



THESIS PRESENTATION

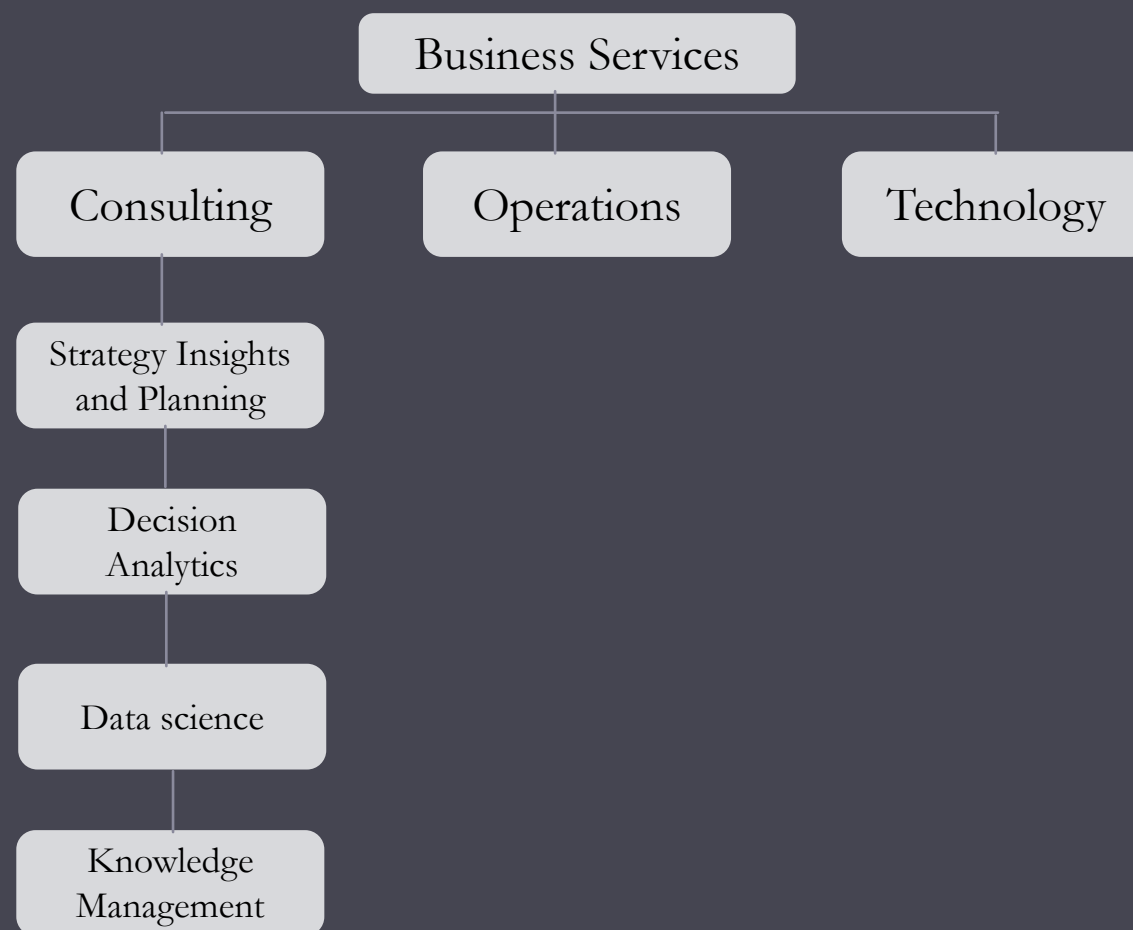
Market Assessment Study of Precision Medicine in Oncology (in USA)

Neha Sarda (0785)
ZS Associates

Guided by :
Dr Seema Mehta

ABOUT THE ORGANIZATION

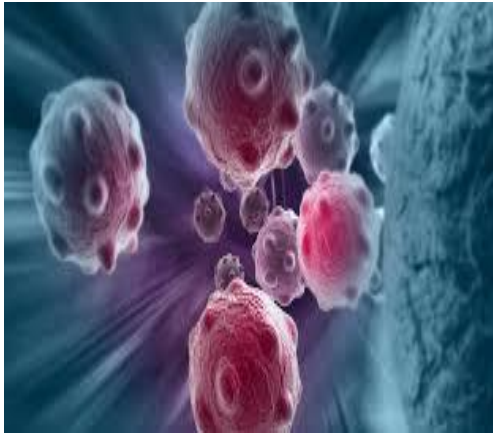
- ❑ Established by founders Zotners and Sinha in 1983 as a professional firm that leverages technology, analytics and expertise to provide solutions
- ❑ More than 6000 professionals serving in 23 offices across the globe
- ❑ Provides clients vast range of marketing and sales-related services in the industry, from customer insights, product development, sales and marketing strategies to sales compensation planning and administration planning



Market Assessment Study of Precision Medicine in Oncology (in USA)

- **OBJECTIVE:** To investigate the Precision Medicine (in oncology) and Companion Diagnostics market w.r.t it's market size in US and assess its scope in other therapeutic areas.
- **MATERIAL AND METHODS:**
 - **STUDY DESIGN:** Observational
 - **SETTING:** ZS Associates, Gurgaon
 - **DURATION OF STUDY:** 3 Months
 - **DATA COLLECTION PROCEDURE:** Data was collected through secondary resources using various combinations of relevant strings and keywords (past ten years data/sources have been considered)
 - **DATA ANALYSIS TOOL:** Following data collection tools were used to derive key information using relevant keywords:
 - Research papers
 - Reports
 - Articles
 - Journal
 - Internet
 - Other databases

CANCER MARKET TRENDS



Exponential increase in cancer burden

From 18 million cases in 2018 to 29 million in 2040



Changing market shape

- Increase in competition among biopharma companies
- Increasing number of approvals
- Boom of biosimilars
- Increasing focus of value amongst payers and providers
- Digitalization in healthcare



Precision Medicine – New face of treatment

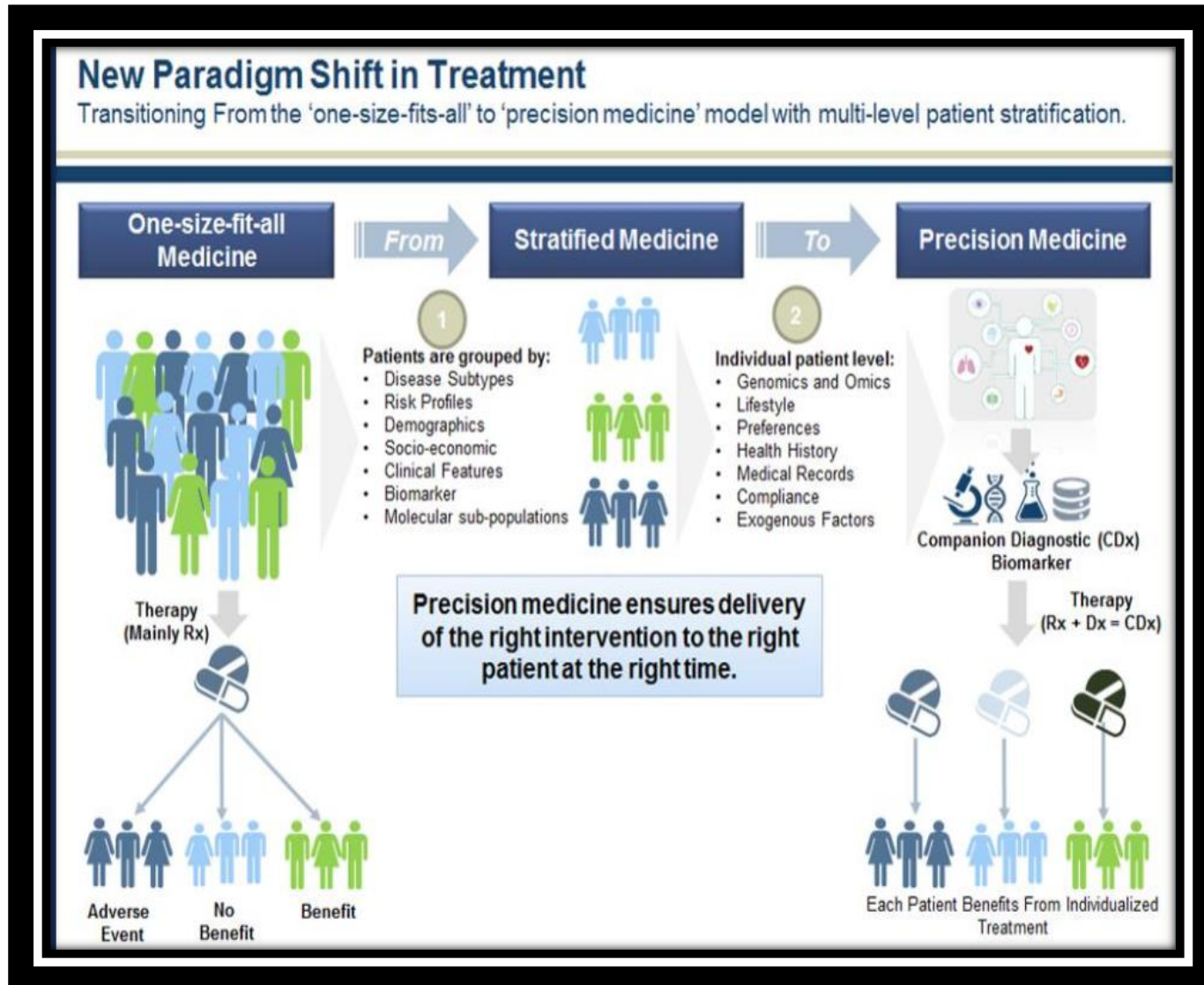
As behaviour of cancer differs from person to person, Personalized healthcare gives the tailor made approach

PRECISION MEDICINE

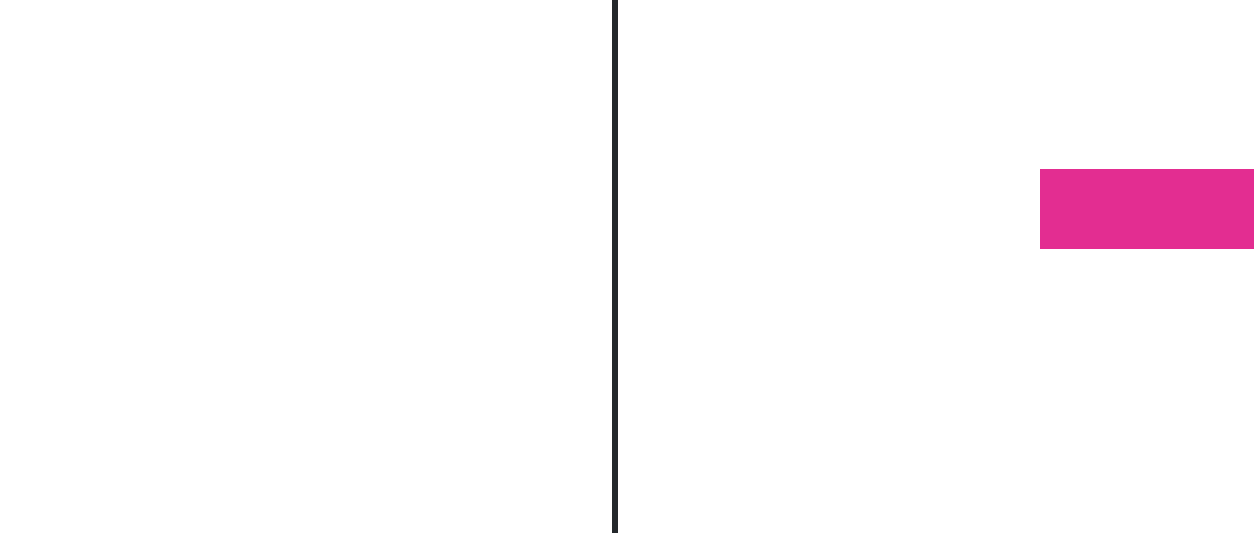
NEW FACE OF TREATMENT FOR CANCER



PRECISION MEDICINE



- **Precision Health by Lyold Minor (Stanford Medicine)** - Preventing the inception of disease by promoting healthy lifestyle and importance of wellness further having a meaningful impact on reducing the healthcare costs
- **Foundation of Precision Medicine –**
 - ✓ Robust data infrastructure
 - ✓ Integration between data sources → electronic health records and their outcomes
 - ✓ Research databases and biobanks



PRECISION MEDICINE IN ONCOLOGY

- Recent advancements in technology have shown that there is tremendous heterogeneity in cancer
- US National research council introduced the Precision medicine concept first in 2011, which had an aim of providing the customized treatments specifically for a patient sub-group on the basis of their genomics study
- The concept of PM in oncology further gained importance due to launch of **PM initiative in US in 2015, which increased the pace of the development of biomarker-driven therapeutic strategies**

There are four main types of biomarkers:

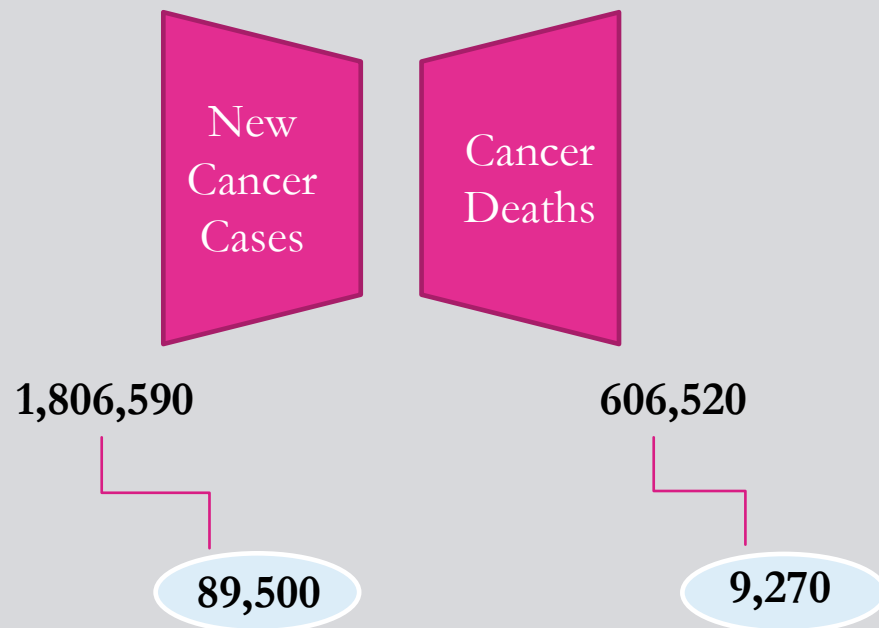
- ✓ pre-disposition (indicating the likelihood of developing the disease)
- ✓ diagnostic (used to confirm the patient has a particular cancer)
- ✓ predictive (determining which cohort of patients may benefit from a particular drug therapy) and
- ✓ prognostic (suggesting how the cancer may develop in the individual)



PRECISION MEDICINE IN US: MARKET SCENARIO

- US estimated mid year population - 331,002,651

According to American cancer society estimates for year 2020 :



Cases in adolescents and young adults aged 15 to 39 years

Governments around the globe are building large genomic repositories and biobanks to push forward the precision medicine approach - **This also led to launch of the Precision Medicine Initiative by Former US President Barack Obama**

Precision Medicine Initiative

Short term goals

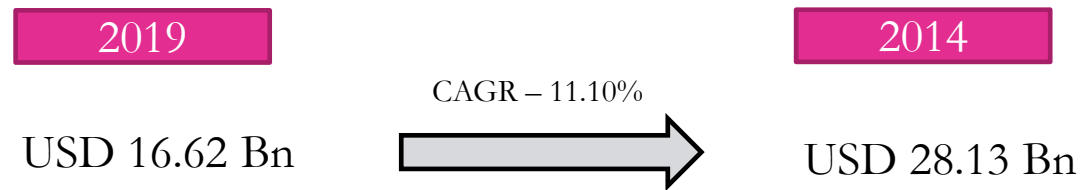
To bring more precision medicine treatments in cancers

Long term goals

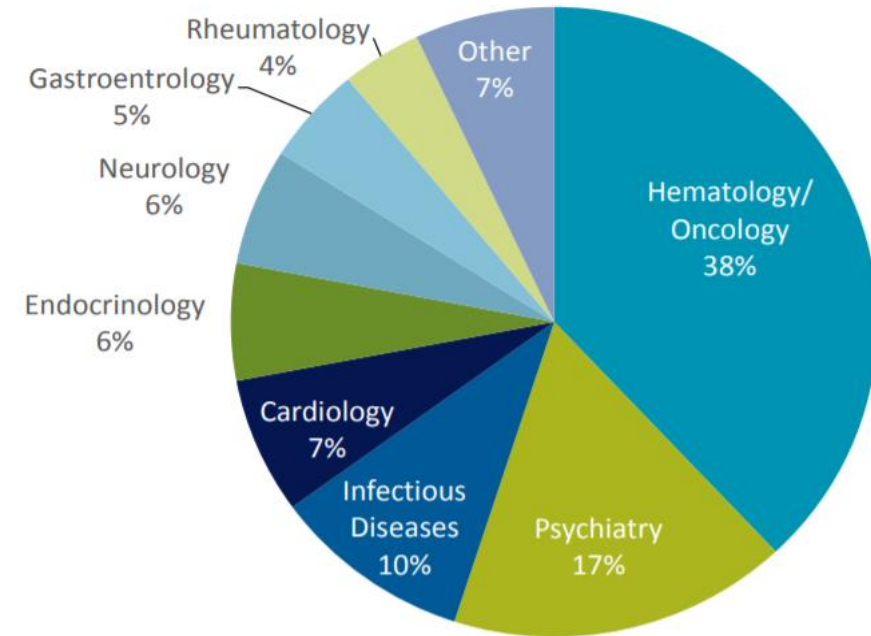
To expand the approach of precision medicine in other therapeutic areas beyond oncology

MARKET SIZE

- Precision Medicine Market in 2019 - **USD 57 billion globally**
 - Estimated to grow over **11% CAGR** between 2020 and 2026
- North America Precision Medicine market –



- North America is the biggest market in terms of share across the globe



Precision Medicine Market Share by therapeutic area

Prominent Companies leading in North America

Pfizer, Roche, Covance, Novartis, Qiagen, Biocrates Lifesciences, Teva pharmaceuticals, Nanostring technologies, Laboratory corporation of America holdings, Tepnel pharma services, Intomics, Ferrer InCode, Silicon Biosystems, Eagle genomics, Medtronic, and Quest diagnostics

GROWTH DRIVERS

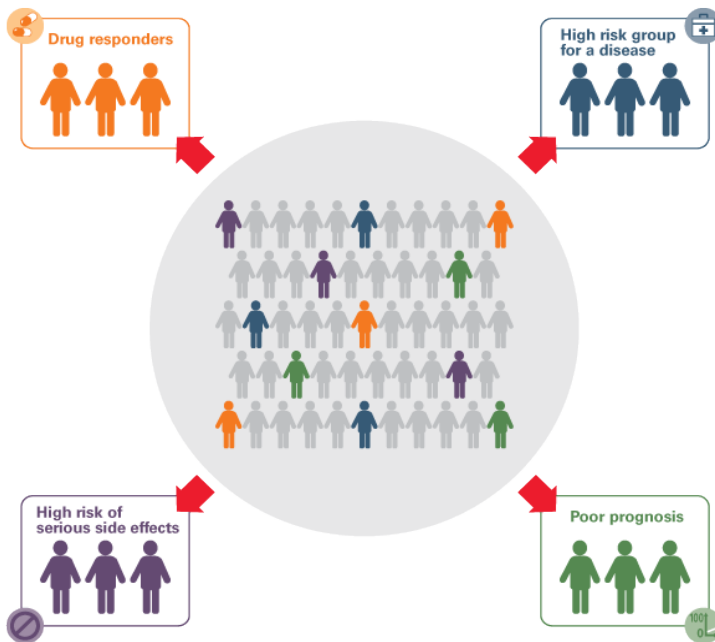
TACKLING TUMORS: Percentage of patients whose tumors are driven by certain genetic mutations that could be targets for specific drugs, by types of cancer.



Percentage of patients with cancer whose treatments could be personalized with specific drugs

- Rising cancer prevalence
- Higher acceptance rate amongst people
- Patient affordability
- The improved understanding of cancers
- Discovery of new therapeutic targets
- Wider range of opportunities for market growth

COMPANION DIAGNOSTICS



According to FDA, “a Companion Diagnostic is an in vitro diagnostic or an imaging tool that provides information that is essential for the safe and effective use of a corresponding therapeutic product.”

Besides FDA, health Canada and EMA had also mandated the biomarker testing prior to prescribing any of the drug. Since the use of companion diagnostics/therapeutics is growing, FDA has also started to publish the list of genomic biomarkers that are considered valid for drug approval

This has led to the need of regulatory path for the use of companion diagnostics in precision medicine - FDA released the first In Vitro Companion Diagnostics Devices Guidelines which states the methods of conducting reviews of a drug along with its companion diagnostic

MARKET SIZE (1/2)

- The global companion diagnostics market is estimated to be worth **USD 7.3 billion by 2024 from USD 3.5 billion in 2019, at 15.7% CAGR**
- The major drivers of the growing companion diagnostics industry are the :
 - ✓ **advantages of companion diagnostics** along with the rising importance of precision medicine,
 - ✓ the increasing number of cancer cases across the globe and so the growing need for targeted therapy
- **Pharmaceutical & biopharmaceutical companies are the ones holding the largest share of the CDx market in 2019**
 - owing to the extensive use of these tests because of the growth of drug market as well as companion diagnostics biomarkers

Advantages of Companion Diagnostics:

- ❑ Ability to identify most beneficial patient for the treatment
- ❑ Highlights side effects of the treatment
- ❑ Monitors response rate of the person towards certain treatment
- ❑ Make the clinical trials more informative and efficient
- ❑ Majorly helps in giving the personalized treatment to the cancer patients

MARKET SIZE (2/2)

Differentiating the CDx market by:

DISEASE INDICATION

- **Lung cancer –**

Projected to grow at more than **18.5% CAGR up to 2025** due to the **growing number of cancers across the globe**

- **Skin cancer –**

Which accounted for over **13%** of overall CDx market revenue in 2018; market is likely to increase owing to **increasing adverse reactions by cosmetics and damage because of harmful sun rays**, which will surge the demand for CDx tests

REGION

- **North America –**

Estimated to **grow more than 18% CAGR through 2025** **owing to the increasing number of cases of chronic diseases and the aging population**

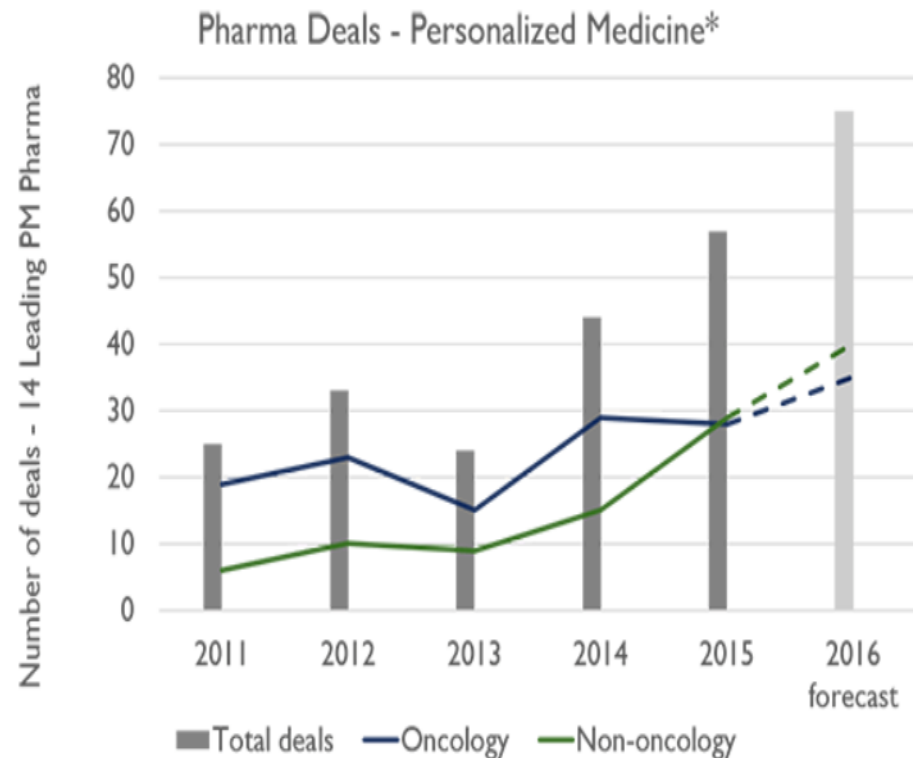
- **Asia Pacific –**

Will see up to **20.5% growth up to 2025** as there are **various government initiatives supporting the approach plus growing patient pool** are the acting boosters for the APAC market

Prominent Companies in Global Market

F. Hoffmann-La Roche AG (Switzerland), Agilent Technologies, Inc. (US), QIAGEN N.V. (Germany), Abbott Laboratories, Inc. (US), Almac Group (UK), Danaher Corporation (US), Illumina, Inc. (US), bioMérieux SA (France), Myriad Genetics, Inc., (US), Sysmex Corporation (Japan), Thermo Fisher Scientific Inc. (US), Abnova Corporation (Taiwan), and Guardant Health, Inc". (US)

PRECISION MEDICINE BEYOND ONCOLOGY



Deals among leading pharma companies for biomarker discovery and companion/ complementary diagnostic development

- There are targeted biomarker therapies for the diseases like:
 - ✓ Diabetes
 - ✓ Inflammatory diseases (such as asthma and rheumatoid arthritis)
 - ✓ Neurological diseases (such as Alzheimer's, Parkinson's and multiple sclerosis)

However, still oncology remains the dominating area.

- In cardiology, precision medicine has advanced to measure the gene variants which increases the risk of diseases

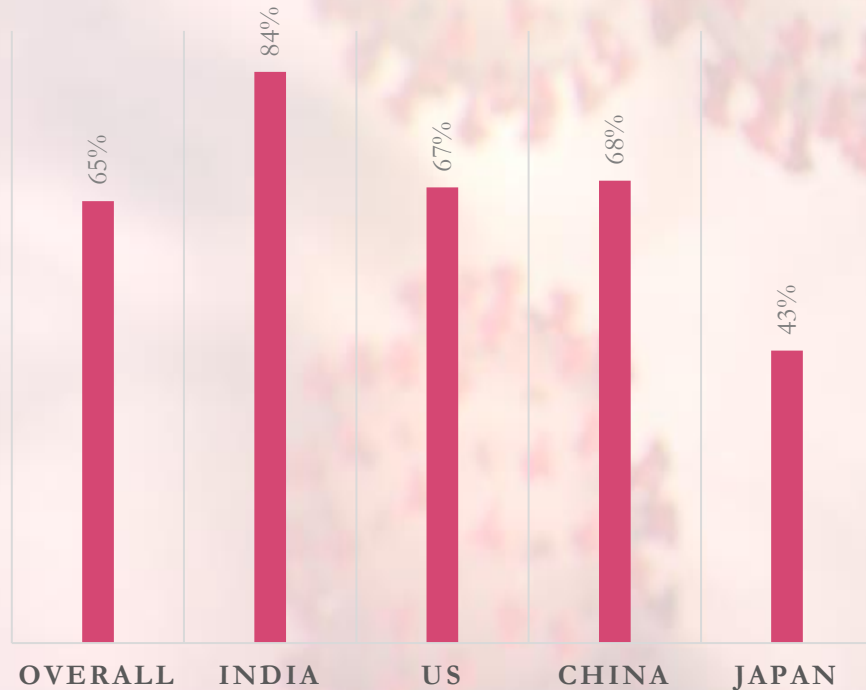
Eg. Roche is developing the CDx for the appropriate selection of the treatment for disease like acute coronary syndrome.

- In Neurology, companies are developing a drug against the amyloid deposits in brain tissue, hypothesized to cause neurodegeneration in Alzheimer's

Eg. Two drugs in late stage phase III of clinical trials for the same are- Biogen's aducanumab and Roche's crenezumab

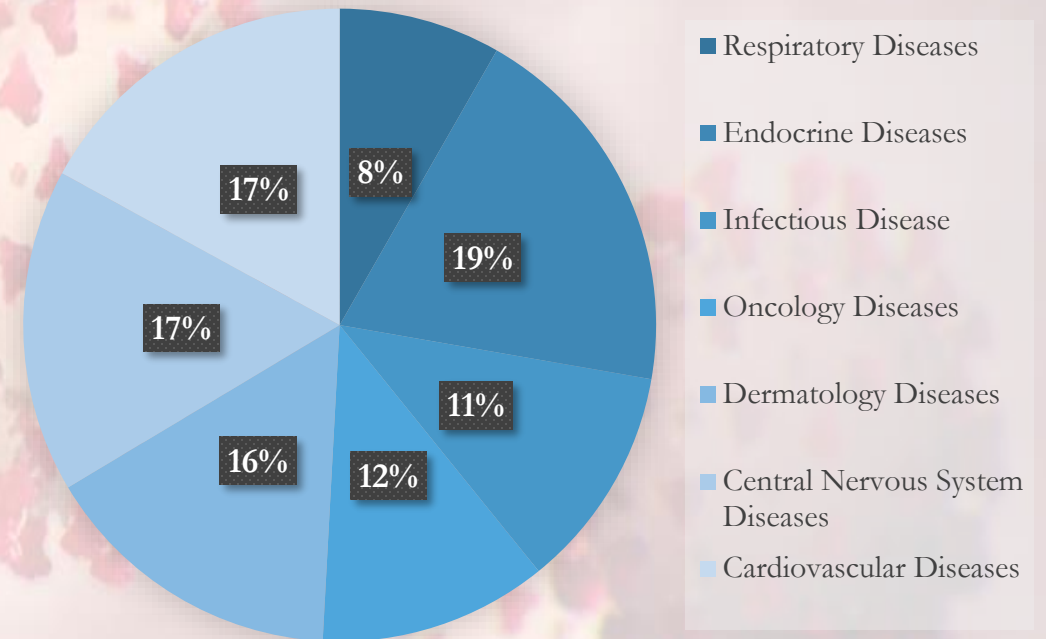
IMPACT OF COVID-19

- According to Medidata, who has been conducting analyses of a number of clinical trials enrollment data (approx. 4600) and have studied 182,000 study sites worldwide, a significant reduction has been observed recently in participation of clinical trials activity:



Percent decrease in the participation in clinical trials across different countries

- The impact of COVID-19 is also not uniform across the various therapeutic areas. Enrollment in studies have decreased in following manner:



Reduction in enrollment across various therapeutic diseases

- Targeted Strategies For Most-At Risk Population:

The Pioneers are now discussing the value of Diagnostic Tools which can help in developing strategies without subjecting the whole population.

- Opening New Opportunities for Personalized Medicine:

The variable effects of this Covid-19 amongst the population, reflects that the disease might have progressed due to some genetic characteristics.

- Targeted Treatments For Oncology Patients with better Response Rate:

Different targeted treatments are approved for different form of cancers from acute myeloid, non-small cell lung cancer, lymphoid leukemia to stage IV melanoma.

- Future Targeted Therapies for Covid-19:

PrecisionLife, AI Precision Medicine Company, is using the current platform to identify 13 high risk genes for COVID-19, and 59 repurposing drug candidates to sepsis.

THE ERA OF COVID-19 HAS LED THE SCIENCE TO MOVE FORTH WITH ADVANCED OPTIONS, TECHNOLOGIES AND APPRECIATE THE PRINCIPLES OF PRECISION MEDICINE



CONCLUSION

- Precision Medicine is set to change general wellbeing
 - Yet not many in the clinical field would not deny the fact we are not prepared at this point
 - Despite having such large number of therapies, matching the patients to right therapy is difficult.
- There are certain barriers mainly at the financial and operational side:
 - The cost associated with genomic testing and companion diagnostics is the biggest challenge for the schemes.
 - Lack of expertise is another challenge as many physicians find it difficult to interpret the results without any specialist which further increases the cost of clinics
- In clinical research and development, moving the drug pipeline forward also becomes a problem
 - cost of manufacturing cell and gene therapies and incorporating new processes into innovative trials is not easy
- Also, providing the safety and efficacy details for these therapies becomes an issue as the current regulations do not accommodate these innovations yet

A stylized illustration of a human figure composed of a DNA double helix and a complex network of colorful molecular structures, set against a light blue grid background. The figure's torso and limbs are formed by a dense, intricate web of various chemical structures, including rings, chains, and clusters in shades of red, yellow, green, blue, and purple. A prominent DNA double helix structure is visible, with one strand in a darker blue and the other in a lighter blue, both with vertical rungs representing base pairs. The background is a light blue grid with faint, larger-scale molecular patterns. The overall composition suggests a connection between genetics, molecular biology, and human health.

QUESTIONS?

Thankyou