



**caBIG**<sup>™</sup> cancer Biomedical  
Informatics Grid<sup>™</sup>

# NCI Clinical Trials Database Implementation Plan

***Ken Buetow, Ph.D.***

*Director,  
Center for Biomedical Informatics  
and Information Technology*

U.S. DEPARTMENT  
OF HEALTH AND  
HUMAN SERVICES

National Institutes  
of Health

May 2007



*“The CTWG envisions an enhanced cancer clinical trials enterprise in which increased participation by the extramural community in the prioritization process more effectively focuses resources on those trials judged most likely to facilitate advances in treatment. The success of this strengthened prioritization process depends on a **shared foundation of comprehensive, up-to-date information about the status of cancer clinical trials.**”*

- CTWG Report

## Four Related Informatics-focused Initiatives



- Establish a comprehensive database containing regularly-updated information on all NCI-funded clinical trials (***Clinical Trials Database***)
- Promote the establishment of a National Clinical Trial Information Technology Infrastructure that is fully interoperable with caBIG™ (***System Interoperability & Harmonization***)
- Develop standard case report forms that incorporate common data elements, in consultation with industry and the FDA (***Case Report Forms***)
- Develop a repository of investigator and site credentials that is recognized and accepted by NCI, industry sponsors, clinical investigators and clinical trial sites (***Investigator & Site Credentialing Repository***)

## Four Related Informatics-focused Initiatives



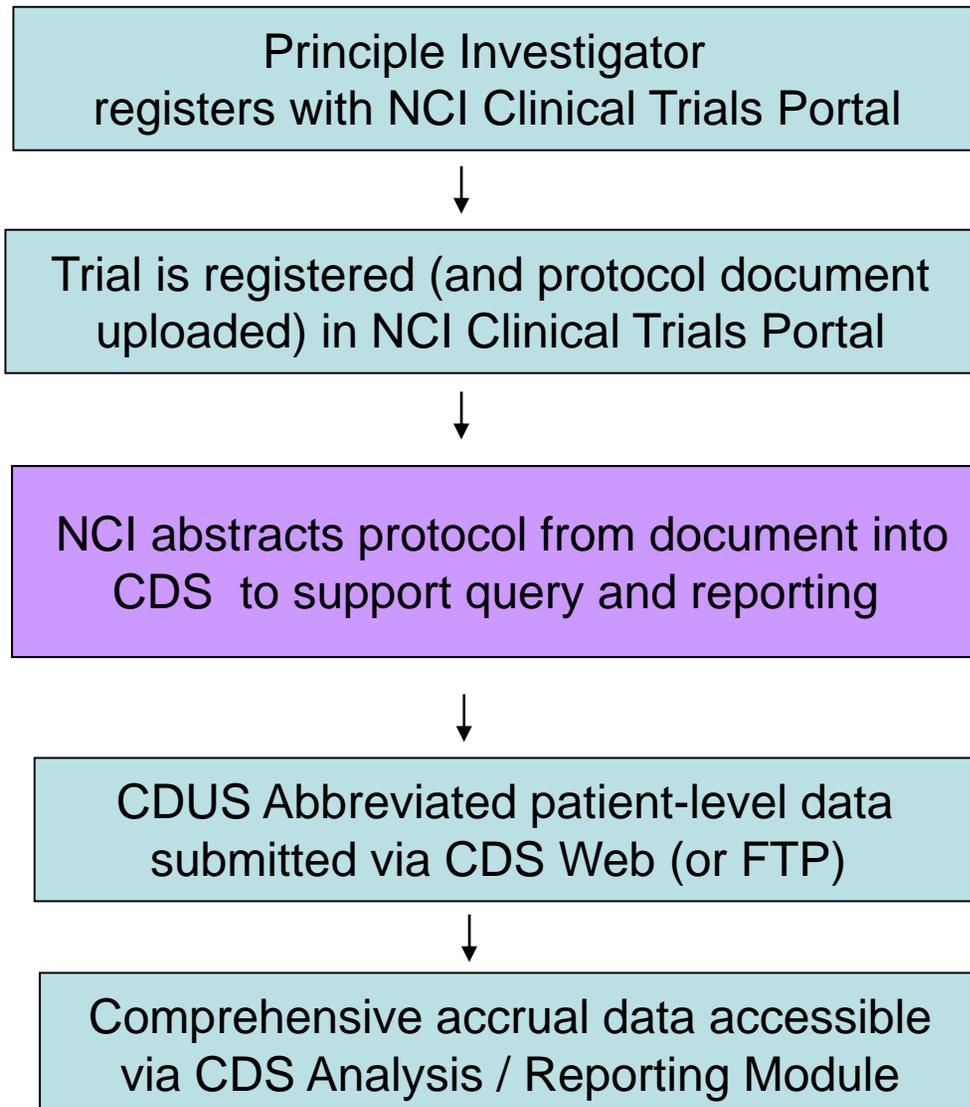
- Establish a comprehensive database containing regularly-updated information on all NCI-funded clinical trials (***Clinical Trials Database***)
- Promote the establishment of a National Clinical Trial Information Technology Infrastructure that is fully interoperable with caBIG™ (***System Interoperability & Harmonization***)
- Develop standard case report forms that incorporate common data elements, in consultation with industry and the FDA (***Case Report Forms***)
- Develop a repository of investigator and site credentials that is recognized and accepted by NCI, industry sponsors, clinical investigators and clinical trial sites (***Investigator & Site Credentialing Repository***)

# Comprehensive, Community- Accessible NCI Clinical Trials Database

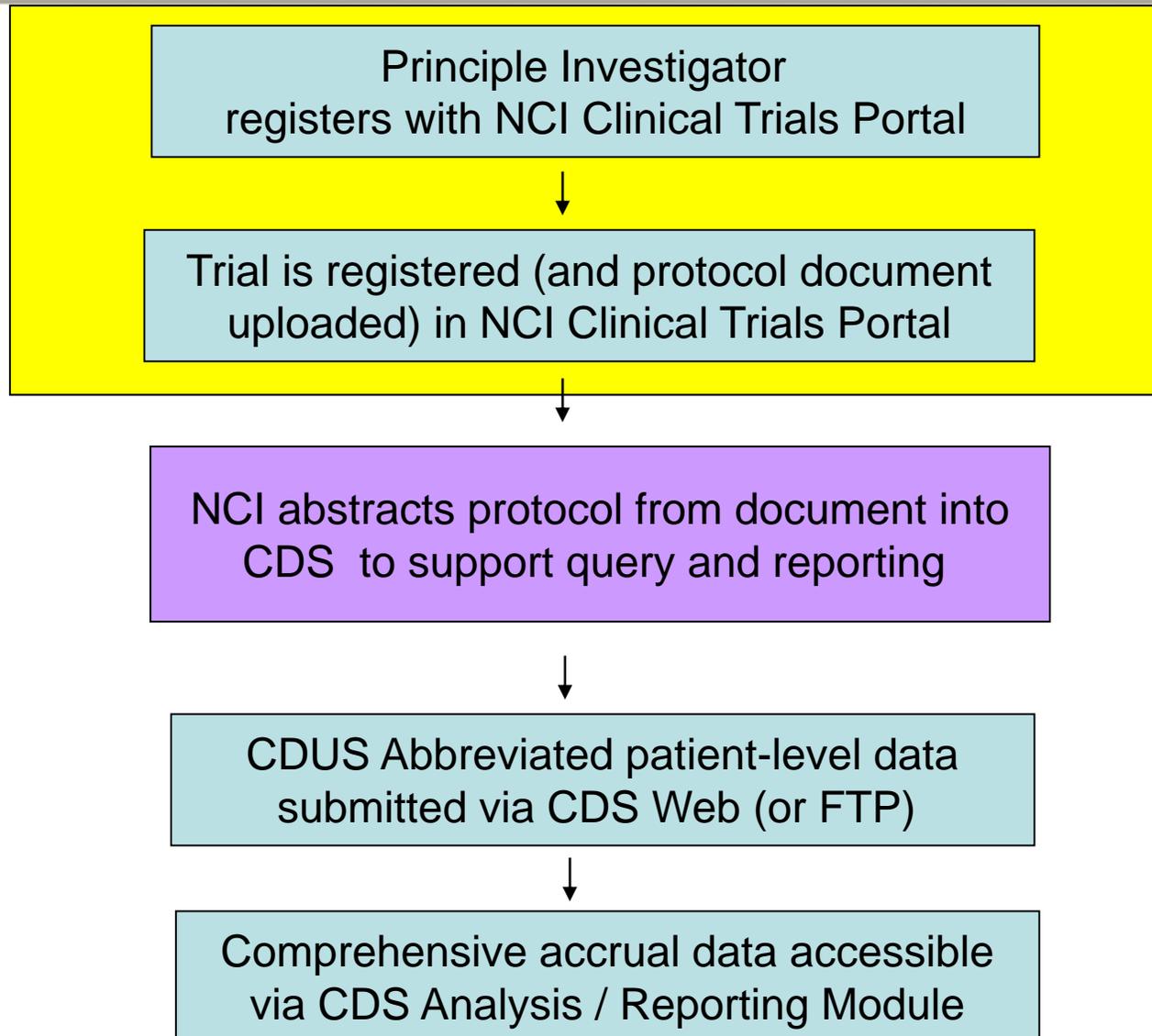


- **A single source for NCI clinical trial data**
- **Transparency on the status of clinical trials**
- **Enhanced ability to mine, compare and analyze data across trials**
- **Potential to expand the database to include data from other sponsors (public and private sector)**
- **Leveraging of NCI's experience and expertise in the design, development and maintenance of clinical trials databases**

# Workflow for Clinical Trials Database



# Workflow for Clinical Trials Database



# Protocol Registration Data Elements: Common Data Elements (CDEs) Identified



- 1. Lead Organization**
- 2. Lead Organization Protocol ID**
- 3. Principal Investigator**
- 4. Sponsor**
- 5. Protocol Title**
- 6. Protocol document/consent document**
- 7. Trial Type**
- 8. Trial Phase**
- 9. Accrual Status**
- 10. Accrual Status date**



National Cancer Institute



caCTUS<sup>™</sup> Cancer Clinical Trial Unified System

caCTUS<sup>™</sup>

- Home
- Search Protocols
- Add a Protocol
- Login/Register
- Help

QUICK LINKS

- [National Cancer Institute \(NCI\)](#)
- [NCI Center for Bioinformatics \(NCICB\)](#)
- [caBIG<sup>™</sup> - Cancer Biomedical Informatics Grid<sup>™</sup>](#)



## Welcome to caCTUS

**Cancer Clinical Trial Unified System (caCTUS<sup>™</sup>)** is a registry system for cancer clinical trial protocols that gives you the tools to:

- [Search for clinical trial protocols](#) submitted by members of the [caBIG<sup>™</sup> community](#). You can view detailed protocol information such as the title, NCI and local identification numbers, study phase, study status, principal investigators, and more.
- [Submit your clinical trial protocols](#) and join our community of contributing scientists.
- [Login/register](#) to enter protocol details into the system.

# Submitter Self Registration – Instant Access



National Cancer Institute



caCTUS™ Cancer Clinical Trial Unified System

caCTUS™

- Home
- Search Protocols
- Add a Protocol
- Login/Register
- Help

QUICK LINKS

- National Cancer Institute (NCI)
- NCI Center for Bioinformatics (NCICB)
- caBIG™ - Cancer Biomedical Informatics Grid™

## My Account

[Help](#)

You may update your account information. Please note: asterisks (\*) indicate required fields.

### Login Information

Email: \*

Password: \*

Re-type Password: \*

### Your Account Profile

First Name: \*

Middle Name:

Last Name: \*

Street Address:

City:

State: \*

Country: \*

Zip/Postal Code:

Phone:

Select Role: \*

Affiliate Organization: \*

[\(Add New\)](#)

# Trial Registration and Protocol Document Upload



National Cancer Institute



caCTUS™ Cancer Clinical Trial Unified System

caCTUS™

Home

Search Protocols

Add a Protocol

Logout

Help

QUICK LINKS

[National Cancer Institute \(NCI\)](#)

[NCI Center for Bioinformatics \(NCICB\)](#)

[caBIG™ - Cancer Biomedical Informatics Grid™](#)

## Add a Protocol Help

Add a protocol into caCTUS by submitting this form. Please note: asterisks (\*) indicate required fields.

### Protocol Details

Local Protocol ID: \*

Monitoring Code: \*

Protocol Title: \*

Protocol Document: \*

Type: \*

Phase: \*

Status: \*

Current Status Date: \*

Protocol Visibility: \*  Private  Public

### Lead Organization/Principal Investigator

Lead Organization: \*

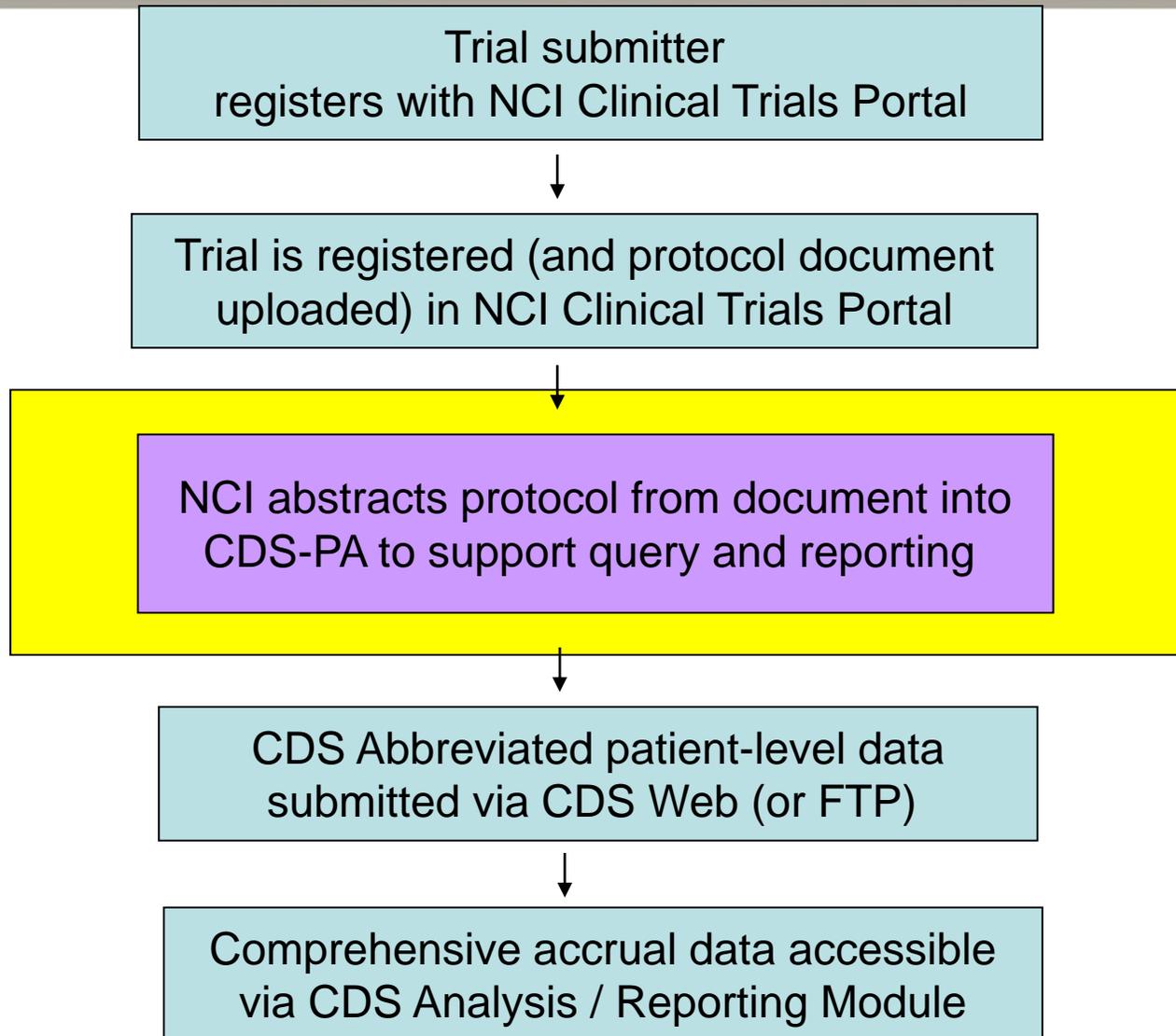
[\(Add New\)](#)

Lead Organization Name:

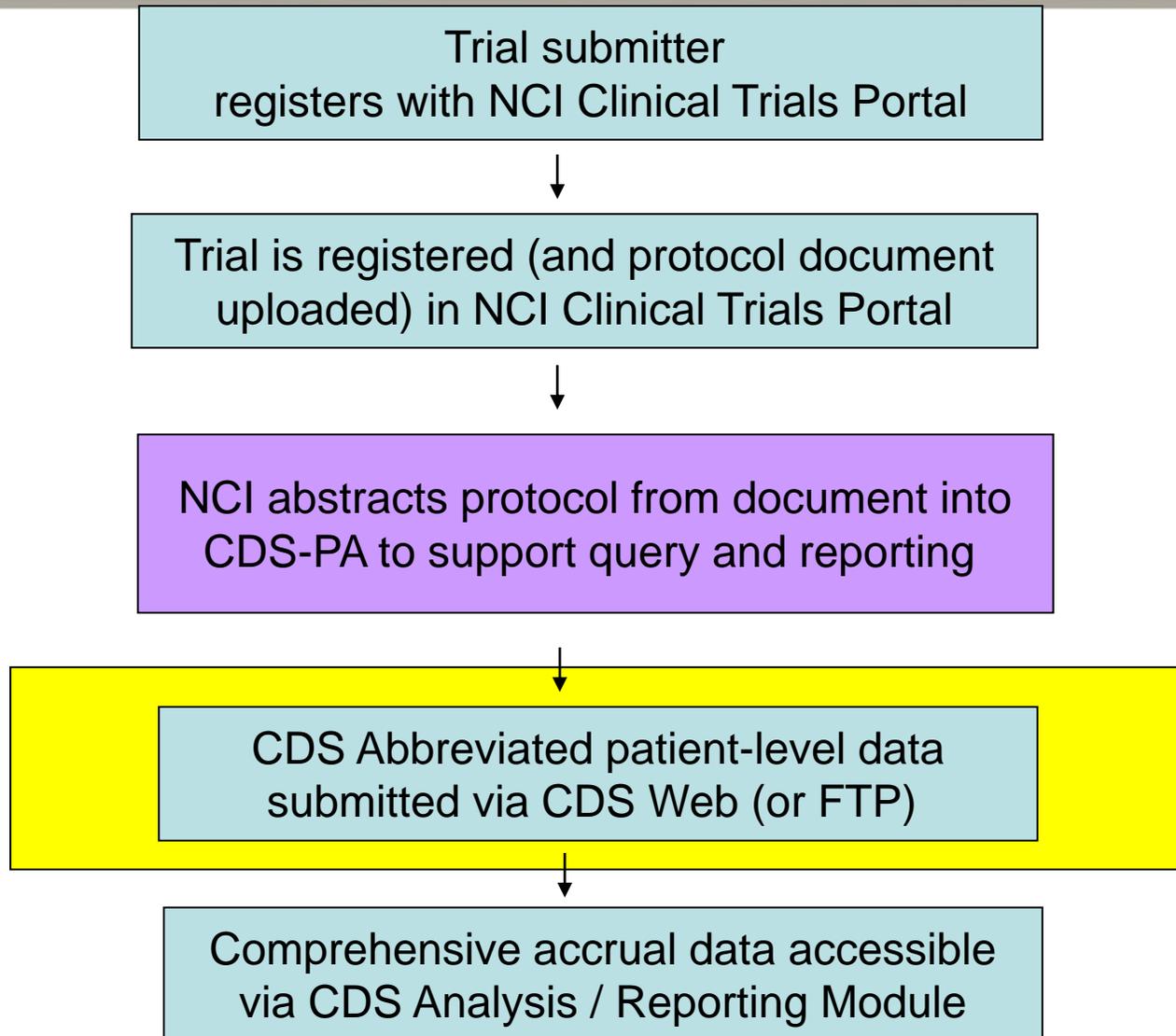
Principal Investigator: \*

[\(Add New\)](#)

## Workflow for Clinical Trials Database: #2



# Workflow for Clinical Trials Database: #3



## caBIG CTMS Steering Committee endorsed systematic reporting of all trials using the Clinical Data Update System (CDUS) core data elements

- Utilized by CTEP and DCP
- Similar content to NCI Center's Program Summary 4
- **Protocol-Specific Data**
  - NCI protocol number
  - Reporting date
  - Data cut-off date
  - Current status
  - Current status date
- **Patient-Specific Data**
  - Patient ID
  - Patient zipcode
  - Patient country code
  - Patient birthdate
  - Patient ethnicity
  - Patient method of payment
  - Date of patient entry
  - Registering institution code
  - Registering group code if applicable
  - Patient gender
  - Patient races table

\*Abbreviated CDUS data set

# CDS Web Accrual / Demographics Screen



Clinical Data System : Data Entry - Microsoft Internet Explorer

Address: https://cdsweb-qa.nci.nih.gov/cdsweb-qa/cdusw03\$.startup?z\_collection\_id=19&z\_doc\_id=652460&z

National Cancer Institute U.S. National Institutes of Health | www.cancer.gov

User: Stephanie Whitley Logoff | Help

**DEMOTESTPROTOCOL18 (07/31/2007)**

- Patient (1234, 04/1955)
  - Administrative Data
  - Baseline Abnormalities
  - Prior Therapies
  - Treatment Courses
  - Responses
  - Late Adverse Events
- Publications
- Correlative Studies
- Phase I End Points MTD
- Phase I End Points DLT
- Trial Comments
- Reports
  - CTC Application
  - View Collection
  - View Protocol Selection
  - Help

**Patients**

Select a patient to proceed

Patient ID	Birth Date (MM/YYYY)
1234	04/1955

Record 1 of 1

ReQuery

Query

New

**Protocol Number: DEMOTESTPROTOCOL18**

**Patient Demographic Data**

<b>Patient ID:</b> Enter the unique code assigned at the time of registration to this study.	1234
<b>Birth Date (MM/YYYY):</b>	04/1955
<b>Gender:</b>	Female
<b>Ethnicity:</b>	Not Hispanic or Latino
<b>Races:</b>	<input checked="" type="checkbox"/> Asian <input checked="" type="checkbox"/> Black or African American <input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Not Reported <input type="checkbox"/> Unknown <input type="checkbox"/> White
<b>Country Name:</b>	United States
<b>Zip Code:</b>	20817

Click to expand

Internet

# CDS Web Accrual / Demographics Screen (continued)



Clinical Data System : Data Entry - Microsoft Internet Explorer

Address: https://cdsweb-qa.nci.nih.gov/cdsweb-qa/cdusw03\$.startup?z\_collection\_id=19&z\_doc\_id=652460&z\_

**National Cancer Institute** U.S. National Institutes of Health | www.cancer.gov

**CDS WEB** User: Stephanie Whitley [Logoff](#) | [Help](#)

**DEMOTESTPROTOCOL18 (07/31/2007)**

- [-] Patient (1234, 04/1955)
  - Administrative Data
  - Baseline Abnormalities
  - Prior Therapies
  - Treatment Courses
  - Responses
  - Late Adverse Events
- [+] Publications
- Correlative Studies
- Phase I End Points MTD
- Phase I End Points DLT
- Trial Comments
- [+] Reports
  - CTC Application
  - View Collection
  - View Protocol Selection
  - Help

**Patients**

Select a patient to proceed

Patient ID	Birth Date (MM/YYYY)
1234	04/1955

Record 1 of 1

[ReQuery](#)

[Query](#)

[New](#)

White

Country Name:

Zip Code:

Payment Method:

Entry Date (MM/DD/YYYY):

Registering Group:

Reg Group ID:

Registering Institution:

Reg Inst ID:

Disease Category:

Disease Sub Category:

Disease Name:

[Save](#) [Delete](#) [Clear](#) [New](#)

*All data elements in bold are mandatory*

# Workflow for Clinical Trials Database: #4



Trial submitter registers with NCI Clinical Trials Portal



Trial is registered (and protocol document uploaded) in NCI Clinical Trials Portal



NCI abstracts protocol from document into CDS-PA to support query and reporting



CDS Abbreviated patient-level data submitted via CDS Web (or FTP)



Comprehensive accrual data accessible via CDS Analysis / Reporting Module

# Available Reports for Selected Protocols



CDS-AR - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <http://wxp-skakar:8988/cdsreports/CDSPeraSelection.do> Go Links >>

National Cancer Institute U.S. National Institutes of Health | [www.cancer.gov](http://www.cancer.gov)

**CDS-AR** **CDS-AR > Reports** **User: Test User1**  
[Log Off](#) | [Help](#)

**Query Condition:**  
Monitoring Method = CDUS - Abbreviated, CDUS - Complete  
AND Protocol Phase = I, I/II, II  
AND Current Trial Status = Active

**CDS-AR Reports**

- Accrual**
  - Accrual By Protocol
  - Accrual By Gender/Race - Protocols
  - Accrual By Gender/Race - Organizations
  - Accrual By Institution
- Adverse Event**
  - Adverse Event
  - Patient Specific Information
  - Subgroup Adverse Event
  - Subgroup Response and Adverse Event
- Correlative Study**
  - Correlative Study
- Demographics**
  - Patient Demographic - Single Protocol
  - Population Demographics
- Dropout**
  - Dropout
- Publication**
  - Publications

Done Local intranet

start 2 Microsoft... /cjs\_data/cd... Oracle Forms... SQL Navigator Microsoft Po... CDS-AR - Mic... 3:26 PM

- **Assemble NCI Policy Implementation Teams to address:**
  - “Legacy” data migration
  - Protocol abstraction
  - Quality Control and Quality Assurance
  - Ensure generation of Summary 4 and ClinicalTrials.gov submissions
- **Develop timeline to coordinate activities**

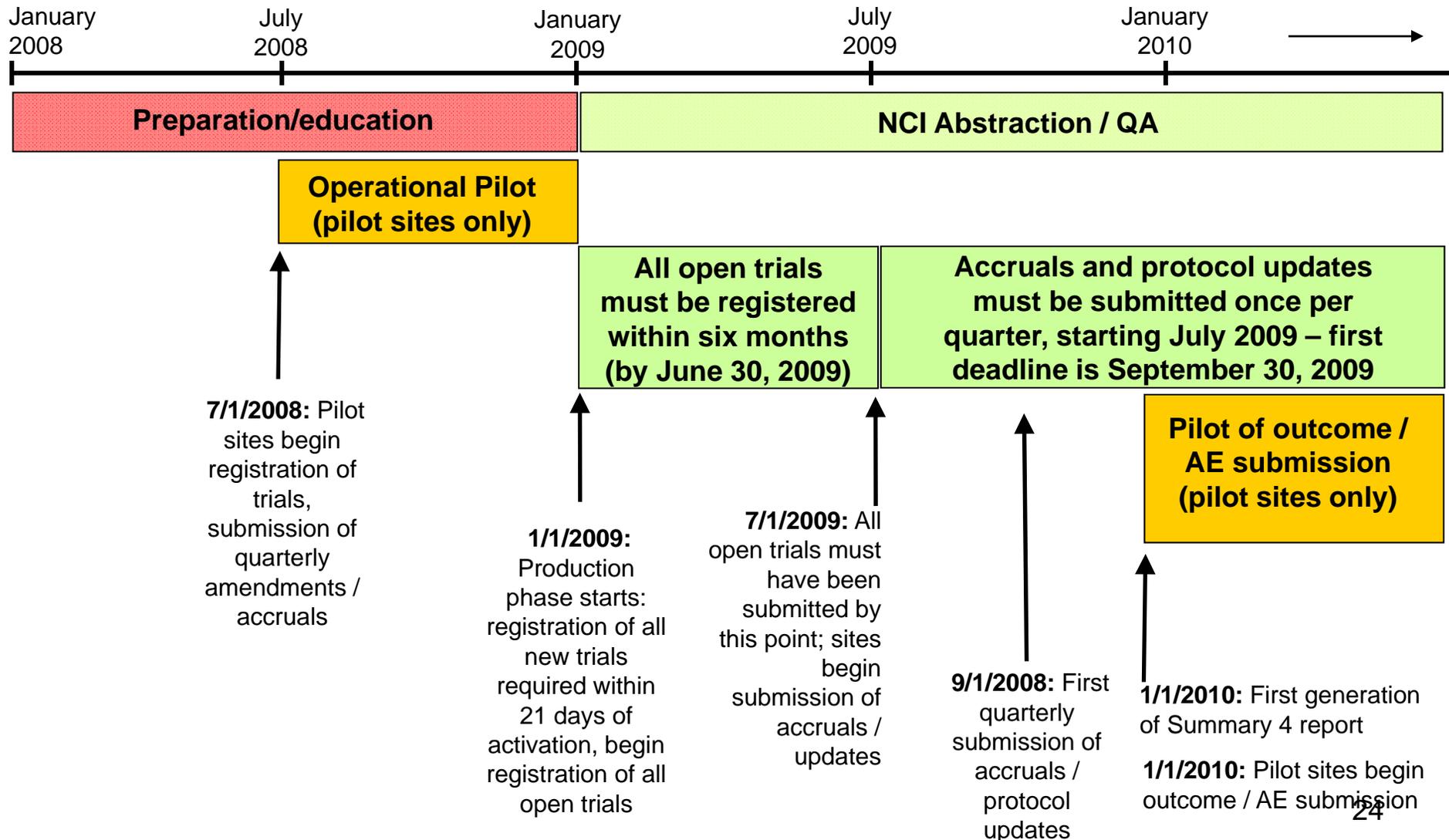
- **Additional** registration/reporting is **not** required for trials already reported to CTEP / DCP – NCI will transfer information
- Reporting is required for **interventional trials only** (for now)
- **For NCI-sponsored trials:** Reporting will be at the PI level (*i.e.*, the PI's office will be responsible for reporting for all sites)
- **For non-NCI-sponsored trials** at NCI-designated Cancer Centers, **including investigator-initiated** : Reporting will be at the site level.

- 
- Initially, **new trials** initiated after production date of 1/1/2009 must be entered **within 21 days after activation**
- **All active trials** must be entered **within six months** (*i.e.*, by 6/30/2009)
- Starting 7/1/2009, **quarterly reporting of all trial updates** will be required (*i.e.*, immediate submission of every amendment is not required)
- Starting 7/1/2009, **quarterly entry of accrual information** will be required.

- Six-month NCI preparation period starting January 1, 2008
  1. Educational documents (including SOPs) being assembled
  2. Informational web site being assembled
  3. Master lists of grant recipients being assembled
  4. Potential sites for the operational pilot will be identified and recruited
  5. Information will be prepared for dissemination to sites about pending requirements
  6. Contracting vehicles for NCI QA / abstraction staff identified and initiated
  7. Help desk staff will be trained
  8. Data elements are being identified, and included within the informatics infrastructure, to fulfill requirements of Cancer Center Summary 4 Report / FDA Amendments Act of 2007

1. Operational Pilot (July-December 2008)
  - Approximately five sites will be selected for pilot
  - Sites will receive compensation for participation in pilot
2. Release 1: Production (January-December 2009)
  - Updated protocol detail data elements to fulfill:
    - Cancer Centers Branch Summary 4 Report
    - Trial registration to NIH per FDA Amendments Act of 2007
  - Quarterly patient-level reporting of accruals starts July 2009
  - Quarterly protocol updates (amendments, etc.) starts July 2009
3. Release 2: Outcome Reporting (pilot starts January 2010)
  - Adverse events and outcomes reporting
  - Reporting of AEs / outcomes to NIH as per FDA Amendments Act
  - A pilot will be required

# Timeline



# Public Law 110-85, aka HR 3580, aka FDA Amendments Act



## One Hundred Tenth Congress of the United States of America

AT THE FIRST SESSION

*Began and held at the City of Washington on Thursday,  
the fourth day of January, two thousand and seven*

### An Act

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and for medical devices, to enhance the postmarket authorities of the Food and Drug Administration with respect to the safety of drugs, and for other purposes.

*Be it enacted by the Senate and House of Representatives of  
the United States of America in Congress assembled,*

#### SECTION 1. SHORT TITLE.

This Act may be cited as the “Food and Drug Administration Amendments Act of 2007”.

#### SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

# Questions?



 National Cancer Institute U.S. National Institutes of Health | [www.cancer.gov](http://www.cancer.gov)

---

**NCI Clinical Trials Portal** User: [amiruddin@mail.nih.gov](mailto:amiruddin@mail.nih.gov) | [Logout](#) powered by  caCTUS™

NCI Clinical Trials Portal

- Home
- Search Protocols
- Add a Protocol
- Login/Register
- Help

**QUICK LINKS**

- [National Cancer Institute \(NCI\)](#)
- [NCI Center for Bioinformatics \(NCICB\)](#)
- [caBIG™ - Cancer Biomedical Informatics Grid™](#)



**Welcome to NCI Clinical Trials Portal**

**NCI Clinical Trials Portal** powered by caCTUS™ is a registry system for cancer clinical trial protocols that gives you the tools to:

- [Search for clinical trial protocols](#) submitted by members of the [caBIG™ community](#). You can view detailed protocol information such as the title, NCI and local identification numbers, trial stage, trial status, principal investigators, and more.
- [Submit your clinical trial protocols](#) and join our community of contributing scientists.
- [Login/register](#) to enter protocol details into the system.

---

[CONTACT US](#) | [PRIVACY NOTICE](#) | [DISCLAIMER](#) | [ACCESSIBILITY](#) | [CACTUS SUPPORT](#)