Oracle® Health Sciences Site Analyze Cloud Service

Using Oracle Site Analyze: For Oracle Site Select Users

Release 23.3
F93842-01
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Oracle Health Sciences Site Analyze Cloud Service Using Oracle Site Analyze: For Oracle Site Select Users, Release 23.3

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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.

1 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 Select clinical study site identification application. Learn about the data dictionary, see 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 site identification team performs in Oracle Site Select. All report data comes from Oracle Site Select where information about sites, documents, feasibility surveys, 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 site identification tasks. For example, site progress data can be used to build a report view a summary of where sites are in the selection process to helps you to identify barriers to site progress. Similarly, cycle time data allows you to visualize elapsed time between, for instance, making a feasibility survey available to a site, and the site's completion of the survey task.

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

Accessing Oracle Site Analyze

If you have the appropriate permissions to access Oracle Site Analyze reports, you'll navigate to Oracle Site Analyze (Tableau) from within the Oracle Site Select application. In the Oracle Site Select top navigation bar, click Dashboards, then click "Analyze reports."

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.

2

About viewing reports and using Tableau

Learn about how Oracle Site Analyze displays the 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.

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 checkbox 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:**
>
> 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 who do not have 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

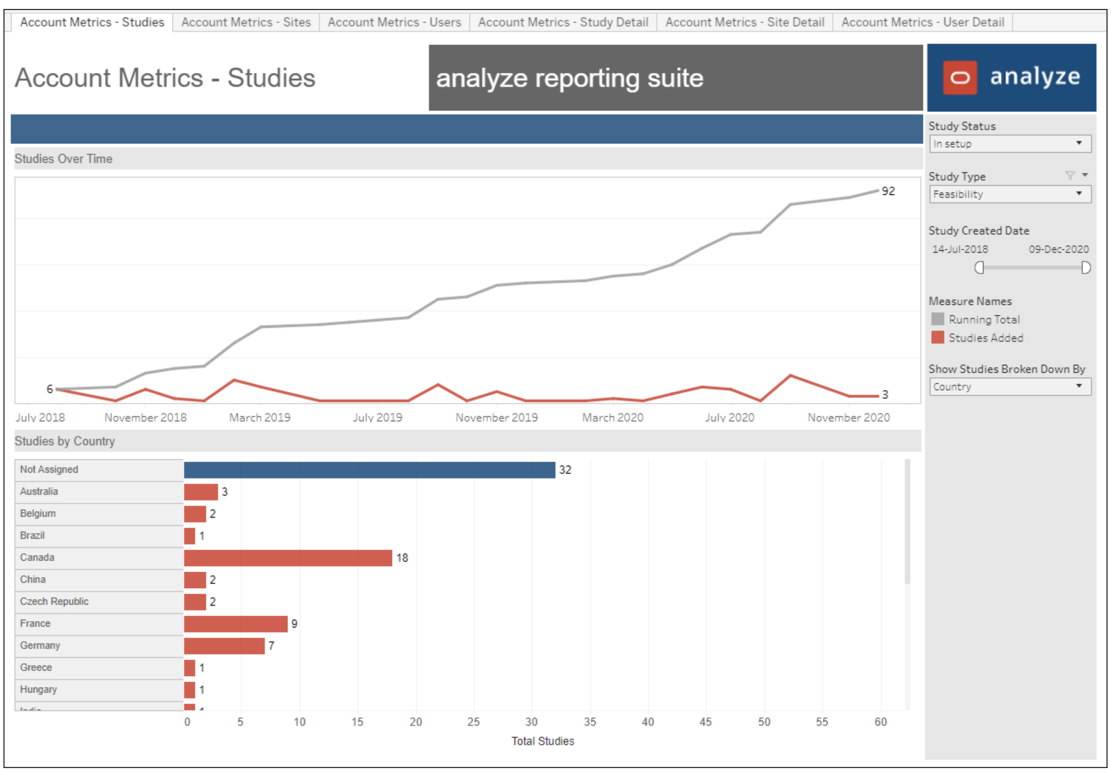
The Account Metrics report workbook, which is intended for Oracle Site Select customers, includes dashboard views of studies, sites, and Oracle Site Select users as well as detailed cross-tab sheets of each.

Dashboards and sheets

Account Metrics - Studies

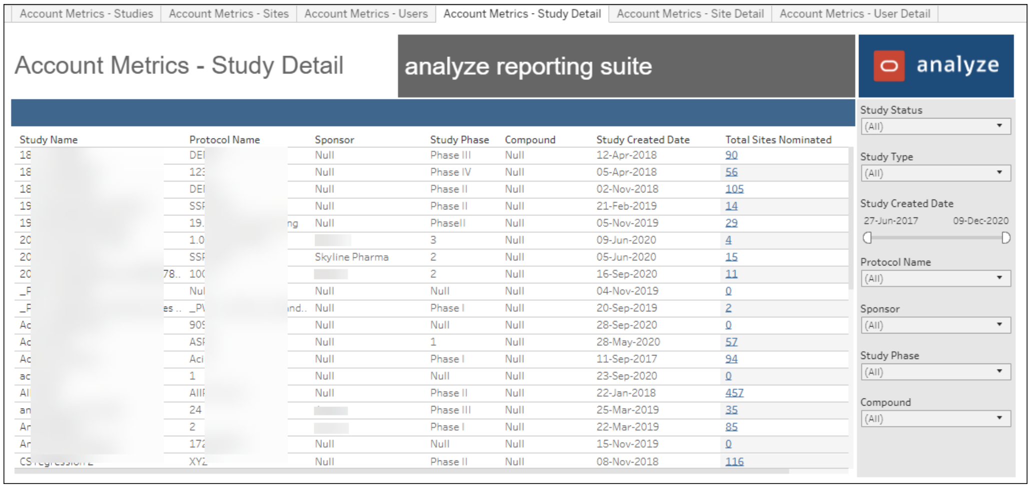
The studies dashboard allows report users to view trends in studies that have been added to Oracle Site Select over time. The top portion of the dashboard includes trending and running total line graphs indicating the number of studies added per month.

Use the filters (Study Status, Study Type, and Study Created Date), in the panel to the right, to include/exclude data from the dashboard view. Use the "Show Studies Broken Down By" filter, at the bottom of the filter panel, to change the dimension (country, sponsor, or phase) displayed in the lower section of the dashboard.



Account Metrics - Study Detail

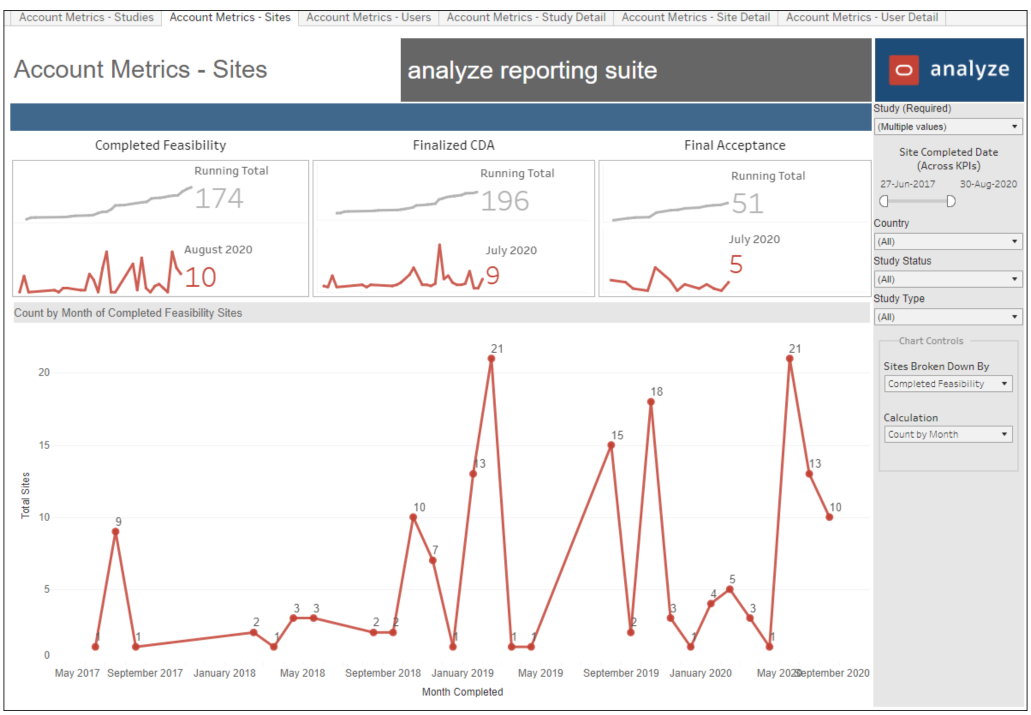
The study detail worksheet allows report users to filter details by study status, study creation date, protocol name, sponsor, study phase, and/or compound. Report users also have the ability to drill directly to site data from the hyperlinked value listed in the "Total Sites Nominated" column.



Account Metrics - Sites

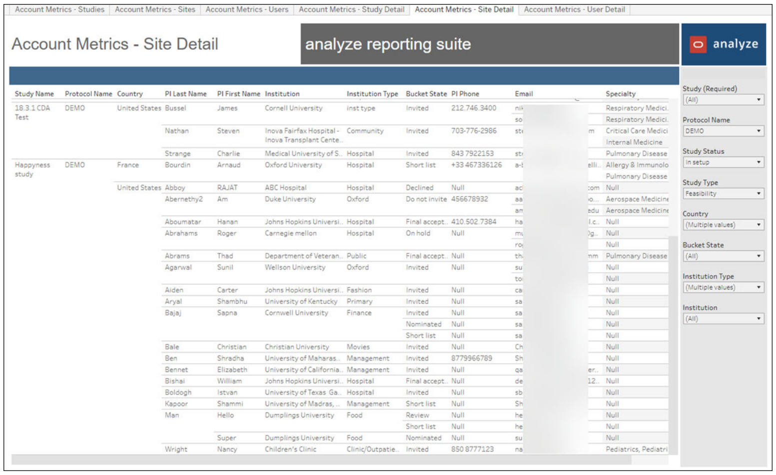
The sites dashboard allows report users to view trends in sites that have completed feasibility, finalized CDAs, and achieved final acceptance in Oracle Site Select over time. Top level KPIs show total number of study sites that have completed feasibility, total number of study sites that have finalized CDAs, and total number of study sites that have reached final acceptance bucket state. A running total line graph indicates total over time and a month-by-month line graph indicates distinct number per month.

At the bottom of the dashboard, a trend vertical bar graph shows the trend in sites added per month based on the parameter a user has selected (feasibility, finalized CDA, or final acceptance). Users can display data by running total or count by month.



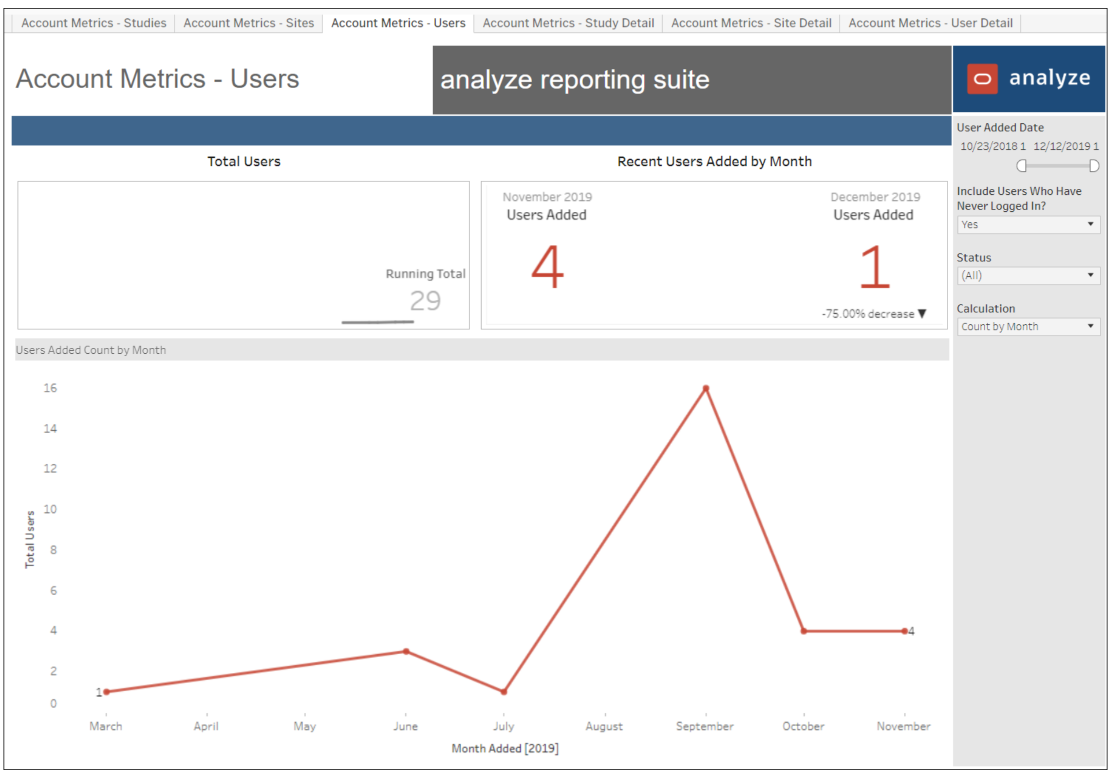
Account Metrics - Site Detail

The sites detail worksheet allows report users to filter details by study, country, and bucket state (e.g., do not invite, invited, short list, etc.).



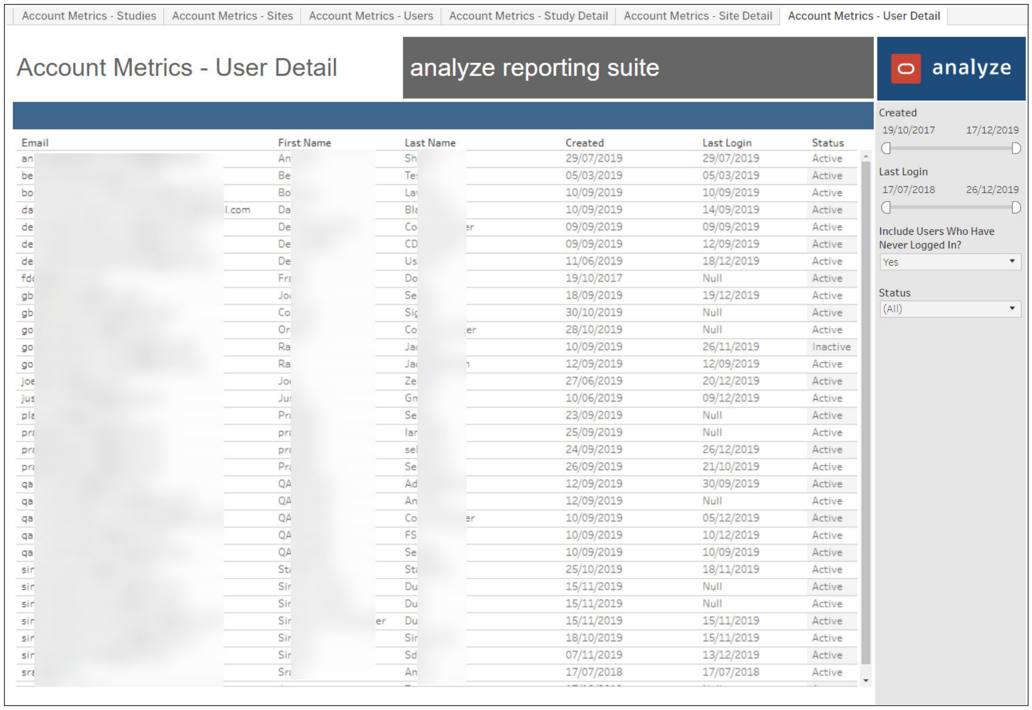
Account Metrics - Users

This dashboard allows report users to view top level KPIs for total Oracle Site Select users added, users added this month, and users added last month. The lower section of the dashboard is a trend bar chart of users added per month. The "Status" filter in the right filter panel makes it easy to toggle between including/excluding inactive users in the aggregations. Report users can also toggle this view between running total and count by month using the "Calculation" filter in the right filter panel.



Account Metrics - User Detail

The users detail worksheet allows report users to filter details by date range for Oracle Site Select user account creation and last login. Report users can also specify if they want to include users who have never logged in and/or view the data by active, inactive, or all users.


Account Metrics - Studies
Account Metrics - Sites
Account Metrics - Users
Account Metrics - Study Detail
Account Metrics - Site Detail
Account Metrics - User Detail
Account Metrics - User Detail
analyze reporting suite
analyze
Email
First Name
Last Name
Created
Last Login
Status
Created
19/10/2017
17/12/2019
Last Login
17/07/2018
26/12/2019
Include Users Who Have Never Logged In?
Yes
Status
(All)

4

Cycle Times

Workbook synopsis

The Oracle Site Analyze Cycle Times workbook, intended for Oracle Site Select customers, allows you to view detailed data related to CDA, Oracle Site Select LITE, Selection, and Survey cycle times.

Dashboards and sheets

Key Cycle Times dashboard

The Key Cycle Times dashboard allows you to configure your cycle time parameters of interest (e.g., start at CDA task available and end at CDA finalized). Choose your preferred parameters from “Select Cycle Start” and “Select Cycle End” drop-down menus.

Once you've selected parameters, the Key Cycle Times dashboard displays cycle times in a box and whisker plot, with cycle time in days. At the upper left of the dashboard, use the following filters to refine the display:

Compare data by

- All
- Region
- Country
- Study
- PI
- Workflow

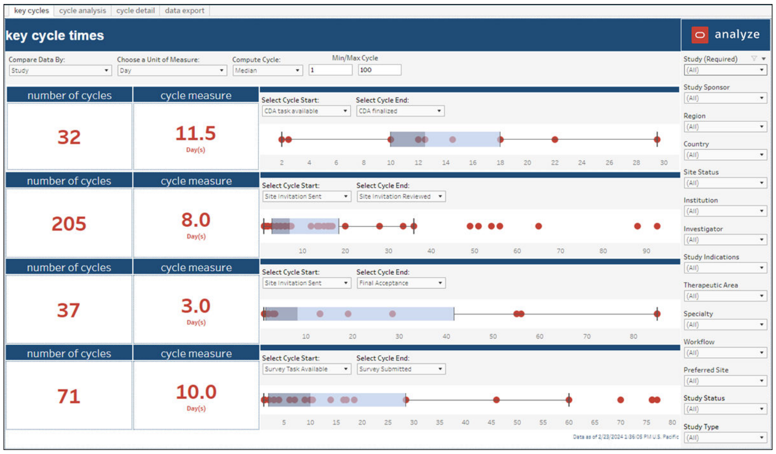
Unit of measure

- Day
- Week
- Month

Compute Cycles by

- Median
- Average

You can also specify the Minimum and Maximum cycles by entering a numerical value (1-100) in the **Min/Max Cycle** fields and use the options in the filter panel to the right to further refine the dashboard by sponsor, study, and more.

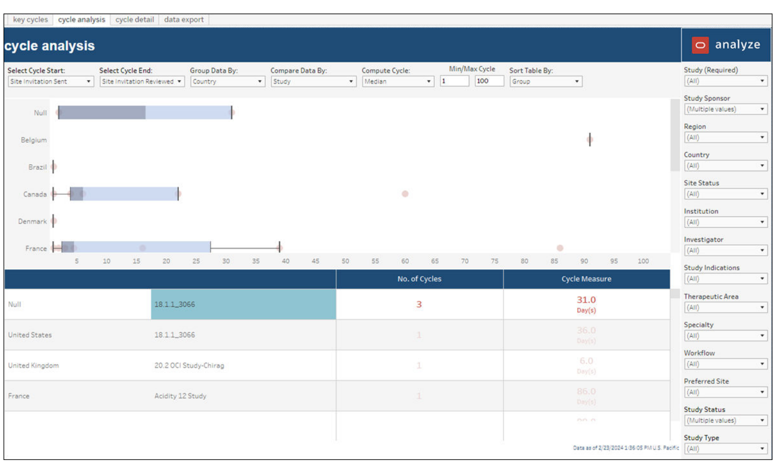


Cycle Analysis

The workbook's second sheet, Cycle Analysis, includes multiple filter options that allow you to adjust the dashboard data to your preferred views to view the data in a tabular format and box and whisker plot. You can adjust the following filters at the top of the worksheet:

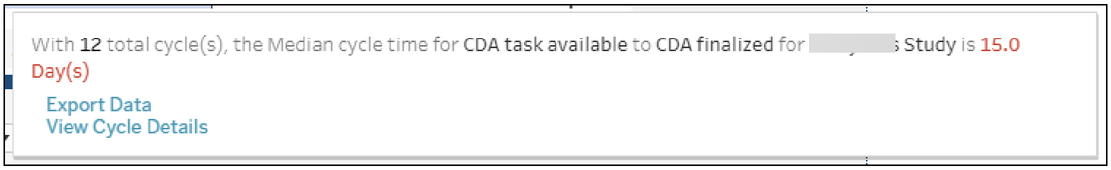
- **Cycle Start**: CDA Task Available, Site Invitation Reviewed, Site Invitation Sent, Survey Submitted, Survey Task Available
- **Cycle End**: CDA Finalized, Final Acceptance, Site Invitation Sent, Survey Submitted, Survey Task Available
- **Slice Data**: All, Region, Country
- **Compare Data**: All, Region, Country, Study, PI, Workflow
- **Compute Cycles By**: Median or Average
- **Unit of Measure**: Day, Week
- **Sort Table**: Data Slice, No. of Cycles, Cycle Median

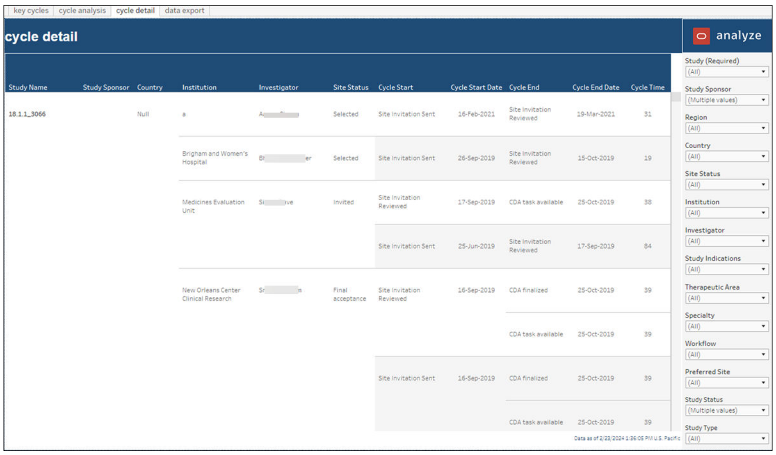
You can also adjust data included in cycle analysis using multiple filter options (e.g., Sponsor, Study Name, Region, Country, Study Status, Study Type, and more) provided in the filter panel to the right.



Cycle Detail

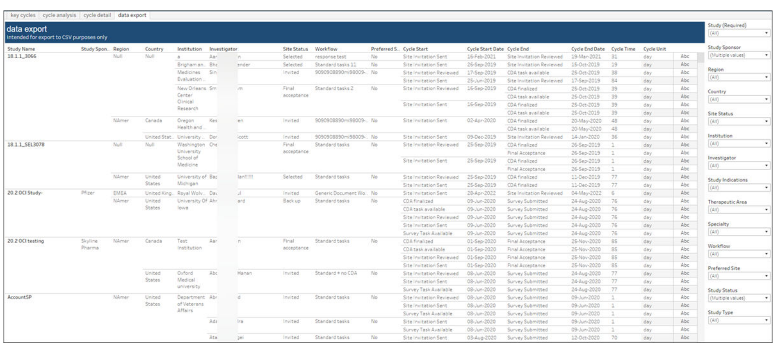
On both the Key Cycle Times and Cycle Analysis worksheets, described above, you can click any cycle point in a whisker plot diagram to access a “View Cycle Details" link. That links to the Cycle Detail worksheet with the data that makes up the value in the whisker plot diagram.





Data Export

The Cycle Times report includes a Data Export worksheet that provides a downloadable version of the data used to create the cycle times metrics. This export worksheet is intended for export to CSV format.



5 Next Actions

Workbook synopsis

The Oracle Site Analyze Next Actions dashboard, intended for Oracle Site Select customers, allows you to monitor site task progress by surfacing available tasks as well as how many days a task has been available. Use this information to evaluate when to follow up with sites who may have tasks that have not progressed for an extended period.

Dashboards and sheets

Next Actions

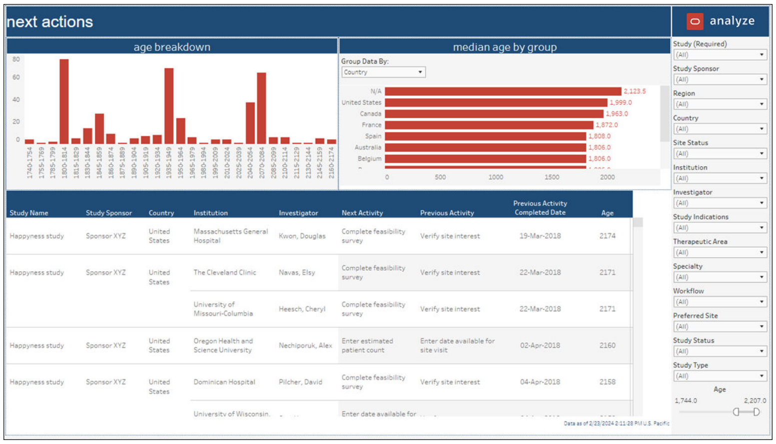
The top of the Next Actions dashboard includes two bar charts. The left chart, Age Breakdown, shows the number of available tasks by number of days the tasks have been available. The chart to the right, Median Age by Group, shows median activity age, and you can adjust this chart to show median by:

- - Assigned user
  - Study
  - Region
  - Country

Click any bar in the Age Breakdown or Median Age by Group bar chart to filter the lower section of the report, which is a tabular view of following data:

- - Study Name
  - Study Sponsor
  - Country
  - Institution
  - Investigator
  - Next Activity
  - Previous Activity
  - Previous Activity Completed Date
  - Age

The filter panel to the right provides a wide range of filters so you can easily subset the report data to a preferred view. In addition to standard filters (e.g., Study Sponsor, Study Name, Region, etc.) the right panel also includes Workflow, Preferred Site, Study Status, Study Type, and Age range filters.


next actions
analyze
age breakdown
median age by group
Group Data By:
Country
N/A
United States
Canada
France
Spain
Australia
Belgium
Study Name
Study Sponsor
Country
Institution
Investigator
Next Activity
Previous Activity
Previous Activity Completed Date
Age
Happyness study
Sponsor XYZ
United States
Massachusetts General Hospital
Kwon, Douglas
Complete feasibility survey
Verify site interest
19-Mar-2018
2174
The Cleveland Clinic
Navas, Elsy
22-Mar-2018
2171
University of Missouri-Columbia
Heesch, Cheryl
Oregon Health and Science University
Nechiporuk, Alex
Enter estimated patient count
Enter date available for site visit
02-Apr-2018
2160
Dominican Hospital
Pilcher, David
04-Apr-2018
2158
Study (Required)
Study Sponsor
Region
Country
Site Status
Institution
Investigator
Study Indications
Therapeutic Area
Specialty
Workflow
Preferred Site
Study Status
Study Type
Age

6
Notes Report

Workbook synopsis

The Oracle Site Analyze Notes Report, intended for Oracle Site Select customers, allows you to view and export notes for one or more studies.

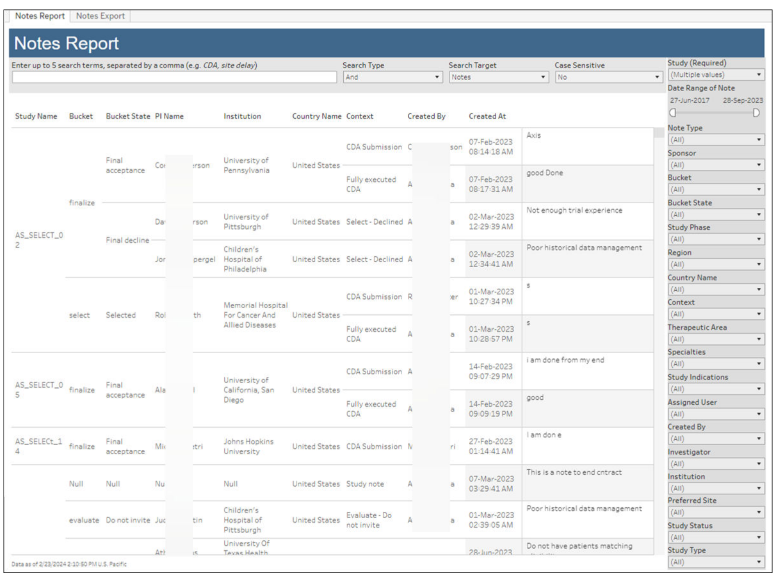
Dashboards and sheets

Notes Report

The Notes Report worksheet provides a tabular view of notes composed for a study. You can optionally filter the report by entering up to five comma-separated search terms at the upper left. Specify:

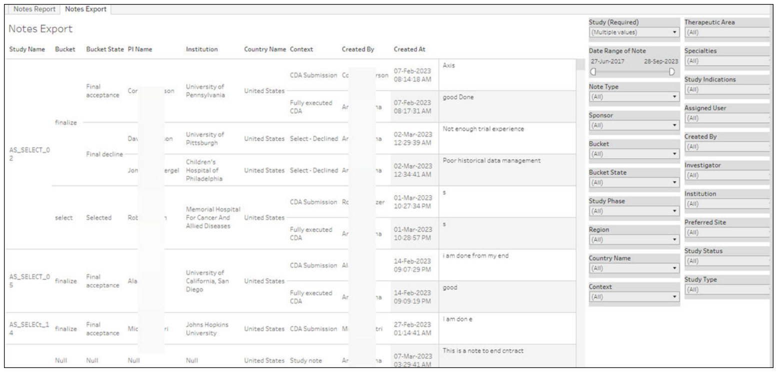
- **Search Type**: And or Or
- **Search Target**: All columns or Notes only
- **Case Sensitivity**: Yes or No

Multiple filter options, to the right, allow you to tailor the available data to your preferred view before exporting. For instance, this worksheet allows you to specify Date Range, Study, Bucket, Bucket State, Note Creator, and more.



Notes Export

The Notes Export worksheet is a simple tabular format designed to be downloaded using Tableau Download. Like the Notes Report worksheet described above, this worksheet also provides a wide range of filters that allow you to filter the data included in the export before downloading.


Notes Report
Notes Export
Notes Export
Study Name
Bucket
Bucket State
PI Name
Institution
Country Name
Context
Created By
Created At
AS_SELECT_02
finalize
Final acceptance
University of Pennsylvania
United States
CDA Submission
07-Feb-2023 08:14:18 AM
Axis
Fully executed CDA
07-Feb-2023 08:17:31 AM
good Done
Final decline
University of Pittsburgh
United States
Select - Declined
02-Mar-2023 12:29:39 AM
Not enough trial experience
Children's Hospital of Philadelphia
United States
Select - Declined
02-Mar-2023 12:34:41 AM
Poor historical data management
select
Selected
Memorial Hospital For Cancer And Allied Diseases
United States
CDA Submission
01-Mar-2023 10:27:34 PM
s
Fully executed CDA
01-Mar-2023 10:28:57 PM
s
AS_SELECT_05
finalize
Final acceptance
University of California, San Diego
United States
CDA Submission
14-Feb-2023 09:07:29 PM
i am done from my end
Fully executed CDA
14-Feb-2023 09:09:19 PM
good
AS_SELECt_14
finalize
Final acceptance
Johns Hopkins University
United States
CDA Submission
27-Feb-2023 01:14:41 AM
I am don e
Null
Null
Null
Null
United States
Study note
07-Mar-2023 03:29:41 AM
This is a note to end cntract
Study (Required)
(Multiple values)
Date Range of Note
27-Jun-2017
28-Sep-2023
Note Type
(All)
Sponsor
(All)
Bucket
(All)
Bucket State
(All)
Study Phase
(All)
Region
(All)
Country Name
(All)
Context
(All)
Therapeutic Area
(All)
Specialties
(All)
Study Indications
(All)
Assigned User
(All)
Created By
(All)
Investigator
(All)
Institution
(All)
Preferred Site
(All)
Study Status
(All)
Study Type
(All)

7 Resource Allocation

Workbook synopsis

The Resource Allocation report, helps managers track and manage assignment of Oracle Site Select user roles, business permissions, and study level access.

Dashboards and sheets

Users and Roles dashboard

The Users and Roles dashboard allows managers to easily view how business roles are defined in Oracle Site Select and which permissions are enabled/disabled for each business role. To help manage permissions across Oracle Site Select, you can also view all roles enabled for any individual user.

The upper section of the Users and Roles dashboard displays:

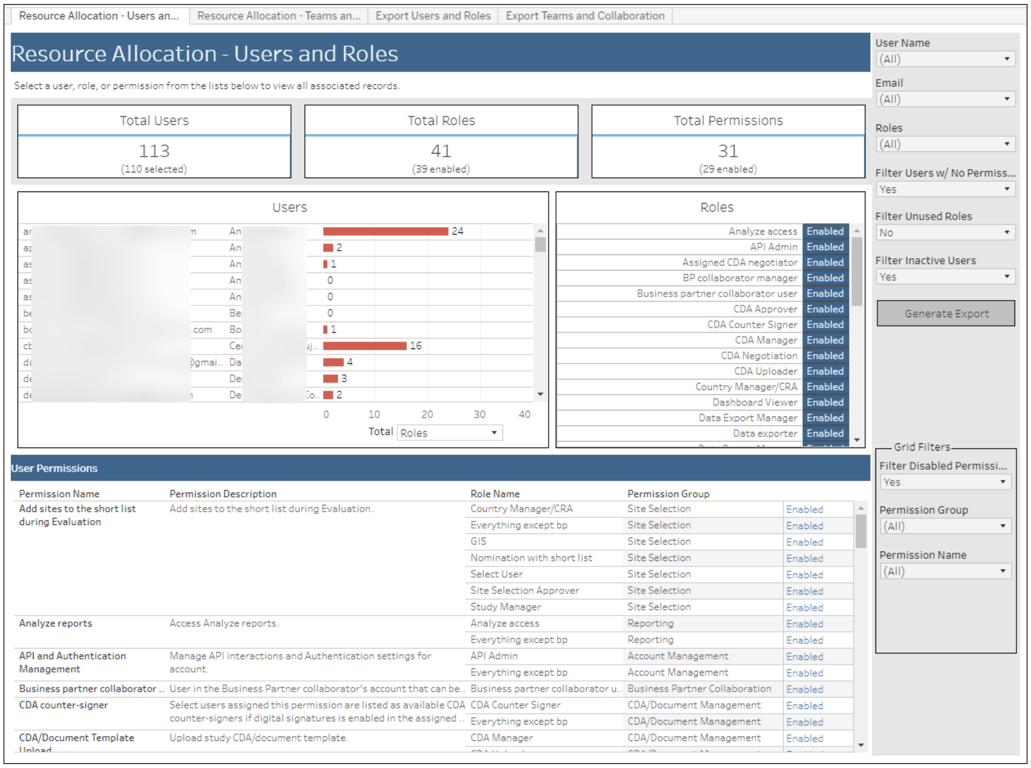
- Total users with (number selected)
- Total roles with (number enabled)
- Total permissions with (number enabled)

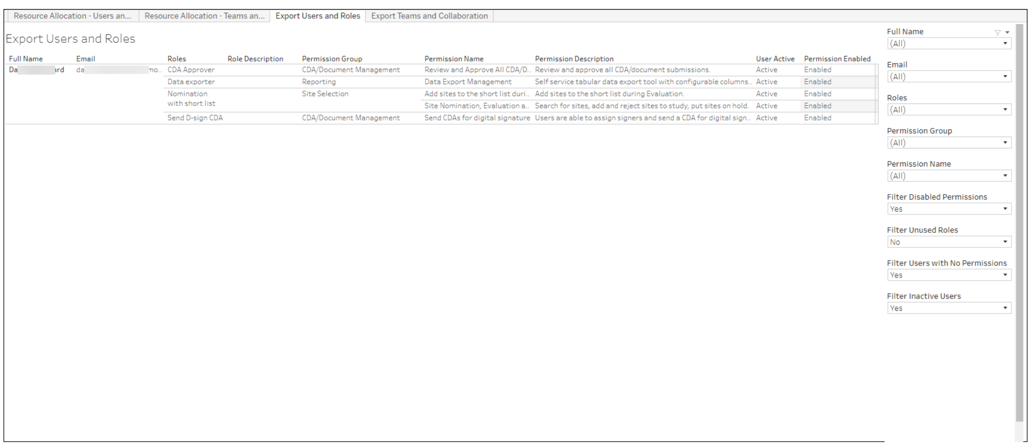
The center of the dashboard includes two tables: Users and Roles

1. **Users** – Includes the individual user's email, name, and enabled permissions count. When you click a table row for an individual user, the "Permissions" table at the bottom of the dashboard filters to display permission details (e.g., name, description, role, group, and enabled/disabled) for that user.
2. **Roles** – Shows each role with "Enabled" (blue) and "Disabled" (red). When you click a role, the lower section of the "Permissions" table at the bottom of the dashboard filters to display permission details related to the selected role.

The dashboard includes multiple filter options in the right panel that allow you to subset users and roles data to your preferred view. Filters like User Name, Email, Roles, etc. apply to the dashboard as a whole, while those in the "Grid Filters" section (Filter Disabled Permissions, Permission Group, and Permission Name) apply only to the Permissions table.

Once you specify preferred filters on the Users and Roles dashboard, the "Generate Export" button in the right filter panel provides a convenient way to download resource allocation detail. By default, filters currently specified on the Users and Roles Dashboard are automatically applied to the export sheet; however, you can adjust the export sheet filters (or remove them) as desired. You can also navigate directly to the Export Users and Roles worksheet to create an export, if preferred.





Teams and Collaboration

The Teams and Collaboration dashboard provides a convenient way for managers to track the ability for individual users to access specific Oracle Site Select studies through team assignment. Similar in design to the Users and Roles dashboard, the Teams and Collaboration dashboard displays:

- All existing teams for a specific account
- All enabled/disabled permissions for each team in an account

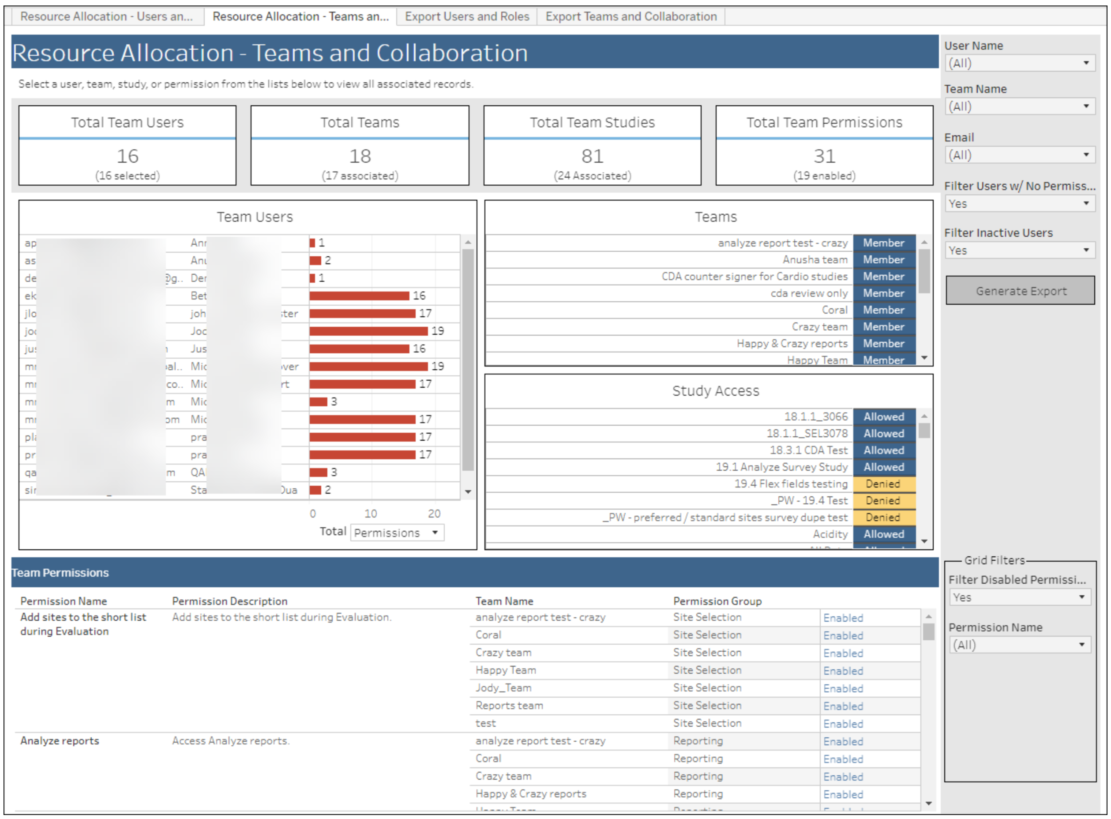
The dashboard itself is easily filtered using a single click. You can choose a Oracle Site Select user's name, a role, or a permission to view information about the selected item. For instance:

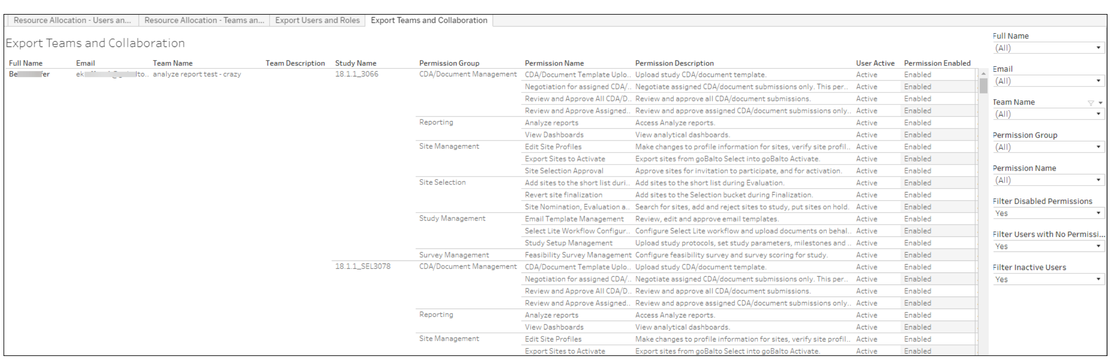
- Click a team name and the dashboard displays a list of all studies members of that team can view

- Click a user's name and the dashboard displays all teams that user is assigned to and all Oracle Site Select studies the user can view

The report also provides multiple filter options in the right panel to subset data to your preferred view. Filters like User Name, Team Name, Email, and Roles apply to the dashboard as a whole, while those in the “Grid Filters” section (Filter Disabled Permissions and Permission Name) apply only to the dashboard's Permissions table.

Once you specify preferred filters on the Teams and Collaboration dashboard, the “Generate Export” button in the right filter panel provides a convenient way to download resource allocation detail. By default, filters currently specified on the Teams and Collaboration dashboard are automatically applied to the export sheet; however, you can adjust the export sheet filters (or remove them) as desired. You can also navigate directly to the Export Teams and Collaboration worksheet to create an export, if preferred.





8 Select Account Reconciliation Dashboard

Workbook synopsis

The Select Account Reconciliation Dashboard report provides metrics that help managers understand monthly study volumes and evaluate the total cost of Oracle Site Select for the business.

Dashboards and sheets

Select Account Reconciliation Dashboard

The Select Account Reconciliation dashboard displays the following top-level Key Performance Indicators:

- Active Studies This Month
- Active Studies Last Month
- Active Studies This Contract Cycle
- Studies Remaining This Contract Cycle
- Total Contract Fees This Year

The center of the dashboard includes a tabular data chart with monthly active study totals, as well as a trend line chart showing active studies per month. Report users can click any month in the chart to filter the table at the bottom of the dashboard.

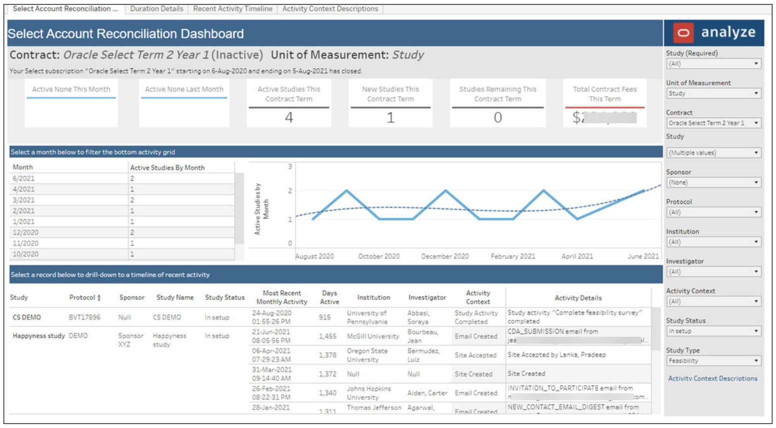
The bottom table includes the following study metadata columns:

- Protocol
- Sponsor
- Study Name
- Study Status
- Most Recent Monthly Activity
- Days Active
- Institution
- Investigator
- Activity with Context

Report users can quickly drill to a study's activity timeline (sample below) by clicking any study name in the bottom table.

Using the filter panel to dashboard’s right, report users can filter the dashboard by Contract, Sponsor, Protocol, and more. Note that the “Unit of Measurement” filter includes a “Study Parsed” option. Study Parsed is the study’s protocol value, which Oracle Site Analyze parses from the Study Name field. This filter option allows report users to group the dashboard data by either Study Name or Study Parsed unit of measurement. The Unit of Measurement selection affects dashboard labels as well. For instance, when a report user selects Study Parsed for Unit of Measurement, the dashboard automatically updates "Active Studies this

Month" to "Active Protocols this Month." This type of context change also happens automatically in the right-side filter panel, where the “Study” filter automatically updates to “Protocol (Parsed).”

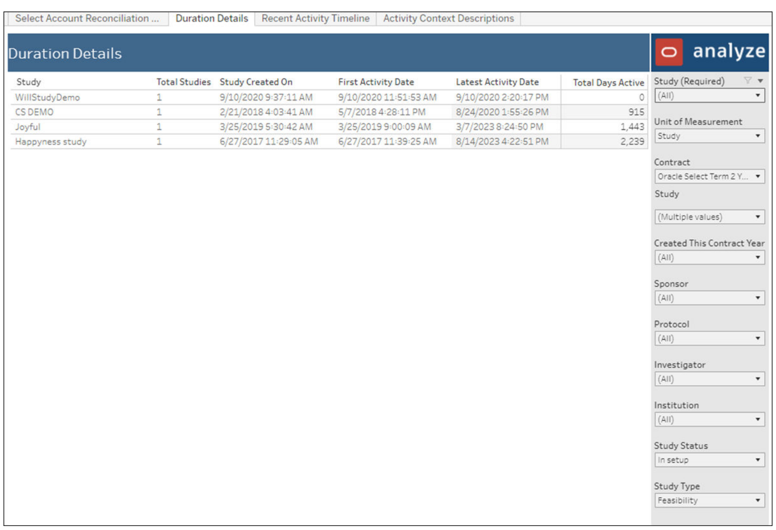


Duration Details

The report's Duration Details worksheet provides the following detail:

- Study Created On timestamp
- First Activity Date timestamp
- Latest Activity Date timestamp
- Total Days Active

Familiar filters (e.g., Sponsor, Investigator, Institution, etc.) are available in the right side panel. Note that the filter panel also includes the updated “Unit of Measurement” filter (described above) with Study and Study Parsed options that allow the report user to see how long the study or protocol has been active.

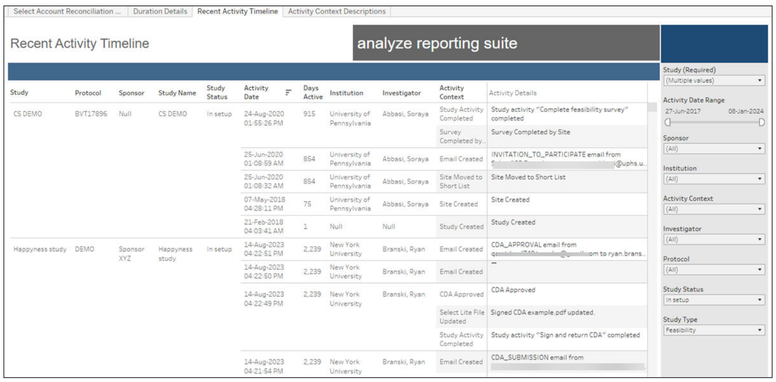


Recent Activity Timeline

The Recent Activity Timeline worksheet will help managers evaluate elapsed time for activity completion. The worksheet provides a tabular view of the following metadata:

- Protocol
- Sponsor
- Study Name
- Activity Date
- Days Active
- Institution
- Investigator
- Activity with Context

The filter panel to the right allows users to subset the view by Sponsor, Study Name, Institution, and more.



Activity Context Descriptions

The Account Reconciliation report also includes a Activity Context Descriptions worksheet that defines standards for activities. Report users can refer to one source to see:

- Activity Context – The activity name (e.g. Study Created, CDA Approved, or Survey Submitted)
- Action Completed By – The actor (e.g. Site, Sponsor/CRO, Site or Sponsor/CRO user on behalf of site)
- Activity Context Description – Standardized activity description

Report users can access the definitions worksheet from a new link in the Select Account Reconciliation Dashboard's filter panel or by navigating to the Activity Context Descriptions tab.

Select Account Reconciliation ... | Duration Details | Recent Activity Timeline | Activity Context Descriptions

Activity Context Descriptions

Activity Context	Action Completed By	Activity Context Description
CDA Approved	Site	Confidential disclosure agreement completed by site
CDA Uploaded	Sponsor/CRO	Confidential disclosure agreement uploaded
Disinterest Reason Created	Site or Sponsor	Site disinterest reason added - comment added to system for specific site disinterest
Disinterest Reason Updated	Site or Sponsor	Site disinterest reason updated - note is changed after initial add
Email Created	Sponsor/CRO	New email record generated - occurs when email communication is sent to site(s) such as CDA, study invitation
Exclusion Reason Created	Sponsor/CRO	Site exclusion reason added to indicate why site will not be included in study
Exclusion Reason Updated	Sponsor/CRO	Site exclusion reason updated - original reason is edited by user
Select Lite File Created	Site or Sponsor/CRO user on behalf of site	File uploaded by Select Lite user
Select Lite File Downloaded	Site or Sponsor/CRO user on behalf of site	File downloaded by Select Lite user
Select Lite File Updated	Site or Sponsor/CRO user on behalf of site	File updated by Select Lite user
Select Lite File Uploaded	Site or Sponsor/CRO user on behalf of site	File uploaded by Select Lite user
Site Accepted	Sponsor/CRO	Site is moved to Final Acceptance
Site Created	Sponsor/CRO	Site from master list is associated with a specific study and moved beyond the master list
Site Declined	Sponsor/CRO	Site is moved to Final Declination
Site Moved to Short List	Sponsor/CRO	Site moved to the short list
Site Selected	Sponsor/CRO	Site reached selection
Study Activity Completed	Site	Select Lite workflow activity e.g; view protocol, sign/return CDA, view CDA is completed
Study Created	Sponsor/CRO	Study added in Select
Survey Completed by Site	Site	Survey submitted by a site
Survey Submitted	Site or Sponsor/CRO user on behalf of site	Survey submitted by CRO/sponsor on behalf of a site

9
Site Profile

Workbook synopsis

The Site Profile Report provides Oracle Site Select users with another method to evaluate site data and make more informed site selection decisions. This report provides a single location where report users can view their CTMS/data warehouse trial data that has been imported *into* Oracle Site Select alongside study data generated *by* Oracle Site Select. For example:

- Trial data from CTMS/data warehouse could include:
  - Study experience
  - Enrollment performance
  - Types of studies
- Study data from Oracle Site Select might include:
  - Survey results
  - Cycle times
  - Study interest

Dashboards and sheets

Site Summary Dashboard

The upper section of the Site Summary Dashboard worksheet is a bar chart with slider filters for:

- Number of studies participated in
- Enrollment performance
- Average survey score
- Average Selection Cycle Time

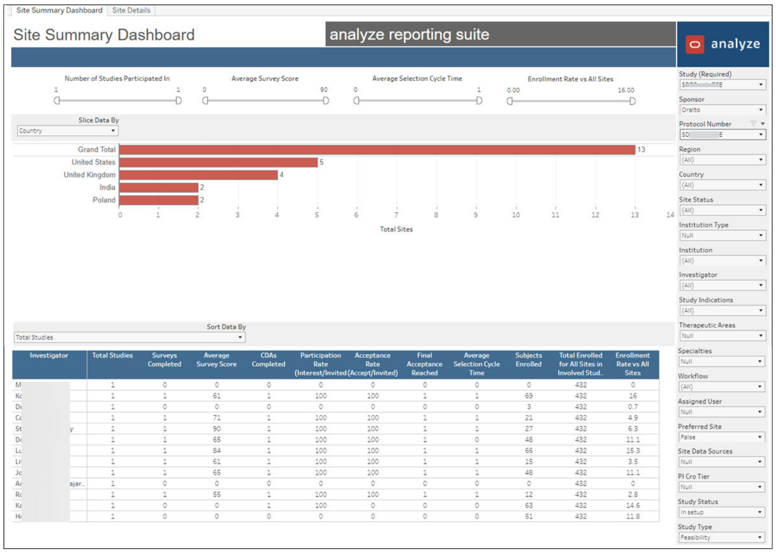
Report users can adjust the filters to a preferred view and the bar chart can be filtered by Country, Study Name, and Therapeutic Area. The number of sites included in the selected filter criteria displays at the dashboard's upper left.

The lower section of the report presents results, by Principal Investigator, in a tabular format. The table includes the following aggregation metrics, any of which can be used to sort the table:

- Studies participated in
- Enrollment performance (calculation based on relative performance per study (1-10 scale)
- Number of Surveys completed
- Average survey score
- Number of CDAs completed

- Average CDA cycle time
- Number of Final acceptances
- Average Selection Cycle time

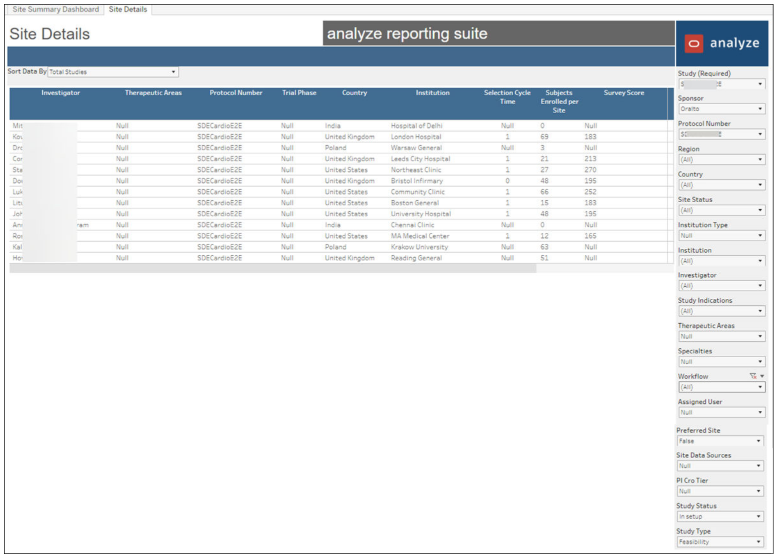
Report users can drill down from the site aggregation metrics to the Site Details Dashboard (described below).



Site Details

The Site Details worksheet is the drill down view to each of the individual studies in which a site participated. The worksheet presents the following data in a tabular view:

- PI Name
- Study Name
- Protocol
- Therapeutic Area
- Phase
- Country
- Institution
- Enrollment Performance
- Survey Score
- Selection Cycle Time


Site Summary Dashboard
Site Details
Site Details
analyze reporting suite
analyze
Sort Data By Total Studies
Investigator Therapeutic Areas Protocol Number Trial Phase Country Institution Selection Cycle Time Subjects Enrolled per Site Survey Score
Null SDECardioE2E Null India Hospital of Delhi Null 0 Null
Null SDECardioE2E Null United Kingdom London Hospital 1 69 183
Null SDECardioE2E Null Poland Warsaw General Null 3 Null
Null SDECardioE2E Null United Kingdom Leeds City Hospital 1 21 213
Null SDECardioE2E Null United States Northeast Clinic 1 27 270
Null SDECardioE2E Null United Kingdom Bristol Infirmary 0 48 195
Null SDECardioE2E Null United States Community Clinic 1 66 252
Null SDECardioE2E Null United States Boston General 1 15 183
Null SDECardioE2E Null United States University Hospital 1 48 195
Null SDECardioE2E Null India Chennai Clinic Null 0 Null
Null SDECardioE2E Null United States MA Medical Center 1 12 165
Null SDECardioE2E Null Poland Krakow University Null 63 Null
Null SDECardioE2E Null United Kingdom Reading General Null 51 Null
Study (Required)
Sponsor
Oralto
Protocol Number
Region
(All)
Country
(All)
Site Status
(All)
Institution Type
Null
Institution
(All)
Investigator
(All)
Study Indications
(All)
Therapeutic Areas
Null
Specialties
Null
Workflow
(All)
Assigned User
Null
Preferred Site
False
Site Data Sources
Null
PI Cro Tier
Null
Study Status
In setup
Study Type
Feasibility

10
Site Progress

Workbook synopsis

The Oracle Site Analyze Site Progress report, intended for Oracle Site Select customers, allows you to view a summary of where sites are in the selection process and helps you to identify barriers to site progress.

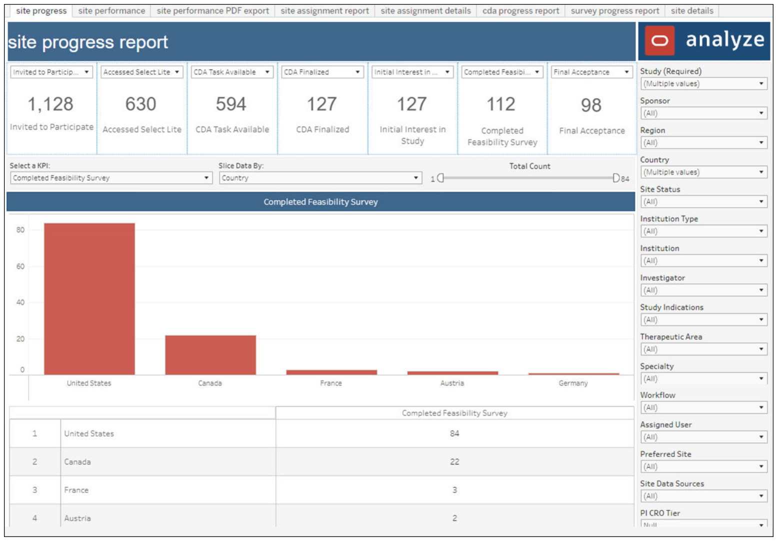
Dashboards and sheets

Site Progress KPI

This worksheet gives you control over the summary Key Performance Indicators (KPIs) and/or bucket state data you prefer to view. You can dynamically control which of the KPIs/ bucket states display in the worksheet, and you can choose up to seven to display in the worksheet's upper section.

- Invited to Participate
- Accessed Select LITE
- CDA Task Available
- CDA Final Review
- CDA Finalized
- Agreed to Confidentiality
- Initial Interest in Study
- Final Interest in Study
- Completed Feasibility Survey
- Final Acceptance
- N/A
- Bucket – Back up
- Bucket – Declined
- Bucket – Do not invite
- Bucket – Final acceptance
- Bucket – Final decline
- Bucket – Invited
- Bucket – Master list
- Bucket – Nominated
- Bucket – Not interested
- Bucket – On hold
- Bucket – Selected
- Bucket – Short list

You can also specify the KPI/bucket state in the lower section of the worksheet. To further refine the view, use the “Slice Data By” filter in the lower section to slice by study, region, or country. Adjust the position of the“Total Count” slide to control the displayed range from lowest to highest value.



Site Performance

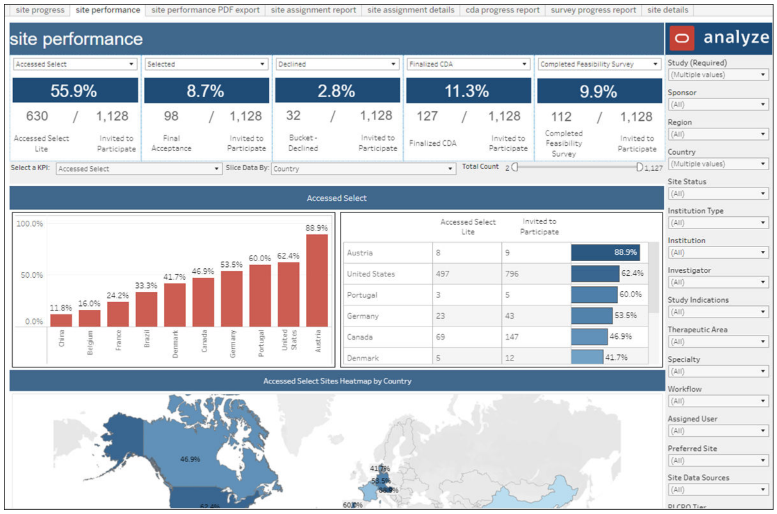
The Site Performance dashboard allows you to easily compare performance metrics across studies and sites, and you can slice data as needed. At the top of the dashboard, selected metrics display as a percentage. Metric calculations are:

- **Accessed Select** – number of sites that accessed Oracle Site Select LITE divided by the number of sites invited to participate
- **Selected** – number of sites selected divided by the number of sites invited to participate
- **Declined** – number of sites who declined to be in the study divided by the number of sites invited to participate
- **Finalized CDA** – number of sites that have completed the CDA divided by the number of sites invited to participate
- **Completed Feasibility Survey** – number of sites that have completed a survey divided by the number of sites invited to participate

The center section of the Site Performance dashboard shows a breakdown of a selected KPI with a bar chart to the left and a table to the right. Slice the data as you prefer – by Assigned user, Study, Region, or Country. You can also adjust the data using the Total Count slider. When you click into a table cell, a tool tip displays a link to “View Site Details.” If clicked, the Site Details worksheet displays with the site information that made up that table cell’s metric.

The dashboard’s lower section is a geographical heat map that reflects countries for which KPI data exist. The map reflects the KPI selected in the center section of the dashboard, and the map displays percentage results in gradient blue (lighter blue, lower percentage through darker blue, higher percentage). When a country has no site data, the map reflects the country in light gray. Click a country to drill to the Site Details worksheet to view site information that made up that country metric.

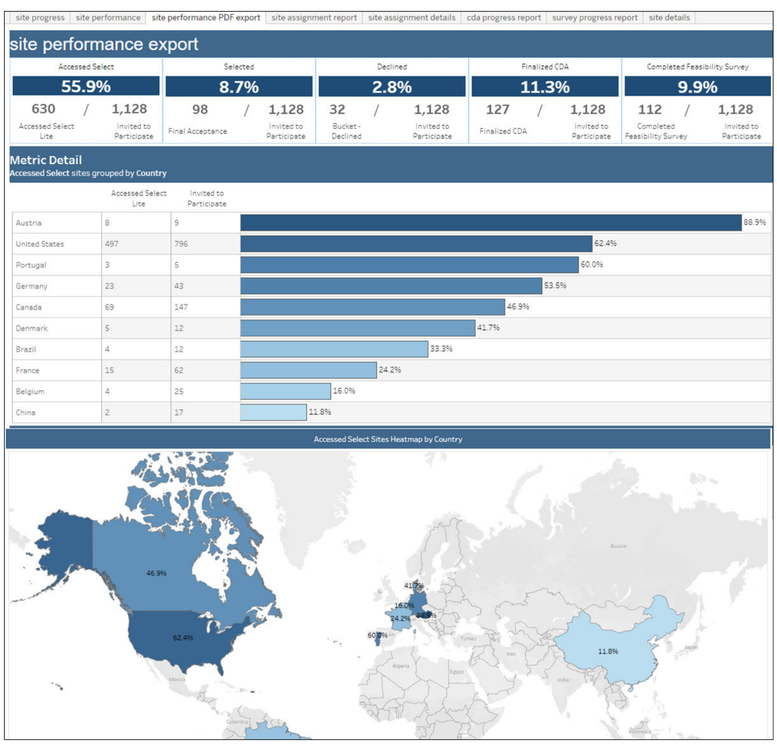
As with all Oracle Site Analyze reports, the Site Performance dashboard's right panel provides a broad range of filters to subset the data.



Site Performance export worksheet

The Site Performance PDF Export worksheet provides a convenient way to export filtered information from the Site Performance Dashboard to a format suitable to share with sponsors.

The export sheet reflects currently selected options and filters from the Site Performance Dashboard, and any adjustments to the dashboard's parameters automatically update the export PDF. By design, the export worksheet does not include a filter panel or other editable parameters (e.g., KPI selectors, Slice data by selectors, etc.).

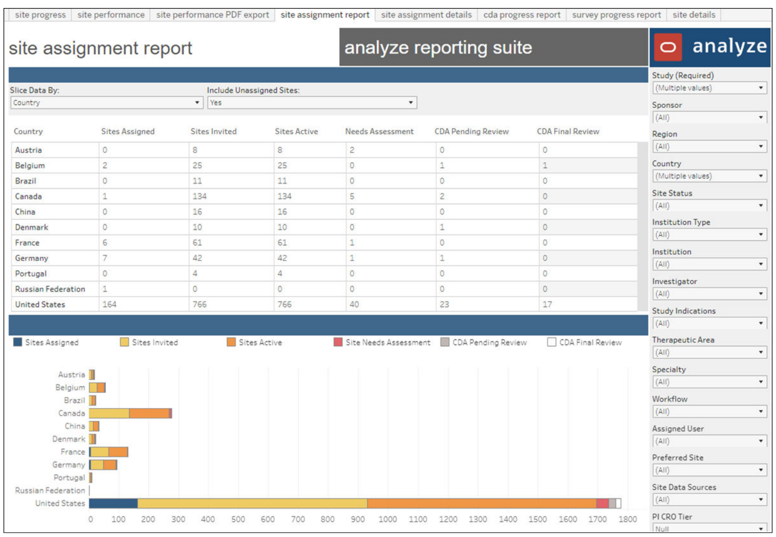


Site Assignment Report

The Site Assignment Report provides a simple way to gain insight into action items and workflow statuses across all the sites to which Oracle Site Select users are assigned. The report includes tabular data for details like:

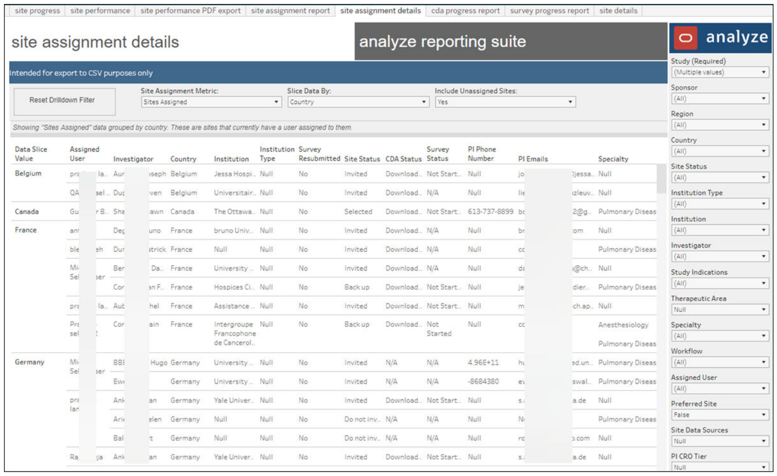
- Study
- Sites Assigned = Number of sites assigned
- Site Invited = Number of sites invited
- Sites Active = Number of sites active (invited but not in a dropped bucket state)
- Needs Assessment = Number of sites with all tasks complete and still in the invited bucket
- CDA Pending Review = Number of CDA uploaded pending review
- CDA Final Review = CDA uploaded final review

The Site Assignment Report also includes a stacked bar chart where you can slice the above data by region, country, study, and assigned users. You can drill to site details, as preferred, from either the tabular data or the bar chart data.



Site Assignment Details

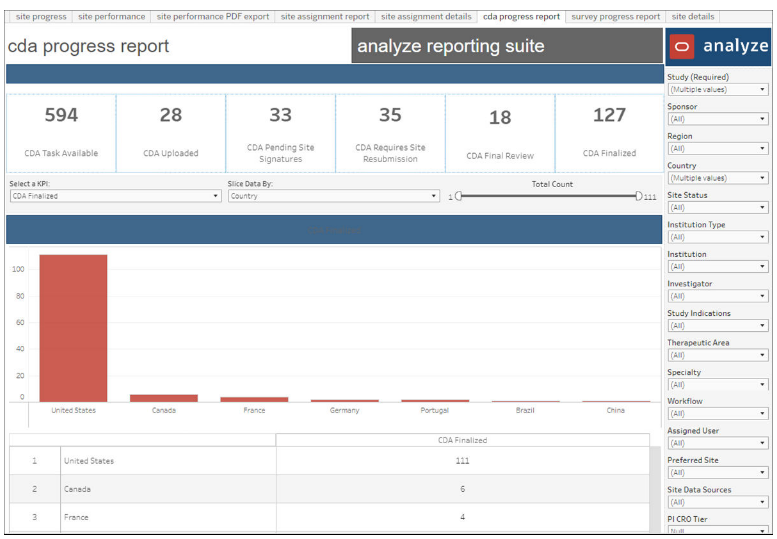
The Site Assignment Details worksheet allows you to filter and export site assignment detail to a CSV format file.



CDA Progress Report

CDA progress metrics represented on this worksheet are:

- CDA Task Available
- CDA Uploaded
- CDA Pending Site Signatures
- CDA Requires Site Resubmission
- CDA Final Review
- CDA Finalized

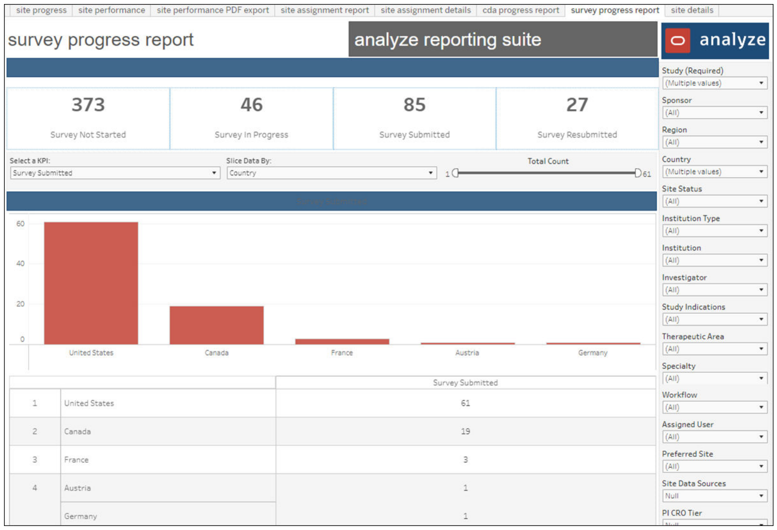


Survey Progress Report

This worksheet has the same user interface as the Site Progress KPI and CDA Progress worksheets. Survey progress metrics represented on this worksheet are:

- Not started (when the site has reached the feasibility survey workflow task)
- In Progress

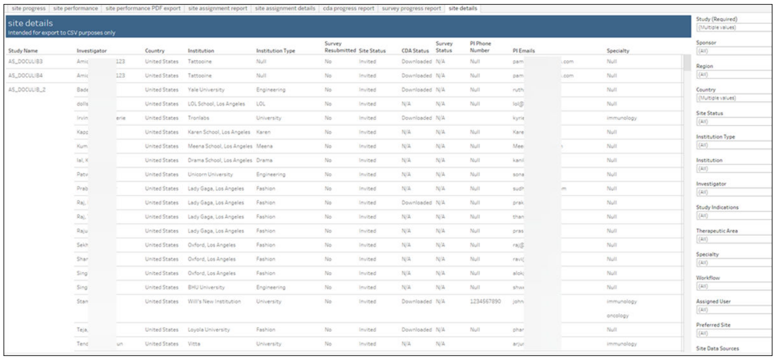
- Submitted
- Resubmitted



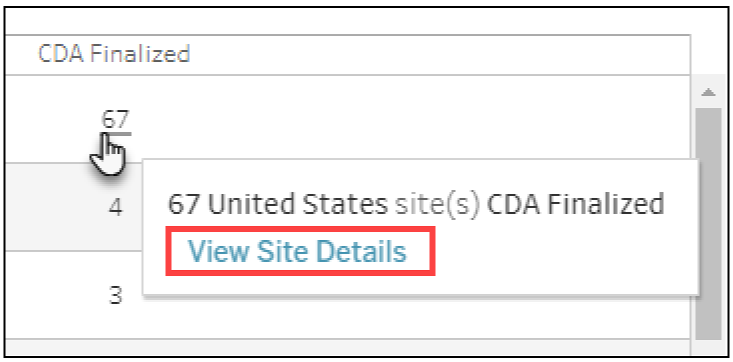
Site Details

This worksheet, which is intended for export to CSV, includes the following data for sites:

- Study Name
- Investigator
- Country
- Institution
- Institution type
- Survey Resubmitted
- Site Status
- CDA Status
- Survey Status
- PI Phone Number
- Email
- Specialty



When you hover over a top KPI or a number in the country table in the Site Progress Report, CDA Progress Report, or Survey Progress Report worksheet, a tooltip displays with a “View Site Details” link. When you click this link, the Site Details worksheet (above) displays details for the sites that make up that specific number.



11
Site Study Interest and Exclusion

Workbook synopsis

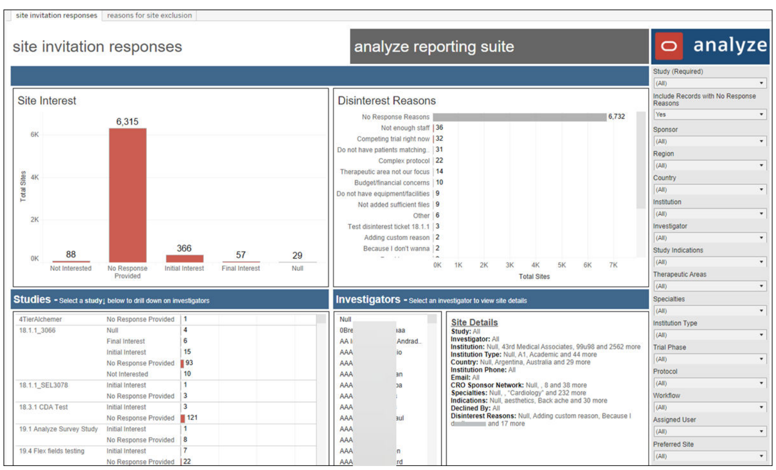
The Oracle Site Analyze Site Study Interest and Exclusion report, intended for Oracle Site Select customers, provides dashboard reports that visualize site invitation response state and reasons for site exclusion or study disinterest.

Dashboards and sheets

Site Invitation Responses

This dashboard provides you with details about invitation response metrics and site disinterest reasons. Interest bar graphs allow you to quickly see the distribution of site invitations by status (e.g., No response, Not interested, Initial Interest, and Final Interest). The dashboard also provides a bar graph to visualize the number of site disinterest reason instances (e.g., Competing trial, Complex protocol, etc.).

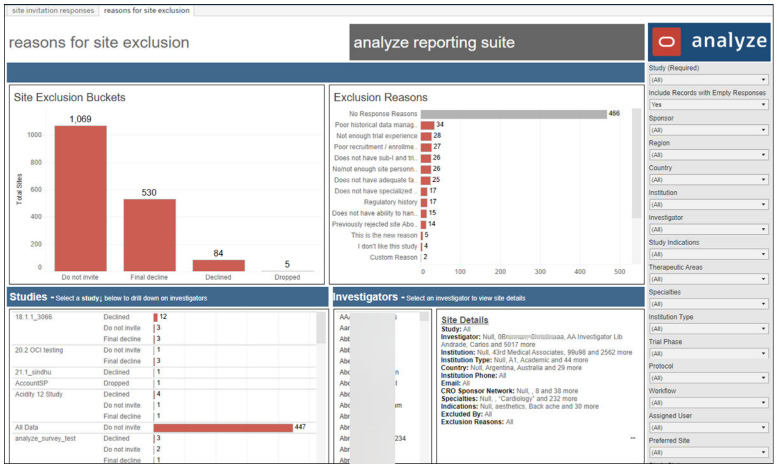
You can adjust a wide range of filters to refine the dashboard to a preferred data view. In the lower portion of the dashboard, you can also drill to investigators and site details.



Reasons for Site Exclusion

This dashboard provides site exclusion data in a similar format to the site invitation responses dashboard. Exclusion bar graphs allow you to quickly see the distribution of excluded sites by bucket status (e.g., Declined, Do Not Invite, Final Decline, and Not Interested). The dashboard also provides a bar graph to visualize the number of reason instances (e.g., Not enough personnel, Regulatory history, Does not have adequate facilities, etc.).

You can adjust a wide range of filters to refine the dashboard to a preferred data view. In the lower portion of the dashboard, you can also drill to investigators and site details.


site invitation responses
reasons for site exclusion
reasons for site exclusion
analyze reporting suite
analyze
Site Exclusion Buckets
1,069
530
84
5
Do not invite
Final decline
Declined
Dropped
Exclusion Reasons
Studies - Select a study below to drill down on investigators
Investigators - Select an investigator to view site details
Site Details

12 Site User Engagement

Workbook synopsis

The Site User Engagement dashboard is designed to help you understand site interactions within Oracle Site Select. The dashboard allows you to view and analyze all site communications sent via email or through the Oracle Site Select site communications portal.

Dashboards and sheets

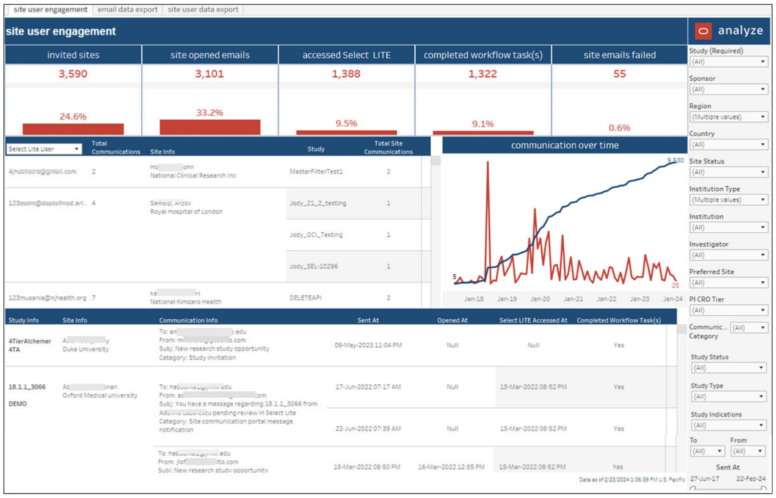
Site User Engagement

The Site User Engagement dashboard allows you to view the following key performance indicators of site engagement in Oracle Site Select:

- invited sites – total invited sites
- opened emails – total emails opened by site users
- accessed Oracle Site Select LITE – total times a user clicked on the Oracle Site Select LITE link in an email
- completed workflow tasks – total times a user clicked on the Oracle Site Select LITE link in an email and completed a workflow task
- site emails failed – total emails sent that failed

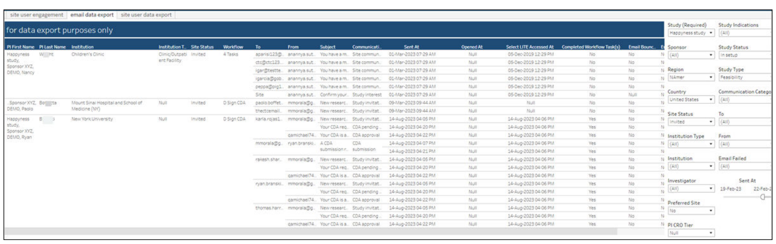
The dashboard also contains a table that shows a summary of all communications by study site, as well as a trend graph that displays the number of site communications and emails per month along with a cumulative total in Oracle Site Select over time. The drop-down list control at the upper left of the center grid allows you to filter the data to Study, Country, or Oracle Site Select LITE user. Click on the numbers in the middle table to filter the bottom table and view the details of each site communication. Click one of the KPIs at the top of the report (e.g., invited sites, site opened emails, etc.) to control the data displayed in the middle and lower section of the report.

Like all Oracle Site Analyze reports, this dashboard provides multiple filtering options in the right filter panel. You can subset the reported data to your preference using filters for Sponsor, Protocol Number, Study, Email Category, Email Sent Date, and more.



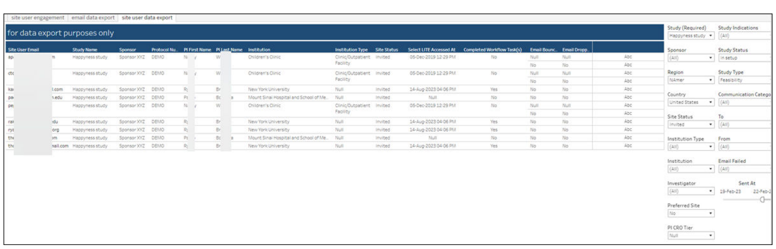
Email Data Export

The Email Data export worksheet allows you to export site data grouped by site user email. This export helps you identify instances when the same email account is used for multiple users. In this export, you'll also see variances in recorded user names, and you can use that data to reconcile user profile information across sites (e.g., identify the CTC across three sites who has variances in name such as missing middle name, suffix, etc.).



Site User Data Export

This worksheet, which we designed specifically for export, provides detailed email communications information. The worksheet provides multiple filters, in the panel to the right, that allow you to adjust content prior to download.



13

Survey Response Analysis

Workbook synopsis

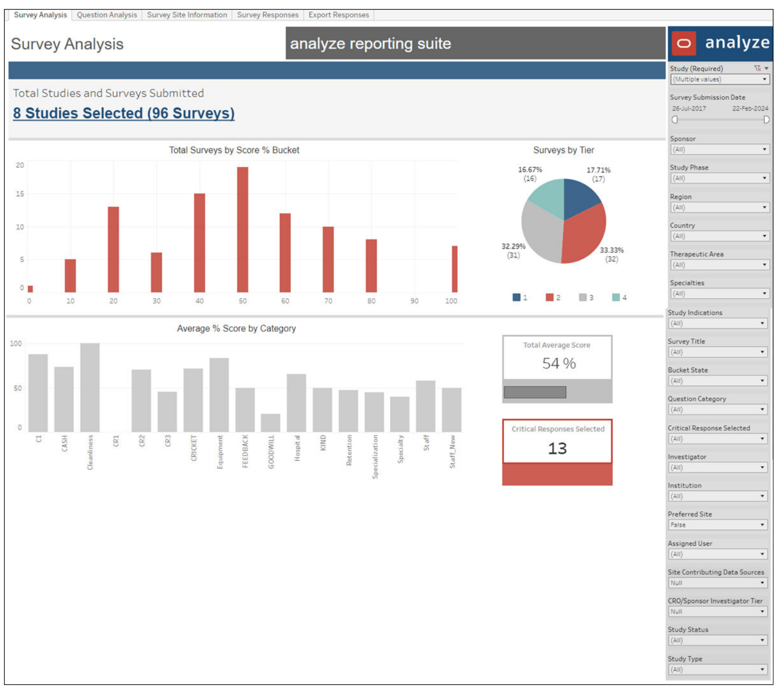
The Oracle Site Analyze Survey Response Analysis workbook, intended for Oracle Site Select customers, provides a detailed dashboard of feasibility survey response data as well as two worksheets designed for data export to CSV.

Dashboards and sheets

Survey Analysis dashboard

The Survey Analysis dashboard provides summary response information for feasibility surveys including: total surveys submitted, survey scores, tiers, and analysis on individual responses to questions. You can drill down into specific studies, surveys, and various other dimensions and export relevant data as needed.

Use the filter options panel, to the right, to limit the scope (e.g., choose a specific study, Therapeutic area, Site status, etc.) and tailor the available data to your preferred view.



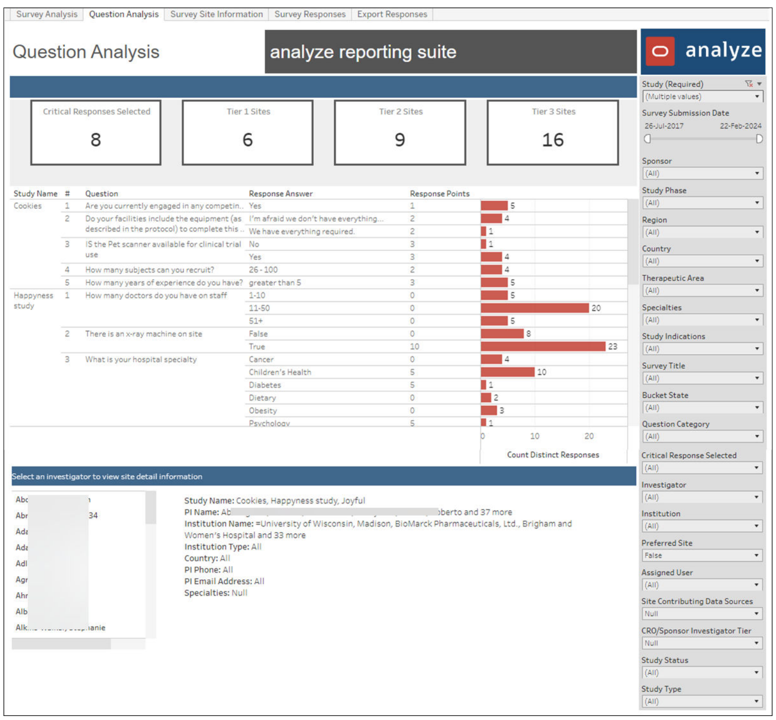
Question Analysis dashboard

The Question Analysis dashboard view allows report users to easily filter down to those sites that selected a specific response to a specific feasibility survey question for site survey analysis. The dashboard has three components:

1. A bar chart that shows the questions and number of responses for each question

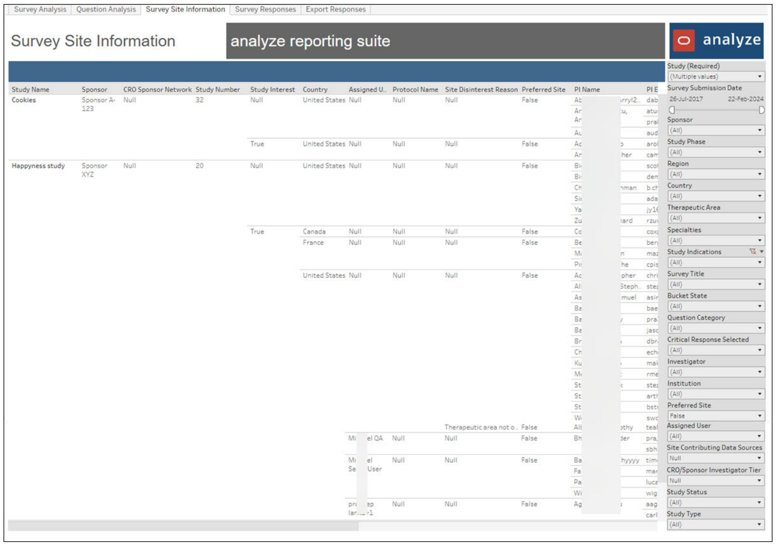
2. A list of all PIs that made up the bar (displays when a report user clicks on a bar)
3. A list of metadata associated with the PI (displays when a report user clicks on a PI name). Metadata includes:
   - study
   - investigator
   - institution
   - institution type
   - country
   - institution phone
   - email
   - specialties

The filter options panel, to the right, allows users to limit the scope (e.g., choose a specific sponsor, study, Therapeutic area, Site status, etc.) to tailor the available data to their preferred view.



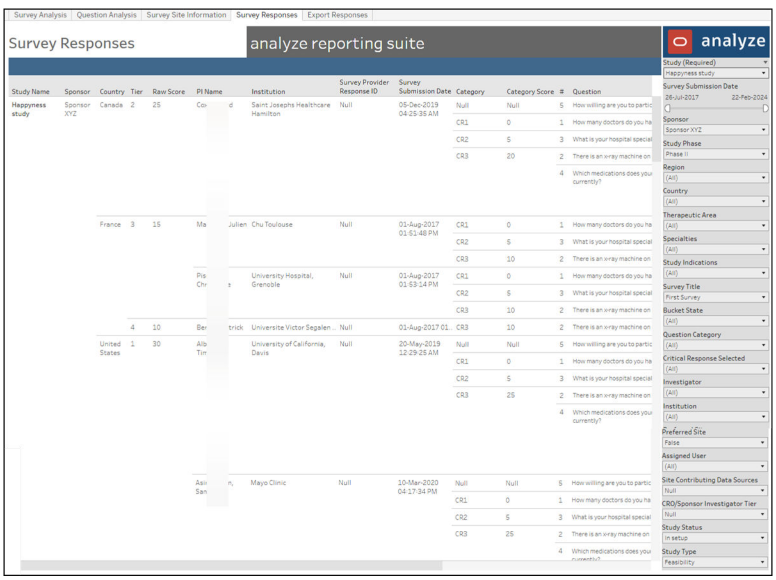
Survey Site Information export

The Survey Site Information export worksheet, which is intended for CSV download, includes detailed PI and institution data. Use the filter options to the right to tailor the available data to your preferred view before export.



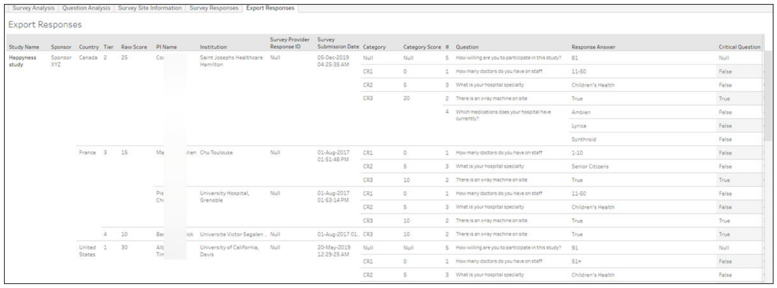
Survey Responses worksheet

The Survey Response worksheet provides an aggregated tabular view that relates to the lower portion of the Survey Response Analysis dashboard. The worksheet's filter panel, to the right, provides many options to adjust the data to your preferred view.



Export Responses worksheet

The Export Responses worksheet has been designed exclusively for export and reflects the filters set on the Survey Responses worksheet (described above).



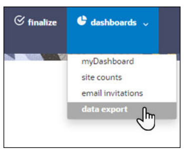
Study Name	Sponsor	Country	Tier	Raw Score	PI Name	Institution	Survey Provider Response ID	Survey Submission Date	Category	Category Score	#	Question	Response Answer	Critical Question
Happyness study	Sponsor XYZ	Canada	2	25	Co	Saint Josephs Healthcare Hamilton	Null	05-Dec-2019 04:25:35 AM	Null	Null	5	How willing are you to participate in this study?	81	Null
									CR1	0	1	How many doctors do you have on staff	11-50	False
									CR2	5	3	What is your hospital specialty	Children's Health	False
									CR3	20	2	There is an x-ray machine on site	True	True
											4	Which medications does your hospital have currently?	Ambien	False
													Lyrica	False
													Synthroid	False
		France	3	15	Ma lien	Chu Toulouse	Null	01-Aug-2017 01:51:48 PM	CR1	0	1	How many doctors do you have on staff	1-10	False
									CR2	5	3	What is your hospital specialty	Senior Citizens	False
									CR3	10	2	There is an x-ray machine on site	True	True
					Pis Ch	University Hospital, Grenoble	Null	01-Aug-2017 01:53:14 PM	CR1	0	1	How many doctors do you have on staff	11-50	False
									CR2	5	3	What is your hospital specialty	Children's Health	False
									CR3	10	2	There is an x-ray machine on site	True	True
			4	10	Be ick	Universite Victor Segalen ...	Null	01-Aug-2017 01...	CR3	10	2	There is an x-ray machine on site	True	True
		United States	1	30	Al Tin	University of California, Davis	Null	20-May-2019 12:29:25 AM	Null	Null	5	How willing are you to participate in this study?	91	Null
									CR1	0	1	How many doctors do you have on staff	51+	False
									CR2	5	3	What is your hospital specialty	Children's Health	False

14
Data Export Utility

The Data Export Utility for Oracle Site Select is a self-service export that allows permissioned Oracle Site Select users to design a CSV extract with specified data columns and filters. Currently, the extract includes data columns for site feasibility, survey response, notes, and study site users.

Permission required to access the utility

You must have at least one Oracle Site Select role with “Data Export Management” permission to access the export utility feature from the Oracle Site Select Dashboards menu. Please contact your super user or administrator if you do not have this permission.

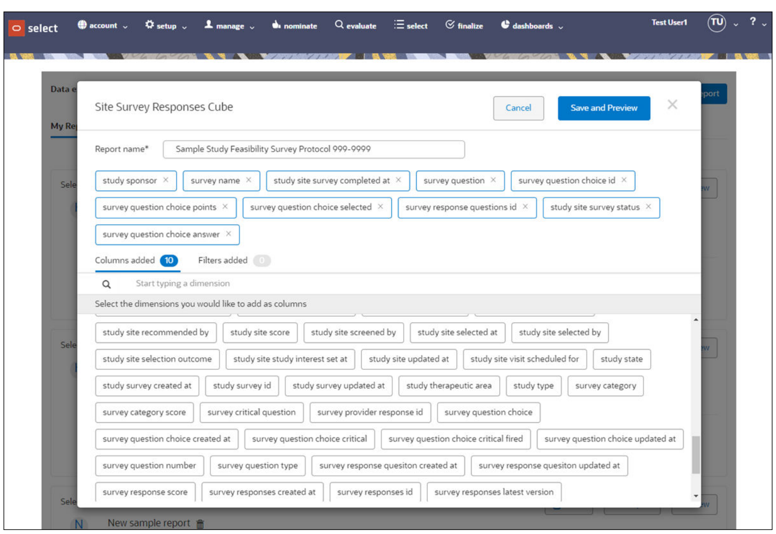


Data extract cubes

Data Extract Cubes

The Data Export Utility allows you to create new extracts based on:

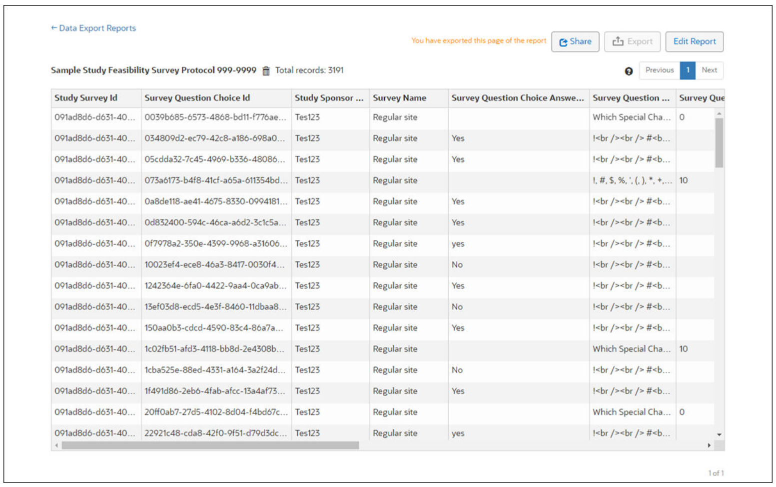
- **Cube** (a multidimensional array of data) – The available data cubes are Note data, Site survey responses, Study site data, and Study-site users. You select one cube per extract.
- **Columns** (dimensions) – For example, PI Name, PI email address, Country, Study, etc. You can add columns in any order.
- **Filters** – For example, Study name, Country, etc. You can also add filters in any order and specify an operator (e.g., contains, equals, is null, etc.) for each filter.



Preview an export

Preview mode allows you to view a previously-created report. Preview mode provides pagination controls and page count to ensure acceptable response time for high-volume reports. Each page can include up to 10,000 rows, and the preview page displays the first 100 records. A "Total records" value displays to the left of the pagination controls to show you the total records returned based on the report's filters.

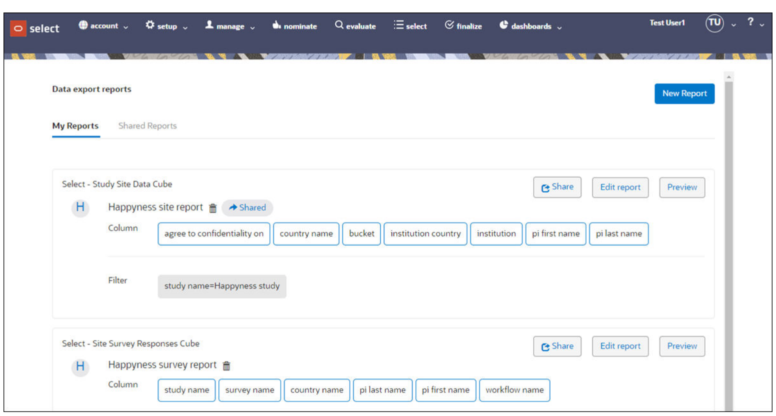
Suppose you click Export when in Preview mode. In that case, the Export function exports the page currently being previewed, and the prompt text, "You have exported this page of the report," displays next to the Export button to indicate the download/export of the report page has started.



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 reports 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 Select, you can access the Data Export Utility to create a unique export that contains your preferred data then 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 an 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 Select, you can access the Data Export Utility to create a unique export that contains your preferred data then export the result to a .csv format file.

1. From the Oracle Site Select top navigation, hover over **Dashboards** and click **Data Export**.
2. On the Data export page, click **New Report**.
3. On the New Report pop-in, choose **Site Survey Responses Cube** from the drop-down list.
4. At the top of the pop-in, enter your preferred **Report name**.
5. Under "Columns added," choose the dimensions you would like to add as columns. You can scroll through the list of available dimensions or search for a specific dimension. As you add dimensions, the "Columns added" count increases.
6. (Optional) Click "Filters added" and choose a field from the left drop-down menu. Next, choose an operator (e.g., equals, contains, etc.). Finally, enter a text value to filter by. All text values are wildcard and case sensitive. For instance, you can use the Filter option to specify a study name.
7. Click **Save and Preview**.

8. 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**.
9. 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 Select top navigation, hover over **Dashboards** 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 of the export's panel, click **Preview**.

Edit an 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 Select top navigation, hover over **Dashboards** and click **Data Export**.
2. On the Data export page, click the **My Reports** tab and locate the report to be edited.
3. To the right of the export's title, click **Edit report**.
4. Adjust the report name, columns, and/or 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 further refine the report 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 Select top navigation, hover over **Dashboards** and click **Data Export**.
2. On the Data export reports page, click the **My Reports** tab and locate the export to be deleted.
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 Select top navigation, hover over Dashboards 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**.