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
**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
Sponsor / CRO Name

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

- Clinicaltrials.gov / Collaborator
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
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

- Randomized / Non-randomized study
- Interventional / Observational study
- Clinicaltrials.gov / Includes Study Design
IND or IDE?

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

Indicate if study population includes these persons
- Children
- Pregnant Women
- Prisoners
- Cognitively Impaired persons
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>
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<tbody>
<tr>
<td>Date protocol sent / Date protocol received</td>
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<td>Date protocol sent / Date protocol received</td>
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<tr>
<td>Date protocol sent / Date protocol received</td>
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<tr>
<td>Date final IRB approval by local IRB</td>
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<td>Date of site approval by central IRB</td>
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<td>Date of site approval by central IRB</td>
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<tr>
<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>
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<tr>
<td>Data of site receipt of draft contract</td>
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<tr>
<td>Date protocol submission by site to local IRB</td>
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<tr>
<td>Date protocol sent / Date protocol received</td>
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<tr>
<td>Date Protocol Sent to Site OR Date Protocol Received by Site</td>
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<tr>
<td>-------------------------------------------------------------</td>
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<tr>
<td>Date protocol sent vs. date protocol receipt by site?</td>
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<tr>
<td>Inclusion of NCI co-op studies for studies that become active as protocol is available or date co-op group activates</td>
</tr>
</tbody>
</table>
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!