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## DataFax 4.0 Setup

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## New Features

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- Modular data collection
- Landscape forms
- TIME field type
- Workflow editor
- New barcode (3 of 9 with checksums)

## Concepts

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- **Code Group**  
Coding information which can be used by multiple data fields (e.g. YESNO)
- **Module**  
Basic unit of storage. Corresponds to SQL table
- **Field**  
Data storage unit. Corresponds to SQL column

## Concepts (con't)

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- **Plate**  
A data collection form. Same as in DataFax 3.x
- **ModuleRef**  
An instance of a module on a plate. Each module may appear multiple times on the same plate (e.g. conmeds)
- **FieldRef**  
An instance of a field in a module.

## Code Groups

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- First thing to decide on and to set up
- All choice/check coding is done via code groups
- Similar to styles on DataFax 3.x
- Example:
  - YESNO
    - Yes
    - No

## Modules

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- Basic data collection unit on a form
- Modules correspond to SQL tables
- Modules do not imply layout on a plate
- All user data fields live in modules
- Modules are reusable
- A special KEYS module holds key information along with patient initials

## Fields

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- Basic types:
  - Text
  - Fixed Point (e.g. numbers with a decimal point)
  - Integer
  - Date
  - Time
- What about choice/check/VAS?  
These are now display styles

## Plates

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- Plates are comprised of one or more modules
- A special KEYS module instance defines the keys and the patient initials on each form
- Can be either portrait or landscape

## ModuleRefs

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- Each module can appear multiple times on a plate.
- Each instance of a module on a plate is called a 'ModuleRef'
- Each ModuleRef contains all the fields that its parent module contains. Each of these fields is called a 'FieldRef'
- The ModuleRef name + the FieldRef name is used to identify the field on QC reports

## FieldRefs

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- FieldRefs are instances of fields
- A FieldRef has a display style which indicates how this field is to appear on the plate (text, choice, barcode)
- Not all fields in a module need to appear on the form. If they don't then they can be assigned default values

## Setup Procedures

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- Define code groups
- Examine forms and determine what the modules are going to be, *OR* design forms based on module libraries
- Create the modules and fields
- Import the plates
- Add appropriate modules to each plate (i.e. create ModuleRefs/FieldRefs)
- Assign boxes to the FieldRefs

## Setup Procedures (con't)

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- If a module repeats on a plate, simply cut and paste – the layout is copied as well
- Change the ModuleRef name to correspond to the label on the form for the QC report

## Repeating Modules

Clinical DataFax Systems, Inc.  
Demo Study

Example Blood Pressure Trial

Form 3

Patient Number
    Patient Initials  
 F M L

**MEDICAL HISTORY**

	No		Yes		Duration Years & Months	Currently on Treatment		Resolved and/or Controlled	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1. Hypertension	<input type="checkbox"/>	<input type="checkbox"/>	→	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Atrial Fibrillation	<input type="checkbox"/>	<input type="checkbox"/>	→	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Other Cardiac EG Arrhythmia	<input type="checkbox"/>	<input type="checkbox"/>	→	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Valvular Heart Disease	<input type="checkbox"/>	<input type="checkbox"/>	→	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## Workflow

- Replaces DF3.x validation levels
- Defines the path each CRF page will take – much more flexible
- Graphical user interface for design

## Workflow Objects

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- **Tasks**  
Represent activities that are performed on CRFs such as data entry
- **Anytime Tasks**  
Tasks that can be performed regardless of where the CRF is in workflow
- **Storage**  
In/Out boxes for tasks

## Workflow Objects (con't)

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- **Connections**  
Used to connect tasks and storage nodes  
Conditions determine whether a CRF passes from one node to another
  - Plates, visits, sites, subjects
  - Users who performed other tasks
  - Previously done tasks: isdone('review')
  - QC

## WorkFlow Objects (con't)

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- Task Node Editor
  - Repeatable task (does this task need to be repeated if a data change occurs?)
  - View only
  - DDE type (none, blank fields, ICR)
  - Set retrieval (single record, by fax, patient, available plates in visit)

## Workflow Creation

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- List tasks that need to be done
- Determine which CRFs need should participate in each task (plate, visit, etc)
- Determine order for tasks
- Add task nodes to workflow diagram
- Add storage nodes (in/out boxes) between task nodes
- Connect the dots
- Set up conditions

## Sites

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- The DF3.x centers database splits into four tables: sites, members, contactinfo and roles
- Allows for multiple people at a site
- Members can share site contact information or have their own
- Sites continue to own patient Ids

## Permissions

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- Implemented via database ROLES
- A user can belong to one or more roles
- Each role can cover permissions for one or more studies
- Hard access control – enforced by database for all tools not just DataFax

## Permissions (con't)

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- Soft access control – enforced by DataFax for things like access to certain reports, certain tools
- Implements those things the database can't natively do