



Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY

Impact

REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Personalized medicine is playing a growing role in development pipelines

12% – 50% of current clinical pipelines involve personalized medicines

- Developing personalized medicines has led companies to change their R&D paradigms, including how they make go/no-go decisions throughout development.
 - Drug developers are teaming with external partners, including academic medical centers and diagnostics developers, to advance the science of personalized medicine.
 - Biomarkers are commonly used in discovery, but an associated biomarker is not a requirement for a compound to move into clinical development.
 - Biomarkers are increasingly used to better understand patient response, but companies often cannot use findings related to use of biomarkers to support regulatory approval.
 - Focus on development of personalized medicines varies significantly by therapeutic area.
 - Developers say companion diagnostics are needed, but should not necessarily be included on the label.
-