Introduction Page

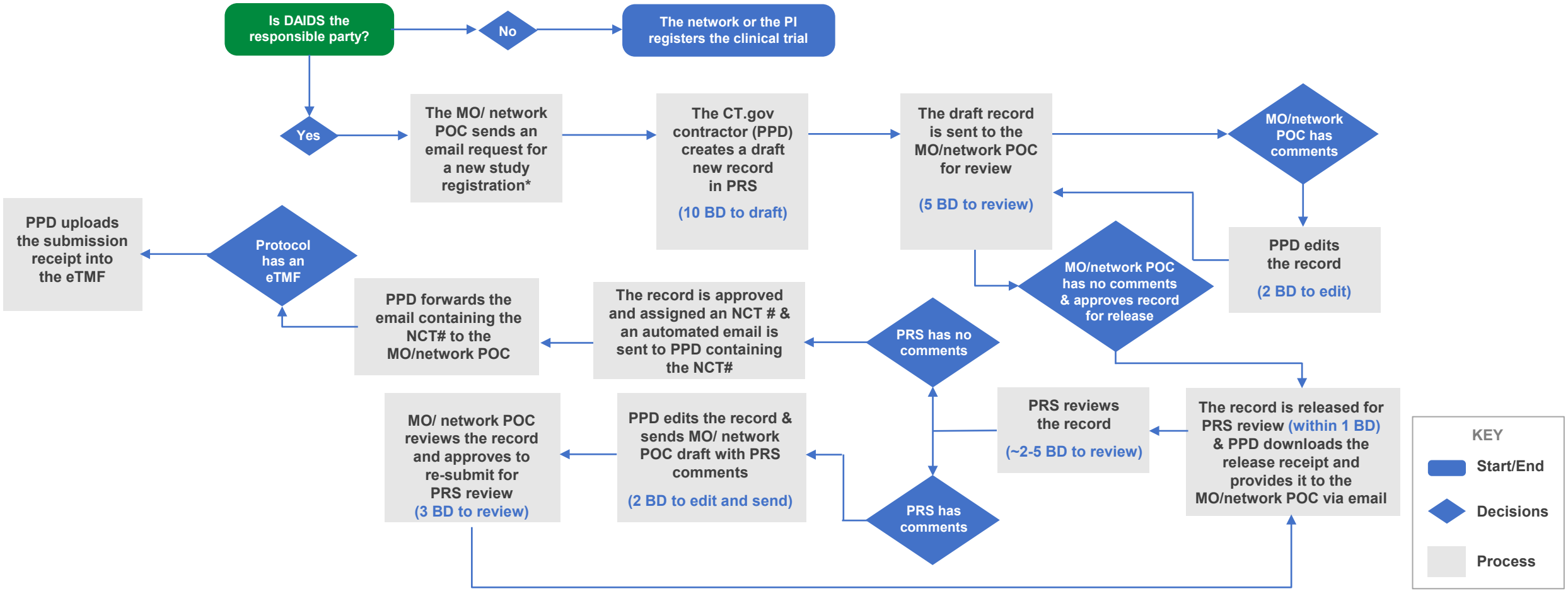
Defining the Responsible Party

- **The ClincalTrials.gov responsible party is defined as the individual or entity responsible for protocol management.**
  - When DAIDS is the IND Holder: NIAID, DAIDS (Sponsor)
  - When it is a non-DAIDS held IND: IND Holder (Sponsor)
  - For Non-IND Network studies: the Network; for Non-Network studies use the appropriate sponsor or institution.
  - For Non-IND Network studies not sponsored by DAIDS: Study Sponsor
  - For VRC Protocols: NIH Clinical Center

Acronyms/Abbreviations

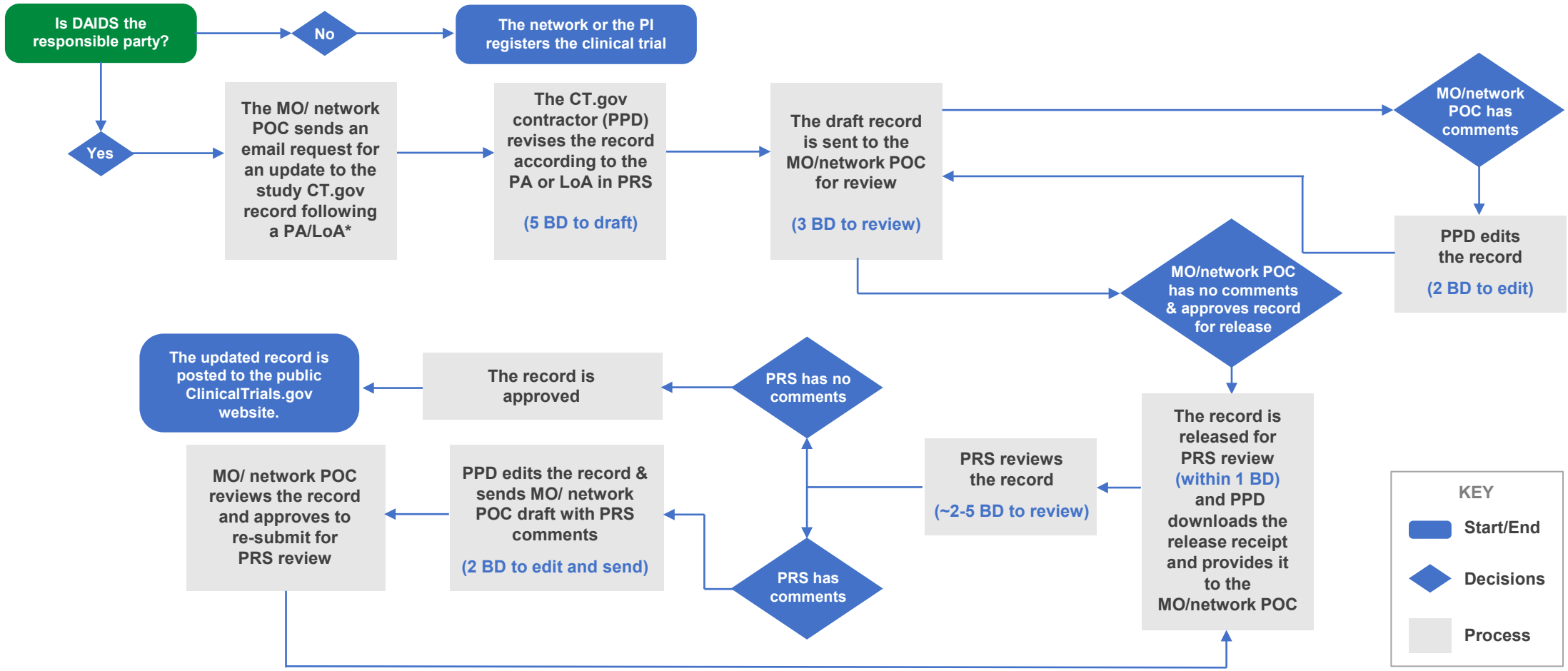
- BD – Business Days
- CT – Clinical Trials
- DAIDS – Division of AIDS
- IND – Investigational New Drug
- IRB – Institutional Review Board
- LoA – Letter of Amendment
- MO – Medical Officer
- NCT – National Clinical Trial
- NIAID – National Institute of Allergy and Infectious Diseases
- NIH – National Institute of Health
- PA – Protocol Amendment
- PI – Principal Investigator
- POC – Point of Contact
- PPD – PPD Development, LP
- PRS – Protocol Registration and Results System
- RfE – Request for Extension
- SDMC – Statistical Data Management Center
- eTMF – Electronic Trial Management File
- VRC – Vaccine Research Center

ClinicalTrials.gov Initial Registration



*The email must include as attachments: the completed CT.gov checklist, copy of the final protocol, the final Site Assignment memo (must contain the site name and address, and site contact name, phone number, and email), and the IRB approval letter (if available at the time of request).

ClinicalTrials.gov Protocol Amendment and Letter of Amendment Updates



*The email must include as attachments: A clean copy of the final amended protocol along with a tracked changes version.

ClinicalTrials.gov Results Reporting