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Life Sciences, Pharmaceuticals and Healthcare

Advancing the utility of imaging biomarkers

Insights from the second Imaging Biomarker Summit

Biomedical imaging is becoming part of bio-pharmaceutical (BioPharma) R&D, in part due to advances in biomarkers – indicators of normal biological processes, pathogenic processes, or BioPharma responses to a therapeutic intervention. As science and technology converge, imaging biomarkers will help screen and treat patients early in their disease process and help address some of society's costliest medical needs. Biomedical imaging plays an integral role in patient care, and can help support the diverse goals of BioPharma research, healthcare, academia and regulatory environments. To meet these goals, it is critical to align collaborative efforts to enhance the utility of imaging technology and thereby reduce overall healthcare and research costs.

The second Imaging Biomarker Summit (IBS II), held in June 2006, explored how the use of imaging as a biomarker could further the FDA's Critical Path vision to increase R&D productivity. [1] The foundation for these discussions was established by the first Imaging Biomarker Summit (IBS I), conducted in December 2005. IBS I focused on vision, barriers and approaches to accelerate imaging biomarker development and use. IBS II brought together a broader group of representatives from the key stakeholder communities.

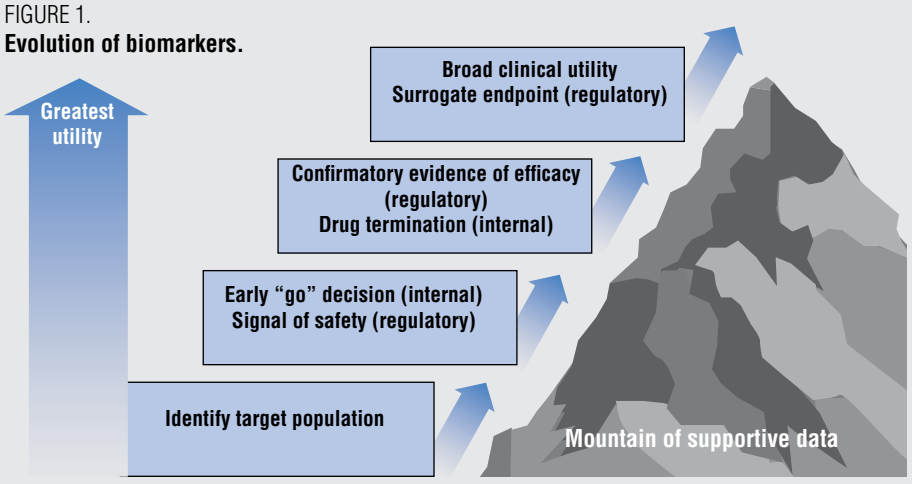
Why are imaging biomarkers important?

Imaging tools can help detect and treat diseases earlier, and potentially reduce the financial burden pressuring healthcare. A broad group of stakeholders is emerging across healthcare, BioPharma, governmental and software vendor industries – all need insights from these technologies.

Imaging biomarkers augment traditional and genetic information to help researchers and medical practitioners characterize tumors, assess target expression and treatment effectiveness, as well as to monitor target inhibition. Biomarkers, however, require a substantial amount of supporting data to evolve from characterizing target populations to become a widely-accepted surrogate clinical endpoint.

Figure 1 depicts the progressive utility associated with more supportive data. Many imaging biomarkers fail to reach surrogate status, because they do not address the target treatment effects or relevant pathophysiology of the disease. More robust imaging can provide new

FIGURE 1.
Evolution of biomarkers.



Source: Stephen A. Williams, Vice President, Head, Global Clinical Technology Pfizer Global Research and Development, The Promise of Imaging Biomarkers presentation, Imaging Biomarker Summit II, June 2006.

insights to improve efficiency in medical practice and clinical research.

IBS II attendees discussed how advanced imaging is helping to compress timelines within clinical trials and substantially reduce the number of study subjects. Despite past progress, IBS II participants highlighted three key challenges:

- Variability in platforms across multiple sites
- Lack of accepted data standards
- Divergent stakeholder priorities and requirements that perpetuate insufficient data sharing.

Collaboration is vital

The resulting vision of IBS II is for imaging biomarkers to become an integral part of medical practice and clinical research to help diagnose, monitor and treat patients. Imaging provides noninvasive approaches that can serve as safety and efficacy markers or ultimately, surrogate clinical endpoints. Collaborative efforts are already underway. Governmental agencies, such as the FDA and NIH, currently provide forums and thought leadership to encourage the BioPharma industry to share information and implement FDA's"critical path"ideas. Other groups, such as NIST and PhRMA, provide collaborative forums endorsing the strategic value of standards.[2]

The IBS II discussions emphasized the importance of the collective effort needed across the ecosystem, highlighting the need for more collaboration and communication. Validation and benchmarking are important requirements for imaging biomarkers to gain acceptance. These can be achieved by establishing common acquisition protocols, setting criteria and agreeing on data standards that will reduce the variability in imaging measurements.

How can IBM help?

IBM Life Sciences R&D Transformation Solutions:

- ***Unstructured Information Management Architecture (UIMA) -*** software architecture for developing and de-ploying unstructured information management (UIM) applications. We can provide our clients a high-level overview of the architecture, introduce its basic components, describe the set of tools that constitute a UIMA development framework, and show them the steps involved in building a simple UIM application, thus highlighting the major UIMA concepts and techniques.
- ***IBM Medical Image Management Solution (MIMS) -*** An industry-specific solution offered as an on-demand service that provides an online collaborative environment for the acquisition and management of medical images to support efficient R&D and timely commercialization. MIMS includes a pre-configured industry information model and best practices to support compliance with industry regulations including 21 CFR Part 11, HIPAA, and GCP.

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References

1 "Innovation or Stagnation; Challenge and Opportunity on the Critical Path to New Medical Products." U.S. Department of Health and Welfare, Food and Drug Administration. March 2004. www.fda.gov/oc/initiatives/criticalpath/whitepaper.html

2 Imaging Biomarker Summit II. Technology/ Standards breakout session. June 29, 2006.

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