

## XS2DataFax

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### How to Minimize Input and Maximize Output

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## Main Project Goals

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- **Minimize Input**
  - Thus reducing the points of failure
  - Reducing the workload
- **Maximize Output**
  - CRF Layout
  - DataFax Setup Files & Test Data
  - Study Setup Documentation
  - SAS Jobfiles & Test Data
- **Standardize Procedures**

## A CRF Layout

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- Nothing more than a combination of
  - Plates
  - Visits
- Once the Plates & Visits are defined, the CRF Layout can be defined by adding Plates to each Visit
- Visits with identical Layouts can be copied
- Plate Optional/Required can be overruled

## Plate Characteristics

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- Plate # and Plate Label
- Can be Optional / Required
- Can have a Visit Date
- Plate Action, Do ICR, Visit # in Barcode
- Can be a Special Plate
  - Missed Visit / Early Termination / Internal Notes / Dummy Plate
- Can be a Standard Plate
  - Version of Standard Plate can be Study/Client dependent

## Visit Characteristics

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- Visit #, Visit Label and QC Label
- Can be any of the DF Visit Types
- Real Visit or DF Generated "Subvisit"
- If Scheduled (P,B,S,T,F,A,E,R,W) must have:  
Visit date on Plate\*/Field, Due & Overdue
- Can have a Missed Visit Plate\*
- Has two sort keys: Letter, Visit #

\* Updates Plate record

## System Generated Characteristics

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- System will generate Subvisits
- Each repetition of a Plate within a Visit will generate a Subvisit
- System will determine Subvisit type
  - Type 'r' for Subvisit with  $\geq 1$  Required Plates
  - Type 'O' for Subvisit with only Optional Plates
- System will assign Page #

## XS2DataFax & CRF Design

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- CRF-Layout report
- Plate Usage report
- Creates empty CRF Structure (option)
  - one Masterpage per Plate
  - one Bodypage per Page, sets Masterpage usage
- Adds Barcodes to CRF pages
- Prints Plateno and Seqno under Barcode for testing purposes
- List of Unique Plates to create DF Postscript file

## XS2DataFax & Company Standards

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- System Stores/Exports Information on
  - Standard Plates
  - Standard Lookup Tables
  - Standard Edit Checks
  - Links between Standard Lookup Tables and/or Standard Edit Checks to Standard Plates
- Using a Standard Plate in a Study will copy all relevant information to that Study

## XS2DataFax & Study Setup

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- CRF Layout is used to generate DataFax files
  - Pagemap
  - Visitmap
  - QC Note sort order
  - Plate Labels (wish list)
- System Stores/Exports information on
  - Missing Values
  - (Default) Centers Database
  - Conditional Plate Map
  - Edit Checks
  - Lookup Tables

## Study Setup Documentation

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- CDS has developed a set of 25 Study Setup Worksheets
- Covers all aspects of Study Setup
- Covers Testing of
  - Plates (Setup)
  - Edit Checks
  - Visit Map
  - QC Reporting

## XS2DataFax & Study Setup Documentation

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- Majority of required Study Setup information is already known in XS2DataFax
- Additional Information from DataFax Setup is imported into XS2DataFax
- Information from XS2DataFax is added to Image of each worksheet
- And Stored as .PDF file
  - Worksheet 3b
  - Worksheet 4
  - Worksheet 8a

## Study Setup & Testing

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- Visit Map Testing
  - Select Visits as Missing Visits
  - Select Pages as Missing Pages
  - Add QC Notes to remaining Pages of Remaining Visits
- XS2DataFax creates Test-Fax report
- Test Dataset is created and imported by DFimport
- Creates Worksheets, e.g. Worksheet 25b
- Documents DataFax Setup, e.g. Variable Details

## Other Features

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- Read DFtips and Annotates CRF
- Imports SAS Export Structure and creates SAS JobFiles
- Creates Unique Datasets to test SAS Export procedures

## Summary

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- XS2DataFax Facilitates and Structures
  - CRF Design
  - Study Setup & Testing
  - Study Setup Documentation
  - SAS Export & Testing