Personalized medicine gains traction but still faces multiple challenges

Key hurdles relate to science, regulation, reimbursement, clinical adoption

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- Biopharmaceutical firms said they expect investment in personalized medicines to increase 33% over the next 5 years.

- Oncology products continue to rank highest in terms of average share of personalized medicines in development across all phases, followed by neurology and cardiovascular drugs.

- Biomarker identification and diagnostic test development ranked highest in terms of scientific challenges, followed by regulatory and reimbursement issues.

- Physician unfamiliarity remains a barrier in the clinical adoption of personalized medicines, while proof of clinical utility poses a major reimbursement hurdle.

Following the initial sequencing of the human genome in 2001, the prospect of tailoring treatments to patients based on biomarker data has attracted growing attention from the biopharmaceutical industry, physicians, patients, and investors. Since 2001, biopharmaceutical sponsors have been committed to developing personalized medicines. Today, 13% of currently marketed drugs have pharmacogenomic information on the label, up from 10% in 2010. Moreover, 20% of FDA approvals in 2014 were personalized medicines.

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 useful diagnostic tests.

This report provides a summary of key findings from a Tufts CSDD survey assessing challenges and opportunities with respect to developing personalized medicines in 2015, and updates a similar survey conducted in 2010.