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Clinical Trial Activation Timelines: Update on Implementation of the Operational Efficiency Working Group Recommendations

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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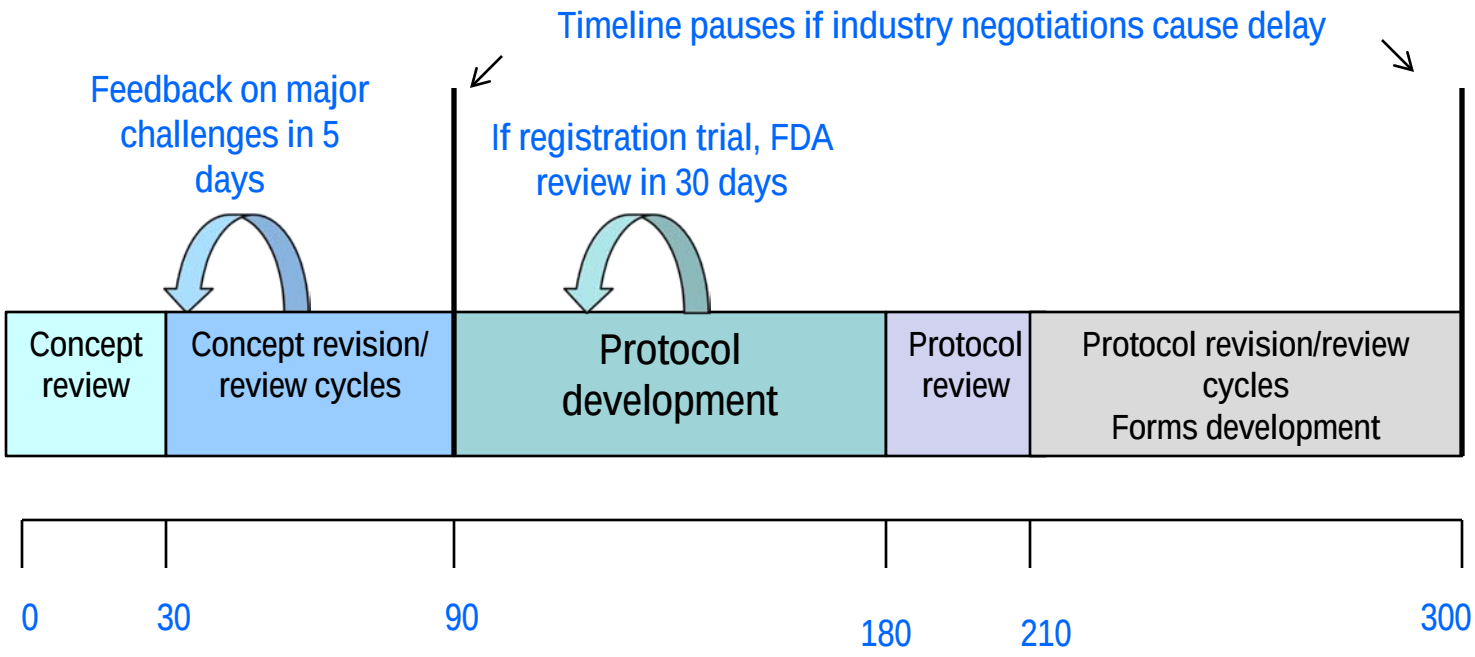
OEWG Target Timeline for Phase 3 trials – 300 days



Timeline excludes contracting, drug supply, FDA review

Protocol terminated if not activated in two years

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Phase III Concepts: Timeline Data as of December 1, 2010

13 Concepts proposing Phase III Trials received since April 1, 2010

- 4 concepts approved
- 3 concepts in review or in time-out (company &/or drug commitment)
- 4 concepts disapproved or withdrawn
- 2 concepts submitted to CTEP awaiting Steering Cmte. Review

Approved Phase III Concepts (4):

Target timeline for Phase III Concept approval = 90 days

- Average number of days for Phase III concept approval by Steering Cmte. (subtracting out the time-outs) = 89.5 days (2 studies)
- Average number of days for ph III concept approval w/o SC (subtracting out the time-outs) = 24 days (2 studies)

Protocols (1):

Target for Phase III protocol submission (from Concept approval) = 90 days

- Average number of days for Phase III protocol submission = 0 days
  ('Concept' submitted with protocol)

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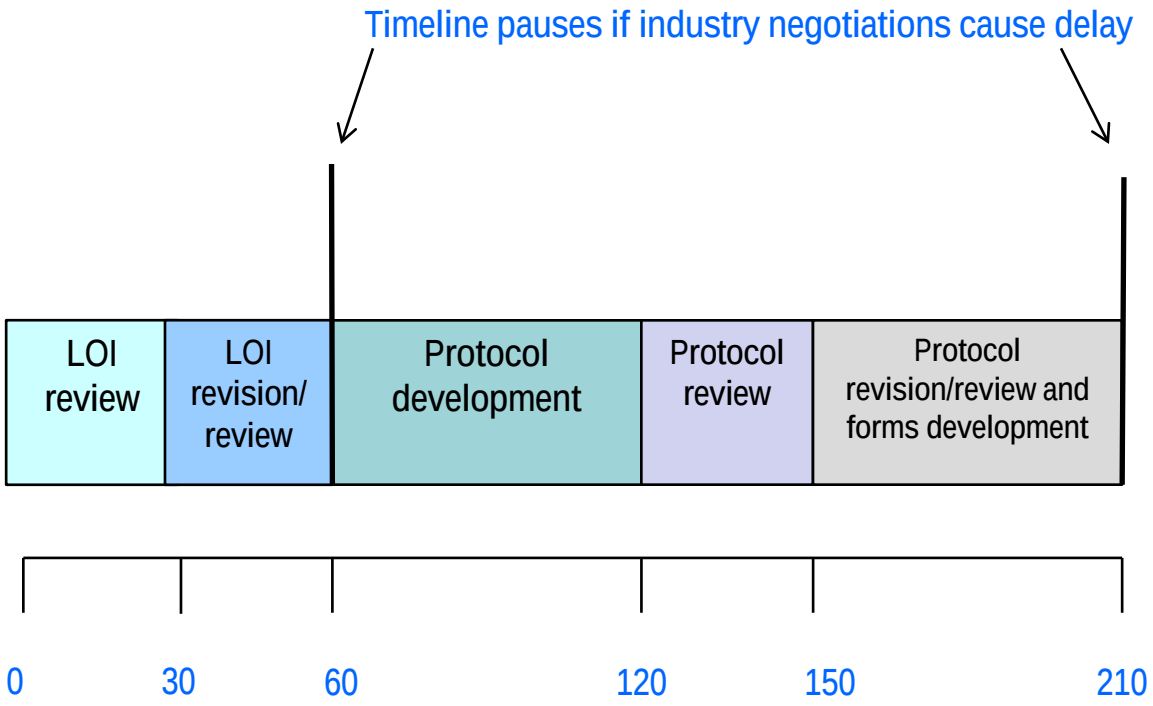
OEWG Target Timeline for Phase 1 and Phase 2 LOIs – 210 days



Timeline excludes contracting, drug supply, FDA

Protocol terminated if not activated in 18 months

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Unsolicited Cooperative Group LOIs (Ph I, I/II, II): Timeline Data as of December 1, 2010

45 Unsolicited Cooperative Group LOIs received since April 1, 2010

- 10 Group unsolicited LOIs approved
- 11 Group unsolicited LOIs in review or in time-out
- 24 Group unsolicited LOIs disapproved, withdrawn, or declined by Pharmaceutical Company

Approved unsolicited Group LOIs (10):

Target timeline for unsolicited Group LOI approval = 60 days

- Average number of days for Group LOI approval (subtracting out the time-outs) = 47 days
- Average time-out length = 16 days (among the approved Group LOIs) for those that did have a time-out (Drug Commitment Time-Outs)

Protocols (6):

Target timeline for protocol submission (from LOI approval) = 60 days

- Average time from Group LOI approval to Protocol submission = 55 days

Target timeline for protocol activation (from protocol submission) = 90 days

- Number of protocols in activation stage: 6
- No protocols have yet been activated

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U01/N01 LOIs: Timeline Data as of **December 1, 2010**

50 U01/N01 LOI's received since April 1, 2010

- 16 U01/N01 LOI's approved
- 16 U01/N01 LOI's in review or in time-out (drug commitment or grant approval)
- 18 U01/N01 LOI's disapproved or withdrawn

Approved U01/N01 LOI's (16):

Target timeline for LOI Approval = **60 days**

- **Average** number of days for LOI approval (subtracting out the time-outs) = **37 days**
- Average time-out length = 27 days (drug commitment)

Protocols (10):

Target timeline for protocol submission (from LOI approval) = **60 days**

- **Average** time from LOI approval to Protocol submission = **55 days**

Target timeline for protocol activation (from protocol submission) = **90 days**

- Number of protocols in activation stage: 10
- No protocols have yet been activated

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Intramural LOIs (Phase I, I/II, II): Timeline Data as of **December 1, 2010**

12 intramural LOI's received since April 1, 2010

- 8 intramural LOI's approved
- 1 intramural LOI's in review or in time-out (drug commitment or grant approval)
- 3 intramural LOI's disapproved

Approved intramural LOI's (8):

Target timeline for LOI Approval = 60 **days**

- **Average** number of days for LOI approval (subtracting the time-outs) = 30 **days**
- Average time-out length = 27 days (drug commitment)
- 0 intramural LOI's have exceeded the 60 day target

Protocols (7):

Target timeline for protocol submission (from LOI approval) = 60 **days**

- **Average** time from LOI Approval to Protocol submission = 47 **days**

Target timeline for protocol activation (from protocol submission) = 90 **days**

- Number of intramural protocols in activation stage: 7
- No protocols have yet been activated

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NCI Initiatives to Achieve OEWG Goals

- Modified/developed internal SOPs to streamline processes and improve communication
- Identified at-risk trials (First quarter of CY11)
- Established teleconference calls to discuss/resolve outstanding issues
- Weekly OEWG coordination committee meetings
- Two OEWG working groups meet via monthly or quarterly conference calls to discuss OEWG processes:
  - OEWG Cooperative Groups Working Group
  - OEWG Early-Phase Clinical Trials Working Group
- Developed secure, role-based, web-portal to share tracking reports with intramural and extramural investigators and support staff

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OEWG Conference Call Process

- Conference calls between the study team and NCI are held to clarify and discuss comments in the Consensus Review, to prevent review iterations that may otherwise slow the approval process.
- Conference calls occur at several key points:
  - LOI's: on-hold, approved pending drug company review, or approved
  - Concepts: pending response to Steering Committee review or approved
  - Protocols: pending response to Consensus review
- 158 conference calls between April 1-December 1, 2010:
  - 56 calls for new LOI's
  - 13 calls for new Concepts
  - 15 calls for new Protocols
  - 75 calls for studies submitted prior to 4/1/2010
- Call participants:
  - Lead reviewer *and* site/Group PI: 96% calls
  - Statisticians: Site/Group: 56% calls; NCI 56% of calls
  - Additional staff: Group: 83% calls; NCI: 77% of calls

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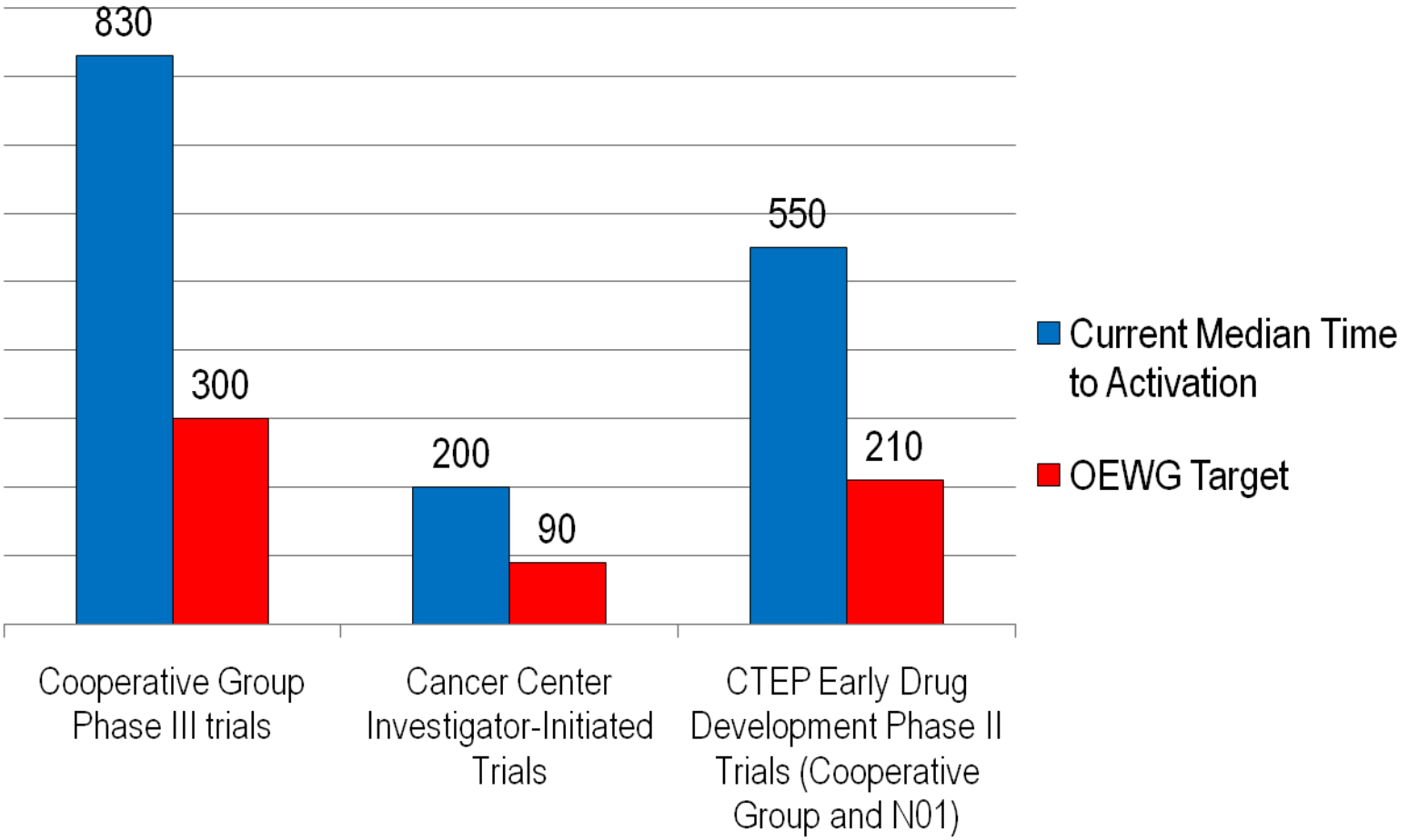
Targets Aggressive But Necessary



Current median time includes IRB approval, industry negotiations, and FDA approval

Commitment will result in significant progress but success will not be fully achieved without incremental funding

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NCI Timeline Reports

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Timeline Reports

The application is primarily for NCI CTEP internal and external collaborators to access data reports generated from the CTEP Enterprise System.

Version 1.0:

The first version of the application will allow users to generate Protocol Development Timeline (PDT) reports to track the amount of time it takes to develop a protocol from Concept or LOI receipt to Protocol Activation. The PDT reports will be available in 4 different formats for comparison and analysis. The users of the application should have an ACTIVE CTEP-IAM account.

LOGIN TO TIMELINE REPORTS

Username:

Password:

Login

Account Management

Forgot Password | Reset Password

Annual Registration | Request New Account

Quick Reference Guide

Quick Reference Guide

Tutorial

Version Information

1.0.0

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