



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/Biotechnology companies:

As alternatives to traditional disease outcomes, biomarkers, including pharmacogenetic markers, surrogates and diagnostics can be used to reduce the size, shorten & render more objective the clinical trials that occupy the bulk of drug development cycles. Approved diagnostic tests can then help products reach peak sales faster or achieve higher peak sales through market expansion and/or penetration. Alternatively, diagnostic tests can be used to increase efficacy or minimize adverse drug events within an objectively defined treatment population, thus facilitating sales of a premium priced "niche" medicine that is differentiated from generic or proprietary competitors.

For diagnostics companies:

The pharmaceutical sector is a major purchaser of diagnostic services and with pressure on pharma to expedite delivery of cleaner, cost-effective drugs, the integration of diagnostics into the drug development pipeline makes a significant difference. Diagnostic-type products can benefit the entire drug development spectrum as well as supporting drugs in the market place.

For Contract Research Organisations (CRO's):

Offering clinical support services that include the application of disease and pharmacodynamic surrogates is an underdeveloped opportunity which will differentiate the proactive CRO.

Therapeutic areas:

Oncology and anti-infectives are particularly receptive to integrated approach but considerable opportunities for integration of medicines & test development lie in neurosciences (Alzheimer's & Parkinson's) and respiratory disease (COPD & asthma). 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.



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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.



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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.