Suggested Projects: Presidential Innovation Fellows
15 - Liberating FDA Data for Rapid Learning and Precision Medicine

The randomized clinical trial drug approval process can require ten years and up to $1 billion. Trailer trucks filled with data arrive at FDA headquarters. FDA (according to PCAST) "currently houses the largest known repository of [unreleased] clinical data." It would be an important advance for a Presidential Innovation Fellow to achieve release in six months.

The National Research Council's Precision Medicine report (Toward Precision Medicine: Building a Knowledge Network for Biomedical Research and a New Taxonomy of Disease - 2011) suggests a new reason to make these data mineable, online. Previously, if clinical trials showed that a new drug was safe and cured 10% of patients with a particular kind of cancer, it would be approved and prescribed for all patients with this type of cancer. New thinking is that genetic and other theories can disclose the differences between the 10% and the 90% so that each drug can be used, with precision, for the patients that it will benefit. The hit-and-miss quality of physicians trying different drugs in different doses to see which gives good results can be put behind us.

Also:

1.) We may not have to spend many years acquiring new data if we can interpret the data that we already have. The FDA databanks have extraordinary, comprehensive, information, for every drug and device (for every medical condition) that ever has been approved by FDA or submitted for approval; also about each of the patients who obtained benefits *and* those who did not.

2.) Rapid progress may be possible. The Precision Medicine report envisions a multi-generation task, like building cathedrals. But if an Innovation Fellow team can create a smart plan for partnership (for example, by also providing free supercomputer time and analysis software, 24x7, for discovery) the private sector could accelerate discoveries by several orders of magnitude.

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