

Biopharmaceutical Companies' Personalized Medicine Research Yields Innovative Treatments for Patients

The last five years have been characterized by increased momentum in personalized medicine. As scientific understanding has grown, and tools and technologies have advanced, more personalized medicines are progressing through development and reaching patients. New research sponsored by the Personalized Medicine Coalition and conducted by the Tufts Center for the Study of Drug Development (CSDD) updates a 2010 study, confirming that the biopharmaceutical sector is making significant progress but faces scientific, regulatory and reimbursement barriers as well as challenges regarding clinical adoption in its efforts to get targeted therapies through development and to patients.¹

"Personalized medicine gains traction but still faces multiple challenges."

- Tufts Center for the Study of Drug Development

Pipeline

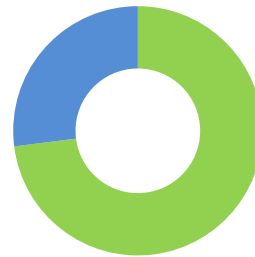
Personalized medicine is rapidly coming of age. Drug development pipelines are full of new targeted treatments that offer hope of effective new treatment options for patients.


- **42%** of all compounds – and **73%** of oncology compounds – in the pipeline have the potential to be personalized medicines.

**42% of All Drugs in Development
Are Personalized Medicines**



**73% of Oncology Drugs in
Development Are Personalized
Medicines**



 Personalized Medicines

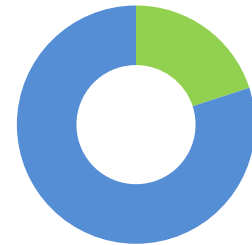
- Biopharmaceutical companies **nearly doubled** their R&D investment in personalized medicines over the past five years, and expect to increase their investment by an additional 1/3 in the next five years.
- Biopharmaceutical researchers also predict a **69%** increase in the number of personalized medicines in development over the next five years.

New Medicines

More targeted drugs are approved by the U.S. Food and Drug Administration each year, and personalized medicines are becoming a larger portion of available new drugs. This means better outcomes for patients and a more efficient health care system.

- According to an analysis by the Personalized Medicine Coalition, in 2014 personalized medicines represented **20%** of all new medicines approved.²
- Today, personalized medicines represent **13%** of all approved medicines, and, according to the Tufts CSDD, **137** approved medicines have genomic information in their label.

20% of 2014 Drug Approvals Were Personalized Medicines



Challenges

Despite these remarkable successes, challenges remain. According to the Tufts study, which based its findings on a survey of biopharmaceutical companies and interviews with executives in the biopharmaceutical and diagnostics industries, key hurdles relate to science, regulation, reimbursement, and clinical adoption.

- Surveyed companies identified scientific discovery as the biggest challenge, followed closely by regulatory and reimbursement barriers.
- Defining appropriate standards for assessing the clinical value of personalized medicine diagnostics is important for reimbursement and uptake.
- A lack of familiarity of personalized medicine among healthcare providers represents another barrier.

“Translating genomic discoveries into personalized medicines entails overcoming substantial scientific, regulatory, and economic challenges, including identifying validated biomarkers, as well as developing personalized therapeutics and clinically relevant diagnostic tests.”

- Tufts Center for the Study of Drug Development

Looking Ahead

These medicines represent innovative approaches to treating disease and offer new options for patients in need. With a policy and regulatory environment that supports progress in personalized medicine, the approvals we have seen in recent years will be followed by many more in years to come. With continued progress personalized medicine will save and improve patients’ lives while also increasing the efficiency of our struggling health system.

¹ Tufts Center for the Study of Drug Development, “Personalized Medicine Gains Traction but Still Faces Multiple Challenges,” *Impact Report*, May/June 2015, Volume 17, Number 3.

² Personalized Medicine Coalition, “More than 20 Percent of FDA’s 2014 Novel New Drugs Are Personalized Medicines,” press release, 28 January 2015, http://www.personalizedmedicinecoalition.org/News/Press_Releases/PMC_Analysis_More_Than_20_Percent_of_FDAs_2014_Novel_New_Drug_Approvals_are_Personalized_Medicines.