

PP25 : Enhancing Research Through Clinical Data Standardization

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Introduction

For every Pharmaceutical Organization, there is a need to standardize heterogeneous Clinical Data for Cross study analysis and faster regulatory submissions. In this poster we provide a Clinical Data Standardization Methodology (CDSM) to help Organizations in building their own Metadata oriented Standardization framework for streamlining the Clinical Trial Process.

Data Standardization framework has largely been considered as a Stand alone framework, but CDSM also focuses on integrating it with the existing Analysis and Reporting system of any Organisation.

This can be considered as an approach which focuses on integrating (co-locating) all the Clinical Data Management, reporting , analytics and Transformation tools which can be called as a "Clinical End to End Submission framework".

Key Considerations for Clinical Data Standardization

- Should bring all Legacy/Ongoing and Planned trials in scope.
- Short-list Target Standard (CDISC/Sponsor Defined).
- Should select appropriate Techniques and Technologies for setting up the Standardization Framework.
- Integration of Standardization Framework with the Analysis system.

Taking the above considerations in scope, CDSM will help the Organizations in building their own Clinical Data Standardization Framework

End to End Clinical Trial processes with Standardized Framework

The Standardized framework forms the base of all the Clinical Data Processes and hence should cover the entire scope of Study Life cycle.

Key Considerations governing the End to End Framework

- Across all the trials, should use generalized CRFs covering all the Therapeutic areas.
- CRFs should also be in sync with the Standard defined in the Standardized framework.
- Parameter based generalized codes for handling the Non uniform source Data variables and then validating the source Data with the Standardized and Analysis Datasets.
- Generalized algorithms for Clinical Data Analysis and automatic provision of generating other Deliverables like Patient Profiles, Define.xml etc. through the same framework.

The standardization solution revolves around three key Process Steps namely Metadata set-up, creation of an effective and user friendly GUI and integration with other Analytics applications.

The standardization approach can be applied to Legacy, On-going (post completion) as well as Future Trials (directly into the new standard).

Standardization Framework

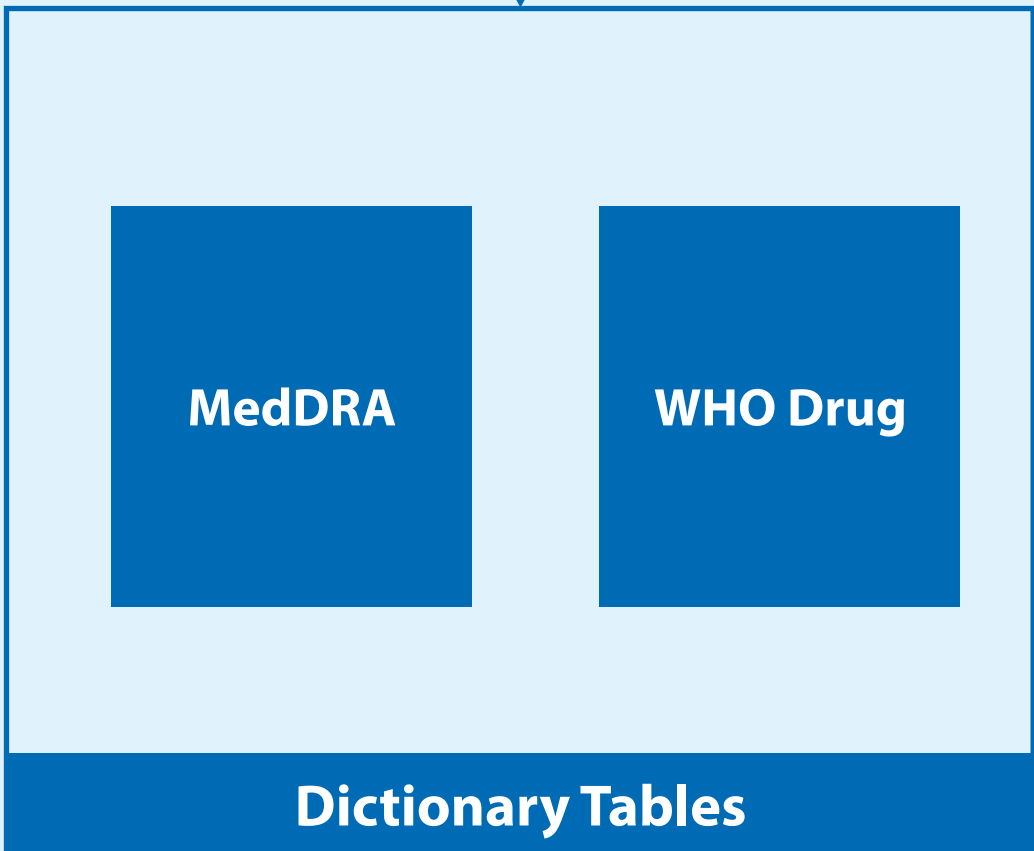
1. METADATA SETUP

Seq	Domain	VariableName	VariableLabel	Type	Role	Core
1DM	STUDYID	Study				
2DM	DOMAIN	Domain				
3DM	USUBJID	Unique				
4DM	SUBJID	Subject				
5DM	RFSTDT	Subject				
6DM	RFENDTC	Subject				
7DM	SITEID	Study				
8DM	INVID	Investigator				
9DM	INVNAM	Investigator				
10DM	BRTHDT	Date/Time				
11DM	AGE	Age		Num	Record	
12DM	AGEU	Age				
13DM	SEX	Sex		Char	Record	
14DM	RACE	Race		Char	Record	
15DM	ETHNIC	Ethnicity		Char	Record	
16DM	ARMCD	Planned				
17DM	ARM	Description				
18DM	COUNTRY	Country		Char	Record	

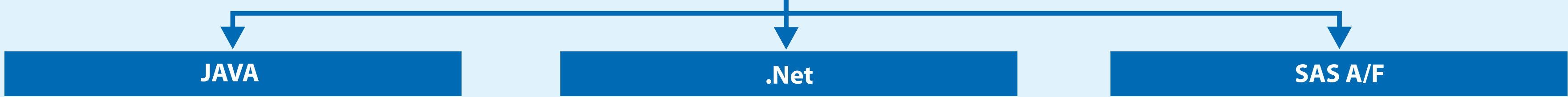
Target Standard Metadata (CDISC / Sponsor compliant)

Code	CodeList Code	CodeList Name	CodeList Values
RC1	R111	Race	WHITE
RC2	R111	Race	BLACK
RC3	R111	Race	ASIAN
RC4	R111	Race	AMERICAN
RC5	R111	Race	AFRICAN
RC6	R111	Race	OTHERS

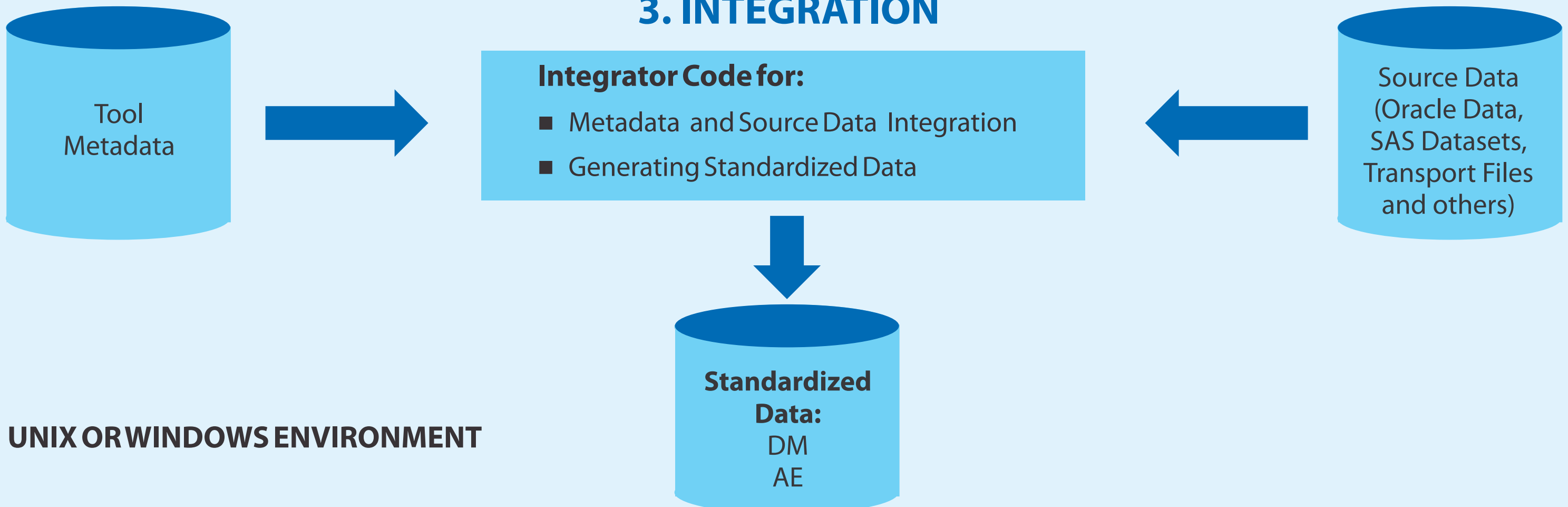
Control Terminology Metadata



2. DESIGNING THE GUI

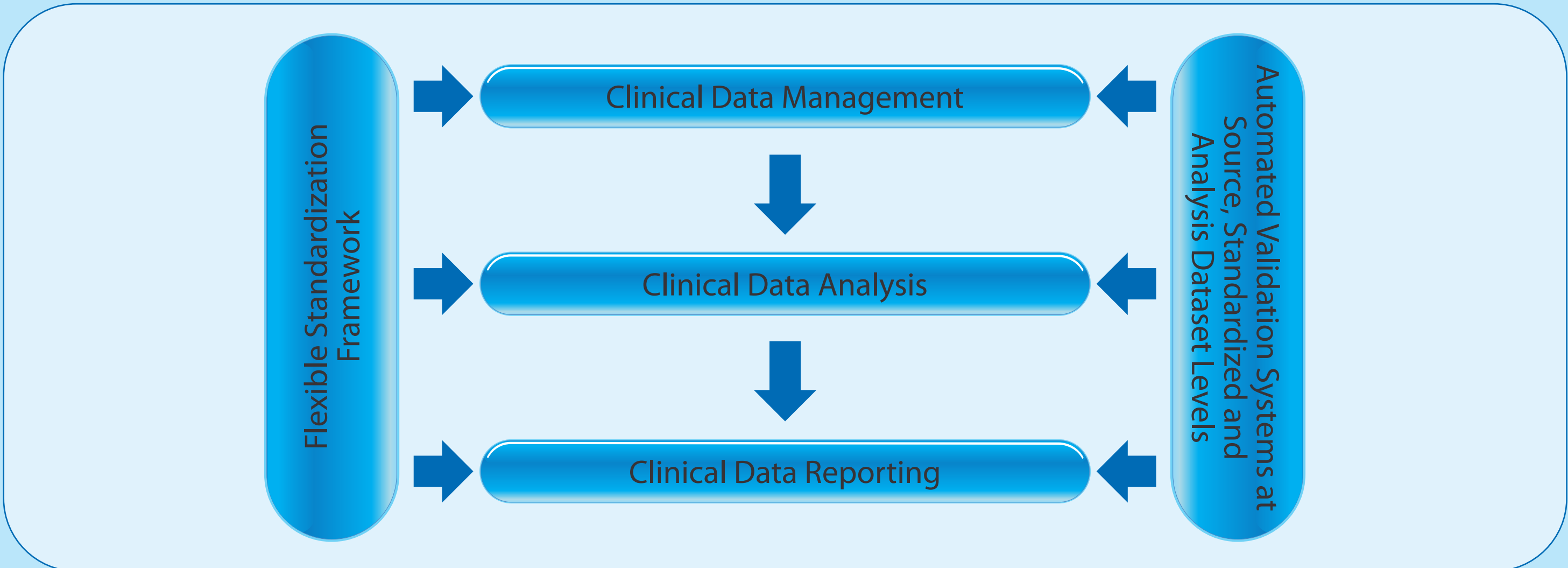


3. INTEGRATION



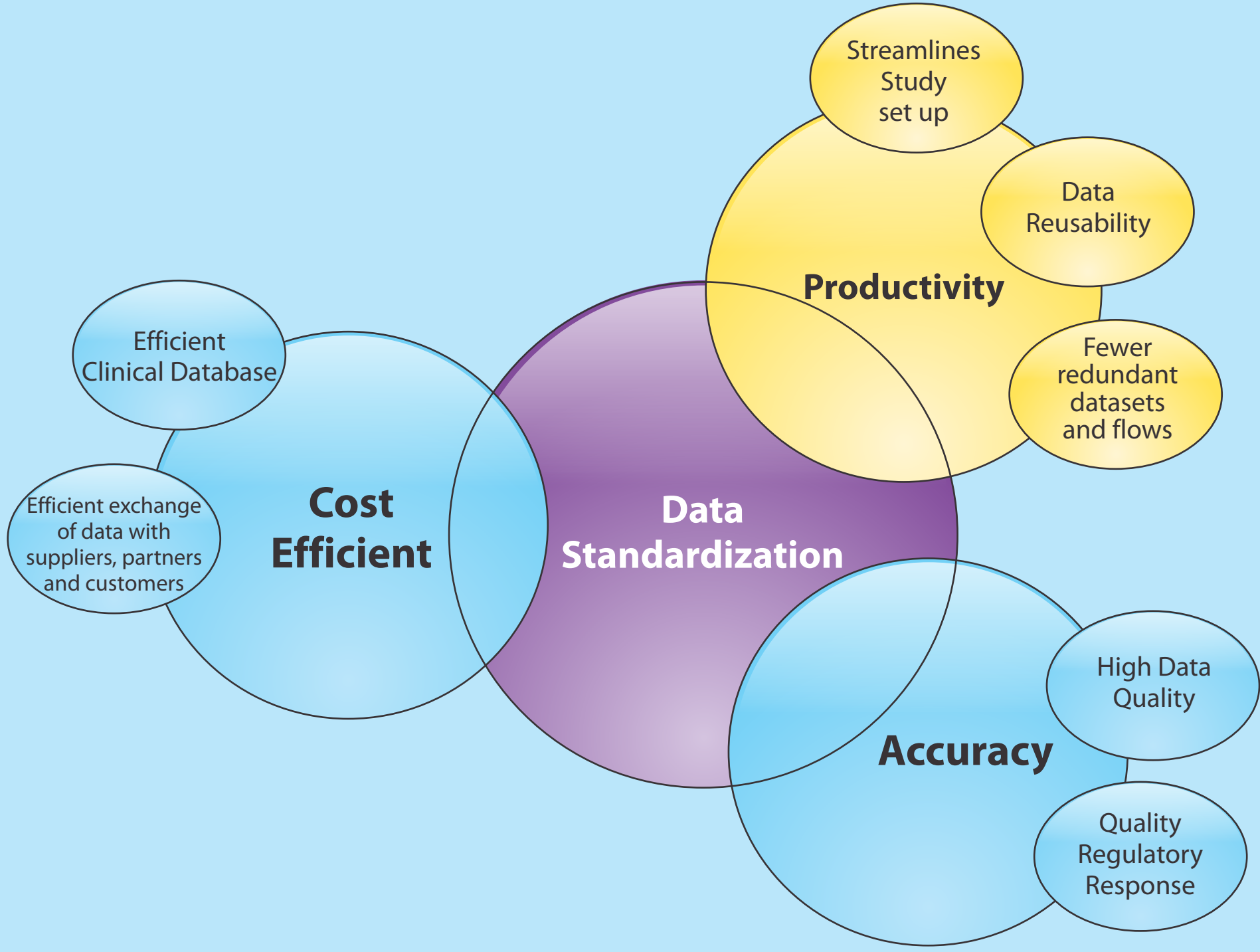
The Integrated approach of the Standardization Framework and the Existing Clinical Trial Data Process systems can be best depicted in the below pictorial diagram showing it's applicability and coverage.

Clinical End to End Submission framework



Conclusion

Integrating the Clinical Trial Data Processing systems with the Standardization Framework can help us in availing the benefits shown below:



Acknowledgement

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