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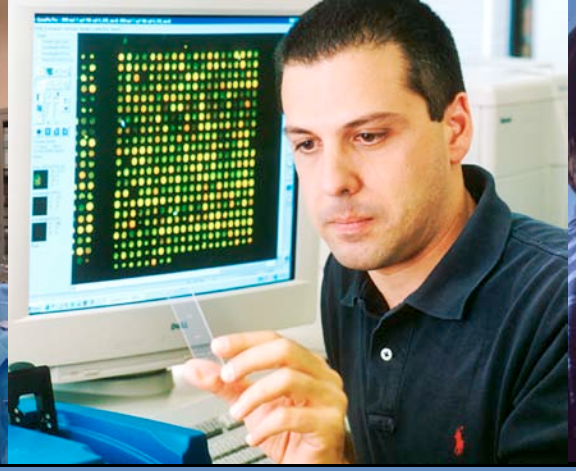

Developing a Report Card for Clinical Trial Activation Timelines: Initial Implementation of the Operational Efficiency Working Group Recommendations

James H. Doroshow, M.D.

National Cancer Advisory Board

Bethesda, MD

September 8, 2010

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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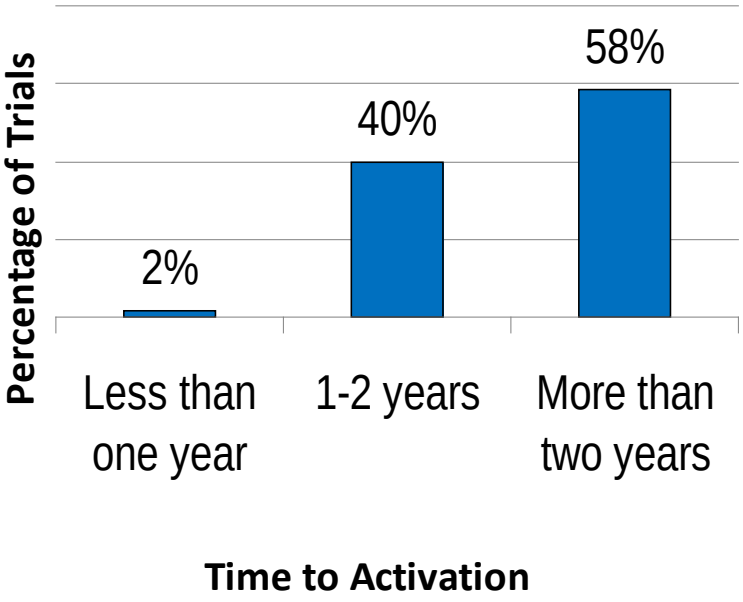
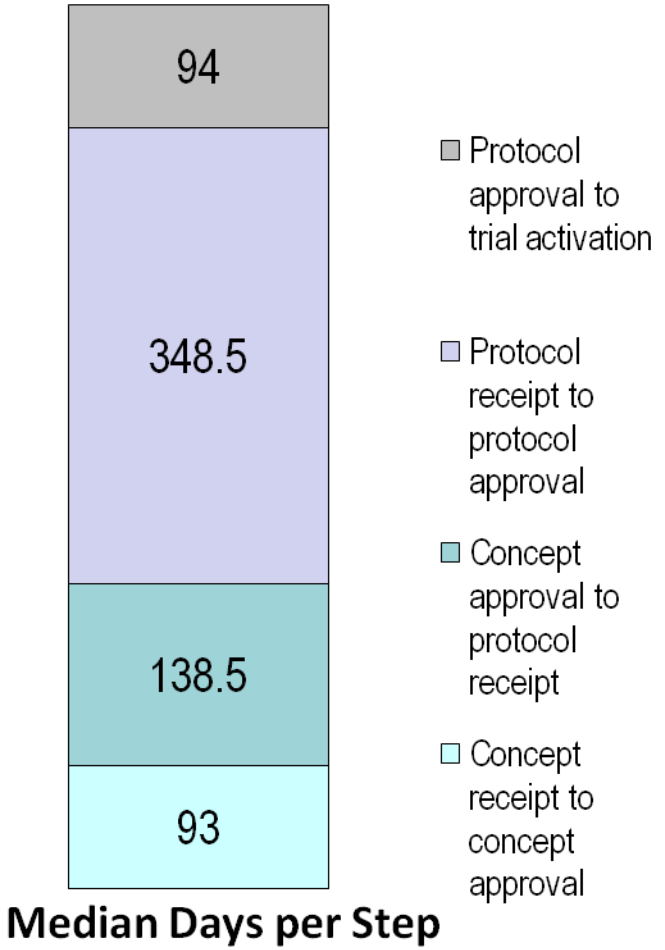
Time to Activation – Current State Cooperative Group Phase III Trials (2006 – 2008)





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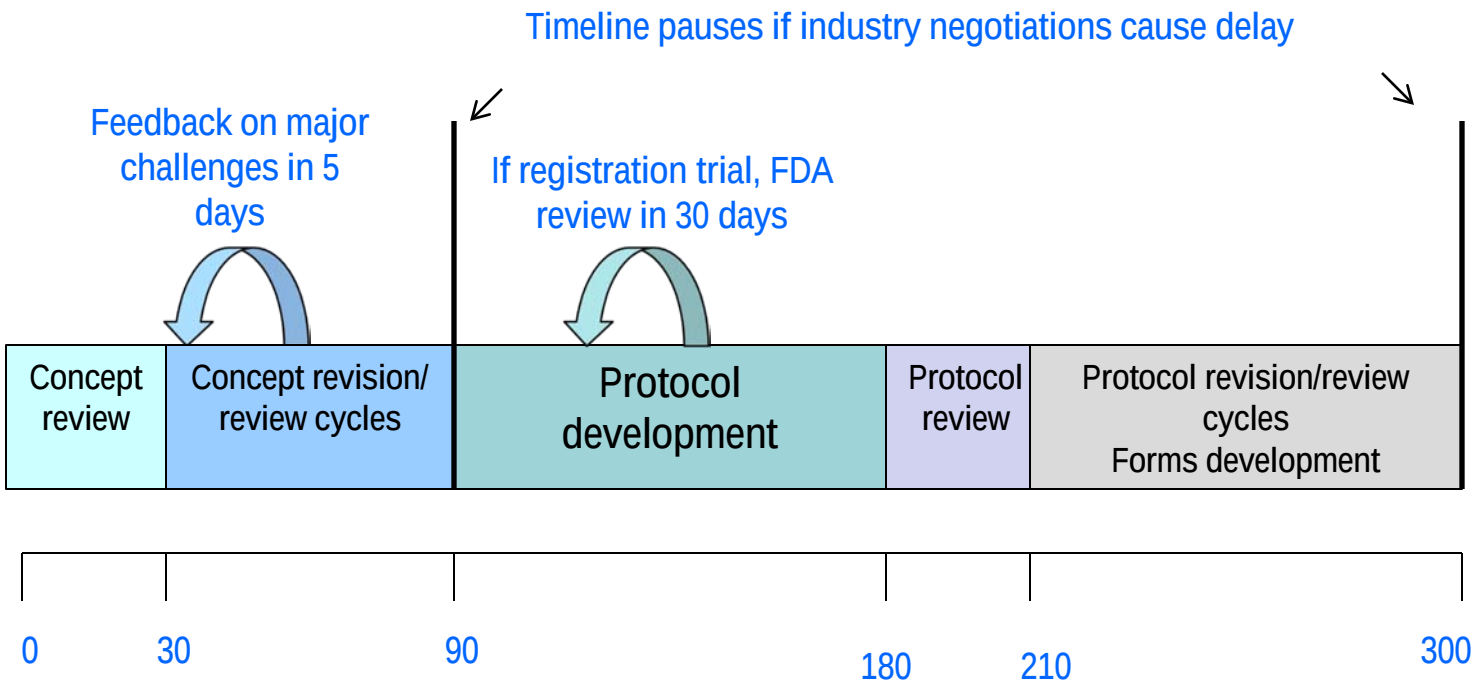
OEWG Target Timeline – 300 days



Timeline excludes IRB, contracting, drug supply, FDA review

Protocol terminated if not activated in two years

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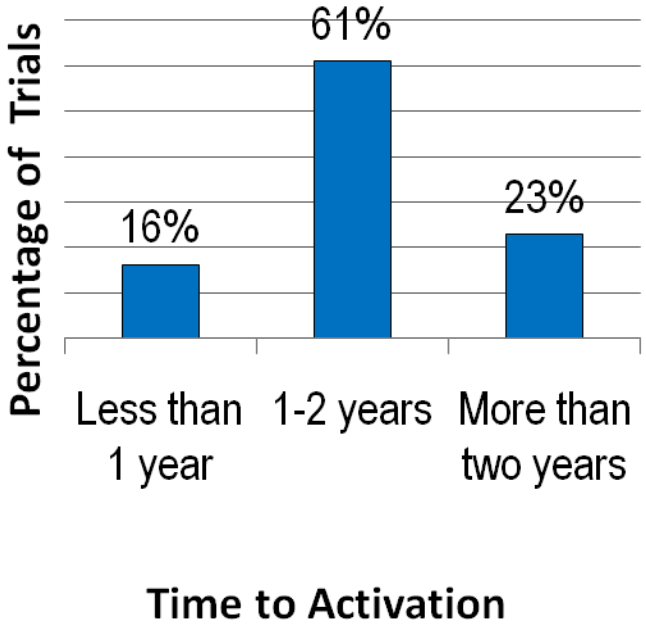
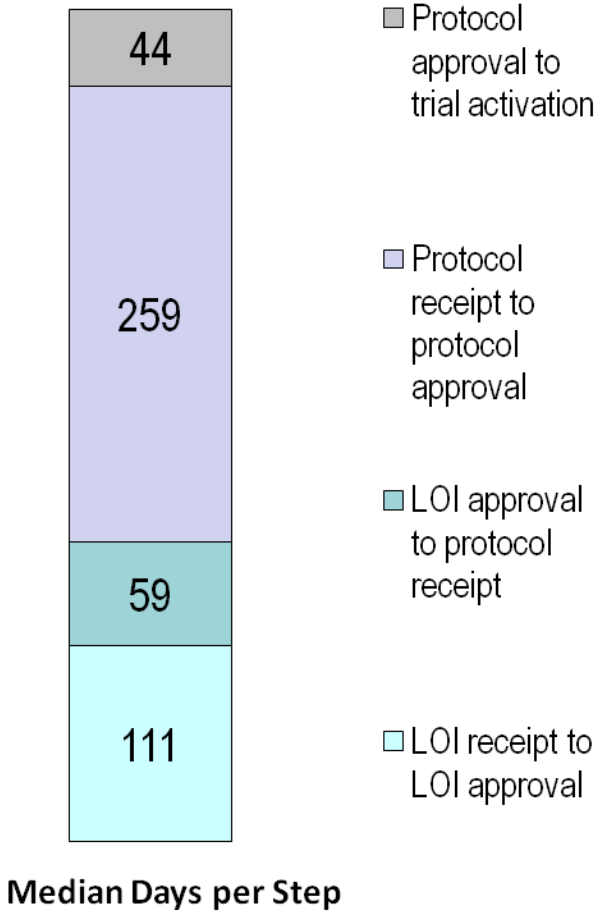
Time to Activation - Current State
N01 & Group Phase II's (2006-2008)





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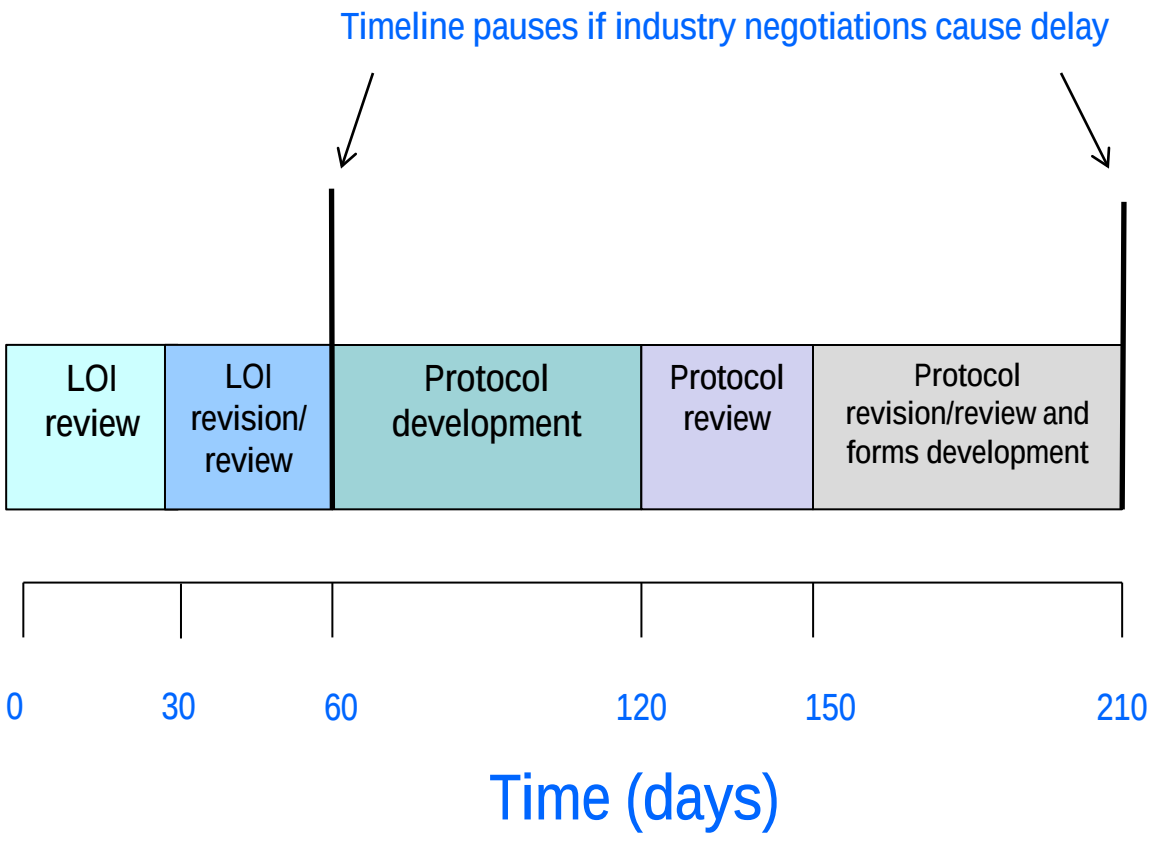
OEWG Target Timeline – 210 days



Timeline excludes contracting, drug supply, IRB, FDA

Protocol terminated if not activated in 18 months

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Phase III Concepts:Timeline Data as of August 20, 2010

18 Concepts Proposing Phase III Trials Received Since April 1, 2010

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

Approved Concepts (3):Target timeline for Concept approval –90 days if Group phase II > 100 pts or Group phase III

- Average number of days for concept approval by Steering Cmte. (without time-outs) = 41 days (n=2)
- Average number of days for ph II concept approval w/o SC (without time-outs) = 40 days (n=1)
- Average time-out length: NA (no time-outs among approved concepts)
- 0 concepts have exceeded the 90 day target

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Group Phase II LOIs:Timeline Data as of August 20, 2010

21 Group LOIs received since April 1, 2010

- 5 Group LOIs approved; 2 protocols submitted
- 4 Group LOIs in review or in time-out
- 12 Group LOIs disapproved, withdrawn, or declined by Pharma

Approved LOIs (5):Target timeline for Group LOI approval – 60 days

- Average number of days for Group LOI approval – 42 days
- Average time-out length – 15 days (among the approved Group LOIs)
- 1 Group LOI has exceeded the 60-day target

Protocols (2): Target timeline for Protocol Submission – 90 days

- Average time from Group LOI approval to Protocol submission – 61 days

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UO1/NO1 Phase I/II LOIs:Timeline Data as of August 20, 2010

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

- 8 U01/N01 LOI's approved; 1 U01/N01 Protocol submitted
- 7 U01/N01 LOI's in review or in time-out (drug commitment or grant approval)
- 5 U01/N01 LOI's disapproved or withdrawn

Approved U01/N01 LOI's (8): Target timeline for LOI Approval – 60 days

- Average number of days for LOI approval (without time-outs) – 36 days
- Average time-out length – 32 days *(all for drug commitment)*
- No LOI's have exceeded the 60 day target

6 other (P50, R01, R21, DoD) LOIs submitted

- 4 in review
- 2 withdrawn/disapproved

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Intramural Phase I/II LOIs:Timeline Data as of August 20, 2010

6 intramural LOI's received since April 1, 2010

- 2 intramural LOI's approved; 2 protocols submitted
- 2 intramural LOI's in review
- 2 intramural LOI's disapproved

Approved intramural LOI's (2): Target timeline for LOI Approval – 60 days

- Average number of days for LOI approval (without time-outs) – 38 days
- Average time-out length – 2 days (drug commitment)
- No intramural LOI's have exceeded the 60 day target

Protocols Submitted (2): Target timeline for Protocol Submission – 60 days

- Average time from LOI Approval to Protocol submission – 59 days

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NCI Initiatives to Achieve OEWG Goals

- Kick-off meeting late March with Groups, Consortia, and Phase I/II UO1s and NO1s to establish common understanding and collaborative procedures
- Hire Project Managers to oversee OEWG processes
- Standardized CTEP consensus reviews and provide comments in Track Change® Mode

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NCI Initiatives to Achieve OEWG Goals (cont.)

- 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
- Developed secure, role-based, web-portal to share tracking reports with intramural and extramural investigators and support staff
- Two OEWG working groups meet monthly via conference calls to discuss OEWG processes:
  - OEWG Cooperative Groups Working Group
  - OEWG Early-Phase Clinical Trials Working Group

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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
- Since April 1, 2010, 80 conference calls:
  - 18 for new LOI's
  - 9 for new Concepts
  - 2 for new Protocols
  - 51 for studies submitted prior to 4/1/2010
- Call participants:
  - Lead reviewer and site/Group PI: 99% calls
  - Statisticians: Site/Group: 49% calls
  - Additional staff: Group: 83% calls

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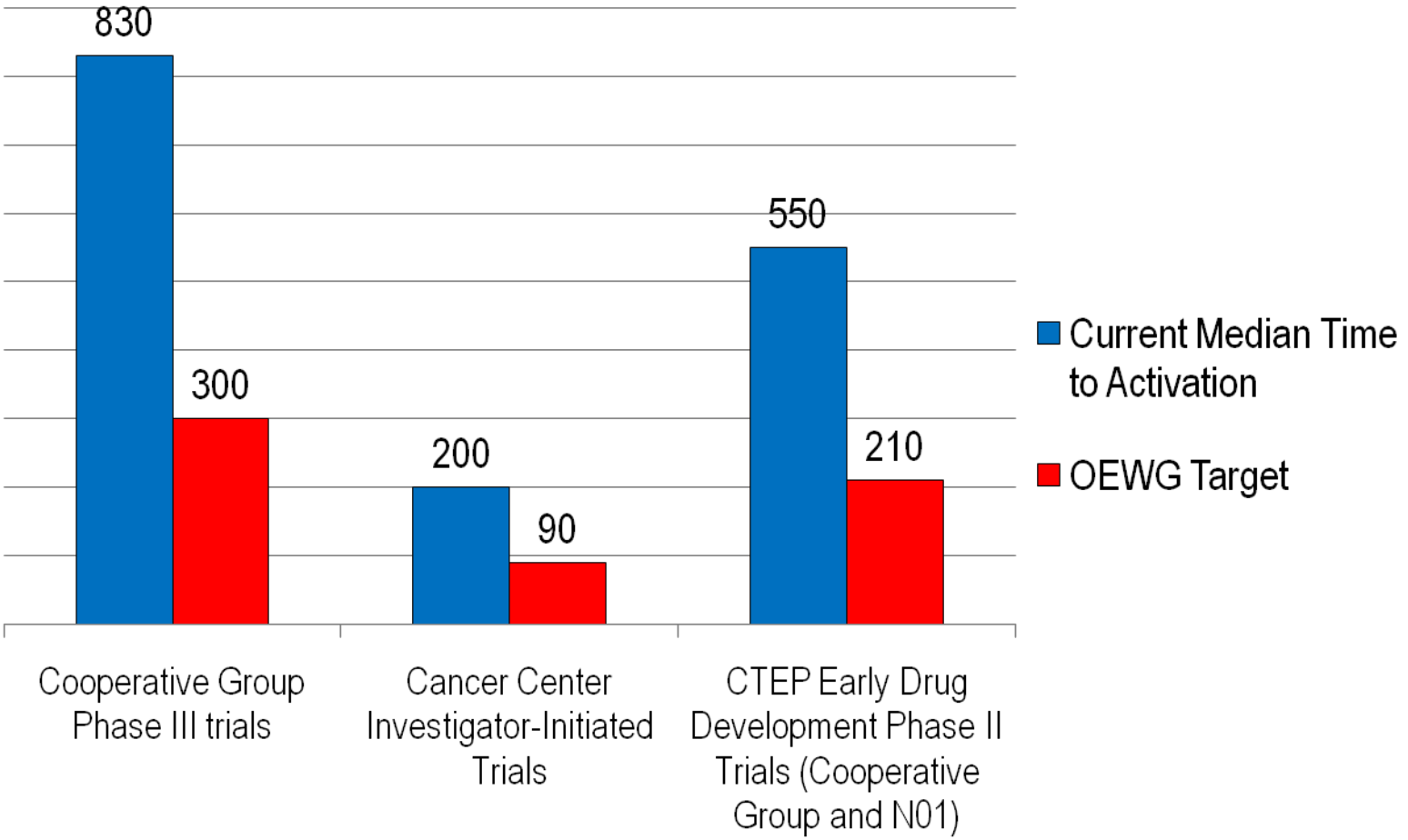
Targets Aggressive But Necessary



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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