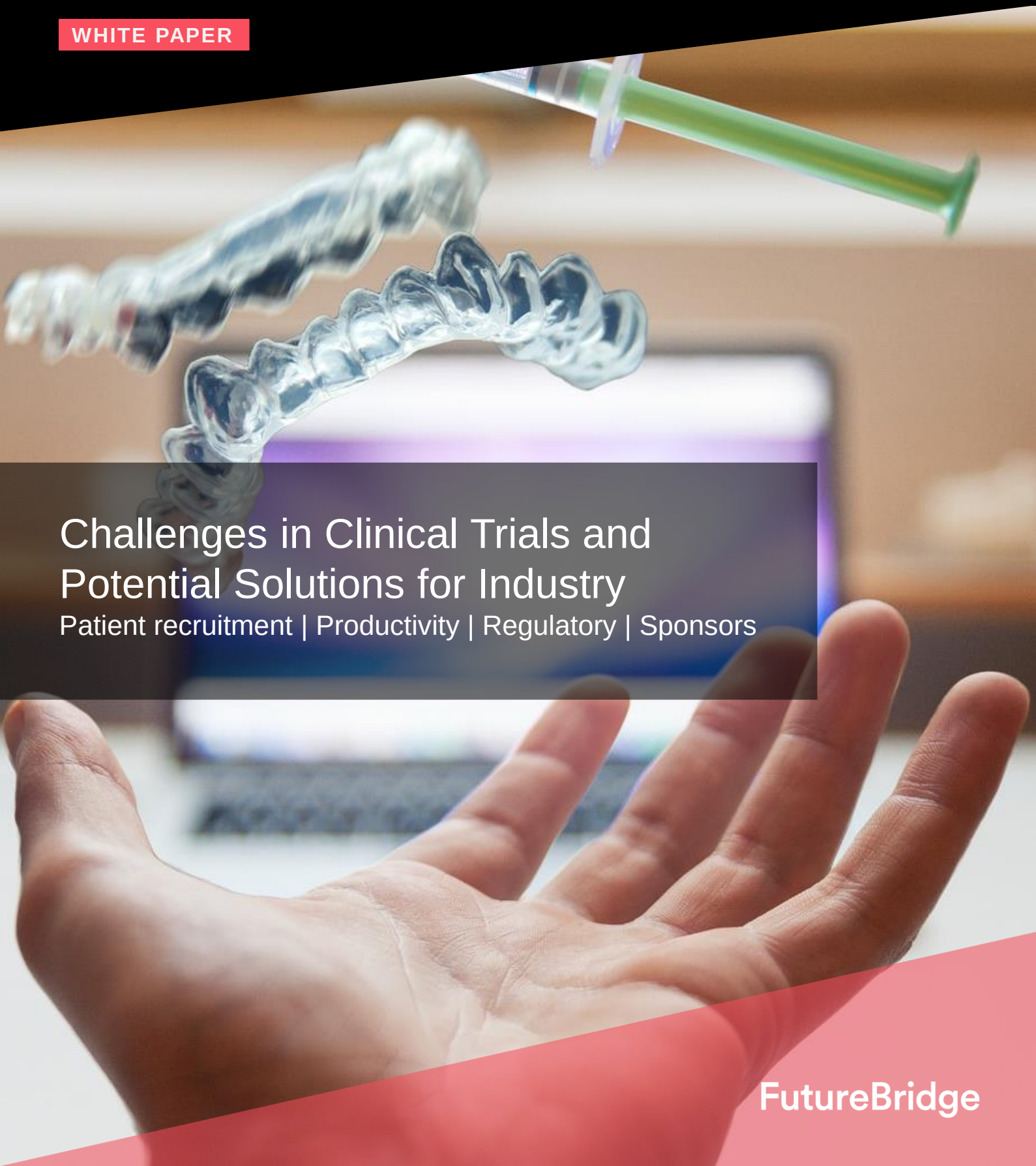
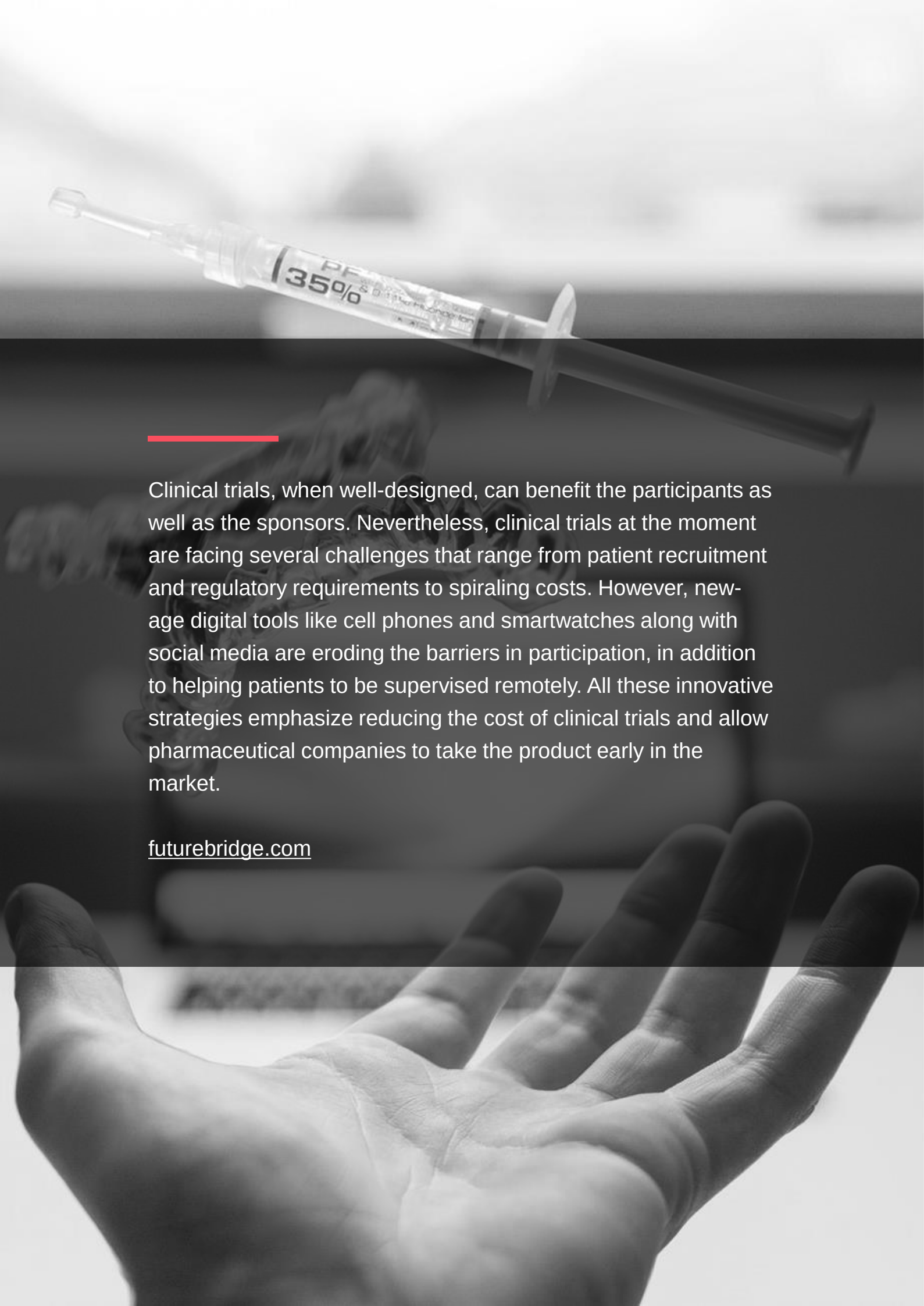
WHITE PAPER



Challenges in Clinical Trials and Potential Solutions for Industry

Patient recruitment | Productivity | Regulatory | Sponsors

FutureBridge



Clinical trials, when well-designed, can benefit the participants as well as the sponsors. Nevertheless, clinical trials at the moment are facing several challenges that range from patient recruitment and regulatory requirements to spiraling costs. However, new-age digital tools like cell phones and smartwatches along with social media are eroding the barriers in participation, in addition to helping patients to be supervised remotely. All these innovative strategies emphasize reducing the cost of clinical trials and allow pharmaceutical companies to take the product early in the market.

futurebridge.com

Introduction

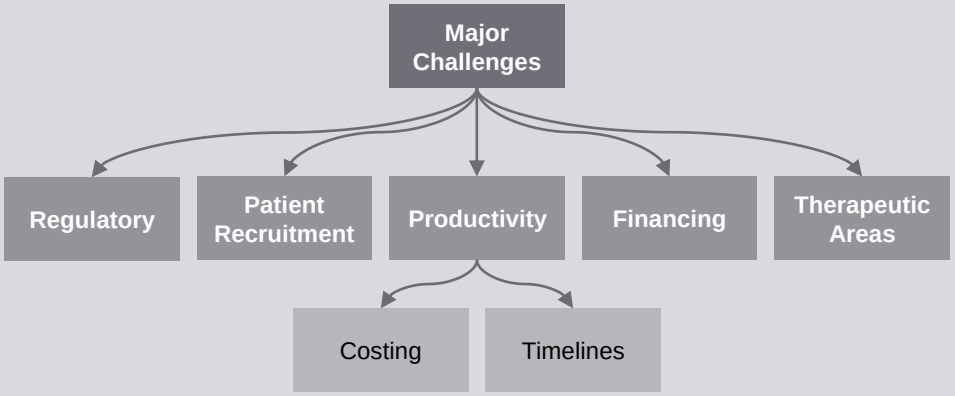
Clinical studies are aimed at assessing a medical, surgical, or behavioral intervention in people. These are primary methods to evaluate if a treatment (which could be a drug, diet, medical device, or any other intervention) is safe and efficacious in people. More often, a clinical trial is carried to understand whether a new treatment is more effective and/or less harmful than the available standard treatment. Before a regulatory agency commends a clinical trial to begin, scientists perform various in-vitro and preclinical studies to assess the possible safety and efficacy of the therapy.

The numbers of clinical trials worldwide are growing by 10-12% per year. The R&D cost has increased at a CAGR of 1.76% over the last decade. Although various innovations are brought to market, the overall productivity of the pharmaceutical industry is stagnant.

In the year 2020, FDA approved 53 novel drugs, the second-highest in the decade since except 2018, where FDA approved 59 novel drugs, despite the COVID-19 pandemic. 40% were first-in-class, 58% for rare disease (orphan drugs), and 42% were designated as breakthrough therapy (up from 27% in 2019) and overall 68% used expedited development and review path.

New molecule entity (NME) and biological license application (BLA) have an upward trend from 2007 to 2019. Disconnect between increased investment/activity but stagnant output highlights the significance of challenges in clinical trial markets. Most commonly observed challenges in clinical trials are patient recruitment, productivity, financing, therapeutic areas, regulatory hurdles, etc. (refer Exhibit 1)

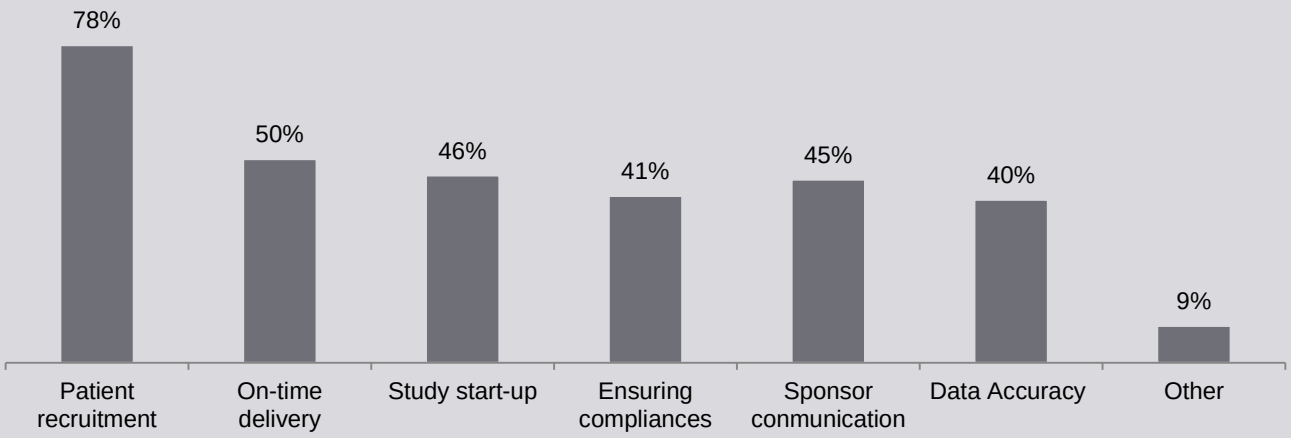
EXHIBIT 1: Major Challenges in Clinical Trial



Source: FutureBridge analysis.

Few other well-known challenges could be data accuracy, sponsor communication, ensuring compliances, and study start up, on-time delivery as depicted in *Exhibit 2.*

EXHIBIT 2: Challenges in Clinical Trials



Source: Martin J (2018)

Randomized controlled trials (RCTs) are extensively recognized as the gold standard for assessing safety and efficacy. The utmost challenging aspect in RCT is the recruitment and retention of patients for a clinical trial that strongly impact the trial outcomes.

If the estimated sample size for a clinical trial is not met then, there are high chances of experiencing an error (e.g. no significant difference in between treatment groups) or bias. This may lead to the disbelief of treatment efficiency and delay market entry of effective therapy.

Sufficient enrollment of patients in a trial is helpful in the assessment of nearly matching real-world evidence. Despite these facts, the importance of patient recruitment remains undervalued, and institutional resources are hardly used for subject recruitment. As poor recruitment is an important bottleneck of an RCT, it is vital to examine the barriers and plan potential approaches to improve the same.

Challenges In Clinical Trials

The most common hurdles, mentioned in scientific literature, to conduct a clinical trial are high financial cost, patient recruitment, retention, and longer timeframes of the trial.

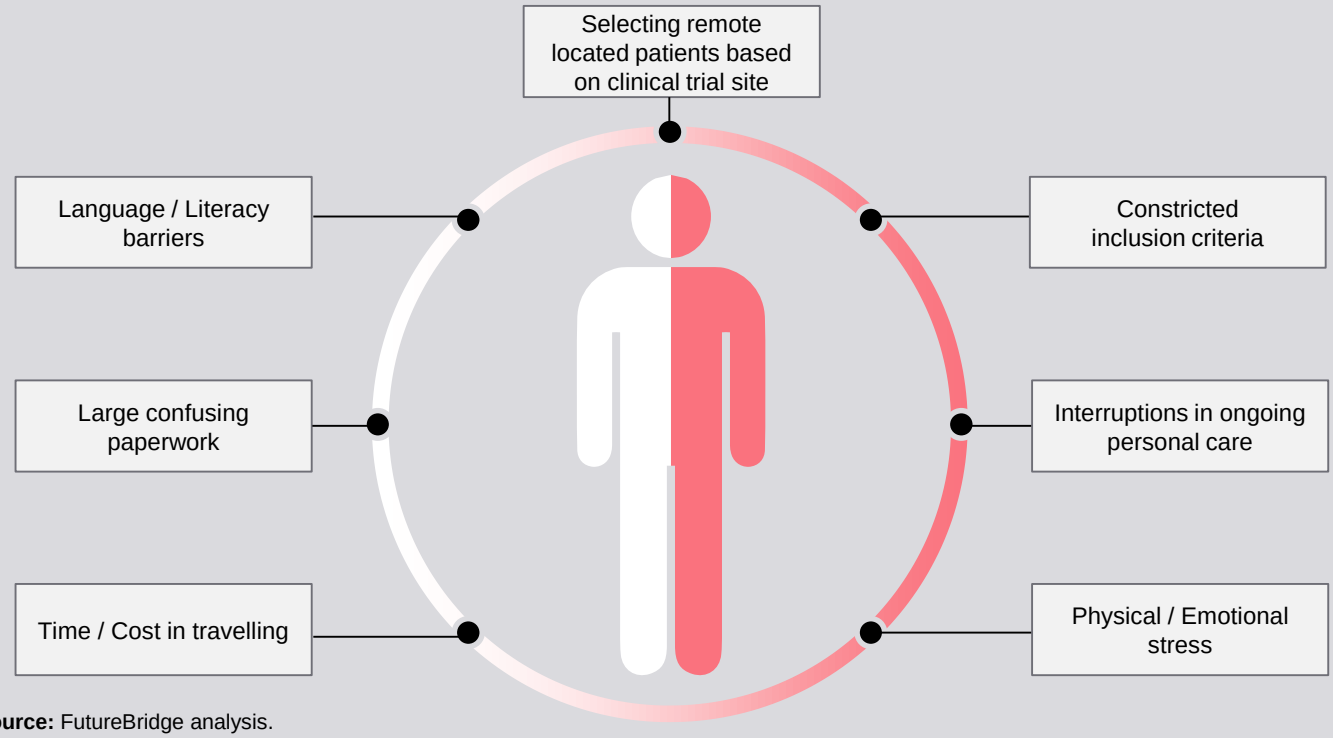
Few challenges explained in detail in the following sections include:

- Patient Recruitment
- Productivity
- Sponsors
- Regulatory Hurdles

Patient Recruitment

Expertise from different pharmaceutical companies and representatives stated that patient recruitment is a major barrier in carrying out a clinical trial which can increase the cost or even cancel the entire trial. Numbers of factors are responsible for difficulties in patient recruitment which are widespread in a clinical trial. Few noticeable factors are expected study size, orphan indications, finding participants as required by protocol, etc. Few other involved factors are depicted in *Exhibit 3.*

EXHIBIT 3: Challenges in Patient Recruitment



Source: FutureBridge analysis.

- For diseases like cancers, admission issues arise as many patients are located in remote areas but, they are selected based on investigators or clinical trial site
- Few trials have constricted patient inclusion criteria that disqualifies many participants who have the disease
- Apart from the above pointers, participating for certain individuals might be inconvenient or burdensome due to interruptions in personal care, physical/emotional stress, time, travel cost, large confusing paperwork, language barriers and literacy barriers

Different companies address the competition among drugs for the same patient pool which often results in multiple companies targeting the same big market at the same time. For example: As the regulatory approval for anti-inflammatory drugs is easy, many sponsors are interested in pursuing these drugs. These companies then compete with each other to enroll patients with specific diseases (COPD, arthritis, multiple sclerosis) on which they test their drug.

Productivity

Costing

There are various debates on cost estimates; with a common agreement that clinical trial cost is rising which is one of the important roadblocks to conduct clinical research. Various studies estimated that the current cost to conduct a clinical trial is between $161 million to $2 billion.

The average cost of developing the drug has risen by 7.4% in the last 2 decades. A survey of 10 pharmaceutical companies, conducted by DiMasi JA, to understand the R&D cost of new drugs highlights that:

- Out-of-pocket cost of developing a new compound is ~$1.4 billion
- However, the cost of compound rejected during clinical testing was linked to the cost of a compound that obtain market approval
- Considering the above pointer, the total pre-approval cost jumps to ~$2.6 billion marking an increase of 80% than the actual cost of developing a new drug
- The cost per subject increases as trials progresses to the next phases of the pipeline
- Estimated costs for various phases are:
  - Phase 1: $15.2 million
  - Phase 2: $23.5 million
  - Phase 3: $86.3 million
- Phase 3 clinical trials have become extensively expensive

TABLE 1: Average Cost of Enrolling Patients in Different Study Phases

Trial Phase	Cost of Enrollment per patient (In '000)	Average Cost per Trial (in '000)	Average Patients/ Trial
Phase I	$16	$1,201	75
Phase II	$22.5	$4,576	203
Phase III	$28.5	$23,700	828
Phase IV	$26	$12,800	422

Source: FutureBridge analysis.

Considering the challenges in costing, macro-level trends standout such as:

- Decreased output of first-in-class drugs from industry in past years than expected due to:
  - High investment in R&D have yielded many drugs and companies are now finding it difficult to develop truly innovative therapies
  - Most of the new drugs are just small variations of the existing drugs, intended to be a little more effective than the ones already in market
  - Even detection of such small effective improvements requires a large number of patients resulting in considerable expenditure on recruitment efforts, data collection, amenability with administrative requirements and other aspects of a trial
- The shift in the biopharmaceutical industry toward chronic and degenerative disease research, which has the potential to secure revenue streams from a large segment of the aging population. However, challenges from a cost perspective are:
  - The trials for chronic conditions (such as arthritis, dementia, cardiac disease, etc.) involve expensive protocols, a larger patient pool and long time-frames
  - Another factor is the increase in the health care cost containment strategies, such as different formulations
  - Detailed data requirements by regulatory bodies

Timelines

The timeframe is another factor that is closely related to cost involved in a clinical trial – as the time taken for complete a trial has increased in recent years. A study has reported that from 2005 to 2018 companies has observed:

- 3% increase in the development cycle
- ~11% increase in regulatory cycle
- Though the PDUFA report in 2011 implies the decrease of few months in drug development process, but the whole process remains lengthy

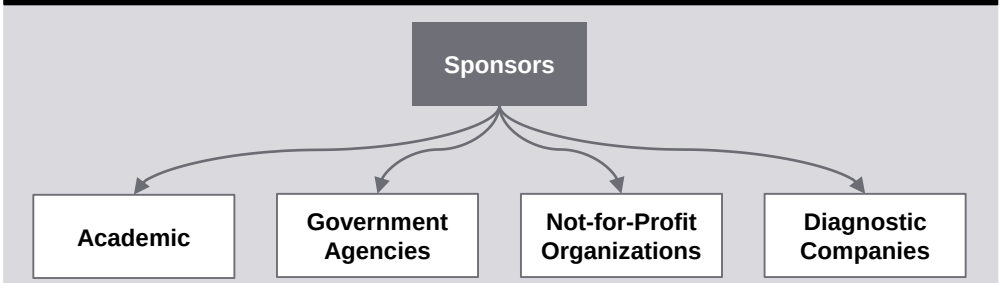
There is a direct correlation of lengthy timeframe to low revenues in the drug lifecycle which increases the drug cost burden. Few factors involved could be:

- Lengthier trial means huge labor costs, and investigators need to be compensated equally
- Opens up the doors for earlier entry of generics impacting return of interest (ROI) significantly
- Companies focusing on chronic diseases requires long trials to determine the safety for the drug to be used for a long time
- Lengthy trials have challenges of patient/ investigator retention which adds up to the total cost
- Number of regulatory barriers and administrative policies delay the trial approval process
- The absence of constant trial infrastructure hence, each trial requires resources to be assembled to a new process

Sponsors

The major sponsors for clinical trials are the pharmaceutical industries. Of the 4,864 trials that were completed in 2018, 86% of trials were sponsored by at least one industry. Nevertheless, various clinical trials in trial registries involve sponsors from other sources like academic, ethical drug development, government agencies, not-for-profit; diagnostic companies *(refer Exhibit 4).*

EXHIBIT 4: Different Sponsors for Clinical Trials



Source: Blazynski C (2019)

Though the trials sponsored by industry are increasing the funding from other sources is decreasing.

- Novartis was the major pharmaceutical sponsor for completing trials in 2018, followed by Roche and AstraZeneca (AZ), and Eli Lilly
- The top 20 pharmaceutical companies spent ~ $95 billion with Roche being the top spender on R&D at $10 billion in 2017

- The intensity of research remains all-time high in the USA, with nearly 50% investments in R&D by US pharma giants
- But funding from NIH or EU Research Program (Horizon 2020) is on decline

NIH Funded Trials

The funding from academics like the National Institute of Health (NIH) is on the verge of decline. NIH funded clinical trials fell from 1589 in 2005 to 930 in 2015 marking a reduction of ~40%. The reason for the decline in the clinical trials funded by NIH could be:

- Partly because of the decline in the NIH budget. The Institute had reserved a budget of $30 billion in the year 2015 which was nominally the same as in budget of $29 billion in 2005
- But the other point that adds up is the inflation during this period. The purchasing power of the assigned budget was 20% lower in 2015 vs. 2005

Funding from Central, European Budget

EU Research and Innovation program, Horizon 2020 (H2020), is the biggest innovation program with €80 billion of funds available in the last seven years (2014 to 2020).

- Various multinational clinical trials seek funding from the H2020 program
- Only 4% of the projects have been awarded funds so far
- High-quality studies with promising intervention from small players or academia face challenges that impacts time & cost of treatment coming to the market

Central and National Funding Combined

The funding program is based on a combination of European and Developing Countries Clinical Trial Partnership (EDCTP). The budget for this program comes from the European Commission, national member countries, and from the private sector and other international partners (€500million to €683million). But challenges in this program include:

- This program funds the trial which is working on malaria, tuberculosis, HIV and also some neglected diseases in developing countries
- The proposed trial should include at least one sub-Saharan country and at least two European countries

Regulatory Hurdles

The process for drug development is a globalized and multi-regional clinical trials for regulatory submission are conducted by various pharmaceutical industries with the aim of reducing the time to market entry but the expected regulatory challenges are:

- There are various contradicting issues in reviewing data from different regional regulatory bodies for New Drug Applications (NDAs)
- The extended periods for conducting trials along with stringent approval process

European Regulatory Agency

A scientific paper published by the European Medicines Agency (EMEA) concluded the results from various clinical studies carried outside of the EU for the EU population. This study pinpoints:

- Various extrinsic & intrinsic factors halt the extrapolation of results from other geographical conditions to EU populations
- Regarding the medical practice, a factor that can complicate the validity of results in different areas is the usage of co-medication and invasive procedures
- The standard of care may have an impact on outcome parameters when the clinical trials involve the use of intensive medical care

USFDA

USFDA has mentioned the Regulatory and Scientific Issues regarding the use of foreign data in support of NDA. The consideration by USFDA highlights:

- The potential heterogeneity in treatment in different regions that need to be considered while planning for a clinical trial
- Using a quality-by-design method in scientific and operation design of a trial
- The quality of trial depends on a well-defined investigational method with clear objectives and their outcome measures along with investigators who are involved in the studies
- USFDA has also proposed overall improvement in oversight and statistical analysis that addresses the features of clinical trials

Pharmaceutical and Medical Devices Agency

In Japan, PMDA is making strenuous efforts to reduce the drug lag and more clinical trials are conducted.

Chinese FDA (CFDA)

The CFDA had deployed guidance on an international trial of the drug in China in January 2015 and was implemented in March 2015. CFDA is looking forward from various pharmaceutical industries to conduct a clinical trial in China with the following highlights from guidelines:

- Multi-center clinical trial must involve two countries including China
- While conducting a trial in China, an international agency must ensure that the trial participants are representative of the overall population in Chinese medical practice

- Sample size should be sufficient to support & conclude that the intervention is safe and effective in Chinese subjects & also sample size must meet the statistical requirements
- Permission should be provided to CFDA for either on-shore or off-shore sites that are involved in multi-center clinical trials.

Other common issues for multi-center clinical trials could be the need of different endpoints by different agencies. Hence, to conduct effective trials, country-independent harmonized guidelines & synchrony between different agencies would be a step forward. This will help the investigators/sponsors with a common understanding and approach for clinical trial procedures, patient management, assessment, and reporting.

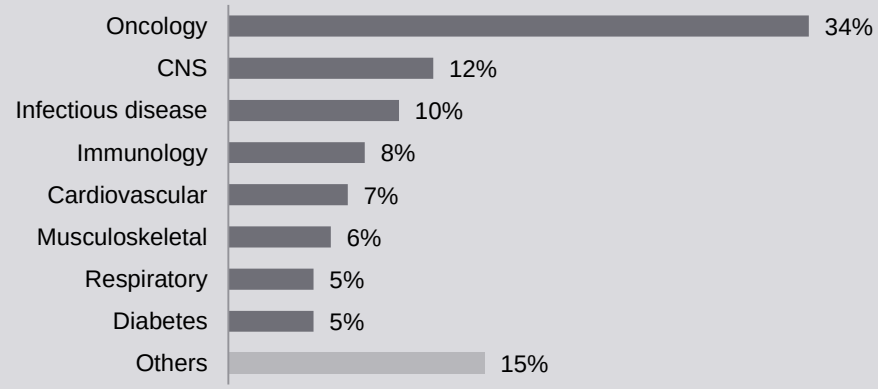
Therapy Specific Challenges

Oncology

There is a big tidal wave in the field of oncology that may intensively change how cancer is diagnosed, treated and monitored in coming years but still, it remains an important unmet medical need. Around 8 million people die of cancer and involved economic burden strains the healthcare system. The amount spent on cancer drug development was ~$110 billion in 2015 and was expected to rise to ~$188 billion in 2026.

Cases related to cancer are projected to rise by ~22 million in the coming years. With this point of view, pharmaceutical industries have reserved a major investment in R&D for cancer-related research. There were 3,436 products in the pipeline for oncology in 2013 and contributed ~34% to total R&D projects *(refer Exhibit 5).*

EXHIBIT 5: Distribution of Products by Therapeutic Area



Source: Ilancheran M (2014).

Oncology trials differ from other therapeutic areas based on three main parameters:

- Patient recruitment
- Cost involved
- Clinical Research Associate (CRA) / Clinical Monitor Skill(CRS)

Patient Recruitment

The Phase I trials of most of the therapeutic areas involve healthy individuals vs. diseased patients in oncology. Most oncology studies have toxic side effects hence; the recruitment of patients in the advanced stage of cancer, for early phase trials, is difficult. This increases the cost of the oncology clinical trials to recruit the right patient pool and retain them.

Numerous factors are responsible for complexities in oncology trials in phase II and III trials. The most important of them include:

- Protocol complexity
- Biomarker search
- Longer timeframe
- Multiple comorbidities
- Varying & higher number of endpoints
- Required size of patient recruitment & retention

Trial Cost

The clinical trial in the oncology is more intense as compared to others due to factors like:

- Severity of the disease
- Higher and heterogeneous regulatory demands. The total cost assigned to investigators per patient keeps on surging for completing all the protocol activities
- Higher cost of the intervention

Clinical Research Associate (CRA) / Clinical Monitor Skill (CRS)

The selection of appropriate CRA/CRS for oncology monitoring remains a challenge for reason such as:

- Though the basic skills required are the same for all therapeutics area, complex diseases such as cancer require specific skillsets and expertise
- The above requirement adds to the Full Time Equivalent (FTE) rate of an oncology CRA as compared to other therapeutic areas
- Need for a large number of CRA to manage all the oncology trial protocols by maintaining quality

Rare Indications

The definitions of rare diseases vary from country to country. A chronic condition affecting <200,000 people is considered as a rare disease in the USA whereas in Europe it is <250,000 people.

- >6000 rare diseases affect ~350 million people globally
- In the US ~10% of the population and EU ~7% of the population is affected with rare diseases
- 250 new rare diseases originate every year
- Only 5% of the rare disease have treatment options
- 85% of rare diseases are because of gene mutations

The drug development process for the rare disease is flourishing with the blockbuster drug in tandem. In the last 5 years, 1/3rd of NMEs developed are for rare diseases the motivations for exploring the rare disease development are:

- Accelerated regulatory review
- Longer market exclusivity than blockbuster drugs
- Companies' attention towards personalized medicine and pharmacogenomics
- Research grants from governments and private organizations
- Tax credits for clinical trials
- Waiver of user fee

Pharmaceuticals Interest in Rare Diseases

Together with cell therapy products, the orphan drug is poised to have a 12% CAGR by 2024 which is double the 6% rate for non-orphan products. As per estimates:

- Leading therapeutic areas for the orphan drug are blood, CNS, and respiratory infections accounting ~50% of the non-oncology orphan drug market
- Celgene, AbbVie and Johnson & Johnson are projected to be leading players in orphan drug, accounting for 28% of worldwide orphan drug sales
- Vertex's triple combination for cystic fibrosis is the most valuable R&D orphan product, with an estimated NPV of $24bn
- In 2018 (vs. 2017), the number of products granted orphan drug designation decreased by 25% in USA, 15% in EU and 25% in Japan

Challenges in Rare Disease Clinical Trials

In multifaceted clinical trials for Phase 3 orphan drugs following are the challenges:

- Patient recruitment and retention
- 28% of phase 3 trials fail due to enrollment challenges

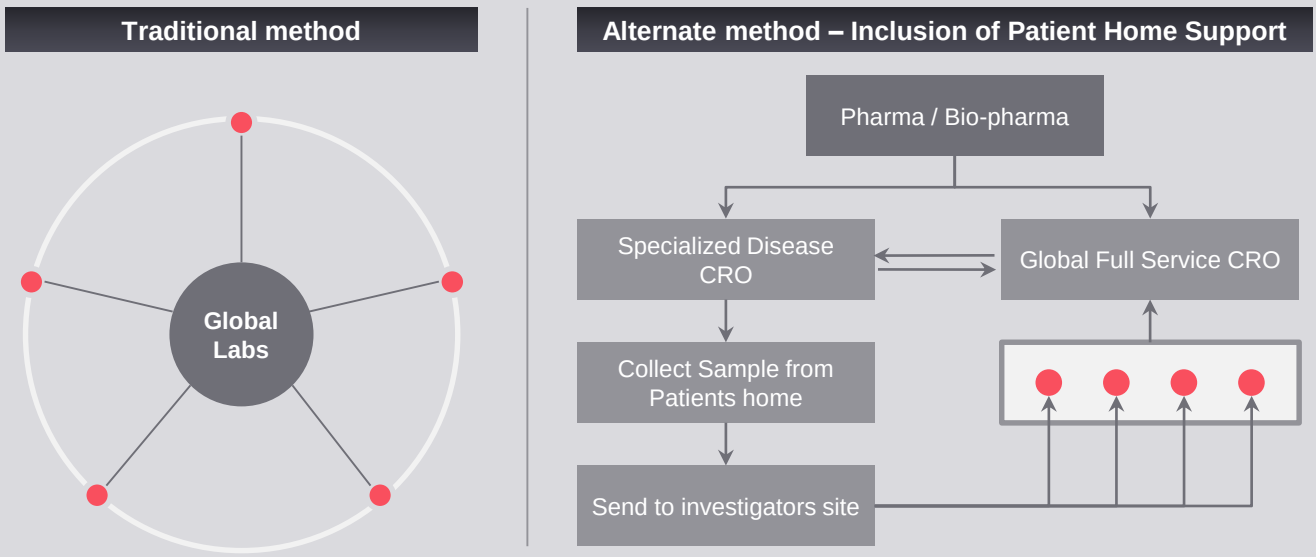
- 50% of rare disease affects children's which further hinder patient recruitment

The participation of every person is immense in phase 3 trials that mostly comprises of 20 to 100 patients to assess the drug's effects the more the patients the more data for regulatory authorities, as well as payers to define the pricing and reimbursement.

Different Methods that Can Be Employed in Patient Recruitment in Rare Disease Clinical Trials

A patient-centric approach is required for patient recruitment *(refer Exhibit 6)*. Patient recruitment and site activation varies upon the prevalence of rare disease rather than multiple locations and waiting for patients to enroll. This will save the cost and also keep the timeline in check.

EXHIBIT 6: Traditional and Alternate Methods for Patient Recruitment



Source: Khaleel S (2015)

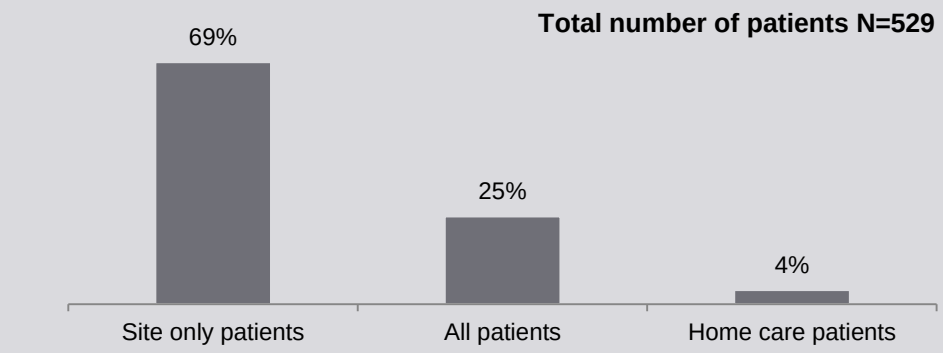
Patient Retention in Rare Disease Trials

Inconvenience faced by the patients:

- Travel long distance to reach trial site
- Sponsors have to pay for logistics for caretakers too so as to prevent dropout *(Exhibit 7)*

The above parameters add up to the overall cost burden of the study.

EXHIBIT 7: Drop Out Rates in Rare Disease



Source: Khaleel S (2015)

Using Patient Registries for Specific Rare Diseases and Creating Patient Support Communities/Groups to Aid in Data Sharing

There are various patient registry developed in collaboration between different countries like

- US (NORD)
- Europe (EURORDIS) and
- Canada (CORD)

These registries contain patient's health-related information such as:

- Patient geography
- Biological data
- Bio-banks with Global Unique Identifier (GUID)

These registries are managed by private, public or not-for-profit organizations and they further help numerous rare disease patients in housing support communities. These communities aid in sharing information on clinical trial in which patients can be benefited.

Neurology Indications

The drug development processes in neurology area are apprehended with high risk and cost and low productivity. A large amount of investment is shifted to therapy areas with a clear path forward, and; currently in terms of nervous system disorder finding a clear rational path is difficult.

Limited Understanding of the Underlying Biology of Disease

As there is vast research going on in the neuroscience stream, particularly in genetics and clinical biology, there are only a few validated biomarkers for nervous system

disorders. Out of those that are identified are ages old in psychiatric diseases like depression, psychosis, and anxiety. The remote location of the brain makes it difficult to evaluate conservative methods such as biopsy. The absence of new and validated targets confines the development of innovative treatments and also restricts the investigators‘ ability to cross-examine the pharmacology of active agents across dimensions (behavior, functional, electrophysiological, etc.) in concept studies.

Insufficient Sharing of Data, Knowledge, and Expertise

There is an increase in demands for data sharing from varied sectors, like:

- Sharing of the data by academicians and industry scientist
- Need to review and revise Health Insurance Portability and Accountability Act (HIPAA) restrictions

High Failure Rates of Clinical Trials

In the process of drug development, thousands of compounds are screened, with only hundreds reaching the preclinical space. Of the 10 compounds that make to human trials, approx. only 1 reach the marketplace. This whole process takes around 10-15 years. There is high rate of failure in clinical trials which continues to negatively impact the research and development productivity.

Operational Challenges Contributing to Variability across Sites

There are many operational challenges such as:

- Inexpert principal investigators (e.g., first-time filers who may not file again)
- Increased expense of experienced investigators
- Protocol nonconformity

The above pointers lead to greater variability and poor performance in clinical trials. Additionally, protocol nonconformity has grown over the year that leads to nearly half of all site deficiencies.

Lack of Clarity on Regulatory Requirements

There is grey area from regulators about what information to be collected as part of clinical submission. For example, information of every patient enrolled in large trials such as:

- the non-serious events or outcomes
- reporting all of the data adds the total expense

It is observed sponsors collect almost all type of data out of concern that regulators may discard their application, if they are not included.

Solution to Challenges

Technology

Various innovative companies such as Clara Health, Seeker Health, etc. are using new-age digital tools like social medial to revise the engagement rules which could assist in connecting researchers with patients more effectively. This process not only helps to shave off the number of months in recruitment but also, helps to find more patients from minority groups and rural areas – these populations need more representation in clinical trials.

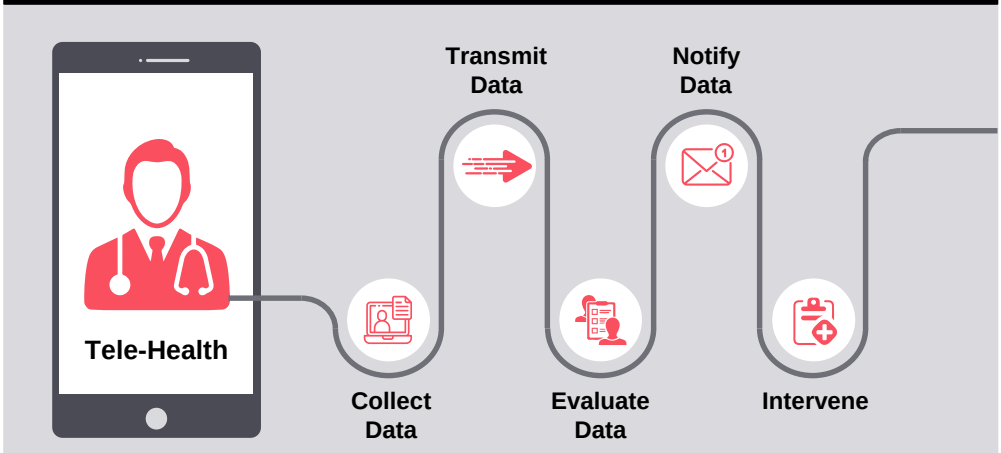
Technology is poised to do more than change the way patients are recruited for clinical trials. The use of integrated telehealth such as:

- Cell phones
- Smartwatches etc.

Such technologies will help in eroding the barriers in participation. This helps patients to be supervised remotely with assistance from a nurse, while study drugs can be shipped to the patient. Science 37s NORA platform (Network Oriented Research Assistant) meets the FDA's digital requirements and further aids sponsors with digital data collection. Science 37s co-founder stated that minority enrollment in their trial pool has increased by 3 times to that of a standard trial.

Although, if there is not much usage of telehealth for virtual trials, industries can use digital tools like Apples Research Kit to develop their apps to connect with patients and gather data on patient-reported outcomes.

EXHIBIT 8: Tele-health Remote Monitoring Process



Source: Tele-Health (2018), FutureBridge analysis.

Modern Marketing, Meeting Institutional Review Board (IRB) Standards

By the use of digital tools, Seeker Health has been involved in 22 clinical trials, which comprise:

- 40% of oncology therapies
- 40% of rare disease, and
- 20% of women health therapies

Seeker Health has developed a process to reach out to patients in economical ways but must pass IRBs. The processes consist of:

- Targeting advertisements at subpopulations that show interest in specific cancer or rare disease
- Avoid trial participants from being influenced by factors other than the ad itself
- Developed a tool that helps in comment suppression that means, the statements are hidden and not accessible to other users

In this way, no misrepresentation about the trial or drug is spread online. There is a need to qualify privacy regulations under the Health Insurance Portability and Accountability Act and the Health Information Technology for Economic and Clinical Health Act.

Reducing Costs, Targeting Discrete Cancer Types

The new-age digital tools emphasize reducing the months in the enrollment process that further helps in reducing cost and allow pharmaceutical companies to take the product early in the market. If this offers solutions to the rising recruitment cost, this may help in reversing the trend.

Following pointers help reduce cost:

- Maintaining research sites that account for 9% to 14% of the clinical trial cost
- The decline in number of people enrolling for a clinical trial, and that unproductive cost accounts for 66% of what industries are spending on trials

Therefore, the shift towards digital tools for trials helps in achieving more outcomes, which further helps small industries to understand whether future work is worth chasing. This type of model is required for oncology-based trials wherein small industries can work on specific solutions and finds patients from all over the region and conduct virtual trials with patients managed by local nurses.

Awareness

There is a huge difficulty in enrolling patients in clinical trials as mentioned earlier. One of the studies carried out by Tuffs Center for Study of Drug Development conducting 150 clinical trials and around 16,000 study sites reported that:

- 11% of the trial sites even fail to enroll one patient and
- 39% do not even meet the enrollment goals

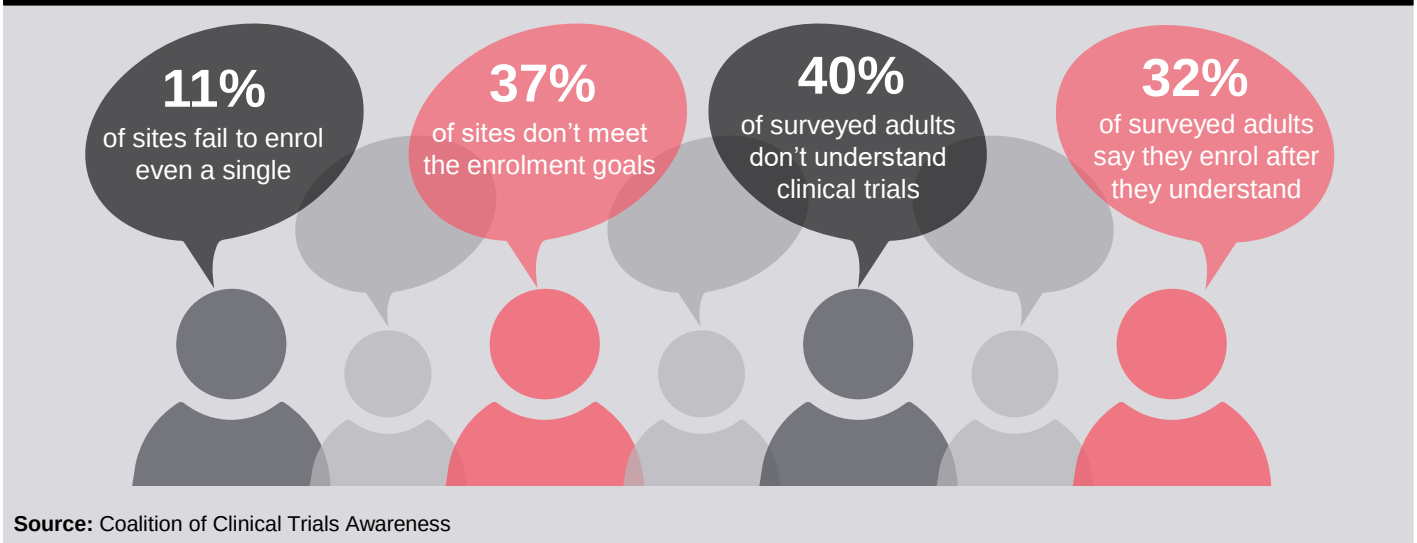
The study on “Public Attitudes towards Participation in Cancer Clinical Trials” surveyed 1000 healthy individuals which showed that:

- 40% did not understand the purpose of clinical trials
- Around 32% of patients who stated that they would be interested to join cancer clinical trials if they are asked to do so

A scientific study also found that Americans have hardly any knowledge of clinical trials and less than 10% reported knowing a lot. Of the half of respondents who are unlikely to participate in the clinical trial were worried about:

- Efficacy or side effects (44%)
- No trust in research organization (20%)
- Cost (15%) and
- Want to wait for treatment approval (18%)

EXHIBIT 9: Awareness of Clinical Trial among People (by numbers)



Source: Coalition of Clinical Trials Awareness

Awareness can reduce barriers to clinical trial participation. The major barrier is about understanding that the clinical trials are available (for patients and physicians), lack of awareness of benefits to society and the efforts to maintaining neutrality with regards to treatment preference. It is long known that a person may or may not benefit from clinical trials, wide-spread involvement by individuals benefits society as a whole that aids to identify new treatments in terms of safety and efficacy. Furthermore promoting information and educating people about the benefits of clinical trials aids more patients in being eager to consider participating in a trial.

Conclusion

Clinical trials are undergoing rapids changes in starting phase of trials that leads to meaningful improvements in patient outcomes. The next generation of clinical trials can address the areas of need such as the inclusion of unrequired patient populations, standardization of drug dosing and duration, better validation of long-term toxicities and design and development of drug combination in patients with acquired resistance. Till the time such studies are carried out, usage of these drugs should be carefully selected to ensure safety.

The participation of various stakeholders is required for the successful design and conduct of the studies. Academic research groups and cooperative trial networks, along with industry partners may be best poised to lead designing studies in understudied populations that may not be studied otherwise.

To implement recruitment of people in clinical trials and for the successful completion trials, it is important to understand that links are required between the barriers and specific model parameters and that requires extensive research. The uses of new-age technologies like in-home testing, usage of cell phones appear to be more effective in reducing cost across the therapeutic areas and trial phases. It has been seen that usage of in-home testing can reduce the per-trial cost by 16% in Phase I, 22% in Phase II and 17% in Phase III depending on therapeutic area. Similarly, use of mobile technologies and relaxing trial enrollment restrictions could have an impact on the cost, that further results in maximum saving which represents ~1% of study cost.

References

1. Dixit R et al. (2017)
2. US FDA Novel Drug summary (2020)
3. US FDA 2016 Novel Drug summary (2017)
4. Martin J (2018)
5. Kadam RA et al. (2016)
6. English R et al (2010)
7. Weisfeld V et al (2011)
8. DiMasi JA et al. (2016)
9. Morgan S et al (2011)
10. Sertkaya A et al. (2014)
11. Cost and Impact in Clinical Trial
12. Sertkaya A et al. (2014)
13. USFDA (2012)
14. Eisenberg P et al. (2012)
15. Blazynski C (2019)
16. Singh A (2019)
17. Singh A (2019)
18. Meinert. L et.al (2019)
19. European Clinical Research Infrastructure Network (Accessed on September 2019)
20. Shenoy P (2016)
21. Khin NA et al. (2013)
22. Basic Principles on Global Clinical Trials (Accessed on 2015)
23. Khin NA et al. (2013)
24. Webster B et al. (2016)
25. Ilancheran M (2014)
26. Christmas L et al (2012)
27. Cyndi R (2014)
28. Ilancheran M (2014)
29. Khaleel S (2015)
30. Orphan Drug Report (2019)
31. Khaleel S (2015)
32. Romano S et al (2019)
33. Taichman DB et al (2016)
34. TCSDD (2015)
35. Duma N et al (2017)
36. Singh R et al (2016)
37. Caffrey M (2017)
38. Gelinas L et al (2017)
39. Sertkaya A et al (2016)
40. Monteleone J (2016)
41. Regulatory Focus 2013
42. Cornis R et al (2016)
43. Tele-Health (2018)
44. Coalition of Clinical Trials Awareness (2016)

North America

55 Madison Ave, Suite 400
Morristown, NJ 07960
USA
T: +1 212 835 1590

Europe

Stadsplateau 7
3521 AZ Utrecht
The Netherlands
T: +31 30 298 2108

United Kingdom

5 Chancery Lane
London EC4A 1BL
United Kingdom
T: +44 207 406 7548

Asia Pacific

Millennium Business Park
Sector 3, Building # 4, Mahape
Navi Mumbai 400 710
India
T: +91 22 6772 5700

futurebridge.com

FutureBridge