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Precision/Personalized medicine: A “golden age”, or major challenges ahead?

Today we are nearly 20 years after the launch of the first poster-child personalized medicine, Herceptin, and more than 13 years after the completion of the Human Genome Project. Driven by both the advancement of biotechnologies and the attraction of the great potential value of personalized / precision medicine, in recent years we have seen solid growth in the number of personalized medicine products.

About ten years ago, we predicted that, drastic reduction of costs of emerging genomic technologies was ready to shift the bottleneck of the personalized medicine field from science-centric to business-centric, i.e. from whether or not it would be scientifically and clinically feasible to discover and develop a biomarker / companion diagnostics, to whether or not a pharma / biotech company would be willing to pursue a biomarker for its product and embrace the idea of patient stratification.

That prediction was proven true, as, in the past decade, more and more pharma / biotech companies considered biomarker an integral component of their product development and commercialization strategy and delivered a steadily growing personalized medicine pipeline and marketed products.

In parallel, regulatory pathways for personalized medicine have been evolving and maturing. Reimbursement challenges for personalized medicine have also been addressed in key markets in the world.

Given those observations, are we now in a “golden age” of personalized medicine? Or, there are other, new major challenges ahead of us? Do many drug development teams still often struggle with a biomarker approach for their drugs? In the high profile example of PD-1/PD L1 immuno oncology products, sharing a similar mechanism of action didn't result in immuno-oncology products with similar biomarkers, or at all. What would those real life examples tell us about the future challenges of personalized / precision medicine?

In this presentation, we will review the history and landscape of personalized/precision medicine, and share our views on how the challenges in the field are evolving for the life science industries, and potential solutions.

Biography

Dr. Hu is currently Senior Vice President and Head of Consulting in the US for the Pharmaceutical and Diagnostics industries at GlobalData Inc., a publicly listed global healthcare business intelligence and management consulting firm with a headquarter in London, UK. Earlier, aside from being the founding President of BioStrat Advisory LLC, for years he was the Managing Partner and Head of Bionest USA, both life science industry strategy consulting firms in the US. An early participant of the Human Genome Project and later involved in the International HapMap Project, Dr. Hu is now a recognized thought leader in the field of personalized / precision medicine (PM) business strategy, advising global pharmaceutical and diagnostics companies on how best to develop and commercialize personalized medicine drug and / or molecular diagnostics, and build internal business processes & capabilities for PM products. He currently serves on the Editorial Board of the peer-reviewed journal Personalized Medicine, in addition to several PM related industry consortia/committees. For example, he was the only representative from the management consulting industry invited to the US FDA Personalized Medicine Initiative, and co-organized / co-chaired a two-day conference / workshop on Personalized Medicine Strategic Decision Making onsite at the US FDA campus. He was also a Member of the BioNJ PM & Molecular Diagnostics Committee. He has been a frequently invited speaker on PM at conferences and to the leadership teams of many pharmaceutical companies, along with some notable business publications on this subject, including two (co) first authored papers in Nature Reviews, and such other journals as Supplement to Science and Personalized Medicine. As part of his extracurricular activities, he holds an Adjunct Professor position at the Chinese National Human Genome Center at Shanghai, Chinese Academy of Sciences, and Senior Advisor & Visiting Professor positions at the Beijing Genomics Institute.

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