

Biomarkers

There is currently significant growth and excitement regarding the science and commercial potential of biomarkers as diagnostic tests and also as tools for use in drug development. Biomarkers are molecules (nucleic acid sequences, proteins, peptides or metabolites) that can be used as indirect indicators to monitor the risk or progression of a disease, to assess the susceptibility of the disease to a given treatment, or to enable personalised therapeutic strategies. Individual biomarkers have been used for many years, but more recently panels of biomarkers have become increasingly important. Market size for biomarkers is now estimated to be in excess of \$6 billion. Following the identification of putative biomarkers, they require assessment against a variety of clinical samples in order to be validated.

In evaluating potential drug therapies, a biomarker may be used as a surrogate for a natural endpoint such as survival or morbidity. If a treatment alters the biomarker, which has a direct connection to improved health, the biomarker serves as a surrogate endpoint for evaluating clinical benefit.

Ithaka Life Sciences Ltd. is well-placed to offer advice and support for commercialisation of biomarkers. Our team has experience in technology evaluation, market assessment and practical implementation of biomarker strategies, covering the research, pharmaceutical & clinical diagnostic market segments. Team members with direct experience include Paul Rodgers, Richard Cumming and Paula Wittels.

Paul Rodgers, Ithaka's Managing Director, worked with the scientific founders at Cambridge University to establish Psynova Neurotech Ltd., which is developing novel biomarkers for neuropsychiatric disorders. He is a director of the company, in which capacity he led a £1.5M seed funding round and played a leading role in securing a landmark deal with Rules Based Medicine Inc that is providing Psynova with funding and a route to market for its first product, a biomarker panel for diagnosis of first onset schizophrenia. Paul is also CEO of e2v biosensors ltd, a wholly owned subsidiary of e2v technologies plc, which is applying a novel immunoassay technology platform to the development of Point of Care tests for biomarkers including Troponin, a biomarker for myocardial infarction. Paul took on this role following completion of a market mapping exercise undertaken for e2v biosensors by a team of Ithaka consultants.

Richard Cumming has over twenty years experience in product development, product management & marketing within Amersham International, Amersham-Pharmacia Biotech and General Electric (GE) Healthcare. In addition to his work with Ithaka, he is part-time marketing director of a company exploiting biomarker technologies for diagnostics.

Paula Wittels has held senior roles at Pfizer Hospital Products and Quintiles Consulting, leading the development and marketing of novel diagnostics and medical devices. She has worked with a wide range of companies including start-ups developing business plans and market access strategies. She has extensive experience with the development and commercialization of new technologies, including protein biomarker immunoassays.