Protocol to Study Live in 15 mins - AI, USDM and BCs in Action

Johannes Ulander / Partner at data4knowledge and CDISC instructor

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Meet the Speaker

Johannes Ulander

Title: Partner

Organization: data4knowledge

20+ years' experience in standardizing clinical data and have been involved in implementing CDISC standards from an end-to-end perspective for the last 15 years. For the last 7 years by using linked data and graph databases.

He is a partner at data4knowledge in Umeå and an authorized CDISC SDTM instructor.

Meet the Contributors

Kerstin Forsberg

Title: Senior Consultant
Organization: data4knowledge

Kirsten Langendorf

Title: Partner

Organization: data4knowledge

Disclaimer and Disclosures

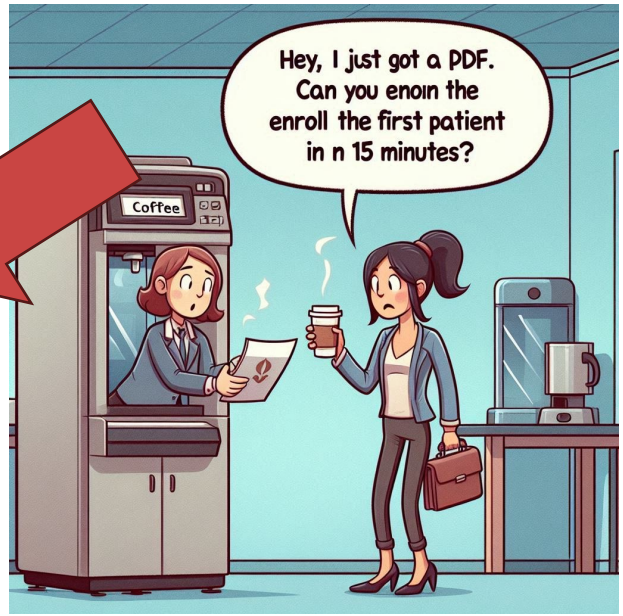
- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

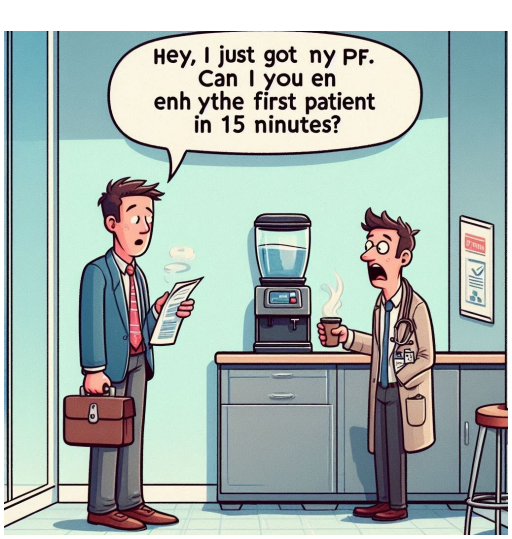
- *The author(s) have no real or apparent conflicts of interest to report.*

Imagine you are asked to build a study in 15 minutes based on a PDF protocol...

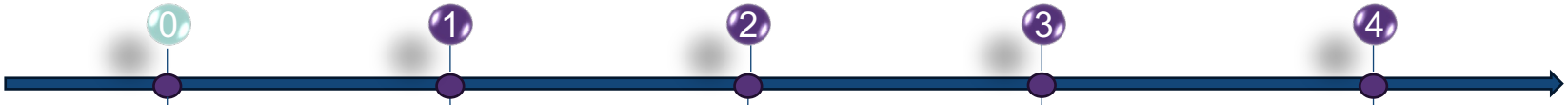
Start the clock!

Imagine you are asked to build a study in 15 minutes based on a PDF protocol...





Agenda as a timeline



- Introduction
- Load legacy protocol
  - *SoA LLM processed*
  - *USDM v4 json generated SoA and Timelines*
- Convert to USDM v3 Excel
  - Add some BC's
- Load Excel
  - *Generate Data Contracts*
- Automation
  - *Activities by visit*
  - *Forms*
  - *Define*
  - *Trial Design Domains*
  - *Enrol Subject*
  - *Enter Data*
  - *SDTM*

What to expect

Eli Lilly and Company: I3Y-MC-JPBL

A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of Fulvestrant with or without LY2835219, a CDK4/6 Inhibitor, for Women with Hormone Receptor Positive, HER2 Negative Local Advanced or Metastatic Breast Cancer

Phase III Trial | 1 version | USDM

View Details | View Protocol | Se

I3Y-MC-JPBL Clinical Protocol

Study Schedule, Protocol I3Y-MC-JPBL
Perform procedure as indicated.

			Baseline		Patients on Study Treatment				Postdiscontinuation Follow-Up	
		Cycle	BL		1		2 – 3	4 and Beyond (if Applicable)	Short-Term Follow-Up[a]	Long-Term Follow-Up[a]
		Visit	0		1		2 – 3	4 and Beyond (if Applicable)	801	802 - 8XX
		Approximate Duration (days)	28		28		28	28	30	Variable
		Relative day within a cycle	≤28	≤14	1	15±3	1[p]	1[p]		
Procedure Category	**Procedure**	**Protocol Reference**								
Study Entry /Enrollment	Informed Consent Form signed[q]	Section 8.1	X[q]							
	Inclusion/Exclusion evaluation	Section 7		X						
Medical History	Medical History			X						
	Historical illnesses	Section 12.2.3		X						

	Cycle	Cycle	Cycle	Cycle	None	None	Unprocessed
	Cycle	Cycle	Cycle	Cycle	Not Found	Not Found	Unprocessed
	None	None	None	None	None	None	
Procedure Category							X
Procedure							X
Protocol Reference							X
Study Entry /Enrollment							X
Informed Consent Form signed	X						
Inclusion/Exclusion evaluation	X						
Medical History	X						X
Medical History	X						X
Historical illnesses	X						

What to expect

Sanofi: ACT15377

A Phase 1/2 open-label, multi-center, safet
preliminary efficacy and pharmacokinetic
study of isatuximab (SAR650984) in combi
with atezolizumab or isatuximab alone in p
with advanced malignancies

Phase I/II Trial | 1 version | USDM

View Details | View Protocol

1.3 SCHEDULE OF ACTIVITIES (SOA)

Evaluation	Screening (up to 28 days before Day 1)		Treatment Phase[a]				End of Treatment (EOT)	Post Treatment Follow-up Phase			Notes
			Cycle 1			Cycle 2 and Beyond		Safety follow-up Period		Survival follow-up	*a* A cycle is 21 days
	D-28 to D-15	D-14 to D-1	D1 (±1)	D8 (± 1)	D15 (±1)	D1 (± 2)	30 (±7) days after last IMPs admin	At 60 (±7) days after last IMPs admin	At 90 (±7) days after last IMPs admin	Every 90 days (±7) after last safety follow-up	
Informed consent/ Inclusion and exclusion criteria	X										**Informed Consent:** Informed consent may be signed prior to D -28.
Demography, Medical/Surgical and Disease History	X										
Physical examination		X (<7days prior to first dose)		X[c]	X[c]	X	X	X	X		Section 8.2.1
Height (at baseline only) /Weight/ ECOG			X	X[c]	X[c]	X	X	X	X		Section 8.2.1

	Day	Day	Day	Day	Day	Day	Day	Day	Day	Day	Nor
	Day	Day	Day	Day	Day	Day	Day	Day	Day	Day	Not Fo
	None	None	None	None	None	None	None	None	None	None	Nor
Informed consent/ Inclusion and exclusion criteria	X										X
Demography, Medical/Surgical and Disease History	X										
Physical examination		X	X	X		X	X	X	X		X
Height (at baseline only)/Weight/ ECOG (HCC,SCCHN,EOC) or Karnofsky PS (GBM)	X		X	X	X	X	X	X	X		X
Vital Signs	X	X	X	X		X	X	X	X		X
Resting O2 saturation for SCCHN	X	X	X	X		X	X				X
12-Lead ECG	X					X					X
Laboratory Assessments											
Pregnancy test (WOCBP only)		X				X	X	X	X		X

What to expect

Unknown sponsor organization: Unknown Identifier

Unknown Study Title

[Trial Phase] Not Applicable

View Details View

	Visit	Visit	Visit	Visit	Visit	Visit	
	Visit	Visit	Visit	Visit	Visit	Visit	
	None	None	None	None	None	None	N
SUBJECT RELATED INFORMATION AND ASSESSMENTS							
Informed consent and Demography	X	X					
Childbearing potential	X	X					
Inclusion criteria	X	X					
Exclusion criteria	X						
Randomisation criteria and randomisation		X					
Medical history, Concomitant illness	X	X					

Live demo

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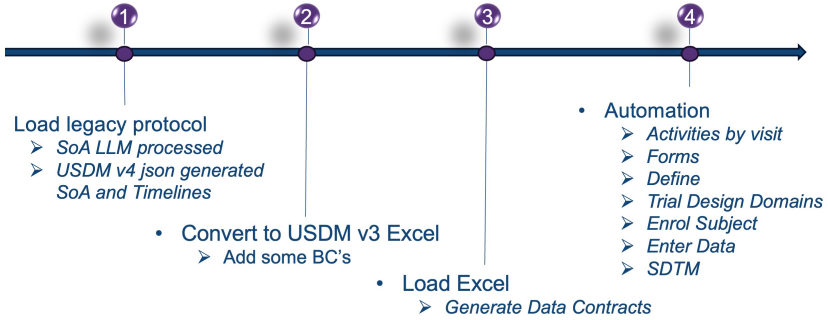
Summary (I hope!)

- Subject enrolled 15 minutes after PDF received



- USDM provides a strong foundation
- LLM needs humans
- Automation: Standards 1 – 0 LLM

Thank You!

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