METADATA DRIVEN APPROACH FOR DATA VISUALIZATIONS AND STANDARDIZATION

17th June 2017- PhUSE SDE Hyderabad, India
Mahesh Kumar Peddiboena

Disclaimer: Content being presented here is my own thoughts and ideas.
PAREXEL is not responsible for content.

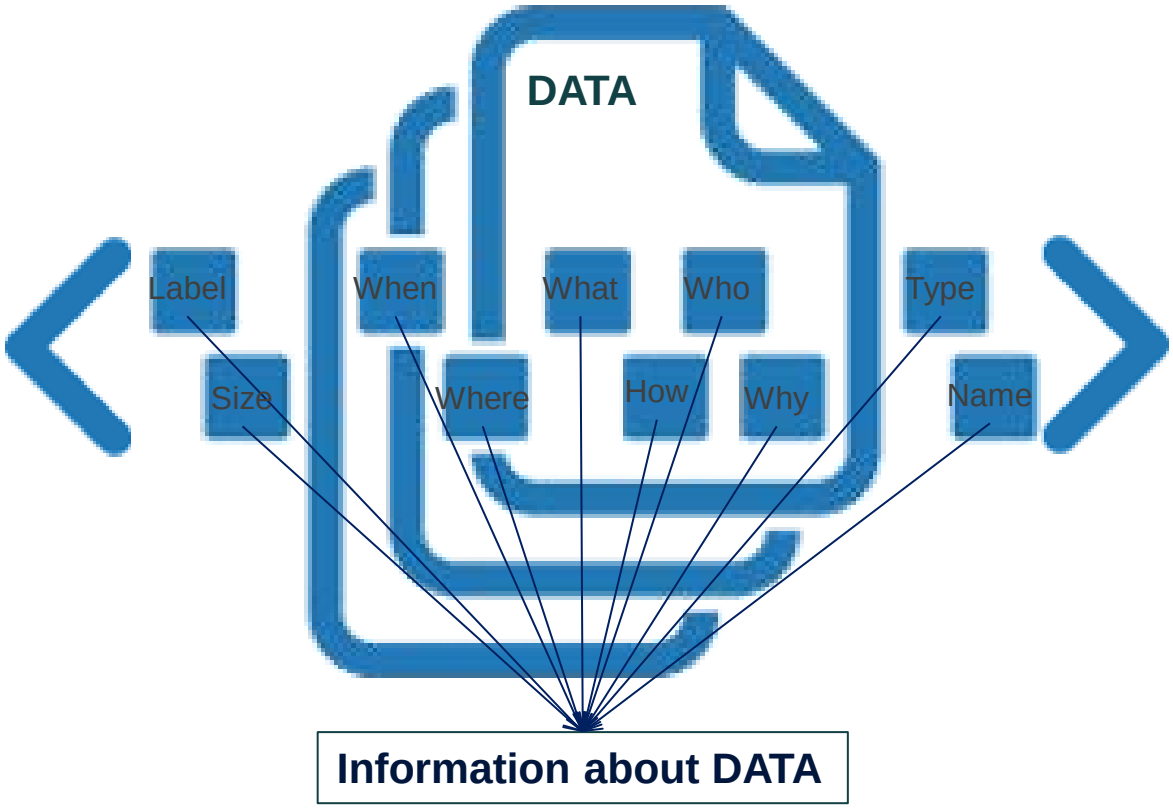
PAREXEL®
YOUR JOURNEY. OUR MISSION.®

AGENDA

- Introduction to Metadata
- Metadata Management Framework
- Business Issues - Solution - Impact
- Role-based users of Metadata Repository
- Metadata Driven Approach using Metadata Repository
- Results

Disclaimer: Content being presented here is my own thoughts and ideas. PAREXEL is not responsible for content.

WHAT IS METADATA?



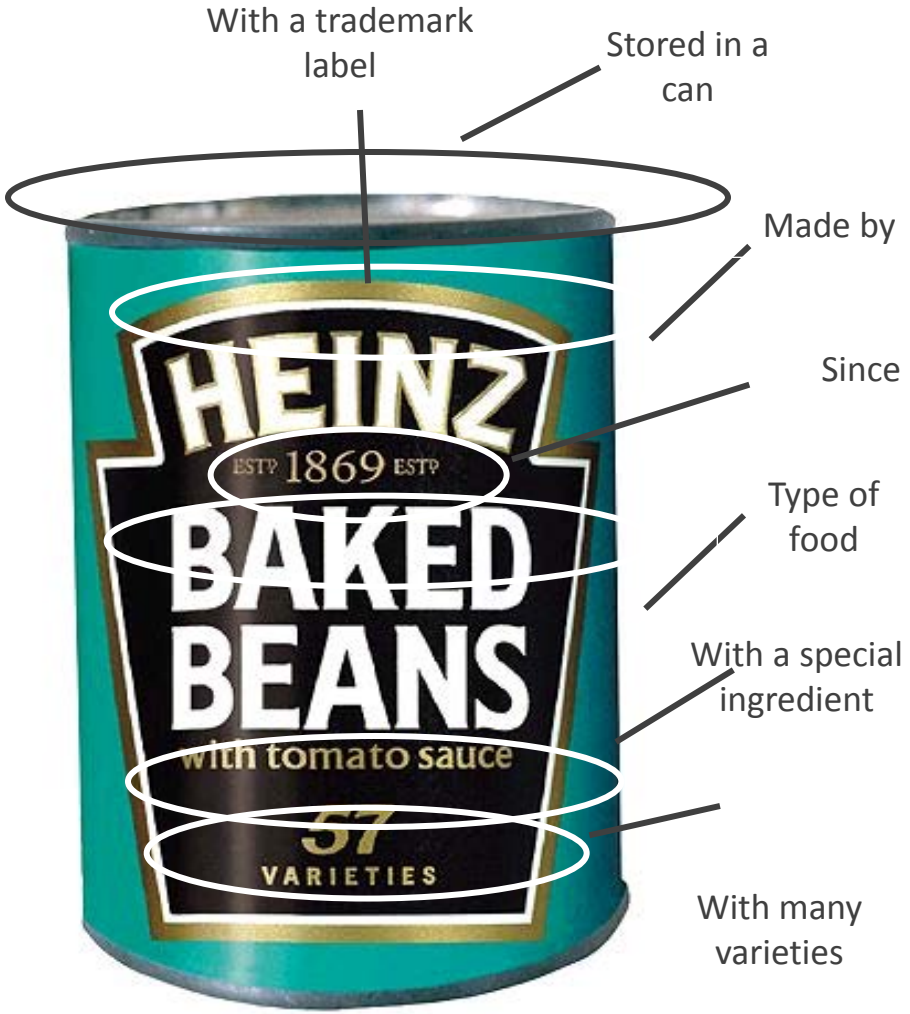
Purpose of Metadata

- Information Resource discovery
- Organize electronic resources
- Facilitate interoperability & legacy, resource integration
- Provide digital identification
- Support archiving & preservation
- Reusability

Metadata is structured information that describes, explains, locates, or otherwise makes it easier to retrieve, use, or manage an information resource.

Disclaimer: Content being presented here is my own thoughts and ideas. PAREXEL is not responsible for content.

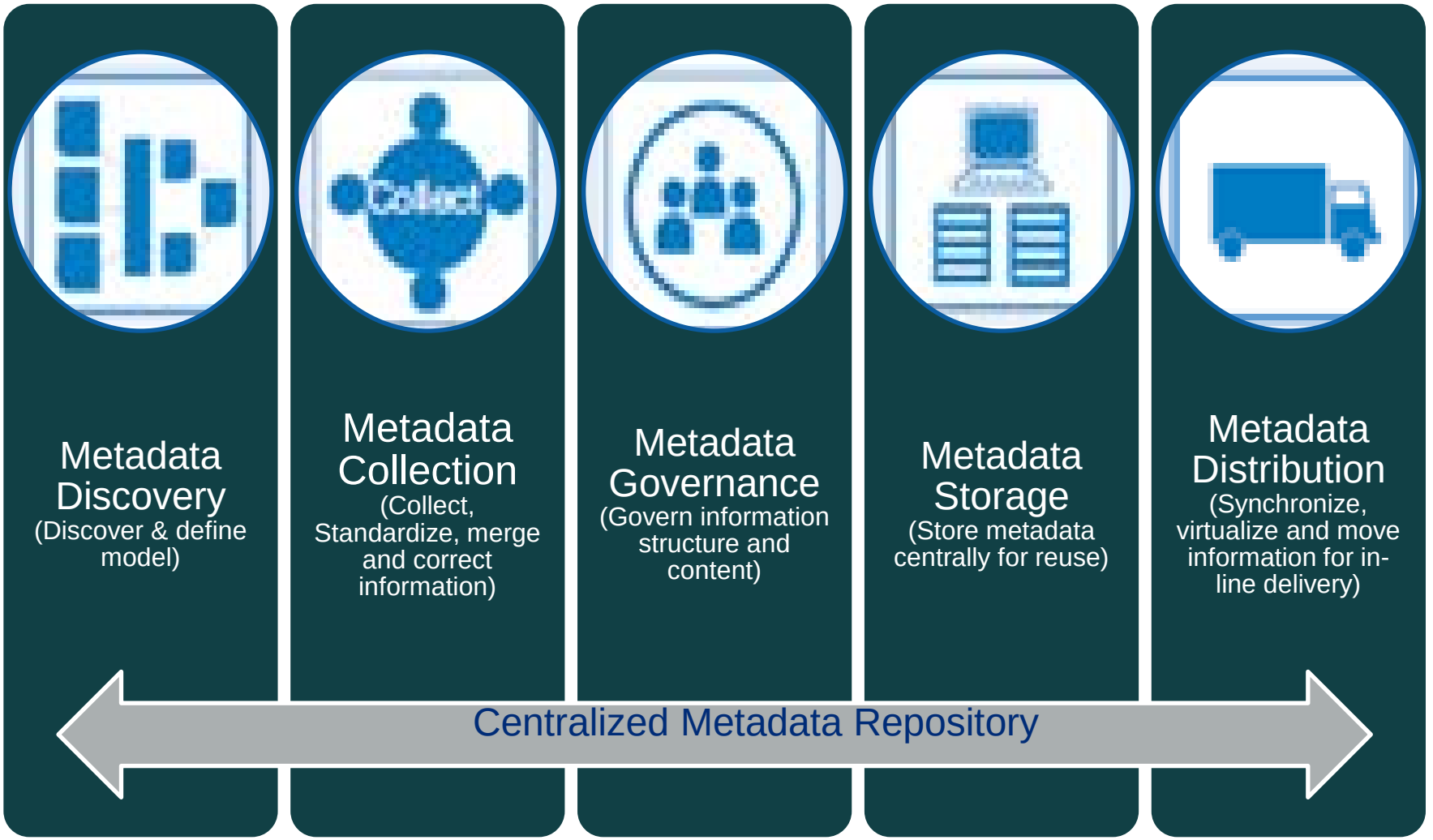
EXAMPLE OF METADATA



Metadata enables you to put context and meaning to things.

It is generated and consumed by every organization and software product.

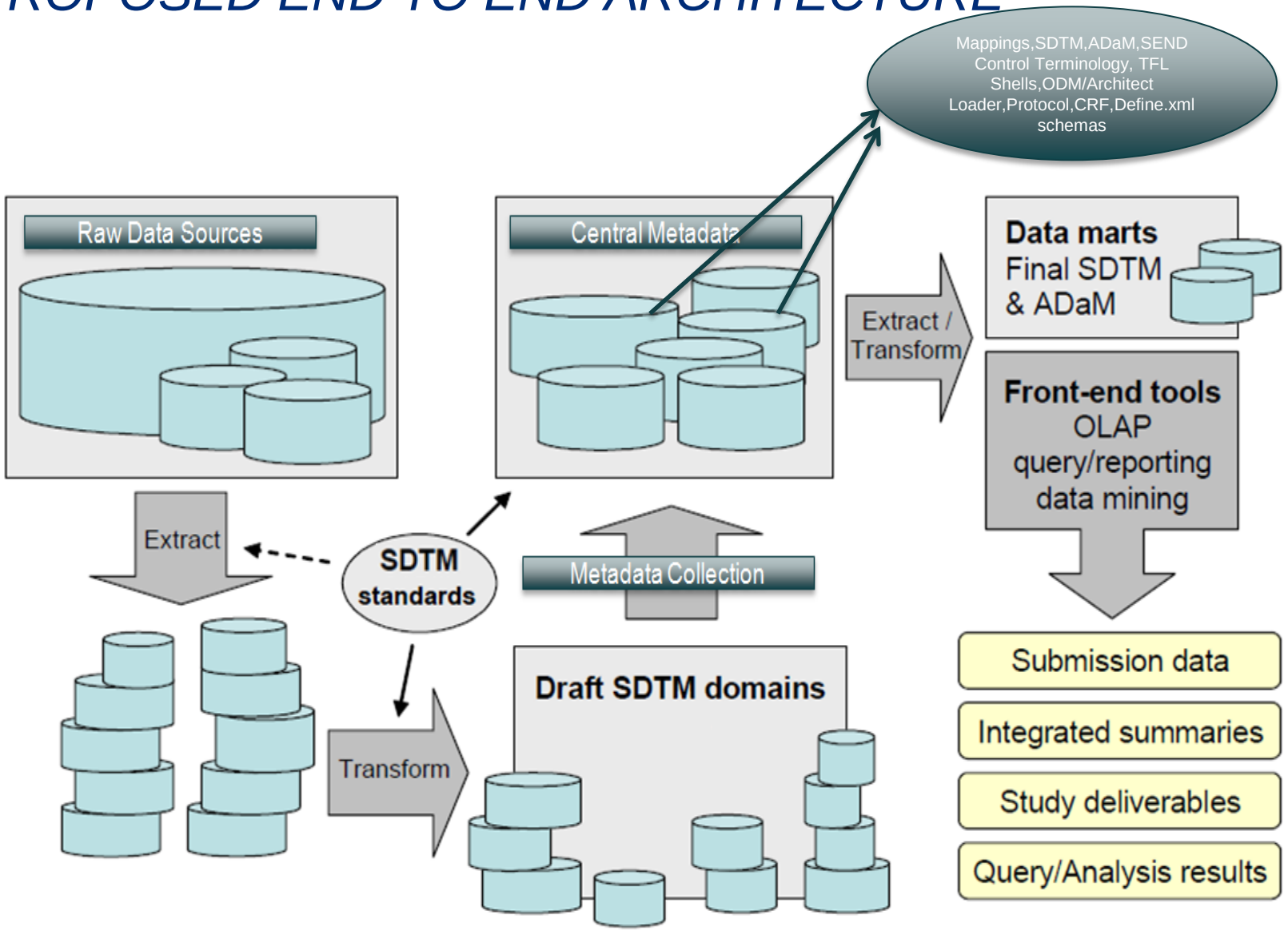
METADATA MANAGEMENT FRAMEWORK



Disclaimer: Content being presented here is my own thoughts and ideas. PAREXEL is not responsible for content.

CONFIDENTIAL

PROPOSED END TO END ARCHITECTURE



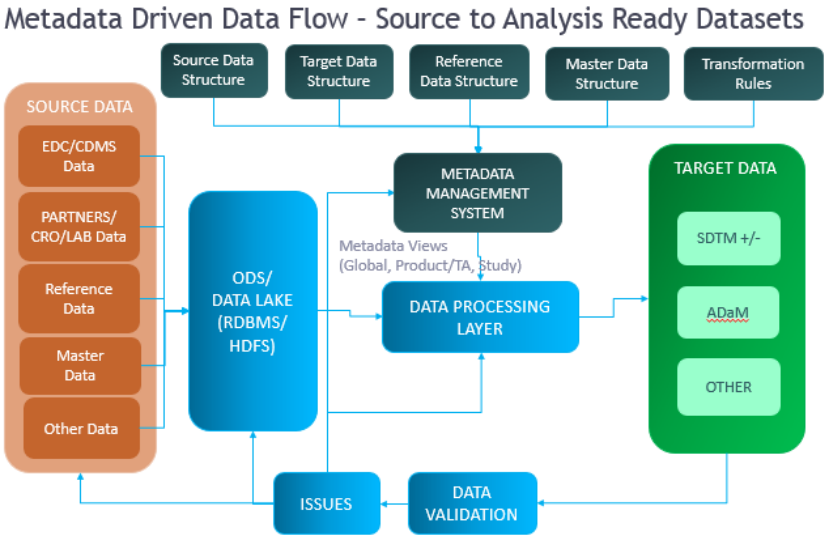
Disclaimer: Content being presented here is my own thoughts and ideas. PAREXEL is not responsible for content.

PAREXEL

METADATA DRIVEN DATA PROCESSING

Business Issue

- How do we provide quicker access to source and analysis ready data?
- How do we adapt to changes in regulatory standards rapidly and apply these changes to business and operational processes?
- How do we bring in more efficiency in the source to target mapping and transformation processes?



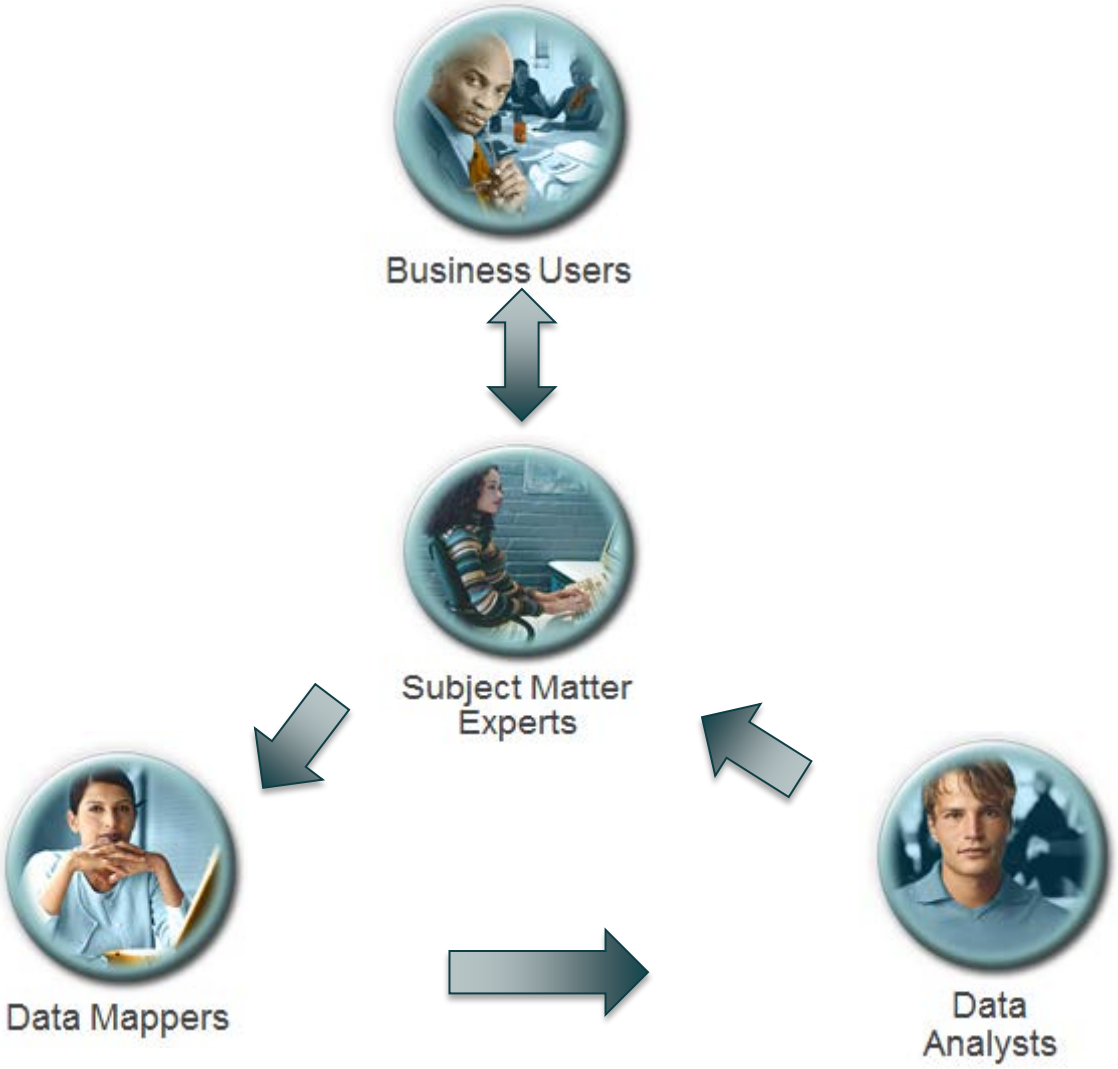
Solution Overview

- Data Ingestion Framework ingests data from Diverse Sources (clinical data, operational data, reference data)
- Populate Structural Metadata (Source/Target/Reference) and Transformational Metadata (rules/derivations) in Metadata Repository
- Dynamic Process applies transformation rules on source data to generate target datasets

Solution Impact

- High Availability of Data (Source, Integrated, Standardized)
- Reusability of Standard Algorithms
- Dynamic Automated Process
- Accelerated Path for Submissions
- Enhanced Support for Product Defense, Data Sharing, Data Mining
- Traceability

ROLE-BASED USERS OF METADATA REPOSITORY



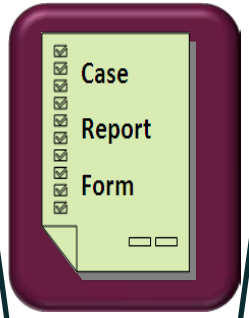
Disclaimer: Content being presented here is my own thoughts and ideas. PAREXEL is not responsible for content.

PHASES IN METADATA DRIVEN APPROACH

Protocol Development

PRM, Placeholder

CRF & Study Designer



CDASH, SDM, Proprietary

Source Data Validation

Edit Checks, Rules at Metadata

Automated CRF Annotation

CDASH, SDM, Proprietary

Data Transformation

SDTM, SUPPQUAL, RELREC, SDTM +, ADaM, Define.xml

Analytics & Reporting

SDTM, SDTM +, ADaM, CTMS

Traceability

Operational, Clinical

Disclaimer: Content being presented here is my own thoughts and ideas. PAREXEL is not responsible for content.

PAREXEL

PROTOCOL DEVELOPMENT

1.0 PROTOCOL SYNOPSIS

Study Title:	A Phase 1, Open-Label, Two-Period, Crossover Study to Evaluate the Relative Bioavailability of a New Tablet Formulation Versus the Current Capsule Formula[illegible] [illegible]dministered in Healthy Adult Volunteers
Protocol Number:	
Study Phase:	Phase 1
Study Objectives:	**Primary Objective:** 1. To compare the relative bioavail[illegible] of PPI-668 when administered as a sin[illegible] oral dose in a tablet formulation vs. in a capsule formulation **Secondary Objective:** 1. To evaluate the safety and tolerability of single oral doses [illegible] in healt[illegible] subjects
Study Design and Duration of Treatment:	This will be an open-label, single-center, single-dose, crossover study. A total of 24 healthy subjects will be enrolled. On Day 1, under a 1:1 randomization scheme eligible volunteers, 12 subjects will receive a single oral dose [illegible] in the for the current capsule formulation and 12 subjects will receive a single oral dose of t[illegible] test tablet formulation [illegible], under fasted conditions. After a one week wash period, on Day 8, subjects will receive under fasted conditions the alternate [illegible] formulation to the one they received on Day 1. Study medication will be administe approximately 0800 hours on Days 1 and 8 after an overnight fast of at least 10 ho Screening will take place within 28 days before Study Day 1. Eligible subjects wil[illegible]

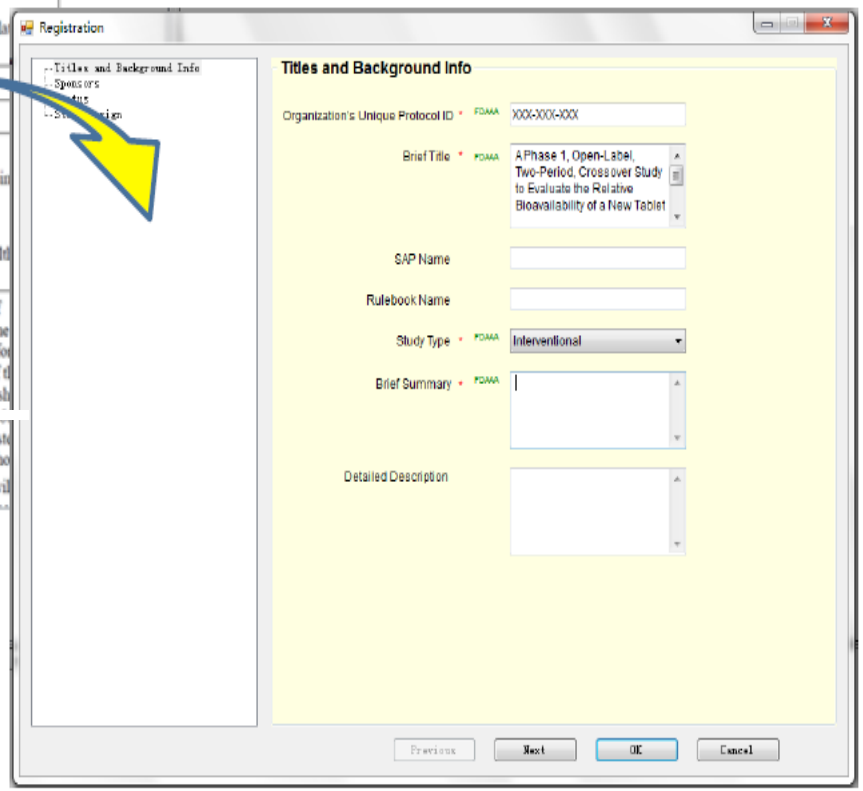


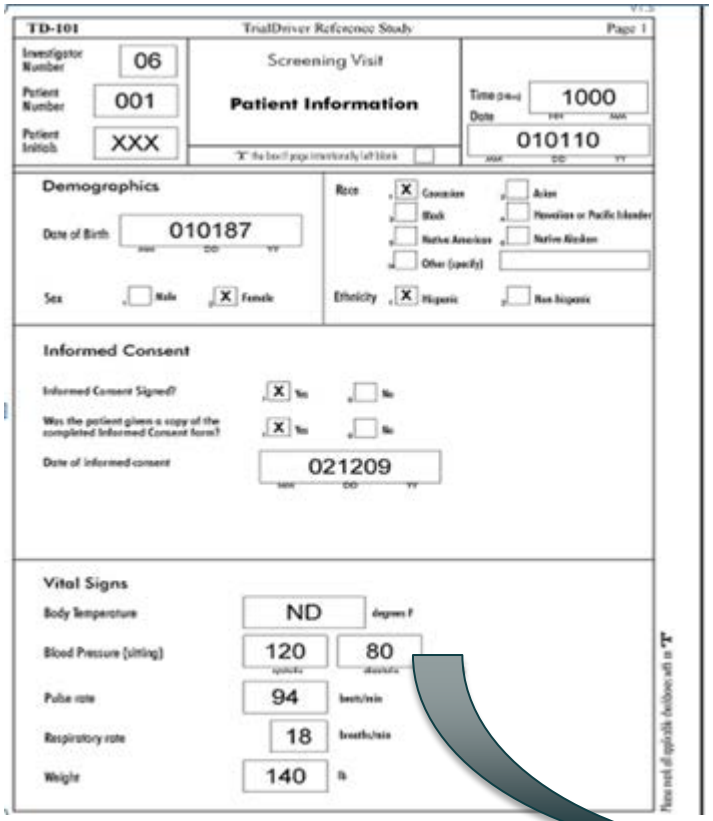
Table 7-1 Schedule of Study Procedures

	Screening[a]	Day -1	Day 1	Day 2	Day 3	Wash-out	Day 7	Day 8	Day 9	Day 10	Day 15 ± 3 days Follow-up
Written Informed Consent	X										
Medical History	X										
Complete	X										X

Disclaimer: Content being presented here is my own thoughts and ideas. PAREXEL is not responsible for content.

PAREXEL

CRF DESIGNER



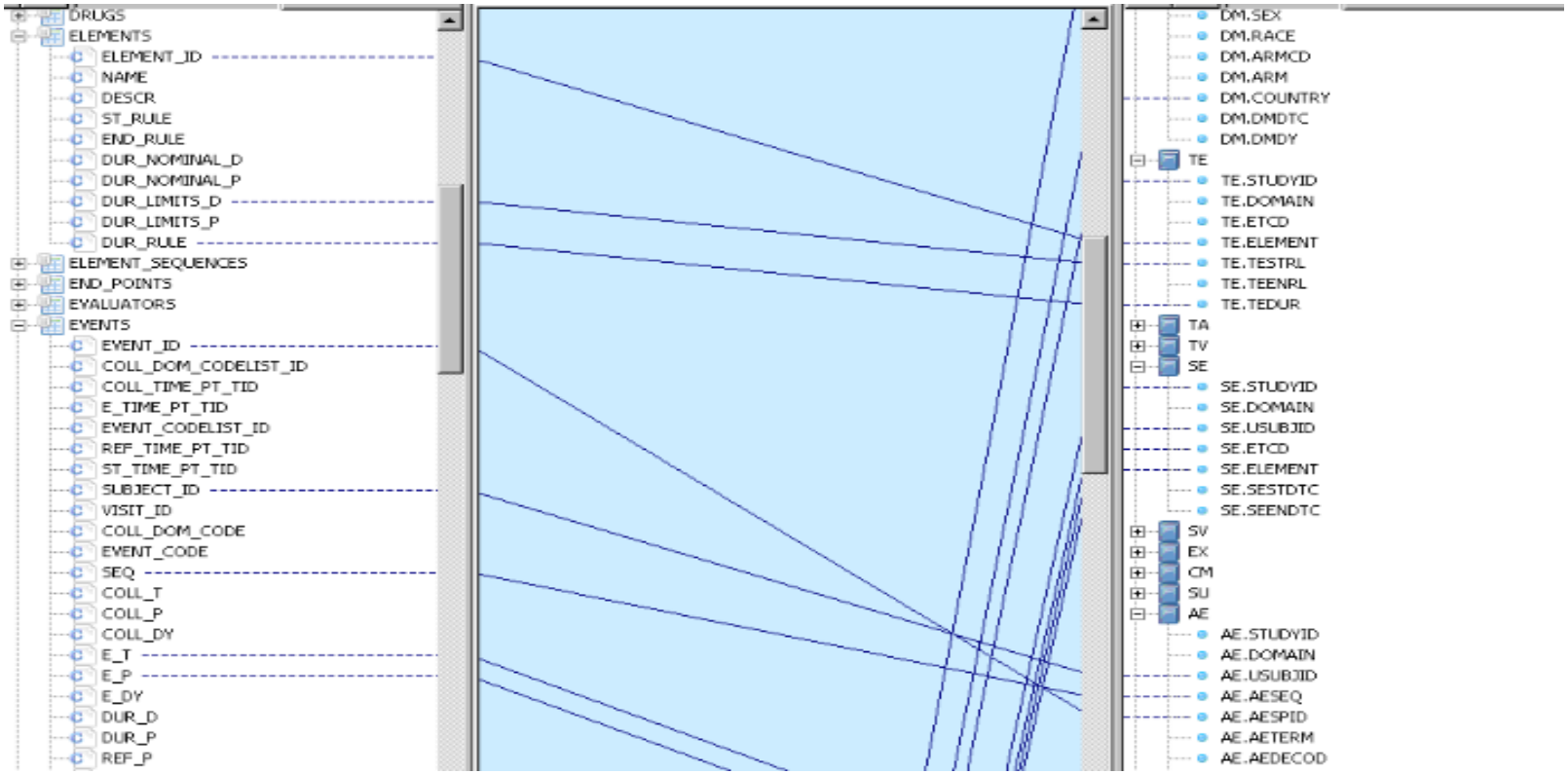
FOID	Variable	Length	Type	Field Type	Codelist
DM	SUBJID	10	Char	Text Field	
DM	SEX	1	Char	Drop Down	Gender
DM	RACE	20	Char	Drop Down	

ODM/Architect Loader

Disclaimer: Content being presented here is my own thoughts and ideas. PAREXEL is not responsible for content.

PAREXEL

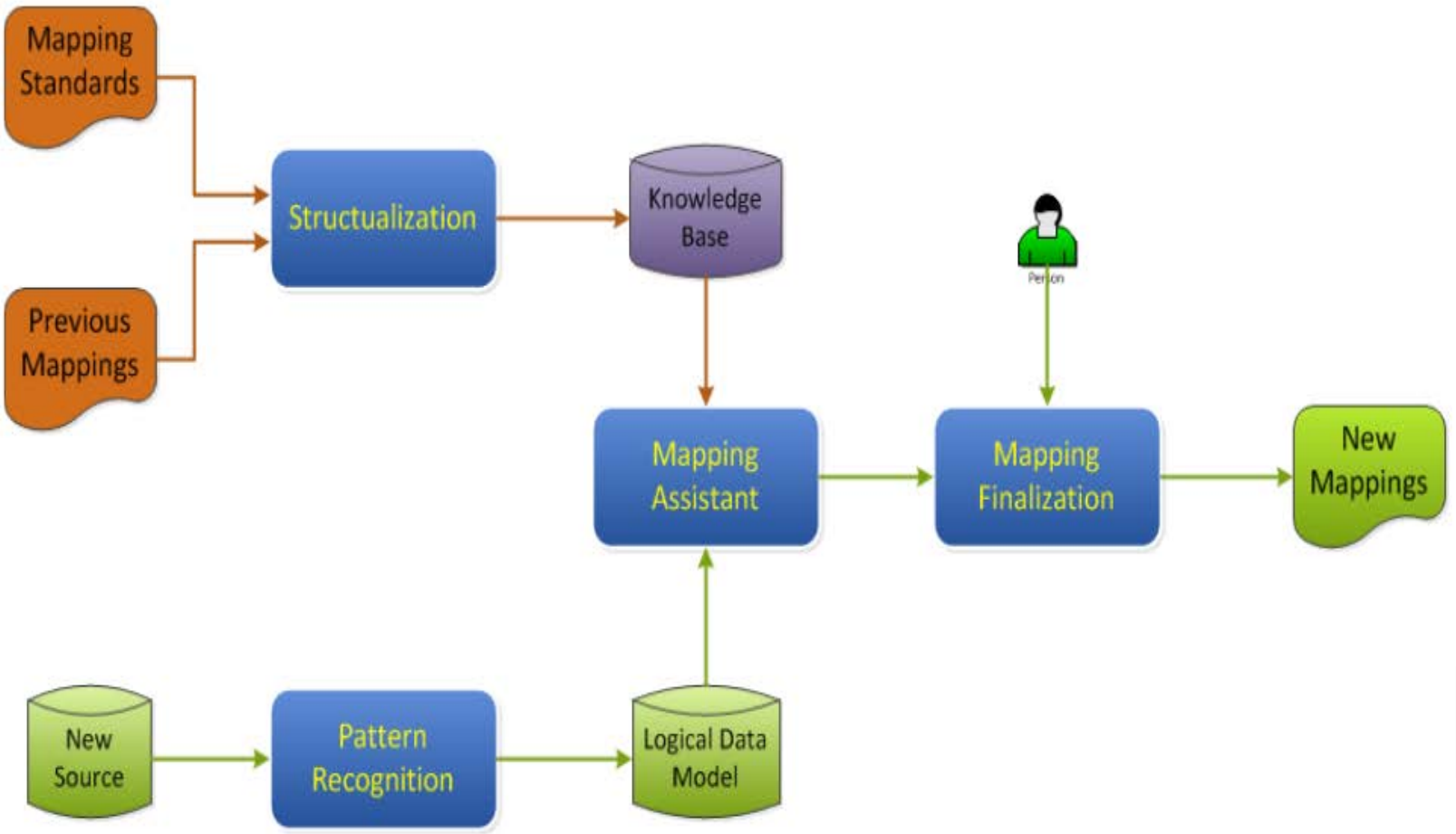
DATA TRANSFORMATION PROCESS



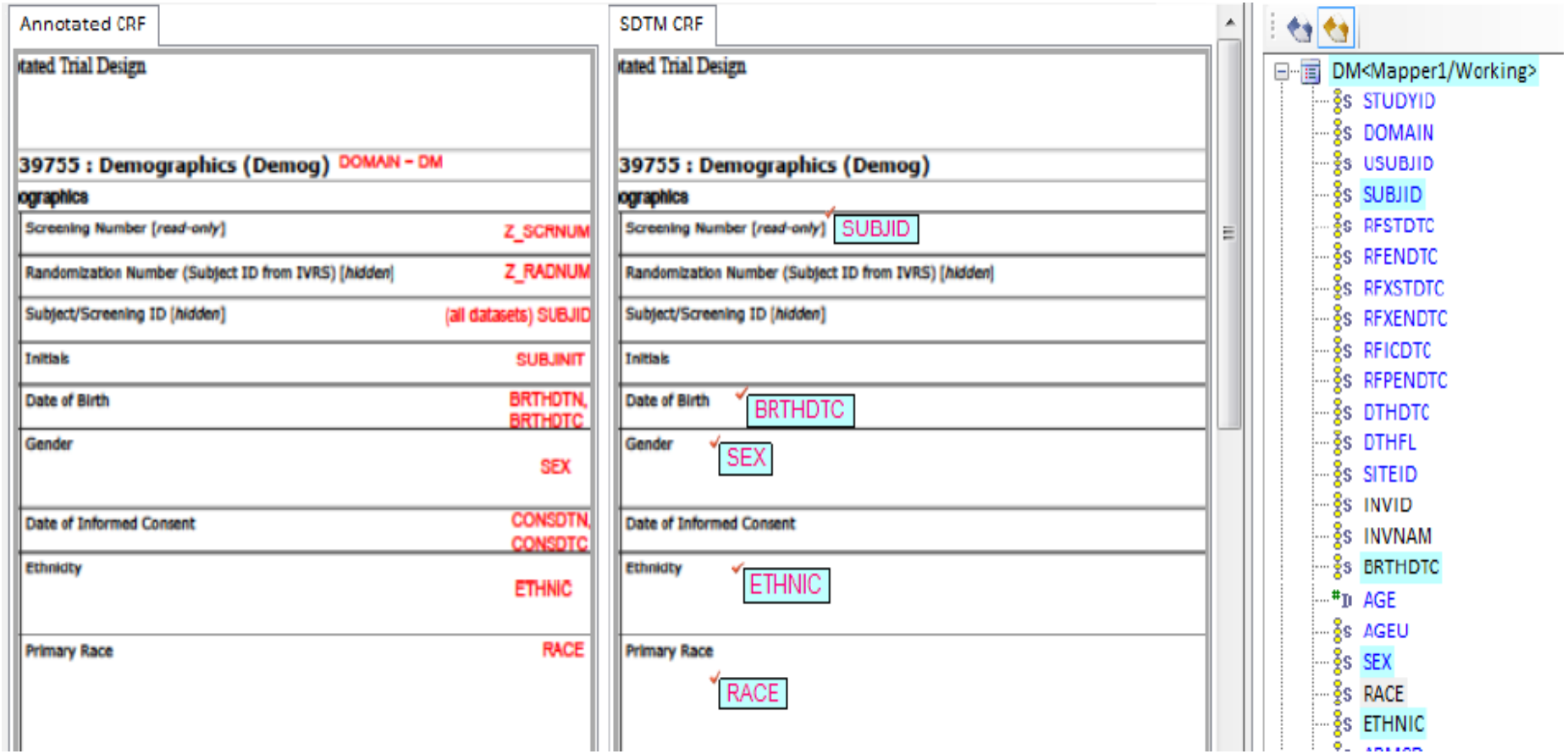
- Proprietary Data is transformed into standard data using metadata level mapping through easy drag and drop functionality
- Standard metadata is accessed from Central MDR.
- The processes are highly traceable, reusable
- Metadata driven approach allows high efficiency as well as time and cost savings

Disclaimer: Content being presented here is my own thoughts and ideas. PAREXEL is not responsible for content.

SEMANTIC BASED DATA STANDARDIZATION



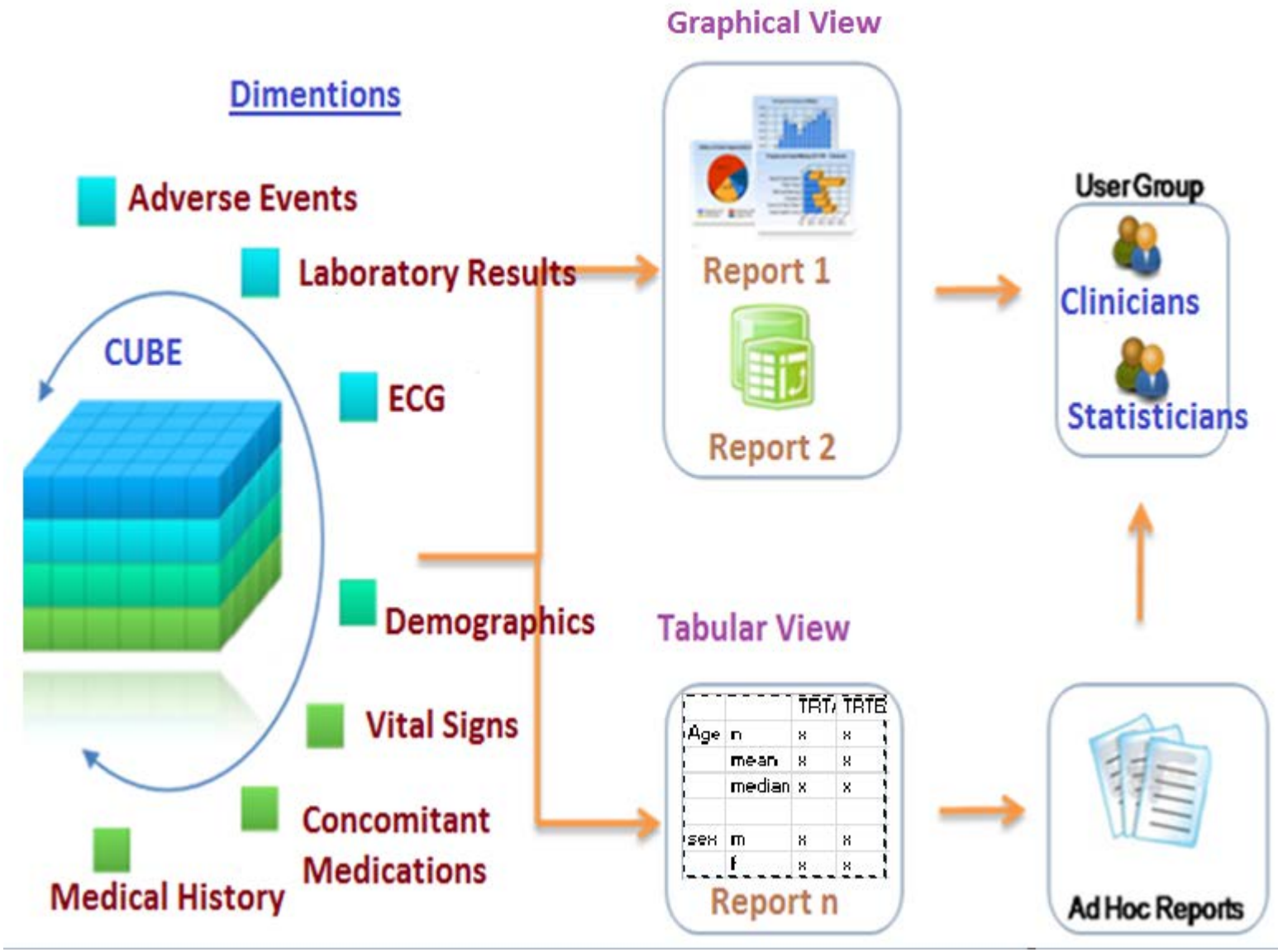
AUTOMATED CRF ANNOTATION



Disclaimer: Content being presented here is my own thoughts and ideas. PAREXEL is not responsible for content.

PAREXEL

OLAP CUBE



Disclaimer: Content being presented here is my own thoughts and ideas. PAREXEL is not responsible for content.

EXAMPLE OLAP VISUALIZATIONS

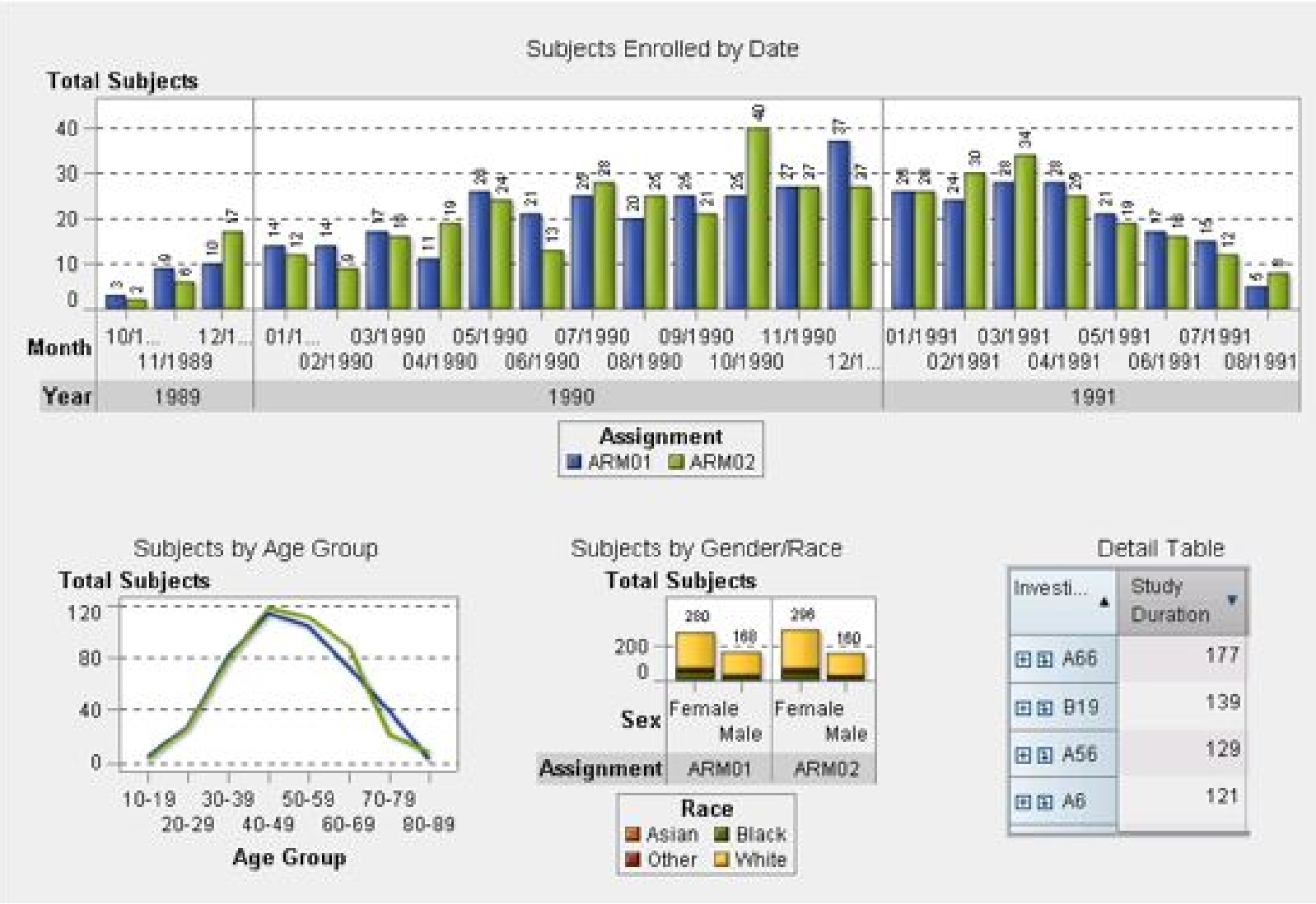
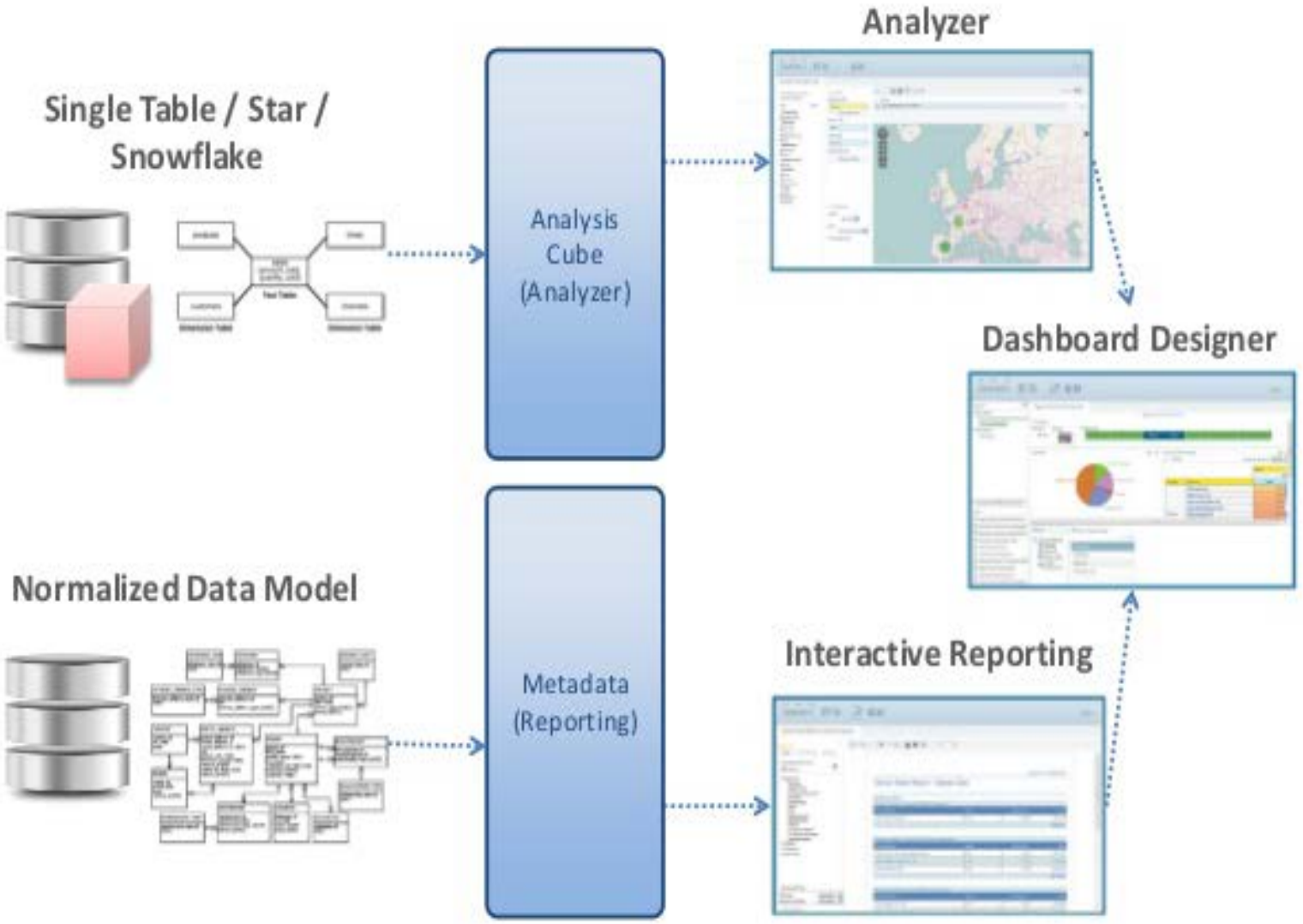


TABLE SHELL METADATA

Table shell metadata

METADATA	T1	TREATMENTS	STATISTIC	INDENT	DATA_SET	VARIABLE	QUANT	WHERE_CLAUSE	DENOMINATOR	BY_DISPLAY_VARIABLE
sps_generate_module	table_base_001									
section_wrap_flag	N									
col_width	AUTO									
col_align	L									
col_label		[Headers]								
col_big_n_label		(N = xx)								
col_n_pct_label										
blank_row										
label	Sex - n(%)			0						
statistic	Male	x (x.x)	n percent	1	adam.adsl	sexn	1			
statistic	Female	x (x.x)	n percent	1	adam.adsl	sexn	2			
blank_row										
label	Age (years)			0						
statistic	n	x	n	1	adam.adsl	age				
statistic	Mean (SD)	x.x (x.x)	mean stdev	1	adam.adsl	age				
statistic	Median	x.x	median	1	adam.adsl	age				
statistic	Q1, Q3	x.x, x.x	q1 q3	1	adam.adsl	age				
statistic	Min, Max	x, x	min max	1	adam.adsl	age				
blank_row										
label	Age - n (%)			0						
statistic	< 65 years	x (x.x)	n percent	1	adam.adsl			.<age<65		
statistic	≥ 65 years	x (x.x)	n percent	1	adam.adsl			age>=65		
blank_row										
label	Age by sex[1]			0						
by_start	!BY_DISPLAY_VARIABLE! subjects - n (%)			1	adam.adsl	sexn				sex
statistic	< 65 years	x (x.x)	n percent	2	adam.adsl			.<age<65	sexn>.	
statistic	≥ 65 years	x (x.x)	n percent	2	adam.adsl			age>=65	sexn>.	
by_end										

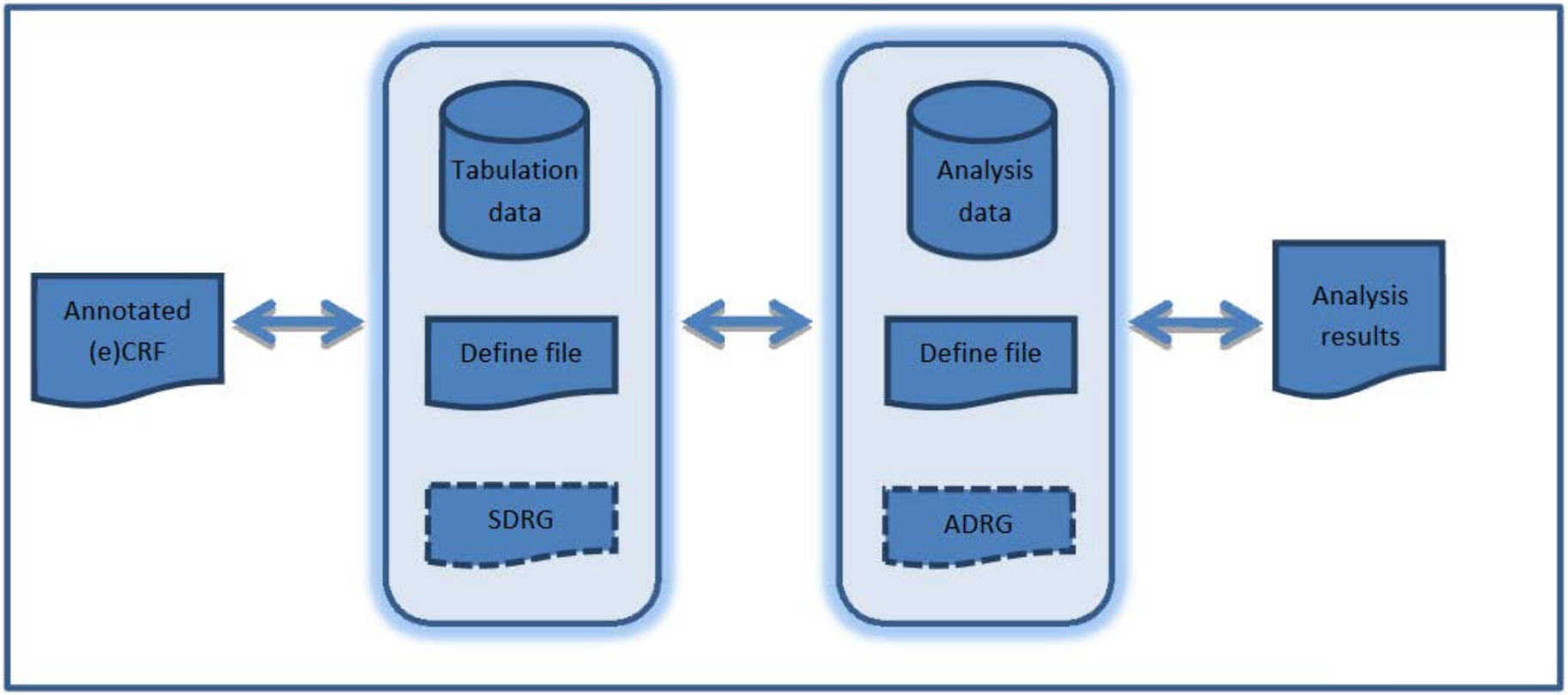
ANALYTICS AND REPORTING PROCESS



Disclaimer: Content being presented here is my own thoughts and ideas. PAREXEL is not responsible for content.

PAREXEL

TRACEABILITY



Disclaimer: Content being presented here is my own thoughts and ideas. PAREXEL is not responsible for content.

RESULTS

- **Auditing and traceability - single data integration repository**
- **Enhanced collaboration – seamlessly share information across user roles**
- **Simplified development – reduce manual steps with integrated platform development**
- **Streamlined information access – promote enterprise adoption through ease of use**
- **Strategic integration with MDR brands – roadmap for success**
- **Compliance to Standards and Regulations- IEC 11179, 21 CFR 11**
- **Reusability- cost effective and efficient**

CONTACT DETAILS

Mahesh Kumar Peddiboena
Statistical Programmer
PAREXEL INTERNATIONAL (INDIA) PVT LTD
Ph. 9032161541
Email: maheshp.cse@gmail.com

Q & A's

Disclaimer: Content being presented here is my own thoughts and ideas. PAREXEL is not responsible for content.

PAREXEL