

THE PROVOCATIVE, PROFOUND, AND DEEPLY AFFECTING
MODERN CLASSIC THAT HAS INSPIRED MILLIONS

AstraZENeca and the ART of Metadata maintenance



AND

THE ART OF
MOTORCYCLE
MAINTENANCE

AN INQUIRY INTO VALUES

Quality

- The Metaphysics of Quality (MOQ) is a theory of reality introduced in Robert Pirsig's philosophical novel, Zen and the Art of Motorcycle Maintenance
- "Quality," or "value," cannot be defined because it empirically precedes any intellectual construction of it. Quality is the "knife-edge" of experience, known to all.
- Quality is the fundamental force in the universe stimulating everything from atoms to animals to evolve and incorporate ever greater levels of Quality. According to the MOQ, everything (including the mind, ideas, and matter) is a product and a result of Quality.

Evolution Towards Quality



Introduction

- WHY
- HOW
 - Process
 - Technology
 - Metadata
 - Program builder
- Technology Overview
- Visions for the future
- Conclusions

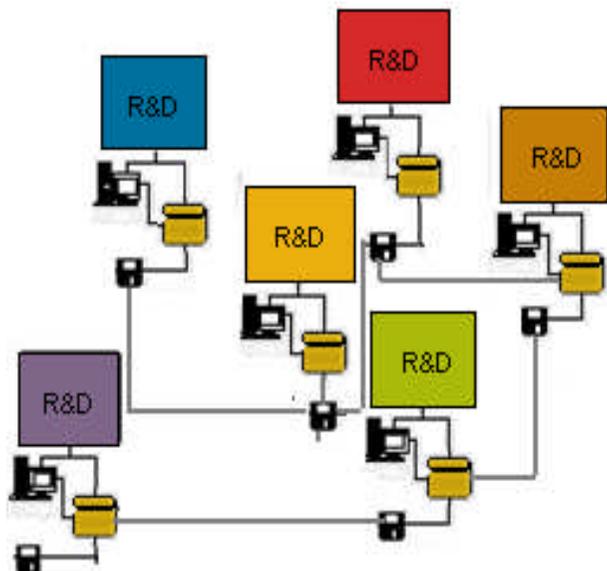


Why?

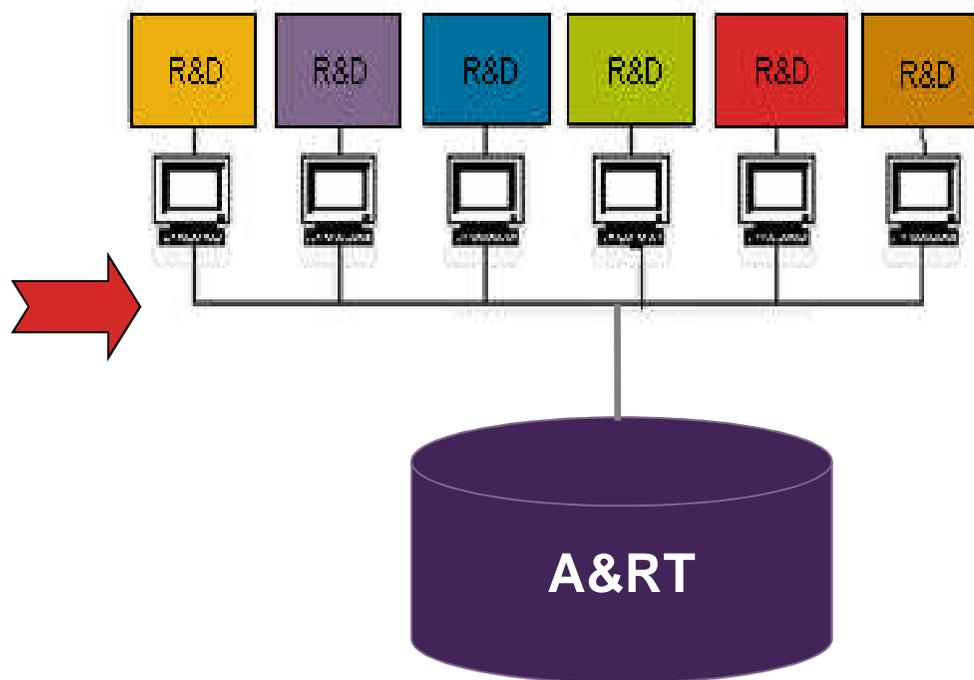
- The Analysis and Reporting landscape within AZ had not changed since the merger
 - 3 Astra companies
 - Zeneca – 2 main R&D sites
 - 6 sites with their own processes and applications
- A&RT had a remit to harmonise:
 - Process
 - Data standards
 - Technology and platform

Initial A&RT vision

Sharing A&R Assets Today



Sharing A&R Assets in A&RT



The HOW (Process - 1)

- **Common processes**

- Drive towards corporate level RAW data standards and introduce ***SDTM*** as a data layer and a revised RDb definition predicated on SDTM
- Create a governance organisation to control ALL data standards
- Introduce standards for data transformations based on RAW / SDTM / RDb data standards
- Extend the governance to include definition and control of statistical and reporting outputs
- Eliminate re-work across sites

The HOW (Process - 2)

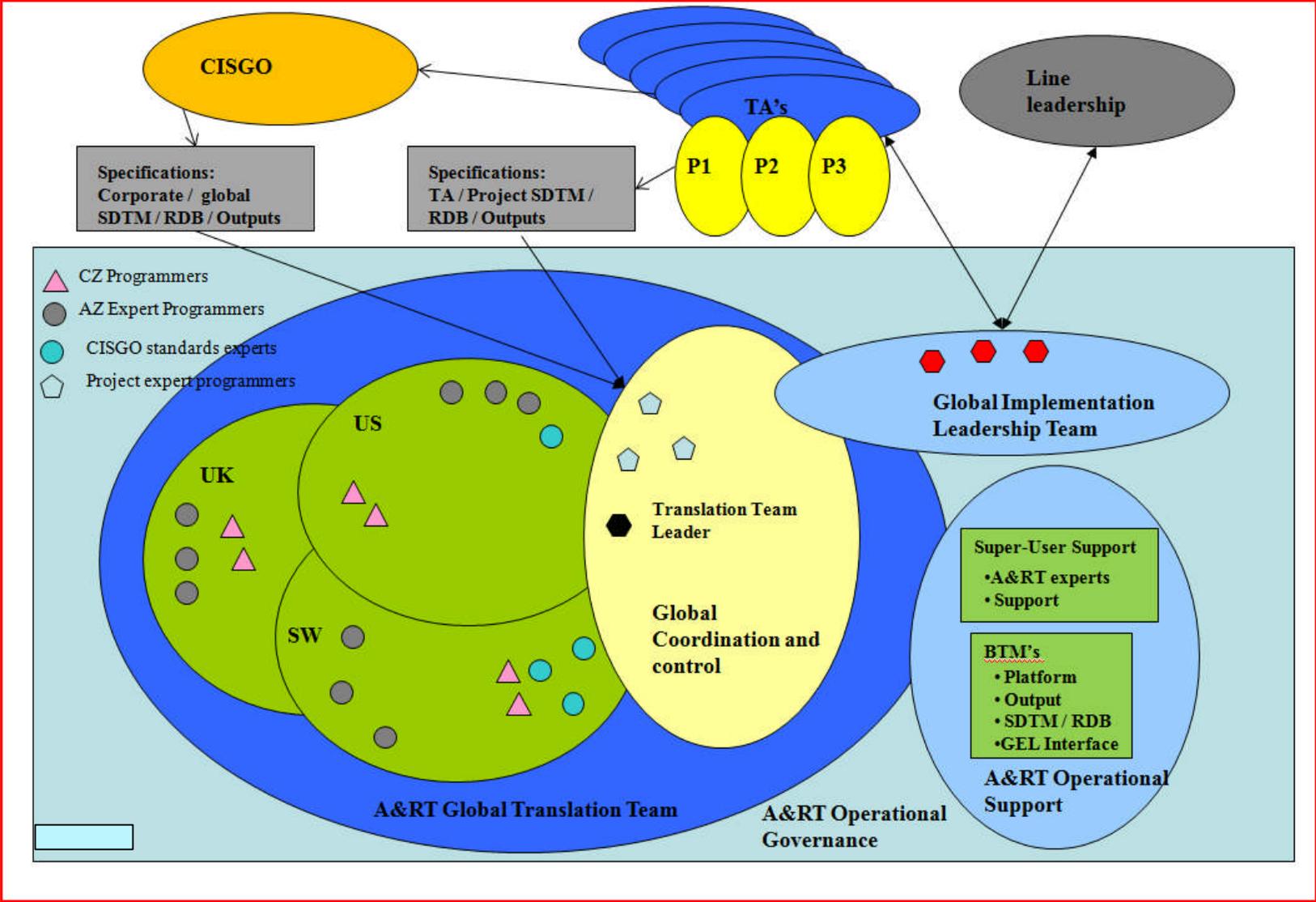
- **Minimising activities on the critical path**

- Upfront planning including early consensus on the content of the Clinical Study Report or other key deliverables
- Start with the definition of all project level standards and make them available to the study
- Create all data specifications as early as possible

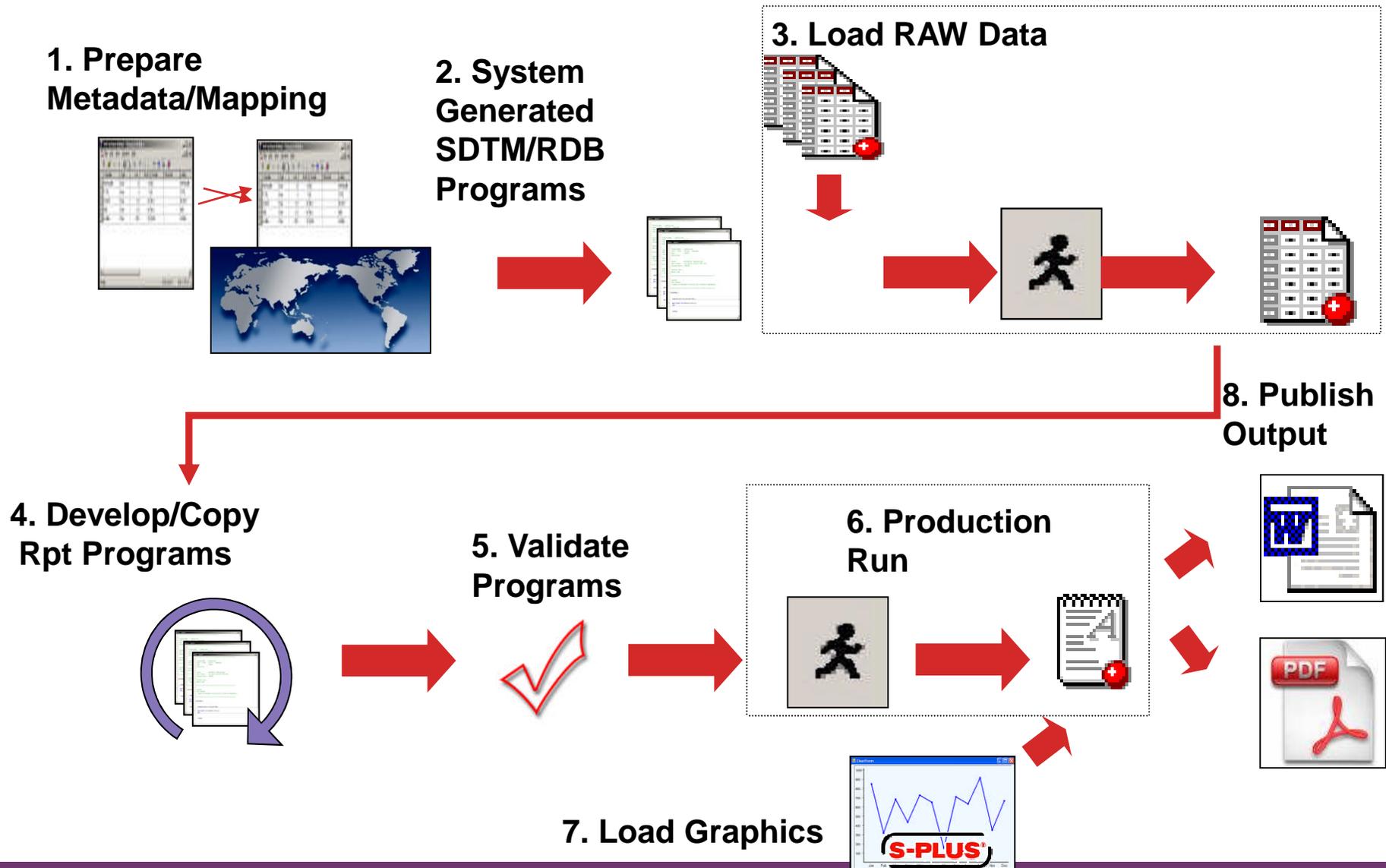
- **Working in Parallel**

- Data capture
- Reporting database specification
- Reporting output specifications
- Draft clinical study report with tables, listings and graphs

High-Level A&RT Governance



Reporting Process Overview



The HOW (Technology)

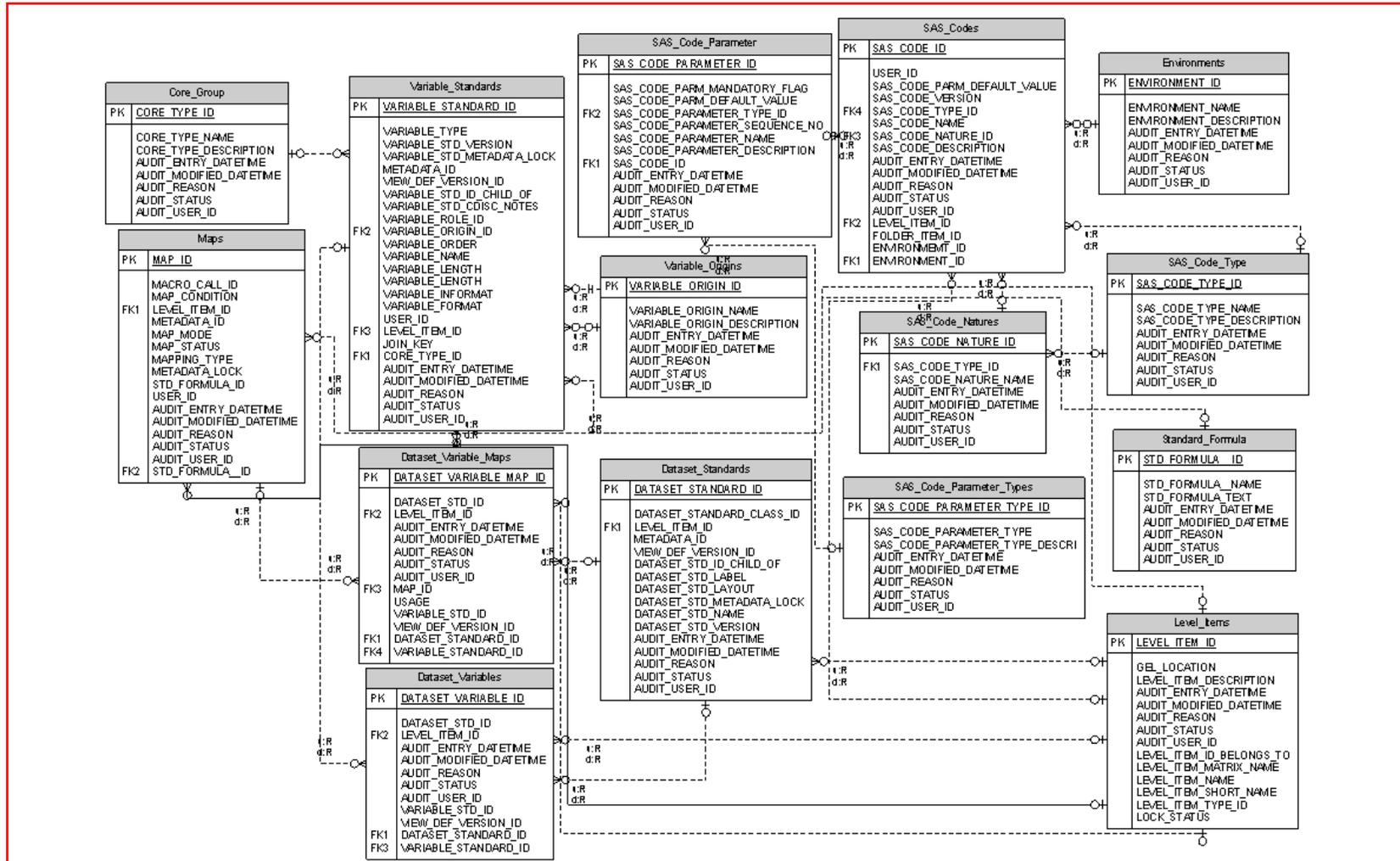
- Following an intense period of technology evaluation against requirements we defined a quest for the following holy grail:
 - Metadata driven
 - Hierarchical representation of all components with inheritance and equivalence
 - Single platform for reporting and analysis
- When reviewed in detail the A&RT application is both sophisticated and complex but the kernel can be summarised thus:
 - *“...a basic UNIX SAS environment with a sophisticated GUI web based front end and a standard structure for environment and libraries with global accessibility and an Oracle database for metadata storage”*

Metadata

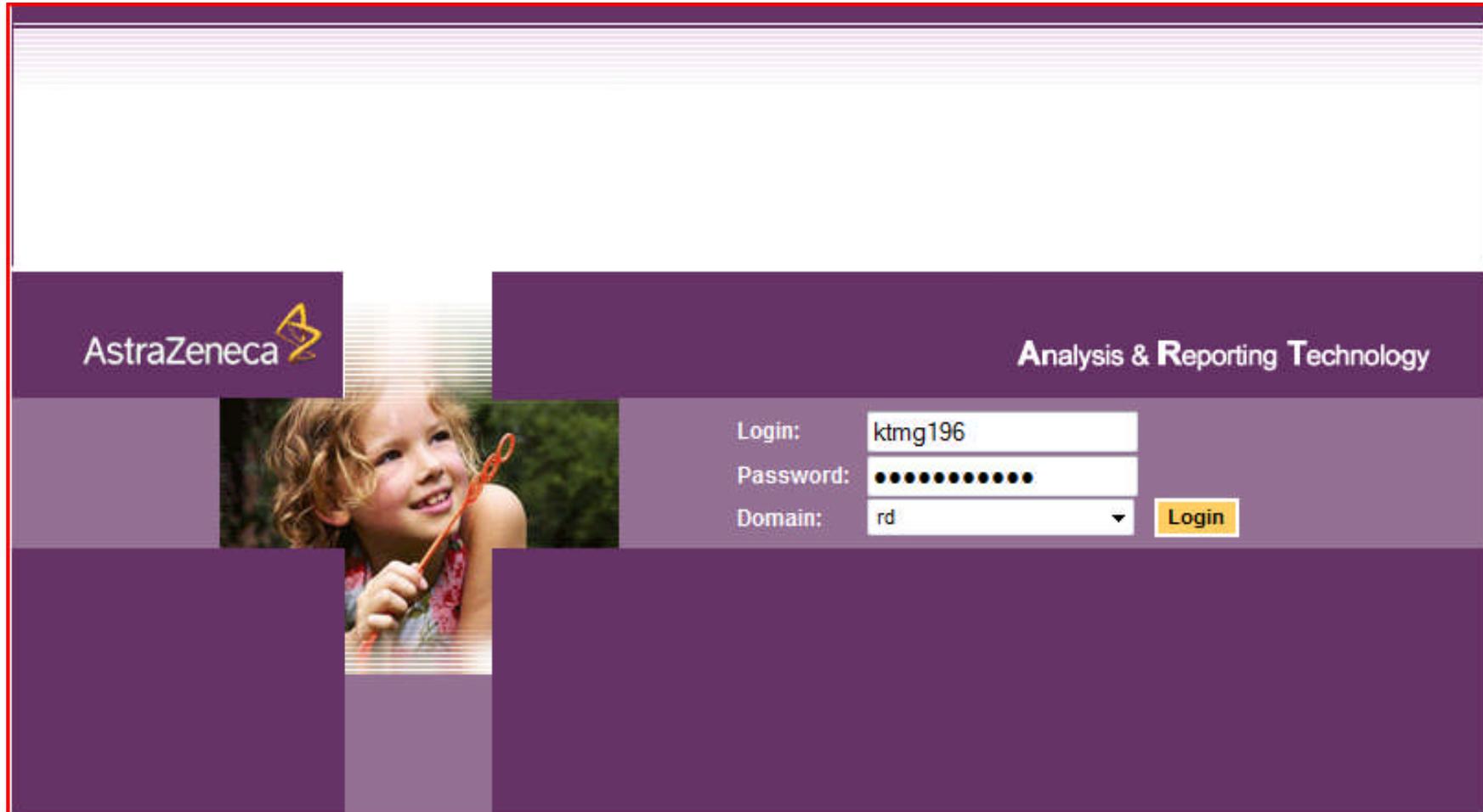
- We collect and maintain metadata for:
 - Environment (DEV / VAL / PROD)
 - Projects
 - Studies
 - Datasets
 - Variables
 - SAS programs / macros
 - Outputs
 - Users

- All stored in an Oracle database

Data Model



The A&RT Web Interface (WI)



AstraZeneca 

Analysis & Reporting Technology

Login:

Password:

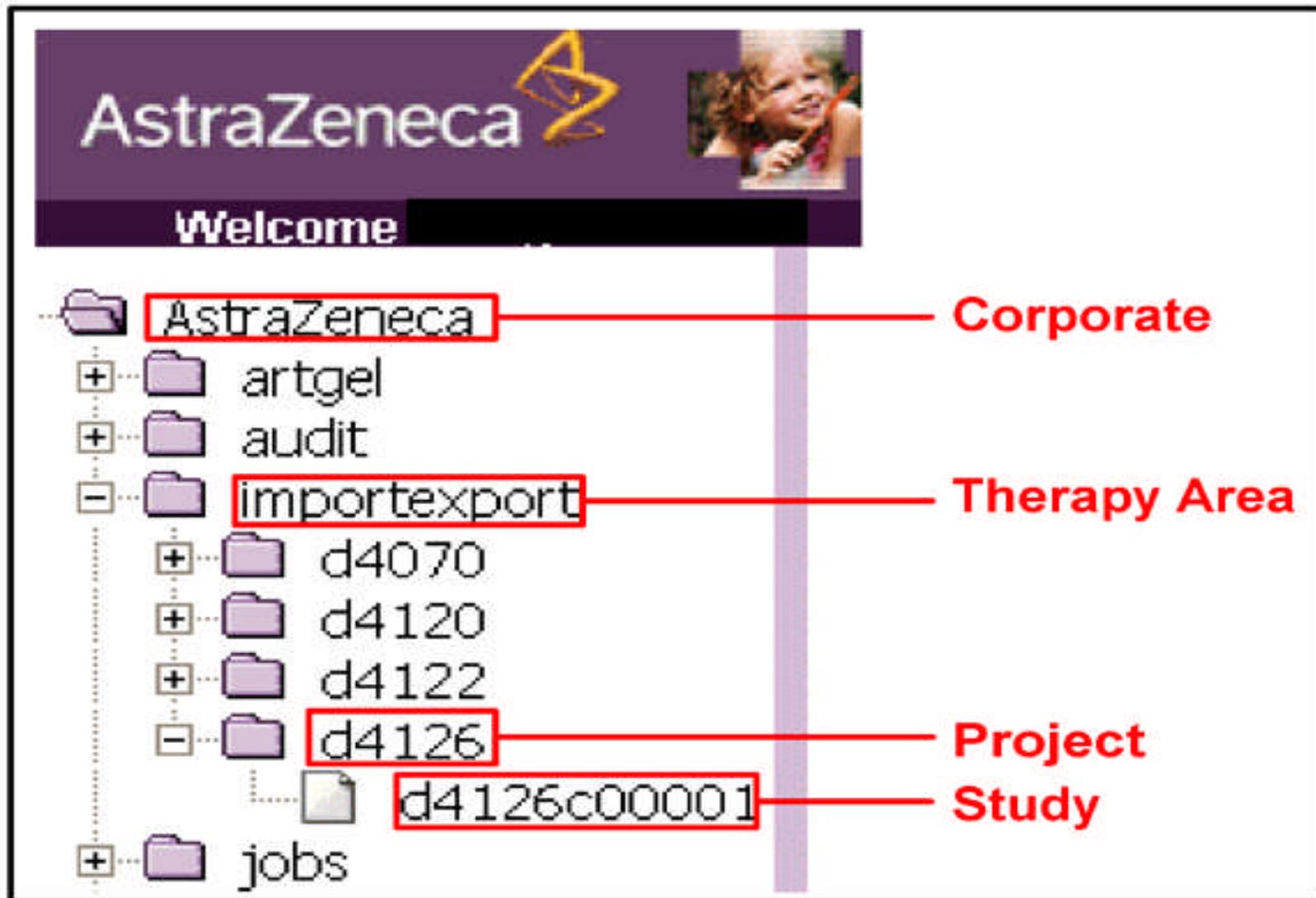
Domain:



Some Basic Definitions

- Hierarchy
 - an arrangement of items (objects, names, values, categories, etc.) in which the items are represented as being "above," "below," or "at the same level as" one another and with only one "neighbour" above and below each level
- Equivalence
 - assigning one object to another
 - Specifying a different dataset name to allow use of a corporate standard
- Inheritance
 - a way to form new classes (instances of which are called objects) using classes that have already been defined. Inheritance is intended to help reuse existing code with little or no modification.
 - “copying” metadata and maps from a higher level in the hierarchy

The A&RT Hierarchy



The A&RT Hierarchy

General | Metadata | Data | Mapping | SAS Code | Jobs | Results | Tools

Inherit SDTM Dataset Definitions

Source

<input type="checkbox"/>	Dataset Name ^	Dataset Label	Dataset Layout	Level	Dataset Class	Ve
<input type="checkbox"/>				ALL	ALL	
<input type="checkbox"/>	AE	Adverse Events	STUDYID USUBJID AESPID	Corporate	EVENTS	3.1
<input type="checkbox"/>	AE	Adverse Events	STUDYID USUBJID AESPID	Project	EVENTS	3.1
<input type="checkbox"/>	AE	Adverse Events	STUDYID USUBJID AESPID	TA	EVENTS	3.1
<input type="checkbox"/>	A_VITREF	Vital signs reference ranges	STUDYID AZTESTCD REFSEX	TA		AZ
<input type="checkbox"/>	CE	Clinical Events	STUDYID USUBJID CECAT CET ERM CESTDTC	Corporate	EVENTS	3.1
<input type="checkbox"/>	CE	Clinical Events	STUDYID USUBJID CECAT CET ERM CESTDTC	TA	EVENTS	3.1
<input type="checkbox"/>	CF	Clinical Findings	STUDYID USUBJID CFCAT CFT ESTCD	Project	FINDINGS	3.1
<input type="checkbox"/>	CM	Concomitant Medications	STUDYID USUBJID CMSPID	Corporate	INTERVENTIONS	3.1
<input type="checkbox"/>	CM	Concomitant Medications	STUDYID USUBJID CMSPID	TA	INTERVENTIONS	3.1

Target - uktrain15

<input type="checkbox"/>	Dataset Name ^	Dataset Label	Dataset Layout	Dataset Class	Version	Mo
<input type="checkbox"/>				ALL		
<input type="checkbox"/>	AE	Adverse Events	STUDYID USUBJID AESPID	EVENTS	3.1.2	Pa
<input type="checkbox"/>	CM	Concomitant Medications	STUDYID USUBJID CMSPID	INTERVENTIONS	3.1	Pa
<input type="checkbox"/>	DM	Demographics	STUDYID USUBJID	SPECIAL	3.1.2	Pa
<input type="checkbox"/>	DS	Disposition	STUDYID USUBJID DSSTDTC DSCAT DSDECOD	EVENTS	3.1	Pa
<input type="checkbox"/>	EG	ECG Tests	STUDYID USUBJID EGDTC EGT ESTCD	FINDINGS	3.1	Pa
<input type="checkbox"/>	EX	Exposure	STUDYID USUBJID EXSTDTC E XTRT	INTERVENTIONS	3.1	Pa
<input type="checkbox"/>	IE	Inclusion/Exclusion Criteria Not Met	STUDYID USUBJID IEDTC IETE STCD	FINDINGS	3.1	Pa
<input type="checkbox"/>	LB	Laboratory Tests	STUDYID USUBJID LBDTC LBT ESTCD LBFAS	FINDINGS	3.1	Pa
<input type="checkbox"/>	MH	Medical History	STUDYID USUBJID MHTERM	EVENTS	3.1	Pa

Equivalence (1)

Create RAW - SDTM Inherit Maps

Define Equivalent Source Modules

Datasets in Present Source

<input type="checkbox"/>	Source	Inherit as	Level
<input type="checkbox"/>	AELOG	AELOG	training
<input type="checkbox"/>	CRIT	CRIT	training
<input type="checkbox"/>	DEM	DEM	training
<input type="checkbox"/>	DOSE	DOSE	training
<input type="checkbox"/>	ECG	ECG	training
<input type="checkbox"/>	GEN	GEN	training
<input type="checkbox"/>	HISM	HISM	training
<input type="checkbox"/>	HISS	HISS	training
<input checked="" type="checkbox"/>	LAB1		
<input type="checkbox"/>	LABU	LABU	training
<input type="checkbox"/>	LBREF	LBREF	training
<input type="checkbox"/>	LFORMATS	LFORMATS	training
<input type="checkbox"/>	MED	MED	training
<input type="checkbox"/>	PHYS	PHYS	training
<input type="checkbox"/>	PHYSF	PHYSF	training
<input type="checkbox"/>	PREG	PREG	training
<input type="checkbox"/>	RAND	RAND	training
<input type="checkbox"/>	SAE	SAE	training
<input type="checkbox"/>	TERM	TERM	training
<input type="checkbox"/>	UNITCONV	UNITCONV	training
<input type="checkbox"/>	VAMS	VAMS	training
<input type="checkbox"/>	VIT	VIT	training
<input type="checkbox"/>	VSREF	VSREF	training

Mapped Datasets in Hierarchy

Filter: training

Select	Source	Level
<input type="radio"/>	AELOG	training
<input type="radio"/>	CRIT	training
<input type="radio"/>	DEM	training
<input type="radio"/>	DOSE	training
<input type="radio"/>	ECG	training
<input type="radio"/>	GEN	training
<input type="radio"/>	HISM	training
<input type="radio"/>	HISS	training
<input checked="" type="radio"/>	LAB	training
<input type="radio"/>	LABU	training
<input type="radio"/>	LBREF	training
<input type="radio"/>	LFORMATS	training
<input type="radio"/>	MED	training
<input type="radio"/>	PHYS	training
<input type="radio"/>	PHYSF	training
<input type="radio"/>	PREG	training
<input type="radio"/>	RAND	training
<input type="radio"/>	SAE	training
<input type="radio"/>	TERM	training
<input type="radio"/>	UNITCONV	training
<input type="radio"/>	VAMS	training
<input type="radio"/>	VIT	training
<input type="radio"/>	VSREF	training

Inherit as

Clear Inherit as

Equivalence (2)

Create RAW - SDTM Inherit Maps

Define Equivalent Source Modules

Datasets in Present Source

<input type="checkbox"/>	Source	Inherit as	Level
<input type="checkbox"/>	AELOG	AELOG	training
<input type="checkbox"/>	CRIT	CRIT	training
<input type="checkbox"/>	DEM	DEM	training
<input type="checkbox"/>	DOSE	DOSE	training
<input type="checkbox"/>	ECG	ECG	training
<input type="checkbox"/>	GEN	GEN	training
<input type="checkbox"/>	HISM	HISM	training
<input type="checkbox"/>	HISS	HISS	training
<input type="checkbox"/>	LAB1	LAB	training
<input type="checkbox"/>	LABU	LABU	training
<input type="checkbox"/>	LBREF	LBREF	training
<input type="checkbox"/>	LFORMATS	LFORMATS	training
<input type="checkbox"/>	MED	MED	training
<input type="checkbox"/>	PHYS	PHYS	training
<input type="checkbox"/>	PHYSF	PHYSF	training
<input type="checkbox"/>	PREG	PREG	training
<input type="checkbox"/>	RAND	RAND	training
<input type="checkbox"/>	SAE	SAE	training
<input type="checkbox"/>	TERM	TERM	training
<input type="checkbox"/>	UNITCONV	UNITCONV	training
<input type="checkbox"/>	VAMS	VAMS	training
<input type="checkbox"/>	VIT	VIT	training
<input type="checkbox"/>	VSREF	VSREF	training

Mapped Datasets in Hierarchy

Filter: training

Select	Source	Level
<input type="radio"/>	AELOG	training
<input type="radio"/>	CRIT	training
<input type="radio"/>	DEM	training
<input type="radio"/>	DOSE	training
<input type="radio"/>	ECG	training
<input type="radio"/>	GEN	training
<input type="radio"/>	HISM	training
<input type="radio"/>	HISS	training
<input checked="" type="radio"/>	LAB	training
<input type="radio"/>	LABU	training
<input type="radio"/>	LBREF	training
<input type="radio"/>	LFORMATS	training
<input type="radio"/>	MED	training
<input type="radio"/>	PHYS	training
<input type="radio"/>	PHYSF	training
<input type="radio"/>	PREG	training
<input type="radio"/>	RAND	training
<input type="radio"/>	SAE	training
<input type="radio"/>	TERM	training
<input type="radio"/>	UNITCONV	training
<input type="radio"/>	VAMS	training
<input type="radio"/>	VIT	training
<input type="radio"/>	VSREF	training

Inherit as

Clear Inherit as

Inheritance

General | Metadata | Data | Mapping | SAS Code | Jobs | Results | Tools

Create RAW - SDTM Inherit Maps

Define Equivalent Source Modules Inherit in progress . . .

Datasets in Present Source

<input type="checkbox"/>	Source	Inherit as	Level
<input type="checkbox"/>	AELOG	AELOG	training
<input type="checkbox"/>	CRIT	CRIT	training
<input type="checkbox"/>	DEM	DEM	training
<input type="checkbox"/>	DOSE	DOSE	training
<input type="checkbox"/>	ECG	ECG	training
<input type="checkbox"/>	GEN	GEN	training
<input type="checkbox"/>	HISM	HISM	training
<input type="checkbox"/>	HISS	HISS	training
<input type="checkbox"/>	LAB1	LAB	training
<input type="checkbox"/>	LABU	LABU	training
<input type="checkbox"/>	LBREF	LBREF	training
<input type="checkbox"/>	LFORMATS	LFORM	training
<input type="checkbox"/>	MED	MED	training
<input type="checkbox"/>	PHYS	PHYS	training
<input type="checkbox"/>	PHYSF	PHYSF	training
<input type="checkbox"/>	PREG	PREG	training
<input type="checkbox"/>	RAND	RAND	training
<input type="checkbox"/>	SAE	SAE	training
<input type="checkbox"/>	TERM	TERM	training
<input type="checkbox"/>	UNITCONV	UNITCONV	training
<input type="checkbox"/>	VAMS	VAMS	training
<input type="checkbox"/>	VIT	VIT	training
<input type="checkbox"/>	VSREF	VSREF	training

Mapped Datasets in Hierarchy
Filter: training

Select	Source	Level
<input type="radio"/>	AELOG	training
<input type="radio"/>	CRIT	training
<input type="radio"/>	DEM	training
<input type="radio"/>	DOSE	training
<input type="radio"/>	ECG	training
<input type="radio"/>	GEN	training
<input type="radio"/>	HISM	training
<input type="radio"/>	HISS	training
<input type="radio"/>	LAB	training
<input type="radio"/>	LABU	training
<input type="radio"/>	LBREF	training
<input type="radio"/>	LFORMATS	training
<input type="radio"/>	MED	training
<input type="radio"/>	PHYS	training
<input type="radio"/>	PHYSF	training
<input type="radio"/>	PREG	training
<input type="radio"/>	RAND	training
<input type="radio"/>	SAE	training
<input type="radio"/>	TERM	training
<input type="radio"/>	UNITCONV	training
<input type="radio"/>	VAMS	training
<input type="radio"/>	VIT	training
<input type="radio"/>	VSREF	training

Message -- Webpage Dialog

 Inherit process has started.

OK

Clear Inheritas Inherit Cancel

Standards Flow/Hierarchy

Corporate



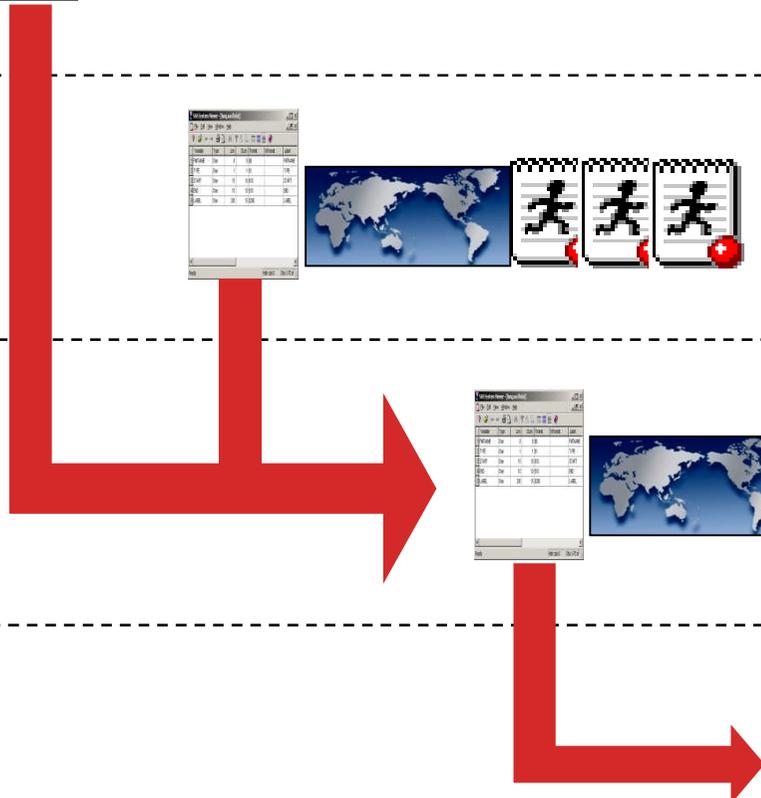
TA



Project



Study

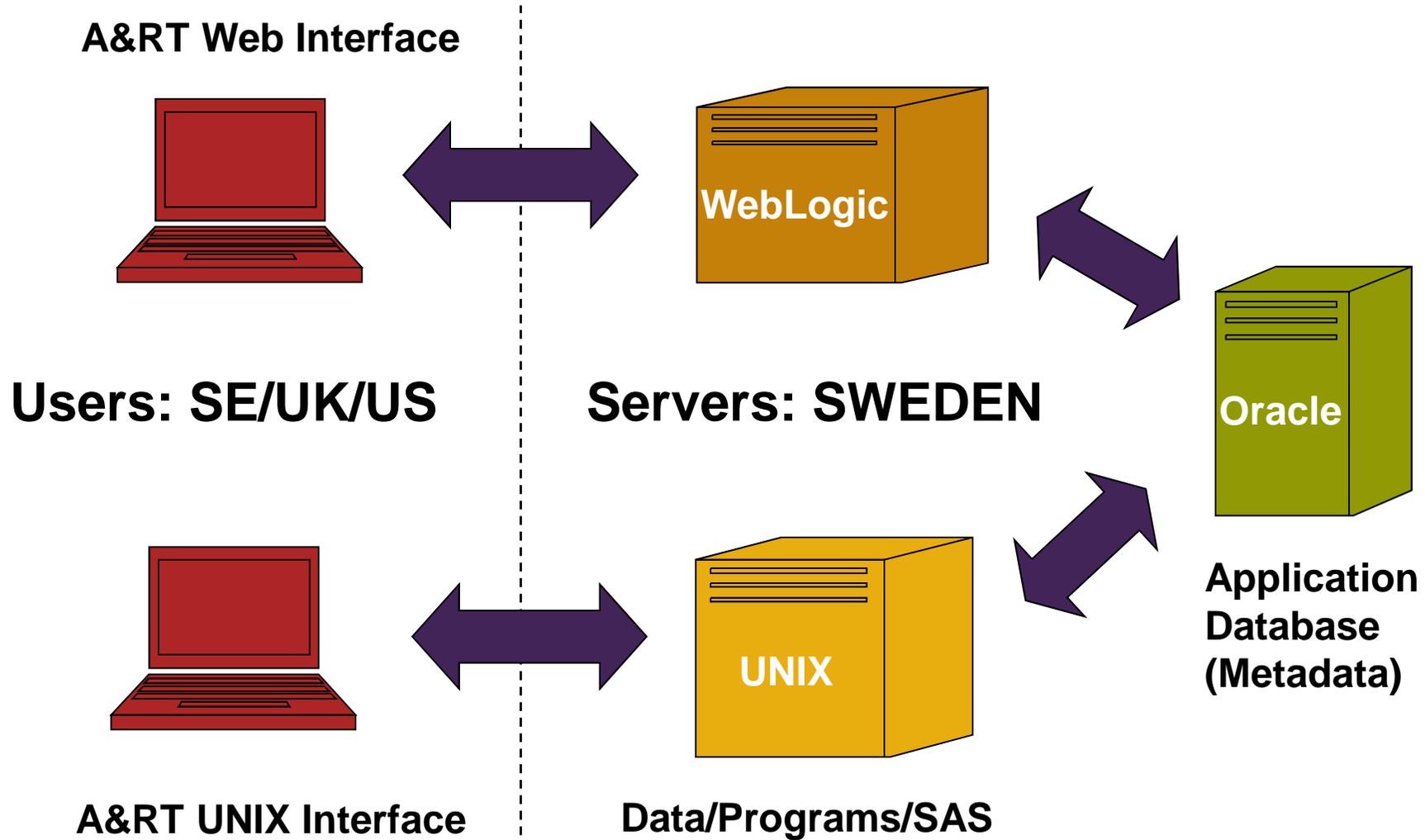


Key Concepts (3)

- **Common tools**

- Implement common software for Analysis and Reporting at all sites
- Create SAS® code fragments for defined data transformations
- Develop and implement libraries of global, reusable computer programs for production of statistical output
- Procure generic SAS reporting macros to create standardized tables and listings.

A&RT Architecture



A&RT: Deliverables

Hard Deliverables
Information
Globally accessible libraries
Metadata database
Tools and automated tasks

Soft Deliverables
Control
Streamlined maintenance
Visibility
Process change

A&RT Mapping Screen

General | Metadata | Data | Mapping | SAS Code | Jobs | Results | Tools

RAW - SDTM Mapping Details Print Export

Total Variables Mapped : 14 | Unmapped : 0

Current Version: 1 | Previous Versions : n/a Lock Table

Add new mapping Refresh

RAW				SDTM					
Domain	Label	Variable	Map Mode ^	Variable	Label	Domain	Core	Status	
<input type="checkbox"/> ALL			Macro Mapping			ALL	ALL	ALL	
<input type="checkbox"/> AELOG	AE Start Date	AE_SDAT	MACRO %dctc (INVAR_DAT=AELOG.AE_SDAT ,I NVAR_TIM=,OUTVAR_DTC=AE.A EDTC)	AEDTDC	Date/Time of Collection	AE	Expected	Draft	
<input type="checkbox"/> AELOG	AE Stop Date	AE_EDAT	MACRO %dctc (INVAR_DAT=AELOG.AE_EDAT ,I NVAR_TIM=AELOG.AE_ETMX ,OU TVAR_DTC=AE.AEENDTC)	AEENDTC	End Date/Time of Observation	AE	Expected	Draft	
<input type="checkbox"/> AELOG	AE Stop Time	AE_ETMX	MACRO %dctc_study (INVAR_DAT=AELOG.AE_EDAT ,I NVAR_TIM=AELOG.AE_ETMX ,OU TVAR_DTC=AE.AEENDTC)	AEENDTC	End Date/Time of Observation	AE	Expected	Draft	
<input type="checkbox"/> AELOG	AE Stop Date	AE_EDAT	MACRO %dctc (INVAR_DAT=AELOG.AE_EDAT ,I NVAR_TIM=AELOG.AE_ETMX ,OU TVAR_DTC=AE.AEENDTC)	AEENDTC	End Date/Time of Observation	AE	Expected	Draft	
<input type="checkbox"/> AELOG	AE Start Date	AE_SDAT	MACRO %dctc (INVAR_DAT=AELOG.AE_SDAT ,I NVAR_TIM=,OUTVAR_DTC=AE.A ESTDTC)	AESTDTC	Start Date/Time of Observation	AE	Expected	Partial	
<input type="checkbox"/>			MACRO %straining_bfl (INVAR_STRESN=LB.LBSTRESN , INVAR_STRESC=LB.LBSTRESC ,I NVAR_TESTCD=LB.LBTESTCD ,W H_TESTCOND=,STR_SAMEDTC=, INLIST_BYVARS=LBFAST,INVAR_ DTC=LB.LBDTC ,INVAR_TRTDTC =,WH_BLCOND=,NUM_BLMETHO D=1,STR_FIRSTDOSEDAYRULE=, OUTVAR_BFL=LB.LBBLFL ,WH_T RT=,INVAR_VAR1=LB.LBFAST ,I NVAR_VAR2=,INVAR_VAR3=,INV AR_VAR4=,INVAR_VAR5=,INVAR _VAR6=)	LBBLFL	Baseline Flag	LB	Expected	Partial	
<input type="checkbox"/> LABXX	Sampling Date	SAMP_DAT	MACRO %dctc (INVAR_DAT=LABXX.SAMP_DAT NVAR_TIM=,OUTVAR_DTC=LB	LB DTC	Date/Time of Collection	LB	Expected	Partial	

Environments

Environment	Purpose
Dev	<ul style="list-style-type: none">▪ SAS Program Creation and Development▪ Informal Analysis/Reporting
Val	<ul style="list-style-type: none">▪ Secure holding of SAS Programs during validation
Prod	<ul style="list-style-type: none">▪ Validated SAS Program execution▪ Formal Analysis/Reporting
Staging	<ul style="list-style-type: none">▪ Loading external files into A&RT

A&RT Project Level

astrazeneca > oncology >

General | Metadata | Data | Mapping | SAS Code | Jobs | Results | Tools

oncology -- Oncology

TA Details

TA Description: Oncology Therapy Area

TA Standards

User list	Actions
Programmer / Biostatistician - 15 Data Loader - 11	

Utility Data

Locked tables : 0 | Open tables : 0

SDTM

Version 1 2009-12-20 10:24:44

RAW - SDTM Mapping SDTM Table SDTM Programs

RDB

Version 1 2009-12-20 10:25:20

SDTM - RDB Mapping RDB Table RDB Programs

Output

Templates	0 in dev	0 in val	0 in prod
Table	0 in dev	0 in val	0 in prod
Figure	0 in dev	0 in val	0 in prod
Listing	0 in dev	0 in val	0 in prod

Macros

Macros	0 in dev	0 in val	0 in prod

Projects Create Project

Actions	Project Code ^	Project name	Project Description	User list
	azd0530	EPT01		Project Administrator - 2
	azd1480	EPT03		Project Administrator - 4
	azd2171	Recentin		Project Administrator - 2
	azd7762			Project Administrator - 2
	d1536			Project Administrator - 1
	d1600			Project Administrator - 1
	d2782	AZD4877		Project Administrator - 3
	d4200	Zactima	AZD6474	Project Administrator - 5
	d4200	Zikaterpa	AZD4854	Project Administrator - 1

Variable-Level Metadata

General | Metadata | Data | Mapping | SAS Code | Jobs | Results | Tools

SDTM Variables Definitions

Print Export

Current Version: 2 | Previous Versions: 1

Variable Details Inherit Import Metadata Add Variable Definition

Actions	Dataset Name	Variable Name	Label	Core Type	Length	Format	Type	Variable Origin	Role	CDISC Notes
	AE			ALL			ALL	ALL	ALL	
	AE	AEACN	Action Taken with Study Treatment	Expected	200		Char	CRF	Record	
	AE	AEACNOTH	Other Action Taken	Expected	200		Char	CRF	Record	
	AE	AEBODSYS	Body System or Organ Class	Expected	200		Char	CRF	Record	
	AE	AECAT	Category	Expected	40		Char	CRF	Grouping	
	AE	AECONTR	Concomitant Medication Given	Expected	200	\$NY	Char	CRF	Record	
	AE	AEDECOD	Dictionary-3 Term	Expected	200		Char	CRF	Synonym for TERM	
	AE	AEDTC	Date/Time of Collection	Expected	40	ISO8601	Char	CRF	Timing	
	AE	AEDUR	Duration	Expected	40	ISO8601	Char	CRF	Timing	
	AE	AEDY	Study Day of Visit/Collection/Exam	Expected	8		Num	Derived	Timing	
	AE	AEELTM	Planned Elapsed Time from Time Point Ref	Expected	40	ISO8601	Char	Protocol	Timing	
	AE	AEENDTC	End Date/Time of Observation	Expected	40	ISO8601	Char	CRF	Timing	
	AE	AEENDY	Study Day of End of Observation	Expected	8		Num	Derived	Timing	
	AE	AEENRF	End Relative to Reference Period	Expected	40		Char	Derived	Timing	
	AE	AEENRTPT	End Relative to Start Time	Expected	40		Char	Derived	Timing	
	AE	AEENTPT	End Reference Time Point	Expected	40		Char	Derived	Timing	
	AE	AEVLINT	Evaluation Interval	Expected	40	ISO8601	Char	CRF	Timing	
	AE	AEGRPID	Group ID	Expected	40		Char	CRF	Identifier	
	AE	AELOC	Location	Expected	40		Char	CRF	Record	
	AE	AEMODIFY	Modified Reported Term	Expected	200		Char	CRF	Synonym for TERM	
	AE	AEOCCUR	Occurrence	Expected	1	\$NY	Char	CRF	Record	
	AE	AEOUT	Outcome of Event	Expected	200		Char	CRF	Record	
	AE	AEPATT	Pattern of Event	Expected	40		Char	CRF	Record	

Metadata can be:

- Imported
- Inherited
- Edited

The A&RT Program Builder

- Written by AstraZeneca
 - interrogates the metadata
 - creates a number of SAS programs
 - Allows creation of our reporting database
- Uses 3 key concepts
 - Keywords
 - SQL
 - SAS macros
- Creates domain level and master programs

Macro Definition

Analysis & Report Transformation UI1010-15 -- Webpage Dialog

RAW - SDTM - Map Variables

TA : training Project : uk study : ukrain15

Mapping mode: Macro Mapping

Select Macro : astrazeneca.dtc Search Macro

Select Macro Parameters

Input Parameters				Output Parameters					
Dataset Type :	SELECT	Source Dataset :	SELECT	Target Dataset:	SELECT				
Name	Suggested Value	Value	Label	Mandatory	Name	Suggested Value	Value	Label	Mandatory
INVAR_DAT		AELOG.AE_SDAT	DAT Variable	Y	OUTVAR_DTC		AE.AESTDTC	DTC Variable	Y
INVAR_TIM		AELOG.AE_STIM	TIM Variable	N					

Save and Accept Save as Draft Cancel

<http://artprod.rd.astrazeneca.net/ART-Mapping-WEB/mapping/editMapFrame.jsp?Method=loadEditMaps&metadataName=SDTM MAI> Local intranet | Protected Mode: On

Macro Parameter Entry Screen

RAW - SDTM - Map Variables

TA : oncology Project : ept06onco study : d1532c0006

Mapping mode: Macro Mapping

Select Macro : astrazeneca.pb_tranhtov Search Macro

Select Macro Parameters

Dataset Type: SELECT Source Dataset: SELECT Target Dataset: SELECT

Input Parameters					Output Parameters				
Name	Suggested Value	Value	Label	Mandatory	Name	Suggested Value	Value	Label	Mandatory
inform_1		"DISPOSITION EVENT"	Formula for target creation 1	Y	outvartran_1		DS.DSCAT	Target variable 1	Y
inform_2		"DACARBAZINE TREATMENT S	Formula for target creation 2	N	outvartran_2		DS.DSTERM	Target variable 2	N
inform_3		"TREATMENT STOPPED DUE TO	Formula for target creation 3	N	outvartran_3		DS.DSDECOD	Target variable 3	N
inform_4		%DTC(INVAR_DAT=DOSDISC.IF	Formula for target creation 4	N	outvartran_4		DS.DSSTDTC	Target variable 4	N
inform_5		UPCASE(S_IPDCRE)	Formula for target creation 5	N	outvartran_5		DS.DSSPFY	Target variable 5	N
inform_6		CASE WHEN SUBJCONT EQ "1"	Formula for target creation 6	N	outvartran_6		DS.SUBJCONT	Target variable 6	N
inform_7		"TREATMENT PERIOD"	Formula for target creation 7	N	outvartran_7		DS.EPOCH	Target variable 7	N
inform_8			Formula for target creation 8	N	outvartran_8			Target variable 8	N
inform_9			Formula for target creation 9	N	outvartran_9			Target variable 9	N
inform_10			Formula for target creation 10	N	outvartran_10			Target variable 10	N
inform_11			Formula for target creation 11	N	outvartran_11			Target variable 11	N
inform_12			Formula for target creation 12	N	outvartran_12			Target variable 12	N
inform_13			Formula for target creation 13	N	outvartran_13			Target variable 13	N
inform_14			Formula for target creation 14	N	outvartran_14			Target variable 14	N
inform_15			Formula for target creation 15	N	outvartran_15			Target variable 15	N
inform_16			Formula for target creation 16	N	outvartran_16			Target variable 16	N
inform_17			Formula for target creation 17	N	outvartran_17			Target variable 17	N
inform_18			Formula for target creation 18	N	outvartran_18			Target variable 18	N
inform_19			Formula for target creation 19	N	outvartran_19			Target variable 19	N
inform_20			Formula for target creation 20	N	outvartran_20			Target variable 20	N
inwhrc1ae		IP_DISC = "1" and module_o=2	Subsetting condition	N					
invar_trangrp		DOSDISC.IP_DISC	Transposition grouping variable	Y					
invar_var1		DOSDISC.IPDCREA	Additional source variable 1	N					
invar_var2			Additional source variable 2	N					
invar_var3		DOSDISC.S_IPDCRE	Additional source variable 3	N					
invar_var4		DOSDISC.IPDC_DAT	Additional source variable 4	N					
invar_var5		DOSDISC.SUBJCONT	Additional source variable 5	N					

Save and Accept Save as Draft Cancel

Program Builder Created SAS programs

General Metadata Data Mapping SAS Code Jobs Results Tools					
Available SAS Programs					
<input type="checkbox"/>	Actions	SAS Programs <input type="text"/>	Env <input type="text" value="AL"/>	Type <input type="text" value="RDB"/>	Description <input type="text"/>
<input type="checkbox"/>	    	ae001.sas	dev	rdb	Program for creation of R_AE domain
<input type="checkbox"/>	    	ce001.sas	dev	rdb	Program for creation of R_CE domain
<input type="checkbox"/>	    	cm001.sas	dev	rdb	Program for creation of R_CM domain
<input type="checkbox"/>	    	co001.sas	dev	rdb	Program for creation of R_CO domain
<input type="checkbox"/>	    	da001.sas	dev	rdb	Program for creation of R_DA domain
<input type="checkbox"/>	    	dm001.sas	dev	rdb	Program for creation of R_DM domain
<input type="checkbox"/>	    	ds001.sas	dev	rdb	Program for creation of R_DS domain
<input type="checkbox"/>	    	dv001.sas	dev	rdb	Program for creation of R_DV domain
<input type="checkbox"/>	    	eq001.sas	dev	rdb	Program for creation of R_EG domain
<input type="checkbox"/>	    	ex001.sas	dev	rdb	Program for creation of R_EX domain

Data Tabulation within A&RT

PRINT

TA : training

Project : test

Study : marktest

STUDY	PART	CENTRE	SUBJECT	PATIENT	LINE	MODULE	VISIT	ECG_I
D4200C0005 7	A	1101.0	E1101001	657.0	1.0	ECG_E	1.0	2007-
D4200C0005 7	A	1101.0	E1101001	657.0	1.0	ECG_E	1.0	2007-
D4200C0005 7	A	1101.0	E1101001	657.0	1.0	ECG_E	1.0	2007-
D4200C0005 7	A	1101.0	E1101001	657.0	1.0	ECG_E	2.0	2007-
D4200C0005 7	A	1101.0	E1101001	657.0	1.0	ECG_E	2.0	2007-
D4200C0005 7	A	1101.0	E1101001	657.0	1.0	ECG_E	2.0	2007-
D4200C0005 7	A	1101.0	E1101001	657.0	1.0	ECG_E	3.0	2007-
D4200C0005 7	A	1101.0	E1101001	657.0	1.0	ECG_E		2007-
D4200C0005 7	A	1101.0	E1101001	657.0	1.0	ECG_E		2007-
D4200C0005 7	A	1101.0	E1101001	657.0	1.0	ECG_E	4.0	2007-
D4200C0005 7	A	1101.0	E1101001	657.0	1.0	ECG_E	5.0	2007-
D4200C0005 7	A	1101.0	E1101001	657.0	1.0	ECG_E	6.0	2007-
D4200C0005 7	A	1101.0	E1101001	657.0	1.0	ECG_E	100.0	2007-
D4200C0005 7	A	1101.0	E1101002	659.0	1.0	ECG_E	1.0	2007-
D4200C0005 7	A	1101.0	E1101002	659.0	1.0	ECG_E	1.0	2007-
D4200C0005 7	A	1101.0	E1101002	659.0	1.0	ECG_E	1.0	2007-
D4200C0005 7	A	1101.0	E1101002	659.0	1.0	ECG_E	2.0	2007-
D4200C0005 7	A	1101.0	E1101002	659.0	1.0	ECG_E	2.0	2007-
D4200C0005 7	A	1101.0	E1101002	659.0	1.0	ECG_E		2007-
D4200C0005 7	A	1101.0	E1101002	659.0	1.0	ECG_E		2007-

Next>>

CLOSE

Metadata and Outputs

- Use of metadata extends to the creation of SAS outputs
- We have bought a SAS reporting application and embedded it into the A&RT architecture
- We do collect information about titles and footnotes
- We also create:
 - logical groupings in preparation for generating PDFs
 - sub-groups to allow further refinement of groupings
 - suffixes to allow the same program to create multiple versions of the output for different destinations or parameter driven outputs.

Output Definitions

View Output

<input type="checkbox"/>	Actions	Output Object [▲] <input type="text"/>	Env dev ▼	Modified on	Title t <input type="text"/>
<input type="checkbox"/>	<input checked="" type="checkbox"/> <input type="checkbox"/> U	artae101xmla.xml	dev	2010-09-14 12:08:55	T1 for artae001a.xml - Dataset=r_ae - Training xml table showing ae data
	<input checked="" type="checkbox"/>	artdm101a.lst	dev		T3 for artdm001
	<input checked="" type="checkbox"/>	artdm102xa.lst	dev	2009-10-30 10:54:50	T3 for artdm102xa.lst
<input type="checkbox"/>	<input checked="" type="checkbox"/> <input type="checkbox"/> U	artdm102xb.xml	dev	2009-10-30 10:54:50	T1 for artdm102xb.xml - dataset = r_dm - Training table output for DM data
	<input checked="" type="checkbox"/>	artds001a.lst	dev	2010-07-19 13:51:25	T3 for artds01a.lst
	<input checked="" type="checkbox"/>	artmh001a.lst	dev	2009-10-30 10:54:50	T3 for artmh001a.lst
	<input checked="" type="checkbox"/>	artsubj001a.lst	dev	2009-10-30 10:54:50	Title 3 for artsubj001a.lst
	<input checked="" type="checkbox"/>	artsubj002a.lst	dev	2009-10-30 10:54:50	Title 3 for artsubj002.lst
	<input checked="" type="checkbox"/> <input type="checkbox"/> U	rikarda.xml	dev		Table Title
	<input checked="" type="checkbox"/> <input type="checkbox"/> U	testspecialcharsb.xml	dev		Test of special characters

A&RT Output Metadata

Output Definitions

Available Output Definitions

Actions	Output Definition#	Output Name	Suffix
 	1	artdm101	a

Output Name: Suffix:

Output Group: Sub Group:

o/p Type: Output#:

Destination: File xtn:

Titles

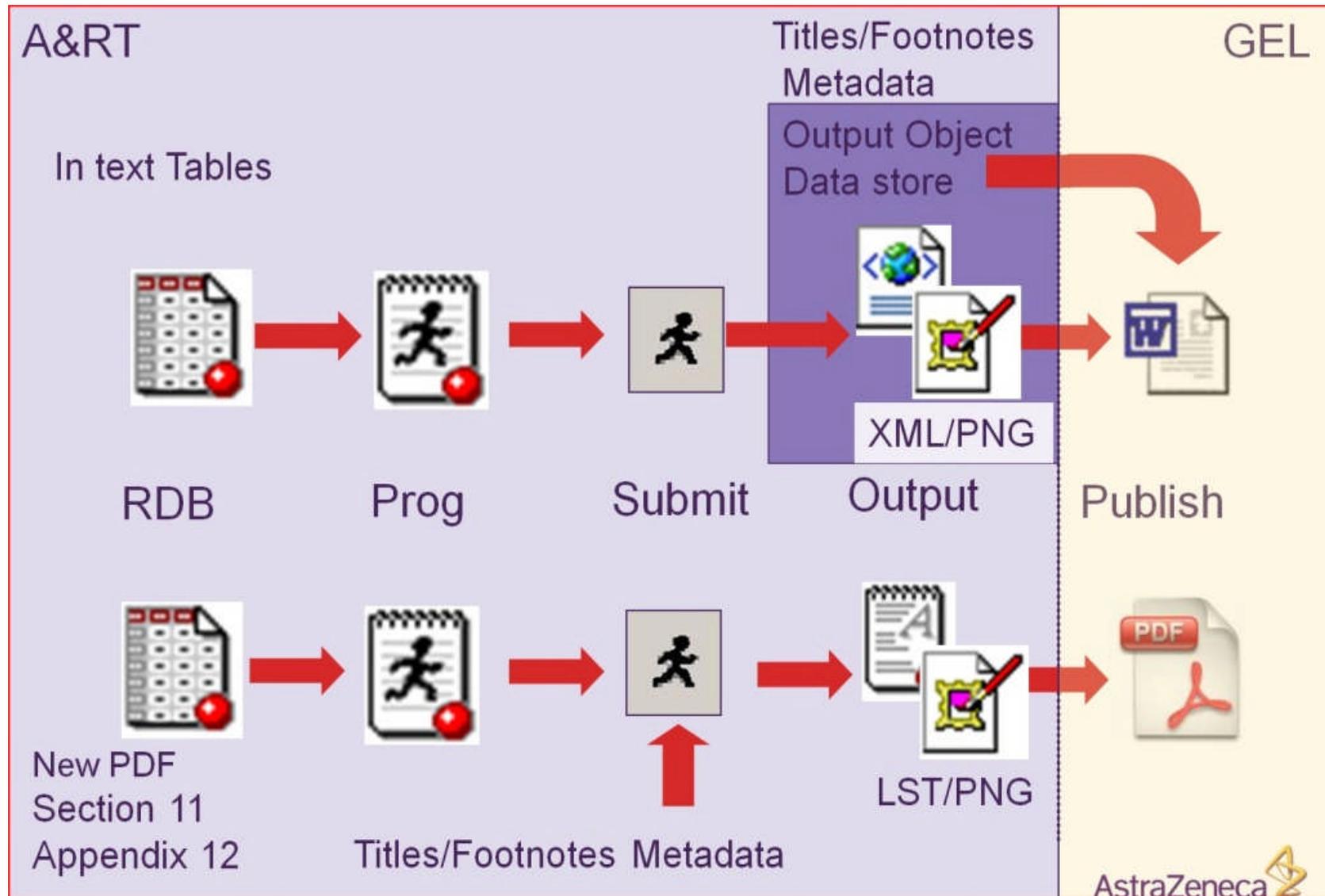
Actions	Title#	Title Text
 	3	T3 for artdm001
 	4	dataset = r_dm
 	5	Training table showing output for dm data

Footnotes

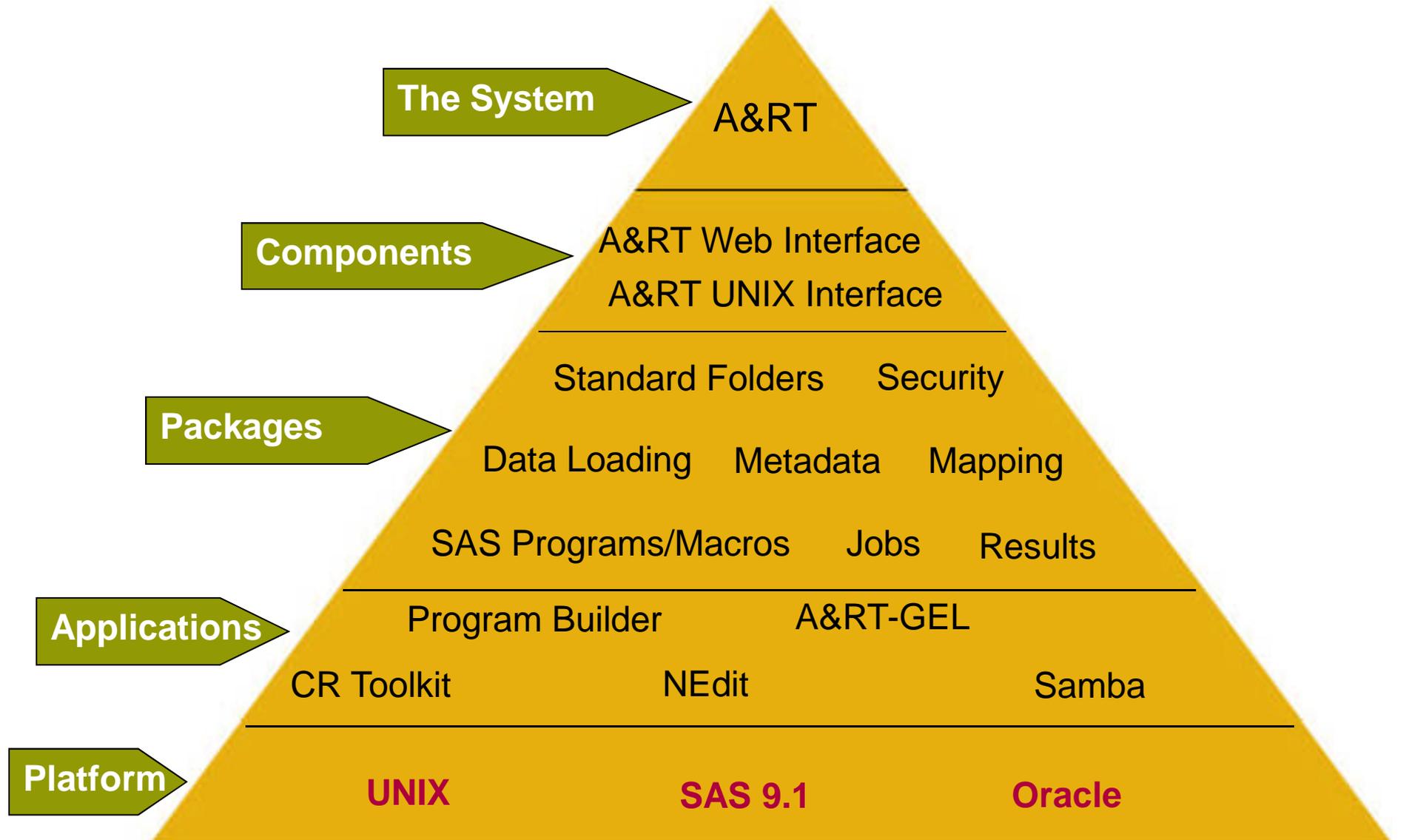
Actions	Footnote#	Footnote Text
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Reporting Touchpoints



Technology Overview



Challenges...

- ...In creating a truly global reporting application:
 - Standard processes
 - Robust data standards
 - Innovative technology
- ...in making it work!

Visions for the future

- Process
 - lifecycle management team
 - Global team for mapping and output templates
 - Global support team
 - ADaM Implementation
- Technology
 - SAS 9.2 / 9.3?
 - SAS Enterprise Guide?
 - Exploitation of metadata for define.xml
 - Impact analysis
 - Metadata creation and import for output programs and maps

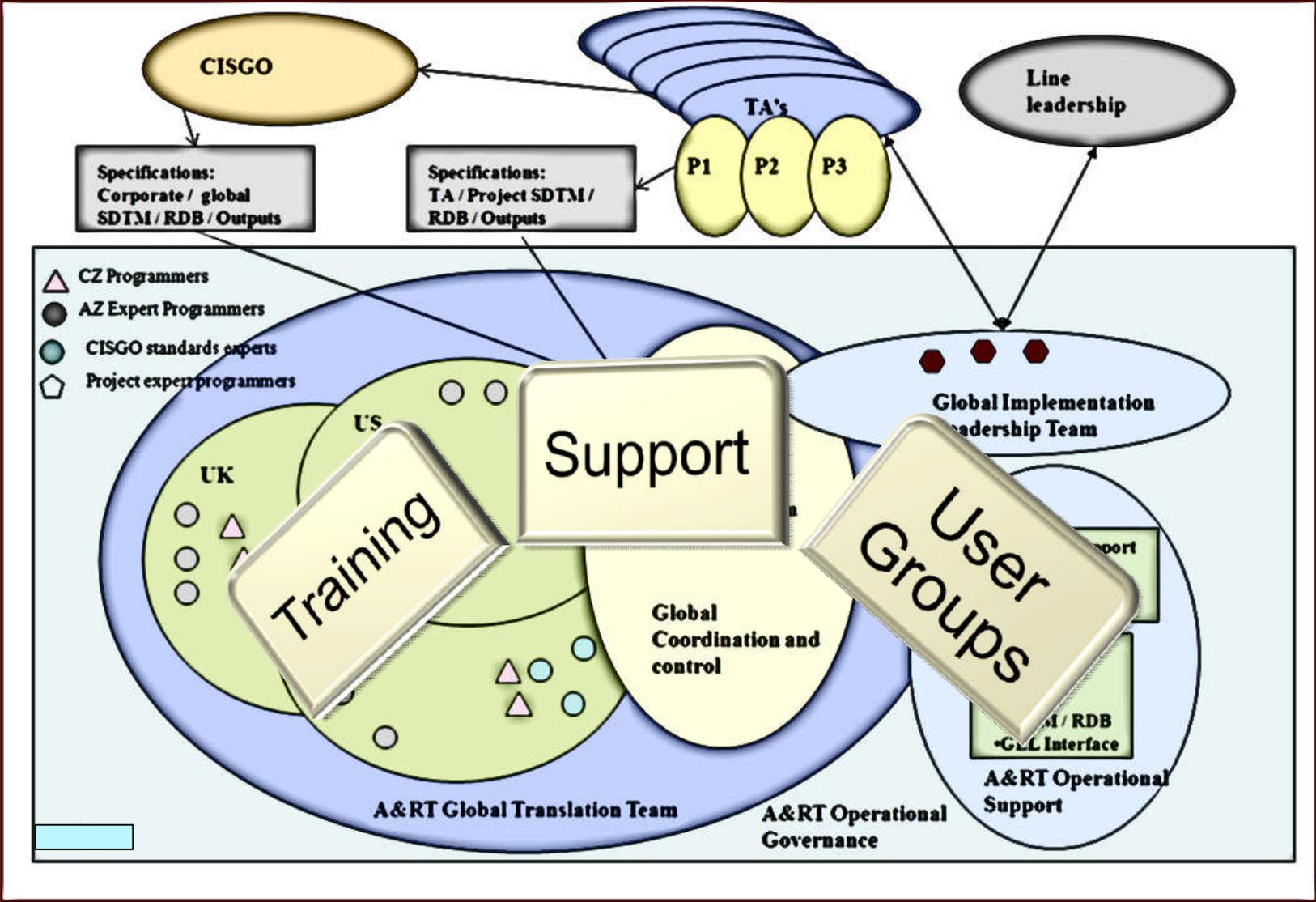
Conclusions

- Introduction of A&RT has required a shift in mindset
- Programmers will start to work in a new way
- Data standards and metadata are key
- Inheritance and equivalence are pivotal for re-usability
- ✓ We need to give our programmers some direction...

Direction



High-Level A&RT Governance



Questions

