Award: ClinicalTrials.gov

January 1, 2004

INNOVATIONS IN AMERICAN GOVERNMENT AWARDS

- AWARD WON: 2004 Winner
- AWARDEE: ClinicalTrials.gov
- DESIGNEE: U.S. Department of Health and Human Services
- JURISDICTION: Federal

Despite ever-advancing technology, providing up-to-date and widely accessible medical information presents a serious challenge. The rate of publication of new medical data and research is astounding: some estimate that nearly 20,000 articles are released each week. The number of publications and databases that present medical information is likewise huge. Furthermore, this information is often conveyed in arcane medical language. As a result, thosewishing to find information on diseases and treatment options often find themselves sifting through too many websites with too much information and too little plain language.

Until 2000, this problem was particularly pressing for those who wished to find information on clinical trials of medical treatments. Not only were medical care providers unable to access information on clinical trials in an efficient manner, but patients were often unable to access it at all, depriving them of both information and the opportunity to seek experimental treatment through trial participation. In response, Congress passed the Food and Drug Modernization Act of 1997, mandating the creation of a centralized, publicly accessible registry for federally

and privately funded trials "of experimental interventions for serious or life-threatening diseases and conditions."

In 1998, the National Institutes of Health (NIH) designated the National Library of Medicine as the organization in charge of creating this registry. In less than two years, after careful consultation with care providers, patient advocates, and numerous government agencies, the project team was able to develop an efficient and effective data management and retrieval system. In February 2000, ClinicalTrials.gov was officially launched, allowing users to access information on the goals, design, and participation requirements of approximately 4,400 clinical trials.

ClinicalTrials.gov was designed to be a centralized, standardized, and current resource for those seeking information on clinical studies. The database presently contains over 9,400 records for both privately and publicly funded studies. Included are over 1,110 records from more than 200 pharmaceutical companies, many of whom participate despite potential commercial risk in order to gain access to a larger recruiting pool. A single, web-based data entry form ensures the uniformity of information from diverse sources, while an automated data-validation system allows for continuous and timely updates and additions. For those users interested in researching treatment options, each trial page also features links to relevant online medical reference sites, including MEDLINEplus, the National Library of Health's consumer health website.

The site was also designed to be as widely accessible and comprehensible as possible, in keeping with the goals of the 1997 legislation. The data for each trial are standardized and presented in a clear, easy-to-read format. Users can run specific key-word searches or browse by condition, sponsor, or geographical location, making it easy to navigate the site's vast amount of information. Furthermore, knowledge of medical terminology is not presumed; the database indexes lay terms so that a search for "heart attack" will retrieve the same information as a search for "myocardial infarction." The site also contains a glossary of terms and answers to frequently asked questions about clinical trials.

ClinicalTrials.gov has developed a successful model for the creation and maintenance of a system that processes and presents large amounts of specialized information to a wide range of users. The site now contains records from trials in all 50 states and more than 90 countries and it has logged over 75 million hits since its launch. In April 2002, *Time* magazine named ClinicalTrials.gov as the country's best overall online health resource. The technology and processes developed by the ClinicalTrials team have proven to be effective and promise to play an important role in the future management and dissemination of critical medical information.

ClinicalTrials.gov, a program of the U.S. Department of Health and Human Services and an Innovations in American Government Finalist, presented before the National Selection Committee in 2004.

ClinicalTrials.gov, an initiative of the U.S. Department of Health and Human Services, provides patients, family members, health professionals, and members of the public easy access to information on federally and privately supported clinical trials for a wide range of diseases and conditions. The program was a 2004 Innovations in American Government Award winner.

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