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

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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:
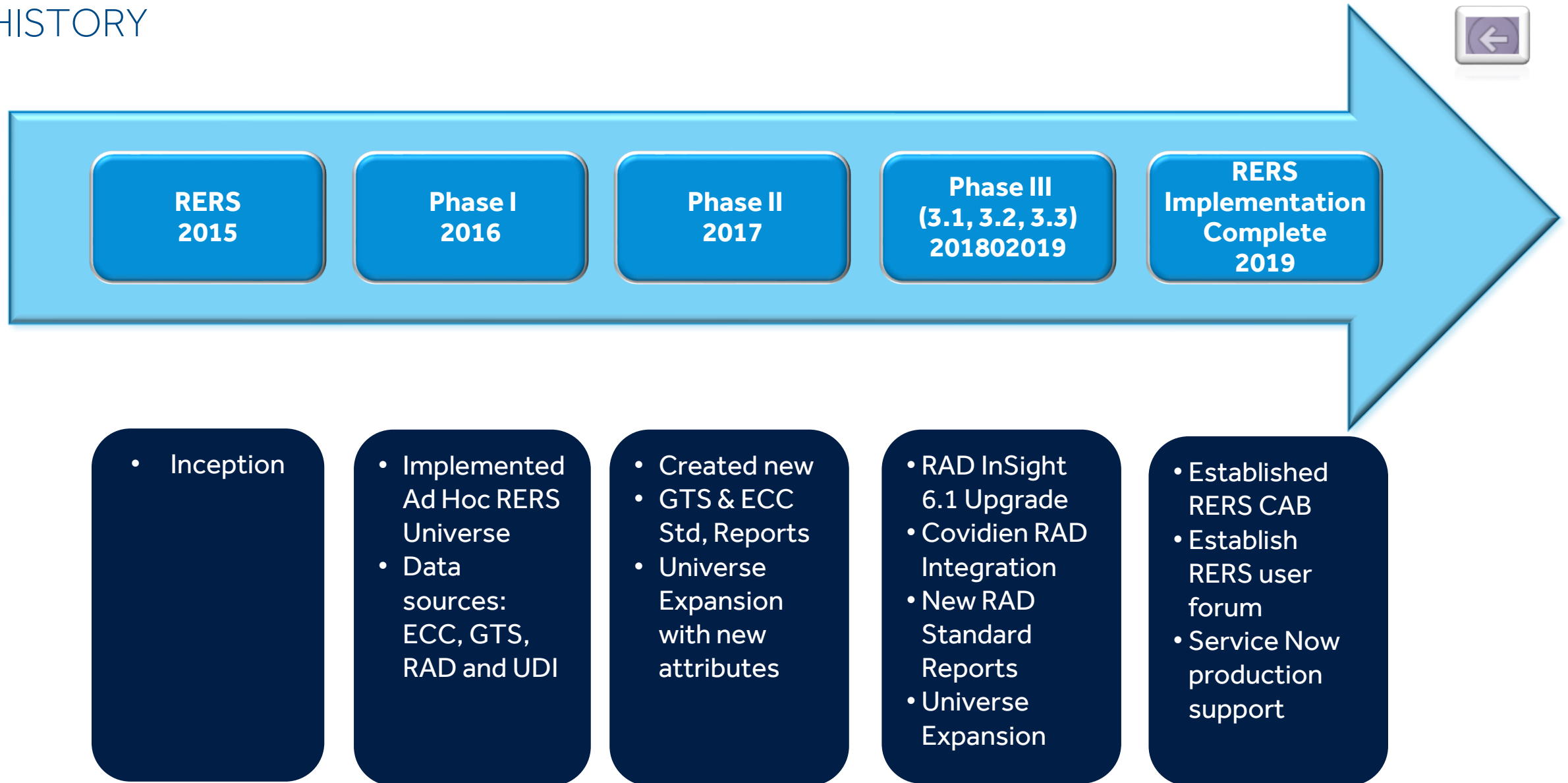
1. RERS history, user requirements and assumptions
2. Framework of universe data sources, processes, design and reporting model
3. Information about BO terminology and definitions
4. Information about universe design and data relationships
5. Self training resources, knowledge base and video library
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

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1. RERS HISTORY, USER REQUIREMENTS AND ASSUMPTIONS

REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING
HISTORY

RERS 2015	Phase I 2016	Phase II 2017	Phase III (3.1, 3.2, 3.3) 201802019	RERS Implementation Complete 2019
• Inception	• Implemented Ad Hoc RERS Universe • Data sources: ECC, GTS, RAD and UDI	• Created new • GTS & ECC Std, Reports • Universe Expansion with new attributes	• RAD InSight 6.1 Upgrade • Covidien RAD Integration • New RAD Standard Reports • Universe Expansion	• Established RERS CAB • Establish RERS user forum • Service Now production support

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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

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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

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

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There are four source data systems in the RERS Universe:

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

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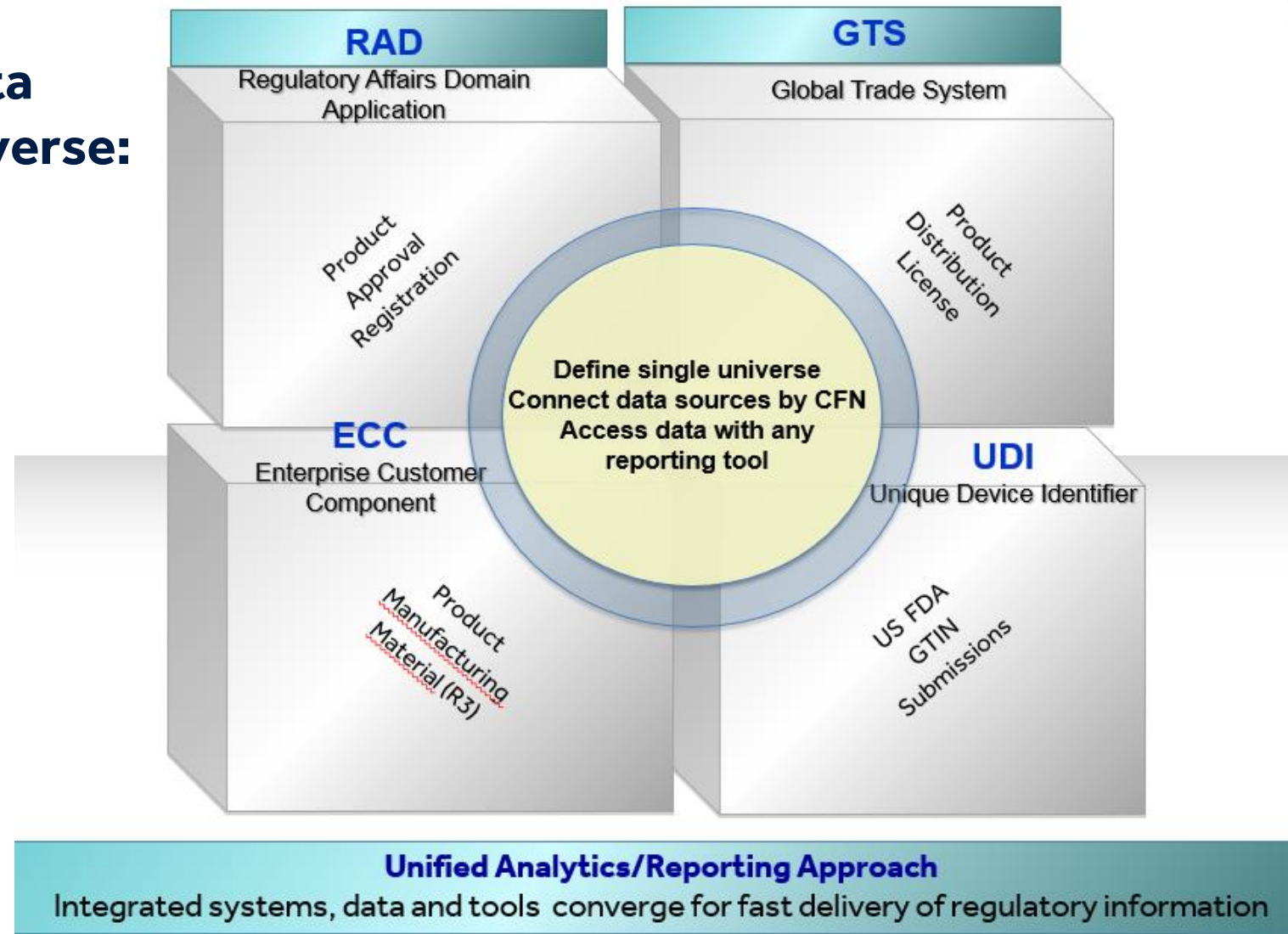
REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING
UNIVERSE DATA PROCESSES

- 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
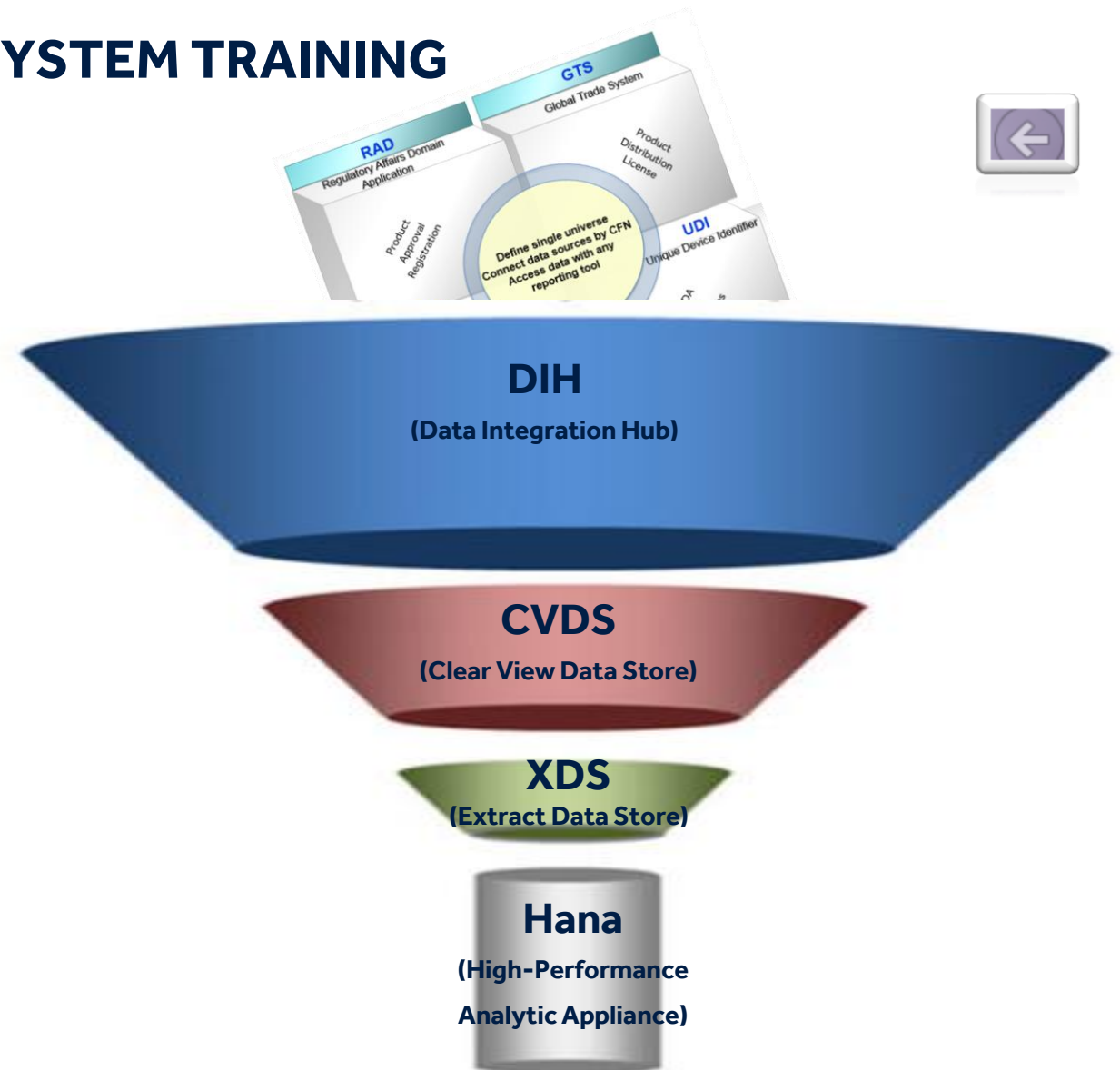
Note: RERS Universe Data is refreshed twice within 24 hours

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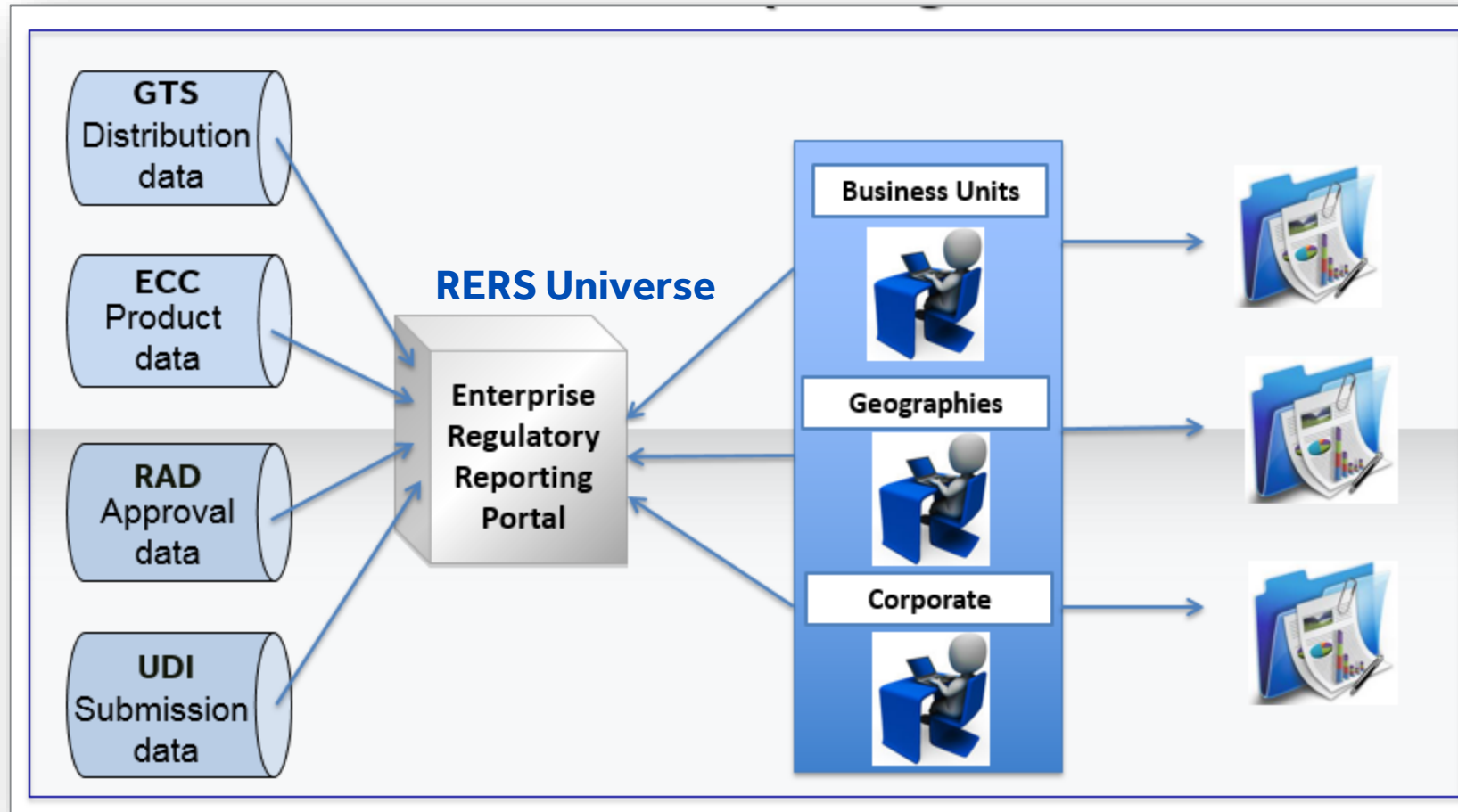
From RERS portal users can:
- **Run Standard Reports**
- **Build Ad Hoc Reports**
- **Create Single System Report**
- **Create Cross Systems report**

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Universe data sources connected via **CFN/Material Number** across four systems
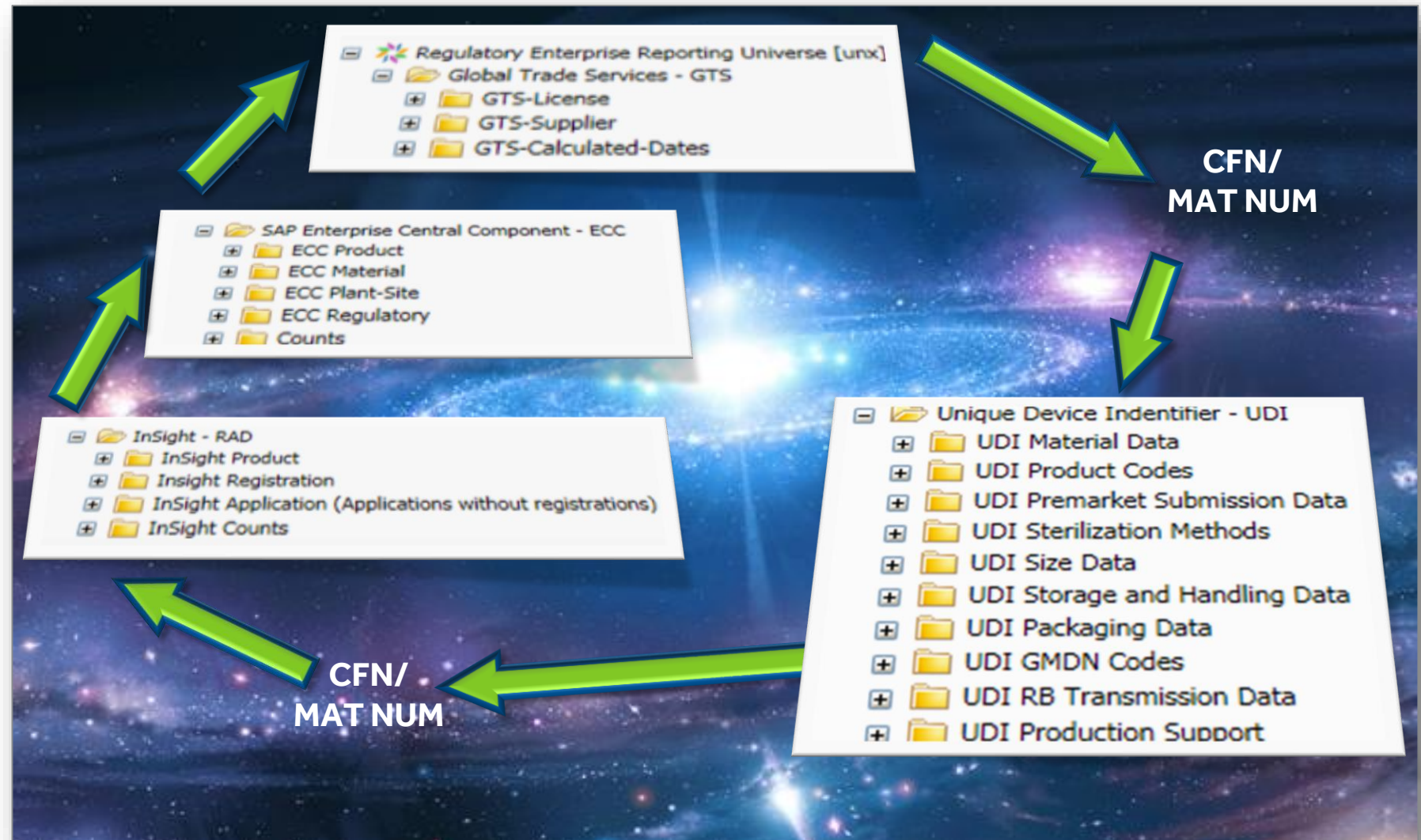
3. UNIVERSE TERMINOLOGY AND DEFINITIONS

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

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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
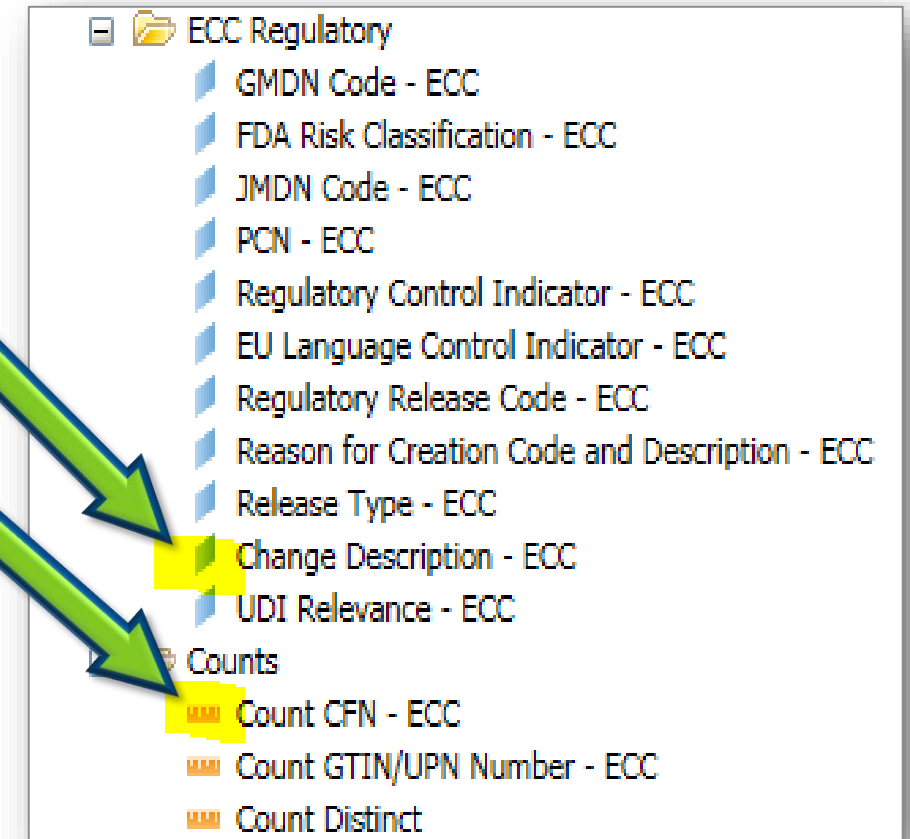
Objects are related within folders and sub-folders

ECC Regulatory
- GMDN Code - ECC
- FDA Risk Classification - ECC
- JMDN Code - ECC
- PCN - ECC
- Regulatory Control Indicator - ECC
- EU Language Control Indicator - ECC
- Regulatory Release Code - ECC
- Reason for Creation Code and Description - ECC
- Release Type - ECC
- Change Description - ECC
- UDI Relevance - ECC

Counts
- Count CFN - ECC
- Count GTIN/UPN Number - ECC
- Count Distinct

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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**

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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?

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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

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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.

InSight - RAD
   InSight Product
   Insight Registration
   InSight Application (Applications without registrations
   InSight Counts

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

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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

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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 l 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 <u>InSight Registrations</u> folder with <u>InSight Application (with/without registration)</u> folder on to same report will produce erroneous result.**

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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

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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

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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

GTS | ECC | RAD | UDI | ⊕

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REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING
SELF-SERVE TRAINING RESOURCES, KNOWLEDGE BASE AND VIDEO LIBRARY

Universe Data Dictionary

Library of Video Shorts

Library of Documents

RA User

RERS Ongoing Support
➢ Monthly RERS CAB for changes and enhancements
➢ Monthly RERS User Forum for knowledge sharing
➢ MIX community for user collaboration

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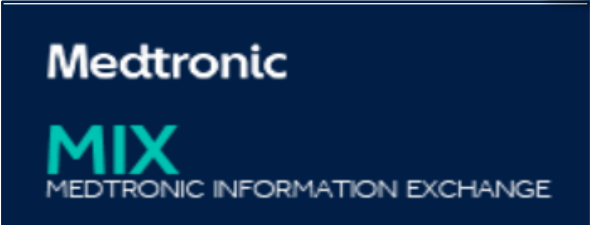
REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING
SECTION SUMMARY #3

1. **There are abundant training and information resources available from the <u>RERS</u> 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.

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6. IMPORTANT TOP 20 UNIVERSE RULES AND 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

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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

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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

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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.
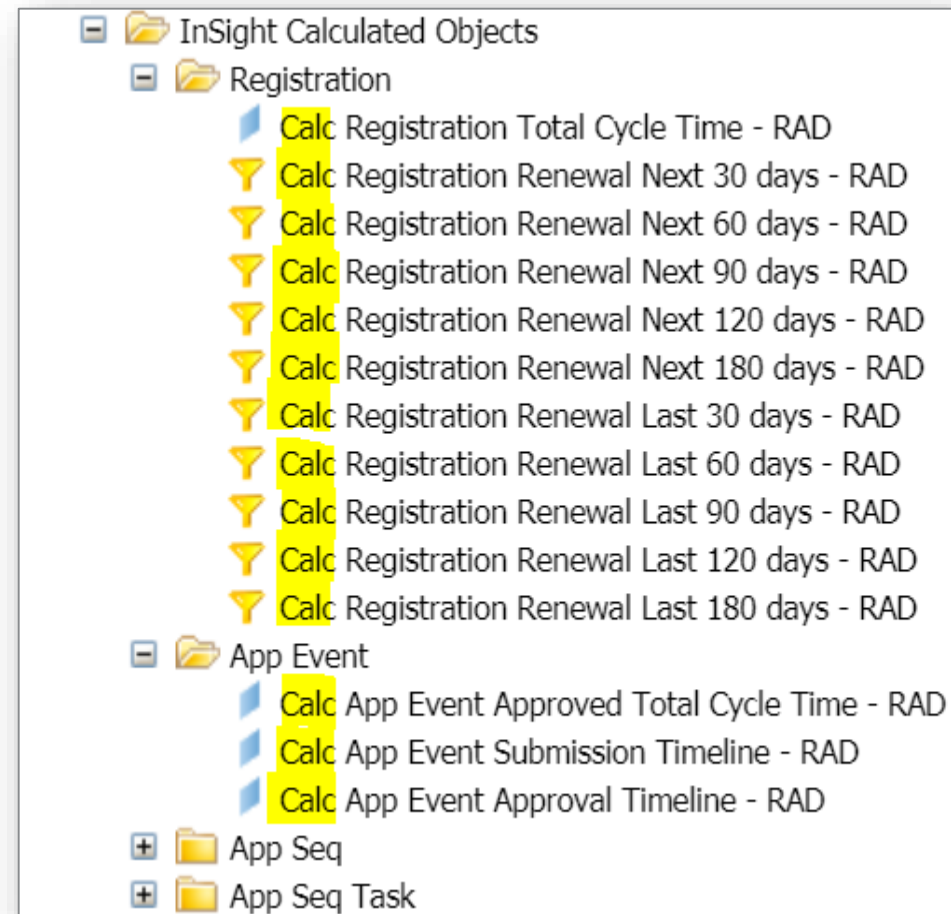   - Use Count objects to aggregate data by row total
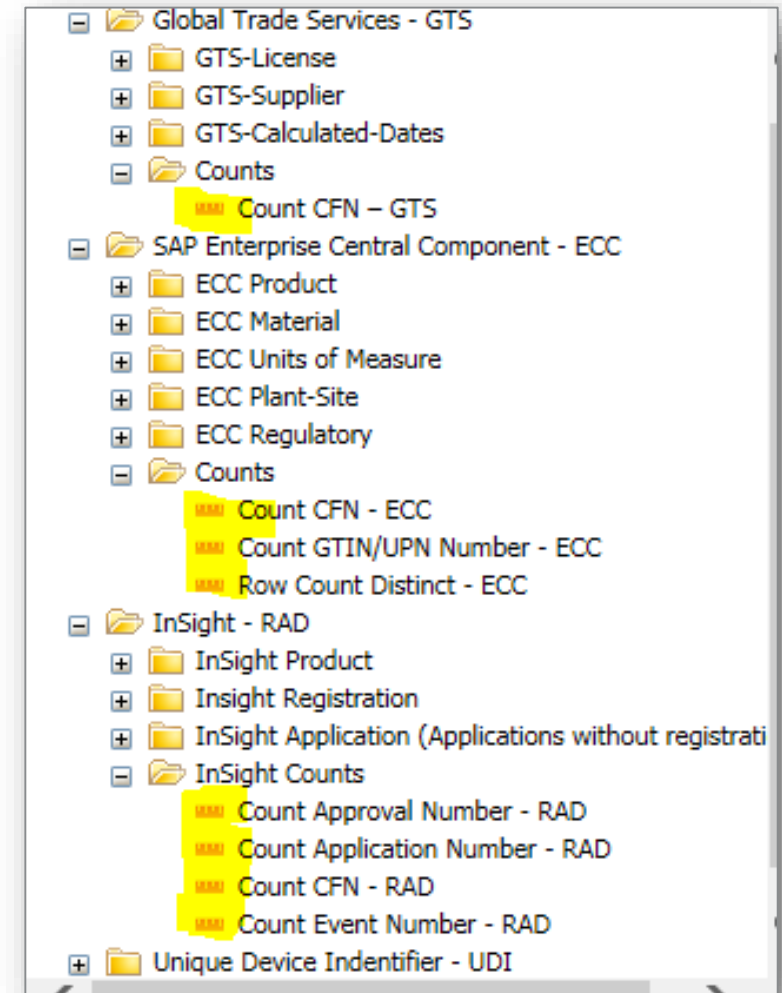
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20. Use built in **precalculated date** objects like for cycle time, renewal time instead of manual calculations

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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.

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7. KEY UNIVERSE 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

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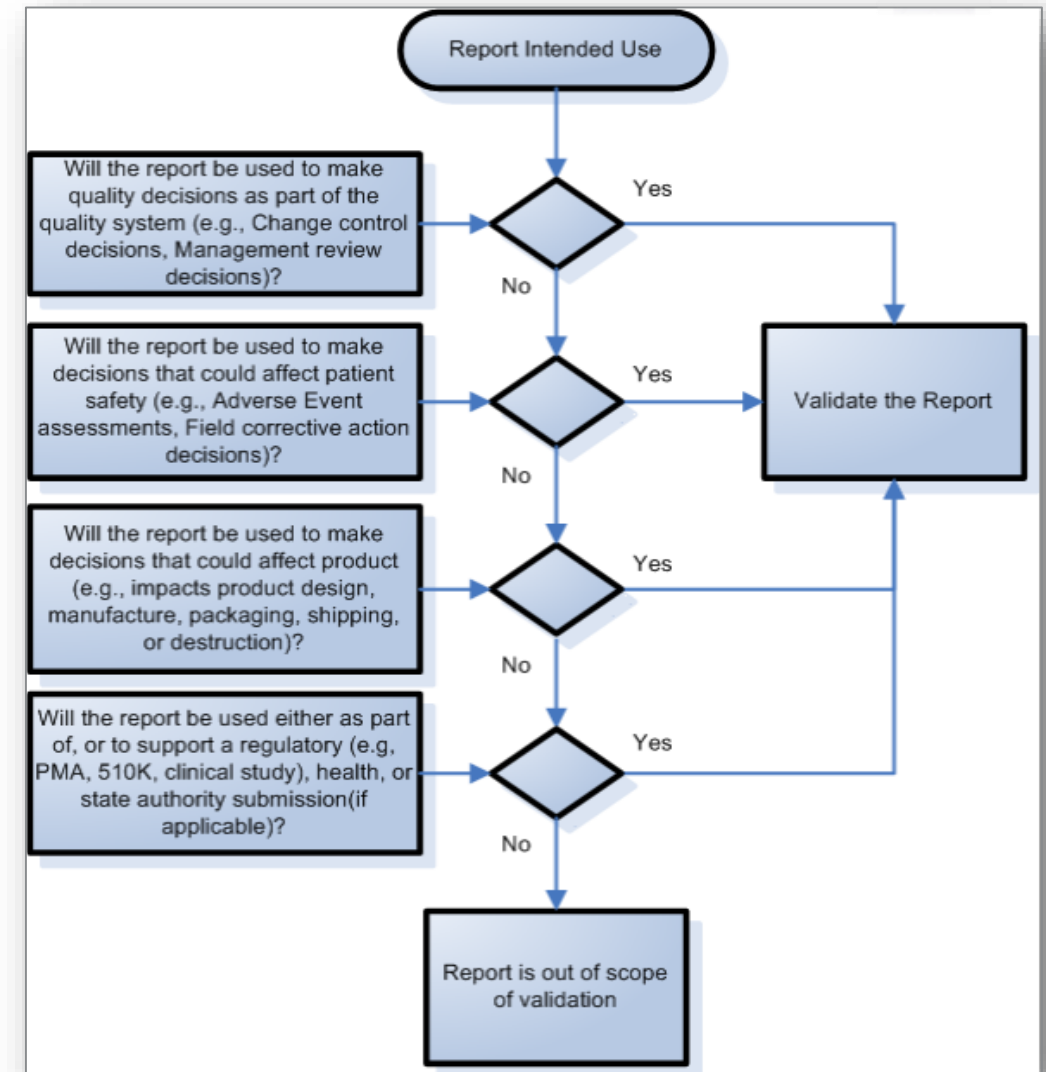
REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING
UNIVERSE KEY CONSIDERATIONS

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

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8. ACCESS TO RERS UNIVERSE AND INITIAL SETUP

➢ 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

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PRODUCTION

| Logon to BI Launchpad |
| What is New in BO 4.1? |
| EUA Applications |

News:

- Welcome to new Global Reporting Environment

http://globalreporting.medtronic.com/

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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**

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

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9. ACCESS STANDARD REPORTS

REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING
BO LOGIN LANDING PAGE

BI BO Launchpad

SAP Business Objects

Welcome: **LUNDHP**   Applications ▼   references   Help ▼ | Log Off

Home | Documents

▼ **My Recently Viewed Documents**
- Current Qtr Call Numbers
- RPL Items

▼ **0 Unread Messages in My Inbox**

No unread messages

See More...

▼ **My Applications**

▼ **My Recently Run Documents**

No recently run documents

▼ **0 Unread Alerts**

No unread alerts

See More...

Click here to view Documents

Click to create Ad Hoc reports

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REGULATORY ENTERPRISE REPORTING SYSTEM TRAINING
STANDARD REPORTS

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

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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/geography
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 R for Matching CFN and Country	
7–GTS and RAD Approval Gap R for Non-Matching CFN and Cou	

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	*This old report will no longer be available after March 30th.*
9-Incorrect Task Association	Shows task associated with incorrect user

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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

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

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Sample standard Report

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**

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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

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