HFU Hochschule Furtwangen University

Is Patient centricity the need of the Clinical Trials landscape in India? How can we achieve Patient Centricity in Clinical Trials?

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by Sarita Thomas
Matriculation no. 266403
Sarita.thomas@hs-furtwangen.de

First supervisor: Prof Paul Taylor,
Professor Marketing,
HFU Business School

Second supervisor: Dr. Sudhir Kumar Jain,
Additional Director & HOD (Epd),
National Centre for Disease Control,
22, Sham Nath Marg,
Delhi- 110054

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Declaration

I hereby declare that the master thesis titled

"**Is Patient centricity the need of the Clinical Trials landscape in India? How can we achieve Patient Centricity in Clinical Trials?**"

which is being submitted in partial fulfilment of the requirement for Master of Business Administration – International Business Management at Hochschule Furtwangen is carried out solely by me, Sarita Thomas.

This master thesis is my own work, based on my personal research. All the information included in the thesis that is based on articles, books, journals, or any kind of digital or personal sources have been thoroughly acknowledged. This paper or similar version of it has neither been previously submitted for academic assessment nor published anywhere. I also certify that I have not plagiarized the work of others to best of my knowledge.

Sarita Thomas
MBA -International Business Management
Hochschule Furtwangen University
Villingen-Schwenningen,
Date - 17-Feb-2021

HFU Hochschule Furtwangen University
Villingen-Schwenningen Campus, Baden-Württemberg,
Jakob-KienzleStr.17
78054 Villingen Schwenningen
Phone +49 7720 307 0
Fax +49 7720 307 3109
E-Mail: info@hsfurtwangen.de

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I am also grateful to all the senior business partners of the various pharmaceutical companies who helped me understand the nuances of patient centricity and spared their valuable time for interviews. Their valuable feedback has helped me come up with the patient centric model based on the customer engagement model.

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Sarita Thomas
Hochschule Furtwangen University
Villingen Schwenningen,
Germany

Date :8-Feb-2021

Abstract

Patient engagement is the most important element in the process of research/development of medicinal products and healthcare management in today's times. In a country like India which has a huge population and limited state of regulatory affairs it becomes important to walk the extra mile to protect the patient lives and truly serve them. Time and again it is seen that there is no or limited focus on patient centric processes and we still tend to focus on sponsors as the key stakeholder.

The author in this thesis aims to focus on the clinical trial landscape of India and determine if there is a need to improve the clinical trial processes. If yes, then what type of change is the audience looking for.

The author tries to introduce the human element in the process and remind us all that it is the 'patients' who are the centre for the drug development process and serving them and alleviating their pain in the true purpose of the process.

The author along with the helping us find a definition of patient centricity in India, also proposes a model that can be used by the Indian pharmaceutical companies to focus on patient centricity at different stages of the drug development cycle within their organisations.

Preface

"The ethical justification for undertaking health-related research involving humans is its scientific and social value: the prospect of generating the knowledge and the means necessary to protect and promote people's health."

- Guideline 1 of International Ethical Guidelines for Health-related Research Involving Humans Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO).

Clinical trials have been based on 3 pillars - quality of information to be produced, relevance of the trials to health conditions, and the contribution of the trials to create and evaluate policies and practices catering to public health. Thus, making it crucial to emphasize on the social value of clinical trials.

Clinical trials (CTs) are the most pivotal element of the drug development cycle. It is the only mechanism to determine the efficacy and safety of a drug about to be launched in the market.

India with its highly diverse pool of potential trial patients, skilled investigators and site staff has always attracted several multinational pharmaceutical companies leading to a boom in pharma industry since the last few decades. Realizing this potential, the pharmaceutical companies and Clinical Research organizations have started setting up subsidiaries and facilities in India to tap this potential. The global clinical trials market is forecasted to touch the USD 30 billion mark in 2025 which is a CAGR of 7.8% compared to 2020. Out of this India is expected to reach USD 3.15 billion by 2025. With a projected CAGR of 8.7%. (Research, December 2018)

India consists of 17.5% of the world's population and 20% of the global burden by diseases. But this does not equate to the number of clinical trials that are approved annually. India accounts for only than 2 percent of worldwide registered Clinical Trials. *(Source Clinicaltrials.gov)*

In addition to the reduced number of clinical trials, inadequate equipment and facilities in hospitals and very long duration of time involved in a clinical trial have been some of the detrimental factors for conducting clinical trials in India.

While a drug patent lasts generally for 20 years, majority of this is covered by the clinical trial, only post which a drug can be marketed and ready for public use. A clinical trial can easily last up to 10 years which makes it important to focus on strategies to prevent further delay in conducting a trial. One of the widely adopted methodology is to recruit patients quickly. Achieving this is not usually easy as the patients participating in clinical trials are not usually financially compensated but only benefit from free treatment, they receive being a part of the trial.

Patients often feel that they are mere guinea pigs in the world of clinical trials and their well-being is not of importance to the sponsors. Can there be a way where both patients and sponsors work together hand in hand to create better treatment opportunities for people globally? Can patients share their feedback and help sponsor develop better processes? Should we move away from sponsor centric trials to patient centric trials? Will this concept work in India?

1. Introduction

1.1. Background

Patients are the centre of clinical trials. This makes patient recruitment the most pivotal process in clinical trials. Current status of patient recruitment and its impact on clinical trials can be realized with the help of the following data

- Globally over 50% of the clinical trials are unable to meet the planned enrolments.
- Late stage trials have shown an average delay of 10.8 months since 2011.
- Patient dropout rates in phase 3 clinical trials tend to exceed by more than 30%
- 80% of clinical trials are delayed by at least one month
- 85% of the clinical trials are unable to retain enough patients till the end of the trial.
- 50% of investigational sites have been able to recruit and enrol only one or no patient. (Hargreaves, 2016)

Each of the above mentioned translates as a huge loss incurred in the process of conducting the clinical trials. Thus, making it critical to find a solution to each of these, including patient recruitment and retention.

From Figure 1. Trend of Clinical Trials registered on Clinicaltrials.gov (Source: www.Patientcetricityontrial.com) it's visible that although there has been a sharp increase in the number of clinical trials registered across the world but its only 8% that manage to complete on time. Also, there is an increase in complex diseases leading to complex trials. This increasing complexity adds to the challenges of running a clinical trial and enrolling patients within the trial. This coinciding with the advent of the internet and the digital age, shifts a huge amount of power to the patients thus reducing the control of the sponsor companies on these trials.

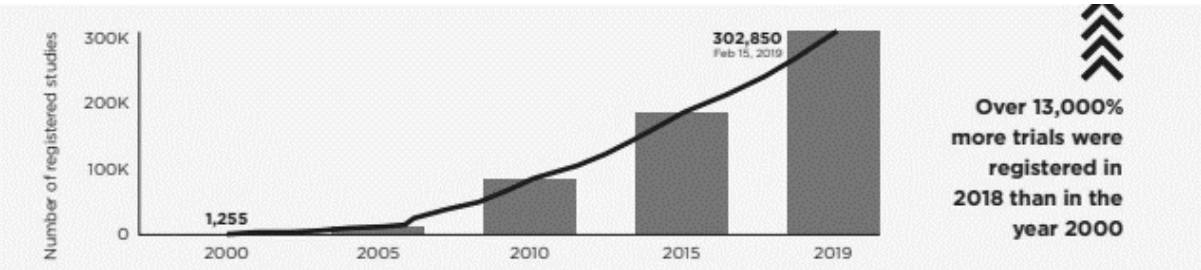


Figure 1. Trend of Clinical Trials registered on Clinicaltrials.gov

Studies have shown that there are three major hurdles for patients to participation (National Institute of Health, 2016)

- 70% of the patients live more than 2 hours travel time from their nearest sites.
- 66.6% of the patients are unaware of the potential trials they could participate.
- 66.6% of the patients lack trust to participate in a clinical trial.

Currently in India follows the age-old sponsor centric approach to clinical trials where importance is given to meeting regulatory requirements, delivering high-quality clinical trial data, and budget. This has led to study designs that focus on timeliness and convenience and not the patients. As per a survey by the Centre for Information and Study on Clinical Research Participation, out of 3150 more than one-fifth of participants considered the clinical trial

experience stressful. The location of the medical centre, the time-consuming study visits, and the cumbersome procedures were cited as reasons for the negative experiences. (Schroeder, 2020)

To successfully complete a clinical trial to launch a medicine in the market, enough patients/people should enrol in the trials and take their medication per clinical trial protocol (CTP) in order to gather high-quality trial data as soon as possible. But this cannot be achieved by designing a trial without considering the needs of patients. Recognizing this, sponsors have started to incorporate patient perspectives into all phases and parameters of their clinical trials. Thus, creating the 'Patient Centric Trial'.

1.2. Objective of Thesis

Patient centricity is the process to develop services and solutions for the patients with them. The processes thus created use insights and inputs from the patients. Due to the low costs and huge population in India, it is the most sorted location for clinical trials in the world. But the limited infrastructure and regulatory environment has led to people being treated as guinea pigs for the launch of a new medicine in the market. Official figures say that there have been over 2,644 deaths during clinical trials for new drugs just during the period between 2005 and 2012 (EPSI-Global, 2017). This makes it important to take into consideration the emotions, well-being and existence of patients, who are at the centre of clinical trials. The concept of patient centricity is well established in the European countries while in India it has just started to garner some attention amongst those in the Indian pharmaceutical community. The immediate question in hand is that should the Indian pharmaceutical companies take a step back from the traditional clinical trial mindset (which is being used since the last 20 years) and include patients in their processes. Will this concept help the Indian audience and provide them the rightful position of a valuable stakeholders in the clinical trial process, or will it make them more vulnerable? Patient centricity is also feared to be used as a marketing gimmick to grab the attention of the patient community and indirectly try to increase the number of patients the sites are able to recruit in a trial. Thus, the objective of this thesis is to understand the clinical trial landscape in India and see if this concept can fit in here given this country's economic, social and ecological condition. Which would help us answer the following research questions:

Research question 1: Are the patients in India satisfied with the current clinical trial processes?

Research question 2: How aware is the Indian population about clinical trials as a treatment option? What does it mean to be patient centric in the Indian clinical trial landscape?

Research question 3: Are patients willing to be partners in the clinical trials process? How can patients be partners to sponsors during a Clinical Trial? Can they contribute across the spectrum of clinical development, even in the design of trial protocols?

It is also important to understand that due to reduced confidence shown by patients on the clinical trial processes, a reduction is seen in the number of patients preferring to participate in clinical trials. This has led to incomplete trials or insufficient number of patient recruitments forcing to discontinue trials. This causes a huge loss to the pharmaceutical companies. Thus, the objective of the thesis is to also find answers to the following research questions:

Research question 4: Should the Indian pharma companies implement patient centricity?

Research question 5: How will implementing patient centricity benefit these pharma companies?

In addition, the thesis also intends to describe an approach / model to best apply patient centricity as per the original definitions in India, one of the biggest markets of the pharmaceutical industry. The concepts from the model could then be applied to other geographies as per their local policies / regulations. The application of the model to other geographies is out of scope of this thesis.

1.3. Design/methodology/approach

The author in this thesis plans to achieve the abovementioned objectives using a mix of primary and secondary data that would combine both qualitative and quantitative methods of analysis.

1.3.1. Primary Data

- Primary data majorly comprises of survey and interviews conducted with the aim specific to the needs of the thesis.
- The data is not subjected to author's personal bias.
- The surveys conducted facilitate the collection of data in real-time and does not refer to any data from existing sources.

Quantitative method

Survey 1

To answer the **Research question 1** the author conducted a patient satisfaction survey to determine the general acceptance of the existing clinical trial processes in India and do the participants feel the need to move towards a different approach.

Population:

- Nationality: Indian
- Profession: Any
- Age group: 23 years and above
- Education: college graduates and above
- Participated in clinical trials previously – Yes

Quota Sample: From the above-mentioned population specific quotas were created to ensure that there is equal representation to avoid introduction of unwanted bias in the survey results. The quotas were based on the following:

- Gender of the participant – Male/ Female
- Age group- 23-45, 46-60 and 70+
- Education qualification- Graduates/ Post-Graduates
- Profession – Working/ not working
- Income group- Low Income/ Middle Income/ High Income
- Geography – North India/ South India / West India/ East India.

Prospective candidates for the survey were contacted via support groups of clinical trial participants on social media platforms. In order to obtain equal representation and a homogenous socio-economic demographic sample the candidates were divided into the above-mentioned strata. The aim is to create a sample that is as representative as possible of the population being studied. A non-probability-based approach is used to divide the

candidates in the above-mentioned strata and obtain equal participation for the survey. This led to shortlisting of 25 participants suitable for the survey.

Survey details:

- The survey consists of 7 multiple-choice questions.
- The questions to the survey can be found in Appendix 2
- The findings to the survey shall be concluded in Case Study 1: Patient Satisfaction Survey

Survey 2

To answer the first part of **Research question 2** 'How aware is the Indian population about clinical trials as a treatment option?' the author conducted a survey to understand the general public perception about clinical trials to understand the general myths or thoughts among people.

Population:

- Nationality: Indian
- Profession: Any
- Age group: 23 years and above
- Education: college graduates and above
- Participated in clinical trials previously – No

Quota Sample: The survey sample was selected using the same sampling process and criteria as explained above.

A non-probability-based approach is used to divide the candidates in the above-mentioned strata and obtain equal participation for the survey. This led to shortlisting of 163 participants suitable for the survey.

Survey details:

- The survey consists of 9 multiple-choice questions.
- The questions to the survey can be found in Appendix 3
- The findings to the survey shall be concluded in Case Study 2: Patient perception survey about clinical trials

Survey 3

To answer the first part of the **Research question 3 '**Are patients willing to be partners in the clinical trials process?', in order to understand the willingness of the general people to participate and contribute in developing the clinical trial processes in India the author conducted a survey.

Population:

- Nationality: Indian
- Profession: Any
- Age group: 23 years and above
- Education: college graduates and above
- Participated in clinical trials previously – Both Yes and No included

Quota Sample: The survey sample was selected using the same sampling process and criteria as explained above. The participants form both the ***Survey1*** and ***Survey2*** are combined to conduct this survey.

A non-probability-based approach is used to divide the candidates in the above-mentioned strata and obtain equal participation for the survey. This led to shortlisting of 188 participants suitable for the survey.

Survey details:

- The survey consists of 5 multiple-choice questions.
- The questions to the survey can be found in Appendix 4
- The findings to the survey shall be concluded in Case Study 3: Willingness to participate in clinical trials

Survey 4

As in the objective mentioned above the author plans to develop a model for patient centricity in India for which one element is understanding the importance of 'Patient Centric Leadership'. Using this survey, the author connects with senior management officials in various pharma companies that are champions of patient centricity to understand the need of a patient centric leadership and what are the critical traits of a patient centric leadership.

Population:

- Nationality: Any
- Profession: Senior Management professionals in Pharmaceutical companies.
- Team/ groups of profession: Patient Advocacy Groups/ Clinical Operations/ Trial Oversight/ Patient Advisory.
- Age group: Any
- Pharmaceutical company: Publicly claims to follow patient centric approach.

Quota Sample: The survey sample was selected using the same sampling process and criteria as explained above. A non-probability-based approach is used to divide the candidates in the above-mentioned strata and obtain equal participation for the survey. This led to shortlisting of 20 participants suitable for the survey.

Survey details:

- The survey consists of 10 multiple-choice questions.
- The questions to the survey can be found in Appendix 5
- The findings to the survey shall be concluded in Patient centric leadership

Interviews

In order to answer **Research question 3 and 4,** structured interviews were conducted with the following interviewees. The questions were shared beforehand, and the responses were documented, which facilitated in finding answers to the research questions and developing a strategic methodology to adopt patient centricity in Indian pharmaceutical companies. (Names of interviews have been anonymised to protect identity)

- Mr. X- Senior Pharma Business Strategist at a leading Healthcare company in India
- Ms. Y: Head of Communications for Global Drug Development at a leading Pharmaceutical company in India
- Mr. Z and Ms A: Patient Advocacy Group leaders at a leading Global Pharmaceutical company.

The details of the interviews can be found in Appendix 1 and section 4.3 Applying the customer engagement model to clinical trials

1.3.2. Secondary Data

The author uses the data already publicly available in public platform to get answers to research questions. The secondary data used are from the below mentioned sources.

- *ClinicalTrials.gov* : All the statistical clinical trial information is collated from the publicly available database of privately and publicly funded clinical studies conducted around the world.
- *The Clinical Trials Registry- India (CTRI):* hosted at the ICMR's National Institute of Medical Statistics (NIMS). It is a free and online public record system for registration of clinical trials being conducted in India.

The author participated in several webinars and expert talks conducted by pharmaceutical companies and research organisations, where panel discussions took place to bring forward the problems faced today by patients and pharmaceutical companies. The feedback and valuable thoughts from the experts were used to analyse the current problem statement posed in the thesis and also develop a solution of the same.

Webinars and expert talks

- Topic: **Navigating the UK regulatory pathway to increase patient engagement with trials**.
  Speakers: Gareth Powell, NIHR, Sophie Evett, Pfizer, Richard Stephens and Keith Wilson, Patient Advocates, Dominic Tyer,
  Conducted by: Pharmaphorum,
  Conducted on: Dec 16 2020 | 68 mins (link here)
- Topic: **Optimizing eConsent for Patient Centricity**
  Sponsored by: CRF Health
  Date: 13 December, 4PM London/11AM New York/11AM ET
- Topic: **Defining Patient centricity going forward**
  KeyNoteTalks at SDCM India Annual conference 5th December 2020
  Speaker: Arno Tellmann: Head of Global Drug Development, Novartis

Models and Concepts

- The Thunderhead's Engagement 3.0 model
- Concepts of the marketing funnel by Elmo Lewis
- Picker's model for patient centricity

1.4. Organization of Thesis

A brief introduction about each Chapter in the study is presented as follows:

Chapter 1	This chapter introduces the problem statement and the need to study to find answers to the addressed problem. The methodology and organizational structure of thesis are also described within this chapter.
Chapter 2	Clinical Trials in India This chapter explains the current process followed in India. It also elaborates the clinical trial landscape in India and situation of the patients in India.
Chapter 3	Patient Centricity This chapter introduces the concept of patient centricity. We also discuss if the concept can be applied to India.
Chapter 4	How to can we implement Patient Centricity in India? This chapter discusses the Customer engagement concepts and tries to apply the same in the landscape of clinical trials. This is then followed by a deep dive into the model which explains how the industry applies the elements described in the model.
Chapter 5	Patient Engagement across clinical trials This chapter focuses on the stages within a clinical trial and how patients can be included in each of the stages to enhance the performance of clinical trials and to be able to achieve the aim of serving the patients.
Chapter 6	Patient centric leadership This chapter elaborates how the application of patient centricity is useless without a leadership that believes in it and is equipped to lead the way with their special competencies.
Chapter 7	Pharmaceutical companies and Patient centricity This chapter discusses how different global pharmaceutical companies have upgraded their vision and mission to onboard patients as stakeholders in their functioning and how the industry measures them on this.
Chapter 8	Conclusion

1.5. Limitations

This thesis proposes a model based on the current public needs. This also includes the response of participants in clinical trials from other geographies that have adopted the concept since the last couple of years. The data available on the behavioural response is not extensive and will not be a 100% indicator of the success or failure of the approach. Nevertheless, this process believes in the immense contribution the trial participants can make and understand that it's time we focus on the human element rather than statistics that are relevant for regulatory purposes.

2. Clinical Trials in India

India is a country with a huge population that is poor and lacks affordable healthcare system. People consider clinical trials as a way of obtaining medical treatment which otherwise could have been costly and out of reach. It has been pointed out by several economists that government contributes only 15% of the Rs 1,500 billion spent in the health sector. While around 5% comes from social and private insurance, 80% is spent by individuals without insurance. 70% of the users of our healthcare system are poor out of which at least the poorest 20% sell assets or borrow to pay for healthcare (Duggal, 2015). This is the major reason why India is considered as a green pasture for Clinical trials.

2.1 The Standard Process

Clinical trials are research conducted in human beings with the purpose of achieving solutions to new therapies, vaccines and diagnostic processes, or new ways of treatments. Clinical trials determine the safety and efficacy of the new drug, diagnostic or treatment. As elaborated on the clinical trial lifecycle show in Figure 2.Clinical Trial lifecycle (source: The life cycle of a clinical trial by MPN Research Foundation)The investigational medicine product is initially tested in the laboratory and on animal studies, post crossing these stage gates they then move into human clinical trials. Clinical trials are divided into different phases as described below (National Comprehensive Cancer network, 2010):-

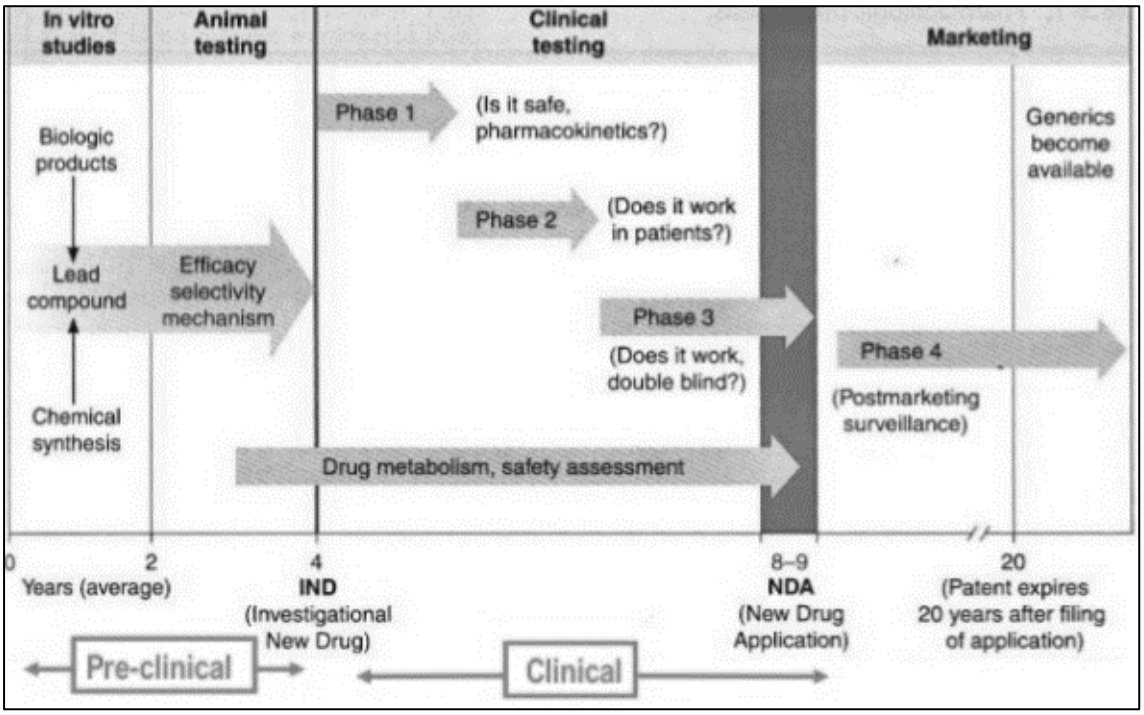


Figure 2.Clinical Trial lifecycle

Phase 0 – In this very first step it is aimed to learn how a drug is processed in the body and how it affects the body. This phase uses only a very small dose of a drug on about 10 to 15 people.

Phase I -Phase I of the trials are aimed to find the best dosage of the drug with least side effects. Very low dosage of the drug is administered to a group of 15 to 30 patients.

Phase II - Phase II of the trials are aimed to further assess safety of the drug. These trials are conducted on a larger group of patients compared to Phase I trials. The drug is often tested among patients with a specific condition.

Phase III- Phase III of the trials compare a new drug to the standard medication for the disease. These trials are aimed to assess the side effects of each drug and conduct a comparative study. These trials are conducted on over 100 patients. At this stage, the treatment groups are randomized. The study will be terminated in case the drug is found to develop side effects or adverse events in the participants of the trial or if one group shows better results than the other as per the agreed standards. For the FDA to approve the use of a new drug for the general public Phase III clinical trials results should be available.

Phase IV- Phase IV trials test drugs newly approved by the FDA. The trial is conducted on several hundreds or thousands of patients. This allows to identify variety of side effects that could either be short-lived or long-lasting and gather understanding of the safety of the new drug. For instance, some rare side effects may only be found in large groups of people.

After the clinical trial phases are successfully conducted, the research team carefully analyses all the information collected during the study to make decisions if the new drug, diagnostic or treatment is ready to be launched to the market or if any further testing is needed.

The following regulations influence and manage the process to conduct Clinical Trials in India (ICMR-NIMS, 2007):

- Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945.
- Central Drug Standards Control Organization's Good Clinical Practice Guidelines, 2005- Indian GCP
- National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017 and National Ethical Guidelines for Biomedical Research Involving Children
- Indian Medical Council Regulations, 2002
- Internal rules and regulations by the hospitals and institutions.

The lifecycle of the new drug as elaborated in Figure 3. Drug Approval process in India (published by CDSO) passes a series of approval processes, the responsibility of which is divided between the Central and the State authorities (CDSO, 2021).

- Submission of Clinical Trial application for evaluating safety and efficacy.
- Requirements for permission of new drugs approval.
- Post approval changes in biological products: quality, safety and efficacy documents.
- Preparation of the quality information for drug submission for new drug approval

In 2007, ICMR's National Institute of Medical Statistics (NIMS) launched the Clinical Trials Registry- India CTRI (www.ctri.nic.in) as a free and online public record system to facilitate the registration of all the clinical trials that are conducted in India. The registration was initially deemed voluntary, but since 2009 this process has been mandated by the Drugs Controller General (India) -DCGI (ICMR-NIMS, 2007).This registration process has facilitated in establishing an unbiased, transparent and accessible to all public record of clinical trials conducted in India.

- Trial involving human participants and based on any intervention should be registered in the CTRI before the first patient enrolment (ICMR-NIMS, 2007).
- All registered trials should publicly declare the identities of their trial investigators, sponsors, interventions, patient population etc. before the enrolment of the first patient.
- Ethics committee approval and the DCGI approval (if applicable) are mandatory for the registration process.
- Multi-country multi centre trials that are registered in any international registry, with India as a participant country, should also be registered in the CTRI.
- The CTRI also captures the investigators details, sites, target sample size and events dates regarding patient enrolment.
- Trial personnel are required to regularly update the trial status or other on CTRI.

It is important to note is that pharma companies can acquire patents on a new molecule as soon as the clinical trial begins in order to maintain their exclusivity over the molecule. The patent is granted for a period of 20 years and it can take anywhere between 2 and 10 years to successfully complete the clinical trials thus reducing the duration for which the company can maintain the exclusive rights to the molecule in the market.

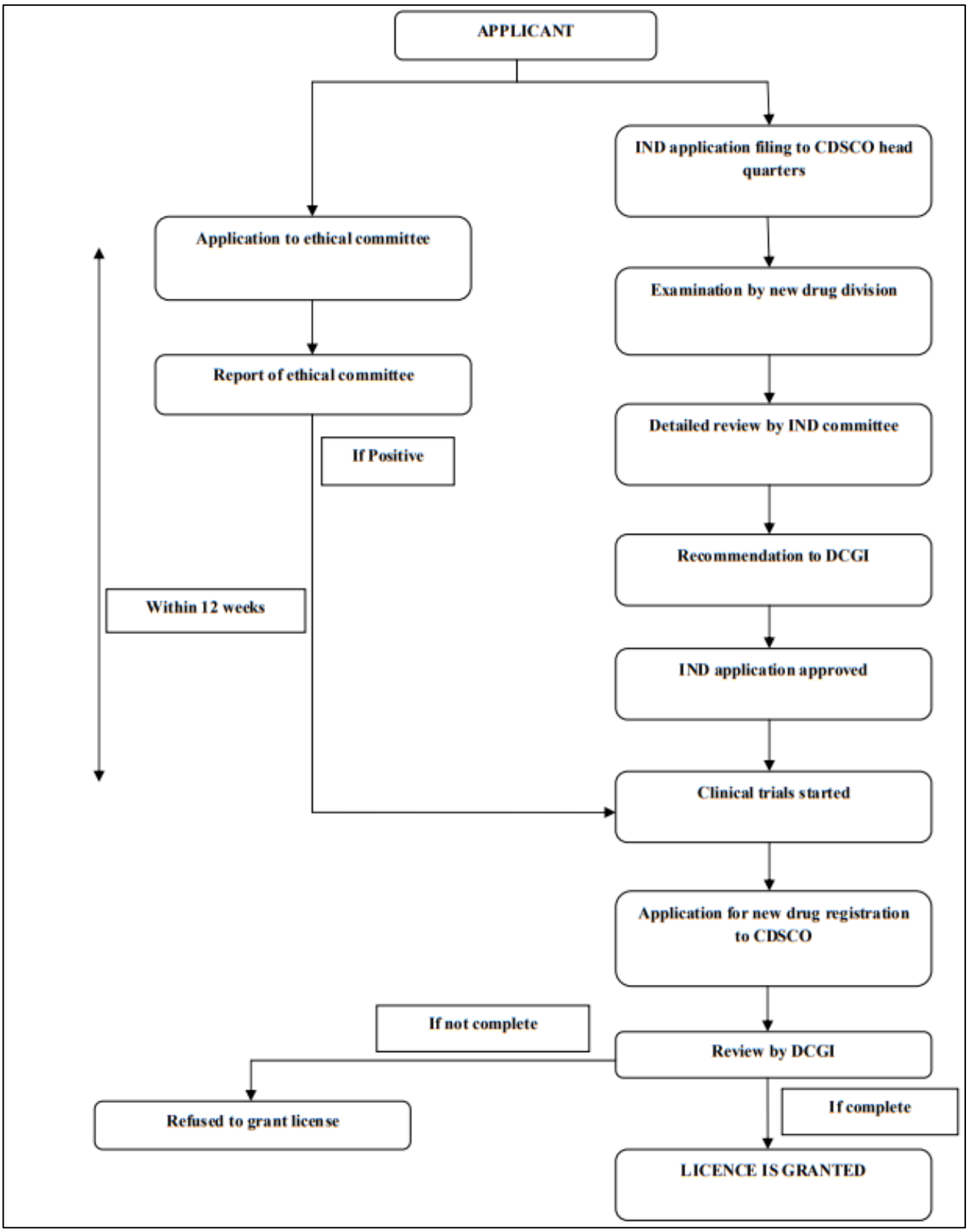


Figure 3. Drug Approval process in India

2.2 The Clinical Trial landscape in India

In the annual year of 2019-2020 around 290,000 clinical trials were conducted out of which only 3,618 (1.2%) were form India. India with its huge population of 17.7% of the world (Worldometer, 2020) and 20% of the global disease burden (Ritchie, 2016)seems to be lagging in the field of clinical research and trials. Around 70 million of the country's population suffers from rare disorders several of which do not yet have a cure.

Mr. Y. S. Chowdary, the Minister of State for Science and Technology & Earth Sciences, Government of India says that it is envisioned to develop India into a global innovation hub by 2022 by providing a conducive environment for growing research and development in the country (GOI, 2018). The government also plans to stimulate the R&D investment in the pharmaceutical sector by providing fiscal incentives and harmonizing processes to develop new drug molecules and new drug delivery systems (Rakesh K. Tekade, 2019).

Interestingly since 2005, when the Indian government introduced product patents on pharmaceuticals, a strong push has been seen to promote clinical trials in India by modifying the policy framework and regulations surrounding it. These changes have favoured international Clinical Research Organizations (CROs) in expanding their scope in India giving them access to the large pool of patients, highly skilled investigators and lower drug development costs in India. This has led to increasing concern over the clinical research ethics followed in India as the Clinical trials are more than 50 per cent cheaper in India compared to developed countries majorly due to cheap human resource, low recruitment cost and lower rate of compensation for any injury sustained or death during the research process (Bhatt, 2004). Figure 4. Relative Patient Pool and Cost-efficiency analysis explains the cost efficiency vs regulatory condition comparison for several prominent countries in the sphere of clinical trials. Cost efficiency is captured by cost of conducting a clinical trial per year compared to the return on investment in a country. Regulatory conditions are defined by the complexity of the regulatory regimes, number of approvals required to publicly launch a medicine in the market in the country and the time taken to get approvals. The below graph is part of the published analysis by A.T. Kearney on the cost effectiveness to conduct clinical trials across the globe. The graph clearly shows that India ranks one of the highest in cost efficiency compared to the developed countries like USA and Germany. Studies indicate this is majorly due to the loose regulatory process leading to faster approval time.

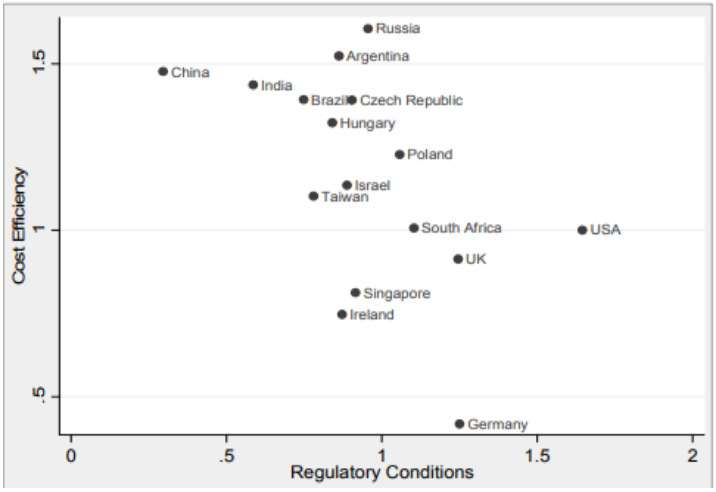


Figure 4. Relative Patient Pool and Cost-efficiency analysis

This has led to increasing concerns of CRO's recruiting illiterate patients without educating them of the risks and benefits of participating in a trial. Also, the concept of informed consent has been taken for granted in many circumstances. Over the last few years, several thousands of people have died due to clinical trials and only a few have received compensation (Bagcchi, 2017). The regulatory authority had to recently cancel registration of at least 10-15 site ethics committees and suspended many others for not properly following rules on clinical trials (Economic Times, 2020). While the Government of India continues to invite pharmaceutical companies to benefit from the foreign investments they bring with them, the poor continues to be the guinea pig (DownToEarth, 2018).

The key issues regarding Clinical Trials in India as seen over the period of time (Abrol, 2018):

1. **Deaths and adverse events**- Hundreds of patients die annually while participating in clinical trials conducted by pharmaceutical companies many of which even go uninformed to the ethics committee.
2. **Exploitation**- People from the lower income group- in need of money are exploited and their ignorance of impact of any trial on their health is taken advantage of.
3. **Regulatory bodies and ethic committee**- The members in the committees formed for the approval process have been seen to have inadequate experience and have conflict of interest. Also, the regulatory process has been slow. This has been catered in the New Drugs and Clinical Trial Rules, 2019 where it was declared that the ethics committee shall now also contain non-affiliated members to facilitate transparency and enable decision making keeping the general population in mind (Appendix 0).
4. **Unethical practices during clinical trials** – As a large proportion of Indians is not well educated, they fall in the trap of unethical clinical trials. Several instances have been registered where the people registered for a treatment were tested for clinical trials without their knowledge (Appendix 0).

2.3 State of Patients in clinical trials conducted in India

Patient recruitment and patient retention is a topic least researched on the Indian audience. While on one side we know that India has a huge population with an immense diversity of genetic and non-genetic diseases, making them the most preferred gene pool to conduct clinical trials, we barely have information on the patients' awareness of trials and their satisfaction post participating in a trial. While world over the clinical trials are struggling to recruit patient, India has been able to recruit better that in the USA. This has been attributed to a huge population being uneducated and gullible.

India entered into the global clinical trial market in 1990's and was not established in the market until the 21st century. This makes India a juvenile amidst the developed players like US and Europe. Interestingly by 2010 the number of clinical trials registered in India were proportional to those to the developed countries. This has the been attributed to the hasty regulatory reforms, judicial and social activism and sensational media reporting as suggested by Suneela Thatte, ex-President of ISCR (Ms Suneela Thatte, 2016).

News like the below mentioned has bombarded the Indian media since a really long time: -

- Tribal girls recruited for trials without parental consent for a study sponsored by the Bill and Melinda Gates Foundation. Several of them died due to adverse events within a period of 3 months.
- The victims of Bhopal Gas tragedy were forced to participate in at least 11trials without proper informed consent.
- Several cases found in Indore, India, where ethical guidelines were violated. 81 patients suffered adverse events but were not attributed to any trial. All trials were halted till the investigation by the state government.
- In 2011, fewer than 40 Ethics Committees were registered in India putting the safety of the subjects of clinical trials at stake. *

*As of 16 Jan 2021, there are 1184 ethics committee registered as per the Central Drugs Standard Control Organization (CDSO, 2021) post the guidelines published in the New Drugs And Clinical Trials Rules, 2019.

With the above-mentioned situation of the Indian patients the author finds that it is even more important to find a method that put back the focus of clinical trials form sponsors and money to patients, whose condition today is deplorable. Since long it has been seen that we have been preferring launching medicines in the market compared to the actual health and safety of the people.

This exploring the concept of patient centricity in the Indian landscape becomes critical. The author hopes to find out if the concept of patient centricity will help in the current situation. And in addition, find a standard method created by compiling the best practices from different pharmaceutical companies that could be best utilised in out socio-economic portfolio.

To begin with lets first understand the concept of Patient centricity.

3. Patient Centricity

3.1 Understanding – The Concept

In today's digital era the patients have access to vast data that helps them make critical decisions. Today patients not only feel the need to decide on their own which trial can suit them the most instead of a doctor forcing them to participate but also demand to participate in critical decision-making in a trial, demand personalized therapies and incorporating their perspective into the development cycle.

Seeing this the pharmaceutical companies are planning to take a step forward to partner with patients. The idea is to make patients a part of the process from the conception with the aim of co-creating solutions that benefit from the symbiotic relationship between the sponsor and the patient. Guy Yeoman from AstraZeneca defines with this concept of Patient centricity as - Putting the patient first and help them achieve the best experience and outcome for them from the clinical trial (Walrath, 2017). This definition comes from the extensive research project conducted by AstraZeneca to identify issues related to importance of clinical trial to patients, healthcare providers and payers. The research elaborates on the patient's perspective as follows: -

- Patients want an ethical and sustained relationship. They want to be involved so as not to be treated as transient commodities but as valuable partners in the process.
- Patients quite rightly expect to be treated with respect and compassion.
- Patients want the sponsors to deliver an experience that they and their families want – and not necessarily what the outcomes the sponsors have.

Thus, conceptually Patient centricity is about the participating patients and their goals when they participate in a clinical study with the ability to provide a personalized experience for each study participant. The journey to achieve this goal starts with the designing if a study but ends only when the patient is satisfied. Picker's 8 principle model for patient centred care, as explained in Figure 5. Patient Centric care model by Picker has been a guideline to many

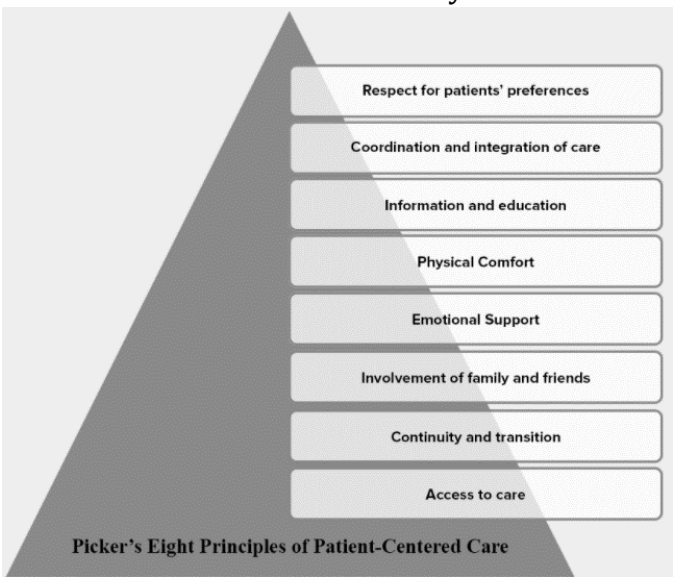


Figure 5. Patient Centric care model by Picker

organizations in this field.
The author breaks down the 'Picker's patient centric model' to elaborate on how one can determine the extent to which a study is patient centric. The characteristics are elaborated as follows:

1. The study meets the standards for patient protection
2. The participating patient agree that the study's endpoints.
3. The study employs principles of precision medicine to focus on the patients most likely to benefit from the study.
4. The study considers the patient's social, cultural and physical environment.
5. The participants agree to the relevance of the study and believe that it contributes to the health of their community.
6. A patient advisory board contributes to the design of the study.
7. Patients feel informed, respected and valued in the study. Thus, being co-owners and share responsibility of the study conduct.
8. Patients are enabled to learn more about the study as per their preference.
9. Post the consent process patient have adequate understanding of the study.
10. Research sites keep in mind the patient's preferences and concerns while interacting with them.
11. Convenient participation. Minimum procedure, pain and discomfort and maximum home visits and virtual visits. Wearable devices are preferred in new studies.

12. Research sites conduct the study keeping in mind the current and emerging medical condition of the patients.
13. Primary care physicians, caregivers, family members, and other patient supporters are addressed equally taken care in a study.
14. Patients are aware of their study data and the overall study results
15. Process should be in place to measure patient-centricity of the study and the satisfaction of the patient.

All these characteristics lead to satisfied participants who recommend their friends to participate in similar studies.

3.2 Can Indian population benefit from patient centricity?

Before trying to determine of the patients today shall benefit from the concept of patient centricity, the author wants to first find if the patients who have already participated in clinical trials need a change in the system. The need could be determined by understanding if the patients are satisfied by the processes in places. The author uses the definition - highly satisfied patients means no need to change the current sponsor centric clinical trial approach and low satisfaction among patients means there is high need to change the current processes. This shall be determined using the below case study.

Case Study 1: Patient Satisfaction Survey

Aim: To understand if patients who have earlier participated in clinical trials think they can benefit from the concept of patient centricity being introduced in the clinical trials procedures.

Participants: As elaborated in section 1.3 Design/methodology/approach

Procedure:

- Patients were connected on Facebook via support groups of clinical trial participants.
- A survey questionnaire was shared with them to gather their feedback (Appendix 2)

Findings:

- Almost 60% of the participants consider their experience with the clinical trial average.
- Almost 20% of the participants consider their experience below average.
- 90% of the participants think that the clinical trial process needs improvement.
- 90% of the participants think that there is not enough transparency in the entire process.
- 85% of the participants consider they needed a doctor/ investigator to make any decision or understand any process during the clinical trial.
- 60% of the participants consider that the process was not formulated keeping them in mind.

Conclusion

It was clear that the general population is never involved in the processes of clinical trials even when they are the key stakeholders and the end users. The Clinical trial design is very sponsor centric and the process are dependent on the regulatory requirements. This burdens the clinical trial participants which possibly is the reason for the average/ below average

experience of the survey participants. With advanced technology and the ease of access of transfer of information patients demand transparency in the process and up to date information medical information to reduce barriers between pharmaceutical companies, physicians and patients.

Patient expectations have also changed over the period. With the advent of enhanced point-of-location services and health measurement devices like FitBit, patients demand an active participation in clinical trials.

Thus, the author concludes that there is very low patient satisfaction and a high demand to change the current processes to an approach more incorporating patient.

Now as it is concluded that there is need to implement a patient centric approach, it is important to determine how to implement it. The author seeks to find existing models or approaches that could be borrowed and implemented in the current context.

4. How can we implement Patient Centricity in India?

In 2012 an industry wide survey was conducted to gather understanding from the top hospital leaders on how to improve the patient experience. The recommendations enlightened that patients do not have high demands but very basic needs that gives them a feeling that they are of importance to the hospital staff. They are well informed and talked to (and not talked at) making them active participants in the entire process. The secondary demands we availability of new facilities, better/clean rooms, better food, quiet time to rest etc (Torpie, 2014).

Although comparing patient as traditional 'customer' could be labelled as an ill-conceived notion and could be claimed to contribute to lack of understanding of patient needs. But in order to engage patients and involve them to co-create a process for clinical trials we can develop some understanding by considering them as customers and the pharmaceutical companies as the service providers. This approach could be a key in enabling us think how to provide value to our customers (patients) and take care of their expectations says a senior Patients Advisory Group member from Boehringer Ingelheim.

4.1 Customer engagement key concepts

Thunderhead.com, a leader in enterprise solutions for customer experience and customer engagement, released Engagement 3.0, an ingenious model for Customer Engagement. A model developed with extensive research using customer research and feedback to redefine customer engagement in our age of digital transformation (ThunderHead, 2019). The research showed that any organization is struggling with its customers as follows:

- Easily disappointed - 58 percent complain to not have been able to see improvements in their relationship with businesses in the last few years.
- Quick to judge and are less willing to forgive.
- 25 percent customers are seen to switch providers after just one negative experience.
- 20 percent of customers feel it takes more than a year to re-establish trust with a company after a mistake
- 19 percent feel they can never trust the company again.
- Prepared to act decisively - 30 percent customers share a bad experience online

In addition, three major challenges were found to undermine the business' ability to build customer engagement:

- Irrelevant and impersonal communications
- Struggle to keep pace with customer expectations.
- Disjointed communications

Thunderhead's model recommends businesses to empower customers and unify silos that exist in their organization by the following:

- Remove organizational barriers that prevent from effectively managing customer experience.
- Learn from every interaction in every channel especially insights from customer behaviour and interaction can help enhance customer experience.
- Avoid working in silos -Provide all relevant departments access to real-time information about customer interactions

To build an engagement it is pivotal to know the customer and as per this model as explained in Figure 6. ThunderHead's Customer Engagement Model, the engagement starts with the exchange of knowledge between the customer and the business. This creates a shared knowledge based on the tacit knowledge.

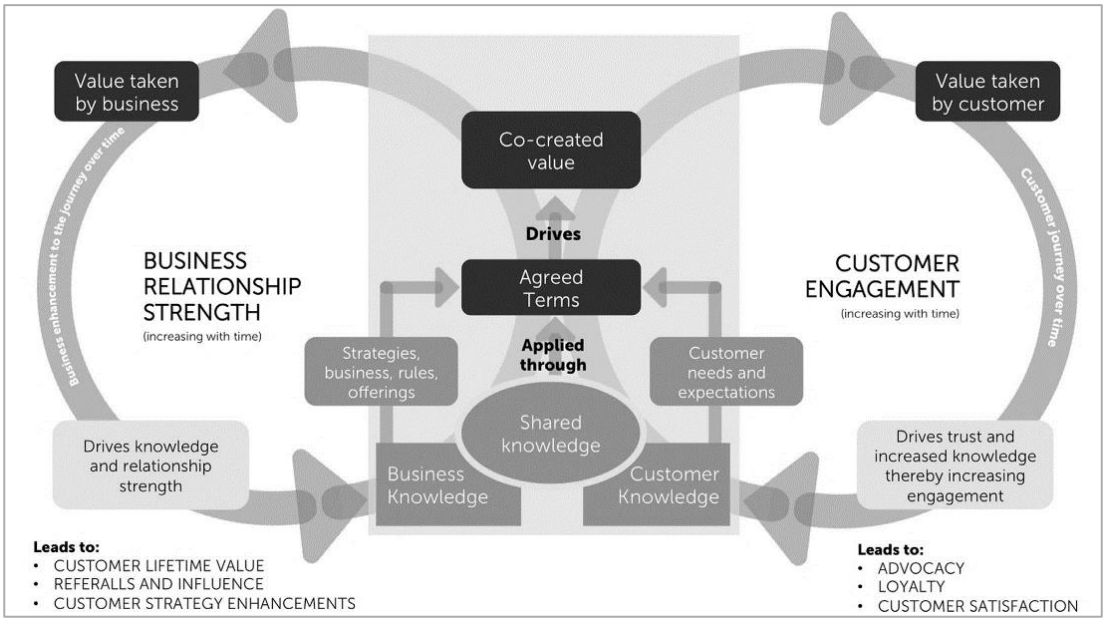


Figure 6. ThunderHead's Customer Engagement Model

The aim is now to convert the tacit knowledge to explicit, as described by Ikujiro Nonaka in The Knowledge-Creating Company (Nonaka, 2007)to make it functional and reusable. In order to create value for both the customer and the business, it becomes important to align the needs and expectations of both the parties involved i.e. the customer and the business. This facilitates both the parties involved to create value from the engagement – and thus referred to as co-created value. The customer determines the value, but it is the business that creates a context at each point of interaction in which the desired value can be co-created.

Thunderhead sees the following (Figure 7. ThunderHead's Key Principles) as the five key principles to deliver good experiences, which build engagement leading to customer satisfaction:

PERSONALISATION	CONTEXTUALISATION	RELEVANCE	KNOWLEDGE	JOURNEYS
Interactions and experiences need to be personalised if engagement is to be built, and must be rooted in an accurate understanding of a customer. Interactions should be tailored from, and informed by, customer preferences, customer information and insights from their journey behaviour.	Businesses need to provide a tailored, adaptive and often predictive experience informed by context. Taking the elements that enable personalisation (profile and history context), in addition knowing what stage and situation a customer is in at a particular time (journey and location context) and how they are technologically interacting at that time (device context) informs an interaction that is contextually appropriate for the customer.	To build effective relationships with customers, businesses need to ensure their interactions are relevant and appropriate. This means for example, not offering a great bank account deal for married couples, when the customer is in fact single.	Trust is an essential component of the engagement equation and can only be generated by using the knowledge that a business has of a customer to shape and inform its interactions at all customer touchpoints. With trust, the knowledge exchange deepens and in turn improves each individual experience and over time the more personalised, contextual and relevant the interactions, the greater the degree of engagement.	Customer engagement is built over the longterm, and requires the ability to look beyond individual interactions and focus on the endto-end customer journey. Effective engagement strategies mandate the ability to evaluate the journeys a customer is on, and align and adapt experiences and measurements accordingly.

Figure 7. ThunderHead's Key Principles

4.2 Understanding the customer

As we talk about the customer engagement model it is crucial to understand the customer at this point in time. The author here takes a pause to understand what makes our customer base and how much aware are they about the general idea of clinical trials. It is based on this basic insight that anyone can now create a methodology to tackle the problem. The author uses the patient perception survey (finding explained below) to gather insights on the general awareness on clinical trials.

Case Study 2: Patient perception survey about clinical trials

Aim: To understand if the general population is aware of the clinical trials and do, they consider it to be a viable treatment option if needed.

Participants: As elaborated in section 1.3 Design/methodology/approach

Procedure

- Patients were connected on Facebook via support groups of clinical trial participants.
- A survey questionnaire was shared with them to gather their feedback (Appendix 3)

Findings:

Amidst the general public there are a variety of several misconceptions about Clinical trials like: -

- Only ill people can participate in a clinical trial
- Children cannot participate in a trial
- All trials are related to testing a new medicine while it can also be related to testing a therapy or device.

- Participants must be approached by the pharmaceutical company and the participant cannot approach the clinical trial to participate.
- 85% of the participants are unwilling to participate in clinical trials as they consider it to be dangerous as they test new medicines.
- 88% of the participants consider that the regulatory environment in India is unreliable.
- Being in a clinical trial is expensive and isn't covered by medical insurance.
- Informed consent is a mere formality of signing a piece of paper.
- Do not know that patients can help in designing a trial

Conclusion:

The above survey can be used to indirectly indicate the mindset of the general Indian population that is not aware about the concept of clinical trials and have developed within themselves several misconceptions that dissuades them from proactively generating awareness about clinical trials and considering it as an option of treatment for the several medical ailments they suffer from or contributing to science for the greater good of mankind.

Having concluded the patient perception part of current clinical trials it is also important to understand the willingness of patients to participate in clinical trials. The authors captures this using a survey the findings for which are captured in the below-mentioned case study.

Case Study 3: Willingness to participate in clinical trials

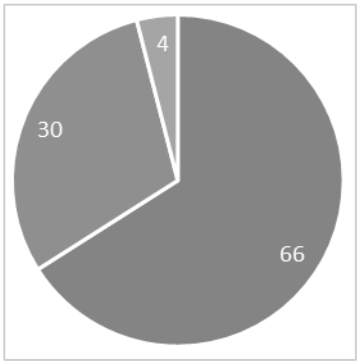
Aim: To gauge the general awareness of people about clinical trials and their willingness to participate in the clinical trials

Participants: As elaborated in section 1.3 Design/methodology/approach

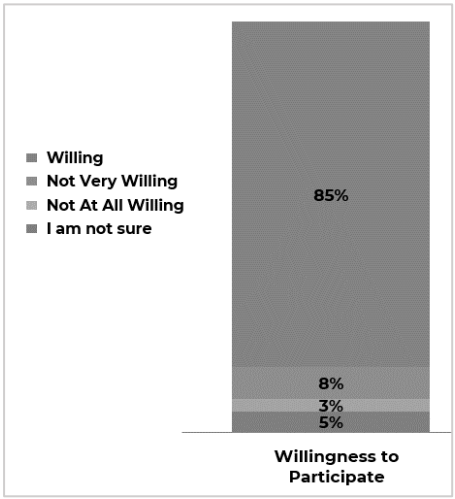
Findings:

General Information on clinical trials

- Almost 30% of the participants had no/very less information about clinical trials.
- Almost 66 of the participants had heard about clinical trials before the survey.
- Only 4% of the participants had known anyone (even in a distant circle of friends) who participated in a trial.



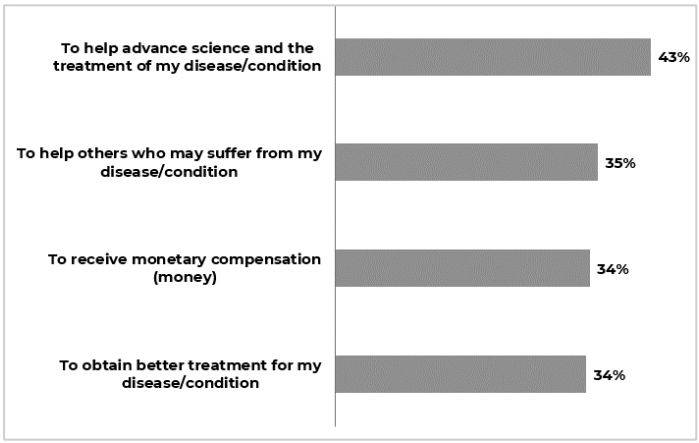
Willingness to participate in clinical trials



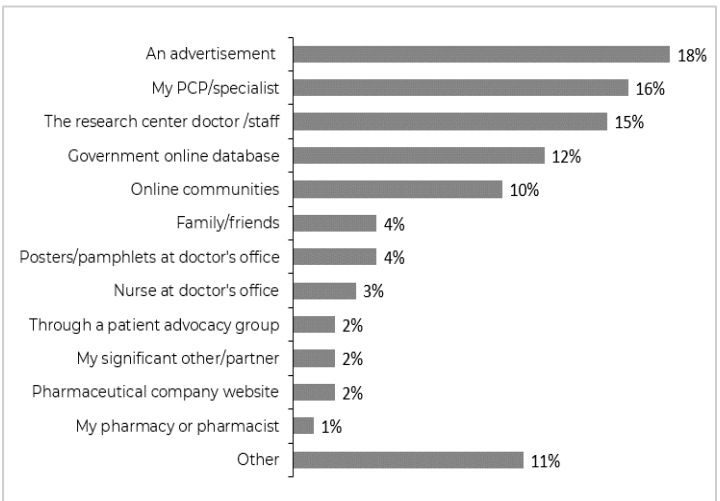
- Almost 85% of the participants were willing to participate in a clinical trial.
- Almost 8% of the participants were not very willing to participate in a clinical trial.
- Only 3% of the participants were not at all willing to participate in a clinical trial.

Reasons to participate in clinical trials

- 43% of the participants were willing to participate in a clinical trial to help advancement of science to achieve better treatment.
- 35% of the participants were willing to participate in a clinical trial to help other who suffer from diseases.
- 34% of the participants were willing to participate in a clinical trial for the monetary benefits and to obtain better treatments for their ailments.



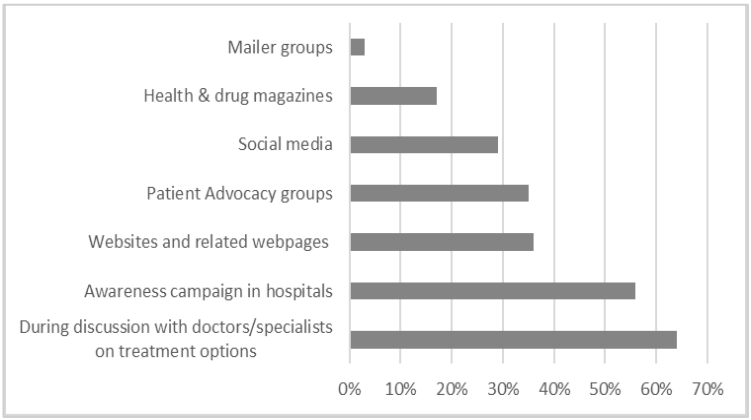
Sources of information on clinical trials



- 18% of the participants get to know about clinical trials via advertisements.
- 16% of the participants get to know about clinical trials from their doctors.
- 15% of the participants get to know about clinical trials from the doctors/staff at research centres.
- 12% of the participants get to know information from CTRI.
- 10% of the participants get to know information from social media communities

Preferred ways to learn more about clinical trials

- 64% of the participants prefer discussing with doctors/specialists on treatment options.
- 56% of the participants prefer awareness campaign in hospitals.
- 36% of the participants prefer Websites and related webpages.
- 35% of the participants prefer Patient Advocacy groups.
- 29% of the participants prefer Social media



Conclusion

The general public lives with several misconceptions about Clinical trials and these need to be countered. At the same time people are willing to participate and to be a part of the process for the greater good of mankind. With focus on patient centricity, the aim of any pharmaceutical company should be to enable people to understand the purpose and motive for conducting the clinical trial.

4.3 Applying the customer engagement model to clinical trials

As advised above let's implement the concepts of customer engagement to patients. For this we use the concepts of The Thunderhead's Engagement 3.0 model as described in section 4.1 an apply to the functioning of a clinical trial. Concepts of the marketing funnel by Elmo Lewis have also been used to build the concept.

The author conducted interviews with Mr. X, a Senior Pharma Business Strategist at a leading Healthcare company in India and Ms. Y, Head of Communications for Global Drug Development at a leading Pharmaceutical company in India to understand how to introduce patient centric models in India.

Summary from the interviews:

- Some companies have made huge efforts towards achieving patient centricity worldwide while others are trying to take mini steps towards it.
- It is critical to empathise with the patients' experience, their values and needs. They are the centre of business.
- Today patients are unaware of the offerings and blindly follow the prescriptions from the doctors. This makes it critical for the pharmaceutical companies to utilise the social media platforms to generate awareness among common public.
- New capabilities should be built dedicated towards patient centic care to hears them out and understand their needs well before claiming to provide with solutions.
- Based on patient portfolio strategies need to be created to focus on each group with a varied channel mix.
- Firms should collaborate with other industries such as IT, telecom, food, and fitness to deliver 360-degree treatment and experience to patients.

- Companies should make their aim and vision clear. With increasing companies claiming to work towards the development of patients, it becomes critical to understand how one company's offering is different form the other.
- It is important to build trust among the patients. There is a lack of trust among the patient community towards clinical trials due to the increased number of unreported deaths and adverse events in the early periods. The medical community needs to put in high efforts to get rid of the mistrust.
- Patients need to feel they are heard.
- We need to remember that clinical trials are for patients and that the development of new medications is solely to ease their pain and suffering.

Combining the concepts from 'The Thunderhead's Engagement 3.0 mode' with the Concepts of the marketing funnel by Elmo Lewis and the summary elaborated above the author puts forward the below mentioned model. The customer engagement model has been repurposed as follows to facilitate the development of a model to help engage patients better in a clinical trial.

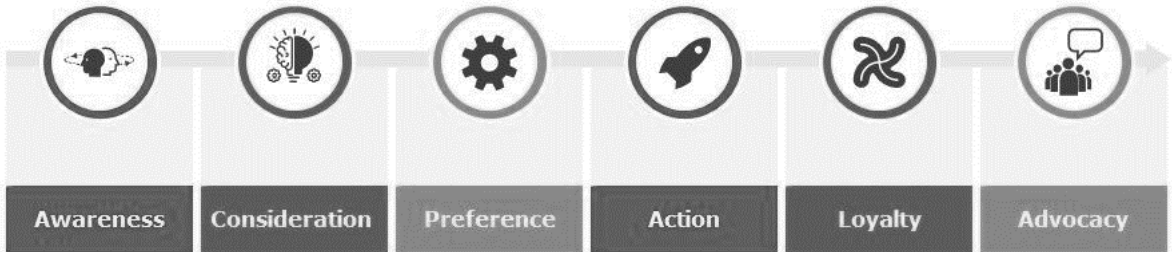
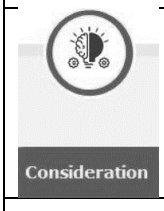
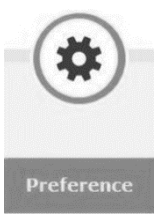
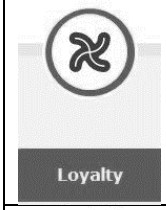


Figure 8. Stages of patient engagement

Stage	Key Purpose/ Goal
	The very first step should be creation of awareness. In terms of marketing, if your customers don't know you and your products, they cannot, and will not buy from you. The pharmaceutical company's goals and mission should be made clear to the customers/patients. Companies must market themselves and create awareness about how they hope to bring a difference. This stage needs to be handled differently for different countries. Indian GCP has laid down strict guidelines for the advertisement of a clinical trial, that should be followed.
	Once the target audience is identified, determine the needs. Also, once a customer/patient is aware of you, they will consider your offering. They will determine if your trial is something they want or need and if they are willing to participate.
	On an interview with a Senior Manager at Novartis, he says: "Don't presume the patients know exactly which trial suits them. They need to be educated and guided to trials that suit them". And it is this education combined with certain deciding parameters like: - Previous clinical trial success rates of the company. Adverse effects in clinical trials conducted before by the company. Company reputation (in general) help patient set their priorities.

	Based on the steps above the patient decides to participate in a trial and contacts the company/ site/ clinical trial personnel. As the patient shows interest in the trial, he/she is tested for the inclusion /exclusion criteria of the trial. In case the patient is found fit to participate he/ she is enrolled.
	One of the most crucial steps, that develops trust between the patient and the trial team. This step determines if the patient stays till the end of the trial or drops out during the process. This stage should implement the Thunderhead's customer engagement model to co-create value and achieve trials goals
	Patient experience and empowerment enables them to advocate for clinical trials of a brand or product through word of mouth. In addition, every customer has access to digital media. Social media connects patients with other prospective patients This is a great way to provide value to your most helpful customers by leveraging the power of social amplification.

4.4 Deep Dive

4.4.1 Awareness

Based on the findings from Case Study 2: Patient perception survey about clinical trials, it is clear that patients are not aware about clinical trials and the plethora of options it leads for their medication. Thus, it becomes important to engage patients.

The Hindustan Times on 26 DECEMBER 2020 reported: **'Bharat BioTech's Covaxin phase III trials face shortage of volunteers in Delhi, Mumbai & Bengaluru'** (TimesNow, 2020)**.** Phase III trials of Covaxin have struggled to recruit even 500 participants in the mega cities of Delhi, Mumbai and Bengaluru.

Studies claim that many of the findings from Case Study 2 could be the contributing factors for the same. Thus before trying to find a solution to 'How' to generate awareness among the people on the clinical trials and how they can inform keep themselves informed to make well thought decisions it is important it is important to understand them and their willingness to participate and contribute to the process.

4.4.1.1 Awareness- Industry practice and lessons learnt

Due to limited transparency of clinical trial data caused by the unclear and a non-streamlined process many of the clinical trials go unnoticed even by the medical fraternity. As seen in **Case Study 3** for a patient the doctors are the most preferred source to gather information about clinical trials. Considering this several pharmaceutical companies in EU and US have started to conduct regular sessions/webinars for the medical association to not only apprise the community on regular basis of their achievements on drug development but also gather inputs from the vast experiences these doctors have gathered over the course of their practice.

From **Case Study 3** we see that websites/ social media are also one of the majorly preferred medium to gather information about clinical trials. In today's time social media plays a crucial role - connecting people, sharing information and enabling businesses to meet their customers. Thus, making it a critical tool to introduce an idea and spread a message. Increasingly companies are using social media campaigns to target an audience that is widespread, rapidly and in a cost-effective manner. Thus, facilitating communication and recruitment using both passive and active methodology. Passive where posting recruitment materials in specific locations like hospitals, clinics and clinical websites so that patients can contact the trial team and active where the trial team/ researchers can approach prospective trial patients. (O'Regan, 2018)

Most of the Indian population is online and almost 80% use the Internet to acquire information. It has been seen in the past that social media has provided an infrastructure for trial investigators to connect with the masses in ways that stimulates interest in new clinical trials with targeted messages to connect patients, caregivers, and families and directing them to potential trial enrolment websites. The below mentioned approach in Figure 9. Clinical Trial awareness process has been developed by studying clinical trial websites developed by 3 major pharmaceutical giants: Bayer, Boehringer Ingelheim and Merck.

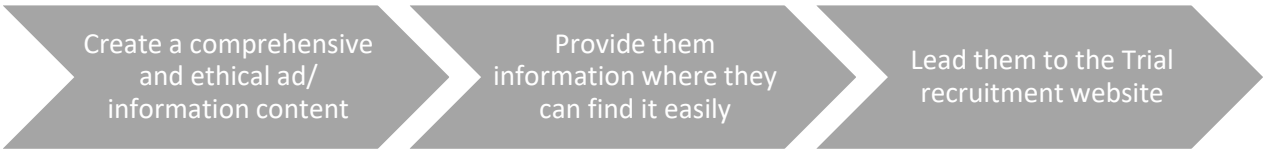


Figure 9. Clinical Trial awareness process

While creating content to be published on social media regarding clinical trial, focus on 'What's In It For Me? (WIIFM)'. Patients should be offered enough information on the research in addition to listing any potential benefits. As every creative content related to a clinical trial should be approved by the ethics committee ensure the content is balance. The benefits id participating in the clinical trial shall be highlighted to the potential participants and they should be provided with incentives.

How can we motivate the people?

- Individual Learning – Motivate participants intrinsically explaining what they might learn from the research. Help them learn about themselves and their condition.
- Impact on Society: ensure your recruitment material lists the ways your participants can help advance medical research, and the impact the results could have on society. How will society benefit from your study? What are your perceived changes and how will they affect patients in the future? This will certainly boost enrolment numbers.
- Potential Improvement- If your patients can gain any potential improvement from your study, be it exercise, or a boosted immune system, try using this as your headline.
- Be Credible- People generally have a distrust of studies; combined with the label 'human guinea pig', we have ourselves quite a challenge. overcome that perception–
- Make It Personal: establishing and developing a relationship with your participants Telling your participants a bit about yourself elevates your credibility.
- Make It Human- Humans are social creatures, and we're more likely to trust in someone if we can identify with them. be relatable, not shocking.
- What Next? - Lead them to your recruitment portal.

The recruitment portals are no longer just for the purpose of recruiting the people but more to support the patients. As Mohammed Ali, Global Head of Digital Development, Global Clinical Operations at Boehringer Ingelheim, says: "This initial release of MyStudyWindow represents an important step towards our vision to bring patients and physicians closer to the clinical trials environment. We plan to establish a next-generation platform empowering patient who consider participating in or to learn about Boehringer Ingelheim studies and research. In addition, we aim to support doctors to find the information they need to consult on and pursue a well-informed treatment." (HealthcareFacilitiesToday, February 27, 2020)

4.4.1.2 Evolution of clinical trial transparency websites of pharmaceutical companies

Then

As in Figure 10. Merck's Clinical Trial repository 2018and Figure 11 it is evident that there used to be clinical websites that merely showed an itemized list of conditions and the studies run by

FIND A STUDY

Like 0 Tweet PRINT

STUDY SEARCH RESULTS

1608 studies found for your search request: All Studies

REFINE SEARCH | Notify Me when this search is updated

Study Title	Study ID	Condition	Status	Minimum Age	Maximum Age	Gender
[11C]MK-6884 Positron Emission Tomography (PET) Tracer Validation Trial (MK-6884-001)	NCT02621606	Alzheimer's Disease	Completed Has Results	18 years	85 years	Both
[18F]MK-3328 as a possible novel positron emission tomography (PET) tracer for the detection of brai...	NCT01385033	Alzheimer's Disease	Terminated (Halted Prematurely)	18 years	85 years	Both
[18F]MK-6240 Positron Emission Tomography (PET) Tracer First-in-Human Validation Study (MK-6240-001)	NCT02562989	Alzheimer's Disease, Amnestic Mild Cognitive Impairment	Completed	18 years	85 years	Both
18F-FLT-PET in Breast Cancer (MK-0000-139)	NCT01015131	Breast Cancer	Completed Has Results	35 years	75 years	Female
30-Week Extension to an Initial Combination Study (24 weeks in duration) of Sitagliptin With Pioglit...	NCT01028391	Type 2 Diabetes Mellitus	Completed Has Results	18 years	N/A	Both

Figure 10. Merck's Clinical Trial repository 2018

Study Details | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Study Type	Interventional
Study Design	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double (Participant, Investigator); Primary Purpose: Treatment
Condition	Type 2 Diabetes Mellitus
Interventions	Drug: Sitagliptin 100 mg q.d.+ Pioglitazone 45 mg q.d. Drug: Pioglitazone 45 mg q.d. + Sitagliptin 100 mg placebo q.d. Drug: Metformin
Enrollment	317

Participant Flow Go to

Recruitment Details	First patient in the 30-week extension study: 21-Sep-2007. Last patient last visit of the 30-week extension study: 23-Jan-2009; 53 study centers worldwide.
Pre-assignment Details	Patients ≥18 years with type 2 diabetes mellitus (T2DM) and hemoglobin A1c (HbA1c) of 8-12% on diet/exercise meeting all other entry criteria were eligible for participation in the 24-week base study. Patients who completed the base study with >75% study drug compliance were eligible to enter the 30-week extension study at participating sites.

Arm/Group Title	Sitagliptin 100 mg q.d. + Pioglitazone 45 mg q.d.	Pioglitazone 45 mg q.d.
Arm/Group Description	The Sitagliptin 100 mg q.d. + Pioglitazone 45 mg q.d. (q.d. = once daily) group includes extension study data from patients who received once-daily coadministered treatment with oral tablets of sitagliptin 100 mg and pioglitazone 45 mg. During the 24-week base study (prior to the entering the extension study), these patients received once-daily coadministered treatment with oral tablets of sitagliptin 100 mg and pioglitazone 30 mg.	The Pioglitazone 45 mg q.d. (q.d. = once daily) group includes extension study data from patients who received once-daily coadministered treatment with oral tablets of placebo to sitagliptin 100 mg and pioglitazone 45 mg. During the 24-week base study (prior to entering the extension study), these patients received once-daily coadministered treatment with oral tablets of placebo to sitagliptin 100 mg and pioglitazone 30 mg.
Period Title: **Overall Study**		
Started	164	153
Completed	150	142
Not Completed	14	11
Reason Not Completed		
Adverse Event	4	0
Lack of Efficacy	0	2

Figure 11. Merck linked CT results on ct.gov in old website

the company. These websites existed merely due to industry-wide transparency policies to disclose all trials and their results within due course of time.

The characteristics of the above shown website are as follows: -

- Study title same as the Clinical trial protocol that possibly could be very technical for people to understand.
- Trial synopsis and summary often linked to the study – these documents are also very technical and are ideally used by researchers in their research work.
- Recruitment criteria- often mentioned as the inclusion and exclusion criteria.
- No additional information provided to the patients, have to search separately via other search engines.
- Standalone website which must be specially searched to view the clinical trials conducted by/ for a pharmaceutical company.

Now

Currently several companies have updated their clinical trial website keeping in mind the end user and with the aim of making these websites the one stop solution for the patients to find all related info (See Figure 12, Figure 13. Boehringer Ingelheim's MSW educates patients on clinical trials Generating awareness among the people about clinical trials to providing them access to clinical trial results translated in a language that can be easily understandable by common man.

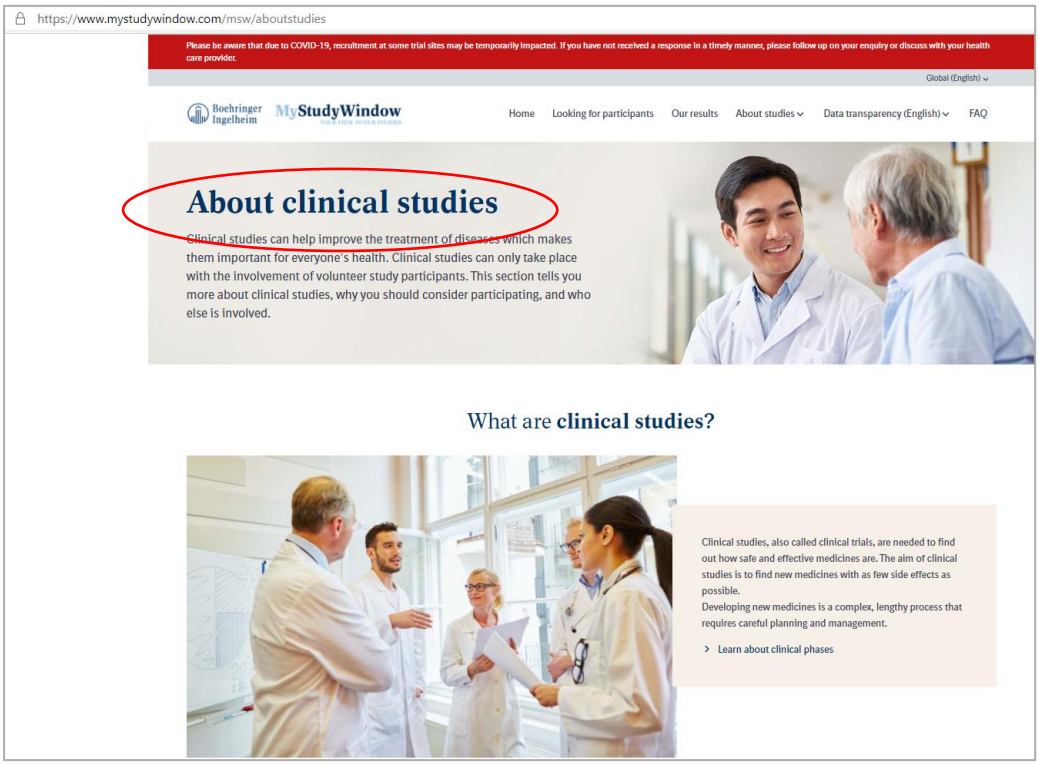


Figure 12. Boehringer Ingelheim's MyStudyWindow launched in Dec 2019

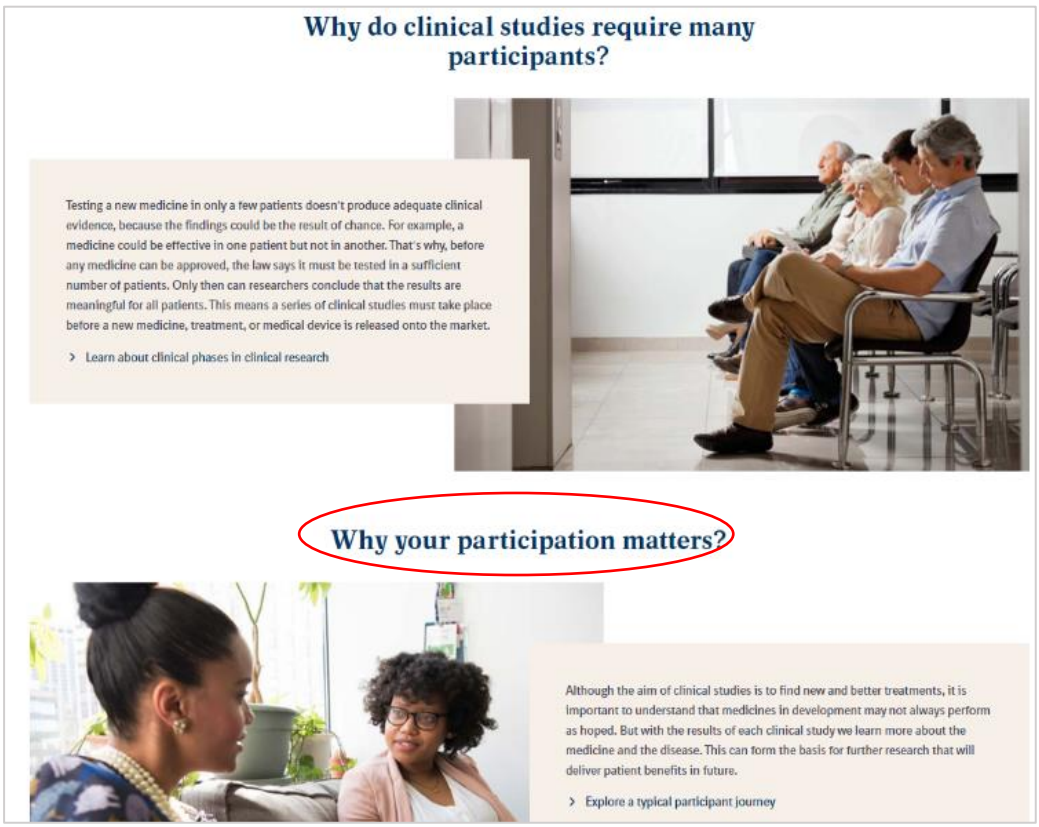


Figure 13. Boehringer Ingelheim's MSW educates patients on clinical trials

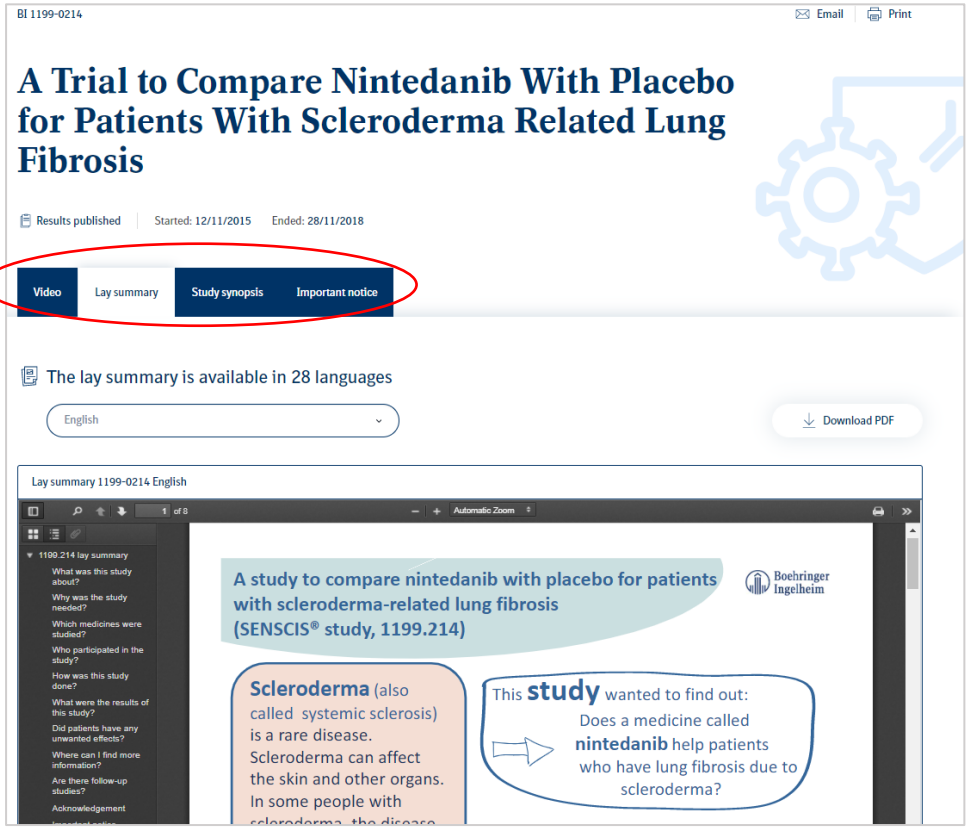


Figure 114. Clinical Trials results shown as Lay summaries for ease of understanding

The characteristics of the above shown website are as follows: -

- Study title is a simplified title written specially in a non-technical format for people to understand.
- Trial synopsis linked to the study – this document is same as that disclosed on clinicaltrials.gov to help researchers in their research work.
- Special Lay Summaries maintained that are trial results translated in simple lay language.
- Additional information provided to the patients, to help them develop clear understanding of their health condition and what type of trials they should be searching for.
- The websites are a complete repository of information to avoid juggling between different website and fall prey to incorrect in search separately via other search engines.

The pharmaceutical companies today aim to create standalone websites disclosing their clinical trials that are completed or still recruiting, specially curated keeping in mind the people who would need it the most like patients, health care professionals, care givers and researchers.

4.4.1.3 Company's mission and credibility

During the phase of 'Awareness' it becomes important to communicate the pharmaceutical company's goals and mission and market themselves to create awareness about how they hope to bring a difference to the lives of mankind. The vision and mission are the most crucial elements of this stage as it informs the patients that its not a journey alone

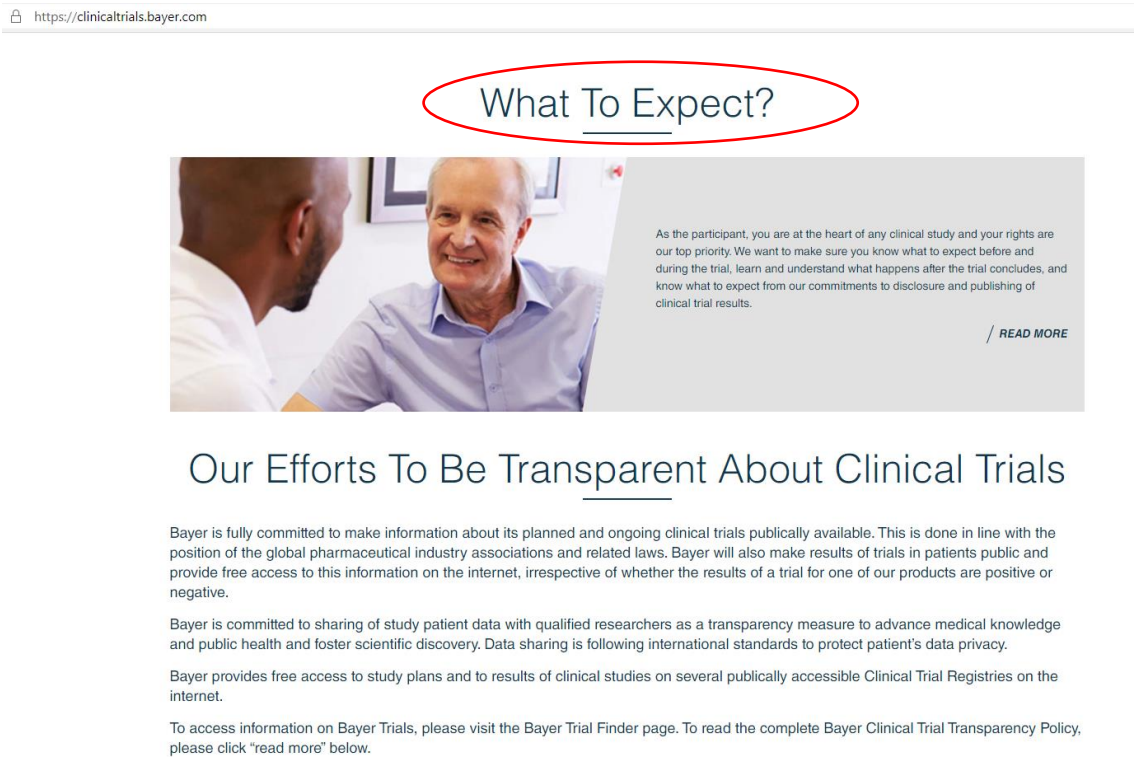


Figure 15. Bayer communicating it vision with the transparency website

4.4.2 Consideration

In this stage the key stakeholder is the patient/ health care professional who is interested in getting information about the clinical trials. And in order to take these stake holders to the above described websites it is important to 'Create a comprehensive and ethical ad/ information content' as described above.

4.4.2.1 Consideration - Industry practice and lessons learnt

As per the general public their morning social media routine includes scrolling through newsfeeds and sharing videos, but there is also a group of people who would like to use social media differently. Social media for them shall be source to their health condition-specific information regarding clinical trials, possible treatment options and tips/ mechanisms to make their treatment journeys less painful. In order to facilitate this several pharmaceutical companies are using the concept of Patient Leader Creative (Agati, 2019).

Patient Leaders are generally people who belong to health care industry and are widely followed on social media. They are seen to share relevant and authentic information online every day and are trusted by their followers. It is seen that when information is presented by influential people (WEGOHealth, 2019):

- 93% of participants talk to their doctor/ health care professional about the information
- 94% of participants will share the information with other people whom they think might be interested in it
- It is more likely to be shared on social media than when shared by the organization/ pharmaceutical company itself.

Studies by WegoHealth show that custom campaigns featuring Patient Leader creatives have outperformed the redundant promotions (See Figure 16. Click through rate comparison between different campaigns). These promotions have received more shares, reactions, and comments leading to a higher click-through rate.

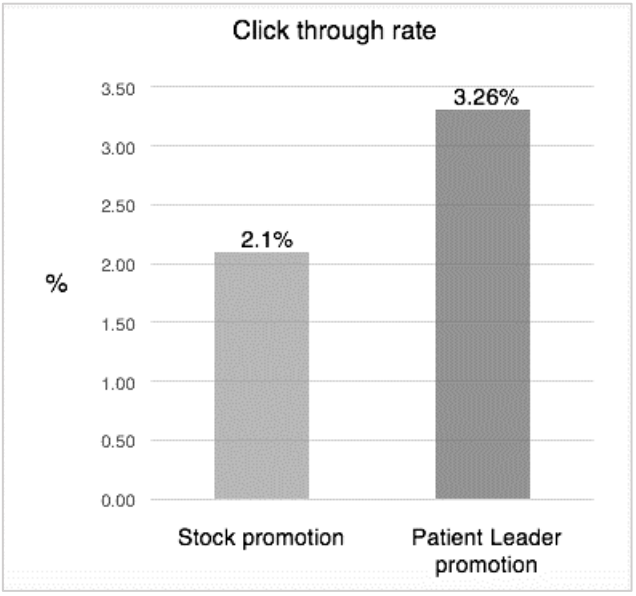


Figure 16. Click through rate comparison between different campaigns

4.4.3 Preference

In India, for the major population interested in Clinical trials investigator/ doctors are the only source to provide information and confirm if they are eligible to participate in any trial. As details of the trials in India are listed on CTRI, it becomes the responsibility of the doctors/ patients to go through the unending list of clinical trials and pick one which they would 'assume' to be the best choice. As mentioned earlier in an excerpt from an interview we shouldn't presume the patients know exactly which trial suits them. They need to be educated and guided to trials that suit them. It is important that patients feel comfortable in reading information about clinical trials and be able to make informed decisions for themselves.

4.4.3.1 Preference - Industry practice and lessons learnt

Companies today are placing the patients at the steering wheel to empower them and give them the confidence to take control of their lives. Patients are enabled to find their trial based on the answers to pre-determined eligibility questions related to their health condition (See

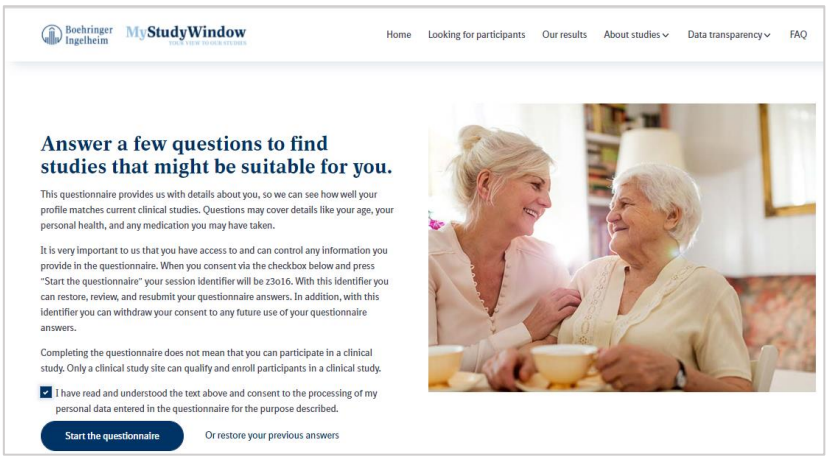


Figure 137. Boehringer Ingelheim's study finder portal

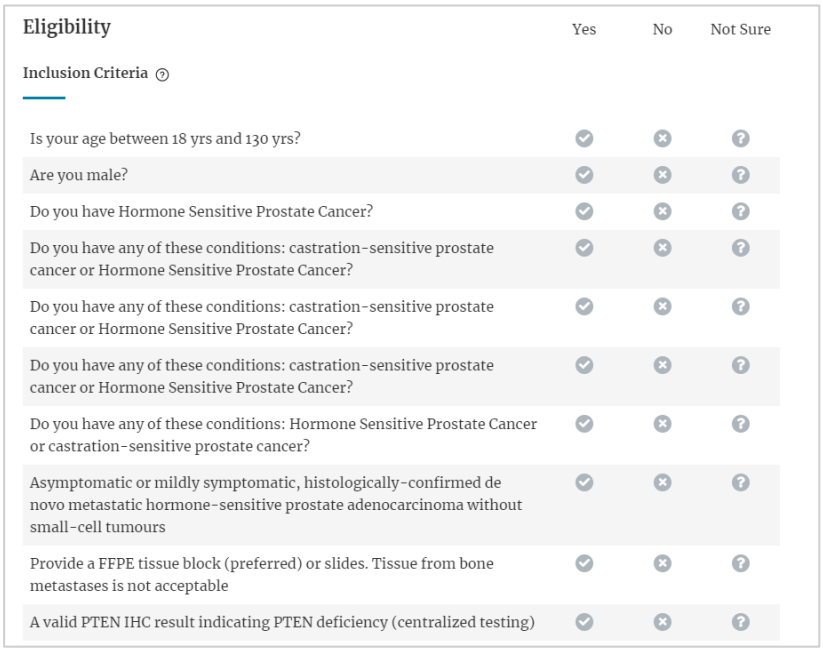


Figure 128. Bayer's Study finder questionnaire sample

Figure 137. Boehringer Ingelheim's study finder portal and Figure 128. Bayer's Study finder questionnaire sample).

Studies prove that patients prefer to make well educated decisions and participate in a trial that they can match to their health conditions. Today in India, we lack a platform where patients can investigate the details of clinical trials and understand the nuances. All involved parties are forced to browse through CTRI which is poorly maintained by the government, making it a point to worry for the common man and not rely on the data shared publicly.

4.4.4 Action

In this stage as the patient has now already reached the website, he/she is in a position to decide which trial to participate and can contact the company/ site/ clinical trial personnel based on the decision. A vast majority of the Indian population is forced to use doctors/ intermediaries to be able to connect with someone responsible for the recruitment process of the clinical trial. The Yale Centre for Clinical Investigation (YCCI) has conducted focus group researches to understand perception of clinical research amongst the common public. Based on the research they implemented a programme - 'Help Us Discover' with the aim to move away from the one-off approach to a more global recruitment strategy that benefits a larger audience. The programme has shown the importance of harnessing the potential of the digital space and its ability to replace big budgets and wasteful spending across all business sectors. This approach has presented to all those with chronic conditions an opportunity to have access to top notch medical care and also in a unique way to contribute to the advancement of medical knowledge (ClinicalTrialsArena, 2012).

4.4.4.1 Action - Industry practice and lessons learnt

Based on 'Help Us Discover', the pharmaceutical companies are using technology to keep up with the needs of the industry. The latest tools are enabling them to stay on the cutting edge of patient recruitment strategy worldwide.

Clinical Trial Finders have been adopted by various international pharmaceutical companies to bring together trustworthy and reliable information on all existing and upcoming trials that are sponsored by the company. The Trial Finder are specially designed for patients, caregivers and healthcare professionals to provide accessible and comprehensive trial information. Search filters enable users to find trials relevant to them and download the information to study offline and contemplate. Several third-party service providers like

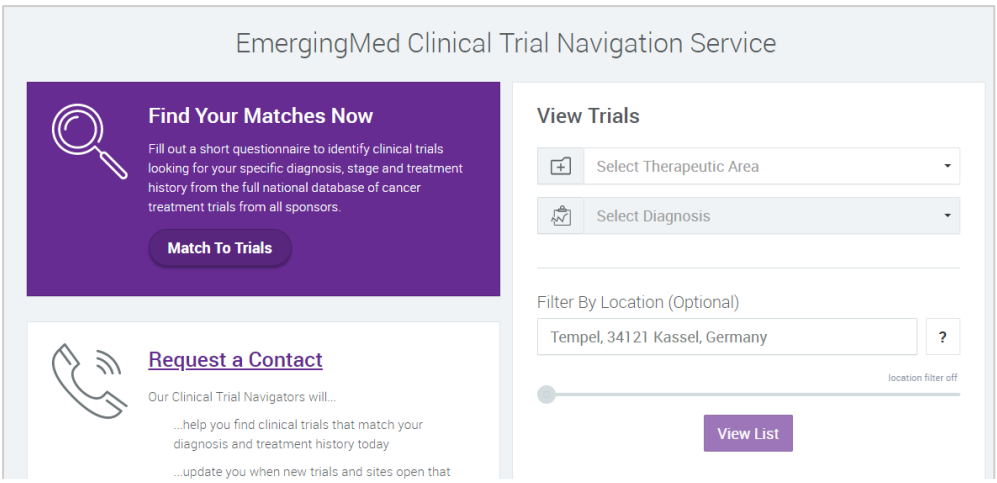


Figure 149. Clinical Trial Navigation Service by EMed

EmergingMed are developing such platforms incorporating the requirements of the users to provide them a seamless experience.

The aim of the Clinical Trial Finder is to help patients find the requisite trial; thus, its job doesn't end at shortlisting the trial as per the eligibility criteria. It should also enable the patients to contact the site directly without the need of a middleman. Websites/ applications that only shortlist the trials do not effectively lead to patients contacting the sites for enrolments, rather the patients tend to terminate their search and find another medium to find the required trial.

Clinical trial finders from Boehringer Ingelheim have incorporated the contact details of the site to enable patients to contact the site and verify directly their eligibility.

Figure20. Boehringer Ingelheim enabling patients to contact sites themselves

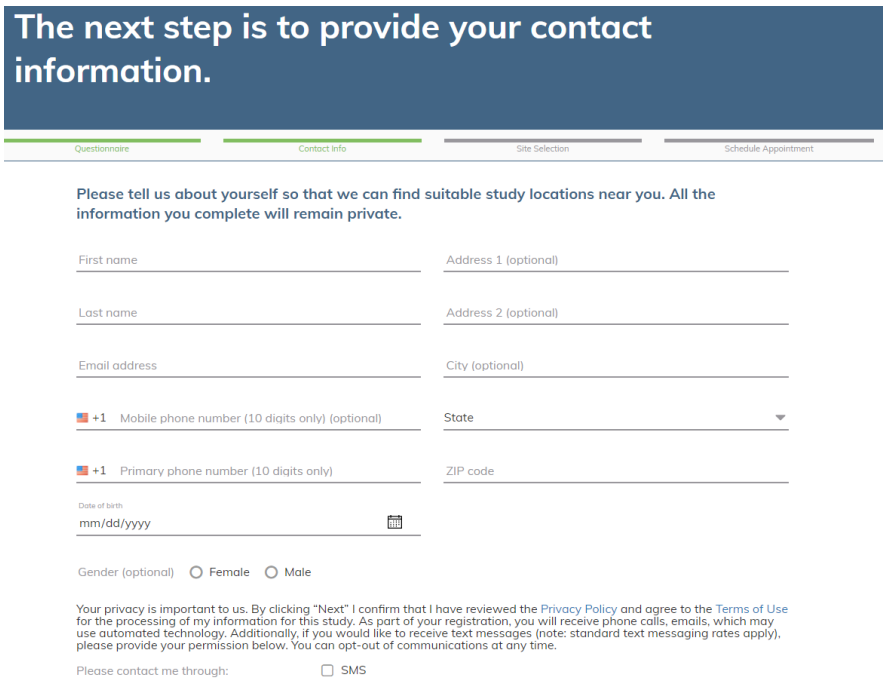


Figure 215. Johnson& Johnsons trial finder enables scheduling of an appointment with the site

A survey was conducted using the same set of audience as of Case Study , it clearly showed that the participants preferred Johnsons & Johnsons method of providing the user with options of the sites where they can participate and then schedule an appointment with the site contact person to take the discussion forward. This takes the ownership of the follow up activities from the patient to the trial coordinator at the site. The patient can now relax while his case is studied and being taken care of.

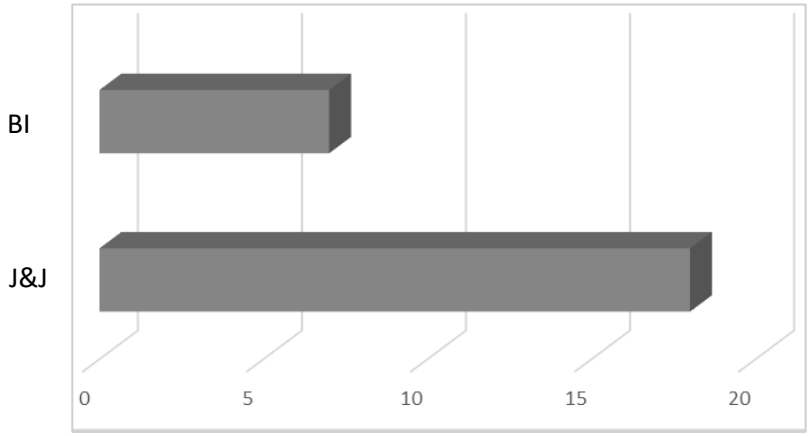


Figure 22. Survey: Preference of the Clinical Trial model (BI & JnJ)

4.4.5 Loyalty

Having reached this stage, the patient would have decided to enrol into a trial or would have already been recruited for trial. Further journey now depends on how the patients are involved and incorporated in the clinical trial process. How the trial respects their participation and feedback become crucial for the process of developing loyal partnership between the organisation and the patients. We shall delve into the details in the section **Patient Engagement across clinical trials** below.

4.4.6 Advocacy

Over the course of the trial it becomes important to build mutual trust between the organisation, site, its staff and the patients. Moreover, patients must be constantly assured that their interest and wellbeing is the heart and soul of the trial. Patient turn to friends, relatives or family doctors for an opinion before filling the informed consent form in the trial. And this is when patient who have previously participated in a trial or a community of clinical trial volunteers can take the role of Patient advocates. They play a crucial role to make the patient feel reassured about their participation and facilitate in patient retention. Patient advocates also communicate the credibility of the process and the trial conducted by sharing their personal experiences or experiences of people they might have known. They also tend to provide the psychological support needed by the patients and their families.

4.4.6.1 Advocacy - Industry practice and lessons learnt

Pharmaceutical companies have been following the approach of creating Patient Advocacy groups or assign specific people the role of Patient Ambassadors who perform the following:

- Understand the end user and connect with them when needed.
- Provide guidance to the patients on how to choose and participate in the trial.
- Provide psychological support when needed.
- Support the local communication about the clinical trials

- Identify spots in local events within the city to share information about the platform
- Guide the user journey in the platform (how to navigate, how to make use of the search, etc)
- Know very well the portal and its functionalities and be able to describe it well to the users.
- Communicate with clarity and simple language how the organisation wants to empower clinical trials customers, especially patients
- Conduct demos with the audience using the portal / How to use the platform?
- Foster and support the development of local multipliers to support the spread of information.

5. Patient Engagement across clinical trials

In order to evaluate how to better engage patient in the clinical trials lets first divide the trial into stages based on the impact on patient life. Thus, the trial can be divided into:

- Pre-Study
- Development Plan
- Study start-up
- Study conduct
- Analysis and dissemination
- FDA approval
- Post approval

The below proposed engagement proposals is inspired by the Pharmaphorum webinar, held in association with the National Institute for Health Research (NIHR) on **Navigating the UK regulatory pathway to increase patient engagement with trials**, conducted by Sophie Evett (feasibility lead with Pfizer), Richard Stephens (patient advocate) , Keith Wilson (Patient research ambassador) and Gareth Powell (BDO, NIHR).

5.1 Pre- Study

A patient-centric trial means the patients are the flagbearers of the trial, leading all the others involved in the study. Patients being the major stakeholder it becomes critical to measure all the outcomes that are important to the patients instead of predefined parameters that are listed by some organisations that doesn't get directly impacted by the outcomes of the trial.

Traditionally, the measures for a trial were selected while creation of the clinical trial protocol by the trial leaders or based on the trial goals, but in recent years there has been an increasing drive to involve patients in the process, supported by the FDA guidelines. Patient preference information (PPI) and patient-reported outcomes (PROs) are developed based on reports that comes directly from the patient based on their perception of their health status and quality of life.

PRO's are scientifically designed, developed, and tested to capture the perceived health status in the participating patient population. Common types of PRO's are based on with rating scales or counts of special health events (e.g., no. of headache/ nausea episodes). Thus, PRO's enable the trial teams to measure what matters. Such measures are also of special interest with the FDA as it enables them to understand how a patient feels, functions, or survives (FDA-CDRH, 2016).

5.2 Development Plan

Studies say that clinical trial performance is enhanced by co-creating trial protocol and design with patients. This makes the studies more attractive and relevant to the participating patients and their families. Thus, increasing the rate of recruitment and patient retention.

Why is including patients in designing the trial important?

• The patients enrolling in a trial have a positive benefit-risk balance

• The trial endpoints capturing treatment outcome are most relevant to the patients.

• Trials are conducted ease patient burden

Involving patients in the design can help identify design elements that are of value to the patients and not only to the regulators. This would facilitate generating patient friendly communication, messages and materials that would help increase the rate of patient enrolment. Till date patient involvement in has been limited to be trial subject while trial design has been solely taken care by the pharmaceutical organizations (Young A, 2017)

In a recent study conducted to investigate the impact of patient and public involvement (PPI) on rates of enrolment and retention in clinical trials and explore how this varies with the context and nature of PPI, it was identified trials that engage patients in study design have a higher probability to enrol participant. Although the retention rates were not impacted by patient involvement in trials (BMJ, 2018). Also, in another study **'Assessing the Financial Value of Patient Engagement: A Quantitative Approach from CTTI's Patient Groups and Clinical Trials Project'** concluded that combining empirical data and subjective parameters obtained by engaging patients can potentially avoid protocol amendments and/or improve patient enrolment and retention leading to considerable monetary benefits to the sponsors of the trial (Bennett Levitan, 2018).

5.3 Study start-up

Traditional informed consent forms are tedious and it's a painful experience to understand it and agree to it and the end. Also, these consent forms, usually certainly paper and sometimes electronic - are not focused on the needs of the patient, thus making the experience bad. Enhanced and thoughtful design of Consent forms not only help improve the current process, but also allow researchers to understand how people absorb information to make an informed decision in a trial.

In a study conducted by the Association of Clinical Research professionals for the study 'Delving into eConsent: Industry Survey Reinforces Patient Centricity' it was seen that patients recommended the features like the ability to flag questions to discuss, multimedia tools and the ability to read consent documents offline as must haves (Pundir, et al., 2020). Incorporating such valuable feedbacks form the patients shall enable them to participate wholeheartedly in the trial.

5.4 Study conduct

During study conduct it is crucial to capture the feedback time to time. It facilitates in timely identification of gaps in the services provided during the clinical trial. Catering these gaps can potentially help in increasing patient engagement. A well-maintained healthcare feedback

system should be in place to capture timely reviews about each episode of care and translate them into the parameter that can be improved to avoid any future gaps.

How can Patient Feedback help?

- Decode Reviews: Gain additional perspective behind each review shared by the patients
- Manage Reputation: Patient can share review and feedback on online/ social media platforms that can be seen by other potential participants. A positive review can lead to referrals and create an online image of the sponsor if it is trustworthy and knowledgeable.
- Improvement of services and care: Help get a 360-degree view of the quality provided compared to the perception that the sponsor has. Several times it is observed that the patients are not vocal enough to voice their opinion, in such cases the patient feedback system shall help in capturing the details
- Competition: Help understand where the sponsors stands in comparison to the competitors wrt industry demand and business.
- Patient drop-out: identify gaps in the services provided and understand issues which might be affecting patient retention and your revenue.

5.5 Analysis and Dissemination

The key to gather support for a clinical trial in the form of patient enrolment and retention and support on social media boosting the company image is trust. And to develop this trust it is important to maintain transparency between researchers and patients.

Once the clinical trial data is locked and available for analysis it becomes important that patients also evaluate the results after the researchers have evaluated it. This is important because the objectives of both these stakeholders are different. An unacceptable event for patient could be an acceptable event for the sponsors. It also becomes important to explain the analysis to the patients. So that they are aware of the output of their contribution.

In order to communicate the results, the trial medical writers create lay summaries in local languages with graphics and illustrations that can facilitate in developing a clear understanding of the trial results in anyone reading the content.

Trial medical writers can work closely with Patient groups to understand their expectation and formulate the content for Lay summaries. The same could be used to develop advertisement campaigns for the trials in future.

5.6 FDA approval

The FDA is committed to protecting the participants of clinical trials, as well as providing reliable information to those interested in participating. Recently, unethical behavior on the part of some researchers has shaken the public trust and prompted the federal government to establish regulations and guidelines for clinical research to protect participants from unreasonable risks.

Although efforts are made to control risks to clinical trial participants, some risk may be unavoidable because of the uncertainty inherent in clinical research involving new medical

products. It's important, therefore, that people make their decision to participate in a clinical trial only after they have a full understanding of the entire process and the risks that may be involved.

5.7 Post approval

5.7.1 Post-Trial Access

As part of clinical trial patients are supported by the sponsors/ investigators in order to receive the medication/treatment on a timely manner as per the protocol. But there are several instances when patients need support even hen the trial is completed. This specifically happens in those scenarios where the market does not have any alternative to offer addressing their treatment needs.

It becomes important to align with patients who have been in this situation and formulate a standard process supporting the same. Several pharmaceutical companies within UK and USA have provisioned the feature of Post-Trial Access (PTA). As per PTA patients who have participated in the clinical trial shall be provided the medicinal product till it is commercially available in the market (Novartis, 2018).

Information related to PTA's should be added to Clinical trial protocols and Informed consent forms to make patients fully aware of the benefits they shall receive in such a situation.

5.7.2 Post marketing surveillance

This practice is critical to monitor the safety of a drug or medical device once it is available in the market. Clinical trials are conducted on a very low number of participants as compared to who shall consume the drug once it is available in the market. This post marketing surveillance (PMS) provides an opportunity to understand and identify and situation / condition that was missed during the trial. PMS captures information via database of direct reporting, monitoring events in case of prescription, electronic health records, patient registries etc. This data is then mined to provide the required information.

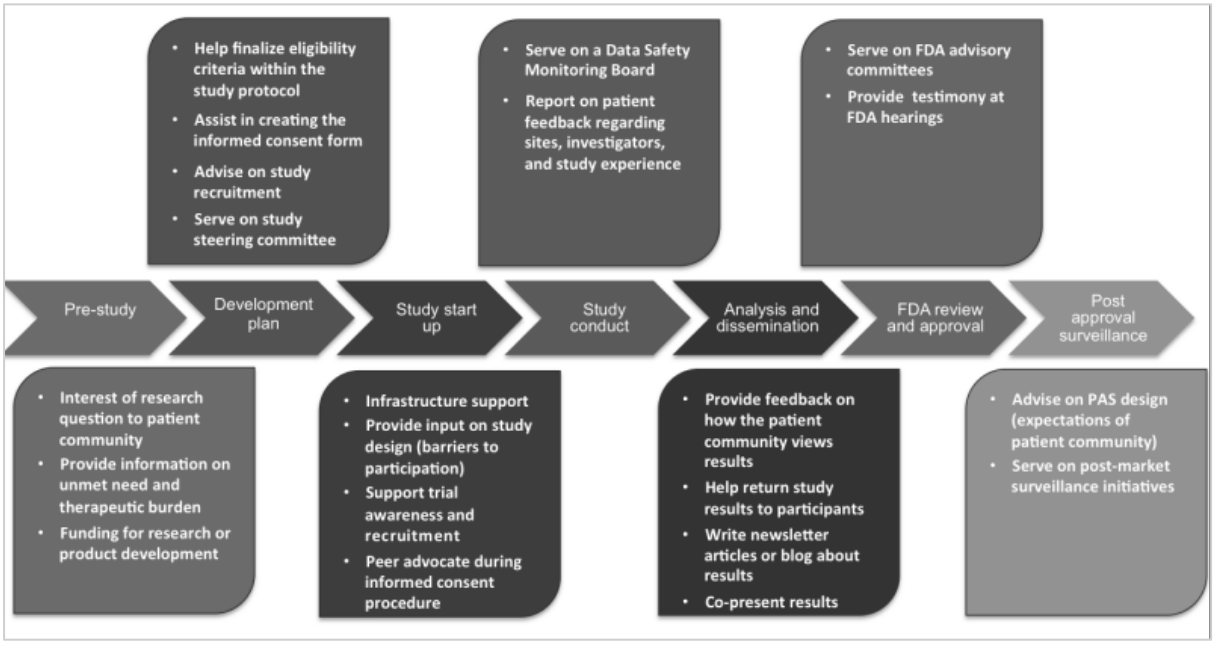
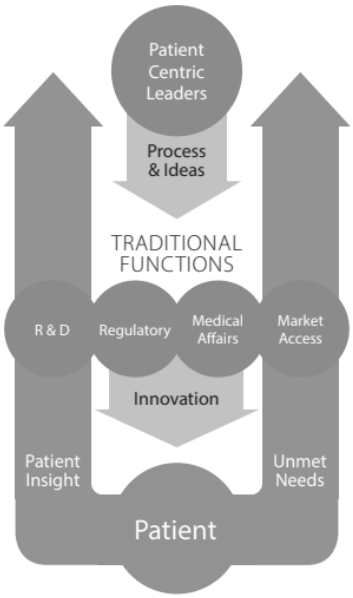


Figure 23. Summary of Patient engagement within a Clinical trial

6. Patient centric leadership

The pharma industry currently faces a shift from being product-driven to being patient-centric. But this paradigm shift can stay only with highly penetrative and long-lasting changes in the value system within the organization. This can be defined by the habits and attitudes of all of who are a part of the system which leads to development of standard process that could be incorporated into our Standard procedures. The current pharma business model has been functional since a several decades and has been successful in making this industry one of the most successful ones. Thus, it becomes really difficult to lead a change. Moreover, it is important to understand that managing an organizational change needs 3 parallel elements: individual, team and the organization itself.

To implement this change based on section x we can come up with the following approach. The leadership of a Patient-centric organization plays a crucial role in driving a change. It should send a clear and unified message for the patient/consumer. This prevents diluting the mission and avoid restricting it by capabilities, domain and capital. The purpose of a strong patient centric leadership should be as follows:



- Shape the patient centric culture in the organization top down
- Facilitate individual change
- Build the whole organization based on this culture by bringing together the teams.
- Ensure that the new culture sustains by modifying the standard operating procedure correspondingly.

A Senior Patient advisory group member at a reputed pharmaceutical firm says- 'An organization is guided by the vision set to it by the leaders. People watch their leaders and emulate them. They thus become the new role models. It becomes essential to increase employee engagement that leads to increase in productivity.'

She helps us understand what has helped her organization, a pioneer in pharmaceutical industry to grow towards their mission of achieving patient centricity.

- Culture is the main ingredient of the recipe.
- 'We are all in it together' – to ensure that a change is integrated in the culture, it must be embraced by all - from the leader to all levels of the organization
- Awareness of the benefits of the change – providing every member of the organization insights to the importance and benefits of the change.
- Coaching – Teach leaders and individuals at all levels to enable them to move away from the narrow customer-focused goals and metrics to a much more comprehensive and holistic approach
- Building momentum for the change, with the change and with all the employees
- Let the culture cross borders of the organization – align all the connected organizations, CRO, communities that are connected, regulatory bodies to enable

incorporating the organizational culture with relevant systems, key performance drivers and indicators, communications, and capabilities
- Adapt the governance structures to the culture
- Incorporate the culture in your daily routines such as meetings, decision-making processes, and measurement.

The degree to which each of the above mentioned are followed determines the degree to which the cultural change succeeds. Get them right and the conditions for a newly competitive, genuinely patient-centric organization can emerge.

6.1 Competencies in a Patient centric leader

As part of this thesis the author conducted a survey among 20 senior management professionals in various pharma companies that are champions of patient centricity on the characteristic traits of a patient centric leader. The survey was developed based on the Leadership Qualities Framework proposed by NHS Institute of Innovation and Improvement 2006. The participants were required to pick from the list the characteristics traits they felt were important in the leader of their organization. The traits are

- Facilitating transformation/cultural change
- Resource management
- Acting with integrity
- Relating to external stakeholders
- Teamwork
- Influencing strategic vision
- Embedding the strategy
- Strategic thinking
- Driving decision making
- Evaluating impact

Case Study 4: Patient centric leadership characteristic traits

Aim: To gauge the importance of characteristic traits in the leadership roles of patient centric organisations and rate the traits which organisation find more important over the other.

Participants: As elaborated in section 1.3 Design/methodology/approach

Findings:

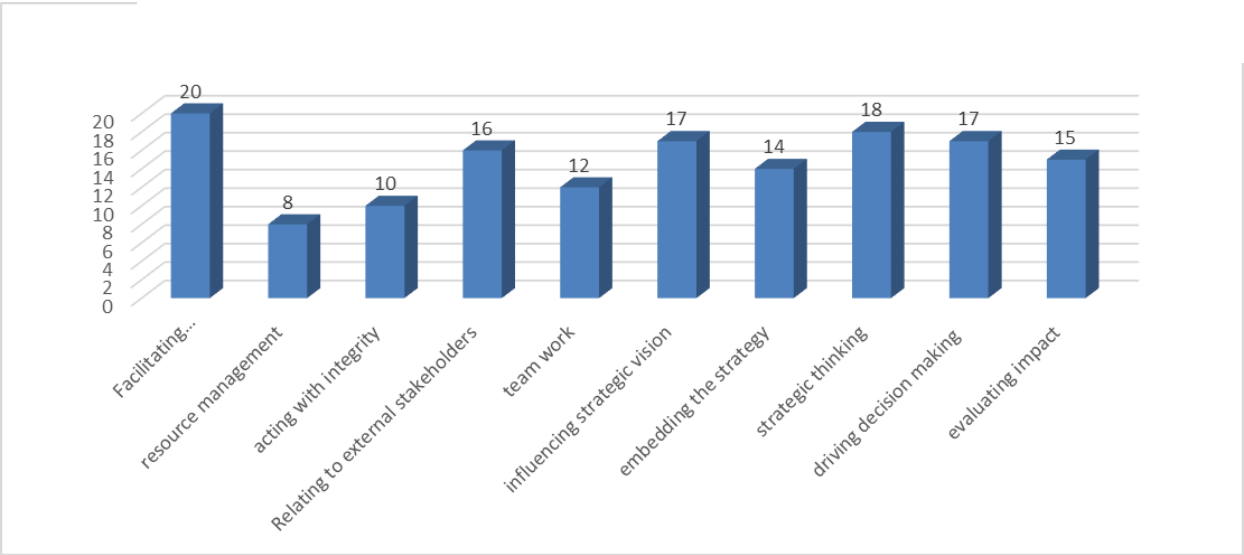


Figure 24. Survey results of the preferred traits for Clinical trial leadership.

As per the survey 'Facilitating transformation/cultural change' and 'Strategic thinking' was seen to be the most critical characteristic traits required in patient centric leadership

The patient-centric leaderships organisational structure varies depending on the organization. As per the interview with Mr. Z and Ms A, Patient Advocacy Group leaders at a leading Global Pharmaceutical company the following need to be considered by patient centric leadership:

- Leaders need to understand how the company is viewed by the patients externally carefully weave the process by which the company interacts with each one of them.
- Leaders must fully understand patient needs, articulate them clearly in the organization and partner with health care providers (HCP's) to facilitate better outcomes.
- Leaders should be able to refine developmental strategies to deliver value to patients.
- Leaders should focus on delivering tailored products and services, to differentiate their organisation from competitors.
- Leaders should enable making patient's experience as part of ongoing business reviews and strategy discussions.
- Leaders should make sure that "emotional/ soft" data isn't overpowered by financial criteria.
- Dedicate resources to gauge people satisfaction and experiences.
- Leaders should analyse the company culture and define methods to induce passion for a culture involving patient care.
- Enable other leaders to induce the same culture in their respective teams.

Figure 21. Patient centric Leadership and attributes elaborates on the competencies needed by the leadership teams to enable patient centricity and the key business/ personal/ influencing attributes.

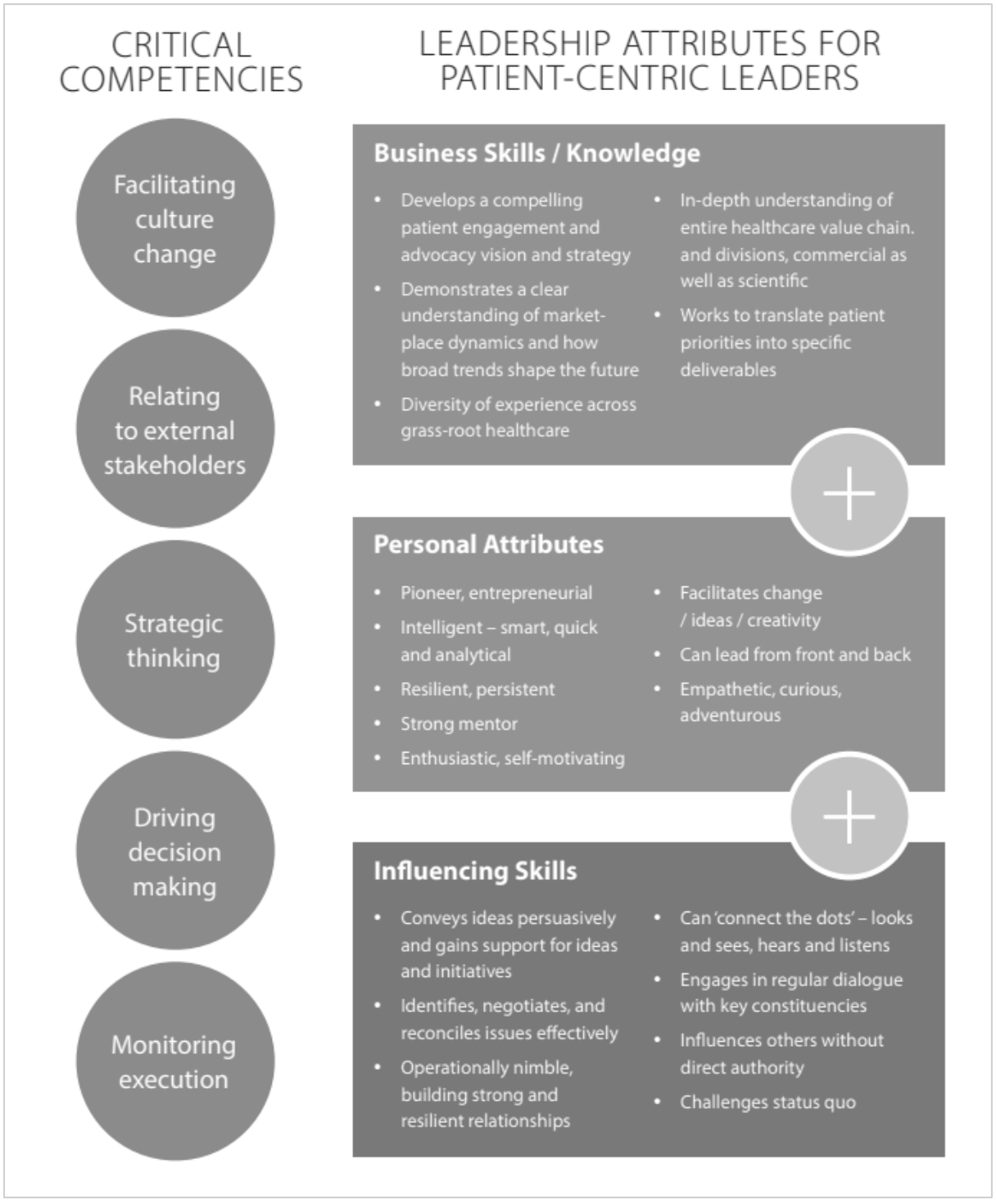


Figure 25. Patient centric Leadership and attributes

7. Pharmaceutical companies and Patient centricity

Over the last decade different pharmaceutical companies have been defining and re-defining Patient centricity for themselves and for the ones linked to their organization. Below mentioned are some examples of the same: -

ASTRAZENCA	"Putting the patient first in an open and sustained engagement of the patient to respectfully and compassionately achieve the best experience and outcome for that person and their family." (Patients focussed medicine development, 2017)
Boehringer Ingelheim	"Patient centricity means putting means putting patients at the heart of everything we do, from how we make everyday decisions, to how we develop our medicine"- inspired by NHS definition (Ingelheim, 2015)
NOVARTIS	"Our Mission to discover new ways to improve and extend patient life" (Source : https://www.sandoz.com/)
Teva	Everything we do from producing pharmaceutical to offering numerous other services – it is all patient driven. (Source: https://www.tevapharm.com/)

Similar updates have been widely spread in the pharmaceutical industry almost since early 2012 when the UK's NHS delivered the concept of "no decision about me, without me," to the pharmaceutical world. NHS England's has been leading this concept by incorporating the motto - "Patients should be at the heart of everything we do" as described in the 'Five-Year Forward View' in October 2014. This concept can be broken down into

- Shared decision-making with more power to make decision s about oneself.
- Being sensitive to the patient's preferences for his/her treatment
- Having right and complete information to make informed decisions.

This concept has been widely acknowledged by several pharmaceutical companies but often overlooked by almost all. The desire of these companies to be patient centric is clear from the redefining of their mission statements but the strategy behind these is still unclear. Studies show that long-term patient centric services have led to great turnover for several companies, offering financial benefits, including market share, as well as product benefits, including safety and quality thus proving to be a great business strategy. In a recent industry-poll, barriers such as resources and finances, were cited as potential roadblocks to adoption. In India, despite the many benefits of enabling better patient-centric care, a recent review by the

Productivity Commission has revealed that India has not moved sufficiently to a patient-centred model across key parts of its healthcare system.

Great efforts are seen by the pharmaceutical companies to implement patient centricity and improve the condition of people, but lots needs to be done than updating the vision and mission of the company. These are steps towards the bigger goal. At this point of the thesis, the author wants to analyse if there is any benefit to the pharmaceutical companies in todays times if they put patients at the centre of the processes.

7.1 How can patient centricity help companies?

A recent survey has shown that pharma companies having the best reputation, from the patient perspective, are very active in supporting patient-centric projects. The corporate reputation of pharma companies from the patient perspective is assessed through the following six indicators:

- Patient centricity
- Patient information
- Patient safety
- Usefulness of products
- Transparency
- Integrity

The survey results have been found to be driven by: -

- Number and value of new drugs
- Post-patent expiry strategy
- Mergers & Acquisitions
- Drug pricing and market access
- Corporate behaviours

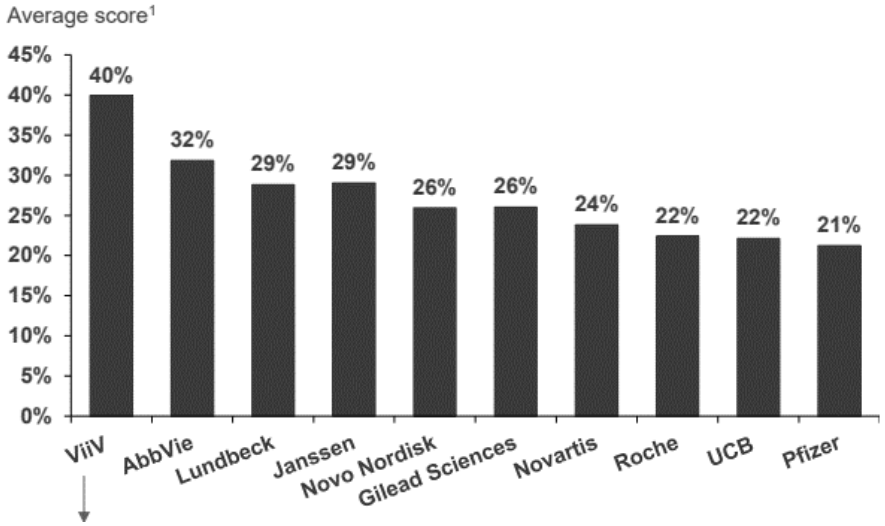


Figure 2166. Patient Centricity score Vs Market share

ViiV has building very strong patient relationships by funding several patient-centric projects supporting general communities even across the world.

In addition, as per the analysis by Smart Pharma Consulting there are 7 P's that constitute the Key pharma stakeholder groups (Smart Pharma Consulting, 2016). Figure 27. 7P Key pharma stakeholder groups shows all the key stakeholders with the varied level of importance to pharma companies. Amongst the seven key stakeholders, two of them - the patients and the patients advocacy groups – have shown increased influence over the last few years.

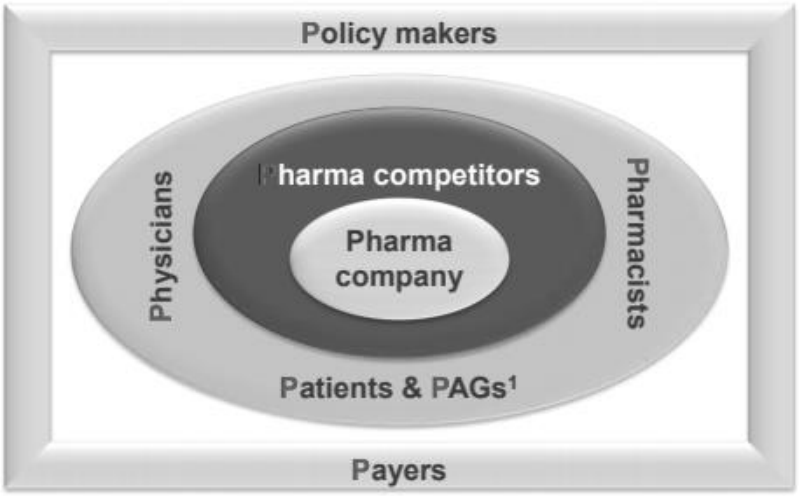


Figure 27. 7P Key pharma stakeholder groups

Patient-centricity is top priority of the heads of healthcare companies today. But apparently there is a different definition to patient-centricity to different groups. As healthcare today has become more patient-centric which is led by consumers, it makes taking patients together in the development processes much more critical. It is key to constantly understand and analyse barriers and drivers of patient behaviour at every stage of the drug development lifecycle for timely achievement of key clinical trial milestones.

8. Conclusion

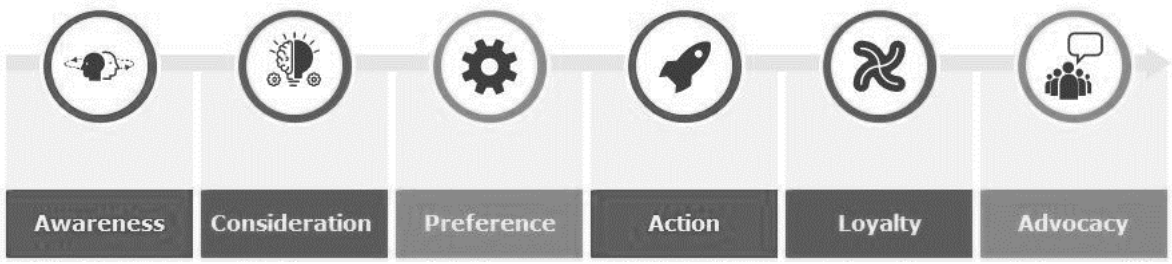
The author believes that the world is experiencing a revolution that is centred around customer and in the context of the thesis it is patients. Today every industry is trying to focus on providing improved choices to customers and enhancing their experiences that is treated as the competitive factor that differentiates every brand form its competitors. Today's increasing emphasis on patient outcomes is also being driven by two major contributing parameters:

- Huge population that is aging day after day
- Increase in chronic ailments among the general population

In addition to the above-mentioned the regulatory conditions of the healthcare system in India has also contributed to this immediate need. At the same time, the technology-driven ability to access health care data has enabled doctors to make quicker diagnoses also patients today are empowered to be a part of the treatment as informed participants and not merely as mute spectators. With the increasing demand for value by governments, patients and pharmaceutical companies, there is a need to commit towards making patient the centre of the process. "Patient-centric" is no more a buzzword but a concept that in case not implemented can lead to high reputational risk. The insights gained by listening to patients can be applied at every stage of a pharma company's efforts, from drug discovery to winning regulatory approval to post-market disease management. As a result, the company will be able to bring drugs to market that better reflect patient needs (and may increase reimbursement and price, as well as prescribed volume for precisely that reason), better align with the reward-for outcomes that governments and payers insist upon, and help patients and providers achieve better outcomes.

Patient centricity is a misused buzzword, but it is critical to embrace it throughout their organisation as it is the only method to fix a broken model.

The model explained in Section 4 can be used as a guidance to implement patient centricity at pharmaceutical companies.



Each of the steps within the model are elaborated in 'How can we implement Patient Centricity in India?'

Indian pharmaceutical companies can learn from the best practices of global pharma companies and use the model above to start their journey of patient centricity.

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Appendixes

Appendix 1

Interview of – Senior Management professional, Indian Society for Clinical Research - taken on 4 Jan 2021 (shall be reused to be published in Economic Times)

The Importance of a Conducive Clinical Research Ecosystem to Encourage More Scientific Research and Development

The last decade witnessed many scientific breakthrough treatments that were important in transforming deadly diseases into manageable chronic conditions, meeting unmet medical needs, elevating the standards of medical care, and helping improve the quality of patients' lives. Clinical research has played a vital role in enabling the delivery of new and improved treatments to patients, but more needs to be done. According to clinicaltrials.gov, India's share of global clinical trials currently stands at 1.56%, which for a country that has the world's highest disease burden and the world's second-largest population, is woefully inadequate. More is needed across the clinical trial ecosystem to create a conducive environment for clinical research in our country.

Encouraging Clinical Research Curriculum

The scope of clinical research in India has grown significantly in recent years, resulting in high demand for professionals specially trained to handle clinical trials.

The introduction of clinical research as a subject across different streams and disciplines of education would ensure that all aspiring medical professionals gain valuable exposure to the field of clinical research at an early stage and understand its role and relevance in the modern world. Furthermore, it is vital to incorporate specializations like clinical biostatistics and clinical data management into existing and future curricula. This would ensure that future investigators have a clear and in-depth understanding of the various nuances of clinical research and trials, and are better equipped to conduct them efficiently and ethically.

Significance of Nurturing Academic Research in Teaching Institutions

Extensive biomedical research leads to the development of new therapies, leading to a remarkable improvement in health care and public health. Indigenous approaches to research often provide vital information about the efficacy and adverse effects of medical interventions, and this is where medical research organizations play a pivotal role. These institutions often have some of the best and brightest research minds and conduct immensely innovative and locally relevant research. We must incentivize academic research in educational and teaching institutions, encouraging them to conduct independent research. It is crucial to ensure that these institutions receive proper funding, as the cost of conducting biomedical research is high. Not doing so would lead to a slowdown of investigator-initiated research, leaving the medical research purely in the hands of the pharmaceutical industry.

Training Requirements for Investigators

With increasingly complex and innovatively designed studies, it becomes critical to ensure that healthcare professionals are capable of evaluating the effect of a proposed intervention in reducing morbidity and improving the quality of life in patients efficiently. It is essential to have qualified, well-trained, and experienced investigators to safeguard study participants and ensure data quality and integrity. There is a requirement for targeted and risk-based approaches to educating investigators on GCP principles and ensuring they have good interpersonal and people-management skills. There needs to be a culture shift- investigators must understand that only being qualified for the job is not enough and must assume greater ownership of their training. A more responsible outlook combined with rigorous ongoing training would lead to active remediation of deficiencies at the clinical site.

Strengthening the role of the Ethics Committee

The primary responsibility of the Ethics Committee is to ensure the protection of rights, safety, and well-being of participants involved in a clinical trial. As per the "New Drugs and Clinical Trials Rules 2019", the ethics committee for any particular trial is required to have 50% of its members as non-affiliates- persons who are not affiliated with the institute or organization in which the committee is constituted. This is a welcome move as it ensures greater transparency and unbiased decision making.

There is an imminent need to strengthen the role of the Ethics Committee to avoid circumstances that put the safety of participants at risk- like dubious informed consent forms and biased recruitment of subjects. It is imperative to ensure an independent, competent, and timely review of all ethical facets of the clinical project proposals received to protect the patient/volunteer rights, safety, and well-being.

Importance of Regulatory Bodies

With the implementation of the New Drugs and Clinical Trials Rules of 2019 notified by the Ministry of Health and Family Welfare, we see a speed-up in clinical trials and the approval process of new drugs in India. To avoid ethical violations, regulatory bodies will need to set up strong systems in place to ensure proper monitoring and compliance. This can be done by adopting digital technology for the conduct of trials and data collection while ensuring patient safety.

Increase Public Awareness

The Covid-19 pandemic has led to increased public awareness of the importance of clinical research and trials in developing treatments and vaccines for several diseases. However, people are still unaware of what clinical trials involve, the drug development process, and how they can participate in trials.

For any research to advance, investigators need participants. Educating the general public about the concept, benefits, and process of clinical trials would significantly increase participant enrollment into studies. Some keyways we can do that are-

- Using simple (layman) language in clinical trial literature that clearly outlines the necessary information a participant would need- guidelines, potential benefits, and risks associated with the study

- Actively disseminating information to healthcare professionals and media in a clear, precise, and jargon-free manner

While there is certainly a need to educate patients and volunteers, it is also imperative to raise awareness about clinical trials amongst healthcare practitioners (HCPs). HCPs can further inform their patients of active studies that they may be eligible for and provide them with the necessary materials and encouragement for participation.

Furthermore, research organizations and HCPs can also make patients aware of clinical trials as a viable treatment option. Patients may want to receive new investigational drugs to treat their health conditions, especially if they aren't responding well to standard treatments.

In the larger context of India's unique healthcare requirements and the growing incidence of endemic diseases and emerging lifestyle diseases, more clinical research is required to develop new and effective medicines and vaccines to tackle the country's mammoth disease burden and unmet medical needs. All stakeholders must work together to build a conducive clinical research ecosystem in the country and create an environment that encourages more research in this technologically advanced world.

Appendix 2

Survey 1 question

Clinical Trials Feedback form

(link - https://forms.gle/AX1EXHx7zM2WRsF96)

1. Have you participated in a clinical trial before?
    a. Yes b. No

2. Rate your experience participating in clinical trials?
    a. Bad
    b. Below Average
    c. Average
    d. Above Average
    e. Good

3. Do you think something should be improved in the clinical trial process?
    a. Yes b. No c. Maybe

4. Do you think you were informed about everything during the process ie. was there enough transparency in the entire process?
    a. Yes b. No c. Maybe

5. Do you think you were dependent on the investigator for any decision-making process/ understanding the process?
    a. Yes b. No c. Maybe

6. Do you think the process was formulated keeping you in mind?
    a. Yes b. No c. Maybe

7. Do you think your feedback could have been included at various stages in the process?
    a. Yes b. No c. Maybe

Appendix 3

Survey 2 question

Clinical Trials- Patient perception feedback form

1. Who do you think participate in clinical trials?
    a. Only ill patients
    b. Anyone can participate
2. Do you think children can participate in clinical trials?
    a. Yes b. No c. Maybe
3. What do you think clinical trials test?
    a. Only new medicine
    b. Therapy
    c. Medical device
    d. None of the above
    e. All the above
4. Who do you think approaches for participation in clinical trials?
    a. Clinical trial team approaches the patients
    b. Doctors approach the patients
    c. Patients can approach a new trial on theor own
    d. None of the above
    e. All the above
5. Would you be willing to participate in a clinical trial?
    a. Yes, I would like to support the scientific community
    b. May be, need to think about it
    c. No, it's very dangerous.
6. What do you think about the clinical trial regulatory process in India? Will you be protected by the regulations?
    a. Yes, I have strong faith in the process
    b. Not sure
    c. It think it is highly unreliable
7. Do you think medical insurances cover clinical trial participations?
    a. Yes b. No c. Maybe
8. What do you think is the purpose of Informed consent forms?
    a. It protects participants rights and ensures proper information is provided during the process
    b. It's just a formality
    c. Not sure
9. Do you think you can support in designing a trial?
    a. Yes b. No c. Maybe

Appendix 4

Survey 3 questions

Clinical Trials- Patient willingness feedback form

1. How aware are you about clinical trials?
    a. No idea
    b. Have heard about clinical trials
    c. Know something about clinical trials.
    d. Fully aware about clinical trials
    e. I have an acquaintance / friend who participated in a clinical trial

2. Are you willing to participate in clinical trials?
    a. Yes, I am willing
    b. Maybe
    c. not very willing
    d. not at all willing

3. In case you ever make your mind to participate in a clinical trial, why would it be?
    a. To help advancement of science to achieve better treatment
    b. To help other who suffer from diseases
    c. For the monetary benefits involved
    d. Obtain better treatments for my ailments

4. From where did you learn /gather information about clinical trials?
    a. Advertisements.
    b. From my doctor
    c. From the doctors/staff at research centres
    d. I read it on CTRI/ other relevant websites
    e. From social media communities

5. How would you like to gather information in future about clinical trials?
    a. Discussing with doctors/specialists on treatment options.
    b. Awareness campaign in hospitals
    c. Websites and related webpages
    d. Patient Advocacy groups
    e. Social media

Appendix 5

Survey 4 questions

Patient Centric Leadership

Select the important qualities you think the leader of a patient centric organization like yours should possess?

	Column 1
Facilitating transformation/cultural change	☐
Resource management	☐
Acting with integrity	☐
Relating to external stakeholders	☐
Teamwork	☐
Influencing strategic vision	☐
Embedding the strategy	☐
Strategic thinking	☐
Driving decision making	☐
Evaluating impact	☐