
Using DataFax's Unique Capabilities in a Global Phase 3 Study

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This Study's Unusual Aspects

- **Sponsor: Large Biotechnology Company**
 - Researching new therapy for a debilitating CNS disease
 - Primary Efficacy Endpoint defined by time to a “symptomatic relapse” after exposure to therapy
 - Symptomatic Relapse is defined as: new or recurrent symptoms not associated with fever or infection that have lasted at least 24 hours and are accompanied by new objective findings by the physician

Unusual Aspects Continued

- Definition of a “symptomatic relapse” has to be determined by an adjudication committee

- Adjudication committee
 - Composed of 3 expert physicians
 - The adjudication must be made *no less than 14 days* after patient reports symptoms
 - Patient and study drug are immediately discontinued if patient has a confirmed relapse

- 30 Countries, 400 sites Participating, >2000 patients

Data Management Specifics

- Before ACI was contacted for this study:
 - A Major CRO was selected for global study management and monitoring
 - Oracle Clinical Data Management system was selected for entry and query management for all CRFs
 - What does DataFax offer for this study that OC can't offer using either Paper or eDC?

OC Challenges:

- A 3 part NCR process was chosen for data collection
 - Monitoring
 - Data Entry
 - 14 day timeline
 - EDC – not an option
- “Oh.. BTW...The relapse data to be adjudicated is on multiple source paper worksheets, not CRFs and we anticipate thousands of patient relapses during the treatment and follow-up phases.... So.. Do you have any ideas how we can do this?”

So... ACI's review of Sponsor Needs

- You (Mr. Sponsor) need a system and process that can:
 - Rapidly receive and convey data from sites to adjudication committee
 - Rapidly receive and convey data from adjudication committee back to sites
 - Tracking of each individual source worksheet
 - Checking if the data contains enough info for committee to determine a relapse

Sponsor needs continued..

- In short, all this information collected, tracked, collated and rapidly provided to 3 “world renowned academic medical experts”* (anywhere they happen to be) so they can :
 - review the data
 - cast a vote on whether they concur or disagree that the patient actually experienced a disease relapse.

Note: “World renowned academic medical experts” can often be a polite term for:

Difficult, arrogant, aloof, grumpy, inaccessible and computer illiterate.

Sponsor needs continued..

- You want ACI to:
 - collect and tally the 3 votes from the committee for each disease relapse
 - immediately notify the treating physician at the site (anywhere in the world) of the committee’s decision.
 - Database the individual votes and the aggregate decision of the committee along with all the patient information.
- And you want this entire process to be completed in less than 14 days.
- Uh... Ok. Sure...we have a an idea...

This looks like a job for....



We just have one question:

- (ACI) “Can we add a barcode and patient identifier to the top of the source worksheets that are provided to the site?”

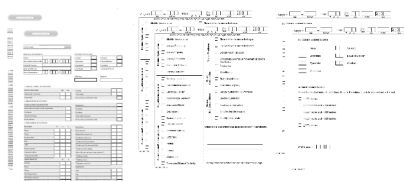
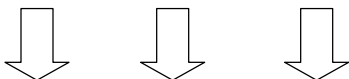
(Sponsor) “Yes, you can add a barcode and ID...Will that help?”



(ACI)...uh...yes

The Plan

- Step One: Add a DataFax Barcode and patient identifier to each source worksheet



That was



The Plan continued..

- Print and ship Bar-coded source worksheets to 400 sites around the world

That was



- Create DataFax Voting Forms for the expert members of the adjudication committee

That was



The Plan continued..

- Create a secure web portal where the collected patient disease relapse forms can be posted.

That was



- Add the ability to immediately notify members of the voting committee

That was



- Enable the ability for the expert members to cast their votes either through fax or electronic form

That was



The Plan continued..

- Ability to notify the patient's treating physicians of the committee's decision.

That was




- Getting all the technology to work as planned....

That was




Challenges

- Getting toll free numbers for certain sites around the world

That was 


Challenges

- Getting the sites around the world to correctly complete patient relapse source worksheets (*in the time allotted*)

That was 

Challenges Continued

- Getting the “world renowned medical experts” (*in the time allotted*) to review the patient disease relapse information and cast their vote...

That was  hard

Solutions

- Better training
- Process improvement
- Better communication

Result

- Having the sponsor award us a *Second Global Study with a similar adjudication committee process because they thought our source collection process using DataFax was great...*

.....Priceless!!