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# DataFax 4 User Requirements

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## 1. Database Changes - SQL

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What Goes in The Database?

Everything!

- data
- QC notes
- CRF images
- schema information
- centers
- visit map
- user permissions
- computed study metrics
- etc.

## WHY SQL?

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- The database standard.
- Many people know it.
- Third party software works with it.
- Database integrity is built in and maintained by the database engine.
- Will provide retrieval capabilities beyond those available in DataFax 3.5.

## Which SQL Database W

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### PostgreSQL 7.1

- best in the free & open software camp

### Oracle 8i

- most popular in the big trusted commercial database camp

### MS-SQL 2000

- the best Microsoft has to offer

## 1. Database Changes

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### Normalized Data Records W

- Data modules (e.g. medications, AEs, etc.)
- Plates are composed of 1+ data modules

### New Keys W

- ID, Plate, Visit,
- Visit Repetition - repeat and interim assessments
- Plate Repetition - continuation pages at the same visit

### New Data Types W

- time, floating point, bar code

## 2. Field Level Meta Data

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Each field which does not have a data value may instead have:

- a missing value code, or
- a partial date

In addition to a data value, missing code or partial date each field may have:

- investigator comment (text field) W
- reason for value entered in the database (text field) W

### 3. QC Notes

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- multiple QCs per field W
- user defined problem codes W
- multi-field QCsW
  - each QC may be attached to more than 1 data field on one or more plates
- QC notes will show last date sent and age (days since creation) W

### 4. Setup Changes

#### Define People within Centers W

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- user defined roles (coordinator, PI, etc.)
- address, phone, fax, email, URL
- does this person receive a QC report, by what method (fax,email,URL), and for which patients?

## 4. Setup Changes

### SQL Database Permissions

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Permissions can be set for each data module.

The database can enforce the following:

Select - permission to export and view records

Insert\* - permission to add new records

Update\* - permission to modify data fields

Delete\* - permission to delete records

\*User permissions can be qualified (using database triggers) for add, delete and modify, but not for select.

## 4. Setup Changes

### New Permissions W

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Data & QC Modules:

- select<sup>1</sup>, insert<sup>1</sup>, update<sup>1</sup>, delete<sup>1</sup>
- by center: select<sup>3</sup>, insert<sup>2</sup>, update<sup>2</sup>, delete<sup>2</sup>
- permission to resolve QC notes<sup>2</sup>

<sup>1</sup> Can be enforced by PostgreSQL, ORACLE or MS-SQL.

<sup>2</sup> Can be enforced by the database using triggers

<sup>3</sup> Can only be implemented at the DataFax tool level.

## 4. Setup Changes New Permissions W

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### Plates: CRF pages and Data Records

- **build set (select)**
  - user must have select permission for 1+ modules in the plate
  - user will not see data for any prohibited modules
- **commit changes (insert,update)**
  - user must have insert/update permission on 1+ modules in the plate
  - user will not be able to enter or change data on prohibited modules
- **deleting CRFs and data records (delete)**
  - user must have delete permission on all modules to delete the CRF
  - user will not be able to delete data from any prohibited modules

## 4. Setup Changes DataFax User Roles W

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### Example Roles

data entry, data review, clinical review, safety

### Defining Roles

- database permissions
- tasks performed

### Benefits

- simplifies setup of individual permissions
- ensures consistency across all role members
- simplifies task coverage during moves, holidays

## 5. Work Flow Management

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### Defined Work Flow Tasks W

- Replaces validation levels 1-7.
- True work flow management including: user permissions, task ordering, task tracking, and avoidance of needless repetition of tasks.
- Status tool will show number of CRFs ready for each task.
- Documentation and tracking of tasks performed by each user.
- Clearer and more accurate work flow reports.

## 6. New Auditing Capabilities

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- **Data changes**
  - who, what, when, why
- **QC notes**
  - added, modified, resolved, deleted
- **Study setup changes w**
  - visit map, centers, etc.
  - CRF changes - plates and variables added, deleted, modified
- **User changes w**
  - added, removed, database and DataFax tool permissions
- **QC report history w**
  - who created it, what QC notes, when transmitted to centers

## 7. Validation Tool

### New Retrieval Capabilities w

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- by user who last validated the record
- by last task performed
- by QCs: status, problem type, etc.
- by QC report number
- by specified conditions involving fields from more than one plate

## 7. Validation Tool

### Double Data Entry w

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#### Performing DDE:

- build sets for DDE in the validation tool
- real time changes, 2nd reviewer wins

#### DDE tracking:

- which records, when, by whom

#### DDE reports:

- summary of what has been completed
- summary of changes made

## 7. Validation Tool

### Refax Processing w

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- Secondary records will not be stored in the database.
- Old values and previous CRF images are preserved in the audit tables.
- Will still be able to review prior images during duplicate resolution.
- A refaxed image will be saved even if it is not made the new primary copy of the CRF.

## 8. Standard Reports

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- Separation of content and format w
- Output: XML tagged content which can be formatted using XSLT w
- Allow new patient and visit identifiers
  - patient initials (as well as patient ID) w
  - visit date (as well as visit number) w
- Document Types: text, XML, PDF, HTML w
- Distribution:
  - by fax, email, URL w
  - any report (not just QC reports) w

## 9. Standard Clinical Trial Metrics

metrics common to all studies

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### Categories

- Center Tracking
- Patient Tracking
- Visit Tracking
- CRF Page Tracking

### Stored in Standard Database Tables

- metrics will be audited and accessible

### Tables will be Updated by

- database triggers where possible
- programs as needed

## 9. Center Tracking

TABLE: Center Performance Metrics W

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- **Center ID**
- **Activity**
  - date of first and last patient entered into the trial
  - number of patients screened, randomized, terminated
  - number of visits and CRF pages (primary and total)
- **Quality**
  - number of CRF pages with: resolved and unresolved QC notes
  - number of QC notes by: use(in/ex), resolved/unresolved
  - number of CRF pages refaxed 1, 2, 3, 4, 5+ times
- **Timeliness**
  - mean/median submission delay
  - mean/median days to QC resolution
  - age (days) of oldest QC note

## 9. Patient Tracking

TABLE: Patient Problem Management W

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- Patient ID
- Problem: Code, Date of Occurrence, Description
  - eligibility, compliance with treatment, patient follow-up, cointervention with a proscribed treatment, etc.
- Action: Code, Who, Due Date, Description
  - none, to be reviewed by adjudicated committee, contact family doctor for forwarding address, etc.
- Outcome: Code, Date of Outcome, Description
  - ongoing, resolved, etc.

## 9. Visit Tracking

TABLE: Reports/Assessments/Visits/Events W

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- Patient ID
- Visit and visit repetition number
- Visit Status
  - done, next scheduled visit, lost, overdue
- Visit Date
  - if done: date of report, assessment, visit or event
  - if next: scheduled visit date
- Processing dates
  - first and last fax (or other source) arrival
- Days overdue
- Days off schedule (if relevant: days early or late)
- Explanation
  - if lost: explanation code and explanation text

## 9. CRF Page Tracking

TABLE: Missing & Lost CRF Pages W

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- Patient ID
- Visit and visit repetition number
- Plate and plate repetition number
- Status: missing, lost
- Reason Code (if lost)
- Explanation (if lost)

## 10. Data Export Tools - DFexport w

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### Data Records

- created from a data module or study plate
- created by joining fields from 2+ modules across plates
- field level meta data: investigator comments, explanation

### Recoding

- replace nulls with missing codes and partial dates
- replace numeric codes with value labels

### Case Selection

- SQL where clauses

### Record Sorting

- SQL order by clauses

### Output Formats

- data records (delimited data fields as in 3.5)
- plain text patient listing (readable report with column titles)
- XML tagged output file

## 10. Data Export Tools - DFsas

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- We do not expect very many changes
- Normalization becomes retrieval from a specified module
- New case selection options using SQL where clauses w

## 11. Visit Map

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- Does anything need to change?
- New plate repetition key:
  - only used for optional, continuation pages
- New visit repetition key:
  - only used for unexpected, interim, optional visits
  - if a visit needs to be scheduled it gets a separate visit number

## 12. Edit Check Language Changes

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### Variable References need more information

There may be 2+ instances of a module on the page.

More keys: ID,Visit,Plate + VisitRep,PlateRep

### New Variable References Syntax W

module[instance].varname[ID,visit,visitrep,plate,platerep]

Examples:

drugname ... variable drugname in the current module.

drugs[1].drugname ... variable drugname in the 1st instance of the drugs module on the current data record.

drugs[1].drugname[,0,0,5,0] ... variable drugname in the 1st instance of the drugs module for same patient at visit 0, visitrep 0 on plate 5, platerep 0.

## 12. Edit Check Language Changes

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### dfaddqc

QC notes may reference more than one data field.

### New dfaddqc Syntax W

Allow the location of QC notes to be a variable list.

First variable in the list is the QC owner.

Example:

```
dfaddqc( {age,birthdt}, 33, "", 1, 2, "" ) ;
```

## 12. Edit Check Language Changes

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### Relative Variable References: e.g. @(T-1)

Useful: allows the creation of generic edit checks.

Dangerous: edit checks break if fields change position.

### EC Parameter List W

Allow edit checks to name data fields in a parameter list.

Example:

Check consistency of "if other specify" type questions.

ECspecify(raceoth,race,4)

ECspecify(surgoth,surg,9)

## 12. Edit Check Language Changes

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Should C style syntax be changed?

C style:

```
if( dose==500 ) {
```

```
  x = 2 ;
```

```
  dfaddqc(...) ;
```

```
  dferror("...") ;
```

```
}
```

New style: W

Visual Basic ?

SAS ?

Other ?

## 13. OTHER

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- Windows (in addition to UNIX) w
- Linux?
- Landscape CRFs?
- Native Resolution Images w
- ICR improvements w
- Defined Forms (a collection of plates)?
- Screening IDs?

## 13. Screening IDs

Are separate screening and patient IDs necessary?

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If yes, what linkage is required and how is it done:

- on QC Reports
- when retrieving records by Patient ID
- in programs/reports that process data by patient
- when creating patient listings
- in audit trail reports
- in edit checks
- when exporting data for other systems
- when using DFsas to create a SAS data set

## 14. Beyond DataFax 4.0

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### Collection of Web CRFs w

- hybrid solution allowing both fax and web CRFs in the same study

### Study Web Site Manager w

- tools for creating and managing a DataFax study web site

### DFvalidate w

- session download for offline review