Calyx RIM for Analytics

Contents

Calyx RIM for Analytics 1

Security for Reports 2

Security for Reports - Analytics Module 2

Security for Reports - Dashboard Module 3

Run an Analytics Report 4

Tips When Running an Analytics Report 4

Actions When Running an Analytics Report 5

Analytics Tree in the Analytics Portal 5

Analytics Tree Right-Click Options 6

Analytics Predefined Reports 9

Manufacturer Report 9

XEVMPD Submissions and Acknowledgements Report 9

XEVMPD Entities 10

XEVMPD Audit 11

XEVMPD Audit Report Results 16

XEVMPD Audit Report Sorting 17

Registration Status with Product Report 18

Registration Status Summary Report 18

Status of Planned Submissions Report 18

Submission Status Dates by Country and Event Type Report 19

Analytics Dashboard Reports 20

Global Registration Activity by Product Family (Top 10 Countries) Report 20

Registration Submissions Due by Month Report 20

Regulatory Maintenance Submissions Report 21

Registration Status Summary by Country Report 21

Registration Status Summary by Product Family Report 21

Task Status Reports 21

Total Pending Approvals (Top 10 Products) Report 22

Total Product Registrations by Month Report 23

Total Submissions by Month Report....23
Total Tasks by Task Type Report.... 23
Worldwide Approvals (Top 10 Regions) Report....24
Add a Dashboard Report to the Dashboard Tab.... 24
Analytics Guided Ad Hoc Reports....26
Create an Analytics Ad Hoc Report....27
Access the ReportCaster Console....28
Calyx RIM for Analytics Reporting Schema....29

Index.... 30

Calyx RIM for Analytics

If you have the necessary security permissions, Calyx RIM® for Analytics enables you to run reports about Calyx RIM activities. For more information about the licenses and the list of modules required to run each report, see *Calyx RIM License Modules* and *Calyx RIM License Modules by Feature*.

These reports include:

— Predefined reports - Calyx RIM provides these tabular reports as part of the product.

— Dashboard reports - Calyx RIM provides these graphical charts. A dashboard report is an analysis of key performance indicators that show the current status of a product.

— Guided ad hoc reports - You can select predefined types of data to include in reports showing customized information in different ways.

— Ad hoc reports - You can design these reports from scratch to provide customized information that you need.

Changes to the reporting views that the Predefined and Dashboard reports use are not supported, unless Calyx asks you to make the changes.

Note: *To access online help for the InfoAssist and ReportCaster modules in Calyx RIM for Analytics, click* Help *on the toolbar.*

Security for Reports

You can set security for reports to specify which reports a user can run.

Calyx RIM for Analytics and Calyx InSight Dashboard are separately licensed modules. To run a report that you want, you must have access to the Calyx RIM for Analytics or Calyx InSight Dashboard module and to other modules required to generate data for the report. Such a module could be, for example, Submission Planning and Tracking (SPT) or Registration Planning and Tracking (RPT).

— Calyx RIM for Analytics enables you to generate reports about Calyx RIM activities. These reports include dashboard reports, predefined reports, guided ad hoc reports, and ad hoc reports (which you define).

Note: *This module includes the Calyx InSight Dashboard module, but you can have InSight Dashboard without the rest of Analytics.*

— Calyx InSight Dashboard provides analysis reports of key performance indicators. InSight Dashboard reports provide senior management with an at-a-glance perspective of the current status of a product, unlocking the business value of Calyx RIM data. Viewing Calyx InSight Dashboard reports, senior managers can quickly understand the current product posture, enabling rapid and informed business decisions.

Note: *This module is included in the Calyx RIM for Analytics module, but you can have InSight Dashboard without the rest of Analytics.*

To find the license module required for each Calyx RIM report, see *Reports* in *LIQUENT InSight License Modules by Feature*.

Security for Reports - Analytics Module

You can set security to allow users to run reports only when they have access to the Calyx RIM for Analytics and other modules required to generate data for the report. For a list of the modules required for each Calyx RIM report, see *Reports* in *LIQUENT InSight License Modules by Feature*.

1. On the Home page, click GO TO > Security Administration.
   A list of current users appears on the *User/Groups* page.
2. Click the `user name`.
3. In the License Modules group, for LIQUENT InSight for Analytics set the user level of access to the Analytics module.
   For descriptions of the access rights granted by each option, see *Access Rights*.
4. In the Entity Security group:

a) For **Ad hoc reports**, set the user level of access to reports created by using InfoAssist.

For descriptions of the security privileges granted by each option, see *Entity Security Options*.

b) For **Reports**, set the user level of access to pre-defined reports.

5. In the **Home Page Access** group:

a) For InSight Dashboard, to enable the user to access InSight Dashboard reports, click **Yes**. To disable access, click **No**.

b) For **Reports**, to enable the user access pre-defined reports, click **Yes**. To disable access, click **No**.

The settings are active immediately.

Security for Reports - Dashboard Module

You can set security to allow users to run reports only when they have access to the Calyx InSight Dashboard and other modules required to generate data for the report. For a list of the modules required for each Calyx RIM report, see *Reports* in *LIQUENT InSight License Modules*.

1. On the Home page, click **GO TO > Security Administration**.
   A list of current users appears on the ***User/Groups*** page.
2. Click the `user name`.
3. In the **Home Page Access** group, for **Dashboard**:
   — To enable the user to access InSight Dashboard reports, click **Yes**.
   — To disable access, click **No**.

```
The settings are active immediately.
```

Run an Analytics Report

You can run a Calyx RIM for Analytics report to view information about Calyx RIM activities. You can run the report from the *home* page or in the Calyx RIM for Analytics portal.

Note: *When you are using Unicode characters, to ensure that characters are displayed correctly, Calyx recommends that you have the Arial Unicode MS font installed on your system.*

1. On the Calyx RIM menu bar, click ANALYTICS.
2. On the *Analytics* page, if you do not see the contents of the tab that has the type of report that you want to run, click:
   — The Dashboard tab - contains graphical charts that provide analysis of key performance indicators showing the current status of a product.
   — The Reporting tab - contains all types of reports: dashboard, guided ad hoc, predefined, and ad hoc. The dashboard and guided ad hoc reports are also available on other tabs. Predefined reports, provided as part of the product, contain tabular information. Ad hoc reports are those that you design to provide customized information in tables or charts.
   — The Guided ad hoc tab - enables you to select predefined types of data to include in reports showing customized information in different ways.
3. Do any of the following:
   — On the Dashboard tab, find the InSight Dashboard report that you want to run. If you do not see the report, add the report to the Dashboard tab.
   — On Reporting tab, expand the nodes containing the report that you want to run, and double-click the report.
   — On the Guided ad hoc tab, expand the nodes containing the report that you want to run, and double-click the report.

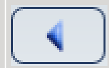
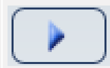
Tips When Running an Analytics Report

When you run Analytics reports, remember the following:

— Each report is saved on a tab above the report section of the page. To see a report that you ran in the current session, click the tab for that report.
— If you click a cell in a tabular report, you can use options to link to Calyx RIM entities, make comments, highlight values and rows, and filter the cell.
— If your Analytics session times out, log in to Calyx RIM again to run an Analytics report.

Actions When Running an Analytics Report

When you run an Analytics predefined report, you can perform the following actions:

Action	Item to Click
Show the report filters. The filter section of the report contains the other options in this list.	
Go back to the previous level of the report (when drill-downs are available).	
Run the report by using the current filters that you selected.	
Reset the filters to the default values.	
Schedule the report to run at a specific time.	
Save the report to a specific folder.	
Generate a PDF copy of the report that can be printed.	
Select the format of a predefined report.	The *`format`* in the Output list.
Select the format of a guided ad hoc report.	The displayed *`format`* option.

Analytics Tree in the Analytics Portal

An Analytics tree is displayed:

— On the Home page.
— In the Calyx RIM for Analytics portal.

In the Analytics tree in the Calyx RIM for Analytics portal, expand any of the following nodes to run a report.

Node	Description
Dashboard	Contains all the InSight Dashboard reports that your Calyx RIM for Analytics license enables you to see. Under this node, expand the folder for the Calyx RIM module related to the report that you want to run. Then double-click the report.

Node	Description
Reports	Contains all the predefined reports that your Calyx RIM for Analytics license enables you to see. Under this node, expand the folder for the Calyx RIM module related to the report that you want to run. Then double-click the report.
My Reports	Contains all reports that you saved from the reports or from InfoAssistant to a specific folder (not saved as a favorite). The report data reflects the criteria that you specified when you ran the reports. The `My Content` folder has reports that you saved and that only you can see. The `Shared` folder has reports that you or other users saved and that all users or some specific users can see. To run a report that you see, double-click the report. To create an ad hoc report, right-click a folder under `My Reports`, point to New, and click the option that you want. InfoAssist opens. Use the InfoAssist online help to create the report.
Favorites	Contains reports that you saved from the reports as favorites in the Analytics portal. Only you can see the reports. Expand the node and double-click the report that you want to run.

Analytics Tree Right-Click Options

In the Analytics tree, you can right-click a node and select from a list of available options in the context menu.

Some of the following options are specific to certain nodes.

Right-Click Option	Description
Add To Favorites	Add a report to the Favorites node.
Add To Mobile Favorites	Add a report to the Mobile Favorites node. ***Note:*** *Calyx RIM 6.2 does not support this option, but future Calyx RIM releases will support it.*
Change Title	Change the name of a subfolder or report in the `My Content` folder.
Copy	Copy a subfolder or report in the `My Content` folder. You can paste the subfolder or report in another location in the `My Content` folder.

<table>
<tr><th>Right-Click Option</th><th>Description</th></tr>
<tr><td>Cut</td><td>Remove a subfolder or report in the <code>My Content</code> folder. You can paste the subfolder or report in another location in the <code>My Content</code> folder.</td></tr>
<tr><td>Delete</td><td>Delete a subfolder or report in the <code>My Content</code> folder.</td></tr>
<tr><td>Duplicate</td><td>In the <code>My Content</code> folder, make a copy of a folder or report and place the copy into the same folder that contains the original folder or report.</td></tr>
<tr><td>Edit</td><td>Change the selected report by using InfoAssist.

Note: You can edit only content that is in the <code>My Content</code> folder and that you created by using InfoAssist. You cannot edit pre-defined and InSight Dashboard reports.</td></tr>
<tr><td>New</td><td>Create a new object in the <code>My Content</code> folder by selecting one of the following options:

— Folder - Create a private subfolder
— Report - Launch InfoAssist to create an ad hoc report
— Chart - Launch InfoAssist to create a chart
— Dashboard - Launch InfoAssist to create a dashboard report
— Document - Launch InfoAssist to create a document (a combination of tables and charts)
— Distribution List - Create a new distribution list for ReportCaster (for scheduling of jobs)</td></tr>
<tr><td>Paste</td><td>Paste a copied or cut subfolder or report to another location in the <code>My Content</code> folder.</td></tr>
<tr><td>Properties</td><td>See the properties of a subfolder or report in the <code>My Content</code> folder.</td></tr>
<tr><td>Refresh</td><td>Update the node contents.</td></tr>
<tr><td>Remove Favorite</td><td>Remove a report from the Favorites node.</td></tr>
<tr><td>Run</td><td>Run the selected report.</td></tr>
</table>

Right-Click Option	Description
Schedule	Used to schedule reports in the `My Content` folder. Reports are distributed by email. ***Note:*** *This option does not work with pre-defined reports and InSight Dashboard reports. To schedule those reports, use the Schedule button from the filters in those reports. Right-click options are available only in the* `My Content` *folder and only for reports created by using InfoAssist.*
Search	Find an object in the node.
Share	Make the selected folder or report available to all users.
Share With	Make the selected folder or report available to specific or users. ***Note:*** *The Groups option uses internal Calyx RIM for Analytics groups that define security. Calyx does not recommend using the Groups option.*
View	See the contents of the tree by title or name.
View Log	See the log containing data about running the report.

Analytics Predefined Reports

Predefined reports are available immediately after Calyx RIM is installed. You do not have to define these reports.

Manufacturer Report

This report provides information about the manufacturers involved in getting a product to market.

For example, this report can show the:

— Manufacturers that make products in a specific product family
— Manufacturers that make a specific substance
— Manufacturers that make the packaging
— Manufacturers that help to prepare the product for market
— Every way in which a specific manufacturer is involved with the product

You can filter the information by specifying the following criteria:

— Manufacturers
— Manufacturer statuses
— Manufacturer status dates
— Last approved dates
— Manufacturer functions
— Association types (related data in the parent PDS nodes)
— Product family types
— Product family names
— Reviewing regions
— Reviewing countries
— Application names
— Product names
— PDS statuses

XEVMPD Submissions and Acknowledgements Report

This report enables you to view the Submission files sent to EMA and Acknowledgement files received from EMA.

You can filter the information by specifying the following criteria:
— Message Sender
— Entity
— Operation Type

— Zip Message Creation Date
— Acknowledgement Status Date

The following entities are available for selection:
— ALL
— Attachment
— Organisation
— Source
— Master File Location
— Approved Substances
— ATC
— Pharmaceutical Form
— Route of Administration
— Authorised Product

The following operation types are available for selection:
— ALL
— Insert
— Update
— Nullify
— Invalidate MA
— Validate

To more easily identify entities for which the EV Code values has been changed by EMA (European Medicines Agency), for 3rd Acknowledgment type files the `Operation Result Description` column of the report displays the EV code followed by the appropriate Entity Name in braces, if the entity with such EV code exists in the system. For example: `+ Added Drug Indication [ 10041655 {Entity Name} ]`. Otherwise, the EV code is followed by Not Defined in braces. For example: `+ Added Drug Indication [ 10041658 {Not Defined} ]`.

XEVMPD Entities

This report provides a mechanism to view the information regarding the XEVMPD entities in Calyx RIM.

You can filter the information by specifying the following criteria:
— Entity
— Operation Type
— Date of Last Updated
— Date Submitted to EMA

The following entities are available for selection:
— ALL
— Attachment

— Organisation
— Source
— Master File Location
— Approved Substances
— ATC
— Pharmaceutical Form
— Route of Administration
— Authorised Product

Note: *Only organisations with MAH (Marketing Authorisation Holder) type are available for selection.*

In the File Type column for Attachment entity report, the file type is presented as a numeric value:
— `1` for `.pdf` files
— `2` for `.doc` files
— `3` for `.docx` files
— `4` for `.xls` files
— `5` for `.xlsx` files

The data is displayed only for entities that are populated with Local Code, EV Code, or both. For the following list of entities, the data is shown in the report only if the Country field is populated with European Union (EU) Countries and European Economic Area (EEA) Countries, but not the EDQM Country:
— Organisation (MAH)
— Master File Location (MFL)
— Authorised Product

XEVMPD Audit

The XEVMPD Audit report provides a mechanism for Calyx RIM users to view the XEVMPD entities fields action information that has been added, updated, or deleted to be able to send their updates to the agency in time based on the provided data.

— The report results are displayed based on the entered filter criteria.
— All Data Administration values, regardless of the `Active` or `Inactive` state, are displayed and available for selection.
— If the Calyx RIM system is unable to return any results based on the selected filter criteria, an appropriate message appears.
— The selected filters that do not contain any data, for example due to the associated dependencies or due to nonexistent in the database data, are available but appear blank.
— The fields that do not contain any data appear without content in the report output.
— The report captures the `Insert`, `Update`, and `Delete` actions performed on the XEVMPD-related entities and its subsequent attributes.

— The filters **XEVMPD Entity Type** and **InSight Entity Type** are multi-select fields.
— The PDS-related entities are displayed in the report output only if the PDS Detail has the **Approved** status.
— Values for the fields with **NULL** in both **Field Data** and **Previous Field Data** fields do not appear in the report layout.
— The hyperlinks to Calyx RIM entities are provided by clicking on the **InSight Entity Name** column value and selecting **Entity Details** option from the pop-up list. The link leads you to the entity for which the link is initiated.

Note: *The exceptions are:*

- *PDS Details, where the link leads to the PDS itself.*
- *Active Ingredient entity does not have the hyperlink.*

The **InSight Entity Name** is displayed as a concatenation of values for the following entities:

— MAH
  - `MAH/Development Sponsor/Organisation Name + Address + City + Country Code`

— ATC
  - `ATC Name + ATC Code`

— Active Ingredient, Excipient, and Adjuvant
  - `[Name] + PP: [Pharmaceutical Product Name]`

  Note: *If the Pharmaceutical Product has been deleted, concatenation is shown as* `[Name] + PP: No PP`.

The XEVMPD Audit report captures the following for all actions on subsequent fields for the XEVMPD-related entities:

— The user that makes the changes
— The date the changes were made
— The content of changes
— The changed entity
— The XEVMPD entity name
— The related entity type and name

The filters that can be used for the XEVMPD Audit report:

Filter Field	Description
User	Multi-select field that is defaulted to **ALL** value. You can select as many users as needed.
Last Updated Date	The date of last update. The default value is set to `6 months from today's date`.

Filter Field	Description
XEVMPD Submission required?	The Yes and No values are available for selection. The field is empty by default. The values are calculated using the formula: — Yes value means that the Last Updated Date is greater than the Date Submitted to EMA. — No value means that the Last Updated Date is less than the Date Submitted to EMA. The field default is to display ALL (all listed values).
XEVMPD Entity Type	Multi-select field with the following values available for selection: — Authorised Product - ATC — Authorised Product - Authorisation — Authorised Product - Authorised Pharmaforms — Authorised Product - Medicinal Product Type — Authorised Product - Presentation Name — Authorised Product - Previous EV Code — Authorised Product - Printed Product Information — Authorised Product - Product Indications — Authorised Products — Pharmaceutical Product — Pharmaceutical Product - Active Ingredient — Pharmaceutical Product - Adjuvant — Pharmaceutical Product - Administration Route — Pharmaceutical Product - Excipient — Pharmaceutical Product - Medical Devices Only values with the selected data are displayed in the search results table. The field default is to display ALL (all listed sections).

Filter Field	Description
InSight Entity Type	Multi-select field with the following values available for selection: — Adjuvant — Application — Component — Component Active Ingredient — Excipient — Full Product Presentation — Indications/Intended Use — Package Set Registration — PDS — PDS Active Ingredient — PDS Substance — Pharmaceutical Product — Product — Reference Active Ingredient — Registration FPP Attachment The field default is to display ALL (all listed sections).
InSight Entity Name	Text field that is defaulted to be empty. Leaving the field without specifying any filtering criteria will display all available entities on the results page.
Product Family Name	Text field that is defaulted to be empty. Leaving the field without specifying any filtering criteria will display all available entities on the results page.
Message Sender	Text field that is defaulted to be empty. Leaving the field without specifying any filtering criteria will display all available entities on the results page.
Calyx RIM Action Type	Multi-select field with the following values available for selection: — Insert — Update — Delete The field default is to display ALL (all listed sections).

The selection rules that are applicable to the XEVMPD Entity Type and InSight Entity Type:

XEVMPD Entity Type	InSight Entity Type
Authorised Product - ATC	Package Set Registration
Authorised Product - Authorisation	Application
Authorised Product - Authorisation	Full Product Presentation
Authorised Product - Authorisation	Package Set Registration

XEVMPD Entity Type	InSight Entity Type
Authorised Product - Authorisation	PDS
Authorised Product - Authorised Pharmaforms	Full Product Presentation
Authorised Product - Medicinal Product Type	Package Set Registration
Authorised Product - Presentation Name	Full Product Presentation
Authorised Product - Previous EV Code	Full Product Presentation
Authorised Product - Printed Product Information	Registration FPP Attachment
Authorised Product - Product Indications	Indications/Intended Use
Authorised Products	Full Product Presentation
Authorised Products	Package Set Registration
Pharmaceutical Product	Pharmaceutical Product
Pharmaceutical Product - Active Ingredient	Component Active Ingredient
Pharmaceutical Product - Active Ingredient	PDS Active Ingredient
Pharmaceutical Product - Active Ingredient	PDS Substance
Pharmaceutical Product - Active Ingredient	Reference Active Ingredient
Pharmaceutical Product - Adjuvant	Adjuvant
Pharmaceutical Product - Administration Route	Component
Pharmaceutical Product - Administration Route	Product
Pharmaceutical Product - Excipient	Excipient
Pharmaceutical Product - Medical Devices	Pharmaceutical Product

Entities from the following list are displayed in the XEVMPD Audit analytics report only if the appropriate Package Set is associated to the corresponding Full Product Presentation:

XEVMPD Entity Type	InSight Entity Type
Authorised Product - Authorisation	PDS
Authorised Product - Product Indications	Indications/Intended Use
Pharmaceutical Product	Pharmaceutical Product
Pharmaceutical Product - Active Ingredient	Component Active Ingredient
Pharmaceutical Product - Active Ingredient	PDS Active Ingredient
Pharmaceutical Product - Active Ingredient	PDS Substance
Pharmaceutical Product - Active Ingredient	Reference Active Ingredient
Pharmaceutical Product - Adjuvant	Adjuvant

XEVMPD Entity Type	InSight Entity Type
Pharmaceutical Product - Administration Route	Component
Pharmaceutical Product - Administration Route	Product
Pharmaceutical Product - Excipient	Excipient
Pharmaceutical Product - Medical Devices	Pharmaceutical Product

XEVMPD Audit Report Results

The filter criteria you select define the data you get for the result set of the Report.

The following columns appear in the XEVMPD Audit Report:
- Product Family Name
- Application Name
- License Code
- Authorised Product Country
- Authorised Product EV Code
- FPP Name
- Message Sender
- Calyx RIM Action
- XEVMPD Entity
- InSight Entity Type
- InSight Entity Name
- Field Name
- Field Data
- Previous Field Data
- Updated Date
- User
- Last Submitted Date (FPP)
- Required XEVMPD Update

The following rules apply to the report results:
- If the EEA Country is populated for the Full Product Presentation, then this value appears in the Authorised Product Country column. Otherwise, the Registration Issue Country is displayed.
- The EV Code of the related Full Product Presentation entity appears in the Authorised Product EV Code column.
- All fields from all entities for the XEVMPD Entity Type > Pharmaceutical Product - Active Ingredient appear if they are populated, regardless of the business logic: Component Active Ingredient, PDS Active Ingredient, Reference Active Ingredient and Substance Detail.
- The Concatenation of the values appears in the InSight Entity Name column for the following fields:
  - MAH: `MAH/Development Sponsor/Organisation Name + Address + City + Country Code`

- ATC: `ATC Name + ATC Code`
- Active Ingredient, Exipient, and Adjuvant: `[Name] + PP: [Pharmaceutical Product Name]`

***Note:** If the Pharmaceutical Product has been deleted, concatenation appears as* `[Name] + PP: No PP`.

XEVMPD Audit Report Sorting

The following default sorting is included to the report output:

— By columns header in alpha-numeric order:
- Product Family Name
- Application Name
- License Code
- Authorised Product Country
- Authorised Product EV Code
- FPP Name
- InSight Entity Type

— By an additional column values which are hidden in the user interface (UI):

InSight Entity Type	Order in the layout
Application	1
PDS	2
Package Set Registration	3
Full Product Presentation	4
Registration FPP Attachment	5
Indications/Intended Use	6
Product	7
Component	8
Pharmaceutical Product	9
Component Active Ingredient	10
Preference Active Ingredient	11
PDS Active Ingredient	12
Adjuvant	13
Excipient	14
PDS Substance	15

Registration Status with Product Report

This report provides the following information:

— For each product in the report, the total number of registrations that have a specific status
— For each registration status, whether the registrations are currently marketed
— The total number of registrations for all specified product families

You can filter the information by specifying the following criteria:

— Regions
— Countries
— Product family type
— Product family
— Registration type
— Products
— Registration status

Registration Status Summary Report

This report provides the number of registrations for a specific product family or country.

You can filter the information by specifying the following criteria:

— Regions
— Countries
— Product family type
— Product family
— Registration type
— Product
— Registration status

Status of Planned Submissions Report

This report lists planned submissions by sequence. A planned submission is an open sequence with the status mapped to the internal status submitted.

The report answers the following questions:

— What are the planned dates for submissions?

- Which planned submissions are upcoming? What therapeutic areas do these submissions relate to? Where are these submissions planned for?
- Which planned submissions are late? What therapeutic areas do these submissions relate to? Where are these submissions planned for?
- Who is responsible for each planned submission?

You can filter the submissions by specifying the following criteria:

- Date range
- Reviewing countries
- Application name
- Therapeutic area
- Sequence filing type
- Sequence owner

Submission Status Dates by Country and Event Type Report

This report shows the projected status dates and actual status dates for events, listed by product family, for each country.

For each event, the report answers these questions:

- What country is the event associated with?
- What event type is the event?
- When was the submission planned and when did it occur?

You can filter the report data to show data only for a specific date range.

- The earliest date that you can select for From Date is 50 years before the current date. The latest date that you can select for To Date is 50 years after the current date.
- To select a date range greater than 20 years, for From Date or To Date, click the down arrow next to the displayed year. A 20-year range appears. To select a year before the first year in the list, click the first year. To select a year after the last year in the list, click the last year. If necessary, repeat these actions until the year that you want is displayed. Then click the year.

You can filter the report data by specifying the following criteria:

- Product family type
- Product family
- Event countries
- Event type
- Event country status

Analytics Dashboard Reports

Analytics Dashboard reports are predefined reports, and are available immediately after Calyx RIM is installed. You do not have to define these reports.

Global Registration Activity by Product Family (Top 10 Countries) Report

This report provides an overview of the top 10 countries with the highest registration count for the product family selected in the filter criteria.

Key questions answered in the Global Registration Activity report include:

— Where is my global registration activity?
— Which countries have had the most recent global registrations?
— What is the status of the global registrations?

Click a `country` column to view a pie chart illustrating registrations by status for the product family and country. Statuses depicted include active, withdrawn, expired, pending, or planned.

Report Data

For the product family selected in the filter criteria, the total number of registrations for each country in the report data represents the package set and product registration types.

Regarding registrations of the EU CP procedure type:

— For a package set registration of the EU CP procedure type, country information is gathered from the package-set-countries (because EU is the country on the registration). Because you are not required to specify package set information when creating a registration, package set registrations of the EU CP procedure type are excluded from the dataset when no package-set-country information is available.
— For a product registration of the EU CP procedure type, registrations created with the EU as the country are excluded from the dataset.

Registration Submissions Due by Month Report

The Registration Submissions Due by Month report shows the number of registration submissions that are due in each month in a specific time period. (The default period is the next year.) The report queries on the next renewal date on the registration entity. You can use this information to determine resource needs for each month.

Key questions answered by this report include:

— How many license renewals are due in each month in a specific time period?

- Which months have the highest number of license renewals due in a specific time period and will require additional resources?
- Which months have the least number of license renewals due in a specific time period, enabling me to spend more time on another project?

You can filter the report data to see data for specific product family types.

For a national, MRP, or DCP application, the registration country is the country associated with the registration. For a CP application, the registration country is always the European Union.

Click the bar for a specific month to see a pie chart showing the number of registration submissions due for each country in that month. If you filtered the data by specifying product families, the chart shows the product family for each submission. To see details on a specific country, click the country segment of the pie chart.

Regulatory Maintenance Submissions Report

The Regulatory Maintenance Submissions report queries Calyx RIM event data and provides metrics on regulatory maintenance submissions for a specific time period, for specific regions and countries. These metrics show how much work the regulatory team accomplished for a given time period and helps with workload and resource planning.

The key question answered by this report is "What is the total number of events that have a specific event country status in a specific time period for specified regions and countries?"

You can filter the report data to see data for specific event types. Each bar in the chart shows the total number of events for the time period that you specified for the report. Click a bar in the chart to see a world map that displays, by event country, the data for the event type that the bar represents.

Registration Status Summary by Country Report

This report provides a map showing the number of registrations for each country that you point to.

Registration Status Summary by Product Family Report

This report provides a pie chart showing the percentage of registrations for each product family represented by a pie sector that you point to.

Task Status Reports

The Analytics dashboard can provide the following task status reports:

- Task Status by Application

— Task Status by Event
— Task Status by Sequence

Each report provides, for each specified application, event, or sequence, and for each specified task type, the number of uncompleted tasks that have had the current status for a time period that falls in a specific range of days. For example, the report could provide the number of tasks that have had the same status for a period from 31 to 59 days. You can use this information to determine what actions need to be taken to redeploy resources to ensure that tasks are completed on time.

Key questions answered by this report include:

— How long have tasks of a specific type been in the current status?
— Which regions are late or delayed in completing tasks?
— How long is each delay?
— Which regions need more resources to complete the tasks?

You can filter the report data to see data for the following:

— A specific time period (The default is the last year)
— Tasks associated with specific regions
— Tasks associated with specific countries

Point to a range of days on a task type bar in the stack bar chart to see the percentage of tasks that have had the current status for a time period in that range. Click a bar to see a table showing details for a specific task type.

Total Pending Approvals (Top 10 Products) Report

The Total Pending Approvals report provides information about pending approvals for the 10 countries that have the largest numbers of pending approvals. A pending approval is an approval that an agency is still reviewing.

The key questions that this report answers are:

— How many approvals (open events) are pending for a product?
— What types of activities and how many activities are currently under review?

To see a pie chart of pending approvals for a product by activity type, click the bar for the product. The activity types are the event types defined in Calyx RIM.

Note: *When more than one Country has the same number of products pending, more than 10 results can appear.*

Total Product Registrations by Month Report

The Total Product Registrations by Month report provides information for detecting monthly trends in the volume of registration submissions.

The key question answered by this report is "What is the number of product registrations that were created for a specific region or country and had a specific registration status during a specific time period?"

You can filter the report data to see data for registrations:

— For a specific time period
— For specific regions or countries
— With a specific license status
— Associated with a specific division
— Associated with a specific event type

The information is displayed on a bar chart, on which a specific color indicates a specific year. To see registration details for a specific month, click the month.

Total Submissions by Month Report

The Total Submissions by Month report illustrates the trend in submission volume on a monthly basis in a line chart.

Key questions answered by this report include:

— How many publishers and other resources will I need to handle next quarter's expected workload?
— How much work did the submission team accomplish last year?
— What workload can I expect an average person or team to complete?
— How should I plan for the workload from a budgetary and resourcing perspective?

By default, the line chart shows submission volume for the current month-to-date and the past 12 months. Use the filter criteria to specify a date range for analysis. To see submission information for a specific month, click the node for that month.

Report Data

The report data includes current sequences with a status that maps to the internal status of `SUBMITTED` with an actual submission date that coincides with the date range specified in the report filter criteria.

Total Tasks by Task Type Report

This report provides the following for each task type that users are performing during a specified time period:

— The number of tasks performed
— For each month, the number of tasks that reached each stage of completion: 0% complete, 30% complete, 45% complete, 80% complete, and 100% complete

The key questions that this report answers are:

— Which types of tasks were completed or are scheduled to be completed in a specified time period?
— How many tasks are planned to be completed in a particular month?
— How many tasks have a particular percentage of work completed in a particular month?

A pie chart shows, for each task type, the number of tasks that users are performing. To view details on a specific task type, click the pie chart slice for the task type.

Worldwide Approvals (Top 10 Regions) Report

The Worldwide Approvals report graphically depicts an overview of the top 10 regions based on the number of approvals. The report also includes an analysis of application types and activity types, which are event types as defined in Calyx RIM.

Key questions answered by the Worldwide Approvals Report include:

— What did our regulatory department accomplish in a specified period?
— Are we meeting our deadlines?
— How many clinical trial applications were completed?
— How many clinical trial applications late?
— On average, how long does it take a line extension to be approved?

The top-level report is a column chart of approvals to date, which can be filtered down to a specified date range. Click an area of interest on a chart to view a bar chart of the approvals for the region presented by activity for each application type.

Report Data

The report data includes closed events (the `Closed` flag on the event is selected) with an `Event Closed As` value that maps to the internal status of `APPROVED` and with an `Event Closed Date` value that coincides with the date range specified in the report's filter criteria. Regions in the report data are determined by the reviewing country of the application with which the event is associated. Application type labels are displayed in the format of *`Activity(Event) Type- App Type Name`*, where *`App Type Name`* is the full name, not the display name, as defined in data administration.

Add a Dashboard Report to the Dashboard Tab

The **Dashboard** tab shows only a few reports by default. You can add more reports to the tab.

1. On the Analytics menu, click Resources.
2. If the Dashboard tab is not displayed, click it.
3. Drag the report to the Dashboard tab.

Analytics Guided Ad Hoc Reports

Analytics guided ad hoc reports enable you to select predefined types of data to include in reports showing customized information in different ways.

Application, Event, Sequence Report

For this report, you select fields about product families, applications, events, and sequences. You can sort the fields the way that you want them to appear in the report. You can filter each type of data that the report is based on.

If you see any of the following links in the report, click the link and the corresponding menu item to see the report data:

- View Comments
- View Associated Products
- View Status History

Create an Analytics Ad Hoc Report

Calyx RIM for Analytics enables you to create ad hoc reports that provide customized information that you need.

1. On the Calyx RIM menu bar, click ANALYTICS.
2. If you do not see the Analytics tree, click the Reporting tab.
3. Under the `My Reports` folder, right-click the `My Content` folder or on a folder under the `My Content` folder, point to New, and click any of the following:
   — Report (This option is for tabular reports.)
   — Chart
   — Dashboard
   — Document (This option is for reports containing both tables and charts.)
4. Use InfoAssist to create the report.

   To access instructions for using InfoAssist or ReportCaster, click Help on the toolbar.

Access the ReportCaster Console

ReportCaster is an application that one or more administrators use to view the job status for scheduled Calyx RIM for Analytics reports.
Administrators use the *ReportCaster Console* interface to manage their schedule job logs.

To access *ReportCaster Console*:

1. On the Calyx RIM for Analytics menu bar, click Tools.
2. Click ReportCaster Console.

Note: *To access instructions for using ReportCaster or InfoAssist, click* Help *on the toolbar.*

Calyx RIM for Analytics Reporting Schema

Name	Description
Calyx RIM for Analytics Reporting Schema Design Approach (PDF)	Summary of the design and purpose of the Calyx RIM for Analytics Reporting Schema.
Calyx RIM for Analytics Reporting Schema v6.2 CHF 4 (XLSX)	Details of the Calyx RIM for Analytics Reporting Schema tables.

Index

A

Analytics 1, 2, 4–6, 9–11, 16–19, 24, 26–29

D

Dashboard 20–24

S

Security 2, 3