RESEARCH MANAGEMENT GROUP

CLINICAL TRIAL SETUP PROCESS

SMART Meeting
October 17, 2017

Stanford Medicine Research Management Group (RMG)
INDUSTRY-FUNDED CLINICAL TRIALS:

STUDY STARTUP PROCESS REFINEMENT

- Establishes consistent intake process
- Provides support to study teams at all stages of process
- Commits to completing process faster with prepared teams
- Defines 2 kickoff meeting types and goals of each
INDUSTRY-FUNDED CLINICAL TRIALS: PATHS TO PTA

- Expedited
  - Study Team, CT RPM, CT CO all ready
  - All required documents submitted to/received by RMG*
  - Budget Finalization Meeting Requested on Study Activation Form
  - Commitment: 90 Days

- Standard
  - Study Team requests additional support and guidance
  - Minimum documents submitted (workbook not required)
  - Budget Development Meeting

*Received within 5 business days
Which path?

Expedited Path

All Minimum Documents Received

CT Assessment

SeRA Record Initiated

CO & RPM Assigned

Budget Finalization Meeting

Standard Path

First Notification of New Study

Documents sent to Intake

Email/Phone communication to gather documents

All Minimum Documents Received

CT Assessment

SeRA Record Initiated

CO & RPM Assigned

Budget Development Meeting

Goal: Expedited studies with IRB Approval - 90 day turnaround
INTAKE: MINIMUM DOCUMENTS

- Protocol
- Contract with Payment Schedule
- Completed Study Activation Form
- Completed Workbook/s & CT

*Send all documents to rmg_ct_intake@stanford.edu*
CTRMG Study Activation Form

- Available on RMG and Spectrum websites
- Replaces Budget Questionnaire
- Must be completed
  (respond “N/A” where applicable)
KICKOFF MEETING:
BUDGET FINALIZATION OR BUDGET DEVELOPMENT?

- Budget Finalization
  - Meeting to review first draft internal budget, discuss final changes and budget negotiation strategy

- Budget Development
  - Discuss study, logistics, and address open questions, regulatory, workbook and process requirements
  - Meeting will establish next steps, timeline, team responsibilities (who will do what)
  - Prepares for budget finalization
CHANGES

- CT RMG Intake will hold and follow-up to gather documents
- Active follow-up for 4-6 weeks then study status ‘inactive’ (email notification will be sent)
- SPO assigned when all minimum documents received
- Two types of Kickoff meetings to meet study team needs
- Expedited Studies – 90 day turnaround
  (Note: IRB approval required prior to contract execution, NOA and PTA setup)
What Type of Kick Off Meeting Do I Need?

**Expedited Path**
- All Minimum Documents Received
- CT Assessment
- SeRA Record Initiated
- CO & RPM Assigned
- Budget Finalization Meeting
- Goal: Expedited Studies with IRB Approval 90 Day Turnaround

**Standard Path**
- First Notification of New Study
  - Documents Sent to Intake
  - All Minimum Documents Received
  - CT Assessment
  - SeRA Record Initiated
  - CO & RPM Assigned
  - Budget Development Meeting

Follow Up To Gather All Minimum Documents
DISCUSSION AND Q&A