

Title: Will companion Dx exist in 2020? "The transition from single CDx paradigms to multi-omic testing"

Date / Venue: Tuesday 13th May, 2014 at 13.30 to 14.20 in the main plenary hall

Chair: Iain D. Miller, Ph.D., Healthcare Strategies Group

Background: The companion diagnostic paradigm emerged in 1998 with the approval of Genentech's Herceptin and an associated test for the Her-2 receptor. Since that time, over 100 drugs have been developed with biomarkers on their labels, although less than 20 companion diagnostic (CDx) tests have been formally approved by the FDA. The pace has been accelerating recently, with several high profile companion products demonstrating significant efficacy gains. In turn, the pharmaceutical community has begun to embrace the potential with a biomarker requirement in most clinical trials in some indications. However, while such combination products have clearly demonstrated their potential, many in the industry believe that multi-omic testing (including NextGen Sequencing) offers improved patient targeting across multiple therapies and represents the future of the field. Recent deals, such as that announced between Amgen and Illumina, have begun to support this hypothesis. The panel will discuss the associated opportunities and challenges of this evolving paradigm.

Key questions for panellists to discuss (subject to refinement after discussions with panel):

- Will multi-omic tests, such as sequencing panels, replace the current one drug-one test paradigm?
- Will pharma embrace a role as a primary sponsor for the emergence of this new generation of tests?
- What level of evidence might regulators and payers require?
- What opportunities does this new paradigm offer for SMEs and investors?

Panel participants

Iain Miller, Founder, Healthcare Strategies Group, **Panel Moderator**Mark Stevenson, President and Chief Operating Officer, Life Technologies (USA)
Richard Watts, VP Companion Diagnostic Partnerships, Qiagen (USA)
Cecilia Schott, Head of Personalized Healthcare, Corp. Dev. & Ventures, AstraZeneca (UK)
Elaine Warburton, CEO of QuantuMDx (UK)



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