Opening the Window on Data Transparency in Clinical Research

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May 19, 2014

Outline

- Collaboration between Rho and ITN Bioinformatics
- Timing for release of data
- Challenges with early release of data

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Collaboration

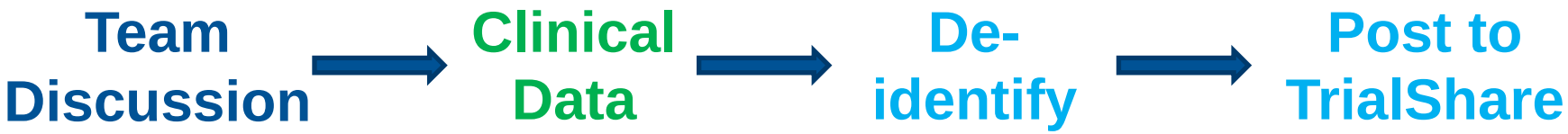
Rho is the SDCC for ITN

- Collect and analyze all clinical data

ITN Bioinformatics Group

- Integrates mechanistic and clinical data
- Manages TrialShare

General Workflow:



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Timing of Data Release

Manuscript

- Released at publication
- Prior to end of study
- Exception for blinded trials
- Analysis datasets
- Documentation for variable derivations

End of Study

- Released after final clinical study report submitted
- Clinical and analysis datasets
- Annotated case report forms

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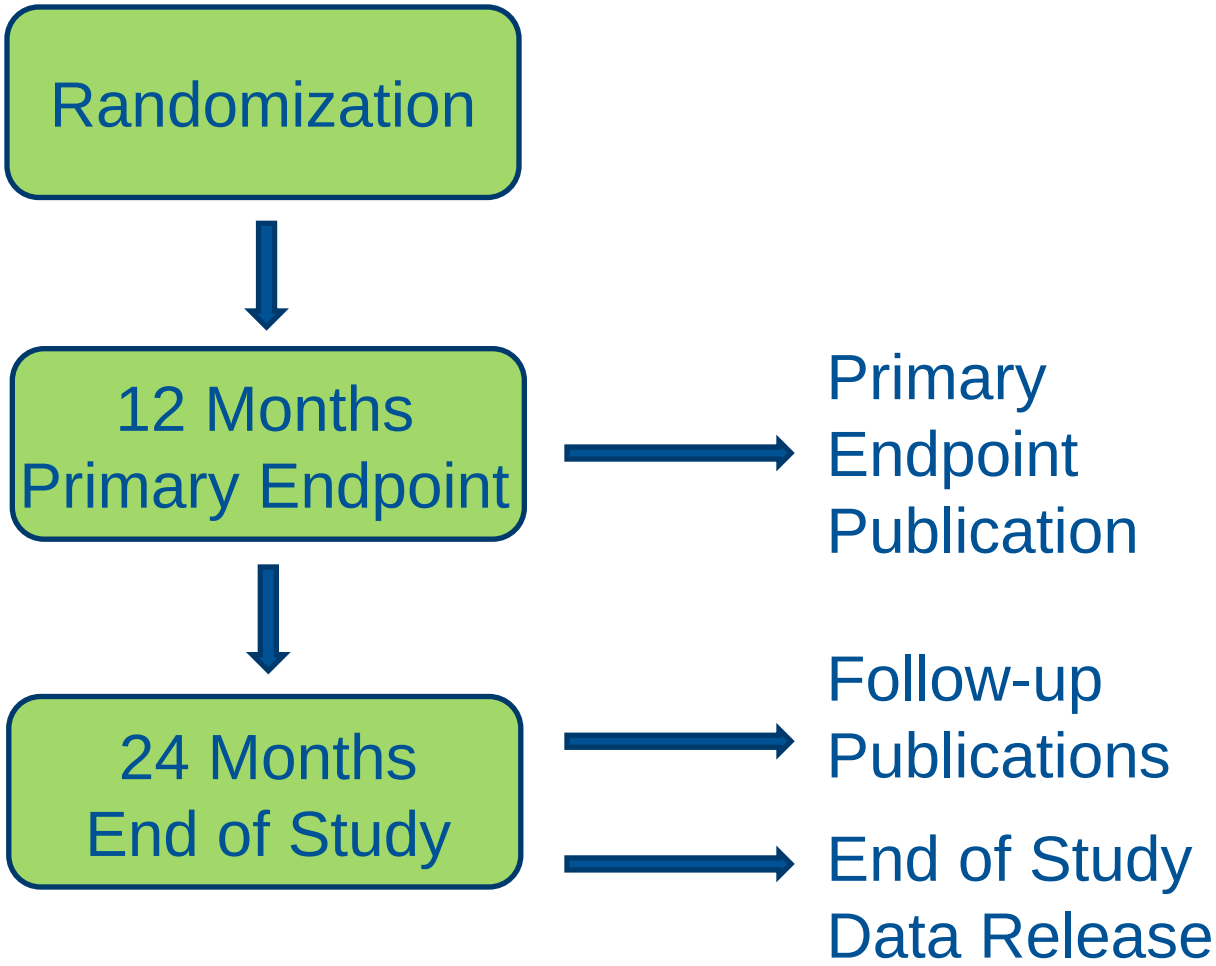
T1DAL Trial Design



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Challenges

- Do we lock the data?
  - What data (all or specific forms)?
  - Subset of patients or subset of visits?
  - Ongoing forms hard to lock (e.g. AEs)
  - What does the EDC system allow?
  - Is the time/cost of locking worth the benefit?
- The answer is different for every trial.
  - Collaborate with ITN and study team

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Challenges

- What data do we share?
  - Only variables used in analyses?
  - Only records used in analyses?
- Don’t share too much because of future publications
- Takes time to subset/modify existing datasets
- The answer is different for every trial.

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Challenges

- What if there are multiple publications?
  - Delineate in system the data for each paper
- Evolving data derivations
  - Multiple releases of data may not match
- Standardization of data

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Conclusions

- No standardized process to share data early
- Think critically for each trial
- Data transparency and reproducible research worth the time and challenges

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This project funded with federal funds from the NIAID, NIH under contract HHSN272200800029C.

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