SCR (Standards Clinical Reporting) a Metadata Driven Reporting System

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SCR Operations Manager

June 13 2012

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Agenda

- What is SCR ?
- SCR Purpose and Scope
- SCR Deliverables and Portfolios
- Detailed components of SCR
  - SCR Front-end GUI
  - “Middleware” – Data Standards Metadata, Deliverable Configuration, etc.
  - SCR Back-End SAS Modules
  - SCR Portal
- Conclusion

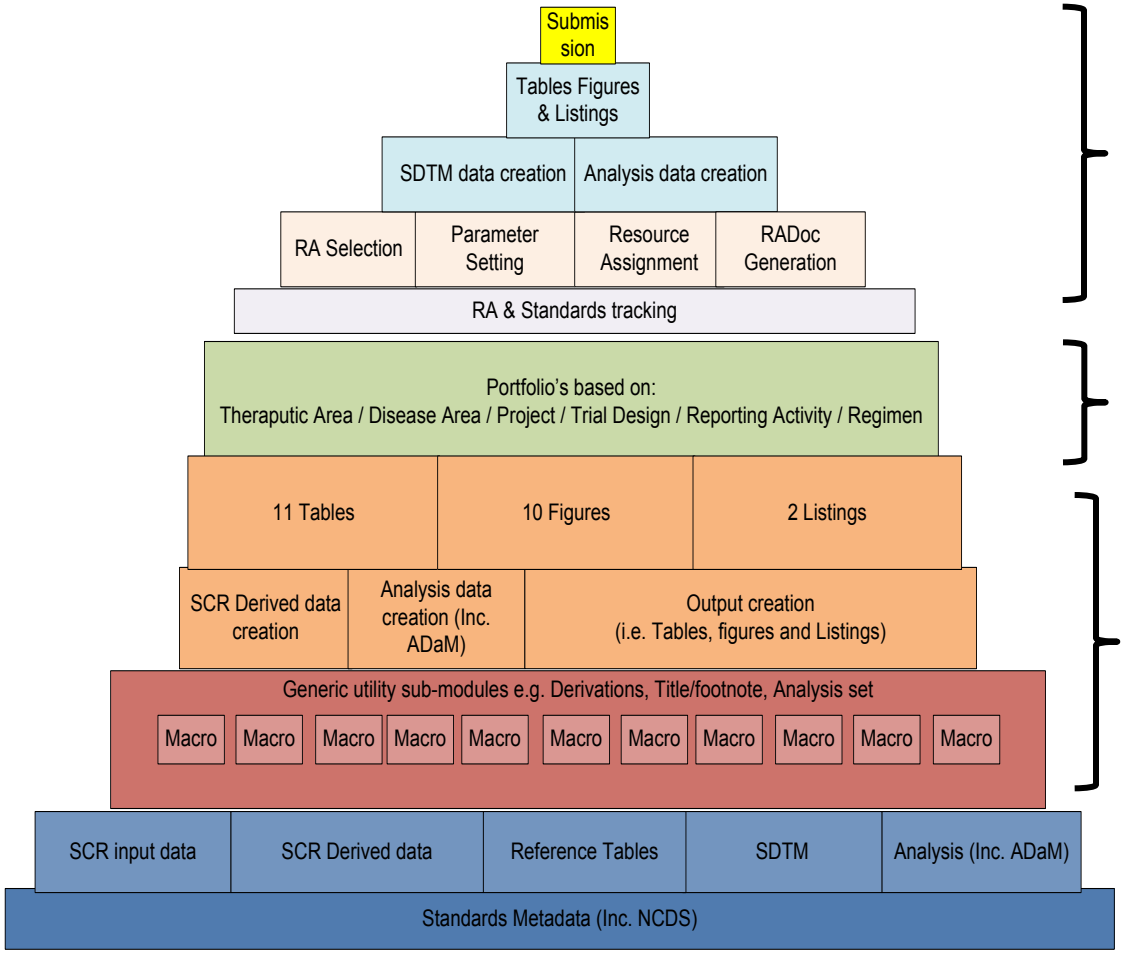
What is SCR?

What is SCR ?

- **SCR** = **S**tandard **C**linical **R**eporting
  - Based on Entimo AG EntimICE platform
- **Reporting system based on reusable metadata to streamlines downstream analysis and reporting**
- Application composed of an **Oracle Database**, a **Front-End** (GUI) and **Back-End** SAS modules. SCR is integrated with Clear Case (Novartis source control system) and sits on GPS (Unix reporting platform)
- **Meta data driven** programming environment for generation of datasets including (SDTM and ADaM) and TLFs for any clinical Reporting activity (RA).
- Library of (several hundreds) standard derivation modules to support reporting activities for all TAs, all trial design (parallel, cross-over, ...), any reporting activity (DMB, IA, CSR, PUB,...)

What is SCR ?

SCR Architecture overview



Reporting Activity Document Functionality – End-Users manipulate metadata controlling library of re-usable objects

Project define and SCR support team implements

Output Governance Deliverable approves

Metadata

SCR contains configurable generic, reusable, metadata driven, SAS macros for analysis and reporting against data collected in Data Standards

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SCR Purpose and Scope

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SCR Purpose and Scope

- SCR is an application that provides fast and efficient planning, setup and execution of Data Analysis & Reporting through reusability of generic elements and a GUI setup facility
- SCR is a highly configurable, flexible application
- SCR is not dependent on data standard because of the generic way it has been developed
- It is fully anticipated that additional deliverables, derivations, and datasets will be developed and configured as the application evolves and SCR becomes more & more widely used.
- Long term goal is to provide ~80% of reporting activity needs
- SCR can be used to create non-standard & non-SCR components e.g. custom outputs

SCR Purpose and Scope

- SCR provides a built-in, intuitive workflow for the Reporting Activity setup and execution (business workflow)
- The interface utilizes a tab structure that requires the User to enter and modify attributes related to the RA in a sequential process
- Users select standard components (portfolios and individual datasets and outputs) from the standards Library.
- Once setup has been completed SCR will generate dataset and report specifications for standard and non-standard deliverables

SCR Purpose and Scope

- SCR provides automatic real-time Reporting Activity tracking reports on the status of the reporting process e.g. number of validated programs
- There is an extended validation tool within SCR which uses user notifications and validations lists to assist users
- Standards metrics for each RA are available online for review (Link)
- Export to the documentum environment is available to deliver reports.

SCR Deliverables and Portfolios

SCR Deliverables and Portfolios

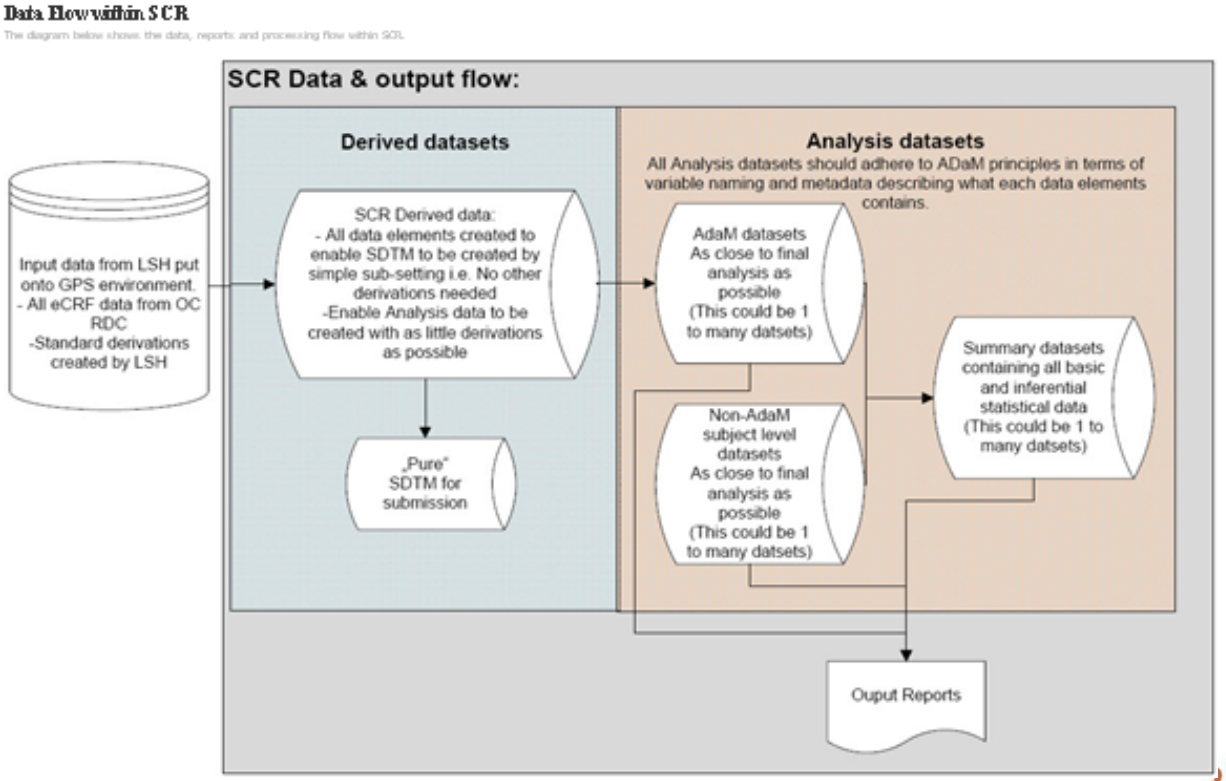
Definition

Definition of a SCR standard deliverable:

A SCR **standard** deliverable is considered to be one single dataset (*SCR derived, Analysis datasets*) or report output (*Table/Listing/Figure*) that has been specifically developed in a generic fashion and configured for one specific type of data analysis.

SCR Deliverables and Portfolios
Types

- Deliverable types
  - SCR Derived Datasets e.g. DDM, DAE, DVS, DCM,..
  - Analysis Datasets e.g. ADSL, ASAE, ADEG, ANSTATAE,...
  - Reports – Tables, Figures and Listings e.g. lb_mxd1_t003p, ae_frq1_t001p,...



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SCR Deliverables and Portfolios

Standard Portfolios

Definition of a portfolio:

An SCR portfolio is considered to be a collection of configured deliverables for the specific purpose of creating a specific Reporting Activity.

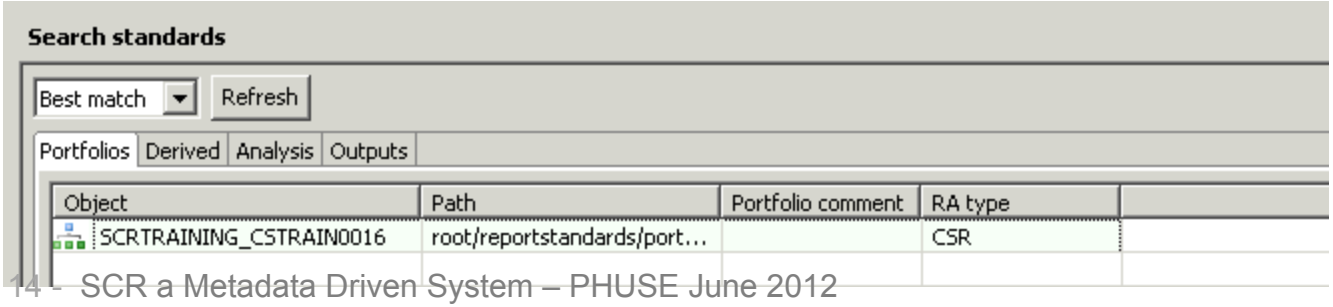
SCR Deliverables and Portfolios

Standard Portfolio Metadata

Welcome | SCR_PQ_CSR

name	visibility	description	value
Portfolio title	normal	The title of a portfolio	CSR for SCR Release 2
Portfolio comment	normal	The comment on a portfolio	CSR for SCR Release 2
Design type	normal	The design type	Hybrid 2/3 Treatment Crossover/Parallel
Protocol phase	normal	The protocol phase	Phase 1
Regimen type	normal	The regimen type	once (per study)
Therapeutic area	normal	The therapeutic area	Translational Science (TS)
Disease area	normal	This is the disease area	CVM: Dyslipidemia
RA type	normal	The type of a reporting activity	CSR
Project	normal	The selection list of all available projects	CCTSTSCR

Portfolio Metadata settings facilitate search of standards portofolio that best match Protocol Metadata of your RA.



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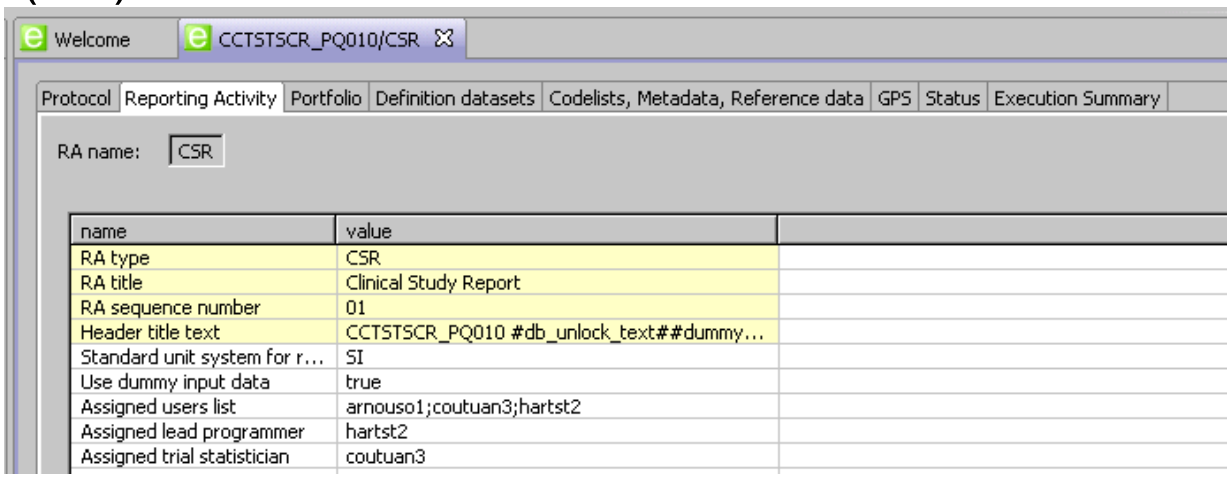
SCR Deliverables and Portfolios

Reporting Activity (RA) - Metadata

- Reporting Activity (RA) attributes
  - RA metadata



  - For each RA end-user will define a collection of deliverables and/or Portfolio
  - a RA-portfolio may include standard deliverables, standard portfolios (i.e. a collection of standard deliverables) and custom deliverables
  - When building or adding to portfolio's any dependencies also get added (e.g. If we copy the AET009 standard deliverable AET009 to a RA-portfolio, ANSTATAE, ANSTATN, ASAE, ADSL, DAE,... and any other dependency also get added)

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SCR Deliverables and Portfolios

SAP (Statistical Analysis Plan) Fragments and Modules

- A SAP fragment is created for each SCR deliverable to show the deliverable specification
- SAP modules are the compiled documents for all individual fragments
- The final SAP modules includes coverpage, TOC, introduction & appendix
- These can be added to for each RA

SCR Deliverables and Portfolios

SAP Fragments – Dataset Template

Dataset Template

Dataset Type	SCR Derived data
Deliverable Name	ddm
Input dataset(s)	Source: dm SCR Derived data: dvs
Creating program	cddm.sas
Description	test description
Unique identifier(s)	DMDY
Sorted variable(s)	DMDY
Notes	test notes

Variable Name	Variable Label	Type C=Char N=Num	Associated Codelist (Type)	Format	Source Dataset / Source Type	Variable Source Derivation
RFSTDTC	Subject Reference Start Date/Time	C	N/A (N/A)	$20.	<sdr> / Derived, SCR Derived	Standard Derivation:- {Assumptions: } - {Logic: } - Derivation version:{}{}
RFSTDTN	Subject Reference Start Date/Time	N	N/A (N/A)	is8601dt.	<sdr> / Derived, SCR Derived	Standard Derivation:- {Assumptions: } - {Logic: } - Derivation version:{}{}
RFENDTC	Subject Reference End Date/Time	C	N/A (N/A)	$20.	<sdr> / Derived, SCR Derived	Standard Derivation:- {Assumptions: } - {Logic: } - Derivation version:{}{}
RFENDTN	Subject Reference End Date/Time	N	N/A (N/A)	is8601dt.	<sdr> / Derived, SCR Derived	Standard Derivation:- {Assumptions: } - {Logic: } - Derivation version:{}{}
INVID	Investigator Identifier	C	N/A (N/A)	$80.	<sdr> / Entered, CRF	
INVNAM	Investigator Name	C	N/A (N/A)	$80.	<sdr> / Entered, CRF	
BRTHDTC	Date/Time of Birth	C	N/A (N/A)	$20.	<sdr> / Derived, SCR Derived	Standard Derivation:- {Assumptions: } - {Logic: } - Derivation version:{}{}
BRTHDTN	Date/Time of Birth	N	N/A (N/A)	is8601dt.	<sdr> / Derived, SCR Derived	Standard Derivation:- {Assumptions: } - {Logic: } - Derivation version:{}{}
BRTHYR	Year of Birth	N	N/A (N/A)	8.	<sdr> / Entered, CRF	
BRTHYRF	Year of Birth	C	N/A (N/A)	$200.	<sdr> / Derived, CRF	
BRTHYRQ	Year of Birth	C	N/A (N/A)	$3.	<sdr> / Derived, CRF	
BRTHDAT	Date of Birth	C	N/A (N/A)	$8.	<sdr> / Derived, CRF	
BRTHDATF	Date of Birth	C	N/A (N/A)	$200.	<sdr> / Derived, CRF	
BRTHDATQ	Date of Birth	C	N/A (N/A)	$3.	<sdr> / Derived, CRF	
BRTHTIM	Time of Birth	C	N/A (N/A)	$6.	<sdr> / Entered, CRF	
BRTHTIMF	Time of Birth	C	N/A (N/A)	$200.	<sdr> / Derived, CRF	
BRTHTIMQ	Time of Birth	C	N/A (N/A)	$3.	<sdr> / Derived, CRF	
BRTHDDT	Derived date of birth	C	N/A (N/A)	$8.	<sdr> / Derived, CRF	
BRTHDDTC	Derived date of birth	C	N/A (N/A)	$20.	<sdr> / Derived, SCR Derived	Standard Derivation:- {Assumptions: } - {Logic: } - Derivation version:{}{}
BRTHDDTN	Derived date of birth	N	N/A (N/A)	is8601dt.	<sdr> / Derived, SCR Derived	Standard Derivation:- {Assumptions: } - {Logic: } - Derivation version:{}{}
BRTHCL	Actual Date of Birth Collection Allowed	C	NOYES (SDTM)	$2.	<sdr> / Entered, CRF	

Report Template

Output Type	Output - Listing
Deliverable Name	dml001
Input dataset(s)	Analysis - ADaM: asdm1
Creating program	cdml001.sas
Description	test description ddddddddd
Macro parameters	Column variables: CCS, ASR, ETHNIC, BRTHDTC, WEIGHT, HEIGHT, BMI, ELBTH, FRMSIZE, BSA ID variables: part arm switch: derivation_usercode: _scr_sortseq: _scr_ods_type:
Treatment label(s)	<no information available yet>
Notes	test notes demo december

CCTSTSCR_PQ009

Post-text Listing 16.2.4-1.1.1 (Page X of Y)
Demographic Information (Adverse event preferred term > 10% in Element code B),
by Description of Arm
Analysis set: Safety

Subset: All subjects younger than 65
Description of Arm: XXXX

Country/ Center/ Subject	Age/ Sex/ Race	Ethnicity	Date Of Birth	Weight[1] (kg)	Height[1] (cm)	BMI[2] (kg/m2)	Elbow Breadth (cm)	Body Frame Size	BSA[2] (m2)
GBR/0001/00502	xx/M/Ca	Hispanic	1975-07-09	xx.x	xxx	xx.x	x.x	Medium	x.x

- Weight & Height are taken from screening vital signs evaluation
- BMI is calculated based on raw data
- my new footnote
- my new footnote

/report/pgm_saf/cdml001.sas@@<version>-DDMMMYYYY:HH:MM:SS Final Version

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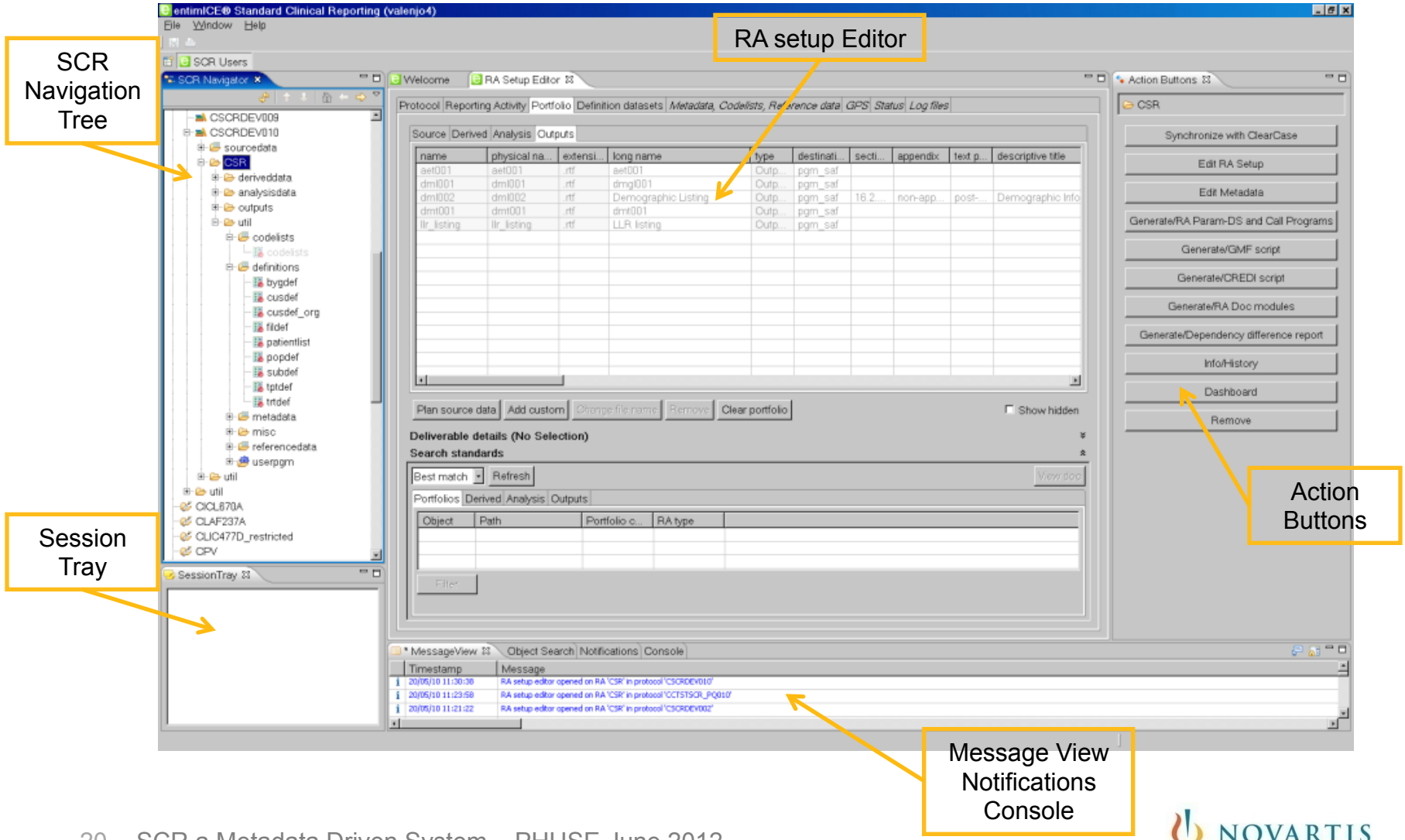
Detailed components of SCR

SCR Front-End (GUI)

SCR Front-End (GUI)

- GUI allows End-Users
  - control all parts of the RA
  - set up and change defaults settings of each RA
  - create, edit, monitor, and execute all aspects of their RA
  - able to load all programs, documentation & metadata from the central repository to their RA for analysis & reporting
- This ensures all files needed to execute the RA are available
- RA setup is more efficient as all parts automatically joined
  - SAP linked to programs & parameters
  - Programs & reports linked to project standards
  - Datasets & reports linked to internal data standards and CDISC

SCR Front-End (GUI)



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Detailed components of SCR

SCR Metadata

“Middleware”

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SCR Metadata

- Strategic difference in SCR design is that it was built based on the concept of being driven by “metadata”
- SCR codes based on metadata requires less actual code maintenance
- Easier to develop generic SAS modules based on metadata
- This strategy brings it’s own constraint’s i.e. we need precise, High quality metadata to drive the application

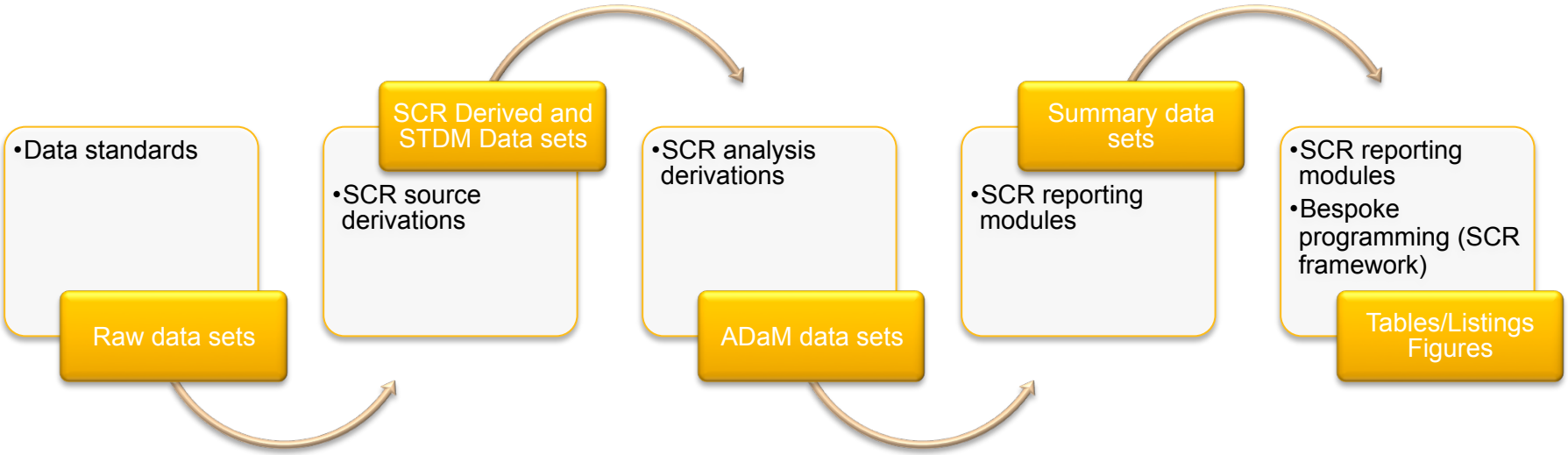
SCR Metadata
Categories

- Internal Data stds.
  - Data elements – name, label, format, etc.
  - Derivations – logic, parameters, specific data domain choices
  - Codelists – central library, data element specific
  - Reference tables - unit conversion, precision, ranges, test category
- SCR Definition data – All analysis & reporting specific definitions e.g. analysis set, sub-grouping selection, etc.
- SCR Metadata – Deliverable metadata, links, RA, and Portfolio metadata

Derivation Concepts

- Derivations are defined once and can be reused across domains and analysis datasets
- Central derivations file contains the description, logic (pseudo-code), assumptions, and other key information for a derivation.
- Domains (including ADaM\analysis) contain the specifics for deriving an element (e.g. contributing elements)

Derivation Concepts
SCR data flow



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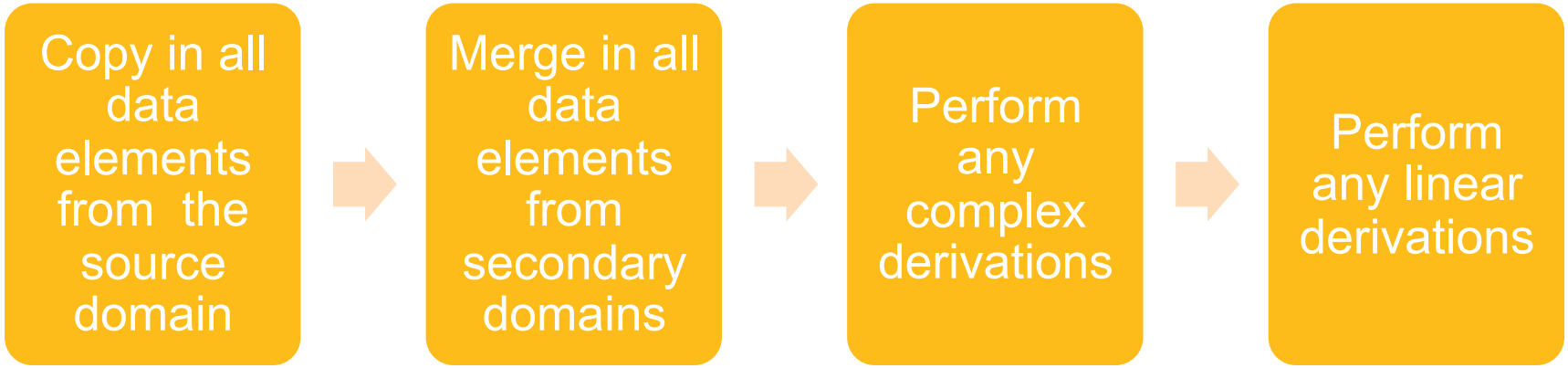
Derivation Concepts
How derivations are processed in SCR

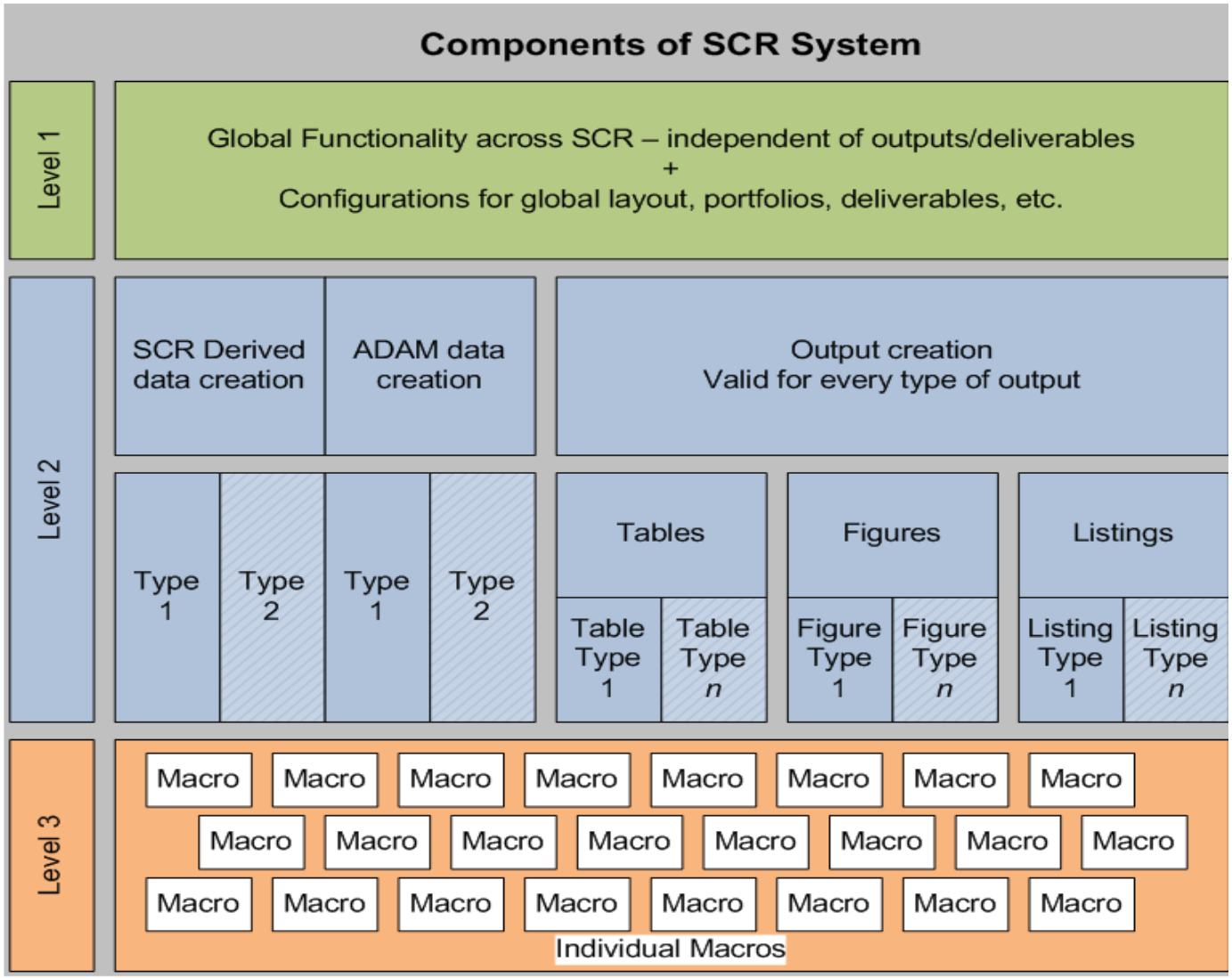


Complex derivations are those which require data manipulation , input from multiple observations or complex merges

Linear derivations are those which are a function of other data elements already present on the domain

SCR Back-end SAS Modules

SCR Back-end Architecture



SCR DB configuration

Standard Programs

Utility Macros

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SCR Back-end Architecture

- **Level 1**
  - The specific configuration created by the SCR administrator within the SCR database. This is made of the deliverable attributes described earlier e.g. parameters, metadata, SAP, linked program (Level 2). Many deliverables may use the same level 2 std. prog.
- **Level 2**
  - Generic Standard Programs with associated parameters. This is comprised of utility (level 3) macros that are built and executed in a set sequence to satisfy requirements for a specific dataset or output.
- **Level 3**
  - Utility macros created in order to fulfil a single specific function needed by level 2. This is the lowest level of macro function created by SCR. Level 3 macros may use other level 3 macros. Examples include, title creation, BMI calculation, AE start date imputation, etc.

SCR Back-end Architecture

- The level 1 parameter setting configuration of the level 2 std. program for each deliverable are stored in the SCR database.
- These parameters my be changed to other standard options when creating a portfolio or RA.
- Main program categories of standard programs (Level 2)
  - Dataset creation program
    - SCR Derived data, Analysis data & SDTM data
  - Report generation program
    - Post-text / in-text - Tables , Figures & Listing
- All SCR programs and macros have been developed in a generic fashion to ensure the maximum opportunity for reusability

Reporting Activity Parameters

- All parameters set within the SCR GUI – RA setup editor are saved within the SCR oracle database
- When setup is complete (or changes have been made), a SAS dataset is created with all parameters held within it (raparams.sas7bdat)
- Standard and custom programs are included
- All SCR programs are designed to source parameters from this file
- This file can be regenerated at any time

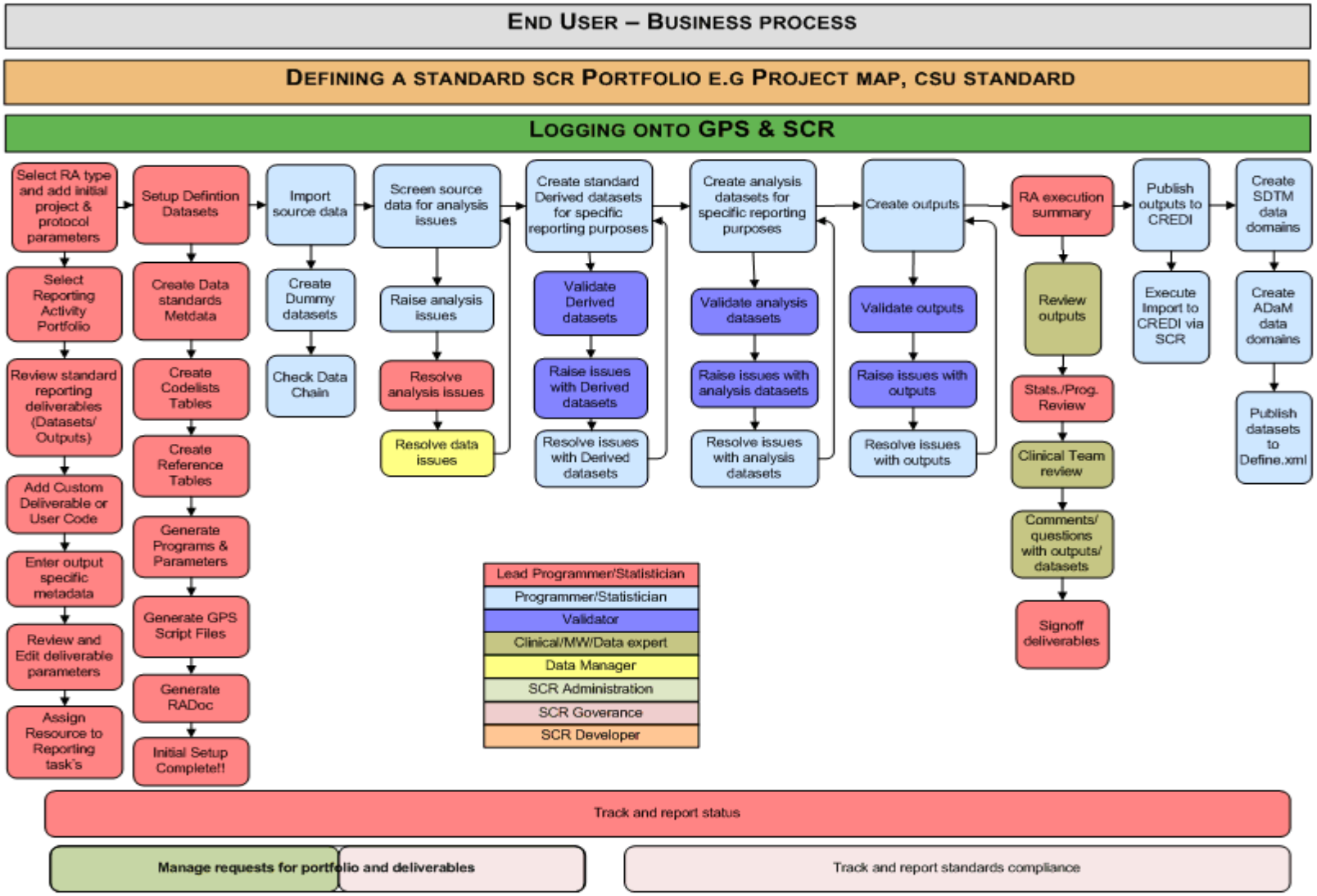
Detailed components of SCR

SCR Portal

The SCR Portal

- The purpose of the SCR Portal is to describe all aspects of how to use the SCR application.
- The SCR portal will allow End-Users, SCR Administrators and SCR Developers to review documentation and get real-time reports from the SCR production database.
- Training material and Schedule, Business Process, FAQ, How-To Videos, SCR Architecture, etc.

SCR Portal
End User Workflow



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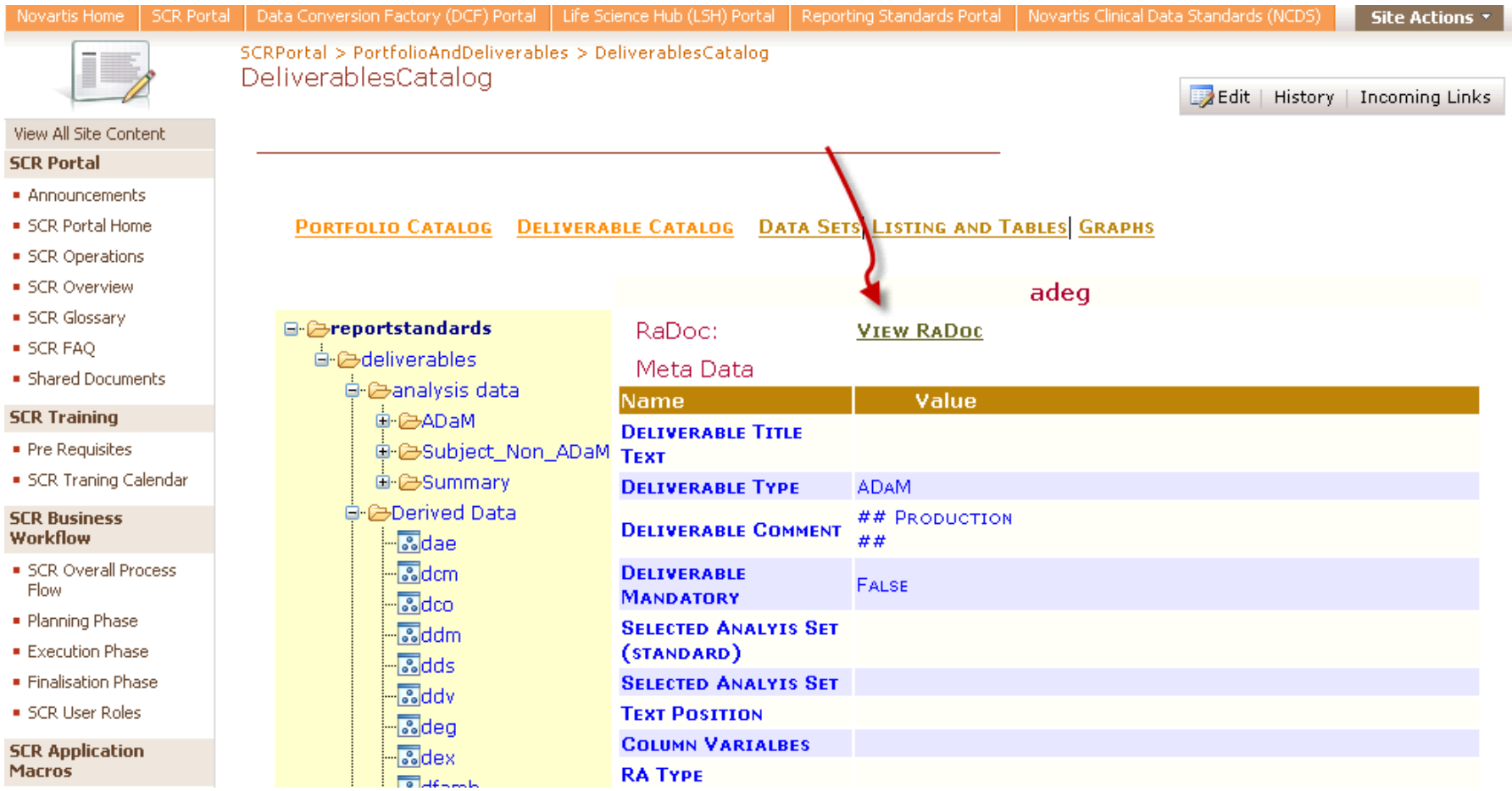
SCR Portal
Deliverables



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SCR Portal
RADoc fragments

Data domain type (Long text)	ANALYSIS, ADAM
Domain name	ADEG
List of input source data domains	AD.ADSL, DR.EG, SF.TPTDEF, SR.RANGES, SR.TESTS, SR.TPTDEF
Creating program	
Dataset description	
Sorted variable(s)	USUBJID
Notes	

Section Break (Continuous)

Variable Name	Variable Label	Type C=Char N=Num	Associated Codelist (Type)	SAS Format/ Display Format	Source Dataset/Source Type	Variable Derivation
EGSEQ	Sequence number	N	N/A (N/A)	8./ N*	EG/Derived, SCR/Derived	Element copied from: -DR.EG.EGSEQ
EGSTRESU	Standard units	C	UNIT (SDTM)	$15./ T*	EG/Derived, SCR/Derived	Element copied from: -DR.EG.EGSTRESU
EGTESTCD	ECG test or examination short name	C	EGTEST (ABBREVIATED)	$8./ T*	EG/Derived, SCR/Derived	Element copied from: -DR.EG.EGTESTCD
PARTTXT	Text description of protocol part	C	N/A (N/A)	$200./ T*	Trial Design/Entered, Protocol metadata	Element copied from: -DR.EG.PARTTXT
PATIENT	Subject identifier	C	N/A (N/A)	$10./ T*	GENERAL COMMON/Entered, CRF	Element copied from: -DR.EG.PATIENT
PRTPART	Protocol part or section	N	N/A (N/A)	3./ N*	Trial Design/Entered, Protocol metadata	Element copied from: -DR.EG.PRTPART
STUDY	Study identifier	C	N/A (N/A)	$15./ T*	GENERAL COMMON/Entered, CRF	Element copied from: -DR.EG.STUDY

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/report/pgm_saf/cdml001.sas@@<version>-DDMMMYYYY:HH:MM:SS Final Version

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SCR Portal

Tracking Tools – Reporting Activity (RA) status

- Provides information to Users and Management on reporting status, and usage of standard outputs

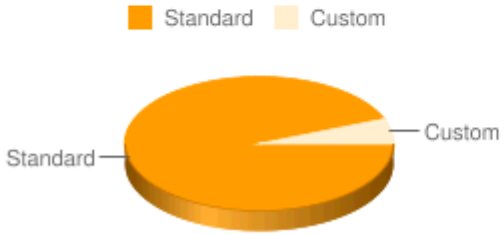
			Programs				Deliverables		
Project Name	Protocol Name	RA Name	Total	Development	Ready-for-QC	Validated	Total	Draft	Production
CCTSTSCR	CCTSTSCR0001	HAQ	2	(2) 100%			2	(2) 100%	
CCTSTSCR	CCTSTSCR0002	HAQ	1	(1) 100%			1	(1) 100%	
CCTSTSCR	CCTSTSCR0003								
CCTSTSCR	CCTSTSCR0004								
CCTSTSCR	CCTSTSCR0005								
CCTSTSCR	CCTSTSCR0006								
CCTSTSCR	CCTSTSCR_PQ001	CSR	24	(15) 62%	(6) 25%	(3) 12%	22	(22) 100%	
CCTSTSCR	CCTSTSCR_PQ002	CSR	22	(22) 100%			21	(20) 95%	(1) 4%
CCTSTSCR	CCTSTSCR_PQ003	CSR	17	(12) 70%	(2) 11%	(3) 17%	17	(17) 100%	

SCR Portal
Tracking Tools

Deliverables of All Reporting Activities

	Total	Standard (%)	Custom (%)	From Portfolio	From Deliverable
	421	94%	6%	274	125

Standard vs. Custom



Standards Utilization Barometer

Deliverables By Project

Deliverables By Project / Protocol

Deliverables By Therapeutic Area

Deliverables By Disease Area

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Conclusion

- Building a Metadata driven reporting system is possible
- It requires High Quality metadata
- Need to allow time for people to get used to reading and interpreting metadata and to understand the data flow between the systems
- It requires support from your organization in term of resources and time
- You need experts at generic SAS coding

Questions?

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