

Short Biographical Note for Biomarker Consortium

Paul Deutsch

I received an A.B. from Harvard College and M.D./Ph.D. in Molecular Pharmacology from Albert Einstein College of Medicine. After clinical training in Internal Medicine and Endocrinology at Mass General Hospital I was Assistant Professor in Molecular Medicine and Endocrinology at Cornell Medical College. I subsequently joined the pharmaceutical industry and for 19 years has been involved in early phase drug development.

At Merck from 1992 through 2003 I had increasing responsibilities in the department of Clinical Pharmacology and considerable experience on the incorporation of biochemical biomarkers in Phase 1 trials. From 2003-2005 I had the opportunity to focus on genomic biomarkers as head of the Department of Clinical Molecular Profiling. The mission of that department was to apply genomics techniques such as gene expression profiling based at the Rosetta subsidiary of Merck to early clinical studies, especially in clinical oncology, for which I also served as acting department head in 2005. I had the experience of utilizing the power of 'omics methodologies in biomarker discover but on the flip side I became aware of the potential for misuse of such technologies. A major limitation of high-dimensional data sets in early clinical studies is that the number of biomarker data points far exceeds the number of clinical observations leading to a high potential for generating false positives.

In 2006, I had the opportunity to join Sanofi as VP and Global Head of Clinical & Exploratory Pharmacology. I'm responsible for early drug development across therapeutic areas, including the integration of clinical pharmacology studies like first-in-man with biomarker and translational objectives. Our department has had many accomplishments in the biomarker arena over the last five years including rigorous utilization of biochemical biomarkers in Phase 1, pharmacological challenge/blockade paradigms for proof of target engagement, extensive use of pharmacogenetics such as in the evaluation of the response to clopidogrel (PLAVIX), and extensive investigation of more novel biomarkers in oncology such as circulating acellular tumor DNA to detect oncogene mutations. I consider myself an advocate of the synthesis of the "pragmatic" and "exploratory" schools of thought in the utilization of biomarkers based on my experience. The field must cast a wide net, but we must also focus lest we get lost in the morass of false positives and terabytes of data.