



Clinical Trials Reporting Program (CTRP) Deployment

CTAC

December 8, 2008

Clinical Trials Database



Trial submitter registers with system



Trial is registered
(and protocol document uploaded)



NCI abstracts protocol from document to
support CDS abbreviated reporting



Submission of Accrual Data



Comprehensive data accessible

CTRP Deployment: Pilot



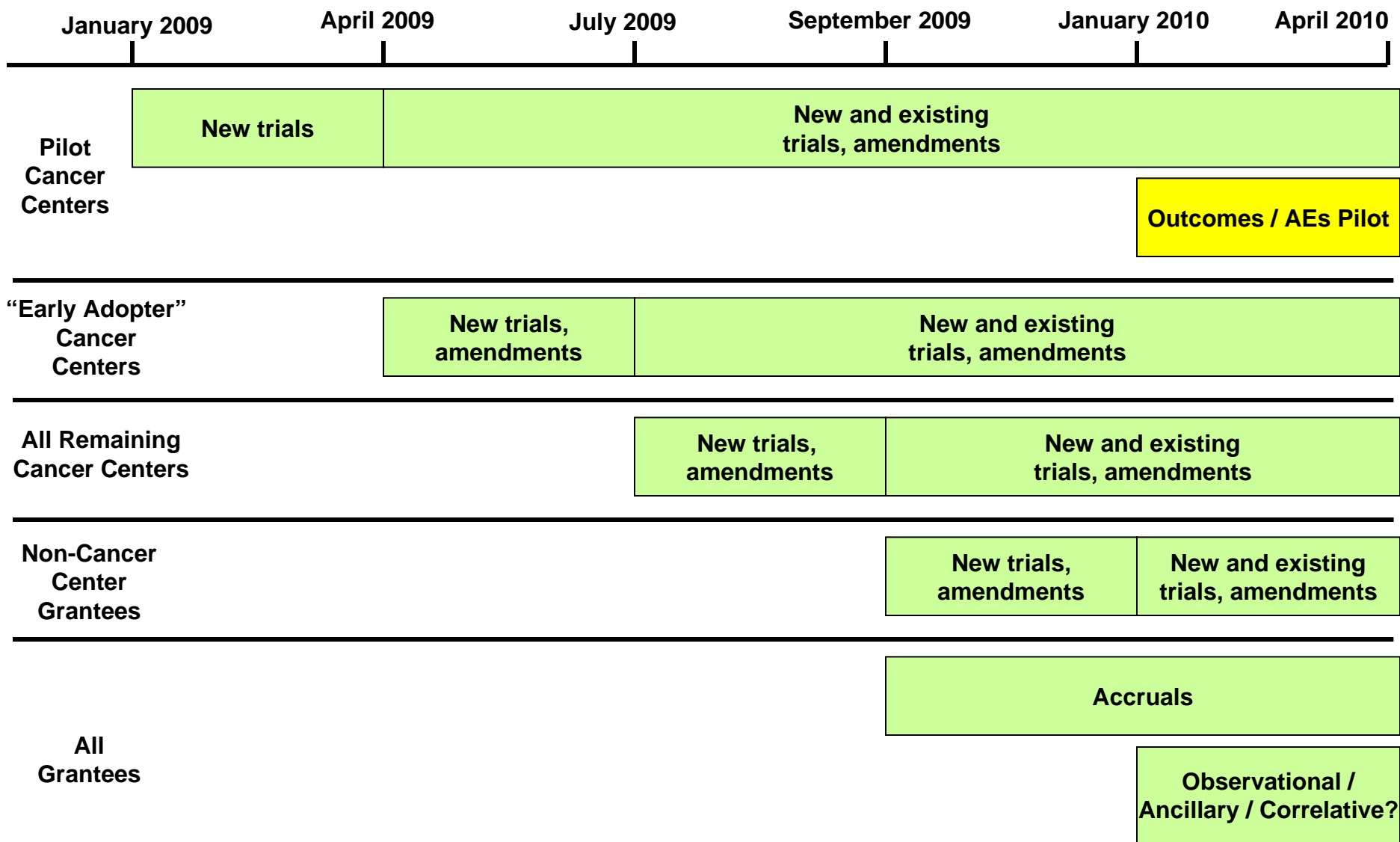
- Operational Pilot began July 7, 2008
- Pilot sites:
 - Dana-Farber
 - Northwestern
 - Mayo
 - St. Jude
 - Wake Forest
- Production systems for trial registration and abstraction “go live” January 5, 2009

Staged Deployment, Learn as We Go



- Interventional trials only for 2009
 - Observational, ancillary/correlative deferred until 2010 at least
- First Quarter of 2009:
 - Five pilot sites only, new trials only, no amendments
- Second Quarter of 2009:
 - Solicited “early adopter” Cancer Centers begin entering new trials, allow amendments, allow existing trials
- Third Quarter of 2009 (*provisional*):
 - All Cancer Centers begin entering new trials
- Fourth Quarter of 2009 (*provisional*):
 - Add Non-Cancer Center grantees begin entering new trials, begin collection of accrual data
- First Quarter of 2010 (*provisional*):
 - Begin pilot reporting of outcomes, adverse events
 - Potentially add observational, ancillary / correlative studies

Timeline



Communications



- National Cancer Advisory Board
- Board of Scientific Advisors
- Cancer Center Directors' Retreat
- AACI (10/6/08)
- NCI Program Directors' meetings
- NCI Bulletin
- First e-mail to all NCI grantees (10/23/08)
- caBIG Clinical Trials Workspace and Steering Committee
- Public web site (www.cancer.gov/ncictrp)



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NCI's Clinical Trials Reporting Program



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Questions about cancer?

- 1-800-4-CANCER
- LiveHelp® online chat

NCI Highlights

- [Treatment of Metastatic Breast Cancer](#)
- [Long-Term Smoking Cessation Cuts Risk](#)

NCI is establishing a new Clinical Trials Reporting Program (NCI CTRP), based on a June 2005 recommendation submitted by the Clinical Trials Working Group (CTWG), which was approved by the National Cancer Advisory Board.

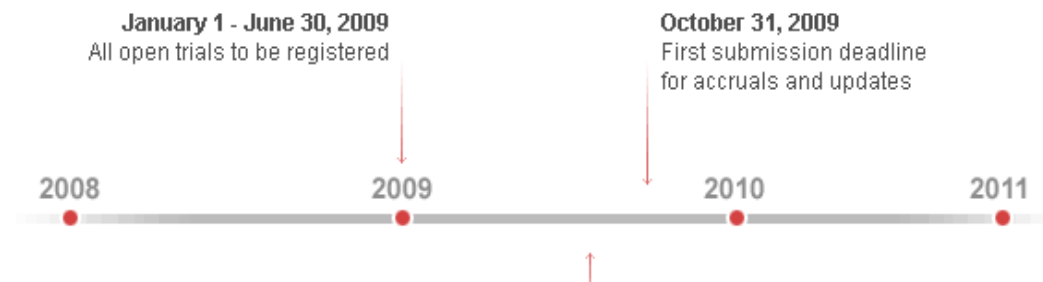
Even though NCI grantees are currently subject to trial reporting requirements, an upgraded set of mandatory reporting requirements will apply starting January 2009. In the long-term, the new reporting measures will help provide critical data to assist NCI in better coordinating research efforts to optimize our nation's investment in cancer research.

NCI clinical trials reporting will include up-to-date information about the status of all NCI-funded and/or sponsored clinical research, regardless of drug development phase, type of intervention or treatment, study design, or program through which funding is provided.

For More Information

- [NCI's Clinical Trials Reporting Program](#)
- [Frequently Asked Questions](#)
- [Background](#)

Timeline



Questions?



Welcome to NCI Clinical Trials Reporting Portal - Windows Internet Explorer

http://localhost:8080/registry/home.action

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NCI Clinical Trials Reporting Portal

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NCI CTRP

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Home

WELCOME TO NCI CLINICAL TRIALS REPORTING PORTAL

NCI Clinical Trials Reporting Portal is a registry system for NCI clinical trials that gives you the tools to:

- * [Search for NCI clinical trials](#) submitted by members of the [caBIG™ community](#). You can view detailed trial information such as the title, NCI and Lead Organization Trial Identifier, phase, status, principal investigators, and more.
- * [Submit your NCI clinical trials](#) and join our community of contributing scientists.
- * [Login / Register](#) to enter protocol details into the system.

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