CDISC GUF 04/10/2016 – RENNES

BY

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KELLYOCG
OUTSOURCING & CONSULTING GROUP

HOW TO GET STARTED WITH SDTM

1. Introduction to SDTM
2. Tools and Documents
3. How to train Expert Users
4. Question / Discussion Forum

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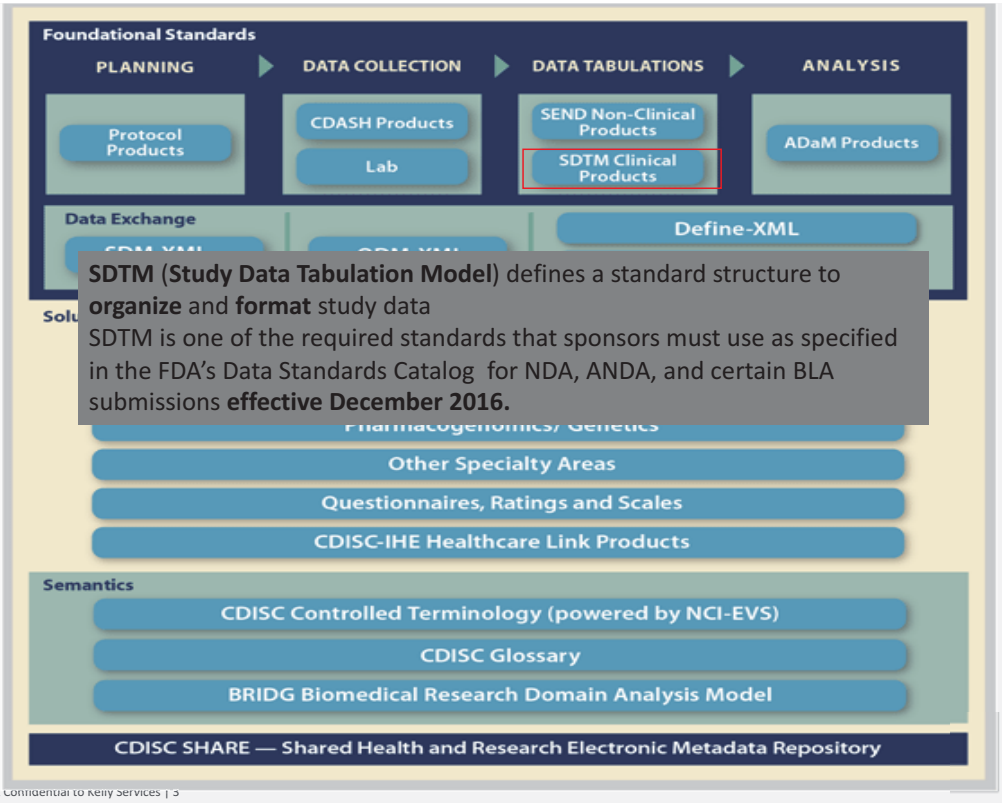

SDTM (**Study Data Tabulation Model**) defines a standard structure to **organize** and **format** study data
SDTM is one of the required standards that sponsors must use as specified in the FDA's Data Standards Catalog for NDA, ANDA, and certain BLA submissions **effective December 2016.**

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SDTM

Two documents :

- The SDTM : the Study Data Tabulation Model
- SDTM Implementation Guide

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DATA CLASSES (General Observation)

The **Interventions** class	The **Events** class	The **Findings** class, observations resulting from planned evaluations or questions
Treatment administered to the subject or other substances self-administered by the subject	planned protocol milestones, occurrences, conditions, or incidents	**Findings About**
Exposure (EX)	Adverse Event (AE)	ECG test Results (EG)
concomitant medications (CM)	Medical History (MH)	Laboratory Test Results (LB)
Substance Use (SU)...	Disposition (DS)...	Questionnaires (QS)...

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DATA CLASS

Special Purpose	**Relationship**	**Trial Design**
Demographics (DM)	Related Records (RELREC)	Trial Summary (TS)
Comments (CO)		Trial Arms (TA)
Subject Visits (SV)….	Supplemental Qualifiers (SUPP--)	Trial Inclusion (TI) …

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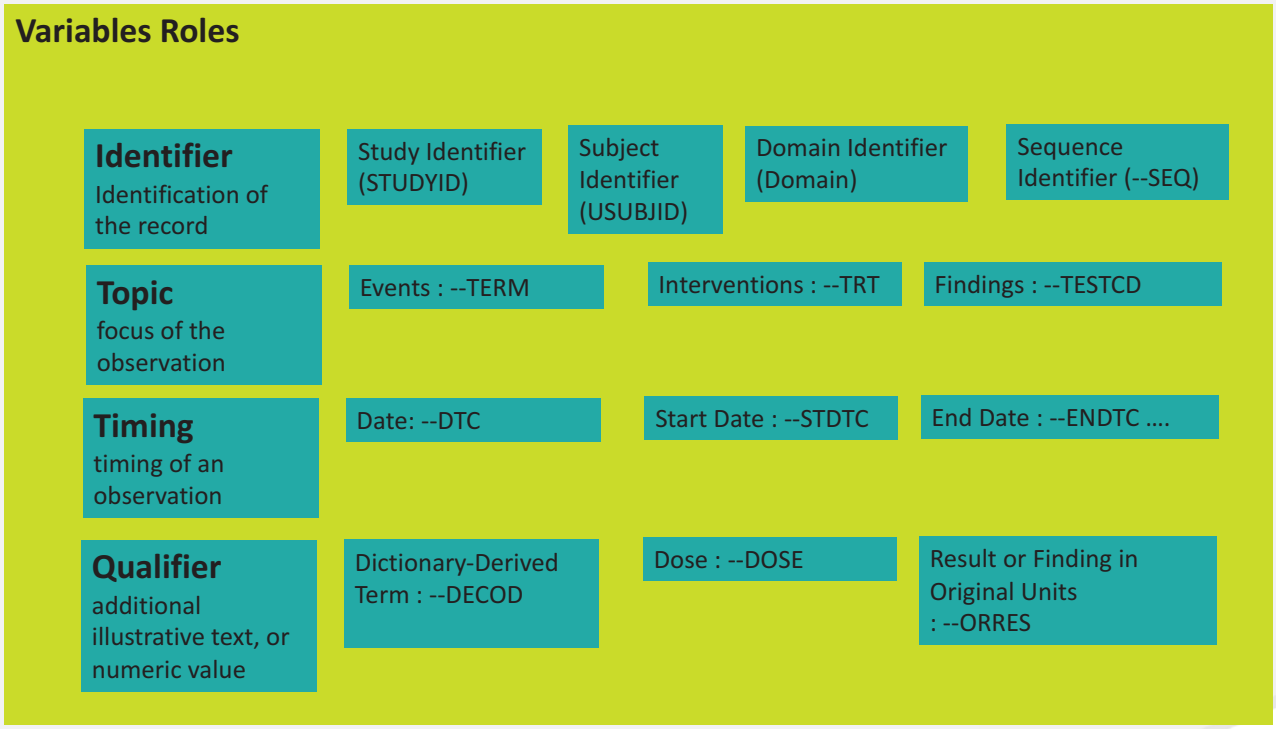
Variables Roles



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2.2.3 The Findings Observation Class

Table 2.2.3: Findings — Topic and Qualifier Variables, One Record per Finding

Variable Name	Variable Label	Type	Role	Description
Topic Variable				
--TESTCD	Short Name of Measurement, Test or Examination	Char	Topic	Short character value for --TEST used as a column name when converting a dataset from a vertical format to a horizontal format. The short value can be up to 8 characters. Examples: PLAT, SYSBP, RRMIN, EYEEXAM.
Qualifier Variables				
--TEST	Name of Measurement, Test or Examination	Char	Synonym Qualifier of --TESTCD	Long name For --TESTCD. Examples: Platelet, Systolic Blood Pressure, Summary (Min) RR Duration, Eye Examination.
--MODIFY	Modified Term	Char	Synonym Qualifier of --ORRES	If the value of --ORRES is modified for coding purposes, then the modified text is placed here.
--CAT	Category	Char	Grouping Qualifier	Used to define a category of topic-variable values. Examples: HEMATOLOGY, URINALYSIS, CHEMISTRY, HAMILTON DEPRESSION SCALE, SF36.

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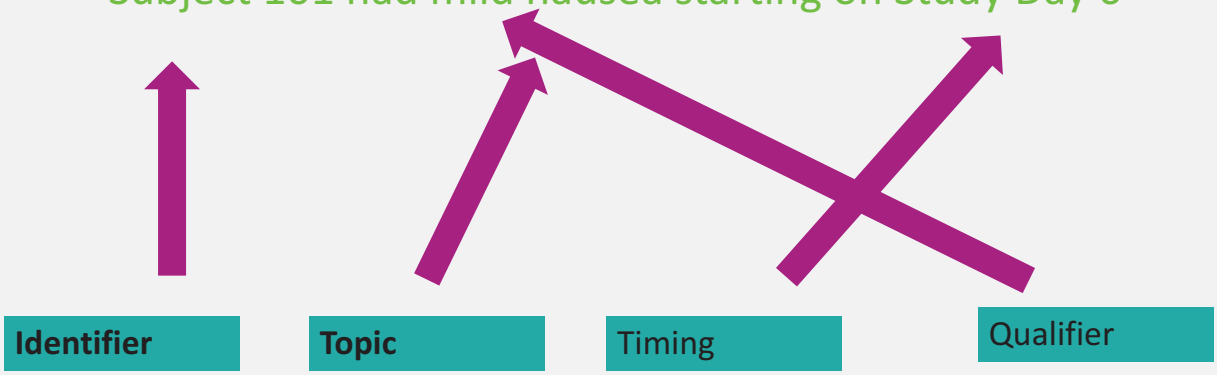
EXAMPLE

"Subject 101 had mild nausea starting on Study Day 6“



Identifier | **Topic** | Timing | Qualifier

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Core Variables

Required	STUDYID, DOMAIN and --SEQ	Topic variables	Cannot be null
Expected	Must be present	Can be nul	
Permissible	Present if collected	Can be null or excluded	Must not be included if always null

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6.3.7 VITAL SIGNS — VS

vs.xpt, Vital Signs — Findings, Version 3.1.2. One record per vital sign measurement per time point per visit per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core	Reference
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req	SDTM 2.2.4
DOMAIN	Domain Abbreviation	Char	VS	Identifier	Two-character abbreviation for the domain.	Req	SDTM 2.2.4, SDTMIG 4.1.2.2, SDTMIG Appendix C2
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req	SDTM 2.2.4, SDTMIG 4.1.2.3
VSSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req	SDTM 2.2.4
VSGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm	SDTM 2.2.4, SDTMIG 4.1.2.6
VSSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database.	Perm	SDTM 2.2.4, SDTMIG 4.1.2.6
VSTESTCD	Vital Signs Test Short Name	Char	(VSTESTCD)	Topic	Short name of the measurement, test, or examination described in VSTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in VSTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g."1TEST"). VSTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: SYSBP, DIABP, BMI.	Req	SDTM 2.2.3, SDTMIG 4.1.1.8, SDTMIG 4.1.2.1, SDTMIG Appendix C1

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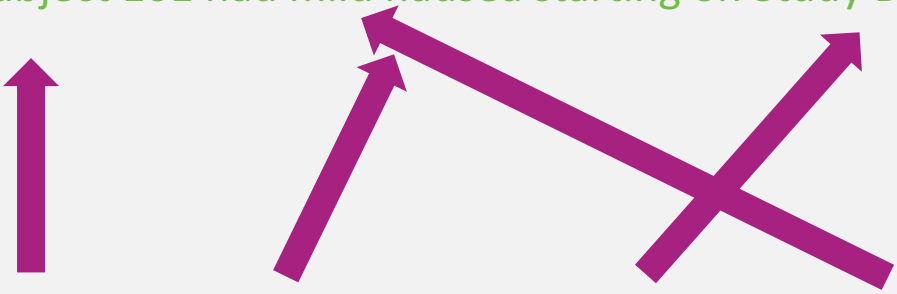
EXAMPLE

"Subject 101 had mild nausea starting on Study Day 6"



Identifier	Topic	Timing	Qualifier
Required	Required	Expected (if date)	Permissible

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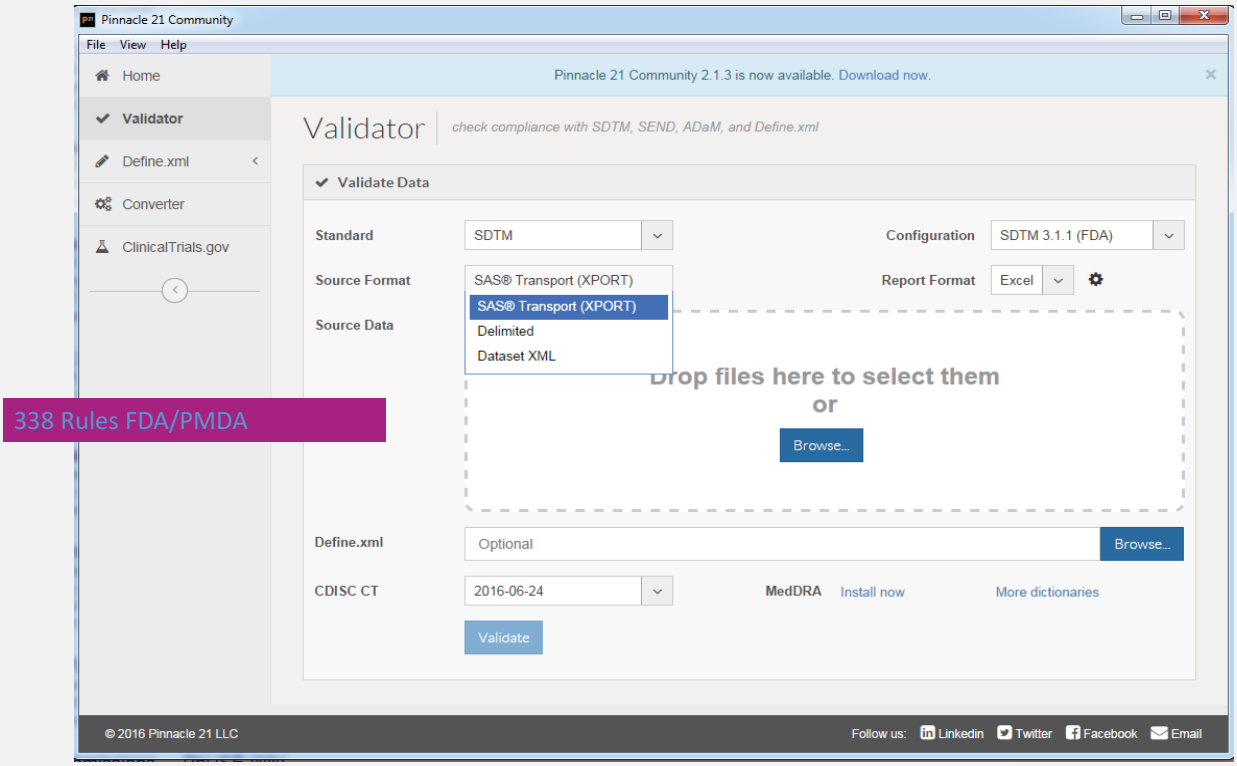
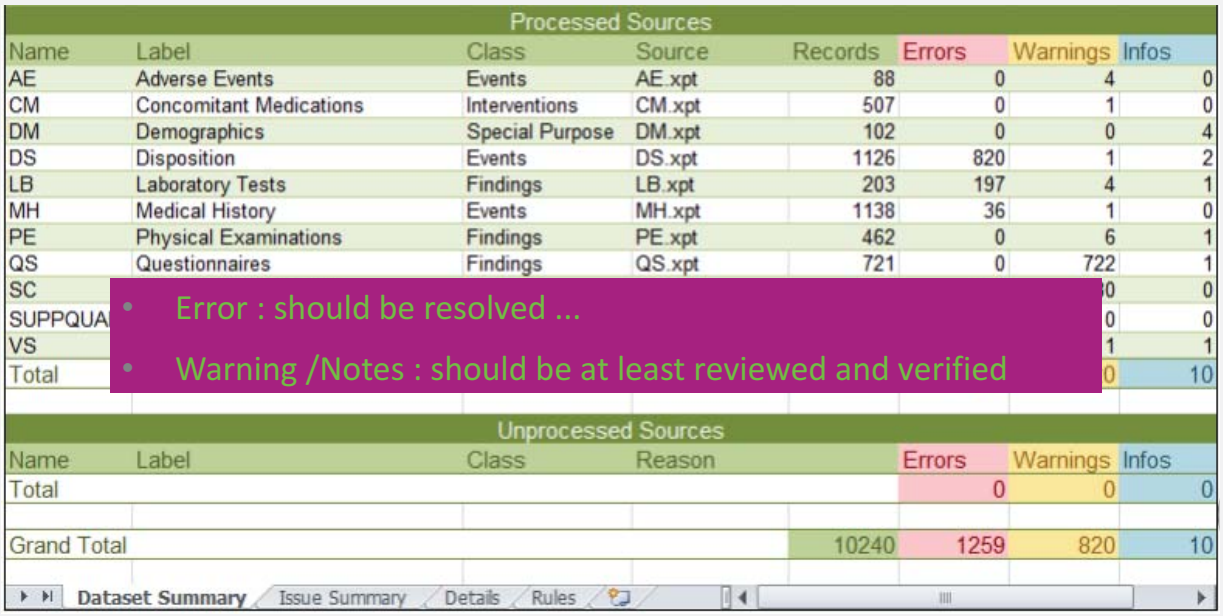
STEPS TO FOLLOW

- Identify to which class the information belong
- Identify to which domain the data should be mapped
- Identify the variables : required, expected, permissible
- Variables not covered in the IG : consider Supplementer qualifier.
- Once your data mapped into SDTM => Validation
  - Pinnacle21 community (former OpenCDISC)



338 Rules FDA/PMDA



Processed Sources

Name	Label	Class	Source	Records	Errors	Warnings	Infos
AE	Adverse Events	Events	AE.xpt	88	0	4	0
CM	Concomitant Medications	Interventions	CM.xpt	507	0	1	0
DM	Demographics	Special Purpose	DM.xpt	102	0	0	4
DS	Disposition	Events	DS.xpt	1126	820	1	2
LB	Laboratory Tests	Findings	LB.xpt	203	197	4	1
MH	Medical History	Events	MH.xpt	1138	36	1	0
PE	Physical Examinations	Findings	PE.xpt	462	0	6	1
QS	Questionnaires	Findings	QS.xpt	721	0	722	1
SC						0	0
SUPPQUA						0	0
VS						1	1
Total						0	10

- Error : should be resolved ...
- Warning /Notes : should be at least reviewed and verified

Unprocessed Sources

Name	Label	Class	Reason	Errors	Warnings	Infos
Total				0	0	0
Grand Total				10240	1259	820	10

Dataset Summary | Issue Summary | Details | Rules

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CHALLENGES WITH SDTM

- Continually changes
  - Need to adopt a strategy to move forward with the implementation of new IG
  - Internal convention and guidance within the company
- New domains, new variables.

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WHERE TO GET THE INFORMATION

http://www.cdisc.org/

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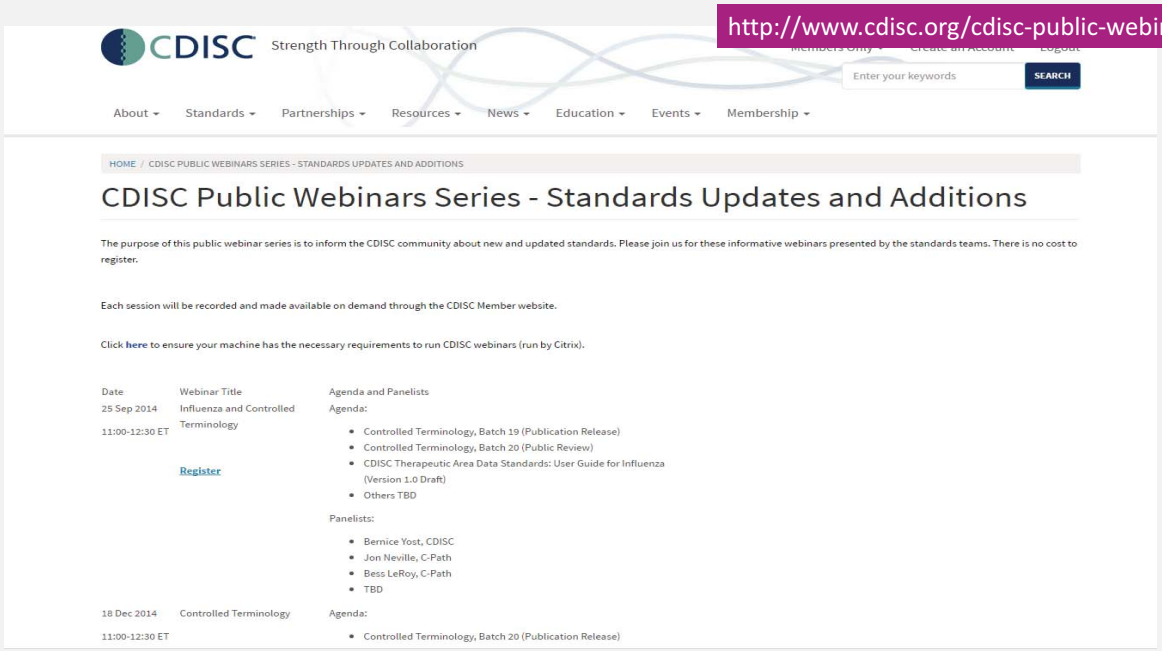
WHERE TO GET THE INFORMATION

http://www.cdisc.org/cdisc-public-webinars



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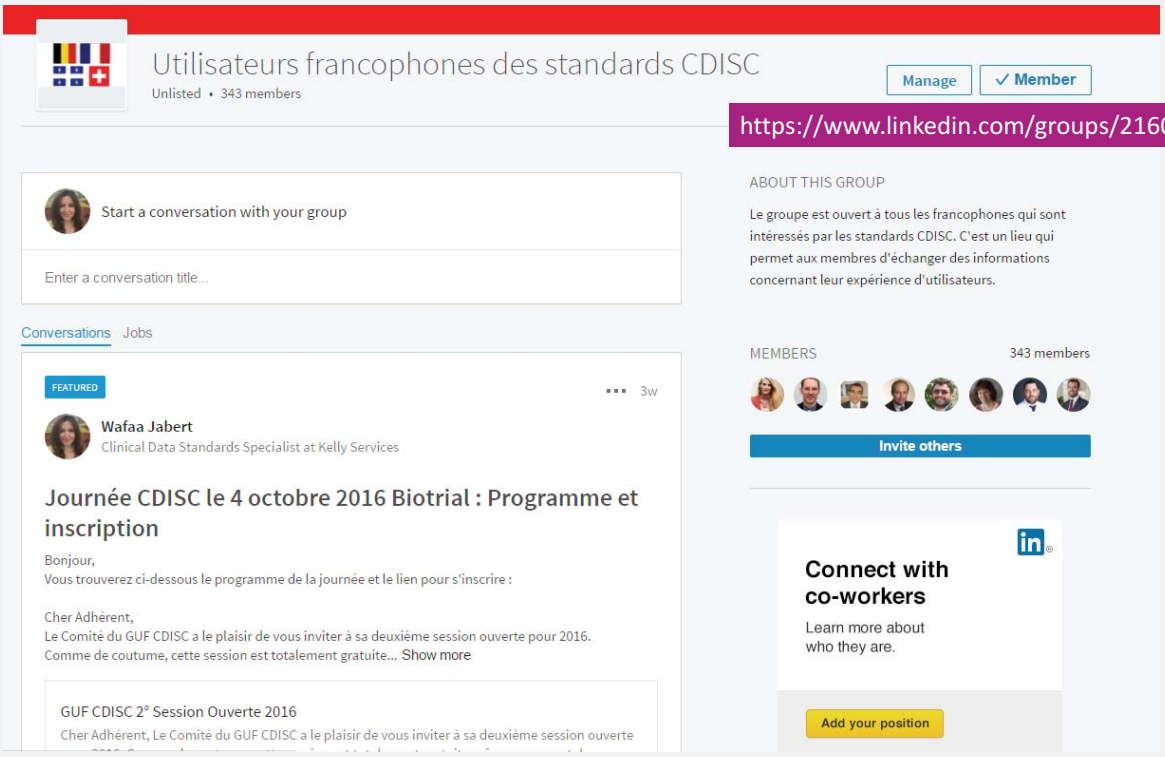
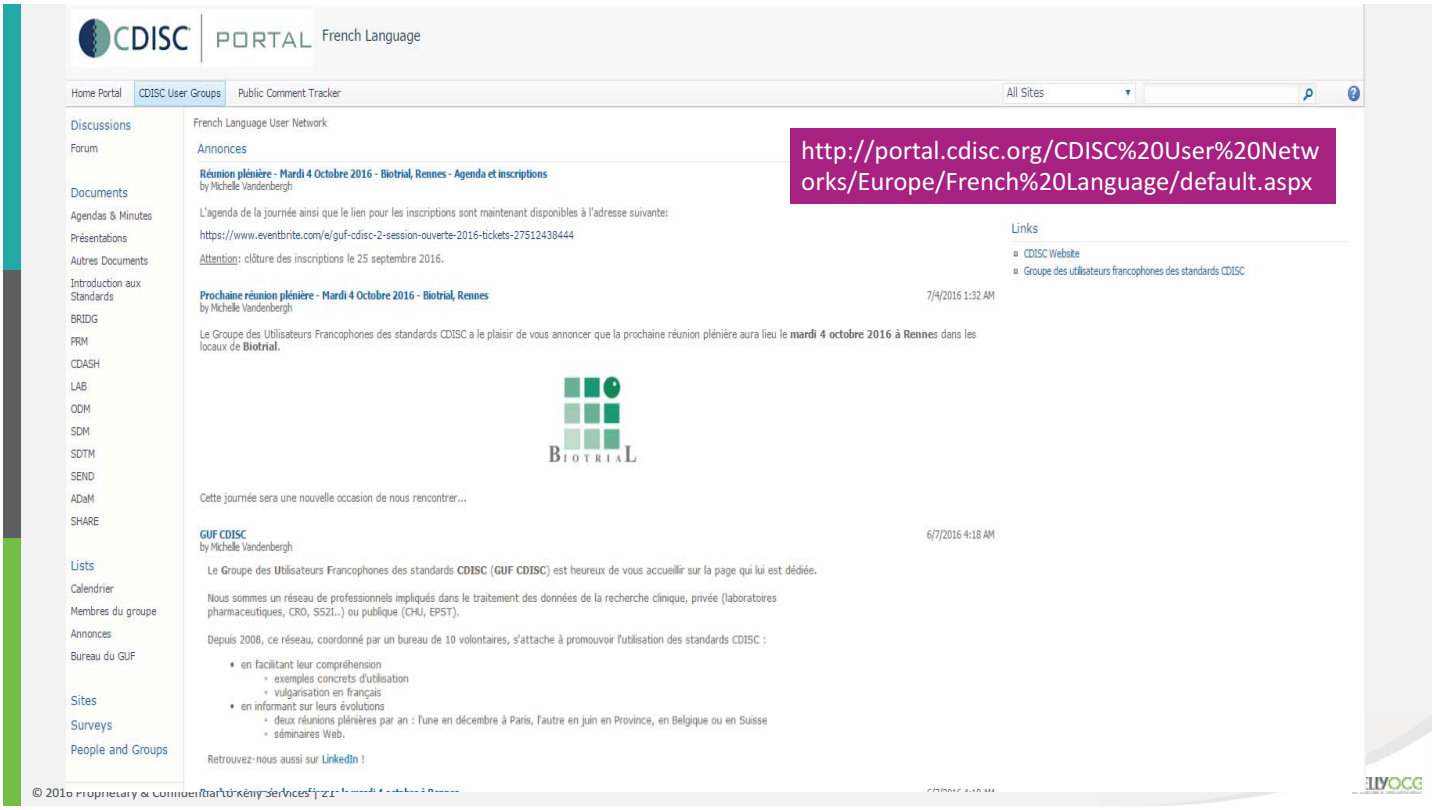
GROUPE UTILISATEURS FRANCOPHONES DES STANDARDS CDISC

- Two public conferences per year (free)
- Webinars
- Documents
- LinkedIn





http://portal.cdisc.org/CDISC%20User%20Networks/Europe/French%20Language/default.aspx

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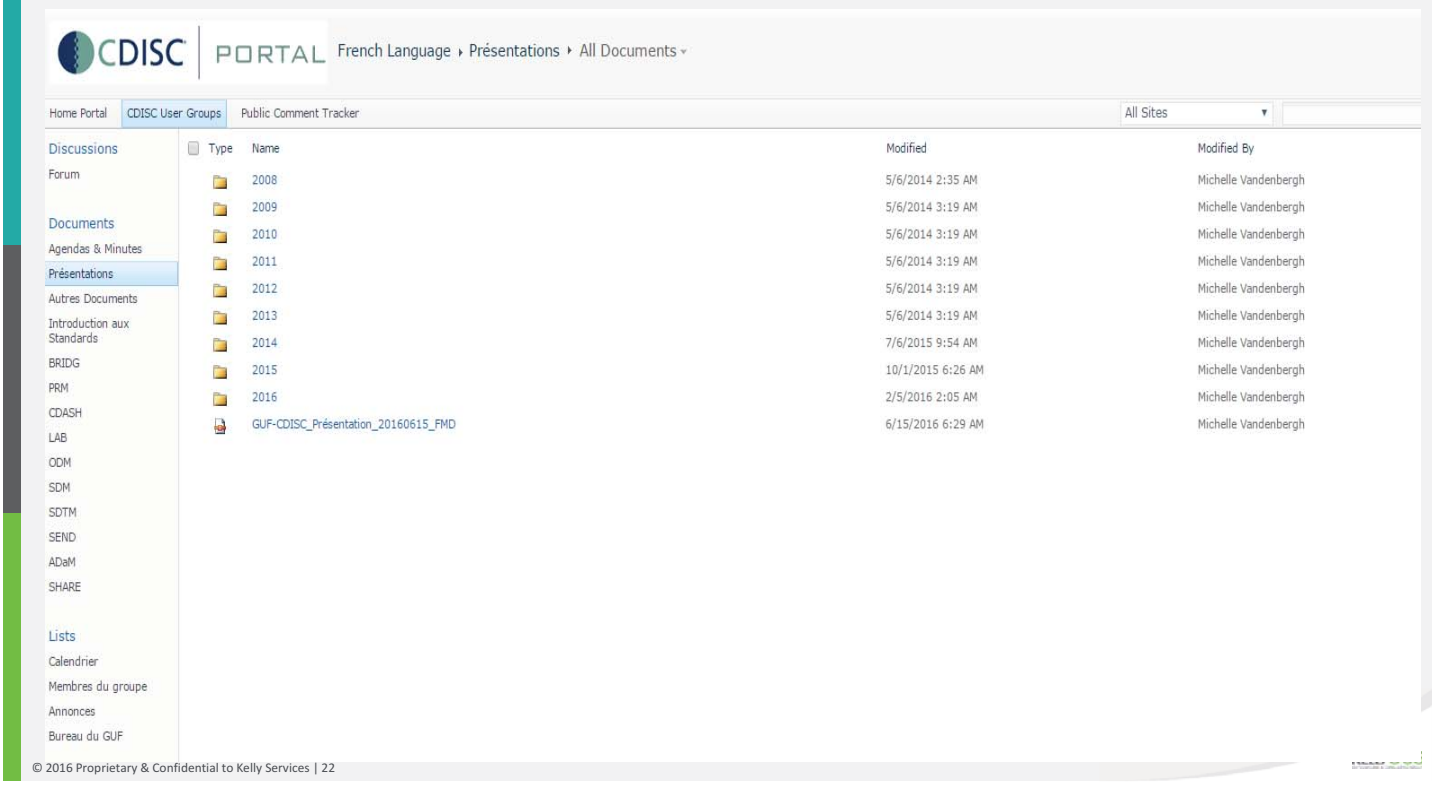

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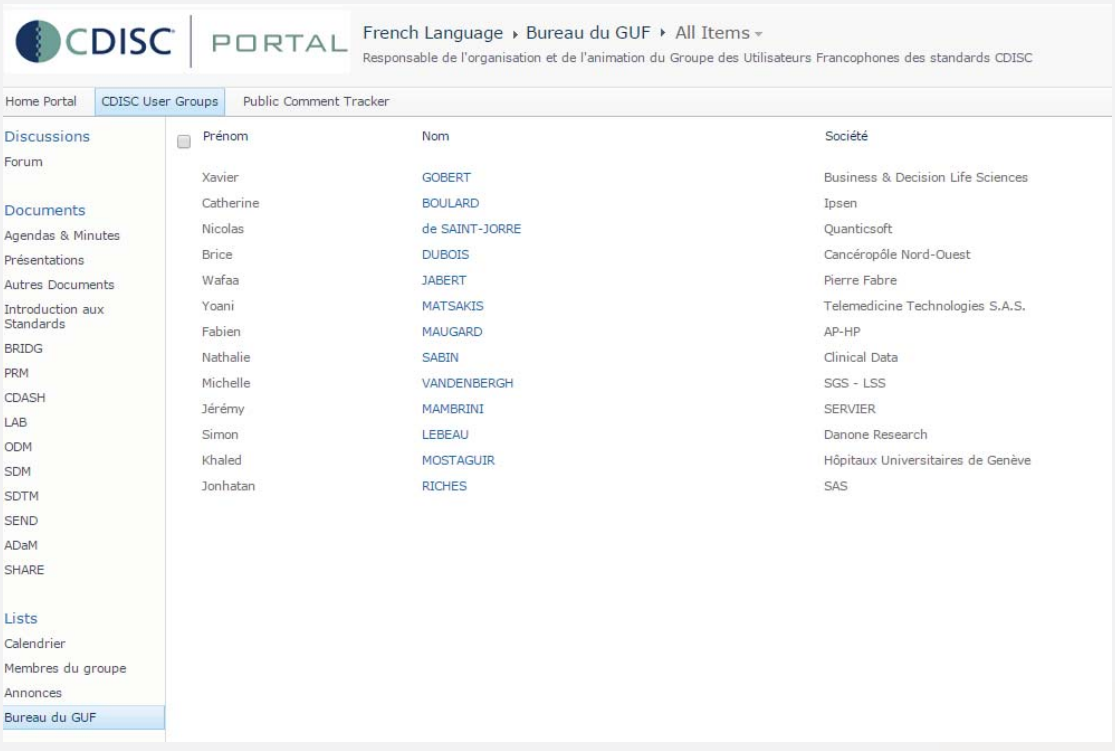
CDISC PORTAL
French Language ▸ Introduction aux Standards ▸ Home
French Language User Network
Home Portal
CDISC User Groups
Public Comment Tracker
All Sites
Recently Modified
Home
How To Use This Wiki Library
Discussions
Forum
Documents
Agendas & Minutes
Présentations
Autres Documents
Introduction aux Standards
BRIDG
PRM
CDASH
LAB
ODM
SDM
SDTM
SEND
ADaM
SHARE
Lists
Calendrier
Membres du groupe
Annonces
Bureau du GUF
CDISC : introduction générale
Le CDISC (Clinical Data Interchange Standards Consortium) est un consortium international à but non lucratif qui vise à promouvoir la standardisation des formats de recueil, d'échange, de soumission et d'archivage de données dans la recherche clinique.
Comme chacun sait, la standardisation dans le traitement des données tend à accélérer l'ensemble des processus liés à la recherche, et donc d'en réduire les coûts.
L'objectif de CDISC est de fluidifier la circulation des données depuis le dossier patient jusqu'à l'analyse statistique et l'archivage, au travers des différentes étapes et des logiciels qui leurs sont associés.
CDISC publie donc une série de standards, pour :
Modéliser / Organiser : BRIDG, PRM, SDM
Recueillir : CDASH, Lab
Echanger (et archiver) : ODM
Soumettre les données aux autorités de santé (pour l'obtention d'une AMM, par exemple) : SDTM (avec Define), SEND
Présenter l'analyse des données à ces mêmes autorités : ADaM
L'adoption des standards CDISC permet donc :
Une harmonisation des formats de variables et des outils de recueil
La facilitation des échanges de données entre différents systèmes d'information (par exemple Dossier Patient Electronique et eCRF)
Un archivage des eCRF à long terme, dans un format ouvert xml
Une soumission des données de la recherche aux autorités de santé dans des formats stricts, leur permettant de retrouver par elles-mêmes les résultats amenés à être publiés (obligatoire pour la FDA aux USA dès 2017)
D'avantage d'indépendance vis-à-vis des éditeurs de logiciels
Etc.
CDISC s'appuie pour beaucoup sur le format xml ; une connaissance approfondie de ce format est donc recommandée pour mieux appréhender l'utilisation de l'ensemble des standards CDISC.
Le format xml permet d'enregistrer des données de manière structurée, mais sous forme de texte. Il s'agit d'un format non propriétaire, contrairement à des formats de type xls ou pdf.
Brièvement, ce format repose sur l'utilisation de balises pour délimiter une variable, ou un groupe de variables.
Prenons l'exemple d'une table très simple contenant une liste de contacts, avec leurs noms, prénoms et e-mails :
NOM PRENOM E-MAIL
Dupont Jean jean.dupont@caramail.com
Dupuis Eveline e.dupuis@yahoo.fr
Dans un fichier xml, ces informations pourraient prendre par exemple la forme suivante :
<REPERTOIRE>
<CONTACT>
<NOM>Dupont</NOM>
<PRENOM>Jean</PRENOM>
<E-MAIL>jean.dupont@caramail.com</E-MAIL>
</CONTACT>


CDISC PORTAL
French Language ▸ Bureau du GUF ▸ All Items
Responsable de l'organisation et de l'animation du Groupe des Utilisateurs Francophones des standards CDISC
Home Portal
CDISC User Groups
Public Comment Tracker
Discussions
Forum
Documents
Agendas & Minutes
Présentations
Autres Documents
Introduction aux Standards
BRIDG
PRM
CDASH
LAB
ODM
SDM
SDTM
SEND
ADaM
SHARE
Lists
Calendrier
Membres du groupe
Annonces
Bureau du GUF
Prénom Nom Société
Xavier GOBERT Business & Decision Life Sciences
Catherine BOULARD Ipsen
Nicolas de SAINT-JORRE Quanticsoft
Brice DUBOIS Cancéropôle Nord-Ouest
Wafaa JABERT Pierre Fabre
Yoani MATSAKIS Telemedicine Technologies S.A.S.
Fabien MAUGARD AP-HP
Nathalie SABIN Clinical Data
Michelle VANDENBERGH SGS - LSS
Jérémy MAMBRINI SERVIER
Simon LEBEAU Danone Research
Khaled MOSTAGUIR Hôpitaux Universitaires de Genève
Jonhatan RICHES SAS

How to get started with SDTM

1. Introduction to SDTM
2. Tools and Documents
3. How to train Expert Users
4. Question / Discussion Forum

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Define a scope and timelines

Do you want to get stared immediately and provide expert services? (outsourcing companies/CRO)

→ Hire an Expert

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DEFINE A SCOPE AND TIMELINES

- Time has been foreseen to share and increase the knowledge.
- Learning is not a straightforward process.
- Time , Energy are the main keys.

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THINK GLOBAL

- CDISC standards are now required for submission of new trial.
- Not only tools for technical department (Data Management, Statistics…), Need to enlarge basic knowledge, presentation to others colleagues, departments….(sales, Q&A…)

To Avoid:

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THINK GLOBAL

- On a company level:
- Define the different stakeholders
- Sales/ Accountancy: foreseen a updates of cost for implementing a new standard, negotiation with clients
- (SDTM in a Data management team will have consequences in a statistical team)

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PERSONAL LEVEL

- Acquiring knowledge:
- Different support (CDISC courses, documentation…) -> see Presentation Wafaa.

Reading and understanding the theory is great but practical exercises are a must.

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PRESENTATION OF OUR SDTM PROGRAM OF MENTOR / TRAINEE

Knowledge sharing by expert to voluntary and motivated trainee.

- Therotical training from basic SDTM to more complex situations
- Practical exercises from basic mapping and annotation (DM,AE...) to more complex (TU/TR, FA, RELREC...)
- Close follow-up(on demand), be present for question (theroritical and practical).

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LEARNING CURVE : LONG AND NOT AN EASY PROCESS

Remember the number of years your spend at school and look back to all the knowledge acquired.

You will not become an expert in 2 weeks !!

Our training progam is over 6 mouth

in order to have autonomous trainee.

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From theory to production environment

- Start with less complex tasks like QC.
- This will help to have high level overview on Final annotation, mapping, dataset.
- And go deeper and deeper to focus on details.
- During a second phase start creation (annotation, mapping, dataset), try , correct, re-do.. (following advice/support of mentor)
- Try to share your knowledge: clear and short presentation to other users will help to structure your own knowledge.

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Question / Discussion Forum

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SDTM Expertise : Who ? Which Team ?

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Versioning of SDTM : How , When

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SDTM : A standard with many specific domains ...

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