PMC
PERSONALIZED MEDICINE COALITION
Celebrating 10 Years

Policy Position: FDA Pharmacogenomic Data Guidelines

Released: March 22, 2005

The Personalized Medicine Coalition is extremely pleased by the FDA's issuance of the Guidance on Pharmacogenomic Data Submissions and the associated Manuals of Policies and Procedures (MaPPs). We applaud the FDA's leadership and vision in paving the way to a new generation of diagnostics and therapeutics based on an understanding of disease at the molecular level.

PMC's membership - which comprises diagnostic and therapeutic innovators, information technology companies, academic medical centers, patient advocacy organizations and health care insurers and providers - sees three main opportunities from this Guidance:

First, it is clear to the PMC that genomic technologies are driving or contributing to much of the current biomedical discovery and development in both industry and academia. Thus, a better understanding of FDA expectations and attitudes in this arena is very helpful to innovators who must carry their products through the regulatory system. In particular, we congratulate FDA on the innovation of the voluntary submissions process. This process allows product sponsors to have broad technical discussions with Agency experts about research data without undue concern that the submitted data will be used for regulatory decision-making. Such a concept is extremely important for progress in this highly complex technology, and is of broad applicability to other emergent and related areas of regulation, such as biomarkers. Several PMC members have already submitted data according to the spirit of this expected Guidance, and we expect others to follow.

Second, it is a major step towards creation of a clear regulatory environment for pharmacogenomics and Personalized Medicine approaches. We know from prior experience in the life sciences industry that when there is regulatory clarity, it is easier for innovation to take place and new products to move expeditiously from bench to bedside.

Third, we are looking forward to additional protocols from FDA in coming months. We expect one on the subject of the co-development of pharmacogenomic diagnostics and therapeutics, which is central to the Personalized Medicine paradigm, and another on the use of microarrays in DNA analysis. Together, the three guidances will constitute an excellent foundation for the establishment of a technically sound but flexible regulatory environment for the development of important new personalized medicines, and a notable landmark in global regulation.

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PMC's members are looking forward to the opportunity to participate in the development of additional FDA protocols, and to advancing towards an era in which the true promise of

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Personalized Medicine can be fulfilled: that is, delivering the most efficacious therapy to patients based on their genetics and molecular makeup.