not Invited: 9 / 67 (13.4 %)

Countries Invited: 263 Not Feasible: 24 / 263 (9.1 %) On Hold: 14 / 263 (5.3 %) Cancelled: 12 / 263 (4.6 %)

Country Level Outcomes: Selected: 76 / 263 (28.9 %) Not Selected: 49 / 263 (18.6 %) Selection Pending: 88 / 263 (33.5 %)
```

• Total Global COLAs: Count of multiple-country COLAs for the selected Therapeutic Area(s) with COLA Launch Date (Study Level) during the time period specified

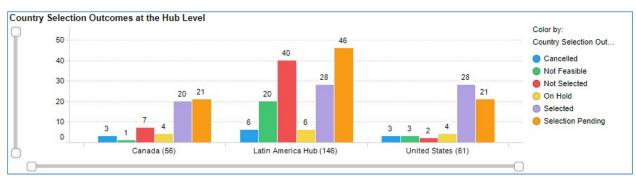
- Invited: Count of multiple-country COLAs for the selected Therapeutic Area(s) with COLA Launch Date (Study Level) during the time period specified to which the selected (filtered) Countries/Hubs/Regions have been invited to participate
- Not Invited: Count of multiple-country COLAs for the selected Therapeutic Area(s) with COLA Launch Date (Study Level) during the time period specified to which the selected (filtered) Countries/Hubs/Regions have been invited to participate
 - o Calculation: Total Global COLAs Invited
- Countries Invited: Count of # of countries that have been invited to participate in multiple-country COLAs for the selected Therapeutic Area(s) with COLA Launch Date (Study Level) during the time period specified
- **Not Feasible**: It has been determined that it is not feasible for the country to participate in the study.
- On Hold: COLA is currently on hold. Study Feasibility Status = "On Hold"
- Cancelled: Feasibility has been cancelled.
 - Study Feasibility Status = "Cancelled"
 - or Final COLA Outcome = "Not Feasible"
 - o or COLA Stage = "COLA Declined"
 - o or COLA Stage = "COLA Withdrawn"
- Selected: Country has been selected to participate in the study. Country Selection = "Selected"
- Not Selected: Country has NOT been selected to participate in the study. Country Selection = "Not Selected"
- **Selection Pending**: It has not yet been determined whether the country will participate in the study. Country Selection IS blank.
- COLA Participation by Region/Hub/Country Let's look at the top visualization



COLA Participation Status is determined by the value of the Study Feasibility Status in FALCON. If a Country/Region/Hub has not been invited to participate in a COLA, the status = "Not Invited"

STUDY_FEASIBILITY_STATUS values	COLA Completed or Ongoing?
Active	Ongoing
Assigned	Ongoing
COLA launch pending	Ongoing
COLA	Ongoing
TLF	Ongoing
Country selection	Completed
Baselining	Completed
On Hold	Completed
Completed	Completed
Cancelled	Completed
blank	Ongoing

 Country Selection Outcomes at the Country/Region/Hub Level – Let's take a look at the second bar chart:

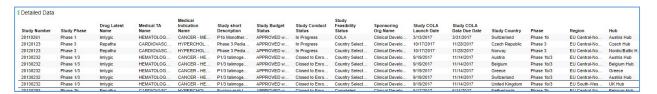


Country Selection Outcome is determined by the following logical waterfall. This same logical waterfall determines the DFM Status which we will review later:



Country Selection Outcome Waterfall:			
Logic	Country Selection Outcome:	DFM Status:	
[STUDY_FEASIBILITY_STATUS] = "Cancelled"	Cancelled	Completed	
[STUDY_FEASIBILITY_STATUS] = "On Hold"	On Hold	On Hold	
[FINAL_COLA_OUTCOME] = "Not Feasible"	Not Feasible	Completed	
[COLA_STAGE] = "COLA Declined"	Not Feasible	Completed	
[COLA_STAGE] = "COLA Withdrawn"	Not Feasible	Completed	
[STUDY_CNTRY_SELECT] = "Selected"	Selected	Completed	
[STUDY_CNTRY_SELECT] = "Not Selected"	Not Selected	Completed	
[STLIDY CNTDY SELECT] is blank	Soloction Donding	Ongoing	

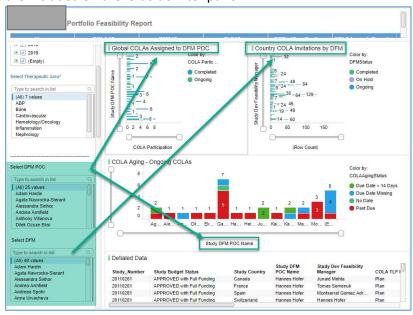
• Detailed Data: The detailed data section provides detailed, country level data based on the filters and markings you have used on the page.



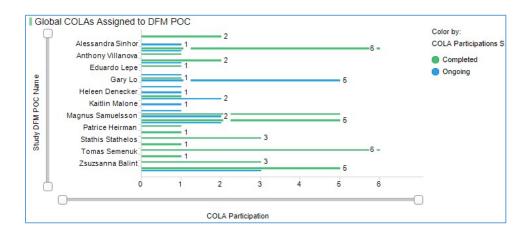
8. DFM View



• Filtering: The DFM View lets you see COLA information by DFM POC or DFM, so those filters are included on the left side filter panel.

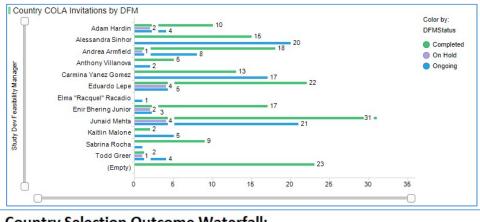


• Global COLAs Assigned to DFM POC: Based on the filtering you have used, this chart will display the status of the COLAs (Study Level) assigned to the DFM POC(s). Study Level COLA Status is determined in the same way as in the COLA View.



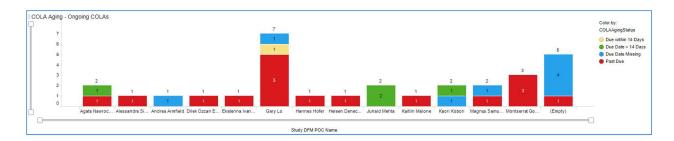
STUDY_FEASIBILITY_STATUS values	COLA Completed or Ongoing?
Active	Ongoing
Assigned	Ongoing
COLA launch pending	Ongoing
COLA	Ongoing
TLF	Ongoing
Country selection	Completed
Baselining	Completed
On Hold	Completed
Completed	Completed
Cancelled	Completed
blank	Ongoing

• Country COLA Invitations by DFM: Based on the filtering you have used, this chart will display the status of Country Level COLA Invitations by DFM. Country COLA Invitation status is derived using the same logical waterfall as the Country Selection Outcome.



Logic	Country Selection Outcome:	DFM Status:
[STUDY_FEASIBILITY_STATUS] = "Cancelled"	Cancelled	Completed
[STUDY_FEASIBILITY_STATUS] = "On Hold"	On Hold	On Hold
[FINAL_COLA_OUTCOME] = "Not Feasible"	Not Feasible	Completed
[COLA_STAGE] = "COLA Declined"	Not Feasible	Completed
[COLA_STAGE] = "COLA Withdrawn"	Not Feasible	Completed
[STUDY_CNTRY_SELECT] = "Selected"	Selected	Completed
[STUDY_CNTRY_SELECT] = "Not Selected"	Not Selected	Completed
[STUDY_CNTRY_SELECT] is blank	Selection Pending	Ongoing

• COLA Aging — Ongoing COLAs: This section of the report looks only at the Study Level of Ongoing COLAs. The chart provides information about where the COLA efforts are in relation to the COLA Data Due Date by DFM POC.



Aging is based on the time between Today's Date and the COLA data due date (Study Level)

- When COLA due date has passed then "Past Due"
- When COLA due date <=7 days, then "Due within 7 Days"
- When between 14 and 7 days until COLA due date then "Due within 14 Days"
- When >14 days to COLA due date then "Due Date > 14 Days"
- When there is no COLA due date entered then "Due Date Missing"
- Detailed Data: The detailed data section provides detailed, country level data based on the filters and markings you have used on the page.



9. TLF View

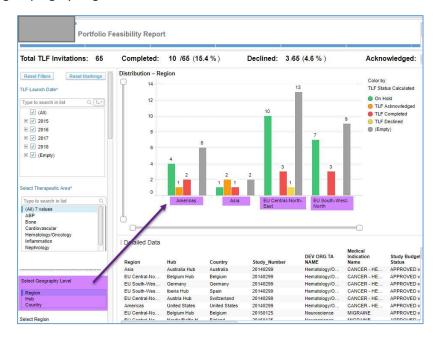


- Inclusion Criteria: Data on the TLF View report is limited to those Countries within a multicountry COLA where TLF Selected is checked.
- Filtering: It is important to understand how the filtering works for this view as the metrics are designed to compare the selected Hub, Region or Country against the total TLF Country Invitations for the time period and Therapeutic Area(s) specified.

The two top filters, **TLF Launch Date** and **Therapeutic Area** control the denominators of the metrics at the top of the page. Be sure to select the proper **period of interest** for your analysis.



 Grouping: The Geographic Level controls the grouping of the chart. In this example we are grouping by Region:



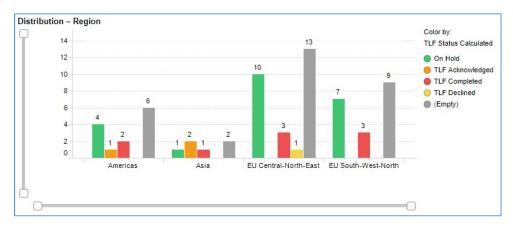
The remaining filters give you the ability to restrict the visualization and metrics to specific Countries, Hubs, Regions, etc.

Metrics: Let's look at the metrics at the top of the page in detail:



- Total TLF Invitations: # of Countries that have been invited to participate in TLF for the selected Therapeutic Area(s) with TLF Launch Date is within the date range specified
- Completed: Countries that have been invited to participate in TLF for the selected
 Therapeutic Area(s) with TLF Launch Date is within the date range specified and the TLF
 has been completed

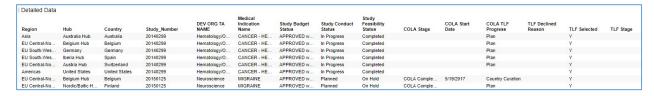
- Declined: Countries that have been invited to participate in TLF for the selected
 Therapeutic Area(s) with TLF Launch Date is within the date range specified and have
 declined to participate
- Acknowledged: Countries that have been invited to participate in TLF for the selected
 Therapeutic Area(s) with TLF Launch Date is within the date range specified and have
 acknowledge that invitation
- Not Required: Countries that have been invited to participate in TLF for the selected
 Therapeutic Area(s) with TLF Launch Date is within the date range specified and have
 indicated that TLF is not required
- TLF Participation by Region/Hub/Country: Let's take a look at the bar chart



TLF Status is determined by the following logical waterfall:

TLF Status:		
Logic	Status	
[STUDY_FEASIBILITY_STATUS] = "Cancelled"	Cancelled	
[STUDY_FEASIBILITY_STATUS] = "On Hold"	On Hold	
[TLF_STAGE] = "TLF Acknowledged"	TLF Acknowledged	
[TLF_STAGE] = "TLF Completed"	TLF Completed	
[TLF_STAGE] = "TLF Declined"	TLF Declined	
[TLF_STAGE] = "TLF Not Required"	TLF Not Required	
[TLF_STAGE] is blank	(Empty)	

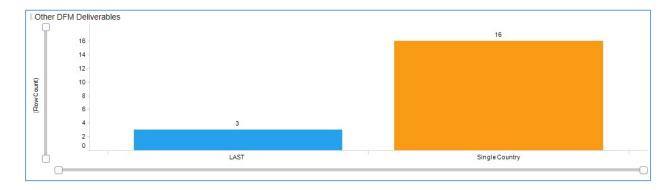
• Detailed Data: The detailed data section provides detailed, country level data based on the filters and markings you have used on the page.



10. COR - Visualizations



- Country Operating Review: The COR Visualizations report was developed specifically to support 2 slides necessary for the Country Operating Review decks.
- Filtering: Use the filters on the left side of the screen to specify the time period for COLA Launch and other criteria for creating the visualization for the Country Operating Review deck.
- Other DFM Deliverables: This bar graph highlights two areas of work that are not included in the COLA View visualizations:
 - LAST: This bar represents the number of COLAs conducted where the Study Management Org = ""Medical Local Affiliate (LAST)"
 - Single Country: This bar represents the number of Single Country COLAs where the Study Management Org is NOT "Medical Local Affiliate (LAST)"



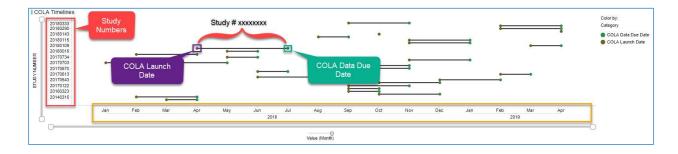
- Rationale for Non-Selection: This table is built out to support the Rationale for Non-Selection slide in the Country Operating Review template.
 - Inclusion Criteria: Country Selection = "Not Selected"
 - Exclusion Criteria: Country Selection/Non-Selection Reason = "CW: When country provides data and then decides to withdraw from COLA"



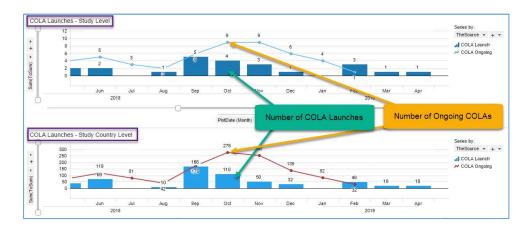
11. COLA Launch Overview



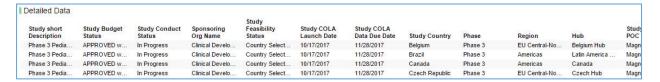
- Description: This report is designed to provide an overview of the monthly COLA Workload (COLAs Launched and COLAs Ongoing) at both a Study and a Country level.
- Filters: Along the left of the screen you will find the filters. Use the filters to narrow down the time period, geographic area, etc.
- COLA Timelines graph: On this graph study numbers are listed along the Y axis and each study is a horizontal line representing the timeline of a study, from COLA Launch Date to COLA Data Due Date. Time is on the X axis.



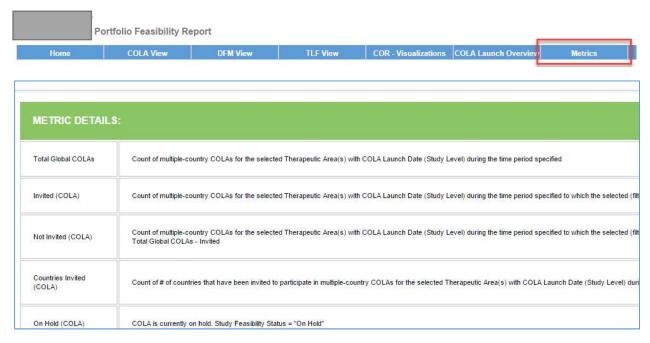
- The next two graphs show us the COLA activity for the given time period and filters.
 - The bars or columns show how many COLA Launches occurred during each month.
 - o The line shows how many COLAs were ongoing during each month.
 - The number of ongoing COLAs includes the number of COLA Launches. So, if we had 1 COLA that launched in a previous month and was still ongoing, and one COLA that launched this month, we would have 1 COLA Launch and 2 Ongoing COLAs represented on the graph.
- COLA Launches Study Level This graph shows the number of COLAs Launched and Ongoing at the Study Level for each month.
- COLA Launches Study Country Level This graph shows the number of Country level invitations were included in the COLAs Launched and Ongoing for each month.



• Detailed Data can be found at the bottom of the report and displays country level details about the COLAs represented on the page.



12. Metrics



• The Metrics page provides information about how the metrics and statuses are calculated in this report.

Links and References

Portfolio Feasibility Report: Link

Glossary

Term	Definition
COLA	Country Operational Landscape Assessment
DFM	Developmental Feasibility Manager
TLF	Targeted Local Feasibility