

FDA Information Technology Review

The November 2007 FDA Science and Mission at Risk report provided a number of findings and recommended courses of action. FDA is currently embarking on a number of Information Technology (IT) infrastructure modernization initiatives that will begin to lay the foundation for improved information science and scientific computing. The following are five findings in the area of Information Infrastructure:

- The Subcommittee believes that there is evidence of important, but slow progress to improve information sciences and technology at the FDA over the past few years, yet significant gaps remain (Finding 3.3.1);
- The FDA lacks the information science capability and information infrastructure to fulfill its regulatory mission (Finding 3.3.2);
- The FDA cannot provide the information infrastructure support to regulate products based on new science (Finding 3.3.3);
- The FDA IT infrastructure is obsolete, unstable and lacks sufficient controls to ensure continuity of operations or to provide effective disaster recovery services (Finding 3.3.4); and
- The IT workforce is insufficient and sub-optimally organized (Finding 3.3.5).

Charge to the Science Board: FDA requests the Science Board to solicit feedback from regulatory scientists, Bioinformatics Board members (the Agency's ITIRB) and other stakeholders of current and projected capabilities of the IT Infrastructure, regarding the implications for systems applications development, computational sciences and ultimately the future performance of IT systems for food safety, post-market surveillance, etc.

The product of this IT review of FDA infrastructure modernization initiatives will be a written document from the FDA Science Board that will include findings and recommendations that address the following questions:

- What progress has FDA made to date in the area of IT infrastructure modernization and what opportunities still exist to upgrade to more robust infrastructure that will support both regulatory activities for new science and future data informatics needs?; and
- What progress has FDA made to date to develop the intramural and extramural capabilities for data harmonization that allow the Agency to

catalyze on the development of multi-sectoral shared health information exchanges to support industry innovation, and what implications and/or constraints does such intra and inter-agency harmonization have for the FDA IT infrastructure, both in cost and in impact to the IT modernization activities (e.g. data center design as an example)?