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
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
Sponsor / CRO Name
University/Organization excluding NIH

U.S. Federal Agency, National Institutes of Health Industry

Federal Government, excluding NIH

Clinical Research Network.gov

NIH-funded

Free Text

a clinical study, may be same as Sponsor/CRO

Responsible party providing financial support for Funder
Protocol ID

- Unique identifier for a given protocol
  - ClinicalTrials.gov NCT # preferred
    OR
  - Protocol number & indicate who assigned # (assigned by the sponsor/funder)
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)
Study Type

ClinicalTrials.gov / Includes Study Design

Interventional / Observational study

Randomized / Non-randomized study
Indicate holder of IND/IDE via drop-down

Other
Investigator
Funder
Sponsor

Indicate IND/IDE (Y/N) via drop-down
Vulnerable Population

- Cognitively Impaired persons
- Prisoners
- Pregnant Women
- Children

Indicate if study population includes these persons

Tick Box & Drop Down
IRB Type

- Indicate type of IRB
  - Central
  - Local
  - Central, Non-Commercial
  - Commercial serving as local IRB
General categorization of disorders consistent with a body system or science of body system

- Use known standard list – ClinicalTrials.gov, Centerwatch, MedDRA
Indication

Specific disease or disorder under a Therapeutic Area being studied

- Adopt same standard to be used for Therapeutic Area
# Cycle Time Metrics

<table>
<thead>
<tr>
<th>CYCLE TIME METRICS (Date to Date)</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Date protocol sent / Date protocol received</td>
<td>Date protocol submission by site to local IRB</td>
</tr>
<tr>
<td>Date protocol sent / Date protocol received</td>
<td>Date final IRB approval by local IRB</td>
</tr>
<tr>
<td>Date protocol sent / Date protocol received</td>
<td>Date of site activation</td>
</tr>
<tr>
<td>Date protocol sent / Date protocol received</td>
<td>Date of final site signature on site contract</td>
</tr>
<tr>
<td>Date final IRB approval by local IRB</td>
<td>Date of site activation</td>
</tr>
<tr>
<td>Date of site approval by central IRB</td>
<td>Date of final site signature on site contract</td>
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<td>Date of site activation</td>
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<tr>
<td>Date of Site Activation</td>
<td>Date of 1st patient Consent</td>
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<tr>
<td>Date of Site Activation</td>
<td>Date of 1st patient visit</td>
</tr>
<tr>
<td>Data of site receipt of draft contract</td>
<td>Date of final site signature on site contract</td>
</tr>
<tr>
<td>Date protocol submission by site to local IRB</td>
<td>Date final IRB approval by local IRB</td>
</tr>
<tr>
<td>Date protocol sent / Date protocol received</td>
<td>Date of site approval by central IRB</td>
</tr>
</tbody>
</table>
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
Local IRB sites only since they drive this process.

Date of Protocol Submission
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?
Sites using Central IRB only

Date of Protocol Approval
<table>
<thead>
<tr>
<th>Sites Using Central IRB</th>
<th>Date of Central IRB Approval</th>
<th>Site approval to conduct trial by central IRB</th>
<th>Protocol pre-approved in most cases</th>
</tr>
</thead>
<tbody>
<tr>
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</table>
Date of Site Receipt of Contract

Receipt of Initial Draft Contract Template
Who is Contract With?

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

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Date of Final Site Signature on Site

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

Contract
Additional approvals needed to approve pre/post IRB submission (e.g. pharmacy, billing compliance)

Indicate # of additional approvals

Indicate pre or post IRB approval
Training Document

Training Type:
- Protocol
- Safety
- GCP

Indicate number to be trained

Indicate location of training
- On-site
- Off-site
- On-line

Activation

Training Documentation needed before
Permission to enroll after completion of all contractual, regulatory, & pre-study start requirements.

Date of Site Activation
First signed consent date for study protocol

Date Site Completed First Consent
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!