

The Business of
Personalized Medicine

BPM SUMMIT



September 9, 2014

San Francisco, CA

South San Francisco Conference Center

personalizedmedicinesummit.com



SUMMIT CO-HOSTED BY:

SUMMIT SPONSORED BY:



The Business of
Personalized Medicine



Welcome

Dear Attendees:

Welcome to the second Business of Personalized Medicine Summit. Thank you for joining us for a program focused on identifying and maximizing business opportunities, overcoming obstacles, and addressing regulatory and legal challenges, all to bring personalized medicine into mainstream healthcare. Our Advisory Board has worked to ensure today's program is unique, thought provoking, and, most important, offers a forum that promotes interactive discussion and sparks ideas.

An extraordinary group of speakers from diverse backgrounds will offer their perspectives on the progress made in this healthcare revolution. In the past year, significant technological advances, such as the "\$1,000 genome," have expanded opportunities for clinical and consumer-driven adoption of personalized medicine. Our experts will share their real-world experiences, lessons learned, and thoughts on the future of the industry. We are grateful to each of our speakers for joining us and providing their thought leadership in this evolving area.

The Summit would like to thank our co-hosts, the Personalized Medicine Coalition and Foley & Lardner LLP for hosting the Business of Personalized Medicine Summit. We would like to thank our sponsors, AmerisourceBergen, Analysis Group, and the California Institute of Regenerative Medicine (CIRM) for helping ensure the Summit is a success. Without the support of these five organizations, the Summit could not have been possible.

To our attendees, we hope you find your time with us today valuable and inspiring. Thank you for coming.

Sincerely,
2014 BPM Summit Advisory Board

AGENDA

Tuesday, September 9, 2014

7:00 – 1:00 pm **Registration Open**

8:00 – 9:00 am **Continental Breakfast**

8:00 – 8:45 am **The Promise of Personalized Medicine: Global Perspectives on Value, Coverage, and Reimbursement**

The promise of personalized medicine holds allure for patients, providers, and payers alike by improving quality of care by targeting therapy, predicting disease course, mitigating risk, while reducing waste of scarce resources. However, several barriers remain which hinder adoption of personalized medicine across the globe, including industry incentive, regulatory pathways, reimbursement policies, and physician decision-making. This roundtable session will explore the role of personalized medicine in today's healthcare system with an overview of stakeholder perspectives. In addition, the future of coverage and reimbursement processes will be discussed to help participants better navigate the path to commercialization for personalized medicines.

Tommy Bramley RPh, PhD, Senior Vice President of Scientific Consulting, Xcenda

9:00 – 9:30 am **Welcome Remarks from Hosts**

9:30 – 10:20 am **Big Data Making an Impact in Healthcare**

This panel of big data trailblazers will discuss their perspectives on how mainstream healthcare is utilizing big data to make a true impact in patient care. Discussion topics include:

- Generating good data, capturing it and converting to clinical use
- Case studies illustrating how big data is making a difference
- What experts would "do differently" next time and other lessons learned

Pablo J. Cagnoni, MD, President, Onyx Pharmaceuticals, Inc.

Ken Chahine, Senior Vice President and General Manager, Ancestry.com

Colin Hill, CEO, President, Chairman, and Co-Founder, GNS Healthcare

Michael Snyder, PhD, Professor and Chair of Genetics and Director of the Stanford Center for Genomics and Personalized Medicine, Stanford University

Panel Moderator: **Samarth Kulkarni PhD**, Partner, McKinsey & Company

10:20 – 11:10 am

Healthcare Economics & Implications of Personalized Medicine

One of the biggest challenges in personalized medicine is how to convert clinical research and product development into a financially sustainable business strategy which can project and generate attractive revenue. Panelists will discuss how to identify and realize opportunities based on current and future market factors. Additional topics to be addressed include; how to generate the evidence necessary to support coverage and reimbursement; the challenges with meeting expectations for data on clinical utility and outcomes improvements; and factors which can help convince companies with development portfolios to invest the time and money during the early phases of the product lifecycle to ensure that necessary data is generated to support product coverage and reimbursement.

Anita Chawla, PhD, Managing Principal, Analysis Group

Ralph Riley, Global Leader for Health Economics and Pricing, Janssen Diagnostics, part of Janssen Pharmaceutical Companies of Johnson & Johnson

David Sayen, Regional Administrator, Centers for Medicare & Medicaid Services

Panel Moderator: **Judy Waltz**, Partner, Foley & Lardner LLP

11:10 – 11:20 am

Networking Break

11:20 – 12:20 pm

Breakout Session #1

Charting New Terrain: Innovative Clinical R&D Models for Personalized Medicine

Personalized and molecular medicine merge drug discovery and diagnostic medicine. As a result, pharmaceutical and diagnostic companies are forming partnerships to develop drugs and companion diagnostic tests. This panel will review the road to successful partnerships from the perspectives of the pharmaceutical and the device manufacturer and research models that are being developed.

The panel will address:

- When in the development of a personalized medicine drug should a device partner be brought in?
- How does a device manufacturer engage pharmaceutical companies in biomarker development?
- How does one manage the regulatory and payor issue?
- How does one value each partner's contribution to the joint effort?
- Examples of successful research collaborations and why they have worked.

Elaine Cheung, Associate Director, Business and Corporate Development, Illumina

Maureen Cronin, PhD, Executive Director, Strategic Information Management, Celgene Corporation

Jamie Dananberg, MD, Executive Vice President, Head, Therapeutic Areas, Takeda Pharmaceuticals

Panel Moderator: **Ashley van Zeeland PhD**, Co-Founder, CEO, Cypher Genomics

11:20 – 12:20 pm

Breakout Session #2

Business Models for Diagnostic Innovators – In Vitro Diagnostic Kit or Laboratory Developed Test?

Personalized medicine marries advances in medical diagnostics and pharmaceutical science to provide new products and tools to predict, diagnose, and monitor disease. Diagnostic technologies can be manufactured and sold as a kit or in vitro diagnostic (IVD) for others to perform the assay or test. Alternatively, the diagnostic test can be offered as a service, operated through a company-owned clinical laboratory or laboratory developed test (LDT). This panel will review the legal and regulatory aspects, as well as the strategic and competitive considerations, for each business model as well as partnership models for LDT and IVDs.

Nate Beaver, Partner, Foley & Lardner LLP

Rob Bookstein, Director, Corporate and Venture Development, Illumina

Christine Meda, Chief Business Officer, IncellDx

Judith C. Wilber, PhD, D(ABMM), F(AAM) CLIA Laboratory Director and Independent Consultant in Clinical Diagnostics

Panel Moderator: **Antoinette Konski**, Partner, Foley & Lardner LLP

12:20 – 2:00 pm

Lunch and Lunch Presentation: Consumer Driven Personalized Medicine

Bringing personalized medicine technology to consumers involves many facets of the healthcare industry. From innovator, to provider to IT and pharmacy, each sector will need to determine how to build business models that drive innovation, accessibility and achieve success. This panel will touch on how different organizations are realizing success and lessons learned along the way.

Topics include:

- What are the implications of personalized medicine being adopted in each sector to business models across the industry?
- Is it possible to integrate business models across the various industry sectors?
- What types of business models will make personalized medicine a reality for consumers?
- Innovating and practicing in today's regulatory environment.

Amy Grogg, PharmD, President, AmerisourceBergen Consulting Services

Jill Hagenkord, MD, Chief Medical Officer, 23andMe

David Tinkelman, MD, Medical Director, Health Initiatives, National Jewish Health

Moderated by: **Kalidip "KC" Choudhury, PhD**

2:15 – 3:15 pm

Breakout Session #3

The Impact of Next Generation Personalized Medicine Technologies: How Disruptive Tech Continues to Advance the Industry

Disruptive technologies change our preconceived ideas of what is possible. Innovators from varied personalized medicine technical backgrounds will discuss research and development in fields such as gene therapy, 3-D tissue generation and genomics. They will describe paradigm shifts in healthcare which will be facilitated by these new technologies and offer their views on provocative questions such as: Is different and new necessarily better? When should innovative new technologies be reimbursed and how do you value them? What needs to change to ensure that patients are acting on informed medical knowledge and not fear, or misinformation?

Curt Herberts, Senior Director, Corporate Development & Strategy, Sangamo BioSciences

Carlos Olguin, Head of Bio/Nano/Programmable Matter Group, Autodesk Research

Kumar Sharma, MD, Founder, ClinMet, Inc., Director, Institute of Metabolomic Medicine, Director, Center for Renal Translational Medicine, University of California, San Diego

Panel Moderator: **Neil Littman**, Business Development Officer, CIRM

2:15 – 3:15 pm

Breakout Session #4

Reimbursement Policy Roundtable

Payment availability and reasonableness for the many innovative diagnostic tests and therapeutics now being brought to market will direct continued progress in personalizing medicine. This panel will review the latest developments in evidence-based reimbursement strategies for emerging products including molecular diagnostic tests. The panel will share their views on potential collaborative opportunities with payors and innovators to maximize the likelihood of coverage and payment decisions and will also discuss recent legislation that has changed the landscape of how diagnostics will be reimbursed going forward.

Paul R. Billings, MD, PhD, Chief Medical Officer (consulting), Genetic Sciences Division, Thermo Fisher Scientific

John Luebker, Senior Director, Health and Wellness, Sam's Club

Danielle Scelfo, Director of Government Affairs, Genomic Health

Paul Sheives, Director, Diagnostics and Personalized Medicine Policy, Biotechnology Industry Organization

Panel Moderator: **Amy Miller, PhD**, Executive Vice President, Personalized Medicine Coalition



3:15 – 3:30 pm **Networking Break**

3:30 – 4:30 pm **The Investment Landscape and Advancing Personalized Medicine Technologies**

This panel will discuss the investment landscape for personalized medicine companies seeking capital to fuel their product development and commercialization activities. The panelists will discuss recent transactions in the personalized medicine space and what is getting financed (and what isn't) in the current environment. The discussion will also examine the following: to what extent is venture capital really available for personalized medicine start-ups, and are there any common threads among the companies getting financed? Are the public markets interested in personalized medicine companies, and if so, where is the interest directed? What are other financing options for personalized medicine companies? Examples of creative partnering transactions will also be reviewed.

Vamil Divan, MD, Senior Research Analyst, Credit Suisse

Jennifer Friel Goldstein, Managing Director Life Sciences, Silicon Valley Bank

Frank Stokes, Managing Partner, Leerink Swann

Panel Moderator: **Curt Creely**, Partner, Foley & Lardner LLP

4:40 – 5:30 pm **Closing Keynote Presentation by Dr. Richard Klausner, Chief Medical Officer & – Interim General Manager, Oncology at Illumina**

5:30 – 6:30 pm **Reception**

