



***Biomarker  
development:  
Lost in translation?***

***Annual Forum***

**PROGRAM**

**JUNE 16, 2011**

**Mount Stephen Club**



## Biomarker development: Lost in translation?

### Welcome

The widespread buy-in of most life science players, has recently allowed reaching a consensus to develop a major initiative in personalized health care. This project will mobilize the entire scientific and medical community from academia and industry. With the joint support of the Ministries of Health and Social Services and Economic Development, of Innovation and Exportation, this federative initiative aims at positioning Quebec among the leaders in the field. The 2011 CQDM/Montreal InVivo symposium on the development of biomarkers is fully coherent with this initiative. By giving the opportunity to world-wide experts to present their views and by gathering them in a panel discussion, this symposium will allow us to better weight the challenges and will certainly contribute to pursue the mobilization efforts of the best resources in Quebec around this major scientific and public healthcare initiative.



**Max Fehlmann**  
President & CEO



**Michelle Savoie**  
General Manager

**Max Fehlmann**  
President & CEO, CQDM

**Michelle Savoie**  
General Manager, Montréal InVivo

### AGENDA



## Biomarker development: Lost in translation?

#### 12 h 30 Registration / Welcome

Max Fehlmann, President & CEO, CQDM  
Michelle Savoie, General Manager, Montréal InVivo

#### 13 h 00 – 15 h 00 Symposium Session

Chairman: **Terry Fetterhoff**, Senior Director, Technology Management, *F.Hoffman-La-Roche Ltd.*

#### Guest Speakers:

**Nicholas C. Dracopoli**, Vice-president, Biomarkers, Ortho-Biotech R&D, *Johnson & Johnson*

**Biomarker applications in oncology drug development**

**Richard Barker**, Chairman of Life Sciences UK  
**Overcoming the barriers to personalized medicine**

**Mark Lim**, Former Deputy Program Director, Program for IMAT, *National Cancer Institute, NIH*  
**Before you analyze a biospecimen for a biomarker-think quality, variability and bias**

**Philippe J. Goix**, President & CEO, *Singulex*  
**Challenges of clinical biomarker development: What can high sensitivity do for you?**

**David de Graaf**, President & CEO, *Selventa*  
**The development of biomarkers for patient stratification in Ulcerative Colitis**

#### 15 h 00 – 15 h 15 Break

#### 15 h 15 – 16 h 30 Panel Discussion (with the guest speakers)

Moderator **Martin Leblanc**, President & CEO, *Caprion Proteomics*

#### Themes for discussion

- 1) Organizational barriers within pharmas for effective implementation of biomarkers in clinical development
- 2) Role of public-private partnerships/consortia in the development of biomarkers
- 3) Strategies for improving the pace and market adoption of companion diagnostics
- 4) Key considerations and priorities in developing Quebec's Strategy for Personalized Healthcare

#### 16 h 30 – 18 h 00 Cocktail

PRESIDENT  
&  
MODERATOR



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PRESIDENT

**Terry Fetterhoff**  
Senior Director, Technology Management  
F. Hoffman-La Roche Ltd.

Terry received a Masters degree in Pathology from University of Western Australia (1981). He then worked at the Denver Children's Hospital from 1982 to 1987 where he oversaw the construction of a 3 laser/5 parameter flow cytometer. In 1987, Mr. Fetterhoff took the position of R&D Manager for Boehringer Mannheim in Indianapolis in which he was responsible for development and manufacturing of Immunology and Biochemical product lines. He became Director of R&D for Boehringer Mannheim Biochemicals in 1995. During this time, the primary research focus was the development of methods to isolate pancreatic islets for subsequent transplantation into diabetics. When Roche acquired Boehringer Mannheim in 1996, Terry was responsible for moving the R&D function to Berkeley where the focus of the research was in vitro protein expression. Currently, Terry is Sr Director of Technology Management and Head of the US Chief Technology Office for Roche Diagnostics in which he oversees the identification and evaluation of emerging technologies relevant to the future of clinical diagnostics, and is responsible for global Open Innovation initiatives within Roche Diagnostics.



MODERATOR

**Martin Leblanc**  
President and CEO,  
Caprion Proteomics

Co-founder of Caprion, Martin led the development and implementation of Caprion's leading proteomics technology and the establishment of a profitable and rapidly growing service business in the field of personalized medicine. Caprion has concluded successful biomarker and target identification alliances with over 30 major pharmaceutical and biotechnology companies.

Prior to Caprion, Martin was successively a management consultant with McKinsey & Company, Vice-President of Sales & Marketing at Advanced Bioconcept Ltd. and then its General Manager following its acquisition by NEN Life Sciences (now part of Perkin-Elmer). Martin is also a member of the Board of Directors of Victrom Human Bionics (TSX: VHB), Mispro Biotech Services, Soricimed BioPharma, Montreal InVivo and the chairman of the Board of the Atlantic Cancer Research Institute.

Martin earned his bachelor's degree in Economics from the University of Moncton prior to completing an M.A. in Economics and Politics at Oxford University as a Rhodes Scholar.

SPEAKERS  
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**Nicholas C. Dracopoli**  
Vice-President, Biomarkers,  
Ortho-Biotech R&D, Johnson & Johnson

**Dr. Nicholas Dracopoli is Vice President of Biomarkers at Centocor R&D, Johnson & Johnson. In this role he is responsible for biomarker discovery, development and applications for oncology products. Previously, he was Vice President of Clinical Discovery Technologies at Bristol-Myers Squibb, and prior to that spent five years in the biotechnology industry at Sequana Therapeutics. Dr Dracopoli obtained his B.Sc. and Ph.D. degrees from the University of London, and completed post-doctoral fellowships at the Memorial Sloan-Kettering Cancer Center and the Massachusetts Institute of Technology (MIT). Subsequently, he served as an Assistant Director at the Whitehead/MIT Genome Center and as a Section Chief at the National Center for Human Genome Research at the NIH before moving to the biotechnology industry. Dr Dracopoli has authored more than 70 scientific publications, and has extensive experience in the fields of genomics, molecular biology and cancer research.**



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Biomarker applications  
in oncology drug development

Currently, only about 10% of oncology compounds entering Phase I clinical trials make it all the way to regulatory approval. The main goals of biomarker research in the pharmaceutical industry are to increase efficiency of the drug development process by improving understanding of the mechanism of action, deeper exploration of PK-PD interactions and predicting the response to novel therapies in clinical development. The development of novel biomarkers by analysis of multidimensional clinical and biological data has enormous potential to impact drug development and improve patient outcomes. However, no complex molecular or protein profiles have been approved by the FDA to drive therapeutic use of any drug. Predictive markers are described in the labels for only a minority of the oncology drugs approved in the US since Herceptin in 1998. These markers all measure the status of the drug target or pathway and do not involve complex molecular or protein profiles. This presentation will discuss why this is the case and show how the nature of the clinical trial process, the limited number of patients enrolled in clinical trials, and the lack of long-term outcome data have severely limited the impact of molecular profiling in the drug approval process and ultimately clinical practice.

SPEAKERS

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**Richard Barker**  
Chairman of Life Sciences UK

Richard Barker has held senior positions in pharmaceutical, diagnostic and biomarker development. Most recently he was Director General of the Association of the British Pharmaceutical Industry. Previously, he was chairman and CEO of Molecular Staging and CEO of Chiron Diagnostics. His book on the future of healthcare: '2030 - The Future of Medicine: Avoiding a Medical Meltdown' positions personalized medicine as one of the key levers necessary to make the future affordable.

## Overcoming the barriers to personalized medicine

Research in academia and industry is adding daily to the list of biomarkers to potentially stratify patient populations, track outcomes and deliver personalized medicine. But the barriers to routine use are still significant: technical and commercial hurdles to creating useable diagnostics, regulatory uncertainty and clinical unfamiliarity, among them. This talk will explore how academia, industry and policymakers need to collaborate to deliver on the potential.



**Mark Lim**  
Former Deputy Program Director,  
Program for IMAT, National Cancer Institute, NIH

Mark D. Lim is currently a consultant to the U.S. Government and also serves on the Strategic Orientation Committee of CQDM and Scientific Advisory Board of the Asian Health Services (Oakland, CA). He was the Deputy Program Director for the Program for Innovative Molecular Analysis Technologies at the National Cancer Institute (NCI), where he previously served as an AAAS Science and Technology Policy Fellow. He received his Ph.D. in chemistry from professor Peter C. Ford at U.C. Santa Barbara and completed an NCI-funded postdoctoral fellowship in Cancer Nanotechnology with professor Charles Craik at U.C. San Francisco.

## Before you analyze a biospecimen for a biomarker-think quality, variability and bias

The qualification of biomarkers to determine clinical utility requires rigorous experimental design considerations that address issues related to bias as well as account for pre-analytical variabilities – combined, these may affect whether a given biomarker's characteristics can be translated to inform a clinical decision or, in a worst case scenario, are due to artifact and noise. Many of the sources of bias and variability begin at the acquisition and processing of a biospecimen (tissue, biofluid, etc.) prior to the analysis of a biomarker. Addressed in this discussion are some examples of pre-analytical variations and sources of bias that serve as case studies to emphasize the need for researchers to be upstream in the patient selection and biospecimen collection/processing processes.



**Philippe J. Goix**  
President and CEO,  
Singulex

Dr. Goix joined Singulex as President and CEO in September 2004. Since then he has spearheaded Singulex's commercial efforts in the life science and diagnostic markets. Prior to joining Singulex, he founded Guava Technologies in 1998 and led Guava to a series of financings that enabled the company's successful commercial launch. Dr. Goix was also a senior scientist at Sandia National Laboratories, Stanford University, and CNRS France, where he developed sophisticated laser-based diagnostic tools to investigate complex fluidic systems. Dr. Goix holds a doctorate in physics from University of Rouen, France and an MBA from the University of San Francisco.

## Challenges of clinical biomarker development: What can high sensitivity do for you?

Discovery efforts have yielded promising biomarker candidates across multiple disease and therapeutic areas. However, the bottleneck for implementing these biomarkers to advance drug development programs is often clinical biomarker qualification and verification. This is especially true for low-abundance biomarkers that are traditionally difficult to quantify in healthy, baseline populations and populations with sub-clinical disease. Increased sensitivity of biomarker detection can significantly improve the clinical utility of low-abundance biomarkers, enabling use during drug development as surrogate markers of disease, efficacy markers for novel therapies, patient selection, or companion diagnostic markers. By incorporating advanced detection technology, pharmaceutical scientists can avoid risk factors that contribute to attrition and therefore accelerate pharmaceutical development by reducing drug development timelines and cost.



**David de Graaf**  
President and CEO,  
Selventa

Dr. David de Graaf joined Selventa in 2010 to define the company's scientific strategy, direction and general operations. Additionally, he is responsible for developing key partnerships that will enhance the company's significance.

Previously, Dr. de Graaf served as the Vice President of Biotherapeutics and Integrative Biology at Boehringer-Ingelheim, where he built a successful portfolio of clinical candidates, initiated key collaborations as well as managed scientific leadership and site operations. He also held roles with increasing responsibilities at Pfizer, AstraZeneca and the Whitehead/MIT Center for Genome Research with a focus on bringing innovative systems biology approaches to the early pipeline.

Dr. de Graaf completed his postdoctoral fellowship at the Weizmann Institute of Science in Rehovot, Israel in pharmacogenomics of human olfactory systems. He also earned a Ph.D. in mammalian genetics from The University of Illinois at Chicago and a Masters of Science degree in evolutionary genetics from the University of Utrecht in the Netherlands. He was awarded a Feinberg Fellowship and is invited frequently to speak at scientific conferences.

## The development of biomarkers for patient stratification in Ulcerative Colitis

Ulcerative Colitis provides patients with an imperfect choice between standard of care therapy (Infliximab) and surgery. Using dataset of gene expression generated from primary disease tissue of 60 patients and relevant controls, we have investigated mechanisms that drive disease in patients refractory to infliximab treatment. These molecular mechanistic disease drivers allow for patient stratification and result in the identification of biomarker panels able to unambiguously identify these patients. Interestingly, some of these mechanisms are exclusive, others only occur together, while others again show no correlation. This information is a powerful tool in the design of new drug therapies for intervention in Ulcerative Colitis.



### Our mission

CQDM is a not-for-profit organization whose mission is to identify, fund and support research projects intended for the development of tools and innovative technologies that will facilitate and accelerate the discovery of new drugs.

### Our programs

Our programs, opened to all researchers in the field, seek to capitalize on the strengths present in Quebec and to increase the competitiveness of the research area.

Priority is given to scientific excellence, innovation and technologies that provide practical solutions to pressing problems in biopharmaceutical research. Projects funded by CQDM are oriented towards the achievement of milestones and clear deliverables.

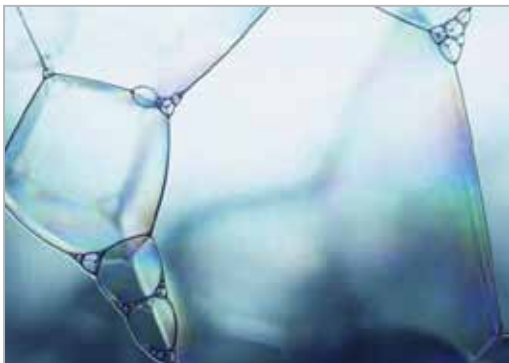
CQDM's unique model is designed to create value within the scientific community as a whole. In addition to representing a significant source of non-dilutive funding for the public and private research network, the use of the technology by the pharmaceutical industry allows for its validation on a large scale. Moreover, the mentoring program was created to maximize the interface between researchers funded by CQDM and the pharma industry, which is a key factor to the success of translational research.

We have recently completed our final selection for the third competition of the Focus program which brings to 11, the number of projects selected within this program for a total of \$17.8M among 18 research entities. In 2011, CQDM has also launched the Explore and the CQDM/Alsace BioValley joint programs.

## Our funding programs

All our programs aim to develop tools or enabling technologies that could strongly impact biopharmaceutical research. The annual competitions are opened to researchers in Quebec from the public and private sectors

Explore	Focus	CQDM/ Alsace BioValley
Unconventional and highly innovative ideas, that could lead to disruptive technologies	Innovative technologies with immediate impact on the discovery or development of new drugs	Collaborative projects between Quebec and Alsace
Early concept validation	Development projects	Development projects
Single or multiple laboratories	Multi-institutional/ multidisciplinary teams	Multi-institutional/ multidisciplinary teams from Quebec and Alsace
Public/ private partnership not required	Public/ private partnership encouraged	At least one private company from Quebec or Alsace
Maximum \$300K over 2 years	Maximum \$2M over 3 years	Maximum \$700K (Quebec)/ €500K (Alsace) over 3 years



**ACTOR  
OF INNOVATION**

**ACTOR  
OF GROWTH**



Montréal InVivo energizes and mobilizes the stakeholders in order to achieve common goals and thereby ensure the competitiveness and growth of the life sciences and health technologies (LSHT) cluster. Montréal InVivo provides important strategic leverage in initiating and coordinating constructive actions intended to overcome the sector's challenges, particularly the greater commercialization of its innovations and the continuation of funding. In this regard, we believe it is critical that the Greater Montréal scientific community becomes involved in the activities of Montréal InVivo in order to support and accelerate the development of the LSHT cluster.

## Montréal InVivo

### The life sciences and health technologies (LSHT) cluster

The LSHT cluster of Greater Montréal is flourishing, thanks to the presence of over 620 organizations within its territory, including 150 research centres and 80 subsidiaries of foreign companies.

The Montréal InVivo cluster comprises over 41,000 qualified employees, making it one of the North America's largest metropolitan areas of its kind. This creative cluster is supported by 11 institutions of higher learning, and ranks 1st in Canada in terms of number of research centres.

In 2007, Greater Montréal was ranked 1st among the 20 largest regions in Canada and the United States for the competitiveness of operating costs in the R&D sector. It is the only place in Canada, and one of few worldwide, where a company can conduct all phases of drug development, from basic research to market release. This productive environment is an important incentive for life science and health technology companies.

### Montréal InVivo

The secretariat of Montréal InVivo is a non-profit economic development organization devoted to the creation of wealth. By mobilizing the stakeholders to face critical challenges such as innovation, and by pursuing actions and implementing its strategic plan, Montréal InVivo aims to ensure the sustainable development, durability and international reputation of the LSHT sector of Greater Montréal.



[www.montreal-invivo.com](http://www.montreal-invivo.com)

