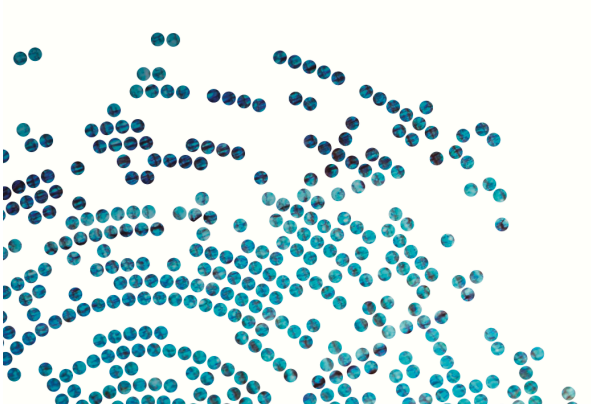
PMC PERSONALIZED MEDICINE COALITION



The Integration of Personalized Medicine into U.S. Health Systems

A Landscape Analysis

BACKGROUND

Providers are increasingly working to integrate personalized medicine into their health care delivery systems. Led by several pioneer institutions, academic health centers and community hospital systems across the U.S. are adopting strategies and processes to overcome clinical implementation challenges. By examining the experiences of these personalized medicine programs, the broader health care community is developing a better understanding of how to integrate personalized medicine into clinical practice. It is not clear, however, what impact the move towards personalized medicine within these pioneering institutions has had so far on the health care system in general. A better understanding of the current landscape for implementation within the U.S. health care delivery system will help clarify the extent to which personalized medicine has penetrated health care and help identify remaining needs. This, in turn, will inform efforts to address the most critical outstanding integration challenges.

OBJECTIVE

With necessary funding, this project will examine varying perspectives and practices in order to capture a holistic picture of the clinical adoption of personalized medicine strategies and technologies within the U.S health care system by querying provider institutions about baseline community, institutional, and service delivery details as well as practice patterns and viewpoints related to personalized medicine and its utilization. This, in turn, can help inform efforts to address the most critical outstanding integration challenges. The landscape analysis will include a representative sample of U.S. health care delivery institutions and could include both quantitative and qualitative results to ensure that a U.S. health system-wide picture of the integration of personalized medicine is captured.

PROJECT OUTLINE

The project, to be completed in 4 - 6 months, will involve a short survey and/or a series of interviews of U.S. health care delivery systems and subsequent analysis that will help demonstrate the current landscape of personalized medicine integration.

PMC's health care working group will guide the project, review survey questions, track progress at various milestones, and ensure an appropriate sample of survey respondents.

Survey respondents will include a representative sample of U.S. health care delivery institutions including academic health centers; urban, suburban, and rural community hospital systems; and integrated payer/provider systems.

CONCLUSION

Many organizations within the personalized medicine community have called for an analysis of the current landscape for personalized medicine implementation in the U.S. This proposal is PMC's answer to that call. We invite your sponsorship of this important project. Interested institutions should contact Daryl Pritchard (dpritchard@personalizedmedicinecoalition.org).

About the Personalized Medicine Coalition

The Personalized Medicine Coalition (PMC), headquartered in Washington, DC, representing innovators, scientists, patients, providers and payers, promotes the understanding and adoption of personalized medicine concepts, services and products to benefit patients and the health system.

HEALTH ADVANCES

PROJECT PROPOSAL

Landscape Analysis: Integration of Personalized Medicine into US Health Systems

Prepared for:

PMC PERSONALIZED MEDICINE COALITION

Revised: July 18, 2018

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PROJECT PROPOSAL

Landscape Analysis: Integration of Personalized Medicine into US Health Systems

BACKGROUND

- As part of its mission, the Personalized Medicine Coalition (PMC) promotes the understanding and adoption of personalized medicine to benefit patients and health systems. In order to successfully carry out this mission, PMC must have a deep understanding of the evolving state of personalized medicine (PM), the current levels of adoption, the key challenges to delivering PM, as well as strategies for overcoming these challenges.
- PMC has recently evaluated several of these aspects of PM, including evaluating the public opinion of PM (Public Perspectives on Personalized Medicine: A Survey of US Public Opinion 2018), identifying key challenges to PM delivery, and outlining the strategies for integrating PM into practice (Strategies for Integrating Personalized Medicine into Healthcare Practices, 2017, *Personalized Medicine*). Building off of this work, PMC would now like to objectively assess the current state of PM adoption across academic and community health systems in the US.
- PMC has asked Health Advances to propose how its professionals would assist in the landscape analysis of the integration of PM into US health systems. Health Advances is well positioned for this work based on its extensive experience working in personalized medicine for both pharma and diagnostics clients. The proposal herein describes our approach for PMC.

OBJECTIVES

The overall objective of this work is to capture a holistic picture of the clinical adoption of personalized medicine strategies and technologies within the US health care system

- Part I
  - Deeply profile 3-4 US health systems to understand in detail the varying perspectives, practices, and institutional program implementation regarding personalized medicine
- Part II
  - Building on these health system profiles, and in collaboration with the project steering committee, develop a PM Adoption Framework or "thermometer" to assess where on the spectrum institutions are in their PM adoption
- Part III
  - Utilizing the PM Adoption Framework, conduct a survey to quantitatively assess PM adoption across a broad number of academic and community health institutions
- Part IV
  - Collaborate with the PMC working group to prepare the results of this study for publication in a PMC project summary document and in a peer-reviewed journal

ACTIVITIES

Kickoff Working Session with Project Team

- At the outset of the project, Health Advances will facilitate a kick-off meeting with the PMC project steering committee. Drawing on its previous experience in the field, Health Advances will prepare a series of questions to guide our discussion and to bring our team up to speed on a wide variety of issues including those listed below.
  - Review of project objectives, methodology, and timing
  - Review previous publications, explore limitations and identify components to leverage moving forward
  - Discuss key questions and working hypotheses
  - Generate a plan for updates and communication with project steering committee

Qualitative Primary Research

- Drawing on the information we synthesize from PMC and Health Advances existing knowledge in companion diagnostics and personalized medicine, we will prepare an interview guide for use in discussions with key professionals across 3-4 health systems, a subset of which will likely include systems represented in the PMC working group.
  - Health Advances intends to have discussions with representatives from hospitals across the personalized medicine integration spectrum, but recognizes that this may not fully align with the final framework given the iterative approach over time.

Interviewee Type	*Key Objectives*	*Number of Interviews*
Hospital System Executives, Personalized Medicine Program Administrators, Laboratory Directors, Clinicians	■ Gain a deeper understanding of how 3-4 health systems have adopted personalized medicine ■ Explore the institutions' perspectives and practices with regards to PM, as well as critical challenges to PM integration and how they may have overcome some challenges ■ Develop a perspective on the range of PM adoption across these different institutions to inform the development of the PM Adoption Framework	*10-12*

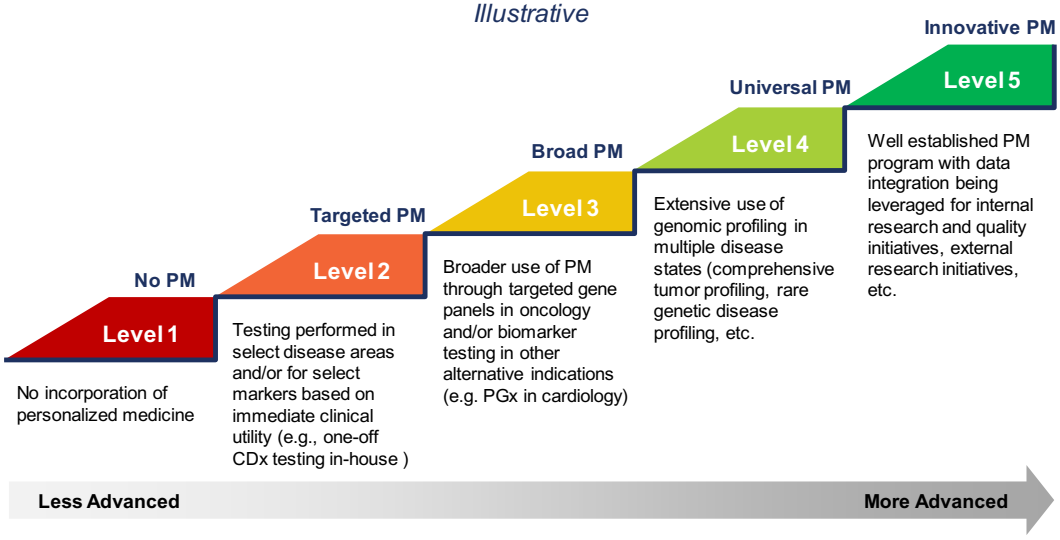
- Interviews will be conducted through scheduled phone conversations lasting approximately 30-60 minutes. At least two Health Advances professionals will attend each interview. Health Advances prefers this sequential "two-on-one" interview format versus traditional focus groups as it maximizes the yield of each interviewee. The team debriefs after each interview and gradually revises its guide to focus on the most salient topics.

Working Session and Development of PM Adoption Framework

Upon completion of the qualitative profiling of 3-4 health systems, Health Advances will facilitate a working session with the PMC project steering committee. The objective of this working session is to align on a PM Adoption Framework with discreet levels of PM adoption which can be used to objectively assess a larger number of health systems. A preliminary illustration a potential framework is shown below:

Personalized Medicine (PM) Adoption Assessment Framework

Illustrative



Note: Health Advances will strive to achieve broad representation from the 3-4 profiled institutions across this framework, but given the iterative approach, this may not be possible.

Quantitative Primary Research

- A quantitative survey with relevant experts (to be determined based on experience with qualitative interviews) will be used to evaluate a large number of health systems across the PM Adoption Framework.

Survey Respondent Type	*Key Objectives*	*Number of Respondents (each at unique institutions)*
Lab Directors or Clinicians (TBD)	■ Objectively assess the level of PM adoption using the PM Adoption Framework ■ Identify the key challenges to adoption of PM, as well as potential ways to overcome these challenges	*100-150*

- Health Advances will be responsible for all survey design, programming, beta testing, fielding, and analysis.
  - Beta testing will be completed with 1-2 experts per survey
  - Data analysis can only be completed once after all responses have been collected
  - Experts will be identified from Health Advances MERLIN database as well as through custom recruiting
- We will review drafts of the survey(s) with the client project team prior to programming. Client will also have the opportunity to beta test the programmed on-line survey link prior to launch.

Manuscript Development


COMMENTARY

TUMOR-BIOMARKER DIAGNOSTICS

Breaking a Vicious Cycle

CLINICAL

Health Economic Analysis of Breast Cancer Index in Patients With ER+, LN– Breast Cancer

- Drawing on the information we synthesize from the institution qualitative profiling, and the quantitative survey, we will work with the PMC project steering committee to develop the PMC project summary document and a manuscript for publication in a peer-reviewed journal
  - Health Advances recognizes that its main charge will be the peer-reviewed manuscript with more of a consultation role for the PMC summary document
  - Health Advances will work with PMC to identify a target list of journals for submission. Please note that Health Advances cannot guarantee publication of this manuscript.

DELIVERABLES AND COMMUNICATION

Health Advances will work to ensure PMC and the working group is internalizing and supporting the direction of the research and manuscript through a series of update calls throughout the project:

- Project kickoff working session (Week 1)
- Biweekly update calls
- Interim presentation (Week 3-4)
  - Health Advances will discuss the results of the health system interviews and workshop the PM Adoption Framework
- Final presentation (Week 7-8)
  - Health Advances will present the results of the quantitative survey and discuss the outline or the manuscript
- Manuscript draft (Week 10-11)
  - Health Advances will deliver an initial manuscript draft to PMC and the working group for review and editing
- Final manuscript editing and submission (Week 13+)
  - Health Advances anticipates one major and one minor round of edits from PMC and the working group – timing will be variable but edits will be incorporated in a timely fashion upon receipt of changes from PMC

RESOURCES AND TIMING

Health Advances will be committed to the project for approximately 13 weeks. Gary Gustavsen, Partner, will lead the project and be ultimately responsible for the delivery to the PMC management team. An additional 2-3 leaders in the diagnostics practice will contribute to the research and development of the publication. In addition, Health Advances' Information Services and Knowledge Management staff will actively participate in the secondary research work outlined and a Graphics Specialist and Case Team Assistant will provide additional support to the team and project throughout the project's duration.

	Timeline	Professional Fees*	Estimated Expenses**	Total
Parts I-IV	*13 weeks*	*$64,000*	*$11,000*	*$75,000*

* Of note, the professional fees quoted represent a significant discount on Health Advances baseline rates.

**Expenses will be invoiced at cost. The bulk of these expenses will consist of expert honoraria.

CAPABILITIES AND RELEVANT EXPERIENCE

Health Advances is a specialized strategy consulting firm focused exclusively on helping clients in the healthcare industry develop strategies that optimize the commercial potential of their products, services, and/or investments. Since its founding in 1992, Health Advances has established a robust and highly regarded global practice.

With a full time staff of more than 150 and offices in Weston, San Francisco, and Zug, Health Advances works across the therapeutic, diagnostic, device and life science sectors and continues to expand the breadth and depth of the experience base it brings to each new project. Our consultants have strong medical, clinical, and business training and extensive work experience, ensuring that each project team is able to quickly add value on each new client assignment.

In addition to the personalized medicine leadership of Gary Gustavsen, Kristen Garner Amanti, and Arushi Agarwal, Health Advances will staff additional consultants experienced in personalized medicine and clinical diagnostics. While we cannot guarantee specific supporting team members at the time of a proposal, below is an example list of Health Advances professionals and their experience.

Personalized Medicine Leadership

Gary Gustavsen, Partner

- Gary Gustavsen joined Health Advances in 2005 and leads its Personalized Medicine Practice. A noted writer and workshop leader in the field of companion diagnostics and personalized medicine, his work focuses on commercialization strategy, indication prioritization, pricing and reimbursement strategy, system economics, and business development opportunities for both diagnostic and therapeutic clients.
- Prior to joining Health Advances, Gary was a researcher at Brookhaven National Lab evaluating a proprietary line of synthetic growth factors. Gary also worked in the Cell & Tissue Technologies group at Becton Dickinson, the Exploratory Cancer Research group at OSI Pharmaceuticals, and most recently the Corporate Strategy group at Millennium Pharmaceuticals. Gary received his Bachelor's degree in Biomedical Engineering from Duke University and his Master's degree in Biomedical Engineering from Stony Brook University.

Kristen Garner Amanti, PhD, Director

- Kristen Amanti joined the Health Advances team in 2010 and is a leader in the Personalized Medicine and Women's Health Diagnostics practices. Her work largely focuses on the development of commercialization strategies, with deep experiences with business development opportunity assessment, deal diligence, international and domestic market assessment, and corporate strategy. She has expertise in precision medicine, companion diagnostics, oncology, women's health, reproductive and pediatric genetic health, hereditary cancer testing, and neonatal screening and is a seasoned workshop facilitator.

- Kristen received her PhD in Cancer Pharmacology from Dartmouth College where her research focused on the development of novel targeted cancer therapeutics. She received her Masters degree in Cell and Molecular Biology and her BA in Biology from the University of Vermont.

Arushi Agarwal, Director

- Arushi Agarwal joined the Health Advances team in 2011 and spends the majority of her time working in the Diagnostics and Life Sciences Practice. Her primary focus is on the development of commercialization and marketing strategies within Personalized Medicine, with expertise across an array of novel diagnostic technologies including Non-Invasive Prenatal Testing, Liquid Biopsy and Next Generation Sequencing Diagnostics.
- Prior to joining Health Advances, Arushi received her Masters in Biomedical Engineering from Columbia University and Bachelors in Biology from the Massachusetts Institute of Technology

Example Team Members

Zoe Michas, Senior Analyst

- Experience in quantitative market research, revenue forecasting, and launch planning in multiple therapeutic areas including women's health, oncology, and rare diseases
- Biogen, Intern in New Product Commercialization group
- Center for Drug Discovery, Research Assistant
- Harvard University, Decision Science Laboratory, Research Assistant
- Harvard University, BA, History of Science

Laura Gullett, Senior Analyst

- Experience in market research, growth strategy, and competitive landscape assessment for pharmaceuticals, diagnostics, and medical devices
- Content area expertise in diagnostics, including reproductive genetics and point-of-care diagnostics
- Roche, Modeling and Simulation Intern
- Harvard University, AB, Chemistry and Physics, magna cum laude

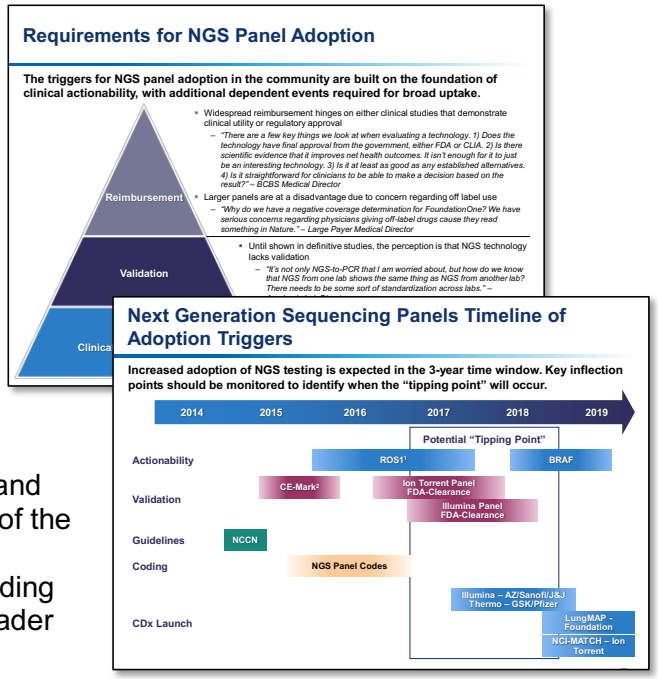
Kelsey Taylor, PhD, Senior Analyst

- Expertise in assessing growth opportunities for contract manufacturers and novel diagnostic technologies
- Massachusetts General Hospital, Graduate Student Researcher
- Harvard University, PhD, Biological and Biomedical Sciences
- Connecticut College, Biochemistry, Cellular and Molecular Biology

Example Projects in Personalized/Precision Medicine

- **Global Strategy for Companion Diagnostic Adoption** – Our team developed a global strategy to increase the use of a companion diagnostic for a key oncology therapeutic for a large pharmaceutical company. Our client was developing a second-generation inhibitor, which would rely on an existing companion diagnostic paradigm; however, this existing paradigm was suboptimal across international markets. Through a large primary research program with oncologists, laboratory directors, and reimbursement experts in 12 geographies, the team identified the major hurdles to using the companion diagnostic today and developed a locally tailored strategy to address these hurdles including alternative technologies, subsidization options, and educational initiatives. The countries were then prioritized for action based on the company's ability to have the most significant near-term impact on testing rates.

- **NGS in Lung Cancer** – Our team was asked to identify diagnostic technologies with potential to impact the lung cancer treatment landscape. We combined internal stakeholder interviews with external interviews with pathologists, oncologists, and diagnostic company executives to determine the inflection points for NGS and blood-based testing adoption. Working with these same stakeholders we also evaluated the impact of these technologies on the client's portfolio and pipeline products. At the conclusion of the project, we proposed several recommendations for company regarding how to minimize risk and remain a leader in personalized medicine.



- **Global Companion Diagnostic Commercialization Strategy** – Our team worked with the senior global brand team of a large pharmaceutical company to develop the global strategy for a novel monitoring diagnostic for a major oncology drug. Thirteen different countries were researched for all aspects of oncology testing, treatment, and payment to develop a full global strategy and a tactical roll-out plan.

- **Business Strategy for an Oncology Diagnostic Company** – Our team worked with a company with a novel ex vivo biomarker platform for capture and analysis of live anatomical pathology samples. This technology has the ability to capture tumor cells live and measure evoked ex vivo biomarkers versus typical biomarker measurement from frozen or FFPE samples. The team worked alongside senior management to define the value proposition and value in multiple markets, the test flow for multiple high value cancer diagnostics, the optimal business model and commercialization strategy, the short term partnership strategy, and the optimal

personnel required for the senior management team. The team also seated the entire scientific advisory board with key opinion leaders in anatomical pathology and oncology.

- **Oncology Outcomes Database** – Our team worked with the National Comprehensive Cancer Network (NCCN) to redefine the strategy for its oncology outcomes database. A key component of the project was a review of the healthcare IT behind competing tumor registries and databases. As part of the operational plan, we identified and vetted potential IT partners who will be developing the infrastructure to leverage existing tumor registries across institutions in order to streamline data collection and access. The resulting data repository will be the leading source for assessing cancer management quality and answering research questions combining comprehensive data fields with intuitive user interfaces while maintaining data quality in an economical way.
- **Oncology Diagnostic Partnering** – Our team worked with a leading personalized medicine diagnostic company on its commercialization strategy for a novel prostate cancer diagnostic test. The team first developed a comprehensive partner database through a detailed look at the prostate health ecosystem. Through in depth interviews with urologists, prospective partners were then assessed on key criteria, including sales force access and quality, product portfolio fit, corporate incentive, and deal history. The top tier companies were further assessed using Health Advances' Partnership Prioritization Tool, which translated the qualitative ratings into a targeted list of ranked potential partners. Partnership rationale slides were then generated for top partners to assist in initial deal conversations.
- **Companion Dx Roll-out Strategy** – Our team worked with a therapeutics leader in an orphan disease to develop its commercialization and roll-out strategy for a novel personalized medicine diagnostic to pair with its leading therapy. A robust secondary program and primary program in the US and five EU countries informed the overall commercialization strategy over the coming months. Simultaneously, the team worked with the individual country sales leaders to prepare their sales force and distribution channels for the launch, including reimbursement considerations across all geographies, advising on the preparation of education materials and working with the company on a phased roll-out based on those countries which were most amenable to the concept.
- **Molecular Go-To-Market Strategy –** For a large diagnostics company, the team conducted a comprehensive analysis of the burgeoning global molecular diagnostics market to inform the company's development and go-to-market strategy for its innovative, fully automated high throughput molecular platform. The team performed detailed analyses of the potential competitors, growth potential, and technology innovation. Detailed secondary and primary research were also used to validate and suggest changes to the company's molecular test menu in development.

HEALTH ADVANCES IN THE INDUSTRY

In addition to our client work, Health Advances frequently publishes and speaks on novel diagnostic strategies across the industry. A sampling of this experience is detailed below:

Select Publications

- Gustavsen, G, Schroeder B, Kennedy, P, et al. Health Economic Analysis of Breast Cancer Index in Patients With ER+, LN– Breast Cancer. American Journal of Managed Care, September 2014
- Cassarino, DS, Gustavsen G, Cole, D, et al. Budget impact analysis of a novel gene expression assay for the diagnosis of malignant melanoma. Journal of Medical Economics, September 2014
- Shore, N, Gustavsen, G, Brawer, M, et al. Clinical utility of a biopsy-based cell cycle gene expression assay in localized prostate cancer. Current Medical Research & Opinion, December 2013
- Hayes, D, Gustavsen, G, et al. Tumor-Biomarker Diagnostics: Breaking a Vicious Cycle. Science Translational Medicine; July 2013.
- Gustavsen, G. Pothier, K. Combatting Complexity: Partnerships in Personalized Medicine. Future Medicine 2013; June 2013
- Peterson, S, Mittal, V, Pothier, K, Matchmaking and Integration In The New World Of Molecular Diagnostics M&A. In Vivo. April, 2013
- Gustavsen, G, Schroeder, B, Kennedy, P, et al. Health economic analysis of breast cancer index in patients with ER+, LN- breast cancer. ASCO Abstract #115628, June 2013
- Mittal, V, Peterson, S, Pothier, K. Molecular Diagnostics M&A: Dormant But Not Done. In Vivo Dec, 2012
- Mittal, V. Ensuring Pharma Doesn't Turn Specialty Markets into Primary Care. In Vivo, March 2012
- Finley, A, Mittal, V. Back to the Future: Next Generation Combination Therapy in Cancer. In Vivo, November 2011

- Gustavsen, G, Pothier, K. Reimbursement Landscape for Novel Diagnostics. BIOtech NOW, January 2011
- Gustavsen, G, Philips, K, Pothier, K. Reimbursement Landscape for Novel Diagnostics: Current Limitations, Real-world Impact, Proposed solutions. Biotechnology Industry Organization, January 2011
- BVGH, Health Advances. The Diagnostics Innovation Map: Innovative Solutions for Diseases of the Developing World, BVGH May 2010
- Gustavsen, G, Pothier K. How to Earn the Economic Payback Diagnostics Companies Deserve. In Vivo 2009 Mar; 27(3)

Select Speaking Engagements

- Gustavsen, G. Evaluating Partnership Needs over the CDx Lifecycle. World CDx Summit, London, March 2018
- Gustavsen, G. Drug & Diagnostic Commercialization – Session Chair. WorldCDx Summit, Boston, October 2017
- Gustavsen, G, Amanti, K, Agarwal, A. Partnership Strategy Evolution over the CDx Lifecycle. Next Generation Diagnostics Summit, Washington DC, August 2017
- Gustavsen, G, Quinn, B, Laser, J, Beuchaw, S. Genomics in the Community: Breaking the Barriers to Deployment of Genomic Medicine outside Academia. Morgan Stanley Healthcare Insights Series, New York, April 2017
- Gustavsen, G, Hawryluk, M, Arrivo, S, Kildal-Brandt, P. Companion Diagnostics: The Evolving Need for Progressive Partnerships. BIO Annual Meeting, San Francisco, June 2016.
- Gustavsen, G, Bunnell, C, Miller, V, Olson, B, Pomerantz, G, Sollano, J. Personalized Cancer Treatment: Better Care, Lower Costs? NEHI Annual Meeting, Boston, May 2016.
- Gustavsen, G, Kaufmann, M. Drug-Companion Diagnostic Adoption & Reimbursement. World CDx Summit, London, March 2016
- Gustavsen, G. System Economic Justification: Tools for Success in the Evolving Reimbursement Environment. Q1 Diagnostic Coverage and Reimbursement Conference, San Diego, February 2016
- Gustavsen, G, Garner, K, Agarwal A, From Biomarkers to Companion Diagnostics, Solutions for Biopharma. Health Advances Institute, Boston, November 2015
- Gustavsen, G. Positioning your Companion Program for Global Success. Next Generation Dx Summit, Washington DC, August 2015
- Gustavsen, G. Connecting the Dots Between Regulatory Approval and Reimbursement. World CDx Regulation, Bethesda, May 2015
- Gustavsen, G, Quinn, B, Thomae, M, Branham, C. Regulatory and Reimbursement Challenges for Clinical NGS. Morgan Stanley Life Science Tools and Genomics Panel Day, New York, May 2015
- Gustavsen, G. System Economic Impact of a Novel Circulating Tumor DNA Test for Third Generation EGFR TKI Biomarker Testing in NSCLC, Poster Presentation,

Association for Value-Based Cancer Care Annual Meeting, Washington DC, May 2015

- Gustavsen, G. Obtaining Evidence to Demonstrate Clinical Utility & Secure Coverage. Diagnostic Coverage and Reimbursement Conference, Boston, December 2014
- Gustavsen, G, Garner, K, Agarwal A. Positioning Your Companion Program for Global Success. World CDx Summit, Boston, September 2014
- Mittal, V, Stolz, L, Blessing, D, Shpilberg, S. Partnering for the Long Haul: Lessons in Alliance Management, San Francisco, July 2014
- Mittal, V, Funderburk, A, Gustavsen, G. Cutting Edge Therapies: How to Combine and Sequence. American Society of Clinical Oncology Annual Meeting, Chicago, June 2014
- Gustavsen, G, Hochberg, D, Garner, K. From Biomarkers to Commercial Diagnostics: Solutions for Biopharma. Health Advances Institute, Boston, May 2014
- Gustavsen, G, Cole, D. Budget Impact Analysis of a Novel Gene Expression Assay for the Diagnosis of Malignant Melanoma, Poster Presentation, Association for Value-Based Cancer Care Annual Meeting, Los Angeles, April 2014
- Gustavsen, G. Health economic impact of Breast Cancer Index (BCI) for late disease management in patients with estrogen receptor-positive, node-negative breast cancer, San Antonio Breast Cancer Summit, December 2013
- Gustavsen, G. with distinguished panel. Developing effective policy strategies for coverage and reimbursement of companion diagnostics, DIA Annual Meeting, Boston, June 2013
- Gustavsen, G. The Future of Pharma-diagnostic Partnerships, Genome-wide Partnering & Deal-making Conference, Boston, MA, March 2012

CONFIDENTIALITY POLICY

We recognize that PMC is relying upon our high integrity and confidentiality. We take this responsibility very seriously. Many of our projects revolve around competitive strategies where the first mover advantage can be substantial, transactions with public companies are involved, confidential medical data, and/or technologies where patent applications have not yet been filed. While we customarily sign clients' Confidentiality and Non-Disclosure Agreements, we also take many steps well beyond:

- Health Advances does not employ "stringers" or contract consulting staff. All of our employees devote their entire professional lives to their employment at Health Advances. Each of these employees is bound to high standards of Confidentiality by strong Employment Agreements and, most importantly, their own personal integrity.
- We use code names for any projects that may include transactions and all related computer files are only accessible to the actual project team assigned to the project.
- Projects involving any patient research or medical data from patients are subject to very specific internal guidelines and controls in regards to the handling of such information and provide for extremely limited access to such data even within the

project team. All data and information derived from patient interviews or medical records is de-identified for inclusion in any analysis or summaries provided to the client.

- Our offices are secured by a card-based security system and guarded by security officers on a 24-7 basis.
- Our offices are also monitored by tape recorded cameras throughout the space.

MARKET RESEARCH PROTOCOL

Health Advances maintains strict control over the collection, use, and retention of confidential information and has implemented security measures that meet or exceed legislative requirements. We can accommodate additional client requirements related to industry guidelines or state disclosure law protocols upon request.

Federal Law

- Physician Payment Sunshine Act (42 CFR 402 and 42 CFR 403)
- Health Information Portability and Accountability Act (HIPAA)
- US Department of Commerce "Safe Harbor" Program – Health Advances is certified for compliance with the European Union Data Privacy Directive
- Telephone Consumer Protection Act of 1991 (TCPA)
- Junk Fax Prevention Act of 2005 (JFPA)
- CAN-SPAM Act of 2003

State Law (Representative List)

- Massachusetts Regulation 201 CMR 17
- Massachusetts has the strongest state privacy law; we continually monitor state laws to ensure compliance
- California Business & Professions Code Section 22575-22579
- Texas Medical Privacy Act
- State "Gift Ban" and Disclosure Laws

Research Industry Guidelines (Representative List)

- National
  - Council of American Survey Research Organizations (CASRO)
  - Advanced Medical Technology Association (AdvaMed)
  - Pharmaceutical Marketing Research Group (PMRG)
  - Pharmaceutical Research and Manufacturers of America (*Ph*RMA)

- International
  - Market Research Society (MRS)
  - European Pharmaceutical Market Research Association (E*ph*MRA)
  - International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
  - International Chamber of Commerce and European Society for Opinion and Marketing Research (ICC/ESOMAR)
  - British Healthcare Business Intelligence Association (BHBIA)
  - European Federation of Pharmaceutical Industries & Associations (EFPIA)