Oracle Life Sciences Site Analyze Cloud Service

Using Oracle Site Analyze: For Oracle Site Activate Users

Release 25.1
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Oracle Life Sciences Site Analyze Cloud Service Using Oracle Site Analyze: For Oracle Site Activate Users, Release 25.1

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1 Accessing and Navigating reports

Learn about getting around in reports and how to filter and export dashboards and worksheets.

Report access

When you have the required permissions to access Oracle Site Analyze reports, you'll navigate to the reports from within Oracle Site Activate.

Please note: Access to reports in Oracle Analytics Cloud requires Oracle Identity Cloud Service (IDCS) authentication. This applies to Oracle Site Analyze release 24.2.1 and all subsequent releases.

Release compatibility

Oracle Site Activate release compatibility

Please note that Oracle Site Analyze reports are not backward compatible to previous Oracle Site Activate releases. For instance, customers who want access to the enhanced reports in 24.2 Oracle Site Analyze must upgrade their Oracle Site Activate release to 24.2 as well. Please contact your Oracle Project Manager or Account Manager for more information about upgrading.

Workbook navigation

Each report workbook includes one or more worksheet tabs, beginning at the lower left of your screen. Click any tab to navigate to the associated dashboard or worksheet.

Filters

You'll find most report data filters in a row along the top of each dashboard or worksheet.

There are three types:

1. **List**: A list filter provides a simple list of values to choose from and lets you see which values are selected and which aren't. Using a list filter, you can optionally exclude selected values, and you'll also have the option to include null values in your report if preferred.
2. **Date**: A date range filter uses calendar controls to adjust time or date selections to limit data to a specific period of time. You'll select a single range of dates. Alternatively, you can use a date range filter to exclude dates within the specified range.
3. **Range**: A range filter works for contiguous numeric data. You'll can specify Start, End, and By properties to limit the range of data included in the report.

Some reports have filters embedded in the report itself. Where this applies, the filter will control only the accompanying dashboard visualization, instead of controlling to the entire worksheet.

Study level filtering

The following reports have study level filtering as of release 24.2.1. Study level filtering on the report means it will limit data shown based on your Oracle Site Activate study permission. Report users who have access to all studies will see all studies available for selection under the report's Study Name filter.

- Contract Module Dashboard

- Milestone and Submission Planning
- Milestone Predictions Dashboard
- Open Activities
- Site IP Release Package Dashboard
- Study Summary Dashboard
- Submissions and Approval Status

Explore and interact with reports

The links below provide instructions for working with Oracle Site Analyze reports built in Oracle Analytics Cloud:

- Navigate to reports from Oracle Site Activate
  You can open the reports Home page and browse to the report you want to view, or for some reports, navigate from within Oracle Site Activate directly to those reports with the current study in context.
- Navigate the reports Home page
  The Home page is a dashboard where you can access your reports. You can organize the display to your preferred view.
- Navigate reports in Catalog view
  Catalog view organizes your reports in a folder structure.
- Favorite a report
  Add your frequently used reports to the Favorites section for quick access.
- Apply a list filter to report data
  The most common filter is List type. List filters allow you to choose one or more values from a list to include or exclude from the dashboard or worksheet.
- Apply a date filter to report data
  When available, date filters let you filter a dashboard or worksheet by a date or date range. You'll choose a specific date or start and end date range values.
- Apply a range filter to report data
  You can expand or reduce the reported data if the dashboard or worksheet includes a Range filter. You'll specify start and end range values as well as optional attributes.
- Undo or Redo edits
  When viewing a workbook, it's easy to undo your last action and then redo it if you change your mind.
- Export report to a file
  You can export a workbook's dashboards and worksheets to Microsoft PowerPoint, Adobe Acrobat, or an image file.
- Maximize and export a visualization
  You can expand some dashboard visualizations and optionally export the image or data.
- Print report dashboards and worksheets
  You can print your workbook's dashboards and worksheets.
- Share a report
  Share a link to the report with others in your organization if preferred. You can share the report or individual worksheets in the original or current (filtered) state.

Navigate to reports from Oracle Site Activate

You can open the reports Home page and browse to the report you want to view, or for some reports, navigate from within Oracle Site Activate directly to those reports with the current study in context.

1. From within Oracle Site Activate, click the **Reports** menu, and select **Analyze reports** to view the reports Home dashboard in a new tab.
2. Alternatively, click **Analyze reports** on the persistent header to navigate directly to one of the following reports in a new tab:
   - **Study Summary Dashboard**
   - **Contract Module Dashboard**
   - **Site IP Release Package Dashboard**
   - **Regulatory Submission and Approval Status**

Navigate the reports Home page

The Home page is a dashboard where you can access your reports. You can organize the display to your preferred view.

1. In the default Home view, click **Workbooks and Reports**, and hover over any report tile to see a brief report description.
2. At the far right, click or to adjust the view to tiles or a list.
3. In either view, you can optionally:
   - **Search** for a specific report
   - **Sort By** (choose from **Modified** (default), **Name**, **Owner**, **Type**, or **Reverse Order**)
   - Favorite a report by clicking its star . The report will be added to the home page's **Favorite Workbooks** view for quick access. Favorited reports have a gold star .
   - Double-click any report tile or row to open the report.

Navigate reports in Catalog view

Catalog view organizes your reports in a folder structure.

1. Click at the upper left and select **Catalog**, then click **Shared Folders**.
2. Click the folder with the reports you want to view.
3. At the far right, click or to adjust the view to tiles or a list.
4. In either view, you can optionally:
   - **Search** for a specific report.
   - **Sort By** (choose from **Modified** (default), **Name**, **Owner**, **Type**, or **Reverse Order**).
   - Favorite a report by clicking its star . The report will be added to the home page's **Favorite Workbooks** view for quick access. Favorited reports have a gold star .
   - Double-click any report tile or row to open the report.

Favorite a report

Add your frequently used reports to the Favorites section for quick access.

1. On the reports Home page or in Catalog view, click a report's star to favorite it.
2. The report will be added to the **Favorites** section on the Home page, and the will be gold.
3. If preferred, click again to unfavorite the report and remove it from the Favorites section.

Apply a list filter to report data

The most common filter is List type. List filters allow you to choose one or more values from a list to include or exclude from the dashboard or worksheet.

1. With the **List** button selected at the top left of the filter modal, click on one or more values in the left column (which represents all available values) to add to the **Selections** column on the right.
2. Optionally, at the bottom of the left column, click **Add** to select all items and move them in bulk to the Selections column.
3. Optionally, use the **Search** field above the left column to find a specific item in the list. To the right of the Search field, optionally click [A] to open the search attributes menu and specify the search type (i.e., Contains, Begins, Ends, Pattern Match, or Case Sensitive).
4. Using the options above the **Selected** column, you can check the check boxes to **Exclude** the values in the Selected column and/or include **Nulls** in the report. To remove the values in the Selected column, click **Clear** at the bottom.

Apply a date filter to report data

When available, date filters let you filter a dashboard or worksheet by a date or date range. You'll choose a specific date or start and end date range values.

1. This filter defaults to **Date Range**. At the lower left of the filter panel, click the drop-down to specify a **Range** of dates, a single **Start at** date, a single **End at** date, or a single **Equal** to date.

   Click the **List** button at the top of the filter panel to see all available values. Ensure the date values you enter when using the Date Range filter fall within the available values.
2. Optionally, click the **List** button, choose one or more individual date values, and move them to the Selections column. You can also click **Add** to select all values in the left column and move them to the Selections column simultaneously.

Apply a range filter to report data

You can expand or reduce the reported data if the dashboard or worksheet includes a Range filter. You'll specify start and end range values as well as optional attributes.

1. This filter type defaults to **Range**. You can manually enter range values for Start and End at the panel's lower left. To the right of **By**, click **None** to open a list of optional attributes to apply to the filter.

   At the filter's right, the Value Distribution visualization updates.

2. Optionally, to the right of **Start** and **End**, click the **Min** and/or **Max** buttons to set the filter to the actual minimum or maximum values

Undo or Redo edits

When viewing a workbook, it's easy to undo your last action and then redo it if you change your mind.

1. In the toolbar at the top of the report, click one or more times. The undo button will be disabled (gray) when there are no other actions to undo.
2. When you've clicked Undo at least once, the button will be enabled. Click to redo the action.

Undo and Redo actions are available to you in your current session, and they revert to unused when you navigate away from the report.

Export report to a file

You can export a workbook's dashboards and worksheets to Microsoft PowerPoint, Adobe Acrobat, or an image file.

1. In the toolbar at the top of the report, click , and in the Export panel, click . Alternatively, you can right-click anywhere on the worksheet and choose **Export** and **File**.
2. In the Export modal, at **Name**, you can optionally modify the default report name.
3. At **Format**, select the file format you want to export to. You can choose **Powerpoint (pptx)**, **Acrobat (pdf)**, **Image (pdf)**, **Data (csv)**, or **Excel (xlsx)**. Note that export options available to you depend upon the worksheet or visualization type and the data. For instance, most visualizations don't provide Data or Excel export options.
4. At **Include**, the export defaults to include all worksheets (i.e., Entire Dashboard) for Powerpoint and Acrobat formats. However, Image (pdf) export will export only the current worksheet.
5. Optionally, turn on the **Include Filters** switch. You can also turn on the **Include Title** switch for Powerpoint or Acrobat formats only. Switches turn green when enabled.
6. Use the **Size** drop-down (Powerpoint or Acrobat formats), to specify a preferred page size.
7. For Powerpoint or Acrobat formats only, you can specify a page orientation. Choose Landscape or Portrait using the **Orientation** drop-down.
8. Click **Save**.

Maximize and export a visualization

You can expand some dashboard visualizations and optionally export the image or data.

1. When viewing a visualization, look to the upper right and click the to enlarge the visualization. Note that this option is not currently available for all charts.
2. Click and choose Export and File.
3. In the File modal, at **Name**, you can optionally modify the default file name.
4. At Format, select the file format you want to export to (e.g., **Powerpoint (pptx)**, **Acrobat (pdf)**, **Image (pdf)**, or **Data (csv)**). Your selection will modify the remaining available options.

5. At **Include**, the file export defaults to include the expanded visualization (Active Visual). Change the file content options by selecting a different export format if preferred.
6. If available, you can optionally turn on the **Include Filters** switch. You can also turn on the **Include Title** switch. Switches turn green when enabled.
7. If available, use the **Size** drop-down (Powerpoint or Acrobat formats) to specify a preferred page size.
8. For Powerpoint or Acrobat formats only, you can also specify a page orientation. Choose Landscape or Portrait using the **Orientation** drop-down.
9. Click **Save**.

Print report dashboards and worksheets

You can print your workbook's dashboards and worksheets.

1. In the toolbar at the top of the report, click , and in the export panel, click . Alternatively, right-click anywhere on the worksheet and choose **Export** and **Print**.
2. In the Print modal, at **Name**, you can optionally modify the default report name.
3. At **Include**, choose **Active Visual**, **Entire Dashboard**, or **All Dashboards**.
4. You can also optionally click **Include Filters**, and **Include Title** to include them in the printed output.
5. At **Size**, use the **Custom** setting (default size) to print using the height and width displayed on your screen and optionally select **Scale Proportionally**. Or, you can choose a different size option (e.g., US Letter, A4, Legal, etc.). You can also specify **Width** and **Height** values if preferred.
6. At **Orientation**, choose **Landscape** or **Portrait**.
7. Click **Print**.

   NOTE: When you print, the pages are re-rendered based on your selected size and orientation. So, if you're printing a table, your printed copy might not contain all of the table's rows and columns in your dashboard or worksheet.

Share a report

Share a link to the report with others in your organization if preferred. You can share the report or individual worksheets in the original or current (filtered) state.

1. Click to open the Export modal.
2. Use the **Start on** drop-down to choose the canvas (dashboard or worksheet) you want the link to point to.
3. Use the **Apply state** drop-down to select **Original state** or **Current state**.
4. Click **Copy Link**, or optionally copy and share the QR code shown in the Export modal

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Standard Reports

Account Metrics

Workbook synopsis

This workbook provides a dashboard view of studies, sites, and users in Oracle Site Activate, as well as detailed cross-tab sheets of each.

Dashboards and sheets

Studies dashboard

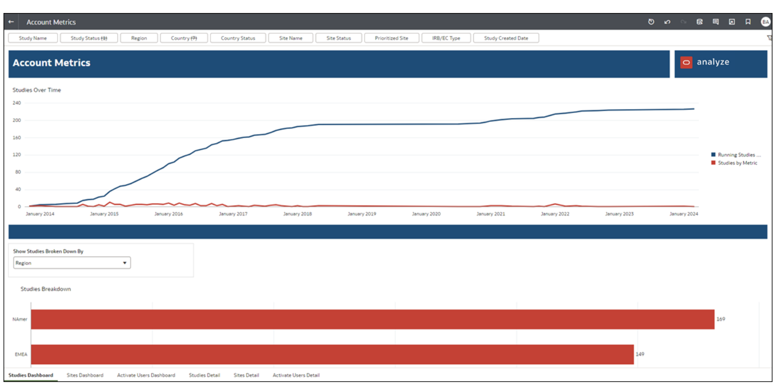
The Studies Dashboard shows:

- Number of studies added to Oracle Site Activate over time
- Breakdown of studies by different criteria (Country, Protocol number, etc.)

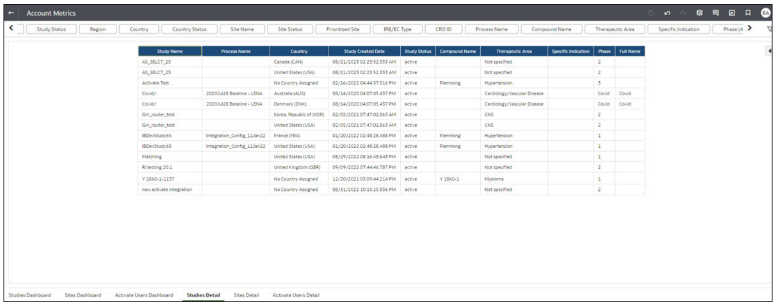
Notes:

- You can view the study detail on the "Studies Detail" worksheet of this workbook. This worksheet provides filters (e.g., Study Name, Therapeutic Area, Phase, etc.) you can use to subset the data in the detail worksheet.
- Right-click a line graph on the Studies Dashboard to navigate to the Studies Detail sheet and see all the studies created in the selected month.
- If there were no studies created for a particular period, you will not see data for that period in the dashboard.
- You can view studies broken down by different attributes captured in Oracle Site Activate, such as Region, Country, Therapeutic Area, etc., as well as by custom flex string values.

Studies Dashboard worksheet



Studies Detail worksheet



Sites Dashboard

The Sites Dashboard shows KPIs for:

- Total sites added
- Total sites used
- Sites added last month
- Sites added this month
- Sites added this week

Below the KPIs, you'll find line graphs for Sites Added Over Time, Sites Used Over Time, and Sites Added This Month. Hover over any point on the graphs to see additional details. You can also use the Site Created Date filter to control the range of the line graphs.

Site used criteria are:

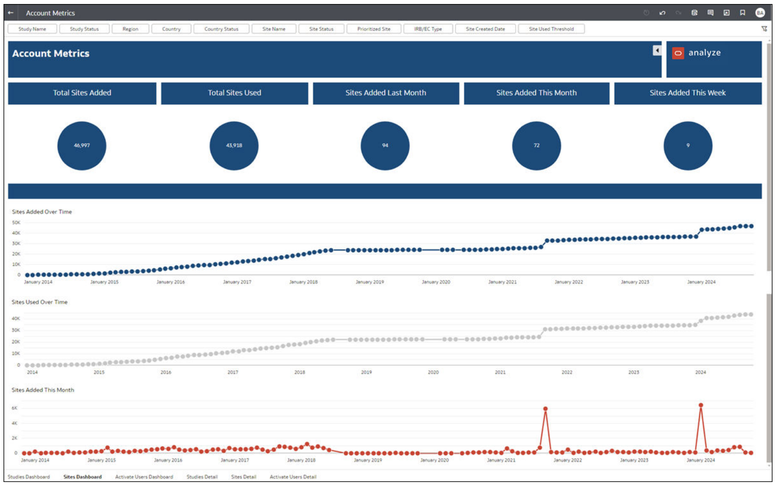
- Site has been in In activation status for longer than an accumulated 30 days
- OR site is IP released status
- OR site is in Activated status

30 days is the default value of the In activation threshold for a site to be considered used and it can be adjusted to any other numbers as needed.

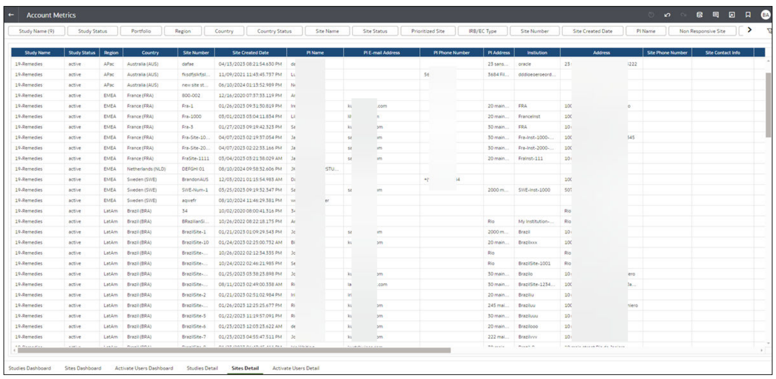
Additional notes:

- You can view the site detail on the "Sites Detail" worksheet of this workbook. This worksheet provides filters (e.g., Study Name, Site Number, etc.) you can use to subset the data in the detail worksheet.
- If there were no sites created for a particular period, you will not see data for that period in the dashboard.

Sites Dashboard worksheet



Sites Detail worksheet



Activate Users Dashboard

This dashboard shows KPIs for:

- Total number of users (excluding Oracle users)
- Total number of users added last month (excluding Oracle users)
- Total number of users added this month (excluding Oracle users)

The sheet also includes two line graphs:

1. **User Added** – Graph lines represent Users Added This Month and Total Users Added. You can hover over any point on the graph lines to see the month, total users added for that month, and total users added. You can also adjust the graph time span with the "User Added Date" filter.
2. **User Logins** – This graph line indicates logins for users in the account. Hover over any point on the graph lines to see the month, logins for that month, and distinct users that logged in that month. You can also adjust the graph time span with the "User Login Date" filter.

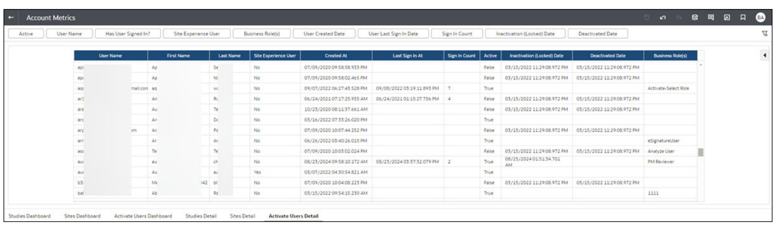
Notes:

- You can view the user detail on the "Activate Users Detail" worksheet of this workbook. The worksheet provides several filters (e.g., User Name, Business Role, Sign in Count, etc.) that allow you to subset the data included in the detail worksheet.

- If there were no users created for a particular period, you will not see data for that period in the dashboard.

Activate Users Dashboard worksheet

Activate Users Detail worksheet



Adoption Dashboard

Workbook synopsis

The Adoption Dashboard provides your organization with a convenient way to evaluate overall Oracle Site Activate usage and adoption through a series of dashboard views. This report is the first in a two-report set that provide user adoption information. The second report is Adoption Dashboard - Artifacts and Activities.

Dashboards

Account Metrics Dashboard worksheet

This dashboard includes Key Performance Indicator (KPI)s for Total Studies, Total Sites, and Total Users. Use the "Choose how to group data" filter to adjust the bar graph groups.

User Analysis Dashboard worksheet

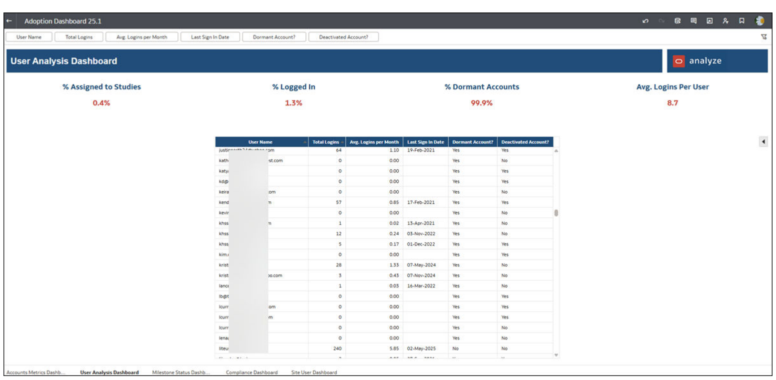
The top section of the User Analysis Dashboard includes the following KPIs for users in the Oracle Site Activate account:

- Percentage of users assigned to studies
- Percentage of users who have logged in
- Percentage of dormant accounts (no login for at least 90 days)
- Average logins per user

The lower section of the dashboard includes tabular data for the following:

- User Name
- Total Logins
- Average Logins Per Month
- Last Sign In Date
- Dormant Account (Yes/No)
- Deactivated Account (Yes/No)

You can easily subset the table data using filters displayed above the worksheet. For instance, you can set the report to include only deactivated and/or dormant users, display data for one or multiple individual users, etc.

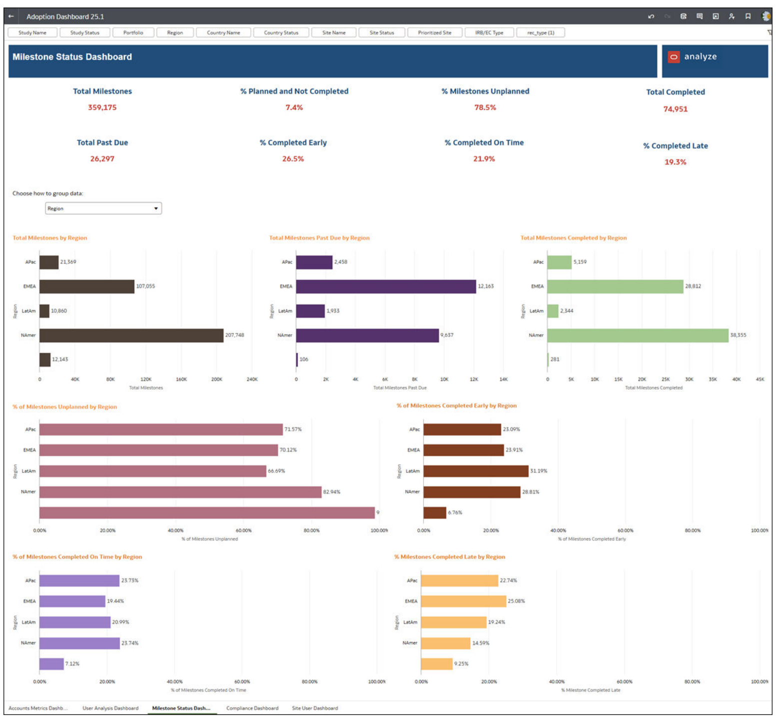


Milestone Status Dashboard worksheet

The top section of the Milestone Status Dashboard displays the following milestone metrics for the Oracle Site Activate account:

- Total Milestones
- % of Milestones Planned and Not Completed
- % Milestones Unplanned
- Total Milestones Completed
- Total Milestones Past Due
- % of Milestones Completed Early
- % of Milestones Completed On Time
- % of Milestones Completed Late

The dashboard's lower section displays multiple bar graphs for milestone data. You can choose how to group the displayed data (e.g., Portfolio, Study, Country, or Region). You also have familiar filters available above the worksheet (e.g., Study Status, Portfolio, Study Name, Region, and Country), as well as filters for Site Status, Site Name, Prioritized Site, and IRB/EC Type.

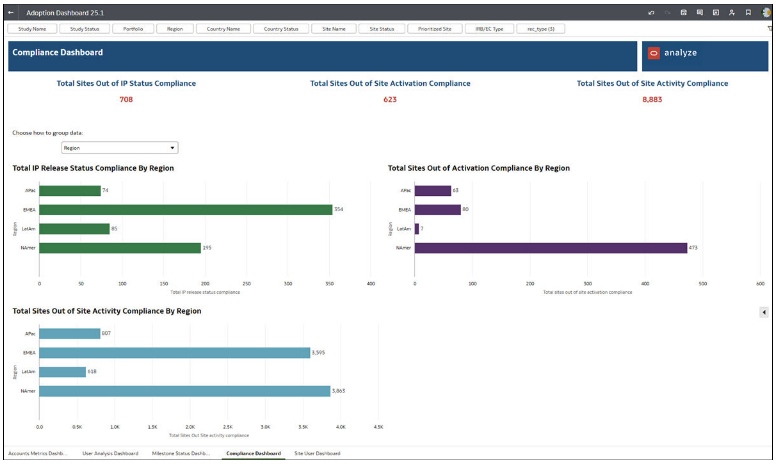


Compliance Dashboard worksheet

The top section of the Compliance Dashboard displays the following milestone metrics for the Oracle Site Activate account:

- Total Sites Out of IP Status Compliance (i.e., sites with "IP release ready" milestone completed and site status is not "IP released")
- Total Sites Out of Site Activation Compliance (i.e., sites that have completed "Essential docs sent to site" milestone more than 200 days ago and "IP release ready" milestone is not completed)
- Total Sites Out of Site Activity Compliance (i.e., sites that have not had an activity completed in over 100 days and "IP release ready" milestone is not completed)

The dashboard's lower section displays compliance data in a bar graph. You can choose how to group the displayed data (Portfolio, Study, Country, or Region). Filter options above the worksheet allow you to subset the data.



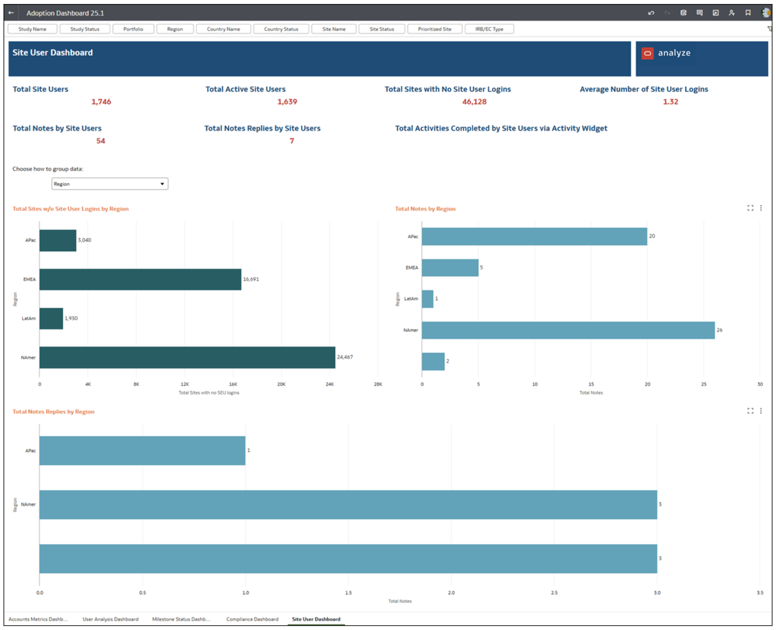
Site User Dashboard worksheet

The top section of the Site User Dashboard displays the following site user, site login, and site notes metrics for the Oracle Site Activate account:

- Total Site Users
- Total Sites with No Site User Logins
- Average Number of Site User Logins
- Total Notes
- Total Notes Replies

The dashboard's lower section displays site user data in a bar graph. You can choose how to group the displayed data (Portfolio, Study, Country, or Region). You can further refine the displayed data using filters above the worksheet.

> **Note**
>
> Please refer to the Site User Dashboard included in the Adoption Dashboard – Artifacts and Activities report to see additional site metrics and visualizations. The Adoption Dashboard – Artifacts and Activities report shows Total activities by site users via activity widget metric and a Total site page activities by region bar graph. Oracle maintains this information separately to ensure acceptable performance for both Adoption reports.



Adoption Dashboard - Artifacts and Activities

Workbook synopsis

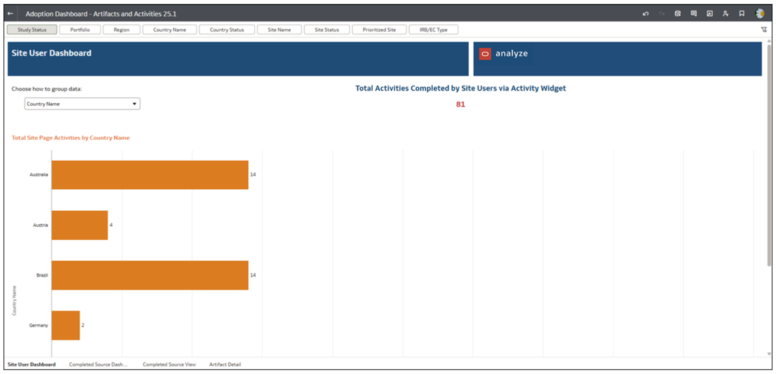
The Adoption Dashboard – Artifacts and Activities report provides your organization with an easy way to evaluate Oracle Site Activate usage and adoption through a series of dashboard views. This report is the second of a two-report set that provide user adoption information. The first report is Adoption Dashboard.

Dashboards

Site User Dashboard worksheet

The Site User Dashboard includes a Total activities completed by site users via activity widget metric and a Total site page activities by region bar graph. You can refine the displayed data using filters above the worksheet.

> **Note**
>
> Please refer to the Site User Dashboard included in the Adoption Dashboard report to see additional site metrics and visualizations. The Adoption Dashboard report's Site User Dashboard includes metrics and visualizations for total site users, site user logins, and site user notes. Oracle maintains this information separately to ensure acceptable performance for both Adoption reports.



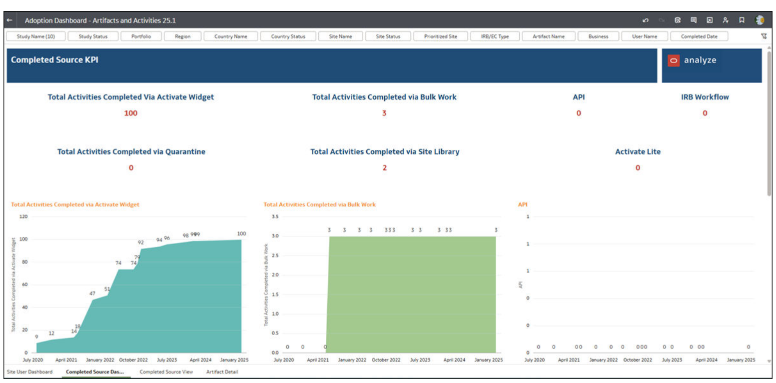
Completed Source Dashboard worksheet

The Adoption Dashboard report also provides a way for you to evaluate how Oracle Site Activate users interact with the application, at the feature level. The “Completed Source Dashboard” worksheet includes the following top-level metrics:

- Total activities completed via Activate placeholder widget
- Total activities completed via Bulk Work
- Total activities completed via API
- Total activities completed via IRB workflow
- Total activities completed via quarantine
- Total activities completed via Site Library
- Total activities completed via Activate LITE

Below the metrics, the dashboard displays visualizations for each KPI listed above. Hover over any point in the visualizations to see details in a tool-tip.

Above the worksheet, select from additional filters to subset the dashboard data (e.g. Study Name, Study Status, Portfolio, Region, etc.). Filters for Site Name, Artifact Name, User Name, etc. allow you to create unique views of individual user interactions with the Oracle Site Activate application.



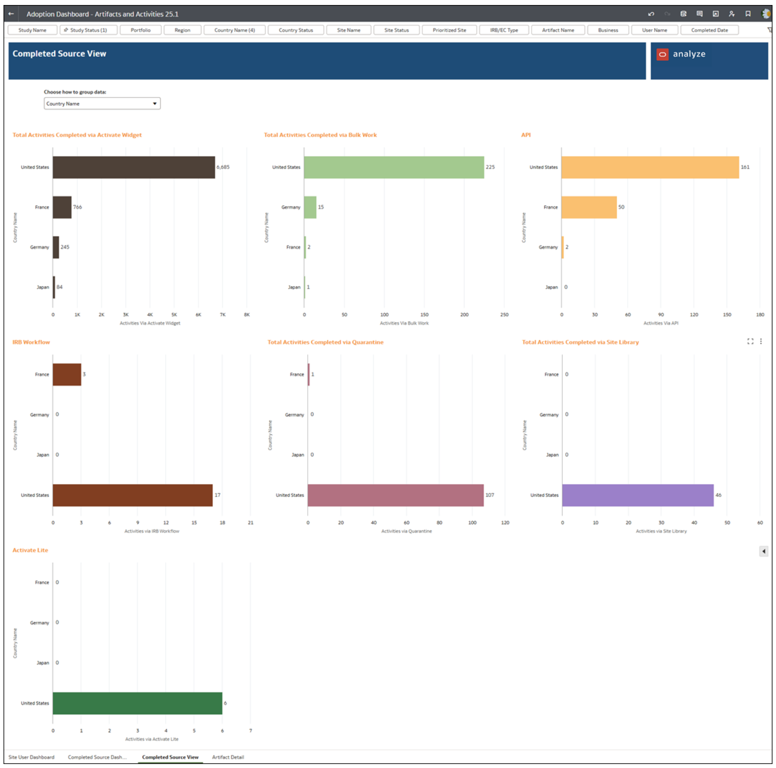
Completed Source View worksheet

The Completed Source View worksheet includes feature usage data in bar chart visualizations and gives you the option to group data by:

- Portfolio

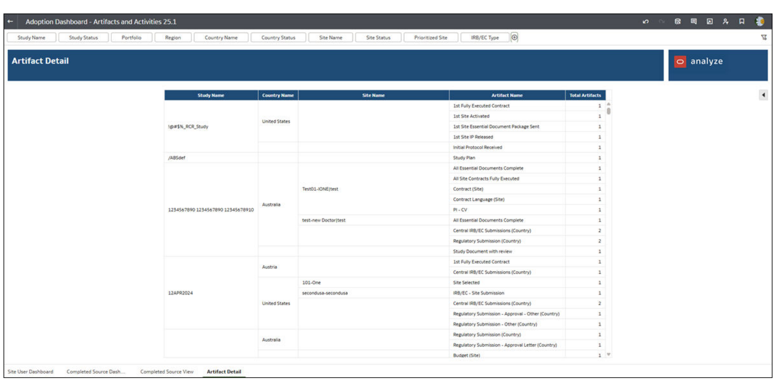
- Study
- Country
- Region
- Artifact
- User
- Business role
- Mastered PI

Again, select from additional filters above the worksheet to subset the dashboard data to your preferred view (e.g. Study Name, Study Status, Portfolio, Region, etc.).



Artifact Detail worksheet

The Artifact Detail worksheet presents data in a tabular view. Use any of the filters displayed above the worksheet to subset the data as preferred.



Compliance Dashboard

Workbook synopsis

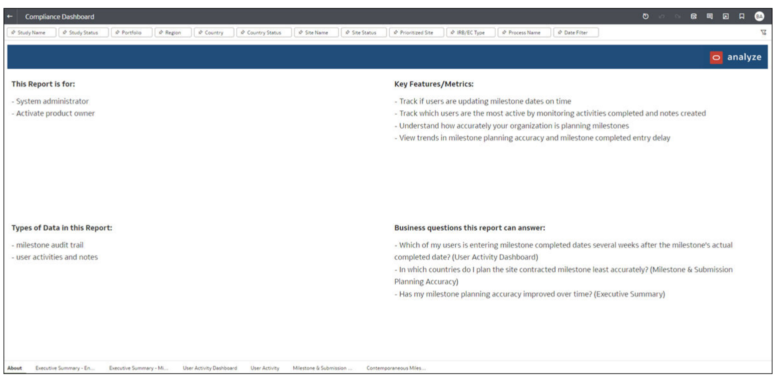
The Compliance Dashboard report allows Oracle Site Activate administrators and stakeholders to understand if users are taking full advantage of the system by monitoring whether users are actively entering in completion dates and accurately entering in planning dates.

Dashboards and sheets

About

The About sheet provides a summary of key report features to help Compliance Dashboard users understand if the report is applicable to his or her role. The About sheet provides details like:

- Study startup roles that would use the report
- Key report features and metrics
- Types of data the report contains
- Examples of how to use the report to answer a business question



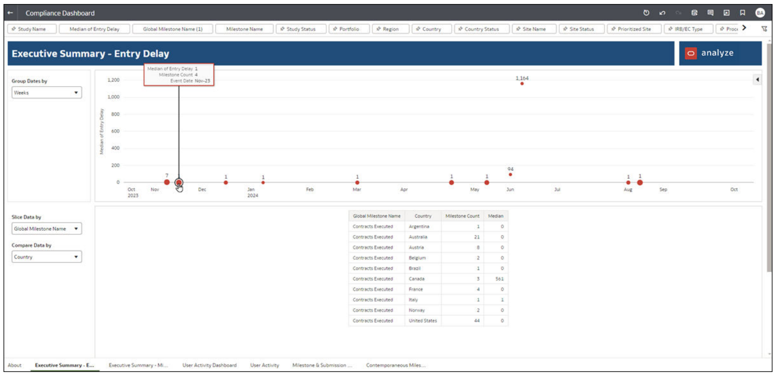
Executive Summary - Entry Delay dashboard and Executive Summary - Milestone Accuracy dashboard

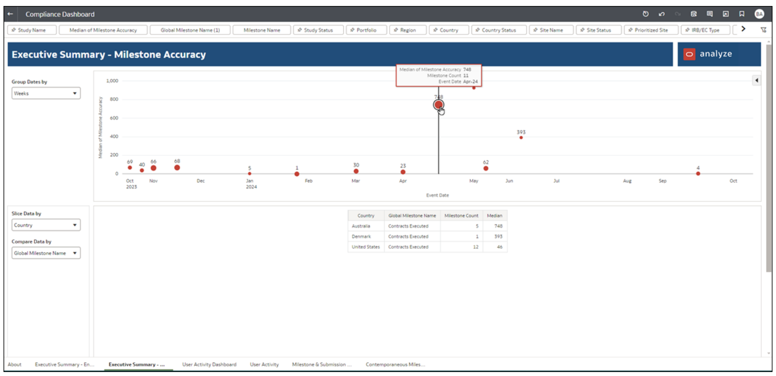
These dashboard worksheets show a high-level summary of milestone date entry and milestone planning accuracy compliance. The top of the dashboards shows total median milestone entry delay or total the total median milestone planning accuracy in an easily understood dot chart visualization. The size of the dots reflect the milestone count. Hover over any dot to view additional delay or accuracy details. Use the Group Dates by filter to adjust data grouping by Years, Quarters, Months, or Weeks.

In the lower section of the worksheets, to the left side, use the Slice Data By and Compare Data by filters to adjust data included in the tabular view.

- "Slice Data By" All, Region, Country, Study Name, Global Milestone Name, User, or Portfolio
- "Compare Data By" All, Region, Country, Study Name, Global Milestone Name, or User

You can also adjust data included in these worksheets using any of the filters displayed above the worksheets (e.g., Study Name, Median of Entry Delay, Global Milestone Name, etc.). Each worksheet will provide filters appropriate to the worksheet data (i.e., Median or Entry Delay or Median of Milestone Accuracy).





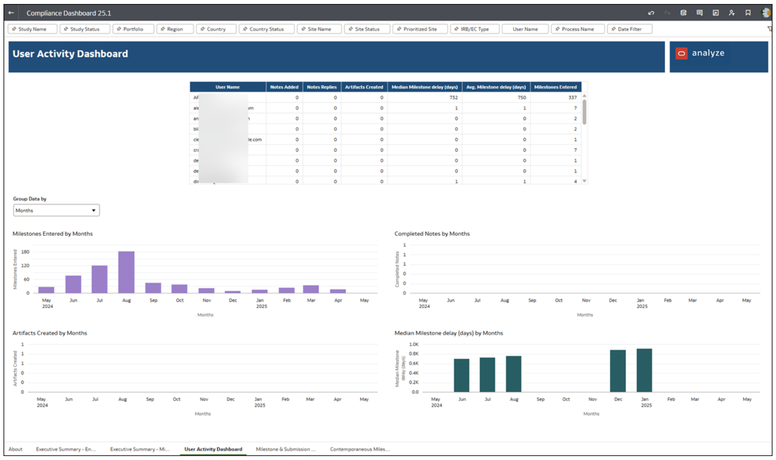
User Activity Dashboard

This dashboard allows for tracking actions of Oracle Site Activate users over time. The upper section of the worksheet displays a sortable table with a single row per user. Each user has the following metrics per row:

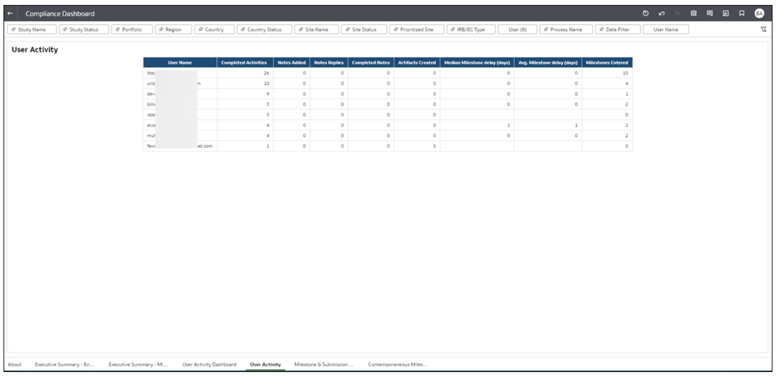
- total notes created in Oracle Site Activate
- total artifacts created in Oracle Site Activate
- median delay in days from milestone completed date to milestone entered date
- average delay in days from milestone completed date to milestone entered date
- total milestones entered in Oracle Site Activate

The lower section of the User Activity Dashboard includes five separate graphs, which you can group by Weeks, Months, Quarters, or Years using the "Group data by" control just above the graphs. The graphs show:

- Milestones Entered
- Completed Notes
- Artifacts Created
- Median Milestone Delay (days)



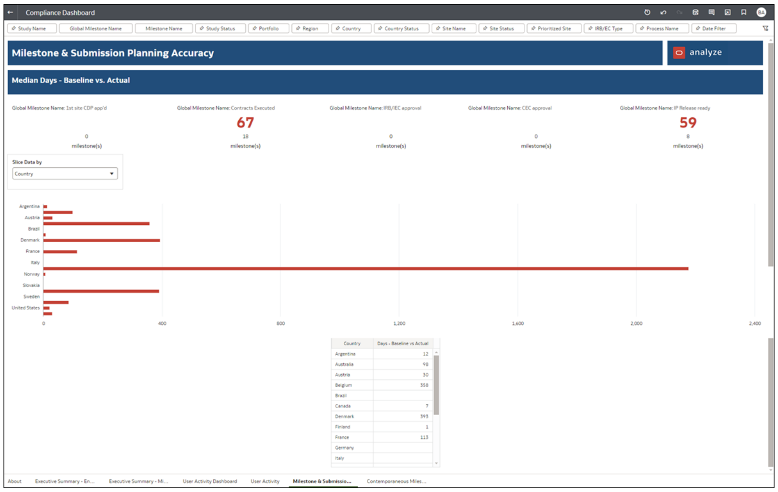
User Activity Detail



Milestone & Submission Planning Accuracy

This worksheet allows you to compare the baseline milestone date to the actual milestone date to understand how accurate your organization is in planning global milestones and identify areas for improvement. The upper portion of the worksheet includes five top-level KPIs that show median of baseline to actual.

The lower section of the worksheet includes bar graph and tabular data visualizations. You can control the dimension that drives the graph and the table using the "Slice Data by" filter in the worksheet. The graph and table metrics are the median of baseline to actual for the selected dimension (e.g., Region, Country, Study Name, etc.).

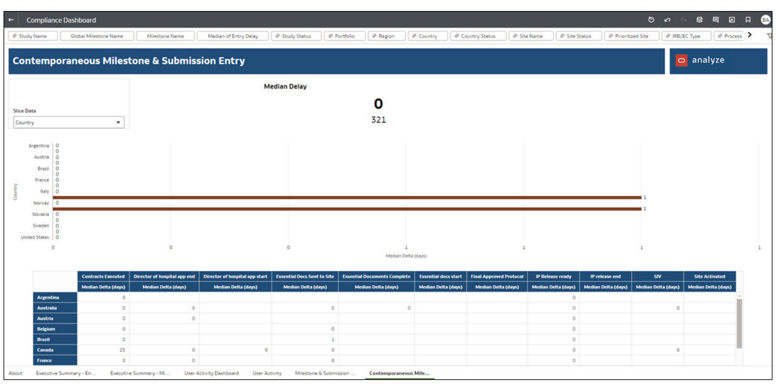


Contemporaneous Milestone & Submission Entry dashboard

This worksheet focuses on comparison of the actual milestone date to the date the milestone was entered. The comparisons show contemporaneous (within the same time period) data entry. This worksheet is intended to help you understand if Oracle Site Activate users are entering data into the system in a timely manner.

At the top of the worksheet, you'll see the Key Performance Indicator for Median Delay, which is controlled by the report level filter. Below, the worksheet includes a bar graph and table that are controlled by the "Slice Data" selector (Region, Country, Study Name, or Portfolio). Graph and table metrics are the median of actual to date entered for the selected dimension.

Use any of the filters displayed at the top of the worksheet to subset the worksheet data to your preferred view.



Contract Module Dashboard

Workbook synopsis

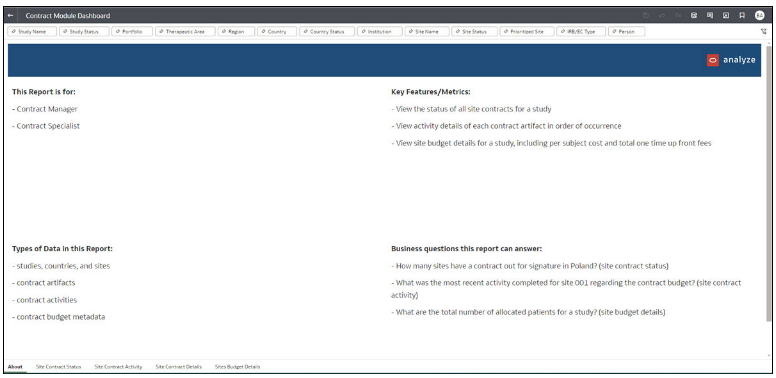
Intended for Oracle Site Activate customers, the Contract Module Dashboard complements the Oracle Site Activate contract module. This report helps contract managers and specialists access the information they need about site contract progress. Managers can use the dashboard to view contract analyst workloads. Other report users can access additional activity data through the dashboard and filter it based on selection.

Dashboards and sheets

About

The About sheet summarizes key Contract Module Dashboard report features to help you understand if the report applies to your role. The About sheet provides details like:

- Study startup roles that would use the report
- Key report features and metrics
- Types of data the report contains
- Examples of how to use the report to answer a business question

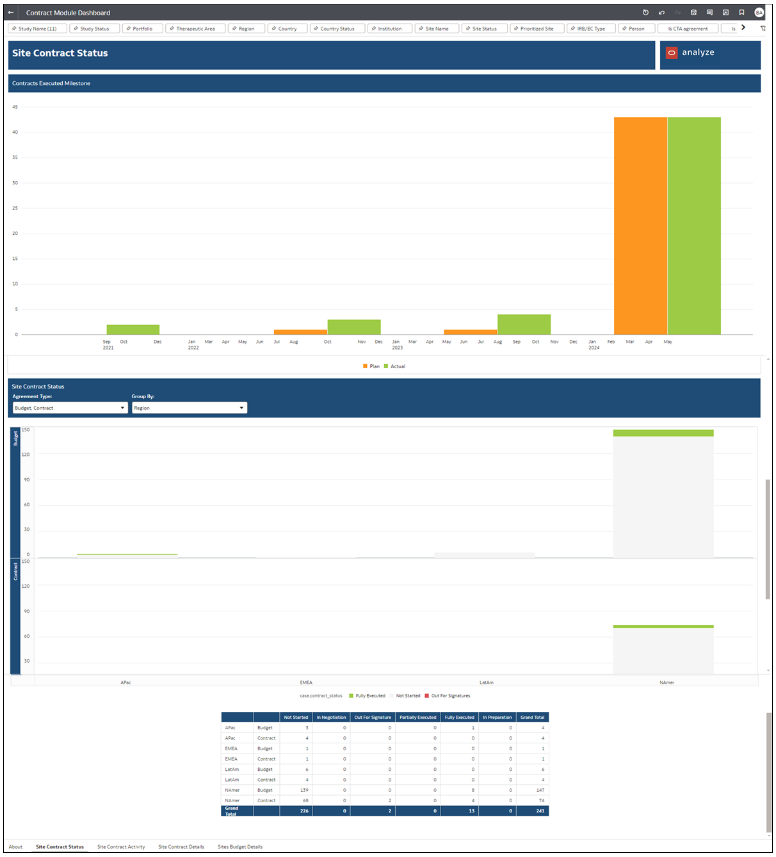


Site Contract Status

This dashboard helps you understand the status of all site contracts and budgets to identify risk areas and ensure that the study stays on schedule. A top bar graph visualizes the contract executed milestone by planned and actual dates.

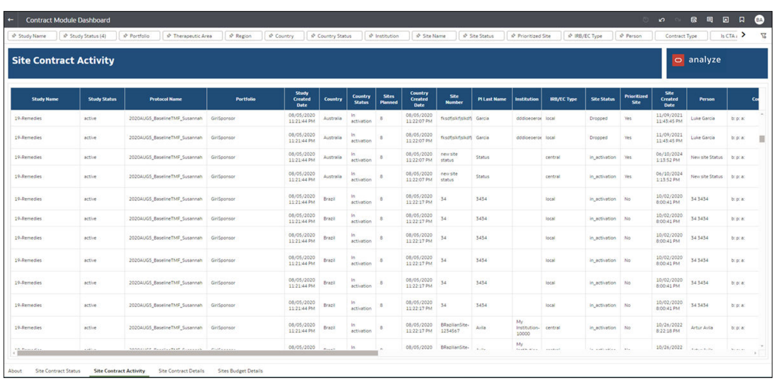
At the center of the sheet, you can select the agreement type to view in bar chart and tabular format. When you select multiple agreement types, the bar charts stack alphabetically based on the types you selected (i.e., Amendment, Budget, Contract, Language). A selectable parameter also allows you to Group data as preferred (e.g., Country, Institution, etc.).Hover over any point in the stacked bar chart(s) to see contract status (e.g., not started, in negotiation, etc.) and other detail (Number of records, data slice, etc.).

> **Note**
>
> Discontinued activities refresh weekly. Data provided in the views for discontinued records is limited compared to what is available in active records. For instance, the Contract Group, Assigned User, Days Open, and other fields are not available and will show as null in Contract Module Dashboard worksheets. If needed, you can temporarily move discontinued records back to active status to appear on the report in full again.



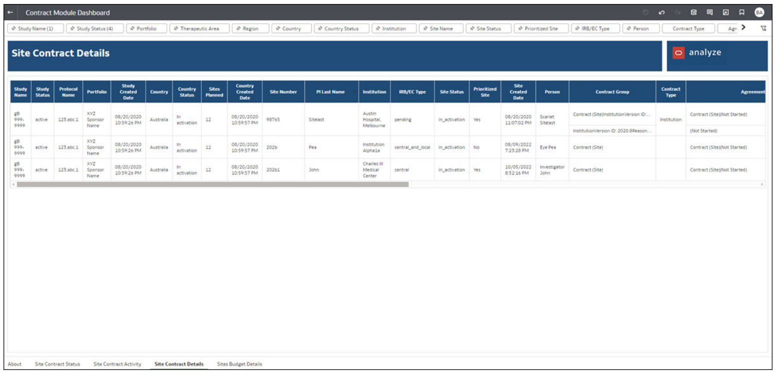
Site Contract Activity

This worksheet shows the detailed activity history of contract artifacts so you can easily track contracts that aren't completed and what action needs to be completed next.



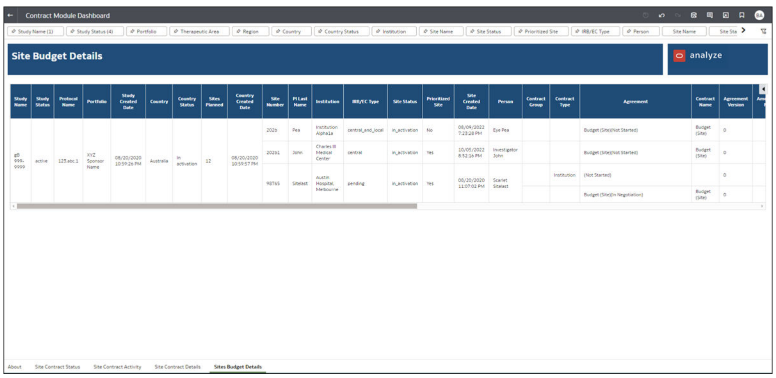
Site Contract Details

This worksheet includes a tabular view of metadata associated with the site contract (e.g., contract group, effective date, contracting party, negotiation information, etc.).



Site Budget Details

This worksheet includes a tabular view of metadata associated with the site budget (e.g., agreement, currency, total one time up front fees, etc.).



Cycle Times

Workbook synopsis

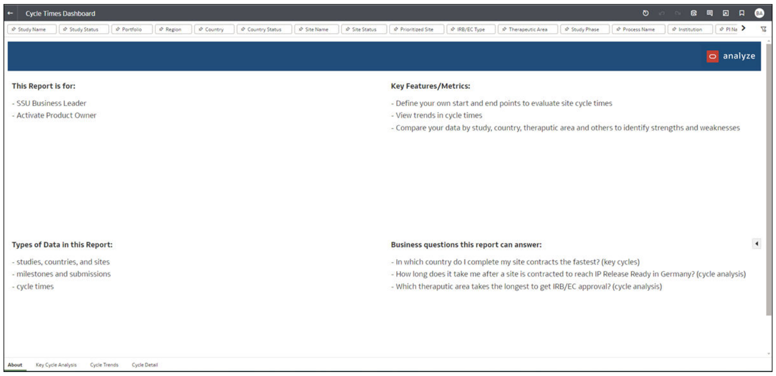
The Cycle Times Dashboard, which is intended for Oracle Site Activate product owners and study startup business leaders, includes key cycle metrics with configurable cycle start and end points. The report includes data for studies created in the past three years.

Dashboards and sheets

About

The About sheet provides a summary of key report features to help Cycle Times Dashboard you understand if the report is applicable to your role. The About sheet provides details like:

- Study startup roles that would use the report
- Key report features and metrics
- Types of data the report contains
- Examples of how to use the report to answer a business question

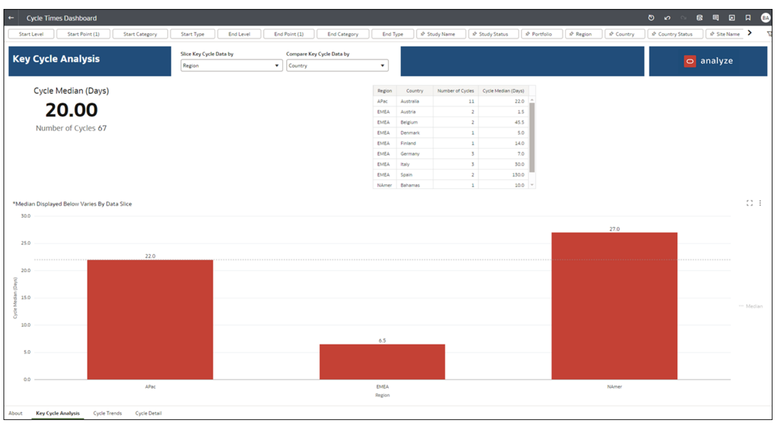


Key Cycle Analysis

The Key Cycle Analysis dashboard provides insight into a single key cycle. Use the filters at the top of the worksheet to select one cycle to see the KPI, bar chart, and table for that cycle. In the report header, use filters to:

- **Slice your data by**: All, Region, Country, Study Name, CRO Study Name, Sponsor Study Name, Therapeutic Area, Study Phase, PI Name, or Portfolio
- **Compare your data by**: All, Region, Country, Study Name, CRO Study Name, Sponsor Study Name, Therapeutic Area, Study Phase, PI Name, or Portfolio

Hover over any point in the bar chart to see additional information in a tool-tip. This report also allows you to drill to the Cycle Detail worksheet for additional information. To drill, right-click on any cell in the table or any point in the bar chart, and select "View Cycle Detail" from the menu.

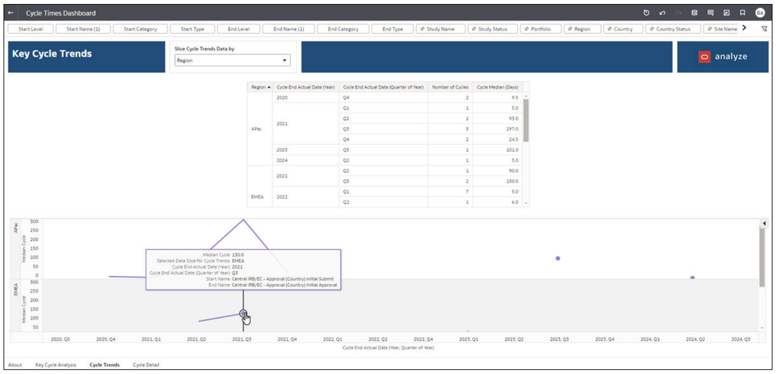


Cycle Trends

The Cycle Trends report simplifies viewing cycle performance over time. On this sheet, you'll use the filter in the report's header to slice data by All, Region, Country, Study Name, CRO Study Name, Sponsor Study Name, Therapeutic Area, Study Phase, PI Name, or Portfolio.

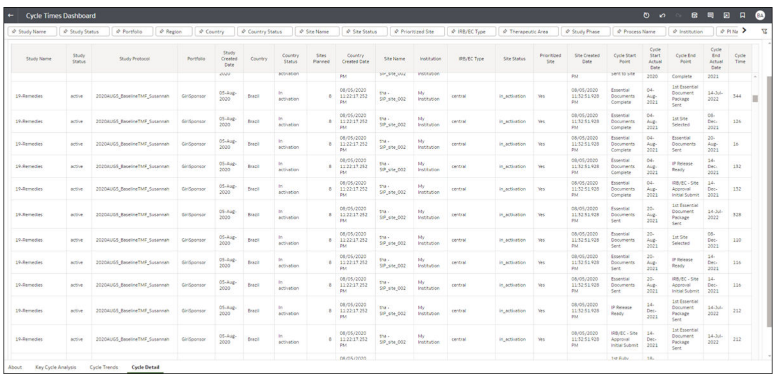
The worksheet's upper section presents the sliced data in a tabular format with columns for Country (sortable), Cycle End Actual Date (Year), Cycle End Actual Date (Quarter of Year), Number of Cycles, and Cycle Median (Days).

In the worksheet's lower section line chart, hover over tool tips provide additional details structured in bullet points. For instance, you'll see Cycle End Actual Date (Year), Cycle End Actual Date (Quarter of Year), Start Name, and End Name in the tool tips.



Cycle Detail

The Cycle Detail worksheet provides a tabular view of Study, Country, Site, and Cycle data. You can drill into the Cycle Detail sheet from the Key Cycle Analysis worksheet, if preferred. Right-click on the table cell or bar chart in the Key Cycle Analysis worksheet and choose "View Cycle Detail" from the menu.



Milestone and Submission Planning

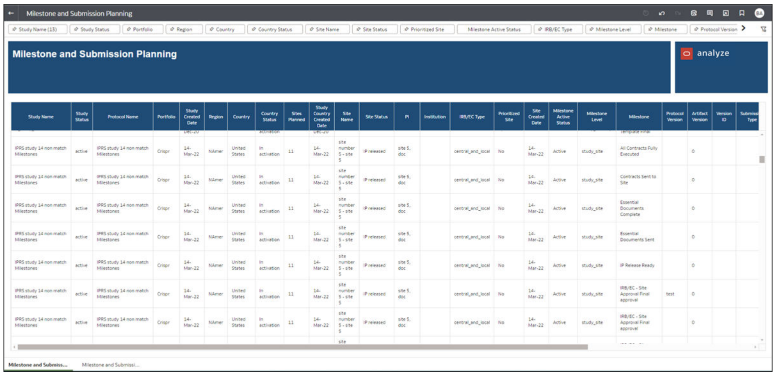
Workbook synopsis

Intended for Oracle Site Activate customers, this workbook lists all the baseline, planned, and completed dates for all milestones and submissions within Oracle Site Activate.

Dashboards and sheets

Milestone and Submission Planning

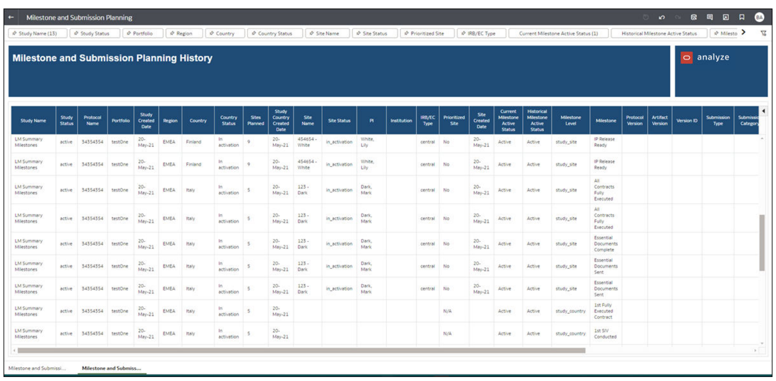
This worksheet lists the baseline, planned, and completed dates for all milestones and submissions and can be used to monitor compliance by highlighting any milestones and submissions that are not planned or completed. Use the Study Name, Country, Site Name, Milestone Active Status, Planned vs. Actual Delta, etc. filters above the worksheet to adjust data to your preferred view.



Milestone and Submission Planning History

The Milestone and Submission Planning report also provides and easy way to evaluate changes to planned dates across milestones and submissions using the Milestone and Submission Planning History worksheet.

Filter the worksheet by Study Name, Site Name, Current and/or Historical Milestone Active status, etc. to view the preferred dataset.



Milestone Prediction Dashboard

Workbook synopsis

This workbook, intended for Oracle Site Activate customers, is a powerful tool that leverages machine learning to inform site planning decisions. The Milestone Prediction Dashboard report, described below, includes two sheets:

1. Milestone Predictions
2. Prediction Analysis

Dashboards and sheets

Milestone Predictions

As with all Oracle Site Analyze reports, a wide variety of filters displayed above the worksheet allow you to subset data to your preferred view. Please note that when you select any filter, the filter's value can change the cycle count and median days displayed in the worksheet.

At the upper left of the Milestone Predictions dashboard, you can choose a Start Milestone (Essential Documents Sent to Site or Initial Protocol Received/Sent) for a cycle time and evaluate different prediction cycles against actual milestone completed dates in the report's trend graphs and table.

Then, choose a Target Milestone (IP Release Ready or Contracts Executed) and view the prediction data in the dashboard's trend graphs and table. You can also specify minimum and maximum cycles using the controls at the top of the dashboard.

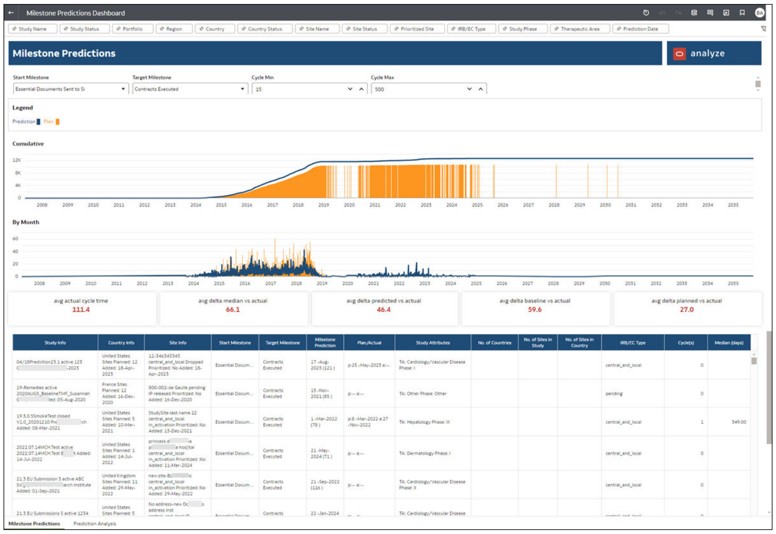
The trend graphs at the top of the dashboard helps you visualize dates. A blue line represents milestone predicted dates, while an orange bar represents milestone planned dates.

Key Performance Indicators display at the center of the worksheet. These are:

- **Average actual cycle time**: Shows how long this cycle typically takes on average.
- **Average delta – median vs. actual**: Shows the variance between actual cycle time and median cycle time. This represents the error between median and actual cycle time.
- **Average delta – predicted vs. actual**: Shows the variance between actual cycle time and predicted cycle time. This represents the error between predicted and actual cycle time.
- **Average delta – baseline vs. actual**: Shows the variance between actual cycle time and baseline cycle time. This represents the error between baseline and actual cycle time.
- **Average delta – planned vs. actual**: Shows the variance between actual cycle time and planned cycle time. This represents the error between planned and actual cycle time.

The bottom of the dashboard is a table that includes columnar data for the following:

- Study Information
- Country Information
- Site Information
- Start Milestone
- Target Milestone
- Milestone Prediction
- Planned/Actual Dates
- Study Attributes
- Number of Countries
- Number of Sites in Study
- Number of Sites in Country
- IRB/EC Type
- Cycle(s)
- Median (days)



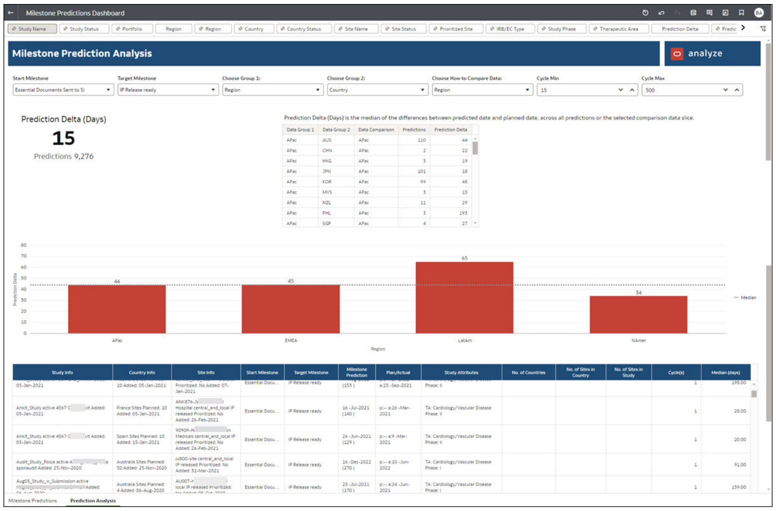
Prediction Analysis

The Prediction Analysis sheet helps you understand the machine learning model's historical performance and allows you to evaluate the areas where predictions are most and least accurate. The worksheet provides tabular and bar chart visualizations; you have multiple options at the top of the worksheet to manipulate the dimensions and aggregations.

First, use the "Start milestone" filter to select either "Initial Protocol Received/Sent" or "Essential Documents Sent to Site" as the milestone you want to visualize. Then, use the Target Milestone filter to select either "IP Release ready" or "Contracts Executed" as applicable. Use the remaining filters and controls at the top of the worksheet to specify grouping, comparison, and Min/Max Cycle values as preferred.

The lower section of the worksheet provides a tabular view of every site prediction. Columns are:

- Study Information
- Country Information
- Site Information
- Start Milestone
- Target Milestone
- Milestone Prediction
- Plan/Actual (dates)
- Study Attributes
- Number of Countries
- Number of Sites in Country
- Number of Sites in Study
- Cycle(s)
- Median (days)



Open Activities

Workbook synopsis

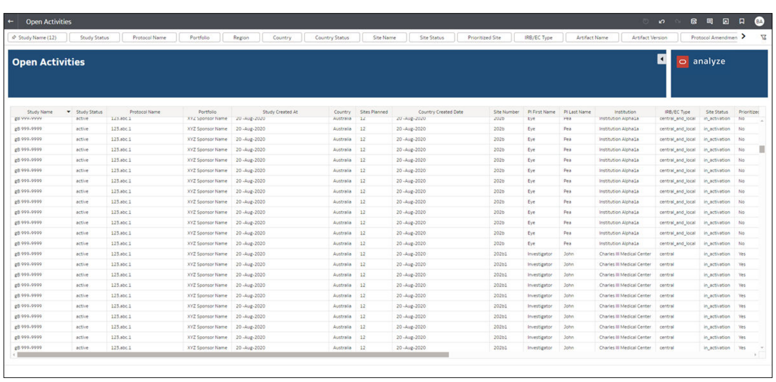
This workbook, which is intended for Oracle Site Activate customers, lists all the open (available to be worked on) activities within Oracle Site Activate and each activity's age (i.e., how long each activity has been open).

Worksheet

Open Activities

This worksheet lists all the open (available to be worked on) activities within Oracle Site Activate and each activity's age (i.e., how long each activity has been open) as well as the primary and backup resources assigned to an artifact activity.

Multiple filters above the worksheet allow you to subset the data to your preference. For instance, you can use the "Assigned User Role" filter to identify unassigned open activities. Using this filter can help to highlight the full amount of remaining work.



Planning Impact Analysis

Workbook synopsis

This report helps surface milestone change trends so you an quickly evaluate why milestone dates are being delayed.

Dashboards and sheets

Planning Impact Analysis dashboard

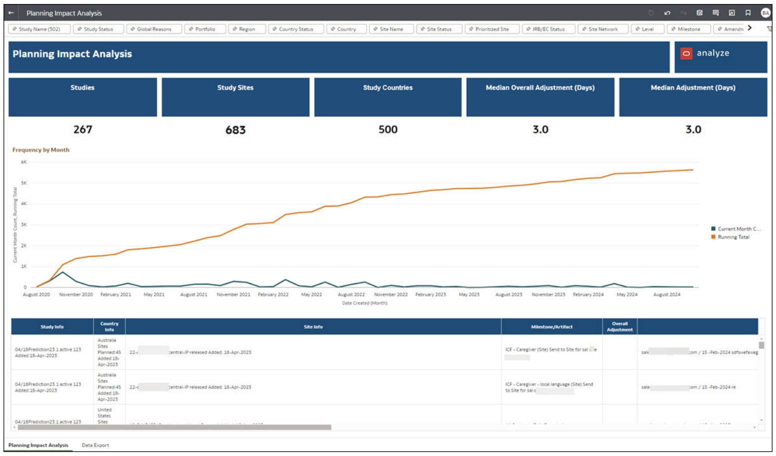
The top of the Planning Impact Analysis worksheet shows five Key Performance Indicators:

1. Studies: number of unique studies in which the search word/term exists in notes and reason for change entries
2. Study countries: number of unique study countries in which the search word/term exists in notes and reason for change entries
3. Study sites: number of unique study sites in which the search word/term exists in notes and reason for change entries
4. Median overall adjustment (days): the difference in the planned date versus prior planned date for the reason for changes that text match to the search word/term (accounts for multiple replans)
5. Median adjustment (days): the difference in the planned date versus prior planned date for the reason for changes that text match to the search word/term (accounts for distinct replans)

The center of the dashboard is a frequency trend line chart with two lines. One line shows distinct appearances of keyword(s) by month, while the other line shows cumulative appearance of keyword(s) by month.

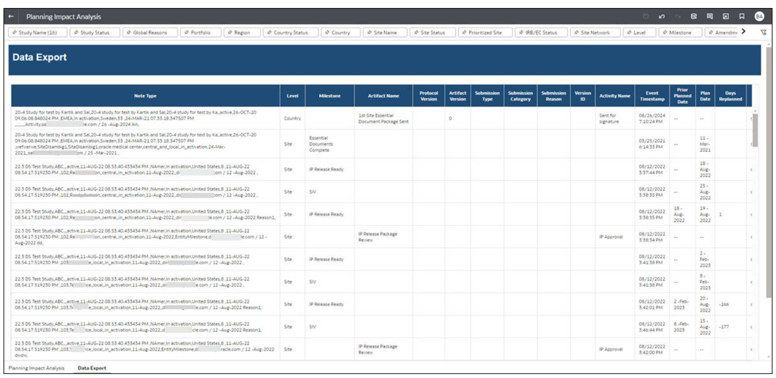
The dashboard's lower section presents the following information in a tabular format:

- Study information
- Country information
- Site information
- Milestone/artifact
- Overall adjustment
- Notes/reasons
- Plan



Data Export

If preferred, you can export the report's content using the Data Export worksheet. As with all Oracle Site Analyze reports, a wide variety of filters are provided at the top of the worksheet that allow you to subset data to your preferred view.



Resource Allocation

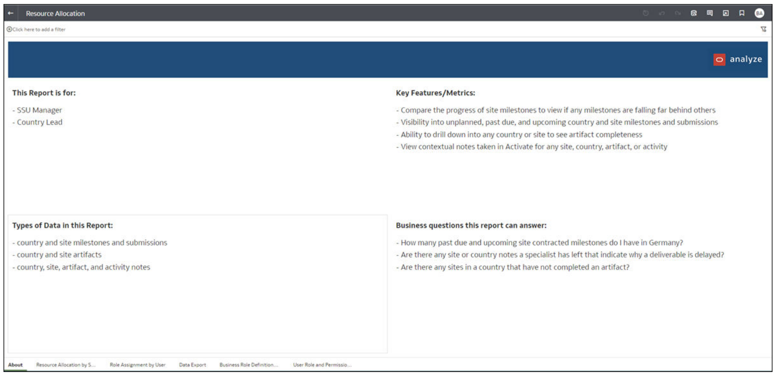
Workbook synopsis

This workbook shows users assigned to sites across all studies within Oracle Site Activate and can be used to identify where resources are overloaded and also unassigned. The workbook also provides worksheets that helps you to track and manage assignment of user roles and business permissions in Oracle Site Activate.

About

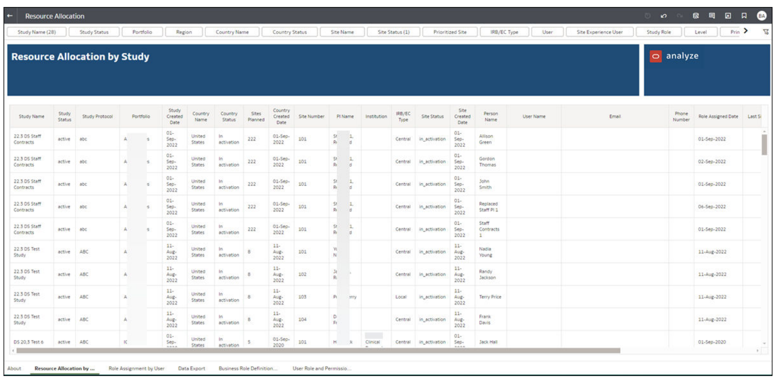
The About sheet provides a summary of key report features to help you understand if the report is applicable to your, or another report user's, role. The About sheet provides details like:

- Study startup roles that would use the report
- Key report features and metrics
- Types of data the report contains
- Examples of how to use the report to answer a business question



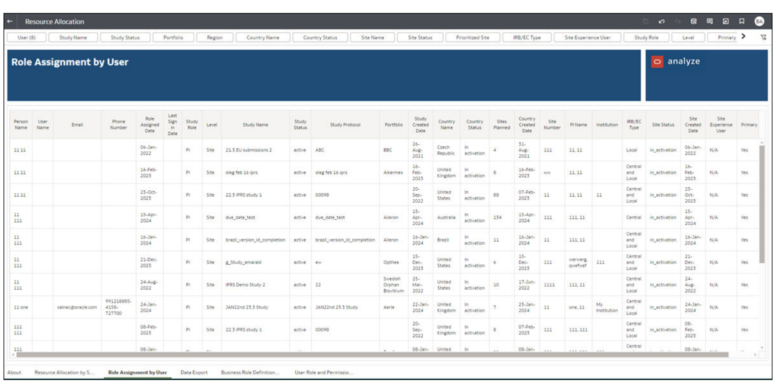
Resource Allocation by Study

This worksheet shows resources assigned to studies in Oracle Site Activate. Use any of the filters at the top of the worksheet to subset the data to your preferred view.



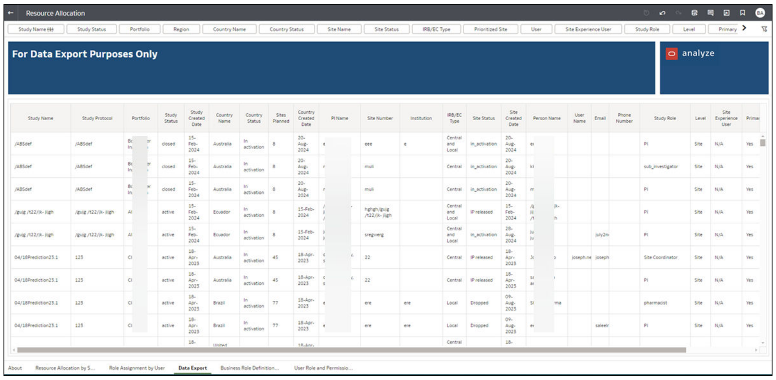
Role Assignment by User

This sheet identifies which users are assigned to business roles within a study and includes site experience users and users with primary assignment flags. Again, the filters at the top of this worksheet allow you to subset the data as preferred.



Data Export

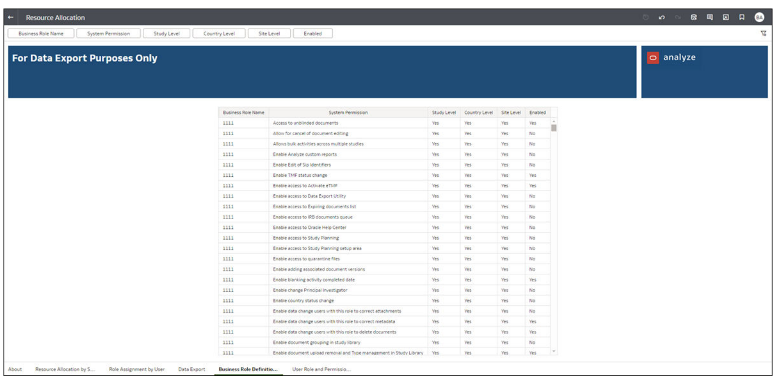
The export sheet provides a convenient way for you to download resource allocation detail. By default, all previously applied filters will be applied to the export sheet.



Business Role Definitions

The Business Role Definitions sheet presents a simple columnar view of business role name and the list of all permissions currently enabled for the role.

Note that this worksheet is intended only for data export use.

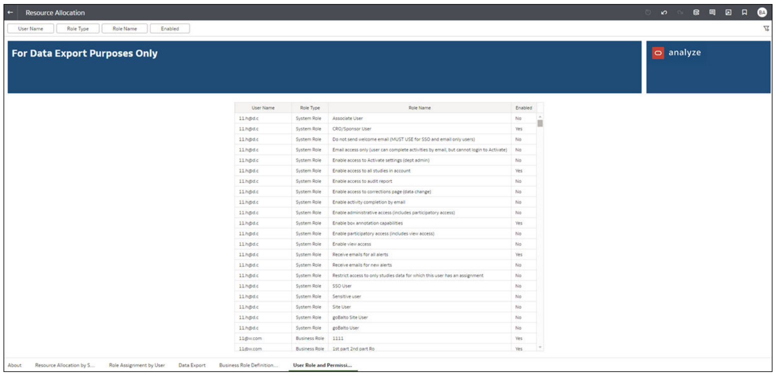


User Roles and Permissions

The User Roles and Permissions" sheet shows which business roles a user is assigned even if they are not assigned to a study, country, or site. You can also use this sheet to view which user level settings an individual user has assigned. The sheet includes:

- User name
- Role type (business role or system role)
- List of business and system roles that user is assigned

Note that this worksheet is intended only for data export use.



Site IP Release Package

Workbook synopsis

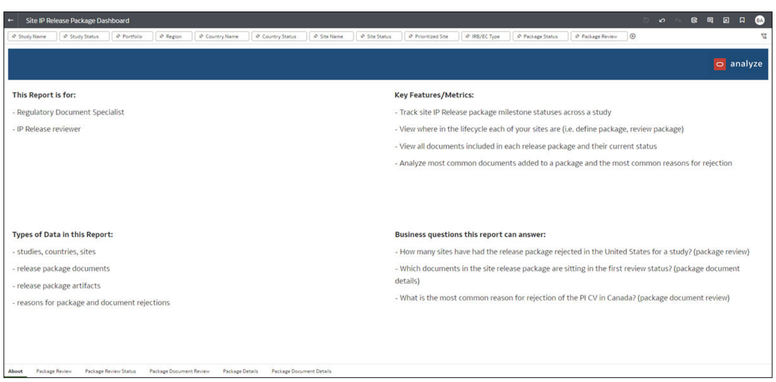
Intended for Oracle Site Activate users, the Site IP Release Package Dashboard workbook allows you to see granular package and document statuses and understand the state of all IP release packages for a study.

Dashboards and sheets

About

The About sheet provides a summary of key report features to help you understand if the report is applicable to your, or another Site IP Release Package report user's, role. The About sheet provides details like:

- Study startup roles that would use the report
- Key report features and metrics
- Types of data the report contains
- Examples of how to use the report to answer a business question



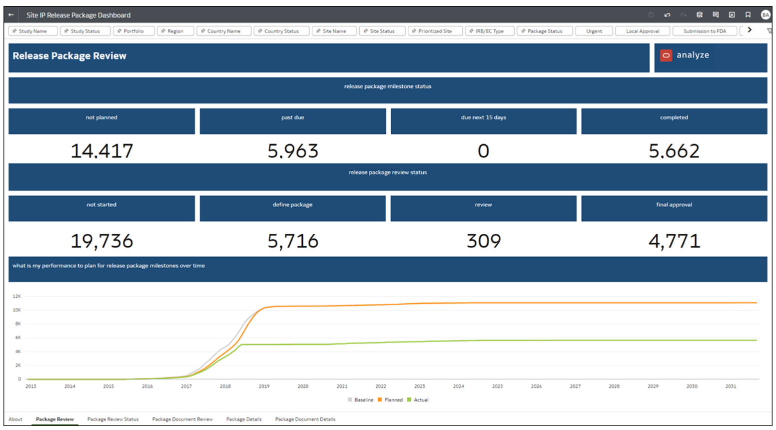
Release Package Review

This dashboard is a high-level summary of overall status of all IP release packages, with a breakdown of package review status and rejection reasons. Use any of the filters at the top of the worksheet page (e.g., Study Name, Country Name, Package status, etc.) to subset the data to your preferred view.

The top of the dashboard shows the following top-level KPIs (based on activity type as specified in the Oracle Site Activate lifecycle):

- release package milestone status (derived from the milestone)
  - not planned
  - past due
  - due next 15 days
  - completed
- release package review status (derived from the lifecycle)
  - not started
  - defined
  - reviewed
  - approved

Below the KPIs, a trend graph shows a comparison of baseline, planned and actual IP Release ready milestone dates.



Release Package Review Status

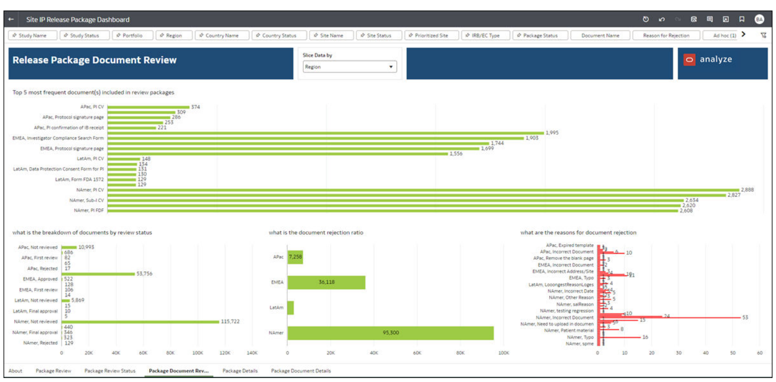
This worksheet includes multiple bar chart visualizations that show the breakdowns of release packages under review (package status) to the left and the reasons for package rejection to the right. Use the filters at the top of the worksheet to subset the data to your preferred view (i.e., Study Name, Package Status, Urgent, Local Approval, etc.).

Release Package Document Review

This dashboard allows you to identify most the most common documents in a package as well as the most commonly rejected documents and their reasons for rejection. Use the report level filters to include/exclude data use the "Slice Data by" filter in the report header to organize included data by Country Name, Region, Study Name, Portfolio, or All.

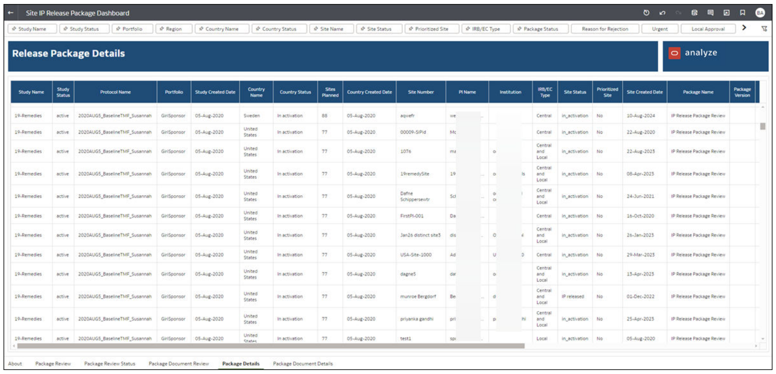
The bottom section is divided into three bar charts as follows:

- The lower left chart shows the breakdown of document review status
- The lower middle chart shows the rejection ratio per parameter selected (portfolio, study, region, country, all)
- The lower right chart shows the count of document rejection reasons



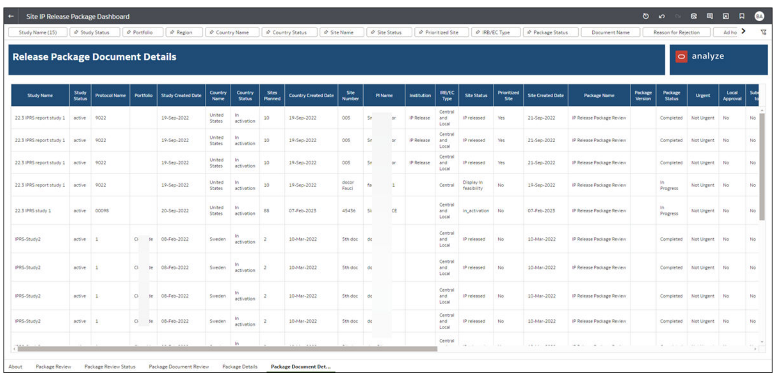
Release Package Details

This worksheet shows you the details of the review package, including package status, document review percentage, document completion percentage, and more.



Release Package Document Details

This worksheet shows you the details of the documents included in the review package. The worksheet identifies package name, version, and status, etc. for each document and shows document detail like type, date, review status, and more.



Site Reconciliation

Workbook synopsis

The Site Reconciliation Dashboard provides metrics to help managers understand the usage of sites in the Oracle Site Activate system as related to your Master Services Agreement. Standard Tableau functionality allows managers to easily download the dashboard and associated worksheets for further analysis or distribution.

Dashboard and sheets

Site reconciliation dashboard

The Sites Dashboard tab provides a trend chart to visualize site fees over time as well as a Rate Card table view of individual and total fees by type, contract, site type, etc. over a selected time period. Managers have multiple filter options to create a preferred view - including filters like Contract, Site Status, Date Range, and more. Finally, the dashboard prominently displays site and fee metrics for the specified Date Range. These metrics include Total number of sites, Total deleted sites, and Total fees, among others. To export the dashboard, use Tableau's standard Download option.

Sites detail sheet

The Sites Detail worksheet, which is intended for export use only, provides comprehensive information about sites as grouped by site type and study name. For instance, the worksheet includes details like site created date, site license expiration date, milestone dates, and days until the site will be dropped. To export this worksheet, use Tableau's Download option located just above the filters panel.

Rate card sheet

The Rate Card worksheet includes the same rate data presented in the Sites Dashboard tab, broken out into a separate sheet. Managers can adjust the data displayed using standard filter controls located to the far right. For instance, filter controls include Contract, Fee Type, Site Type, and Date Range, among others. Use the Download option, located just above the filter panel, to export and distribute Rate Card information as necessary.

Site status history

The Site Status History worksheet provides details of changes to a site's status (e.g., In activation, IP released, Dropped, etc.) and allows managers to easily view changes to a site's status over time. This sheet provides several filters (Study Status, Study Name, Country Name, Site Number, Site Type, and Current Site Status) that allow managers to create a preferred view. To export this worksheet, use Tableau's Download option located just above the filters panel.

Study status history

The Study Status History worksheet allows managers to easily view study status changes over time. Managers have the option to filter the sheet's data to one or more study, and columns included in the sheet are sortable to reach a preferred view. Columns include: Study Name, Study Status, Study Created At date, Prior Status, Status, and Set/End Dates. To export this worksheet, use Tableau's Download option located just above the filters panel.

Study Summary

Workbook synopsis

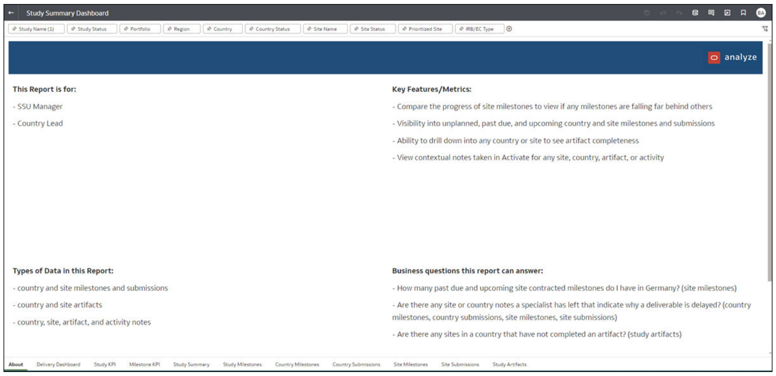
The Study Summary workbook, which is intended for Oracle Site Activate customers, provides easy interpretation of overall study status; visibility into unplanned, past due, and upcoming milestones; and milestone and submissions progress at the country and site level. Detailed sheets, described below, complement the Study KPIs dashboard sheet, enabling you to quickly pinpoint milestones and submissions that are upcoming or past due.

Dashboards and sheets

About

The About sheet provides a summary of key report features to help Study Summary report users understand if the report is applicable to his or her role. The About sheet provides details like:

- Study startup roles that would use the report
- Key report features and metrics
- Types of data the report contains
- Examples of how to use the report to answer a business question



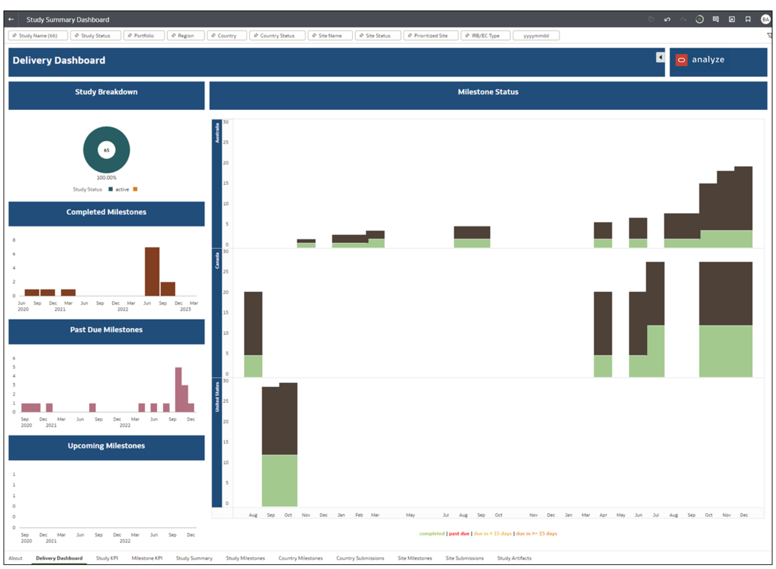
Delivery Dashboard

The Study Summary report's Delivery Dashboard is intended to help you to understand how remaining study milestones are distributed over time (day, week, month) so that your organization can correctly balance workload and achieve expected outcomes.

In a column on the left side of the dashboard, you'll find:

- Study status breakdown (active, inactive, completed, etc.)
- Completed milestones heat map (weekly trend of milestones completed, with darker green meaning more milestones completed that week)
- Past due milestones heat map (weekly trend of milestones past due, with darker red meaning more milestones past due that week)
- Upcoming milestones heat map (weekly trend of milestones planned, with darker orange meaning more milestones planning that week)

The remainder of the Delivery Dashboard sheet reflects milestone status. For each country, the dashboard shows a weekly trend of milestones past due, completed, due in less than 15 days, due in greater than 15 days. The milestone statuses are represented by stacked bar chart.



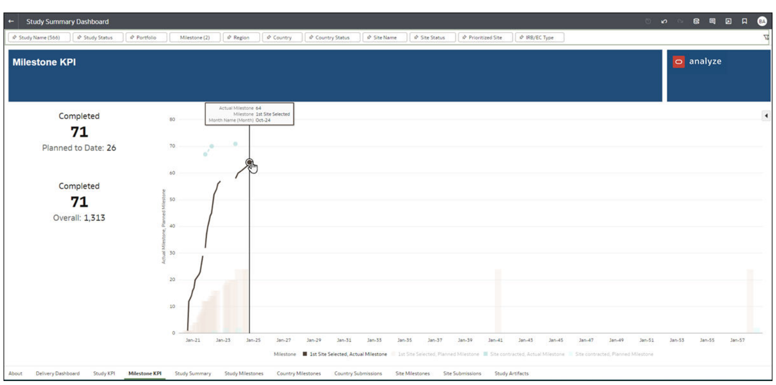
Study KPI Dashboard

This dashboard provides a high level graphical view of progress to plan over time for milestones and submissions. Hover-over tool tips for graphs provide additional details. Use any of the filters provided at the top of the worksheet to subset the dashboard's data to your preferred view.

Milestone KPI Dashboard

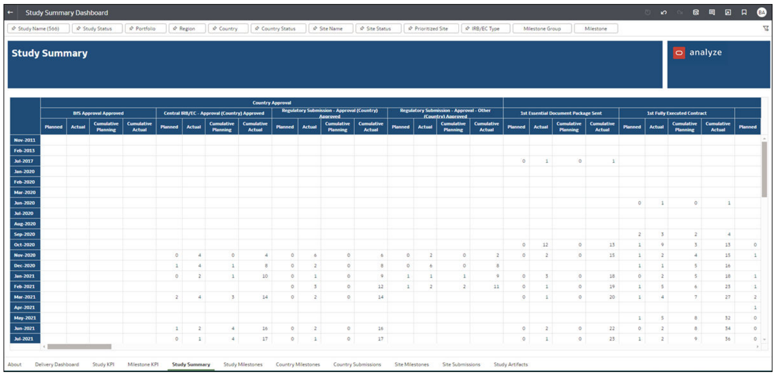
The Milestone KPI dashboard allows you to view details for a single milestone, which you select using the Milestone selection filter at the top of the worksheet. You can subset the data shown using any of the other filters at the top of the worksheet.

Hover over any point in the dashboard's bar chart to see additional detail for that milestone (e.g., actual or planned, month, milestone name).



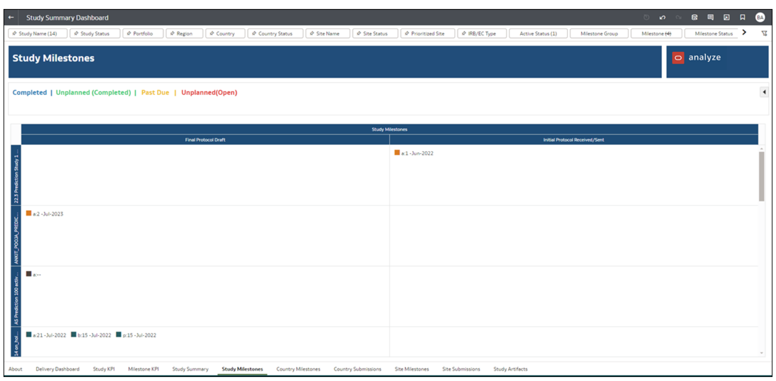
Study Summary

This worksheet provides a detailed tabular view of country and site global milestones, broken down by month, over the length of the study to date. This data is a detailed representation of the high-level graphical representation in the Study KPI dashboard.



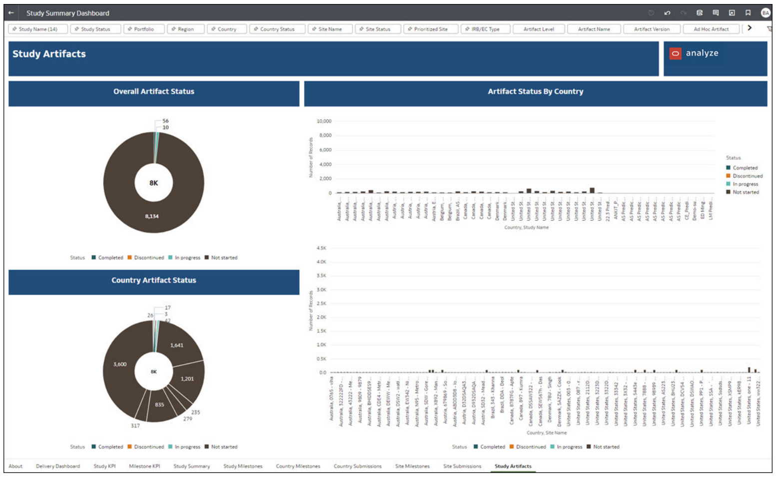
Study Milestones, Country Milestones, Country Submissions, Site Milestones, and Site Submissions

Each of the milestone and submissions worksheets is designed to help you understand if the study, milestones, and submissions are on track. These worksheets have similar layout with study, milestone, and associated data listed vertically in shaded cells on the left side or the worksheets. Where appropriate, the worksheets indicate the artifact or submission version (as applicable) in a vertical row header cell or a column cell.



Study Artifacts

The Study Artifacts dashboard provides a comprehensive view of artifact status (e.g., total artifacts completed, % of artifacts completed, in progress, not started, and discontinued, etc.) and bar charts showing the breakdown of Artifact Status by Country and Study. As with all reports, you can adjust the included/excluded data using the filters above the worksheet.



Submissions and Approval Status

Workbook synopsis

This workbook, intended for Oracle Site Activate customers, shows country and site submission and approval activities and status, as well as all documents associated with a submission package.

Dashboards and sheets

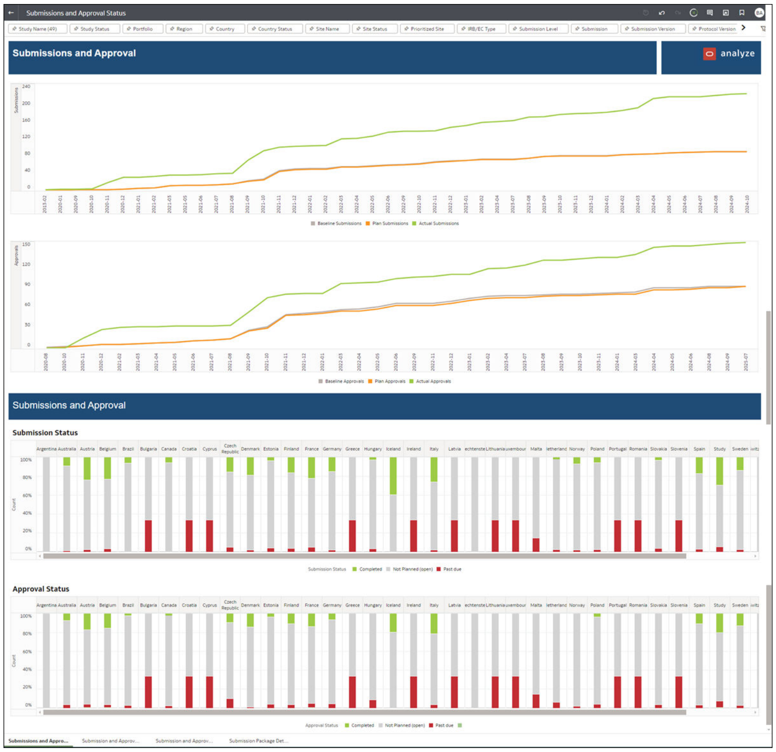
Submissions and Approvals Dashboard

The Submissions and Approvals dashboard provides an at-a-glance view of a study's submissions and approvals so you can easily identify countries that are falling behind.

The dashboard's top level trend graph shows baseline, planned, and actual dates for all initial submissions and final approvals in two separate graphs. You can shift focus to baseline, planned, and actual by clicking a trend line in the graph.

The lower section of the dashboard displays submission and approval data in a stacked bar graph. The graph shows the number of submissions not planned (open), past due, and completed by country. Click on any bar in the graph to drill down to that detailed data in the Study Submissions worksheet.

Use the filter options above the worksheet to subset the dashboard's data to your preferred view. Among others, filter options allow you to filter by submission level, version, category and type, as well as protocol version.

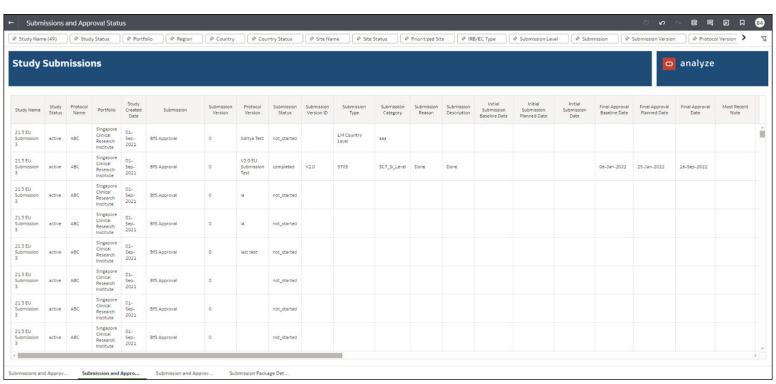


Submission and Approval Status

This worksheet shows the submission and approval activities for all submissions in a study and includes the most recent note and note replies related to the submission, if available. Hover over tool tips, in the Initial Submission and Final Approval columns, provide summary detail. When appropriate, the Submission Info column includes information related to study level (EU) submissions. For example, the Submission Info column includes validation, Part 1, or Part 2 package description as well as “Reporting” with a Yes or No value for the member state displayed in the Country column.

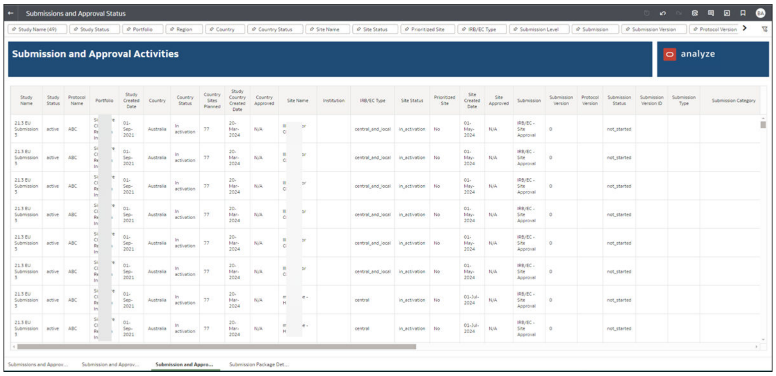
The Submission and Approval Status worksheet also provides columns like Reporting Member State, Country Approved, Country Info, Ready for Submission, Site approved, and Site Info that will help you track the site and country status within a study level submission.

This sheet provides multiple filters that allow you to subset data to you preferred view. Filters include: Study Name, Study Status, Portfolio, Country, Site Status, Site Name, Submission Level, Submission, Submission Version, Protocol Version, and Final Approval Date, among others.



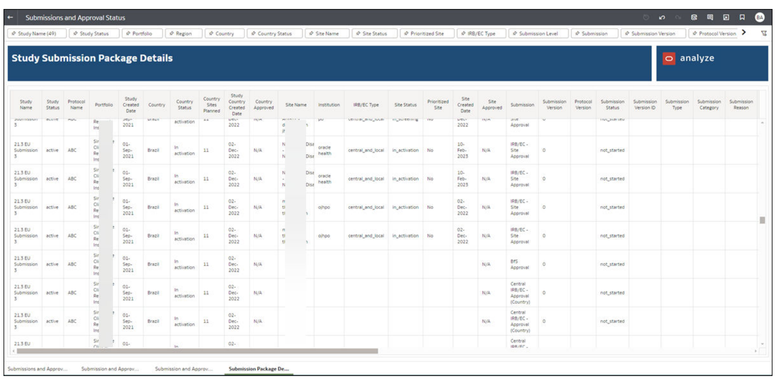
Submission and Approval Activities

The Submission and Approval Activities worksheet includes submission activities information (e.g., Received, Compiled Package, etc.) as well as the sites included in the submission. For instance, the worksheet shows the submission's metadata like status, type, and version ID and more. Site data includes the site name, site creation date, approval, status, etc.



Submission Package Details

This worksheet lists all the documents included in the associated submission package along with the document status. Use the filters above the worksheet to search for specific documents or filter for documents that are not yet completed.



TMF Status Dashboard

Workbook synopsis

This report is intended for customers that have licensed and enabled Oracle eTMF functionality. We designed this report to help managers use data and visualizations to evaluate TMF data and activity.

Dashboards and sheets

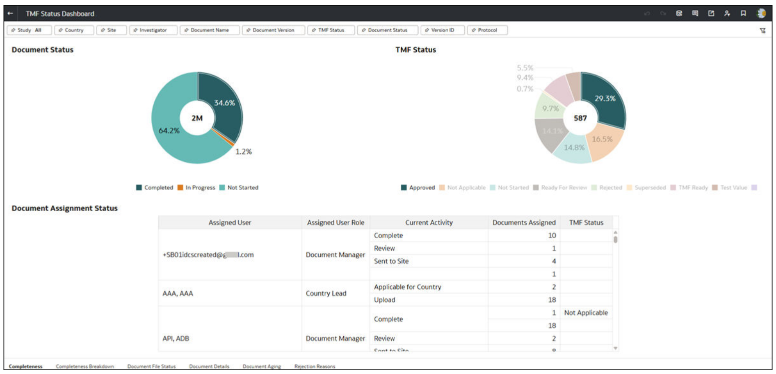
Completeness Dashboard

This worksheet includes interactive pie charts for Document Status and TMF Status. Hover over any portion of the charts to view count, status, and percentage details. You can filter this worksheet by Study, Country, Site, Investigator, TMF Zone, TMF Section, TMF artifact, Document Name, Document Version, TMF Status, Document Status, Version ID, and Protocol.

The Document Assignment Status section provides a tabular view of document assignment data with the following columns:

- Assigned User
- Assigned User Role
- Current Activity
- Documents Assigned
- TMF Status

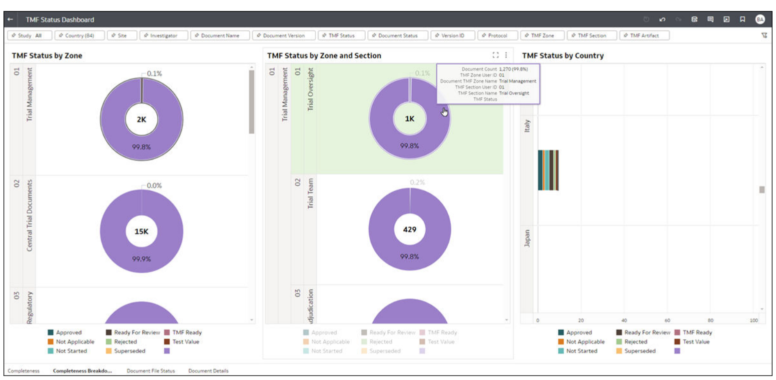
You can optionally drill down to document details from the visualizations on the worksheet. Right-click and choose “View Document Details” from the menu. This option opens the Document Details worksheet with the selected document(s).



Completeness Breakdown

This worksheet provides visualizations of TMF Status by Zone, Zone and Section, and Country. You can filter this worksheet by Study, Country, Site, Investigator, TMF Zone, TMF Section, TMF artifact, Document Name, Document Version, TMF Status, Document Status, Version ID, and Protocol.

Hover over any chart on this worksheet to view details in a tool tip. Note that this worksheet also supports detail drill down. Right-click on any visualization and choose “View Document Details” from the menu.

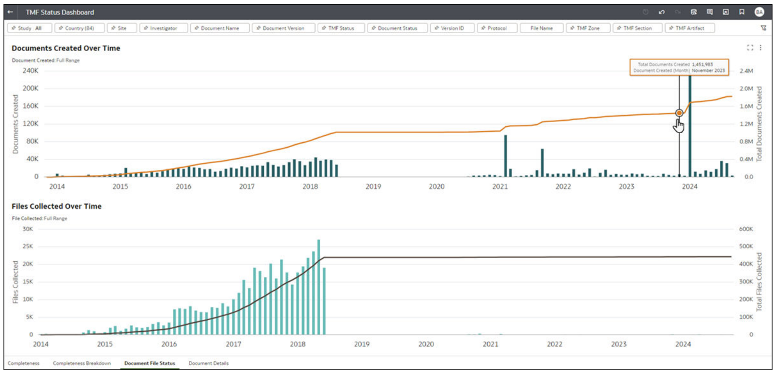


Document File Status

This worksheet visualizes Documents Created over Time and Files Collected Over Time. You can filter this worksheet by Study, Country, Site, Investigator, Document Name, Document

Version, TMF Status, Document Status, Version ID, Protocol, File Name, TMF Zone, TMF Section, and TMF artifact.

Hover over any point in the Documents Created Over Time and Files Collected Over Time bar charts to see details in a tool tip. Again, right-click to choose “View Document Details” if preferred.



Document Details

This worksheet is a tabular view of document information. You can filter this worksheet by Study, Country, Site, Investigator, TMF Zone, TMF Section, TMF artifact, Document Name, Document Version, TMF Status, Document Status, Version ID, and Protocol.

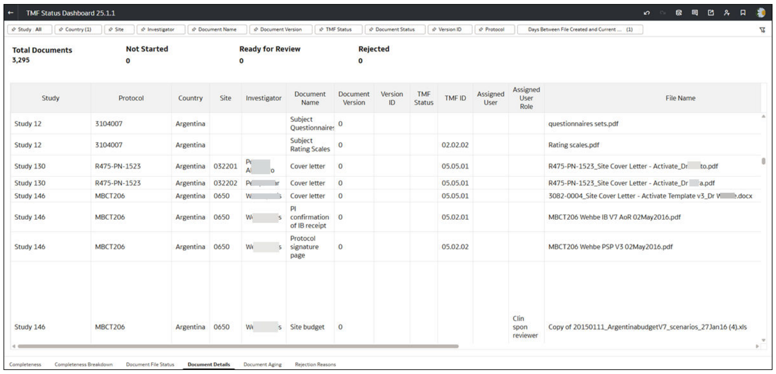
At the top of the worksheet, you’ll see a summary with counts for any documents in these actionable TMF statuses :

- Total Documents
- Not Started
- Ready for Review
- Rejected

The Document Details worksheet shows data, as available, in the following columns:

- Study
- Protocol
- Country
- Site
- Investigator
- Document Name
- Document Version (e.g., 0, 2, 4, 0.1, 1.1, etc.)
- version ID
- TMF Status
- TMF ID
- Assigned User
- Assigned User Role
- File Name
- Files Version (e.g., “3” if it is the 3rd attachment on the document)

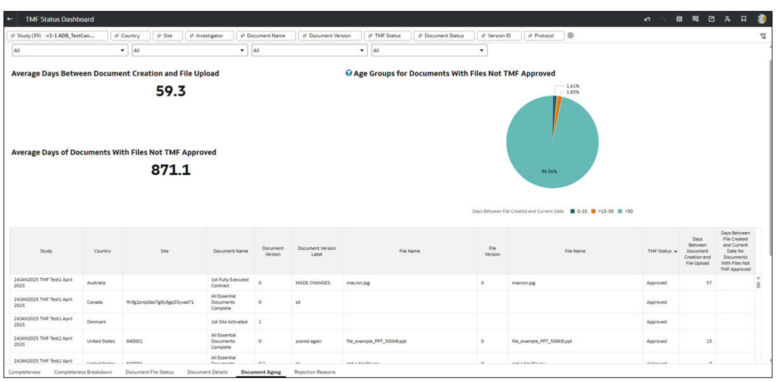
- Completed vs Total Activities (e.g., 2/3)
- Last Completed Activity
- Activity Decision
- Current Activity
- Last Note
- Last Note By



Document Aging

The Document Aging sheet allows you to review key metrics for eTMF, such as the average time between artifact creation and file upload, and the average number of days documents with files remain not TMF-approved. You can also view a pie chart with an age breakdown for documents not yet approved, sorted into brackets like 0–15 days, 15–30 days, and more than 30 days, with flexibility for these ranges to adjust based on your data. To see a specific time bracket, click any slice in the chart to filter the worksheet results to the associated artifacts or documents. To clear the pie slice filtering, click white space anywhere surrounding the pie chart.

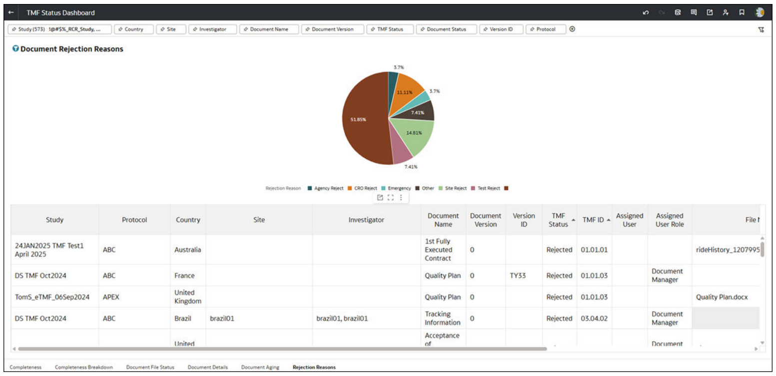
Worksheet filtering options let you focus on specific TMF sections, zones, artifacts, artifact names, studies, countries, or sites. These filters help you identify patterns or areas for follow-up.



Rejection Reasons

The Rejection Reasons sheet helps you track the most common reasons documents are rejected and includes the latest note for each rejected document, when available.

The sheet features a pie chart. Click any slice to filter the table to that rejection reason's data like Study, Document Name, TMF Status, etc. To clear the pie slice filtering, click white space anywhere surrounding the pie chart.



3

Data Export Utility

The Data Export Utility for Oracle Site Activate is a self-service export that allows permissioned Oracle Site Activate users to design a CSV extract with selected data columns and filters. The utility includes data columns for study sites, study level documents, study notes, milestones, submissions, artifacts, and activities.

Permission required to access the utility

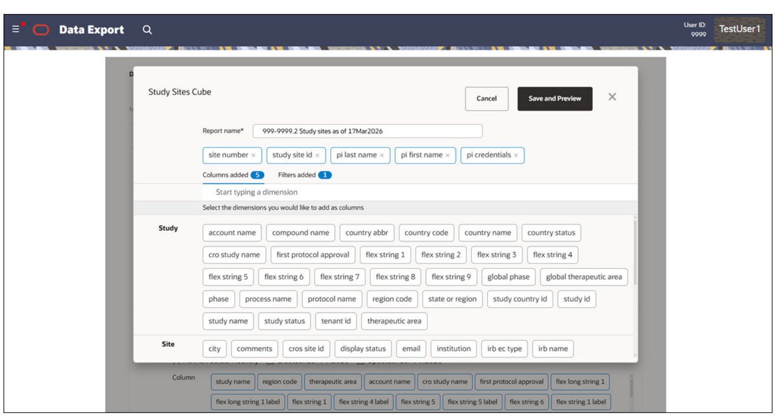
You must have at least one business role with “Enable access to the Data Export Utility” permission to access the export utility from the Oracle Site Activate Reports menu. The Data export option does not display in the Reports drop-down menu if you do not have permission. Contact your super user or administrator to request access for your user account.

Data extract cubes, columns, and filters

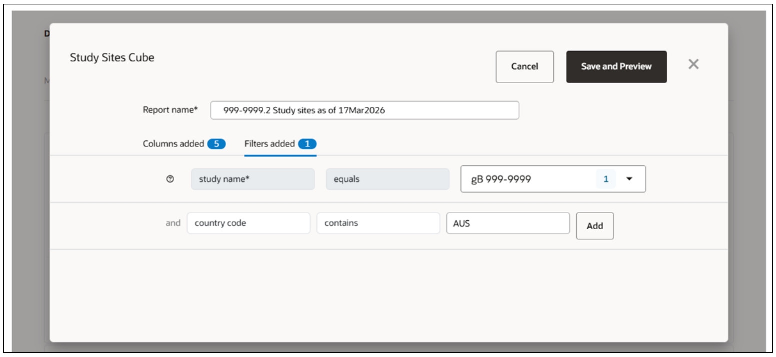
You can create new extracts, for one or more studies, based on:

- **Cube** – You'll select one cube per extract. The data cubes are:
  - Study Notes
  - Study Sites
  - Study Level Documents
  - Study Submission
  - Study Artifact
  - Study Milestones and Submissions
  - Study Activity
- **Columns** (dimensions) – You can add columns in any order
- **Filters** – You can add filters in any order

You'll see columns categorized into groups in each data cube. For instance, the Study Sites cube groups columns into Study, Site, Date, and Principal Investigator categories. When you create or edit a report, available columns display in alphabetical order within grouped categories.



The utility's Filter list sorts alphabetically so you can quickly find your preferred filters. For study name, you can select one, multiple, or all studies. For other filters, select a field from the drop-down menu, an operator (e.g., Contains, Equals, etc.) and enter a text value for an individual filter you would like to find. If you add a date or timestamp filter, specify the start and end dates for the date range. All text values are wildcard matches and case sensitive. To add multiple filters, click **Add** to add a new field.



The utility displays a "No matching records found" message if the columns and filters you selected for the export will not return any data. In this case, update your selections to refine the data included in the export.

You'll see report data only from those studies to which you currently have access. The Data Export Utility "Study" filter hides a study when you no longer have explicit access to it and will also hide any deleted study. Existing Data Export Utility reports are still available to you, even when created with a study to which you no longer have access. When you access or preview the report again (after initial creation), the report's study filter automatically updates to exclude any unavailable study and its data. This applies reports you create and to those reports that have been shared with you.

Asynchronized report download

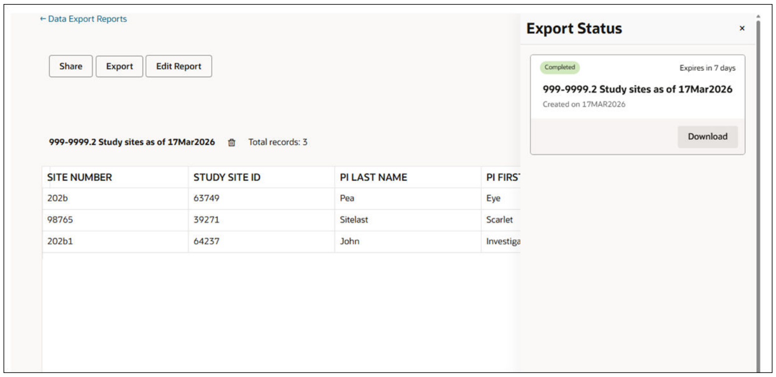
You can download entire Data Export Utility reports asynchronously, whether you are viewing your own or shared reports. On both the homepage and the Preview page, you'll see an Export button. When you click Export, the system generates a ZIP or CSV file containing all report data, not just the information on the current page.

Export features include both individual user and account-level limits to ensure efficient operation. You may have up to two exports in progress at a time, while your organization's account can support up to 10 at once. If you reach either limit, or if an export is already running for the specific report, the Export button is disabled. When you hover over the disabled button, a tool tip appears, explaining the reason, such as an export queue limit or a running export for that report.

The Export Status button, located to the left of the New Report button on the homepage and in the upper right of the report Preview page, helps you track in-progress and available exports. The button shows the following states:

- no icon when no export is running or available for download
- a spinner icon when at least one export is in progress
- a badge showing the number of exports available for download when no export is running but some are ready

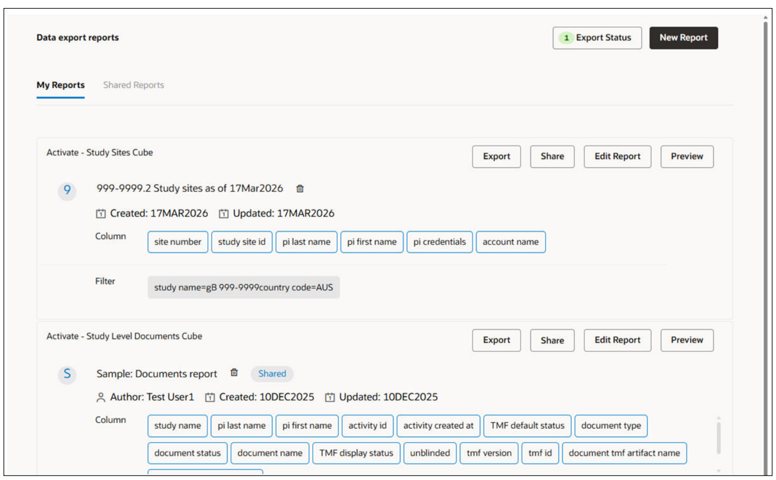
Click Export Status to open a drawer showing any exports in progress or available downloads. Export Status displays all your exports, including both your reports and shared reports. Every successful export file you generate is available for download for seven days before expiring. If an error occurs during report generation, an error message displays that you must acknowledge, and the failed export will not be listed in the Export Status drawer.



Share exports with other users

You can optionally share reports you've created with other users in your account who have permission to access the Data Export Utility. The Data export reports page includes two tabs:

1. **My Reports**: lists all reports you created
2. **Shared Reports**: lists all report shared with all Data Export Utility users in the account



On the My Reports tab, you can Export, Share, Edit, or Preview a report using the button options at the upper right of each report. When you click Share, a modal displays where you'll set the report's access type as Private or Shared. Private, the default selection, means only you can access the report. Shared means you allow others in your account to have access to the report.

You can identify a shared report by the "Shared" status label displayed on the report's title line, and you'll also see author and created and/or updated dates as applicable. You can unshare a report you've shared at any time; click Share again to change the access type from Shared to Private. You can also edit your shared reports as preferred, and other Data Export Utility users will see the updated report in their Shared Reports list.

Modify a report shared with all users in the account

The Data Export Utility supports user-specific filters on shared reports. This lets you personalize shared report views without impacting the base report or other users' views.

When you access a report from the Shared Reports tab on the home page or from the report preview page, you'll see an Edit Report button. Click to open the edit report modal, with the focus on the “Filters added” tab. Here, you can view the filters from the original report and modify them by adding or removing filters. The adjustments you make are unique to you, so your changes do not affect others in the account. You can also navigate to the “Columns added” tab to review which columns are included and their order, but you cannot add new columns or change their sequence; column changes are reserved for the report's original author.

After updating filters, click Save and Preview to view the report with data filtered by your chosen filters. Your exports from the report will use the filters you specified.

The latest filter values appear in the “Filter” section on the Shared Reports tab for easy reference. If the original report author updates the shared report (e.g., changing which columns are included), you'll see the updated columns, but your user-specific filters remain unchanged.

- Create a new export
  If you have the appropriate business role permission in Oracle Site Activate, you can access the Data Export Utility to create a unique export that contains your preferred data and export the result to a .csv format file.
- View existing export
  The Data export report page lists all of your previously-created reports, as well as any reports authored by others and shared with you.
- Edit existing export
  The My Reports tab on the Data export reports page lists all of your previously created reports, and you can edit any of them as you prefer.
- Delete an export
  When you no longer need a report you created, you can delete it as necessary.
- Share or unshare an export
  Share an export when you want others in your account to have access to an export you authored. When you no longer want others to have access, change the report's access level from Shared to Private.

Create a new export

If you have the appropriate business role permission in Oracle Site Activate, you can access the Data Export Utility to create a unique export that contains your preferred data and export the result to a .csv format file.

1. From the Oracle Site Activate top navigation, hover over **Reports** and click **Data export**.
2. On the Data export reports page, click **New Report**.
3. On the New Report pop-in, choose **Study Sites Cube**, **Study Level Documents Cube**, **Study Milestones and Submissions Cube**, **Study Notes Cube**, **Study Artifact Cube**, **Study Activity Cube**, or **Study Submissions Cube** from the drop-down list.
4. Click **Continue**.
5. At the top of the pop-in, enter your preferred **Report name**.

6. Under **Columns added**, choose the dimensions you would like to add as columns. You can scroll through the list or search for a specific dimension. As you add dimensions, the "Columns added" count increases.
7. Click **Filters added**. The "study name" filter is required. Click the drop-down list and select one, multiple, or all studies to include in the export. To add additional filters, choose a field from the drop-down menu (below the study name field), choose a filter operator (e.g., Equals, Contains, etc.), and enter a text value to filter by. All text values are wildcard and case sensitive. Click **Add** to include another filter.
8. Click **Save and Preview**.
9. You can optionally Share the report with other users in your account. At the upper left in Preview mode, click **Share**. In the share modal, confirm selection of the Shared option, and click **Save**.
10. In Preview mode, click **Export** to generate a CSV file, or click **Edit Report** to adjust the report data before exporting.

View existing export

The Data export report page lists all of your previously-created reports, as well as any reports authored by others and shared with you.

1. From the Oracle Site Activate global navigation, hover over **Reports** and click **Data export**.
2. On the Data export reports page, click the **My Reports** or **Shared Reports** tab and locate the export you want to view.
3. At the far right, click **Preview**.

Edit existing export

The My Reports tab on the Data export reports page lists all of your previously created reports, and you can edit any of them as you prefer.

1. From the Oracle Site Activate global navigation, hover over **Reports** and click **Data export**.
2. On the Data export reports page, click the **My Reports** tab and locate the report to be edited.
3. At the upper right, click **Edit Report**.
4. Adjust the report name, columns, and filters as preferred.
5. Click **Save and Preview**.
6. At the upper left, click **Export** to generate a CSV file, or click **Edit Report** to adjust the report data before exporting.

Delete an export

When you no longer need a report you created, you can delete it as necessary.

1. From the Oracle Site Activate global navigation, hover over **Reports** and click **Data export**.
2. On the Data export reports page, click the **My Reports** tab and locate the report to be edited.

3. To the right of the export's title, click delete ().
4. In the confirmation modal, click **Yes, delete report**.

Share or unshare an export

Share an export when you want others in your account to have access to an export you authored. When you no longer want others to have access, change the report's access level from Shared to Private.

1. From the Oracle Site Activate global navigation, hover over **Reports** and click **Data export**.
2. On the Data export reports page, click the **My Reports** tab and locate the export you want to share.
3. Click **Share**.
4. In the confirmation modal, select **Shared,** and click **Save**.

   To unshare an export, return to the confirmation modal and select **Private (Accessible by author only)**, then **Save**.