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# Integration Case Study: Advanced Randomization, Web-Based Tools, and DataFax

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# Abstract

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- Real-time (baseline correcting) randomization paradigms are not a new idea
- One researcher client of the Clinical Research Unit recently co-authored a paper on a method that lies somewhere between full minimization and a coin toss
- This method is known as minimum sufficient total balance randomization
  - <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3474894/>
- Naturally, they wanted us to implement it the day after publication release in a large international Stroke RCT
- This presentation is an integration case study for the first trial using this randomization paradigm

# Challenge

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- Randomize patients using novel methodology, in real time, on the web/mobile phones, etc.
- Ensure that DataFax remains the master data source for study data
- Provide real-time randomization assignment so clinical actions can continue without unnecessary delay
- Ensure algorithm has access to most correct data for any subsequent randomization

# Tools Involved

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- DataFax 4.3.1
  - Standard install on RHEL running on virtualized infrastructure
  - Dumping hourly to MySQL using DFSQLLoad controlled by a python wrapper called by a CRON Job
- Custom web-based study management tool
  - Django/Python/MySQL Web Application developed internally running on virtualized infrastructure

# Randomization Paradigm

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- Variable Bias, Coin Toss Randomization
  - 8 baseline variables
  - Mix of continuous and categorical data elements
  - Each variable tested in real time to see if inclusion in one treatment over the other would result in baseline imbalance
  - If test is positive, record a vote supporting randomization bias toward balanced group allocation
  - If sufficient votes recorded, bias coin by pre-determined amount (60/40 vs 50/50 vs 40/60, for example)

# Details of the DataFax Study

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- 60 plates/25 sites/7 countries
- Currently randomizing ahead of expectations
- Randomization plate is used as primary record creation trigger
- Otherwise unremarkable as far as DataFax feature use is concerned

# Details of the Study Manager Application

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- Features
  - Window reminders
  - Document management
  - Payment notification
  - Recruitment monitoring
- **Randomization**

# Randomization Workflow

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- Go to study website, sign in, user role limits which sites you can randomize patients to, fill out baseline form, and click Randomize
- A modal window will show you your selections; if happy, choose accept
- User will then see randomization

*[live demo]*

# Randomizer > DataFax Inbound Integration

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- Data Inbound
  - We chose to use email-based pdf submission over the simpler workflow of direct data insertion
    - Reason: Ensure that randomization data management is equivalent in process to other forms and provide “paper” copy of randomization form for audit purposes
    - We still use a change tracking layer ‘django-reversion’ in randomization site data for overzealous auditors

# DataFax > Randomizer Outbound Integration

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- Data Outbound
  - Given the possibility of data entry error into randomization site or OCR/fax processing error at DataFax layer, the Randomization plate is subject to full QC and monitoring processes
  - Should any of these processes introduce change to randomization data, randomization system is configured to pull most recent DataFax data prior to any new randomization assignment
  - This ensures that each subsequent randomization uses the best data available and that any bias introduced due to incorrect randomization data has the potential to be minimized as new randomizations come in

# Questions & Acknowledgements

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