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OpenCDISC Community V2.0

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Agenda

- OpenCDISC Tools
- Technical Updates
- Information Resources
- Experience Exchange

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OpenCDISC Community Tools

OpenCDISC COMMUNITY | *an open source toolkit for the CDISC professional*

Where would you like to begin?

Validator

Check compliance with SDTM, SEND, ADaM, and Define.xml

Define.xml Generator

Create compliant Define.xml 2.0 for SDTM, SEND, and ADaM datasets

Data Converter

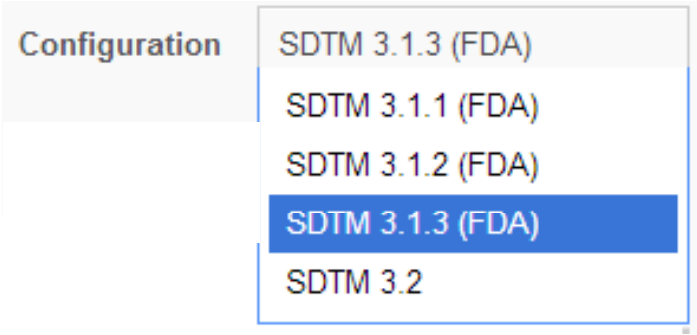
Convert data between SAS XPORT, Excel, CSV, and Dataset-XML

ClinicalTrials.gov Miner

Aggregate clinical outcomes and site info across trials and therapeutic areas

Validator

- Implementation of FDA SDTM Validation Rules
  - OpenCDISC checks overwritten by FDA checks for FDA supported SDTM versions
  - Severity now limited to ERROR and WARNING
  - New checks for Trial Summary (TS)
  - Planned updates: 1-2 per year



- See …/config/CHANGELOG.txt for further details

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Define-XML v2.0 Generator

Define.xml Generator

Create compliant Define.xml 2.0 for SDTM, SEND, and ADaM datasets

- Create preliminary Excel specification
  - from XPTs (select files and desired CDISC standard version)
  - from define.xml (based on Define-XML v1.0 or v2.0)
- Edit Excel specifications
  - according to Define-XML v2.0 standard
- Create define.xml
  - based on the edited Excel specification file
  - according to Define-XML v2.0 standard
- Current recommendation:
  wait for announced bug fixes and always run Define-XML validation

In theory at least

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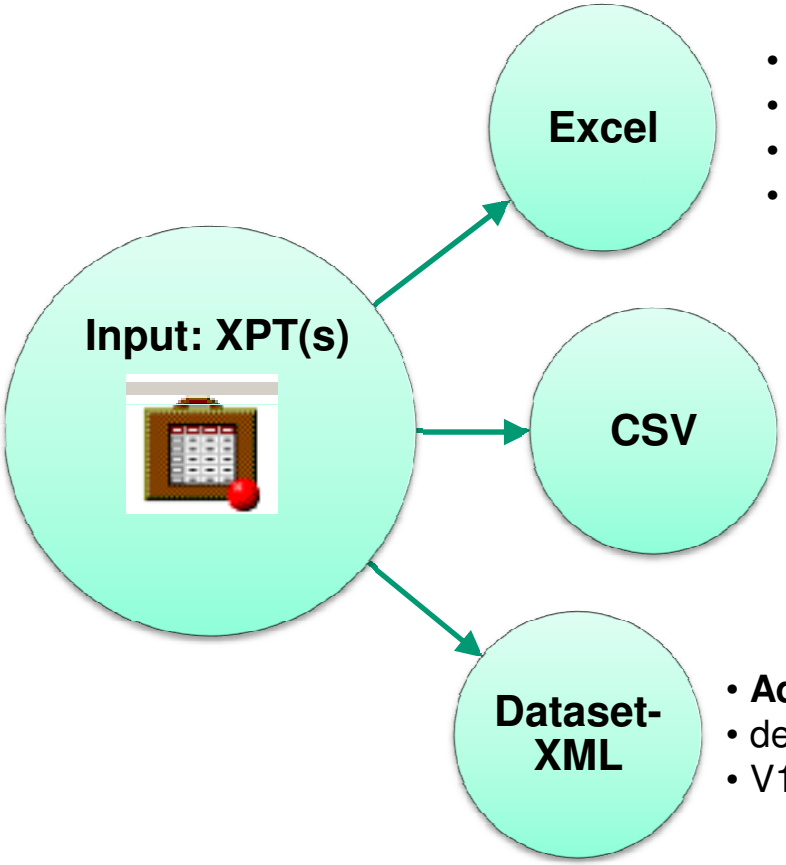
Data Converter

Data Converter

Convert data between SAS XPORT, Excel, CSV, and Dataset-XML



- **Sheets:**
- Dataset metadata
- Variable metadata
- <dataset name>

- **Additional input:**
- define.xml
- V1.0 or V2.0

In theory at least

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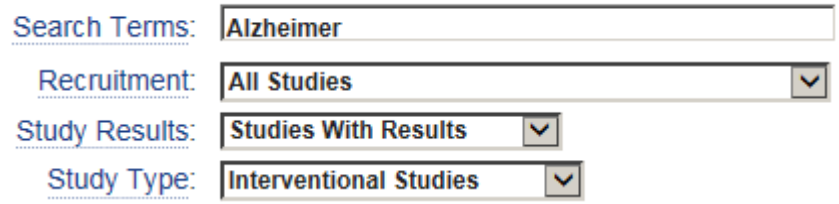
ClinicalTrials.gov Miner

ClinicalTrials.gov Miner

Aggregate clinical outcomes and site info across trials and therapeutic areas

- ✓ Use case
  - References for therapeutic area standards development
- ✓ Writes search results (outcomes/sites) to Excel files for further reference

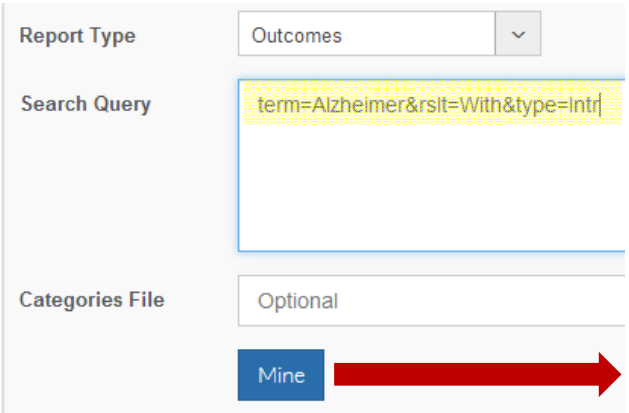
ct.gov search mask



URL

https://www.clinicaltrials.gov/ct2/results/refine?term=Alzheimer&rslt=With&type=Intr

OpenCDISC GUI



Excel Output

SEQ	Categorization	End_Point_Title	End_Point_TimeFrame	Saftey_Issue_YN	End_Point_Details	End_Point_Type	Core_Ext_Other_Study	Study_ID	Official_Title	Sponsor_Name	Phase	Study_Type	Data_Source	Conditions	Intervention
1		Number of Participants With	Brief neuropsychological	Yes	All cause dementia based on	Primary		NCT00010803	Ginkgo Biloba Preventi	National Center for	Phase 3	Interventional		Dementia|Alzheimer's Disease	Ginkgo biloba|Placebo
2		Number of Participants With the	6 months	No	Myocardial infarction (MI),	Secondary		NCT00010803	Ginkgo Biloba Preventi	National Center for	Phase 3	Interventional		Dementia|Alzheimer's Disease	Ginkgo biloba|Placebo
3		Progression of Cognitive Decline in	6 months/annually	No	Rate of annual change by	Secondary		NCT00010803	Ginkgo Biloba Preventi	National Center for	Phase 3	Interventional		Dementia|Alzheimer's Disease	Ginkgo biloba|Placebo
4		Beck Depression Inventory II	Pre-intervention intake	No	21-item self-report instrument	Primary		NCT00056316	Reducing Depress	University of Missouri.	Phase 1/Phase 2	Interventional		Depression	Basic Education|Behavioral Skills
5		Primary Outcome: Beck	Post-intervention, assessed 4-	No	21-item self-report instrument	Primary		NCT00056316	Reducing Depress	University of Missouri.	Phase 1/Phase 2	Interventional		Depression	Basic Education|Behavioral Skills
6		Negative Affect Schedule	Pre-intervention intake	No	10 item self-report assessment	Secondary		NCT00056316	Reducing Depress	University of Missouri.	Phase 1/Phase 2	Interventional		Depression	Basic Education|Behavioral Skills
7		Secondary Outcome: Negative	Post-intervention, assessed 4-	No	10 item self-report assessment	Secondary		NCT00056316	Reducing Depress	University of Missouri.	Phase 1/Phase 2	Interventional		Depression	Basic Education|Behavioral Skills

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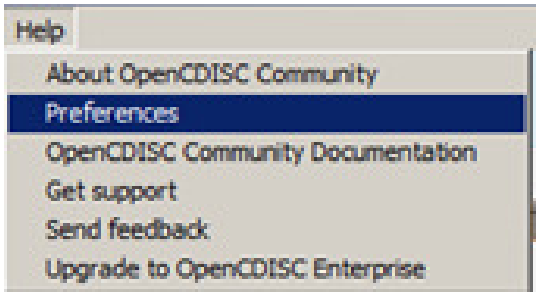
Technical Updates



- Different downloads available
  - Windows (64-bit), Windows (32-bit)
  - Mac OS X
- Performance Settings
  - Initial Memory, Maximum Memory, Thread Count
- Application Settings
  - Enable Autoupdates, Participate in OCC improvement program Y/N
- Recent OpenCDISC/CDISC/FDA updates shown on OpenCDISC Community Home Interface

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Information Resources

- OpenCDISC Website: www.opencdisc.org
- OpenCDISC Webinars
  - FDA Validation Rules
  - OpenCDISC Community V2.0
  - FDA Final Guidance on Study Data Standards
- Webinar Videos, Slides, Q&A available at Pinnacle 21 Blog: http://www.pinnacle21.net/blog/
- Test Data: CDISC sample datasets/define.xml at www.cdisc.org

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Experience Exchange

- Who has used OpenCDISC Community?
- Who has used the new tools besides the validator?
- Any general/specific comments you want to share?
- Any feedback on the implementation of SDTM (FDA) validation rules?
- Do you use the OpenCDISC auto-update function?
- Have you ever looked at the OpenCDISC Forum?
- Have you considered contributing to the Forum? Why? Why not?
- Have you ever used the send feedback function?