

Membership Kit



PersonalizedMedicineCoalition.org

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Millennium: The Takeda Oncology Company

Robert Wells, HealthFutures, LLC

Phyllis Whiteley, Ph.D.

MDV-Mohr Davidow Ventures

Dear Colleague,

“It was the best of times, it was the worst of times,” Dickens wrote about the era of the French Revolution. Something similar could be said about the drug discovery and development systems in the United States today, which face unprecedented financial and political challenges on one hand and the promise of revolutionary medical breakthroughs on the other.

High on the list of those breakthroughs expected to transform medicine in coming years is the advent of personalized medicine, the use of new methods of molecular analysis to better manage a patient’s disease or predisposition to disease. Personalized medicine, most observers believe, is likely to change the way drugs are discovered and medicine is prescribed. But the political and financial systems that will support personalized medicine are not yet in place. The mission of the Personalized Medicine Coalition (PMC) is to build the foundation that underpins the development of personalized medicine as a viable solution to some of the challenges patients, physicians, and society face.

The PMC, an educational and advocacy group dedicated to advancing the understanding and adoption of personalized medicine, was founded in 2003 to promote new ways of thinking about health care. It plans to provide a forum where interested parties – pharmaceutical, biotechnology, information technology, diagnostic companies, academic health centers, health care providers, insurance companies, medical societies, patient advocacy groups, and governmental agencies – can consider the public policy issues that, along with science and investment, will determine personalized medicine’s future. We will address all the issues, including privacy, regulation, and reimbursement among others, that will determine personalized medicine’s success.

I invite you to become a member of the PMC and join us in working to accelerate the adoption of personalized medicine. As a PMC member, you will be able to participate on our committees, attend our events, develop networking and business development opportunities, and, most importantly, contribute to a unique organization that is positioned to ensure that public opinion and policy are aligned with personalized medicine’s new emerging scientific paradigms. With your leadership, we can ensure that the promise and potential of personalized medicine will be realized.

For more information about membership and participation, please visit our website at www.personalizedmedicinecoalition.org, or contact me directly.

Sincerely yours,



Edward Abrahams
Executive Director

Personalized Medicine Coalition Fact Sheet

What is the Personalized Medicine Coalition?

The Personalized Medicine Coalition (PMC), representing a broad spectrum of academic, industrial, patient, provider and payer communities, seeks to advance the understanding and adoption of personalized medicine concepts and products for the benefit of patients. By employing new methods of molecular analysis to better manage a patient's disease or predisposition towards a disease, personalized medicine aims to achieve optimal medical outcomes by helping physicians and patients choose the disease management approaches likely to work best in the context of a patient's genetic and environmental profile.

The Coalition seeks to promote discussion and understanding that will lead to the development of sound public policy on matters that will affect the realization of the promise of personalized medicine.

The PMC has four goals:

- Provide opinion leadership with respect to the evolving discussion of public policy issues that affect personalized medicine;
- Help educate the public, policymakers, government officials and private sector healthcare leaders about the public and personal health benefits of personalized medicine;
- Serve as a forum for identifying and informing others of those public policies that may impede the ability to deliver the promise of personalized medicine; and
- Create a structure for achieving consensus positions on crucial public policy issues and supporting changes needed to further the public interest in personalized medicine.

What are the benefits of membership?

Members of the PMC join us in working to accelerate the adoption of personalized medicine. Our members participate on our committees, attend our events, develop networking and business development opportunities and contribute to a unique organization that is positioned to ensure that public opinion and public policy are aligned.

By joining the PMC, organizations gain the opportunity to advance and shape the future of personalized medicine by:

- Identifying and building consensus on the most important issues
- Forging relationships with other stakeholders
- Sharing best practices
- Creating a favorable public policy environment for the advancement of this field

Executive Director

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HealthFutures, LLC

IBM Healthcare and Life Sciences

Laboratory Corporation of

America (LabCorp)

Medco Health Solutions, Inc.

Millennium: The Takeda

Oncology Company

MDV-Mohr Davidow Ventures

PhRMA

Technic Solutions, LLC

XDx

For membership information,
please contact:

Edward Abrahams, Ph.D.

Personalized Medicine Coalition
1225 New York Avenue, N.W.
Suite 450
Washington, DC 20005
Phone 202-589-1770
Fax 202-589-1778

cabrahams@
PersonalizedMedicineCoalition.org

Who joins the PMC?

PMC membership encompasses a broad spectrum of academic, industrial, patient and healthcare provider constituencies. Membership is open, but not limited, to universities and academic medical centers, non-profit research entities, relevant trade associations, patient advocacy groups, government officials (ex-officio), healthcare organizations, healthcare providers, payers, information technology companies and research-based commercial companies that offer an array of products and services including research tools, diagnostic technologies and products, screening services and therapeutic interventions.

What are the PMC's Programs?

The PMC holds both members-only and public meetings, exploring the issues in personalized medicine that may require new or revised policies.

Selected past programs have included leaders from every part of the healthcare enterprise, including:

- Brook Byers, Kleiner Perkins Caufield & Byers
- Carolyn Clancy, M.D., Agency for Healthcare Research and Quality
- Francis S. Collins, M.D., Ph.D., National Human Genome Research Institute
- Denis A. Cortese, M.D., Mayo Clinic
- Harvey V. Fineberg, M.D., Ph.D., Institute of Medicine
- Newt Gingrich, Center for Health Transformation
- Raju Kucherlapati, Ph.D., Harvard-Partners Center for Genetics and Genomics
- Eric Lander, Ph.D., Broad Institute
- Michael O. Leavitt, U.S. Department of Health and Human Services
- Mark Levin, Millennium Pharmaceuticals
- Mark McClellan, M.D., Ph.D., The Brookings Institution
- Elizabeth Nabel, M.D., National Heart, Lung, and Blood Institute
- George Poste, D.V.M., Ph.D., The Biodesign Institute at Arizona State University
- W. J. Billy Tauzin, PhRMA
- Andrew C. von Eschenbach, M.D., U.S. Food and Drug Administration
- Janet Woodcock, M.D., U.S. Food and Drug Administration

What will the PMC Do?

As a rapidly emerging field with the potential to profoundly change the way medical treatments are discovered and used, personalized medicine has numerous implications — from regulations about drug approval, to laws about healthcare privacy, to policies regarding reimbursement. These implications deserve careful exploration and discussion.

The PMC works with existing organizations to improve understanding of personalized medicine and the interrelated issues that it raises, in a way that avoids duplication of efforts and leverages their activities. It also allows federal and state policy makers to participate in this educational process with private sector healthcare leaders, helping all to better understand the science and the policy issues.

Personalized Medicine Coalition Mission and Principles

The Personalized Medicine Coalition (PMC), representing a broad spectrum of academic, industrial, patient, provider, and payer communities, seeks to advance the understanding and adoption of personalized medicine concepts and products for the benefit of patients.

I. The Personalized Medicine Coalition

The Personalized Medicine Coalition exists to advance the understanding and adoption of personalized medicine concepts and approaches for the ultimate benefit of the patients who need them.

The Coalition seeks to serve as a source of information on public policy matters that will affect the realization of the promise of personalized medicine.

The membership of the PMC is open, with the goal of attracting universities and academic medical centers, non-profit research entities, relevant trade associations, patient organizations, government officials (ex-officio), healthcare organizations, healthcare providers, information technology companies, and research-based commercial companies that offer an array of products and services including research tools, diagnostic technologies and products, screening services, and therapeutic interventions.

II. Operational Guidelines

The Personalized Medicine Coalition is guided by the following operational principles:

- The PMC serves as an umbrella organization for stakeholders who are conducting personalized medicine education in both the public and private sectors;
- The PMC offers stakeholders a forum to discuss public policy and regulatory issues affecting personalized medicine — and, where possible, to develop consensus positions on key issues;
- The PMC collaborates with member organizations and outside experts in identifying, analyzing and addressing ethical, legal and social implications of personalized medicine; and
- The PMC provides networking opportunities for the many and varied stakeholders in personalized medicine.

III. Vision

The vision of personalized medicine is to better use characteristics of the individual (and his or her disease) to help identify which of the many treatment alternatives to use in addressing a medical problem.¹ Rapid advances in biology and information technology, as well as progress in sequencing the human genome and the genomes of viruses and bacteria, offer new building blocks and tools to advance medicine in both its scientific and clinical domains.

- **Research and development:** A personalized medicine approach may allow the expanded use of biomarkers for more focused and targeted drug development. More sophisticated knowledge about the role of individuals' genetic and biological characteristics in disease may help expedite development of drugs that more effectively treat diseases in specific populations.
- **Clinical practice:** Personalized medicine also may improve diagnostic and prognostic processes through screening methodologies that identify patients in particular disease subgroups and/or those predisposed to a particular disease. Better use of biomarkers also could result in more informed selection and dosing of medicines, thus reducing side effects and improving efficacy. Through improved determination of likely outcomes of drug treatments — which in turn may help physicians decide when, whether and how to treat patients — personalized medicine may help improve the quality and cost effectiveness of medical interventions

¹ The concept of tailoring a patient's treatment is not new. The wide variation in innovator medicines available to treat a specific condition today already allows a certain level of personalized care. Doctors and patients often engage in a process of trial and error to find the right medication to alleviate a particular patient's condition, with the minimum of undesirable side effects. Numerous factors — genetic differences, environmental influences, diet, competing co-morbidities — affect which drug works best in a specific patient. Sequencing of the human genome now allows us to investigate in more detail the genetic differences among patients and populations, and the effects of those differences on the metabolism and response to various drugs. In an era of personalized medicine, patients will still be assessed and treated based on information gleaned from studies of groups or populations, but through better definition and understanding of more precisely defined groups it is hoped that clinical predictability will be improved for individuals in those groups. In effect, we believe that the personalization of medicine as it exists today will be practiced more precisely and uniformly in the future. However, we think it is unlikely that science will afford us a one-to-one prediction between the genetics of the individual and the selection of the "right" drug — a physician will still need to consider the improved diagnostic information regarding the specific patient and exercise his or her discretion in selecting the medication he or she feels is most appropriate.

IV. Definition of Personalized Medicine

Personalized medicine means different things to different people. Some have suggested that personalized medicine is the application of genomic data to better target the delivery of medical interventions. Others have suggested that it is a crucial tool in the discovery and clinical testing of new products. And others have suggested that it involves the application of sophisticated, clinically useful diagnostic tools that may help determine a patient's predisposition to a particular disease or condition. In fact, personalized medicine can encompass all of those concepts.

In theory, personalized medicine is the management of a patient's disease or disease predisposition, by using molecular analysis² to achieve the optimal medical outcomes for that individual — thereby improving the quality of life and health, and potentially reducing overall healthcare costs.

In practice, personalized medicine is a comprehensive approach utilizing:

- Molecular analysis of both patients and healthy individuals to guide decisions throughout all stages of the discovery and development of pharmaceuticals and diagnostics; and
- Applying this knowledge in clinical practice for a more efficient delivery of accurate and quality healthcare through improved prevention, diagnosis, treatment, and monitoring methods.

V. Public Policy Issues Impacting Personalized Medicine

Several clusters of significant public policy issues mark the pathway to the growth and acceptance of personalized medicine. While none of these issues is unique to personalized medicine, government regulation of clinical trials, intellectual property rights, licensing practices, healthcare reimbursement, and privacy are among the areas that may need to be re-examined. Currently, public policy decisions in the healthcare arena are made in a fragmented and uncoordinated way, without consideration of the impact one decision could have on other policy issues. For providers of products and services to be able to deliver on the promise of personalized medicine, policymakers must intelligently and comprehensively review the array of issues that affect the science and clinical practice of personalized medicine. The PMC exists because there is real risk that public health and medical practice will suffer unintended consequences unless policymakers coordinate their efforts. The next generation of medical practice — personalized medicine — demands a coherent, integrated approach to the legal, financial, social and professional issues that will shape its development and application.

Intellectual Property

A strong intellectual property system is necessary to stimulate investment in innovation. It is essential that government patent systems offer protection for innovations relating to personalized medicine, as well as high quality patent examination that allows patents of appropriate scope and quality.

Regulatory Oversight

The development of personalized medicine may require that regulatory bodies adopt some new approaches to product approval. This will entail new guidance about the processes for obtaining approval to commercialize new therapeutics, including when and under what circumstances the use of a new drug must be preceded and/or accompanied by the use of a diagnostic or screening test. These clinical trial rules will influence the drug, biotechnology, diagnostic and device industries.

Public and Private Sector Reimbursement

If the healthcare system is to secure the full benefits of personalized medicine, it must provide full and fair reimbursement for new technologies, products and services, based on market principles to the extent possible. The unit cost of new products could be greater than the products they are replacing; yet these new products may offer superior results for the smaller pool of patients for whom they are appropriate. The reimbursement system — both governmental and private payers — must have coverage and payment policies that support the timely adoption of new personalized medicine technologies, including both diagnostics and therapeutics.

² In addition to genes, environmental factors — such as diet, exposure to toxins, viruses, etc. — are also involved in disease processes.

Moreover, the issue of whether the government should encourage or subsidize — though targeted grant programs — the development of the infrastructure to permit the application of personalized medicine presents its own policy dilemma. For example, both medical education about genetics and information technology (IT) systems in healthcare institutions will need to be improved to permit the use of more complex pharmacogenomic data and more detailed and accurate health history data in research and in clinical practice.

Privacy, Confidentiality and Patients' Rights

The protection of patient privacy and other rights is critical to creating public confidence in the collection of the data necessary for the practice of personalized medicine. Patients may be less willing to provide tissue and blood samples, or to disclose medical history information, if they fear that their data will be misused or their privacy will be violated. Appropriate informed consent for both research and treatment also is critical. Thus, assuring effective protection of sensitive information is a necessary prerequisite to the collection of the individually identifiable data that allow personalized medicine research and practice. Specific issues that may need to be addressed include: the potential impact on insurability and/or employment of “orphan patients” or “non-responders”; the potential for our society to use genetic characteristics in discriminatory ways; the implications for an ethnic group of genetic testing results that are common to a significant percentage of its members; the effects of predictive genetic test results on the personal responsibility and psychological well-being of the individual who is tested; and the rights and well-being of “third-party” non-consenting family members of an individual who undergoes a predictive genetic test.

VI. Goals

The goals for the PMC are:

- To provide opinion leadership with respect to the evolving discussion of public policy issues that affect personalized medicine;
- To work, with others as appropriate, to help educate the public, policymakers, government officials, and private sector healthcare leaders regarding the public and personal health benefits of personalized medicine;
- To serve as a forum for identifying and informing others of those public policies that may impede the ability to deliver the promise of personalized medicine; and
- To work toward creation of a structure for achieving consensus on those public policy issues, if any, for which changes are needed to further the public interest in personalized medicine.

VII. Strategy

The PMC's strategy for meeting its goals includes:

- Working with existing organizations, including relevant professional and trade associations, to improve the understanding of personalized medicine and the interrelated issues it raises;
- Developing consensus on the principles that ought to govern the development of public policy affecting personalized medicine, including policies regarding intellectual property, regulatory approval, reimbursement, patient privacy and dignity, confidentiality, and protections against misappropriation of personalized data; and
- Educating policymakers in the federal government, state officials when appropriate, and private sector healthcare leaders about the importance of personalized medicine and identifying concrete steps that they can take to facilitate the positive evolution of personalized medicine.

In order to implement its strategy and achieve its goals, the PMC may undertake tactics to advance the concepts of personalized medicine. These may include activities internal to the participating industries, the think tank community, the medical community, and the reimbursement community. Specific tactics may also include external steps relative to government policymakers, public education, and press-related measures.

Become a Personalized Medicine Coalition Member

PMC membership encompasses a broad spectrum of academic, industrial, patient and healthcare provider constituencies.

Membership is open, but not limited, to universities and academic medical centers, non-profit research entities, relevant trade associations, patient advocacy groups, government officials (ex-officio), healthcare organizations, healthcare providers, payers, information technology companies and research-based commercial companies that offer an array of products and services including research tools, diagnostic technologies and products, screening services and therapeutic interventions.

By joining the PMC, organizations ensure that they are afforded the opportunity to advance and shape the future of personalized medicine by:

- Identifying and building consensus on the most important issues
- Forging relationships with other stakeholders
- Sharing best practices
- Creating a favorable public policy environment for the advancement of this field

The annual dues structure for the PMC is as follows:

The Personalized Medicine Coalition is guided by the following operational principles:

Large corporation	\$20,000
Small public corporation	\$10,000
Private corporation >50 FTE	\$5,000
Private corporation <50 FTE	\$2,500
Professional society	\$5,000
Strategic partner	\$2,500
Research and educational institution	\$2,500
Venture capital firm	\$2,500
Patient advocacy group	\$500

For membership information, please contact:

Edward Abrahams
Executive Director
Personalized Medicine Coalition
1225 New York Avenue, N.W., Suite 450
Washington, DC 20005

Phone: 202-589-1770
Fax: 202-589-1778
eabrahams@PersonalizedMedicineCoalition.org

* To fill out this application online go to www.PersonalizedMedicineCoalition.org/application

ORGANIZATION INFORMATION

Organization Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Phone: _____ Fax: _____ Website: _____

Please list your organization name exactly as you would like it to appear on PMC materials:

Organization Description: Please provide a short description of your organization (100-150 words) as it relates to personalized medicine. This profile will appear on the PMC website and other materials published by PMC. This information can be changed at a later date.

PAYMENT INFORMATION	MEMBER LIST INFORMATION
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The annual dues structure for the PMC is as follows.
 Please check the box appropriate for your organization:

- | | |
|---|----------|
| <input type="checkbox"/> Large corporation | \$20,000 |
| <input type="checkbox"/> Small public corporation | \$10,000 |
| <input type="checkbox"/> Private corporation >50FTE | \$5,000 |
| <input type="checkbox"/> Private corporation <50FTE | \$2,500 |
| <input type="checkbox"/> Professional society | \$5,000 |
| <input type="checkbox"/> Strategic partner | \$2,500 |
| <input type="checkbox"/> Research and educational institution | \$2,500 |
| <input type="checkbox"/> Venture capital firm | \$2,500 |
| <input type="checkbox"/> Patient advocacy group | \$500 |

Please check the box next to the PMC member list category appropriate for your organization:

- | | |
|---|--|
| <input type="checkbox"/> Agency partners | <input type="checkbox"/> IT/Informatics companies |
| <input type="checkbox"/> Clinical laboratory testing services | <input type="checkbox"/> Large biotech/ Pharmaceutical companies |
| <input type="checkbox"/> Consumer genetic testing services | <input type="checkbox"/> Patient advocacy groups |
| <input type="checkbox"/> Diagnostic companies | <input type="checkbox"/> Research and educational institutions |
| <input type="checkbox"/> Emerging biotech/ Pharmaceutical companies | <input type="checkbox"/> Research tool companies |
| <input type="checkbox"/> Health insurance companies | <input type="checkbox"/> Strategic partners |
| <input type="checkbox"/> Industry and Trade associations | <input type="checkbox"/> Venture capital |

Amount enclosed \$ _____

Check # _____

Make check payable to:
 Personalized Medicine Coalition
 1225 New York Avenue, N.W., Suite 450
 Washington, DC 20005
 Phone 202-589-1770

Press Release – Do we have your permission to use your organization name in a press release announcing your new membership with PMC?

YES / NO

ESSENTIAL CONTACTS

Working Contact Name _____ Title _____
Address _____
City _____ State _____ Zip _____
Phone _____ Fax _____
Email _____

Dues Contact Name _____ Title _____
Address _____
City _____ State _____ Zip _____
Phone _____ Fax _____
Email _____

President/CEO Name _____ Title _____
Address _____
City _____ State _____ Zip _____
Phone _____ Fax _____
Email _____

**Chief Scientific
Officer/Science
Contact** Name _____ Title _____
Address _____
City _____ State _____ Zip _____
Phone _____ Fax _____
Email _____

Public Policy Name _____ Title _____
Address _____
City _____ State _____ Zip _____
Phone _____ Fax _____
Email _____

Other Name _____ Title _____
Address _____
City _____ State _____ Zip _____
Phone _____ Fax _____
Email _____

If you have additional contacts that wish to receive correspondence from PMC, please attach a separate sheet.

Mail completed application and payment to:

Personalized Medicine Coalition, 1225 New York Avenue, N.W., Suite 450, Washington, DC 20005 Phone 202-589-1770
eabrahams@PersonalizedMedicineCoalition.org www.PersonalizedMedicineCoalition.org

PMC COMMITTEES

The following committees would welcome your participation. Please indicate below who you would like to appoint from your organization to serve on the following committees:

CLINICAL SCIENCE

The Clinical Science Committee evaluates the emerging applications of science and technology in personalized medicine, and serves as an advisory resource for other committees and for the PMC. It helps guide policies that govern communications and programs related to personalized medicine in an effort to advance it in the public sphere. The committee oversees material published on PersonalizedMedicineCoalition.org and in the PMC's other publications. It also reviews PMC communications and programs for scientific and technical accuracy.

Clinical Science Name _____ Title _____
Address _____
City _____ State _____ Zip _____
Phone _____ Fax _____
Email _____

PUBLIC POLICY

The Public Policy Committee governs, under a set of rules previously established by the PMC Board, the adoption of all of the organization's public policy positions, and oversees the strategies by which they are communicated to target audiences, including all branches of the federal government as well as other non-governmental agencies.

Public Policy Name _____ Title _____
Address _____
City _____ State _____ Zip _____
Phone _____ Fax _____
Email _____

*Involvement on PMC committees is open to all dues-paying members.
Participation on multiple committees from individual companies and institutions is encouraged.*

Personalized Medicine Coalition Members

AGENCY PARTNERS

Centers for Disease Control and Prevention
 Centers for Medicare and Medicaid Services
 National Cancer Institute
 National Human Genome Research Institute
 U.S. Food and Drug Administration

CLINICAL LABORATORY TESTING SERVICES

Kimball Genetics, Inc.
 Laboratory Corporation of America Holdings (LabCorp)
 Quest Diagnostics

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23andMe, Inc.
 DNA Direct, Inc.
 Navigenics, Inc.

DIAGNOSTIC COMPANIES

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 Almac Diagnostics
 AssureRx, LLC
 Aureon Laboratories, Inc.
 Aviiir
 Axial Biotech, Inc.
 BD (Becton, Dickinson and Company)
 BG Medicine
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 Caris Dx
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 Curidium Medica
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 deCode Genetics, Inc.
 The DNA Repair Company
 DNAVision s.a.
 Expression Analysis, Inc.
 Gen-Probe Incorporated
 GeneDx
 Genelex Corporation
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 Genomas, Inc.
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DIAGNOSTIC COMPANIES *continued*

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 BIO (Biotechnology Industry Organization)
 PhRMA

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5AM Solutions, Inc.
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 Millennium: The Takeda Oncology Company
 Pfizer Inc

PATIENT ADVOCACY GROUPS

Alliance for Aging Research
 Hypertrophic Cardiomyopathy Association-HCMA
 National Alliance for Hispanic Health
 National Brain Tumor Society

RESEARCH & EDUCATIONAL INSTITUTIONS

AACC (American Association for Clinical Chemistry)
 American Institute for Medical and Biological Engineering (AIMBE)
 American Medical Association
 American Society of Human Genetics (ASHG)
 Association for Molecular Pathology (AMP)
 Baylor College of Medicine
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 Children's Hospital Oakland Research Institute
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 Cincinnati Children's Hospital Medical Center
 Cleveland Clinic Genomic Medicine Institute
 College of American Pathologists
 Coriell Institute for Medical Research
 The Critical Path Institute(C-Path)
 Duke University
FasterCures
 Genome British Columbia
 The George Washington University Medical Center

RESEARCH & EDUCATIONAL INSTITUTIONS *continued*

Georgetown University School of Nursing & Health Studies
 H. Lee Moffitt Cancer Center & Research Institute, Inc.
 Helix Health LLC
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 Institute of Genomic Medicine, UMDNJ-New Jersey Medical School
 Institute for Genomics & Systems Biology,
 The University of Chicago and
 Argonne National Laboratory
 The Jackson Laboratory
 Marshfield Clinic
 Mayo Clinic
 National Coalition for Health Professional Education in Genetics (NCHPEG)
 National Foundation for Cancer Research
 National Pharmaceutical Council
 National Jewish Medical and Research Center
 The Ohio State University Medical Center
 Partners HealthCare Center for Personalized Genetic Medicine
 PENN Medicine
 University of Utah
 Vanderbilt University Medical Center

RESEARCH TOOL COMPANIES

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STRATEGIC PARTNERS

Arrowhead Publishers and Conferences
 Boston Healthcare
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Mintz Levin
National Pharmaceutical Council
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5AM Ventures
Burrill & Company
Kleiner Perkins Caufield & Byers
Lemhi Ventures
MDV-Mohr Davidow Ventures
Pappas Ventures
Third Rock Ventures, LLC