



Hands-On Experience

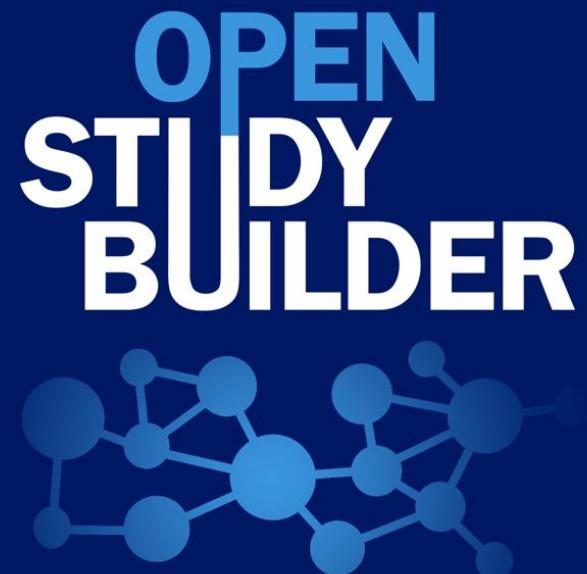
COSA OpenStudyBuilder
Workshop: CDISC 360i –
Design and Build with
OpenStudyBuilder

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



Nicolas de Jaint Jorre

Lead Product Architect (Novo Nordisk)



Charles Shadle

CDISC 360i (CDISC)



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





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

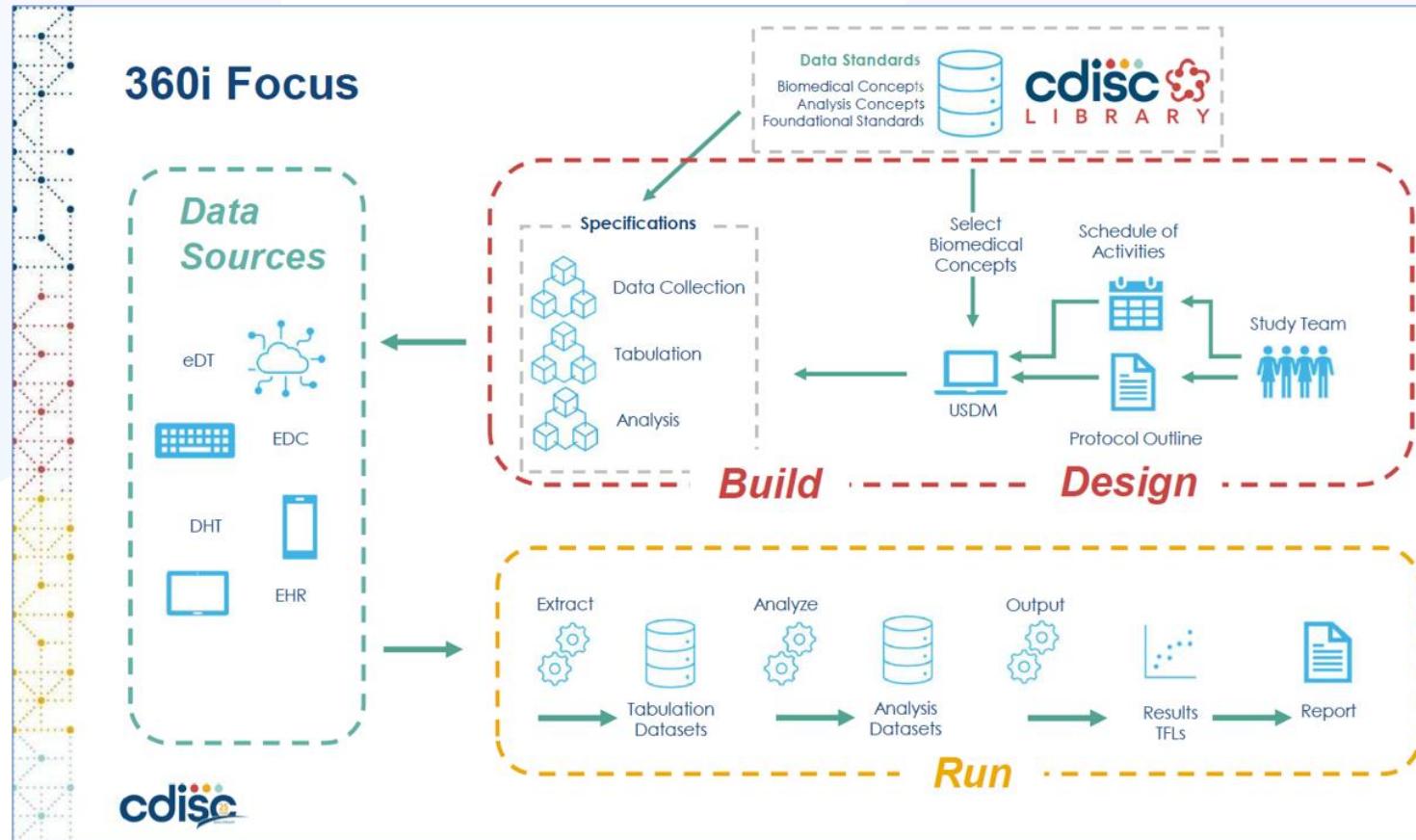




Open Source

Standards alone are not sufficient
Challenges are too complex
Isolated solutions are inadequate

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

WIFI

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





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

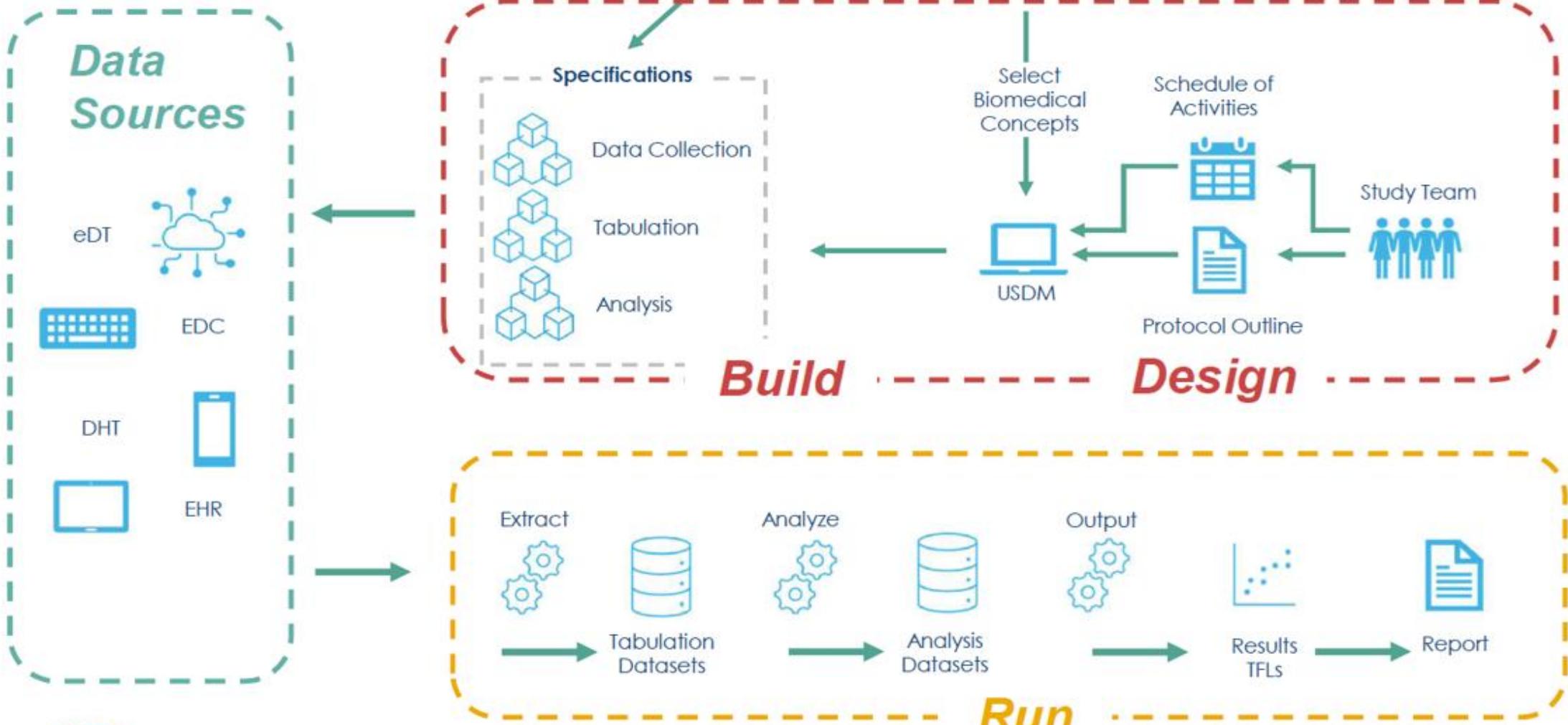
- Videos stopping and not too fast
- explain data specification relationship
- Explain how to maintain items
- Community maintenance of items
- Additional explanations, e.g. links to detailed documentation (rough explanation direct, deeper linking)
- More introduction
- Link to CDISC / Interaction





End-2-End &
Digital Data Flow

360i Focus



OpenStudyBuilder

Options by Controlled Terminology (CDISC or Sponsor Terms)

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

Library / Code Lists / Sponsor / All / CTCodeList_000002 / Terms

VisitType (CTCodeList_000002) - TIMELB / Terms listing

Code List Summary

Search Select rows

	Library	Sponsor name	Name status	Name date
⋮	Sponsor	Early discontinuation	Final	Apr 22, 2024, 1:10 PM
⋮	Sponsor	End of treatment	Final	Apr 22, 2024, 1:10 PM
⋮	Sponsor	End of trial	Final	Apr 22, 2024, 1:10 PM



OpenStudyBuilder

Protocol Content with Semantics

To compare the effect of **Compound** relative to **Comparator** on **ActivityInstance**

Proportion of subjects with **ActivityInstance Operator NumericValue Unit**

Disease control rate of **Compound + Compound cohort**

Overall response rate of **Compound + Compound cohort**



OpenStudyBuilder

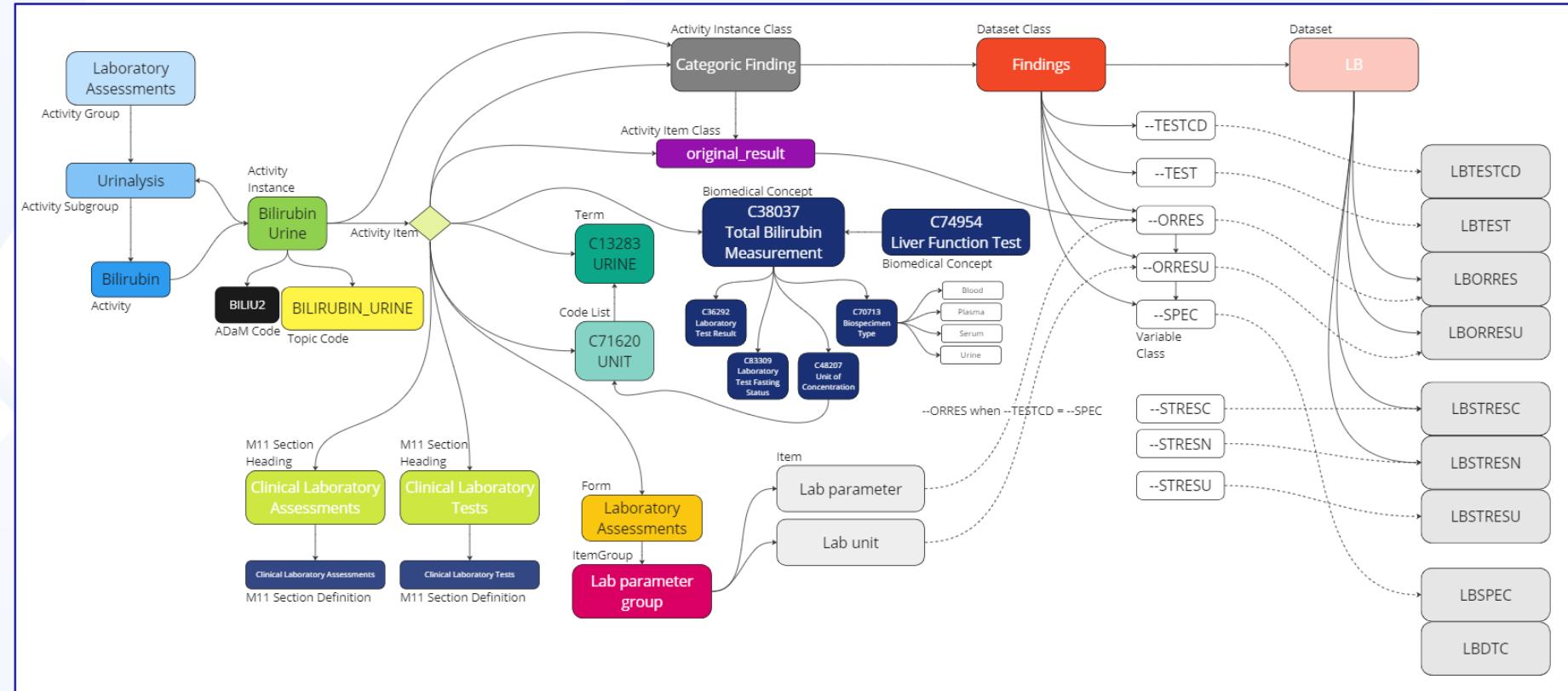
Connecting bits & pieces
- Biomedical Concepts

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

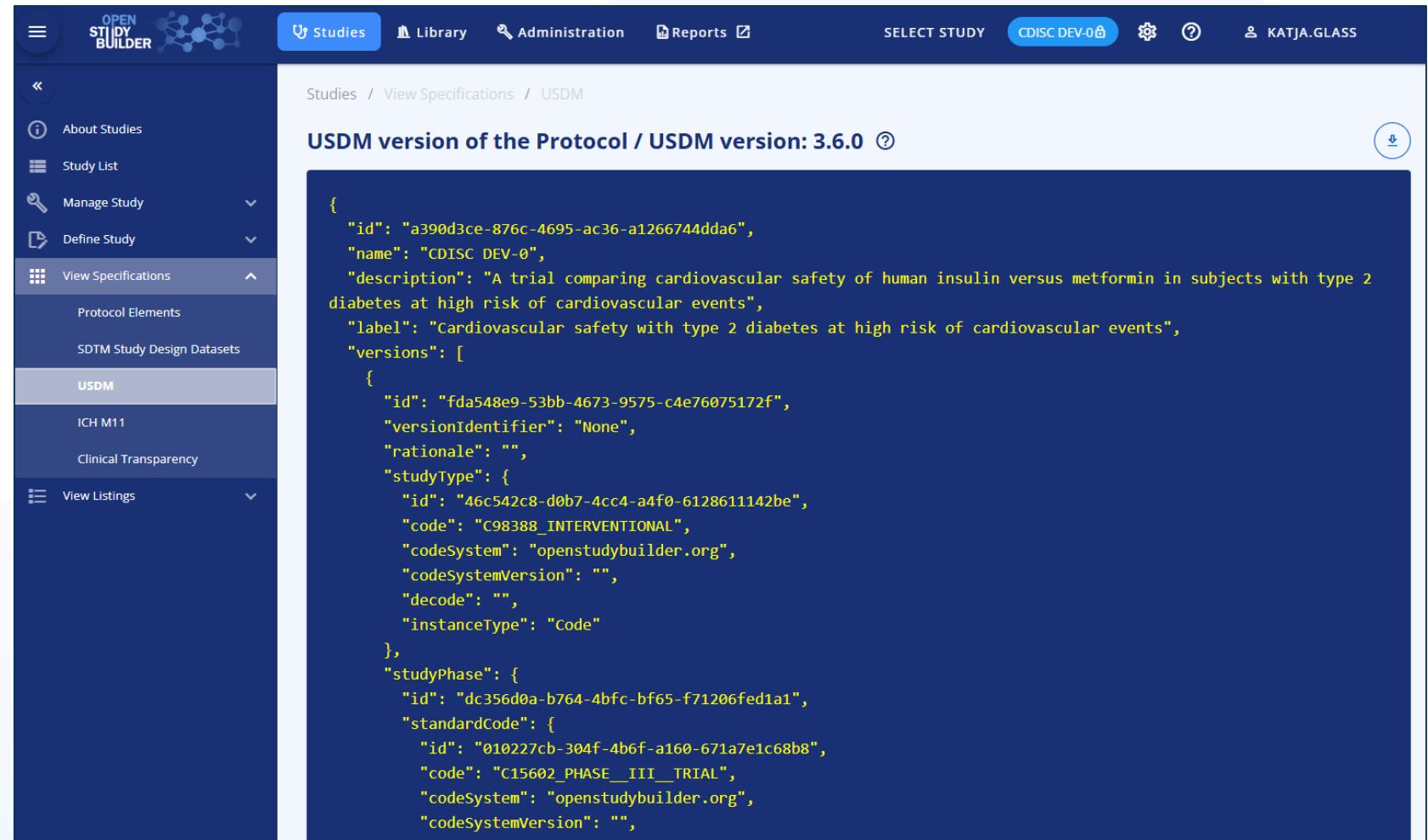
Connect to Flow - define once & use many

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



Downstream support as of now

➤ USDM Export



The screenshot shows the Open Study Builder application interface. The left sidebar has a dark blue background with white text and icons. It includes sections for About Studies, Study List, Manage Study, Define Study, View Specifications (which is expanded to show Protocol Elements, SDTM Study Design Datasets, and USDM), ICH M11, Clinical Transparency, and View Listings. The main content area has a white background with a dark blue header bar. The header bar contains the Open Study Builder logo, navigation links for Studies, Library, Administration, Reports, and a user account for KATJA.GLASS. Below the header, the URL is Studies / View Specifications / USDM. The main content title is "USDM version of the Protocol / USDM version: 3.6.0". The content area displays a JSON representation of a study protocol, starting with an object containing an ID, name, description, label, and versions. The "versions" array contains one element, which is another object with an ID, version identifier (None), rationale, study type (with its own ID, code, code system, etc.), and study phase (with its own standard code and code system).

```
{
  "id": "a390d3ce-876c-4695-ac36-a1266744dda6",
  "name": "CDISC DEV-0",
  "description": "A trial comparing cardiovascular safety of human insulin versus metformin in subjects with type 2 diabetes at high risk of cardiovascular events",
  "label": "Cardiovascular safety with type 2 diabetes at high risk of cardiovascular events",
  "versions": [
    {
      "id": "fda548e9-53bb-4673-9575-c4e76075172f",
      "versionIdentifier": "None",
      "rationale": "",
      "studyType": {
        "id": "46c542c8-d0b7-4cc4-a4f0-6128611142be",
        "code": "C98388_INTERVENTIONAL",
        "codeSystem": "openstudybuilder.org",
        "codeSystemVersion": "",
        "decode": "",
        "instanceType": "Code"
      },
      "studyPhase": {
        "id": "dc356d0a-b764-4bfc-bf65-f71206fed1a1",
        "standardCode": {
          "id": "010227cb-304f-4b6f-a160-671a7e1c68b8",
          "code": "C15602_PHASE_III_TRIAL",
          "codeSystem": "openstudybuilder.org",
          "codeSystemVersion": ""
        }
      }
    }
  ]
}
```

Downstream support as of now

- USDM Export
- M11 Display

Studies / View Specifications / ICH M11

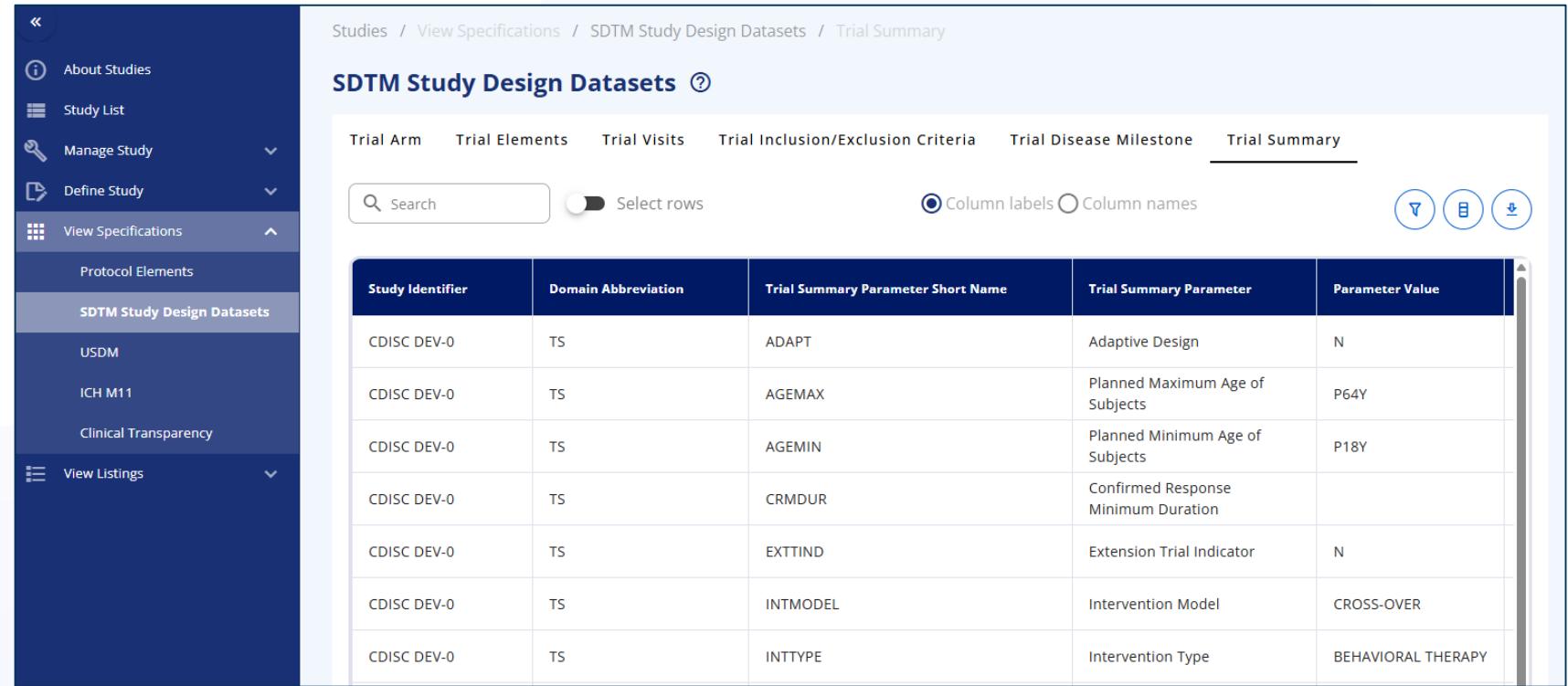
ICH M11 version of the protocol

ICH M11 Template - Study Study_000001

Protocol Full Title:	A trial comparing cardiovascular safety of human insulin versus metformin in subjects with type 2 diabetes at high risk of cardiovascular events [Protocol Full Title] The protocol should have a descriptive title that identifies the scientific aspects of the trial sufficiently to ensure it is immediately evident what the trial is investigating and on whom, and to allow retrieval from literature or internet searches.
Sponsor Confidentiality Statement:	CDISC DEV-0 [Sponsor Confidentiality Statement] Insert the Sponsor's confidentiality statement, if applicable, otherwise delete.
Protocol Number:	Study_000001 - DRAFT [version] A unique alphanumeric identifier for the trial, designated by the Sponsor, is a standard part of trial data, and should be included for most trials.
Amendment Number:	[Amendment Number] Enter the amendment number. If this is the original instance of the protocol, indicate Not Applicable.
Amendment Scope:	[Amendment Scope] [Country/Region Identifier] Acceptable entries for amendment scope are: "global" or "Country-specific/Regional" Use the ISO-3166 region or country identifier (for example, DE or EU). For global trials delete the Country/Region Identifier field.
Compound Number(s):	[Compound Number] Enter the Sponsor's unique identifier for investigational compound(s) in the trial. Add or delete additional fields as needed.
Compound Name(s):	[Nonproprietary Name], [Proprietary Name], [Additional Proprietary Name] Delete this line from the table if a nonproprietary name has not yet been assigned. Omit proprietary name fields if not yet established.
Trial Phase:	C15602_PHASE_III_TRIAL [Trial Phase], [Description of Trial Phase Other] Acceptable entries are: "Early Phase 1", "Phase 1", "Phase 1/Phase 2", "Phase 2", "Phase 2/Phase 3", "Phase 3", "Phase 4", or "Other". For trials combining investigational drugs or vaccines with devices, classify according to the phase of development.

Downstream support as of now

- USDM Export
- M11 Display
- Design Datasets



The screenshot shows the Open Study Builder application interface. On the left is a dark sidebar menu with the following items:

- About Studies
- Study List
- Manage Study
- Define Study
- View Specifications** (selected)
- Protocol Elements
- SDTM Study Design Datasets** (selected)
- USDM
- ICH M11
- Clinical Transparency
- View Listings

The main content area has a header: Studies / View Specifications / SDTM Study Design Datasets / Trial Summary. Below the header is a title: **SDTM Study Design Datasets** with a help icon. A navigation bar below the title includes tabs: Trial Arm, Trial Elements, Trial Visits, Trial Inclusion/Exclusion Criteria, Trial Disease Milestone, and **Trial Summary**. There are also search, selection, and column labeling buttons.

Study Identifier	Domain Abbreviation	Trial Summary Parameter Short Name	Trial Summary Parameter	Parameter Value
CDISC DEV-0	TS	ADAPT	Adaptive Design	N
CDISC DEV-0	TS	AGEMAX	Planned Maximum Age of Subjects	P64Y
CDISC DEV-0	TS	AGEMIN	Planned Minimum Age of Subjects	P18Y
CDISC DEV-0	TS	CRMDUR	Confirmed Response Minimum Duration	
CDISC DEV-0	TS	EXTTIND	Extension Trial Indicator	N
CDISC DEV-0	TS	INTMODEL	Intervention Model	CROSS-OVER
CDISC DEV-0	TS	INTTYPE	Intervention Type	BEHAVIORAL THERAPY

Downstream support as of now

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

VS Using sdmig_mastermodel_3.2_NN15

Variable	Cdisc	Label/Description	Type	Length	Displ...	Code...	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	Assigned	Identifier	Two-character abbreviator	50
USUBJID	true	Unique Subject Identifier	text [C]	60				Req	Assigned	Identifier	Identifier used to uniquely i	60
SPDEVID	false	Sponsor Device Identifier	text [C]	40				Perm	Assigned	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 bloc	90
VSREFID	false	Reference ID	text [C]	40				Perm		Identifier		100

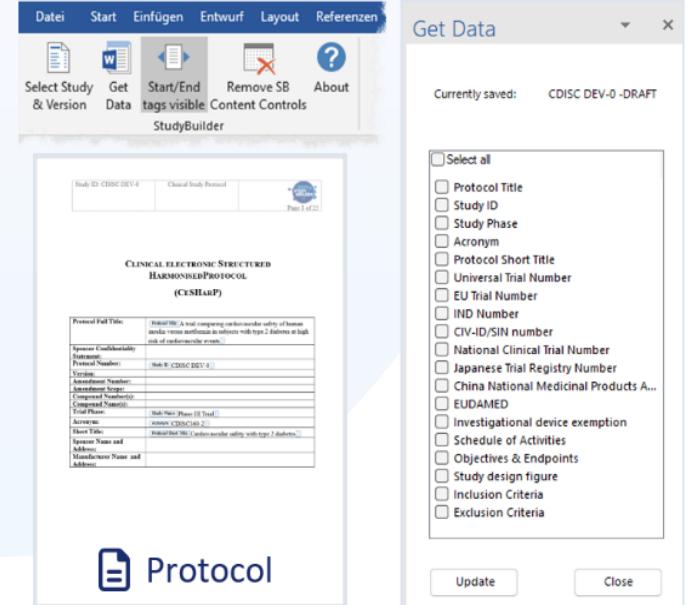
Downstream support as of now

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

OpenStudyBuilder Ribbon (Word add-in)



- ✓ One-way connection
- ✓ Code recognized the document type
- ✓ User-friendly ribbon and “fly-out” in Word
- ✓ Styles ensure proper formatting in Word



The screenshot shows the Microsoft Word ribbon with the "OpenStudyBuilder" tab selected. A "Get Data" fly-out menu is open, displaying a list of clinical trial protocol fields such as Protocol Title, Study ID, Acronym, and so on. The "Protocol" button at the bottom left of the fly-out menu is highlighted.

Downstream in development

- CRF Library
- Study CRF & aCRF
- EDC Automation

Template OSB New

Annotated CRF

[Show help](#) [Show instruction](#) [Show sdtm](#) [Show keys](#)

Informed Consent and Demography [Form]

(?) Please complete this Informed Consent and Demography form at the very beginning of the study General item design notes: Integration: A: Argus, Ax: Forms attached in Argus, C: CPR Dashboard, IW: IWRS, P: Impact, R: Reports, RT: RTSM General item design notes: Integration: A: Argus, Ax: rms attached in Argus, C: CPR Dashboard, IW: IWRS, P: Impact, R: Reports, RT: RTSM Oracle item des N notes: Key: [*] = Item is required. Sex: Populated by IWRS. Item to trigger Childbearing potential form to appear if response = Female. Subject No.: Populated by IWRS and mapped from ENR to Inf Cons/DemogOracle item design notes: Key: [*] = Item is required. Sex: Populated by IWRS. Item to trigger Childbearing potential form to appear if response = Female. Subject No.: Populated by IWRS and mapped from ENR to Inf Cons/Demog

↳ Informed Consent item group [ItemGroup]

(?) Please complete the Informed Consent item group before any other information

	ALM Study ID	
	<p>(?) Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or the EDC system. This field can be included into the database or populated during SDTM-based dataset creation before submission.</p>	<p>10 digit(s)</p> <p>(!) Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or the EDC system. This field can be included into the database or populated during SDTM-based dataset creation before submission.</p>
	<p>Date informed consent obtained</p> <p>(?) This will be the same information on informed consent used in the SDTM Disposition domain</p>	<p>tt.mm.jjjj</p> <p>10 digit(s)</p>
	<p>Time informed consent obtained</p> <p>(?) This will be the same information on informed consent used in the SDTM Disposition domain</p>	<p>--:--</p> <p>5 digit(s)</p>



Hands-On



Checkout Features

CDISC-0

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

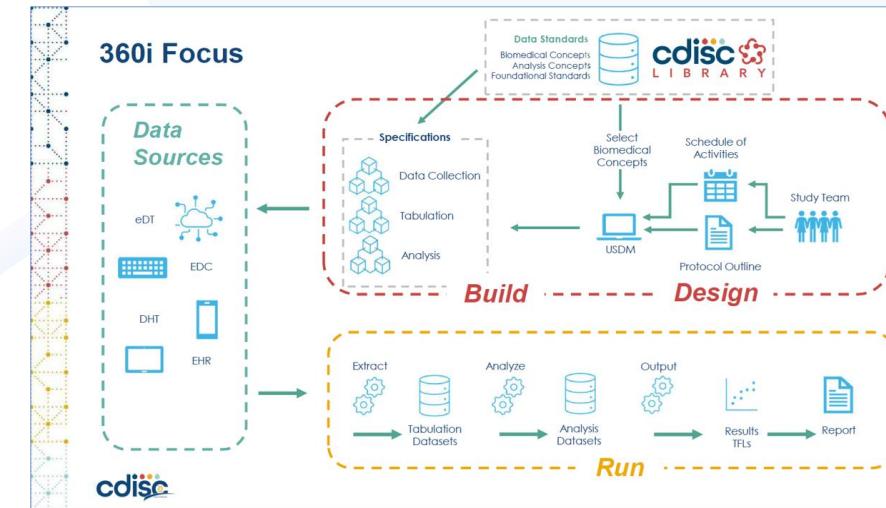
- Browse Library
 - Activity & Activity Instances



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 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 -3	
9:00 - 9:30	CDISC Welcome	
9:10 - 9:30	Keynote Presentation: Standardization and Interoperability in Rare Diseases, the Journey from Efficiency to Equity, the Duchenne Experience	
9:30 - 10:30	CDISC 360i and State of the Standards	
10:30 - 11:00	Morning Break, International and Geneva Foyers, Floors -1 & -2 (Poster Session in Geneva Room, Floor -4)	Session 2, Tracks D & E The Future of TMF (TMF Track) Location: Europa Ballroom, Floor -2
11:00 - 12:00	Session 2, Tracks A,B, & C The European Landscape of Clinical Research and Health Care Location: International Ballroom, Floor -2	11:00 - 12:00 TMF Introduction
11:00 - 11:20	ICH M11	11:15 - 12:00 ICH E6 R3 and the TMF
11:20 - 11:40	EU Initiatives	12:00 - 12:30 TMF RM V4
11:40 - 12:00	EMA Update	
12:00 - 12:30	Panel Discussion	
12:30 - 13:30	Lunch + Poster Session International & Geneva Foyers, Floors -1 & -2 (Poster Session in Geneva Room, Floor -4)	
13:30 - 15:00	Session 3A: Digital Data Flow Location: Zurich, Floor -2	Session 3B: Artificial Intelligence and Machine Learning Location: London, New York, Floor -3
13:30 - 14:00	ICH M11, TransCelerate, CDISC & H2L Vulcan: Making the Electronic Protocol a Reality	Leveraging AI to Simplify SDTM Standards and Streamline Clinical Data Management
14:00 - 14:30	Protocol to Study Live in 15 Mins, AI, USDM and BCA in Action	Demonstration by Taxis Consultancy Services
14:30 - 15:00	Bringing the USDM Model to the Catwalk	How to Leverage Next Generation Tools Today to Improve Processing and Enhance Efficiency
15:00 - 15:30	Navigating Post-Go-Live Changes in Automated Clinical Study Management: The Impact of USDM / M11 for IDC and Beyond	TMF Technology Trends: Insights from TMF Data
15:30 - 16:00	AI for Standards Library Search	Exploring the Role of TMF Metrics and How to Use Them for Purpose Beyond Inspection Readiness?
16:00 - 17:30	Session 4A: CDISC 360i Location: Geneva, Floor -3	Requirements of the 2023 EPA CSV Tab of the CDISC TMF RM
16:00 - 16:30	Breaking Down Silos with CDISC 360i: A Technical Roadmap	Afternoon Break, International and Geneva Foyers, Floors -1 & -2
16:30 - 17:00	Enhanced Biomedical Concepts: A Different Perspective on Supporting CDISC 360i	Session 4B: Risk Based Approaches in Clinical Trials & Operations Location: Geneva, Floor -3
17:00 - 17:30	CDISC 360i, and the Worms that Turned	Session 4C: Academic Learning Opportunities Location: Geneva, Floor -3
18:00 - 22:00	Interchange Evening Networking Event, Upstage Geneva (Must Preregister to Attend)	Session 4D: Fundamentals of TMF Risk Based Approaches Location: Geneva, Floor -3
16:00 - 16:30	Unraveling the Complex Web of Data Relationships	What Does a Risk Based Approach to Ready Mean? Summary
16:30 - 17:00	Enhancing Clinical Data Quality Through Standardized Metrics for Non-GCP Data Collection	TMF as a Foundation for Success: Streamlining Operations and Reducing Delays in Study Start
17:00 - 17:30	Ensuring RECap Data integrity Sub-Team SDTMIG 4.0 Updates and Open Topics	TMF Risk Management: Implementing Risk Identification by the CDISC Risk Tool
17:30 - 18:00	Closing Remarks	The "3 Identifiers" of a TMF Reference Model
18:00 - 18:30	Panel Risk Based Approaches in Line with CH3/R3	TMF Completeness - A Major Component of Inspection Ready TMF



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”
-