An appraisal of drug development timelines in the Era of precision oncology

Supplementary Materials

Supplementary Table S1: Description of FDA special access programs for drug development

Program	Description	Start
Orphan Drug Designation	Provides a special status for a drug or biological intended to treat a rare disease. Qualifies the sponsor for development incentives, including tax credits.	Jan/1983
Fast Track	Designed to facilitate the development and review of drugs to treat serious and unmet needs. FDA offers more frequent meetings and written communication for Fast Track drugs and a rolling review for NDA/BLA application.	Nov/1997
Accelerated approval	Allows FDA to approve promising therapies based on a positive effect upon "surrogate endpoints" that are likely to predict clinical benefit. After approval, the sponsor may be required to conduct post-marketing trials to confirm benefits.	Oct/1992
Priority Review	Designed to expedite the approval phase of new molecular entities from the standard 10 months to less than 6 months. The designation is determined at the time of BLA or NDA application.	Oct/1992
Breakthrough Designation	Intended to expedite the development and review of drugs for serious or life-threatening conditions. Includes all fast track program features plus more intensive FDA guidance. Requires preliminary clinical evidence demonstrating substantial improvement over existing therapies.	Jul/2012

BLA: biologic license application; NDA: new drug application.

Supplementary Table S2: List of included drugs and their respective timeline information, including access to FDA special programs. See Supplementary_Table_S2

Supplementary Table S3: Classification of drugs according to the criteria used to define a biomarker-driven treatment. See Supplementary_Table_S3