Integrating Two Databases for Re-Consent Tracking in a Large Randomized Clinical Trial

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Overview

- Background
- The problem: tracking re-consent
- iDataFax as a site management tool
  - How it works
  - What we collect
  - Pros & cons
  - Integration with the clinical database
- Tracking re-consent: our solution
- What have we learned?
- Looking to the future
About PHRI

To conduct trans-disciplinary research to improve major health outcomes in common and neglected conditions affecting Canadians and populations across the world. – PHRI Mission Statement

FAST FACTS

- 35 Researchers
- 250 Research Team
- 200,000 sq. ft. Research Space
- 34 Research Fellows
- 1,250 Published Papers
- 80 Global Trials
- 1,500 Centres
- 1,000,000 Enrolled Participants
About the Study

- Large, simple randomized clinical trial with major cardiovascular outcomes
  - 30,000 pts, 600 sites, 30 countries
- Most sites and site management coordinators (SMCs) are experienced in trials, including other PHRI studies
- Reduced on-site monitoring, focus on central and remote monitoring – beyond monitoring
- Two iDataFax databases:
  - Clinical Study Database: Clinical data management
  - Site Essential Document Database: Site management and monitoring
Beyond Monitoring: The Risk-Based Approach

- Conducting efficient, effective, high-quality research
  - Sensible guidelines for the conduct of clinical trials
  - Transcelerate BioPharma
  - Clinical Trials Transformation Initiative (CTTI)
  - ICH E6(R2) GCP Addendum – June 2015

- Not just reducing the frequency of monitoring visits or how many source data points are verified
- Build quality into the protocol and study oversight
- Focus on the risks that matter
- Use innovative methods to identify the risks
The Problem: Tracking Re-Consent

Problem:
- Multiple consent form revisions: one global, some local

Requirements:
- Ensure that participants are informed of updated information about the study and IP in a timely manner
- Identify participants who did not re-consent at the next visit after ethics approval of the consent amendment
- Minimize additional efforts by SMCs and site staff

How do we monitor re-consent remotely?
iDataFax as a Site Management Tool

PHRI Site Management

- Essential document collection and review
- Monitoring site performance and quality
- On site monitoring, SDV, SDR, action items
- Site identification and activation
- Remote and central monitoring and oversight
How It Works
How It Works (continued)

Site-Specific Essential Documents
- 1: Confidentiality Agreement
- 2: Site Suitability Assessment
- 3: Site Information

Personnel-Specific Essential Documents
- 10: Personnel Specific
- 90: Personnel Info Sheet
What We Collect

**Participant Specific**
- Source documents for remote SDV
- Consent verification
- Protocol deviations

**Site-Specific**
- Confidentiality agreement
- Site suitability assessment
- Ethics approval
- Monitoring reports
- Action items
- Safety reporting
- Site SOPs

**Personnel-Specific**
- Contact Info
- Role delegation
- CV
- Medical license
- Financial disclosure
- GCP training
- Debarment check

**National Lead / Country-Specific**
- Summary of qualifications
- CV
- GCP training
### Pros and Cons

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<th><strong>Pros</strong></th>
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| - Familiar system to PHRI staff, SMCs, and sites  
- Save time developing and troubleshooting a new system  
- Standard and custom reports  
- Integration with the clinical database  
- Accessible by all parties for submission, entry, review, oversight  
- Edit checks help ensure the quality of the information  
- Better than relying on paper and manual spreadsheets | - Not designed for this type of data collection  
- Not intended for hierarchical collection of data – country / site / personnel  
- Variation between countries  
- Readability of documents can be poor  
- Complexity of access levels by site, SMC, sponsor, etc.  
- Integration between databases is not seamless |
Uniting the Site-Essential Documentation and Clinical Study Databases

- Two databases – one purpose
  - Patient safety, study integrity, data quality
- The usual:
  - Joint custom reports on site status and performance
- The challenge:
  - Using site-level information to identify missing or inconsistent participant-level data
- The tools:
  - SAS and library file
  - Batch MPQC edit check cron job
Tracking Re-Consent: Step 1

- Problem: Consent form revisions mid-trial. We need a way to track participant re-consent
Tracking Re-Consent: Step 2

- We need a way to query participants for missing consent forms.
Tracking Re-Consent: The Solution
What Have We Learned?

- Using iDataFax for site management has given us opportunities for implementing a risk-based approach that may have been more difficult/complex in another system.

- DataFax is not an ideal system for the purpose, but has its advantages!

- Can future versions of DataFax be more adaptable to this kind of use?
Looking to the Future

- Easier to use for monitors and sites
- Flexibility for multi-site documentation
- More integration between systems
- Enhanced tools for risk-based site management
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Questions?