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# DataFax CRF Creation

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## Introduction

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Framemaker mostly used for DataFax CRF design

Cross-platform capability through MIF files

Allows Read/Write access from other programs

## Masters & Bodies

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### Master Pages & Body Pages

- Similar to Plates & CRF Pages
- Each Bodypage refers to a Masterpage
- Masterpage contains Study & Plate barcode; Bodypage contains Visit barcode
- One Masterpage for each Plate
- One Bodypage for each CRF page

## CRF File Usage

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'CRF File' serves multiple purposes:

- CRF
- Background image in Validation tool (and iDataFax)
- Documentation
  - Annotated CRF
  - CRF as Study documentation
  - CRF containing test data, etc

## Automated Handling

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- Inhouse developed XS2DataFax (XS) application assists in CRF File Handling
- CRF structure created in XS
  - Plates
  - Visits
  - Pages (which plate in which order in which visit)
- Study barcode and Plate/Visit barcode stored in 256/512 separate files

## Generate Default CRF

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- Once the CRF structure is known, XS generates default CRF:
  - MIF File with one Bodypage per CRF page
  - One masterpage per Plate
  - Reference on each Bodypage to Masterpage
  - Corresponding Barcode on each Master-/Bodypage
- For each Standard CRF page, XS copies content into Masterpage

## Scripted Unix/Windows processes

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- Program 'wrexec' is used to execute Unix scripts from Windows
- Parameters are passed from XS to scripts
- Process flow is handled by 'Press Enter when .... is finished'
- Allows to dynamically create scripts in Windows and execute in Unix

## Example 1: Barcode Testing

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### Final CRF imported into DataFax

- DFgs is invoked to convert .PDF to .TIFF
- DFinotify imports Final CRF into DataFax
- XS reads 'DFin.dat' and validates Plate/Visit information against pre-defined CRF information

Here is an example of a new data record from **DFin.dat**

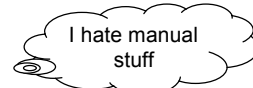
```
0|0|9145/0045001|099|4|1|0123||92/01/01|||
```

This record has new record status, has not yet been validated, contains the data from fax image \$(PAGE\_DIR)/9145/0045001, and belongs to study 99, plate 4, visit 1, and patient id 123.

## Example 2: 'User Friendly' CRF

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- XS creates .CSV file with Bookmarks
  - By Visit
  - By Plate
- Bookmark file needs to be manually merged with .PDF of CRF
- Creates User Friendly access to CRF (and another check)



## Example 3: Validation Tool Background Images

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### XS converts CRF file into '\_DFX' file

- Single Bodypage for each Masterpage
- Deletes all (confusing) information on Bodypages (Visit name, etc.)
- Deletes pagenumbers
- Replaces specific Visit Barcode (e.g. Visit 20) with generic Visit Barcode (e.g. Visit 0)
- Creates Bookmarked file

### Example 4: SAS Test data

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- XS automatically creates SAS test data

ASCII records formatted according to each Plate definition

- DFimport imports records into DataFAX
  - DFprintdb creates a CRF with testdata
  - Test CRF sorted by Plate & Visit
- CRF with test data can be used to validate SAS Output

### Example 5: Annotated CRF

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#### XS imports DFschema and DFtips

- Reads ‘\_DFX’ file and overlays Schema information on each CRF Page
- Annotation content can be adjusted:
  - DataFAX Annotated CRF (var#.generic name)
  - SAS Annotated CRF (dataset.variable)

## Example 6: Multi-language CRF

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DataFax ideally suited to handle data from multi-language studies: Multiple CRF versions, single Setup

Several ways to handle CRF Design:

- Framemaker: conditional text
- Framemaker: multiple files
- Indesign: single file / multiple layers

## Adobe Framemaker versus Indesign

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### Framemaker

- Single Masterpage per Bodypage

### Indesign

- Multiple Masterpages per page
- Multiple Layers per file
- Layers can be turned On/Off
- Masterpages and Layers are combined into a single 'view'

## Multi-language CRF in Indesign

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- Master pages to contain common information, e.g. Study Name, Study barcode, common layout
- Layer 1: boxes and DataFax fields
- Layer 2 – N: each language text

## Time for Questions

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