National Cancer Institute

caBIG™ cancer Biomedical Informatics Grid ™

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

CTWG Theme: Coordination

"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)***

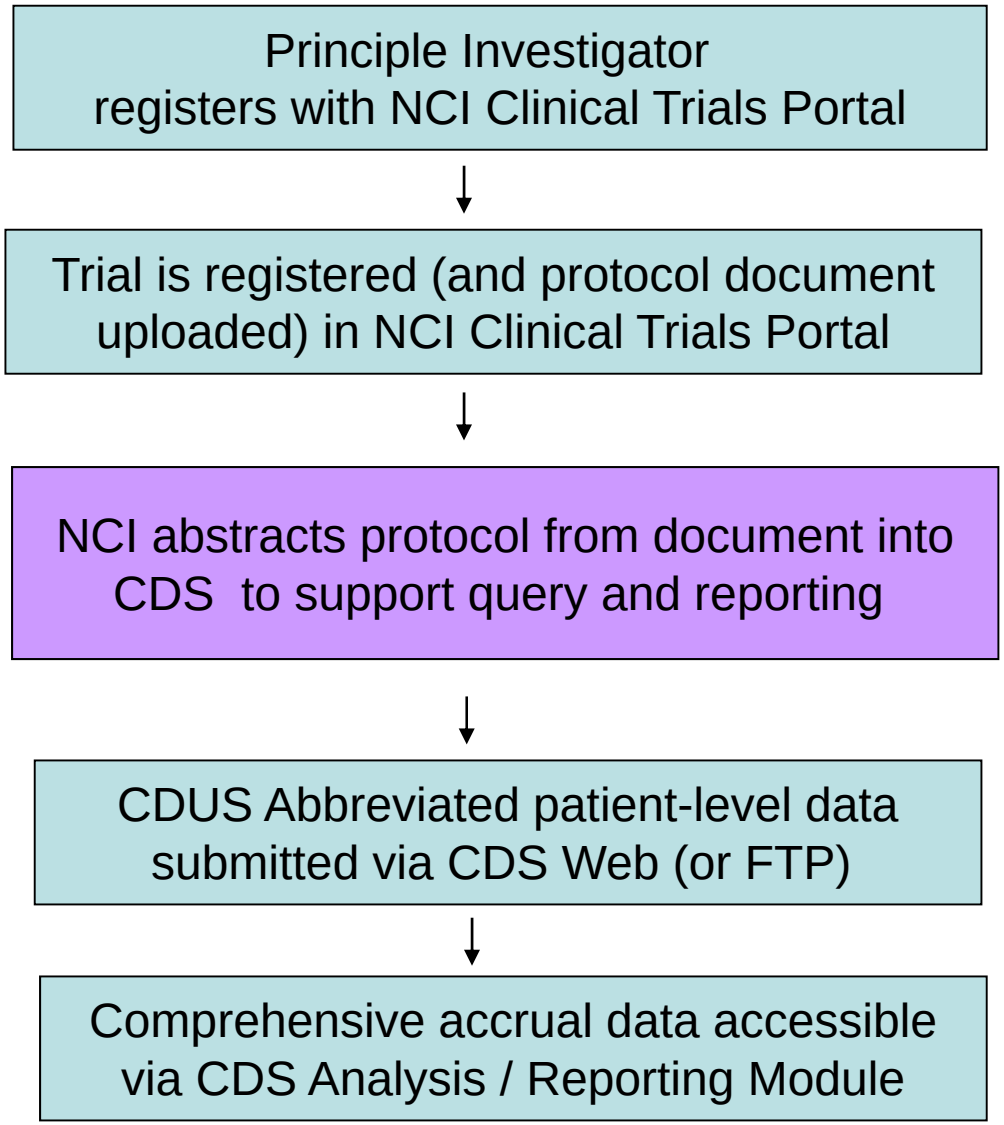
Four Related Informatics-focused Initiatives

- 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)***

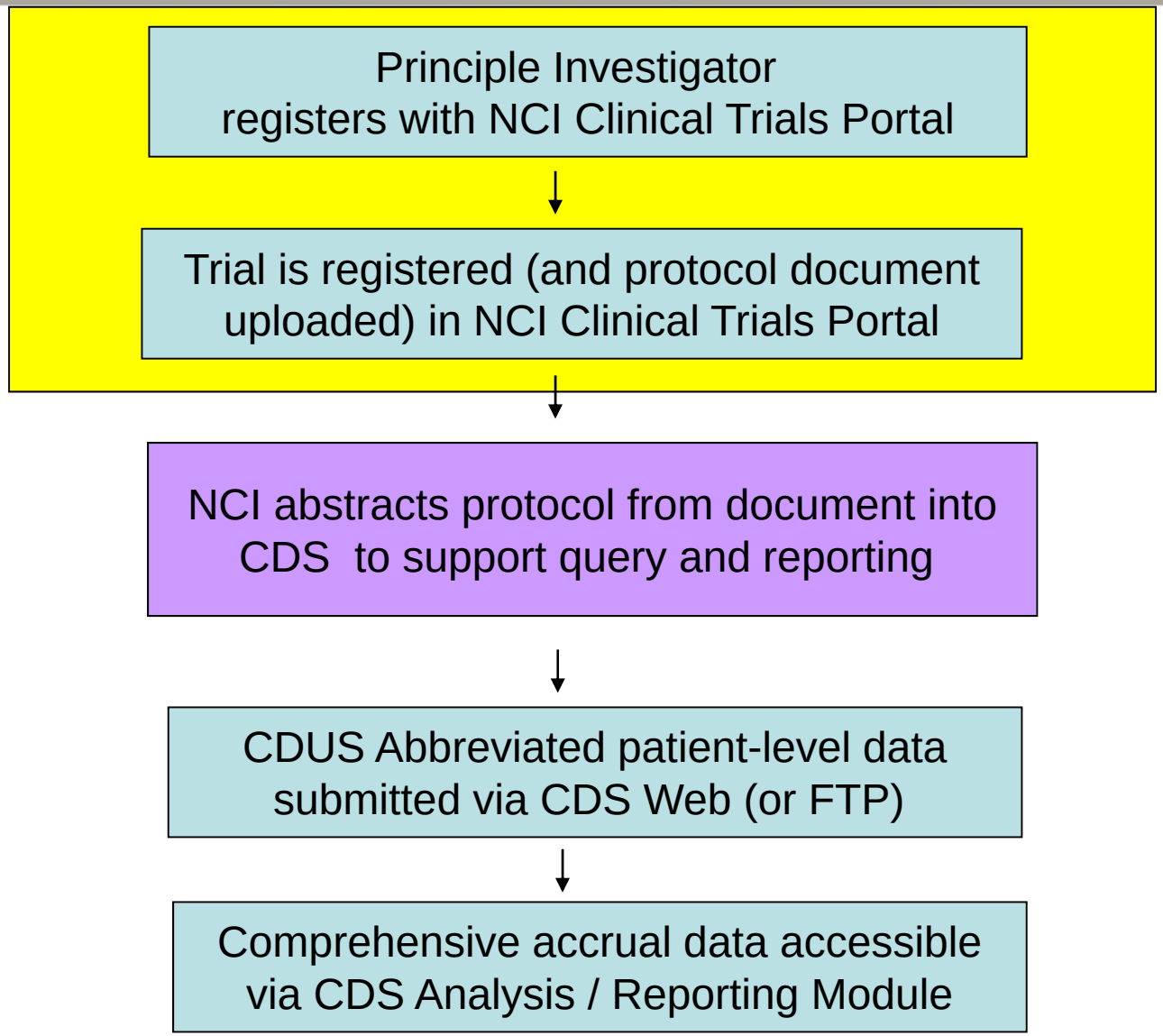
Comprehensive, Community- Accessible NCI Clinical Trials Database

- **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

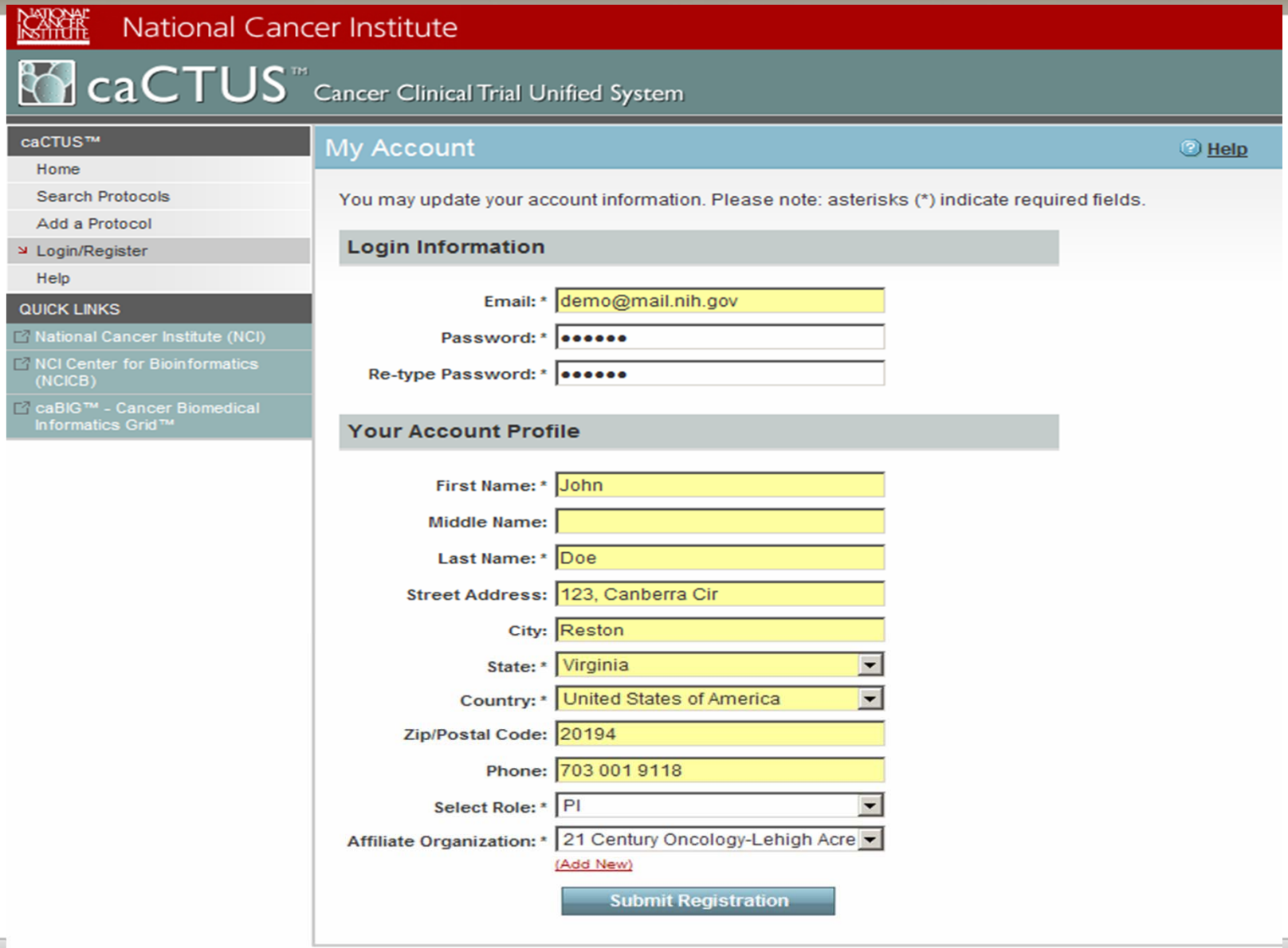


Protocol Registration Data Elements: Common Data Elements (CDEs) Identified

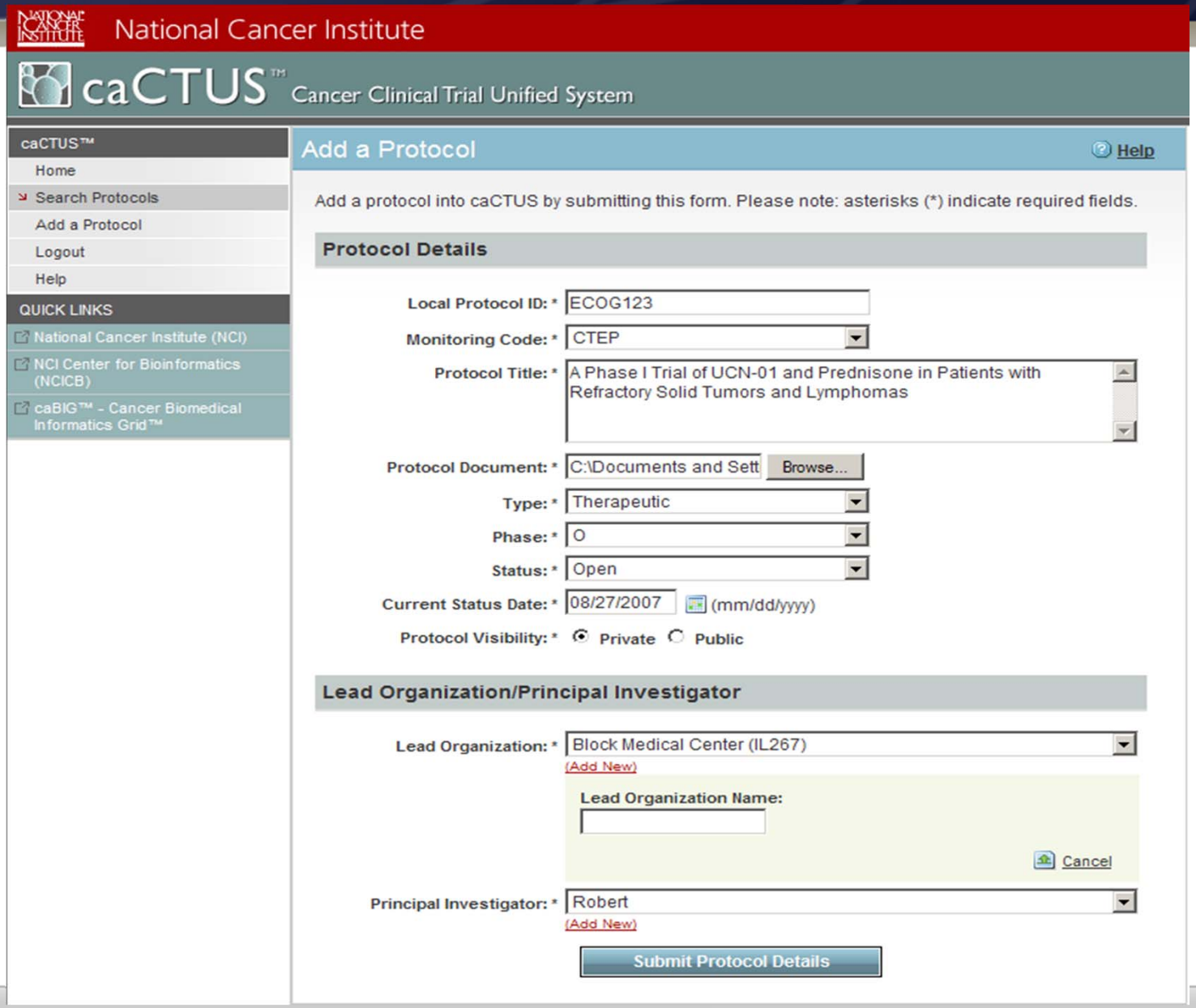
1. Lead Organization
2. Lead Organization Protocol ID
3. Principal Investigator
4. Sponsor
5. Protocol Title
6. Protocol document/consent document
7. Trial Type
8. Trial Phase
9. Accrual Status
10. Accrual Status date

NCI Clinical Trials Portal

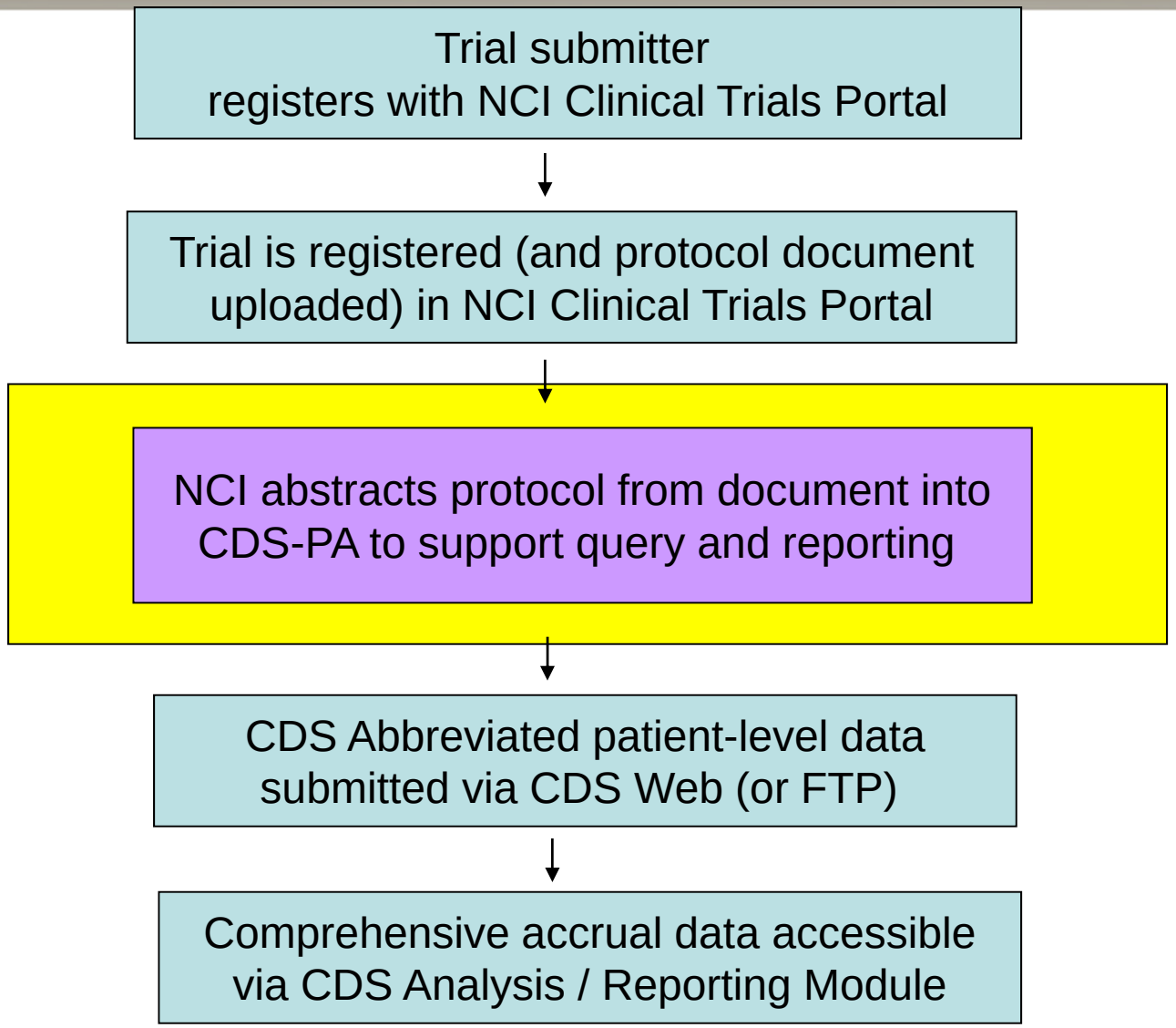
Submitter Self Registration – Instant Access



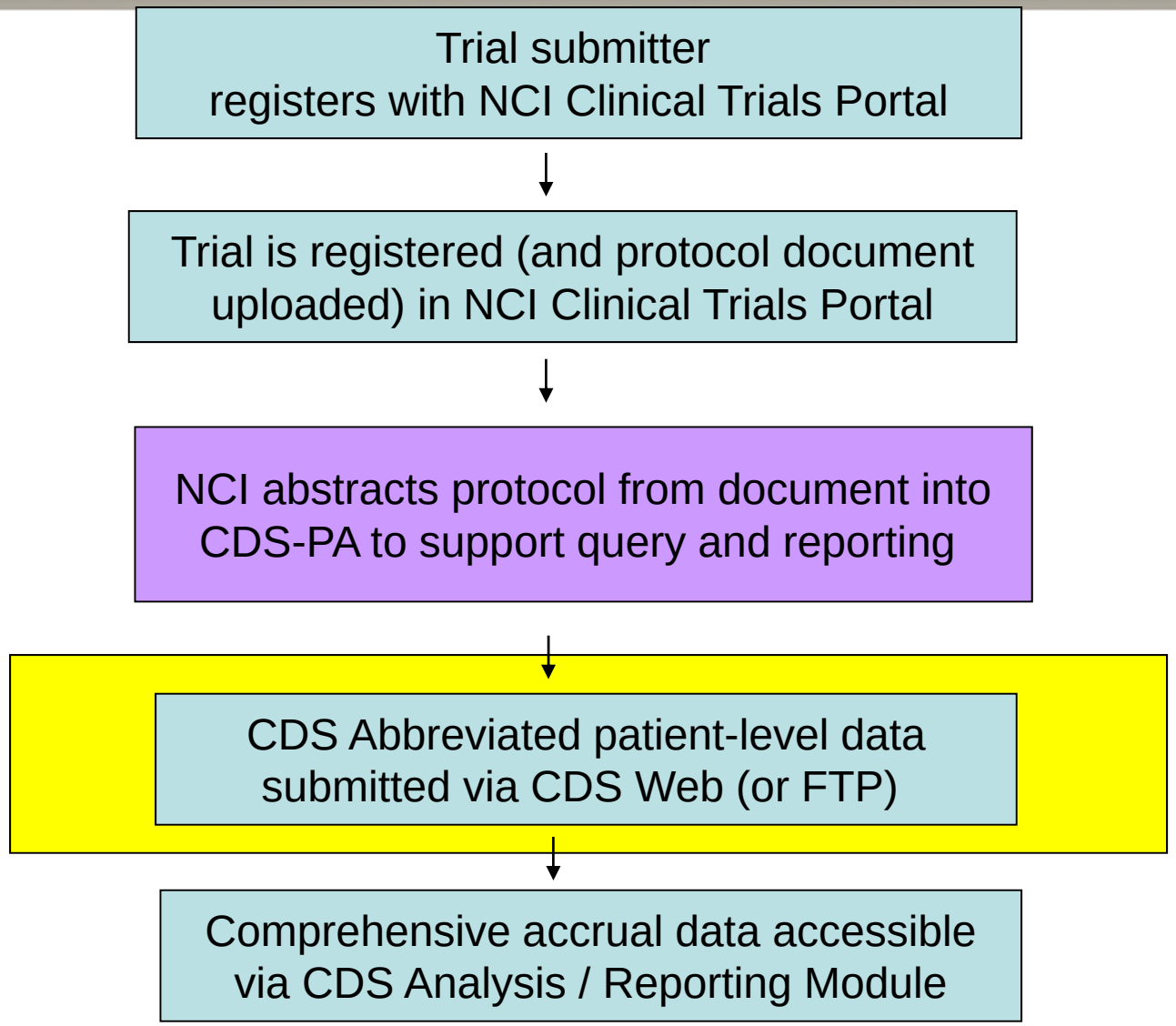
Trial Registration and Protocol Document Upload



Workflow for Clinical Trials Database: #2



Workflow for Clinical Trials Database: #3



CDUS Content

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

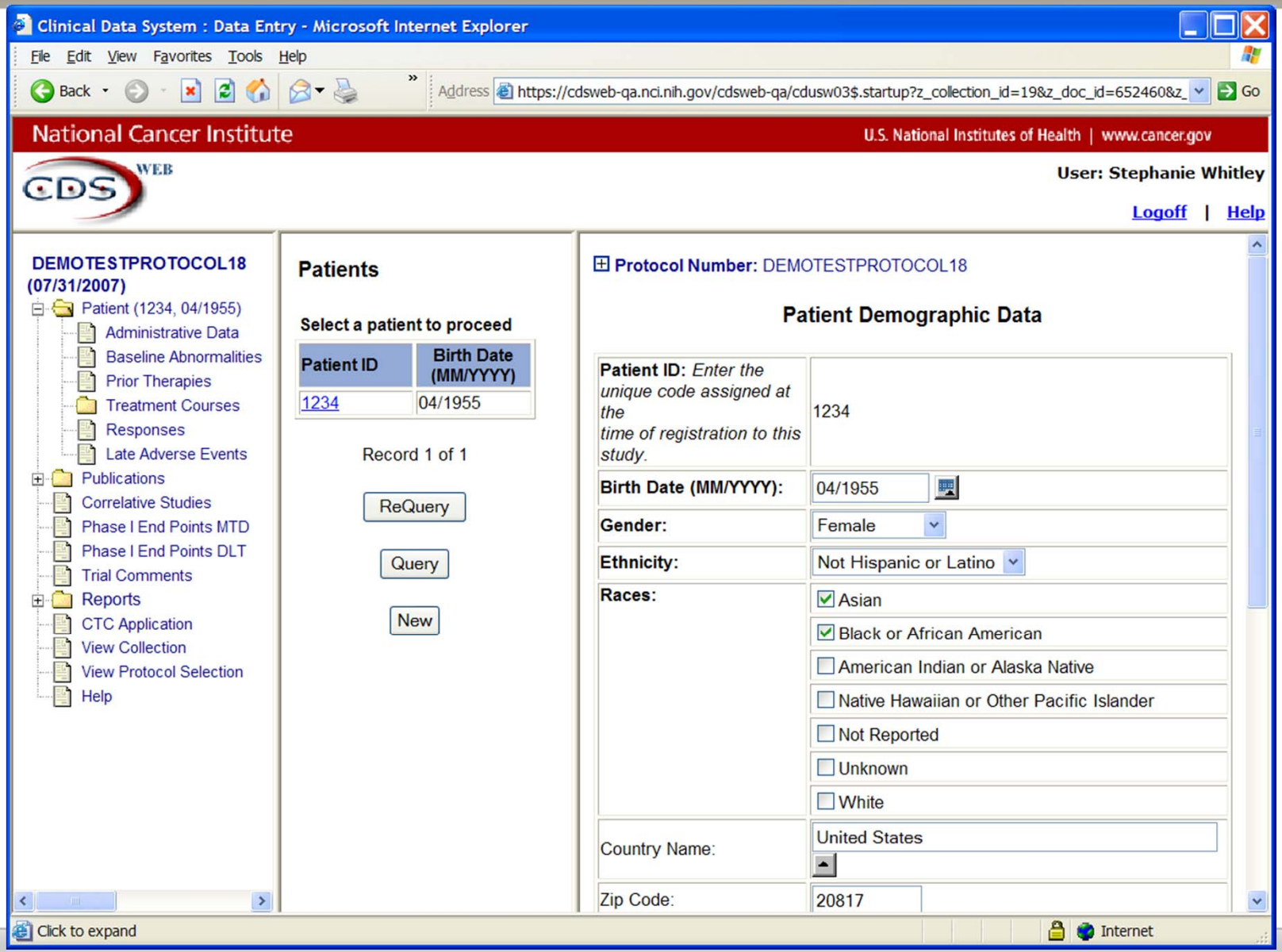
- Utilized by CTEP and DCP
- Similar content to NCI Center's Program Summary 4

- **Protocol-Specific Data**
  - NCI protocol number
  - Reporting date
  - Data cut-off date
  - Current status
  - Current status date

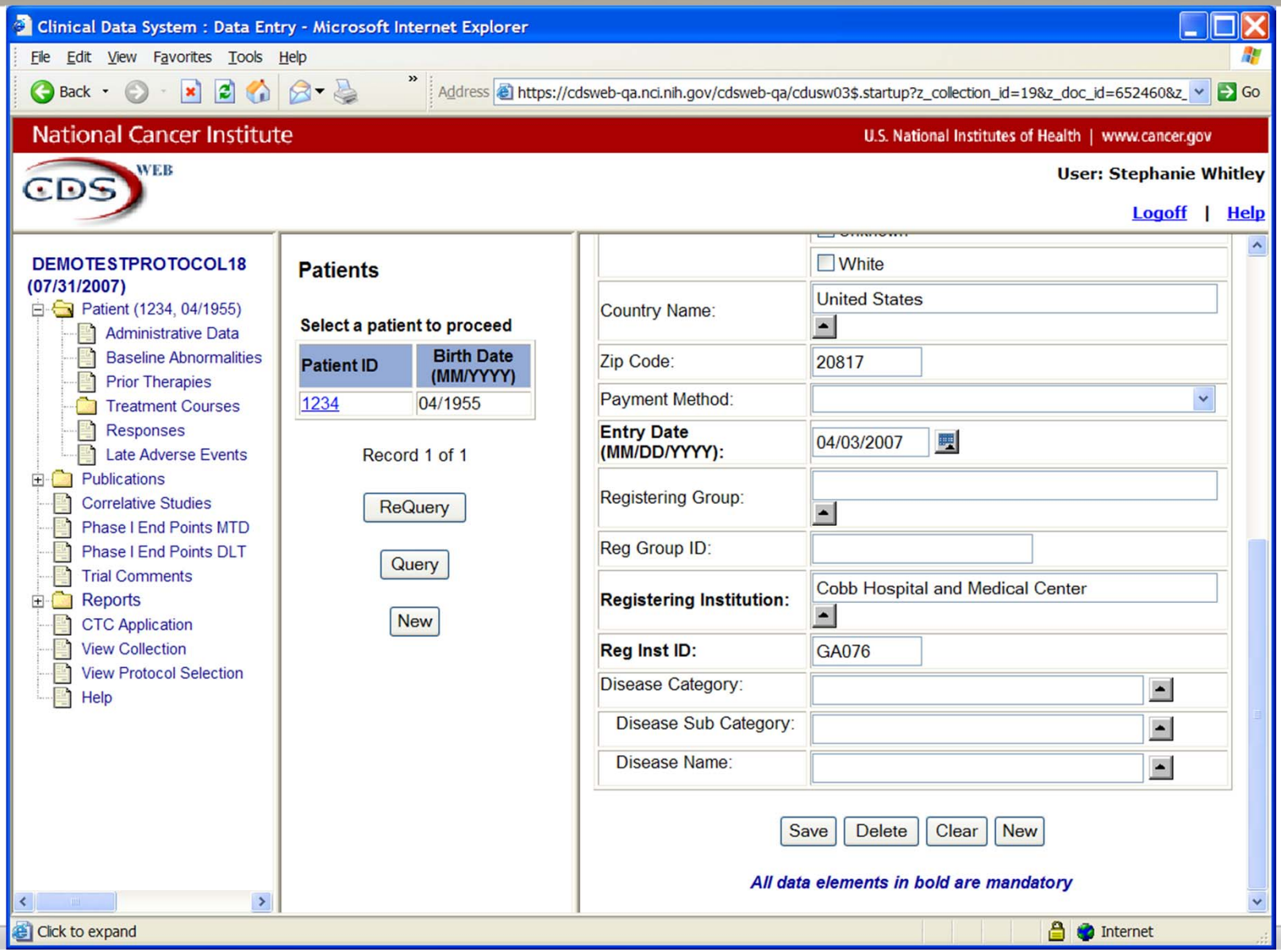
- **Patient-Specific Data**
  - Patient ID
  - Patient zipcode
  - Patient country code
  - Patient birthdate
  - Patient gender
  - Patient races table
  - Patient ethnicity
  - Patient method of payment
  - Date of patient entry
  - Registering institution code
  - Registering group code if applicable

*Abbreviated CDUS data set

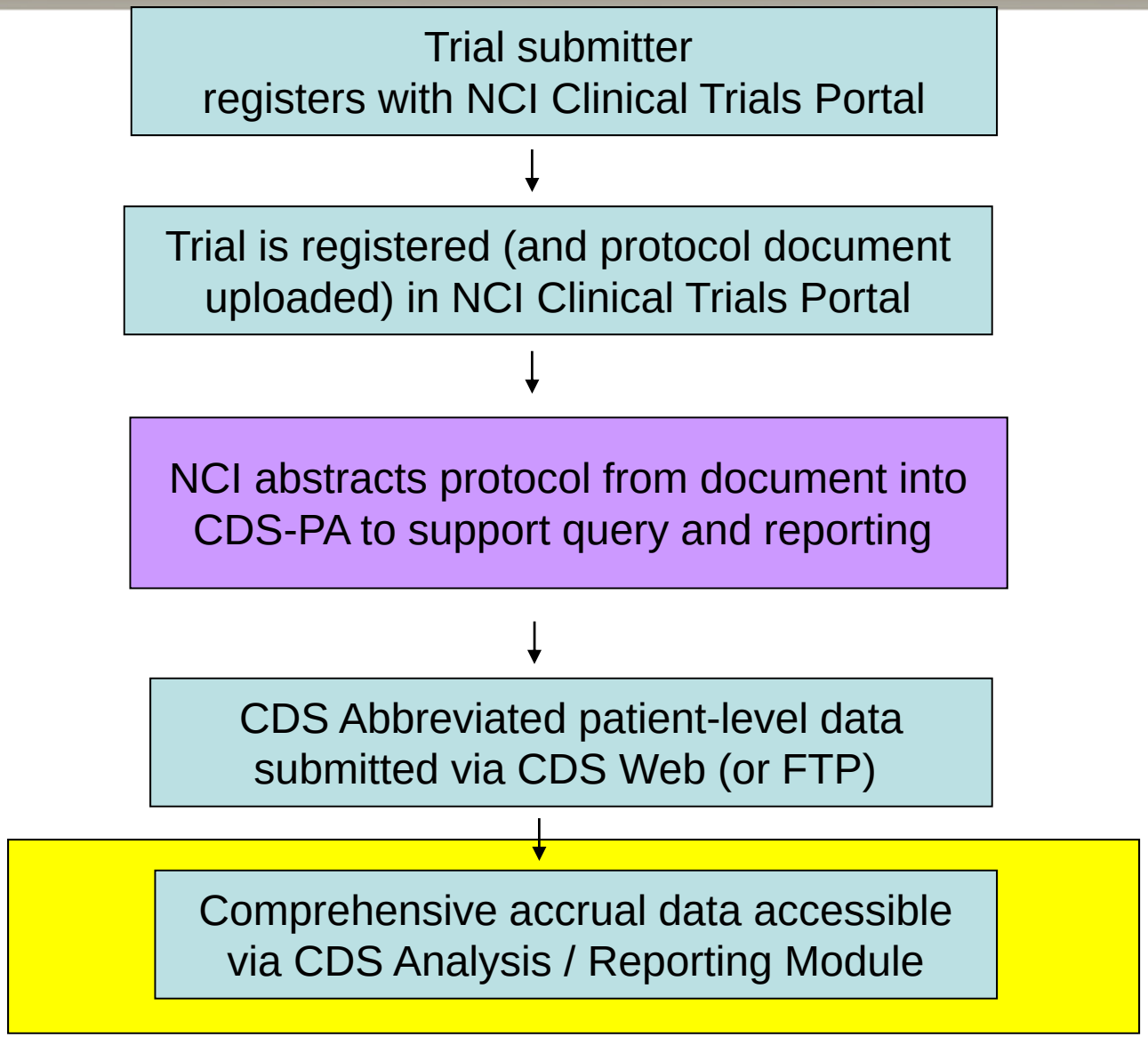
CDS Web Accrual / Demographics Screen



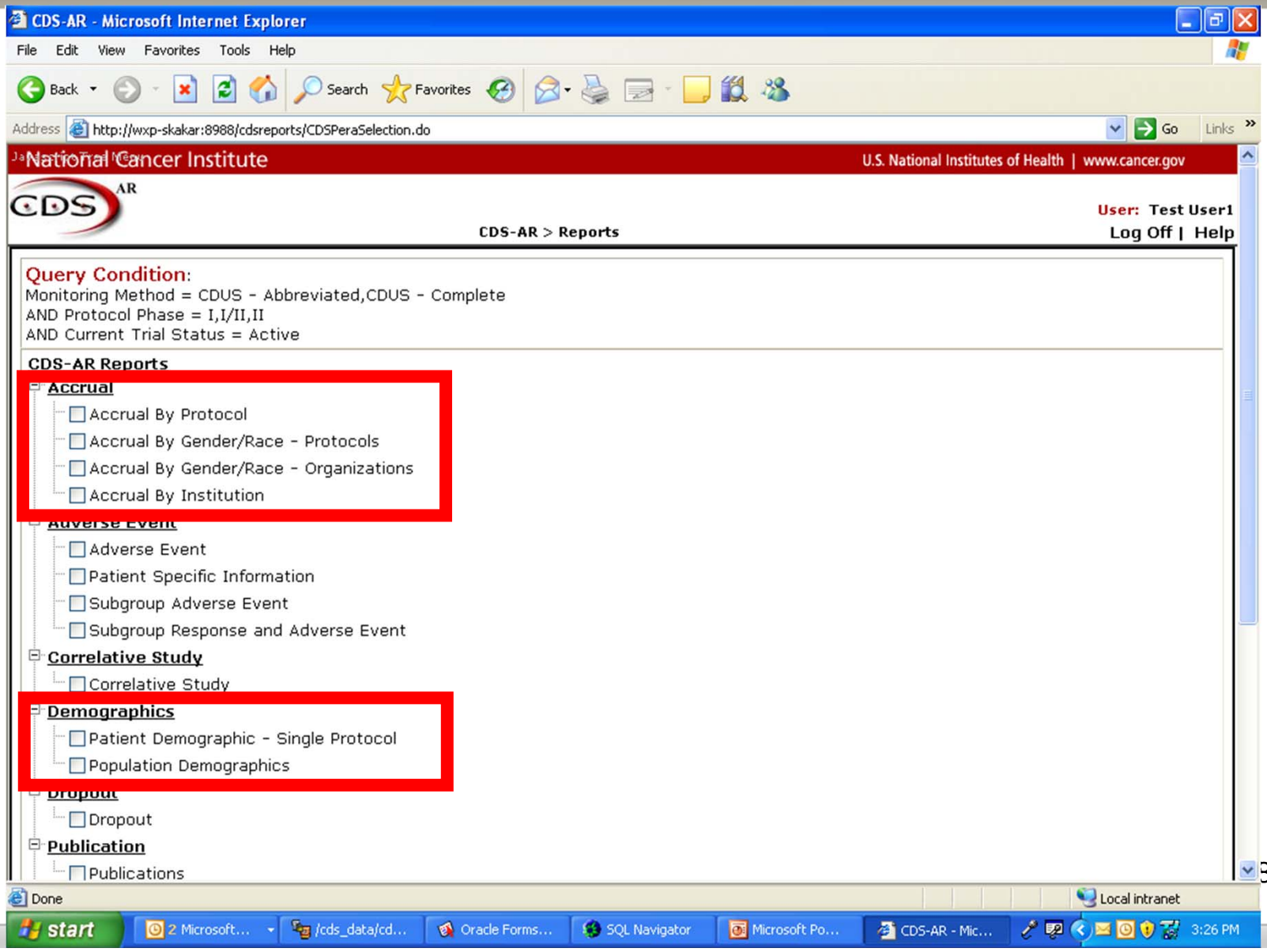
CDS Web Accrual / Demographics Screen (continued)



Workflow for Clinical Trials Database: #4



Available Reports for Selected Protocols



Next Steps for the Clinical Trials Database

- **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**

Moving Forward – Who/what is reported

- **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.

Moving Forward - Timelines

.

- 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.

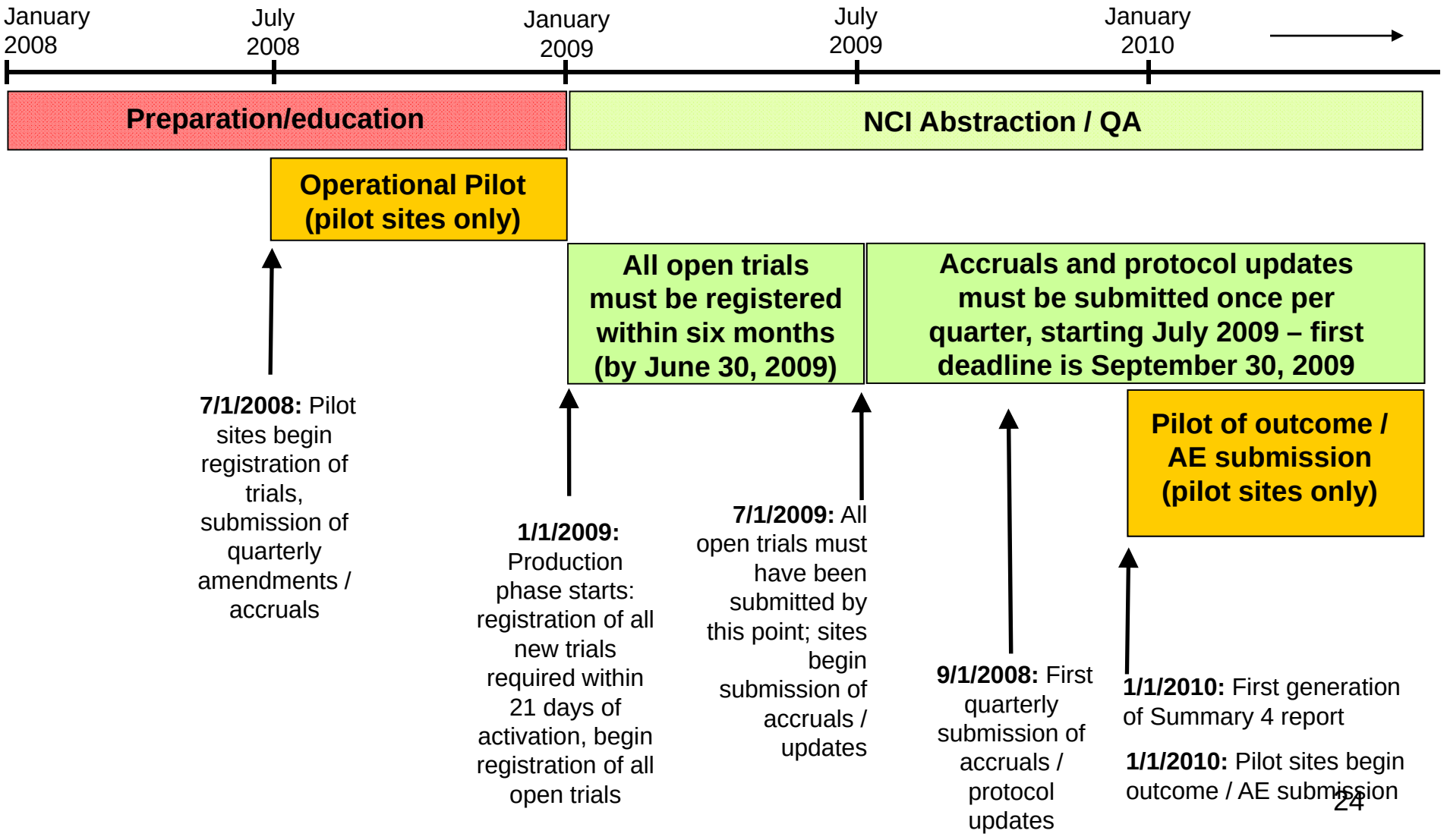
Phased Deployment: Preparation

- 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

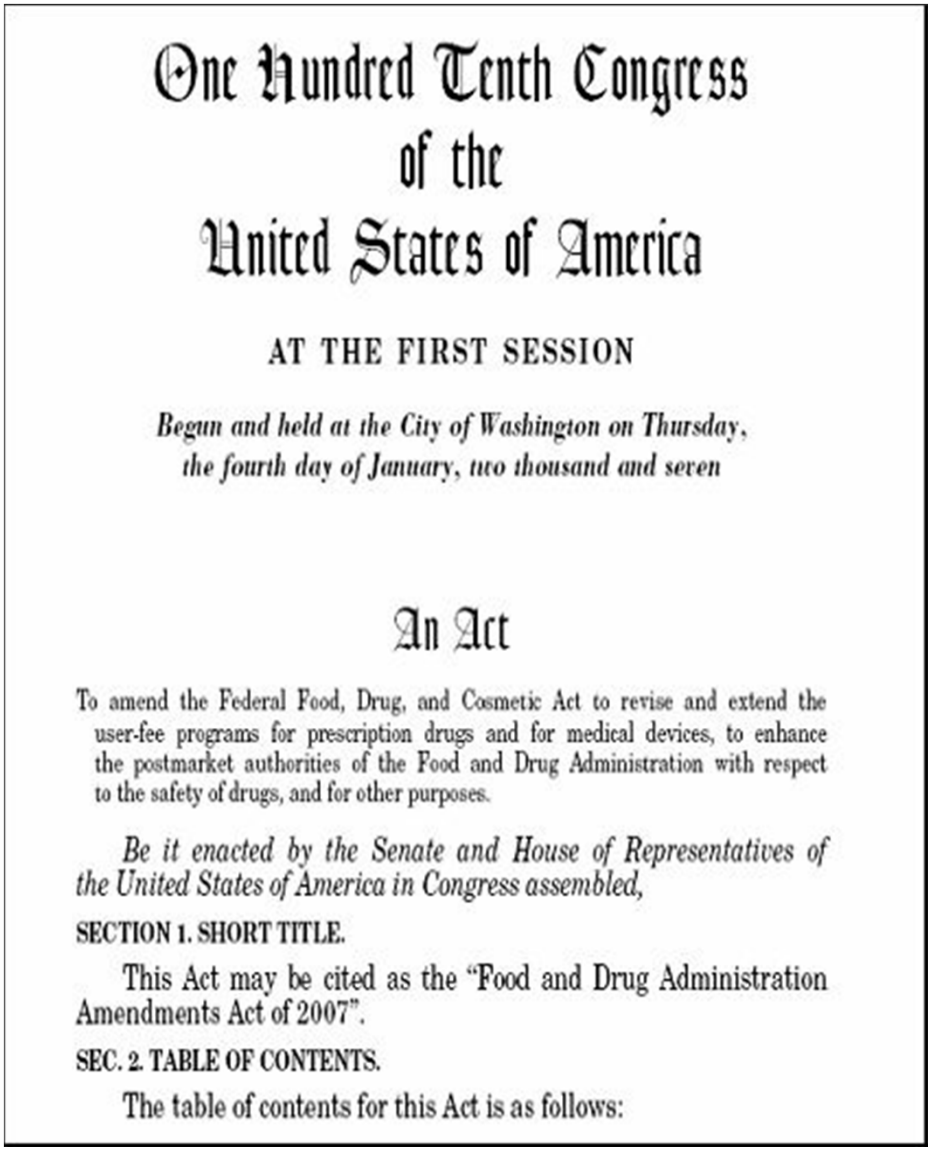
Phased Implementation: Deployment

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


January 2008
July 2008
January 2009
July 2009
January 2010
Preparation/education
NCI Abstraction / QA
Operational Pilot (pilot sites only)
All open trials must be registered within six months (by June 30, 2009)
Accruals and protocol updates must be submitted once per quarter, starting July 2009 – first deadline is September 30, 2009
Pilot of outcome / AE submission (pilot sites only)
7/1/2008: Pilot sites begin registration of trials, submission of quarterly amendments / accruals
1/1/2009: Production phase starts: registration of all new trials required within 21 days of activation, begin registration of all open trials
7/1/2009: All open trials must have been submitted by this point; sites begin submission of accruals / updates
9/1/2008: First quarterly submission of accruals / protocol updates
1/1/2010: First generation of Summary 4 report
1/1/2010: Pilot sites begin outcome / AE submission

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

Begun 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,

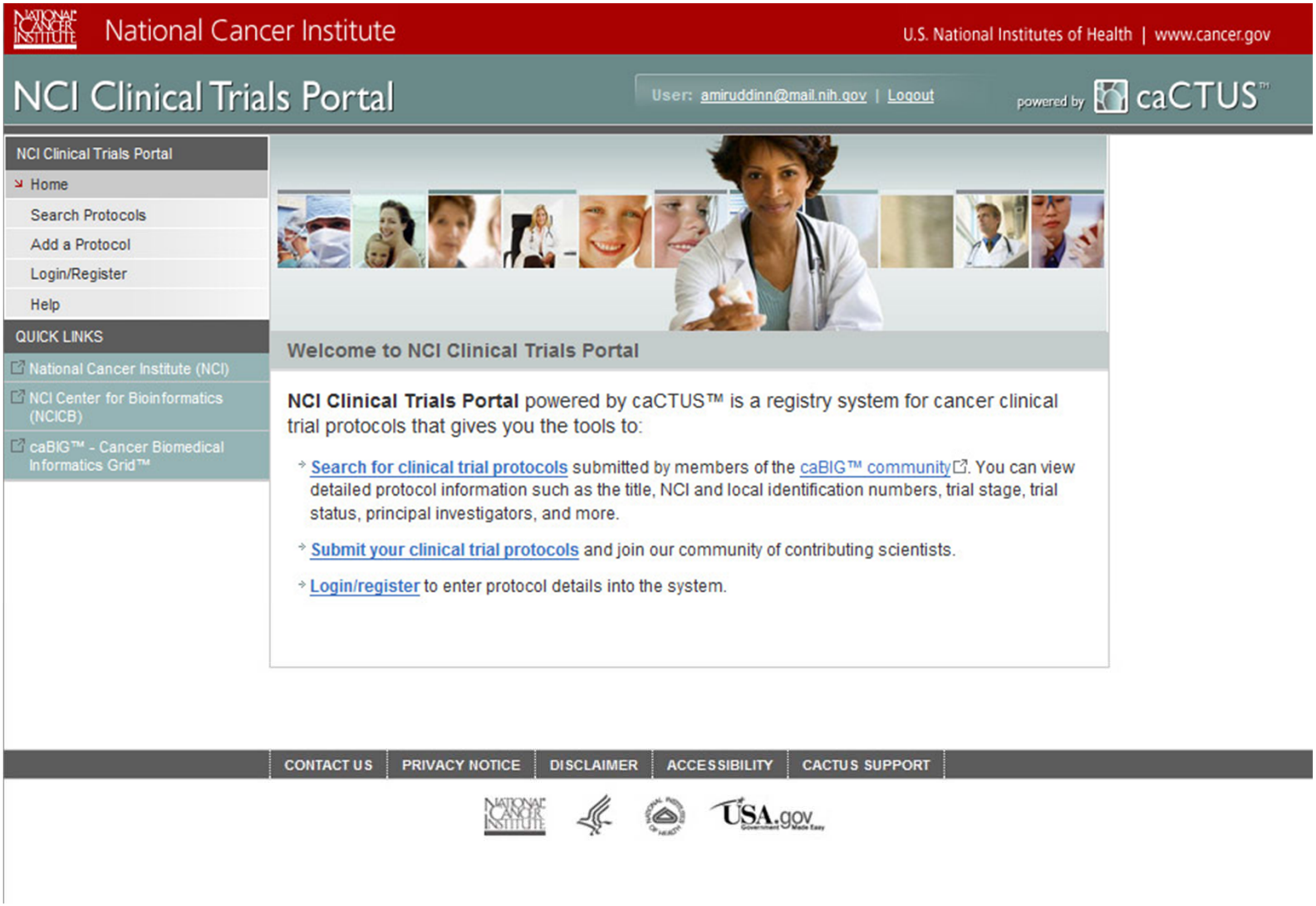
SECTION 1. SHORT TITLE.

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
NCI Clinical Trials Portal
User: amiruddinn@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
USA.gov