WHITE PAPER

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Unmet Needs and Challenges in Personalized Medicine – Oncology

FutureBridge

Personalized medicine (commonly referred to as targeted therapy or precision medicine) enables providers to deliver ‘right treatment to the right patient at the right time.’ In cancer, personalized medicine plays a pivotal role and involves quantitative measures for analysis at molecular and genomic levels to prevent, diagnose, and treat the disease effectively. In 82 targeted oncology drugs approved by USFDA till 2017, 37 somatic variations (pharmacogenomics information) were included in labelling. Personalized medicine requires support from industry players in terms of investments in new systems and technologies and utilization of existing information and technologies to leverage personal characteristics. Despite the promise of personalized medicine in cancer, various technical, developmental, organizational, ethical, legal, social, and economic challenges have to be considered to ensure the smooth integration of personalized medicine into the cancer care system.

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Executive Summary

Cancer is a complex disease with a high economic burden and requires an effective treatment strategy. This evolving need for effective treatment is addressed by personalized medicine. In cancer, personalized medicine plays a pivotal role and involves quantitative measures for analysis at molecular and genomic levels to prevent, diagnose, and treat the disease effectively. Personalized medicine provides targeted treatments to patients in contrast to the traditional “one size fits all” approach. Personalized medicine (commonly referred to as targeted therapy or precision medicine) enables providers to deliver ‘right treatment to the right patient at the right time.’

Personalized medicine aids clinical outcomes in terms of efficacy, safety, and QoL, and further reduces the economic burden for patients, payers, and struggling healthcare systems. Personalized medicine in oncology has witnessed tremendous early success in Breast Cancer and Chronic Myeloid Leukemia (CML) by targeting HER-2 and Philadelphia chromosome modifications respectively, which is evident by the decreased mortality rates or increasing five-year survival rates.

All stakeholders (industry, regulatory bodies, payers, and prescribers) are keen to replicate this success in other cancers and are progressively focusing on personalized medicine as compared to other treatment approaches. Targeted therapies commonly accompanied by companion diagnostics help oncologists easily accommodate personalized medicine in cancer care. Physicians use diagnostic tests to identify specific biological markers that help determine which medical treatments will work best for each patient.

The healthcare industry focuses on targeted therapies due to the prevailing pressure on costing and reimbursement models. Governments of several developed nations have emphasized on the uptake and effectiveness of personalized medicines in cancer. This emphasis of key stakeholders indicates that more personalized medicines would be available in the near future. Personalized medicine has several advantages over traditional oncology clinical practice; however, there exist technical, developmental, organizational, economic, and ethical challenges, which need to be overcome to enhance the integration of personalized medicine in clinical practice.

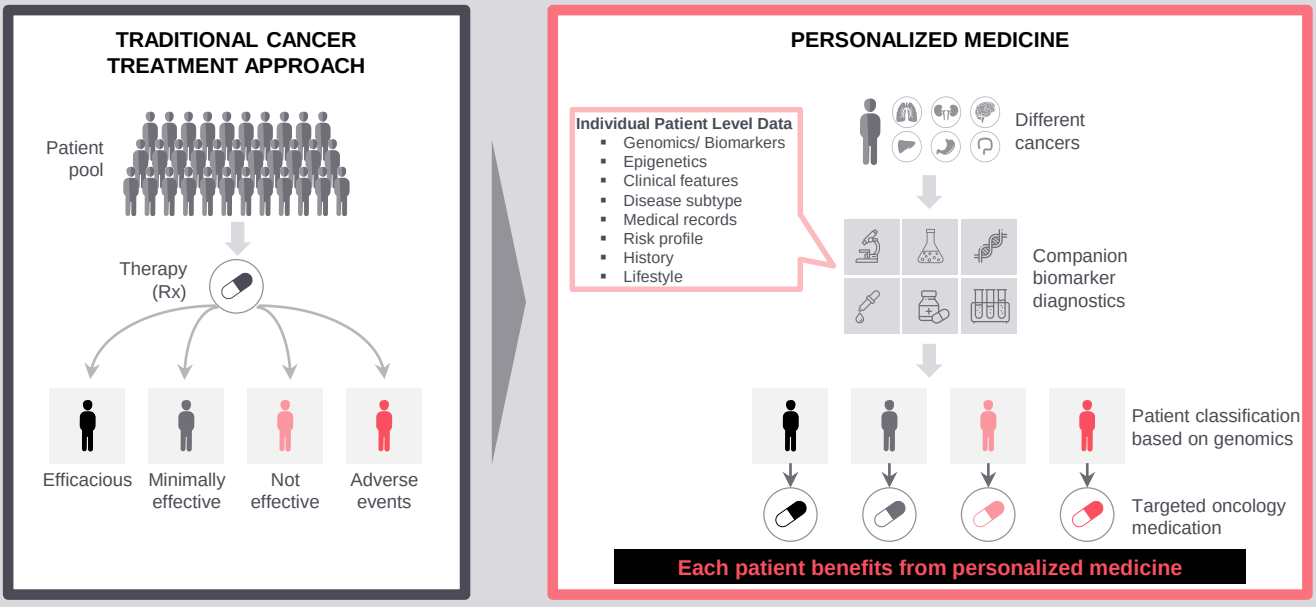
Over the years, research has been undertaken in the field of personalized medicine. Apart from targeted drug therapies, personalized medicine in the future will witness developments in RNA sequencing analysis and CRISPR/Cas9 tool and gene therapies, which have the potential to change the cancer care scenario.

Introduction

Cancer is a complex disease and often arises due to a combination of errors occurring at cellular and genetic levels (genetic malfunctions). It is associated with higher mortality rates, higher treatment costs, low treatment success rate, and highly diminished QoL. The concept of personalized medicine has evolved to address the growing need for effective cancer treatment. Personalized medicine is a form of medicine that uses information about a person's genes, proteins, and environment to prevent, diagnose, and decide effective treatment strategies that are tailored to the genetic profile of each patient's cancer. Genetic information helps in determining the efficacy of a drug, making a prognosis, or aiding in the process of identifying treatments that cause fewer side-effects as compared to the standard treatment options in a given set of patients with similar genomic profile.[1, 2]

Among researchers and healthcare professionals, 'personalized medicine' is often used synonymously with terms such as 'genomic medicine,' 'precision medicine,' 'targeted therapy' and 'precision oncology.' The key focus is to enable accurate diagnosis and effective treatment of cancer at the molecular level by moving beyond the traditional approach of stratifying patients into treatment groups based on histology and site of cancer.[3]

EXHIBIT 1: Approach of Traditional Cancer Care in Comparison with Personalized Medicine



Prior to personalized medicine, most patients with a specific type and stage of cancer usually receive the same treatment irrespective of their genomic data. Over time, it has become evident that traditional treatments did not work in a similar manner in all patients, i.e., the same drug for the same condition in one person may act differently in another person, as inherited genes affect the way bodies process and respond to drugs. These observations led to further research in the field of pharmacogenomics to determine differences in people and tumor response to drugs.[4]

The convergence of clinical oncology, laboratory diagnostics, and molecular pathology that provides a more holistic view of an individual patient is one of the most important factors driving the development of personalized cancer medicine. Personalized medicine has led to a paradigm shift in care delivery through the elimination of bias involved in guesswork, variable diagnoses, and treatment strategies based on generalized demographics.

Different Applications of Personalized Medicine:

- Determining if an individual has certain genetic mutations that could put him/her at a higher risk for developing cancer
- Selecting screening strategies to lower the risk
- Matching patient's genomics with treatments to decide on the effectiveness and side-effects of treatment
- Determining whether patients would be eligible to receive a specific treatment based on their genomic profile

The overall approach of personalized medicine can be defined as a predictive, preventive, participatory, and precision healthcare service delivery model, which allows prescribers to move from a "one size fits all" cancer treatment approach (using radiation, surgery, and chemotherapy) to a more targeted technique. A person with cancer still may receive a standard treatment plan, such as surgery to remove a tumor. However, oncologists are currently armed with genomics knowledge and targeted therapies for efficient personalized cancer treatment to witness better outcomes and improved quality of life.[5]

[1] NIH. Impact of cancer genomics on precision medicine for the treatment of cancer. https://cancergenome.nih.gov/cancergenomics/impact

[2] NIH. NCI dictionary of cancer terms. https://www.cancer.gov/publications/dictionaries/cancer-terms?cdrid=561717

[3] Annals of Oncology. Delivering precision medicine in oncology today and in future. https://academic.oup.com/annonc/article/25/9/1673/2801220/Delivering-precision-medicine-in-oncology-today

[4] Cancer Net. Personalized and targeted therapies. http://www.cancer.net/navigating-cancer-care/how-cancer-treated/personalized-and-targeted-therapies/what-personalized- cancer-medicine

[5] Genome Medicine. Integrating precision cancer medicine into healthcare—policy, practice, and research challenges. https://genomemedicine.biomedcentral.com/articles/10.1186/s13073-016-0362-4

Achievements and Developments of Personalized Medicine in Oncology An Overview

The targeting of the overexpression of HER-2 in Metastatic Breast Cancer with Trastuzumab was the first example of targeted treatment. However, targeted treatment of an oncogene with a specifically designed small molecular inhibitor is best explained by Imatinib in the treatment of Chronic Myeloid Leukemia (CML) by targeting the DeBCR-ABL fusion gene.[1] Both, these treatments had notable success and generated a query for safe and effective cancer care based on somatic variations.

Data related to the prevalence of genomic changes in different cancer types is increasing. Keeping in view the heterogeneity of cancer types, targeted therapy is still at its nascent stage.

However, this data helps drug developers, regulatory bodies, and payers to strategize their approach towards any given indication.[6, 7, 8]

TABLE 1: Examples of Personalized Medicine and Implications

Drug	Brand	Cancer Type	Biomarker	Description
Efficacy				
Imatinib	Gleevec	CML	BCR-ABL fusion gene	Works by Inhibiting altered enzyme produced by BCR-ABL fusion
Trastuzumab	Herceptin	Breast Cancer	HER-2	Works only for women having HER-2 positive breast cancer
Gefitinib	Iressa	Lung Cancer	EGFR	Targets tumors positive for EGFR mutations
Disease Prognosis				
Cetuximab	Erbitux	Colon Cancer	KRAS	Patients having KRAS gene mutation derive little benefit from these drugs
Side-Effects				
Irinotecan	Camptosar	Colorectal Cancer	UGT1A1	Altered UGT1A1 gene makes it harder for body to break down irinotecan, thus causing serious side-effects

Genomic research results have started to impact the practice of medicine in cancer prevention and treatment. A few examples of genomics integration in clinical practice are mentioned below in *Table 2*.[5]

TABLE 2: Examples of Genomic Data Usage in Cancer Care

Contribution of genomic information to precision cancer medicine	Typical example(s)
Cancer risk reduction ***(through genetic testing)***	▪ BRCA1/BRCA2 in hereditary breast cancer and ovarian cancer ▪ MSH2/MSH6/MLH in hereditary nonpolyposis colorectal cancer ▪ RB1 in retinoblastoma
Early detection	▪ Liquid biopsies
Accurate diagnosis	▪ Using molecular markers in tumor classification like HER-2 for Breast Cancer
Targeted therapy	▪ EGFR inhibitors to treat EGFR mutation carriers ▪ BRAF inhibitors to treat BRAF V600E carriers ▪ Tyrosine-kinase inhibitor to treat BCR–ABL fusion protein

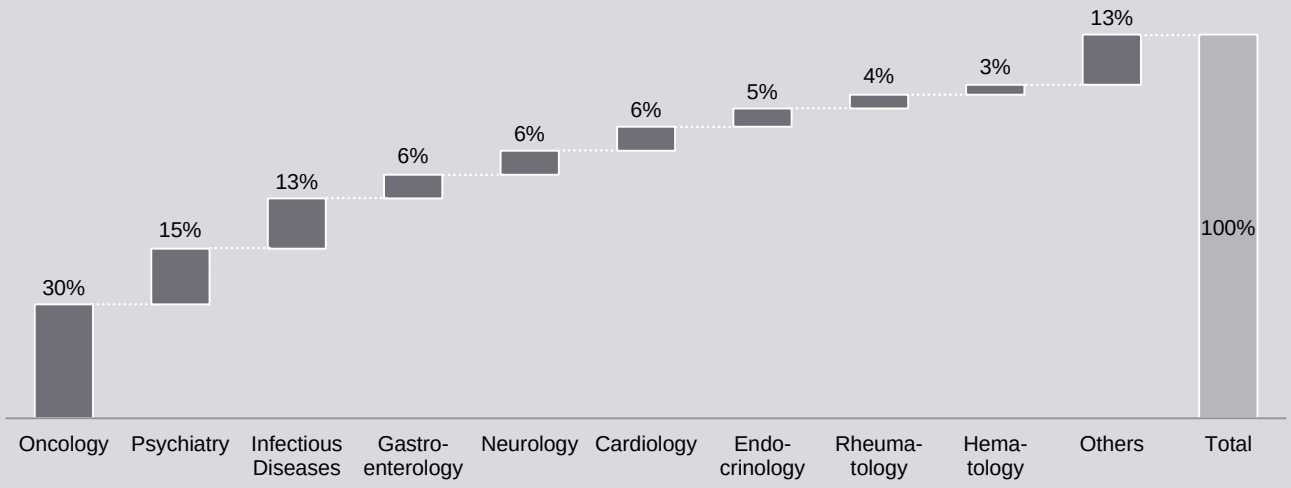
Though at the evolving stage, the integration of personalized medicine in cancer care has witnessed several advantages and benefits. The benefits of personalized medicines could be seen at grass root levels in terms of early & accurate diagnosis, decreased mortality rates, increased survival rates, and decrease in healthcare burden.[9, 10]

Personalized medicine is gaining increased traction in oncology compared with other indications. In 2014, approximately 73% of oncology medicines under-development were aimed at personalized medicine approach compared with 42% for non-oncology indications.[11]

Over the past few decades, scientific knowledge and technological advances in genomics have increased exponentially, enabling diagnostic-based targeted therapies. These advancements have led to large-scale genome sequencing projects involving million-person cohorts providing a large pool of quantitative and qualitative data, which will assist in undertaking precision medicine initiatives. The need to integrate this genomic data into the clinical workflow for chronic diseases has created an opportunity for key players such as IBM Watson. This company works on bringing the concept of knowledge engineering on the forefront to bridge some technical and organizational gaps of personalized medicine.

EXHIBIT 2: Personalized Medicines under Development in Oncology vs. Non-oncology Indications

EXHIBIT 3: Distribution of USFDA Approved Pharmacogenomics Labelled Drugs by Indication



[6] Pharmacy Times. Specialty pipeline highlights. http://www.pharmacytimes.com/publications/health-system-edition/2016/september2016/specialty-pipeline-highlights-

[7] Roche. HER2-positive breast cancer. http://www.roche.com/dam/jcr:2ac14009-bbe8-4991-a460-acfa600d7e2a/en/med-her2-cancer.pdf

[8] Pathogenesis. HER2: An emerging biomarker in non-breast and non-gastric cancers. http://www.sciencedirect.com/science/article/pii/S2214663615000036

[9] Cancer Research UK. Breast cancer mortality statistics. http://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/breast-cancer/mortality#heading-Two

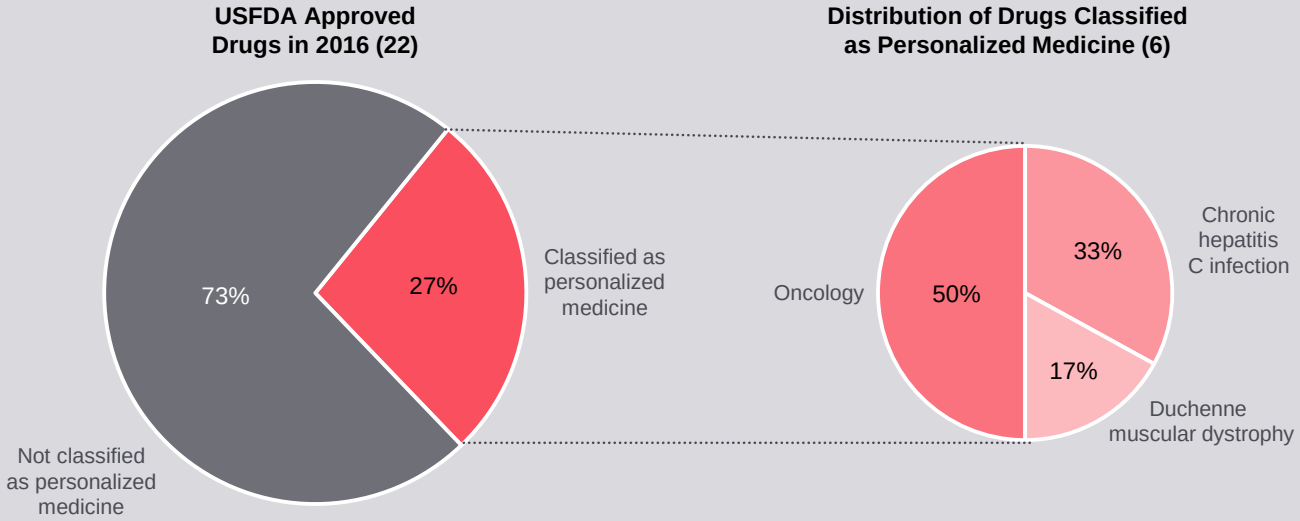
[10] Cancer Journal for Clinicians. Cancer statistics, 2017. http://onlinelibrary.wiley.com/doi/10.3322/caac.21387/full

[11] Forbes. Drug industry bets big on precision medicine: Five trends shaping care delivery. https://Www.Forbes.Com/Sites/Reenitadas/2017/03/08/Drug-Development-Industry-Bets-Big-On-Precision-Medicine-5-Top-Trends-Shaping-Future-Care-Delivery/#1e4e1b0d5d3a

USFDA Approvals for Targeted Therapies

Till March 2017, 192 drugs in 19 different indications were approved by the US Food and Drug Administration (USFDA) that had pharmacogenomics information in labeling. This drug labeling contains information on genomic biomarkers and describes clinical response variability, the risk for adverse events, genotype-specific dosing, polymorphic drug target, and other related information that enables them to be a targeted therapy. It also indicates that personalized medicine has evolved at a faster pace in the field of oncology compared with other indications.[12]

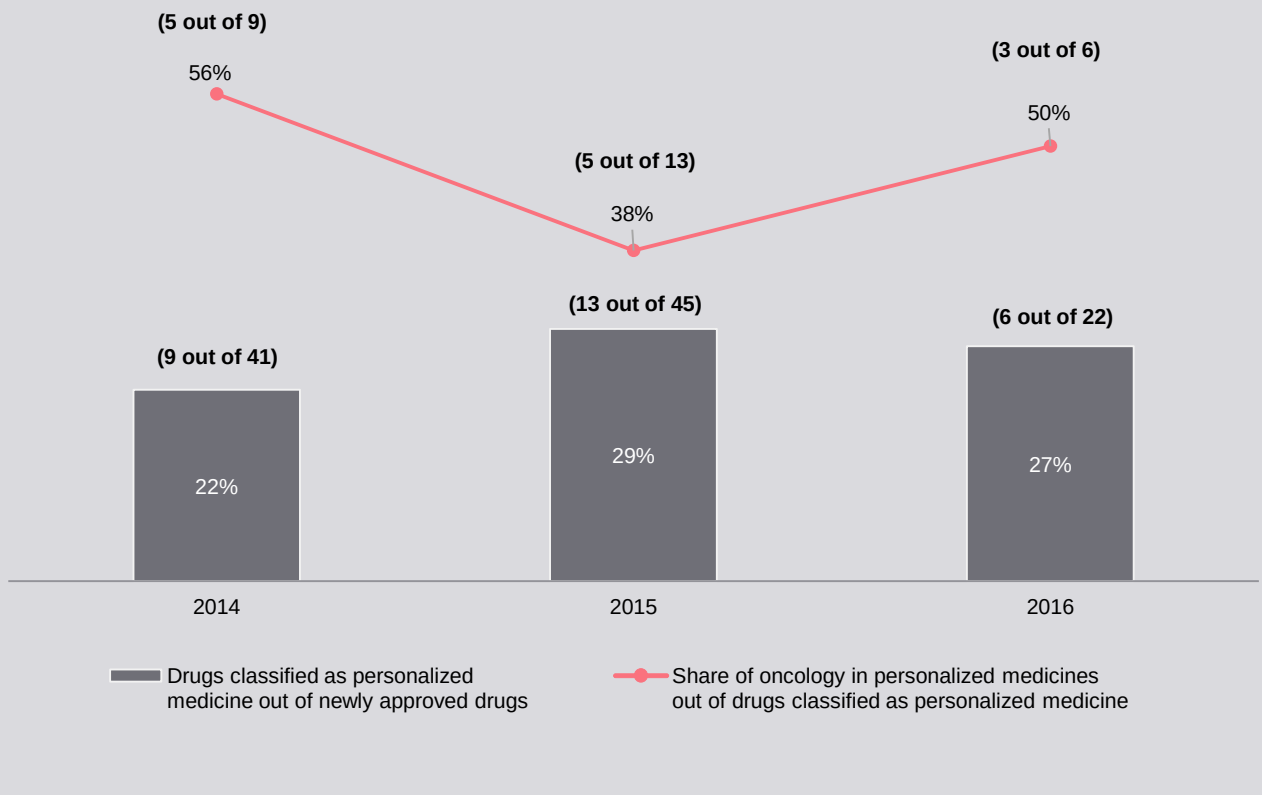
EXHIBIT 4: Classification of USFDA Approved Drugs in 2016



In 82 targeted oncology drugs approved by USFDA till 2017, 37 somatic variations (pharmacogenomics information) were included in labeling. Out of 37 somatic variations, ESR1, BCR-ABL1, PGR, and HER2 are the most prominent targets that were evaluated as compared to other targets.12 out of 22 newly approved drugs by USFDA in 2016, 6 drugs were classified as personalized medicines. Out of the 6 new personalized medicines, 3 were approved for oncology.[13]

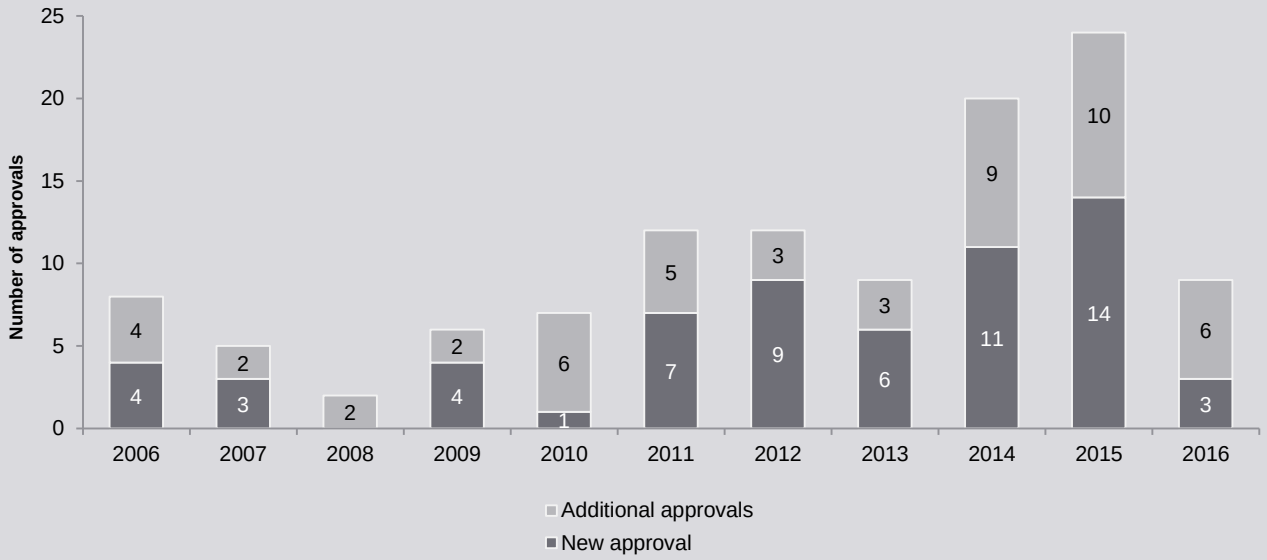
From 2014 to 2016, more than 20% of newly approved drugs by USFDA were classified as personalized medicines, and oncology cornered a major share in these personalized medicines.[13, 14, 15]

EXHIBIT 5: New Personalized Medicines Approved by USFDA and Share of Oncology in Personalized Medicine – 2014 to 2016



The total number of targeted therapies in oncology by approval type from 2006 to 2016 is presented in the figure above. The approval of targeted therapies by USFDA was at a peak between 2011 and 2012 as compared to the previous years. In 2013, the approval process had witnessed a decline due to various factors; one of these factors could be changing the perspective of regulatory bodies on cost-benefit analysis. However, targeted therapies gained traction between 2014 and 2015. Additional approvals for existing therapies as targeted therapy too witnessed considerable growth during this period.[13, 16]

EXHIBIT 6: USFDA Approved Targeted Therapies for Oncology by Approval Type: 2006-2016



[12] USFDA. Table of pharmacogenomic biomarkers in drug labeling. https://www.fda.gov/drugs/scienceresearch/researchareas/pharmacogenetics/ucm083378.htm

[13] Personalized Medicine Coalition. Personalized medicine at FDA: 2016 progress report. http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PM-at-FDA.pdf

[14] Personalized Medicine Coalition. More than 20 percent of the novel new drugs approved by FDA in 2014 are personalized medicines. http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/fda-approvals-personalized-medicine-2014_adjusted.pdf

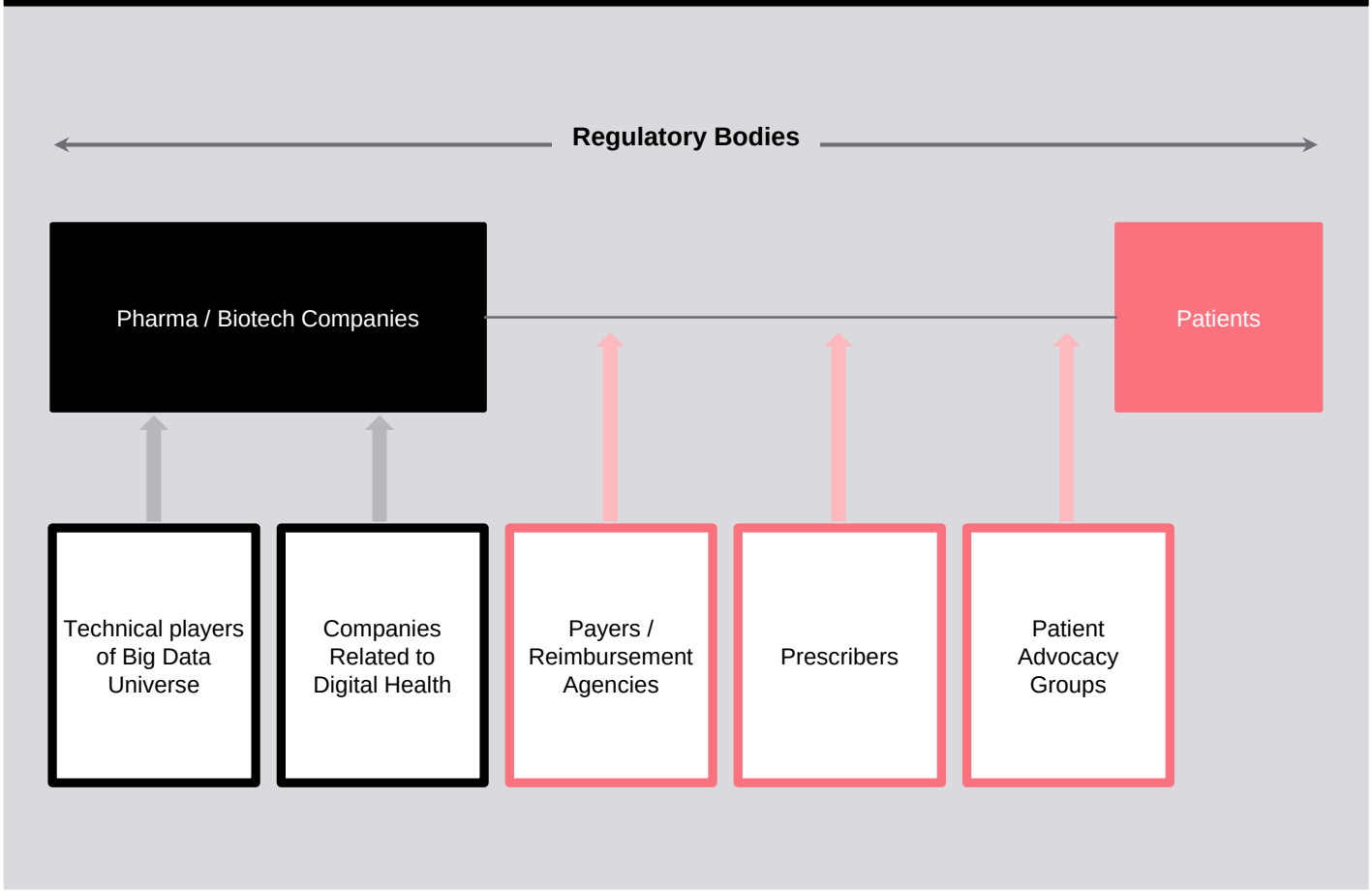
[15] Personalized Medicine in Oncology. Personalized medicine at FDA: 2015 progress report. http://www.personalizedmedonc.com/publications/pmo/february-2016-vol-5-no-1/personalized-medicine-at-fda-2015-progress-report/

[16] PHARMA. Cancer medicines: Value in context. http://phrma-docs.phrma.org/sites/default/files/pdf/cancer_chart_pack.pdf

Approach of Various Stakeholders Towards Personalized Medicine in Oncology

It has been observed that conventional medicines provide treatment benefits to a limited number of patients. Most of the blockbuster drugs in the US has helped 5-20% patients, which defines imprecision in medicine. This situation is further supported by the fact that 30% of acute hospital admissions every year are due to the side-effects of cancer treatment. Thus, the need to decrease healthcare costs and adopt value-based reimbursement models has burdened regulatory bodies and payers. This has a negative impact on the healthcare industry. The pressure of costs/reimbursement models and evolving healthcare digitalization are transitioning healthcare from "one-size-fits-all" approach to patient-centric targeted therapies with good outcome.

EXHIBIT 7: Various Stakeholders in Personalized Medicine



Pharma/Biotech Industry

Low operating margins and the need to decrease Research & Development (R&D) costs are forcing pharmaceutical companies to change their existing business model of blockbuster drugs and consider strategies, such as personalized medicine to augment their areas of focus and open-up new revenue streams. However, personalized medicine requires support from industry players in terms of:

Investments in new systems and technologies through:

- Accelerating R&D focus on personalized medicines
- Deals like mergers/acquisitions/partnerships/licensing

Utilization of existing information and technologies to leverage:

- Additional approvals of existing targeted therapies for new cancer indications[11]

Focused approach towards personalized medicine indicates the increased commitment of the healthcare industry towards this area, and thus, more targeted cancer therapies are expected to emerge in the near future.

Regulatory Bodies/Payers

Regulatory bodies and payers alike acknowledge the benefits of personalized medicine and are emphasizing on cancer care by expanding their scope to preventive measures apart from diagnosis and treatment. This approach ensures a good future for personalized medicines. Regulatory bodies in different geographies have emphasized on the uptake and effectiveness of personalized medicines in cancer, owing to the social and economic burden. Regulatory bodies/payers are focused on:

- Technical aspects of personalized medicine in oncology
- Cost-benefit analysis of these targeted therapies

Some examples of the initiatives undertaken by regulatory bodies are mentioned below:

1. USFDA:

Investment

- The US government invested $215 million to launch the Precision Medicine Initiative in 2015, which aims to accelerate the progress toward personalized

medicine. Cancer is a major focus of the Precision Medicine Initiative in near-term goals, along with all other health issues.[17]

Amendments in guideline documents/policies

- In 2016, the USFDA responded to the increasing demand for regulatory clarity on precision medicine by issuing two draft guidance documents, which provide a flexible and streamlined approach to the oversight of tests that detect medically important differences in a person's genomic makeup.[18]
- In 2016, Congress passed the 21st Century Cures Act that encourages the FDA to modernize its current model for considering real-world evidence, patient experience, and molecular pathways in drug evaluation as they relate to clinical trial designs.[19]
- In 2017, the reauthorization of the Prescription Drug User Fee Act (PDUFA) provided revised provisions for the continued timely review of new drugs and biologic license applications, and addressed the expanded FDA efforts in regulatory science, drug development, drug safety, and information technology. PDUFA includes several provisions that offer clarity in areas, such as biomarker qualification, patient-focused drug development, and the use of innovative clinical trial designs, which are key for the regulatory success of targeted therapy.[20]

2. EMA:

Amendments in guideline documents/policies

- Acknowledging the need to use precision medicine in the right patient: The European Medicines Agency (EMA) guideline on anticancer drug evaluation recommends the development of biomarker diagnostic methods early in clinical development, and specifies that a diagnostic assay complying with the regulatory requirements is available at the time of licensure for targeted therapies.[3]

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[17] American Cancer Society. Personalized medicine: Redefining cancer and its treatment. https://www.cancer.org/latest-news/personalized-medicine-redefining-cancer-and-its-treatment.html

[18] FDA News Release, July 6, 2016. Draft guidances on next generation sequencing-based tests. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm509814.htm

[19] H.R.6 - 21st Century Cures Act. https://www.congress.gov/bill/114th-congress/house-bill/6

[20] FDA Medical Product User Fee Reauthorization: In Brief. https://www.everycrsreport.com/files/20170130_R44750_5a58ddb2492d54e09dd8a9351fa5826f651b6083.pdf

Challenges of Personalized Medicine in Oncology

Despite the promise of personalized medicine in cancer, various technical, developmental, organizational, ethical, legal, social, and economic challenges have to be considered to ensure the smooth integration of personalized medicine into the cancer care system. A few of the challenges have been described below: [1, 3, 5, 21, 22]

- Difficult targets
- Lack of standardized taxonomy based on genomics
- Lack of evidence-based clinical approach
- Heterogeneity in diagnostics methodology
- Development of resistance for targeted therapies

A. Technical challenges

- All types of cancer do not have personalized treatment options. Personalized medicines for some identified targets are difficult to develop owing to the target's structure and/or the way its function is regulated in the cell. One example is Ras, a signaling protein, which is mutated in as many as one-quarter of all cancers. Till date, no effective Ras signaling inhibitor has been developed with existing technologies.
- Currently, cancer taxonomy classification exists on phenotypic variations (histology or tissue of origin); however, updated taxonomy is required depending on somatic variations (genes involved, mutation status, or other biochemical features) for selecting an appropriate personalized medicine.
- A well-known drawback of genomics-driven cancer medicine is the risk of large-scale genomic data generation without an evidence-based clinical approach for data analysis and interpretation.
- Heterogeneity in diagnostics methodology giving false-positive or false-negative results could lead to selecting inappropriate personalized medicines in cancer care.
- Heterogeneity exists over the lifetime of cancer, with differing patterns of genetic changes that cause resistance to targeted therapies (resistance could be developed in two ways: the target itself changes over time through mutation and/or the tumor finds a new pathway to achieve tumor growth). For this reason, targeted therapies work best in combination with other chemotherapeutic agents.

B. Drug Development Challenges

- The first step in developing personalized medicine is to identify and validate a biomarker that could be targeted to treat cancer effectively. This research process is time-consuming and costly.
- After identifying the targetable biomarkers, incorporation of these findings in clinical practice becomes a lengthy process. As a few cancer patients may exist with given changes in targeted biomarker, the availability and accessibility to

- Costly and time-consuming biomarker validation
- Low availability of patients with complex and lengthy eligibility criteria for clinical trials

adequate tissue samples for reproducing and validating the research assays in the real world scenario may be challenging.

- Clinical trials of targeted therapy may be complex, time-consuming, and costly, owing to the fact that for molecular trials, patients with lengthy and complex eligibility criteria are required. A large number of patients need to be screened for trial eligibility.
- Other challenges in clinical trials of targeted therapies include lack of investigator interest and time, low patient awareness, regulatory burden, statistical approaches, and ethical considerations.

C. Organizational challenges

- Lack of harmonization among different stakeholders
- Need to transfer knowledge engineering tools to prescribers

- Some personalized medicines are only offered through a clinical trial and are not yet considered as standard treatment options.
- Delivering on the promise of personalized medicine needs a massive effort from payers, pharmaceutical companies, government agencies, and patient advocacy groups. All stakeholders should approach to precision medicine in a harmonized manner on a single platform for increased usage.
- The integration of genomic and clinical data to translate information as guidance for clinical decisions is a daunting task. However, it is simplified using artificial intelligence tools. This knowledge engineering needs to be transferred to prescribers for filling the research-healthcare gap.

D. Economic challenges

- Increased out-of-pocket expenditure for targeted therapy as compared to traditional drugs
- Dynamics in payers and regulators perspective on cost-benefit ratio of personalized medicine
- Lack of insurance coverage for companion diagnostics

- Personalized treatments are expensive as compared to conventional medicines. The overall cost-benefit ratio may favor targeted therapies when various components are considered, such as doctor visits, hospital admissions, QoL, treatment success rates, and five-year survival rate. However, out-of-pocket expenditure for personalized medicine is higher when compared with other conventional drugs. This economic burden might levy some hindrance to increased adoption of personalized medicine.
- Dynamics on value and definition of value metrics and cost-effectiveness in personalized cancer medicine from payers and regulators perspective are not uniform.
- Insurance or reimbursement plans do not cover the costs of the accompanying companion diagnostics, which is costly and time-consuming.
- As pricing exceeds the ‘cost-effectiveness thresholds’ used to approve new treatments, access to newer personalized therapies is often restricted.

E. Ethical challenges

- Complete genome sequencing of an individual patient and increased utility of genome sequencing raises ethical concerns beyond cancer care, which include:
  - Privacy
  - Data Protection
  - Discrimination

Upcoming Fields of Personalized Medicine

Research & development activities have indicated that personalized medicine is transforming the current focus of targeted therapies to concepts, such as epigenetics, gene therapy, and others. If approved, these therapies will immensely benefit cancer patients.

Proteomics: Researchers are working on standardizing the existing proteomic technologies and developing new approaches to make it more effective by the robust identification of protein biomarkers.[23] Proteomic biomarkers can indicate the presence or absence of a disease in its earliest stage apart from the risk prediction of genetic analysis.

Epigenetics: There is an increasing understanding of genomic changes that alter the structure and chemistry of DNA without altering its sequence. These changes known as ‘epigenetic’ changes can influence the behavior of the genes and may turn them “on” or “off.” Epigenetic factors have been linked to various chronic diseases, and cancer is one among them. The National Institute of Health (NIH) has developed the ‘Roadmap Epigenomics Project’ to study the role of epigenetics in human diseases.[24]

RNA Sequencing Analysis: Advances in personalized medicine are not confined to DNA. Analyzing mRNA transcripts can, in certain instances, detect gene expressions that cannot be done with DNA analysis. RNA sequencing analyses indicate future development possibilities of personalized medicine in cancer.[25, 26]

CRISPR/Cas9: Clustered Regularly Interspaced Short Palindromic Repeat/Cas9 RNA-based Nucleases (CRISPR/Cas9) is a gene editing tool that allows targeted genome editing for correction of mutations. The CRISPR technology has allowed the development of efficient and reliable ways to make precise changes to the genomes of living cells, which benefits a wide array of diseases from congenital blindness to cancer.[27]

Gene Therapy: Medical researchers are developing ways to introduce a healthy copy of a gene by replacing a mutated gene through 'Gene therapy.' The first gene therapy that received regulatory approval (from EMA in 2012) was alipogene tiparvovec (Glybera) for a rare form of familial dyslipidemia.[28] Several other gene therapies are under phase III trials and have shown remarkable benefits as well as an excellent safety record.

[21] NIH. Targeted cancer therapies. https://www.cancer.gov/about-cancer/treatment/types/targeted-therapies/targeted-therapies-fact-sheet

[22] Medpace. Personalized medicine in oncology and the implication for clinical development. https://www.medpace.com/personalized-medicine-in-oncology/

[23] SomaLogic. http://www.somalogic.com/diagnostics/

[24] NIH. Roadmap epigenomics project. http://www.roadmapepigenomics.org/

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[28] uniQure. Gene therapy: Glybera (alipogene tiparvovec) http://www.uniqure.com/gene-therapy/glybera.php

Conclusion

Precision medicine's targeted, customized approach to healthcare has a widespread impact on genomics and medical devices, and as a result, it is creating new business models for enterprises across the healthcare sector.

New technologies are enabling precision medicine to offer critical benefits to the market. These include the ability to improve patient outcomes on chronic diseases, an increase in the product pipeline and speed-to-market for life sciences companies, and the ability to quickly eliminate high-risk development paths.

Personalized medicine in cancer is evolving exponentially as compared to other indications and is set to be armed with more targeted therapies in the near future. Existing medical, scientific, regulatory, and financial barriers are key challenges that need to be overcome.

Personalized medicine has shown great promise in cancer care; however, it needs support from all stakeholders. It is essential that the healthcare industry, regulatory bodies, payers, and oncologists should be on the same platform to increase the usage and incorporation of personalized medicine in clinical practice.

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