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Amplifying Impact and Value Through A Strategic Global Approach

Himabindu Gaddipati M.D, EMTM
Mandar Kulkarni, Ph.D
Archit Sahai

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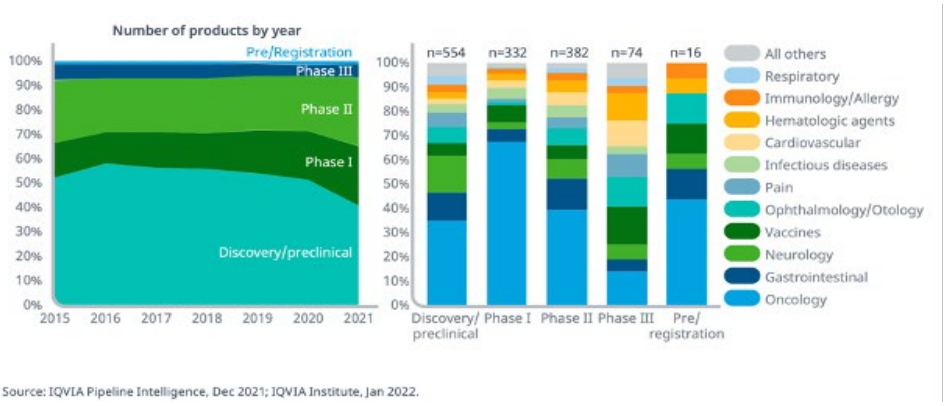
EMCIF Market Potential Report

Promises and challenges for biopharma and diagnostic companies in the oncology market

The global cancer burden is estimated to have risen to 19.3 million new cases and was responsible for nearly 10 million deaths in 2020 as per the World Health Organization[1,18]. Oncology market is growing at an alarming pace and is clearly the leading therapy area for innovation for biopharma and diagnostic companies- in terms of size of the pipeline of therapies in clinical development, level of spending on oncology medicines, number of novel active substances being launched and growth in R&D activity.

More than 40% of next-generation biotherapeutics in development in 2021 were for oncology and in early stages[2]

Exhibit: Next-generation biotherapeutic products pipeline by phase and therapeutic drug class [2]

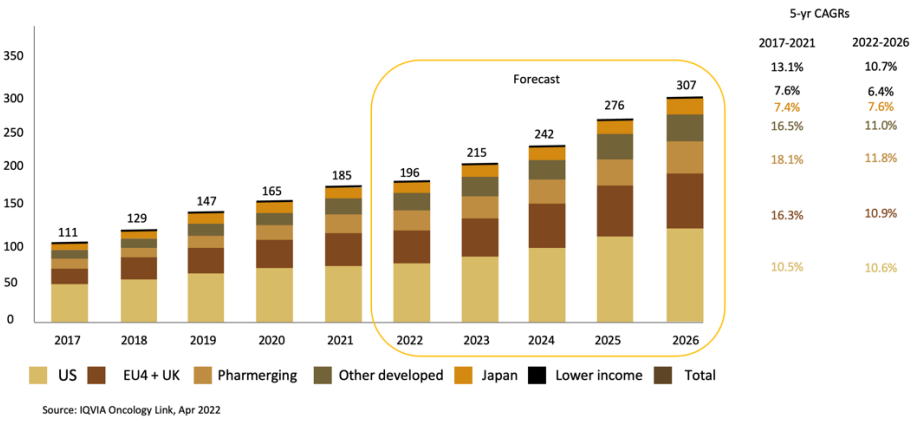


Source: IQVIA Pipeline Intelligence, Dec 2021; IQVIA Institute, Jan 2022.

- **Rise in spending on oncology medicines:**

Cancer medicine spending rose to $185Bn Globally in 2021 and is expected to reach more than $ 300 Bn by 2026[2]

Exhibit: Oncology Spending by region, US $Bn [2]



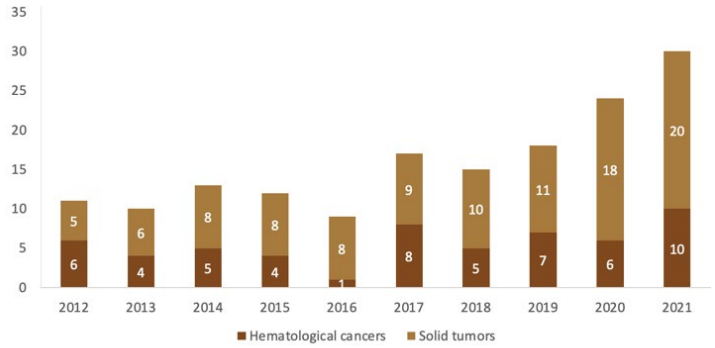
Source: IQVIA Oncology Link, Apr 2022

New product launches and brand volume is driving significant growth in major markets such as the U.S. and major European countries. Recently, to some extent this growth is offset by losses of exclusivity and impact of biosimilars, which is expected to be amplified in the near future.
At the same time, China's oncology spending now exceeds the rest of the emerging countries and is driven by expanded access to new therapies.[2]

- **Accelerated innovation in oncology:**

A record 30 oncology novel active substances (NASs) were launched globally in 2021, with 159 total since 2012 [2]

Exhibit: Global oncology launches of novel active substances (NAS), 2012-2021 [2]



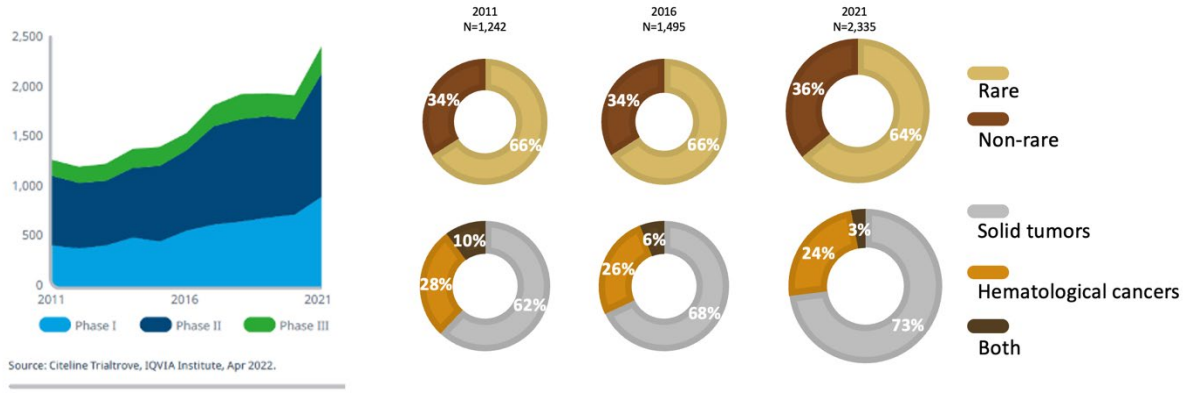
Source: IQVIA Institute, Apr 2022.

The number of NASs for oncology has grown significantly from an average of 11 each year between 2012-2016 to an average of 21 new oncology launches between 2017-2021.[2]
Oncology drugs are increasingly receiving accelerated approvals and orphan or breakthrough designations, and a small but increasing number are proceeding from patent filing to product launch in less than 5 years. [2]

- **Growth in R&D activity:**

Oncology trials starts reached historically high levels in 2021,
Up 56% from 2016 and mostly focused on rare cancer indications[3]

Exhibit: Oncology clinical trial starts by year, 2011-2021[3]



Generally, most cancer research focuses on metastatic or advanced cancers, but early cancer trials and vaccines have more than doubled in 10 years. Emerging biopharma companies (with less than $500 million in annual sales and less than $200 million per year in R&D spending[2]) were responsible for 68% of the oncology pipeline in 2021, up from 45% a decade ago.[3]

Despite this significant growth in oncology market, the model for developing new cancer therapeutics is becoming unaffordable with rising cost and time for bringing new cancer therapeutics and solutions to market- **$1-$2.8 billion over a decade with inherent inefficiency and redundancy-** impacting the affordability and accessibility of cancer innovations especially for people in low- and middle-income countries (LMICs).[4]

At the same time, biopharma companies are facing increased risk of revenue erosion as **the product life cycles are reduced by almost fivefold since the 1990s because of faster innovation cycles, more competition, and more reliance on generics and biosimilars by the payers**.[5]

Also, there has been a shift of focus away from high-incidence tumors to rare tumors, which has led to the target populations becoming narrower and requires a more sophisticated approach to patient stratification . Therefore, the primary challenge faced by the life sciences companies to develop new treatments for rare cancers is a smaller consumer population. Most of these rare cancer treatments will have annual peak sales of less than $250 million.[6]

A majority of rare-cancer therapies will have peak sales of less than $250 million[6]

Exhibit: Rare-cancer assets launched or planned to launch in 2018-23 by global peak sales, %

[1] Not risk adjusted; n=151.
Source: EvaluatePharma 2020, Evaluate Ltd.

McKinsey & Company

This also leads to an increase in trial complexities for rare cancers. **Such delays can cost between $600,000 for niche drugs to $8 million for blockbuster drugs with each day the drug is not clinically approved and launched in the market**. For instance, based on a study, the value of one year earlier access to trastuzumab for breast cancer patients would be $8 billion in additional patient benefit, and that to rituximab for non-Hodgkin's lymphoma, $310 million.[7]

What are the biggest innovation and investment opportunities in oncology?

Innovation in oncology has seen a remarkable pace over the past decade because of the following 3 key trends that are shaping oncology market in a big way- immunotherapy, next-generation multi-omics including liquid biopsy and artificial intelligence technologies.

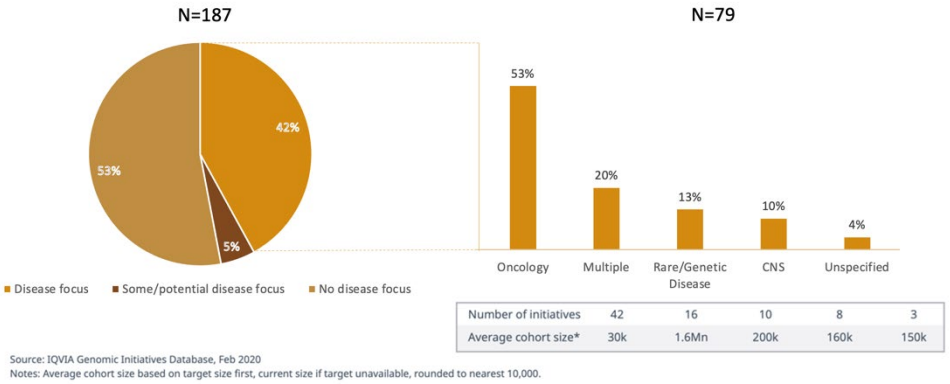
The healthcare industry is shifting from 'one-size fits all approach' to more personalised care and precision therapies as scientific advances are resulting in tumors becoming increasingly well characterized. This fundamental shift in healthcare model is driving most of the innovation in oncology.

A. **Exponential growth in genomics** (genomics, proteomics, metabolomics, transcriptomics, etc.) is transforming the diagnosis and treatment of cancer. With next generation sequencing becoming more and more cost efficient and accurate, precision medicine is not only helping in better treatment selection at individual level but also leading to explosion of data at population level and creating a big market for big data and analytics in healthcare as well.

   The integrative multi-omics approach is also helping the biotech and pharma researchers to accelerate the drug discovery and development process for targeted therapies that is rapidly improving the clinical value and large-scale adoption of these techniques in routine clinical practice as well.
   For instance, rapid advances in liquid biopsy research, a non-invasive way of molecular profiling, is potentially impacting the outcomes at every step of a patient's journey from early diagnosis, screening, treatment selection to post-treatment monitoring.

   According to Emergen Research, the global tumor genomics market size was USD 21.42 billion in 2020 and is expected to reach USD 56.54 billion in 2028 and register a revenue CAGR of 12.8% during the forecast period, 2021-2028.[8]

Exhibit: Number of Genomic Initiatives by Disease Area Focus[16]



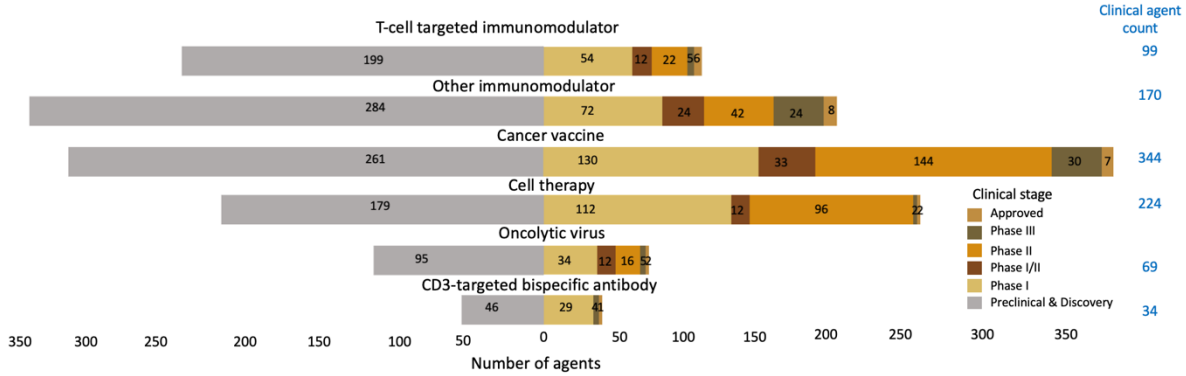
Number of initiatives	42	16	10	8	3
Average cohort size*	30k	1.6Mn	200k	160k	150k

Source: IQVIA Genomic Initiatives Database, Feb 2020
Notes: Average cohort size based on target size first, current size if target unavailable, rounded to nearest 10,000.

B. Expanding immuno-oncology market-

Immuno-oncology is the fastest growing segment within the oncology space. The global immuno-oncology drugs market size is expected to grow from $ 60.32 billion in 2021 to $ 120.37 billion in 2026 at a CAGR of 14.3%.[9] Companies have increased their investment in immuno-oncology combination studies, with more than 200 mechanisms now being investigated as PD-(L)1 or CTLA-4 combination partners and immuno-oncology assets are estimated to represent approximately half of the top-ten pharma company pipelines. [10]

Exhibit: The overview of 2004 immuno-oncology (IO) agents. Six classes of IO agents are identified on the basis of different mechanisms of actions.[17]



Source: Annals of Oncology, January 2018

Massive growth in immuno-oncology drugs - market monoclonal antibodies, immune checkpoint inhibitors, immune system modulators- is also driving growth in new technologies that are enabling development and efficient utilisation of these therapies such as-

- Immuno-oncology assays for R&D and 3D bio-printing platforms as theranostic tools
- CAR-T and CRISPR-Cas9 platforms
- Personalised cancer vaccines, allogenic cell therapies and emergence of bi-specifics as a competitor to CAR-T therapies.

C. AI/ML Technologies

AI applications in healthcare are gaining traction as integration of AI/ML in cancer care is improving accuracy and speed of diagnosis, aiding clinical decision-making and leading to better health outcomes. For example, it has already produced results in radiology, where FDA approved the first AI-based software to process images rapidly and assist radiologists in detecting breast cancer in screening mammograms.

AI-guided clinical care has the potential to play an important role in reducing health disparities, particularly in low-resource settings.

Key applications of AI in oncology are seen in:

- Improving Cancer Screening and Diagnosis
- Aiding the Genomic Characterization of Tumors
- Accelerating Drug Discovery
- Improving Cancer Surveillance

The NCI has supported several projects in this area and According to a study by Fatpos Global, the use of artificial intelligence in the cancer market is expected to pass USD $ 5.3 bn by 2030 and have a CAGR of 34.4% 2020 - 2030. The report also suggests that the market will grow, mainly due to the rise in the inflow of patient health-related digital data.[11]

What is the untapped latent potential for innovation in emerging nations?

With 60% of the total population, Asia is emerging as the largest opportunity for the healthcare industry. At present, Asia accounts for 30% of all global pharmaceutical spending and has seen a massive growth of around 40% in cancer treatment market from $107 billion spent in 2015 to roughly $150 billion spent in 2020, driven by significant rise in cancer patient base in countries such as India and China.[12]

Currently there's a huge gap in access to cancer care in low- and middle-income countries (LMICs) as they have merely 5% share of global resources for fighting cancer even though most of the increase in the global cancer burden in the next 50 years will come from LMICs and currently 70% of deaths from cancer occur in these countries. [13,14]

Most companies and health systems struggle to curb these rising costs because traditionally almost all anti-cancer therapies are being developed in High income Countries (HICs) leading to huge disparities in pricing and accessibility of such treatment options for LMICs. A World Health Organization technical report showed that these countries had considerably lower availability of anticancer medicines, or availability only with higher out-of-pocket patient payments, especially for higher-cost medicines.[14] Given the exponential costs of some of these drugs, cost/benefit ratio becomes an extremely important factor to consider for patients suffering from cancer in LMICs.

Cancer drug development is a resource-intensive process and one of the major reasons for the high development cost is that even research is highly skewed toward HICs. For instance, of all phase 3 trials of anti-cancer therapies conducted worldwide between 2014 and 2017, only 8% were initiated and conducted in LMICs.[14] Moreover, factors such as scarcity of reliable data and registries, lack of research infrastructure, and lack of innovative funding models make it difficult for the innovators to carry out R&D in LMICs, leading to suboptimal pathways for enabling access to cutting-edge cancer solutions.

A country like India is a promising destination to become a global hub for innovation in oncology as it is called the pharmacy of the world and ranks third worldwide for pharmaceutical production by volume and exports pharmaceuticals to more than 200 countries. However, ever-changing regulatory framework and intellectual property rights policies has kept big companies on the fence to enter the Indian market for R&D and clinical

trials. Reforms such as The New Drugs and Clinical Trial Rules, 2019 ("CT Rules") are transforming the clinical trials ecosystem in India by making the system of clinical trial regulations more precise and predictable for all stakeholders.

Currently, **India accounts for 18% of the world's population but is home to just 1.4% of the global clinical trials**. The Indian clinical trial market size is expected to grow at an unprecedented rate of 8.2% from 2022 to 2030.[15]

Infrastructure in India with a large medical community, IT expertise, diverse pool of patients, high cancer burden, cost effectiveness and pro-innovation policy trends provide the necessary ingredients to attract global life sciences companies to see India as the key destination for innovation.

However, it takes an entire ecosystem to support complex innovation in the space of oncology. Meaning, we need an organisation that can act as a linchpin by integrating various value chain players and can offer a platform to innovators that gives them easy access to consolidated research facilities, industry ready workforce, support in navigating through the complexities of IP and regulatory policies, collaboration with academic medical centres for clinical research and with other start-up companies that offer complementary solutions and skill sets.

Building such an ecosystem and increasing participation from LMICs to globalize early development of oncology innovations can be a game-changer for both LMICs and HICs, helping innovators to reshape the current model of cancer treatment by:

- Accelerating the trial recruitment process because of access to larger treatment naïve population with more advanced disease.

- Expanding availability of promising products in LMICs with growing market share early on in a product's life cycle by avoiding the delays in new launches (market & regulatory approvals).

Hence, improving the access of otherwise expensive therapies to a wider population at a relatively lower cost because of lower cost of development while boosting revenues and profits for life sciences companies.

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