Proposed Data Element Definitions

for WS 3

Revised Cycle Time Proposal

- Protocol sent to site
- IRB decision date
- Contract sent to site
- Contract executed
- Site Activation
- First patient consented

Sub-groups can form to address additional metrics

Objectives

- Data Elements
- Cycle Time Metrics

Investigator Name

- Principal Investigator
  - Last Name
  - First Name
  - Degree (drop down)

Site Type

- Description of physical location where clinical trial is being conducted
  - Academic
  - Hospital Based
  - Private Practice / Stand-alone Clinic
  - Group Practice / Physician Group
  - Stand-Alone Clinical Research Center
  - Government Center

Drop Down

Sponsor / CRO Name

- Responsible company or person(s) providing operational support for a clinical study (protocol, study drug, monitoring)

  - *Clinicaltrials.gov* **Collaborator**

Free Text

Funder

- Responsible party providing financial support for a clinical study; may be same as Sponsor/CRO
  - NIH-funded

Clinicaltrials.gov
Clinical Research Network
Government, excluding U.S. Federal
Industry
National Institutes of Health
U.S. Federal Agency, excluding NIH
University/Organization

Free Text

Protocol ID

- Unique identifier for a given protocol
  - **ClinicalTrials.gov NCT # preferred**

    OR
  - Protocol number & indicate who assigned # (assigned by the sponsor/funder)

Free Text

Study Phase

- Indicate Phase (Phase I-IV)
- "Other" category included for observational studies
- Hybrid studies – e.g. Phase I/II, Ph. IIIB – document as higher level (Ph. IIIB = Ph. IV)

CT.gov Drop Down

Study Type

- Randomized / Non-randomized study
- Interventional / Observational study

- *Clinicaltrials.gov / Includes Study Design*

Tick Box & Drop Down

IND or IDE?

- Indicate IND/IDE (Y/N) via drop-down
- Indicate holder of IND/IDE
  - Sponsor
  - Investigator
  - Funder
  - Other

Tick Box & Drop Down

Vulnerable Population

- Indicate if study population includes these persons
  - Children
  - Pregnant Women
  - Prisoners
  - Cognitively Impaired persons

Tick Box & Drop Down

IRB Type

- Indicate type of IRB
  - Central
  - Local
  - Central, Non-Commercial
  - Commercial serving as local IRB

Drop Down

Therapeutic Area

- General categorization of disorders consistent with a body system or science of body system
  - Use known standard list – ClinicalTrials.gov, Centerwatch, MedDRA

Drop Down

Indication

- Specific disease or disorder under a Therapeutic Area being studied
  - Adopt same standard to be used for Therapeutic Area

Drop Down

Cycle Time Metrics

CYCLE TIME METRICS (Date to Date)	
Date protocol sent / Date protocol received	Date protocol submission by site to local IRB
Date protocol sent / Date protocol received	Date final IRB approval by local IRB
Date protocol sent / Date protocol received	Date of site activation
Date protocol sent / Date protocol received	Date of final site signature on site contract
Date final IRB approval by local IRB	Date of site activation
Date of site approval by central IRB	Date of final site signature on site contract
Date of site approval by central IRB	Date of site activation
Date of final site signature on site contract	Date of site activation
Date of Site Activation	Date of 1st patient Consent
Date of Site Activation	Date of 1st patient visit
Data of site receipt of draft contract	Date of final site signature on site contract
Date protocol submission by site to local IRB	Date final IRB approval by local IRB
Date protocol sent / Date protocol received	Date of site approval by central IRB

Date Protocol Sent to Site OR Date Protocol Received by Site

- Date protocol sent vs. date protocol receipt by site?
- Inclusion of NCI co-op studies for studies that become active as protocol is available or date co-op group activates

Date of Protocol Submission

- Local IRB sites only since they drive this process

Sites Using Local IRB: Date of Final IRB Decision

- Local IRB Sites only
- Approval / Non-approval
- Value Benefit of number of times a protocol was sent back for clarification / revision?

Date of Protocol Approval

- Sites using Central IRB only

Sites Using Central IRB: Date of Central IRB Approval

- Site approval to conduct trial by central IRB
- Protocol pre-approved in most cases

Date of Site Receipt of Contract

- Receipt of Initial Draft Contract Template

Who is Contract With?

- Party (Investigator, Institution) indicated on contract that agrees to provisions of the contract
  - Sub-field question – Is there Master Agreement in place?

Date of Final Site Signature on Site Contract

- Final signature date after agreement of terms from both sides (sponsor / site)

Number of Additional Committee Approvals

- Additional approvals needed to approve pre/ post IRB submission (e.g. – pharmacy, research billing compliance)
  - Indicate pre or post IRB approval
  - Indicate # of additional approvals

Training Documentation needed before Activation

- Training Type: Protocol, Safety, GCP
- Indicate number to be trained
- Indicate location of training
  - Onsite
  - Off-site
  - On-line

Date of Site Activation

- Permission to enroll after completion of all contractual, regulatory, & pre-study start requirements

Date Site Completed First Consent

- First signed consent date for study protocol

Date of Site's First Study Visit

- First study visit completed
  - Not necessarily first signed consent

Investigator Expertise / Interest

- Investigator experience – similar trials / # done within 5 years
- Primary Research Coordinator / Study Nurse experience
- Likelihood that investigator will do trial like this again

Additional Comments

- Thank you!