RSS/Credentialing/CIRB/OEWG aka“Alphabet Soup”

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Central Protocol Operations Program

Alliance New Investigator Training
Alliance Chicago May 2017 Group Meeting

Presentation Objectives

- Understand NCI and CTSU Infrastructure, Services, and Policies Supporting You, Your Clinical Trial and all NCI Clinical Trials
  - Operational Efficiency Working Group (OEWG)
  - Central Institutional Review Boards (CIRB)
  - Cancer Trials Support Unit (CTSU)
  - Regulatory Support System (RSS)

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NCI Operational Efficiency Working Group (OEWG)

- Working Group Goals
  - Identify institutional barriers prolonging time from concept approval to accrual of first patient
  - Establish working group to recommend strategies to implement plans to reduce time to activation of group and cancer center trials
  - Focus on timeliness of trial activation
- Constitution: 10 Group Chairs, 8 Cancer Center Directors, Investigators, Statisticians, Protocol Specialists, Community Oncologists, NCI Clinical Trials Leadership and Staff, Pharma, Patient Advocates, FDA, CMS, CTSU
- Launched 2009, Announced March 2010, Implemented January 2011

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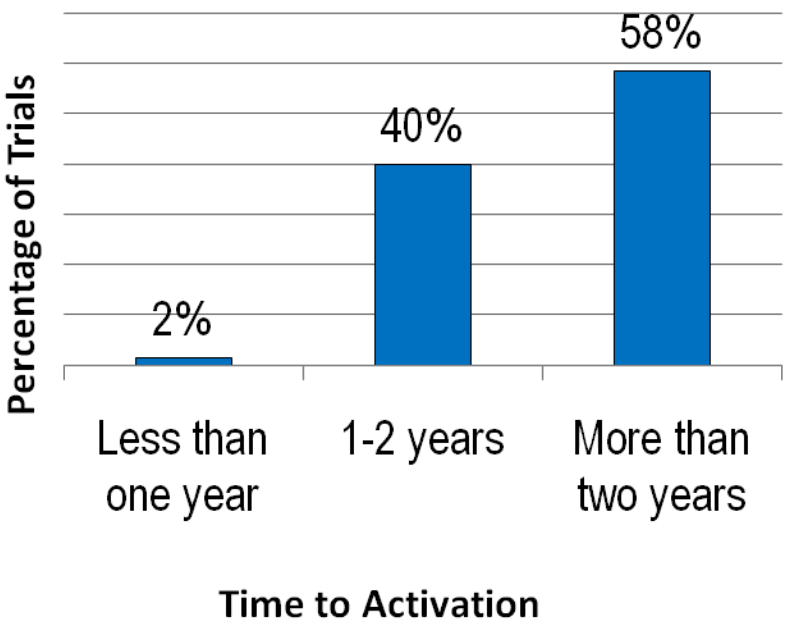
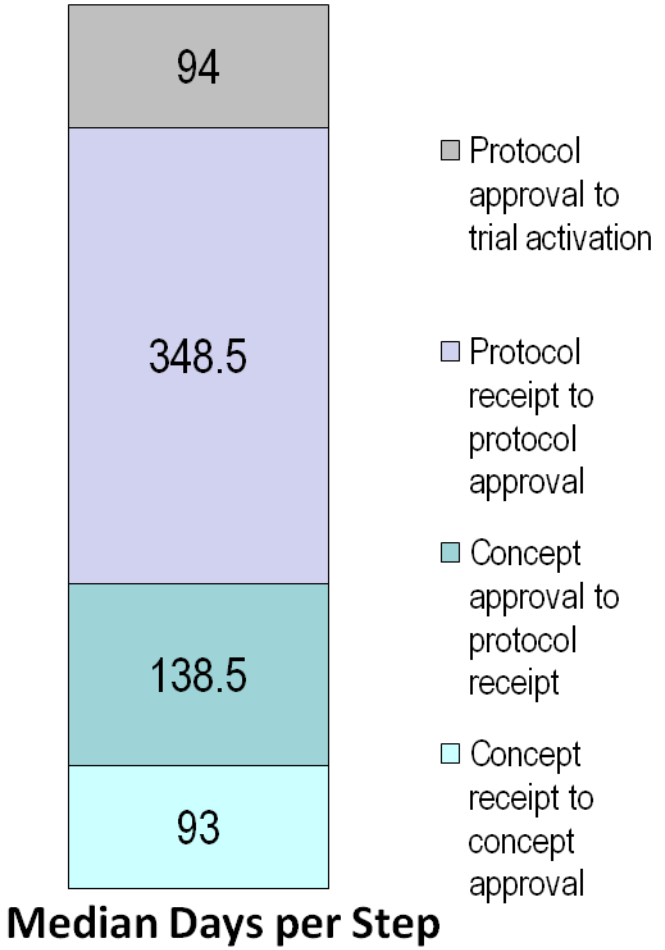
Time to Activation – Current State
Cooperative Group Phase III Trials (2006 – 2008)





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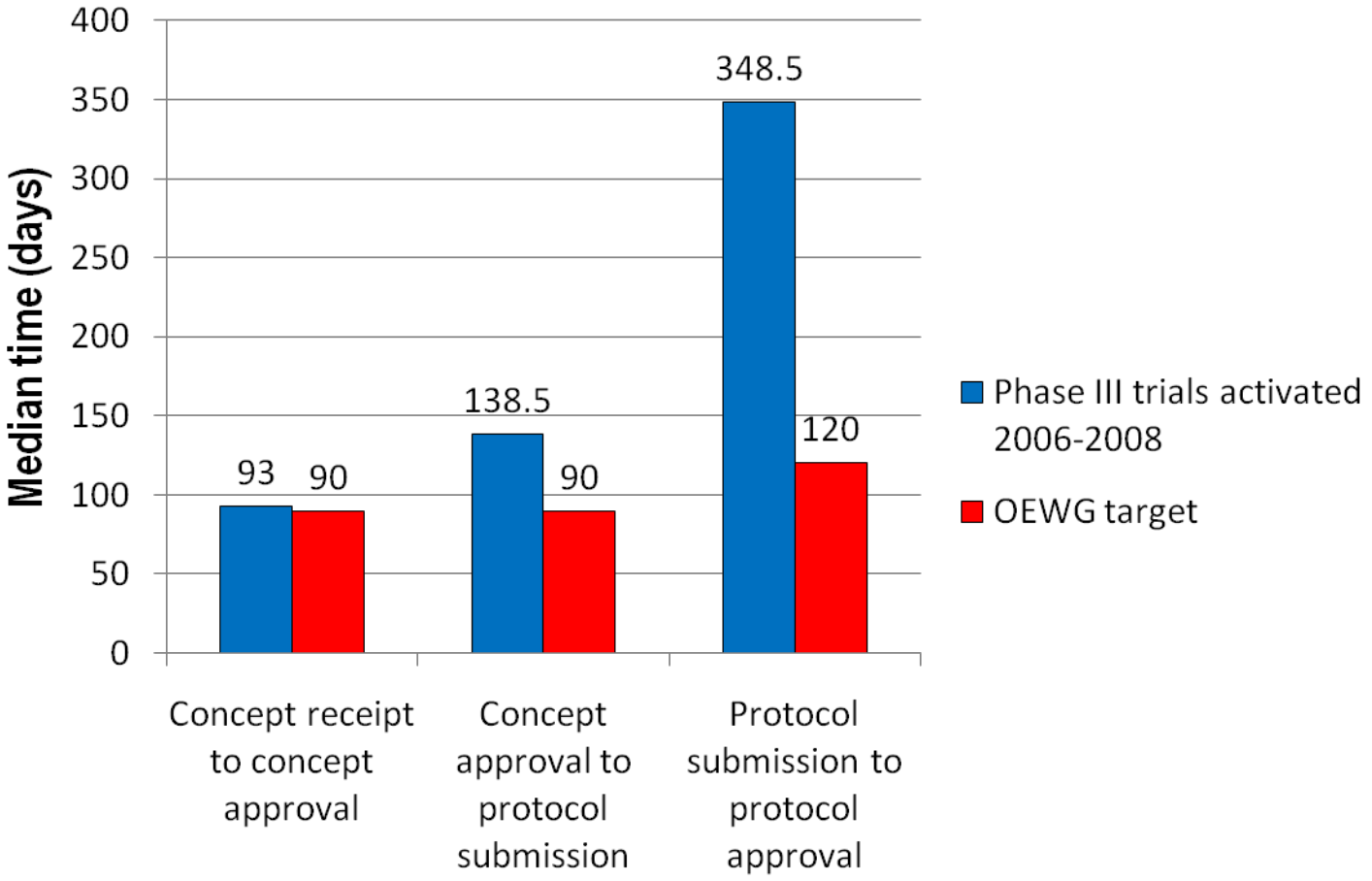
Time to Trial Activation
Current vs OEWG Target



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

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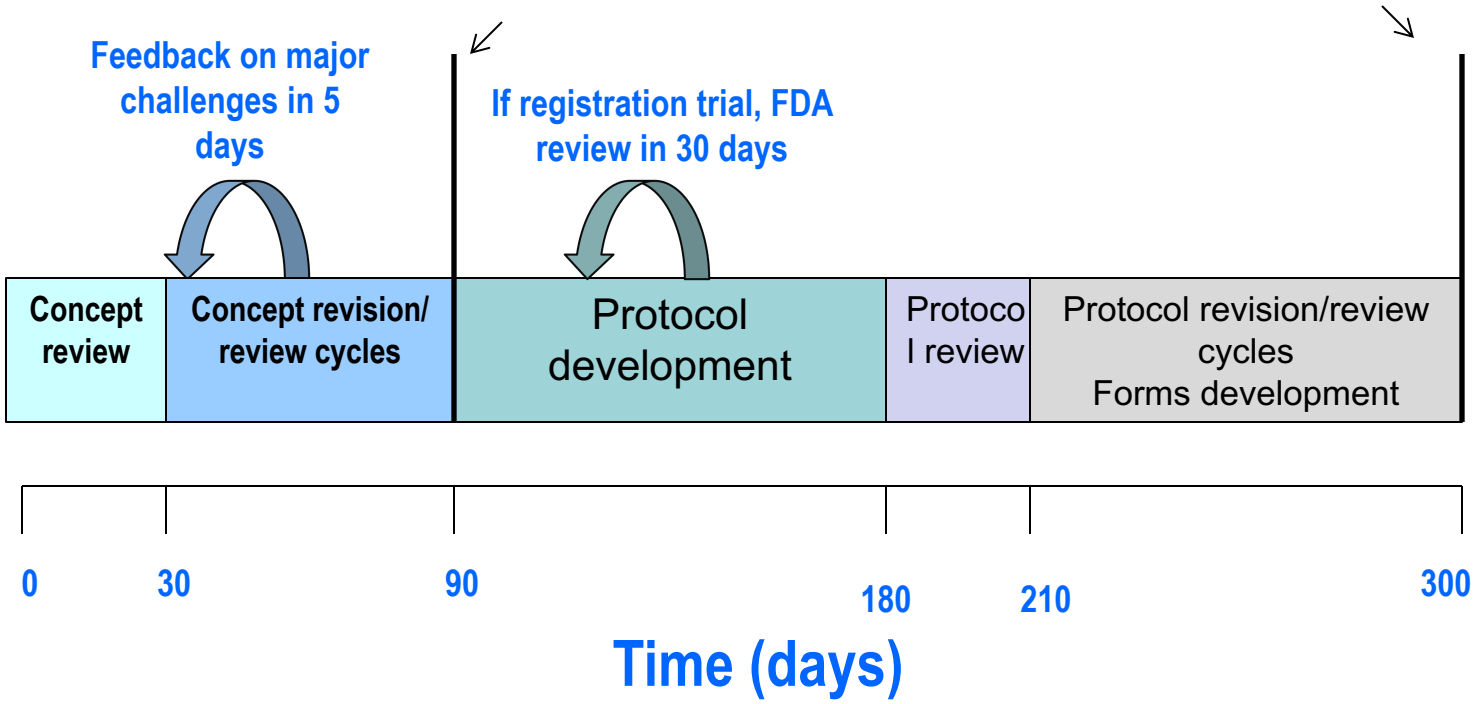
OEWG Target Timeline – 300 days



Protocol terminated if not activated in two years

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Phase 3 Concepts OEWG Timeline

OEWG timeline for opening a trial to enrollment, for Phase 3 Concepts:

Target timeline: 300 days

Absolute deadline: 540 days

Concept approval stage: 90 days (Day 1 – 90)

Protocol authoring stage: 90 days (Day 90 – 180)

Protocol approval and open to enrollment: 120 days (Day 180 – 300)

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Cooperative Group Phase 2 (and 1/2) Concepts OEWG Timeline

OEWG timeline for opening a trial to enrollment, for Cooperative Group Phase 2 (and 1/2) Concepts:

Target timeline: 210 days

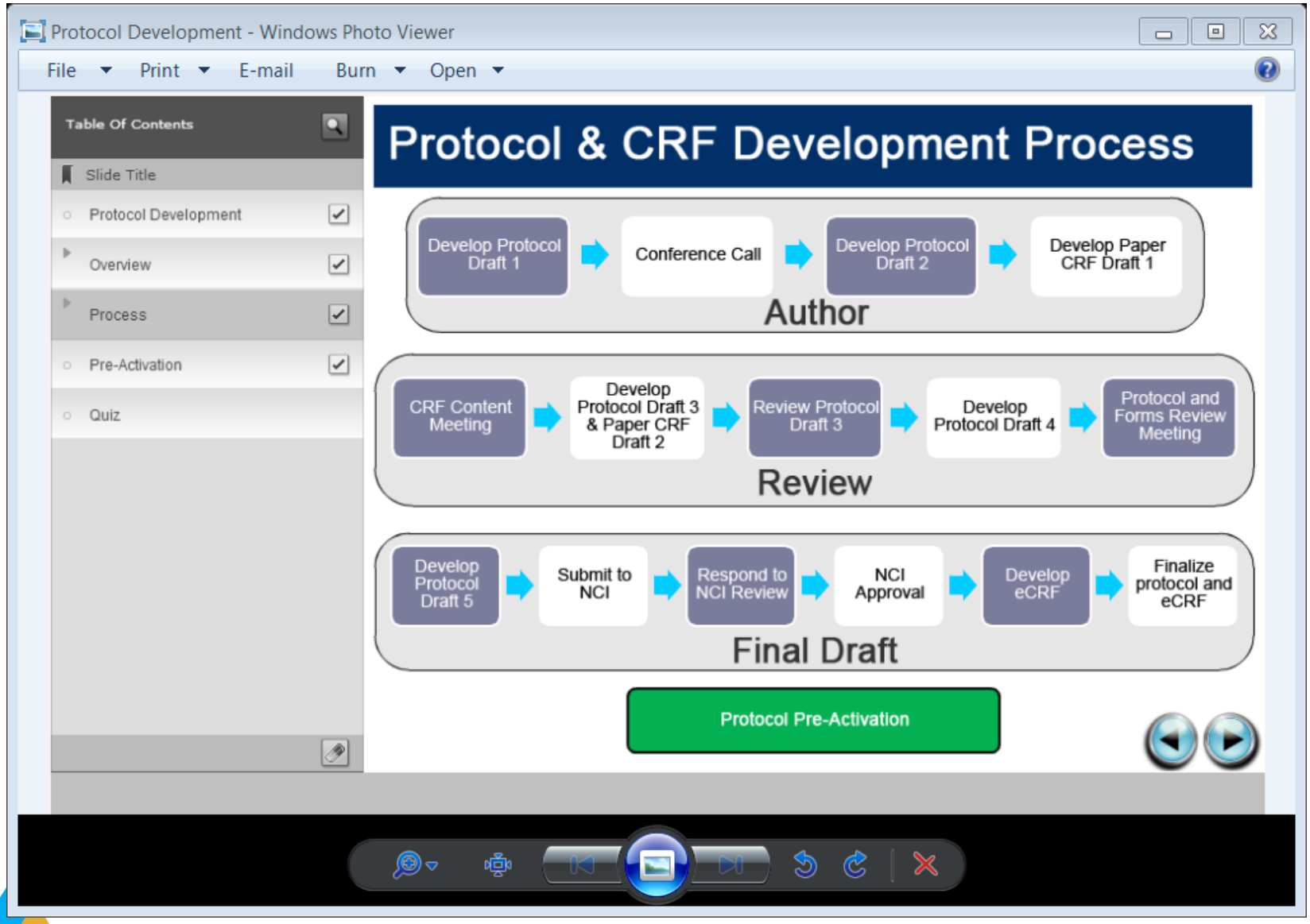
Absolute deadline: 450 days

Phase 2 concept approval stage: 60 days (Day 1 – 60)

Protocol authoring stage: 60 days (Day 60 – 120)

Protocol approval and open to enrollment: 90 days (Day 120 – 210)

Alliance Protocol Development



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NCI Operational Efficiency Working Group

- OEWG timelines drive protocol and forms development and protocol activation
- Development and activation is a complex, collaborative effort involving multidisciplinary co-chairs, biostatisticians, nurses, clinical research professionals, patient advocates, protocol coordinators, forms developers, IT staff, and an Alliance Executive Officer
- Alliance Protocol Coordinators and Executive Officers can help navigate Alliance and NCI processes. Get to know them. Heed their guidance.

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NCI Central Institutional Review Board (CIRB) Benefits

- Beneficial for patients and research
  - Oncology-specific, multidisciplinary Boards
  - Dedicated initial, local context, and amendment review
  - Open trials faster (especially for rare diseases)
- Beneficial for investigator and research staff
  - Eliminates protocol roundtrips to IRB
  - Eliminates need for amendment review, continuing renewal, and adverse events
  - Eliminates/reduces completing IRB applications

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NCI CIRBs

- Randomized phase II and phase III trials overseen by one of 4 NCI CIRBs
  - Early Phase CIRB
  - Late Phase CIRB
  - Cancer Prevention and Control CIRB
  - Pediatric CIRB
- OEWG protocol activation timelines include CIRB review and approval

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Cancer Trials Support Unit (CTSU)

- Facilitates and harmonizes activities across NCI CTEP National Clinical Trial Network (NCTN) and NCI DCP National Community Oncology Research Program (NCORP)
- Streamlines clinical trials processes, eg. patient registration
- Facilitates access to Alliance, SWOG, NRG Oncology, ECOG-ACRIN, Canadian Cancer Treatment Group protocols

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CTSU Services

- CTSU Web Site (www.ctsu.org)
  - Protocol Documentation (protocol, CRFs, study funding sheet, National Coverage Analysis, etc.)
  - Regulatory Portal Submission
  - Oncology Patient Enrollment Network (OPEN) Web-based, 24-7 Registration System
- Regulatory Support System (RSS)
  - Individual and Institutional Rosters
  - Comprehensive local IRB information and protocol specific requirements (PSRs)

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Conclusions

- CTSU systems infrastructure is designed to interact among the web-based applications (investigator, institution, protocol-specific requirements, IRB approval)
- CTSU systems are designed to alleviate institutional burden, facilitate physician access to NCI clinical trials, and support patient enrollment
- Alliance Protocol Coordinators and Executive Officers work with and understand CTSU system interactions. Consult and rely on them.

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Thank You

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