



What is JANUS?

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Data standards

- Consist of...
 - Data format (SDTM)
 - User guide
 - Units of measure
 - Controlled terminology
 - Clinical entity definitions
- Together, enabling...
 - Clear communications
 - Standard analyses
 - Standard tools
 - Reviewer training
 - Cross-study comparisons
 - Patient-level meta-analyses

All of these benefits are assisted by—and some of them depend upon—having all of these standardized datasets in one place...

Janus

...which (sticking with the mythology theme) is an Oracle database

SDTM-JANUS

	SDTM	JANUS
Observational data	Many domains	One table
Relationships	Several mechanisms	One mechanism
Constraints	Forgiving	Strict

Implementation

- FDA
 - Not yet requiring SDTM, but encouraging its use and getting it fairly often
 - Database exists, being used experimentally
 - Massive effort to develop as FDA-wide central repository for clinical and pre-clinical study data
 - Ahead of routine use, initiatives to convert legacy data in half a dozen therapeutic areas
- Others
 - caBIG (NCI), various pharma companies

Use for Diabetes

- FDA JANUS
 - Running
 - Some support
 - Secure access
- Non-FDA JANUS
 - Can replicate existing
 - Can be funded PRN
 - You control access
 - Answer questions you want
 - As much as you want