

Pharma Innovation

EXPERT OPINION

Genomics – what the leading edge of health research means to Canadian's and Canada's pharma sector

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What is genomics? Simply stated, genomics is the branch of science that studies the genome – the genetic material of a given individual encoded in its DNA. In human beings, this genetic material is carried in our chromosomes which are located in each one of our cells.

The publication of the human genome sequence (the Human Genome Project) in 2003, constituted a major scientific turning point in the development of genomics. Now, with the information provided by this large multinational project, we are able to better understand how our genetic makeup influences our



health. More than 10 other human genomes have been sequenced and published since then and many more are now being sequenced, generating great amounts of data that are already having a strong impact on healthcare and medical practice.

On drug development, advances in genomic technologies and its applications are revolutionizing and impacting the entire drug discovery process. The biopharmaceutical industry is adopting genomic strategies for tar-

get discovery, efficacy and safety profiling as well as biomarker discovery and validation. As key contributors in the development of personalized medicines, pharmaceutical companies and other life-science players are becoming increasingly interested in developing biomarkers and companion diagnostics to help prescribe the right medication to the right patient at the right time and at the right dose.

The development of genetic tests is a new imperative tool to improve efficacy and safety profiles even more when one considers the enormous costs associated with drug discovery and the mounting costs of treating adverse drug events.

There are currently five companion diagnostic tests approved by the Food & Drug Administration that are required before using some

medications (e.g. CCR5-Selzentry for patients with HIV, EGFR-Erbitux for patients with head & neck cancer and for patients with colon cancer, HER2/neu-Herceptin for patients with breast cancer). Another 15 tests are now recommended by the FDA. The development of companion diagnostics is evolving rapidly and will be an essential element to our health care system to improve drug response and reduce costs.

Genetic biomarkers are used to stratify the individuals in a given population who will respond, or not, to some drug treatments. The development of specific genomic biomarkers already helps the development of targeted drugs with better efficacy and tolerability.

Large and well characterized patient cohorts are imperative to providing clinical vali-

dation of biomarkers. Accordingly, medical research needs access to genomic data in large sets of patients in order to unravel the genetic causes of common and rare diseases. As such, several countries, including Canada (CARTaGENE, led by Dr. Pavel Hamet), have launched large population studies that are well coordinated with international cohorts such as the Public Population Project in Genomics (P3G).

Many believe Canada has opportunities to develop unique approaches to personalized medicine, given its universal health care coverage, international leadership in human genetic research and access to provincial health databases for evaluation of safety and effectiveness of therapeutic interventions.

In his commentary *Personalized medicine: A transformative*

approach is needed published in the Canadian Medical Association Journal in February, 2009, Dr. Tom Hudson, president of the Ontario Cancer Research Institute wrote, "There clearly is a benefit to research in personalized medicine: prevention and screening strategies targeting high-risk individuals, avoidance of serious adverse outcomes, and better matching of therapies to disease and individual profiles."

As such, genomics is providing a solid foundation for the development of tomorrow's biotechnological tools. The stakes are high, since genomics is already unlocking the secrets to some of the major diseases of our times: cardiovascular diseases, diabetes, cancer and diseases of the central nervous system, like Alzheimer's, to name just a few.

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Canada Research Chair weighs in on genomics' future

"At present, the era of blockbuster medications where 'one size fits all' is on its decline.

Acutely aware of this reality and benefiting from huge progress of genomic, proteomic and biomarker research, the pharmaceutical industry, including its Canadian members, is progressively adapting to changing scenery by collecting and analysing pharmacogenomic data

: aimed at improvement of targeting as well as avoiding individual side effects of novel medications.

: Naturally, their studies are performed within populations selected for their specific clinical trial, best fitting to obtain needed information. In order to validate how such information will apply to general population, data from population based genetic studies, such as

: CARTaGENE will become an essential asset to industry in translating from narrow clinical trial into general population to ascertain efficacy as well as safety of new therapies, on our way to more Personalised, Precision Medicine."

**Pavel Hamet, MD, PhD,
Canada Research Chair in Predictive Genomics**