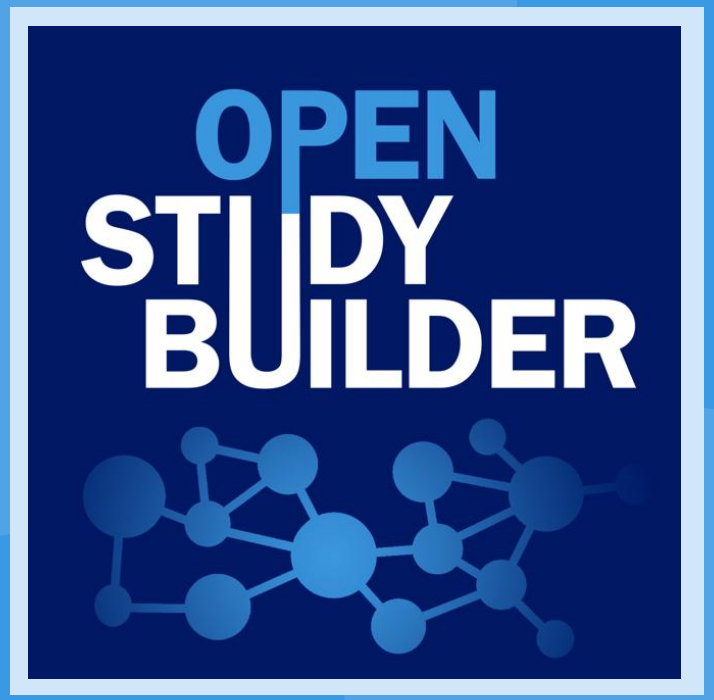
Hands-On Experience

COSA OpenStudyBuilder Workshop: CDISC 360i – Design and Build with OpenStudyBuilder

WIFI

- IHG One
- GVACP



Agenda

- Introduction
- Hands-On
- Insights & Experiences
- End-2-End & Digital Data Flow
- Hands-On
- Exchange & Summary

Introduction

Today with you

Mikkel Traun

Solution Architect

Charles Shadle

CDISC 360i (CDISC)

Nicolas de Jaint Jorre

Lead Product Architect (Novo Nordisk)

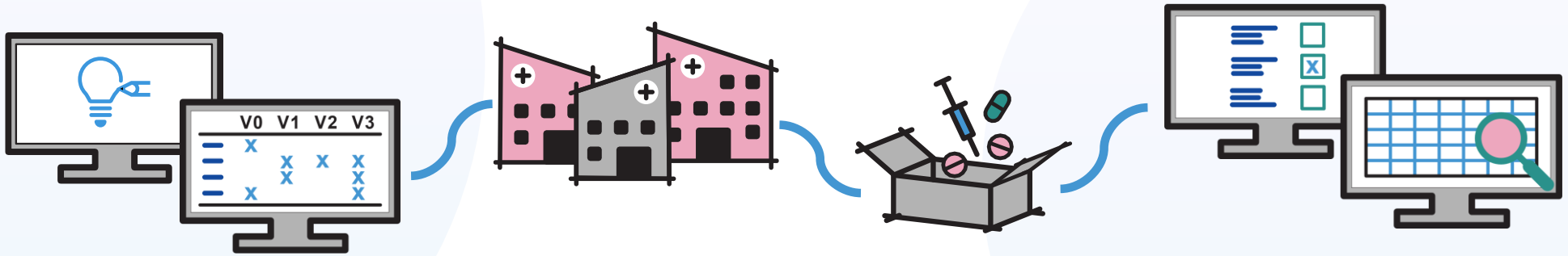
Katja Glaß

Community Manager (independent)

Schedule

09:00	Introduction & Hands-On
11:00	Morning Break
11:30	Hands-On, Insights & Discussion
13:00	Lunch
14:00	Hands-On, Discussion & Closeout
15:00	Coffee Break

Process Automation



An efficient and scalable study journey connected by one digital data flow and simplified by one common data model.

Way to Connected Data Landscape

A Metadata Data Repository and a Study Definition Repository

End-to-end automation from structured protocol to submission deliverables using concept-based standards

Core Elements

- Clinical Metadata and Study Definition Repository
- API layer
- OpenStudyBuilder application / Web UI

Open Source

MDR & SDR

Open Source

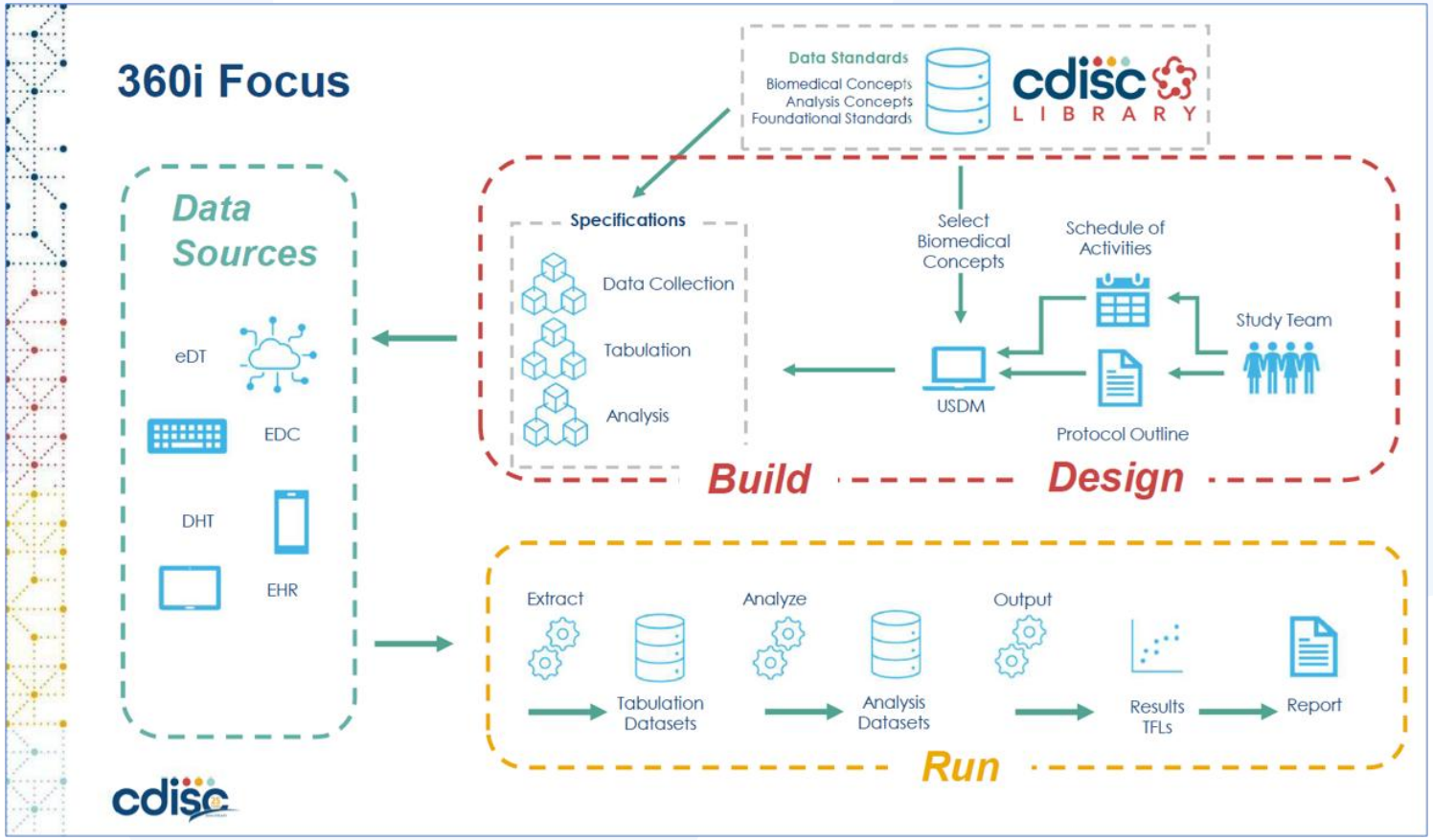
Standards alone are not sufficient

Challenges are too complex

Isolated solutions are inadequate

360i

From Vision to Implementation



Hands-On

Hands-On

Pre-Requisite

- Laptop + Sandbox account
- Note, mails might be exposed due to audit-trail

Modified	Modified by
May 6, 2025, 1:29 PM	katja.glass@glacon.eu
May 6, 2025, 1:29 PM	katja.glass@glacon.eu

- Exercises at https://openstudybuilder.com/workshop_2025

Hands-On

CDISC Pilot Study

- Protocol (here)
- USDM (here)
- SoA modified for workshop

Type	Pre Treatment		Treatment					Post Treatment
Epoch	Screening		Treatment 1	Treatment 2			Treatment 3	Follow-up
Visit (V)	V1	V2	V3	V4	V5	V6	V7	V8
Timing of Visit (Weeks)	-2	-0,3	0	4	8	20	24	26
Visit Window (Days)	0/+7	-1/0	±7	±7	±7	±7	±7	±7
Subject Related Information								
Informed Consent Obtained	X	-	-	-	-	-	-	-
Sex	X							
Race	X							
Ethnicity	X							
Date of Birth	X							
Systolic Blood Pressure (Vital Signs)	X							
Medical History/Concomitant Illness	X	-	-	-	-	-	-	-
Alcohol Habits	X	-	-	-	-	-	-	-
MMSE	X	-	-	-	-	-	-	-
X-Ray	X	-	-	-	-	-	-	-

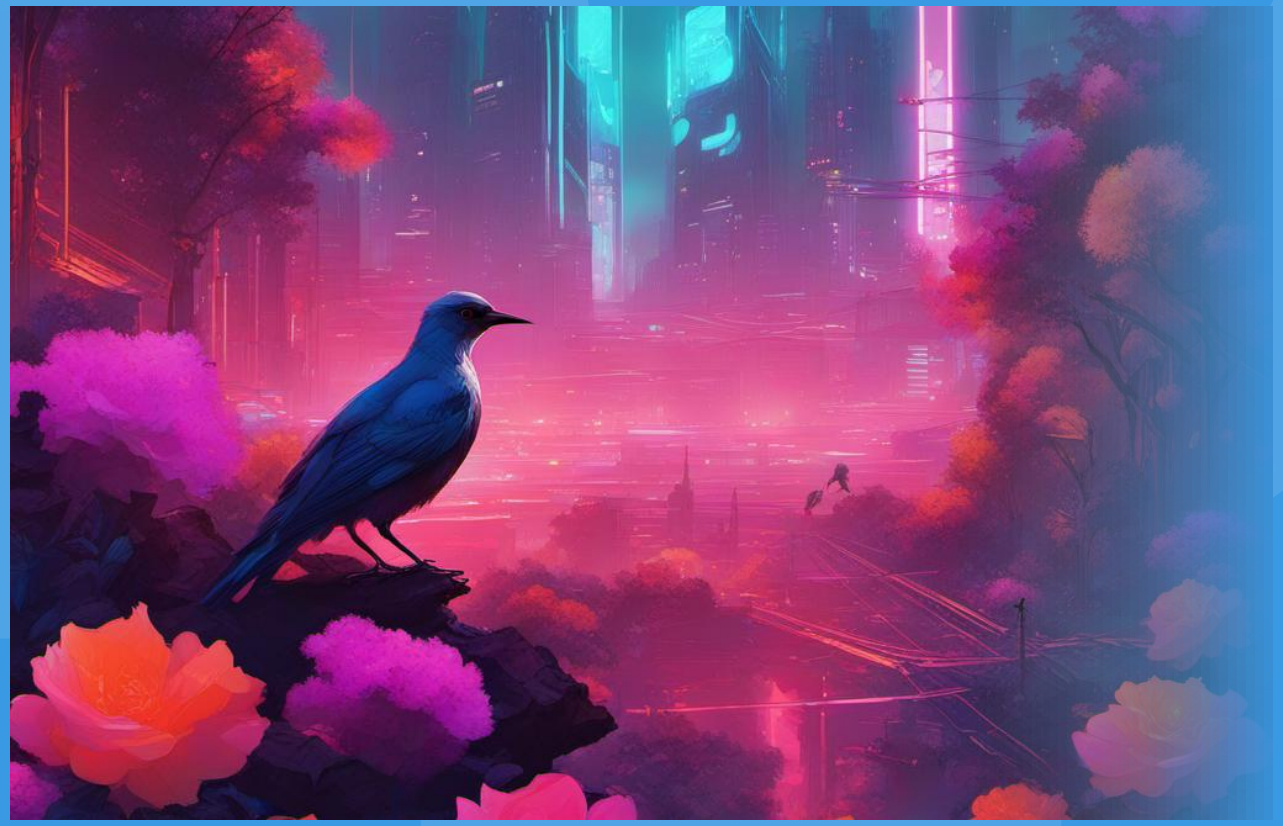
Hands-On

- Build teams (1-3 people)
- Access exercise https://openstudybuilder.com/workshop_2025
- Log into sandbox https://openstudybuilder.northeurope.cloudapp.azure.com/
- Make notes

- Create a new Study
- Setup epochs, visits, activities
- Optional – new activity, create data specification
- Optional – additional study details

WIFI

- IHG One
- GVACP



Insights & Experiences

Insights

- Copy from Study
- Copy activities from a template study
- Reorder activities
- Bulk edit activities
- Sub-studies
- Special visits

Feedback

Success

- Overview
- Examples

Issues

- data specifications tricky
- test data

- reduce to fewer visits & activities

Opportunities

- Videos stopping and not too fast
- explain data specification relationship

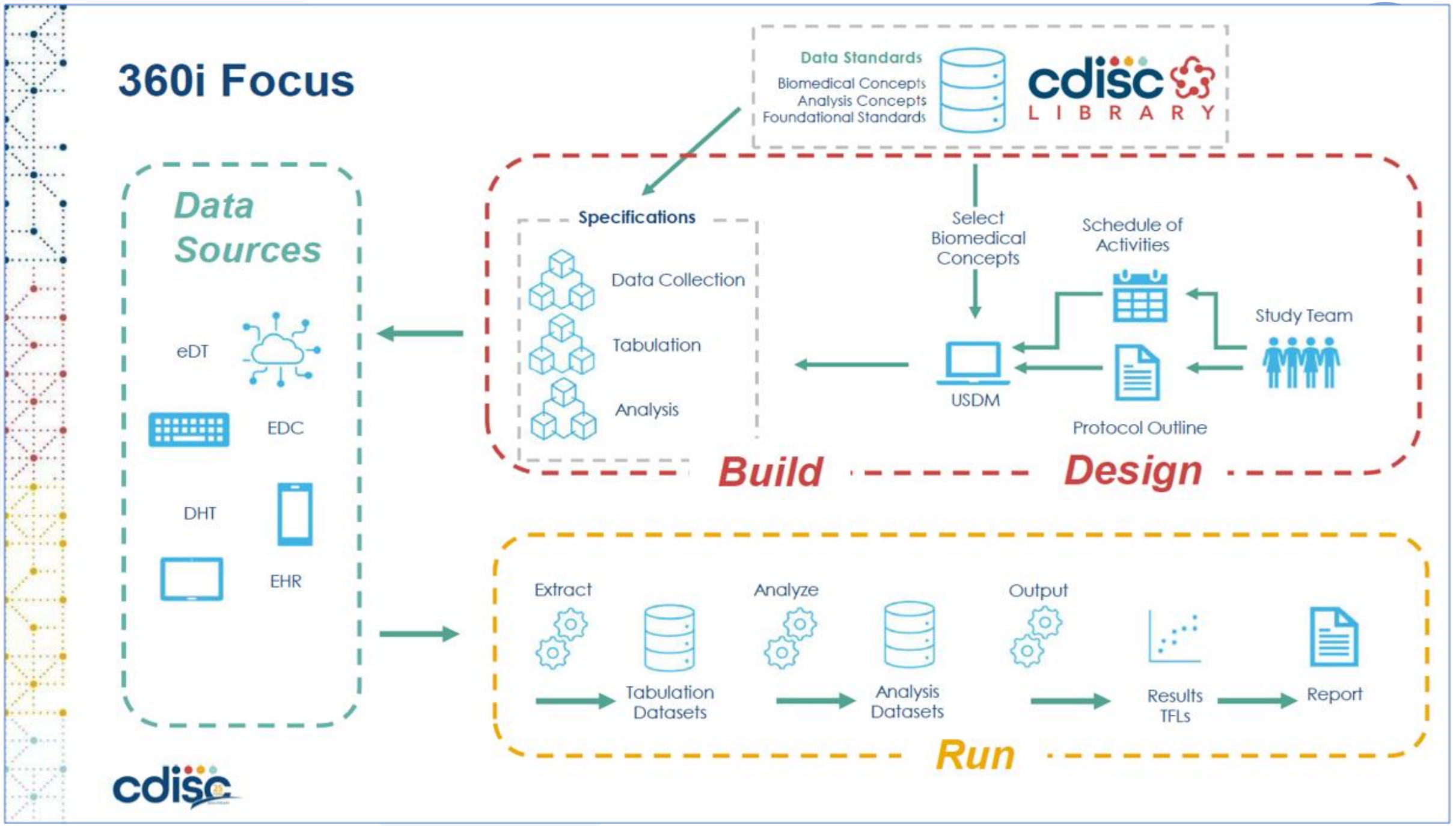
- Explain how to maintain items
- Community maintenance of items

- Additional explanations, e.g. links to detailed documentation (rough explanation direct, deeper linking)

- More introduction
- Link to CDISC / Interaction

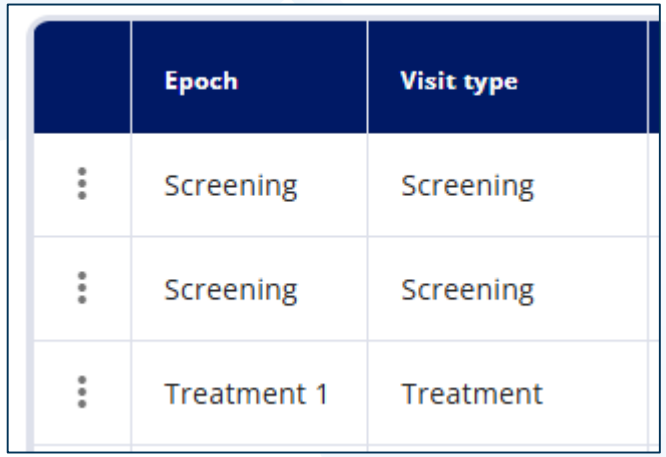
End-2-End &
Digital Data Flow

360i Focus

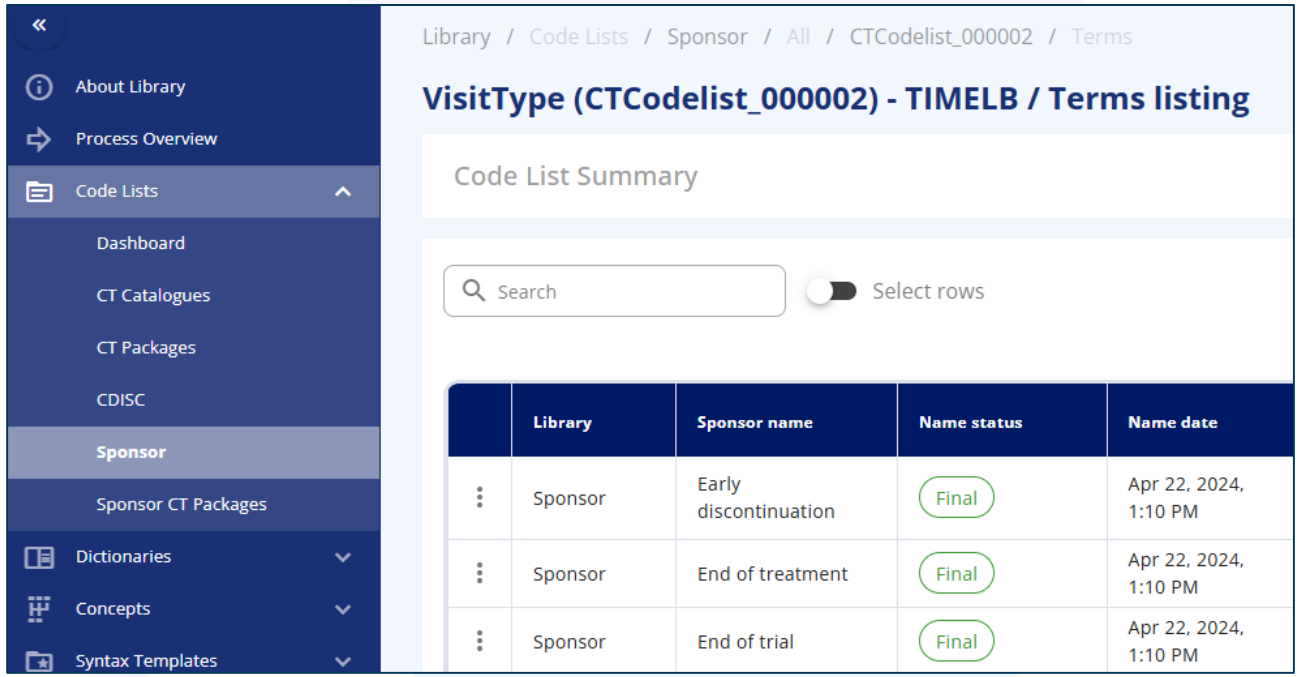

Data Standards
Biomedical Concepts
Analysis Concepts
Foundational Standards
cdisc LIBRARY
Data Sources
eDT
EDC
DHT
EHR
Specifications
Data Collection
Tabulation
Analysis
Select Biomedical Concepts
Schedule of Activities
Study Team
USDM
Protocol Outline
Build
Design
Extract
Analyze
Output
Tabulation Datasets
Analysis Datasets
Results TFLs
Report
Run
cdisc

OpenStudyBuilder

Options by Controlled Terminology
(CDISC or Sponsor Terms)



	Epoch	Visit type
⋮	Screening	Screening
⋮	Screening	Screening
⋮	Treatment 1	Treatment



OpenStudyBuilder

To compare the effect of Compound relative to Comparator on ActivityInstance

Protocol Content with Semantics

Proportion of subjects with ActivityInstance Operator NumericValue Unit
Disease control rate of Compound + Compound cohort
Overall response rate of Compound + Compound cohort

OpenStudyBuilder

Connecting bits & pieces
- Biomedical Concepts

Activity groupings

Activity group	Activity subgroup
Laboratory Assessments	Glucose Metabolism
Laboratory Assessments	24 Hour Urine Collection
AE Requiring Additional Data	Laboratory Assessment
Laboratory Assessments	Urinalysis

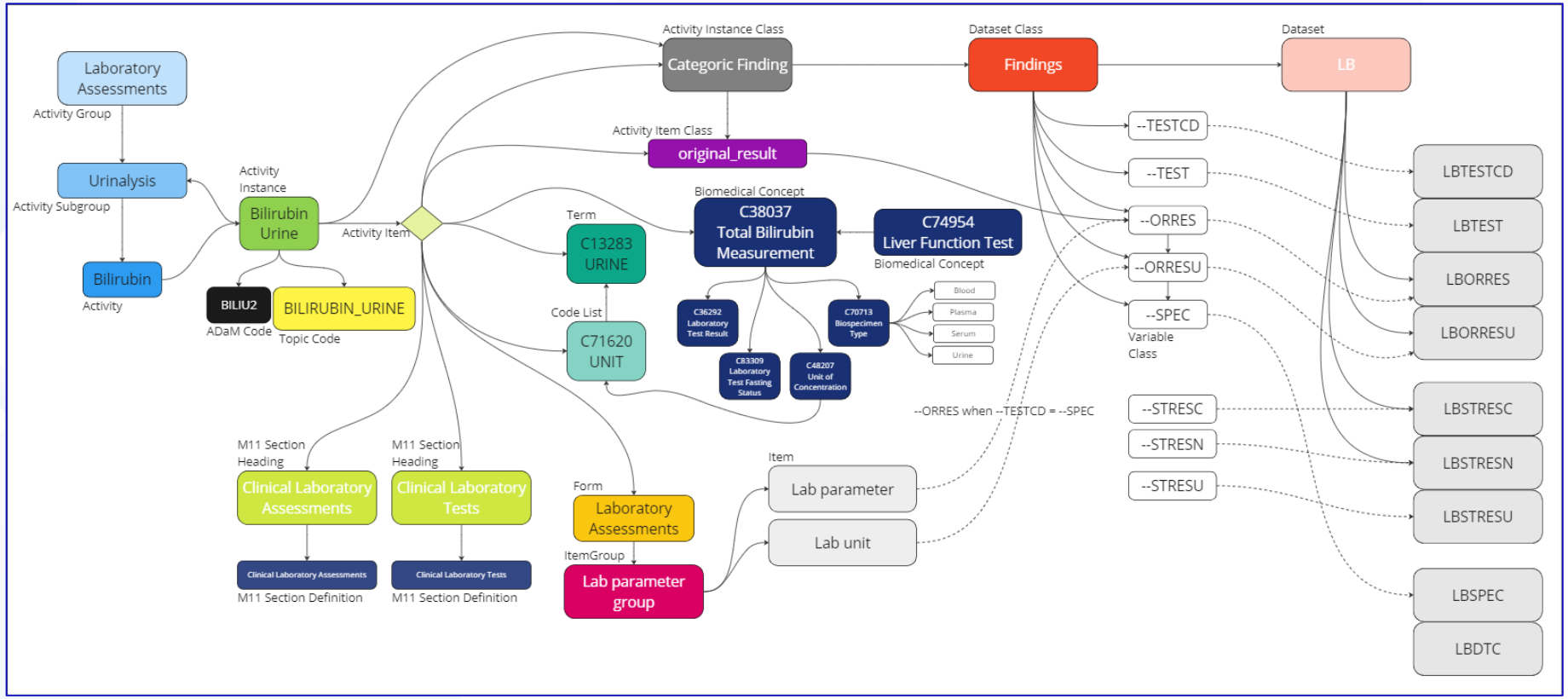
Activity instances

Name	Definition	Version	Status	Activity instance class	Topic code	ADaM parameter code
BG Super GL Analyzer		1.0	Final	NumericFinding	BG_SUPER_GL_ANALYZER	BGSUPGLA
BG Super GL Analyzer		0.1	Draft	NumericFinding	BG_SUPER_GL_ANALYZER	BGSUPGLA
Blood Glucose		1.0	Final	NumericFinding	GLUCOSE_BLOOD	GLUCB
Blood Glucose		0.1	Draft	NumericFinding	GLUCOSE_BLOOD	GLUCB
Fasting Plasma Glucose		1.0	Final	NumericFinding	FPG_PLASMA	FPG
Fasting Plasma Glucose		0.1	Draft	NumericFinding	FPG_PLASMA	FPG
Fasting Serum Glucose		1.0	Final	NumericFinding	FSG_SERUM	FSG
Fasting Serum Glucose		0.1	Draft	NumericFinding	FSG_SERUM	FSG
Glucose		1.0	Final	NumericFinding	GLUCOSE	GLUC05

Biomedical Concepts drive Digital Data Flow

Connect to Flow - define once & use many

- Protocol definition
- CRF utilization
- EDC specification
- SDTM definition
- ADAM definition

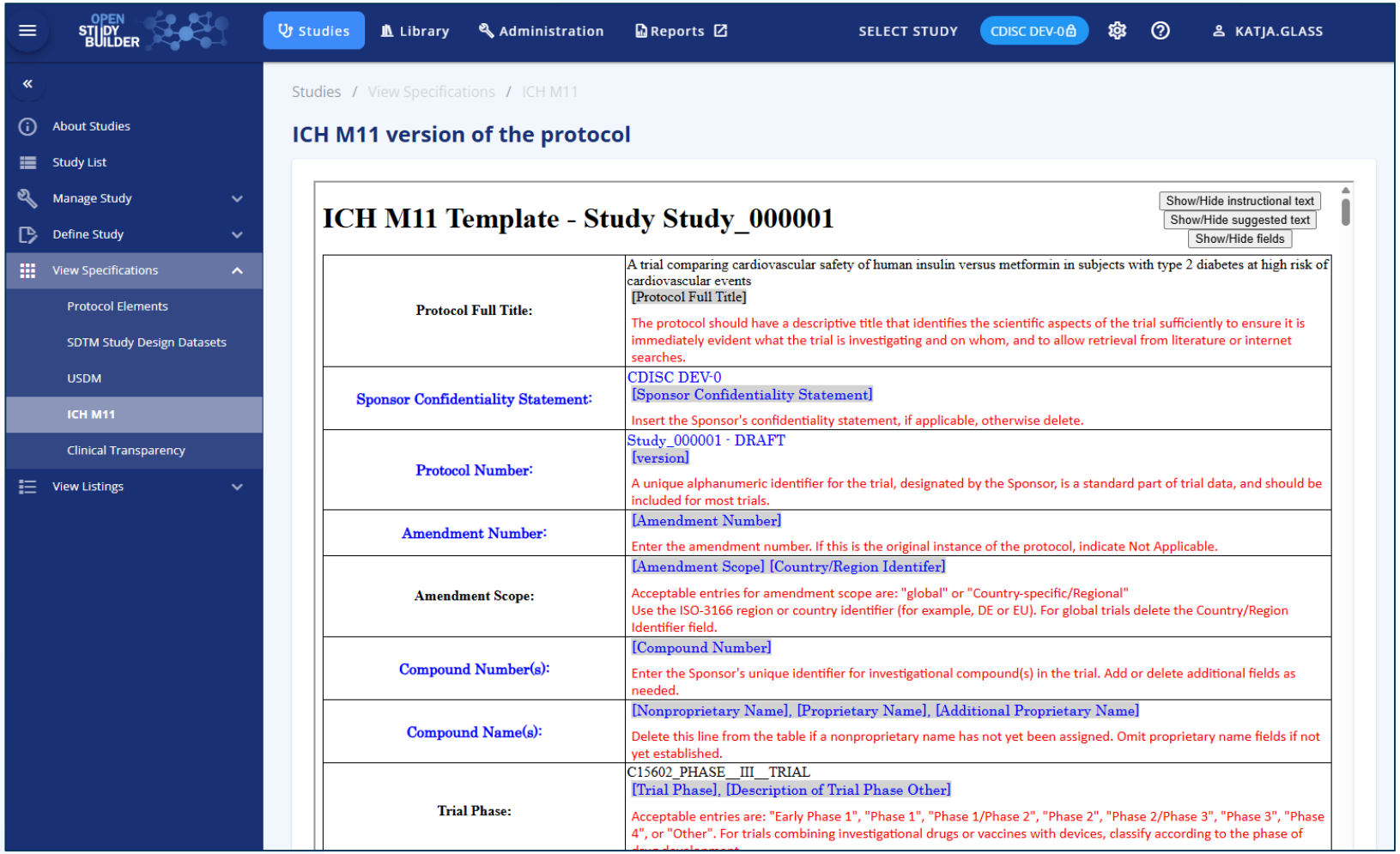


Downstream support as of now

- USDM Export

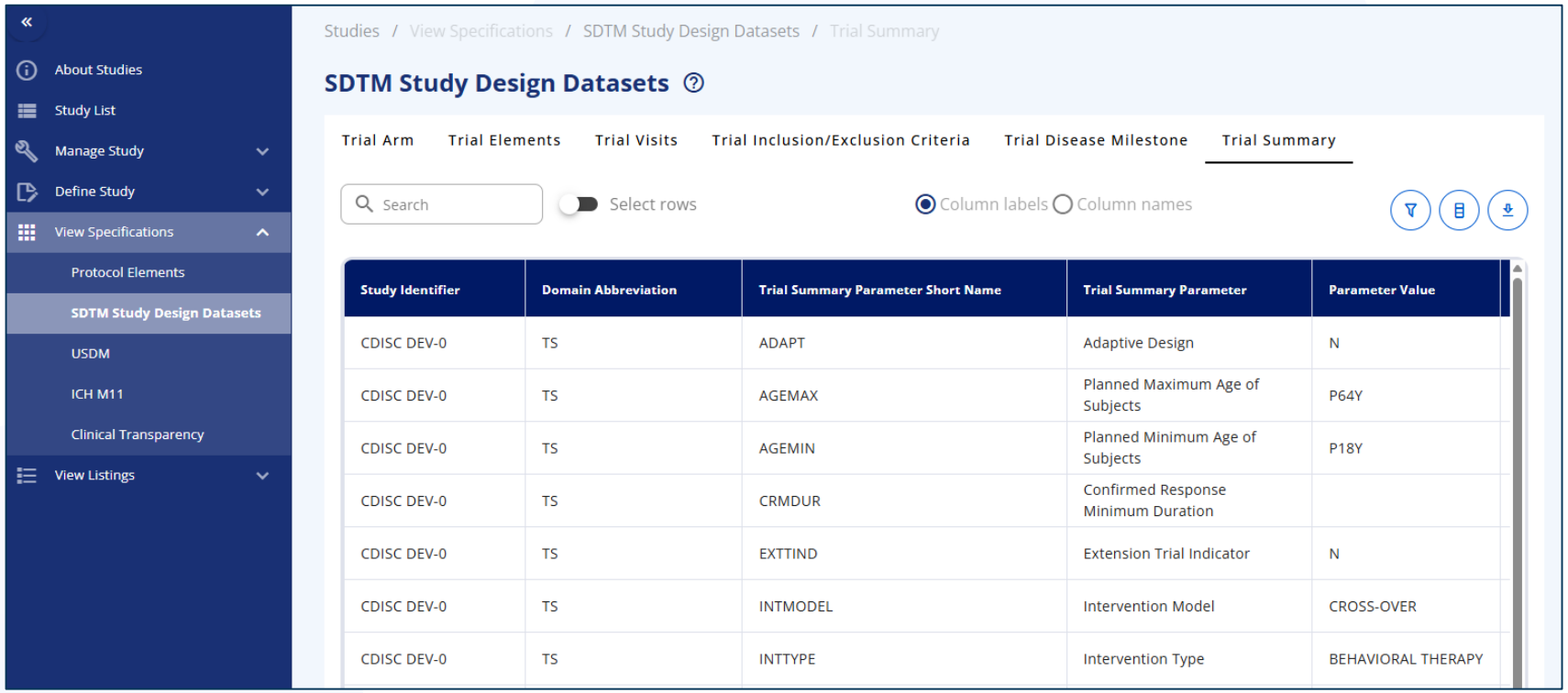
Downstream support as of now

- USDM Export
- M11 Display



Downstream support as of now

- USDM Export
- M11 Display
- Design Datasets



Downstream support as of now

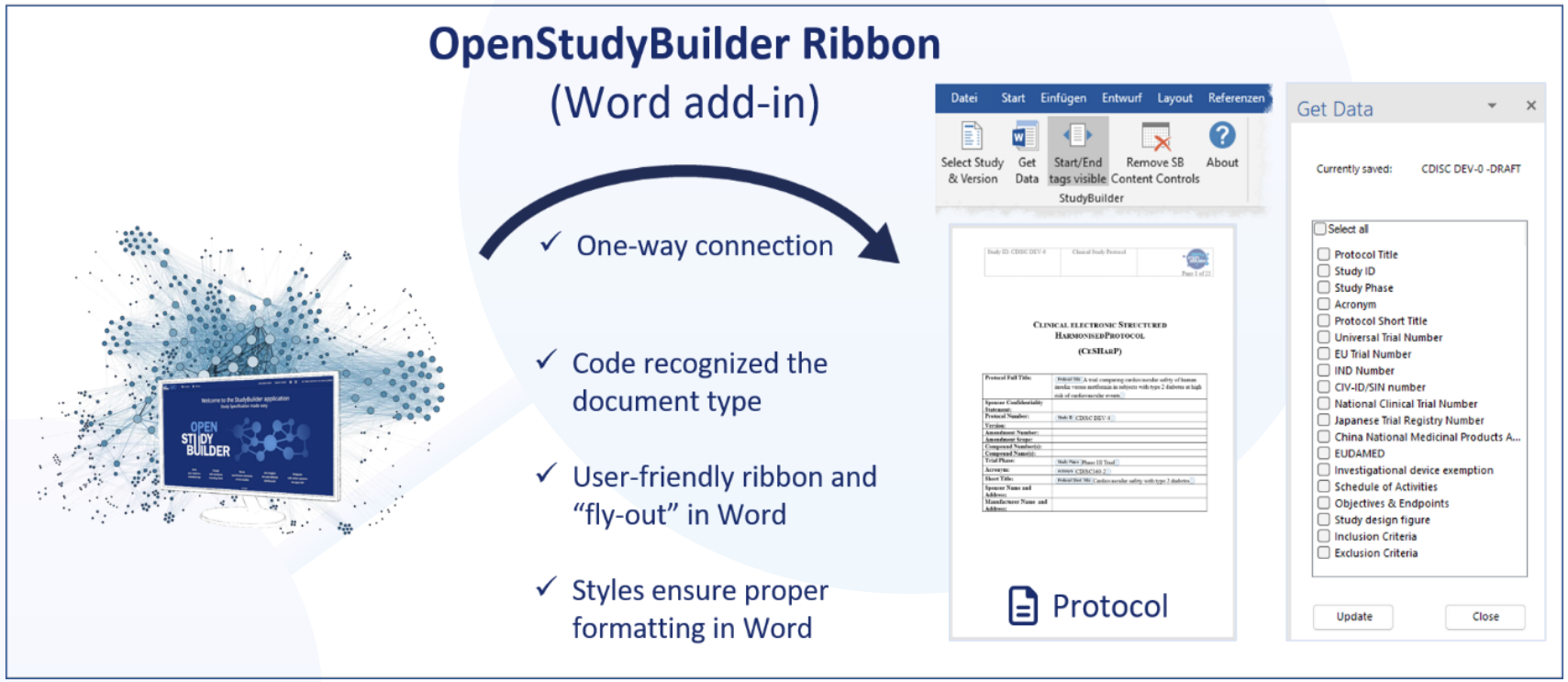
- USDM Export
- M11 Display
- Design Datasets
- Transparency Export
- Define.xml (in development)

VS Using sdtmig_mastermodel_3.2_NN15

Variable	Cdisc	Label/Description	Type	Length	Displ...	Codel...	Term	Core	Origin	Role	Comment	Order
CDMS_SUB_EVT	false	CDMS Repeat Sequence N	integer	8				Perm		RecordQualifier		10
SRC_FIND_COLL	false	CDW SRC Finding Collecti	text [C]	80				Perm		RecordQualifier		20
TOPIC_CD	false	CDW Topic Code	text [C]	80				Perm		Topic		30
STUDYID	true	Study Identifier	text [C]	40				Req	Protocol	Identifier	Unique identifier for a stud	40
DOMAIN	true	Domain Abbreviation	text [C]	8			VS	Req	Assigne	Identifier	Two-character abbreviatior	50
USUBJID	true	Unique Subject Identifier	text [C]	60				Req	Assigne	Identifier	Identifier used to uniquely i	60
SPDEVID	false	Sponsor Device Identifier	text [C]	40				Perm	Assigne	Identifier	Sponsor-defined identifier	70
VSSEQ	true	Sequence Number	integer	8				Req	Derived	Identifier	Sequence Number given to	80
VSGRPID	true	Group ID	text [C]	60				Perm		Identifier	Used to tie together a block	90
VSREFID	false	Reference ID	text [C]	40				Perm		Identifier		100

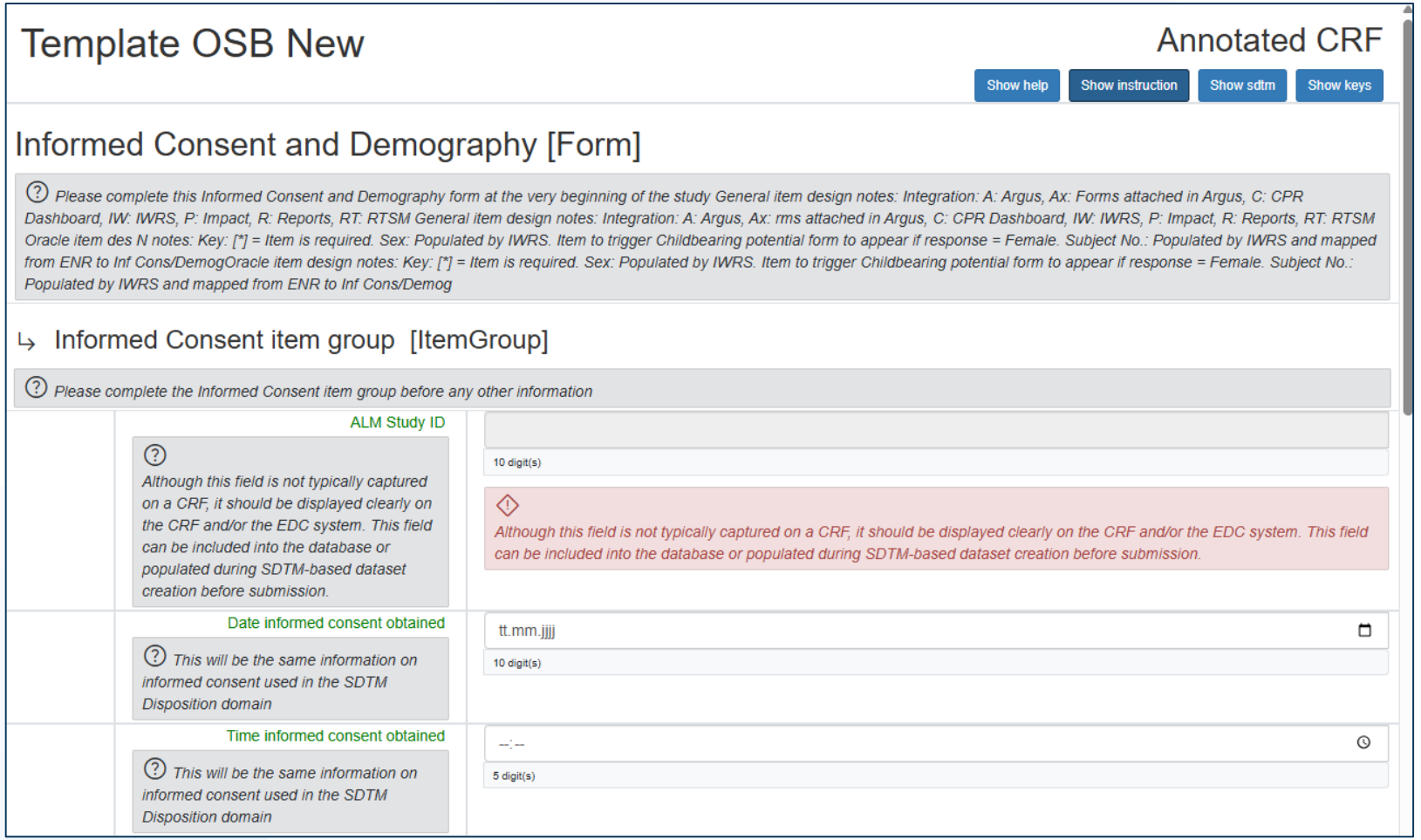
Downstream support as of now

- USDM Export
- M11 Display
- Design Datasets
- Transparency Export
- Define.xml (in development)
- Word Add-In



Downstream in development

- CRF Library
- Study CRF & aCRF
- EDC Automation



Hands-On

Checkout Features

CDISC-0

- USDM Export
- M11 Display
- Design Datasets
- Transparency Export
- Define.xml (in development)
- Word Add-In

- Browse Library
  - Activity & Activity Instances

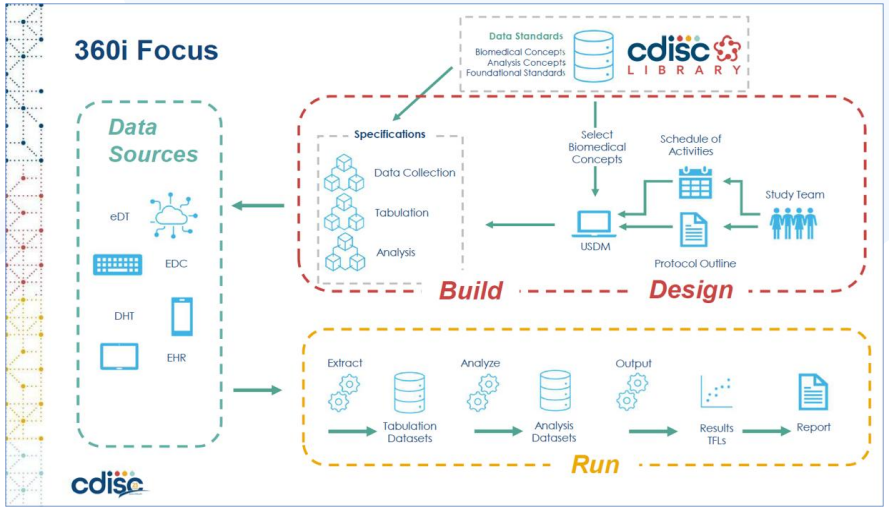
Questions

CDISC 360i

Standards alone are not sufficient

Challenges are too complex

Isolated solutions are inadequate



Interchange Program

- Wednesday 13:30 – 15:30 Digital Data Flow
- Wednesday 16:00 – 17:30 CDISC 360i
- Thursday 13:30 – 15:30 Highway to Automation
- Friday CDISC 360i Workshop

CDISC+TMF Europe Interchange Agenda
Geneva | 14-15 May 2025
Day 1

9:00 - 10:30	Session 1: Opening Plenary (All Attendees), Location: International Ballroom, Floor -2				
9:00 - 9:10	CDISC Welcome				
9:10 - 9:50	Keynote Presentation: Standardization and Interoperability in Rare Diseases, the Journey from Efficiency to Equity, the Duchenne Experience				
9:50 - 10:30	CDISC 360i and State of the Standards				
10:30 - 11:00	Morning Break, International and Geneva Foyers, Floors -1 & -2				
11:00 - 12:30	Session 2, Tracks A,B, & C: The European Landscape of Clinical Research and Health Care Location: International Ballroom, Floor -2			11:00 - 12:30	Session 2, Tracks D & E The Future of TMF (TMF Track) Location: Europe Ballroom, Floor -2
11:00 - 11:20	ICH M11			11:00 - 11:15	TMF Introduction
11:20 - 11:40	EU Initiatives			11:15 - 12:00	ICH E6 R3 and the TMF
11:40 - 12:00	EMA Update			12:00 - 12:30	TMF RM V4
12:00 - 12:30	Panel Discussion				
12:30 - 13:30	Lunch + Poster Session | International & Geneva Foyers, Floors -1 & -2 (Poster Session in Geneva Rooms, Floor -1)				
13:30 - 15:30	Session 2A: Digital Data Flow Location: Zurich, Floor -2	Session 2B: Artificial Intelligence Location: Londres, Floor -2	Session 2C: Innovation Showcase Location: New York, Floor -2 SESSION SPONSOR: tcs	13:30 - 15:30	Session 2D: Technology in TMF Management Location: Munich & Paris, Floor -2 SESSION SPONSOR: Agatha	Session 2E: TMF Culture and Engagement Copenhague & Lisbonne, Floor -2
13:30 - 14:00	ICH M11, TransCelerate, CDISC & HL7 Vulcan: Making the Electronic Protocol a Reality	Leveraging AI to Simplify SDTM Standards and Streamline Clinical Data Management	Demonstration by Tata Consultancy Services	13:30 - 14:00	How to Leverage Next-Generation Tools Today to Optimize TMF Processing and Enhance Efficiency	The Danish TMF Network
14:00 - 14:30	Protocol to Study Live in 15 Mins, AI, USDM and BCs in Action	Let Robots Sort It Out: Smarter CDISC Open Rules with AI	CDISC Standards Implementation: Best Practices and Case Studies in Success	14:00 - 14:30	TMF Technology Trends: Insights from eTMF Data	Panel: Building a Unified TMF Culture Strategy: Engaging End Users, Clinical Functional Areas, and Collaborating Clinical Partners
14:30 - 15:00	Bringing the USDM Model to the Catwalk	The Role of Data Standardization in AI-Driven Clinical Research	Demonstration TBD	14:30 - 15:00	Exploring the Role of TMF Metrics and KPIs in Trial Innovation - Is There a Purpose Beyond Inspection Readiness?	Elevate Your TMF Inspection Readiness with a Focused Preparation Program
15:00 - 15:30	Navigating Post-Go-Live Changes in Automated Clinical Study Builds: Optimizing USDM / M11 for EDC and Beyond	AI for Standards Library Search	Demonstration TBD	15:00 - 15:30	Requirements of the 2023 EMA Guideline on Clinical Systems and CSV Tab of the CDISC TMF RM	Panel: Culture Change Driving Inspection Success
15:30 - 16:00	Afternoon Break, International and Geneva Foyers, Floors -1 & -2					
16:00 - 17:30	Session 4A: CDISC 360i Location: Zurich, Floor -2	Session 4B: CDISC Foundational Location: Londres, Floor -2	Session 4C: Academia Location: New York, Floor -2	16:00 - 17:30	Session 4D: Risk Based Approaches Location: Munich & Paris, Floor -2	Session 4E: Fundamentals of TMF Copenhague & Lisbonne, Floor -2
16:00 - 16:30	Breaking Down Silos with CDISC 360i: A Technical Roadmap	Unraveling the Complex Web of Data Relationships	Pioneering Efforts to Expand CDISC Standards in Japanese Academic Research	16:00 - 16:30	What Does a Risk Based Approach Really Mean? Summary of the TMF RM Risk Initiative	TMF as a Foundation for Success: Streamlining Operations and Ensuring Data Integrity
16:30 - 17:00	Enhanced Biomedical Concepts: A Design Perspective in OpenStudyBuilder Supporting CDISC 360i	Enhancing Clinical Data Quality and Consistency with Value Level Metadata for Non-CRF Data Collection	The Importance of CDISC Standards when Retaining, Archiving, and Preserving Clinical Trial Records and Data	16:30 - 17:00	TMF Risk Management: Developing A Plan for Mitigating Risk Identified by the CDISC Risk Tool	The "5 Identities" of a TMF Reference Model
17:00 - 17:30	CDISC 360i, and the Worm that Turned	CDISC Protocol Deviation Sub-Team SDTMIG 4.0 Updates and Open Topics	Mapping REDCap Data into SDTM: A Case Study of Healthy Volunteer Research Data	17:00 - 17:30	Panel: Risk Based Approaches in Line with ICH E6 R3	TMF Completeness - A Major Component of Inspection Ready TMF
19:00 - 22:00	Interchange Evening Networking Event, Uptown Geneva (Must Preregister to Attend)					

OpenStudyBuilder Links

Getting Started

Checkout available resources!

- Project website: https://openstudybuilder.org
- Newsletter: LinkedIn
- Demonstration Video: YouTube
- Demonstration Flow: Homepage
- Repository (Solution, Description): GitLab
- Slack: Join
- Email: openstudybuilder@gmail.com
- Request sandbox access: Sandbox

https://openstudybuilder.com/status/

Exchange & Summary

Success

- xxx

Issues

- xxx

Opportunities

- graphical overview – what we are looking for – endpoint in view (scope & context, vision)

Thanks!

OpenStudyBuilder Links

- Project Homepage: https://openstudybuilder.com/
- Newsletter: https://www.linkedin.com/newsletters/openstudybuilder-6990328054849916928/
- YouTube Demonstration (30'): https://youtu.be/dL5CY0BwfEs
- Demonstration Flow: https://openstudybuilder.com/info_demo/
- GitLab (Solution, Description): https://gitlab.com/Novo-Nordisk/nn-public/openstudybuilder
- Slack: https://join.slack.com/t/openstudybuilder/shared_invite/zt-19mtauzic-Jvrhtmy7hGstgyilvB1Wsw
- E-Mail: openstudybuilder@gmail.com
- Sandbox: Mail openstudybuilder@neotechnology.com – Subject "Request Sandbox access"