



Integrated Medicines Ltd

“Enabling personalisation of medicines by integration of surrogates & diagnostics with development & promotion of proprietary medicines”



Background

Most large healthcare consultancies (PWC, IBM, BCG) agree that widespread adoption of personalised medicines is some 10 to 15 years away. Integrated Medicines Limited (IML) provides a roadmap towards personalised medicines by initially focussing on the co-development of surrogates & diagnostics with proprietary medicines. This integrated approach can, in part, be achieved by (a) pharmaceutical companies realising the value, to their products, of biomarkers transitioning through validated surrogates to approved diagnostics; (b) diagnostics providers recognising that their products can positively impact development & promotion of medicines; and (c) associated businesses, e.g., CRO's & (bio)technologists, diligently supporting this novel approach. External pressures are also guiding change in that healthcare providers are demanding more cost-effective therapies, regulators are demanding new entities that have demonstrable efficacy, and physicians & patients are gaining greater awareness of disease pathogenesis & treatment options. IML provides services and products that embrace this new paradigm.

Services

IML offers a number of outsourcing services that compliment the core capabilities of customer organisations:

- IML can articulate the various benefits of an integrated medicines approach at a strategic level to influence greater internal awareness and/or support;
- IML can design, implement and manage integrated projects and programmes, including clinical research with bespoke contract & academic partners;
- IML can identify the most appropriate diagnostics, surrogates or biomarkers, and their potential vendors, to sustain integrated programmes;
- IML can guide and manage third party business development relations between pharma and OEM diagnostics companies, technology developers and CRO's.

.... & Products

To support opportunities identified through our services, IML offers products in two forms via discovery labs, GLP partners and OEM relationships:

- (1) A shorter term option of providing a diagnostic test manufactured exclusively for the purpose of supporting (a) the launch & marketing of a late-stage medicine; (b) the line-extension of an approved medicine into additional disease indications; or (c) the rescue of a failing medicine by favourably changing the risk-to-benefit ratio.
- (2) A longer term option of developing an entirely novel companion test, beginning anywhere in the continuum from biomarker discovery through clinical validation of surrogate biomarkers and ending with an approved diagnostic, conducted in parallel with the development programme of the associated medicine.

In overall support of these products and services, IML will proactively influence the external acceptance of integrated testing and development & marketing of medicines through contact with representative professional, trade and lobby organisations.

Potential benefits for pharmaceutical companies

The ability of objective tests to select patients for therapy and to monitor their responses can positively impact both drug development and marketing.

Development:

The benefits are reflected in costs savings*, where, as alternatives to traditional outcomes, surrogate biomarkers (including PGx), can be used to shorten clinical trials (savings ~\$130M), reduce size of clinical trials (savings ~\$12M), ameliorate attrition risk (savings ~\$158M) and expedite regulatory approval (savings ~\$14M). [*Based on a \$897M/15 year development programme].

Marketing:

The benefits are revenue generating, in that approved diagnostic tests can help products reach peak sales faster (add \$1bn), achieve higher peak sales through greater market penetration (add \$200M) or simply increase Rx (add \$100M). Blockbuster sales (≥\$1bn pa) based on volume are supplanted by blockbuster sales of a premium priced "niche" medicine, which is differentiated from generic or proprietary competitors.

ROI:

Substantial. Case study: investment of ~\$5million by Aventis in the tailored development and regulatory approval of Pharmanetics' Enox Test has the potential to double the current ~\$1billion pa sales of Lovenox.

Therapeutic areas:

Oncology, e.g., EGFR inhibitors, and anti-infectives, e.g., HIV therapies, are particularly receptive to integrated approach of test-and-treat. Considerable opportunities for integration of medicines & test development lie in neurosciences (Alzheimer's & Parkinson's) and respiratory disease (COPD & asthma). However, examples are already evident in metabolic disease (diabetes therapies & glucose monitoring), urology (prostate cancer & PSA tests) and cardiovascular (lipid lowering statins & cholesterol testing).

About IML management

Edward D Blair PhD MBA

is a molecular biochemist with 15 years experience in the **pharmaceutical** industry, recently as a Director of Applied Diagnostics & Surrogates at GlaxoSmithKline and is a visiting scholar at the University of Cambridge. He has been directly involved in pharma R&D from target identification to clinical trials, notably with Amprenavir (HIV) and Relenza (influenza). He has developed programmes that support the strategic integration of surrogate biomarkers & diagnostics into the drug development pipe-line from candidate selection to approval & launch. His broad therapeutic area experience includes viral, respiratory, liver and neurodegenerative disease, frequently in collaboration with esteemed academic groups. He is an expert in the field of virology having edited two books and co-authored over thirty papers & five patents.



Contact details: +44 (0)1954 718122,
eddie.blair@integratedmedicines.co.uk

Tito Bacarese-Hamilton PhD

is a clinical biochemist with over 20 years research and industrial experience in the **diagnostics** industry (Amersham, Serono, Quant-immune) and in the medical & life sciences. He is an Honorary Researcher at Imperial College of Science, Technology & Medicine in London, a founder of a protein chip company and also a successful consultant providing technical services to the diagnostic and pharmaceutical sector. He has devoted his research career to the study and determination of diagnostic markers in biological fluids and has developed and launched numerous products into commercial markets. He is an acknowledged expert in the development of immunoassays for clinical diagnostic applications, particularly, but not exclusively, in the urology and oncology therapeutic areas.



Contact details: +44 (0)1932 345948,
tito.bacarese.hamilton@integratedmedicines.co.uk

The IML board comprises Drs Blair & Bacarese-Hamilton, Professor Chris Lowe (Cambridge), Professor Andrea Crisanti (Imperial) plus a chair & advisors from business management. IML is supported by UK DTI grants and is seeking additional funds to sustain market research, business development and an IP portfolio.