

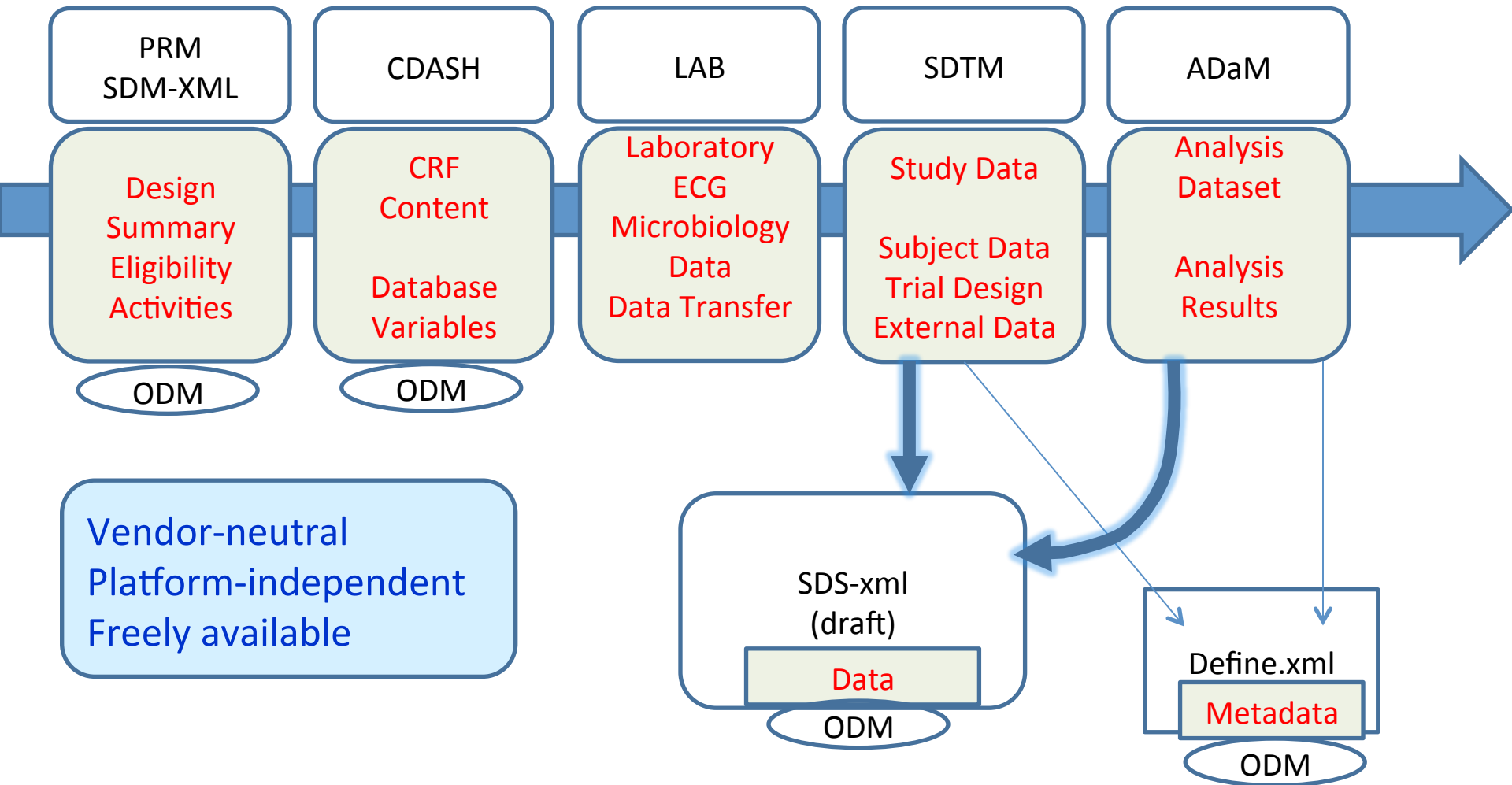
CDISC Standards in Clinical Research

Mandar Oak

Agenda

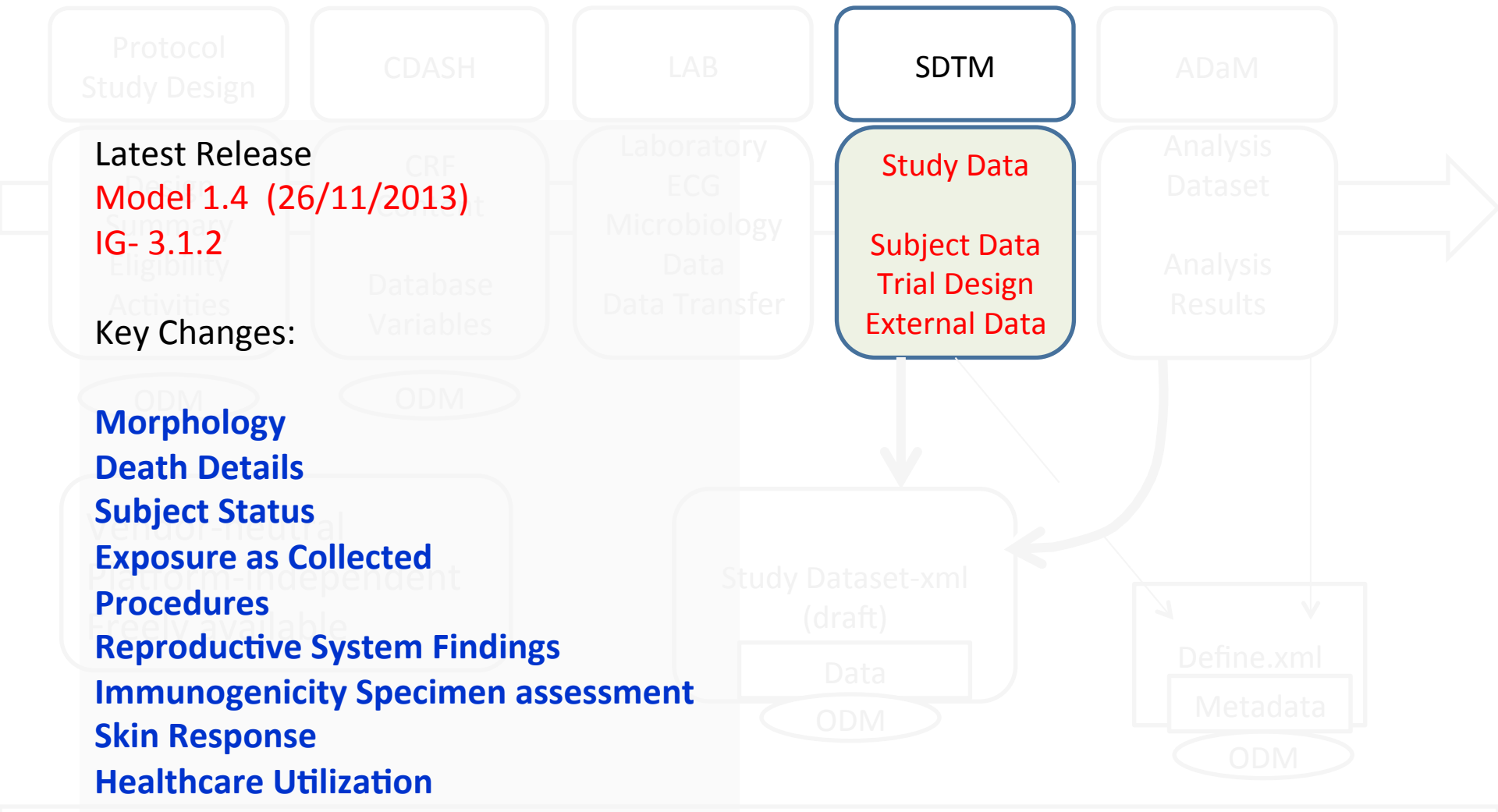
- Standards important to data managers and statistical programmers
- Recent developments

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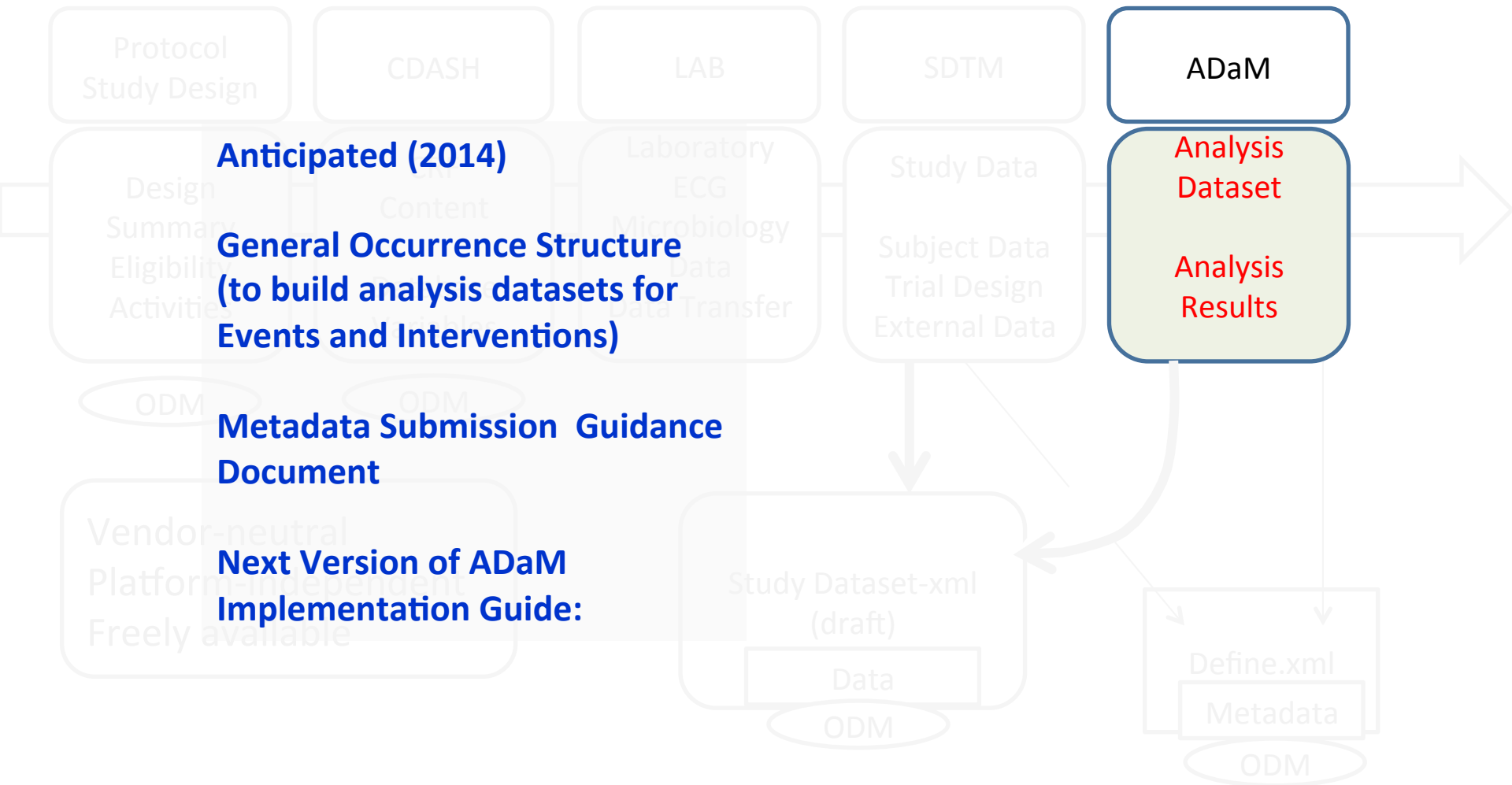
Therapeutic Area Implementations

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Therapeutic Area Implementations

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Asthma Therapeutic Area Guide

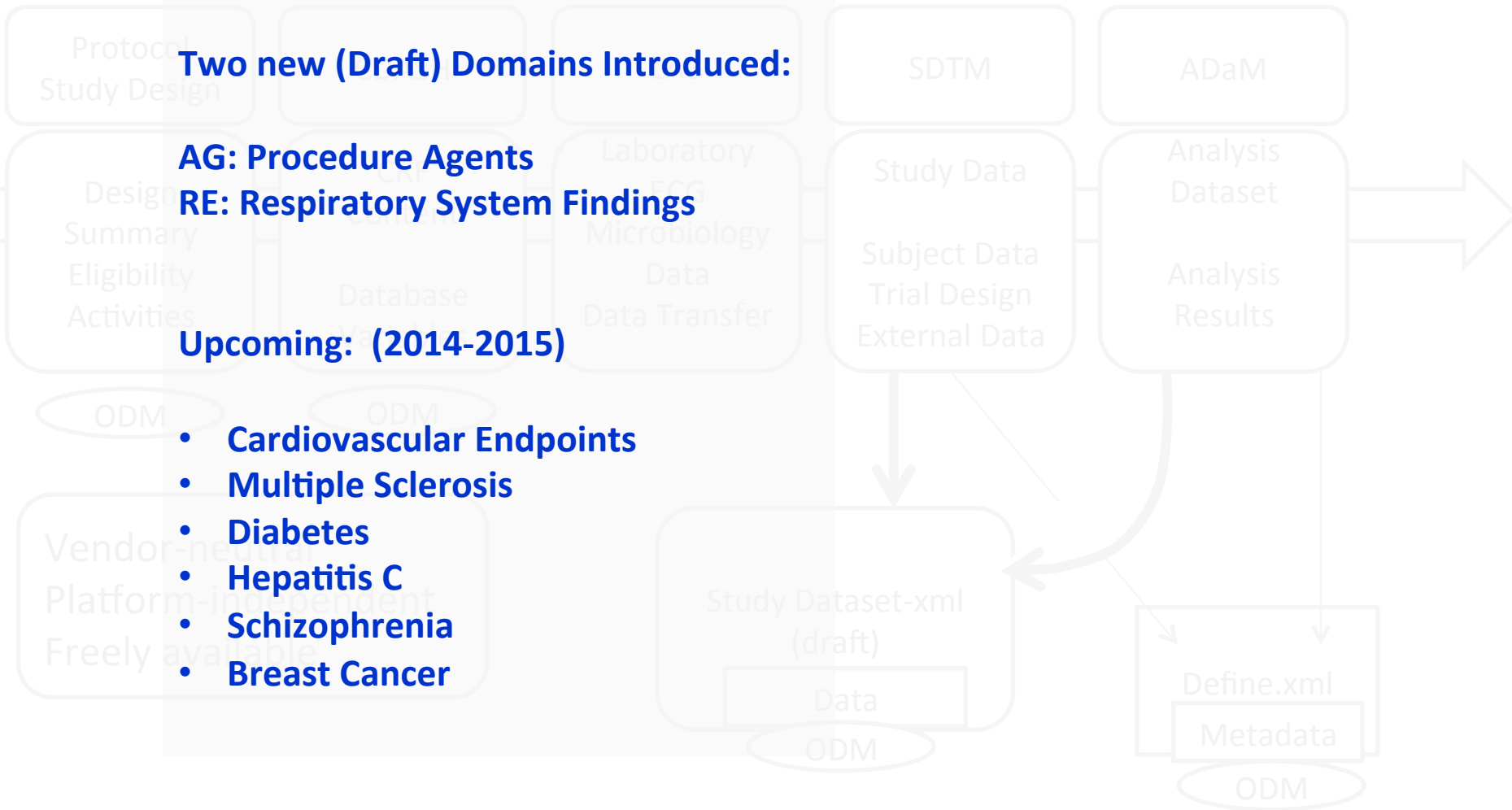
Two new (Draft) Domains Introduced:

AG: Procedure Agents

RE: Respiratory System Findings

Upcoming: (2014-2015)

- Cardiovascular Endpoints
- Multiple Sclerosis
- Diabetes
- Hepatitis C
- Schizophrenia
- Breast Cancer



Therapeutic Area Implementations

Variable	Where	Type	Length / Display Format	Controlled Terms or Format	Origin	Derivation/Comment
AVAL	PARAMCD IN ("ACITM01" (Word Recall Task) , "ACITM02" (Naming Objects And Fingers (Refer To 5 C) , "ACITM03" (Delayed Word Recall) , "ACITM04" (Commands) , "ACITM05" (Constructional Praxis) , "ACITM06" (Ideational Praxis) , "ACITM07" (Orientation) , "ACITM08" (Word Recognition) , "ACITM09" (Attention/Visual Search Task) , "ACITM10" (Maze Solution) , "ACITM11" (Spoken Language Ability) , "ACITM12" (Comprehension Of Spoken Language) , "ACITM13" (Word Finding Difficulty In Spontaneous Speech) , "ACITM14" (Recall Of Test Instructions))	integer	8		Derived	QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	PARAMCD EQ ACTOT (Adas-Cog(11) Subscore)	integer	8		Derived	Sum of ADAS scores for items 1, 2, 4, 5, 6, 7, 8, 11, 12, 13, and 14, see Analysis Data Reviewers Guide (Page 3) for details on adjusting for missing values. Analysis Data Reviewer's Guide (analysis-data-reviewers-guide.pdf)

Define 2-0-0 Released

Better Support for Value level Metadata (WhereClause)

Can Be Printed!

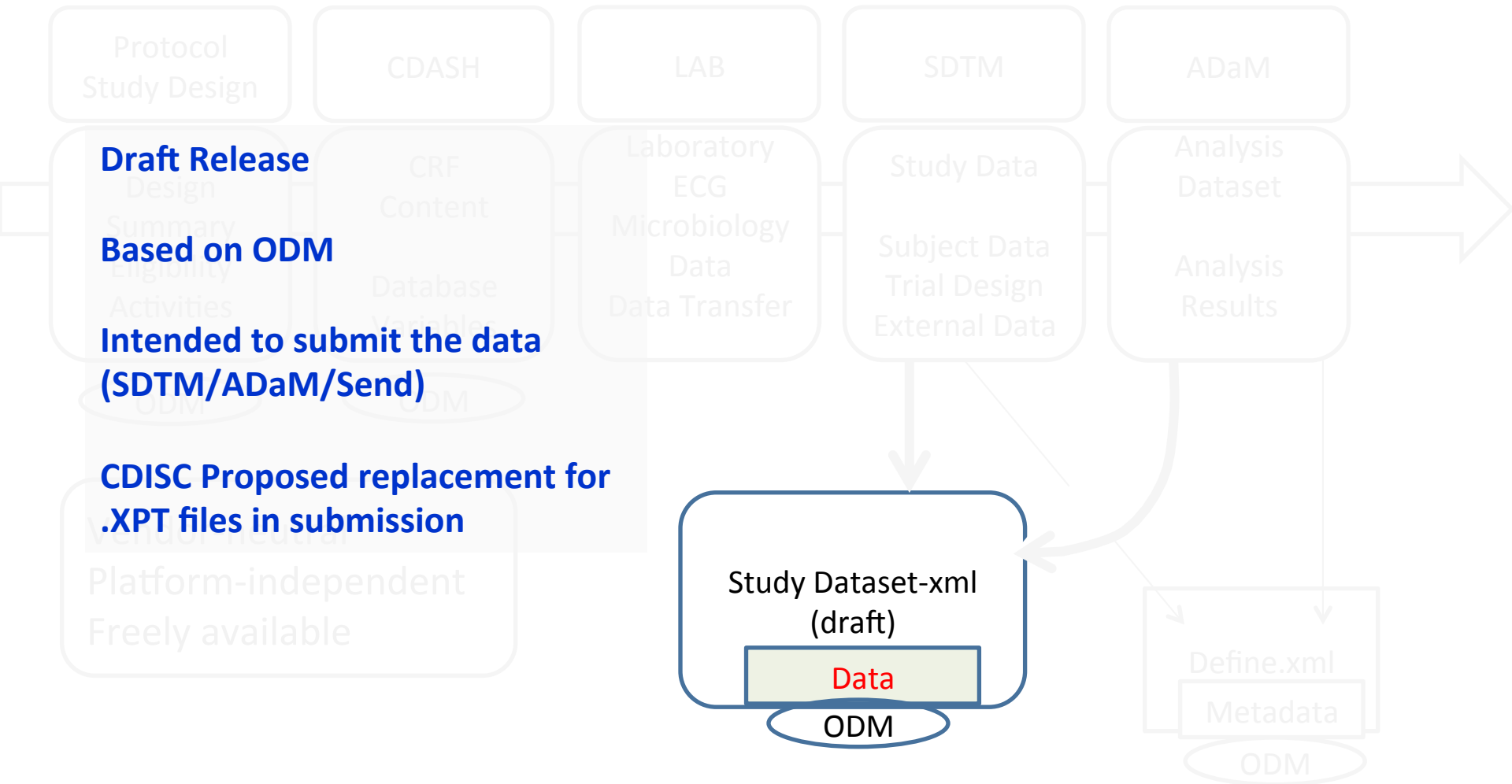
Define.xml

Metadata

ODM

Therapeutic Area Implementations

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Therapeutic Area Implementations

DID I FINISH ON TIME?