

Exploring Challenges,
Progress, and New Models for
**ENGAGING
THE PUBLIC**

in the
**CLINICAL
RESEARCH
ENTERPRISE**

Clinical Research Roundtable Workshop Summary

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Engaging The Public In The Clinical Research Enterprise Clinical Rese 2003 Pb

Robert D. Toto, Michael J. McPhaul



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Exploring Challenges, Progress, and New Models for Engaging the Public in the Clinical Research Enterprise Institute of Medicine, Board on Health Sciences Policy, Clinical Research Roundtable, 2003-07-25 This report is a summary of a workshop focused on exploring the role of the public in the Clinical Research Enterprise The Clinical Research Enterprise depends upon practitioners policy makers and others for participation in trials ethical review of research and continued support of research funding However the role of the public has expanded beyond this traditional model as consumers have begun to demand a role in the formulation of the research agenda and in the design review and pursuit of research This report identifies four major challenges to the Clinical Research Enterprise enhancing public participation in clinical research which includes making the system safer and faster developing the necessary information systems that are needed to make the clinical research enterprise a coordinated and seamless whole fostering an adequately trained workforce and ensuring adequate funding for clinical research In addition the report identifies two translational blocks from basic science into clinical practice and from the clinical identification of things that work into broader application to improve medical care and the public's health This workshop summary addresses the contribution of the public to overcoming these obstacles

Transforming Clinical Research in the United States Institute of Medicine, Board on Health Sciences Policy, Forum on Drug Discovery, Development, and Translation, 2010-11-22 An ideal health care system relies on efficiently generating timely accurate evidence to deliver on its promise of diminishing the divide between clinical practice and research There are growing indications however that the current health care system and the clinical research that guides medical decisions in the United States falls far short of this vision The process of generating medical evidence through clinical trials in the United States is expensive and lengthy includes a number of regulatory hurdles and is based on a limited infrastructure The link between clinical research and medical progress is also frequently misunderstood or unsupported by both patients and providers The focus of clinical research changes as diseases emerge and new treatments create cures for old conditions As diseases evolve the ultimate goal remains to speed new and improved medical treatments to patients throughout the world To keep pace with rapidly changing health care demands clinical research resources need to be organized and on hand to address the numerous health care questions that continually emerge Improving the overall capacity of the clinical research enterprise will depend on ensuring that there is an adequate infrastructure in place to support the investigators who conduct research the patients with real diseases who volunteer to participate in experimental research and the institutions that organize and carry out the trials To address these issues and better understand the current state of clinical research in the United States the Institute of Medicine's IOM Forum on Drug Discovery Development and Translation held a 2 day workshop entitled *Transforming Clinical Research in the United States* The workshop summarized in this volume laid the foundation for a broader initiative of the Forum addressing different aspects of clinical research Future Forum plans include further

examining regulatory administrative and structural barriers to the effective conduct of clinical research developing a vision for a stable continuously funded clinical research infrastructure in the United States and considering strategies and collaborative activities to facilitate more robust public engagement in the clinical research enterprise *Public Engagement and Clinical Trials* Institute of Medicine, Board on Health Sciences Policy, Forum on Drug Discovery, Development, and Translation, 2012-03-17 Clinical trials provide essential information needed to turn basic medical research findings into patient treatments New treatments must be studied in large numbers of humans to find out whether they are effective and to assess any harm that may arise from treatment There is growing recognition among many stakeholders that the U S clinical trials enterprise is unable to keep pace with the national demand for research results The IOM along with the Mount Sinai School of Medicine held a workshop June 27 28 2011 to engage stakeholders and experts in a discussion about possible solutions to improve public engagement in clinical trials **The Role of Purchasers and Payers in the Clinical**

Research Enterprise Institute of Medicine, Board on Health Sciences Policy, Clinical Research Roundtable, 2002-06-14 In a workshop organized by the Clinical Research roundtable representatives from purchaser organizations employers payer organizations health plans and insurance companies and other stakeholder organizations voluntary health associations clinical researchers research organizations and the technology community came together to explore What do purchasers and payers need from the Clinical Research Enterprise How have current efforts in clinical research met their needs What are purchasers payers and other stakeholders willing to contribute to the enterprise This book documents these discussions and summarizes what employers and insurers need from and are willing to contribute to clinical research from both a business and a national health care perspective **Sharing Clinical Research Data** Forum on Drug Discovery, Development, and Translation, Forum on Neuroscience and Nervous System Disorders, National Cancer Policy Forum, Roundtable on Translating Genomic-Based Research on Health, Board on Health Sciences Policy, Board on Health Care Services, Institute of Medicine, 2013-05-21 Pharmaceutical companies academic researchers and government agencies such as the Food and Drug Administration and the National Institutes of Health all possess large quantities of clinical research data If these data were shared more widely within and across sectors the resulting research advances derived from data pooling and analysis could improve public health enhance patient safety and spur drug development Data sharing can also increase public trust in clinical trials and conclusions derived from them by lending transparency to the clinical research process Much of this information however is never shared Retention of clinical research data by investigators and within organizations may represent lost opportunities in biomedical research Despite the potential benefits that could be accrued from pooling and analysis of shared data barriers to data sharing faced by researchers in industry include concerns about data mining erroneous secondary analyses of data and unwarranted litigation as well as a desire to protect confidential commercial information Academic partners face significant cultural barriers to sharing data and participating in longer term

collaborative efforts that stem from a desire to protect intellectual autonomy and a career advancement system built on priority of publication and citation requirements. Some barriers like the need to protect patient privacy present challenges for both sectors. Looking ahead, there are also a number of technical challenges to be faced in analyzing potentially large and heterogeneous datasets. This public workshop focused on strategies to facilitate sharing of clinical research data in order to advance scientific knowledge and public health. While the workshop focused on sharing of data from preplanned interventional studies of human subjects, models and projects involving sharing of other clinical data types were considered to the extent that they provided lessons learned and best practices. The workshop objectives were to examine the benefits of sharing of clinical research data from all sectors and among these sectors including, for example, benefits to the research and development enterprise and benefits to the analysis of safety and efficacy. Sharing Clinical Research Data Workshop Summary identifies barriers and challenges to sharing clinical research data, explores strategies to address these barriers and challenges including identifying priority actions and low hanging fruit opportunities, and discusses strategies for using these potentially large datasets to facilitate scientific and public health advances. Envisioning a Transformed Clinical Trials Enterprise for 2030: Proceedings of a Workshop National Academies Of Sciences Engineering and Medicine, National Academies of Sciences Engineering and Medicine, Health And Medicine Division, Board On Health Sciences Policy, Forum on Drug Discovery Development and Translation, 2022-08-09. The evolution of health care is expanding the possibilities for integration of clinical research into the continuum of clinical care. New approaches are enabling the collection of data in real world settings and new modalities such as digital health technologies and artificial intelligence applications are being leveraged to overcome challenges and advance clinical research. At the same time, the clinical research enterprise is strained by rising costs, varying global regulatory and economic landscapes, increasing complexity of clinical trials, barriers to recruitment and retention of research participants, and a clinical research workforce that is under tremendous demands. Looking ahead to 2030, the Forum on Drug Discovery Development and Translation of the National Academies of Sciences Engineering and Medicine convened a public workshop for stakeholders from across the drug research and development life cycle to reflect on the lessons learned over the past 10 years and consider opportunities for the future. The workshop was designed to consider goals and priority action items that could advance the vision of a 2030 clinical trials enterprise that is more efficient, effective, person centered, inclusive, and integrated into the health care delivery system so that outcomes and experiences for all stakeholders are improved. This Proceedings of a Workshop summarizes the presentations and discussions that took place during the four part virtual public workshop held on January 26, February 9, March 24, and May 11, 2021. **Clinical Research** Robert D. Toto, Michael J. McPhaul, 2012-03-28. This book will serve as a road map for students and junior researchers seeking to successfully design, implement, and publish clinical research. It covers the basic elements of research proposals and implementation, including regulatory approvals, continuing regulatory oversight, investigational new drug, and

device applications monitoring patient safety recruitment clinical assessments laboratory assessments provision of treatment and on going quality control The authors provide instruction on how to integrate research resources to successfully conduct a clinical research project and offer guidelines on collection quality control and analysis of data A companion website will include the fully searchable text and links to Journal of Investigative Medicine s Research Tools and Issues feature

Role of Purchasers and Payers in the Clinical Research Enterprise ,2002 Envisioning a Transformed Clinical Trials

Enterprise in the United States Institute of Medicine,Board on Health Sciences Policy,Forum on Drug Discovery, Development, and Translation,2012-10-13 There is growing recognition that the United States clinical trials enterprise CTE faces great challenges There is a gap between what is desired where medical care is provided solely based on high quality evidence and the reality where there is limited capacity to generate timely and practical evidence for drug development and to support medical treatment decisions With the need for transforming the CTE in the U S becoming more pressing the IOM Forum on Drug Discovery Development and Translation held a two day workshop in November 2011 bringing together leaders in research and health care The workshop focused on how to transform the CTE and discussed a vision to make the enterprise more efficient effective and fully integrated into the health care system Key issue areas addressed at the workshop included the development of a robust clinical trials workforce the alignment of cultural and financial incentives for clinical trials and the creation of a sustainable infrastructure to support a transformed CTE This document summarizes the workshop

Principles and Practice of Clinical Research John I. Gallin,Frederick P Ognibene,2012-05-31 This expanded third edition provides an introduction to the conduct of clinical research as well as more comprehensive and expansive content about the infrastructure necessary for a successful clinical research organization or enterprise With authors who are experts in clinical research in both the public and private sectors this publication provides essential information to clinical investigators who wish to develop and conduct well designed patient based research protocols that comply with rigorous study design ethical and regulatory requirements

Opportunities to Address Clinical Research Workforce Diversity Needs for 2010

National Research Council,Institute of Medicine,Board on Health Sciences Policy,Policy and Global Affairs,Committee on Women in Science and Engineering,Committee on Opportunities to Address Clinical Research Workforce Diversity Needs for 2010,2006-07-21 Based on a 2003 workshop this study describes current public and private programs and recommends ways to recruit and retain more women and underrepresented minorities into clinical research especially physician scientists and nurses Federal sponsors should improve data collection evaluate existing training programs and increase the diversity of study section review panels Public and private sponsors should create funding mechanisms with flexible career paths and universities and professional societies should both play enhanced roles in fostering diversity A significant push is needed to recruit minorities into nursing and provide more clinical research training for nurse scientists nursing students and nursing faculty

Designing Clinical Research Stephen B. Hulley,Steven R. Cummings,Warren S. Browner,Deborah G.

Grady, Thomas B. Newman, 2013-05-08 *Designing Clinical Research* sets the standard for providing a practical guide to planning tabulating formulating and implementing clinical research with an easy to read uncomplicated presentation This product incorporates current research methodology including molecular and genetic clinical research and offers an updated syllabus for conducting a clinical research workshop Emphasis is on common sense as the main ingredient of good science The book explains how to choose well focused research questions and details the steps through all the elements of study design data collection quality assurance and basic grant writing

Careers in Clinical Research Institute of Medicine, Division of Health Sciences Policy, Committee on Addressing Career Paths for Clinical Research, 1994-02-01 Transforming biological discoveries into medical treatment calls for a cadre of health professionals skilled in patient oriented research Yet many factors discourage talented persons from choosing clinical research as a profession This new volume lays out the problem in detail with specific recommendations to the federal government the biotechnology and pharmaceutical industries professional organizations the health care industry organized medicine and the nation s universities and academic health centers The volume explores How clinical research is conducted what human resources are available and what research opportunities lie ahead Why health professionals become discouraged about clinical research How the educational system has failed in this area and what programs stand out as models How funding affects the supply of researchers This practical book will be of immediate interest to public and private agencies funding research research administrators medical educators health professionals and those pursuing a career in clinical investigation

Strategies for Ensuring Diversity, Inclusion, and Meaningful Participation in Clinical Trials National Academies of Sciences, Engineering, and Medicine, Health and Medicine Division, Board on Population Health and Public Health Practice, Roundtable on the Promotion of Health Equity and the Elimination of Health Disparities, 2016-08-24 Even as the U S population becomes steadily more diverse minorities and women remain underrepresented in clinical trials to develop new drugs and medical devices Although progress in increasing minority participation in clinical trials has occurred participation rates do not fully represent the overall population of minorities in the United States This underrepresentation threatens the health of both these populations and the general population since greater minority representation could reveal factors that affect health in all populations Federal legislation has sought to increase the representation of minorities and women in clinical trials but legislation by itself has not been sufficient to overcome the many barriers to greater participation Only much broader changes will bring about the meaningful participation of all population groups in the clinical research needed to improve health To examine the barriers to participation in clinical trials and ways of overcoming those barriers the National Academies of Sciences Engineering and Medicine held a workshop in April 2015 This publication summarizes the presentations and discussions from the workshop

Ethical Conduct of Clinical Research Involving Children Institute of Medicine, Board on Health Sciences Policy, Committee on Clinical Research Involving Children, 2004-07-09 In recent decades advances in biomedical research have helped save or

lengthen the lives of children around the world With improved therapies child and adolescent mortality rates have decreased significantly in the last half century Despite these advances pediatricians and others argue that children have not shared equally with adults in biomedical advances Even though we want children to benefit from the dramatic and accelerating rate of progress in medical care that has been fueled by scientific research we do not want to place children at risk of being harmed by participating in clinical studies Ethical Conduct of Clinical Research Involving Children considers the necessities and challenges of this type of research and reviews the ethical and legal standards for conducting it It also considers problems with the interpretation and application of these standards and conduct concluding that while children should not be excluded from potentially beneficial clinical studies some research that is ethically permissible for adults is not acceptable for children who usually do not have the legal capacity or maturity to make informed decisions about research participation The book looks at the need for appropriate pediatric expertise at all stages of the design review and conduct of a research project to effectively implement policies to protect children It argues persuasively that a robust system for protecting human research participants in general is a necessary foundation for protecting child research participants in particular

Large Simple Trials and Knowledge Generation in a Learning Health System Institute of Medicine, Board on Health Sciences Policy, Forum on Drug Discovery, Development, and Translation, Roundtable on Value and Science-Driven Health Care, 2013-12-05 Randomized clinical trials RCTs are often referred to as the gold standard of clinical research However in its current state the U S clinical trials enterprise faces substantial challenges to the efficient and effective conduct of research Streamlined approaches to RCTs such as large simple trials LSTs may provide opportunities for progress on these challenges Clinical trials support the development of new medical products and the evaluation of existing products by generating knowledge about safety and efficacy in pre and post marketing settings and serve to inform medical decision making and medical product development Although well designed and implemented clinical trials can provide robust evidence a gap exists between the evidence needs of a continuously learning health system in which all medical decisions are based on the best available evidence and the reality in which the generation of timely and practical evidence faces significant barriers Large Simple Trials and Knowledge Generation in a Learning Health System is the summary of a workshop convened by the Institute of Medicine's Roundtable on Value considers the concepts of LST design examples of successful LSTs the relative advantages of LSTs and the infrastructure needed to build LST capacity as a routine function of care identifies structural cultural and regulatory barriers hindering the development of an enhanced LST capacity discusses needs and strategies in building public demand for and participation in LSTs and considers near term strategies for accelerating progress in the uptake of LSTs in the United States

Clinical Trials Curtis L. Meinert PhD, 2012-02-17 First published in 1986 this landmark text is the definitive guide to clinical trials written by one of the leading experts in the field This fully updated second edition continues to be the most authoritative reference text on randomized clinical trials It contains a

wealth of practical information on the design conduct and analysis of both single center and multicenter trials No other book on clinical trials offers as much detail on such issues as sample size calculation stratification and randomization data systems design development of consent forms publication policies preparation of funding requests and reporting procedures While the basics of design conduct and analysis of clinical trials remain the same there have been significant changes since the first edition of Clinical Trials was published two decades ago In this new edition the author discusses the refinements and improvements made to methods and procedures changes in the policies and guidelines underlying trials as well as requirements for registration of trials He also discusses current practices for data sharing for gender representation for treatment effects monitoring and for ethical standards of clinical trials The importance of the randomized controlled trial has grown significantly over time and they are now the cornerstone of all evidence based medicine Still rich in tables checklists charts and other resources for the trialist the second edition of Clinical Trials is an indispensable reference for clinicians biostatisticians epidemiologists and anyone involved in the design and implementation of a clinical trial

The Law and Regulation of Clinical Research Pamela A. Andanda, 2006 **Guidelines on Good Clinical Research Practice**, 1988

Clinical Research and the Law Patricia M. Tereskerz, 2012-04-24 CLINICAL RESEARCH AND THE LAW The legal implications of conducting clinical research and trials are becoming more complex Everyone involved in clinical research increasingly needs to be aware of not only the ethical issues at stake but also how the law affects medical practice and research Much of clinical research and trial law and litigation is comparatively recent and researchers need to ensure current compliance on a wide range of issues including standards and duty of care conflicts of interest establishing clinical trials informed consent research contracts the disclosure and withholding of clinical trial results Clinical Research and the Law comprehensively discusses these topics and provides the answers to the legal questions and potential pitfalls encountered in medical research It is an up to date practical guide for clinical investigators and their institutional administrators particularly risk managers and research administrators as well as healthcare administrators and members of institutional review boards This book is also a key resource for medical students postgraduate research students practicing attorneys and counselors for teaching hospitals and institutions undertaking clinical research and contract research organizations

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