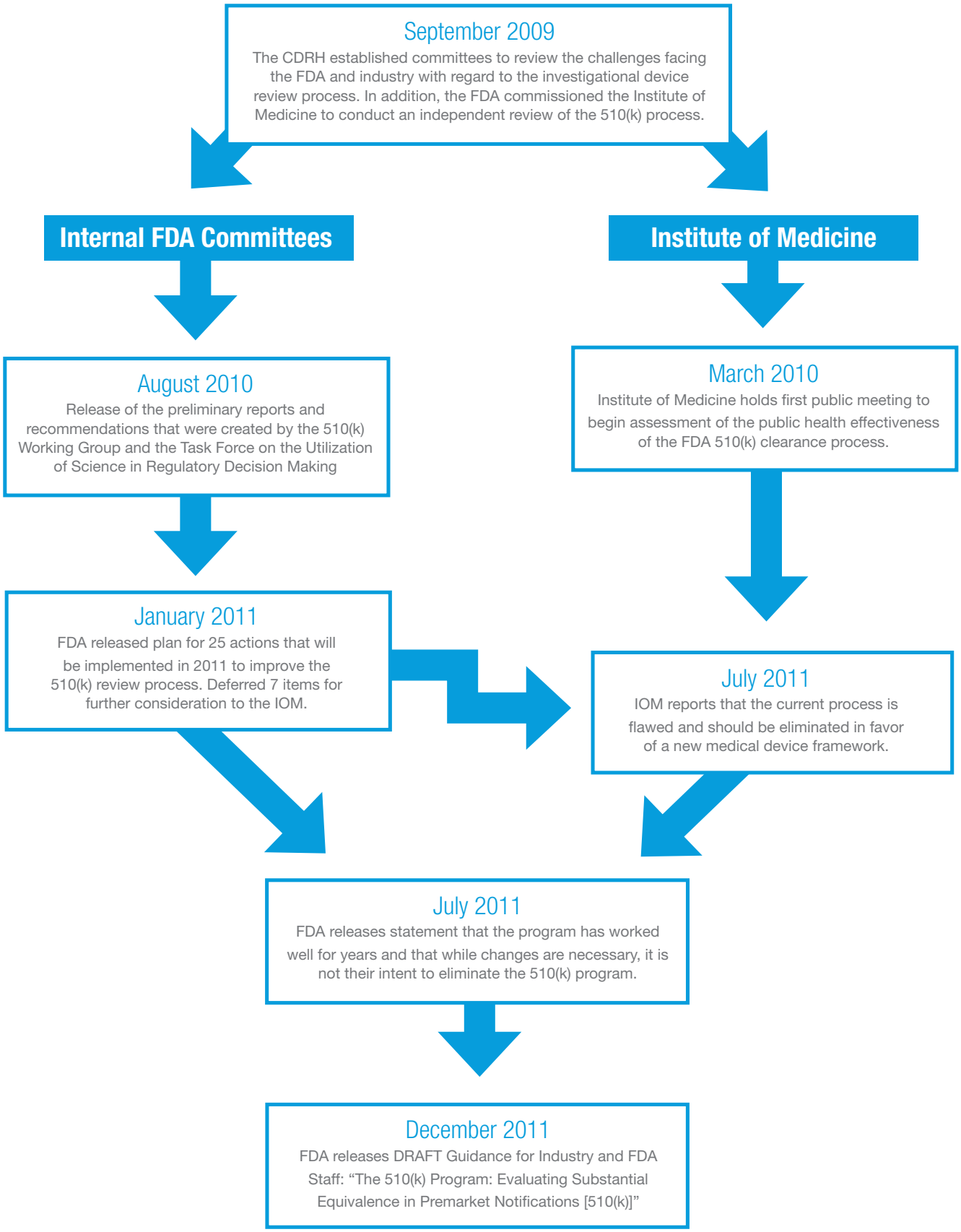
September 2009
The CDRH established committees to review the challenges facing the FDA and industry with regard to the investigational device review process. In addition, the FDA commissioned the Institute of Medicine to conduct an independent review of the 510(k) process.
Internal FDA Committees
Institute of Medicine
August 2010
Release of the preliminary reports and recommendations that were created by the 510(k) Working Group and the Task Force on the Utilization of Science in Regulatory Decision Making
March 2010
Institute of Medicine holds first public meeting to begin assessment of the public health effectiveness of the FDA 510(k) clearance process.
January 2011
FDA released plan for 25 actions that will be implemented in 2011 to improve the 510(k) review process. Deferred 7 items for further consideration to the IOM.
July 2011
IOM reports that the current process is flawed and should be eliminated in favor of a new medical device framework.
July 2011
FDA releases statement that the program has worked well for years and that while changes are necessary, it is not their intent to eliminate the 510(k) program.
December 2011
FDA releases DRAFT Guidance for Industry and FDA Staff: "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]"