

AHRQ's Centers for Education & Research on Therapeutics (CERTs): A Partner for Drug Safety Surveillance

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CERTs Program

- ◆ **US Congress authorized in FDAMA 1997; reauthorized in Healthcare Research and Quality Act of 1999**
- ◆ **Administered by AHRQ, in consultation with FDA, as cooperative agreements**
- ◆ **Network of seven academically-based research centers; four additional centers pending**
- ◆ **Funded through public and private sources, including core AHRQ support**
- ◆ **291 Projects; 138 Partners**
- ◆ **> 200 Peer-Reviewed Publications**

Congressional Authorization

(2) REQUIRED ACTIVITIES:

(A) The conduct of state-of-the-art **research** ...

(i) To increase awareness of—

- (I) **new uses of drugs**, biological products, and devices;
- (II) **ways to improve the effective use of drugs**, biological products, and devices; and
- (III) **risks of new uses and risks of combinations of drugs** and biological products.

(ii) To **provide objective clinical information** to the following individuals and entities:

- (I) **Health care practitioners** and other providers of health care...
- (II) **Pharmacists, pharmacy benefit managers** and **purchasers**.
- (III) **Health maintenance organizations** and other managed care...
- (IV) **Health care insurers** and **governmental agencies**.
- (V) **Patients** and **consumers**.

Congressional Authorization

(2) REQUIRED ACTIVITIES- Continued

(A) The conduct of state-of-the-art **research ...**

(iii) To improve the quality of health care while reducing the cost of health care through—

- (II) an increase in the appropriate use of drugs, biological products, or devices; and**
- (II) the prevention of adverse effects of drugs, biological products, and devices and the consequences of such effects, such as unnecessary hospitalizations.**

(B) The conduct of **research on the comparative effectiveness, cost-effectiveness, and safety of drugs, biological products, and devices.**

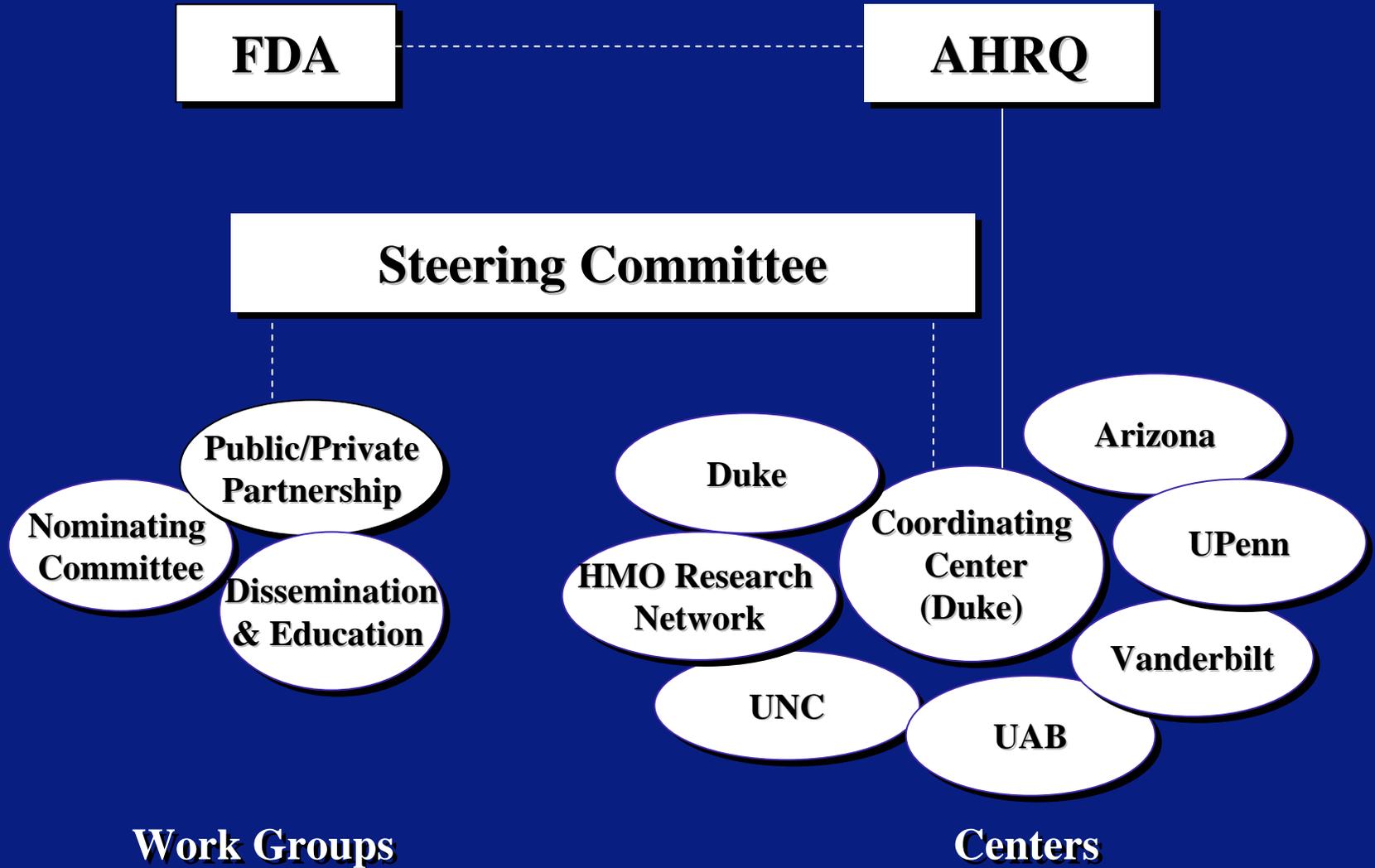
CERTs Model for Public-Private Partnerships

- ◆ **Authorized by Congress as a public-private partnership program**
- ◆ **Investigators work closely with FDA, industry and other public and private organizations, BUT remain independent**
- ◆ **CERTs focus on research and education activities that are in the public interest and would not otherwise be done, e.g.**
 - **safety concerns associated with older, off-patent therapies**
 - **rare effects of newly marketed drugs**
- ◆ **As research program, CERTs can focus on drug safety issues outside of FDA's purview as a regulatory body as well as partner with FDA for work within its purview**
- ◆ **Steering Committee with members from the public and private sector; advisory to the CERTs**
- ◆ **Subcommittee to conduct conflicts review**

CERTs Vision and Mission

- ◆ **Vision:** To serve as a trusted national resource for people seeking to improve health through the best use of medical therapies.
- ◆ **Mission:** To conduct research and provide education that will advance the optimal use of drugs, medical devices, and biological products.

CERTs Structure



CERTs Centers

Center	Emphasis
Duke University Medical Center	Therapies for disorders of the heart and blood vessels
HMO Research Network	Drug use, safety, and effectiveness in delivery systems serving defined populations
University of Alabama at Birmingham	Therapies for musculoskeletal disorders
University of Arizona Health Sciences Center	Drug interactions that result in harm
University of North Carolina at Chapel Hill	Therapies for children
University of Pennsylvania School of Medicine	Therapies for infection; antibiotic drug resistance
Vanderbilt University Medical Center	Prescription drug use in a Medicaid population

CERTs Contributions to Drug Safety: RESEARCH

- ◆ **Risks and benefits of individual drugs, drug classes, or combinations**
- ◆ **Actual use**
 - **Patterns of use**
 - **Quantifying inappropriate and unsafe use**
 - **Understanding risk management**
- ◆ **Tools and strategies to increase appropriate use**
- ◆ **Safety surveillance methods**

Actual Use

- ◆ **Example:** The CERTs, in collaboration with CDRH/FDA and the Society for Thoracic Surgeons, evaluated the trends in use and outcomes of transmyocardial revascularization (TMR) in community practice. The study found a widespread use of TMR in combination with CABG (an off-label indication) and some estimations of patient-specific risks associated with TMR, though additional studies are needed.
- ◆ **Potential:** Monitor patterns of use of a wide array of therapeutic agents, addressing inappropriate use and identifying predictors of inappropriate use.

Safety Surveillance Methodology

- ◆ **Example:** FDA is co-sponsoring a pilot study with the CERTs -- using data extracts created via AHRQ funded safety studies -- to assess when adverse drug reactions discovered after marketing could have been identified through routine screening of administrative datasets.
- ◆ **Example:** The CERTs have developed an Internet-based international registry for drug-induced arrhythmias (QTdrugs.org). The registry was used to detect that IV Methadone induced torsades de pointes (after 45 years of monitored administration in MMT centers). The CERTs subsequently determined the mechanism.

Convening Experts

- ◆ **The CERTs held a series of expert “think tank” workshops to**
 - **(1) review how therapeutics risk information is assessed, communicated and managed**
 - **(2) identify research questions that improve health outcomes.**
- ◆ **Collaboration with AHRQ, FDA and PhRMA**

CERTs Contributions to Address Drug Safety Issues

- ◆ **Clinical expertise**
- ◆ **Methodological expertise**
 - **Drug risks, benefits & use**
 - **Interventions to improve appropriate use**
 - **Safety surveillance approaches**
 - **Resources: population databases, delivery system research laboratories**
- ◆ **Dissemination & education**
 - **Clinicians, patients and policymakers**
 - **Future clinicians and researchers**
- ◆ **Convener of stakeholders**

THE WAY FORWARD

- ◆ **Improving drug safety will take getting ALL of us on the same road map (and heading the same direction!)**

