Oracle® Life Sciences Site Analyze Cloud Service

Using Oracle Site Analyze: For Oracle Site Activate Users

Release 23.2
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Oracle Life Sciences Site Analyze Cloud Service Using Oracle Site Analyze: For Oracle Site Activate Users, Release 23.2

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Contents

Preface

This preface contains the following sections:

- Documentation accessibility
- Diversity and Inclusion
- Related resources
- Access to Oracle Support

Documentation accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc.

Diversity and Inclusion

Oracle is fully committed to diversity and inclusion. Oracle respects and values having a diverse workforce that increases thought leadership and innovation. As part of our initiative to build a more inclusive culture that positively impacts our employees, customers, and partners, we are working to remove insensitive terms from our products and documentation. We are also mindful of the necessity to maintain compatibility with our customers' existing technologies and the need to ensure continuity of service as Oracle's offerings and industry standards evolve. Because of these technical constraints, our effort to remove insensitive terms is ongoing and will take time and external cooperation.

Related resources

Product documentation and other supporting materials are available on the Oracle Help Center.

Access to Oracle Support

Oracle customers that have purchased support have access to electronic support through Support Cloud.

Contact our Oracle Customer Support Services team by logging requests in one of the following locations:

- English interface Customer Support Portal (https://hsgbu.custhelp.com/)
- Japanese interface Customer Support Portal (https://hsgbu-jp.custhelp.com/)

You can also call our 24x7 help desk. For information, visit https://www.oracle.com/life-sciences/support/ or visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs if you are hearing impaired.

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About the data dictionary, access, and user roles

Oracle Site Analyze is the reporting and visualization application that supplements reports available in the Oracle Site Activate clinical study startup application. This section provides an introduction to the data dictionary, instructions for accessing Oracle Site Analyze, and more.

Getting started with Oracle Site Analyze

Oracle Site Analyze reports allow you to view status and other data about the activities that your study team performs in Oracle Site Activate.

In Oracle Site Analyze you can view standard reports created by Oracle. Report data comes from Oracle Site Activate where information about sites, documents, submissions, milestones, and the status of activities related to them are tracked and managed.

A data dictionary that reflects your work

The Oracle Site Analyze data dictionary is built to provide insight on common study startup tasks. For example, study milestone data can be used to build a report showing planned versus expected study milestones, while cycle time data items give you the ability to identify bottlenecks or improve processes.

Whatever your reporting needs, one or multiple items in the Oracle Site Analyze data dictionary can meet them.

Accessing Oracle Site Analyze from Oracle Site Activate or Oracle Site Select

Navigation

If you have the appropriate permissions to access Oracle Site Analyze reports, you'll navigate to reports from within the Oracle Site Activate or Oracle Site Select application. In the Oracle Site Activate top navigation bar, click Reports, then click Analyze reports. In the Oracle Site Select top navigation bar, hover over the Dashboards menu, then click Analyze reports.

Study level permissions

For both Oracle Site Activate and Oracle Site Select, you must have study level access to view specific studies in certain reports. Oracle Site Analyze enforces study level permissions for the following reports:

Oracle Site Activate

- All Activities + Notes
- Contract Module Status
- Delivery Dashboard
- Documents and Submissions
- Milestone and Scheduled Activity Planning

- Open Activities
- Regulatory Submissions and Approval Status
- Site IP Release Package Dashboard
- Study Summary Dashboard

Oracle Site Select

- Survey Response Analysis
- Site Study Interest and Exclusion
- Site Progress
- Study Level Notes

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 21.4 Oracle Site Analyze must upgrade their Oracle Site Activate release to 21.4 as well. Please contact your Oracle Project Manager or Account Manager for more information about upgrading.

Roles control access to information

Oracle Site Analyze controls who has access to certain data views. There are two roles:

1. **business intelligence (BI)**: This super user role can view all reports, and create or edit reports.
2. **view only**: Users with this role can view a subset of the standard Oracle Site Analyze reports and reports that BI users share with them.

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About viewing reports and using Tableau

Learn about the Oracle Site Analyze project dashboard and workbooks and see how users can export and share report data.

Project dashboard and workbooks

When you log into Oracle Site Analyze, you'll see a list of projects - each of these projects include workbooks that contain standard reports

For the following reports, Oracle Site Analyze users will view only those studies that they have permission to view in Oracle Site Activate:

- All Activities + Notes
- Contract Module Dashboard
- Milestone and Submission Planning
- Milestone Prediction Dashboard
- Open Activities
- Site IP Release Package Dashboard
- Study Summary Dashboard
- Submissions and Approval Status

For the following reports, Oracle Site Analyze users will view only those studies that they have permission to view in Oracle Site Select:

- Next Actions
- Notes Report
- Site Progress
- Site Study Interest and Exclusion
- Survey Response Analysis

With any Oracle Site Analyze report, you can sort and filter the data. You can restore any changes you make to the original format or save them permanently. You can also turn off automatic updates, so the data you see remains consistent during your editing experience. Subscribe to reports and receive email updates daily or weekly when the report data changes.

On the Workbooks page, you can select the check box next to a report to access additional features.

- **Edit**: allows you to edit the report, if you have appropriate permissions
- **Download**: saves the report (you can use the Tableau desktop application to open downloaded reports)
- **Tag**: you can associate the report with a category you define; this way, you can easily find the report by filtering by the category name

- **Permissions**: allows you to determine who can view, interact with, and edit reports (if you have been granted permission to control permissions)
- **Move**: use this to move the report to another folder or project in the workbook
- **Change owner**: not enabled for view only users
- **Extract refresh**: not enabled for view only users
- **Tabbed views**: allows you to view all reports in the workbook as tabs
- **Delete**: allows you to delete the workbook, if you have appropriate permissions

Export formats

You can export your report data in the following formats:

- spreadsheet (single or multiple tab)
- Adobe Acrobat (PDF) format
- Microsoft PowerPoint
- image (PNG) format

> **Note:**
>
> We recommend that you use either spreadsheet or PDF format. If your report contains charts, graphs, or other images, those are not included when you export in spreadsheet format. Additionally, when you export a dashboard, you see only what appears on your screen; to export all pages in a report, always export the entire report.

Sharing web views

You can share Oracle Site Analyze reports with others on your study team or external partners. When you share, recipients receive an email that contains a link to view the report.

> **Note:**
>
> Anyone with whom you share a report must have Oracle Site Analyze access. However, you can export an Oracle Site Analyze report and send it to those without access.

Procedures

The links below redirect to Tableau online documentation.

- Explore and analyze data in a view
- Save your work
- Manage subscriptions
- Refresh data or pause automatic updates
- Download views and workbooks

- Use custom views

3 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

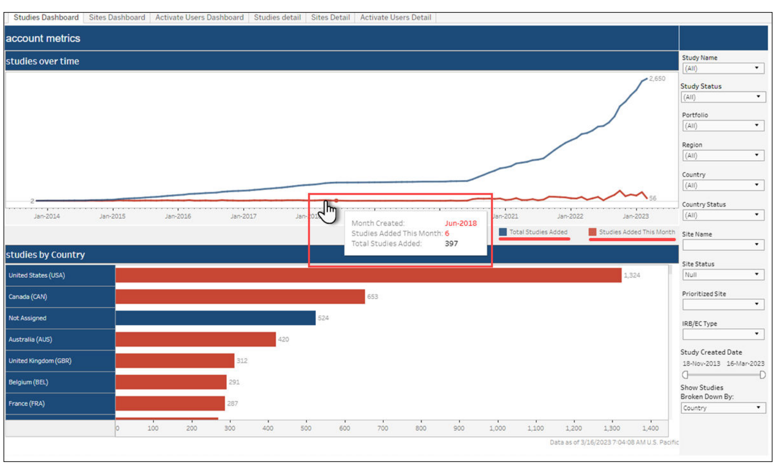
The Studies Dashboard shows:

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

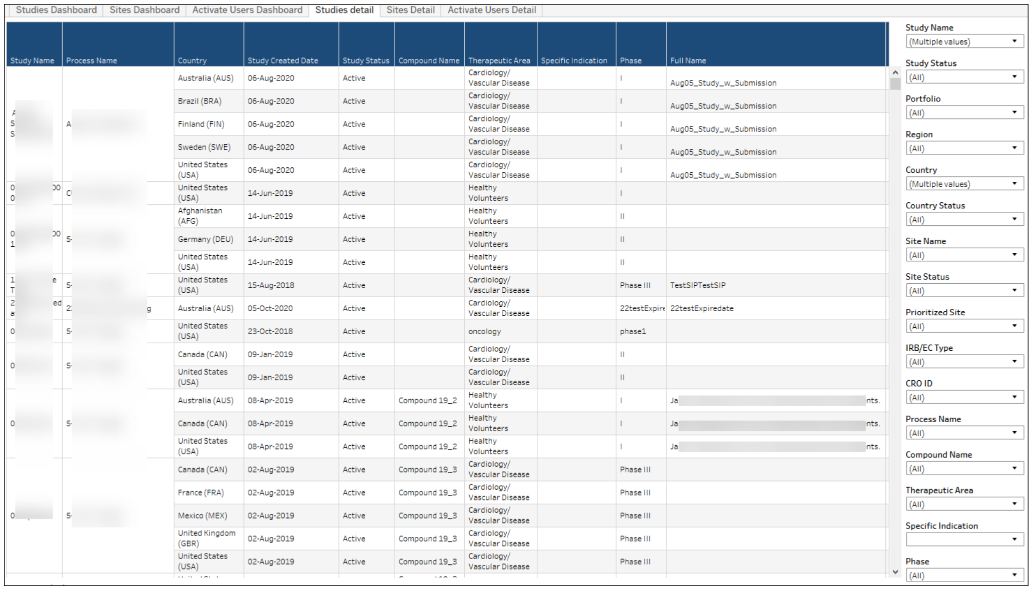
Notes:

- 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.
- 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 sheet



Studies Detail sheet



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, in the filter panel to the right, to control the range of the line graphs.

You can also use the Site Used Date filter in the right side panel to filter the report's Total Sites Used KPI and Sites Used Over Time graph to a specific date range based on when a site is marked as used. The site used date is the earliest of IP release status date, Activated status date, and In activation status + threshold days.

Site used criteria are:

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

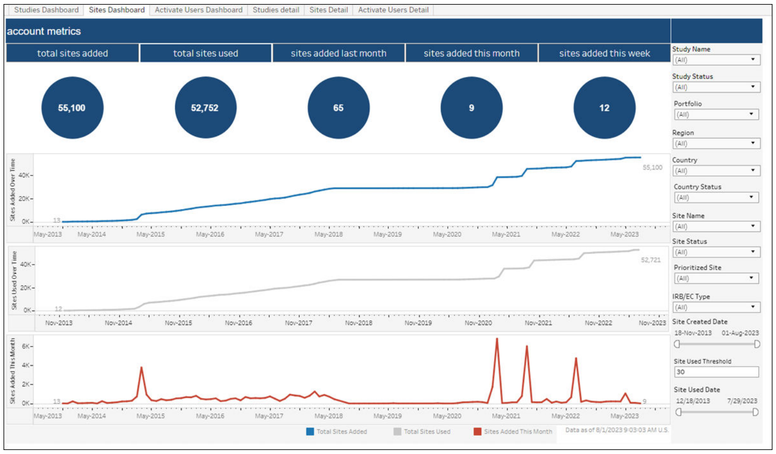
30 days is the default value of the in activation threshold for a site to be considered used and it can be adjusted to any other numbers as needed.

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.

- 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.

Sites Dashboard sheet



Sites Detail sheet

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)

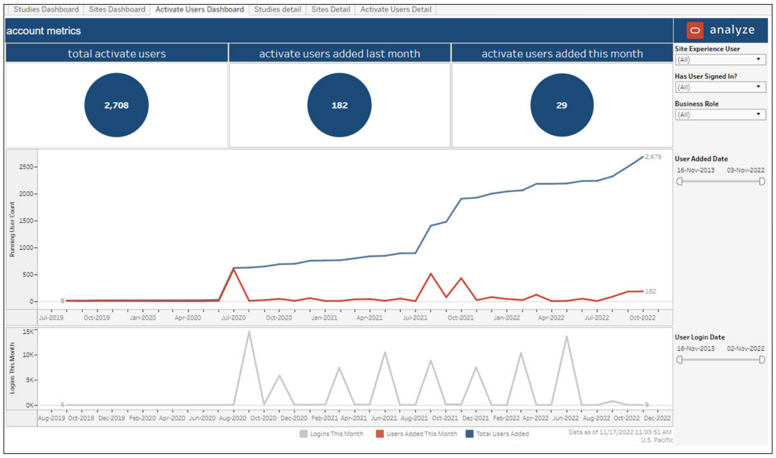
The sheet also includes two line graphs:

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 timespan with the "User Added Date" filter to the right of the graph.
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 timespan with the "User Login Date" filter to the right of the graph.

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 sheet



Activate Users Detail sheet

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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.

Dashboards

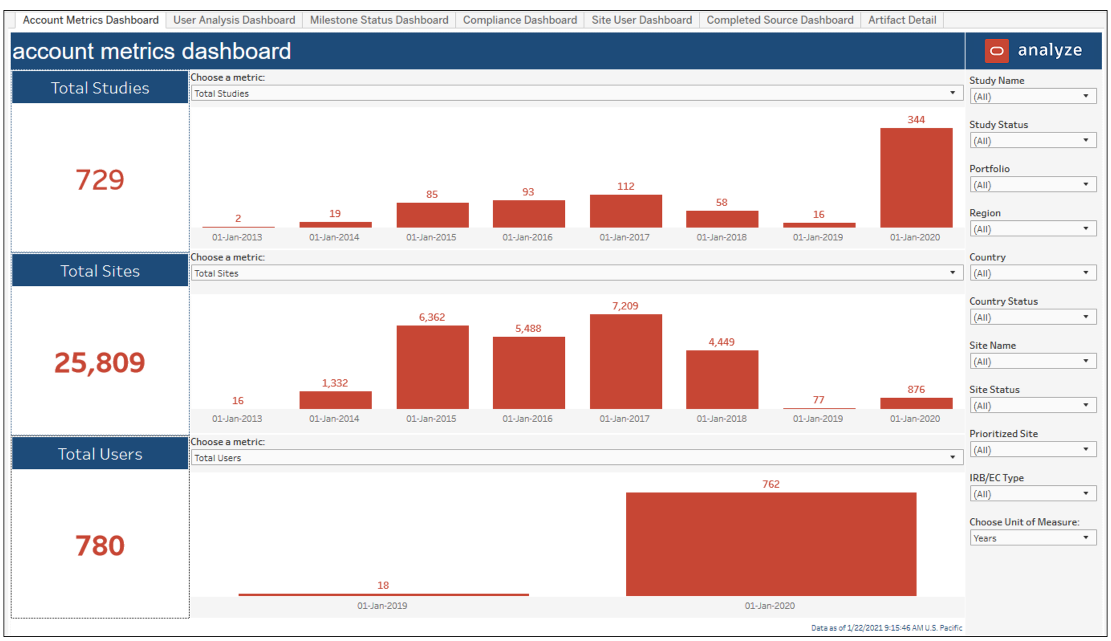
Account Metrics Dashboard

This dashboard includes three Key Performance Indicator (KPI) areas with:

1. Total for a selected KPI across all Oracle Site Activate
2. Trend bar graph of a selected KPI
3. Trend by parameter selected that includes year, quarter, month, week

You can adjust in which KPIs display in the three sections. Choose from:

- Total Studies – trended by study created date
- Total Sites – trended by site created date
- Total Users – trended by user created date



User Analysis Dashboard

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

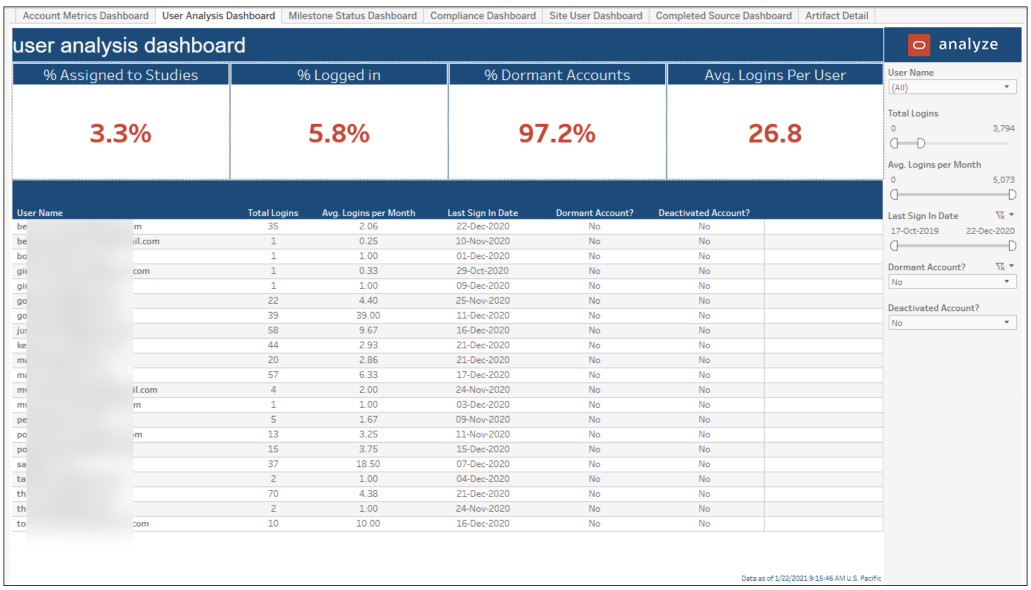
- Percentage of users assigned to studies
- Percentage of users who have logged in

- 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 options in the filter panel. For instance, you can set the report to include only deactivated and/or dormant users, display data for one or multiple individual users, etc.

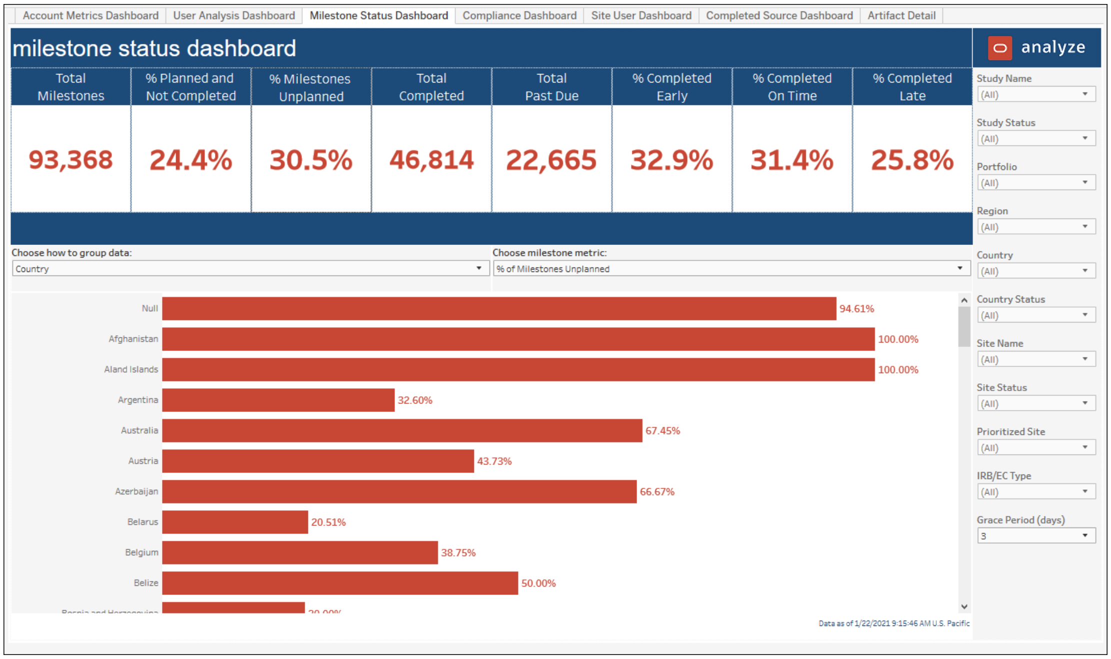


Milestone Status Dashboard

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 milestone data in a bar graph. You can choose how to slice the displayed data (Portfolio, Study, Country, or Region) and choose the milestone metric to graph (selected from the metrics listed above). You also have familiar filters available in the filter panel (e.g., Study Status, Portfolio, Study Name, Region, and Country), as well as filters for Site Status, Site Name, and Grace Period.

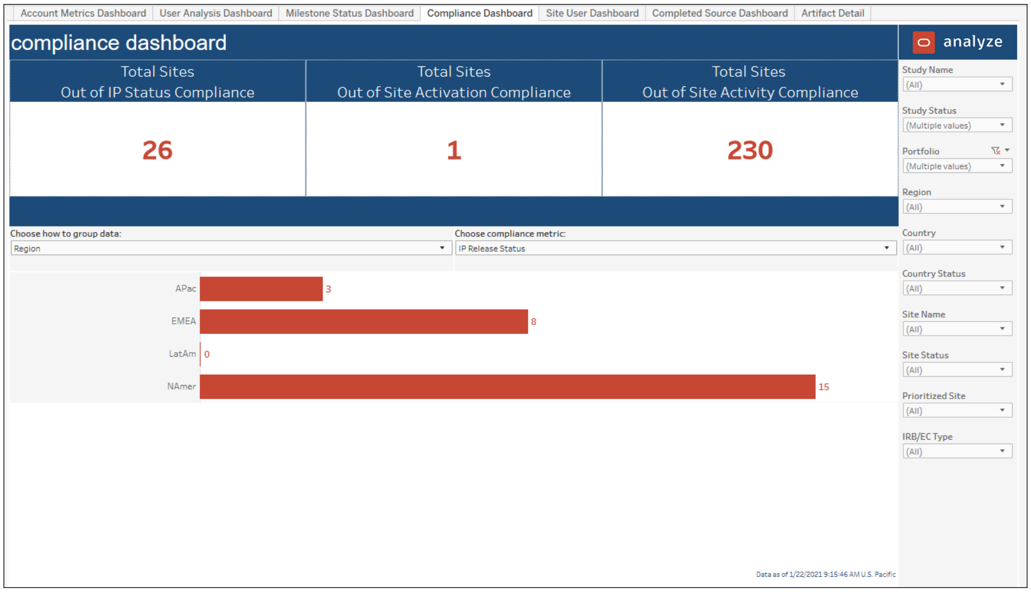


Compliance Dashboard

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 slice the displayed data (Portfolio, Study, Country, or Region) and choose the compliance metric to graph (IP Release Status, Site Activation, or Site Activity). Filter panel options allow you to subset the data by any combination of: Study Status, Portfolio, Study Name, Region, Country, Site Status, and Site Name.

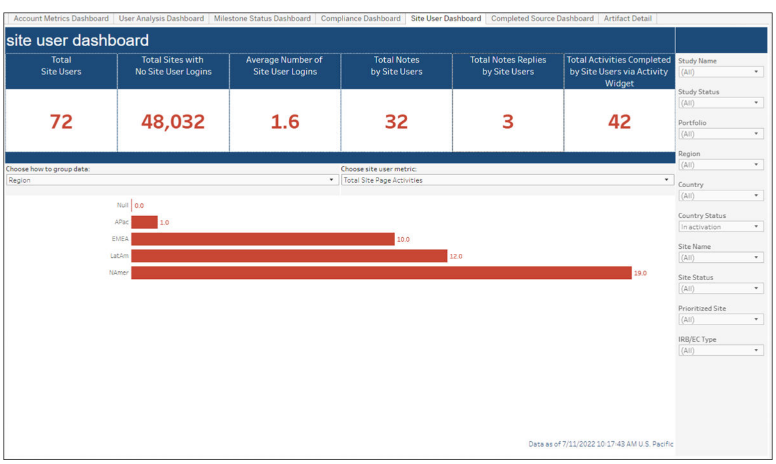


Site User Dashboard

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
- Total Activities Completed via Widget

The dashboard's lower section displays site user data in a bar graph. You can choose how to slice the displayed data (Portfolio, Study, Country, or Region) and choose the site user metric to graph (Site Experience Users, Sites w/o SEU logins, etc.). You can further refine the displayed data using filters available in the filter panel to the right (e.g., Study Status, Portfolio, Study Name, Region, Country, Site Status, and Site Name).



Completed Source Dashboard

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. A new “Completed Source Dashboard” worksheet includes the following top-level metrics:

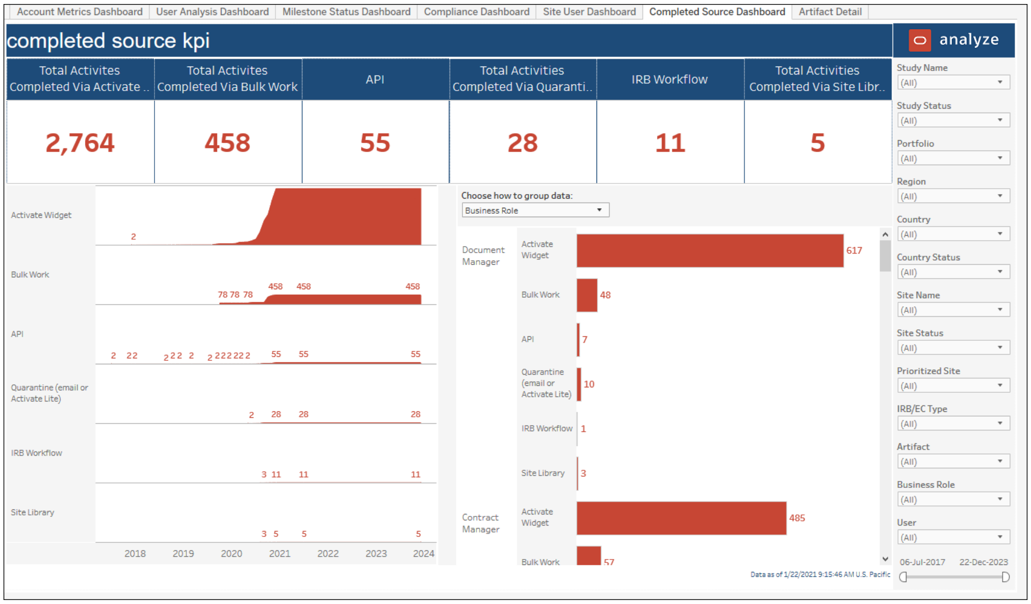
- Total activities completed via Activate placeholder widget
- Total activities completed via quarantine (email or Activate LITE)
- Total activities completed via bulk work
- Total activities completed via site library

Below the metrics, the dashboard displays two visualizations of Oracle Site Activate feature use.

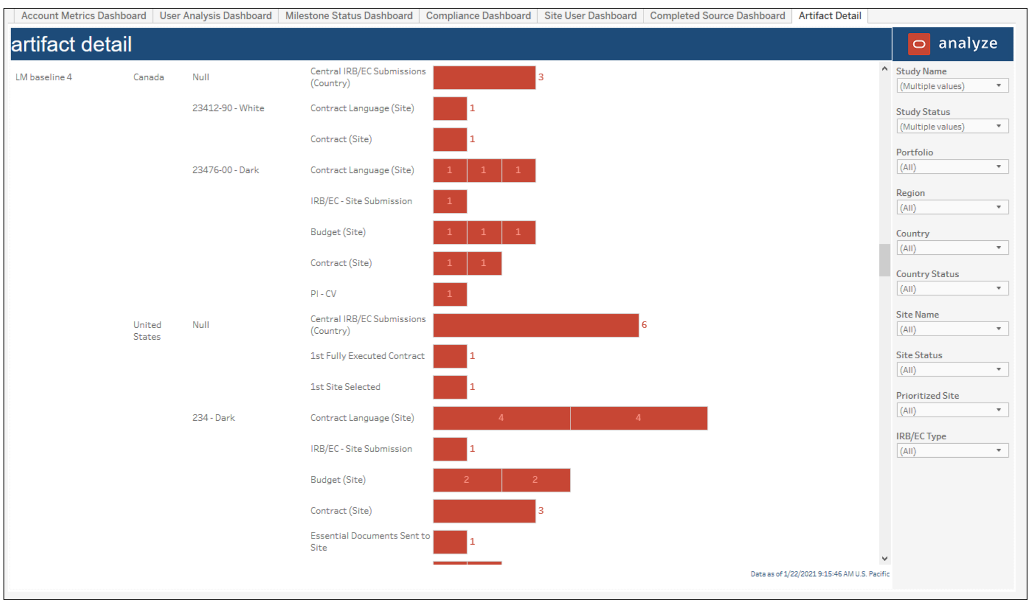
1. To the left, a trend graph shows a trend of activities completed over time via Oracle Site Activate placeholder widget, quarantine (email or Activate LITE), bulk work, and site library
2. To the right, a bar chart shows total counts of activities completed by Oracle Site Activate placeholder widget, quarantine (email or Activate LITE), bulk work, site library. Report users can group the bar chart data by:
    a. Portfolio
    b. Study
    c. Country
    d. Region
    e. Artifact
    f. User
    g. Business role
    h. Mastered PI

Click any of the KPIs at the top of the dashboard to filter the data displayed in the dashboard’s trend graph and bar chart.

In the dashboard’s right panel, you can also select from additional filters to subset the dashboard data. For example, filter by Study Status, Portfolio, Study Name, Region, and country. Filters for Site, Artifact, Business Role, and User also allow you to create unique views of individual user interactions with the Oracle Site Activate application.



Artifact Detail



5
All Activities + Notes

Workbook synopsis

Intended for Oracle Site Activate customers, this workbook makes it easy for users to evaluate artifact activities and any related notes. Report users can filter activities by a single user and export that filtered data if preferred.

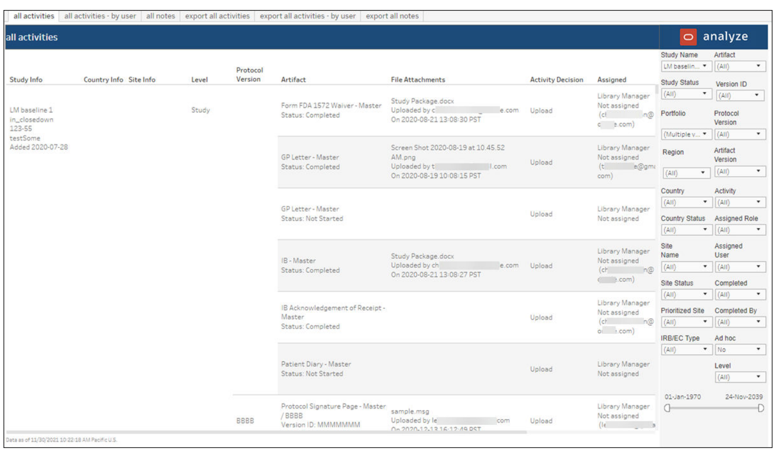
Worksheets

All Activities

This worksheet lists the activities for all artifacts for a study within Oracle Site Activate. The File Attachments column shows detail about file attachments uploaded for an artifact, including the file name, the user who uploaded the file, and the date/timestamp of upload. Each record also shows the business role and Oracle Site Activate user assigned to the task, as well as the date the activity was completed.

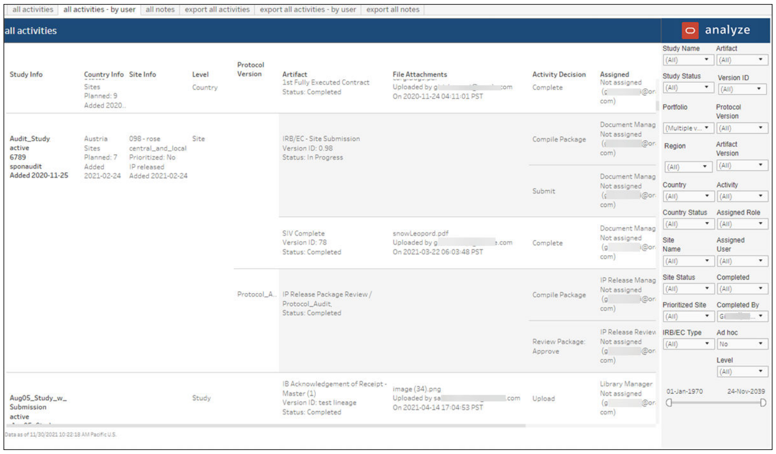
There are multiple filters on the right-hand side of the worksheet that you can use to find specific tracking items based on study name or status, portfolio, date range, clinical level (country, site, or study), and many others.

If an activity has been completed, the user name listed is the name of the user who completed the activity. If the activity is still outstanding, the name listed is the primary user for the assigned business role.



All Activities by User

This worksheet allows report users to filter the sheet by a single user.

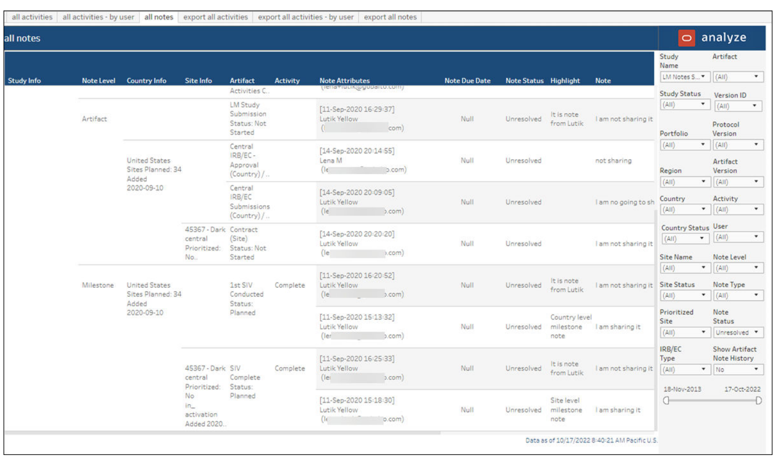


All Notes

This worksheet lists all notes entered for a particular artifact activity, which Oracle Site Activate user entered the note, and when that user entered the note.

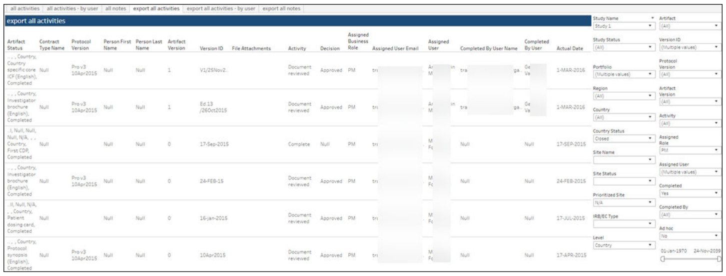
Multiple filters on the right-hand side of the worksheet allow you to find specific tracking items based on study name and status, date range, portfolio, site name, user, and more. You can also filter the worksheet by Note Type (All, Activity, Artifact, General Country, or General Site).

For general artifact notes, you can filter by the “Show Artifact Note History” filter with yes or no options. When you select “yes,” the report includes only the most recent note update for a general artifact note. When you select “no,” the report includes the entire audit trail of all changes to a general artifact note.



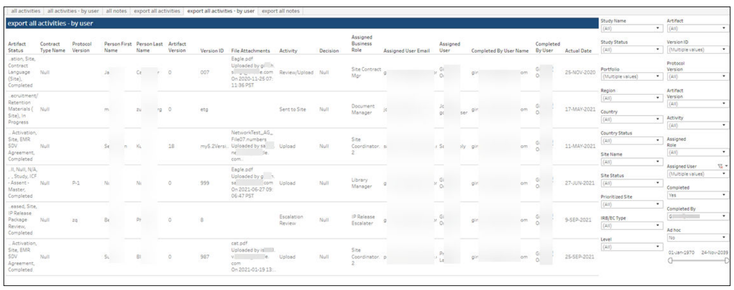
Export All Activities

This worksheet, which is intended for export, provides detailed activity information. The worksheet provides multiple filters that allow you to adjust content before download.



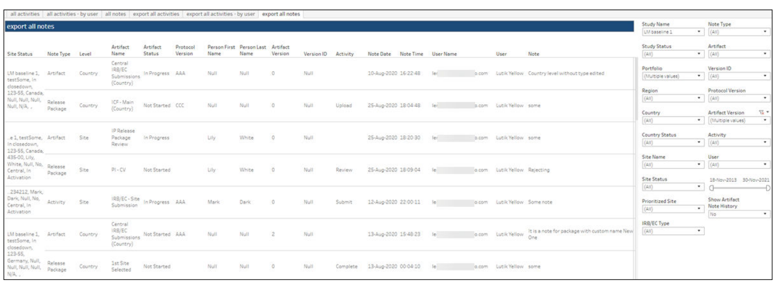
Export All Activities by User

This worksheet is intended for export only. You can filter the sheet by a single user across all relevant studies and export in a preferred download format (e.g., PDF, crosstab, etc.) or share via URL with permissioned users.



Export All Notes

This worksheet, which is intended for export, provides detailed notes information. The worksheet provides multiple filters that allow you to adjust content before download.



6 Analyze Adoption Dashboard

Workbook synopsis

Using the Analyze Adoption Dashboard, Oracle Site Activate customers can easily monitor the adoption of Oracle Site Analyze within their organizations to understand which reports are used most frequently and which users log into the application most often.

Analyze Adoption

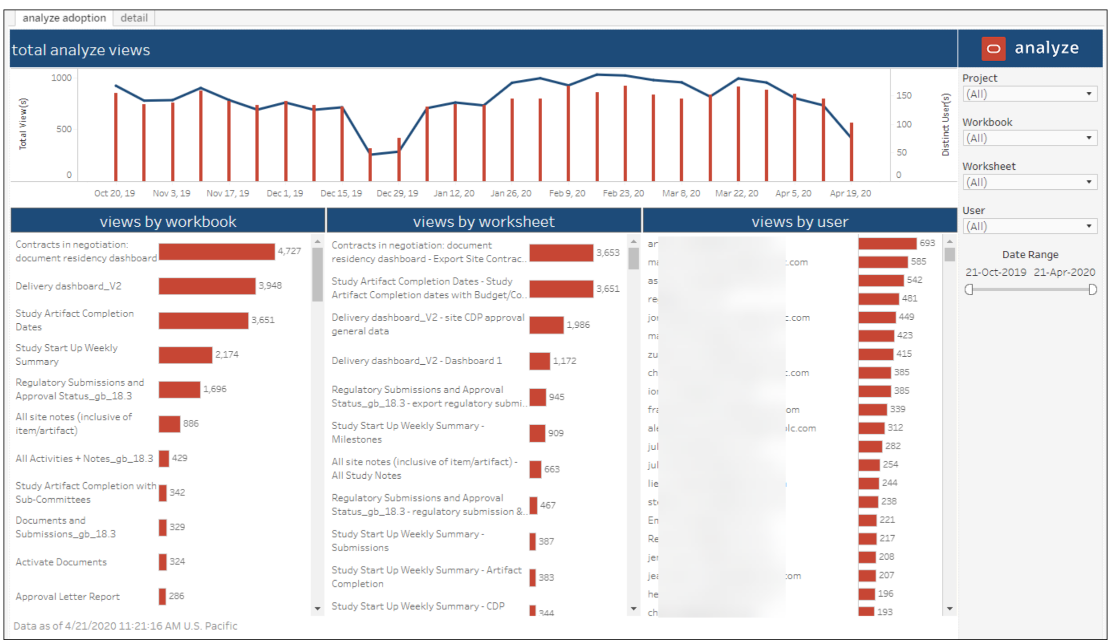
The Analyze Adoption sheet includes a trend graph in the upper section, with:

- Number of views per year, quarter, month, week, day
- Number of distinct user logins per year, quarter, month, week, day

you can also hover over a bar in the trend graph to view date and distinct user counts.

The report's lower section includes three horizontal bar charts, all of which act as filters when clicked:

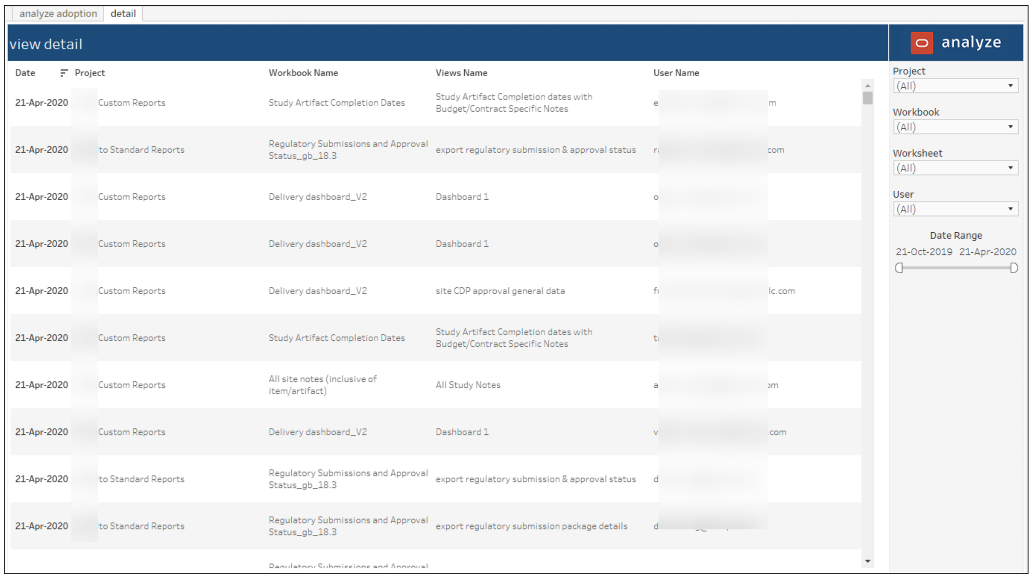
- Number of views by workbook
- Number of views by worksheet
- Number of views by user



Detail

The Analyze Adoption Dashboard also includes a "Detail" sheet, which you can access directly or drill into from the Analyze Adoption sheet. The Detail sheet provides the following data in tabular format:

- Date viewed
- Project
- Workbook name
- View name
- User name



7 Compliance Dashboard

Workbook synopsis

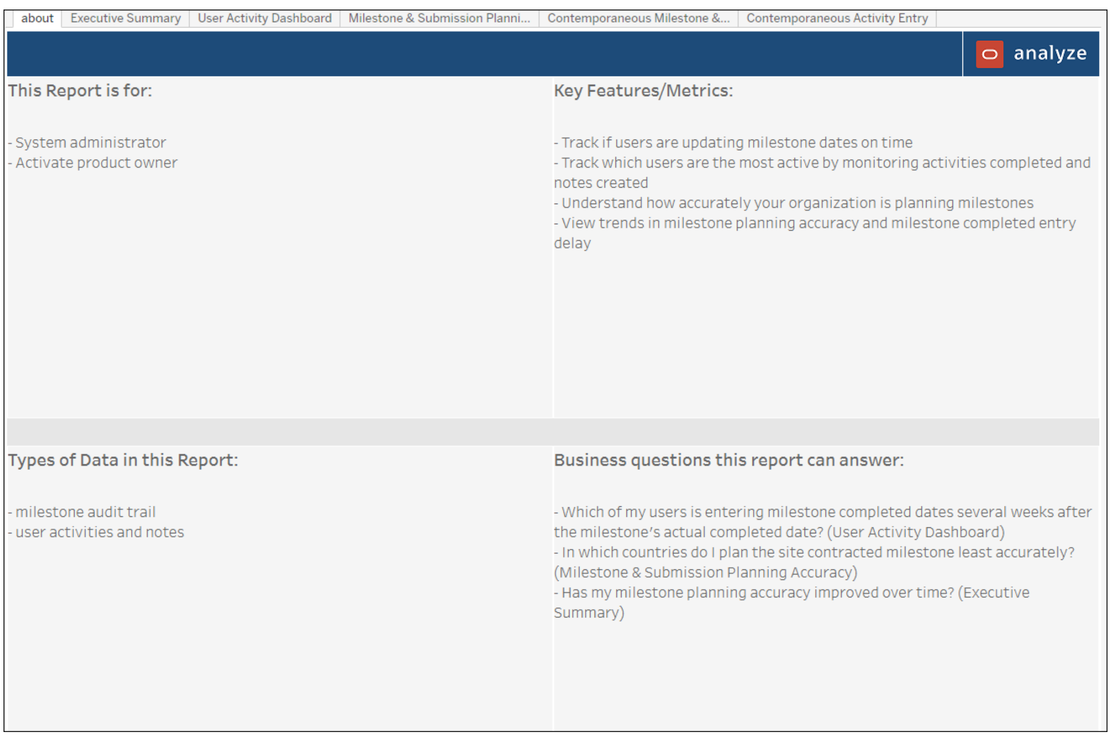
Intended for Oracle Site Activate customers, the Compliance Dashboard allows Oracle Site Activate administrators and stakeholders to understand if users are taking full advantage of the system by monitoring whether users are actively entering in completion dates and accurately entering in planning dates.

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:

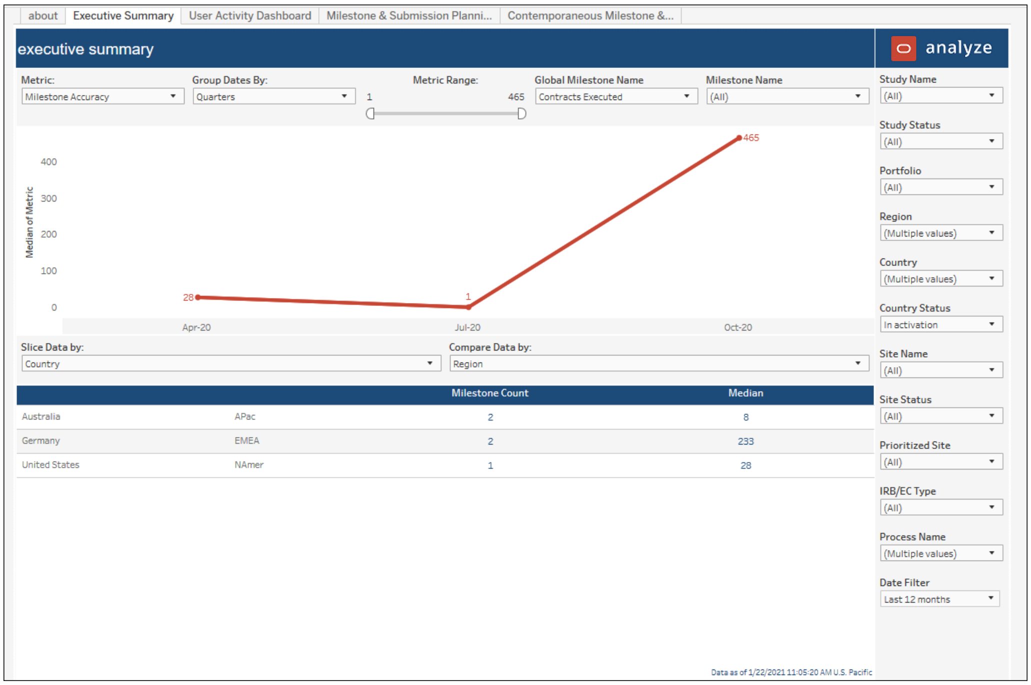
- Study startup roles that would use the report
- Key report features and metrics
- Types of data the report contains
- Examples of how to use the report to answer a business question



Executive Summary Dashboard

This dashboard is a high-level summary of overall milestone date entry compliance and milestone planning accuracy compliance. The top of the dashboard includes a trend chart showing the total median milestone entry delay or the total median milestone planning accuracy across all Oracle Site Activate by week/month/quarter/year. The bottom table can be adjusted to a preferred view using several parameters:

- "slice data by" all Oracle Site Activate, portfolio, region, country, study, global milestone, user
- "compare data by" all Oracle Site Activate, portfolio, region, country, study, global milestone, user
- a slider filter allows a user to control the compliance threshold
- "select a metric" allows a user to toggle the table between entry delay and planning 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:

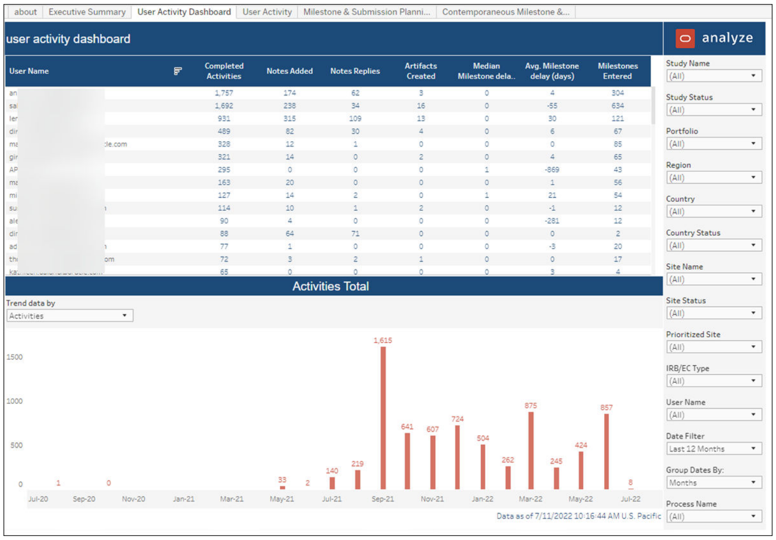
- total activities completed in Oracle Site Activate
- total notes created in Oracle Site Activate
- total artifacts created in Oracle Site Activate
- median delay in days from milestone completed date to milestone entered date
- average delay in days from milestone completed date to milestone entered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

The lower section of the dashboard displays a trend graph with the option to trend to:

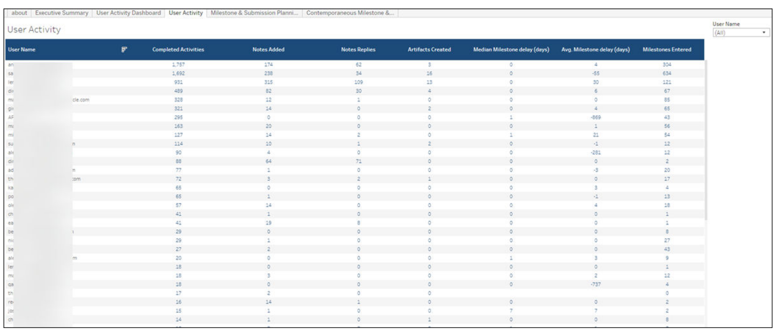
- Activities
- Artifacts Created
- Delay
- Milestones Entered

- Notes

When you click on a user name in the top table, it will filter the bottom trend chart to only show that user.



User Activity Detail



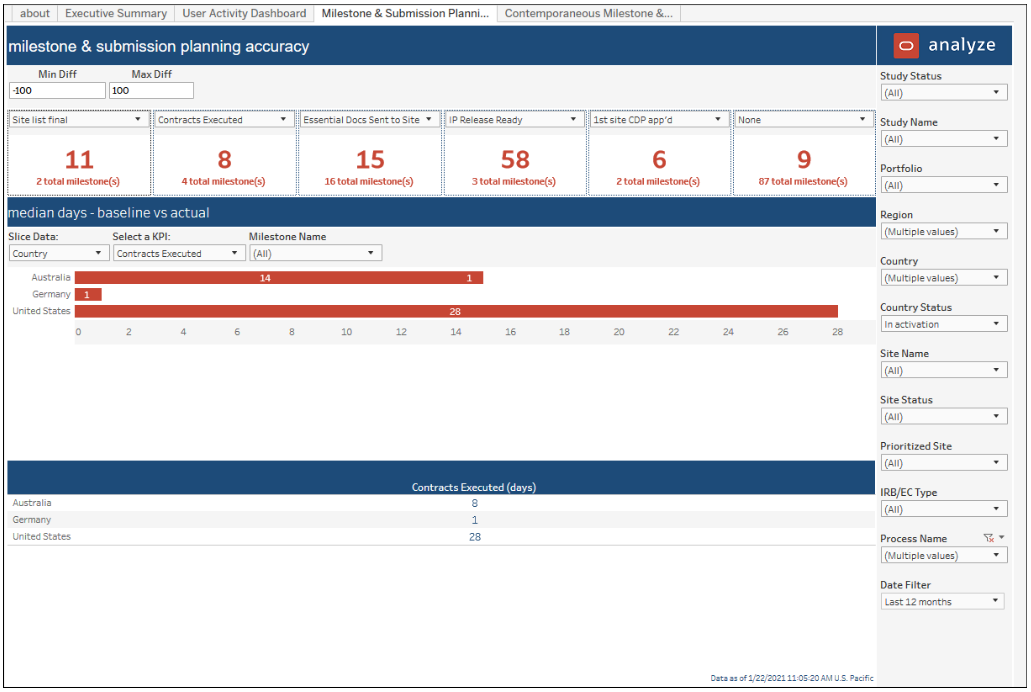
Milestone & Submission Planning Accuracy

This worksheet allows you to compare the baseline milestone date to the actual milestone date to understand how accurate your organization is in planning milestones and identify areas for improvement. The upper portion of the worksheet includes six top-level KPIs that show median of baseline to actual. You can dynamically select any milestone or submission from a drop-down list.

The lower section of the worksheet includes a bar graph and table that are controlled by two parameters:

1. Slice Data – shows which dimension drives the graph and table (i.e., study, region, country, portfolio)
2. Select a KPI – shows which milestone or submission will be used for the graph and table

The graph and table metrics are the median of baseline to actual for the selected dimension.



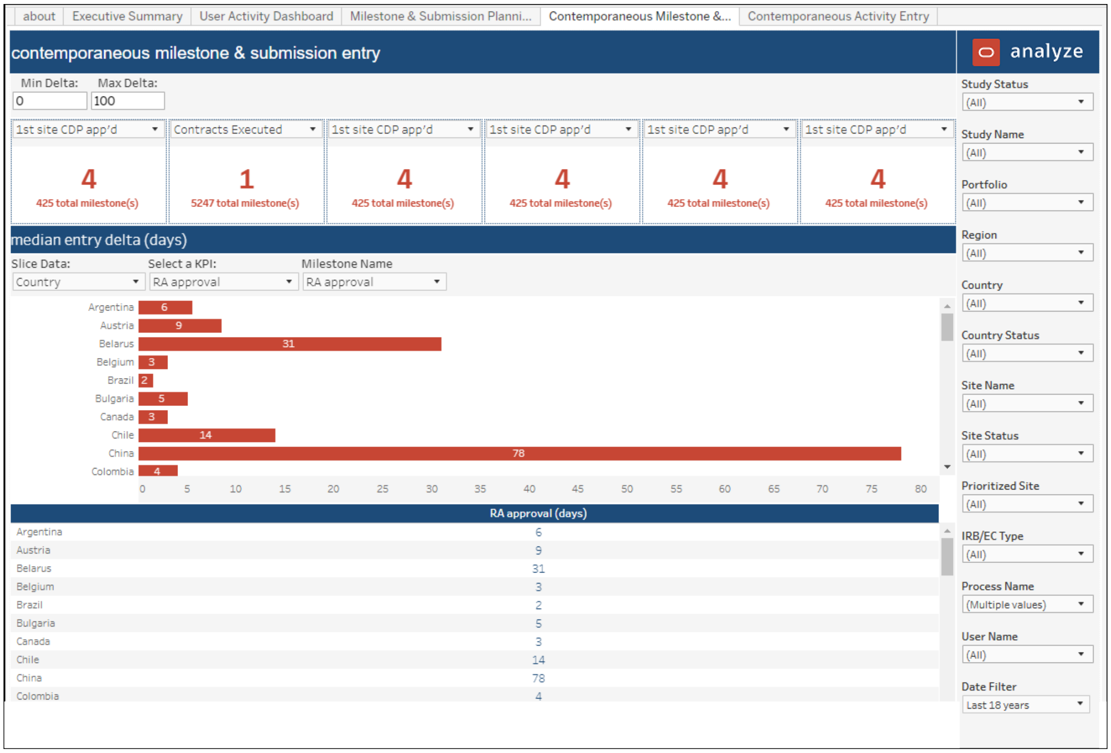
Contemporaneous Milestone & Submission Entry dashboard

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. The upper portion of the worksheet includes six top-level KPIs that show median of actual to date entered. You can dynamically select any milestone or submission from a drop-down list.

The lower section of the worksheet includes a bar graph and table that are controlled by two parameters:

1. Slice Data – shows which dimension drives the graph and table (study, region, country, or portfolio)
2. Select a KPI – shows which milestone or submission will be used for the graph and table

Graph and table metrics are the median of actual to date entered for the selected dimension.



Contemporaneous Activity Entry dashboard

This dashboard helps report users evaluate the timeliness of data through calculated comparisons of actual activity date completion versus date an activity was entered in Oracle Site Activate. The comparisons show contemporaneous (within the same time period) data entry.

The dashboard's top section is a configuration pane where report users can specify:

- **Slice data by**: study, region, country, or portfolio
- **Contemporaneous threshold**: (days)
- **Sort by**: % Contemporaneous or Median Entry Delta
- **Sort order**: Ascending or Descending

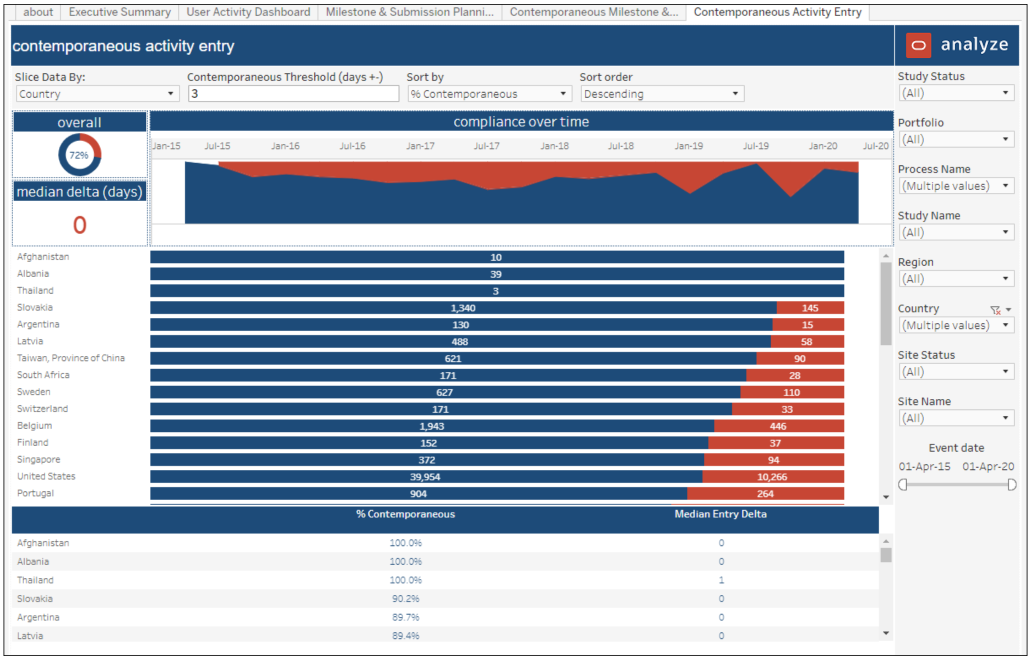
At the upper left, the dashboard displays two KPIs: a pie chart that shows contemporaneous vs non-contemporaneous activities as a percentage and median delta number of days.

To the right of the KPIs, a trend chart shows compliance over time as % of activities that are contemporaneous vs non-contemporaneous.

The center of the dashboard includes a stacked bar chart. The selected "Slice data by" parameter, at the top of the dashboard, controls the chart's dimension. The chart shows data color coded as contemporaneous (blue) vs. non-contemporaneous (red), and hover-over tool tips provide additional detail.

The bottom of the dashboard shows the following in table format:

- Selected "Slice data by" dimension
- % Contemporaneous
- Median entry delta


about
Executive Summary
User Activity Dashboard
Milestone & Submission Planni...
Contemporaneous Milestone &...
Contemporaneous Activity Entry
contemporaneous activity entry
analyze
Slice Data By:
Country
Contemporaneous Threshold (days +-)
3
Sort by
% Contemporaneous
Sort order
Descending
Study Status
Portfolio
Process Name
Study Name
Region
Country
Site Status
Site Name
Event date
01-Apr-15
01-Apr-20
overall
72%
median delta (days)
0
compliance over time
% Contemporaneous
Median Entry Delta

8
Contract Module Dashboard

Workbook synopsis

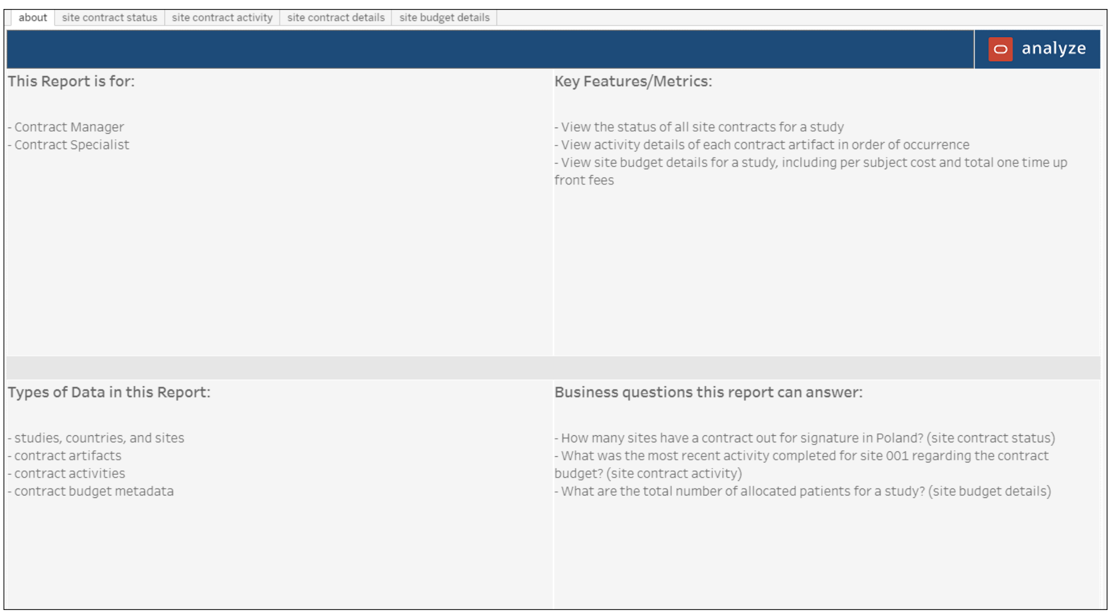
Intended for Oracle Site Activate customers, the Contract Module Dashboard complements the Oracle Site Activate contract module. This report helps contract managers and specialists access the information they need about site contract progress. Managers can use the dashboard to view contract analyst workloads. 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 report features to help Contract Module Dashboard users understand if the report applies to their roles. 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



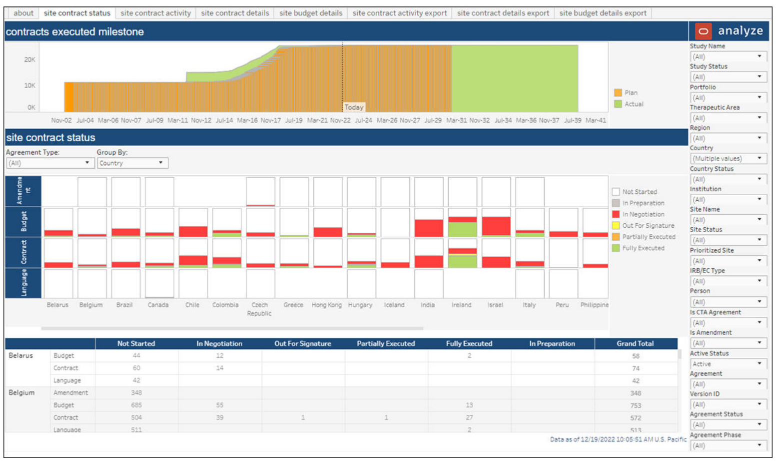
Site Contract Status

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 indicates the site contract executed milestone by baseline, planned, and actual dates.

At the center of the sheet, you can select the agreement type to view in bar chart format. When you select multiple agreement types, the bar charts stack alphabetically based on the types you selected (i.e., All, Budget, Contract, Contract Language). The color coded, stacked bar chart(s) indicate contract status (e.g., not started, in negotiation, etc.). A selectable parameter allows you to slice agreement status by all, region, country, study, or portfolio, and you can also Group data as preferred (e.g., Country, Institution, etc.).

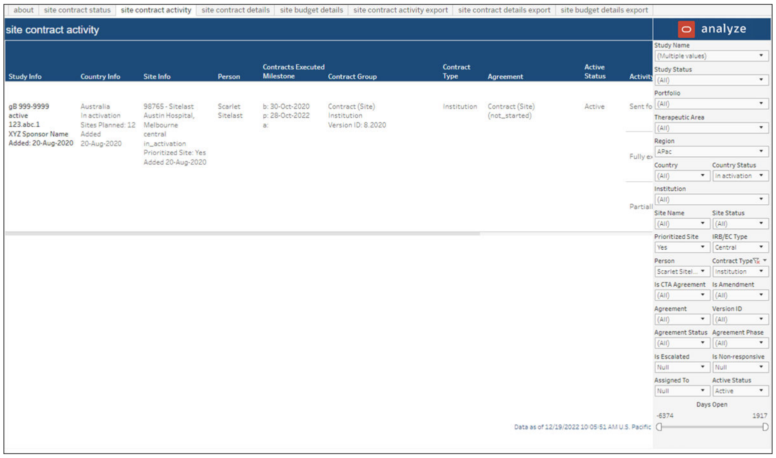
The filter panel to the right provides multiple options that allow you to subset data included in the Site Contract Status dashboard. For instance, you can filter the Agreement status, Agreement phase, Person (e.g., staff member or PI), Active status, and much more.

> **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.



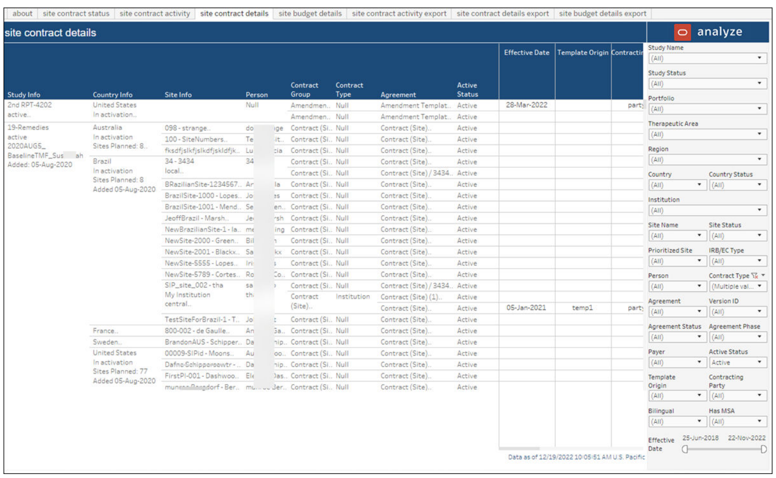
Site Contract Activity

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. The Contract Module Dashboard report includes a dedicated export tab for Site Contract Activity that reflects the data on the Site Contract Activity worksheet. You can filter the export before download as preferred.



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.).

9
Cycle Times

Workbook synopsis

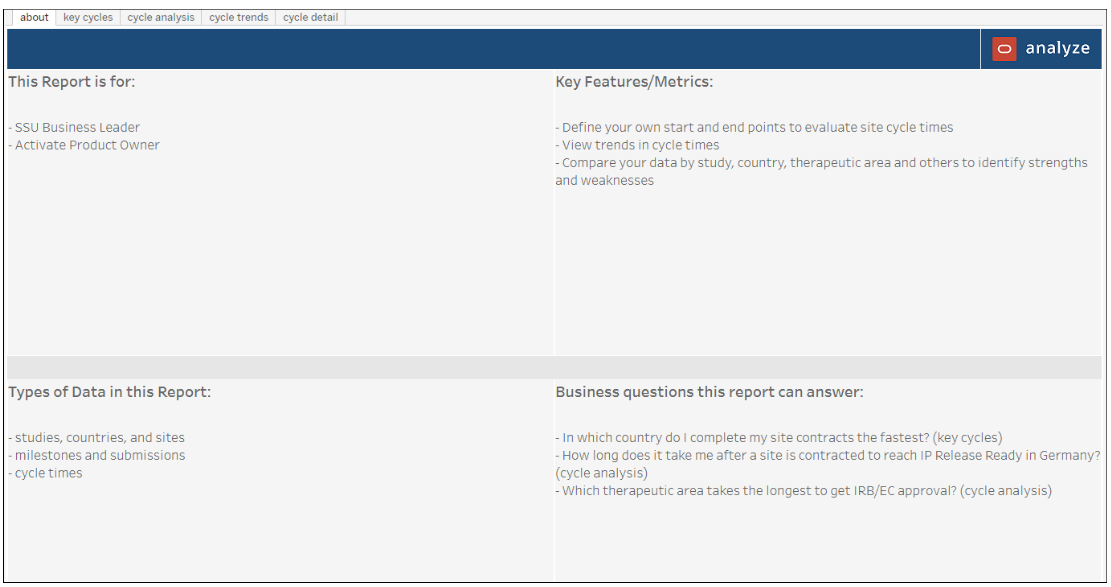
This Cycle Times Dashboard, which is intended for Oracle Site Activate customers, includes key cycle metrics with configurable cycle start and end points. Users can save their own custom views with the cycles that provide the most value to them.

Dashboards and sheets

About

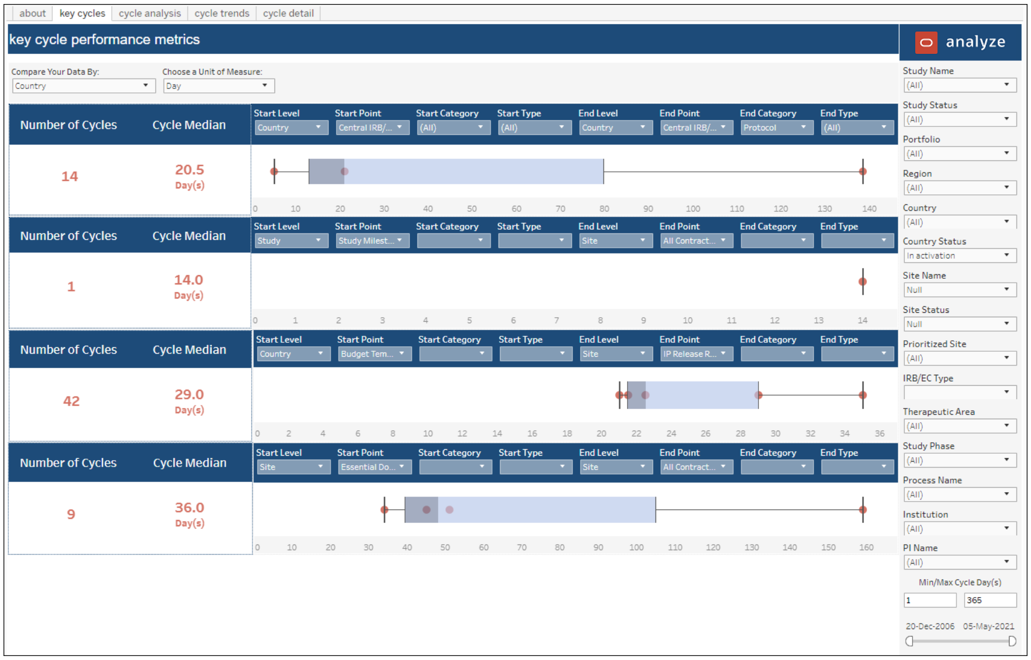
The About sheet provides a summary of key report features to help Cycle Times Dashboard users understand if the report is applicable to that user's role. The About sheet provides details like:

- 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



Key Cycles

The Key Cycles report provides an at-a-glance view of four key Oracle Site Activate cycle times in a single dashboard view. For both start and end, report users will specify the level, point, category and type for each of the four key cycles. The key cycles display in a horizontal row with the number of cycles, median cycle time, and a box and whisker plot controlled by a "Compare your data by" parameter. Report users can also optionally adjust the view to day, week, or month.

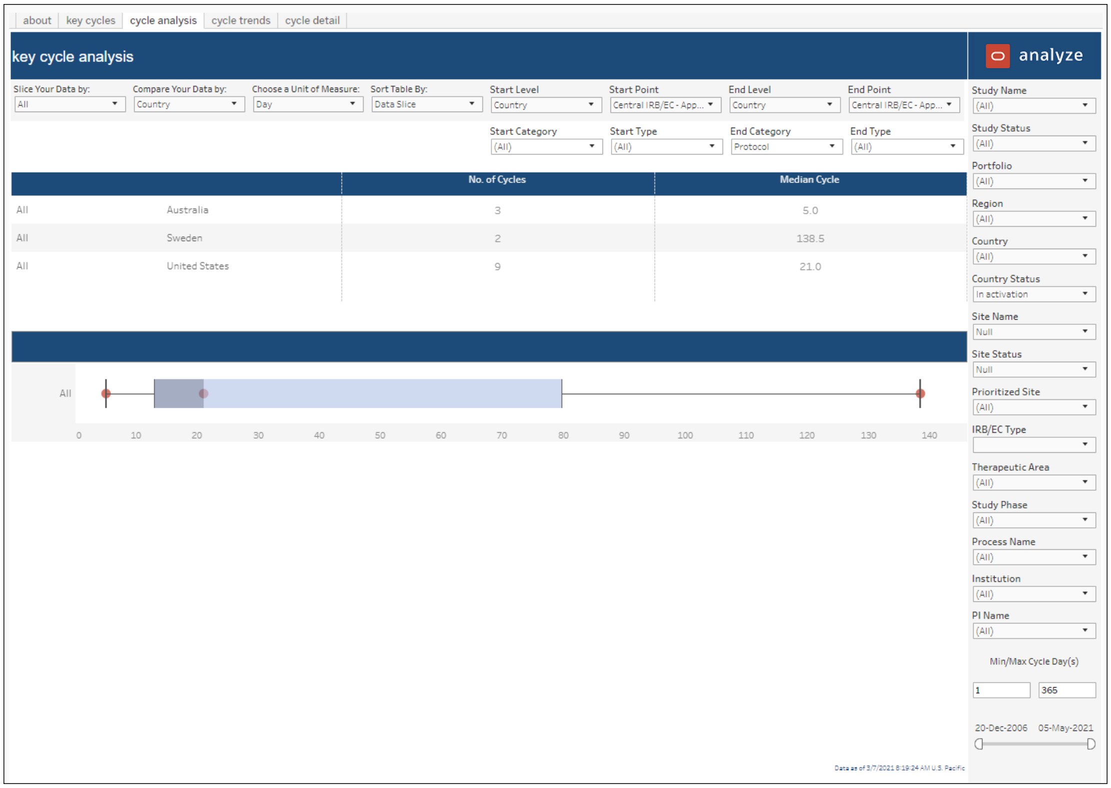


Cycle Analysis

The Cycle Analysis report provides deeper insight into a single key cycle. This sheet helps report users identity operational strengths and weaknesses that may lead to business process changes and faster cycle times in the future. Parameters that control data display on this sheet are:

- Select a cycle (start and end level, point, category, and/or type)
- Slice your data by: All, Portfolio, Region, Country, Study, Therapeutic Area, Study Phase, PI Name
- Compare your data by: All, Portfolio, Region, Country, Study, Therapeutic Area, Study Phase, PI Name
- Choose unit of measure: Day, Week, Month
- Sort table by: Data Slice, Number of Cycles, Median Cycle

The upper section of the analysis sheet presents data in a tabular format with drill to detail functionality, while the lower section of the report presents data in a box and whisker plot format (dimensions based on "Slice data by" parameter and dots based on "Compare data by" parameter).

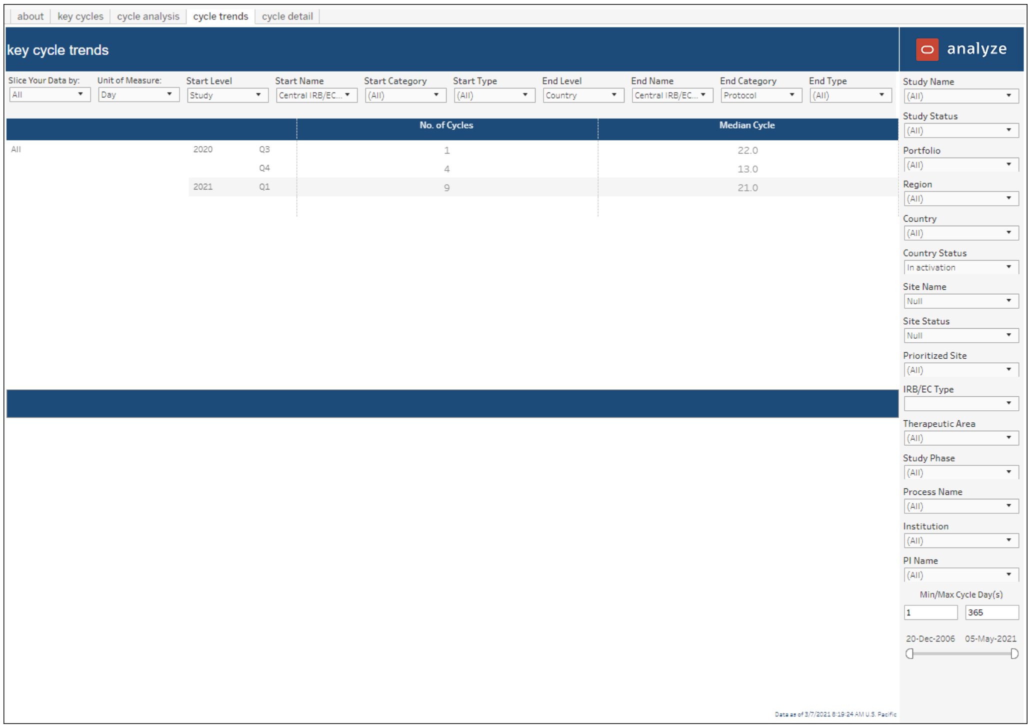


Cycle Trends

The Cycle Trends report simplifies viewing cycle performance over time. On this sheet, report users will specify the start and end level, category, and/or type for the key cycle for which trending displays. Additional parameters for display are:

- Slice your data by: All, Portfolio, Region, Country, Study, Therapeutic Area, Study Phase, PI Name
- Choose unit of measure: Day, Week, Month
- Sort table by: Data Slice, Number of Cycles, Median Cycle

The upper section of the Cycle Trends sheet presents data in a tabular format. The lower section's trend graph is a line chart that renders the median cycle time based on selected parameters.

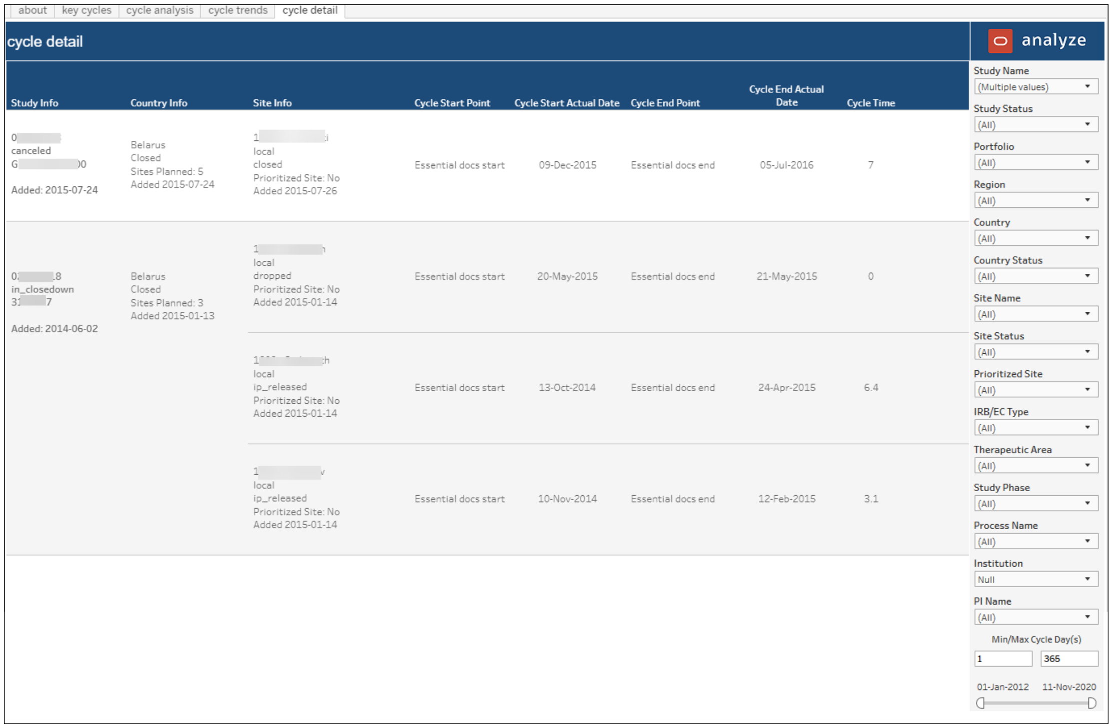


Cycle Detail

The Cycle Detail includes a table with the following data:

- Study
- Country
- Site
- Cycle start point
- Cycle start actual date
- Cycle end point
- Cycle end actual date
- Cycle time

Report users can drill into the Cycle Detail sheet from the Key Cycles and Cycle Analysis sheets.


about
key cycles
cycle analysis
cycle trends
cycle detail
cycle detail
analyze
Study Info
Country Info
Site Info
Cycle Start Point
Cycle Start Actual Date
Cycle End Point
Cycle End Actual Date
Cycle Time
canceled
Added: 2015-07-24
Belarus
Closed
Sites Planned: 5
Added 2015-07-24
local
closed
Prioritized Site: No
Added 2015-07-26
Essential docs start
09-Dec-2015
Essential docs end
05-Jul-2016
7
in_closedown
Added: 2014-06-02
Belarus
Closed
Sites Planned: 3
Added 2015-01-13
local
dropped
Prioritized Site: No
Added 2015-01-14
Essential docs start
20-May-2015
Essential docs end
21-May-2015
0
local
ip_released
Prioritized Site: No
Added 2015-01-14
Essential docs start
13-Oct-2014
Essential docs end
24-Apr-2015
6.4
local
ip_released
Prioritized Site: No
Added 2015-01-14
Essential docs start
10-Nov-2014
Essential docs end
12-Feb-2015
3.1
Study Name
(Multiple values)
Study Status
Portfolio
Region
Country
Country Status
Site Name
Site Status
Prioritized Site
IRB/EC Type
Therapeutic Area
Study Phase
Process Name
Institution
Null
PI Name
(All)
Min/Max Cycle Day(s)
1
365
01-Jan-2012
11-Nov-2020

10 Milestone and Submission Planning

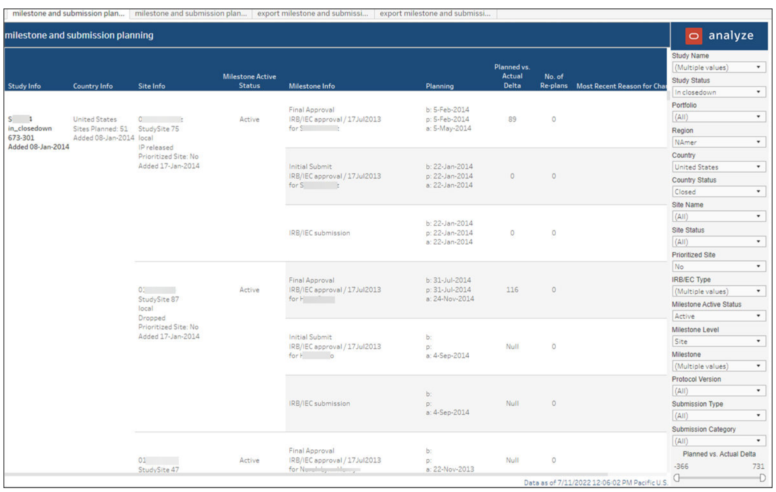
Workbook synopsis

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 filters to the right to adjust data included in the report by Study Name, Country, Site Info, Event Name, Milestone Active Status, Prioritized site, etc.

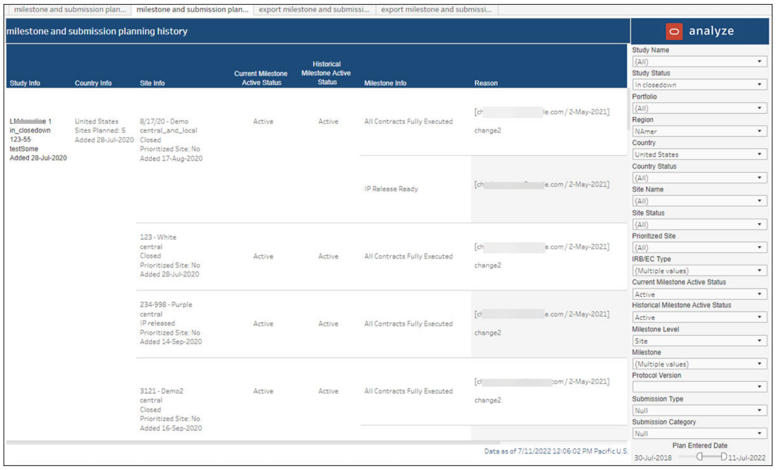


Milestone and Submission Planning History

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. The history sheet is a tabular report that includes the following columns:

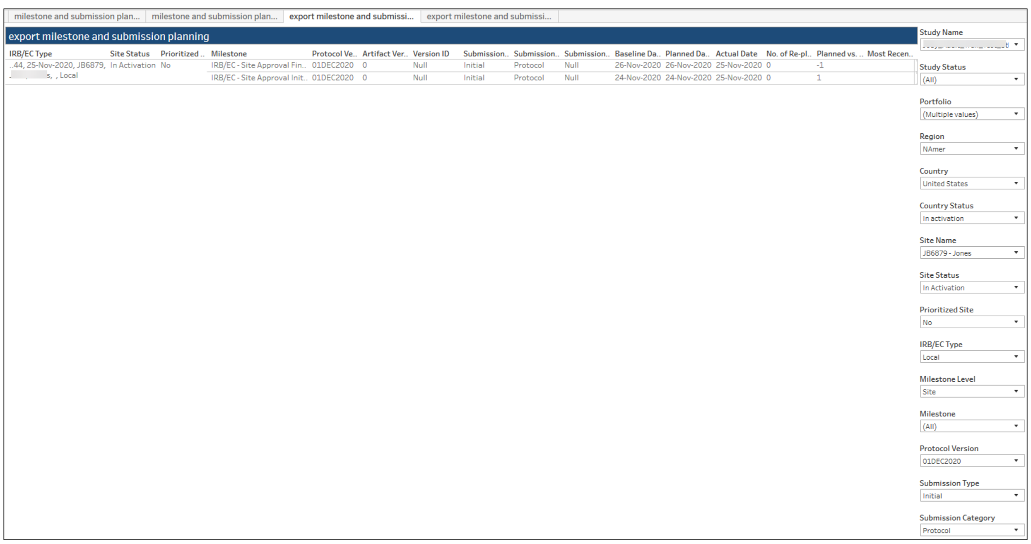
- Study information
- Country information
- Site information
- Milestone information
- Reason (individual who changed the date and reason, if available)
- Prior planned date
- Planned date (current)

You can filter the report using any of the filters in the right panel. For instance, you can filter planning history data by study, site, current or historical milestone active status, submission type, and more.



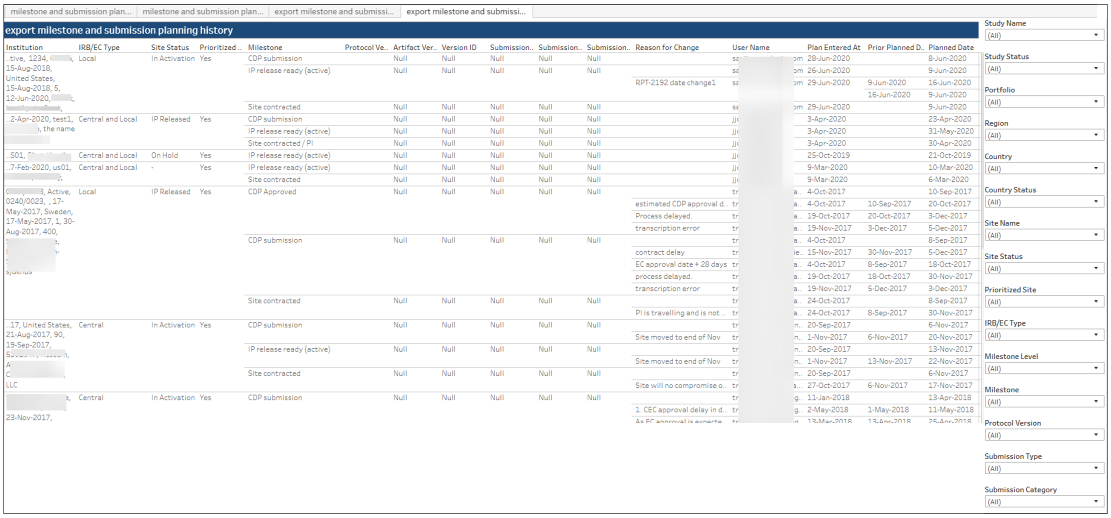
Export Milestone and Submission Planning

Use the Export Milestone and Submission Planning sheet to export detailed planning information. You can filter data included in the export by Study Status, Portfolio, Country, Submission Type, and more.



Export Milestone and Submission Planning History

Use the Export Milestone and Submission Planning History export sheet to export historical planning information. Use the options in the filter panel to the right to filter data by Study Status, Portfolio, Country, Submission Type, and more.


milestone and submission plan...
milestone and submission plan...
export milestone and submissi...
export milestone and submissi...
export milestone and submission planning history
Institution
IRB/EC Type
Site Status
Prioritized ..
Milestone
Protocol Ve..
Artifact Ver..
Version ID
Submission..
Submission..
Submission..
Reason for Change
User Name
Plan Entered At
Prior Planned D..
Planned Date
Study Name
Study Status
Portfolio
Region
Country
Country Status
Site Name
Site Status
Prioritized Site
IRB/EC Type
Milestone Level
Milestone
Protocol Version
Submission Type
Submission Category

11 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

At the upper left of the Milestone Predictions dashboard, you can choose a Start Milestone for a cycle time and evaluate different prediction cycles against actual milestone completed dates in the report’s trend graphs and table. Choose one of the following as the Start Milestone:

- Contracts Executed
- Essential Documents Sent to Site
- Initial Protocol Received/Sent

Then, choose a 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 fields at the top of the dashboard.

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

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

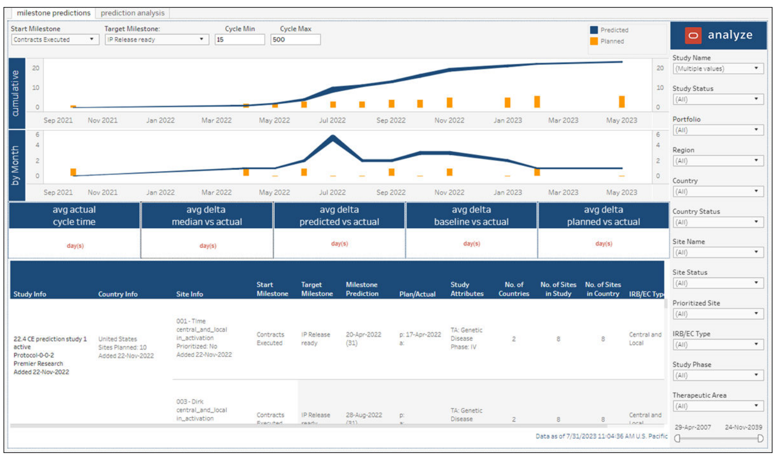
- **Average actual cycle time**: Shows how long this cycle typically takes on average.
- **Average delta – median vs. actual**: Shows the variance between actual cycle time and median cycle time. This represents the error between median and actual cycle time.
- **Average delta – predicted vs. actual**: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

As with all Oracle Site Analyze reports, the right panel provides a wide variety of filters that allow you to subset data to your preferred view.



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 sheet is a box plot visualization; you have multiple options to manipulate the dimensions and aggregations of the box plot(s).

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 "Data Slice" parameters to specify from the following list of data slice options:

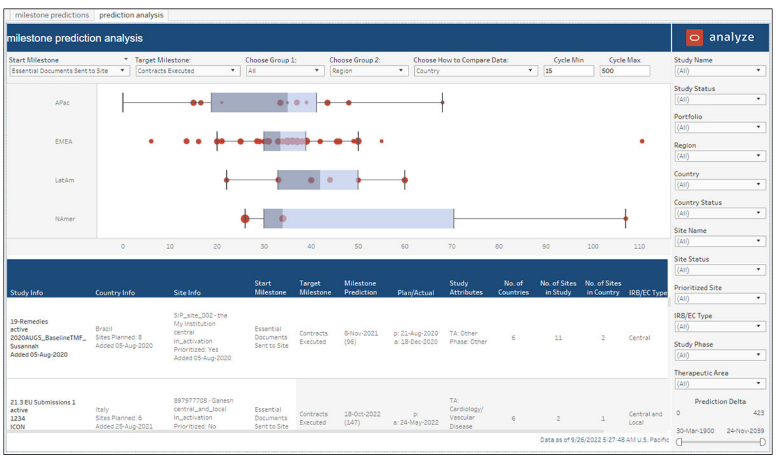
- Portfolio
- Therapeutic Area
- Phase
- Region
- Country
- Study
- Site
- PI
- All

Using the "Data Compare" parameter, you can control the aggregation of each point in the box plot. Compare options are the same as above, except no "All" option. "Cycle Minimum" and "Cycle Maximum" parameters also allow you to refine the view.

Plot details display on hover over (Upper Whisker, Median, Lower Hinge, etc.), and you can also drill to Site Details by hovering over any point on the plot and clicking the "View Detail" link in the tool tip.

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

- Study Information
- Country Information
- Site Information
- Milestone Prediction
- Plan/Actual (dates)
- Study Attributes
- Number of Countries
- Number of Sites in Study
- IRB/EC Type
- Cycle(s) and Median (days)



12
Open Activities

Workbook synopsis

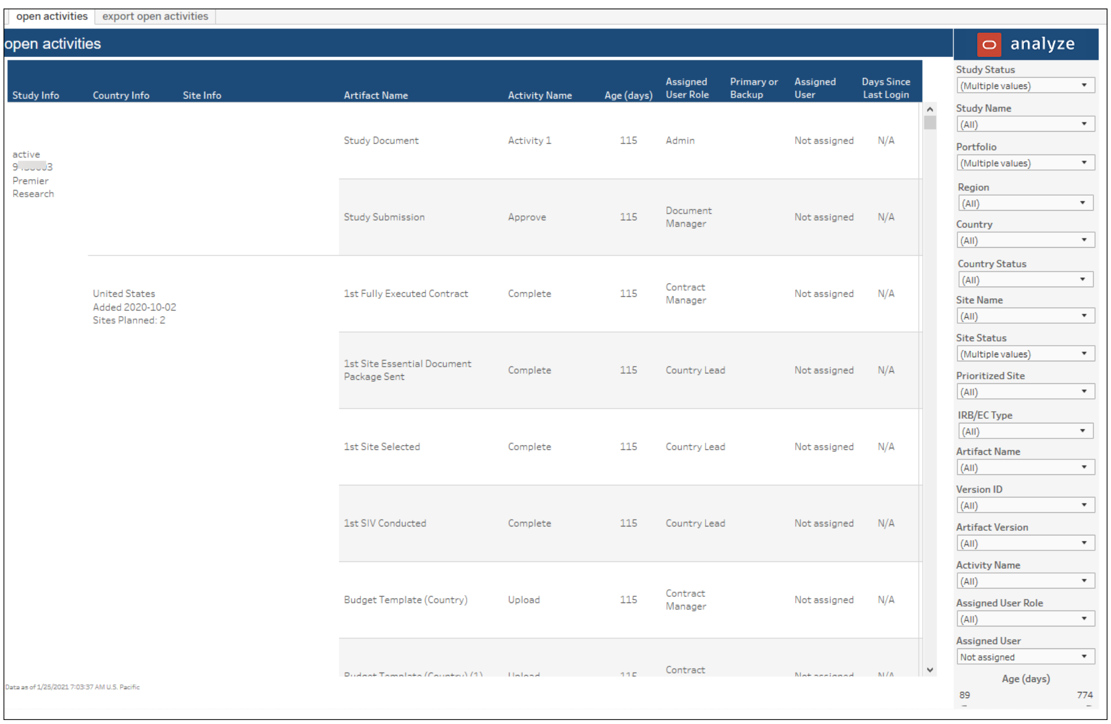
This workbook, which is intended for Oracle Site Activate customers, lists all the open (available to be worked on) activities within Oracle Site Activate and each activity's age (i.e., how long each activity has been open).

Dashboards and sheets

Open Activities

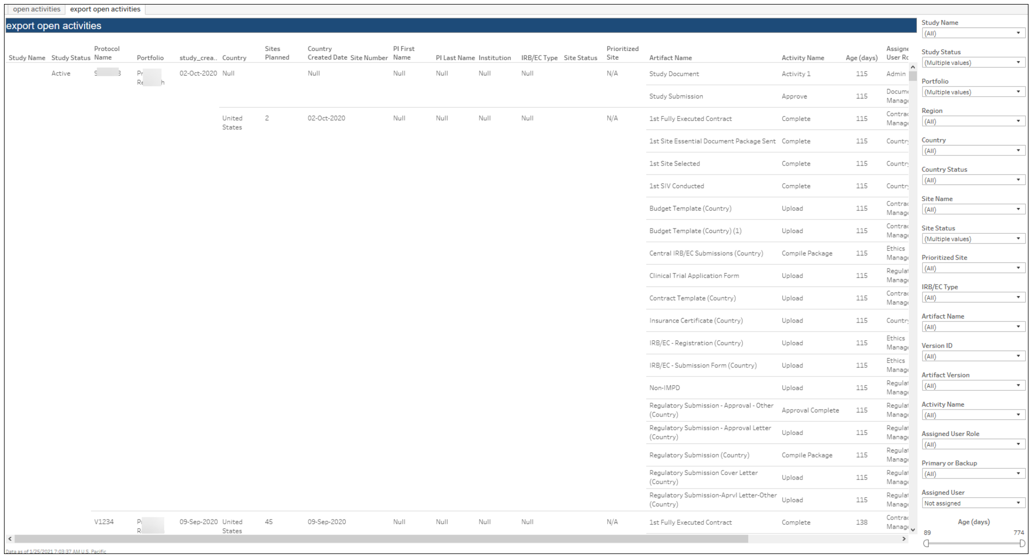
This worksheet lists all the open (available to be worked on) activities within Oracle Site Activate and each activity's age (i.e., how long each activity has been open) as well as the primary and backup resources assigned to an artifact activity.

Multiple filters to the right 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.



Open Activities Export

This worksheet lists additional details for the activities and can be used for export to .csv format. Use the filters to the right to subset the details sheet to specific activities, users, date range, etc.



open activities
export open activities
export open activities
Study Name
Study Status
Portfolio
Region
Country
Country Status
Site Name
Site Status
Prioritized Site
IRB/EC Type
Artifact Name
Version ID
Artifact Version
Activity Name
Assigned User Role
Primary or Backup
Assigned User
Age (days)

13 Planning Impact Analysis

Workbook synopsis

This workbook provides a simple text search tool that searches "Reason for change" entries and Notes across Oracle Site Activate milestones and submissions. 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 Planning Impact Analysis worksheet includes the following components at the top of the dashboard:

- Search field that supports one to five free text, comma-separated entries
  - Search type (and, or) selector
  - Case sensitivity selector

> **Note:**
>
> You must enter at least one search term. The report will not return "all" data if the search field is left blank. Additionally, the Study Name filter, in the right side panel, is a relevant filter and will contain studies only after the initial search returns matching results. These behaviors are expected and by design.

The center of the dashboard displays five Key Performance Indicators:

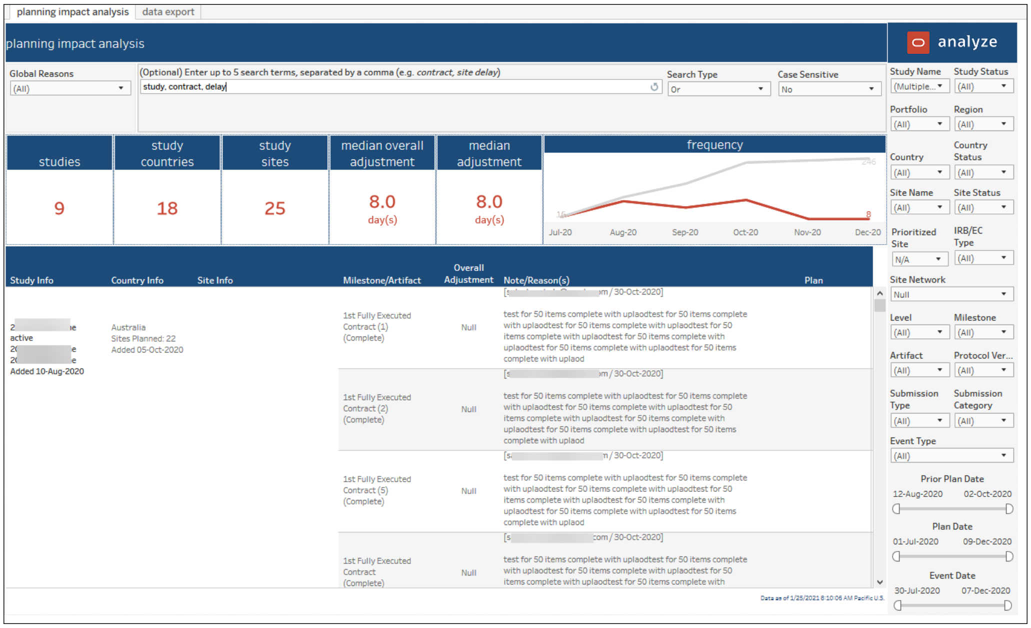
1. Studies: number of unique studies in which the search word/term exists in notes and reason for change entries
2. Study countries: number of unique study countries in which the search word/term exists in notes and reason for change entries
3. Study sites: number of unique study sites in which the search word/term exists in notes and reason for change entries
4. Median overall adjustment: 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: 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 also includes 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:

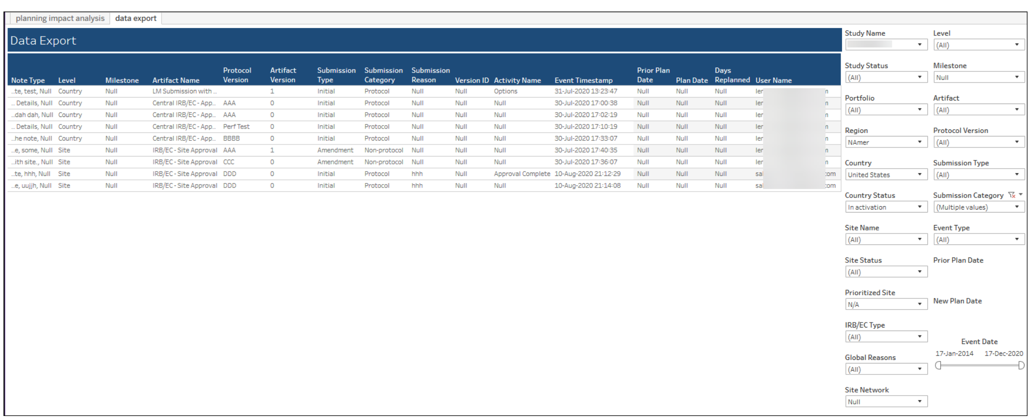
- Study information

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



Data Export

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



14

Resource Allocation

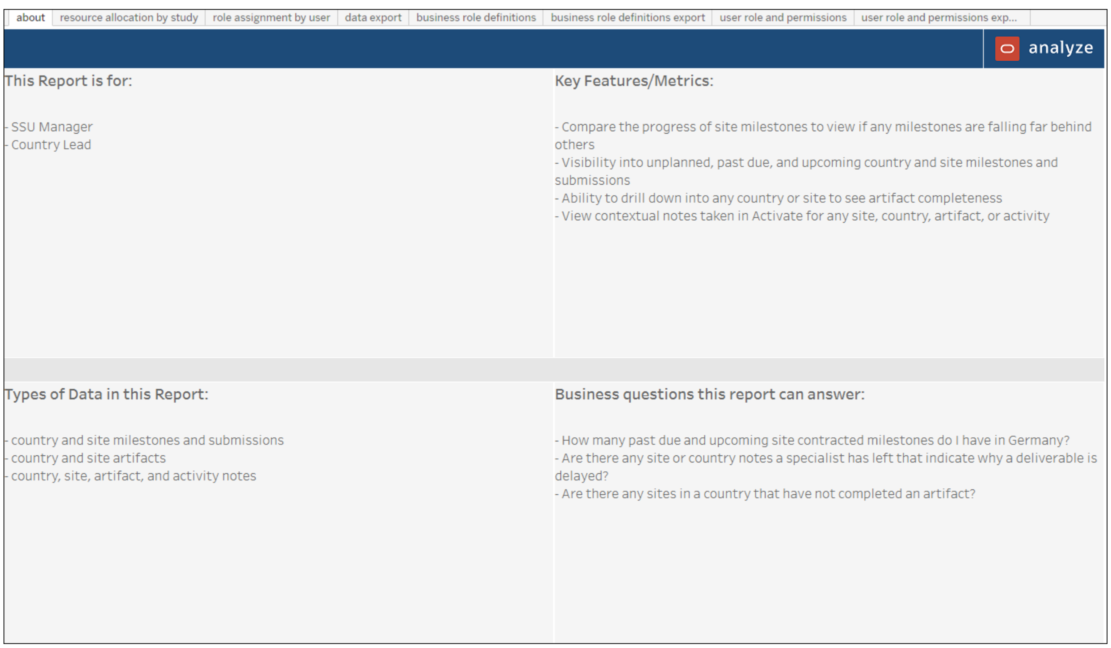
Workbook synopsis

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 help you to track and manage assignment of user roles and business permissions in Oracle Site Activate.

About

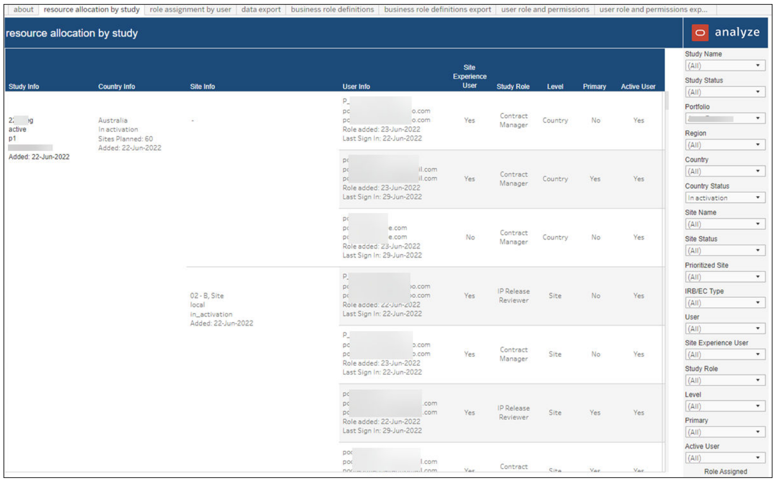
The About sheet provides a summary of key report features to help you understand if the report is applicable to your, or another report user's, role. The About sheet provides details like:

- 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



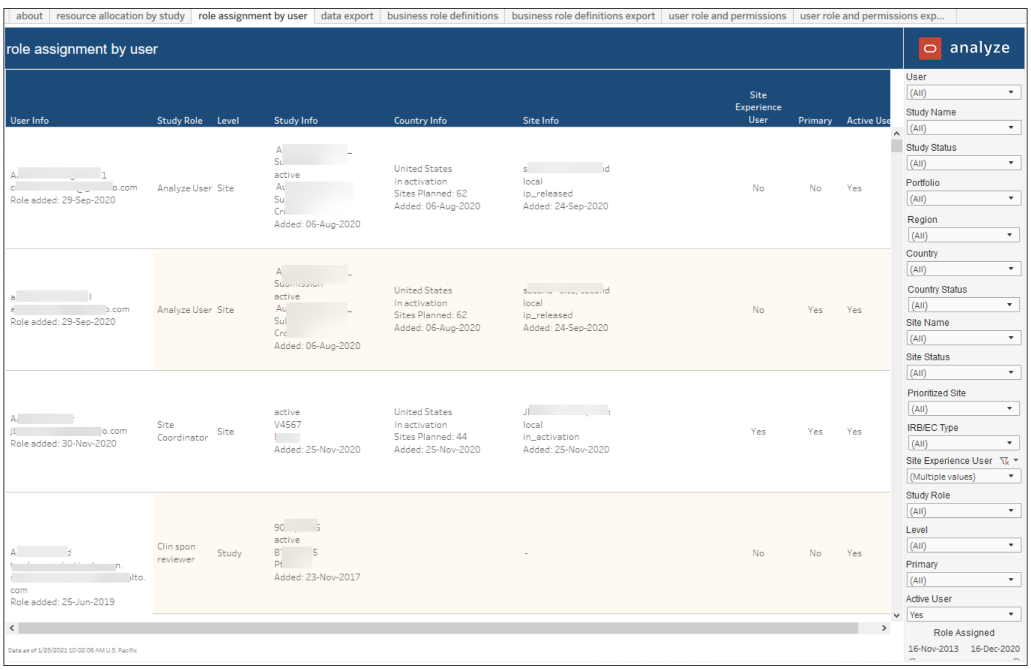
Resource Allocation by Study

This sheet shows resources assigned to studies in Oracle Site Activate, grouped by country or user. You can filter the data using the options to the right (Study Name, Study Status, Country Name, Active Users, and more).



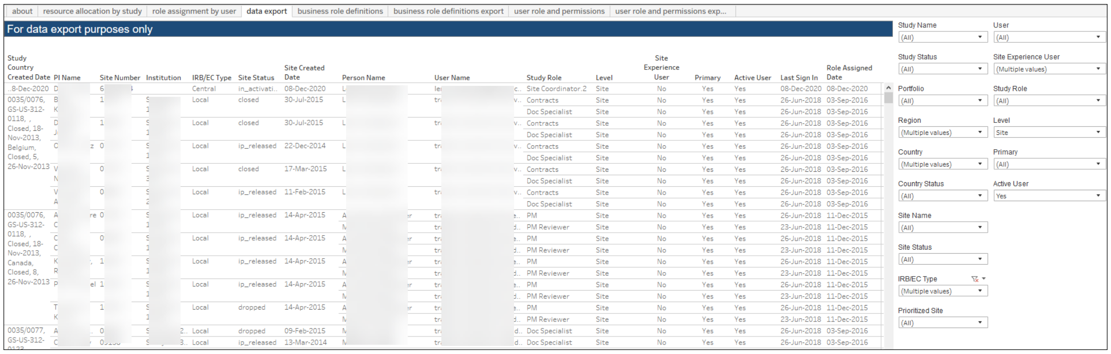
Role Assignment by User

This sheet identifies which users are assigned to business roles within a study and includes site experience users and users with primary assignment flags. You can filter the data using the options in the filter panel displayed to the right.



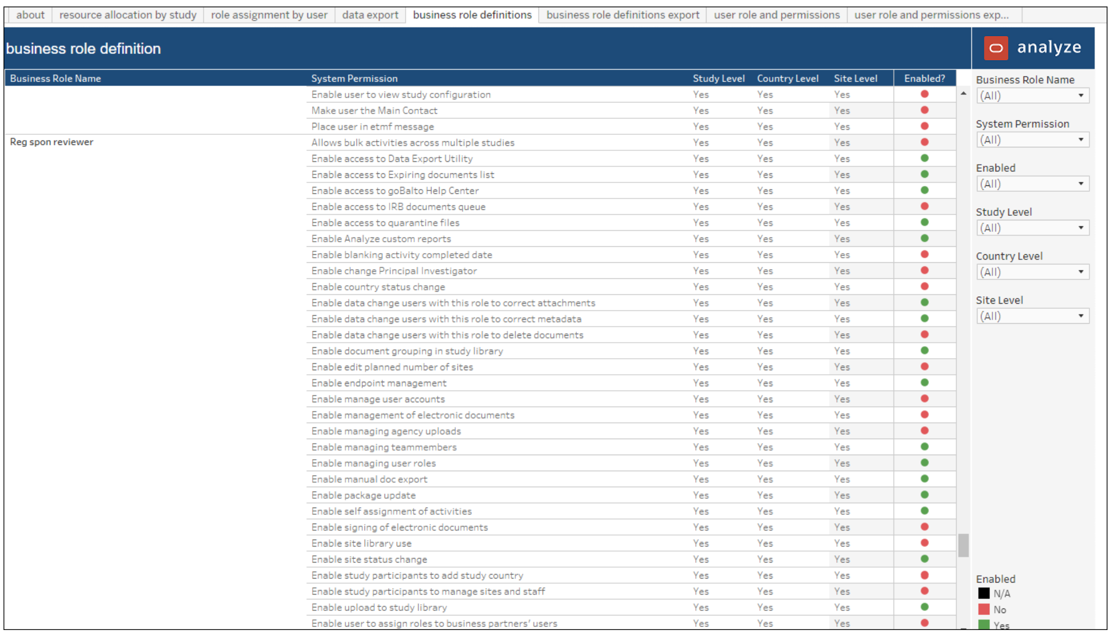
Data Export

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

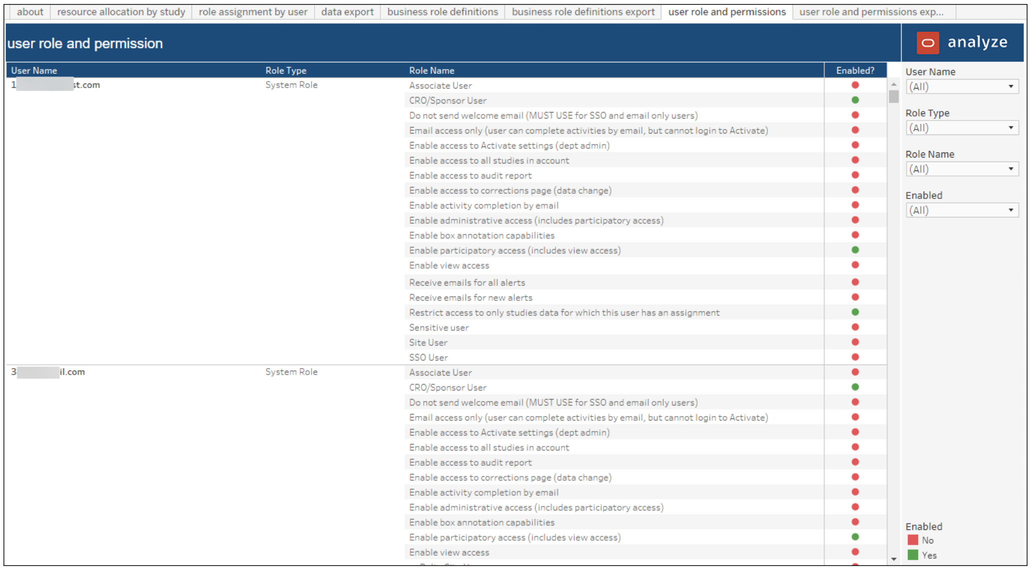
The Business Role Definitions sheet presents a simple columnar view of business role name and the list of all permissions currently enabled for the role. The Resource Allocation report also includes a "Business Role Definitions Export" sheet you can use to export the business role information.



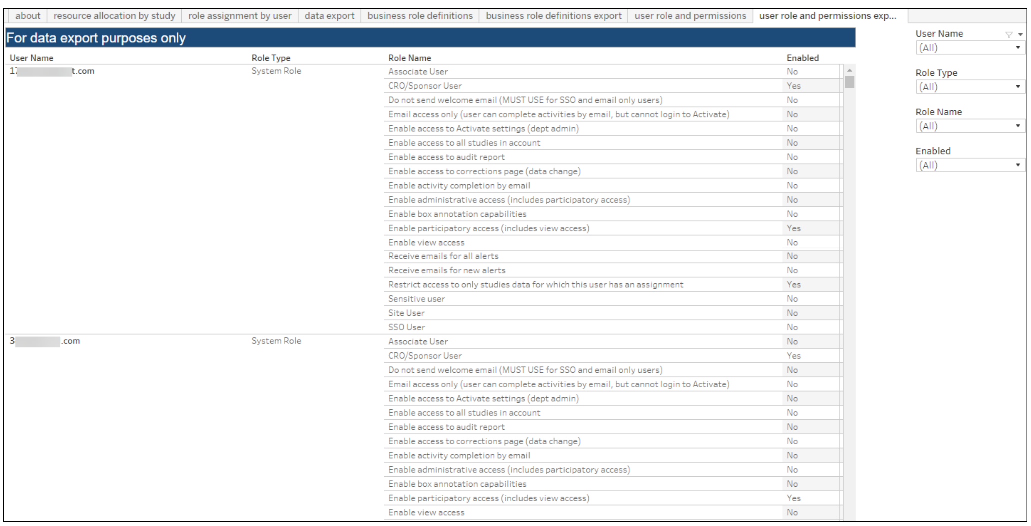
User Roles and Permissions

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



A User Roles and Permissions Export sheet, designed exclusively for export of the roles and permissions data, is also available in the Resource Allocation report.



15
Site IP Release Package

Workbook synopsis

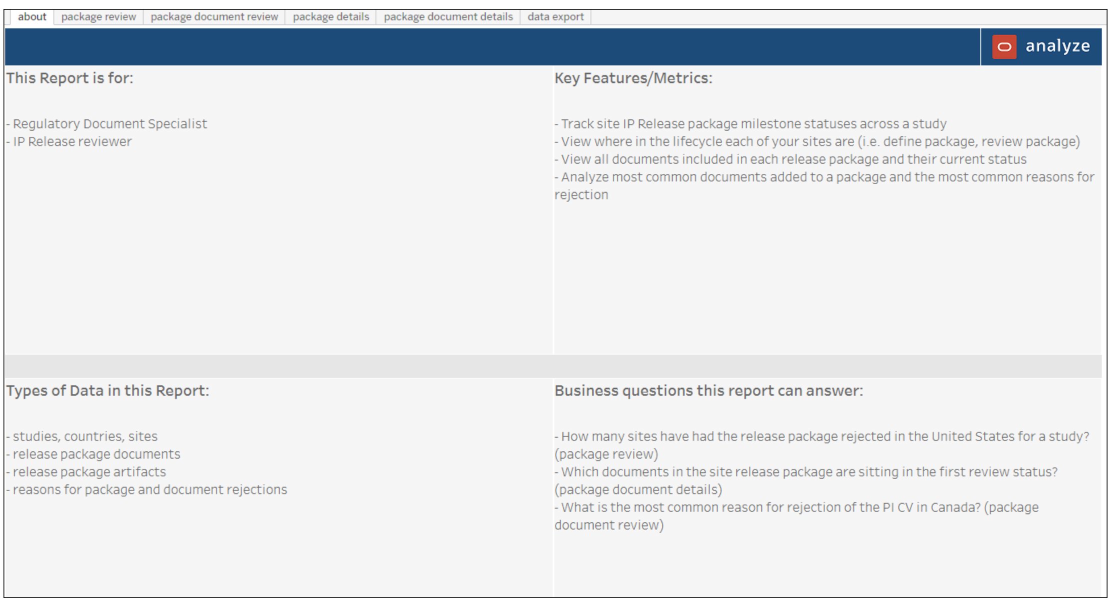
Intended for Oracle Site Activate users, the Site IP Release Package Dashboard workbook allows you to see granular package and document statuses and understand the state of all IP release packages for a study.

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.

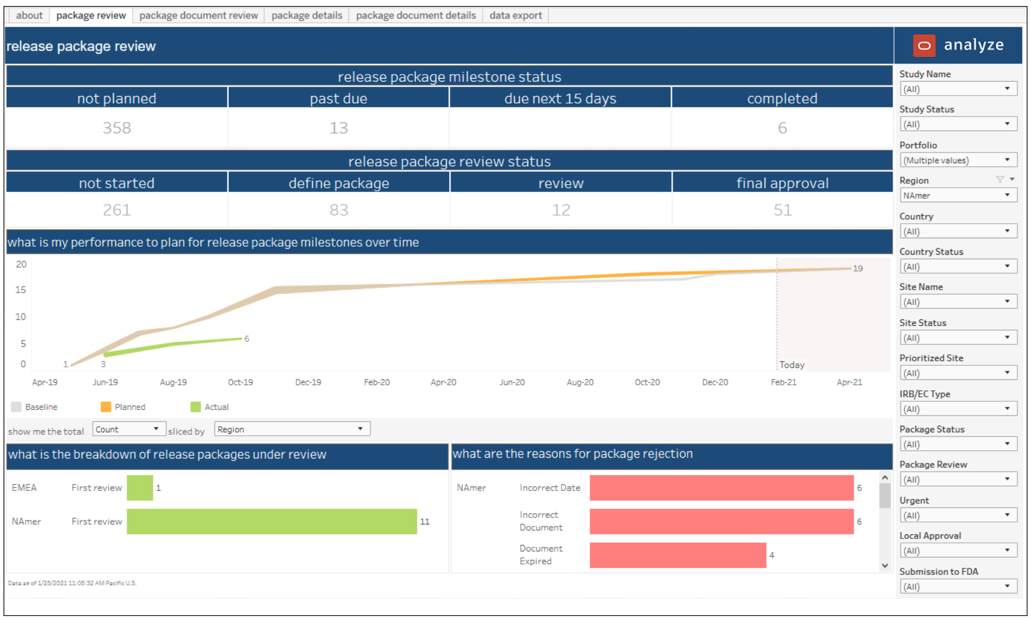
The top of the dashboard displays the following top-level KPIs (based on activity type as specified in the Oracle Site Activate lifecycle):

- 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

A trend graph, in the middle section of the dashboard, shows a comparison of baseline, planned and actual IP Release ready milestone dates. The bottom of the dashboard includes two bar charts – with the left bar chart showing package status and the right bar chart showing reasons for package rejection.



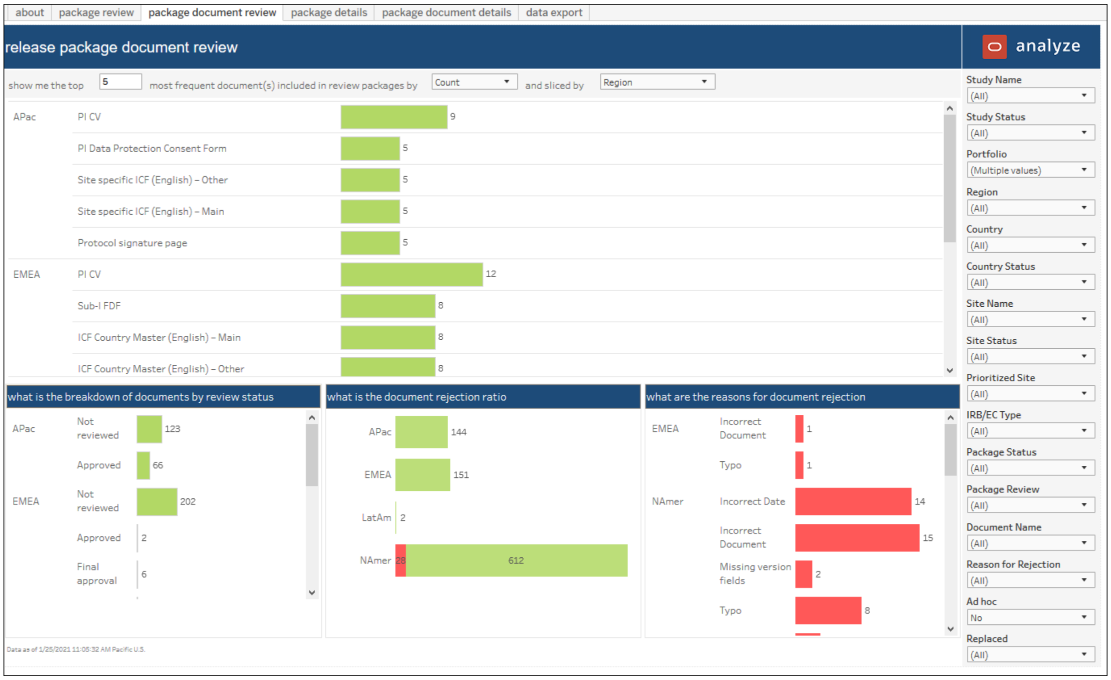
Release Package Document Review

This dashboard allows you to understand most the most common documents in a package as well as the most commonly rejected documents and their reasons for rejection.

At the top of the dashboard, a horizontal bar chart displays the count or percentage of document name included in a package, sorted in descending order. Each of the bars in this upper chart acts as a filter for data displayed in the lower section of the dashboard.

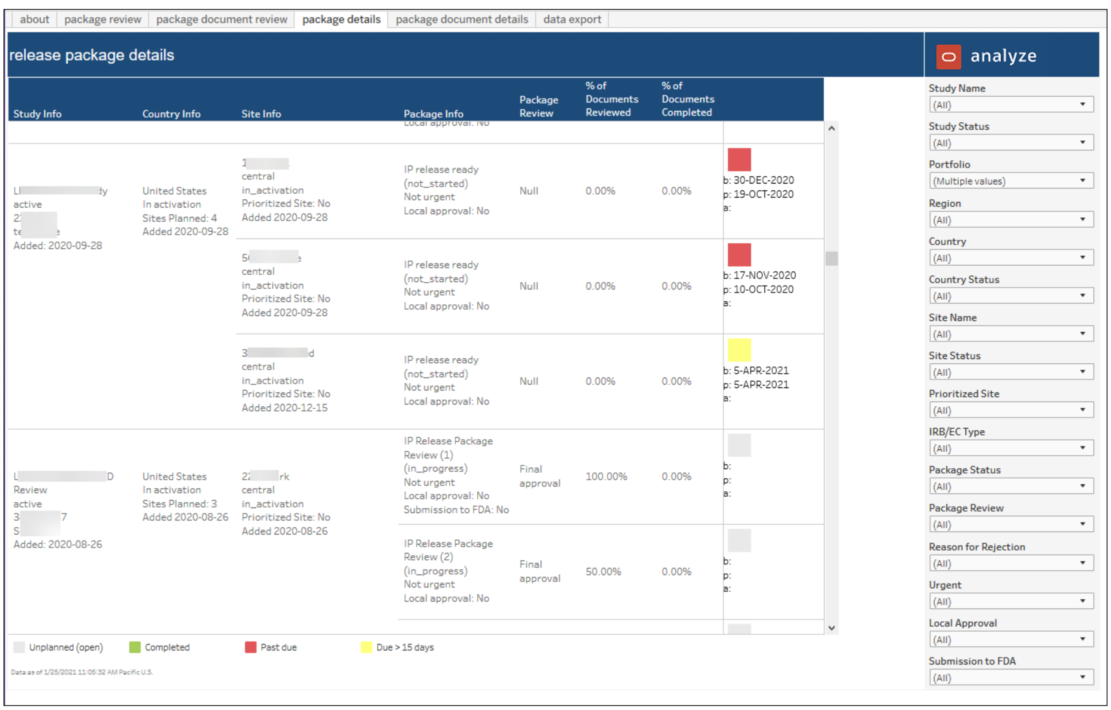
The lower section is divided into three horizontal bar charts as follows:

- 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



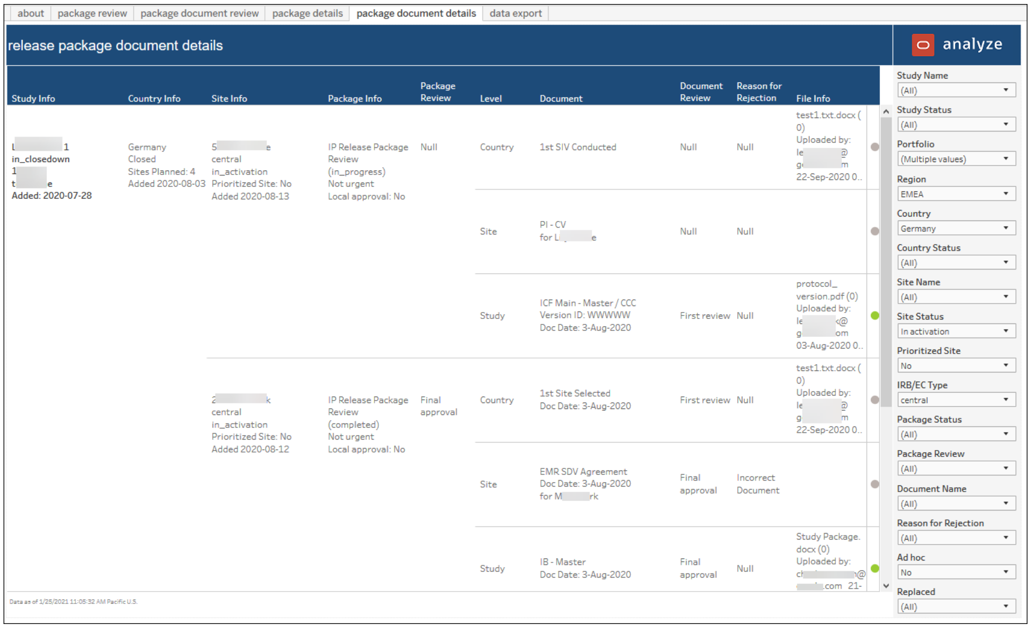
Release Package Details

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



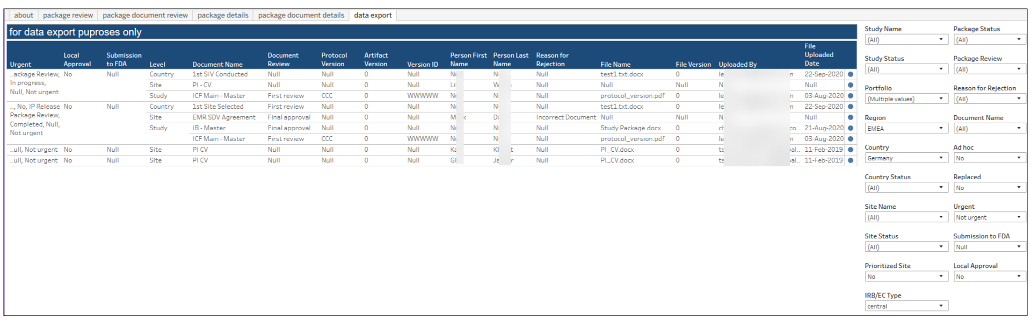
Release Package Document Details

This worksheet shows you the details of the documents included in the review package, including package status, document status, and rejection reasons.



Data Export

This worksheet allows you to export the package details to Microsoft Excel or CSV.



16

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.

17 Study Startup Industry Benchmarking

Workbook synopsis

This dashboard gives Oracle Site Analyze users a unique view into their own organization's cycle-time performance relative to others in the industry. Benchmarks are available by country and therapeutic area. Currently, this dashboard focuses on three cycle times for Oracle Site Activate:

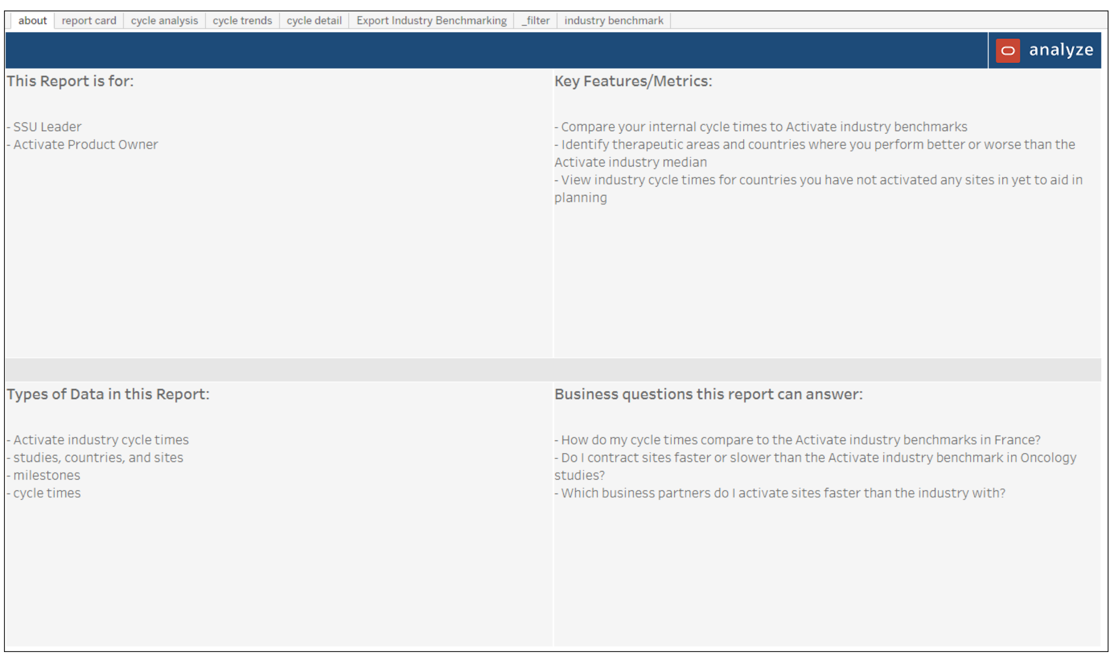
1. Essential docs sent to site – Contracts executed
2. Contracts executed – IP release ready
3. Essential docs sent to site – IP release ready

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 Study Startup Industry Benchmarking 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



Industry Benchmark

The workbook's Industry Benchmark worksheet is a configurable dashboard view. You can specify the following data points to visualize cycle time comparisons in the dashboard:

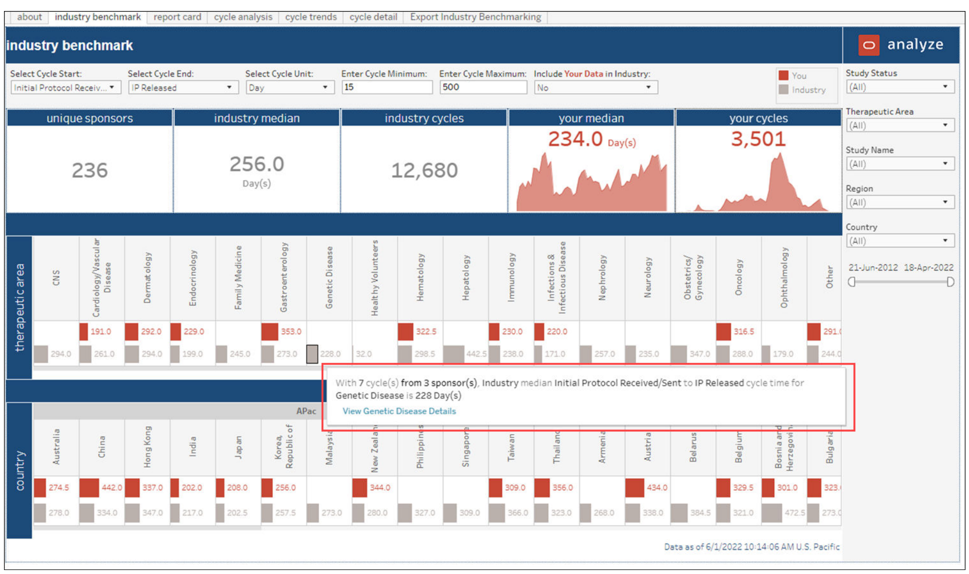
- Cycle start
- Cycle end
- Cycle unit
- Cycle minimum
- Cycle maximum

The configuration section at the top of the dashboard includes an optional "Include my data" setting. When set to Yes, your organizational data is included in the dashboard's industry comparison. With the cycle time configuration values either selected or entered, the Industry Benchmark dashboard's top section displays these key performance indicators:

- Unique sponsors
- Industry median
- Industry cycles
- Your median (with a trend graph below)
- Your cycles (with a trend graph below)

The dashboard's lower section presents therapeutic area and country benchmark tables. Both tables include a bar chart of the industry median and your median. Hover over functionality allows you to access site details in both benchmark tables including, for instance, the total sponsor count in the tool tips for industry data.

You can optionally filter the dashboard by: Study Status, Therapeutic Area, Study Name, Region, Country, and date range.



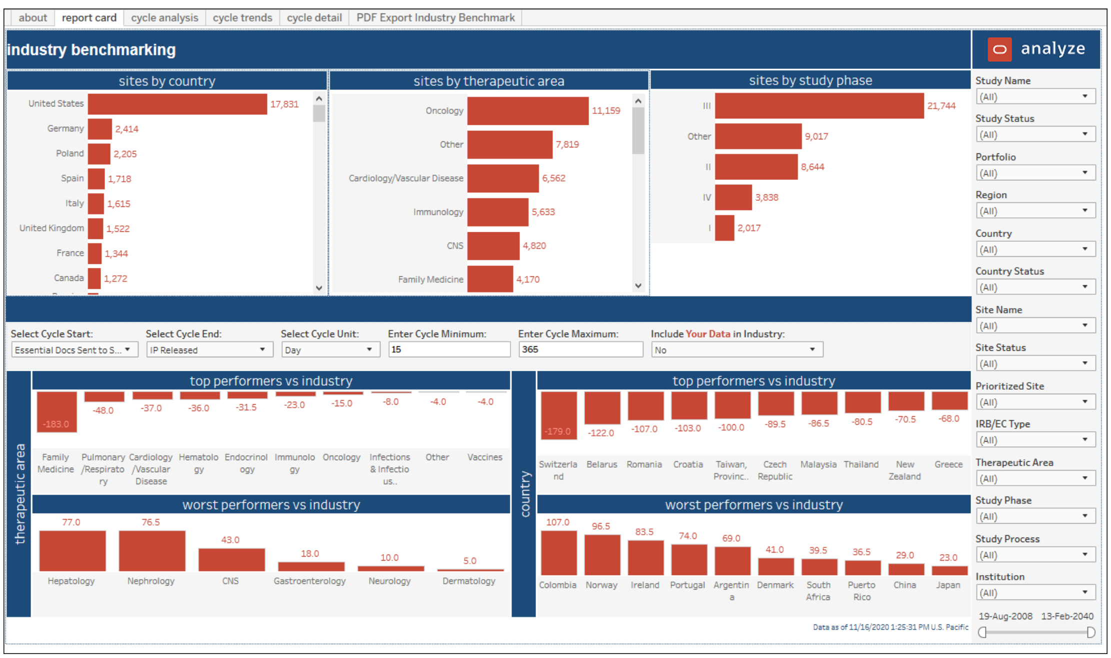
Report Card

The upper portion of the Report Card dashboard displays your statistics: site count by country, site count by therapeutic area, and site count by study phase. Using the options to the right, you can filter the dashboard by study status, study name, therapeutic area, region, country, institution, cycle end date, and minimum number of cycles completed. You can also optionally exclude negative cycle times from the dashboard's calculations.

The lower half of the report card worksheet provides you with performance bar chart visualizations. The left side includes two therapeutic area bar charts that show top performing therapeutic area vs. industry and worst performing therapeutic areas vs. industry. The lower right includes two vertical bar charts by country that show top performing countries vs. industry and worst performing countries vs. industry.

You can filter the performance section by selecting:

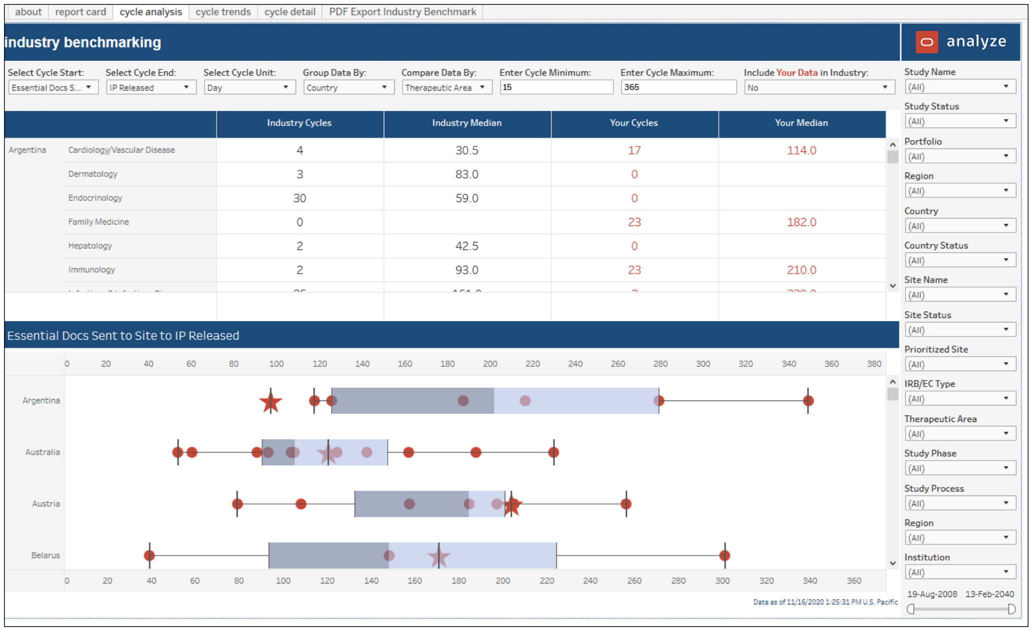
- Cycle Start
- Cycle End
- Cycle Unit
- Cycle Minimum
- Cycle Maximum
- Include Your Data in Industry (Yes/No)



Cycle Analysis

The second tab in the Study Startup Industry Benchmarking workbook is a cycle analysis dashboard. The upper portion of the dashboard includes a tabular version of the cycle time diagrams at the bottom of the dashboard. You can quickly see the exact values of the industry medians compared with your account medians.

The lower section of the dashboard displays median cycle time vs. industry benchmark as a whisker plot diagram. Hover over any star to view the Oracle industry benchmark. Hover over any circle to view your own median cycle time over cycles. Hover over any bar to view upper, median, and lower values.



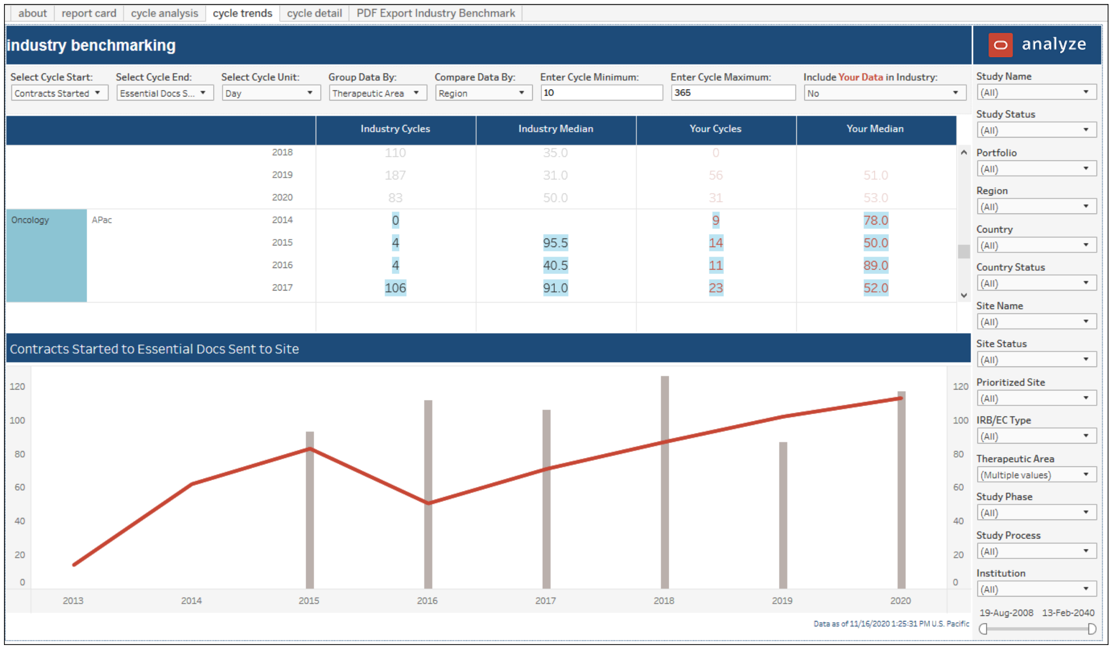
Cycle Trends

The Cycle Trends sheet provides an easy method to evaluate performance over time and compare your organization's cycle times to industry cycle times by month, quarter, or year. Trend data is presented in line graph format in the lower section of the report, and the upper section presents columns for the following data points:

- trend by parameter
- your number of cycles
- your cycle median
- industry number of cycles
- industry median

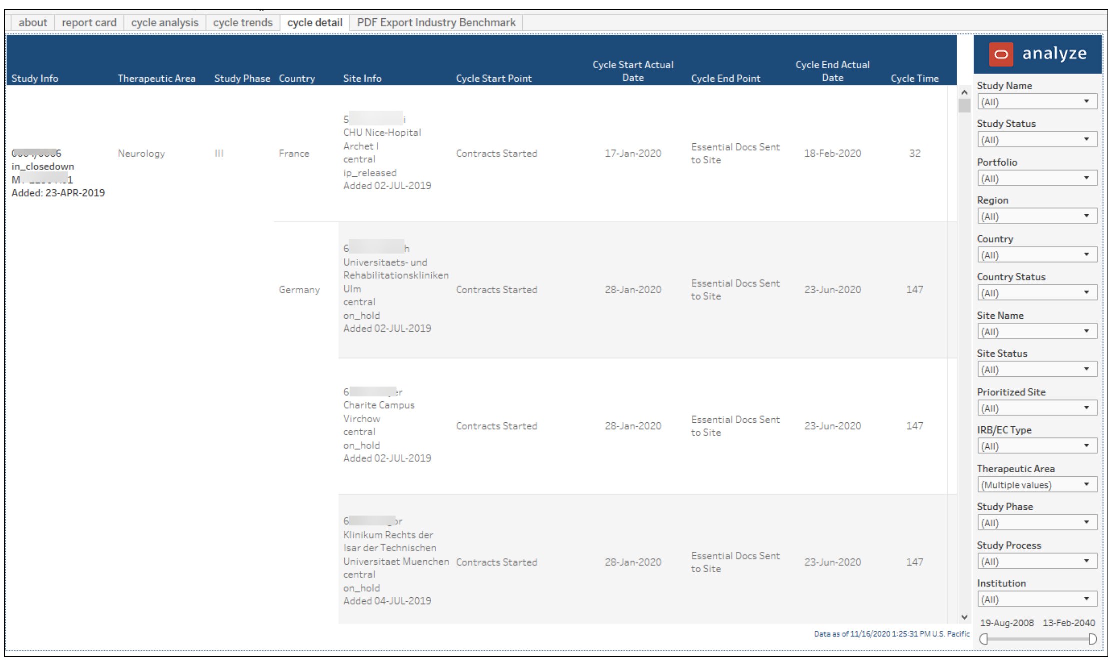
When you click a data point in the upper section (e.g., user clicks on a country name or a Benchmark Median count), the trend graph below displays the data point in the graph. You can then hover over points in the graph to view median, benchmark median cycle time, and/or your organization's median cycle time.

The report also includes a toggle in the filter selection panel that allows you to easily include and exclude your own organization's data from the industry benchmark for therapeutic areas and countries.



Cycle Detail

The Cycle Detail worksheet includes a tabular view of data used to create cycle benchmarking comparisons.



Export Industry Benchmarking

The Export Industry Benchmarking worksheet gives you a simple way to export high-level benchmarking metrics to PDF or CSV format. The PDF or CSV format report can then be shared with other interested parties, as preferred.

The export worksheet presents benchmark metrics in tabular format with the following columns:

- Data slice – reflects the “Group data by” dimension selected on the Cycle Analysis worksheet
- Data compare – reflects the “Compare data by” dimension selected on the Cycle Analysis worksheet
- Industry Cycles
- Industry Median
- Your Cycles
- Your Median

When you export the worksheet, the PDF or CSV version includes the worksheet data in the same format it appears in the browser.

about | report card | cycle analysis | cycle trends | cycle detail | PDF Export Industry Benchmark

Industry Benchmarking
Contracts Started to Essential Docs Sent to Site

		Industry Cycles	Industry Median	Your Cycles	Your Median
Cardiology/ Vascular Disease	APac	7	125.0	60	56.0
	EMEA	207	108.0	693	72.0
	LatAm	50	159.5	151	120.0
	NAmer	92	73.5	712	43.0
Endocrinology	APac	27	105.0	0	
	EMEA	54	103.0	9	93.0
	NAmer	45	21.0	3	14.0
Gastroenterology	APac	26	19.0	6	44.5
	EMEA	89	94.0	48	55.5
	LatAm	3	179.0	0	
	NAmer	74	31.0	36	32.0
Neurology	APac	97	77.0	13	52.0
	EMEA	416	111.0	18	74.0
	LatAm	35	173.0	0	
	NAmer	533	31.0	87	53.0
Oncology	APac	356	83.0	138	66.0
	EMEA	806	131.0	1,031	94.0
	LatAm	97	211.0	83	155.0
	NAmer	345	62.0	622	63.0

18
Study Summary

Workbook synopsis

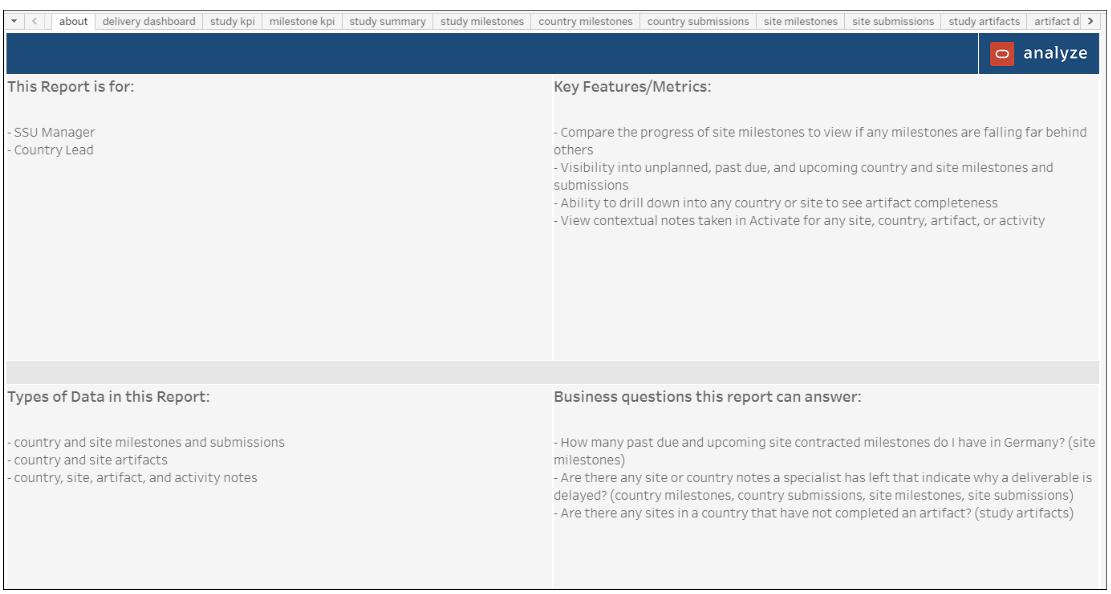
The Study Summary workbook, which is intended for Oracle Site Activate customers, provides easy interpretation of overall study status; visibility into unplanned, past due, and upcoming milestones; and milestone and submissions progress at the country and site level. Detailed sheets, described below,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

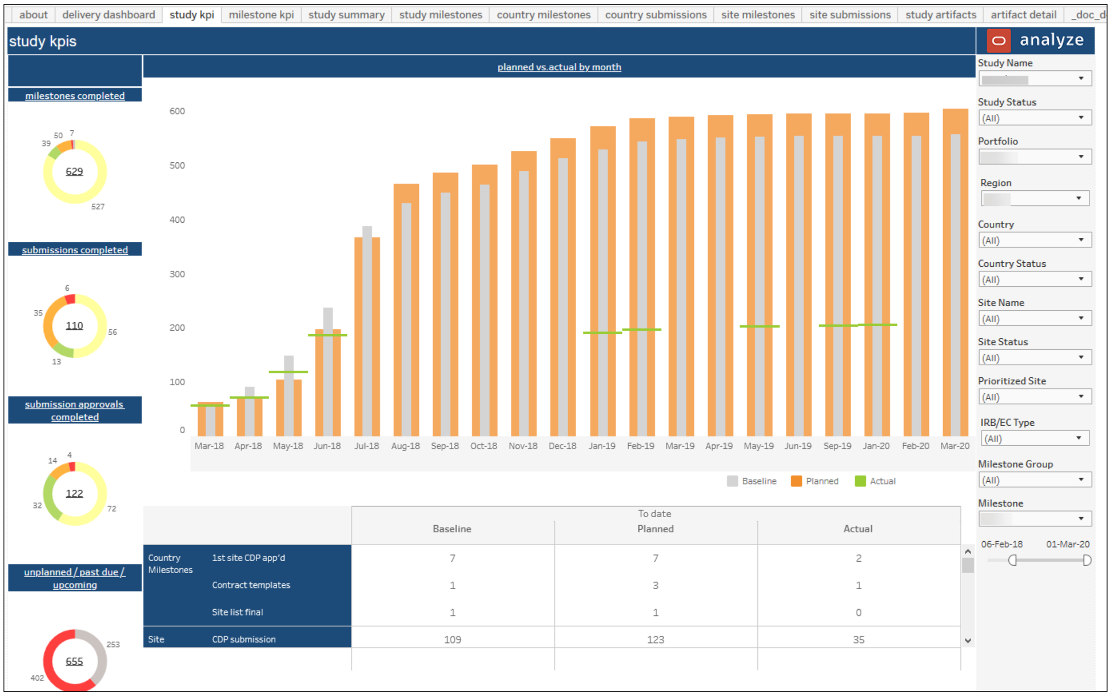
- Completed milestones heat map (weekly trend of milestones completed, with darker green meaning more milestones completed that week)
- Past due milestones heat map (weekly trend of milestones past due, with darker red meaning more milestones past due that week)
- Upcoming milestones heat map (weekly 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.

Additionally, the milestone status dashboard includes shaded line graphs over the bar charts to show you the relative volume of milestones each week. You can use the line graphs to interpret milestone volume at a glance.

Study KPI Dashboard

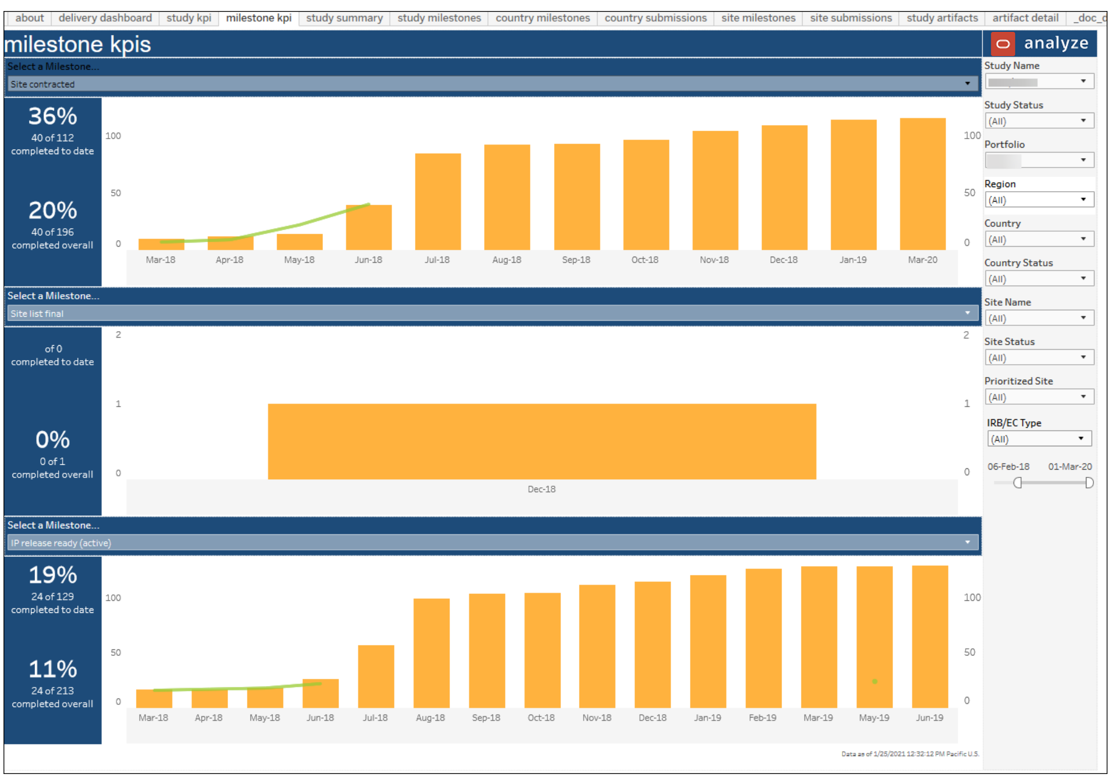
This dashboard provides a high level graphical view of progress to plan over time for milestones and submissions. Hover-over tool tips for circle and bar graphs provide additional details. You can filter the dashboard by: Study Status, Portfolio, Study Name, Country, Site Status, Site Name, Milestone Group, Milestone, and date range.



Milestone KPI Dashboard

The Milestone KPI dashboard allows comparison of up to three milestones at one time. Top level KPIs show:

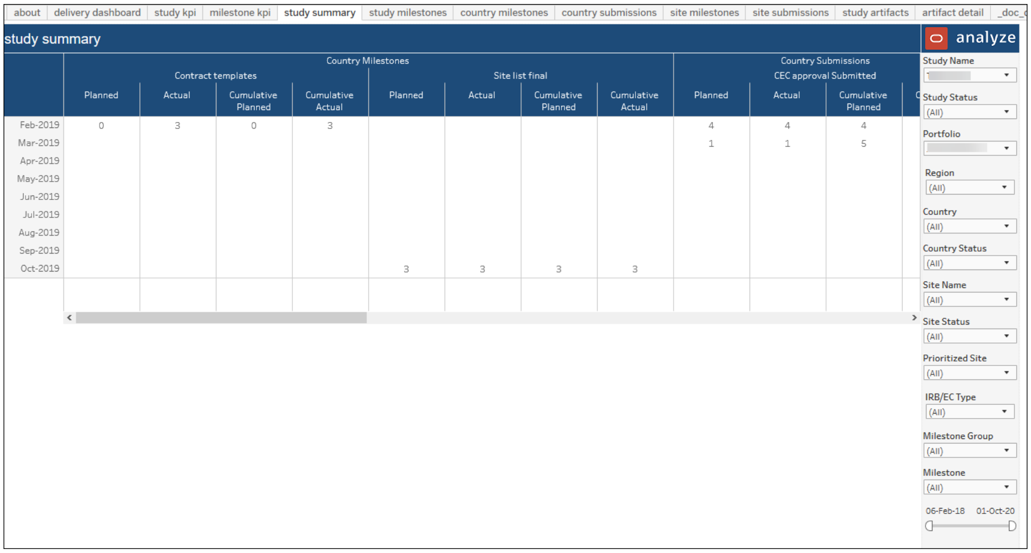
- **% planned to actual -** total number of milestones completed divided by the total number of milestones planned up to the current day
- **% actual to total -** total number of milestones completed divided by the total number of milestones created



Study Summary

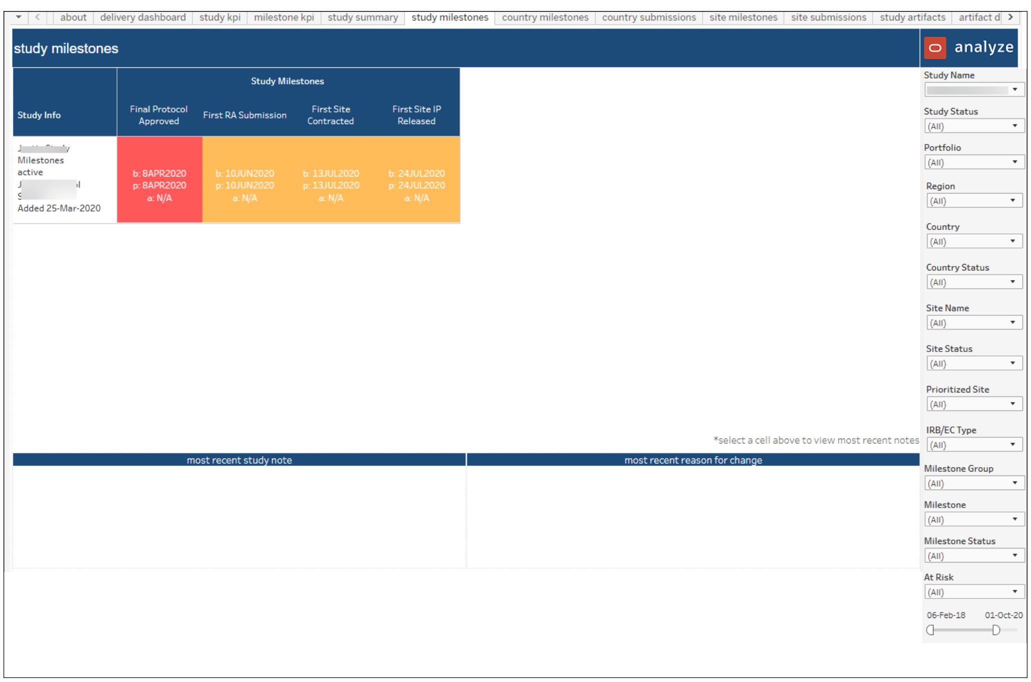
This worksheet provides a detailed tabular view of country and site global milestones, broken down by month, over the length of the study to date. This data is a detailed representation of the high-level graphical representation in the Study KPI dashboard.

You can filter this worksheet for a particular global milestone, or for any number of global milestones. This dashboard can also be filtered to look at data for the duration of the study to date, or other date range.



Study Milestones

The Study Milestones dashboard worksheet allows you to review milestones at the study level. The worksheet is intended to help you understand if the study is on track.

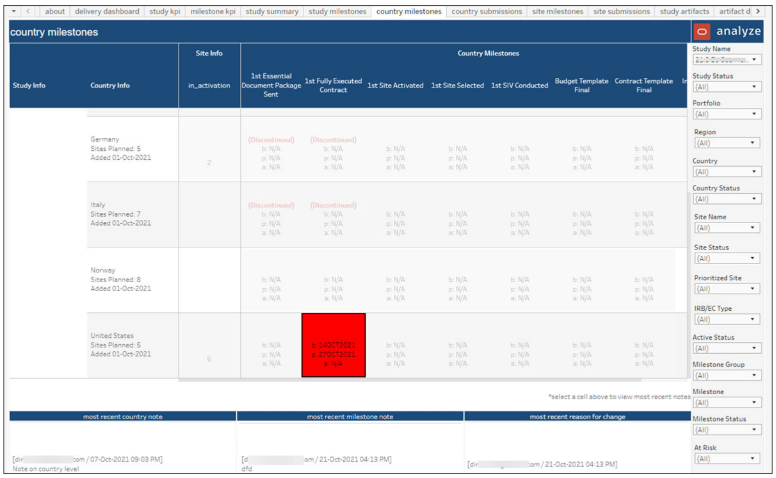


Country Milestones

This sheet details country milestone data by site and milestone dates. Hover over tool tips (over the red and green boxes) provide additional information, such as "Latest re-plan note," if appropriate. The sheet provides multiple data filters llike Study Status, Portfolio, Study Name, Country, Active Status, Milestone Group, Milestone, Milestone Status, and date range.

You can also access notes related to country milestones on this sheet.

- Click on a country milestone and the most recent country note, most recent milestone note, and most recent reason for change note will display at the bottom of the dashboard
- Click on a country name and a link will display in the tool tip that you can click on to be taken the All Notes worksheet, which will display all notes for that country
- Click on a country name and a link will display in the tool tip that you can click on and be taken the All Notes worksheet, which will display all notes for the country milestones

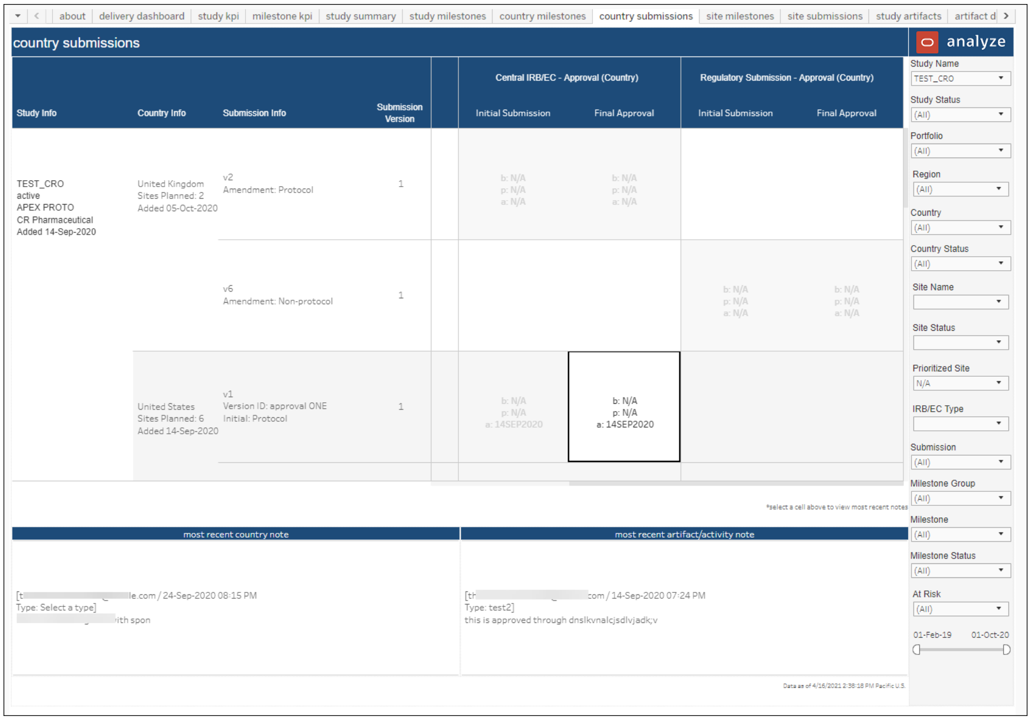


Country Submissions

This dashboard details study country regulatory submissions data. Hover over tool tips (over the red and green boxes) provide additional information, such as "Latest re-plan note," if appropriate. You can filter this sheet by Study Status, Portfolio, Study Name, Country, Submission, Milestone Group, Milestone, Milestone Status, and date range.

You can also access notes related to country submissions on this sheet.

- Click on a country submission and the most recent artifact/activity note related to that submission and the most recent country note will display at the bottom of the dashboard
- Click on a country name and a link will display in the tooltip that you can click on to be taken the All Notes worksheet, which will display all notes for that country
- Click on a country name and a link will display in the tooltip that you can click on and be taken the All Notes worksheet, which will display all notes for the country submissions

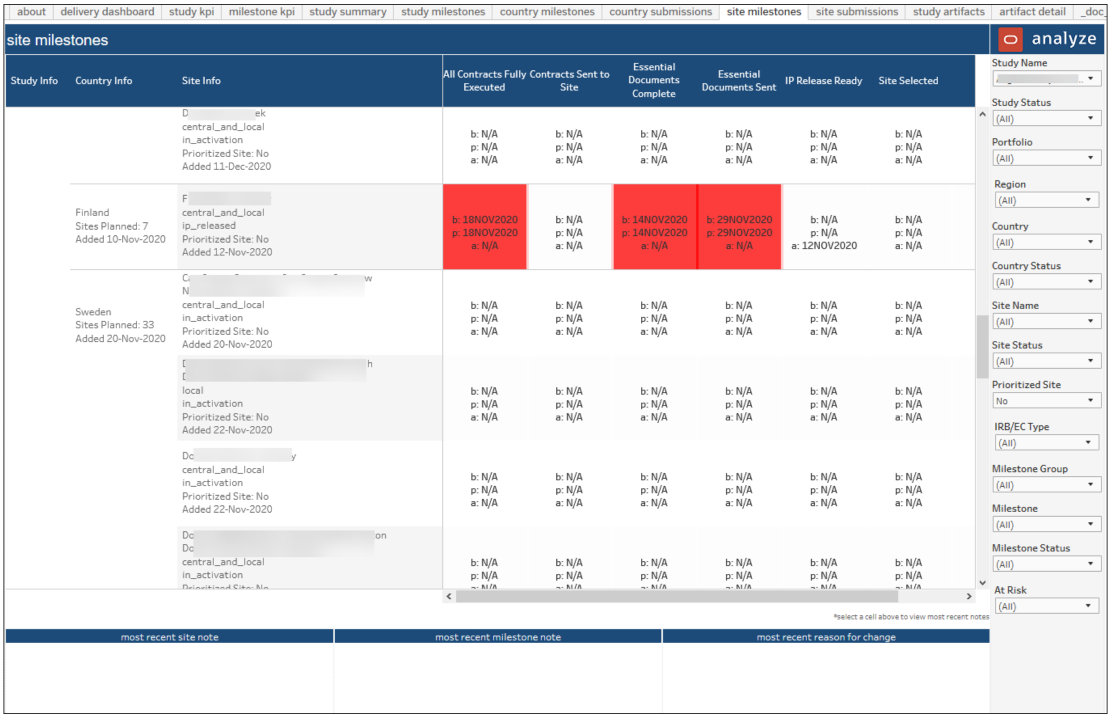


Site Milestones

This worksheet details completed and past due milestones at the site level. Hover over tool tips (over the red and green boxes) provide additional information, such as "Latest re-plan note," if appropriate. You can filter this sheet by Study Status, Portfolio, Study Name, Country, Site Status, Site Name, Milestone Group, Milestone, Milestone Status, and date range.

You can also access notes related to site milestones on this sheet.

- Click on a site milestone and the most recent site note, milestone note, and reason for change will display at the bottom of the dashboard
- Click on a site name and a link will display in the tool tip that you can click on to be taken the All Notes worksheet, which will display all notes for the site
- Click on a site and a link will display in the tool tip that you can click on and be taken the All Notes worksheet, which will display all notes for the site milestones

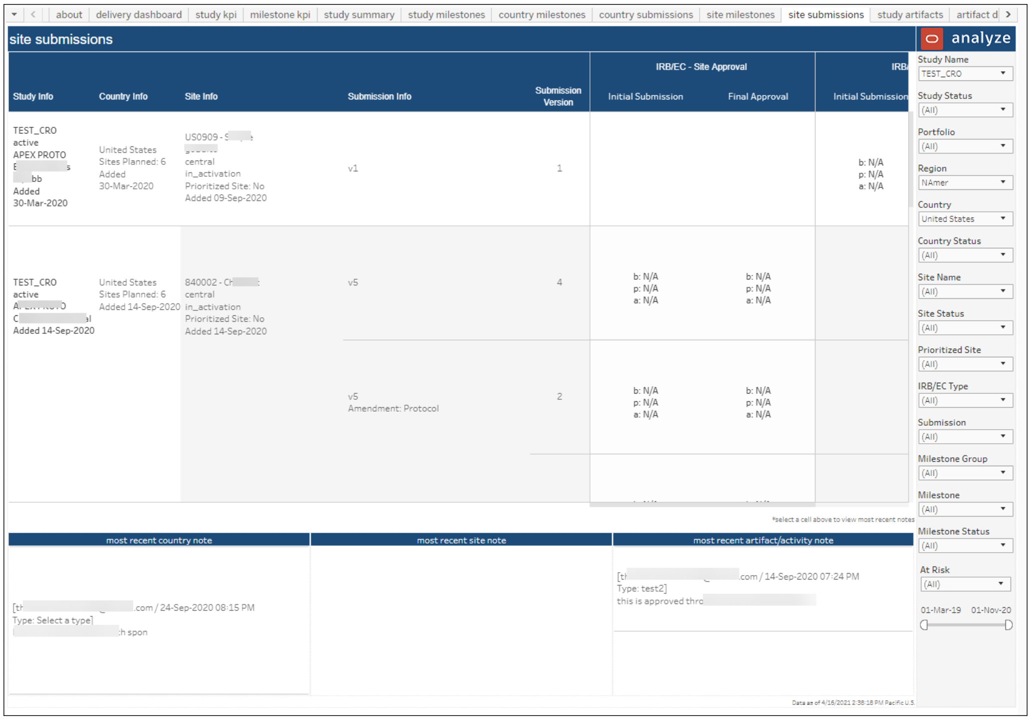


Site Submissions

This worksheet details completed and past due submissions at the site level. Hover over tool tips (over the red, green, and white boxes) provide additional information, such as "Latest re-plan note," if appropriate. You can filter this sheet by Study Status, Portfolio, Study Name, Country, Site Status, Site Name, Submission, Milestone Group, Milestone, Milestone Status, and date range.

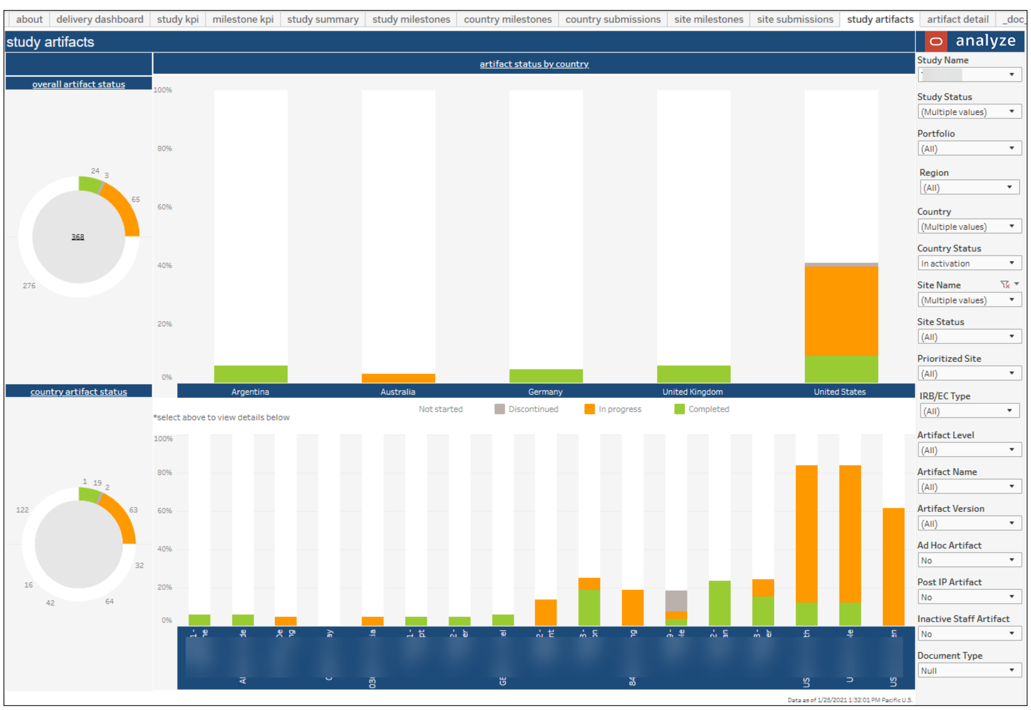
You can also access notes related to site submissions on this sheet.

- Click on a site submission and the most recent artifact/activity name and the most recent site and country notes will display at the bottom of the dashboard
- Click on a site name and a link will display in the tool tip that you can click on to be taken the All Notes worksheet, which will display all notes for the site
- Click on a site and a link will display in the tool tip that you can click on and be taken the All Notes worksheet, which will display all notes for the site submissions



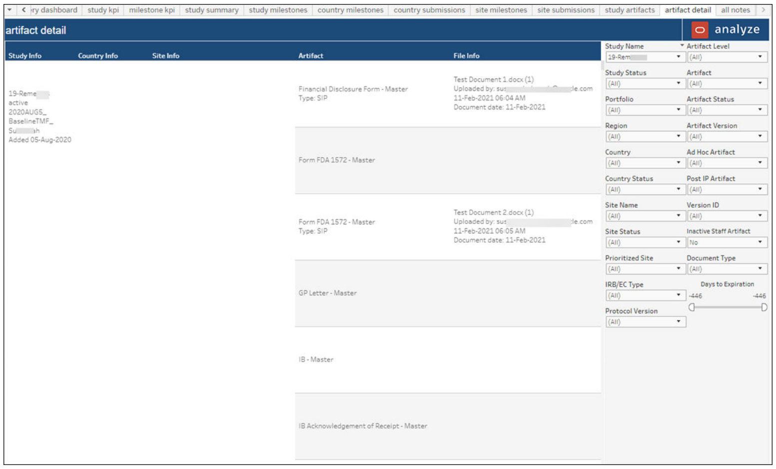
Study Artifacts

The Study Artifacts worksheet provides a comprehensive view of artifact status (e.g., total artifacts completed, % of artifacts completed, in progress, not started, and discontinued, etc.). You can drill into a Study Artifact Dashboard from the Country Milestones, Country Submissions, Site Milestones, and Site Submissions sheets. From the Study Artifact Dashboard, you can then drill into the Artifact Detail sheet.



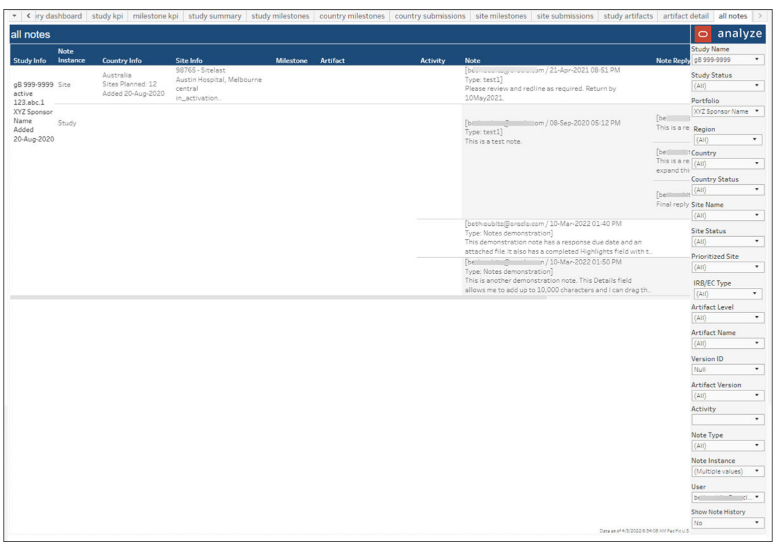
Artifact Detail

The Artifact Detail worksheet includes the status of each individual artifact at the site. The filter panel to the right side of the worksheet provides multiple options for subsetting artifacts. For instance, you can filter by Artifact, Artifact Status, Artifact Version, and more.



All Notes

The All notes worksheet includes detailed note text associated with study artifacts. Using the options in the filter panel to the far right, you can filter the All Notes worksheet by study status, portfolio, study name, country, site status, and more.



19
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

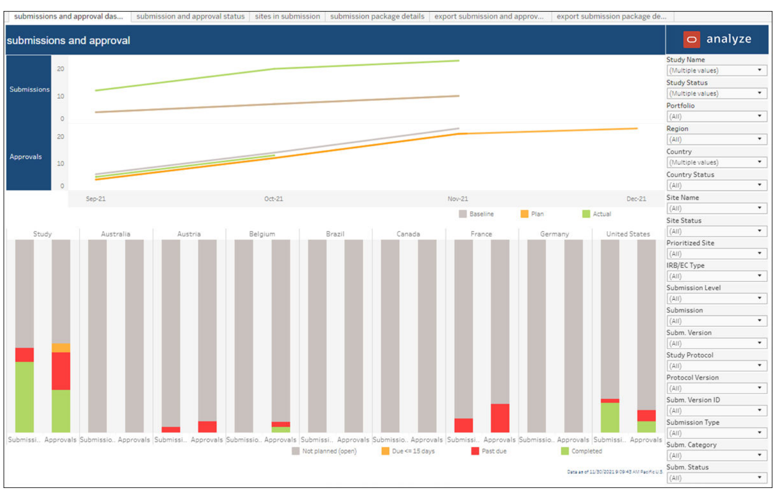
Submissions and Approvals Dashboard

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 options in the filter panel to subset the dashboard's data to your preferred view. Among others, the filter panel includes options to filter by submission level, version, and category, as well as protocol and protocol version.



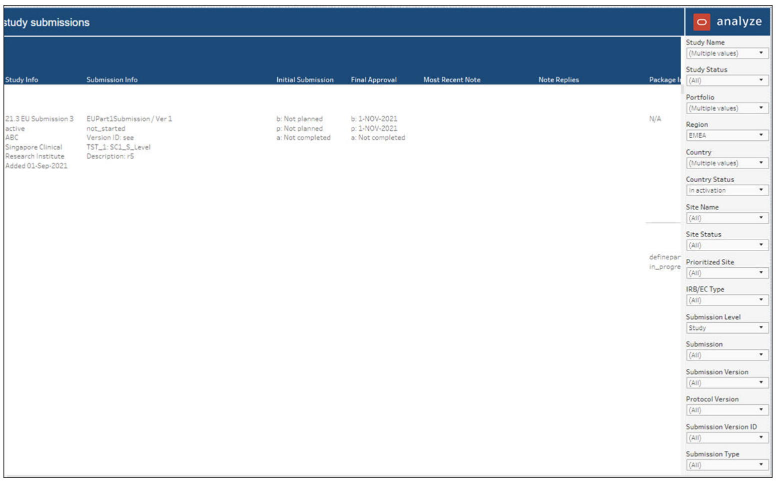
Submission and Approval Status

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.

Click on submission dates on the Submissions and Approval Status worksheet, to see the sites associated with the country submission (if any) display in a table at the bottom of the worksheet.

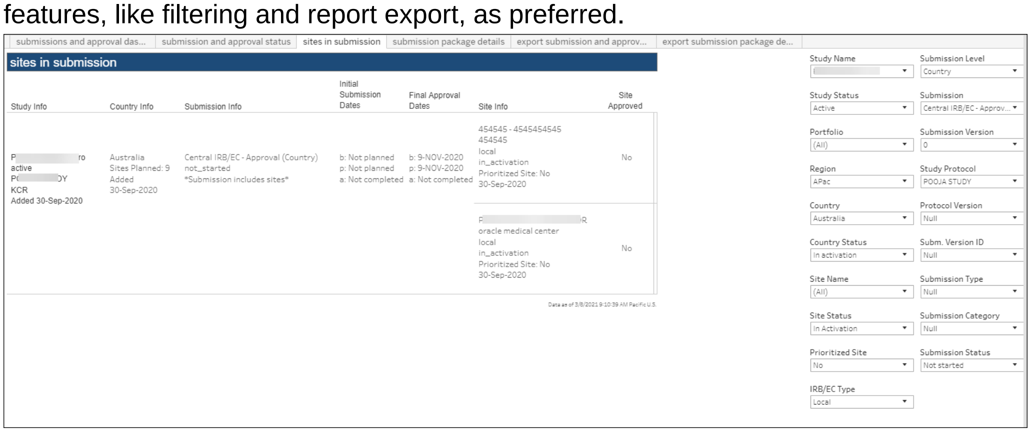
The Submission and Approval Status worksheet also provides columns like "Reporting Member State," "Country Approved," "Country Info," "Ready for Submission," "Site approved," and "Site Info" that will help report users to track the site and country status within a study level submission.

This sheet provides multiple filters to allow users to drill to the preferred view. Filters are: Study Status, Portfolio, Study Name, Country, Site Status, Site Name, Submission Level, Submission, Submission Version, Protocol Version, Submission Version ID, Submission Type, Submission Category, and Submission Status.



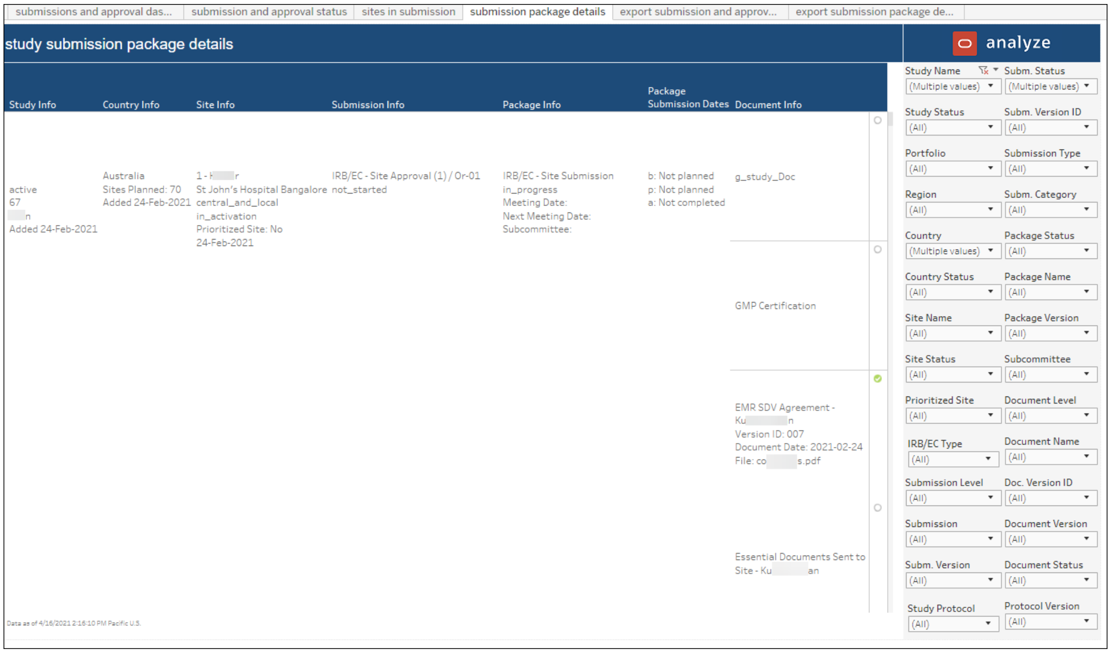
Sites in Submission

The Sites in Submission worksheet allows report users to leverage standard reporting features, like filtering and report export, as preferred.



Submission Package Details

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

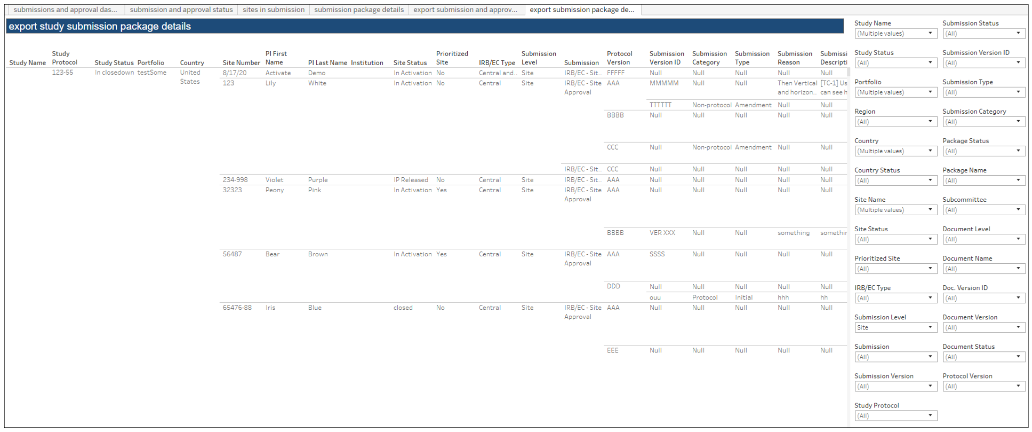


Export Submission & Approval Status

This worksheet, which is intended for export, provides detailed submission and approval status information, including detailed notes related to the submission reason. The worksheet includes multiple filters that allow you to adjust content prior to download.

Export Submission Package Details

This worksheet, which is intended for export, provides detailed study submission package information. The worksheet provides multiple filters, in the panel to the right, that allow you to adjust content prior to download.


export study submission package details

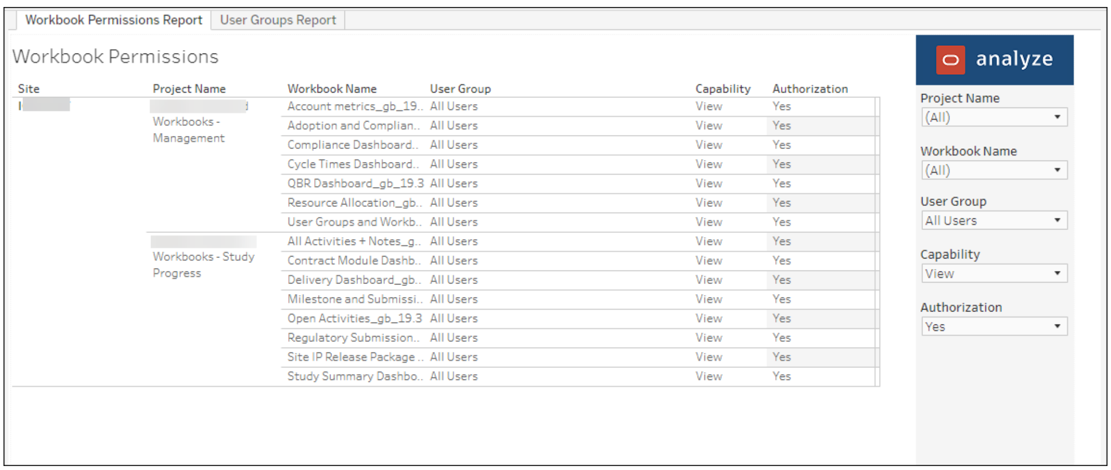
20 User Groups and Workbook Permissions

Workbook synopsis

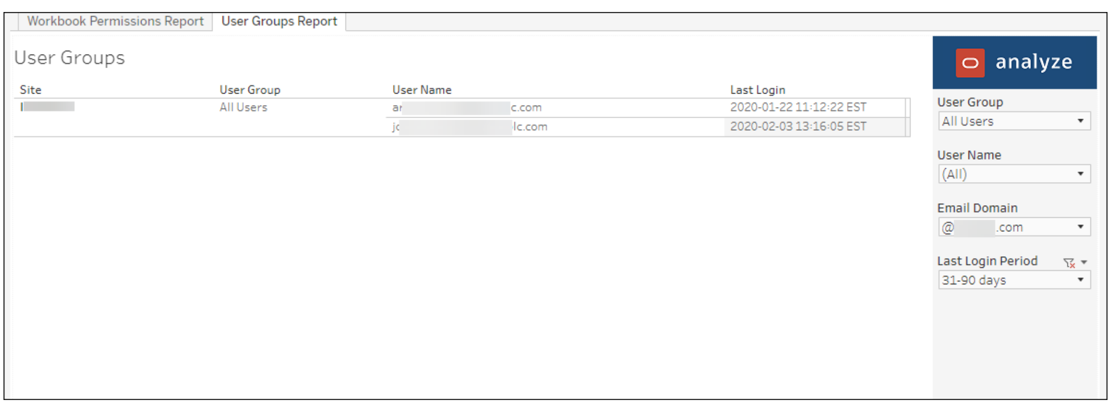
The User Groups and Workbook Permissions report provides information related to user accounts and groups setup in Oracle Site Analyze for Oracle Site Activate users. The report lists each user, the group with which the user is associated, and the permissions for the workbook(s) associated in that group. This report is intended for managers who are responsible for ensuring that report access across users and groups is properly assigned.

Report samples

Workbook Permissions



User Groups



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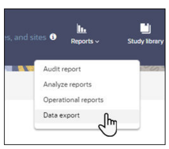
Data Export Utility

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. Currently, the extract includes data columns for study sites, study level documents, milestones and submissions, and 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.

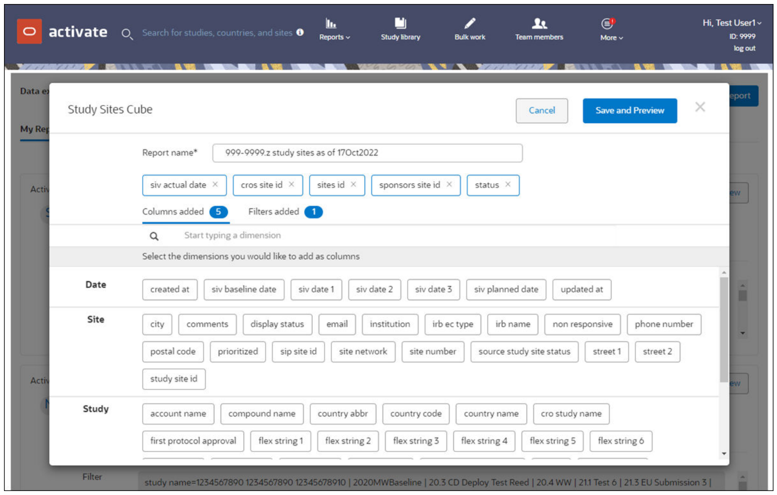


Data extract cubes

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

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

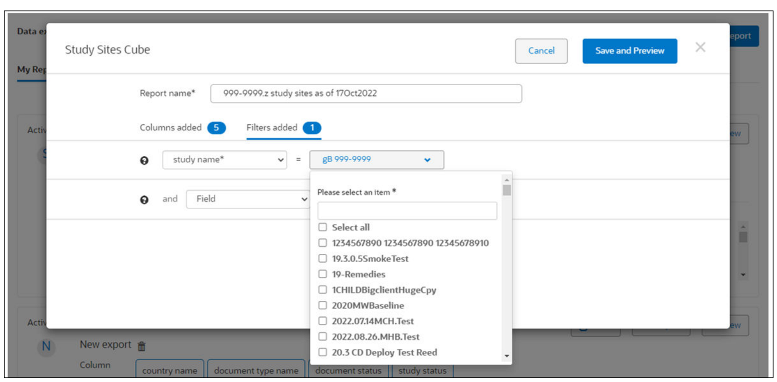
You'll see columns categorized into groups in each data cube. For instance, the Study Sites cube groups columns into Date, Site, Study, and Principal Investigator categories. When you create or edit a report, available columns display in alphabetical order within grouped categories.



Note:

The Data Export Utility user interface does not display columns in grouped categories when users view reports created in a 22.2 or earlier release. This is expected behavior.

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. All text values are wildcard matches and case sensitive. To add multiple filters, click **Add** to add a new field.



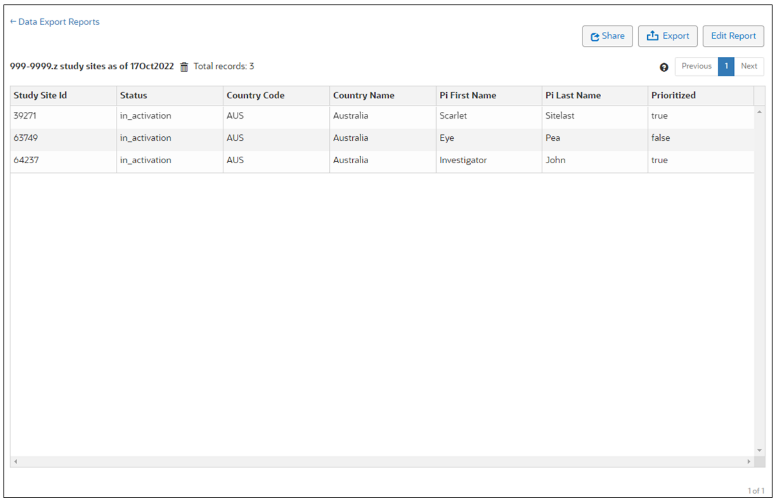
The utility displays a "No matching records found" message if the columns and filters you selected for the export will not return any data. In this case, update your selections to refine the data included in the export.

Additionally, 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.

Preview an export

Export preview mode includes pagination controls and page count to ensure acceptable response time for multistudy reports that could include high data volume. The utility displays up to 100 records in Preview mode, and each individual previewed page can include up to 10,000 rows. Additionally, a "Total records" value displays to the left of the pagination controls and shows the total records returned based on the report's filters.

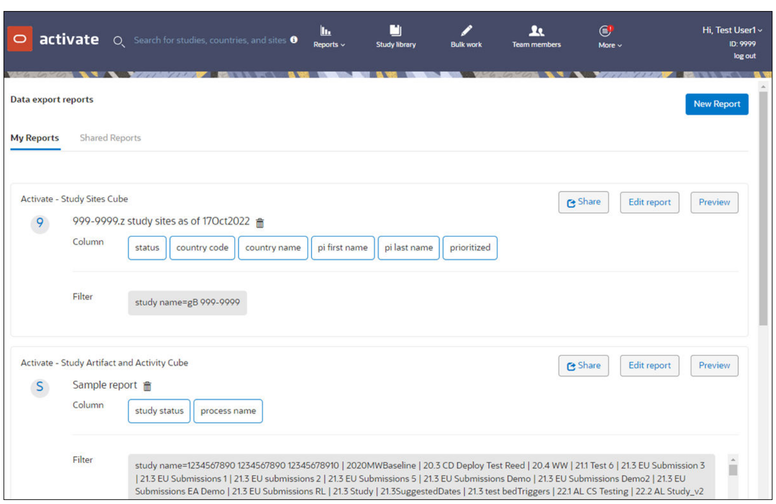
When clicked, the Export function exports the page currently being previewed, and the prompt text, "You have exported this page of the report," displays next to the Export button to indicate the download/export of the page of the report has started.



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



Provided you are the report author, you can Share () that report from the My Reports tab, or share the report while in Preview mode. When you click Share, a modal displays where you'll set the report's access type as:

- **Private (Accessible by author only)** – default selection
- **Shared (Read only to other DEU users)**

The Data Export Utility indicates a shared report ( ), and as report author, you can unshare your report at any time by returning to the access type modal to select "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.

Shared reports are read only for all users except the report author, who has full access to edit, delete, etc. When non-authors view shared reports, they do not have the option to edit or delete; however, they can Preview and Export shared reports as preferred.

- 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 back 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 right in Preview mode, click **Share**. In the share modal, confirm selection of the Shared option, and click **Save**.
10. At the upper right 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 top 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 top 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 far right, click **Edit report**.
4. Adjust the report name, columns, and filters as preferred.
5. Click **Save and Preview**.
6. At the upper right, 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 top 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 back to private.

1. From the Oracle Site Activate top 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 (Read only to other DEU users)**, and click **Save**.

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