

# Clinical Research Market: Global & India



Module 13 Topic 1

# Market Analysis – Global Clinical Trials 2018

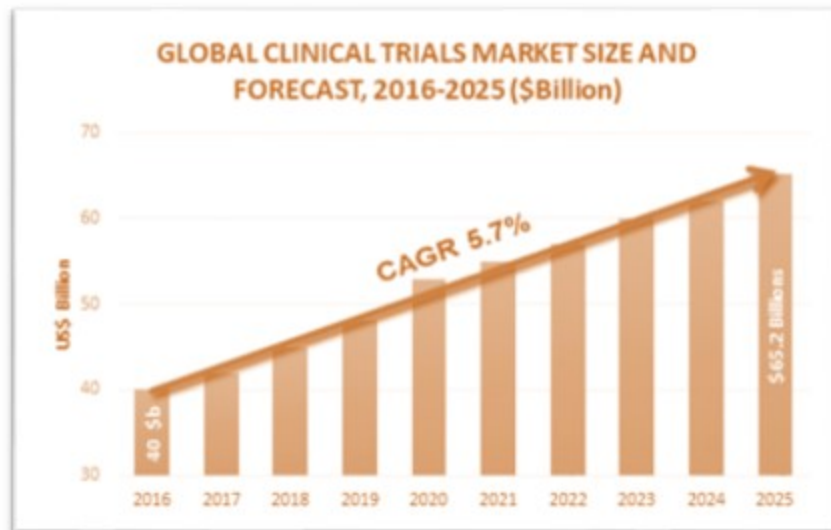
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- The Global Clinical Trials Market size was valued at USD 40.0 billion in 2016 and is expected to grow at a CAGR (Compound annual growth) of 5.7% over the forecast period and expected to reach USD 65.2 billion by 2025
- The growth in this market is primarily driven by factors such as globalization of clinical trials, development of new treatments, evolution in technology, and increasing demand for CROs to conduct clinical trials



# Market Analysis – Global Clinical Trials 2018

Growing prevalence of disease and incidence of new disease is expected to give further boost to the clinical trial market



# Market Analysis – Global Clinical Trials 2018

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- Globalization of clinical trials has led to increase in investment in new product development in emerging countries thereby, having a positive impact on overall market
- The availability of the vast array of services from drug discovery to post-marketing surveillance has further simplified the life for mid-size and small-scale pharmaceutical and biotechnological organizations by providing them the option to outsource what they think is beyond their core expertise



# Market Analysis – Global Clinical Trials 2018

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- Growing prevalence of disease and incidence of new disease is expected to give further boost to the clinical trial market
- Worldwide population has varied disease profile with emerging countries having the most diverse disease profile





# Market Analysis – Global Clinical Trials 2018

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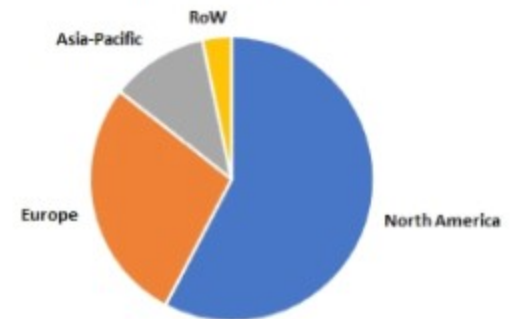
- This is expected to boost the clinical trial of new or rare disease which otherwise would not have found any sponsors
- More number of patients having a specific disease would act as a stimulus for biopharmaceutical companies to invest more in clinical trials for a disease segment



# Global Clinical Trials Market share by Region

The United States and Canada have the highest market share in the clinical trials market, followed by Europe where Germany leads the market followed by Poland and Western Europe

GLOBAL CLINICAL TRIALS MARKET SHARE BY REGION, 2025 (Value%)



# Global Clinical Trials Market share by Region

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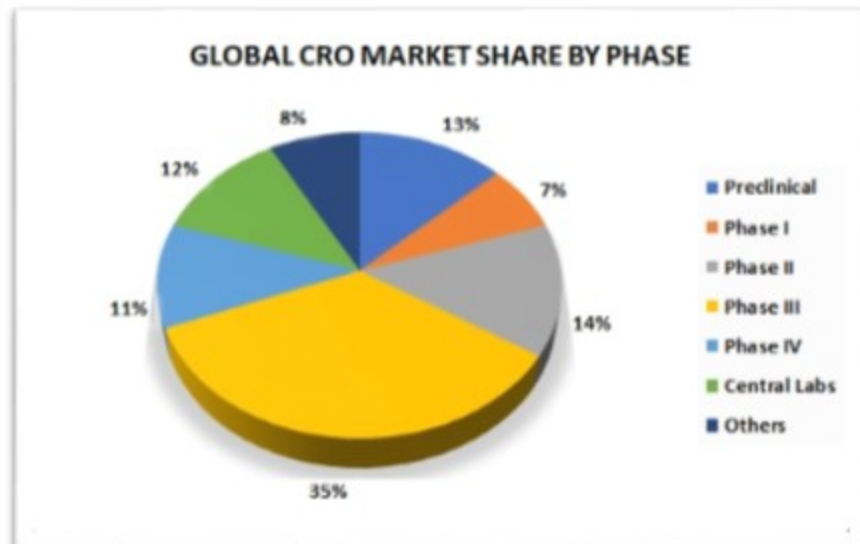
- Asia is one of the fastest growing markets
- Stimulating factors for growth of the market in Asia-Pacific countries are,
  - Increasing outsourcing of clinical trials,
  - Availability of large and diverse patient population,
  - Presence of less stringent regulatory guidelines as compared to developed nations,
  - Comparatively less cost of conducting clinical trials in Asia-Pacific countries are





# Growth trends of the Global CRO Market

- The value of the global CRO market in 2014 was estimated at about \$27 billion, and it reached to \$32.7 billion by 2017 with CAGR of 6.6 %.



# Growth trends of the Global CRO Market (contd)

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- A significant part of this market growth happened on the account of clinical trial phases II to IV, with their total share of the revenue by trial phase being about 60%



# Growth trends of the Global CRO Market (contd)

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- Medical research in Phase I accounts for as little as 7% of the generated revenue
- The share of central laboratory research makes 12%, and another 13% is earned by preclinical services



# Growth trends of the Global CRO Market

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- One of remarkable trends in the growth of this industry is the entry of several midsize companies into the top 20 league of multibillion revenue giants.
- The other notable trend refers to industry leaders' ownership status, with more of top CROs going public.
- This trend indicates industry's healthy growth and inspires mid-size companies for further development.



# Growth trends of the Global CRO Market (contd)

Fig. 1 Estimated growth returns

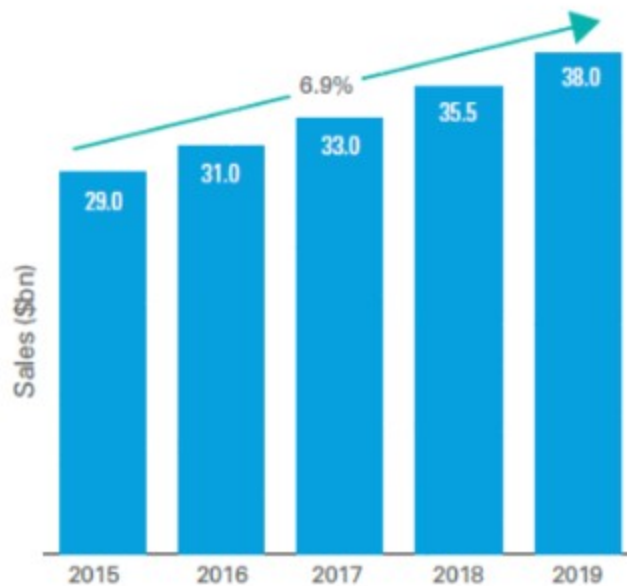
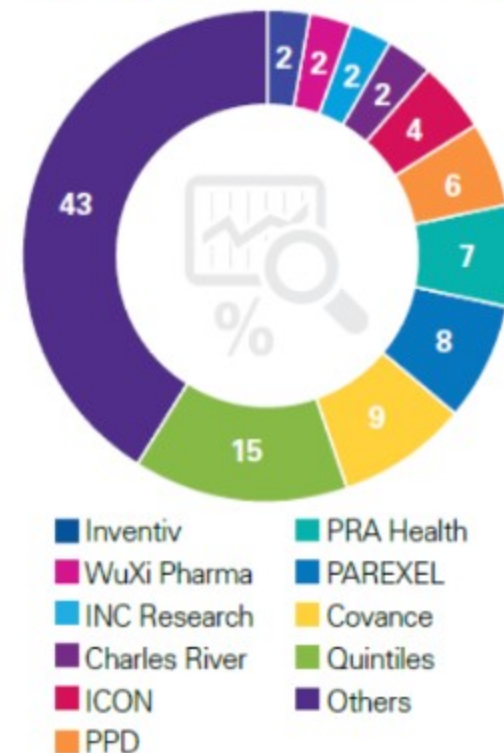
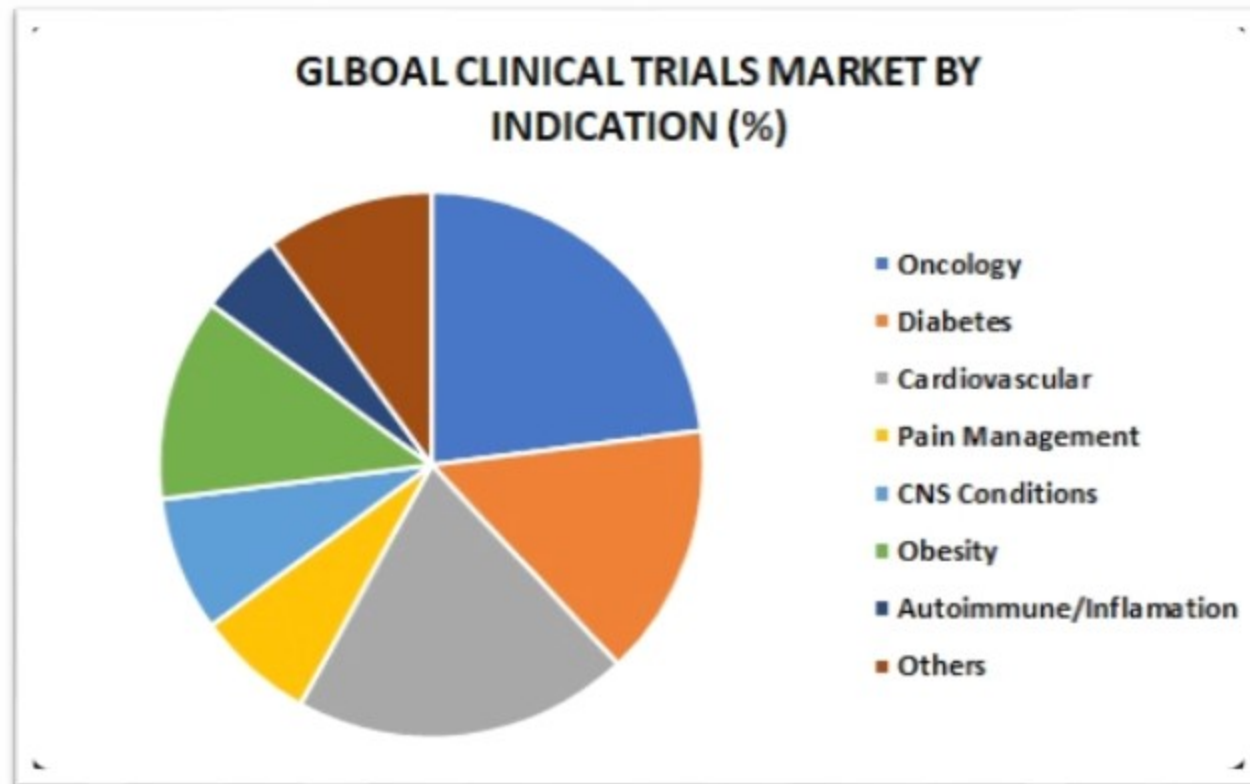


Fig.2 Highly fragmented markets





# Indication Insights and CT market



# Indication Insights and CT market

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- Based on indication, the oncology segment is anticipated to witness the fastest growth
- According to various sources, more than USD 38.0 billion is currently spent by the healthcare industry towards preclinical and clinical development of oncology therapy product
- Hence, it is anticipated to grow at a lucrative CAGR and contribute over USD 15.0 billion towards the clinical trials market by 2025



# Indication Insights and CT market

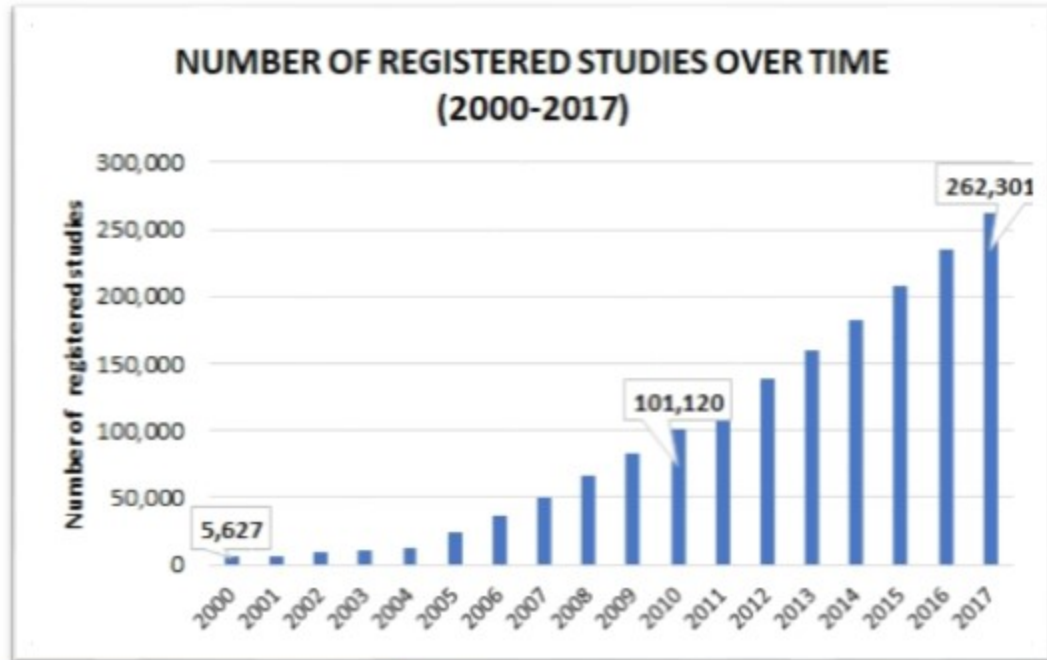
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- Pain management is identified as the most lucrative segment over the forecast period owing to the increasing incidence of chronic conditions that may lead to severe pain
- Furthermore, the rising investigation for new Non-Steroidal Anti-Inflammatory Drug (NSAID) and analgesic molecules is expected to be the vital impact rendering driver for this segment's growth
- In the study, pain management has been further classified into chronic and acute pain, wherein acute pain is expected to witness the fastest growth



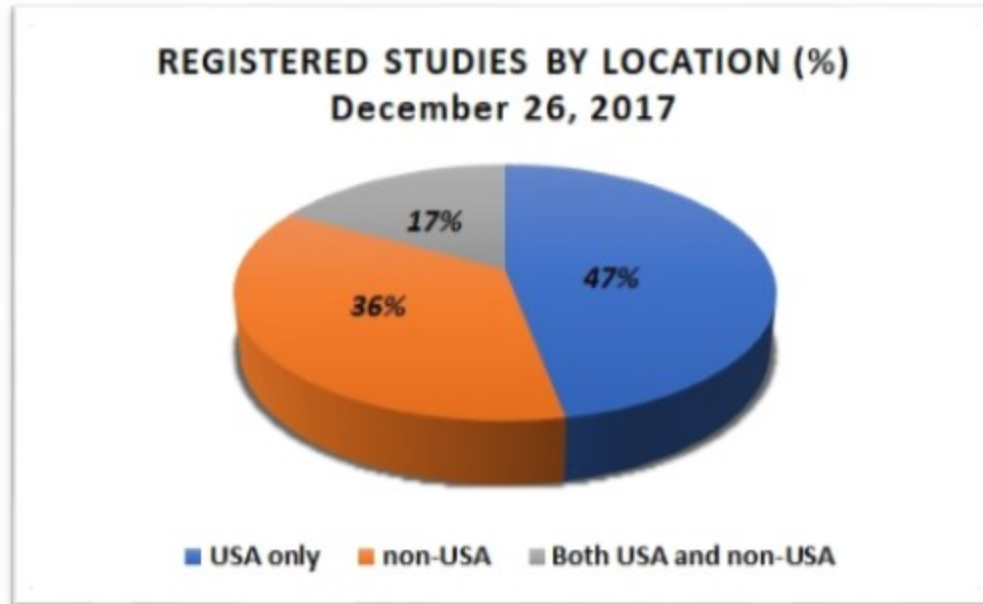
# Number of Registered Studies Worldwide over Time (2000-2017)

The total number of studies registered in 2000 is 5,627 and every year it is constantly increasing the number of studies registered in 2010 is 101, 120 and finally as of December 26, 2017 the total number of studies registered worldwide is 262, 301



# Registered Studies by Location

As of December 26th, 2017 the total number of clinical trials studies registered worldwide is 262,301, in this 36% studies are registered in USA, 47% in non-USA and 17% in both USA and non-USA





# Recruiting Studies by Location (contd)

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- As of December 26th, 2017 the total number of recruiting studies is 45,773, from this 57% of recruitment is in non-USA, 38% in USA and 5% recruitment in both USA and non-USA



# Clinical Research Market: Indian Scenario

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- The market clocked an impressive compounded annual growth rate of 17.46% over the period 2005-2016
- By 2020, the Indian pharmaceutical market is expected to be among the global top three by incremental growth and is expected to be the sixth largest market in the world in terms of absolute size



# Clinical Research Market: Indian Scenario

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- After the slowing down experienced in 2013, the clinical trials industry in India is seeing an upward trend
- There are several reasons behind the positive growth in clinical phase 1 and phase 2 trials in India, the least being the proactive approach and business-friendly 'Make in India' initiative of the Indian government
- 107 clinical trial NOC approvals were granted in 2013 and this number jumped to 150 in 2014. The rebound continued into 2015 as well



# Reasons of robust growth in the Indian clinical research sector

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- Simplification of Regulatory Procedures
- Latest Proactive Steps Taken by the Government
- Encouragement to Local Stakeholders in Clinical Research
- Global Incentives to Grow



# Simplification of Indian Regulatory Procedures

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- Ambiguity and uncertainty regarding regulatory procedures had lead to a slowdown in the number of clinical trials approved in the country.
- But new updates have made the approval process quicker, predictable and in line with global practices.





# Simplification of Indian Regulatory Procedures (contd)

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- Revised clinical trials' guidelines allow compensation to be paid only up to the point that the drug resulted in an adverse reaction in a patient participating in the trial
- This is a significant change from the earlier rule which stated that compensation has to be paid irrespective of whether the drug caused the serious adverse event or not



# Simplification of Indian Regulatory Procedures (contd)

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- Regulatory procedures have also made it clear that audio visual recording of informed consent is not mandatory in all cases
- The Central Drugs Standard Control Organization (CDSCO) set up online licensing portal SUGAM in March 2016 for import and registration of drugs and medical devices. The online services have been extended to pharma companies to submit and apply for clinical trials as well



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# Latest Proactive Steps Taken by the Government

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- In order to bring India back on the global clinical research map, the Drug Controller General of India is also mulling on providing online NOC (no objection certificate) to pharma companies to conduct clinical trials in India
- If this comes through, relevant documents can be submitted online reducing the time and effort required to submit hard copy at the office
- The applicant need not be physically present at the office at any point in time and can monitor the status of the application on the portal



# Latest Proactive Steps Taken by the Government

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- The government aims to speed up approvals, remove middlemen and bring about transparency with these new guidelines
- Simple and hassle-free application processes will help streamline the clinical trial industry and attract global companies to India





# Encouragement to Local Stakeholders in Clinical Research

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- The new circular released by CDSCO removed the restriction that did not allow investigators to conduct more than 3 clinical trials at any given period in time
- The DCGI has put the onus on the Ethics Committee to take into consideration the complexity and nature of clinical trials and grant permission for trials accordingly
- This is a major boost to experienced investigators and key opinion leaders (KOL) to leverage their expertise and drive industry growth in India



# Encouragement to Local Stakeholders in Clinical Research

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- Indian government has also revised the mandatory requirement that clinical trials can only be carried out at sites that have more than 50 hospital beds
- The Ethics Committee can use discretion to decide whether the clinical trial site is suitable for the trial or not
- It is mandatory that the site has emergency medical care and rescue arrangements required for the clinical trial



# Global Incentives to Grow

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- The US is the biggest drug market in the world with an estimated market value of around US\$ 413 billion in 2015
- The Food and Drug Administration (FDA) regulates the US drug market and Indian pharma companies and CROs also comply with FDA norms and regulations
- With the election of Donald Trump as the new US President-elect, the policies of the new government will also have an impact on Indian pharma and clinical research industry



# Global Incentives to Grow

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- The President-elect has voiced his support for safe, effective and cheaper drug imports and this could be a big boost to Indian pharma companies that supply about 40% of the total generic drugs consumed in the US
- Trump has also generally promised to increase funding to research agencies including National Institute of Health, which too could augur well for the industry



# Clinical Research: The India Advantage

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- India's economy shows signs of robust growth, and increased spending on healthcare needs is expected to drive revenue growth for pharma companies
- The Indian pharma industry today is the third largest market globally in terms of volume and 14th largest by value
- According to reports by McKinsey and PwC, the domestic pharma market is expected to grow at CAGR of 15 to 20 percent annually to be a USD 49 billion to 74 billion market by 2020





# Clinical Research: The India Advantage

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- India offers a large and diverse genetic pool of a treatment-naïve population for clinical trials
- According to PwC, India, with a population of more than 1.2 billion and projected to increase to 1.6 billion by 2050, is set to become the most populous country in the world, outnumbering even China
- Given increasing difficulty in sourcing patients for clinical trials in developed countries, the concept of expanding the pool of available patients in emerging countries, combined with cost savings, makes India well positioned



# Clinical Research: The India Advantage

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- India has the highest number of FDA-approved manufacturing plants outside the U.S.
- With increasing focus on constraining healthcare costs in the U.S., India's low-cost manufacturing capabilities combined with high quality standards are advantageous



# Clinical Research: The India Advantage

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- The emergence of chronic diseases like cancer, diabetes, cardio vascular system (CVS) and central nervous system (CNS) disorders may drive demand for newer therapies
- With the highest disease burden among all countries, India specifically offers a tremendous opportunity in contributing data for oncology trials as
  - The Indian oncology community is increasingly using genomic testing for their patients;
  - India has an increasing ability to generate quality genomics data and identify patients based on their genomic profiles; and
  - India has a cancer incidence of one million patients and a prevalent population of 2.5 million cancer patients.



# Clinical Research: The India Advantage

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- India also has proven capabilities in medical skills, IT capacity, and a large pool of scientific manpower with 200 years of shared legacy with the United States in medical education and medical practice
- With a 12 to 13 percent year-on-year growth, the Indian pharma industry is rapidly achieving a distinctive position in the global pharma space with contract research services and clinical trials



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