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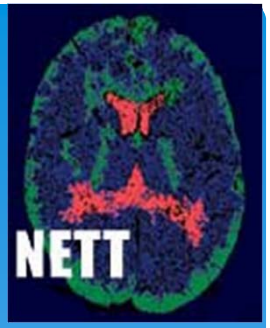

Strategies for Trial Operational Error Prevention

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Consequences of errors

* Can compromise subject safety
* Can negatively effect the study results
* Can effect the standard of care of thousands of patients

Capturing operational errors

* Define errors to be captured at study start
* Capture should be consistent
* Capture should be derived from the data

Critical operational errors

* Eligibility
* Randomization
* Treatment administration
* Data collection

Preventing operational errors, in general

* Keep it simple!
* Focus on safety and outcomes
* Protocol must be consistent and clear
* Minimize efforts at the site
* Base study procedures on site procedures
* Pilot test procedures

Preventing operational errors, in general

* Back up plans
* Tool box: Manual of Procedures, Standard Operating Procedures, Training
* 24 hour hotline support
* Primary SC support
* Immediate feedback
* Network of experienced sites

Preventing informed consent errors

* Prevention is critical in terms of ethics
* Site education
* 100% monitoring of ICs

Preventing eligibility errors

* Don’t let pressure to recruit/budget constraints compromise your science
* Require evidence of eligibility prior to randomization
* Collect the raw data, Check the math
* Define EIC based upon version of protocol approved at site.

Preventing randomization errors

* Brief user instructions
* Clear definition of time of randomization
* Centralized emergency randomization plan
* Matching placebo
* Clear indication of treatment assignment

Preventing randomization errors

* Explain that randomization is irreversible
* Ensure study drug accountability is accurate
* Proper user permission management
* Re-validate randomization procedures, after changes

Preventing study drug administration errors

* Pharmacy manual
* Proof of randomization assignment
* Double check the Pharmacy
* Real time reminders

Preventing data collection errors

* Prevent bias
* Intuitive CRFs
* Data validation checks
* Clearly defined visits
* Streamlined data collection
* Certification
* Allow proxy data, when appropriate
* Withdrawal of consent vs withdrawal from tx

Summary

* Keep it simple
* Plan ahead
* If it can go wrong, it will

Questions?