Focus is New Backend

- Client tools stay largely the same
- Migration path from 3.8.1+
- Transitional tools
Motivation

- Modern platform for future
- Increase in limits
- Single source of setup information
- Much faster audit history
- Better concurrency
- Full transactional capability
- Better integrity
- CDISC compatibility

SQL database

- PostgreSQL
- Fully transactional
- Referential integrity
- Multithreaded
- Enterprise features like Replication
- Everything moves into the database (images, setup, data)
- Each study lives in its own schema
## Benefits

- No more resorting at server shutdown
- Data is always in sorted state
  - faster searches
- Hyper-normalized data structure removes need for database restructuring
- Uncommitted changes are automatically rolled back in event of a crash
- Backups can be done with a consistent view of the database

## SQL Permissions

- SQL database enforces Read/Modify/Delete permissions at Table level
- Admin can create customized views into data and grant permission on tables for 3rd party tools
- DataFax triggers prevent unauthorized modification or deletion of audit trail data
- DataFax provided functions for evaluating read/modify/write permissions at record level for SQL views
Audit Trail

- Data, Setup, User/Role information is audited
- Records timestamp as well as session that made change
- Each record stores when it became current and when it ceased to be current
- Easy to generate a view of what the database contained at an arbitrary point in time

Hyper-normalized Data

- Each data field is a row in database
  - vs. existing records being all fields on plate
- Rapid record history
- Each data field is attributed to who changed it and when
- No plate restructuring necessary
  - Plates assembled in real-time
  - No performance impact in testing to date
Example

<table>
<thead>
<tr>
<th>KEYREF</th>
<th>ITEMID</th>
<th>EFF_TIME</th>
<th>EFF_SESS</th>
<th>EXP_TIME</th>
<th>EXP_SESS</th>
<th>VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1234</td>
<td>29</td>
<td>2012/03/07 13:32:05.56</td>
<td>A892-1232-4</td>
<td>Infinity</td>
<td>A892-1232-4</td>
<td>DEF</td>
</tr>
<tr>
<td>1234</td>
<td>29</td>
<td>2011/12/22 09:31:47.81</td>
<td>F751-9521-A</td>
<td>2012/03/07 13:32:05.56</td>
<td>A892-1232-4</td>
<td>ABC</td>
</tr>
<tr>
<td>1234</td>
<td>35</td>
<td>2012/03/07 13:32:05.56</td>
<td>A892-1232-4</td>
<td>Infinity</td>
<td>2012/03/07 13:32:05.56</td>
<td>Headache</td>
</tr>
<tr>
<td>9451</td>
<td>29</td>
<td>2011/12/29 15:11:08.11</td>
<td>8A7D-881A-0</td>
<td>Infinity</td>
<td>A892-1232-4</td>
<td>GHI</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SESSION</th>
<th>USERID</th>
<th>LOGIN</th>
<th>LOGOFF</th>
<th>TOOL</th>
<th>LOCATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>F751-9521-A</td>
<td>martin</td>
<td>2011/12/22 08:37:32.21</td>
<td>2011/12/22 17:03:56.61</td>
<td>iDataFax</td>
<td>192.168.3.1</td>
</tr>
<tr>
<td>8A7D-881A-0</td>
<td>david</td>
<td>2011/12/29 09:08:41.41</td>
<td>2011/12/29 18:01:38.01</td>
<td>iDataFax</td>
<td>192.168.2.10</td>
</tr>
<tr>
<td>A892-1232-4</td>
<td>martin</td>
<td>2012/03/07 13:29:01.39</td>
<td></td>
<td>iDataFax</td>
<td>192.168.3.9</td>
</tr>
</tbody>
</table>

New Keys

- Addition of Visit repetitions and Plate repetitions
- Visit repetitions can be used instead of visit ranges
- CDISC related
Modules

- Group a series of fields on a page
- The module can be placed on the page multiple times
- Aids in normalization
- CDISC also uses this
- Module libraries (e.g. CDISC domains)

Modules Example

<table>
<thead>
<tr>
<th>Patient Number</th>
<th>Patient Initials</th>
<th>MEDICAL HISTORY</th>
<th>Currently on Treatment</th>
<th>Duration Years &amp; Months</th>
<th>Resolved and/or Controlled</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1. Hypertension</td>
<td>No</td>
<td>10</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Atrial Fibrillation</td>
<td>Yes</td>
<td>6</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Other Cardiac Arrhythmia</td>
<td>No</td>
<td>0</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Valvular Heart Disease</td>
<td>No</td>
<td>0</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5. Myocardial Infarction</td>
<td>No</td>
<td>0</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6. Kidney Disease</td>
<td>No</td>
<td>0</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7. Diabetes</td>
<td>Yes</td>
<td>10</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Form 3

Example Blood Pressure Trial

Plate #003

Visit #001

DataFax #203
Modules

- Each module gets a name
- Define fields for Condition, Yes/No, Duration, Treatment and Resolved
- The module can then be placed on the plate multiple times

<table>
<thead>
<tr>
<th></th>
<th>No</th>
<th>Yes</th>
<th>Duration</th>
<th>Currently on Treatment</th>
<th>Resolved and/or Controlled</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Hypertension</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

Edit Check Changes

- Variable names (e.g. DURATION) refer to fields in the current module by default
- References to fields in other modules require addition of module notation
  - MEDHIST[1].DURATION
Limits

• Number of studies increased
• Number of visits increased
• Number of plates increased

Barcode

• Existing barcode limited to 255 studies, 511 plates and 511 visits
• Investigating using 2-D barcode like QR codes which can encode much more data
• Includes error correction features
Images and other Media

- Secondary records completely gone
  - We still keep track of previous images
  - Duplicate primaries no longer possible
- MEDIA table tracks images and other types of information (audio, video, documents)

API

- Currently DataFax is connection based
  - Locks are held by the connection
  - Network connection remains open for the duration of the client tool session
- Will move to session based
  - Client tool opens/closes network sessions as required
- Allows for Web interfaces, mobile clients
- Move to XML or JSON based API
- Foundation to build on
DEMO