



Partnerships in Personalized Medicine Conference

July 27-28, 2009
Munich, Germany

RECOGNIZING THE OPPORTUNITY IN PERSONALIZED MEDICINE THROUGH PARTNERSHIP IN THE DEVELOPMENT AND COMMERCIALIZATION OF COMPANION DIAGNOSTICS

Conference Overview:

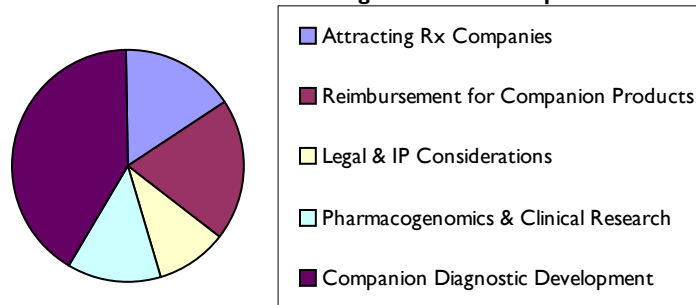
As personalized medicine continues to play an increasingly vital role in the treatment and prevention of disease, the need for accurate, fast, and cost-effective diagnostic tests will continue to fuel the industries exponential growth. Research and development in areas of genetic sequencing and molecular diagnostics have made tremendous breakthroughs in the past several years and are enabling healthcare providers to make decisions on the proper therapies for patients; in ways that have never before been possible. Selecting a therapy based on an optimized level of therapeutic benefit not only provides a faster route to recovery but also prevents potentially harmful courses of treatment, or treatments that will have a low level of effectiveness. The key to personalized medicine however, is not the therapies themselves, but access to timely, efficient, accurate diagnostic tests.

For manufacturers of diagnostic tests, partnering with developers of therapies at the ground level, in conjunction with therapeutic discovery and development offers a tremendous benefit to both organizations. Development in tangent enables more data to be collected through well designed, thorough clinical studies, and also provides diagnostic companies with greater access to samples, physicians and patients. These partnerships also have the benefit of identifying additional uses for the diagnostic test, the therapy, as well as refinements in criteria for utilization.

Unfortunately, most diagnostic – therapeutic partnerships are not established at a ground level, and are the result of tremendous efforts on both sides of the equation. Challenges abound for organizations in both finding appropriate matches between their test and therapy, and even after identifying a potential partner, the challenges have only begun. Contractual negotiations and IP/Patent protection are critical in the establishment of partnerships, as are challenges in the sales & marketing of companion diagnostics.

This conference program will provide a platform for both diagnostic and therapeutic companies to come together to discuss the challenges and inherent opportunities that exist in partnerships established to enhance personalized medicine and companion diagnostics. Through case studies that highlight the successes in development, regulatory hurdles and commercialization of these companion tests, to round-table discussions that delve into specific therapeutic areas such as cancer, heart disease and diabetes.

Areas of Interest for Diagnostic Partnerships



Distinguished Presenters Include:

Stephen Little, PhD
Chief Executive Officer
DxS, Ltd.

Berwyn Clark, PhD
Chief Scientific & Development Officer
Lab21 Limited

Michael Haas, PhD
Director Central Marketing
Phadia

Chantal Parpex, MD
President
CDC Innovations

Dr. Anne T. Bruinvels
Founder & Chief Scientific Officer
Curidium

Kari Stefansson, MD
Chief Executive Officer
deCODE genetics

Dr. Peter Meyer, LL.M.
Partner
Simmons & Simmons

Joseph Ferrara
President
Boston Healthcare

Nick McCooke
Chief Executive Officer
Pronota

Neil Butler
Chief Executive Officer
Vivacta

Peer Schatz
CEO
QIAGEN

Dr. Andreas Guhl
Director, Health Outcomes Unit
NHS Innovations

Invited Presenters:

Thorsten Gutjahr
Head of Biomarker Discovery
Roche

Dr. Peter de Boer
Director, Experimental Medicine
Johnson & Johnson

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8:00 Registration & Coffee

8:50 Chairperson's Opening Remarks & Conference Welcome

9:00 Molecular Testing and Diagnostics in the Continuum from Innovation to Patient

The advent of molecular testing technologies has given rise to much closer links between discovery, development and, where required, post-launch companion diagnostics. By aligning platform technologies and approaches, significant time and cost savings can be achieved in the development process while effectiveness, efficiency and safety can be maximized. The value of this continuum from discovery through to diagnostics is significant for pharmaceutical companies and allows fast reactions in adaptive trials. In addition, it supports the adoption to the needs of theranostic approaches to prescription and treatment which favour the incremental cost effectiveness ratio (ICER) in healthcare and has given rise to new business opportunities and models.

Peer Schatz, *CEO*

QIAGEN

9:50 Creating Commercially Viable Partnerships with IVDs for Personalized Medicine

Perhaps the greatest challenge for in vitro diagnostic manufacturers in creating meaningful partnerships with pharmaceutical companies to advance the use and integration of personalized medicine into today's healthcare systems is ensuring commercial value on both sides of the partnership. These companion diagnostics make a tremendous impact in the methods of identifying the most appropriate course of treatment for individual disease states, but the creation of commercial value for partners is extremely difficult to obtain because of low reimbursement rates for diagnostic tests. Working in tangent with pharmaceutical companies is just the first step in negotiating the perilous route of commercializing viable in vitro diagnostic companion products.

Kari Stefansson, MD, *Chief Executive Officer*

deCODE genetics

10:40 Coffee & Networking Break

11:00 The Emergence of Companion Diagnostics & Pharmacogenetics

New developments in molecular diagnostic tools are rapidly changing the traditional treatments of scores of diseases, while also causing a tremendous shift in the development of both pharmaceutical and diagnostic tests. Targeted companion diagnostics are enabling physicians and healthcare providers to make treatment determinations that are not only more accurate but which ultimately result in more efficient and effective therapeutic decisions for patients, reducing expenditures as well as ensuring a higher level of patient safety. Understanding the historical development of companion diagnostics and pharmacogenetics will provide insight for executives as to where this exciting industry is going.

Berwyn Clark, PhD, *Chief Scientific & Development Officer*

Lab21 Limited

11:50 Delivering a Companion Diagnostic for a Targeted Cancer Therapy

DxS is a personalized medicine company that works in partnership with drug companies to co-develop companion diagnostics to aid doctors in selecting therapies for patients. The DxS K-RAS assay is the companion diagnostic for colorectal therapies Vectibix (Amgen Inc., pantumumab) and Erbitux (Merck / Imclone / BMS, cetuximab).

- The role of personalized medicine in cancer treatment
- Challenges in bringing a companion diagnostic to market
- Case Studies:
 - Colon cancer: Vectibix, Erbitux & K-RAS
 - Lung cancer: Iressa and EGFR
- Regulatory hurdles
- Lessons learned

Stephen Little, PhD, *Chief Executive Officer*

DxS, Ltd.

12:40 Luncheon for All Attendees, Speakers & Sponsors

2:00 Integrating Companion Diagnostics and Therapeutic Development from the Outset of Discovery

In order to truly integrate personalized medicine into today's healthcare environment, it is essential for organizations to integrate the development of companion diagnostics at the outset of the discovery of a drug candidate. Encouraging the co-development of therapies and diagnostics will ensure that both products are ultimately established in the market and are designed to be used in conjunction with each other. This session will discuss the integration of companion diagnostics alongside drug candidates and will provide a road map for the path ahead.

Dr. Anne T. Bruinvels, *Founder & Chief Scientific Officer*

Curidium

2:50 Pharmaceutical Perspective on Companion Diagnostics and Personalized Medicine

As drug manufacturers continue to discover new, more targeted therapies, the quest for companion diagnostics will become increasingly vital to the eventual commercialization of their products. Benefits that pharmaceutical companies are experiencing through partnerships for personalized medicine and companion diagnostics include:

- More efficient clinical trials
- More effective clinical trials
- Safer products and reduced adverse events
- Higher price points for better performing products
- Competitive advantages

Invited Dr. Peter de Boer, *Director, Experimental Medicine*

Johnson & Johnson

3:40 Coffee & Networking Break

4:00 Panel Discussion: Initiating Partnership Discussions between Pharmaceutical & Diagnostic Manufacturers

For diagnostic and pharmaceutical corporations alike, one of the greatest challenges in working together is the initial contact and agreement processes. For diagnostic companies, there is a need to understand from the pharmaceutical companies what types of communication are most desirable as well as the preferred channels for initiating discussions. From the perspective of pharmaceutical companies, there is a great need to understand what the capabilities are of diagnostic companies, and what types of resources can be brought into the partnership. Ensuring a clear understanding of the partnering process will enable companies to enter into their agreements with a full understanding of the parameters and goals of the partnership. During this panel discussion, diagnostic and pharmaceutical companies will come together to discuss:

- What pharmaceutical companies are looking for
- Best methods for approaching potential partners
- Understanding the parameters of the partnership
 - R&D, co-development
 - Sales & marketing partnerships
- Recognizing the depth of resources on each end

Michael Haas PhD, *Director Central Marketing, Phadia*
Stephen Little PhD, *CEO, DxS, Ltd.*

4:50 Legal Considerations in Partnerships for Personalized Medicine: Managing IP Protection

As pharmaceutical and diagnostic companies open themselves up to partnerships, they also run the risk of exposing their intellectual property. While many organizations hire outside legal firms to assist them in the protection of their intellectual assets, it is critical that executive level staff have a solid understanding of IP and Patent protection. This session will provide groundwork of knowledge related to:

- Risks associated with licensing agreements
- IP protection
- Due diligence and partnership negotiations

Dr. Peter Meyer, LL.M., *Partner*

Simmons & Simmons

5:40 Closing Remarks and Day One Conclusion

Day Two Conference Sessions: Tuesday, July 28th

8:30 Registration & Coffee

9:00 Opening Remarks

9:10 Internal Development Approaches to Personalized Health Care

Organizations that are developing both targeted tests and therapies to treat specific diseases are finding tremendous benefits from the cross-collaboration and synergies within their research organizations. While not a common approach, the strategy is being applied in several organizations with a varying level of success. This case study will discuss innovations within the Roche Personalized Health Care and Diagnostic Business units, who are successfully co-developing tests and therapies which will enable safer and more effective treatment of a variety of diseases, and will also provide insight into how Roche is also establishing outside partnerships to drive innovation.

Invited Thorsten Gutjahr
Head of Biomarker Discovery

Roche

10:00 Strategic Marketing for Companion Diagnostics: Extracting Value from Personalized Medicine

Given the impending significant changes in health care priorities and policies, and the current economic situation, how can diagnostic companies find and deliver increased value demanded by the marketplace? Clearly, the personalization of therapy through companion diagnostics is one potentially powerful way to achieve this goal. In this presentation an industry expert and consultant will examine the evolving value proposition for companion diagnostics and associated biopharmaceuticals, and discuss:

- Strategic considerations driving the marketing plan
- Identifying winning value propositions for both the therapy and diagnostic
- The impact of reimbursement and regulatory considerations on positioning and marketing
- Case studies from previous diagnostic-therapeutic combinations with Dako

Joseph Ferrara
President

Boston Healthcare

10:50 Coffee & Networking Break

11:10 Personalized Medicine and Targeted Cancer Therapy: Why Should the NHS Pay for It?

- NHS & NHS Innovations London Overview
- Gathering convincing economic & outcomes data
- Establishing cost-effectiveness thresholds
- Overcoming reimbursement hurdles to gain market access
- Understanding the impact of positive NICE Technology Appraisals
- Real-world implementation of personalized medicine in oncology case studies

Dr. Andreas Guhl

Director, Health Outcomes Unit

NHS Innovations, London

12:00 Companion Diagnostics: Targeted Therapy Management through Long-Term Compliance Aid

Diagnostics that can direct therapeutic treatment and manage dose adjustment aids therapy deployment. Identifying patients that need the therapy, and ensuring efficacy is optimised adds both value and clinical utility to the Pharmaceutical partner. An additional key benefit of the use of IVD tests is their value in enhancing patient compliance with therapies, by ensuring the patient recognizes the benefit of the treatment, and maintaining an appropriate dose. There are many examples of how these tests are enhancing the overall compliance with courses of treatment, from diabetes to lipid testing to thyroid and other disorders. This presentation will highlight clinical benefits of the integration of diagnostic tests into routine standards of care and the benefits that patients will receive from this type of testing and disease management.

Neil Butler

Chief Executive Officer

Vivacta

12:50 Luncheon for All Attendees, Speakers & Sponsors

2:00 Exhibiting the Clinical Utility of Personalized Medicine and Companion Diagnostics

During the development of any in vitro diagnostic test, it is imperative that manufacturers can substantiate the clinical utility of their test. Ensuring tests can meet rigorous clinical studies will be the first step in the eventual commercialization of a new companion diagnostic. For pharmaceutical companies, working together with diagnostic manufacturers in a co-development scenario is especially attractive, but not without its challenges.

Nick McCooke

Chief Executive Officer

Pronota

2:50 Market Access: Preventing Diagnostic Tests from Becoming the Bottleneck

As companies come together in the development and commercialization of new medical therapies and tests, there are all too often instances where one test or the other becomes a bottleneck in the process, preventing both products from adequately moving forward. Steps must be taken at the outset of the partnership to ensure that the diagnostic test does not hinder the commercialization of new products.

- Establishing realistic time lines for product development
- Considering regulatory barriers in front-end development
- Addressing and troubleshooting potential delays

Siemens

3:40 Venture Capital Perspective on Personalized Medicine

Although today's marketplace is one of caution as investors evaluate potential capital infusions, venture capital is still alive and well for organizations that present strong business cases for their in vitro diagnostic tests. Highlighting potential partnerships with pharmaceutical and biotech companies will only enhance the value of products from an investment and commercialization perspective.

- Recent deal making in diagnostic, pharmaceutical and personalized medicine
- Uncovering the hype of personalized medicine from an investment perspective
- Highlighting what VC firms are looking for in organizational structures and investment proposals
- Routes to successfully obtaining venture capital

Chantal Parpex, MD

President

CDC Innovations

4:30 Day 2 Closing Remarks and Conference Conclusion