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# DataFax and Oracle Clinical: A Toolkit for Clinical Study Data Management

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## Outline

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- What We Did
- Why We Did It
- Background
- System Description
- Work Steps
- Pros & Cons
- Conclusion

## What We Did

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- Selected an Upcoming Clinical Study
- Implemented
  - Oracle Clinical Database
  - DataFax Data Management System
- Extract Data from DataFax
- Load the Extracted Data into Oracle Clinical

## Why We Did It

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- Interest in Remote Data Entry
- Combine Our Two Flagship Systems
  - DataFax - User Interface
  - Oracle Clinical - Data Storage
- Maintain Data in Single System

## Background: Medtronic Overview

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Cardiac Rhythm Management  
Clinical & Outcomes Research  
Information Systems

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## Background: A Plethora of Data Management Tools

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- SIR
- MicroSoft Access
- ClinTrial
- Custom Built PowerBuilder/Oracle
- Other Custom Built Applications
- Oracle Clinical
- DataFax

## Background: What is Oracle Clinical?

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- Oracle Solution for the Pharmaceutical Industry
- Capabilities
  - Data Storage (Long Skinny Table)
  - Data Entry
  - Data Validation
  - Data Access

## Background: Interest in Remote Data Capture

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- Pen-based Trials
- Asynchronous Custom Builds
  - SAS
  - RDBMS
- Web
- DataFax

## Background: Pacing Study

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- Randomized
- Worldwide Clinical
  - US
  - Canada
  - Europe/Africa/Middle East
- Investigate Efficacy of Pacing Features

## System Description: What New Tools Were Used?

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- C Shell Scripts
- Unix Crontab
- Oracle Tools
  - SQL\*Load
  - SQL+
- E\*Gate
- DOS Scripts
- ftp
- Macro Express

## Work Step: Build the Data Management Systems

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- DataFax
  - Framemaker
  - Objects
  - 78 Plates
  - QC Checks . . .
- Oracle Clinical
  - Qs, DVGs, QGs
  - Data Entry System
  - Data Validation System . . .

## Work Step: DFexport

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- Process
  - CRF-Specific Scripts

```
/opt/datafax/bin/DFexport.rnc -w -s primary -v "1-7" -p -V 3 45 15 plate15.1mofollowup
/opt/datafax/bin/DFexport.rnc -w -s primary -v "1-7" -p -V 3 45 16 plate16.1mofollowup
/opt/datafax/bin/DFexport.rnc -w -s primary -v "1-7" -p -V 3 45 58 plate58.1mofollowup
/opt/datafax/bin/DFexport.rnc -w -s primary -v "1-7" -p -V 3 45 17 plate17.1mofollowup
/opt/datafax/bin/DFexport.rnc -w -s primary -v "1-7" -p -V 3 45 18 plate18.1mofollowup
/opt/datafax/bin/DFexport.rnc -w -s primary -v "1-7" -p -V 3 45 19 plate19.1mofollowup
/opt/datafax/bin/DFexport.rnc -w -s primary -v "1-7" -p -V 3 45 20 plate20.1mofollowup
/opt/datafax/bin/DFexport.rnc -w -s primary -v "1-7" -p -V 3 45 21 plate21.1mofollowup
/opt/datafax/bin/DFexport.rnc -w -s primary -v "1-7" -p -V 3 45 72 plate72.1mofollowup
```

### – Master Script

```
echo " "
echo "This Script Extracts Data from DataFax. No User Action is Required"
echo " "
echo "Removing Plate-specific Files from Previous Execution . . ."
cd /usr/uidwal/dfexport/at500pnev/
/usr/bin/rm -f /usr/uidwal/dfexport/at500pnev/plate*.*
echo " "
echo "Exporting 1 Month Follow-up CRF Data. . ."
1month_plates
echo "Exporting Death CRF Data . . ."
death_plates
echo "Exporting Implant CRF Data . . ."
implant_plates
```

## Work Step: DFexport

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- Mechanics
  - Crontab M-F Evening
  - Logs Emailed for Review
  - Assessment: Smooth & Seamless

## Work Step: Intermediate Oracle Tables

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- Process
  - Design 78+ Oracle Tables

```
SQL> describe enrollment9;
-----
Name                               Null?    Type
-----
DFSTATUS9                           VARCHAR2(20)
DFWALID9                             VARCHAR2(20)
DFRASTER9                            VARCHAR2(12)
DFSTUDY9                             VARCHAR2(20)
DFPLATE9                             VARCHAR2(20)
DFSEQ9                               VARCHAR2(20)
ID_009                               VARCHAR2(20)
QCFREP_009                          VARCHAR2(20)
ICD_009                              VARCHAR2(20)
CORR_009                             VARCHAR2(200)
ASIGN_009                            VARCHAR2(20)
APRINT_009                           VARCHAR2(25)
SIGINT_009                           DATE
CNAME_009                            VARCHAR2(25)
ASNO_009                             VARCHAR2(20)
DFSCREENSTAT9                       VARCHAR2(20)
DFCREATE9                            VARCHAR2(17)
DFMODIFY                             VARCHAR2(17)
STUDY_ID                             VARCHAR2(20)
```



## Work Step: Conform Data in the Intermediate Tables to OC Format

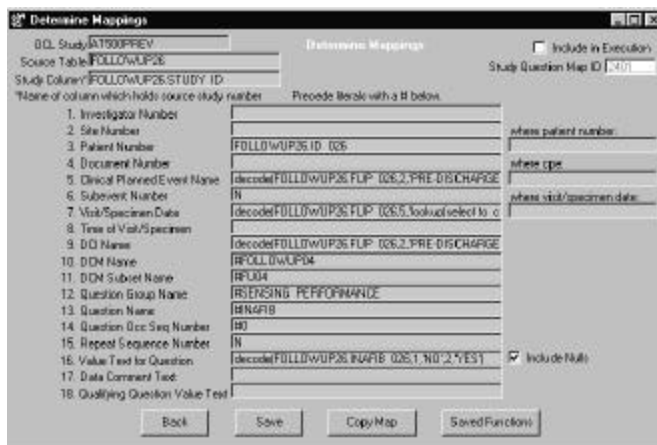
- Process

- E\*Gate ‘... an easy-to-use tool that rapidly and efficiently batch loads your data into Oracle Clinical ...’
- E\*Gate Scripts Must Account for the Fields of 19

investigator	0018 char	investigator	O
site	1120 char	site	O
patient	2528 char	patient	M
document number	3120 char	document # (does blank for both hand)	O*
clin_plan_event_name	3120 char	clinical planned event	M
subevent number	3132 num	subevent number	O
dtl_dtm	7380 char	Site date (YYYYMMDD)	M
dtl_tm	8180 char	Site of visit (HHMMSS)	O
dtl_name	8210 char	DCI name	M
dtl_sname	11710 char	DCI name	M
dtl_ssubct_name	13310 char	DCI subset name	M
dtl_qgroupid_name	14010 char	question group name	O
dtl_qname_name	17010 char	question name	M
dtl_qseq_num	18110 num	question occurrence sequence number	M
report_seq	18110 num	report sequence number	M
value_text*	18200 char	value text for the question	O
data_comment_text	24000 char	data comment text	O
qualifying_value	18200 char	qualifying question value text, if applicable	O**
work	60700 char	work	O

## Work Step: Conform Data in the Intermediate Tables to OC Format

- E\*Gate Map Construction
- 1211 Maps Created





## Work Step: Conform Data in the Intermediate Tables to OC

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- **Mechanics**

- Execute E\*Gate Maps M-F using Macro Express
- Assessment: Somewhat Rough & not without incident
  - Writing/Maintaining E\*Gate maps tedious, particularly decodes
  - Validation time consuming
  - Recording of Macros tedious
  - Macro Express is non event driven thus as data grew so did timing issues
  - Macro Express eventually abandoned for comprehensive map execution

## Work Step: Oracle Clinical Batch Data Loader

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- **Process**

- Pre-requisites
  - Define Investigators
  - Define & Manage Patient Positions
- Aggregate Files to be Loaded
- Delete & Refresh Required
- Conduct Load
- Monitor Load Logs

## Work Step: Oracle Clinical Batch Data Loader

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- **Mechanics**
  - Macro Express M-F
  - Assessment - Fairly Rough & with Incidents
    - Macro Express abandoned, performed *ad hoc* as files grew in size
    - Required close monitoring
    - Close Contact with DBAs required
      - Oracle Resource planning required
      - Rollback Segment Issue

## Work Step: System Validation

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- **Validation Required:**
  - DataFax Data Management System
  - Oracle Clinical Database
  - Data Transfer System
- **Validation Process:**
  - Test Plan
  - Plan Approval
  - Execution & Exceptions/Resolution

## Pros

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- Used Standard Tools
- Process developed for loading externally collected data
  - device performance data
- Intermediate Oracle Tables very useful
- Learned vast amounts about internals of systems we use
- Close collaboration with study team

## Cons

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- Duplicity of Effort
  - Data Entry
  - Data Storage
  - Data Validation
  - System Validation
  - Centers Database
- European Colleagues did not participate

## Cons

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- Staff Training/Resources
- Coordination with DBAs
- Cascade
  - Changes in CRFs resulted in changes to:
    - DataFax
    - Oracle Clinical
    - E\*Gate
    - Intermediate Oracle tables

## Conclusion

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- Would we do this again?