



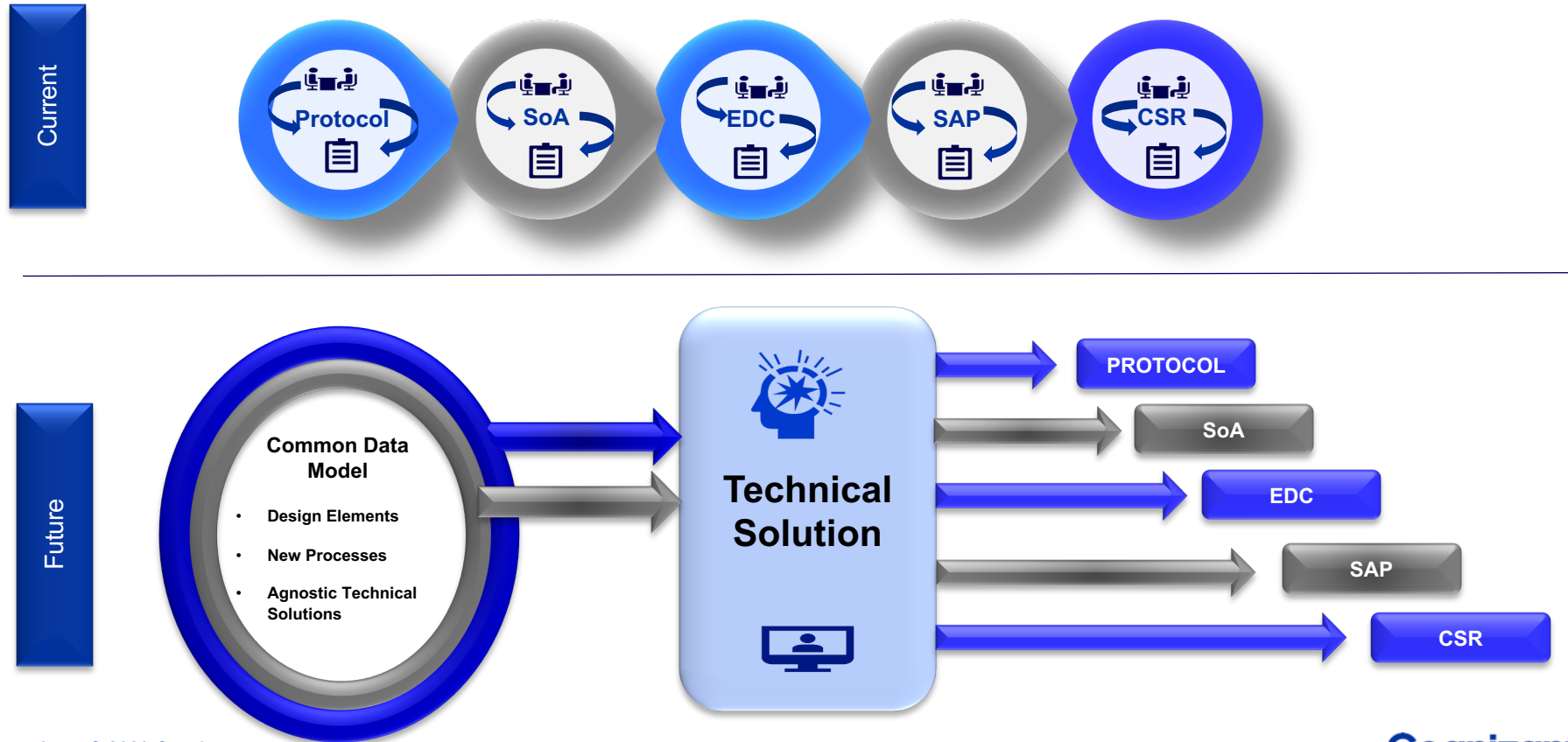
Digital data flow - A solution for Study Start up and Amendments

- 
- 1 TranCelerate's Digital Data Flow vision
 - 2 Our POV on Digital Data Flow Acceleration in Clinical Trials
 - 3 Cognizant's Setup Accelerator solution
 - 4 Demonstration

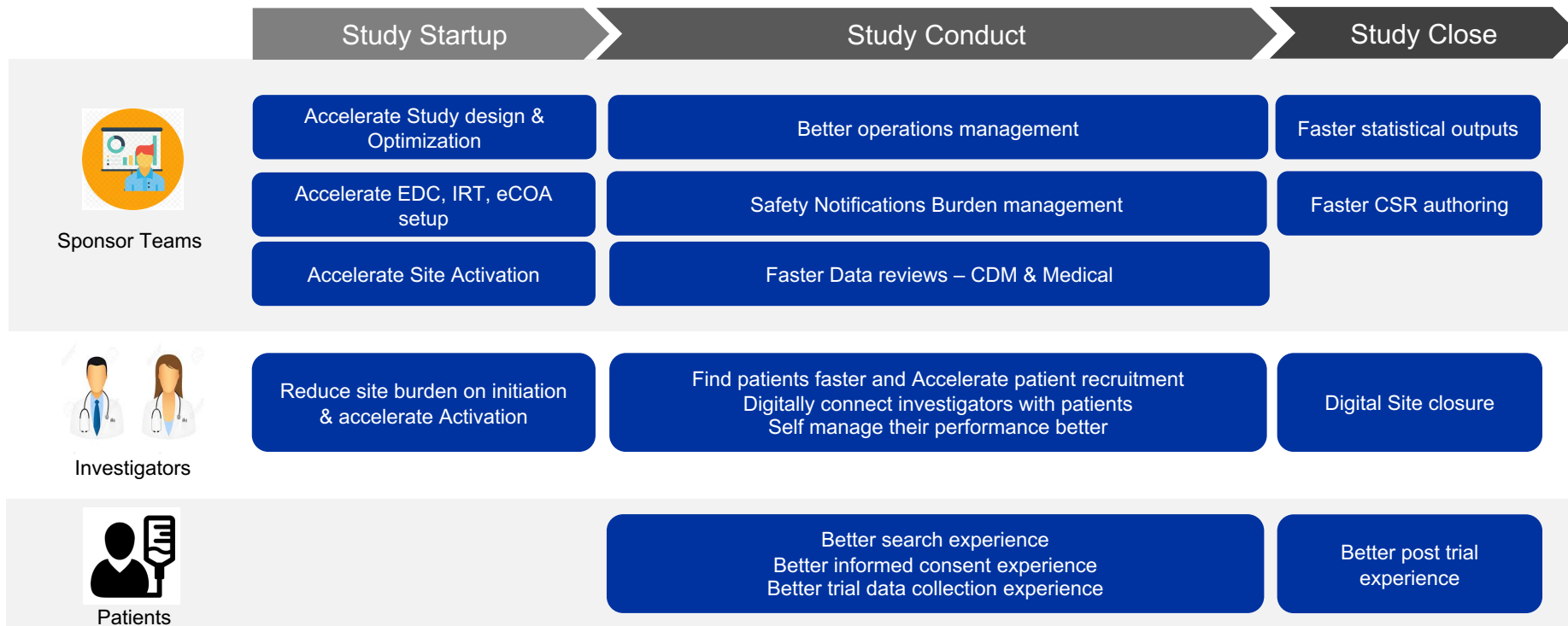


AGENDA ITEMS

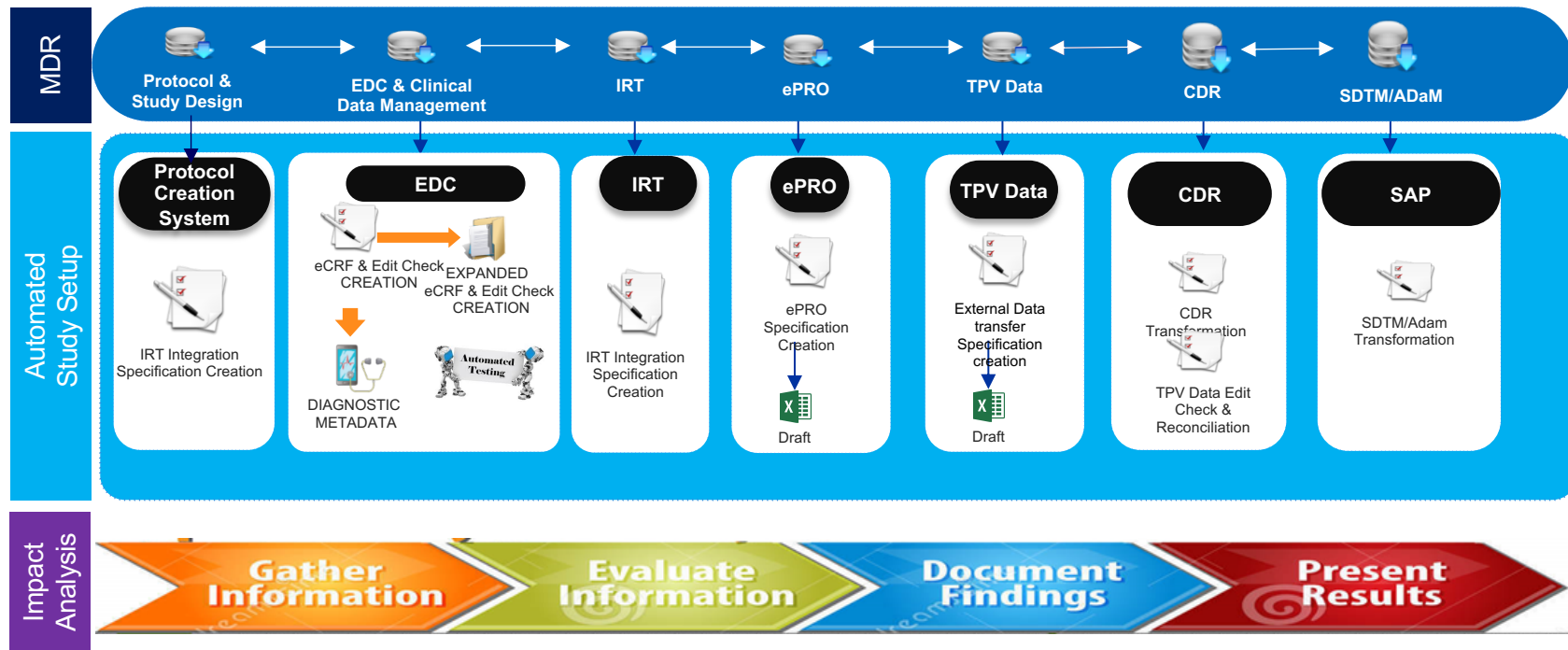
TransCelerate's view on "Current vs Future" Digital Data Flow



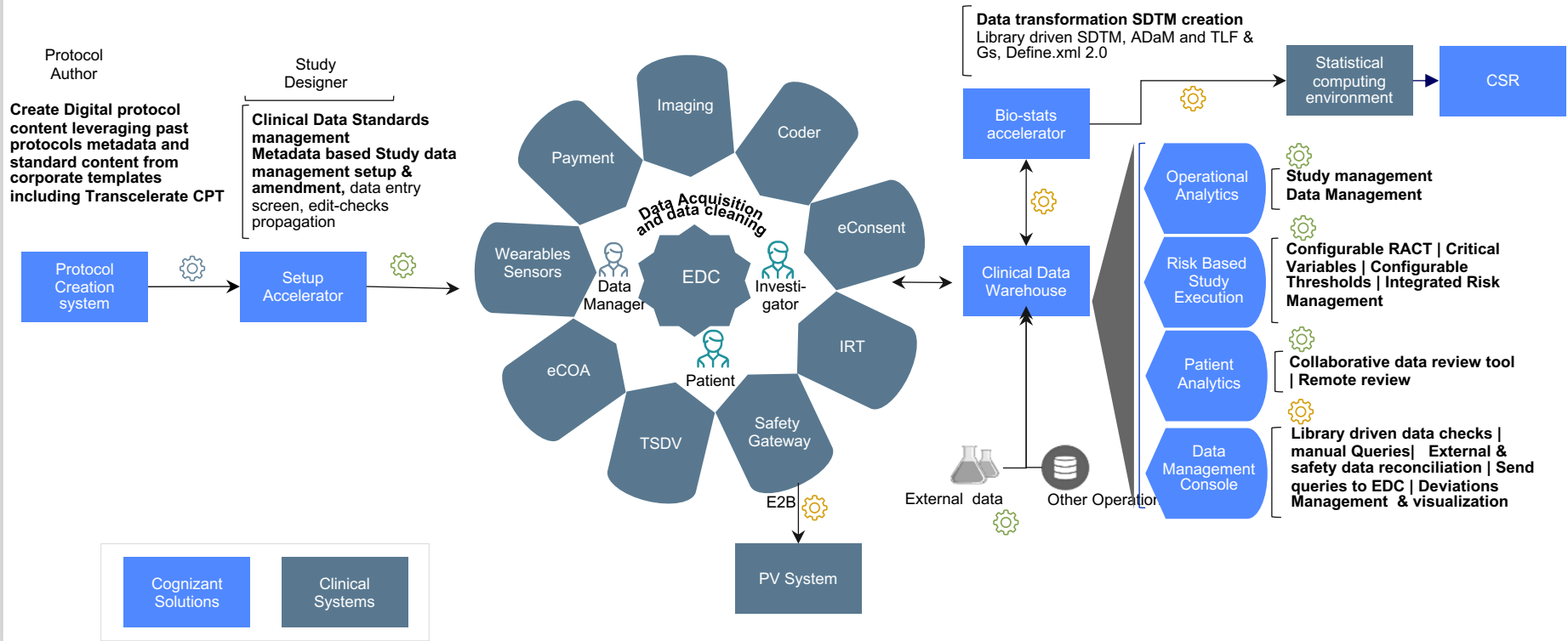
Areas where Digital interventions can accelerate clinical trials & improve experience



Functional Architecture



Protocol to CSR Data Automation Platform



Setup Accelerator

Metadata Management

Protocol Elements

Data acquisition & processing

Statistical analysis standards

Study Build

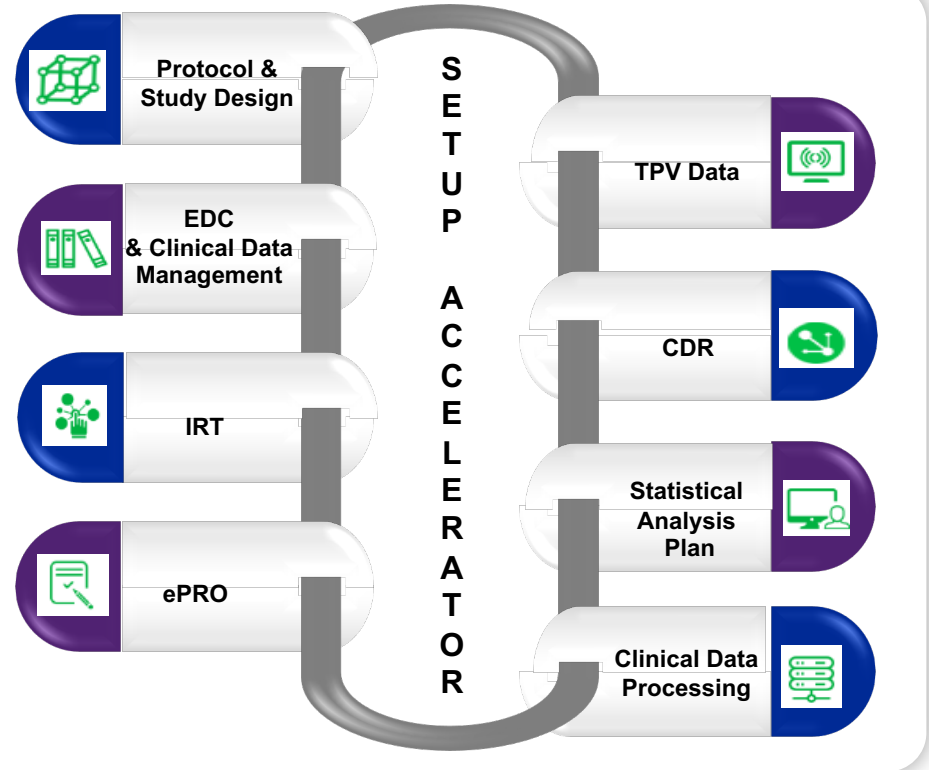
eCRF & edit checks

Integration with EDCs

Impact Assessment

Traceability

Governance Workflows



Setup Accelerator – Summary of Features

Metadata Governance

Protocol Standards

- Global/TA/Study Specific Template
- Sections Management
- Fields Management
- Codelist Management

Data Collection Standards

- EDC Standards
 - CRF Standards
 - Edit Check Standards
 - Custom Function Standards
- Third Party Vendor Standards
- IRT Standards
- ePRO Standards

Clinical Data Processing Standards

- Pre-processing Mapping data model
- SDTM+

Statistical Computing Standards

- SDTM mapping
- ADaM mapping

Automated Study Setup

EDC Study Setup

Third Party Vendor Specification

IRT Setup/Specification

ePRO Setup/Specification

Clinical Data Processing Setup

- Pre-processing Mapping data model
- SDTM+

Statistical Computing Setup

- SDTM mapping
- ADaM mapping

Automated Impact Analysis

Collect Information

- MDR Version Change
- Protocol Amendment

Impact Analysis Detail

- Study Stage/ Data processing CRF, Edit checks, CF
- Mapping, Pre-processing, SDTM
- Site Interactions
- TSDV Signature

Help in Decision Making

- Upfront Decision to implement

Post Production Template

Stakeholders Review

eApproval

Traceability Version Control

Key Reports

Object Traceability Report

Audit Trail Reports

System Performance Reports

User Activity Reports

EDC Setup

- Study Quality Report
- Version Control Report
- Auto/Manual Testing Report

Mapping/Transformation Report

Study Reports

- All Specifications
- Annotated CRF
- SDTM annotated CRF
- Define.XML

Impact Analysis Report

- MDR Version Change
- Protocol Amendment Reports
- PPC & Impact Analysis
- Stakeholder Approval Reports

SYNCHRONIZATION

TRACEABILITY & WORKFLOW

COMPLETE AUDIT TRAIL

Takeaway



Differentiators

- Flexible in integrating data sources
- Role Based Security Permissions
- Streamlined review and approval workflow
- Aligned with Transcelerate's Study Design Document



Leveraging AI/ML

- AI/ML based recommendations for study design and other specifications



Vision

- Encourages automated Clinical reuse, Transform document Content to Data
- Automating configuration and enabling flow of information
- Moving electronic source to Sponsor DB and connect standards across Healthcare and Clinical Research

Demonstration

Home Page

 SetupSmart

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Super User



HOME

 METADATA MANAGEMENT

 STUDY BUILD

 IMPACT ANALYSIS


Protocol Standards


Data Collection Standards (RAW)


Clinical Data Processing Standards (CDP)


Statistical Computing Standards


eDC


Third Party Vendor Data Transfer


IRT Setup


Interactive Response Technology (IRT)


Clinical Data Processing Setup

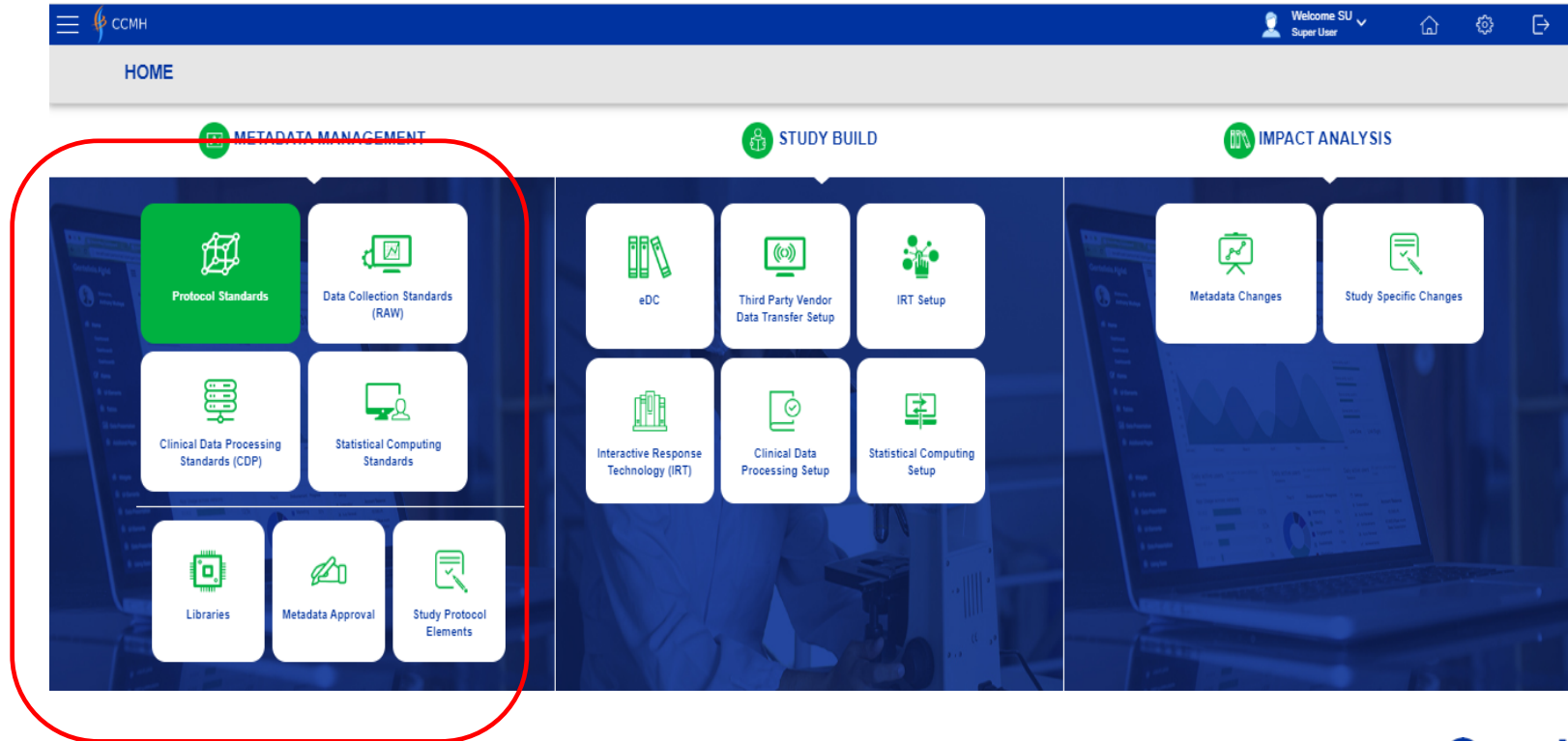

Statistical Computing Setup


Metadata Changes


Study Specific Changes

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Protocol Standards



Protocol Library Section view

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Protocol Library Sections

Protocol Library Fields

Protocol Library Codelist

Protocol Library Codelist Value

Download

PROTOCOL LIBRARY > GLOBAL

Section Listing

+ ADD SECTION

SECTION

SEND FOR APPROVAL

Select	Actions	Category Name	Status	Section Name	Section No.	Help Text	View
☐				Search Section Name.....	Search Dictionary Section No.		
☐		Protocol Summary		Synopsis	1.1		
☐		Protocol Summary		Schema	1.2	Define Schema- Demo	
☐		Protocol Summary		Schedule of Activities (SoA)	1.3		
☐		Introduction		Study Rationale	2.1	Define Study Rationale	

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Study Protocol Elements



[STUDY PROTOCOL ELEMENTS](#) > DM2018NC01 | 1.00

Visits Domain **Schedule** IE

Forms	Form Short Name	Screening	Baseline	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	EOS	Followup	AE	CM	Unscheduled
Informed consent	IC	Y												
Enrollment	ENR	Y												
Demographics	DM	Y												
Full physical examination including height and weight	PH	Y												
Medical history (includes substance usage)	MH	Y												
Past and current medical conditions	MH1	Y												
Urine pregnancy test (WOCBP only)	URIN	Y												
Laboratory assessments (include liver chemistries)	LB	Y												Y
ECG collection	ECG	Y												Y
Vital signs	VS	Y	Y	Y	Y	Y	Y	Y	Y					Y
Randomization	RAND		Y											
Study intervention	STUDYIN			Y	Y	Y	Y	Y	Y					
AE review	AE											Y		
SAE review	SAE											Y		

Clinical Data Processing Standards view

 CCMH

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CLINICAL DATA REPOSITORY

Standards

Select Standard

Global Standard

SUBMIT

Domain Selection

 ADD FORM

 ADD DOMAIN

☐	Domain Name Search a Field	Source	Form Name	Form OID	Calculation	Variable Mapping	Review Status
☐	DM	EDC	Demographics	DM	Pseudo Code		Send for review
☐	AE	EDC	Adverse Events	AE	Pseudo Code		Send for review
☐	CM	EDC	Concomitant Medications and Supplements	CM	Pseudo Code		Send for review
☐	VS	EDC	Vital Signs, Vital Signs1, Vital Signs2	VS, VS1, VS2	Pseudo Code		Send for review
☐	MH	EDC	Medical History	MH	Pseudo Code		Send for review

SDTM Standards view

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STUDY DATA TABULATION MODEL

Standards

Select Standard

Domain Selection

☐	Domain Name Search a Field	Source	CDR Table	Calculation	Variable Mapping	Review Status
☐	DM	CDR	T_DM	Pseudo Code		Send for review
☐	AE	CDR	T_AE	Pseudo Code		Send for review

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eDC Study Build view

 CCMH

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HOME

 METADATA MANAGEMENT

 STUDY BUILD

 IMPACT ANALYSIS

 Protocol Standards

 Data Collection Standards (RAW)

 Clinical Data Processing Standards (CDP)

 Statistical Computing Standards

 eDC

 Third Party Vendor Data Transfer Setup

 IRT Setup

 Interactive Response Technology (IRT)

 Clinical Data Processing Setup

 Statistical Computing Setup

 Setup Study eCRFs and Edit Checks

 Study Specific Approvals

 Metadata Changes

 Study Specific Changes

eDC CRF design view

CCMH

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FORM SELECTION- 08OCT2020
Select all the required forms

Back to EDC

+ COPY FORMS FROM EDC LIBRARY/STUDIES

Form List - CDASH Library

☐ Select All

☐ Demographics
☐ Vital Signs
☐ Concomitant Medications/Adverse Events
☐ Adverse Events (Extension Study)

☐ Demographics (Extension study)
☐ Vital Signs (Serial)
☐ Concomitant Medications and Supplements

☐ Medical History
☐ Vital Signs (Unscheduled)
☐ Adverse Events

SAVE

1 2 10

Selected Form

+ ADD FORM

DELETE FORM

SEND FOR APPROVAL

Select	Form Status	Actions	Source	Form Name	Help Text	View Restriction	Entry Restriction	View Fields	Additional Info
☐	All			Search a Form					
☐	●	  	CDASH Library	Medical History					

eDC design specification download view

The screenshot shows the 'SetupSmart' application interface. The top navigation bar is blue and contains a menu icon, the 'SetupSmart' logo, and a user profile 'Welcome SU Super User' with a dropdown arrow. Below the navigation bar is a horizontal menu with 13 items: EDC, Form Selection, Field Selection, Verify & Restrictions, Visit Selection, Visit Matrix, Dynamics, ECOA, Edit Checks/Validations, Derivation, Download (highlighted in green), Reports, and Synchronize. The main content area has a light gray header with the text 'DOWNLOAD SPECIFICATION- D2020'. Below this, there are two sections: 'Specification Generation' and 'Specification Download'. The 'Specification Generation' section contains three input fields: 'Create New Version' (a dropdown menu), 'Version Number' (a text input field), and 'Primary Form ID' (a dropdown menu with the text 'Select Primary Form ID'). Below these fields is a green button labeled 'GENERATE'. The 'Specification Download' section contains one input field: 'Select Existing Version' (a dropdown menu with the value '3'). Below this field is a green button labeled 'DOWNLOAD'. The footer of the application is a dark gray bar with the text 'Cognizant © 2019 Rights Reserved' on the right side.

SetupSmart

Welcome SU
Super User

EDC Form Selection Field Selection Verify & Restrictions Visit Selection Visit Matrix Dynamics ECOA Edit Checks/Validations Derivation Download Reports Synchronize

DOWNLOAD SPECIFICATION- D2020

Specification Generation

Create New Version

Version Number

Primary Form ID

GENERATE

Specification Download

Select Existing Version

DOWNLOAD

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Impact Assessment view

CCMH

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HOME

METADATA MANAGEMENT

- Protocol Standards
- Data Collection Standards (RAW)
- Clinical Data Processing Standards (CDP)
- Statistical Computing Standards

STUDY BUILD

- eDC
- Third Party Vendor Data Transfer Setup
- IRT Setup
- Interactive Response Technology (IRT)
- Clinical Data Processing Setup
- Statistical Computing Setup

IMPACT ANALYSIS

- Metadata Changes
- Study Specific Changes
- Study Amendment eCRFs and Editchecks
- Study Specific Approval

Impact Analysis Details view

CCMH

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EDCForm SelectionField SelectionVerify & RestrictionsVisit SelectionVisit MatrixDynamicsECOAEdit Checks/ValidationsDerivationDownloadReportsSynchronizeChange Request

CR REQUEST - 08OCT2020 - CR1

Change RequestImpact AnalysisImpact Analysis Summary

Impact Analysis

View Filter - All -Export As -ReviewRejectApprove

S.No	Select	Edit	Status	To be updated by DM						
				Type Of Request	Form/Editchecks/Derivation OID	Field OID	Dictionary Name	Subsection	DM/SDG Comments	ID Clarifications
	☐		All	Request Type	OID	OID	Dictionary Name	Subsection		
1	☐			Field Update	DS_STU	DS_RESPONSE		FEC: 'V_DS_REASON_MISS_GLIB' added		
2	☐			Field Update	DS_STU	DS_AE		FEC: 'V_DS_REASON_MISS_GLIB' added		
3	☐			Field Update	DS_STU	DS_CONSENT_SPEC		FEC: 'V_DS_REASON_MISS_GLIB' added		
4	☐			Field Update	DS_STU	DS_LOST_FOLLOW_UP		FEC: 'V_DS_REASON_MISS_GLIB' added		
5	☐			Field Update	DS_STU	DS_SPEC		FEC: 'V_DS_REASON_MISS_GLIB' added		
6	☐			EditCheck Addition	V_DS_REASON_MISS_GLIB			EditCheck Addition		
7	☐			Field Update	DS_STU	DS_RESPONSE		FEC: 'V_DS_REASON_PRES_GLIB' added		

Approved Rejected In Progress Under Clarification

150

Thank You
