CDER Prioritizes Individualization of Patient Treatment

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On the 26th of July, the FDA's Center for Drug Evaluation and Research (CDER) published a draft report entitled "Identifying CDER's Science and Research Needs." The document describes seven major regulatory science needs CDER believes are important to its mission.

Of most interest here, the seventh category CDER identifies is "Enhance Individualization of Patient Treatment." This document amplifies the themes recently sounded in the FDA's Draft Guidance Concerning In Vitro Companion Diagnostic Devices that was released a few weeks ago. In short, CDER is emphasizing the importance of, and encouraging further research into, qualifying different biomarkers for making decisions concerning dosing, patient selection for efficacy, and patient exclusion for safety. Clearly, CDER has the expectation that many clinical trials and approved treatment regimens will have one or more integrated diagnostic genetic tests and that personalizing treatments will lead to better patient outcomes. But, as suggested in the report, large public/private collaborations will be necessary to identify novel biomarkers and to develop the tools to properly validate them for clinical use.