

RERS

REGULATORY ENTERPRISE REPORTING SYSTEM AD HOC UNIVERSE & STANDARD REPORTS TRAINING

DESCRIPTION:

This course provides an overview of Medtronic's Regulatory Enterprise Reporting System (RERS).

DURATION: 30 minutes

March, 2020 | Confidential, for internal use only



Medtronic
Further, Together

REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

OBJECTIVES

This course provides users from both Regulatory Affairs and Regulatory Operations functions with an overview of the Regulatory Enterprise Reporting System including:

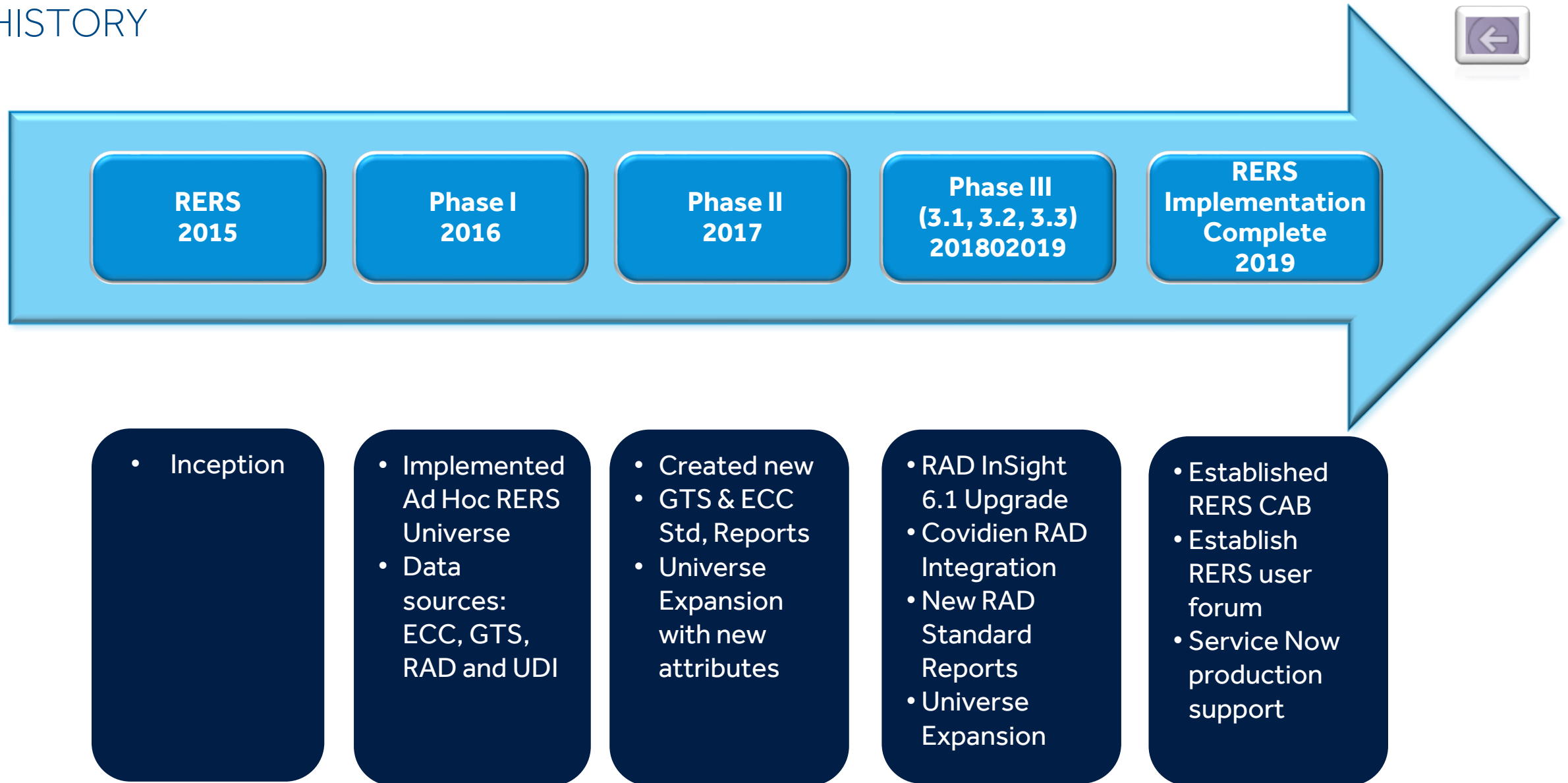
1. [RERS history, user requirements and assumptions](#)
2. [Framework of universe data sources, processes, design and reporting model](#)
3. [Information about BO terminology and definitions](#)
4. [Information about universe design and data relationships](#)
5. [Self training resources, knowledge base and video library](#)
6. [Important top 20 universe rules and guidelines](#)
7. [Key universe considerations](#)
8. [Access to RERS universe and initial set up](#)
9. [Standard reports](#)
10. [Production support process](#)

[Summary 1](#) | [Summary 2](#) | [Summary 3](#) | [Summary 4](#) | [Summary 5](#)

1. RERS HISTORY, USER REQUIREMENTS AND ASSUMPTIONS



REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING HISTORY



REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

USER ASSUMPTIONS



Assumptions

- Users from BUs and countries are SMEs of regulatory source system:
 - *RAD-InSight 6.1*
 - *SAP-GTS*
 - *SAP-ECC*
 - *SAP-UDI*
- Solid understanding of regulatory business process and its data
- Users actively engaged in RERS user forum meetings and MIX community

REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

USER REQUIREMENTS



Requirements

- Complete Cornerstone training to maintain and gain access to RERS
- Utilize self training resources and video library posted on RERS site
- Basic understanding of BO reporting tool and run reports
- SME users participate from BU/region during monthly RERS CAB (Change Advisory Board) meeting

2. FRAMEWORK OF UNIVERSE DATA SOURCES, PROCESSES, DESIGN & REPORTING MODEL

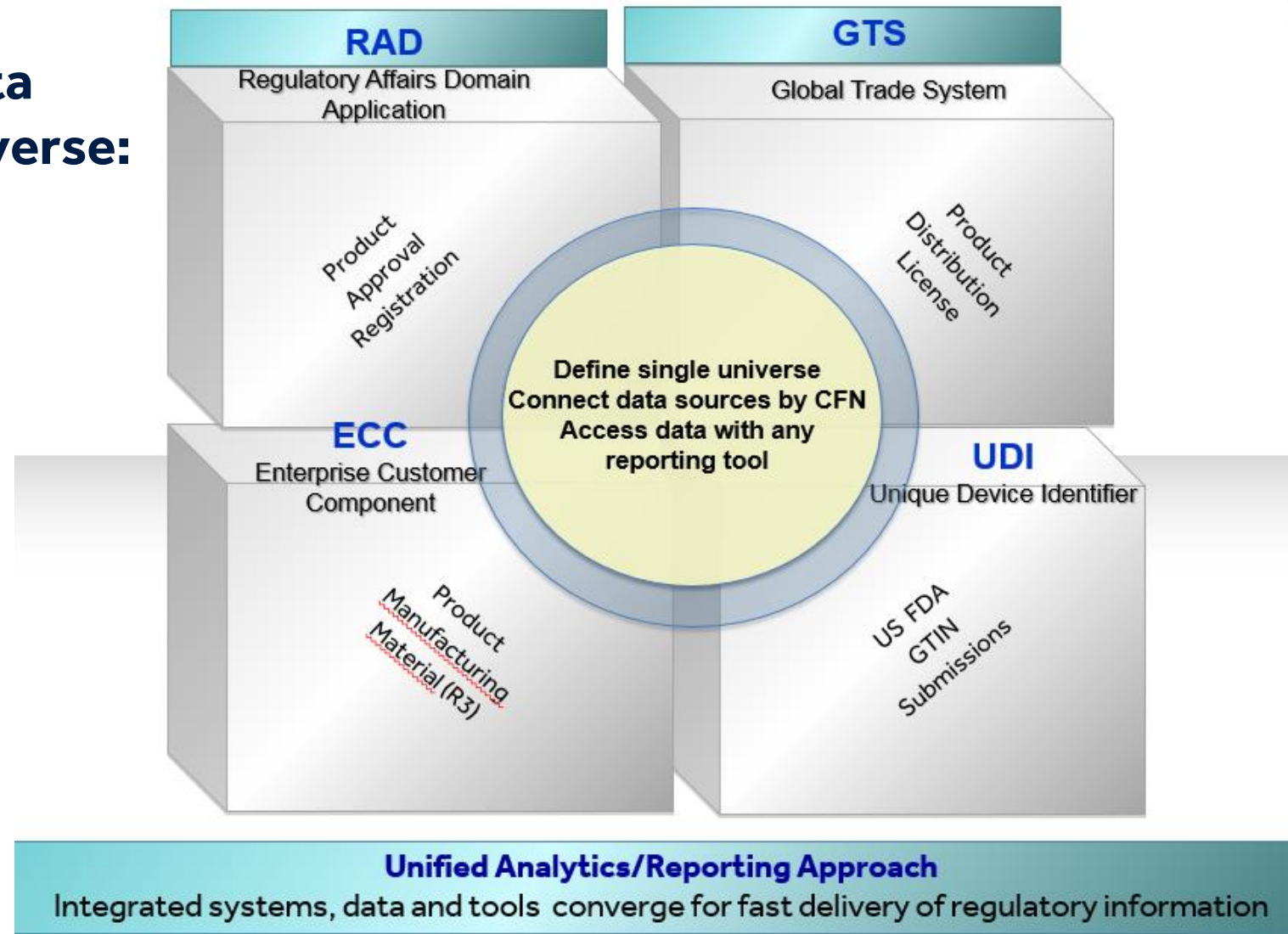


REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

UNIVERSE DATA SOURCES

There are four source data systems in the RERS Universe:

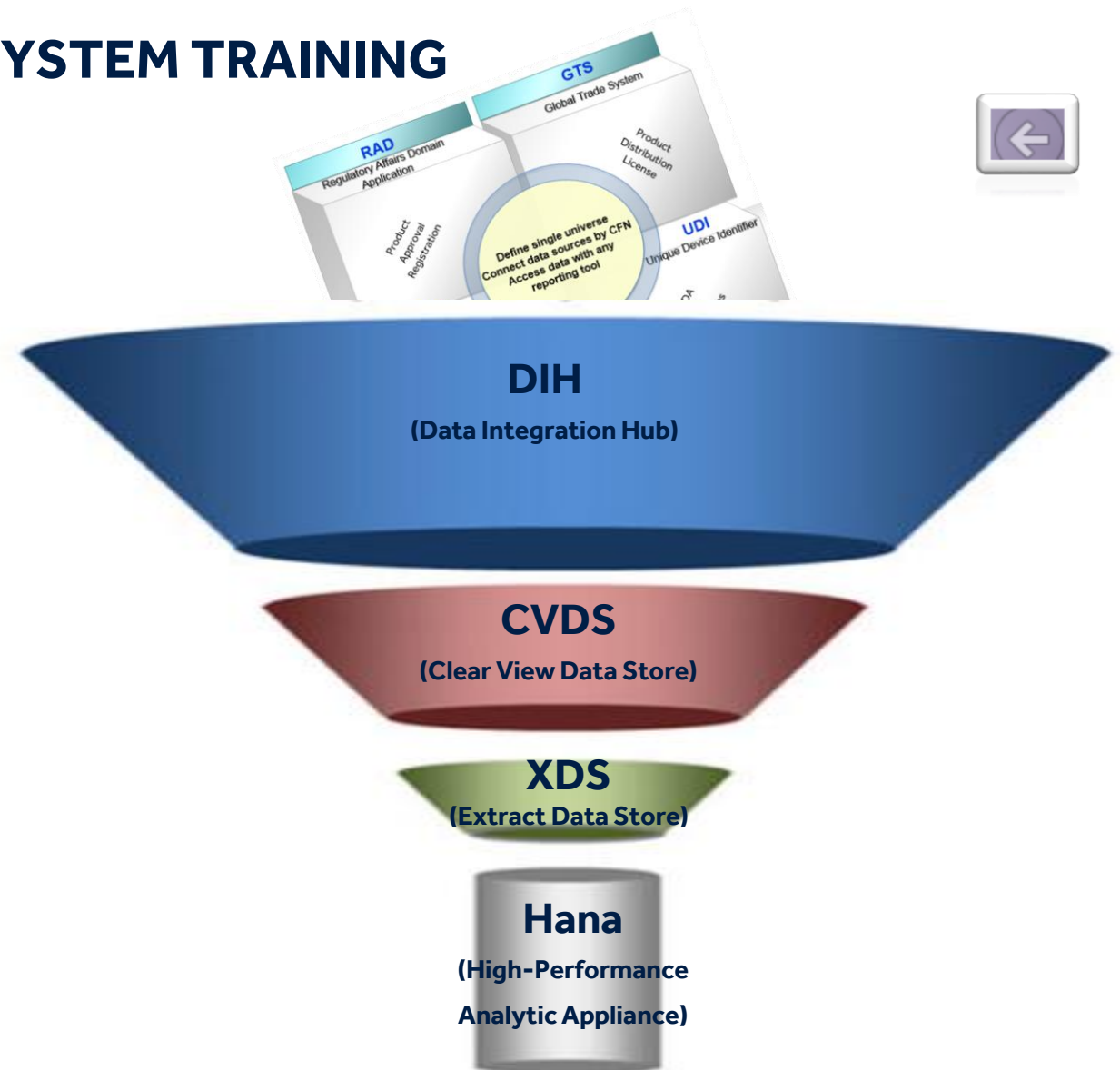
- RAD InSight
- SAP GTS
- SAP ECC
- SAP UDI



REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

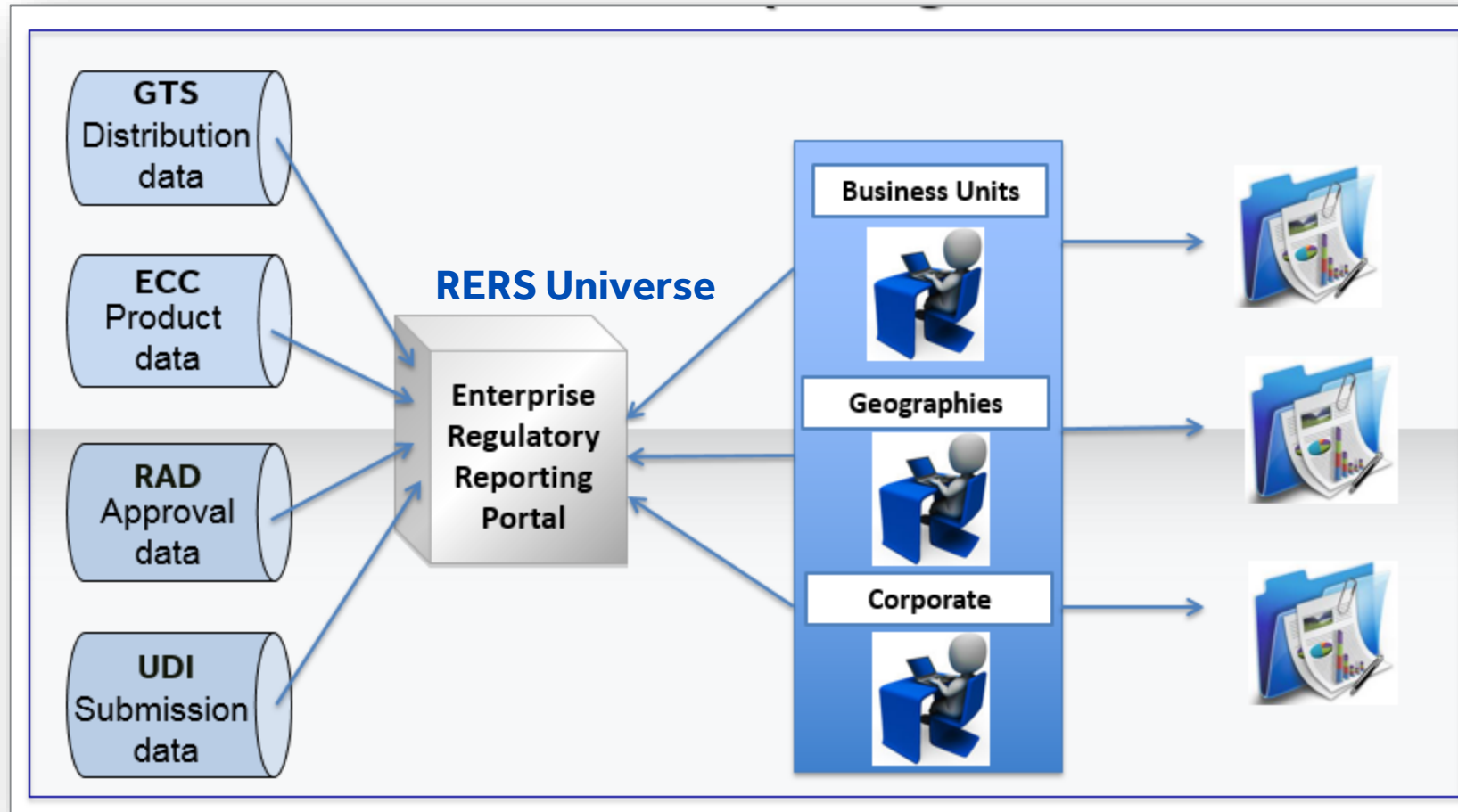
UNIVERSE DATA PROCESSES

- Source data from four systems are processed through various data layers
- Data are normalized and linked in these layers based on business rules
- HANA is the final semantic layer for reporting tool
- End users access data from the HANA layer via self service Business Objects reporting tool



REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

SELF-SERVICE REPORTING MODEL



From RERS portal users can:

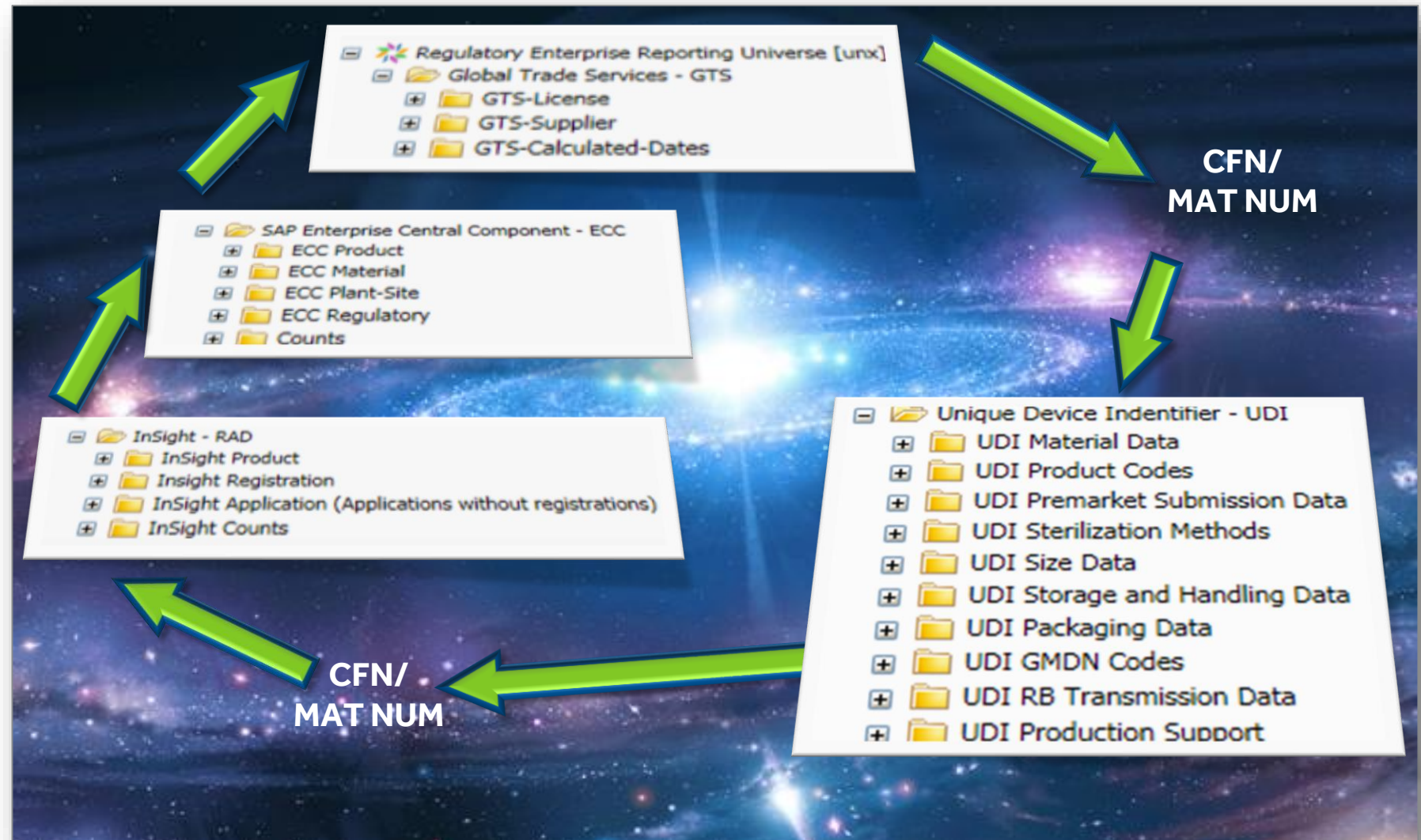
- Run Standard Reports
- Build Ad Hoc Reports
- Create Single System Report
- Create Cross Systems report

REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

UNIVERSE DESIGN LAYOUT



Universe
data
sources
connected
via
**CFN/Material
Number**
across
four
systems



3. UNIVERSE TERMINOLOGY AND DEFINITIONS



REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

UNIVERSE TERMINOLOGY & DEFINITIONS



BO Webi:

- Business Objects Web Intelligence is a SAP query and analysis tool for reporting

BO Universe:

- Universe serves as a “Semantic Layer” for users to interface
- Layer between front-end reporting tool i.e. BO Webi and backend data sources i.e. RAD InSight
- BO Universe is basically made up of files and folders with objects and classes, which map to data sources

Ad hoc Report:

- Created on-demand and with no set schedule or criteria
- Allow users to create specific and customized queries on demand

Standard Report:

- Predefined reports with fixed filters and criteria
- Reports are tested, verified and backed up in BO server
- Reports are run on demand or on schedule by users
- Resides in BO public folders and has authorized user access

REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

UNIVERSE TERMINOLOGY & DEFINITIONS, CONTINUED



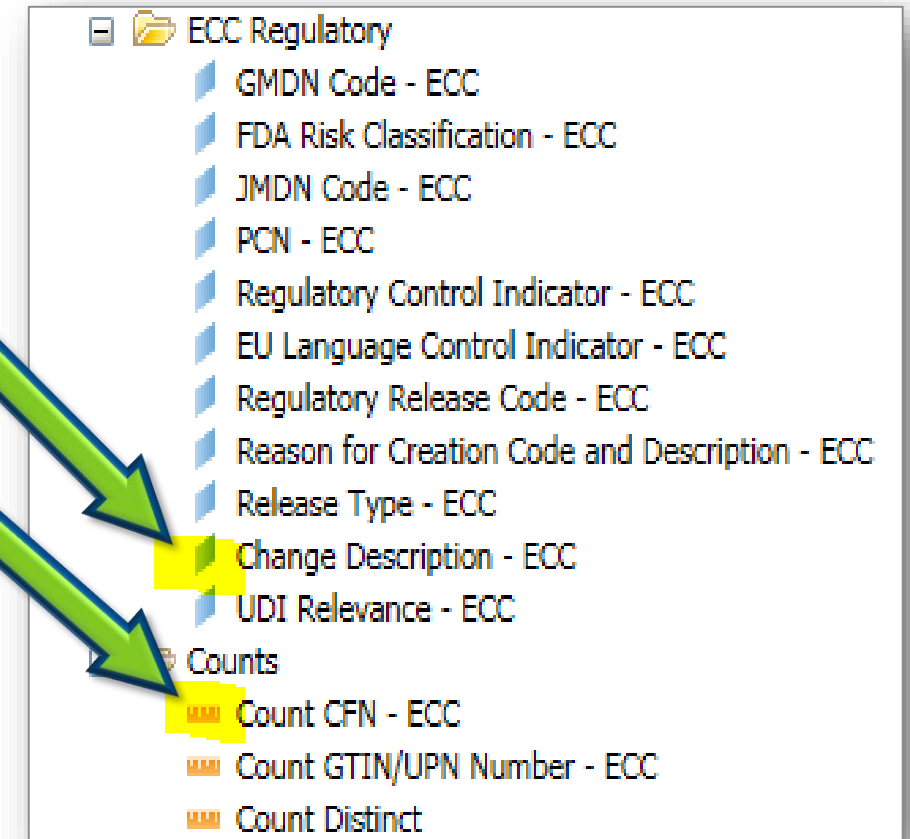
Object: It is a data attribute which maps and named to be consistent with source application. Objects can be qualified as different types:

Dimension objects (denoted by a **blue** icon) typically bring character-type data e.g. names, descriptions or dates

Measure objects (denoted by an **orange** icon) bring numeric data or data that is calculated like Count objects e.g. Count-CFN

Class: Equivalent to folder, a logical grouping of objects within the universe

Subclass: Equivalent to sub-folder, which can be further divided into subclasses containing related objects



Objects are related within folders and sub-folders

REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

SECTION SUMMARY #1



- 1. There are four data source systems in the RERS universe: SAP-GTS, RAD InSight, SAP-ECC, SAP-UDI**
- 2. RERS users must have basic understanding of source systems, data and their regulatory process.**
- 3. End users access data from the HANA data layer via self service Business Objects reporting tool.**
- 4. From the RERS universe users can:**
 1. Run standard report
 2. Build ad hoc reports
 3. Create single system report
 4. Create multiple cross systems report
- 5. RERS universe is designed like Folder and Sub-Folder structure that are called Class and Sub-Class.**
- 6. Source data attributes in the RERS universe are called Objects, which are character dimension or calculated measure object types**

4. UNIVERSE DESIGN & DATA RELATIONSHIPS





What is unique about RERS universe?

Objects/Attributes are joined across and between source systems to link data

- By common CFNs
- By common GTIN/UPN/Material attributes

What does it mean?

REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

UNIVERSE DESIGN & DATA RELATIONSHIPS, CONTINUED



Important !

1. When data is pulled across multiple systems into a single report, it will **NOT** bring those records where there is missing CFN in any one system
 - Report will only bring matched records across all systems

Please see sample report with query objects: CFN-GTS, CFN-ECC, CFN-RAD, CFN-UDI & etc.

Report brings all rows of matching CFNs from all four system. If a CFN is missing in any one column then the entire row will not show up on the report

CFN - GTS	CFN - ECC	CFN - RAD	Version or Model Number (CFN) - UDI	Count CFN – GTS	Count CFN - ECC	Count CFN - RAD
000-2090	000-2090	000-2090	000-2090	1	1	1
000505	000505	000505	000505	2	2	2
001253	001253	001253	001253	1	1	1
001254	001254	001254	001254	1	1	1

REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

UNIVERSE DESIGN & DATA RELATIONSHIPS, CONTINUED



Important !

2. Objects are also joined within their source systems
 - RAD-Application → Registration → Product → Event
 - GTS/ECC- License → Product → Material → Legal Reg
3. Objects can be pulled from multiple classes onto a report, where they are logically related
4. Some objects do not logically relate to each other and should not be combined within a single report

For Example:

Mixing objects from **InSight Registrations** folder with **InSight Application (with/without registration)** folder on to same report will produce erroneous result.



Stay within Registration folder to access **registered application, product, event and task records**

REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

UNIVERSE DESIGN & DATA RELATIONSHIPS, CONTINUED



Important !

5. Multiple systems with similar product data create many to many relationships in data which results in multiple/duplicate data rows in a report
6. When lots of objects are brought into a report, it will show repeated rows, when any single column value is different including NULL value

CFN - GTS	Count CFN - GTS	CFN - ECC	Count CFN - ECC	Material Number - ECC	Count Material Number - ECC
000-2090	1	000-2090	1	000-2090	1
000-2090	1	000-2090	1	00643169620193	1
000-2090	1	000-2090	1	00673978001760	1
000505	1	000505	1	00613994236401	1
001203	1	001203	1	00681490013369	1
001253	1	001253	1	00681490013376	1
001253	1	001253	1	20613994964520	1

7. Bringing objects like CFN/UPN/Material Number all such number attributes on to a report could easily bring over a million rows.
8. It is important to lower row counts by using **query filters, date parameters and count objects to avoid:**

* Duplicate rows * Partial results * Stalling reports

REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

SECTION SUMMARY #2



1. **Data attributes in the RERS universe are connected across source systems via common CFN or GTIN/UPN/Material I Number**
2. **When attributes are brought from all systems onto a single report, it will only bring records where all four systems has same matching CFN and possibly with repeated rows due to multiple data joins.**
3. **Mixing objects from InSight Registrations folder with InSight Application (with/without registration) folder on to same report will produce erroneous result.**

5. SELF TRAINING RESOURCES, KNOWLEDGE BASE AND VIDEO LIBRARY



REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

SELF-SERVE TRAINING RESOURCES, KNOWLEDGE BASE AND VIDEO LIBRARY



RERS site:

Standard report links, training, resources and reference materials all posted

<http://sitebuilder2.medtronic.com/corporate/Regulatory/Pages/Systems/EnterpriseRegulatorySystemsReporting.aspx>

RERS (REGULATORY ENTERPRISE REPORTING SYSTEM) HOME PAGE

GTS/ECC STANDARD REPORT LINKS	REPORT DESCRIPTION Click here for report detail FDD (functional design document)
1-Material Attributes Report	Provides information on materials from both ECC and GTS to help users determine whether a material should be added to a GTS license for a specific country/geography
2-Identify Material Released to Status 30 in Last Week	Shows which materials have had Cross Plant Status moved to 30 in a specified timeframe
3-Identify Material Sales Org Extension	Indicates whether a specific material is extended for sales to a sales organization and whether this material is extended to a specific plant location or distribution center
4-Identify Product Classification for Use with PCN	Displays the risk classification for a specific product in a country and identifies whether a PCN must be sent to a specific country based on that classification
5-Identify GTS License Renewals	Helps users determine when their approval expires

RAD STANDARD REPORT LINKS	REPORT DESCRIPTION Click here for report detail FDD (functional design document)
1-RAD Registration Summary Report	Shows registration product information by geography to track where products are approved for sale and when licenses are set to expire
2-RAD Application Summary Report	Presents approval status information of products in a geography including date information at the application level
3-RAD Product Family Summary Report	Identifies product/product family attributes assigned to a CFN as well as product attributes for products in a specific product family
4-RAD Product Family Registration Report	Displays registration information for approved product families

HELPFUL LINKS & RESOURCES

- RERS Business Objects Login
- Open Ticket for RERS Issue
- New User - Request Access To RERS

- RERS Library
- RERS Universe Data Dictionary
- RERS Universe Usage Metric
- RERS CAB Page

MIX - RERS
MEDTRONIC INFORMATION EXCHANGE

==== ROAD SHOW ====

USER TRAINING LINKS

- RERS How to Get Started
- RERS Training Video Library
- RERS Standard Report Summary

- RERS WebEx Training
- RERS Training Slide Deck

- RERS Reference Guideline
- RERS Batch Attributes Guideline

REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

SELF-SERVE TRAINING RESOURCES, KNOWLEDGE BASE AND VIDEO LIBRARY



Library of Video Shorts

There are short 5-8 minutes video shorts in VBrick library showing how to use BO tool for both beginner and advanced users

Link to library is posted under Training Link on RERS site

USER TRAINING LINKS

- RERS How to Get Started
- **RERS Training Video Library**
- RERS Standard Report Summary
- RERS WebEx Training
- RERS Training Slide Deck
- RERS Reference Guideline
- RERS Batch Attributes Guideline



The screenshot displays the Medtronic Regulatory Affairs website. The header includes the Medtronic logo and 'REGULATORY AFFAIRS' in a large blue box. Below the header is a navigation bar with links: HOME, ADVOCACY & GOVERNANCE, NEW & CHANGING REQUIREMENTS, STANDARDS, REGULATORY INFORMATION MANAGEMENT, and CORPORATE PMO. The main content area is titled '(RERS) Regulatory Enterprise Reporting System Training' with a 'VIDEO LIBRARY' sub-header. The page is organized into several sections: 'Introductory Videos' with links for new users; 'Standard Report for Beginners' with a list of 5 video topics; 'Ad-hoc Report for Beginners' with a list of 8 video topics; 'RERS for RAD InSight 6.1' with 2 video topics; and 'Ad-hoc Report for Intermediate-Advanced Users' with a list of 10 video topics. A large green arrow points from the 'RERS Training Video Library' link in the left sidebar to the video library section on the right.

Medtronic REGULATORY AFFAIRS

HOME ADVOCACY & GOVERNANCE NEW & CHANGING REQUIREMENTS STANDARDS REGULATORY INFORMATION MANAGEMENT CORPORATE PMO

(RERS) Regulatory Enterprise Reporting System Training

VIDEO LIBRARY

Introductory Videos

1. [Accessing RERS & Setting Preferences \(New Users\)](#)
 - a. [Instructions for Requesting Access to RERS](#)
 - b. [Link to RERS Production URL](#)

Standard Report for Beginners

1. [Standard Report Basics](#)
2. [Viewing Standard Report Results](#)
3. [Creating Saved Variants](#)
4. [Using Saved Variants](#)
5. [Exporting Ad-hoc or Standard Reports to Excel](#)

Ad-hoc Report for Beginners

1. [Ad-hoc Reporting Basics](#)
2. [Exporting Ad-hoc or Standard Reports to Excel](#)
3. [Saving Reports](#)
4. [Sending Reports](#)
5. [Locating Ad-hoc Reports](#)
6. [Filtering Ad-hoc Reports](#)
7. [Using Count Measures in Ad-hoc Reports](#)
8. [Techniques to Limit Results](#)

RERS for RAD InSight 6.1

1. [Ad-hoc vs Standard Reports for InSight Data without CFNs Associated](#)
2. [Working with InSight Calculated Objects](#)

Ad-hoc Report for Intermediate-Advanced Users

1. [Naming or Re-naming Reports](#)
2. [Adding Prompts to Ad-hoc Reports](#)
3. [Adding Page Numbers to Ad-hoc Reports](#)
4. [Repeating Table Headers & Footers Across Pages](#)
5. [Using Drill-Downs and Snapshots in Reports](#)
6. [Adding Count or Sum functions to Ad-hoc Reports](#)
7. [Adding a Query Summary Tab to Ad-hoc Reports](#)
8. [Adding Section Breaks to Ad-hoc Reports](#)
9. [Additional Pre-Defined Cell Options for Enhancing Ad-hoc Reports](#)
 - a. Document Name
 - b. Last Refresh Date
 - c. Drill Filter
10. [Tip for adding a long list of values to a report filter](#)

REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

SELF-SERVE TRAINING RESOURCES, KNOWLEDGE BASE AND VIDEO LIBRARY



Universe Data Dictionary:

Contains objects/attributes in multiple tabs mapped from source systems data:

- Name
- Description
- Data sources
- Technical definition
- Location
- Other Details

Business Data Dictionary	
Reporting Universe Field Label	Field Description
CFN - GTS	Customer facing number. Used for gap reporting to find any licenses in GTS that have been created, but not associated to a product.
Legal Regulation Code - GTS	A Legal Regulation is a country or geography that has specific legal requirements for medical device regulations.
Legal Regulation Code and Description - GTS	A Legal Regulation is a country or geography that has specific legal requirements for medical device regulations.
License Number - GTS	License number is a unique auto-assigned number by the system. This number starts with a 2 and is 18 digits long.
External License Number - GTS	External license number is entered by the user and has the following format: approval number_YYYY/MM/DD with a few exceptions.
License Type - GTS	License type corresponds to the types of approvals or approval restrictions.
License Creation Date - GTS	The date the specific license was created
<div><div>GTS</div><div>ECC</div><div>RAD</div><div>UDI</div><div>+</div></div>	



REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

SELF-SERVE TRAINING RESOURCES, KNOWLEDGE BASE AND VIDEO LIBRARY



Library of Video Shorts

Medtronic

REGULATORY AFFAIRS

HOME

ADVOCACY & GOVERNANCE

NEW & CHANGING REQUIREMENTS

STANDARDS

REGULATORY INFORMATION MANAGEMENT

CORPORATE INFO

(RERS) Regulatory Enterprise Reporting System Training

VIDEO LIBRARY

Introductory Videos

1. Accessing RERS & Setting Preferences (New Users)

a. Instructions for Requesting Access to RERS

b. Link to RERS Production URL

Standard Report for Beginners

1. Standard Report Basics

2. Viewing Standard Report Results

3. Creating Saved Variants

4. Using Saved Variants

5. Exporting Ad-hoc or Standard Reports to Excel

Ad-hoc Report for Beginners

1. Ad-hoc Reporting Basics

2. Exporting Ad-hoc or Standard Reports to Excel

3. Saving Reports

4. Sending Reports

5. Locating Ad-hoc Reports

6. Filtering Ad-hoc Reports

7. Using Count Measures in Ad-hoc Reports

8. Techniques to Limit Results

RERS for RAD InSight 6.1

1. Ad-hoc vs Standard Reports for InSight Data without CFNs Associated

2. Working with InSight Calculated Objects

Ad-hoc Report for Intermediate-Advanced Users

1. Naming or Re-naming Reports

2. Adding Prompts to Ad-hoc Reports

3. Adding Page Numbers to Ad-hoc Reports

4. Repeating Table Headers & Footers Across Pages

5. Using Drill-Downs and Snapshots in Reports

6. Adding Count or Sum functions to Ad-hoc Reports

7. Adding a Query Summary Tab to Ad-hoc Reports

8. Adding Section Breaks to Ad-hoc Reports

9. Additional Pre-Defined Cell Options for Enhancing Ad-hoc Reports

a. Document Name

b. Last Refresh Date

c. Drill Filter

10. Tip for adding a long list of values to a report filter

Universe Data Dictionary

Business Data Dictionary	
Reporting Universe Field Label	Field Description
CFN - GTS	Customer facing number. Used for gap reporting to find any licenses in GTS that have been created, but not associated to a product.
Legal Regulation Code - GTS	A Legal Regulation is a country or geography that has specific legal requirements for medical device regulations.
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License Type - GTS	License type corresponds to the types of approvals or approval restrictions.
License Creation Date - GTS	The date the specific license was created

Library of Documents

ENTERPRISE REPORTING LIBRARY

Type	Name
Folder	1-Production
Folder	2-Current-P
Folder	3-Prior-Rele
Folder	4-Testing
Folder	Others
File	1-Request-f
File	2-Regulator
File	3-Regulator
File	4-Enterprise
File	4-Regulator

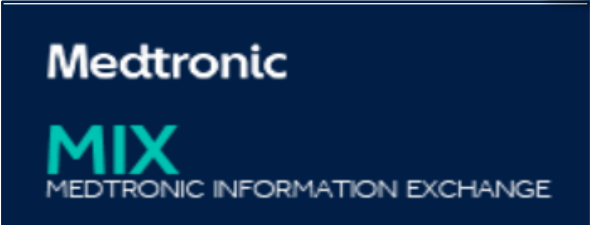
USER TRAINING LINKS

- RERS How to Get Started
- RERS Training Video Library
- RERS Standard Report Summary
- RERS WebEx Training
- RERS Training Slide Deck
- RERS Reference Guideline
- RERS Batch Attributes Guideline

RA User

RERS Ongoing Support

- Monthly RERS CAB for changes and enhancements
- Monthly RERS User Forum for knowledge sharing
- MIX community for user collaboration



REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

SECTION SUMMARY #3



1. **There are abundant training and information resources available from the [RERS](#) site**
2. **Universe Data Dictionary contains** definition, description of attributes, data table names and other details from all source systems in the RERS universe.
3. **Video Library contains** quick video shorts of WebEx demonstrations, instructions and steps for how to use RERS and BO tool.
4. **Training Document Library** contains repository of RERS training, guidelines and supporting documents.
5. **Standard Report** links are posted on the RERS site. These reports are available for authorized users to run as needed for operation and metric.
6. **RERS CAB (Change Advisory Board)** is for BUs and regions. Regulatory SME users are voting members of CAB for changes and enhancements.
7. **RERS User Forum and MIX Community** are user groups meet for discussions and collaboration.

6. IMPORTANT TOP 20 UNIVERSE RULES AND GUIDELINES



REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

IMPORTANT TOP 20 GENERAL UNIVERSE RULES & GUIDELINES



BO Tool & Set up *(please see video shorts library for hands-on instructions).*

1. Make sure preferences in **IE** is set up in HTML mode for easy BO function
2. Chrome browser is not recommended
3. Sessions time outs for IE and BO Server are set to 30 minutes
4. Keep idle session < 15 min in edit/design mode to avoid timeout
5. Universe refreshed twice daily
6. RERS universe data volume/row limit is set to 1 million *(if more rows then report will have partial result and yellow warning sign appears at the bottom right corner of BO report)*
7. Recommend query filter list item limit < 1000 (E.g. GTIN or CFN list)
8. Filter list Items must be separated by semicolon (E.g. 1234;3456;78) for query search

REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

IMPORTANT TOP 20 GENERAL UNIVERSE RULES & GUIDELINES



9. Limit rows by building small query & avoid all-encompassing report.
10. Limit rows by using specific filters such as Date Ranges, BUs, Divisions, Countries, CFN/GTIN/UPN list and etc.
11. Be careful to select objects from appropriate class. For instance, do NOT mix objects from the **RAD Registration** folder with **RAD Application (with/without registration)** folder
12. Remove unnecessary objects and extra columns from query to avoid excessive underlying joins which slows down query
13. For ad hoc query do quick refresh before running query
14. Do quick search on attribute names from universe navigation panel instead of looking for objects through each folder

Please review video shorts library how to do initial set up and above tips

REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

IMPORTANT TOP 20 GENERAL UNIVERSE RULES & GUIDELINES



15. Separate queries must be created if a full set of data is desired from each source system. Use objects within the desired system class.

For example:

- A RAD query should only include objects from the RAD folders
 - A UDI query should only include objects from the UDI folders
16. For combined query across systems, universe will enforce query to be joined by CFN/Material numbers. It will merge attributes with like-flavors of data (E.g. Query with GTS –CFN with RAD CFN will **only** bring matching CFN records from both systems)
17. Save ad hoc report first in your BO inbox and then export it to Excel
18. Schedule report to run at server if it is a big query

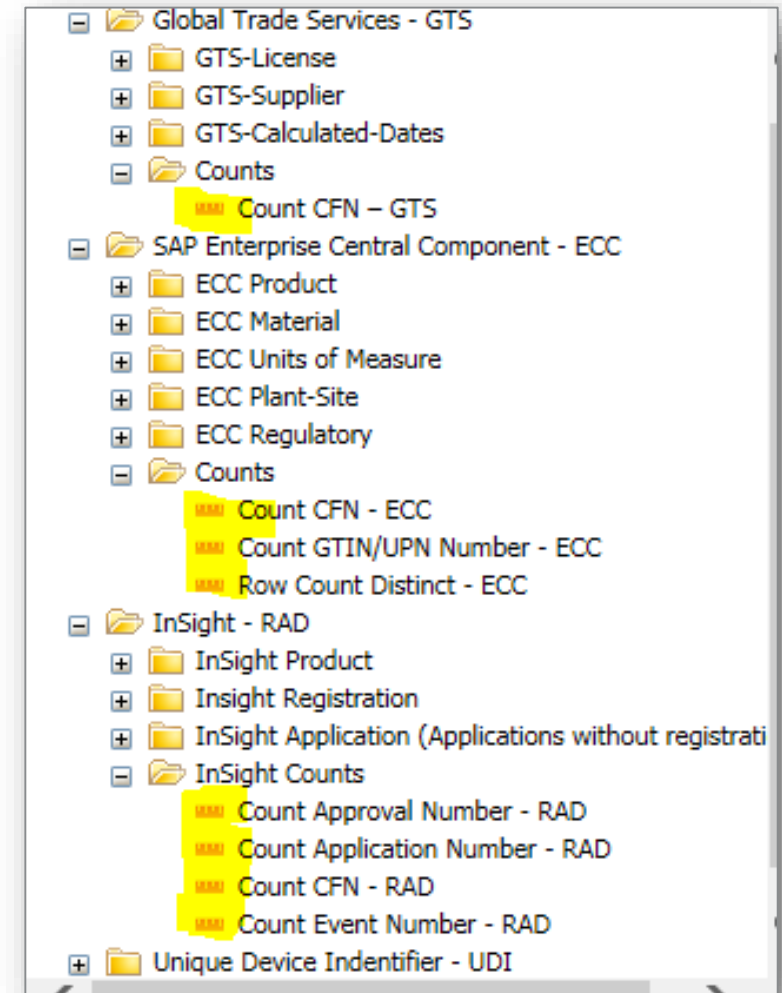
REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

IMPORTANT TOP 20 GENERAL UNIVERSE RULES & GUIDELINES



Important !

19. Use **Count** objects in query when pulling number attributes onto report like CFNs, GTINs, License and Registration numbers
- Due to multiple systems and data joins report returns multiple rows of CFN and GTINs.
 - Having Count objects in query minimizes duplicate rows and partial result error.
 - Use Count objects to aggregate data by row total

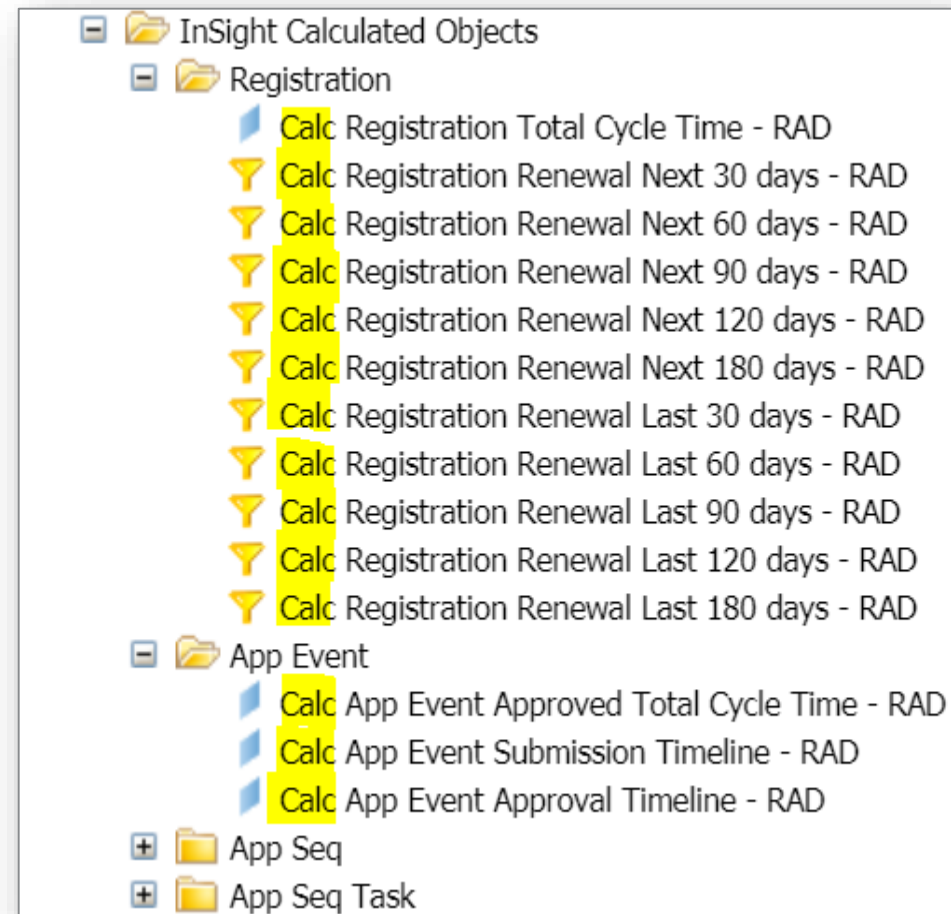


REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

IMPORTANT TOP 20 GENERAL UNIVERSE RULES & GUIDELINES



20. Use built in **precalculated date** objects like for cycle time, renewal time instead of manual calculations



REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

SECTION SUMMARY #4



- 1. The maximum number of rows that can be returned from RERS universe on to a report is one million.**
- 2. Users can and must narrow/limit their search queries from the RERS universe. This practice brings manageable data set and prevents BO server from crashing and slowing down reports.**
- 3. Users can utilize various methods to limit their query search. They can utilize the following ways:**
 - Use Count Objects, it eliminates duplicate rows and also help with data aggregation**
 - Use query filters with attributes like dates, country, business division, BUs**
 - Build small initial query first and test it before building all encompassing data set**
 - Remove unnecessary objects from query to minimize table joins and speed up queries.**

7. KEY UNIVERSE CONSIDERATIONS



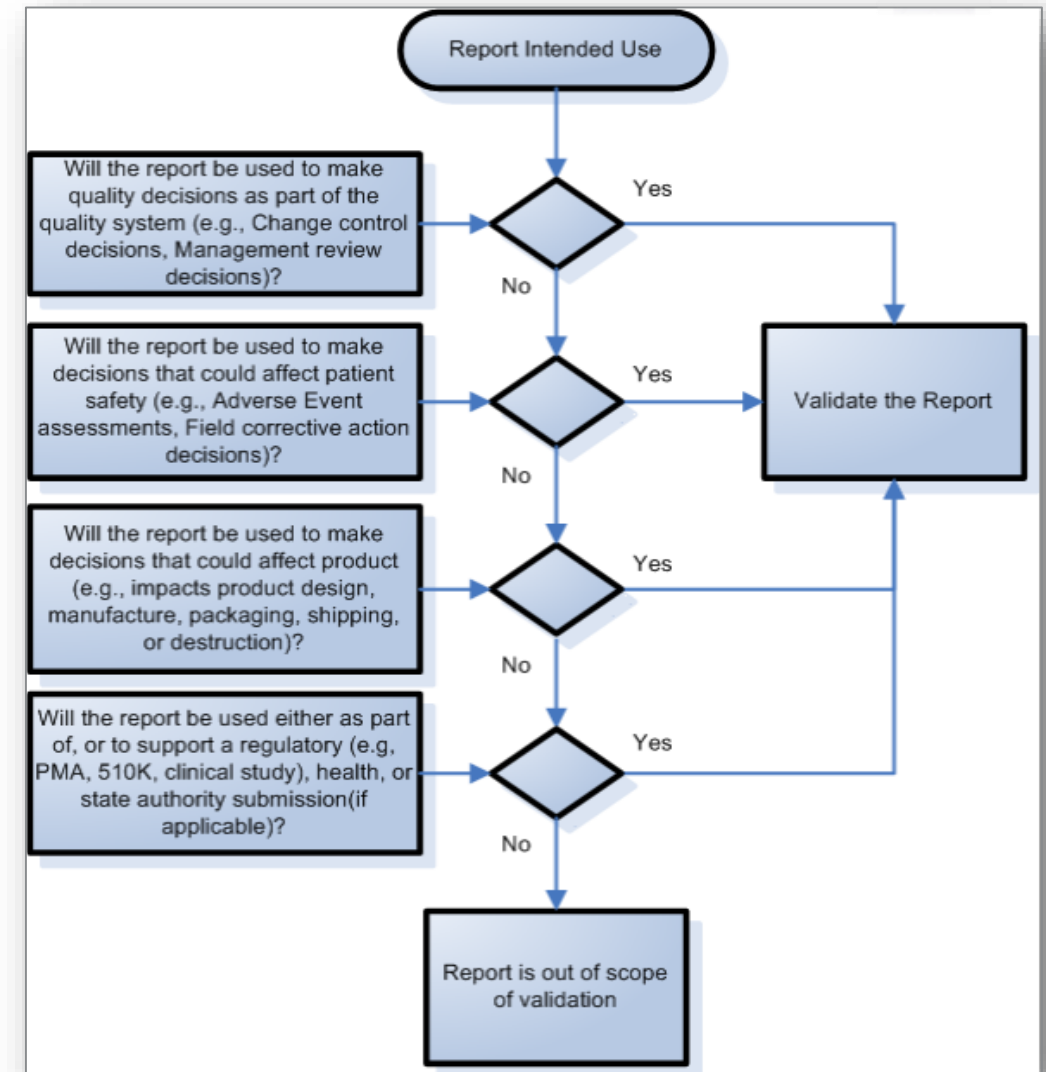
REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

UNIVERSE KEY CONSIDERATIONS

Need Report validation and verification process for **Audit, Quality and CAPA** purpose

- Users will be required to validate their report and document per Medtronic System Compliance Methodology (MSCM) report validation process: **SOP130918-SOP**
- Please visit MSCM site for validation process and training:
<http://sitebuilder2/sharedservices/MSCM/SitePages/Report%20Validation.aspx>

RERS UNIVERSE IS NOT VALIDATED



REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

UNIVERSE KEY CONSIDERATIONS



Date & Time Zone

- It's important to note that dates may be reflected differently due to time zone differences, this may impact reporting results
- All times written in the source system and reporting environment are in Greenwich Mean Time (GMT)
- The reporting environment displays GMT as standard default

Transactions created after 4 pm on the West Coast, 6 pm in the Midwest, or 7 pm in East Coast will show in the following day for reports

8. ACCESS TO RERS UNIVERSE AND INITIAL SETUP



REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

ACCESS TO RERS UNIVERSE



- Service Now process set up to request access for new user (steps are posted on [RERS site](#))
- User must submit request for **Regulatory AdHoc** access to RERS universe and reports
- User must submit separate request for **Regulatory AdHoc Restricted** for Batch Reports
- **User must complete RERS Cornerstone training to gain and retain access**

Network User Name
Network Password
Authentication=LDAP



<http://globalreporting.medtronic.com/>

REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

INITIAL UNIVERSE PREFERENCE SETUP



Important !

- Use **Internet Explorer** (do not use Chrome)
- After login, click on **Preferences**
- Select **Web Intelligence**
- Select **HTML** and then **Save**

The screenshot shows the SAP Web Intelligence interface. The top navigation bar includes 'Home', 'Documents', and 'Applications'. The 'Applications' dropdown menu is open, and the 'Preferences' option is highlighted with a red circle and a green arrow pointing to it. The 'Preferences' window is displayed, showing a list of categories on the left: 'General', 'Locales and Time Zones', 'Analysis edition for OLAP', 'Web Intelligence', 'BI workspaces', and 'Crystal Reports'. The 'Web Intelligence' category is selected and highlighted with a green arrow. The 'Web Intelligence' settings are shown on the right, with the 'HTML' option selected under 'View' and 'Modify (creating, editing and analyzing documents):'. The 'HTML' option is highlighted with a green arrow. The 'Modify' section also shows 'HTML' selected, with a green arrow pointing to it. The 'Select a default universe:' section shows 'Regulatory Enterprise Reporting Universe.unx' selected, with a 'Browse ...' button next to it. The 'When viewing a document:' section shows 'Use my preferred viewing locale to format the data' selected.

REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

CHANGE DEFAULT UNIVERSE SETTINGS



- Click on **Preferences** and **Web Intelligence** links and **Browse**
- Select **Regulatory Enterprise Reporting Universe.unx** and then **Save**

The screenshot shows the SAP Web Intelligence Preferences dialog box. The 'Web Intelligence' tab is selected in the left sidebar, indicated by a green arrow. The 'View' section has 'HTML (no download required)' selected. The 'Modify (creating, editing and analyzing documents):' section has 'HTML (no download required)' selected. The 'Select a default universe:' section has 'Regulatory Enterprise Reporting Universe.unx' selected, indicated by a green arrow. The 'Browse...' button is highlighted in yellow, with a green arrow pointing to it. A secondary dialog box is shown, titled 'Web Intelligence', with the instruction 'Select a default universe:'. It lists several universes, with 'Regulatory Enterprise Reporting Universe.unx' selected and highlighted in yellow.

Web Intelligence

Select a default universe:

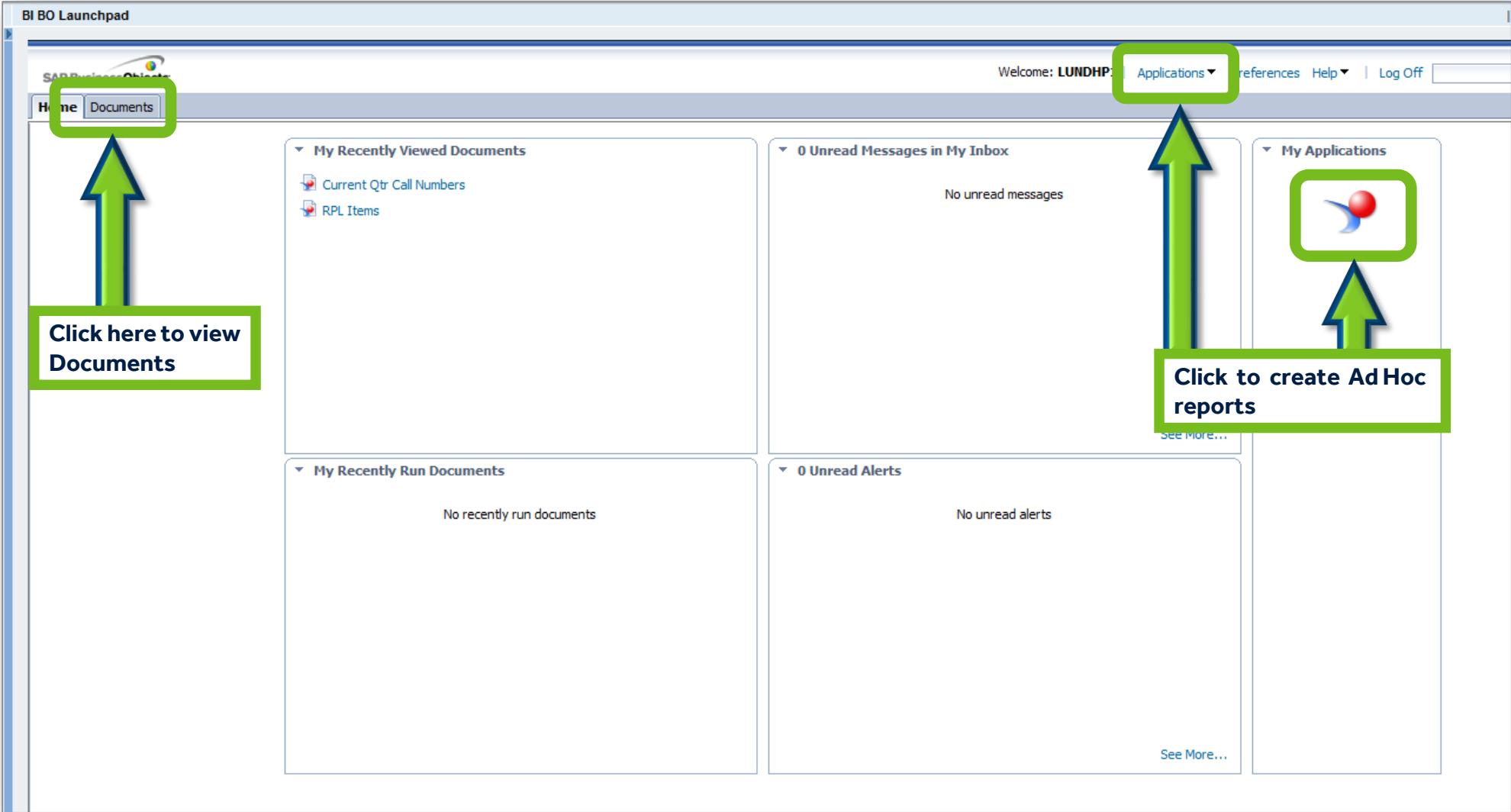
Universe
<input type="radio"/> RPA_Lab_Tracking
<input type="radio"/> CRDM PXM Supp Data.unx
<input type="radio"/> Global Sales Adhoc.unx
<input type="radio"/> Regulatory Affairs Domain (RAD).unx
<input checked="" type="radio"/> Regulatory Enterprise Reporting Universe.unx
<input type="radio"/> GTIN Attributes.unx
<input type="radio"/> GCH.unx
<input type="radio"/> DHR Review Universe

9. ACCESS STANDARD REPORTS



REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

BO LOGIN LANDING PAGE



REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

STANDARD REPORTS



- Click on **Documents** tab and **Folder** link at the bottom
- Navigate to RERS standard report location

The screenshot displays the SAP interface with the 'Documents' tab selected. The 'My Documents' pane on the left shows a tree structure under 'My Favorites' with folders like '.REG', 'ASEAN-Reports', 'GTS-UniverseReport', 'EU-MDR-Reports', 'RegEnterpriseReport', 'TRAINING', '~WebIntelligence', 'Analysis Summ Other Rep', and 'CAPA'. The 'Folders' link at the bottom is highlighted. The 'My Documents' pane on the right shows a tree structure under 'Public Folders' with folders like 'Enterprise Reporting', 'ADHOC', 'GCH', 'Neuro Data Discovery', 'Regulatory Enterprise Reporting', 'Regulatory Standard Reporting' (highlighted), 'Scheduled Reports', 'SABA', and 'Infolytik'. The 'Regulatory Standard Reporting' folder is highlighted. The 'Report List' pane on the right shows a list of 15 reports.

Title
01-Material Attributes Report
02-Material Sales Org Extensions Report
03-Materials Released to Status 30 by Sales Orgs
04-Product Classification for Use with PCN Report
05-GTS License Renewals Report
06-GTS License Renewals - Auto Report
07-GTS and RAD Approval Gap Report for Matching
08-GTS and RAD Approval Gap Report for Non-Ma
09-RAD Product Family Summary Report
10-RAD Product Family Registration Report
11-RAD Registration Summary Report
12-RAD Application Summary Report
13-RAD Application Event Summary Report
14-RAD Sequence Summary Report
15-RAD Task Summary Report

REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

STANDARD REPORTS



Standard Reports are also directly available from the **RERS site** with BO user access

GTS/ECC STANDARD REPORT LINKS	REPORT DESCRIPTION Click here for standard report detail FDD (functional design document)
1-Material Attributes Report	Provides information on materials from both ECC and GTS to help users determine whether a material should be added to a GTS license for a specific country/region.
2-Identify Material Released to Status 30 in Last Week	
3-Identify Material Sales Org Extension	
4-Identify Product Classification Use with PCN	
5-Identify GTS License Renewal	
6-GTS and RAD Approval Gap Report for Matching CFN and Country	
7-GTS and RAD Approval Gap Report for Non-Matching CFN and Country	

RAD STANDARD REPORT LINKS	REPORT DESCRIPTION Click Here for report detail FDD functional design document
1-RAD Registration Summary Report	Shows registration product information by geography to track where products are approved for sale and when licenses are set to expire
2-RAD Application Summary Report	Presents approval status information of products in a geography including date information at the application level
3-RAD Product Family Summary Report	Identifies product/product family attributes assigned to a CFN as well as product attributes for products in a specific product family
4-RAD Product Family Registration Report	Displays registration information for approved product families
5-RAD Application Event Summary Report	Shows status of CFNs for given geographies, information for global events, country specific submission and approval times, and status change information
6-RAD Sequence Summary Report	Identifies sequences for a given period, filing types, manufacturing changes being processed, and sequence status of submissions
7-RAD Task Summary Report (New)	Replaces the Covidien Interim Detailed Task Status Report. Displays status information on task requests submitted by a specific geography
8-RAD Weekly Task Summary Report	<i>This old report will no longer be available after March 30th.</i>
9-Incorrect Task Association	Shows task associated with incorrect user

REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

RUN STANDARD REPORTS



Please utilize the extensive video library on [RERS SITE](#) and watch the following video shorts:

- Standard Reports for Beginners
- Ad-hoc Reports for Beginners
- Ad-hoc Reports for Intermediate-Advanced Users

Medtronic
Further Together

Prompts

Available prompt variants

Prompts Summary

- * Reg Application Region - RAD **Canada;Latin America;Eu**
- * Business Unit - RAD
- * Registration Approval Status - RAD
- Business Division - RAD
- Registration Country Name - RAD
- Class of Trade - RAD
- Product Family Name - RAD
- Reg Application Type - RAD
- RAD Expiration Date >=
- RAD Expiration Date <=
- Registration Approval Date - RAD >=
- Registration Approval Date - RAD <=

Reg Application Region - RAD

Type values here

Refresh Values

Reg Application Region - ...

- Apac
- Canada
- Ceegi
- European Union**
- Greater China
- Latin America
- Mea
- Rest Of World
- United States

Canada
Latin America
European Union

January 28, 2020 1:54:34 AM GMT-06:00

* Required prompts

OK Cancel

Note:
Select required filter values and optional values as needed to run reports

REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

STANDARD REPORTS

Sample standard Report



Navigation
Pane

Multiple
Report Tabs

Home Documents Web Intelligence GTINs sales org exte... GTS and RAD Approval G... GTINs Released to Statu...

Web Intelligence Track Drill Filter Bar Freeze Outline Reading Design

Navigation Map

- RAD Registration Summary Report
- Standard Report
 - Australia
 - Medical Supplies
 - MSP-Chart Paper
 - MSP-HBS-Return Electrodes
 - Neurovascular
 - RTG-NV Alligator
 - RTG-NV Apollo
 - RTG-NV Axiom Coils
 - RTG-NV Axiom Prime Coils
 - RTG-NV Concerto Coils
 - RTG-NV Echelon Micro Catheter
 - RTG-NV Hydrophilic Guidewires
 - RTG-NV Marathon
 - RTG-NV Marksman
 - RTG-NV Navien
 - RTG-NV Onyx
 - RTG-NV Peripheral Blood Clot Therapy
 - RTG-NV Pipeline Embolization
 - RTG-NV Rebar
 - VT-HyperBalloons
 - VT-Solitaire
 - Vascular Therapies
 - Peripheral
 - Cerebral Devices

Medtronic Further, Together

GTINs Sales Org Extensions

Last Refresh: 11/27/16 4:19:29 AM GMT-06:00

EUREG - European Regulatory

06 - Diabetes

D3 - MINIMED

CFN - ECC	CFN Description - ECC	GTIN/UPN Number - ECC	GTIN/UPN Description - ECC	PCN - ECC	Other Market Limitation (OML) Code - ECC	Other Market Limitation (OML) Description - ECC	Sales Organization Code - ECC	Sales Organization Description - ECC	Plant Code - ECC	Legal Regulation Code - GTS	Legal Regulation Code and Description - GTS	Cross Plant Material Status Code - ECC
MMT-715WWL A	PUMP MMT-715WWL A PRDGM INS V2.1 CL FR	0061399432 6218	PUMP MMT-715W WLA PRDGM INS V2.1 CL FR		CEM	No other market restrictions	S009	MDT Europe	1030	EUREG	EUREG - European Regulatory	50
MMT-715WWL A	PUMP MMT-715WWL A PRDGM INS V2.1 CL FR	0061399432 6218	PUMP MMT-715W WLA PRDGM INS V2.1 CL FR		CEM	No other market restrictions	S009	MDT Europe	1030	EUREG	EUREG - European Regulatory	50
MMT-715WWL A	PUMP MMT-715WWL A PRDGM INS V2.1 CL FR	0061399432 6218	PUMP MMT-715W WLA PRDGM INS V2.1 CL FR		CEM	No other market restrictions	S009	MDT Europe	1030	EUREG	EUREG - European Regulatory	50

Standard Report Unformatted Query Summary

10. PRODUCTION SUPPORT PROCESS



REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

PRODUCTION SUPPORT



Service Now

- Call Help Desk x44111 if urgent reporting issue
Priority P2-level (i.e., BO system is down, logging issue, error messages)
- Send e-mail to help desk for any universe or report-related issues:
 - Default is priority P3-level
 - Medtronic IT Service: medtronicprod@service-now.com
- Log ticket in Service Now
<https://medtronicprod.service-now.com/it/home.do>

Note: when emailing or calling IT help desk or logging ticket, it must be routed to:

- Assigned Group: **BI support BO**
- Configuration Item: **EABI Enterprise Reporting**

REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING

SECTION SUMMARY #5



1. **RERS access request will be granted upon completion of RERS Cornerstone training and certificate attached to the Service Now ticket request.**
2. **You can access standard reports from both BO public folder location or from the RERS site.**
3. **You can get visual demonstrations and instruction of how to run standard/ad hoc reports, how to use RERS universe and BO tool from the RERS Video Library.**
4. **RERS universe is not validated. So users need to do report validation and verification for Audit, Quality and CAPA purpose by following MSCM (Medtronic System Compliance Methodology) procedure.**
5. **For RERS production issue open Service Now IT help desk ticket, and it must be routed to**
Assigned Group: BI support BO
Configuration Item: EABI Enterprise Reporting