NIH Forum on Data Standards in Clinical Trials

Applying Data Standards to the DAIDS Clinical Trial Networks

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Disclaimer

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National Institute of Allergy and Infectious Diseases
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DAIDS-supported clinical trials research

- Active protocols: >350
- In development: >100
- Countries: ~50
- Sites: ~200

Clinical Trial Networks

- AIDS Clinical Trials Group (ACTG)
- HIV Prevention Trials Network (HPTN)
- HIV Vaccine Trials Network (HVTN)
- International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT)
- International Network for Strategic Initiatives in Global HIV Trials (INSIGHT)
- Microbicide Trials Network (MTN)

Data Management Centers

- Frontier Science and Technology Research Foundation (FSTRF)
- Statistical Center for AIDS Research and Prevention (SCHARP)
- University of Minnesota
- Regulatory Support Center Contract (RSC)

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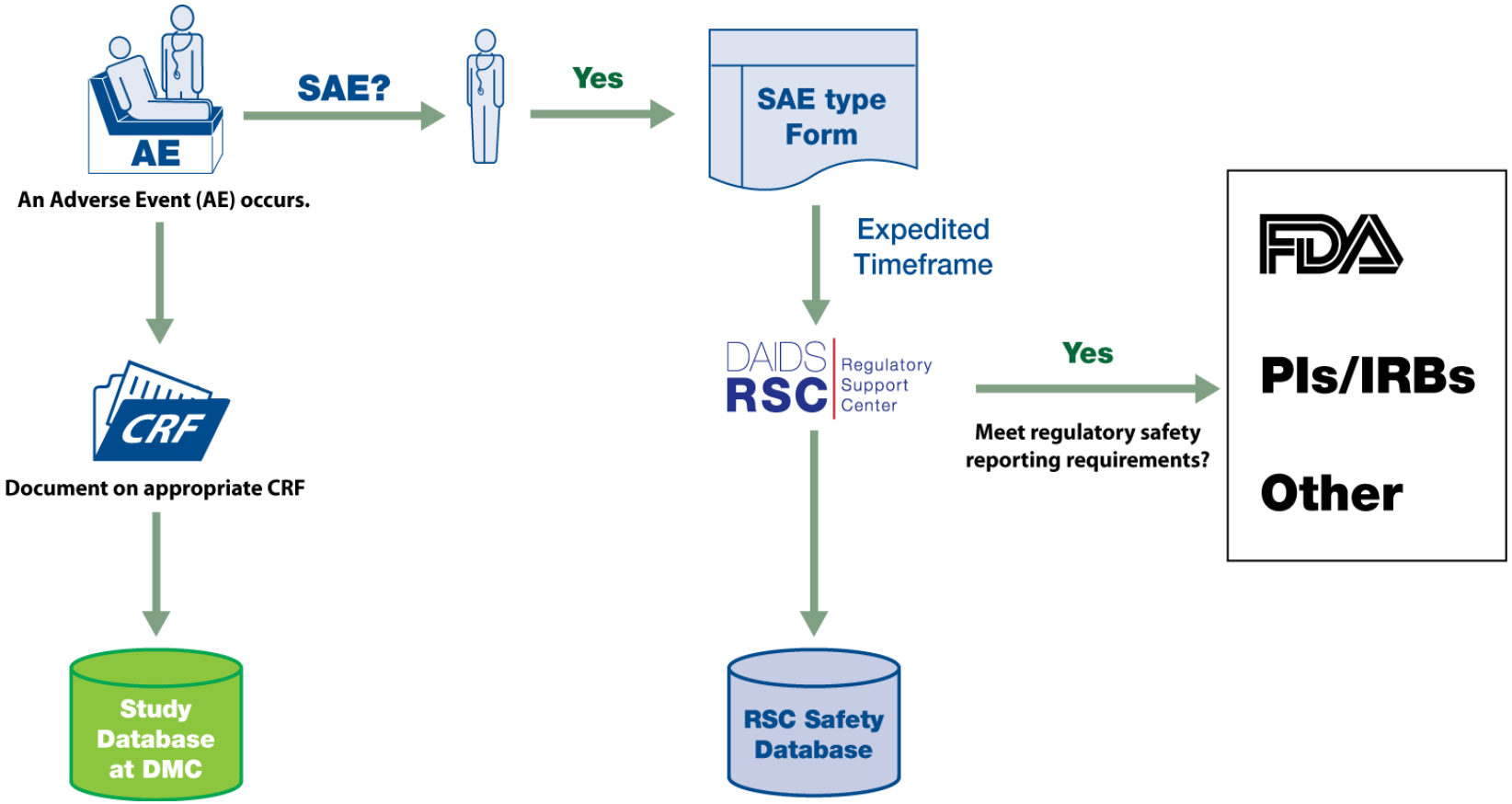
Safety Data Flow for DAIDS Clinical Trials



Data Harmonization

- Some harmonization activities currently between DMCs
- MedDRA coding routinely used
- Currently recompeting clinical trial networks and DMCs
- New RFAs require use of CDISC SDTM Module
  - Enables improved pharmacovigilance activities
  - Prepares for future FDA requirement
- Why only require SDTM?
  - Ensures that data will be available in standard format
  - These are grants, so do not want to be too prescriptive

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