SKYLIMIT RESEARCH PRIVATE LIMITED

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Dt. 05.03.2024

To,

The Assistant General Manager
Punjab National Bank,
MCC, Sector 1, Noida

Sir,

Reg: Proposal for sanction of term loan Rs. 30.00 crores

In the above subject, we submit our proposal for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine companies/manufacturers mandated by the authorities as per the stringent regulatory guidelines.

Name and address of the unit: -

M/s Skylimit Research Private Limited.

Unit location:

Constitution: Company is limited by Shares with authorized capital of Rs.10.00 lacs and paid up capital of Rs.1.00 lac.

Introduction of the project: The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability / Bioequivalence studies dictated for the drug/ medicine/ pharmaceutical companies/ manufacturers by the stringent regulatory guidelines. In life sciences, a contract research organization (CRO) is a company that provides support to

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the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

A CRO may provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. CROs are designed to reduce costs for companies developing new medicines and drugs in niche markets. They aim to simplify entry into drug markets, and simplify development, as the need for large pharmaceutical companies to do everything 'in house' is now redundant. CROs also support foundations, research institutions, and universities, in addition to governmental organizations.

Many CROs specifically provide clinical-study and clinical-trial support for drugs and/or medical devices. However, the sponsor of the trial retains responsibility for the quality of the CRO's work. CROs range from large, international full-service organizations to small, niche specialty groups. CROs that specialize in clinical-trials services can offer their clients the expertise of moving a new drug or device from its conception to FDA/EMA marketing approval,[6] without the drug sponsor having to maintain a staff for these services.

Organizations who have had success in working with a particular CRO in a particular context (e.g. therapeutic area) might be tempted or encouraged to expand their engagement with that CRO into other, unrelated areas; however, caution is required as CROs are always seeking to expand their experience and success in one area cannot reliably predict success in unrelated areas that might be new to the organization.

Definition, regulatory aspects

The International Council on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, a 2015 Swiss NGO of pharmaceutical companies and others, defined a contract research organization (CRO), specifically pertaining to clinical trials services as "A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions." It further details the sponsor's responsibilities in its good clinical practice guidelines.

- A sponsor may transfer any or all of the sponsor's trial-related duties and functions to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor. The CRO should implement quality assurance and quality control.
- Any trial-related duty and function that is transferred to and assumed by a CRO should be specified in writing. The sponsor should ensure oversight of any trial-related duties and functions carried out on its behalf, including

trial-related duties and functions that are subcontracted to another party by the sponsor's contracted CRO(s).

- Any trial-related duties and functions not specifically transferred to and assumed by a CRO are retained by the sponsor.
- All references to a sponsor in this guideline also apply to a CRO to the extent that a CRO has assumed the trial-related duties and functions of a sponsor.

Guidance from the US FDA published in 2013 also speaks to the responsibility of the sponsor to oversee work of the CRO, including the circumstance where risk-based monitoring has been delegated to the CRO. 2021 saw a major update to US FDA regulations related to providing the agency with information about CROs and how they "comply with FDA regulations".

Market size and growth

As of 2023, there were over 1,600 CROs in the world, despite continued trends toward consolidation. Many CROs have been acquired while others have gone out of business. The industry is fragmented, with the top 30 companies controlling 56% of the market in 2020 and around 57% in 2023. In 2023 global CRO market stood at USD 82,396.40 million and is projected to reach USD 129,926.3 million by the end of 2029, exhibiting a CAGR of 11.4% in the forecast period.

Top CROs by annual revenue:

As of 2020, there was a 15.5% increase in R&D spending from 2015 to 2020. The list of contract research organizations includes the following notable companies worldwide:

1. Labcorp Drug Development, USA ($14.00B revenue in 2020)
2. IQVIA ($11.35B revenue in 2020)
3. PPD, Inc. ($4.68B revenue in 2020)
4. Syneos Health ($4.41B revenue in 2020)
5. Charles River Laboratories ($2.92B revenue in 2020)
6. ICON PLC ($2.79B revenue in 2020)
7. Parexel ($2.44B revenue in 2017)
8. Wuxi Apptec ($1.01B revenue in 2017)
9. Medpace ($0.92B revenue in 2020)

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BA/BE CROs of Indian origin and future prospective

The key to making profits in the generic drug market is reaching the market as early as possible by getting proper regulatory approval. Generic medicines play an essential role in the pharmaceutical market because of their lower cost than branded drug molecules. Manufacturers of Generic Pharmaceuticals need not begin from scratch and carry out R&D, preclinical research, and early phase clinical trials.

Instead, they need to show that their drug has a similar Bioavailability and Bioequivalence (BA/BE) as the branded drug. Regulatory bodies carry out a thorough inspection of the manufacturing plant and the clinical trial site and analyze the trial data to check if there has been any data fraud or manipulation.

Generic drug manufacturers thus have to follow the ICH guidelines on good manufacturing, laboratory, and clinical practices to bring a drug ethically to the market.

BA/BE trials are required to prove that the study drug is bioequivalent to the already marketed drug for the same indication. A generic pharmaceutical company always wants to submit BA/BE trial data of their product on time to get regulatory approval to market their drug without any delay. However, developing and executing BA/BE studies ethically under the GCP guidelines is not a cakewalk. Instead, it needs proper planning and a team of investigators, clinicians, medical writers, pharmacokinetics, bioanalytical scientists, biostatisticians, nurses, phlebotomists, and pharmacists. Thus, CROs dealing with BA/BE studies are the choice of many generic drug manufacturers.

India has around 76 BA/BE study centers as of June 10, 2021, under the new clinical trials rule 2019. We present the ten best CROs of Indian origin (headquarter in India) that we consider leading the BA/BE service provider market and have ample opportunity to grow more in 2022.

These ten companies are solely selected based on the data available on their website and the number of years they have been in the BA/BE industry. However, this article does not prove that the other BA/BE CROs are down in performance or not suitable to conduct BA/BE study.

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1. Syngene International Limited, Bangalore

Founded in the year: 1993
Group Companies: Biocon, Biocon Biologics, Biocon Academy, Bicara Therapeutics
Key Financial Information of FY 2021:
Companies Net Worth: increased by 10.52%
Operating Revenues: INR 2184 crores (12% growth compared to FY 2020)
Profit After Tax (PAT): INR 382 crores (4% growth)
EBIDTA : increased by 15.14%

Brief about BA/BE services by Syngene International Limited

Syngene International provides a comprehensive solution for Clinical Development of Generic Drugs.

Till date the organization has successfully completed approximately 700 BA/BE studies. The bioanalytical facility for BA/BE studies is GLP-complaint, spreaded across 7500 square feet and has been successfully audited by the USFDA, ANVISA, UK MHRA, and EMA. Syngene International has more than 150 validated assays developed for BA/BE studies.

2. Vimta Labs, Hyderabad

Founded in the year: 1984
Subsidiary Company: Emtac Laboratories Private Limited
Company operational in different cities across India: Hyderabad, Pune, Vizag, Bangalore, Cochin, Ahmedabad, Kolkata, and Nellore.
Key Financial Information of FY 2021:
Companies Net Worth: increased by 12.35%
Operating Revenues: INR 209.05 crores (13.6% growth compared to FY 2020)
Profit After Tax (PAT): INR 21.26 crores
EBIDTA : increased by 75.55%

Brief about BA/BE services by Vimta Labs, Hyderabad

Vimta Labs have 23 years of experience in execution of BA/BE studies. They carry experience of handling studies of different dosage forms including Injectables, ODS, Patches, Oral Suspensions, and Topical formulations.

They have Experience in conducting BA/BE study on highly variable drugs, BA/BE studies in special populations, patient-based PK studies, 505 b (2) submissions, Apple Sauce fed studies, Steady state studies, and other BA/BE studies involving Complex designs.

3. Lambda Therapeutic Research Limited, Ahmedabad

Founded in the year: 1999
Global presence of the company in different locations: India, USA, Representative offices in UK (London), Poland (Warsaw), USA, and Canada.
Key Financial Information of FY 2021:
Companies Net Worth: increased by 19.79%
Operating Revenues: INR 100 cr-500 cr
EBIDTA: increased by 60.69%

Brief about BA/BE services by Lambda Therapeutic Research Limited, Ahmedabad

Lambda Therapeutic Research Limited has 21 years of experience, expertise, and capabilities in handling BA/BE studies. The CRO has capability to conduct studies in different dosage forms like injectables, inhalation, topical products, nasal sprays, suppositories, vaginal products, transdermal, ointments, intravaginal and rectal products, and all oral dosage forms. Till date the CRO has experience of conducting more than 7000+ BA/BE studies. Lambda offers global access to 100+ clinical beds inclusive of 85+ specialized beds designed for specific studies. All the facilities of Lambda Therapeutic Research have been successfully inspected by leading regulatory agencies.

4. Veeda Clinical Research, Ahmedabad

Founded in the year: 2004
Group Companies: Bioneeds, Ingenuity Bioscience
Key Financial Information of FY 2021:

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Companies Net Worth: increased by 1.19%
Operating Revenues: INR 195.8 crore (22.7% growth compared to FY 2020)
Profit After Tax (PAT): INR 62.9 crore
EBIDTA: decreased by -85.23%

Brief about BA/BE services by Veeda CR

With 17 years of experience, Veeda Clinical Research has grown to be a Clinical Research Organization of choice for many pharmaceutical and biopharmaceutical companies worldwide. Veeda Clinical research has 77 successful regulatory Audits from regulatory bodies like **USFDA, MHRA, ANVISA, WHO, NPRA, ANSM, AGES, MCC**, and **DCGI.** Veeda Clinical Research has experience in handling BA/BE studies related to Special population like female volunteers, volunteers with ovarian cancer, and geriatrics.
Complex Generics Studies related to

Long Acting Injectables
Rectal Suppositories
Inhalational drugs
Transdermal Patch
Glucose Clamps
PK endpoints and Adhesion study

Healthy Volunteers and patient-based BA/BE studies

Oral DDS

Urine PK studies

505 (b)(2) submissions

Fasting and fed BA/BE studies

The CRO has experience of conducting BA/BE studies in healthy volunteers with different dosage forms.

Coming to infrastructure, Veeda CR has:

State of the art **negative-pressure** room for dosing activity for respiratory medications.

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588 BEDS + 20 SPECIAL CARE beds
Bioanalytical Facilities

46 LC-MS/MS MACHINES

2 ICP-OES

Watson LIMS

Storage Capacity

45 Deep freezers with capacity to store 11,25,000 samples at -80 °C

3 Walking type stability chambers with overall capacity to store 34000 Ltr for retention at room temperature

4 Humidity chambers with overall capacity of 3200 Ltr

4 Pharmaceutical refrigerators having storage capacity of 3550 Ltr at 2-8 °C

5. Cliantha Research Limited, Ahmedabad

Founded in the year: 2004
Global presence of the company in different locations: USA (facilities in Florida and Project management in New Jersey), Canada (facilities in Mississauga, Winnipeg, and Scarborough), and Portugal (project management)
Company operational in different cities across India: Ahmedabad, Noida, and Vadodara
Key Financial Information of FY 2021:
Companies Net Worth: increased by 6.34%
Operating Revenues: INR 100cr-500cr
EBIDTA: decreased by -37.47%

Brief about BA/BE services by Cliantha Research Limited

Cliantha Research Limited is a full-service CRO with 17 years of experience in handling BA/BE studies for different dosage forms like chewable tablets, suspension, injection, sublinguals, granules, rectal, transdermal, vaginal, nasal spray, gel, lotion, inhalation aerosol, and topical cream.

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The CRO has more than 600 validated assays for BA/BE studies and has impeccable regulatory history with USFDA, WHO, MHRA, Health Canada, AGES, AEMPS, MCC, MOH, ANSM, MOPH, ANVISA, CAP, and NABL.

6. Sipra Labs Limited, Hyderabad

Founded in the year: 1994
Headquarters: India
Key Financial Information of FY 2021:
Companies Net Worth: increased by 2.37 %
Revenue/Turnover: INR 1 cr-100 cr
EBIDTA: decreased by -13.91%

Brief about BA/BE services by Sipra Labs Limited, Hyderabad

Sipra Labs comes with more than 20 years of experience in providing comprehensive BA/BE services to different leading generic and innovator pharmaceutical industries. Till date, the CRO has an experience of conducting 1600+ BA/BE studies and has more than 150 validated methods. The CRO has 2 clinics with 80 beds facility along with ICU with central online monitoring system for hassle free execution of BA/BE trials in humans. Sipra has supported many global and indigenous pharmaceutical players for their dossier submissions to highly regulated markets like US, Europe and Japan.

7. Raptim Research Private Limited, Navi Mumbai

Founded in the year: 2002
Headquarters: India
Global presence of the company in different locations: India, USA (Marketing Team)
Key Financial Information of FY 2021
Companies Net Worth: increased by 16.31%
Operating Revenues: INR 1cr-100 cr
EBIDTA: decreased by -47.01%

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Brief about BA/BE services by Raptim Research Private Limited

Raptim has conducted more than 1100+ BE studies and has about 30,000 healthy volunteer data bases. The CRO has experience in designing and executing BA/BE studies involving psychotropic substances, drugs with long half-lives, teratogenic drugs, endogenous substances, depot injections and many more. Raptim Research is also experienced in conducting BA/BE studies involving non-oral dosage forms and specific populations.

The CRO also has experience and expertise in special studies like In Vivo Tape Stripping studies, Glucose Clamp studies, Skin Blanching studies, Dermal Microdialysis, skin irritation/sensitisation studies, and Veterinary BA/BE studies.

8. Aizant Drug Research Solutions

Founded in the year: 2005
Key Financial Information of FY 2021:
Companies Net Worth: decreased by -0.81%
Operating Revenues: INR 100-500 crores
Total Assets: Increased by 2.03%
EBIDTA: decreased by -48.57%

Brief about BA/BE services by Aizant Drug Research Solutions, Hyderabad

With over 16 years of experience and capabilities as a CRO in the BA/BE industry, Aizant Drug Research provides the following Pharmacology and Bioanalytical benefits to their clients:

State-of-the-art facilities with global access to 160+ beds

Tie up with multispecialty hospital to perform specific studies

Excellent scientific expertise in handling complex and unstable molecules in BA/BE studies

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Excellent services in Medical Writing, Biostatistics, and Clinical Data Management

Robust recruitment & housing options customizable to sponsor / study requirements

Experience of Proof-of-concept studies, Patient PK Studies, Food Interaction Studies, Clinical end point studies and Clinical Trials

Independent ethics committee/ Institutional Review Board

Volunteer database

Male: 8000+

Female: 2000+

Access to post-menopausal women database

State-of-the art Liquid Chromatography and Tandem Mass Spectrometry (LC-MS/MS) instruments with a capacity of 4000 samples per week

9. Axis Clinicals, Hyderabad

Founded in the year: 2004
Global presence of the company in different locations: India, United States, and Mexico
Key Financial Information of FY 2020:
Companies Net Worth: increased by 31.01%
Operating Revenues: INR 100 cr-500 cr
EBIDTA: increased by 122.61%

Brief about BA/BE services by Axis Clinicals, Hyderabad

Axis Clinicals as a CRO have around 17 years of experience in conducting BA/BE studies for different dosage forms including Solid Dosage Forms (Tablets, Capsules, Soft Gels, Sprinkles, Immediate Release, Extended Release, Delayed Release and Sustained Release), Orally Dispersible Formulation, Liquid

Formulations, Suspensions & Syrups, Parenterals (Intra Muscular, Intra Venous & Subcutaneous), Inhalational Dosage Forms (Sprays Nasal & Oral, Metered Dose Inhaler, Dry Powder Inhaler), Transdermal Gel, Dermal Patches, and Skin Blanching Studies.

They also have experience in conducting studies in patient populations (PK/PD studies).

The infrastructure capabilities of the company for BA/BE studies in India include 330 beds (192 beds in Hyderabad and 138 beds in Ahmedabad), Refrigerated Centrifuges, Humidity Chambers, and -30°C and -80°C storage facility.

The company has successfully completed 38 regulatory audits (31 USFDA Audits, 4UK MHRA Audits, 2 WHO Audits, 1 audit from AEMPS of Spain, 1 audit from INFARMED of Portugal, 1 from NPRA of Malaysia, 1 audit from GCC, and 1 audit from MCC of South Africa.

10. Jeevan Scientific Technology

Founded in the year: 1999
Headquarters: India
Key Financial Information of FY 2021 (standalone basis)
Operating Revenues: INR 41.4 crores
Total Profit: INR 11.3 crores
EBIDTA: INR 18.85 crores

Brief about BA/BE services by Jeevan Scientific Technology, Hyderabad

Founded in 1999 as Jeevan Softech Pvt.Ltd, Jeevan scientific technology later started medical writing services in 2011. In December 2014, 15 years after its foundation, the organization inaugurated the corporate and bioanalytical facility which was inspected and approved by CDSCO in March 2015. Jeevan Scientific has started BA/BE studies since 2016. Till date the company has completed 80 Pivotal and 123 pilot studies. The organization has experience in working for different regulatory bodies like USFDA, EMA, Canada, WHO, and

PEPFER. Jeevan scientific offers BA/BE studies on oral dosage forms, injectables, suspensions, and liquid dosage form.

Benefits of Clinical Research Services in India

The pharmaceutical industry in today's times is reeling under the pressure of rising costs, stricter regulatory norms and shorter life cycles of products and is turning towards the Asian countries for conducting its clinical research studies. The existence of a strong intellectual base and low-cost structure has made India one of the favourite destinations among the whole lot.

Clinical Research India Advantage

Clinical trials are needed to evaluate the efficacy of new medicines which work towards the betterment of patients. One of the popular global hubs for conducting these clinical trials is India and the reasons for the same can be listed as follows:

- A progressive attitude and support of the Indian government
- Availability of sufficiently sized patient pool
- Presence of highly skilled and motivated medical and paramedical staff
- Well-equipped hospitals
- Strong information technology
- Low-cost manufacturing abilities

Clinical Research Services in India- Enabling Clinical Trials to get off a Good Start

The drug development journey is a complex one and the requirements of regulatory compliance, sophisticated technologies and harmonized protocols can put a spoke in getting your drug to the market. Availability of clinical research services in India makes this task much simpler besides controlling the costs of development and reducing chances of late phase failure. The benefits of these services can be obtained all through the four phases of clinical trials starting from Phase I to Phase IV. Benefits at each phase are listed below.

Patient Recruitment

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- Forecasting, monitoring and managing patient recruitment is of utmost importance.
- Offering a total scale of patient outreach.
- On-site support assistance like training, data provision and any other.
- Minimizing delays in the start of your clinical trial

Phase I Trials

- Presence of testing units within the hospital offers immediate access to a state-of-the-art environment for conducting Phase I safety studies.
- High doctor to bed ratio & quality paramedical staff
- Combination protocols
- Target patients assured of safety studies
- Pharmacological consulting services

Phase II-III Trials

- Availability of skilled clinical team with wide experience in therapeutic area
- Availability of comprehensive range of e-Clinical technologies (e-Prudent), technologies that enhance efficiencies, data accuracy and lead to cost reductions and speedier development times.
- Application of best practices and proven measures of site management
- Provision of customized and optimized clinical process

Phase IV Trials

- Provision of supplementary information on the benefits, risks and best use of the drug after it gets the approval from the regulatory authority.

Summarizing

- Clinical trials need to be undertaken using correct methods which comply with ethical considerations and Good Clinical Practice. This places a significant burden on medical institutions conducting clinical trials. Clinical research services provider offers dedicated support to biotechnology and pharmaceutical companies right through all stages of their clinical trials. The gambit of clinical operation services provided by the service provider includes the latest technology, the required

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infrastructure, knowledge and the experience needed to take the clinical trials to successful fruition.

Clinical Research Industry in India

Issues and Opportunity

Clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. This article dwells on the scope, nature and business opportunities and challenges the Indian clinical research industry offers.

Clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Importance of Clinical Research in New Drug Development

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth $1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry

totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US $146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs $282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

Why India is Preferred Destination for Clinical Research?

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

Population

India represents 15% of the world population having a huge population base of over one billion. This population is genetically, culturally and socioeconomically diverse. This is very important as compared to their Caucasian counterparts as Asians react differently to drugs. India also has the largest pool of English-speaking people in the world as English is the primary language of education and communication

Patients

India has the largest and diverse pool of patients. The Indian advantage in clinical development is clearly the speed of patient enrolment and thereby shorter timelines for clinical trials. In India, many people still live in large, joint

and extended families making them attractive recruits for genetic linkage studies. India is also home to a wide variety of diseases ranging from tropical infections to degenerative diseases. The highest number of cancer and diabetes patients is found in India. It is also home to more than one billion people, including 30 million with cardiovascular diseases and other diseases as given in the Exhibit.

Physicians

India has high patient–physician ratio. There is no dearth of medical, pharmacy and science graduates and plenty of trained professionals are available in the field of medicine.

Clinical Research in India: Benefits to Stakeholders

Clinical research holds tremendous scope and opportunities not only for trained medical, pharmaceutical and paramedical professionals, but also for regulatory authorities, government and the society at large. It will make available the state-of-the-art therapy for many deserving Indian patients who have hitherto been deprived of such therapeutic advances.

Patients who participate in clinical trials study will have access to the latest medication or treatment; get free medical care, which includes costs of investigations and medicine. And though they participate in the trial voluntarily after signing an informed consent, they are not bound to continue to participate in the trial as the consent can be withdrawn at any time. Patients also receive more frequent and focused consultations leading to an improvement in the quality of healthcare. Investigators and physicians who conduct clinical trials get firsthand knowledge and experience with the most recent drugs. Physicians also get global recognition by working on the same research platform as other international experts on the project. They also get extensive training in the internationally accepted Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) guidelines. They have access to the latest medicines to use in their patients. It also provides an opportunity for the publication of clinical trial research study. Hospitals and clinical sites where the research is conducted will get a boost in infrastructural development, get recognized globally and will have collaboration opportunities with educational institutes.

EXHIBIT

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Disease	Patient Population
Asthmatic patients	40 million
Diabetic patients	34 million
HIV positive people	8-10 million
Epileptic patients	8 million
Cancer patients	3 million
Alzheimer's disease	1.5 million
Hypertensive population	15%
Schizophrenia	1%
Source: Igate clinical research International	

Clinical Research in India: Major Issues

Unethical Approach in the Recruitment of Subjects

To protect the interests of the clinical study participants, a written informed consent of participants is usually required before the recruitment of participants in clinical trial study takes place. It has come into the limelight that poor and uneducated patients, who do not understand the meaning and purpose of trials, are lured into it for monetary gains. Subsequently, they may become victims of the possible side effects of trials. High levels of illiteracy and abject poverty in rural India combined with the pressure from the sponsors of clinical research study for early completion of clinical trial, sometimes lead to unethical recruitment of patients. An increase in the literacy level and improvement in socioeconomic levels are expected to improve the awareness of patients along with their rights regarding the approval they give for clinical trial studies. Subject willingness is very critical in clinical trials. The GCP guidelines stress the need for documentation of the whole informed consent process of clinical study participants. A strict adherence to the study protocol by the on-site investigators and the study team members will help protect the rights of the clinical study participants.

Inadequate GCP (Good Clinical Practices) and GLP (Good Laboratory Practices) and GMPs (Good Manufacturing Practices) Training

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Certain uniform guidelines for GCP and GLP need to be followed while conducting clinical trials and generating clinical trial data. Out of the large pool of medical professionals in India, only a handful are GCP- trained and experienced in conducting clinical trials. A major plan is required at the beginning of the clinical trial to train doctors in the basics of GCP. Each year the number of GCP trained personnel is steadily increasing in India. Sponsors, Contract Research Organizations(CROs) and Site Management Organizations (SMOs) are making efforts to train more and more numbers of clinical investigators and ethics committee members on the principles and practice of GCP. All these steps will ensure the timely and economic completion of the clinical trials.

Multifaceted Regulatory Affairs in India

The Drugs Controller General of India (DCGI) is responsible for regulatory approvals of clinical trials in India. The DCGI's office depends on external experts and other government agencies for clinical research advice. Additional permissions are required for the export of blood samples to foreign central laboratories. All this usually takes about 3 months in India, compared to 30 days required for US FDA approval. There are some instances of clinical research firms violating DCGI norms. While clinical study sponsors claim to take responsibility to insure the subjects involved in the clinical trial, the reality is that insurance in clinical research is yet to gain grounds in India. Indian regulations are getting more and more stringent and ethical committees are playing a very significant role. Clinical trials are to be conducted as per ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use) and GCP norms. The ICH-GCP guidelines, critical for reliable clinical research, have been mandated in India. Indian regulatory authorities including the DCGI and Indian Council of Medical Research ICMR) have is sued the Indian version of GCP which is in compliance with ICH-GCP guidelines.

The Deficiencies in the Functioning of the Ethics Committees

Though ethics is an important part of clinical and medical research, it is very often neglected. The ICMR guidelines for clinical trials insist on the set ting up of Institutional Ethics Committees (IEC) at the unit levels. The IEC's responsibility is to supervise, scrutinize and approve the clinical trial before the study begins and also to conduct periodic reviews of the progress of the clinical trial. Many clinical research institutions in India, however, either do not have

an IEC or there is inadequate representation of the non-technical personnel. Without adequate representation of persons from a non-functional background, the opinion of the IEC is likely to be unfair and biased in favor of the clinical study. The clinical research guidelines clearly specify the need for such personnel in the IEC. Some institutes have IEC but do not have a regular schedule of committee meetings, lack Standard Operating Procedures (SOPs) or do not have a proper member representation according to the ICMR guidelines. However, things are changing fast for the better. The ICMR has a Central Ethics Committee on Human Research (CECHR). This committee audits the functioning of these IECs composed as per the ICMR guidelines. The DCGI's office, in collaboration with WHO, ICMR and many committed research professionals, has been conducting training programs for members of the ethics committees across the country.

Opportunities for Clinical Research in India

Despite all the above pitfalls, India is in a position to attract more and more firms around the globe to conduct their clinical trial studies in India. The Indian regulatory system is
being simplified and laws are being amended to facilitate the entry of global clinical trials. Massive and concerted efforts are on to train clinical research professionals and increase the base of clinical investigators and supporting staff. Many educational institutes are now offering specialized programs in clinical research. India has a large pool of English-speaking, highly qualified and experienced scientists and clinical research professionals. The DCGI has simplified the global clinical trial approval process by agreeing to accept clinical trials approved in recognized countries. The DCGI has implemented new guidelines for global clinical trials in India from December 1, 2006. All these initiatives are certain to improve the existing situation and are likely to boost the number of clinical trials in the country. In brief, clinical research is emerging as a sunrise sector in India.

One of the major reasons why clinical trials are coming to India is that in the developed countries it is increasingly becoming difficult to get subjects (people willing to undergo trials). This ultimately leads to delay in the drug development process.

However, in India, sponsors have the plenty of opportunity to recruit subjects. In India, a large section of the population being unable to afford their own medical treatments, opt for such clinical trials as they are assured of treatment and healthcare, which would have not been available otherwise. Hence, India

has one of the highest subject return rates in the world. At present, 20-22% of global trials are being held in India and analysts project that by 2028, up to 50% of global clinical trials will take place outside US and Western Europe, and India will emerge a favorable destination.

Clinical Research: Growth Prospects and Market Opportunity

India's pharmaceutical market, the second largest in Asia, is estimated at US$ 11.78 bn in 2023 and projected to grow up at CAGR of 13.6% to US $ 15.94 bn by 2028. The clinical research industry is a major employer of medical and scientific staff and with the growth of clinical research market the demand for qualified personnel is also on the increase. It is a knowledge industry driven by doctors, patients, pharmaceutical, biotech, diagnostic and IT companies. Clinical trial study is a very data and quality-intensive work. The scope of any error is very limited and involves high degree of ethics, both personal and professional. More and more pharma companies /clinical research organizations / site management organizations are entering the clinical research industry in India.

Basically, clinical research is a human resource-intensive enterprise. Each step in the process of planning and executing a clinical trial study requires highly qualified individuals.

Some of the most knowledge intensive parts of the clinical research process relate to activities that require knowledge of the therapeutic area, clinical expertise and research experience. The clinical research industry requires the services of a diverse range of specialists like medical professionals with specialization in internal medicine and pharmacology, nurses, phlebotomists, quality control and quality assurance personnel, data entry personnel, pharmacokinetic specialists, bio statisticians, analytical chemists, laboratory technicians, medical writing group, diagnostic technicians, etc. From a qualifications perspective it employs post doctorates, medical doctors, post graduates in the fields of organic chemistry, molecular biology, microbiology, biotechnology, pathology, biochemistry, pharmacology, etc. The India Clinical Trials Market has reached a valuation of USD 1.55 Billion in 2023 creating a demand of 50,000 professionals by 2023. Trained pharmacists and clinicians can fill this wide gap. They will be involved in the various aspects of clinical research starting from site-monitoring, site-management, clinical data management, data analysis, report writing, report submission, presentation and publication. A number of factors favor the recognition of India as the hub for clinical research due to which the MNCs have identified it as their ideal destination. There are numerous government-funded medical and pharmaceutical institutions having state of-the-art facilities, which can serve

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Director

as ideal centers for multi-centered clinical trials. In terms of cost efficiency, India works out to be a cheaper option as the cost to conduct a trial here is lower by 50 to 75% than that in either US or EU. R&D costs in India are much less than those in the developed countries and it is possible to conduct both New Drug Discovery Research (NDDR) and Drug Delivery System (DDS) programs at competitive rates. Additionally, while clinical trials cost approximately $800 to $950 mn abroad, they cost about Rs.600 cr in India.

Globally, there has been recognition of the Indian advantages which attract pharmaceutical companies to adopt collaborative outsourcing strategies for clinical trials. According to industry estimates, the cost of phase I trial is 50% and phase II 60%, lower in India. Considering the fact that less than one-third of the drugs tested in clinical trials actually reach the market, the study of drugs in humans needs to be logical, with sound scientific basis in both conception and execution. The rigors of research should be adopted so as to maximize the benefits to mankind at minimum costs and risks. Clinical research industry has grown around the world at an unparalleled rate in the past few years. The clinical trial market worldwide is worth over US$ 65 bn and the industry has employed an estimated 4,15,000 people in the US and over 90,000 people in the UK, and they form one-third of the total research and development staff. These large numbers can be attributed to the fact that this industry is fast growing and dynamic and hence offers lucrative job opportunities.

Conclusion

India is emerging as a natural choice and ultimate destination for contract clinical research services. Clinical research is a rapidly growing industry in India. India's lower infrastructure costs and the rapidity of subject recruitment for clinical trials, which compress clinical trial timelines, offer a favorable cost benefit to sponsors and clients. A huge population with a diversity of diseases, competitive costs, high enrolment rates, good patient compliance and retention rate, sound infrastructure facilities and favourable regulatory environment are the benefits of conducting clinical research in India. Many pharmaceutical organizations and clinical research firms have started extracting the vast potential that India has and are conducting clinical trials in India on a big scale. As clinical trial study costs are 50-60% lower in India than the trials conducted In developed countries, more and more MNCs are thronging to India to conduct their clinical trials.

Brief profile of the company and its Directors:

Skylimit Research Private Limited

Director

The company was incorporated on 11.12.2023 as a private limited company having CIN no. U32502UP2023PTC193875. The authorized capital of the company is Rs. 10.00 lacs and paid-up capital is Rs. 1.00 lacs. The company has proceeded for increase of the authorized capital of the company to Rs. 15.00 Crores and paid-up capital to Rs. 10.00 crores. The promoter directors are having ample experience in pharmaceutical/ Bioavailability/ Bioequivalence and Clinical Research areas.

1.Name of the entity: Skylimit Research Private Limited

2.PAN: ABMCS2859R

3.Registered address of the entity: VILLA-2/9, LAND 2, JAYPEE GREENS, GREATER NOIDA, UP-201306

Works/CRO location at Plot No. 28, Sector- 155, Noida, Gautam Budh Nagar, Uttar Pradesh.

4.Contact Number: _Mobile: 9719193909

5. E-mail IDs for document/data sharing: skylimitresearch@gmail.com

6. Constitution: Company Limited by Shares

7. Nature of business: Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/ pharmaceutical companies/manufacturers

8.GSTIN (if available): Uttar Pradesh- 09ABMCS2859R1Z6

Udyog Aadhar Number [UAN] (if available): UDYAM-UP-28-0099655

9.IEC (if applicable): NA

10.Date on which entity was established: Date of Incorporation 11.12.2023

CIN No. of the Company: U32502UP2023PTC193875

11. Details of owner/partner/promoter/director:

Name/ Designation	Date of birt	UDIN No.	PAN/ Aadhar No.	Qualification	Experience

Skylimit Research Private Limited

Director

Karan Pratap Rawat, Director	02/01/2000	08163436	GXWPS7371P 806698463827	Graduate	04 years
Yash Pratap Singh, Director	11/08/2001	10075889	MSCPS9247R 226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R 714667948713	Post Graduate	03 years

No director or a relative/near relation (as specified by RBI) of a director of a banking company or a relative/near relation (as specified by RBI) of a senior officer of any bank (as specified by RBI) is the Applicant(s), or a partner of our concern, or a trustee, member, director, manager, employee of our concern, or of subsidiary, or our holding company, or a guarantor on my/our behalf, or holds substantial interest in our concern or my/our subsidiary or holding company.

12. Caste: NA Sub-caste: NA

13. Details of associate/group entity:

Name	PAN	Primary Activity	Bank
NA	NA	NA	NA

14. Current Shareholding/Profit-sharing pattern:

Name	Shareholding/Profit-sharing %
Karan Pratap Rawat, Director	NA

Skylimit Research Private Limited

Director

Yash Pratap Singh, Director	NA
Sandeepika Sharma/ Director	NA

15. Status regarding statutory obligations [To be verified by SM]:

Pollution Control Board (PCB) certificate	Yes
Lease agreement validity	31.01.2029 automatically renewable after expiry of the lease period for another tenure of 05 years
Environmental clearance certificate	Yes
Latest GST/VAT return filed	NA
Latest Income tax return filed	NA
Other statutory dues clearances	NA

S No.	Heading	Details
1a	Name of the Entity	M/S Skylimit Research Private Limited
1b	Nature of business (Manufacturing / Service / Trading / Others	Clinical Research Organization (CRO) unit for conducting Bioavailability/ Bioequivalence studies dictated for the drug/medicine/ pharmaceutical companies/manufacturers
2a	Registered Office Address	VILLA-2/9, LAND 2, JAYPEE GREENS, GREATER NOIDA, UP-201306

Skylimit Research Private Limited

Director

2b	Factory Address	Plot No. 28, Sector- 155, Noida, Gautam Budh Nagar, Uttar Pradesh.
2c	Branch Address	NA
3	Contact Details:	
A	Telephone Number	9719193909
B	E-mail IDs for document/data sharing:	skylimitresearch@gmail.com
C	Mobile Number	9719193909
4	Constitution (Sole Proprietorship/Partnership Firm/Pvt. Ltd./Public Ltd./LLP/Trust/HUF)	Private Ltd.
5	Date of Establishment/Incorporation	11.12.2023
6	Details of registration with government authorities (along with the Validity), as applicable	All registrations are submitted
A	PAN	ABMCS2859R
B	GSTN	09ABMCS2859R1Z6
C	- Legal Entity Identifier (LEI) number for overall banking exposure more than 50 crores	NA
D	Udyam Registration Certificate (URC) (if available):	UDYAM-UP-28-0099655

Skylimit Research Private Limited

Director

E	Importer Exporter Code (IEC) (if applicable):	NA
7	Caste / Sub-Caste	General
8	Details of applied facilities (Amount of facility and purpose of loan)	Total Rs. 30.00 crores

Brief of Present Proposal: -

The present proposal is for sanction of fresh term loan limits as under:

Amt. in Rs. Crores

Nature of limit	Existing limits	Limits now requested	Rate of Interest/commission	Margin	Tenor
Fresh Open Term Loan	0.00	30.00	TL;- Repo + 2.50% i.e. 9.00%	25%	96 months including moratorium of 12 months.
Total limits/overall exposure	**0.00**	**30.00**			

Project details

In the dynamic landscape of marketing generic products in regulated markets, the imperative for Bioavailability/Bioequivalence (BA/BE) studies is dictated by stringent regulatory guidelines. These studies, comprising clinical and bioanalytical phases, are pivotal in establishing the equivalence of generic and

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Director

reference products. The clinical phase involves scrutinizing drug products on human volunteers, while the bioanalytical phase entails intricate analysis of drugs in biological matrices to compare test and reference products. A comprehensive bioanalytical setup is indispensable for this purpose.

Clinical research plays a vital role in the burgeoning pharmaceutical industry, offering support across all stages of drug development. With a consistent upward trajectory in pharmaceutical and biotechnology R&D expenditure, organizations, both large and small, are increasingly outsourcing clinical study-related work to Contract Research Organizations (CROs). The future growth trajectory of businesses appears secure, driven by the continuous expansion of the clinical research domain.

Success in this arena hinges on the implementation of Good Clinical Practice (GCP) to ensure quantity, timeline adherence, and cost-effectiveness, ultimately contributing to heightened profitability. The outsourcing trend, coupled with the adoption of novel technologies and robust project management, forms the cornerstone of long-term success in the clinical research landscape.

Despite the challenges inherent in the dynamic clinical research industry, strategic decision-making can create a financially attractive business environment with commendable profit margins. Recognizing that clinical research is an evolving field, aligning with the right developments and innovations ensures sustained growth over the years.

Key objectives:

- Establishment of a Clinical Research Organization (CRO).
- Attainment of regulatory accreditation through the establishment of a Good Clinical Practice (GCP) compliant setup.

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Director

In the fiercely competitive global drug development arena, the modern clinical research organization must prioritize agility and success. The proposed setup report for a clinical research organization encompasses a comprehensive list of equipment, accessories, cost analyses comparing industry and in-house options, regulatory approval strategies, Standard Operating Procedure (SOP) development, manpower planning, revenue budgeting, and the critical breakeven point.

Financial analysis

The financial calculation encompasses a detailed evaluation, comparing the actual study subject cost with the vendor industry cost. Additionally, it includes the comprehensive financial outlook for the Clinical Research Organization (CRO), covering the total investment, three-year revenue budget, and the crucial breakeven point.

Subject cost estimation

Yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost (INR)
Clinical			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
Total Clinical	Total Clinical Study cost for 30 subjects	5,40,000	7,65,000

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Bioanalytical			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 **Plus** 7,50,000X 25 = Rs. Rs. 1,87,50,000 **Sub-total = Rs. 3,22,50,000**	7,65,000 X 25 = Rs. 1,91,25,000 **Plus** 12,00,000X 25 = Rs. Rs. 3,00,00,000 **Sub-total = Rs. 4,91,25,000**
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 **Plus** 7,50,000X 2 X 25 = Rs. 3,75,00,000 **Sub-total = Rs. 6,45,00,000**	7,65,000 X 2 X 25 = Rs. 3,82,50,000 **Plus** 12,00,000X 2 X 25 = Rs. 6,00,00,000 **Sub-total = Rs. 9,82,50,000**
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average	**Rs. 32,50,000**	**Rs. 32,50,000**

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Director