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LIQUENT InSight® Best Practice

Report Publishing

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Contents

1. Document Purpose

The purpose of this document is to provide a Best Practice guide for the management of Report Publishing in LIQUENT InSight® Publisher.

2. Scope

This document describes the process for using LIQUENT InSight® Publisher to manage study reports within the existing InSight data model for report-level publishing. The configurations discussed here have not been fully vetted against the full InSight Platform to determine potential impacts on Registration management, and should be examined prior to implementation in a customer environment to take those factors into account.

The current InSight Data Model is designed around managing regulatory submissions in a hierarchy that allows relationships and categorizations among Product Family, Country, Application, Event, and Sequence. It was originally believed that the use of Standalone Assemblies, independent of the Product Family could be used to manage study report publishing needs. However, through various implementations, it has become clear that similar categorization of report assemblies is desired. Making the configuration updates described below allows for organization of Report assemblies within the existing data model. Future enhancements should be considered to allow for report-specific labels in the Interface when constructing these types of assemblies.

3. Data Administration Activities

The Data Administration activities in LIQUENT InSight® Publisher.

Background

Within InSight, Standalone Assemblies can be used for study report publishing, however, there is currently no filtering on the Standalone Assemblies page and where many studies are being managed, this can be come unwieldy. Liquent is investigating future updates to the InSight data model that would provide this additional classification. In the interim, the proposed solution is to create entries for Report-specific countries, application types, procedure types, event types and filing types in Data Administration for managing the different report types. This allows association of the Report assemblies with their respective Product Families and allows for the introduction of a hierarchy for managing the reports. Additionally, security can be enabled such that report publishers only have access to see the Report Countries and are restricted from seeing the submissions stored under each product family.

Many of the labels within the UI are currently eCTD-submission specific, so an understanding of the InSight Product Family/Application/Event/Sequence hierarchy is required to map the Report organizational options to the existing InSight data model. To manage the reports under this hierarchy, the following parallels are drawn:

Current InSight Label	Equivalent Report Term
Product Family	The product for which the report is being produced
Application	High-level report type (e.g. Nonclinical pharmacodynamics, Nonclinical pharmacokinetics, toxicology, Biopharmaceutic, Human PK, Human PD, Safety and Efficacy
Event	Means to group like report sub-types together in the hierarchical display
Sequence	The identifier of the report itself that includes description of the report sub-category through the Filing Type (e.g. primary pharmacodynamics, single-dose toxicity, bioavailability, controlled clinical, uncontrolled clinical

The sections below describe the Data Administration updates to facilitate this report hierarchy and categorization.

Countries and Regions

Within Data Admin, the following Countries have been added for managing Reports:

- Clinical Reports
- Nonclinical Reports

When new countries are added, they default to associate with the Rest of World Region. If instead, a separate Region for managing Reports is desired, from Data Administration, select Region Values from the Other section. Click Add New to create a New Region Named ‘Reports’ and move Clinical Reports and Nonclinical Reports to the Selected Countries box in the Associated Countries section.

NOTE: Should additional components of the InSight platform be licensed for registration tracking and management in the future, discussions with the Consulting organization should take place to determine the best method for migrating and/or continuing to manage this information without impact to the Registration Management components.

To restrict Report publisher users to only see/create assemblies within this Report Category, from the Quick Links menu select Administration > Security. Select the User/Group you would like to modify and from the Application Country Rights section, Change the Country Rights from All to Selected and move the Clinical Reports and Nonclinical Reports values from the Available to the Selected box.

Application Types

For report publishing, the Application will equate to the top-level report type within the category of Clinical or Nonclinical Reports. New Application Types should be created to reflect this classification as needed. A suggested list of Application Type values is below:

Application Type/Name/Display Name	**Selected Countries**
Pharmacology Reports	Nonclinical Reports
Pharmacokinetics Reports	Nonclinical Reports
Toxicology Reports	Nonclinical Reports
Biopharmaceutic Reports	Clinical Reports
Pharmacokinetics using Human Biomaterials Reports	Clinical Reports
Human Pharmacokinetic Reports	Clinical Reports
Human Pharmacodynamic Reports	Clinical Reports
Efficacy and Safety Reports	Clinical Reports
Post-marketing Reports	Clinical Reports

Procedure Types

There are standard procedure types configured with InSight. The National procedure type is an all-purpose procedure type and the Report countries should be associated with this type. The other procedure types relate mostly to management of European regulatory submissions to address the various needs of the different marketing authorization procedures in Europe.

Event Types

Event Types are used for submissions to classify the purpose of the submissions grouped under them. For report publishing, a single additional Event Type of Report can be created to categorize the Report entities. Naming conventions should be developed for the Event Name to reflect the Filing Types described below to group like reports together under the main Report Type in the left-hand navigation tree.

Filing Types

For report publishing, the Filing Type on the Sequence will equate to the sub-report type within the category of Clinical or Nonclinical Reports. Matching this to the Event Name will allow users to easily identify the report type either by using the navigation tree or looking at the Sequence Attributes. New Filing Types should be created to reflect this classification as needed. A suggested list of Filing Type values is below:

Filing Type/Name/Display Name	**Selected Countries**
Primary Pharmacodyanmics	Nonclinical Reports
Secondary Pharmacodynamics	Nonclinical Reports
Safety Pharmacology	Nonclinical Reports
Pharmacodynamic Drug Interactions	Nonclinical Reports
Analytical Methods and Validation	Nonclinical Reports
Absorption	Nonclinical Reports
Distribution	Nonclinical Reports
Metabolism	Nonclinical Reports
Excretion	Nonclinical Reports
Pharmacokinetics Drug Interactions	Nonclinical Reports
Other Pharmacokinetic Studies	Nonclinical Reports
Single-Dose Toxicity	Nonclinical Reports
Repeat-Dose Toxicity	Nonclinical Reports
Genotoxicity	Nonclinical Reports
Carcinogenicity	Nonclinical Reports
Reproductive and Developmental Toxicity	Nonclinical Reports

Filing Type/Name/Display Name	Selected Countries
Local Tolerance	Nonclinical Reports
Other Toxicity	Nonclinical Reports
Bioavailability	Clinical Reports
Comparative BA/BE	Clinical Reports
In vitro-In vivo Correlation	Clinical Reports
Bioanalytical and Analytical Methods	Clinical Reports
Plasma Protein Binding	Clinical Reports
Hepatic Metabolism and Drug Interaction	Clinical Reports
Other Human Biomaterials	Clinical Reports
Healthy Subject PK and Initial Tolerability	Clinical Reports
Patient PK and Initial Tolerability	Clinical Reports
Intrinsic Factors PK	Clinical Reports
Extrinsic Factors PK	Clinical Reports
Population PK	Clinical Reports
Healthy Subject PD and PK-PD	Clinical Reports
Patient PD and PK-PD	Clinical Reports
Controlled Clinical	Clinical Reports
Uncontrolled Clinical	Clinical Reports
Analyses of Data from More than One Study	Clinical Reports
Other Clinical	Clinical Reports
Postmarketing Reports	Clinical Reports

4. Creating and Organizing Reports

The first step in creating the report is to create the hierarchy to store it within InSight and associate it with the appropriate Product Family.

If this is the first Nonclinical or Clinical report being created in InSight for this product:

- Select Wizards > Create Submission Wizard
- Choose Initial Application and click Next
- Set the following:
    - Family Name – the Product Family Name for which you are creating a report
    - Reviewing Country – Clinical or Nonclinical Report
    - Application Type – the top-level report type (Nonclin PD, PK, Tox, Biopharm, etc)
    - Procedure Type – National
    - Application Code – An abbreviated version of the application type or the full value if desired.
    - Application Name – Should match the value for Application Type in order to display the appropriate hierarchy in the navigation tree.
    - Event Code – The report sub-type (Primary Pharmacodynamics, Secondary Pharmacodynamics,
      Single-Dose Toxicity, Comparative BA-BE Reports, etc) – Identify naming conventions for this that will ensure consistency for all reports.
    - Leave the other defaults and click Next
- Click Next at the Create Confirmation Screen
- On the Create Submission Summary Screen, click on the link in the line for An Event was created.
- Edit the Event and update the Event Name to match the Event Code, update the Event Type to Report and click Save. The Event Name is what will display in the left-hand navigation tree.
- From the Event Attributes page click on the link to go to the Sequence.
- Edit the Sequence and change the Sequence Name to identify the report being published. This is what will display in the left-hand navigation tree. Select the appropriate report sub-type from the Filing Type drop down and click Save.

If this is the first top-level report type in its classification (Nonclin PD, PK, Tox, Biopharm, Human PK, etc):

- Select Wizards > Create Submission Wizard
- Choose Major Update and click Next
- Select the following:

o The appropriate Report Type from the Application Code drop down

o Enter a value for the Event Name that corresponds to the report sub-type (Primary Pharmacology, Secondary Pharmacology, Comparative BA/BE reports, etc). Use naming conventions for this value as this will display in the left-hand navigation tree.

- Optionally provide a value for Event Code
- Set the Event Type to Report
- Select the report sub-type from the Filing Type drop downs
- Leave all other defaults and click Next

- Click Next at the Create Confirmation Screen
- On the Confirmation Summary Screen, click on the link for A Sequence was created
- Edit the Sequence and update the Sequence Name to identify the report being published. This is what will display in the left-hand navigation tree. Click Save.

If this is a report for which other reports of the same type already exist in InSight:

- Select Wizards > Create Submission Wizard
- Choose Amendment and click Next
- Select the following:
    - The appropriate Report Type from the Application Code drop down
    - Enter a value for the Event Name that corresponds to the report sub-type (Primary Pharmacology, Secondary Pharmacology, Comparative BA/BE reports, etc). Use naming conventions for this value as this will display in the left-hand navigation tree.
    - Optionally provide a value for Event Code
    - Set the Event Type to Report
    - Select the report sub-type from the Filing Type drop downs
    - Leave all other defaults and click Next
- Click Next at the Create Confirmation Screen
- On the Confirmation Summary Screen, click on the link for A Sequence was created
- Edit the Sequence and update the Sequence Name to identify the report being published. This is what will display in the left-hand navigation tree. Click Save.

If this is a report for which other reports of the same type already exist in InSight:

- Select Wizards > Create Submission Wizard
- Choose Amendment and click Next
- Select the following:
    - The appropriate Report Type from the Application Code drop down
    - Select the Report sub-type from the Event Name and Filing Type drop downs
    - Leave all other defaults and click Next
- Click Next at the Create Confirmation Screen
- On the Confirmation Summary Screen, click on the link for A Sequence was created
- Edit the Sequence and update the Sequence Name to identify the report being published. This is what will display in the left-hand navigation tree. Click Save.