BREAKING THE SCIENTIFIC BOTTLENECK

CLINICAL RESEARCH: A NATIONAL CALL TO ACTION

PARKINSON’S DISEASE
AIDS
ALZHEIMER’S
DIABETES
CANCER
ARTHРИTIS

NOVEMBER 1999
The Clinical Research Summit project was convened by the Association of American Medical Colleges, The American Medical Association and Wake Forest University School of Medicine; chaired by Dr. William H. Danforth, Chancellor Emeritus, Washington University of St. Louis; and supported by the Burroughs Wellcome Fund, the Commonwealth Fund, the Robert Wood Johnson Foundation, the John. D. and Catherine T. MacArthur Foundation, the Merck Company Foundation, The Pew Charitable Trusts, and the Ethics and Leadership Fund at Wake forest University.

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Our Commitment to America

The broad and ambitious agenda set forth by leaders drawn from across the clinical enterprise, and outlined on the subsequent pages, cannot be completed overnight. It will take the concerted effort of all Americans, working together, over time to achieve our mutually beneficial goals. The participants in the Clinical Research Summit project do not intend to issue this national call to action and then step aside expecting others to carry the load. We recognize that there is much that we as individuals, organizations, institutions, and industries can do to reform our own systems and processes and thereby contribute to the advancement of this agenda. You can expect to hear more from us, both individually and in some cases collectively, about the progress that we are making. In turn, we invite policymakers and the public to challenge us not only to do our part, but to do even more when more makes sense. The conveners and participants in the Clinical Research Summit project look forward to working with all Americans to improve the quality of health care for all people.
Clinical Research: A National Call to Action

Medicine and science stand poised on the threshold of some of their greatest advances. At no time in human history has the potential been greater for translating biological knowledge and technological capability into powerful tools for preventing and treating disease and caring for our communities’ health. Dramatic progress in the basic sciences has vastly increased our understanding of the causes of disease and opened up previously unimagined options for treatment and prevention. The burgeoning biotechnology industry has helped to revolutionize the development of new drugs. The mapping of the human genome is almost complete, and the fruits of genetic research alone promise to transform medical knowledge and practice beyond our wildest dreams. Before us lie virtually limitless possibilities for preventing and treating the major diseases of humankind and enhancing the health of our citizens and their communities.

At the same time, a new set of challenges threatens our ability to make the most of these scientific opportunities. Today’s cost-conscious and competitive health care marketplace has had a major impact on funding streams that have long been available to support biomedical and health research and the training of scientists. The rapidly expanding capability of information technology, while a boon to many administrative and financial functions in the health care system, has not been sufficiently exploited for research purposes.

Clinical research is the “neck of the scientific bottle,” through which all scientific developments in biomedicine must flow before they can be of real-world benefit to the public. Landmark developments in genetics, bioengineering, neuroscience, and molecular and structural biology will mean little in practical terms if clinical researchers are unable to “translate” this science into new and effective medical and health practices. Nor will the practices be of maximum benefit to the public without the analysis of health services and epidemiological researchers. Without a robust national program of clinical research that enjoys the participation and harnesses the full strength of all components of the health sector, the impact of revolutionary advances in the biomedical and health sciences on the health of the public will be blunted.

The problem confronting all Americans is that the vitality of our country’s clinical research enterprise is at risk. Many elements of the complex ecosystem that support clinical research are shifting or eroding, threatening the nation’s ability to successfully translate research advances into effective, efficient treatments, cures, and strategies of disease prevention at the bedside, in the clinic, and in the community. The return on America’s substantial and ongoing financial investment in medical research can only be realized if all stakeholders — from the public, to the professionals, to the policymakers — join together to promote a cohesive national agenda for clinical research.
Unprecedented Unity of the Health Care Enterprise Regarding Clinical Research

Recognizing that what is at stake is the quality of health care in this country and the world, a broad cross-section of stakeholders in the health care enterprise banded together in unprecedented unity to develop an action agenda to address this burgeoning national problem. More than 175 representatives from government and the private sector, funders of clinical research, the pharmaceutical industry, corporate and government purchasers of health care, health plans and insurance companies, patient advocates and ethicists, diverse health care professionals, and academic health centers were enlisted by the Association of American Medical Colleges (AAMC), the American Medical Association (AMA) and Wake Forest University in a Clinical Research Summit project that was supported by seven foundations and took 18 months to complete.

Throughout the various stages of the project, participants put aside individual concerns to hammer out a broad and inclusive agenda. A fundamental part of this agenda is the recognition of nine core problems that confront the clinical research enterprise. These include:

- There is not an agreed-upon definition of clinical research and its components.
- Clinical research is not adequately understood or valued by the public.
- There is a lack of data on clinical research funding and productivity.
- There is insufficient funding for the conduct of some types of clinical research.
- There are insufficient numbers of clinical investigators.
- There is insufficient emphasis on incorporating research findings into clinical practice.
- There is inadequate coordination of clinical research among research entities and disciplines.
- The ability of academic health centers to conduct clinical research is at risk.
- There is a lack of a comprehensive, dynamic clinical research agenda.

To address these nine problems, Summit participants developed a set of goals, objectives and recommendations. These are briefly summarized on the following pages and fully described in the Report of the Graylyn Consensus Development Conference, a companion to Clinical Research: A National Call to Action.

In delivering this report to the American people, the conveners and participants of the Clinical Research Summit project affirm their desire to continue to work together to realize the scientific promise that will benefit all of humankind.
A National Call to Action: 9 Core Problems and Recommendations

1 No Agreed-Upon Definition of Clinical Research

Fundamental to an effective national call to action is an inclusive and comprehensive definition of clinical research. The definition unanimously agreed to by Clinical Research Summit participants addresses not only the complexity, but the interconnectedness of the separate categories of clinical research.

Clinical research is: a component of medical and health research intended to produce knowledge valuable for understanding human disease, preventing and treating illness, and promoting health.

Clinical research embraces a continuum of studies involving interaction with patients, diagnostic clinical materials or data, or populations, in any of these categories: disease mechanisms; translational research; clinical knowledge, detection, diagnosis, and natural history of disease; therapeutic interventions including clinical trials; prevention and health promotion; behavioral research; health services research, including outcomes; epidemiology; community-based and managed care-based research.

2 Clinical Research Is Not Adequately Understood or Valued

The public clearly understands and supports basic medical research such as that funded by the National Institutes of Health (NIH), seeing in it the promise of cures and prevention for debilitating diseases and better treatments for disability. Less recognized and appreciated is the nature of clinical research and the unique challenges it faces as a distinct component of medical and health research. Even various segments of the government and the health care community do not fully grasp and appreciate the crucial role of clinical research. This is reflected in inadequate funding and other support for some categories of clinical research. Many clinical research trials go begging for participants — for example, fewer than 4 percent of cancer patients participate in clinical trials. Segments of the public are wary of researchers’ need for access to archived medical and health information databases, despite the tremendous importance of such data to improving health outcomes and enhancing the public health.
The Summit recommends:

- The uniform definition of clinical research developed by Summit participants, deliberately inclusive of the broad scope and complexity of clinical research, should be universally endorsed by all parties in the clinical research enterprise. This definition should be used to help inform and educate the public about clinical research, as well as to monitor its financial support and workforce needs.

- The ethical foundations of clinical research must be reinforced. Federal protections (or their equivalent) for human research subjects should be applied irrespective of funding or venue. Training for health professionals in the ethical framework of clinical research should be expanded.

- Public understanding of clinical research and confidence in clinical research ethics must be strengthened through dialogue that promotes mutual understanding. The research community should develop separate and coordinated strategies to enhance public understanding of, support for, and participation in clinical research, with special efforts made to reach out to populations now underrepresented in clinical research. All entities involved in clinical research should seek out means to restore trust between the scientific community and populations that have been subject to questionable or unethical research practices.

3 Lack of Data on Clinical Research Funding and Productivity

The lack of systematic data on the funding of clinical research by industry, government, foundations, and health plans is a major problem. Better information is necessary in order to determine the appropriate levels of investment needed for the different categories of clinical research, in order to mobilize an effective national response to compelling scientific opportunity and pressing health needs.

The Summit recommends:

- Mechanisms should be established to track and disseminate the aggregate levels of financial support for clinical research provided by public funders, industry, foundations, voluntary organizations, health plans and insurers, academic health centers, hospitals, and other health care providers. Data on the funding of and participation in clinical research should be reported regularly by all funding entities and made available to groups with an interest in the vitality of clinical research.

- A national strategy should be developed for a federal-private sector partnership to fund the creation of broad-based clinical information systems. A substantial investment is needed to meet the requirements of health services and population-based research and the advancement of evidence-based medicine.
4 Insufficient Funding for the Conduct of Some Types of Clinical Research

While funding for basic biomedical research has increased at unprecedented rates in recent years, Summit participants believe that certain categories of clinical research are underfunded. Particularly in need of increased funding are research on clinical knowledge, diagnosis, and the natural history of disease, and critically important bi-directional “translational” research, which draws upon the collaborative efforts of both basic and clinical scientists. Significant new funding is also needed for research on primary and secondary prevention and health promotion, health services research, epidemiology, and community-based health issues.

The Summit recommends:

- In the current climate of public enthusiasm for expanding the funding of medical research, efforts should be made to strengthen support for clinical research at NIH, the Centers for Disease Control and Prevention, the Agency for Health Care Policy and Research, and the Department of Veterans Affairs. Funding for population-based research through these agencies should also be substantially increased by leveraging the multiple sources of funding in the public and private sectors.

- Funding for clinical research infrastructure, particularly information technology systems, should be increased so that information systems can be enhanced and made more responsive to the needs of the full spectrum of clinical research.

5 Insufficient Numbers of Clinical Investigators

An infusion of dollars will mean little if there are insufficient appropriately trained clinical investigators. There has been a marked decline in the number of physician-investigators, a vital part of any successful clinical research system. Although NIH has been strengthening its institutional training programs, as well as its early and mid-career clinical research awards, workforce development requires more focus by federal funders, foundations, accrediting bodies, academic health centers, and the health industry as a whole.

The Summit recommends:

- A process should be established to monitor and promote workforce career development across the health professions, in order to meet the needs and promote the different categories of clinical research and foster the development of a cadre of well-trained clinical investigators across all health disciplines, specialties and sub-specialties.
An ongoing high-profile forum should be initiated to discuss strategies that could include: recruiting more trainees from underrepresented communities, building upon promising training models developed at academic health centers and the NIH, evaluating new clinical research development awards at NIH, and examining investigator loan repayment and salary support programs.

6 Insufficient Emphasis on Incorporating Research Findings Into Clinical Practice

A broadened agenda of clinical research is needed, related more specifically to health outcomes and designed to assess the effectiveness of methods for incorporating evidence-based practice into clinical care. For example, the scientific community has failed to tap the potential for population-based clinical research offered by integrated health systems and practice-based networks. There is also particular need to establish a “real world” capacity to effectively assess surgical procedures and behavioral interventions with the same rigorous study design now being utilized for testing drugs.

The Summit recommends:

- Support for efforts by industry and the NIH should be furnished to develop mixed academic/non-academic clinical trials sites. One attractive model is the “hub and spoke” organization pioneered by the National Cancer Institute.

- Incentives should be provided to managed care organizations and other providers to participate directly in clinical research. Grants from federal and private funders should also be structured to encourage collaboration among academia, industry, private health care providers, and managed care.

- Practice networks and managed care organizations should expand their clinical trials capabilities, as well as their health services, prevention, and epidemiological research. This will vastly expand the scope and venues for clinical research.

7 Inadequate Coordination of Clinical Research Among Research Entities and Disciplines

One barrier to a more efficient and effective clinical research enterprise has been the historical fragmentation of research in a culture built around separate “silos” of knowledge and expertise. Collaboration is crucial, but until now it has meant more talk than action.

The Summit recommends:

- Federal agencies supporting clinical research should develop grants that foster coordination and collaboration among research disciplines and entities.
The General Clinical Research Center (GCRC) program of the NIH should be expanded to become more comprehensive and to foster development of collaborative research networks and training programs across institutions. For example, affiliated sites might be funded as supplements to the GCRC, with the goal of developing multi-institutional collaborative networks.

Health professions schools within academic medical centers should establish policies that foster cross-disciplinary collaboration.

Ability of Academic Health Centers to Conduct Clinical Research Is at Risk

During the period of the consensus conference, in 1998, there were scattered reports of financial difficulties at some academic health centers. Participants noted this with the comment that the ability of these institutions to conduct clinical research may be at risk. Since then, evidence of financial distress has become much more widespread and is affecting some of the most prestigious and traditionally strong research institutions in the country.

The Summit recommends:
- The ability of medical schools, other health professions schools, and teaching hospitals to conduct clinical research and train investigators must be supported and strengthened.

Lack of Comprehensive, Dynamic, Clinical Research Agenda

In the absence of an ongoing, credible, independent, and broadly representative entity for monitoring and advocating for clinical research, it is unlikely that the multiple goals and objectives set forth by the Summit participants can be woven into a cohesive national action plan for clinical research. Broad representation means: academia; health care systems; organized medicine, nursing, public health, pharmacy and dentistry; managed care organizations and the health insurance industry; health-related foundations; patient advocacy groups; bioethicists; the pharmaceutical, biotechnology and medical devices industries; and the purchasers of health care.

A successful clinical research agenda will require the commitment, participation, and support from all sectors of the health care enterprise.

The Summit recommends:
- A visible, credible, and broadly representative entity should be established to focus continuing national attention on the needs, priorities, and future progress of clinical research.
The First Step

National Clinical Research Roundtable: The First Step

An important first step toward the realization of this ambitious national agenda is the establishment of a Clinical Research Roundtable, to help inform and strengthen the processes necessary to nurture a robust, coherent clinical research enterprise. In response to the recommendations of the Clinical Research Summit project, the Institute of Medicine and the Commission on Life Sciences at the National Academies have agreed to convene such a Roundtable. This broadly representative group will help to focus national attention on the needs, priorities, and future progress of clinical research. The Roundtable will provide a forum for the parties interested in clinical research to identify and discuss the major barriers to the conduct of clinical research and develop strategies and approaches to overcoming them. It will be representative, continuing the inclusiveness of the Summit process; credible, as an autonomous and independent national body; visible, with a broad national focus; responsive—able to address both long-term and immediate issues; and capable of establishing an accountable process.

The Roundtable will be able, through workshops and other activities, to disseminate its findings and to propose formal studies that might be conducted by the National Academies.

- **Workshops:** The Roundtable will convene periodic workshops and other public events to explore approaches to the resolution of both short-term and long-term problems affecting clinical research. Workshops and published reports from the workshops will provide opportunities for those with an interest in clinical research, beyond the Roundtable’s membership, to continue to participate in sustaining an environment for the conduct of high quality clinical research.

- **Membership:** Up to 25 members will be chosen for their professional and policy making perspective, as well as their scientific or public policy credentials. Members may include federal and private funders of clinical research, policymakers, health professionals, industry representatives, consumers, and active clinical researchers.

- **Meetings:** The Roundtable will meet up to four times a year. Two of the meetings will be held in conjunction with a Roundtable workshop.
**Convening Events:**

**July 17, 1997**  
“Preventing the Extinction of the Clinical Research Ecosystem,” written by James Thompson, M.D., and Jay Moskowitz, Ph.D., Wake Forest University, published in *JAMA*

**October 9, 1997**  
AAMC, AMA, and WFU convene Executive Committee to respond to *JAMA* article

**November 1, 1997**  
Executive Committee convenes first “Clinical Research Summit” planning meeting – Washington, D.C.

**December 5, 1997**  
Executive Committee convenes second “Clinical Research Summit” planning meeting – Dallas, Texas

**Focus Groups:**

- **March 13, 1998**  
  Test focus group

- **April 24, 1998**  
  Representatives of corporate and government purchasers of health care and selected health economists

- **May 29, 1998**  
  Representatives of industry, government and foundations

- **June 4, 1998**  
  Representatives of health plans and insurance companies

- **June 11, 1998**  
  Trainees and recent fellowship graduates

- **June 12, 1998**  
  Mid-level clinical investigators representing translational, clinical trials, and population-based research

- **June 25, 1998**  
  Representatives of patients, consumers, advocacy organizations, and biomedical ethicists

- **July 1, 1998**  
  Representatives from nursing, psychology, public health, dentistry, pharmacy, and genetic counseling

- **September 10, 1998**  
  Representatives of AMA specialty and sub-specialty organizations

- **September 15, 1998**  
  Representatives of leading basic science organizations

- **September 25, 1998**  
  Leaders of medical schools and teaching hospitals

- **November 20-22, 1998**  
  Clinical Research Summit Retreat at Graylyn International Conference Center, Winston-Salem, North Carolina

- **September 10, 1999**  
  Clinical Research Summit event planning committee meeting

- **November 15, 1999**  
  Clinical Research Summit concluding event
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