# CDISC: Getting started and preparing for what's next

Craig Dilks
Clinical DataFax Systems Inc.


## What is CDISC?

- CDISC
- SDTM
- CDASH
- Other CDISC standards

| Standard | Description |
|---|---|
| Study Data Tabulation Model (SDTM) | The content standard for regulatory submission of case report form data tabulations from clinical research studies. |
| Analysis Data Model (ADaM) | The content standard for regulatory submission of analysis datasets and associated files. |
| Operational Data Model (ODM) | The XML-based content and format standard for the acquisition, exchange, reporting or submission, and archival of case report form (CRF)-based clinical research data. |
| Laboratory Data Model (LAB) | The content and format standard for data transfer between clinical laboratories and study sponsors/CROs. |
| Case Report Tabulation Data Definition Specification (CRTDDS) – (define.xml) | The XML-based content and format standard referenced by the FDA as the specification for the data definitions for CDISC SDTM datasets. This standard, also known as define.xml, is an extension of the ODM. |
| Standard for Exchange of Nonclinical Data (SEND) | An extension of the SDTM standard for submission of data from pre-clinical studies. |
| Protocol Representation (PR) | The content and format standard supporting the interchange of clinical trial protocol information. This is a collaborative effort with Health Level Seven (HL7). |
| Trial Design Model (TDM) | The content standard that defines the structure for representing the planned sequence of events and the treatment plan of a trial. This is a subset of the SDTM and Protocol Representation. |
| Clinical Data Acquisition Standards Harmonization (CDASH) | A CDISC-led collaborative initiative to develop the content standard for a minimum set of data collection fields in case report forms. This standard is based upon the SDTM. |
| Terminology | The controlled standard vocabulary and code sets for the all CDISC models/standards. |
| Glossary | The CDISC dictionary of terms and their definitions, related to the electronic acquisition, exchange and reporting of clinical research information. Abbreviations and acronyms are also listed. |

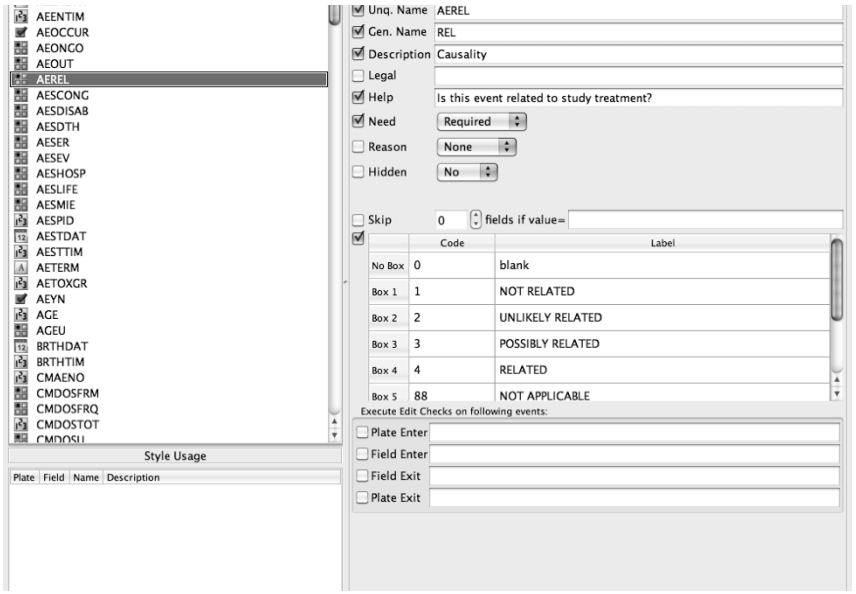
## What's Important?

- Understand intent of the CDISC standards
- Work with regulatory affairs within your organization to create electronic data collection systems that comply with the data submission requirements of the relevant regulatory agencies
- Minimize or eliminate recasting datasets to meet regulatory requirements after the data has been collected

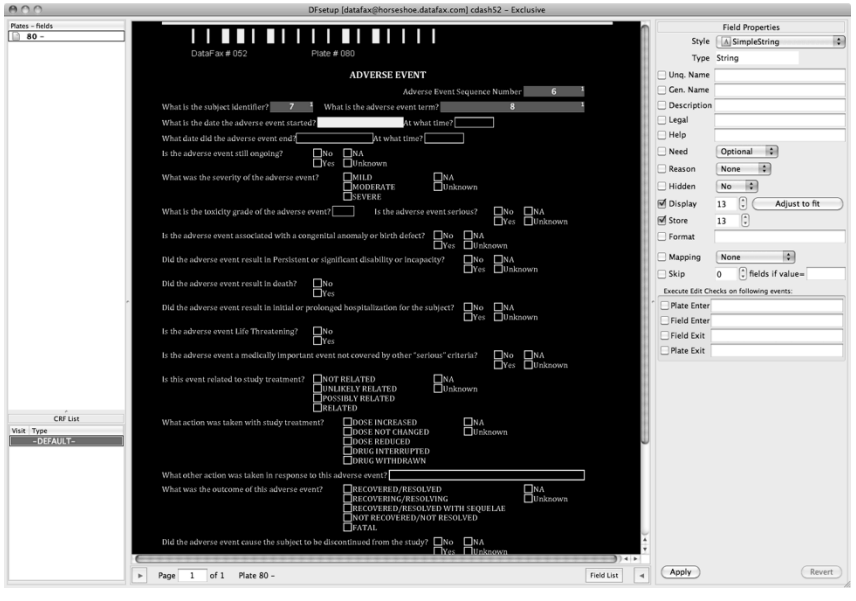
## Challenges

- DataFax 4 Setup tool starts with a layout
- CDISC CDASH/SDTM starts with a schema definition and controlled terminology independent of layout
- Extend DataFax concept of what a style is
- DataFax 5 – Database will include pre-defined variable definitions for the CDASH/SDTM domains
- User extensible (within the standard)

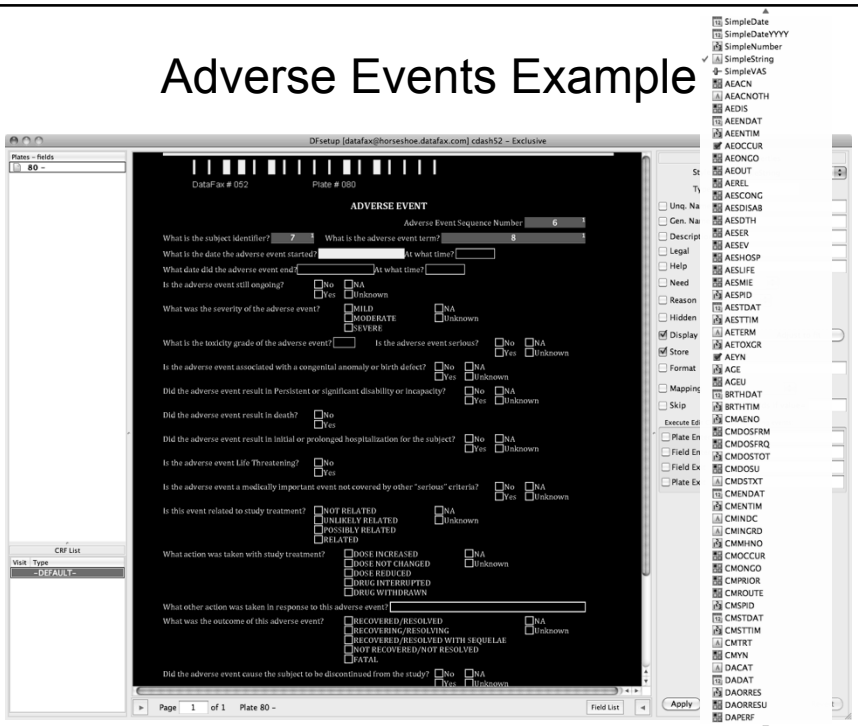
# DFsetup 4.2




# Adverse Events Example



## Adverse Events Example




## Exporting Data Today

- No solution for DataFax 4.x except for DFsas and SAS CDISC tools or custom programming (or both)
- Stick to CDASH/SDTM controlled terminology from the start to avoid remapping issues at submission preparation time

## DataFax 5 ODM Export

- Conform to ODM.xsd
- SDTM variable metadata (define.xml)
- CDISC Certified

## CDISC Monday BofF Summary