

# Creating Define.xml 2.0 with OpenCDISC

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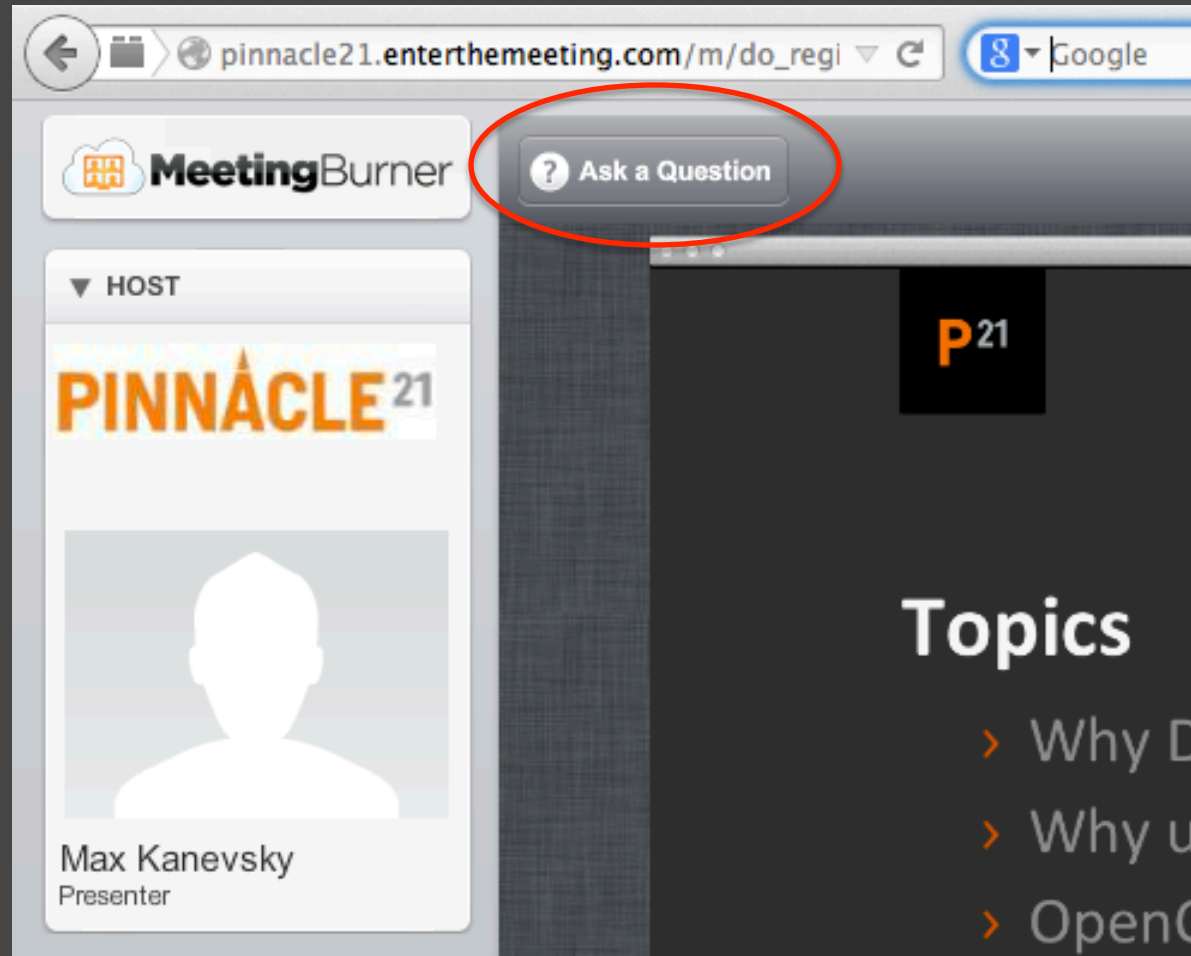
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# Webinar Topics

- › Why Define.xml is important?
- › Why upgrade to Define.xml 2.0?
- › OpenCDISC Define.xml Designer Demo
- › Community vs. Enterprise
- › Questions and Answers

## Q & A

- › At any time during the webinar, click the “Ask a Question” button
- › Questions will be answered at the end



# Why Define.xml is important to FDA?

“A properly functioning define.xml file is an important part of the submission of electronic study datasets. ... An insufficiently documented define file is a common deficiency that reviewers have noted.”

– FDA Study Data Technical Conformance Guide

## Why Define.xml is important to FDA?

- › Describes the format and content of the submitted SDTM, SEND, and ADaM datasets
- › Documents traceability from dataset variables back to annotated CRFs
- › Allows reviewers to quickly familiarize themselves with submission data
- › Avoids unnecessary queries
- › Often printed out by reviewers and used as a desktop reference

# Common Define.xml Deficiencies

- › Non-compliant structure
- › Missing, incorrect, or inconsistent content
  - › Missing or incorrect CRF page numbers (Origin)
  - › Missing or incomplete controlled terminology
  - › Missing or incorrect derivation Methods
  - › Missing or incomplete value level metadata
- › Deficiencies are observed in ~75% of all submitted Define.xml files
- › Many deficiencies are due to limitations in Define.xml 1.0



# Why Define.xml is important to CROs and Sponsors?

- › A great way to communicate expected deliverables
  - › What tests should be collected at each visit
  - › What are acceptable values for test XYZ
- › Automatic study specific validation with OpenCDISC
  - › Study specific codelists
  - › Study specific value level metadata

## Why upgrade to Define.xml 2.0?

- › Define 1.0 is outdated
- › A way to define Value Level metadata that actually works
- › A more formal and clear way to specify Origin
- › Explicit references to standard CT
- › More ways to provide comments
- › Formal expressions for methods
- › References to external documents

# OPENCDISC DEMO

# OpenCDISC Version Comparison

	Community	Enterprise
Client Interface	Desktop	Web Hosted
Create fully compliant Define.xml 2.0 for following standards	SDTM, SEND, ADaM	SDTM, SEND, ADaM and company custom
Convert Define.xml 1.0 to 2.0	✓	✓
Extract metadata from SAS datasets	✓	✓
Extract origin page numbers from annotated CRFs		✓
Merge metadata from external specifications		✓
Generate Define.pdf		✓
Validate Define.xml content in real-time		✓
Compare metadata with standards and other studies		✓
Create and manage multiple versions		✓
Track changes between versions		✓