CDISC GUF Webinar

20 Mai 2021

Merci pour votre participation

Conditions de ce Webinar

Votre son sera **éteint** tout au long du webinar

Ce webinar est enregistré

Questions?

Ecrivez les dans la section Q&A. Après chaque présentation, il y a aura un temps pour y répondre

Problèmes de sons?

Quittez et redémarrez l'application Zoom

Les slides de la presentation et l'enregistrement de ce webinar seront disponibles dans quelques jours

Ce webinar n'est pas une formation homologuée par le CDISC et n'a pas été developpée sous les CDISC Operating Procedures.

GUF CDISC

Groupe des Utilisateurs Francophones du CDISC

- Groupe LinkedIn
  https://www.linkedin.com/groups/2160071/
- Lien sur le site wiki du CDISC
  https://wiki.cdisc.org/display/FRUN
- Une section dans chaque CDISC Newsletter trimestrielle

GUF CDISC

Catherine	BOULARD	Ipsen	
Nicolas	de SAINT-JORRE	Quanticsoft	
Nicolas	DUFOUR	Bioprojet Pharma	
Karen	FANOUILLERE	SANOFI	Présidente
Umit	GULER	Théa Pharma	
Wafaa	JEBERT	Ichnos Sciences	Secrétaire
Pierre-Yves	LASTIC		Vice-président
Isabelle	LAUGEL	Life Sciences Expertise	
Julie	Le BOULICAUT	eXYSTAT	
Simon	LEBEAU	Danone Research	Vice-président
Jérémy	MAMBRINI	Airbus	
Yoani	MATSAKIS	Telemedicine Technologies S.A.S.	
Fabien	MAUGARD	AP-HP	
Khaled	MOSTAGUIR	Hôpitaux Universitaires de Genève	
Marc-Antoine	PRODHOMME	Janssen Pharmaceutical	
Jonathan	RICHES	SAS	
Nathalie	SABIN	OXMO CDM	
Michelle	VANDENBERGH	SGS - Life Sciences	Secrétaire

CDISC GUF Webinar

20 mai 2020

• CDISC European Interchange news	Nicolas De Saint Jorre
• Export SDTM depuis un outil EDC	Gilbert Bellachen & Pascale Youinou
• FDA Technical Guide and SDTM/IG Differences	Nick De Donder

Nicolas De Saint Jorre

Project Data Manager at XClinical GmbH / CEO@quanticsoft

CDISC Europe Interchange news

Du 28-04-2021 au 30-04-2021

Agenda du 28 au 29 Avril 2021

28-04-2021

Session 1: Opening Plenary

Session 2: Global Regulatory Updates, Part I

Session 3: CDISC Updates

Session 4A: ADaM
Session 4B: Real World Data
Session 4C: CDISC Foundational, Part I

29-04-2021

Session 5A: COVID-19 Topics
Session 5B: Tech-Enabled Standards

Session 6A: CDISC Foundational, Part II
Session 6B: Global Submissions

Product Demonstration: Covance by LabCorp

Session 7: CDISC 360 Update

Session 8: Closing Plenary - Regulatory Presentations, Part II

Agenda du 30 Avril 2021 TechniCon

TECHNICON

TechniCon Session 1

Jozef Aerts
XML4 Pharma
Director

Sunithra Aiyangar Vakkaramari Ramesh
Zifo RnD Solutions
Clinical Systems Analyst

Ed Chappell
Formedix Ltd
Solutions Consultant

Dave Iberson-Hurst
A3 Informatics
Partner

Dmitry Kolosov
Parexel
Statistical Programmer

Kirsten Langendorf
A3 Informatics
Head of Product Delivery

Johannes Ulander
S-Cubed
Principle Consultant

1:00 PM - 3:30 PM CEST

TECHNICON

TechniCon Session 2

Brian Carlsen
West Coast Informatics, Inc
Director of Clinical Informatics

Nathan Johnson
eClinical Solutions
Director of Data Engineering

Robert O'Connor
Agios Pharmaceuticals
Associate Director, Clinical Data Systems

3:30 PM - 5:00 PM CEST

Session 1

PLENARY

Session 1: Opening Plenary

Jesper Kjær
Danish Medicines Agency
Director of DKMA Data Analytics Centre

8:59 AM - 10:10 AM CEST

Présentation des multiples sources de données

Illustration via la revue de grandes études depuis les années 2000… jusqu'à 2014

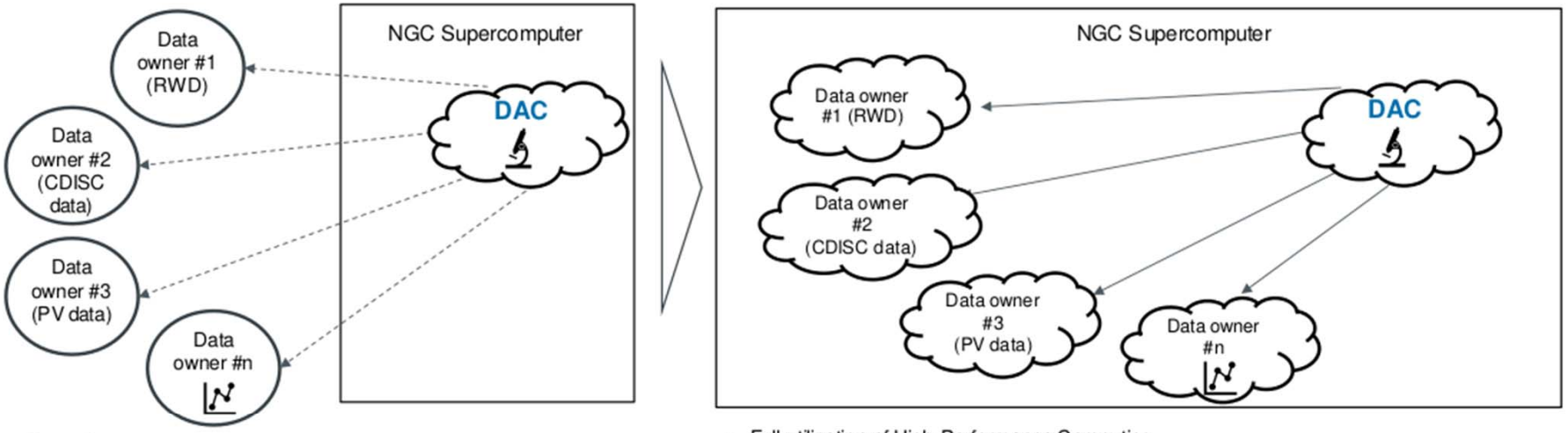
2014: Début de l'utilisation de CDISC

Grande différence entre les données dites "randomized controlled trials" (RCTs) versus "Healthcare data in Electronic Healt Records (EHRs)" mais également en dehors des EHRs

Session 1

How DAC will connect the data silos in Life Science

Connecting real world, industry patient level and other data sources on the National Genome Centre

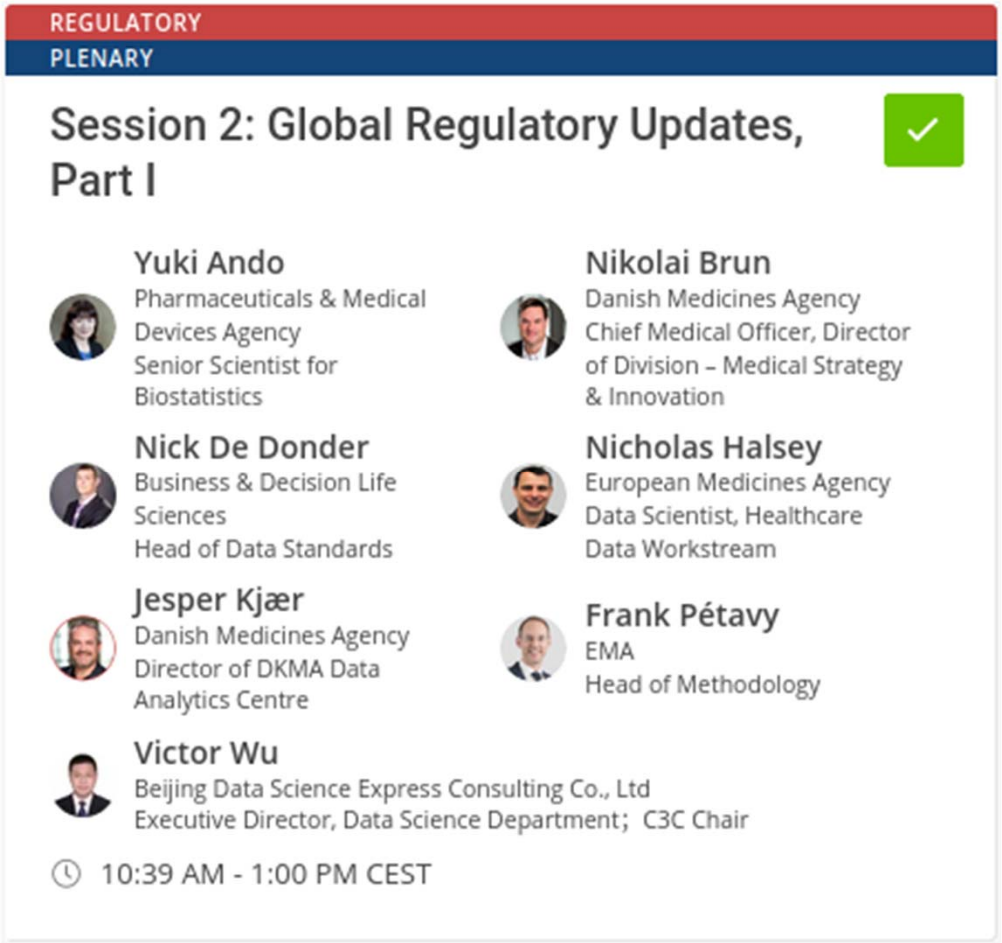


- Data silos
- High transaction costs
- Low level of cross-fertilization of data
- Not full utilization of High Performance Computing

- Full utilization of High Performance Computing
- Private cloud to cloud hosting
- Realtime data access in highly secure computer environment into analysis / data lake platform
- Full traceability of data use and reproducibility of analysis
- Ability to control access to fully anonymized data and permissioned access for researchers
- Allowing for future development such as automated additional data collection, real time AI/ML into data analysis

DAC DATA ANALYTICS CENTRE | LÆGEMIDDELSTYRELSEN DANISH MEDICINES AGENCY

Session 2: Global Regulatory Updates, Part I



PMDA Update par *Dr. Yuki Ando, PMDA*

HMA – EMA Joint Big Data Task Force: From Recommendation to Implementation par *Frank Pétavy, EMA*

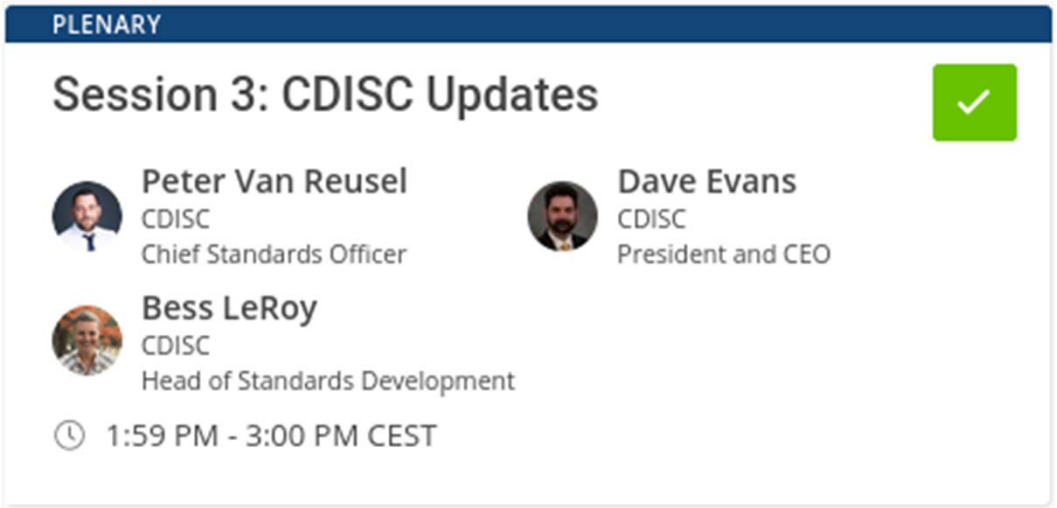
Roundtable Discussion: One Submission to Different Authorities - A Dream?

- Dr. Yuki Ando, PMDA
- Dr. Nikolai Constantin Brun, DKMA
- Nicholas Halsey, EMA
- Jesper Kjær, DKMA
- Frank Pétavy, EMA
- Victor Wu, CDISC China Coordinating Committee (C3C) Chair

Documents disponibles sur le site:

- HMA – EMA Joint Big Data Task Force: From Recommendation to Implementation
- Roundtable Discussion: One Submission to Different Authorities - A Dream?

Session 3: CDISC Updates



Session Chair: *Peter Van Reusel, CDISC CSO*

State of the CDISC Union par *David Evans, CDISC President & CEO*

State of CDISC Standards par *Bess LeRoy, CDISC Head of Standards Development*

Documents disponibles sur le site:

- *State of CDISC Standards*
- *State of the CDISC Union*

CDISC Update

Standards and TAUGs Published in the Last Year

Foundational Standards

- SENDIG v3.1.1
- SEND Conformance Rules v3.0
- SDTM Metadata Submission Guidelines v2.0
- Conformance Rules for Define-XML v2.1

Therapeutic Area User Guides

- Heart Failure Therapeutic Area User Guide v1.0
- Diabetes Type 1 Therapeutic Area User Guide v1.0 - Pediatrics and Devices Modules
- Psoriasis Therapeutic Area User Guide v1.0
- Acute Kidney Injury Therapeutic Area User Guide v1.0

Other Documents Published in the Last Year

COVID-19 Resources

- Interim Guide
- Ongoing Studies
- Resources for Public Health Researchers

Example Documents

- LOINC LB Mapping Spreadsheet

CDISC Update - ADaM QRS Supplements

Development of ADaM QRS Supplements

- First Questionnaire Supplement to the Analysis Data Model Implementation Guide - Geriatric Depression Scale Short Form (GDS SHORT FORM)

New QRS Supplements

	Short Name (--CAT)	SDTM Domain/ADaM Dataset	Permission	Version Release Date
Kurtzke Functional Systems Scores	KFSS	RS	Public Domain	Version: **2.0** **3 Apr 2021**
Abnormal Involuntary Movement Scale	AIMS	RS	Public Domain	Version: **2.0** **3 Apr 2021**
Eastern Cooperative Oncology Group Performance Status	ECOG	RS	Public Domain	Version: **2.0** **3 Apr 2021**
Karnofsky Performance Scale	KPS SCALE	RS	Public Domain	Version: **2.0** **3 Apr 2021**
Inflammatory Bowel Disease Questionnaire	IBDQ	QS	Granted	Version: **1.0** **3 Apr 2021**
Disability Rating Scale	DRS	RS	Public Domain	Version: **2.0** **3 Apr 2021**

https://www.cdisc.org/standards/foundational/qrs

FOLLOWS STANDARD DEVELOPMENT PROCESS OUTLINED IN COP-001

POSTED FOR 30-DAY PUBLIC REVIEW

PUBLISHED IN BATCHES MULTIPLE TIMES A YEAR

CDISC Update - Conformance Rules Operational Group

Conformance Rules Operational Group (CROG)

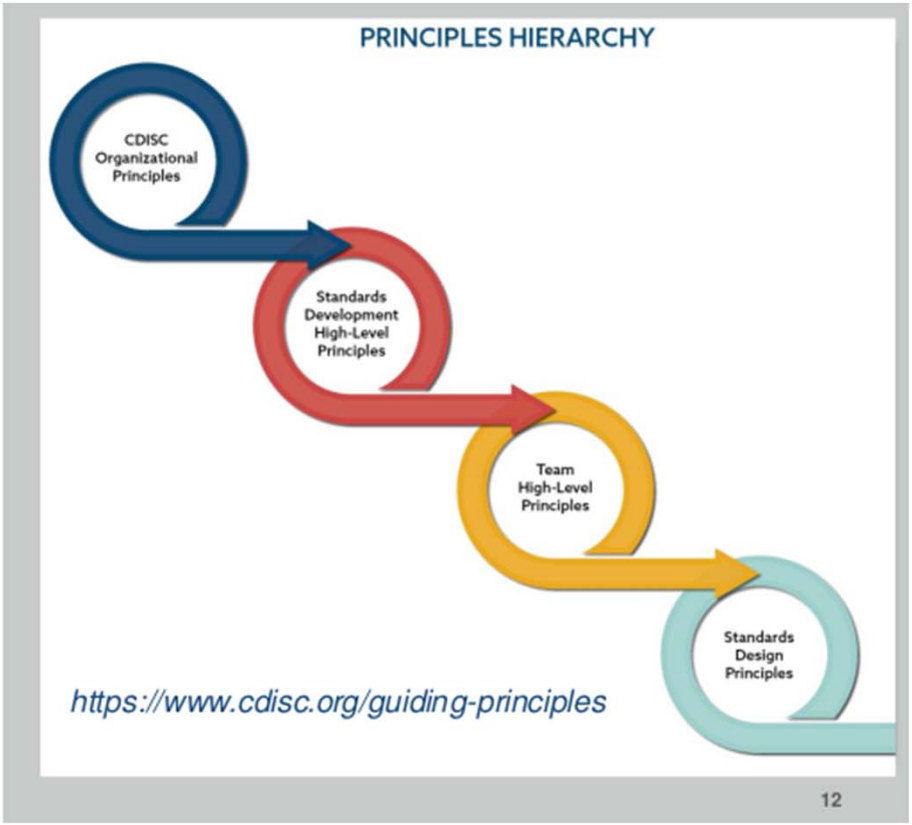
- Operational group representing all CDISC Foundational teams
- Harmonize as much as is reasonable
- Help define and support a clearly defined structure for management within the CDISC Library
- Boost knowledge and expertise across teams that develop rules

Development of Rules Catalog for Each Standard

- The published rules catalog is cumulative (e.g., SDTMIG v3.3, SDTMIG v3.4)
- When the current catalog is published, the previous catalog will be archived but accessible from the CDISC website for that standard
- Teams may also publish a supplemental “read me” document with additional information about rules (e.g., development approach)

CDISC Update - Guiding Principles

CDISC Guiding Principles



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CDISC Update - CDISC Primer

CDISC Primer

- Content to introduce new users to CDISC

- Topics covered:
  - How to get started with CDISC
  - Links among CDISC standards
  - Traceability

https://www.cdisc.org/primer

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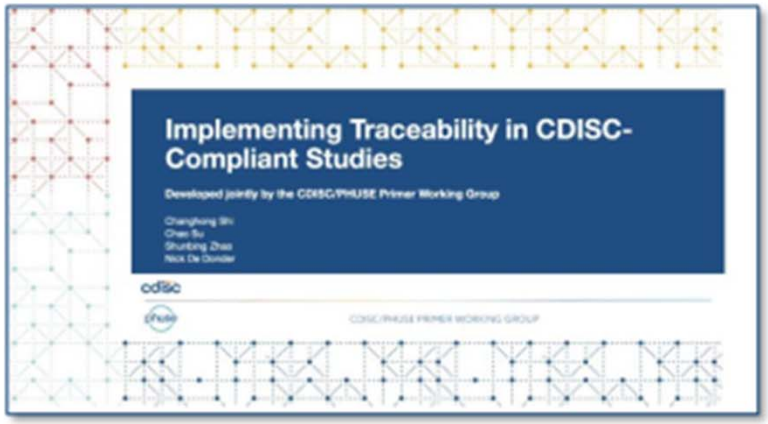
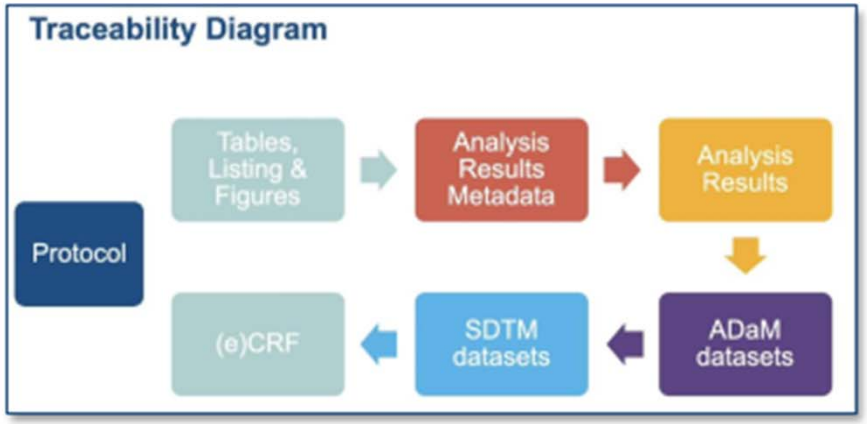
CDISC Update - Traceability

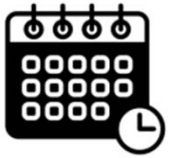
Traceability





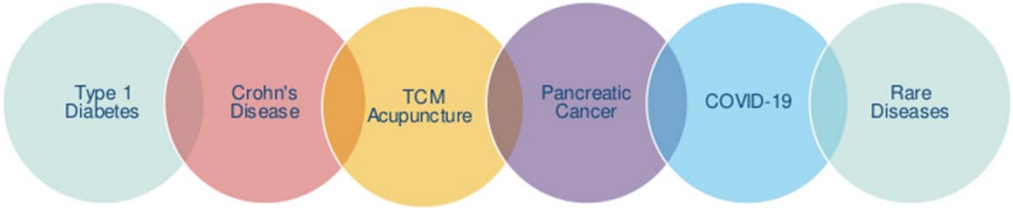
CDISC “What Are We Working On Now?”

Updated Standards Release Schedule



- Moving away from the former November release schedule
- Informative content and Normative Standards released once completed COP-001
  - Normative content is released with conformance rules
  - Relevant CDISC Library content released at time of publication
- CT and QRS released quarterly
- To provide predictability and transparency, a specific foundational standard will be released no more than once every other year, with a preferred cadence of 3-5 years

Therapeutic Area User Guides Currently In Development



https://www.cdisc.org/standards/in-development

CDISC “What Are We Working On Now?”

FHIR to CDISC Mapping

- Fast Healthcare Interoperability Resources (FHIR) is a new standard published by HL7 for exchanging healthcare information electronically
- Goal of mapping is to achieve greater interoperability and exchange of data from Electronic Health Records (EHRs) **to** clinical research submission-ready datasets
- Scope: Adverse Events, Adverse Events, Medications, Concomitant Medications, Demographics, Medical History, Procedures, Vital Signs, Laboratory Test Results
- Mappings jointly balloted by CDISC and HL7 using their respective governance processes

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2021 Anticipated Foundational Standards Publications

- ADaM OCCDS v1.1 and Conformance Rules
- ADaM Traceability Examples
- ADaMIG Medical Devices v1.0 and Conformance Rules
- ADaMIG Non-compartmental Analysis v1.0 and Conformance Rules
- ADaMIG v1.3 and Conformance Rules

- CDASH v1.2
- CDASHIG v2.2
- SDTM v2.0
- SDTMIG v3.4
- SEND Conformance Rules v4.0

CDISC “What Are We Working On Now?”

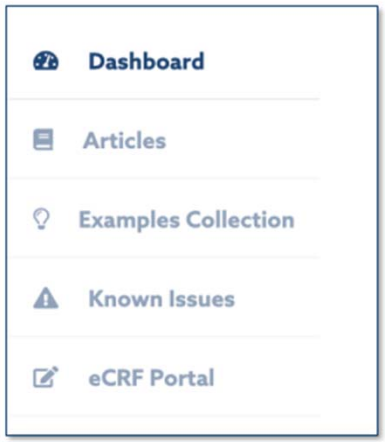
SDTMIG-PGx v1.0 Deprecation

- CDISC will be deprecating SDTMIG-PGx v1.0 and much of its content will be subsumed into the upcoming release of SDTMIG v3.4
- Certain domains will be deprecated and others will be incorporated into SDTMIG v3.4
  - The provisional PF domain will be deprecated and superseded by the GF domain
  - The BE, BS, and RELSPEC domains will be incorporated into the SDTMIGv3.4 as is and may be updated in a future version of the SDTMIG
  - The provisional PG, PB, SB domains will be deprecated. Re-instantiation of this content may be considered in the future if valid use cases are presented to CDISC
- Why is this change being made?
  - Domains are applicable to other SDTMIG laboratory domains (LB, MB, MS, MI, etc.)

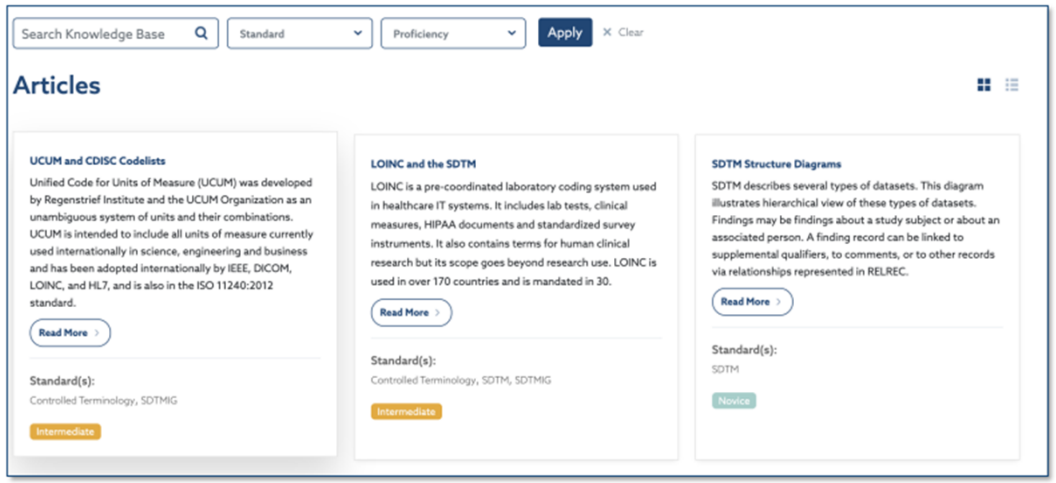
Pharmacogenomics/Genetics

CDISC - Knowledge Base

CDISC Knowledge Base



- An open, assessible, searchable and user-friendly interface on the CDISC Website to host new and existing website content for CDISC implementers
- Contains articles, known issues, eCRF portal, and examples collection



CDISC - CDASH eCRF Portal

CDASH eCRF Portal

- The eCRF Portal adds functionality to the CDASH model.
  - Visual representation of CRF layout with CDASH annotations
  - Machine-readable ODM format
- Will include:
  - CRFs from the CDASH Implementation Guide
  - CRFs from Questionnaires, Ratings and Scales (QRS instruments)
  - CRFs from Therapeutic Area User Guides
- Formedix offered the CDISC community MDR use at no cost to help deliver the eCRF Portal.

CDASH eCRF Portal – Project Status

- 22 eCRF Packages posted on the CDISC website - publicly available
- New CRFs to be added incrementally

ADaM - Améliorations

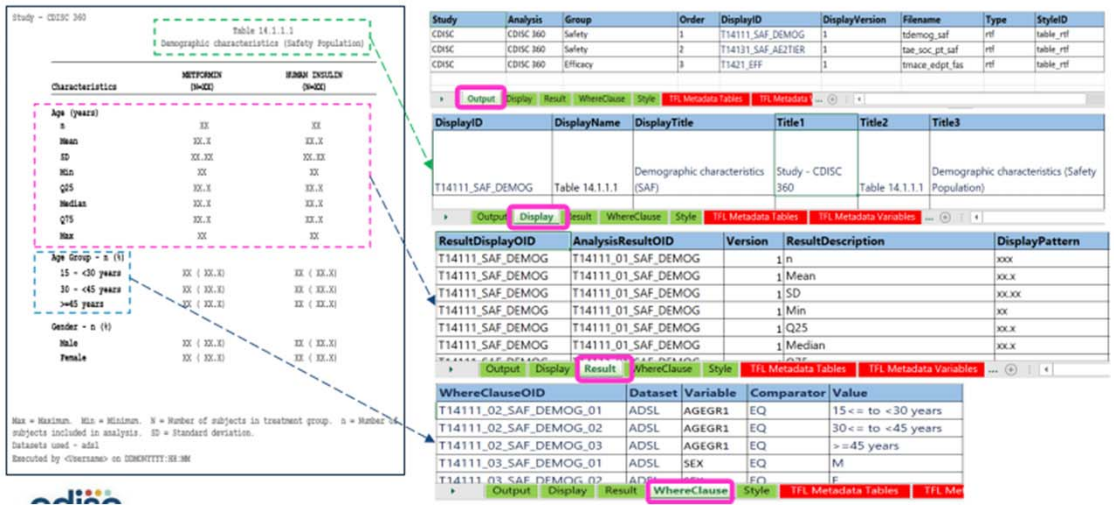
Enhancing ADaM standards

Add features that support automation of analysis results by extending Analysis Results Metadata (ARM) for Define-XML

Create a standardized structure for analysis results to support reuse and dynamic data display generation

Decrease implementation variability by tightening the standardization of ADaM metadata for generally accepted analyses

Extending Analysis Results Metadata (ARM) for Define-XML



Safety User Guide - Suite du projet CDISC 360

Safety User Guide Purpose

- Safety User Guide is aiming to align collection, tabulation, analysis and display of the most common safety data collected in research

- The Safety User Guide will compile information needed from collection, tabulation through analysis for commonly performed safety analyses to reduce variability across implementations

Les Biomedical Concepts - A venir et Avenir?...

Biomedical Concepts: What's Next?

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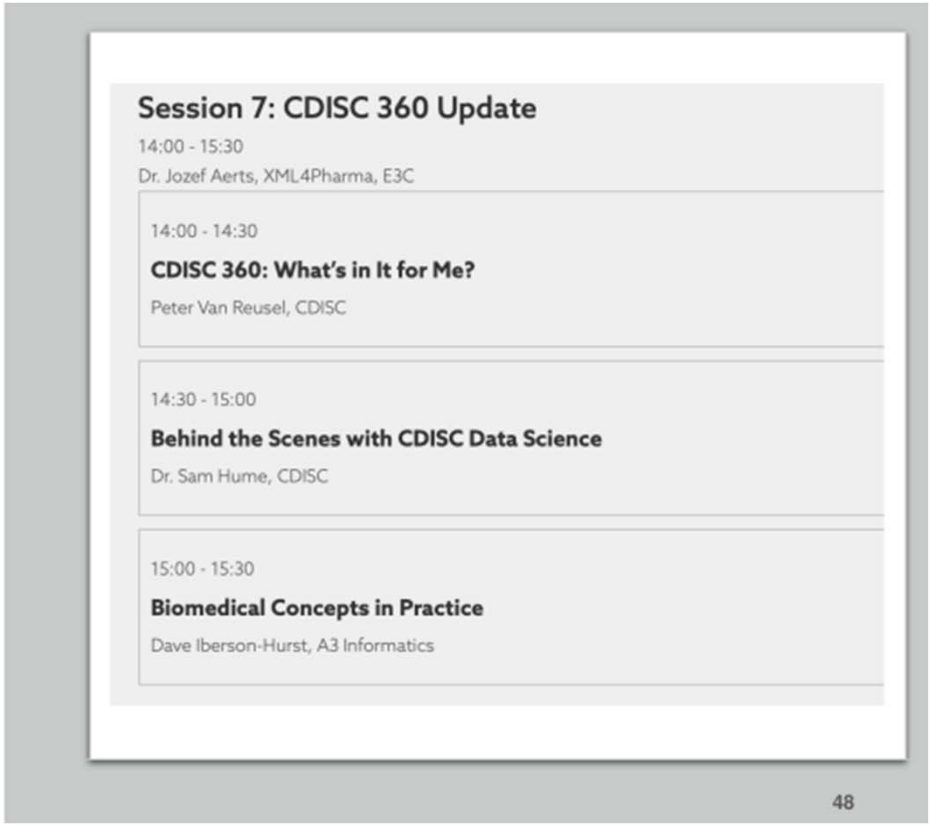


Non-standard Variable (NSV) Registry

Purpose and Goals

- NSVs and Supplemental Qualifiers appear in Therapeutic Area User Guides and Implementation Guides but are not always used consistently
- Ensure the development teams use the NSVs consistently
- Help identify NSVs for promotion to the model/IG
- Allow CDISC users to access the NSV information so they can use them within their organizations

Fragment Database

Search

FRAGMENT KEYWORD

6 Character Fragment:

5 Character Fragment:

4 Character Fragment:

3 Character Fragment:

2 Character Fragment:

1 Character Fragment:

Filter Reset

Fragment Database Results

Status	Fragment Keyword	6 Character Fragment	5 Character Fragment	4 Character Fragment	3 Character Fragment	2 Character Fragment	1 Character Fragment
APPROVED	ACTION	ACTION	ACTON	ACTN	ACN	AC	A
APPROVED	ADJUSTMENT	ADJUST	ADJST	ADJT	ADJ	AJ	A
APPROVED	ANCHOR	ANCHOR	ANCHR	ANCR	ANR	AN	A
APPROVED	ASSAY		ASSAY	ASAY	ASY	AS	A
APPROVED	BASELINE	BASLNE	BASLN	BSLN	BLN	BL	B
IN-REVIEW	BIRTH		BIRTH	BRTH	BTH	BT	B
IN-REVIEW	BODY			BODY	BOD	BD	B
APPROVED	CANCER	CANCER	CANCR	CANC	CAN	CA	C
APPROVED	CATEGORY	CATGRY	CATGY	CATG	CAT	CT	C
APPROVED	CHARACTER	CHARCT	CHARC	CHAR	CHR	CR	C
IN-REVIEW	CLASS		CLASS	CLAS	CLS	CS	C
APPROVED	CLINICAL	CLINCL	CLINC	CLIN	CLN	CL	C
APPROVED	CODE			CODE	COD	CD	C
APPROVED	COMMENT	COMMNT	COMNT	COMT	COM	CO	C
IN-REVIEW	CONCOMITANT				CON	CM	C
APPROVED	CONDITION	CONDTN	CNDTN	COND	CND	CN	C
IN-REVIEW	CONGENITAL			CONG			
APPROVED	COUNTRY	CONTRY	CNTRY	CTRY	CNR	CR	C
APPROVED	CRITERIA	CRITRA	CRITR	CRIT	CRT	CR	C
IN-REVIEW	DAY				DAY	DY	
IN-REVIEW	DEATH				DTH		
IN-REVIEW	DECODE		DECOD				
IN-REVIEW	DERIVED				DRV		
IN-REVIEW	DESCRIPTION			DESC			
APPROVED	DETAILS	DETAIL	DETAL	DETL	DTL	DE	D
IN-REVIEW	DISABILITY		DISAB				
IN-REVIEW	DOSAGE			DOSE	DOS		

CDISC Certification!

Session 4 - A, B et C...

FUNDAMENTALS

Session 4A: ADaM

Jesse Anderson, MPH
FDA-CDER
Project Management Officer

Niels Both
S-cubed ApS
CDISC Standards Specialist

Bess LeRoy
CDISC
Head of Standards Development

Anna Bladström
S-Cubed
Principal Consultant

Silvia Faini
Cytel
Principal Statistical Programmer

Angelo Tinazzi
Cytel, Inc.
Senior Director, Standards, Systems, CDISC Consulting, Statistical Programming

3:29 PM - 5:30 PM CEST

REAL WORLD DATA

Session 4B: Real World Data

Sonia Araujo
IQVIA
Director, Product Management

Rhonda Facile
CDISC
Vice President, Partnerships and Development

Jon Neville
CDISC
Senior Standards Developer

Akshay Deverakonda
NIH
Data Visualization Analyst

Kit Howard
CDISC
Sr Dir, Education & Standards Development

Stijn Rogiers
SAS
Principal Industry Consultant

3:29 PM - 5:00 PM CEST

FUNDAMENTALS

Session 4C: CDISC Foundational, Part I

Malathi Hari
LEO Pharma A/S
Senior Professional Statistical Programming 1

Amy Palmer
CDISC
Head of Standards Development

Audrey Walker
Charles River Laboratories
Director, SEND

Lou Ann Kramer
CDISC
Sr Director, Standards Development

Alana St. Clair, MBA
CDISC
Project Manager

3:29 PM - 5:00 PM CEST

Session 5 A et B

Session 5B

Implementation of an MDR par *Andrea Rauch, Bhatia Mayank (TCS), Charusheela Thakur (TCS), Boehringer Ingelheim Pharma GmbH & Co. KG*

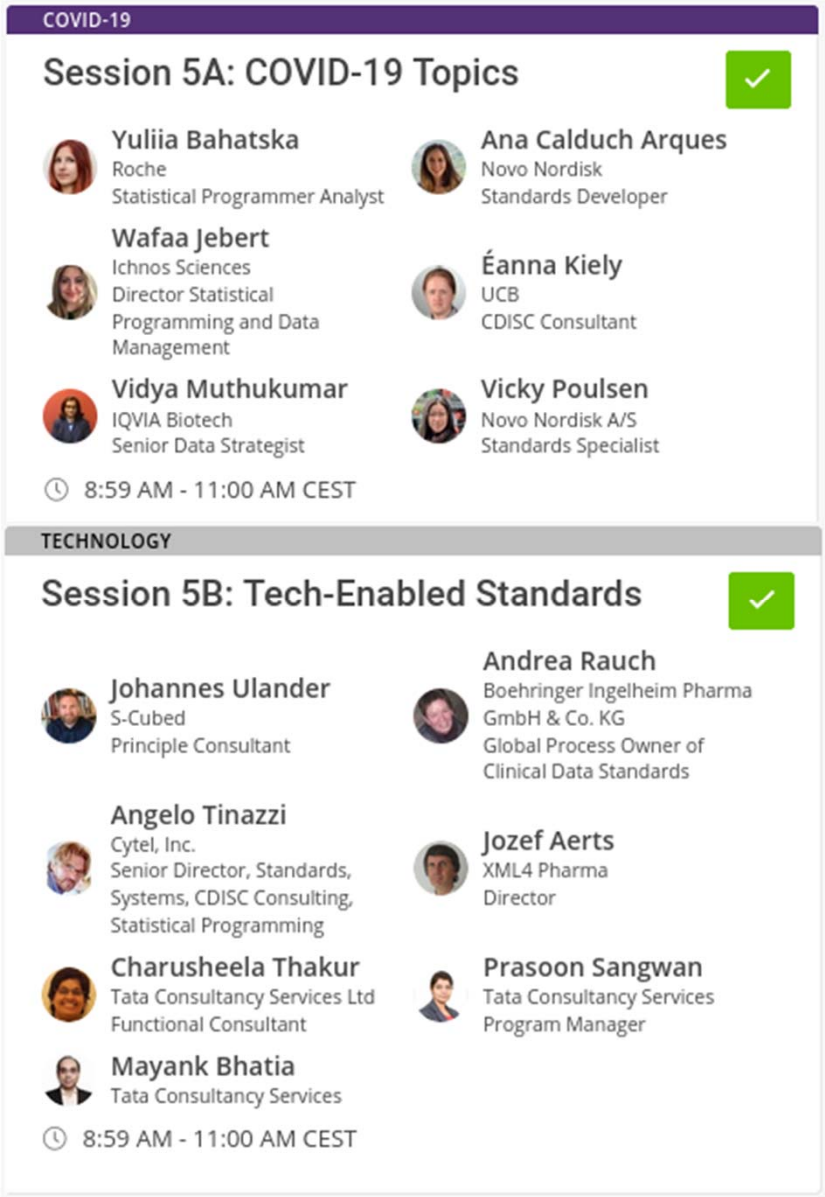
Accelerating SDTM Generation with AI/ML par *Prasoon Sangwan and Mayank Bhatia, Tata Consultancy Services*

Yes, You Can Access the CDISC Library from SAS par *Angelo Tinazzi, Cytel Inc*

Automated Generation of CDISC Biomedical Concepts Starting from Healthcare Terminologies par *Dr. Jozef Aerts, XML4Pharma*

Documents disponibles pour la Session 5B:

- Implementation of an MDR
- Accelerating SDTM Generation with AI/ML
- Yes, You Can Access the CDISC Library from SAS
- Automated Generation of CDISC Biomedical Concepts Starting from Healthcare Terminologies



Session 6A et 6B

FUNDAMENTALS

Session 6A: CDISC Foundational, Part II

Silvia Faini
Cytel
Principal Statistical Programmer

Yugo Miki
ClinChoice K.K.
Associate manager

Erin Muhlbradt
NCI-EVS
Clinical/Biomedical Information Specialist and CDISC Terminology Program Lead

Vicky Poulsen
Novo Nordisk A/S
Standards Specialist

Ward Puttemans
UCB
Clinical Data Standards Manager

11:29 AM - 1:00 PM CEST

REGULATORY

Session 6B: Global Submissions

Jasmine Kestemont
Innovion BVBA
Consultant

Éanna Kiely
UCB
CDISC Consultant

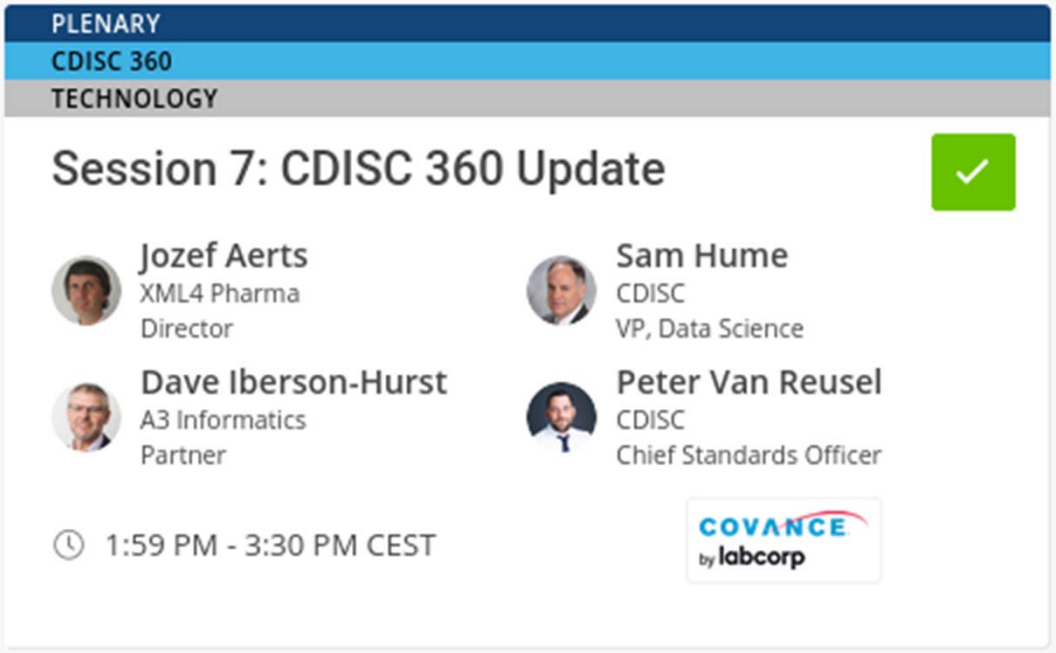
Simon Lundberg
Astrazeneca
Director, Statistical Programming

Daniil Teplitskii
UCB
Clinical Data Standards Manager

Victor Wu
Beijing Data Science Express Consulting Co., Ltd
Executive Director, Data Science Department; C3C Chair

11:29 AM - 1:00 PM CEST

Session 7 - CDISC 360 Suite



CDISC 360: What's in It for Me? par *Peter Van Reusel, CDISC*

Behind the Scenes with CDISC Data Science par *Dr. Sam Hume, CDISC*

Biomedical Concepts in Practice par *Dave Iberson-Hurst, A3 Informatics*

Documents disponibles pour la Session 7:

- CDISC 360: What's in It for Me?
- Behind the Scenes with CDISC Data Science
- Biomedical Concepts in Practice

Les 4 piliers de l'implémentation du projet CDISC 360

Implementing 360: Projects

STANDARDS DEVELOPMENT

1. Complete E2E Foundational Standards

- **Project:** eCRF Portal
- **Project:** Analysis Results Standard
- **Project:** Safety User Guide

2. Enrich Foundational Standards

- **Project:** Mining Define.xml's

STANDARDS DELIVERY

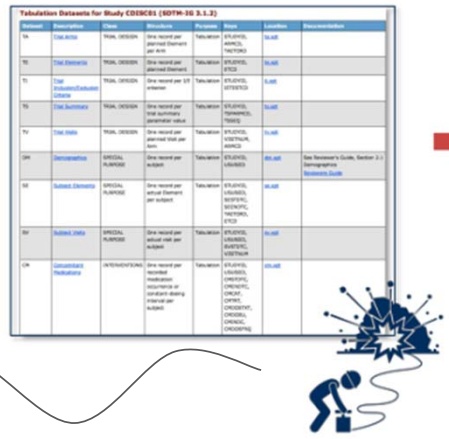
3. Extend CDISC Library Model

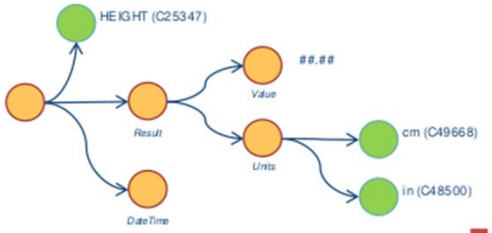
- **Project:** Model concepts
- **Project:** Add QRS content

4. Collaborate with Industry

- **Project:** Use mining Define.xml project as prototype for collaborative curation process

Load Concepts into CDISC Library





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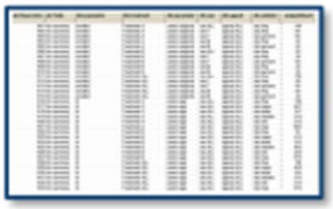
Biomedical Concept Layer

Biomedical Concept Layer

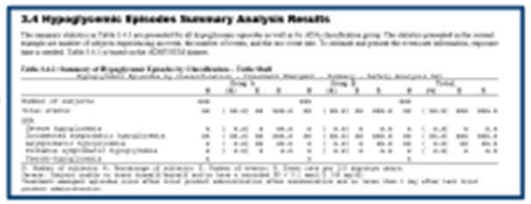
Presentation Layer

Data Collection

Data Aggregation



Analysis



Analysis Results

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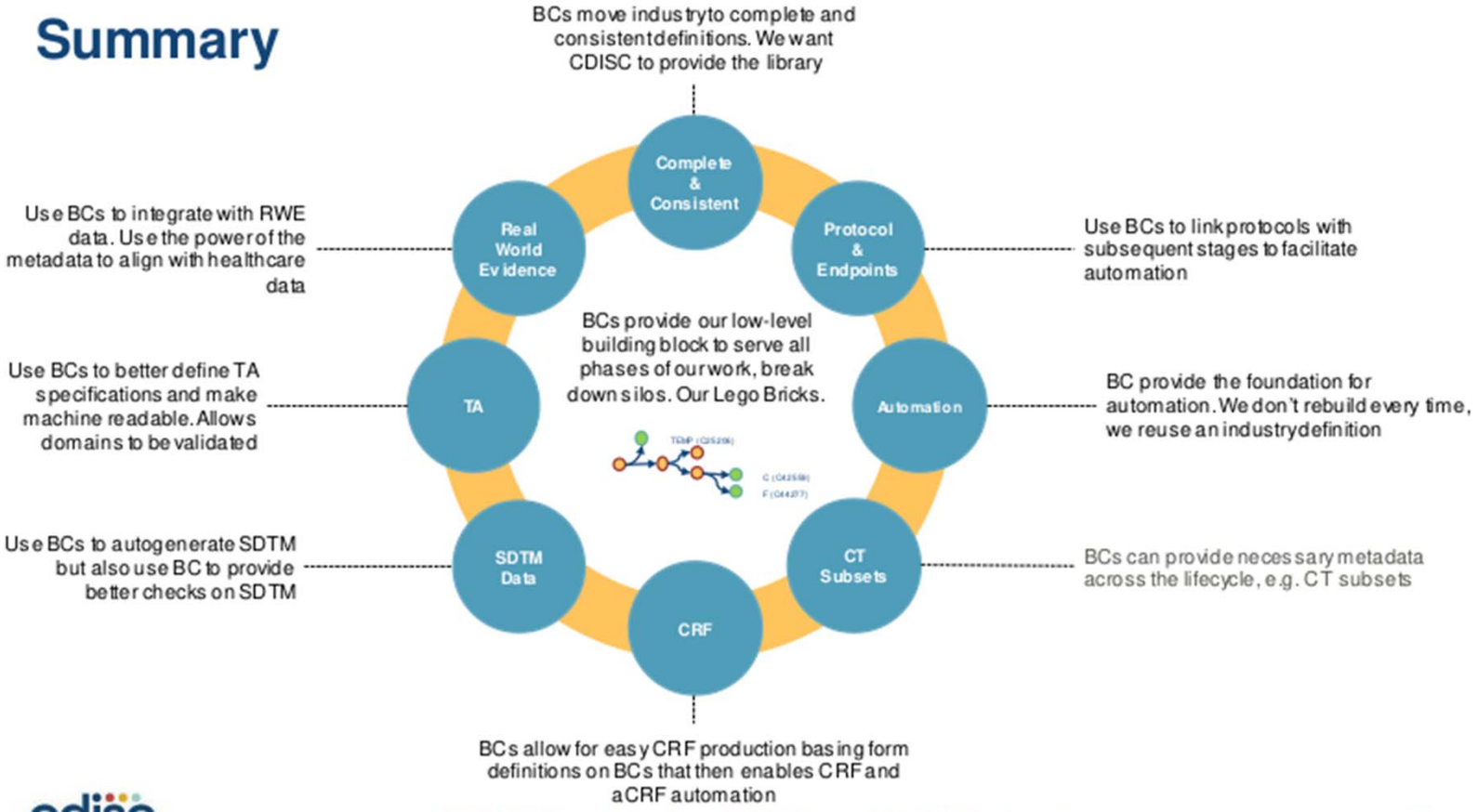
Data State

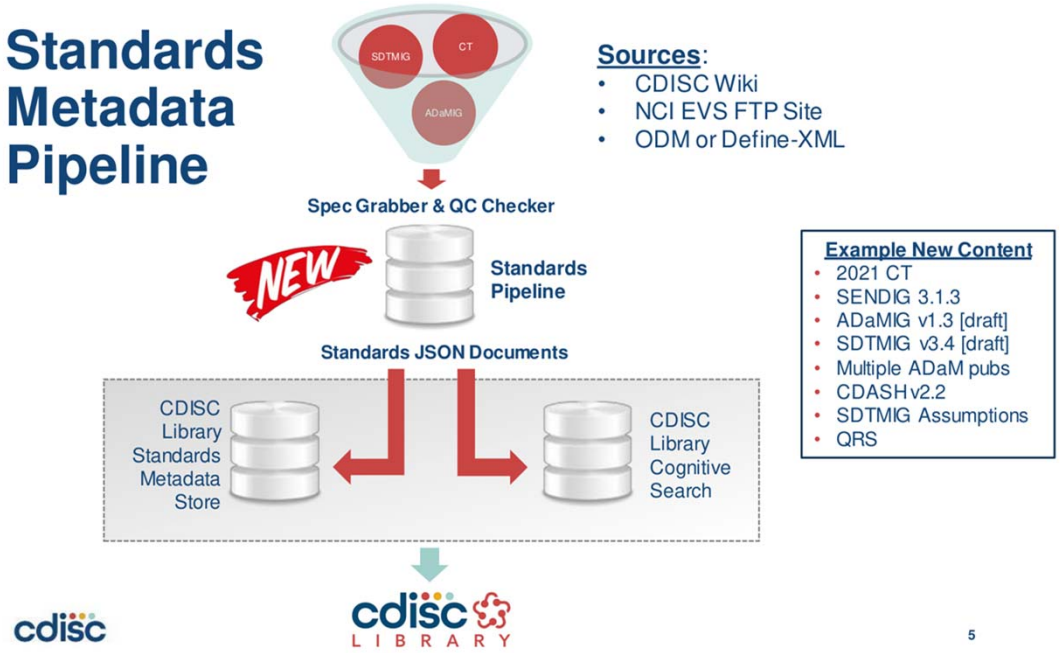
Data Flow

Puis: Présentation des Biomedical Concepts



Sam Hume et ses bonnes nouvelles!!

Nouvelle version de la Library



Sources:
- CDISC Wiki
- NCI EVS FTP Site
- ODM or Define-XML

Example New Content
- 2021 CT
- SENDIG 3.1.3
- ADaMIG v1.3 [draft]
- SDTMIG v3.4 [draft]
- Multiple ADaM pubs
- CDASH v2.2
- SDTMIG Assumptions
- QRS

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Comparaison de version entre 2 modèles!!!

Diff to Compare Standards Versions

Diff example output comparing SDTMIG v3.3 against v3.2 for the VS domain

Action	Impact	Change Level	Class	Dataset Name	Variable Name	Attribute (updated)	Attribute (previous)
Value Update	Core	Major	Findings	VS	VSBLFL	Perm	Exp
Value Update	CDISC Notes	Minor	Findings	VS	VSPOS	Position of the subject during a measurement or examination. Examples: "SUPINE", "STANDING", "SITTING".	Position of the subject during a measurement or examination. Examples: SUPINE, STANDING, SITTING.
Add	Variable	Major	Findings	VS	EPOCH	EPOCH	
Add	Variable	Major	Findings	VS	TAETORD	TAETORD	
Add	Variable	Major	Findings	VS	VSLOBXFL	VSLOBXFL	

Feature highlights:
- Describes values add/update/delete, with before & after side-by-side
- Works with any standard
- Works with both successive and skipped versions
- JSON media type & Excel export.
- Color coded

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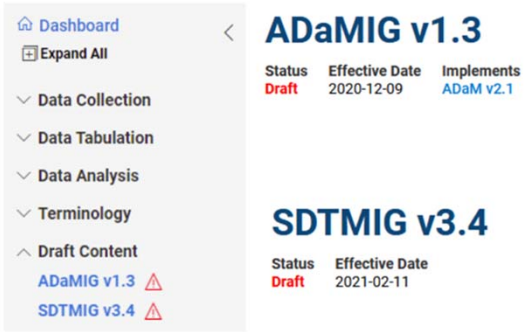
Encore et encore!!!

Draft Content for Preview

Data Standards Browser



API

- `/mdr/products/DraftContent`
- `/mdr/sdtmig/3-4`
- `/mdr/adam/adamig-1-3`

New Library Content: Coming Soon…

- Questionnaires, Ratings & Scales (QRS)
- ODM media type
- Implementation Guide Assumptions
- Conformance Rules
- Initial CDISC 360 Content (draft)
- Quarterly CT packages
- New Foundational Standards ersions

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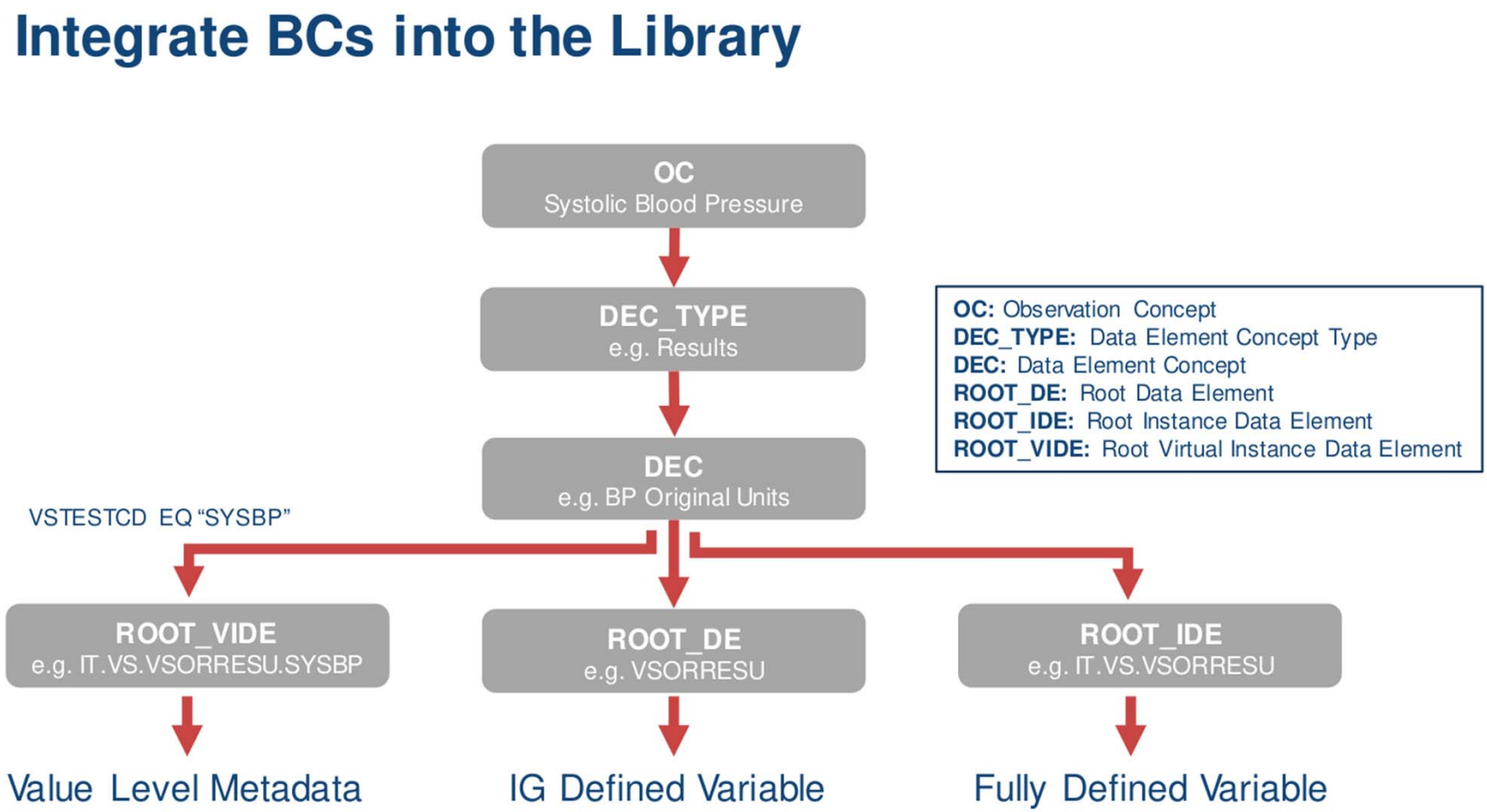
CDISC 360 et la Library...



Mise à jour de l'ODM 2.0

Examples of Use Cases Targeted by ODM v2.0

Study Setup	Integration	Data Exchange	End-to-end Standards
• Study Design Model	• Enhanced semantic representation	• JSON support	• Enhanced MethodDef
• Flexible metadata representations beyond CRFs	• Improved HL7 FHIR support	• REST API	• Biomedical Concept representation
• Matrix forms	• Data Queries	• Updated Dataset-XML / JSON	• Traceability enhancements with Trace-XML

COSA pour Open Source Alliance!!

CDISC Open Source Alliance (COSA)

Mission: The CDISC Open Source Alliance supports, promotes, and sometimes sponsors open source and free software development projects that create tools for implementing or developing CDISC standards to drive innovation in the CDISC community.

- Provide a directory for open source projects
- Conference sessions & webinars
- Hackathons & workshops
- Sandbox environment & test data
- Community building
- Information exchange
- Open-source best practices
- Licensing guidance

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Email cosa@cdisc.org for more information

Session 8

Session Chair: *Nick De Donder, Business & Decision Life Sciences, E3C Co-Chair*

New Drug Therapy Approval Success During Challenging Times par *Dr. Mary Thanh Hai, Deputy Director, Office of New Drugs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration*

Closing Keynote Presentation: Facilitating the Development of COVID-19 Vaccines par *Dr. Peter Marks, Director, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration*

Documents disponibles:

- FDA-CDER Presentation
- Closing Keynote Presentation: Facilitating the Development of COVID-19 Vaccines

30-04-2021 - TechniCon Session 1

Qurie – Our own SDTM Bot par *Sunithra Aiyangar Vakkaramari Ramesh, Zifo RnD Solutions*

System Automation for CDISC Standards: SDTM-ETL par *Dr. Jozef Aerts, XML4Pharma*

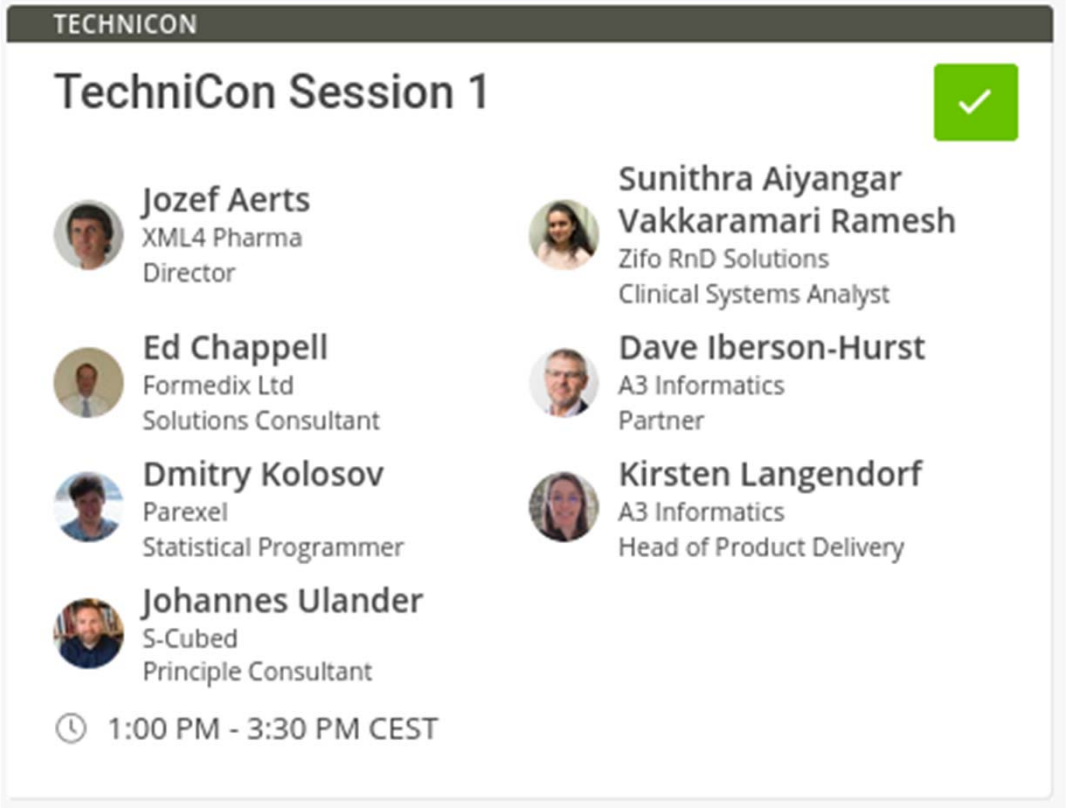
System Automation for CDISC Standards: A3 MDR par *Dave Iberson-Hurst, Kirsten Langendorf, and Johannes Ulander, A3 Informatics*

How to Comply with CDISC Standards in Clinical Trial Design and Build par *Ed Chappell, Formedix*

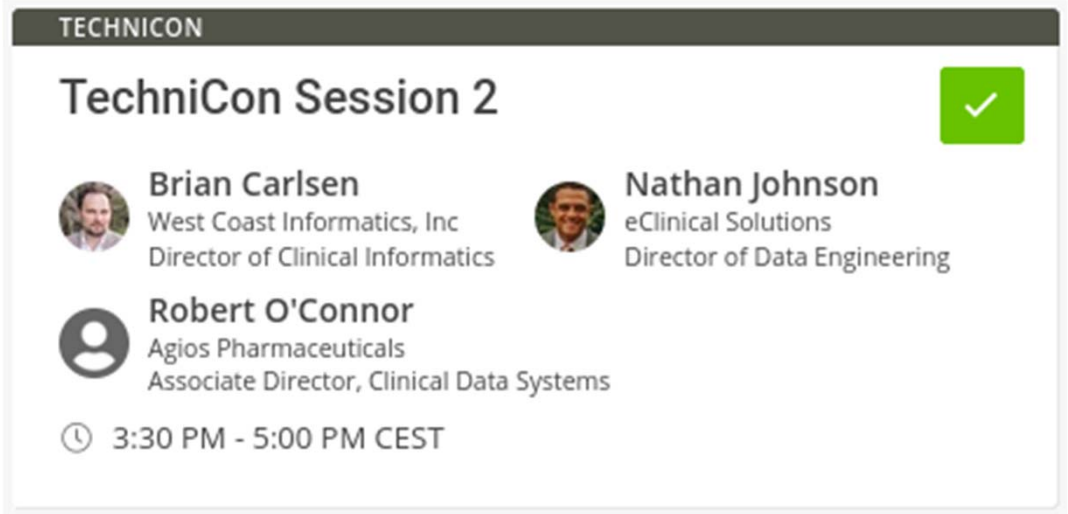
Mobile CDISC Library Browser par *Dmitry Kolosov, PAREXEL*

Documents disponibles:

- *Qurie – Our own SDTM Bot*
- *System Automation for CDISC Standards: SDTM-ETL*
- *System Automation for CDISC Standards: A3 MDR*
- *How to Comply with CDISC Standards in Clinical Trial Design and Build*
- *CDISC Library Browser*



30-04-2021 - TechniCon Session 2

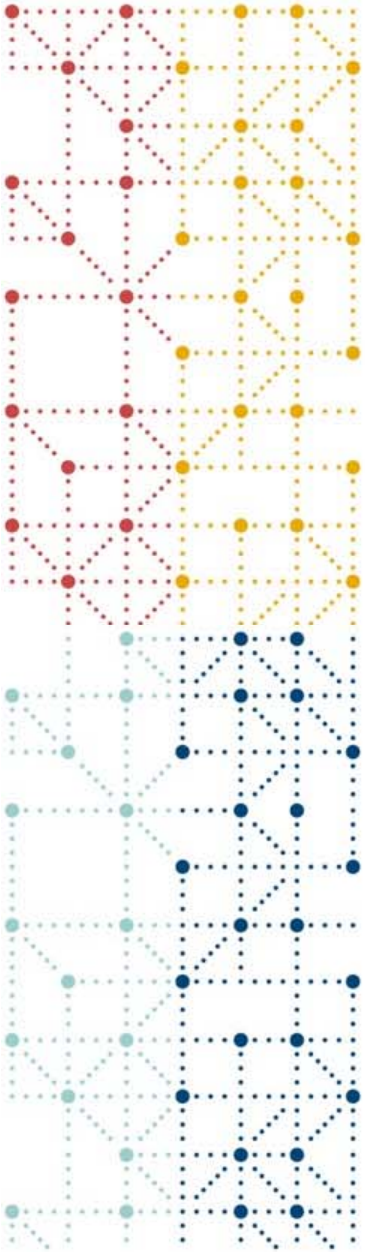


System Automation for CDISC Standards: elluminate® **par** *Nathan Johnson, eClinical Solutions; and Bob O'Connor, Agios Pharmaceuticals*

National Cancer Institute Enterprise Vocabulary Services (EVS) REST API par *Brian Carlsen, National Cancer Institute EVS*

Document disponible:

- National Cancer Institute Enterprise Vocabulary Services (EVS) REST API



Thank You!

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Gilbert Bellachen
Director Business Development - Anju Software

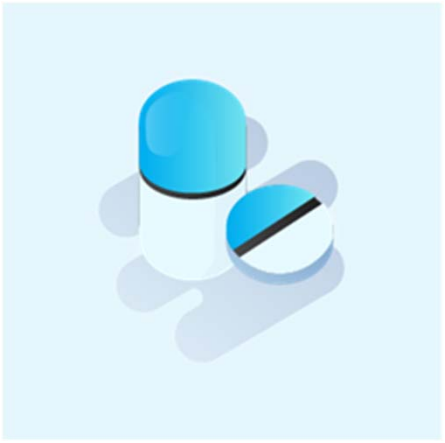
Pascale Youinou
Project Manager Biometrics - Business and Decision Life Sciences

YOUR Platform | YOUR Way

Anju Sotfware

Anju Adaptive Life Sciences Platform

Anju Clinical Suite



Anju Medical Affairs Suite

Anju Data Suite

YOUR Platform | YOUR Way

The eClinical Product Suite

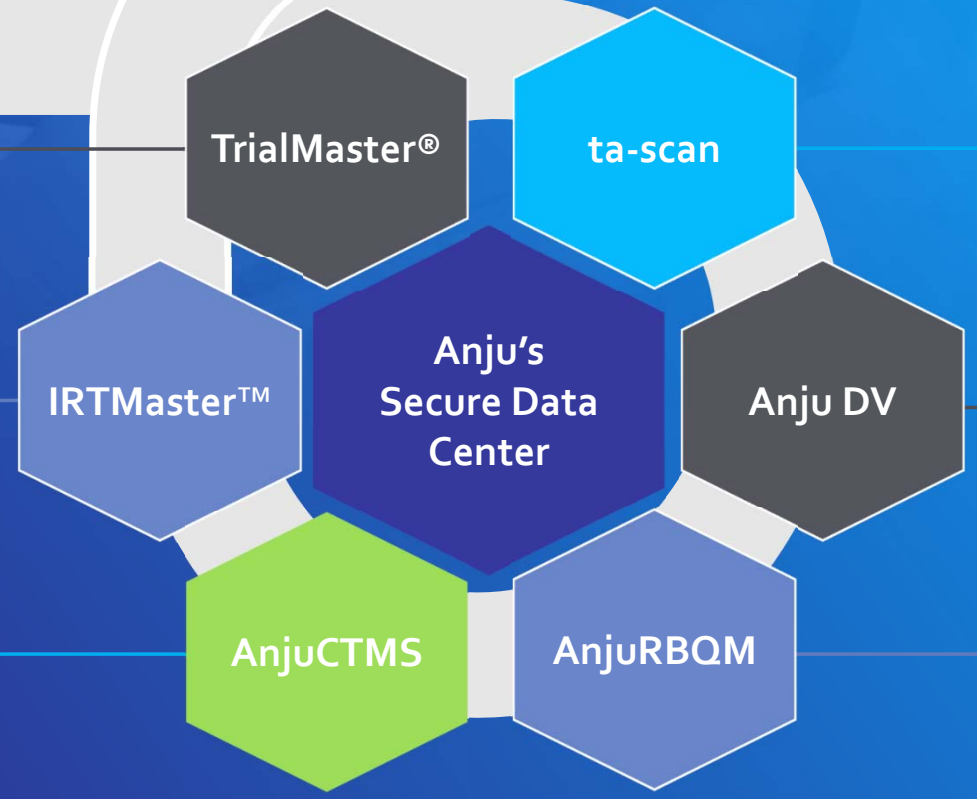
INNOVATION | QUALITY | PRODUCTIVITY | SCALABILITY

Expanding the borders of clinical data

- EDC with built-in ePRO
- Direct SDTM export, reporting tools
- Dynamic Monitoring
- Autoencoder data dictionaries

- Randomization and supplies management
- Support for adaptive trials
- Study build through UI

- Document tracking with eTMF,
- Event tracking SVR toolkit,
- Finance module, inventory tracking, protocol deviations, issues, SAEs



- Market Intelligence
- KOL identification
- Feasibility reports
- Payment information

- Data analytics & visualizations
- Study risk management and monitoring
- Cross-study reporting

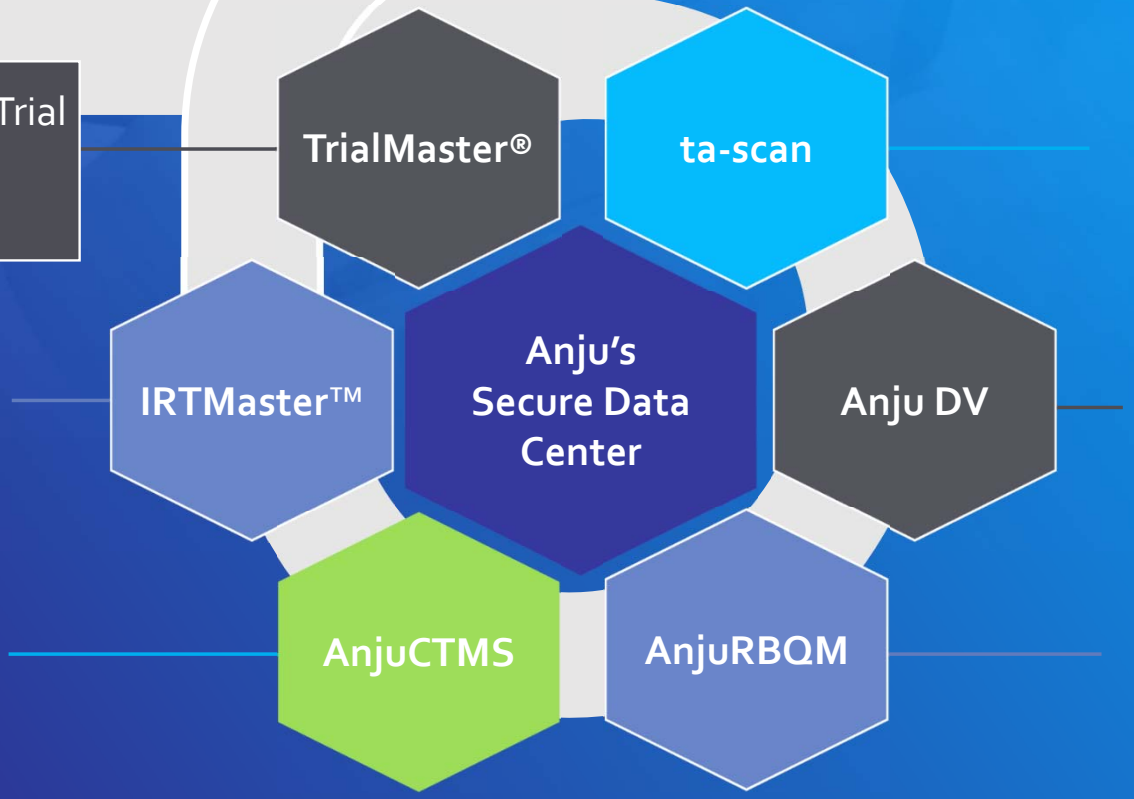
- Closed loop risk management
- Study risk management and monitoring
- Integrated reports and insights

The eClinical Product Suite

INNOVATION | QUALITY | PRODUCTIVITY | SCALABILITY

Expanding the borders of clinical data

- Direct SDTM export from Trial Master
- Reporting tools



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Business & Decision
Life Sciences

SDTM Automation in EDC system

20 May 2021

AGENDA

- Case Introduction
- Programming of SDTM data within EDC system - Benefits
- Programming of SDTM data within EDC system - Challenges
- Conclusion

#Data #DataDriven
#DataStrategy #DataIntegration
#DataViz #DataStandards
#DataScience #Datagovernance
#HealthCare #DataAnalysis
#ClinicalTrials
#ArtificialIntelligence
#AdvancedAnalytics
#MachineLearning #Digital
#Chatbot #Biometrics #CRO
#ClinicalData
#LifeSciencesExperts
#Whodrug #MedDRA
#Pharmacovigilance
#ClinicalResearchLifeCycle
#MedicalWriting
#MedicalInformation
#MedicalReview #SDTM
#ADaM #CDISC #Innovation
#RegulatorySubmissions
#Protocol #Coding

Business & Decision
Life Sciences

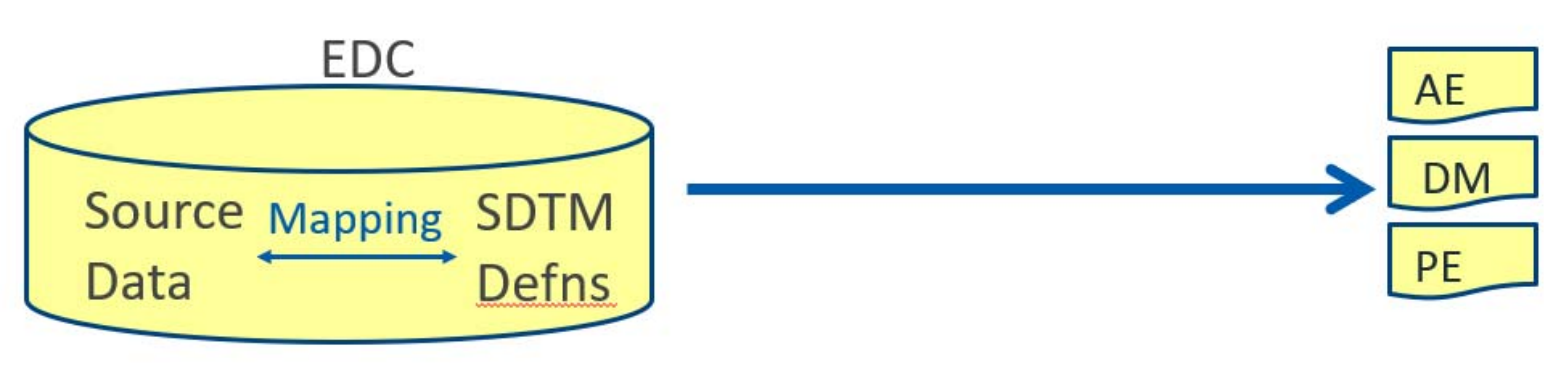
CASE INTRODUCTION

- Biometrics Study → from database build to statistical analysis
- SDTM data required for:
  - Data Monitoring - Visualization dashboards
  - SDTM Data available as quick as possible for different DSMB, SRC, and all other meetings
  - SDTM data available as quick as possible for statistical team for statistical analysis

SDTM build module available in Anju TrialMaster EDC

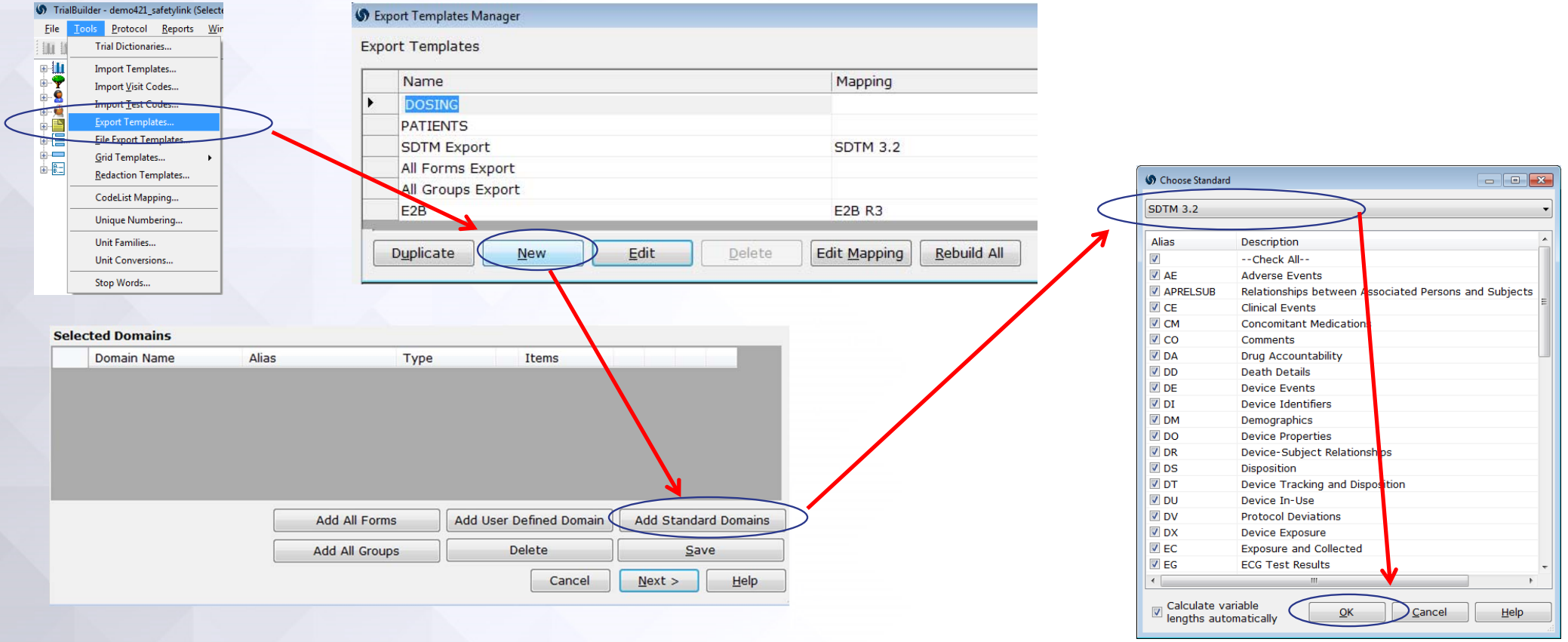
PROGRAMMING OF SDTM DATA WITHIN EDC SYSTEM

- Training from Anju team + Certificate
- Programming done within a specific SDTM Module, using export template available
- Standard templates are available for all SDTM domains for programming
- The latest available mapping template is following the SDTMIG V3.2
- There is also the possibility to import standards library (if available) in ODM format
- SDTM Programming is done in parallel with study set-up, so SDTM Data can be available from the FPFV.

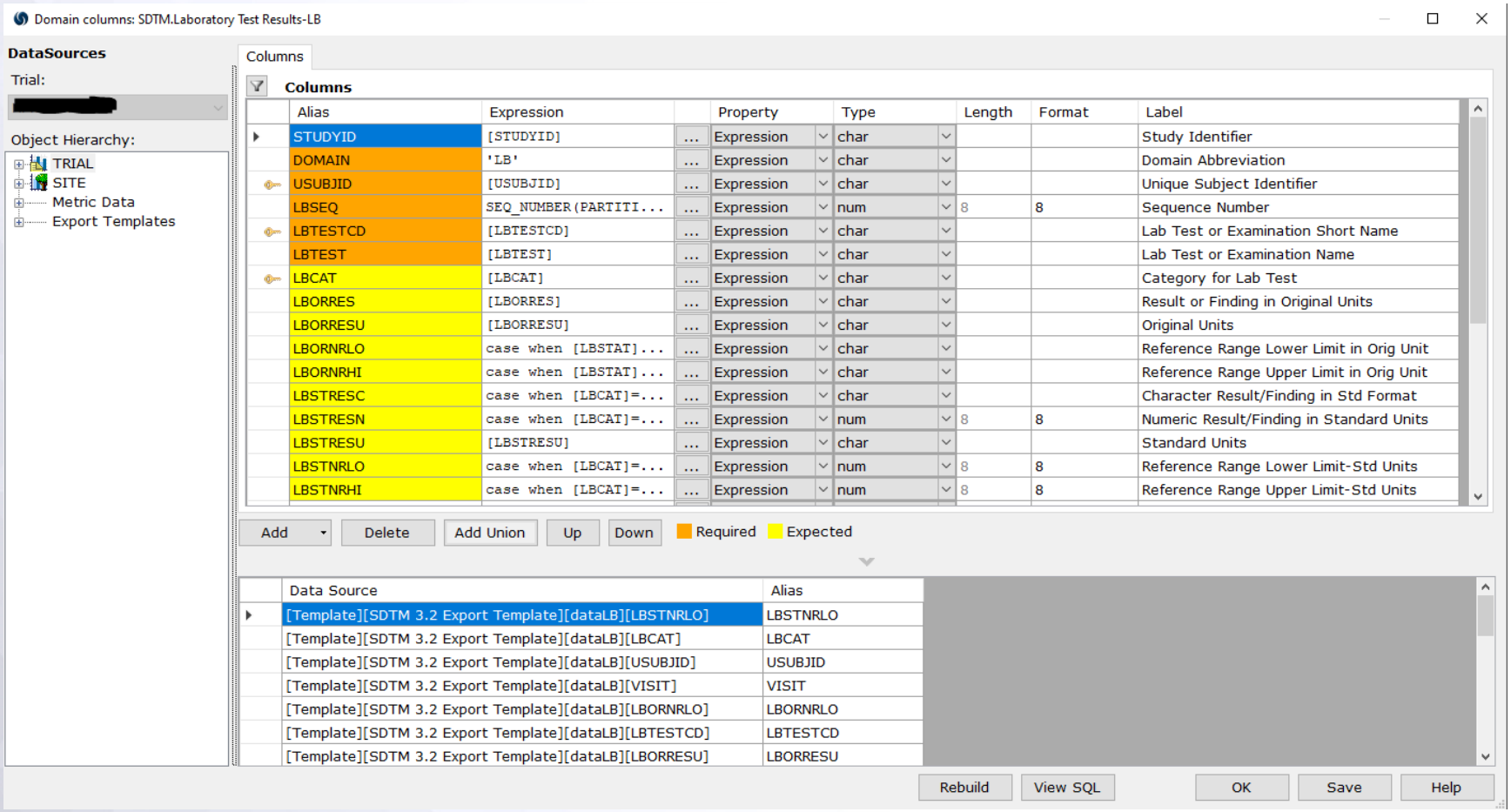


PROGRAMMING OF SDTM DATA WITHIN EDC SYSTEM

- Create a new Export Template:

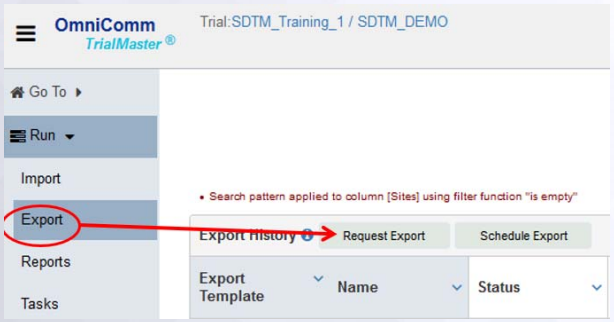


PROGRAMMING OF SDTM DATA WITHIN EDC SYSTEM – EXPORT TEMPLATE MODULE

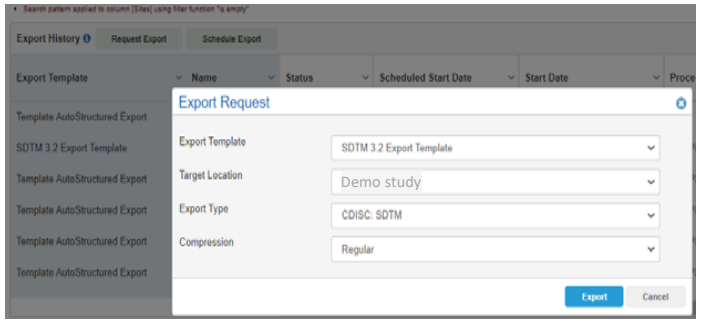


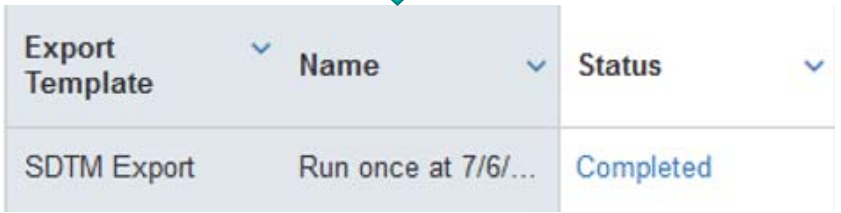
PROGRAMMING OF SDTM DATA WITHIN EDC SYSTEM - BENEFITS

- Easy to use for end-users
- How to extract your data in SDTM:
  - Request an export

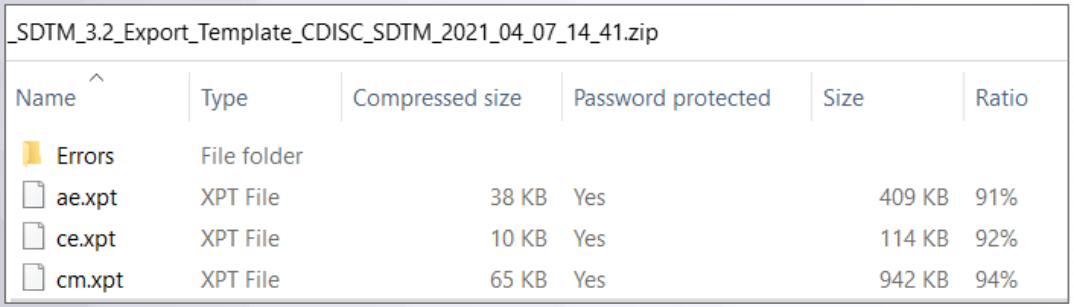


wait for …. few minutes



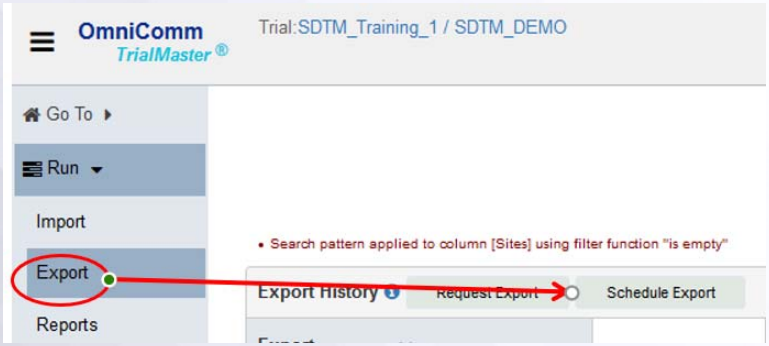


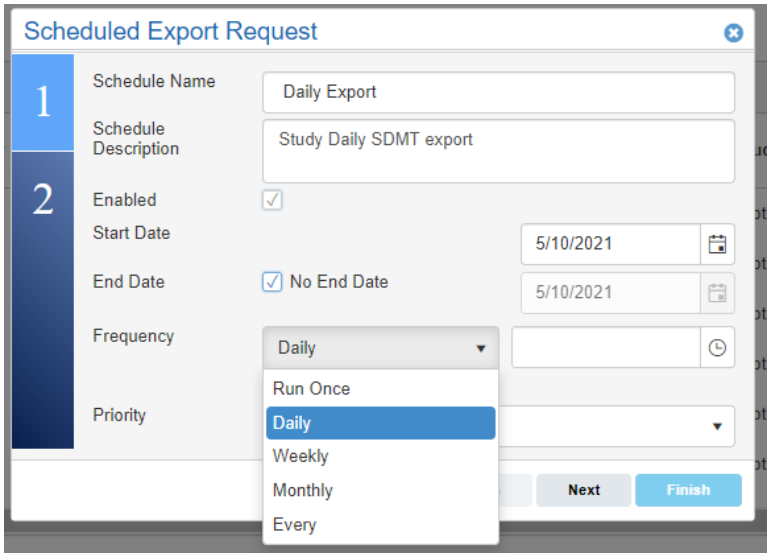
download a zip file (in .xpt format)

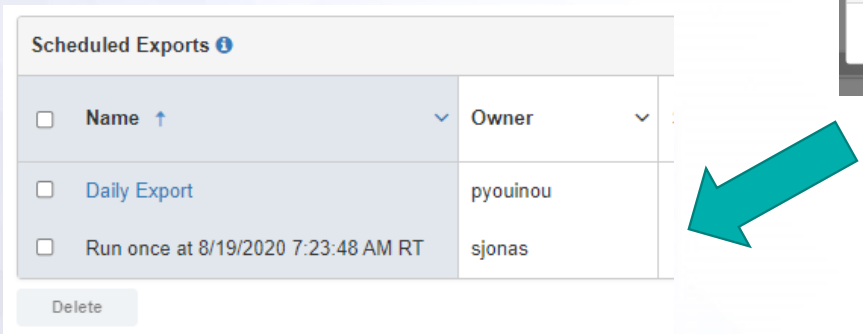


PROGRAMMING OF SDTM DATA WITHIN EDC SYSTEM - BENEFITS

- SDTM Data can also be exported on demand by the end user or by scheduling tasks to run on the server at a predetermined time and frequency

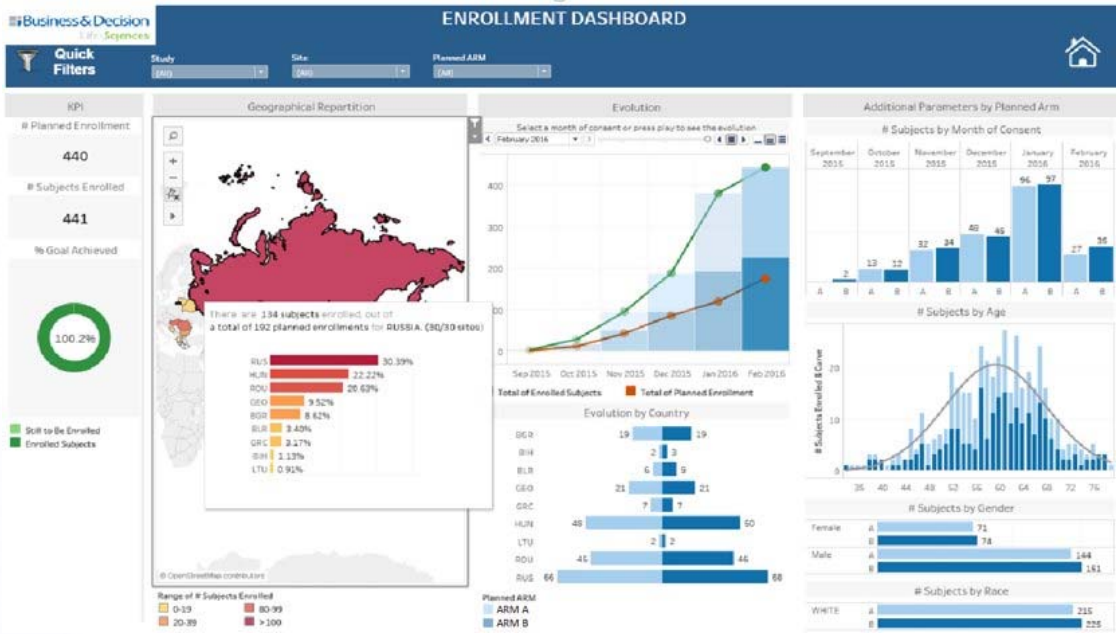




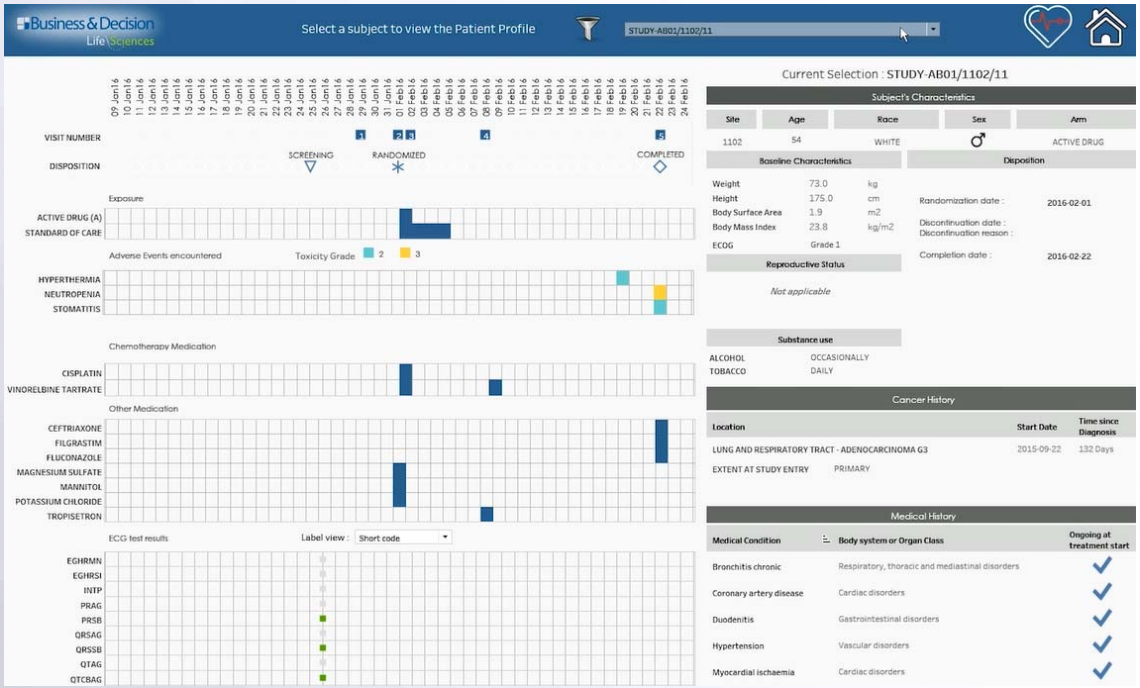


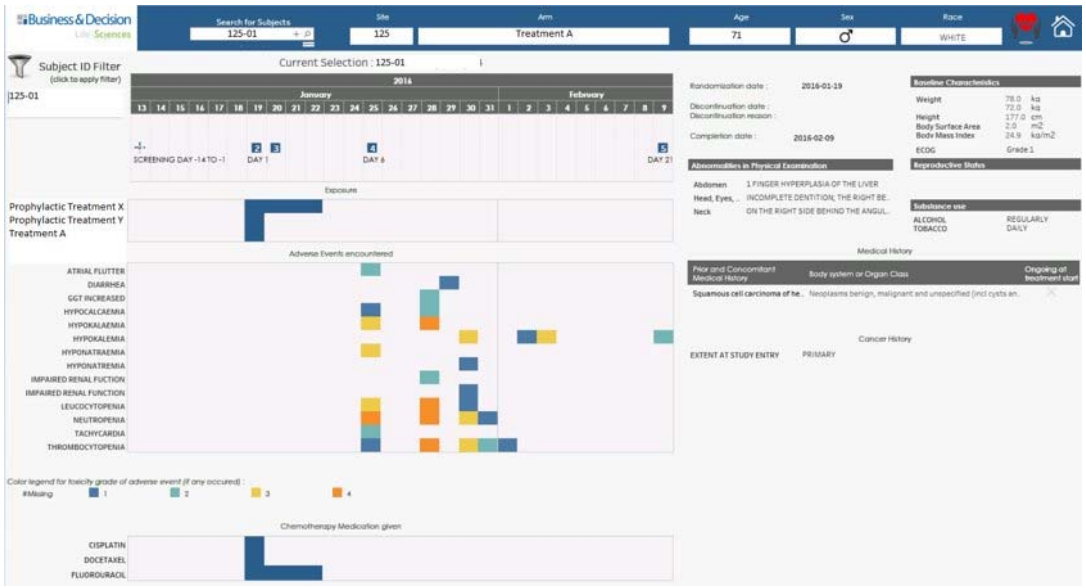
PROGRAMMING OF SDTM DATA WITHIN EDC SYSTEM - BENEFITS (I)

- Real time SDTM extraction allows building Data Visualization dashboards enabling data monitoring in real time. NOTE: Visualization Dashboards are created outside EDC system by BDLS team using Tableau



PROGRAMMING OF SDTM DATA WITHIN EDC SYSTEM – BENEFITS (II) – PATIENT PROFILE





PROGRAMMING OF SDTM DATA WITHIN EDC SYSTEM – BENEFITS (III)

- SDTM data available for STAT immediately (or at any moment in time) and for data review meetings (IDMC, DSMB, SRC, etc.)
- Possibility to program external data that are integrated and/or uploaded data in TrialMaster (Questionnaires, IWRS, Lab Ranges, etc.) to be converted into SDTM automatically → part of the vendor issues are solved
- No additional time needed for data conversion for Submission, shorten the time for final analysis

PROGRAMMING OF SDTM DATA WITHIN EDC SYSTEM – CHALLENGES

Mostly from programming point of view:

- Good knowledge of the system and good programming skills

are required

- Very good knowledge of SDTM is required as SDTM template contains issues (missing variables, sorting, etc.). In case SDTM template is to be corrected, it is managed by Anju team via scripts → time consuming

  Example: Domain SV is missing EPOCH variable

- Only one Clinical Database Administrator / Programmer can work on the export template module at the time → time consuming

PROGRAMMING OF SDTM DATA WITHIN EDC SYSTEM – CHALLENGES

- After the study GO LIVE, any update in SDTM domains implies a Mid Study Change which require deployment by Anju team (in UAT and production environments).

- Anju SDTM Module experts are based in US only → time-zone difference to be taken into account when you have a question or issue

Time consuming

CONCLUSION

- Beneficial and useful solution to help in review / monitoring of your data in real time. It allows to have your data in SDTM at any moment in time during the course of your study.
- It's quite challenging to set-up, so it needs careful consideration before the start of the project:
  - Need careful understanding at the beginning of the project of all analyses to be performed during the course of your study.
  - All planned meetings (e.g. DSMB, SRC, IDMC, etc.) where your SDTM & ADaM outputs are required quickly and within short timelines should be taken into account as well.
- In case only a mid-project/interim analysis & DBL is planned, a standard conversion process outside the EDC system can be sufficient.

THANK YOU FOR YOUR ATTENTION

Q&A

QUESTIONS ASKED AND POST MEETING NOTES

- Define.xml:

Define.XML and Annotated Casebook are not included in the TrialMaster SDTM Capability. Consequently , the Define.xml is handled out of the EDC system

- AutoMapping:

AutoMapping on matching item name gives enough to get started. Best practice is to have the database variables matching as much as possible the CDASH/SDTM standard names in order to have the automapping option working better and complete as much as possible variables

- Localisation

Data Repositories and Anju project teams are based in Germany. Anju SDTM Experts are based in US

Meet the Speaker

Nick De Donder

Title: Head of Data Standards

Organization: Business & Decision Life Sciences

Nick De Donder graduated as a biomedical scientist from the University of Ghent, Belgium in 2007 and has been employed since 2008 by Business & Decision Life Sciences at their headquarters in Brussels. He has been moving from being a Data Integration Specialist to Project Manager to Line Manager for the Data Standards team. Since 2020 he is Head of Data Standards. Nick is a member of the SDS team, an authorized CDISC trainer for SDTM and Newcomers and a PHUSE committee member since 2017. In 2019 he joined the E3C and is now co-chairing it.

FDA Technical Guides & SDTM/IG Differences

Nick De Donder – E3C Chair

Agenda

- Background
- Example
- SDS Tracking

Background – FDA Technical Guides

- The FDA released several technical guidance's which offer support to sponsors submitting data in SDTM format
- These documents include:
  - FDA Technical Conformance Guide
  - FDA Standards Catalog
  - Vaccines Technical Specifications Document
  - FDA Rejection Criteria
- •In some cases, the guidance can be different to the SDTM/IG.
- •The SDS (SDTM) team is beginning to track differences and gather supporting content to describe discrepancies

Discrepancy Between FDA Guidance and SDTM Human Clinical Trial Standards for Variable --DUR

- FDA - Submitting Study Datasets for Vaccines to the Office of Vaccines Research and Review Guidance for Industry –Technical Specifications Document December 2019; Section 3.1 page 3
  - The start day/date (--STDY/--STDTC) and the end day/date (--ENDY/--ENDTC of the reactogenicity event should be identical in both the CE and AE domain; whereas the duration (--DUR) should report the time that the event occurred as part of the assessment interval and as part of the continuance separately (e.g., an event that lasted 6 days in the assessment interval and 3 days beyond the assessment would be reported as Clinical Event Duration (CEDUR) = 6 days and Adverse Event Duration (AEDUR) = 3 days)

Discrepancy Between FDA Guidance and SDTM Human Clinical Trial Standards for Variable --DUR

- SDTMIG v3.3 section 4.4.3.1
  - As defined by ISO8601, an interval of time is the part of a time axis, limited by two time "instants“ such as the times represented in SDTM by the variables --STDTC and --ENDTC. These variables represent the two instants that bound an interval of time, while the duration is the quantity of time that is equal to the difference between these time points.
  - Duration is frequently used during a review; however, the duration timing variable (--DUR) should generally be used in a domain if it was collected in lieu of a start date/time (--STDTC) and end date/time (--ENDTC). If both --STDTC and --ENDTC are collected, durations can be calculated by the difference in these two values and need not be in the submission dataset.

Misalignment

- The definition of duration; i.e., the time between --STDTC and --ENDTC vs. time within assessment interval or part of continuance
- Collection/population of both actual (--STDTC and --ENDTC) and relative (--DUR) timing variables.

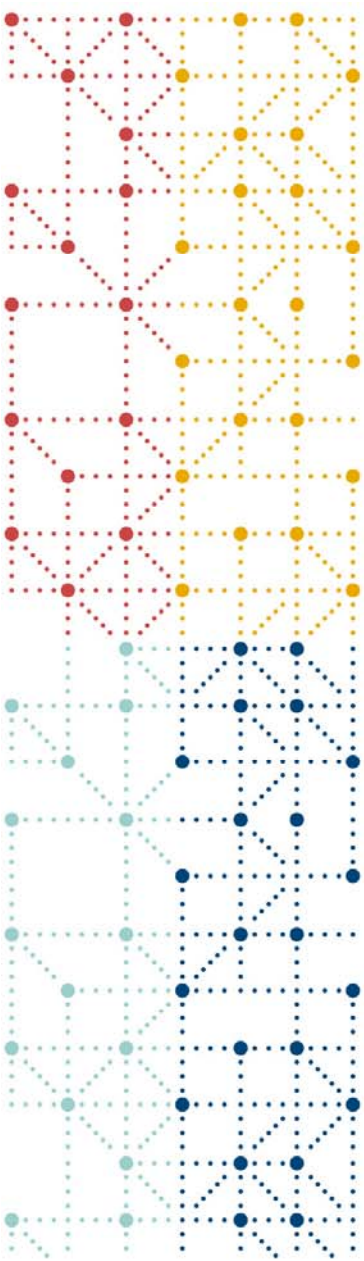
SDS Team Tracking

- At present, tracking will be used to:
  - Support further discussion
  - Explore how we can better collaborate to mitigate discrepancies
  - Determine next steps and future directions
- The current goal is to summarize an initial set of differences identified by end of April and to continue tracking as it adds value.
- Differences identified will be summarized in a to-be-defined tracking/list.
- It is planned that this misalignment of FDA and CDISC guidance will be presented in an upcoming FDA/CDISC Technical meeting (monthly meetings).
- https://wiki.cdisc.org/display/FDA/FDA+Collaboration+-+Tech+Specs+Home

E3C & European Networks Input

- SDS welcomes your feedback and contributions.
  - if public (on the CDISC Wiki or other) please send a description and a link to the location of the relevant content to the SDS Leadership Team
  - if private please send a description and a copy of the relevant content to the SDS LT
- The E3C and European Networks can be kept informed new processes for storing this information, etc. as developed.
- Additional feedback and suggestions are also welcome.

#	Name	Email	SDS	Send
1	Christine Connolly	christine.connolly@emdserono.com	Lead	To
2	Kristin Kelly	kkelly@pinnacle21.com	Incoming Lead	CC
3	Mike Hamidi	mhamidi@csg-inc.com	Past Lead	CC
4	Dana Booth	dbooth@cdisc.org	Project Manager	CC



Thank you