DEATILED PROJECGT REPORT

M/S SKYLIMIT RESEARCH PRIVATE LIMITED

(A Clinical Research Organization)

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**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. The company has proceeded for increase of the authorized capi9tal to Rs. 12.00 crores.

**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 the [life sciences](https://en.m.wikipedia.org/wiki/Life_sciences), a contract research organization (CRO) is a company that provides support to the [pharmaceutical](https://en.m.wikipedia.org/wiki/Pharmaceutical_industry), [biotechnology](https://en.m.wikipedia.org/wiki/Biotechnology), and [medical device](https://en.m.wikipedia.org/wiki/Medical_device) industries in the form of research services [outsourced](https://en.m.wikipedia.org/wiki/Outsourcing) on a contract basis.

A CRO may provide such services as biopharmaceutical development, [biological assay](https://en.m.wikipedia.org/wiki/Biologic_assay) development, commercialization, [clinical development](https://en.m.wikipedia.org/wiki/Clinical_development), [clinical trials](https://en.m.wikipedia.org/wiki/Clinical_trials)  management, [pharmacovigilance](https://en.m.wikipedia.org/wiki/Pharmacovigilance), [outcomes research](https://en.m.wikipedia.org/wiki/Outcomes_research), and [real world evidence](https://en.m.wikipedia.org/wiki/Real_world_evidence). CROs are designed to reduce costs for companies developing new medicines and drugs in [niche markets](https://en.m.wikipedia.org/wiki/Niche_market). They aim to simplify [entry into drug markets](https://en.m.wikipedia.org/wiki/Market_entry_strategy), 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](https://en.m.wikipedia.org/wiki/Clinical_trial#Economics) 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](https://en.m.wikipedia.org/wiki/Food_and_Drug_Administration)/[EMA](https://en.m.wikipedia.org/wiki/European_Medicines_Agency) marketing approval,[[6]](https://en.m.wikipedia.org/wiki/Contract_research_organization#cite_note-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](https://en.m.wikipedia.org/wiki/International_Council_on_Harmonisation_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](https://en.m.wikipedia.org/wiki/Clinical_trial) 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](https://en.m.wikipedia.org/wiki/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](https://en.m.wikipedia.org/wiki/Quality_assurance) and [quality control](https://en.m.wikipedia.org/wiki/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](https://en.m.wikipedia.org/wiki/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](https://en.m.wikipedia.org/wiki/Regulatory_risk_differentiation) 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**[**:**](https://en.m.wikipedia.org/w/index.php?title=Contract_research_organization&action=edit&section=3)

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](https://en.m.wikipedia.org/wiki/Labcorp) Drug Development, USA ($14.00B revenue in 2020)
2. [IQVIA](https://en.m.wikipedia.org/wiki/IQVIA) ($11.35B revenue in 2020)
3. [PPD, Inc.](https://en.m.wikipedia.org/wiki/PPD,_Inc.) ($4.68B revenue in 2020)
4. [Syneos Health](https://en.m.wikipedia.org/wiki/Syneos_Health) ($4.41B revenue in 2020)
5. [Charles River Laboratories](https://en.m.wikipedia.org/wiki/Charles_River_Laboratories) ($2.92B revenue in 2020)
6. [ICON PLC](https://en.m.wikipedia.org/wiki/ICON_PLC) ($2.79B revenue in 2020)
7. [Parexel](https://en.m.wikipedia.org/wiki/Parexel) ($2.44B revenue in 2017)
8. [Wuxi Apptec](https://en.m.wikipedia.org/wiki/WuXi_AppTec) ($1.01B revenue in 2017)
9. [Medpace](https://en.m.wikipedia.org/wiki/Medpace) ($0.92B revenue in 2020)

# **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.

## ****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.

1. **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.

## ****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.

## ****Veeda Clinical Research, Ahmedabad****

**Founded in the year:**2004

**Group Companies:**Bioneeds, Ingenuity Bioscience

**Key Financial Information of FY 2021:**

**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.

**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 ℃

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 ℃

## ****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](https://www.cliantha.com/main/pdf/Resource-Library/Downloads/BA_BE_Dosage_Form_Experience.pdf).

The CRO has more than [600 validated assays](https://www.cliantha.com/main/pdf/Resource-Library/Downloads/Assay_List_Cliantha_Group-Dec-21_External_Final.pdf) 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.

## ****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.

## ****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%

## ****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.

## ****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

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

## ****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.

## ****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](https://en.wikipedia.org/wiki/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](https://www.biospherecro.com/) 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**

* 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](https://www.biospherecro.com/) provider offers dedicated support to biotechnology and pharmaceutical companies right through all stages of their clinical trials. The gambit of [clinical operation services](https://www.biospherecro.com/clinical-operation/) provided by the service provider includes the latest technology, the required infrastructure, knowledge and the experience needed to take the clinical trials to successful fruition.

# **Clinical Research Industry in India**

**Issues and Opportunity**

* Industry

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.

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| EXHIBIT | |
| 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**

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 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:**

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](mailto: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 birth | UDIN No. | PAN/  Aadhar No. | Qualification | Experience |
| 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 |
| 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 |
| 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 |
| 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 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.

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 |
| **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 number of 60 subjects in each Pivotal study) in a year @ 65000/- per study | **Rs. 32,50,000** | **Rs. 32,50,000** |
| **Overall Cost** | Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year | **Rs.10,00,00,000** | **Rs.15,06,25,000** |

Based on the proposed Clinical Research Organization setup and the above assumptions, a notable difference is evident in the actual study subject cost compared to the vendor industry cost, representing a substantial gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

**Study timelines**

The study timelines encompass various phases, namely the clinical phase, bioanalytical phase, statistical phase, and report generation.

**Clinical phase:**

Subject Screening: Approximately 10 days

Subject In-house: Approximately 10 days

Ambulatory Visit: Approximately 2 days

Total Duration for Clinical Phase (Normal): 22-24 days

**Bioanalytical phase:**

Method Development: Approximately 10 days

Method Validation: Approximately 8 days

Subject Sample Analysis: 16 days (Considering a minimum of 3 subjects each day for a 30-subject study)

**Statistical phase:**

Statistical Analysis: 2 days

**Report generation:**

Report Compilation: 15 days

|  |  |
| --- | --- |
|  | |
| **5.0 Clinical research organization set-up timelines and approvals** |  |
| The Clinical Research Organization setup spans the following durations: | |

1. Structural Set-Up - 4 months
2. Bed and Instrument Set-Up - 2 months

**Total: 6 months**

The entire setup, along with documentation (SOP preparation, logbook preparation, manpower recruitment, and personnel training), is anticipated to be completed within a 6-month period.

**Approvals/third-party agreements for bioanalytical laboratory**

Approvals and agreements include:

Biowaste disposal approval from the local municipal corporation

Pollution board approval for chemical and biowaste disposal.

|  |  |
| --- | --- |
| **5.2 Plan for regulatory inspection** |  |
|  |

* DCGI approval is required, planned post-setup completion.
* Initial three months of pilot study samples to identify operational gaps and ensure SOP implementation.
* Subject to regulatory inspection upon submission of pivotal studies to regulatory agencies (e.g., USFDA, EU, Canada, WHO, ANVISA).

|  |  |  |
| --- | --- | --- |
| **6.0 Clinical research organization layout** | |  |
| The layout comprises clinical, bioanalytical, and administrative areas. | | |
| **6.1 Clinical department:** |  | |
|  |

* Screening area
* Clinical unit (recreation, dining, phlebotomy)
* Pharmacy
* Sample separation area
* Emergency care unit.

|  |  |
| --- | --- |
| **6.2 Bioanalytical department:** |  |
|  |

* Instrument room
* Sample preparation room
* Balance room
* Deep freezer room
* Store room
* Scientist room
* Washing area.

**Administrative area:**

* HR and Admin
* Report writing
* Quality assurance
* Archival.

1. **Land & Building:**

The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida , which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year.

**Power Load and water connections : -**

The Lessor has agreed to provide a 54 KW power load in the premises and further power load can be enhanced from the power distribution companies whenever there is such requirement. The leased property is situated in the Authority notified Institutional/industrial area and there is no problem in getting the requisite power load and water connections.

**Installed capacity of unit:-**

The leased premises are sufficient to smoothly conduct upto 250 studies each year and after touching this milestone, the company will explore additional premises in the neighbourhood.

**Clinical research organization investment/ Total Project Cost**

The establishment of the new Clinical Research Organization involves a comprehensive setup, covering clinical, bioanalytical, and administrative areas, including instrument installation, engineering works/fittings, manpower requirements and preliminary expenses.

**Details of Plant/Machineries/ Equipment required for the CRO**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| S.No | Details of the equipment/Plant/ Machinery/Item | Name of vendor/supplier/ Contractor | Invoice no. & date | Invoice value with GST INR |
| 1 | Haier make Freezer, 230V/50 Hz. Model : DW-86L828J Type Upright - 86°C ULT Freezer  Capacity : 828 Litres | Care Biosystems India Pvt. Ltd Mumbai | No.- CBS/ srpl/2024/01 dated 12.01.2024 | 46,02,000.00 |
| 2 | 600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus | Agilent Technologies I Pvt Ltd  Block C RMZ Centinnial, Plot no 8A,8B,8C,8D  Dodanukundi Industrial Area, ITPL Road  Mahadevpara Post Banglore 560048 | IN-J9AB1S-124-  10522553 dated 12.01.2024 | 56,29,001.20 |
| 3 | 600 bar HPLC with UV detector and OpenLab CDS 2.7 Workstation plus | Agilent Technologies I Pvt Ltd  Block C RMZ Centinnial, Plot no 8A,8B,8C,8D  Dodanukundi Industrial Area, ITPL Road  Mahadevpara Post Banglore 560048 | IN-J9AB1S-124-10522553  Quotation Date: 12 January 2024 | 46,85,507.96 |
| 4 | FLD single wavelength | Agilent Technologies I Pvt Ltd  Block C RMZ Centinnial, Plot no 8A,8B,8C,8D  Dodanukundi Industrial Area, ITPL Road  Mahadevpara Post Bangalore 560048 | IN-J9AB1S-124-10522553  Quotation Date: 12 January 2024 | 11,83,419.64 |
| 5 | SCIEX Triple Quad 4500 System  Upgradeable to QTRAP functionality with PN 5049829  Enhanced high performance triple quadrupole LC-MS/MS mass  spectrometer.- Two Numbers  Plus  TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers  Plus  CABLE\* POWER INDIA 10A/250V- Twenty Numbers | SCIEX India Pvt. Limited  Registered office: 3rd floor, Unit # 9215, B-Wing, Art Guild House, Phoenix Market city, LBS Road, Vimersia Media technologies Pvt Limited Kurla West, Mumbai,  Maharashtra 400070. Phone: 022 3026 7000. | SCIEX-Delhi/HT/Skylimit/174282/24 dated 12.01.2024 to be imported from Singapore/Netherland for total CIP, Delhi for USD 6,32,000.00 Plus 18% GST = USD 7,45,760.00 converted to INR @ 84.50 = Rs. 6,30,16,720.00 | 6,30,16,720.00 |
| 6 | SCIEX Triple Quad 5500+ System  QTRAP Activated-  Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap- Two Numbers  Plus  TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers  Plus  CABLE\* POWER INDIA 10A/250V- Twenty Numbers | SCIEX India Pvt. Limited  Registered office: 3rd floor, Unit # 9215, B-Wing, Art Guild House, Phoenix Market city, LBS Road, Vimersia Media technologies Pvt Limited Kurla West, Mumbai,  Maharashtra 400070. Phone: 022 3026 7000 | SCIEX-Delhi/HT/Skylimit/174281/24 dated 12.01.2024 to be imported from Singapore/Netherland for total CIP, Delhi for USD 7,22,200.00 Plus 18% GST = USD 8,52,196.00 converted to INR @ 84.50 = Rs. 7,20,10,562.00 | 7,20,10,562.00 |
| 7 | Logan Water Jacketed Automated Transdermal Diffusion Cell System(24CellSystem) | SANGUINE BIO INSTUMENTS Flat No. 103, Sai Vinayaka Residency, Road No. 2, NBR Colony, Meerpet, Saroor Nagar (M), R.R. Dist., Hyderabad | SBI/LGN/SKY/91324/186/2023-24 dated 11.01.2024 to be imported from Somerset County, New Jersey, USA for total CIP, Delhi for USD 2,63,740.00 Plus 18% GST = USD 3,11,213.20 converted to INR @ 84.50 = Rs. 2,62,97,515.40 | 2,62,97,515.40 |
| 8 | Supply & Installation of Walk in Freezer Room with Ante Room as  per the Annexure I A - Basis of Design ( Including 15 Rft Copper  Piping for the distance between IDU & ODU) 20’ W x 15’L x 8’ Ht. (300 Sqft.) | BLUE COOL SOLUTIONS  G-62, Ground Floor, Shagun Arcade, Near Dindoshi Bus Depot, Dr. A K Vaidya Marg,  MALAD – EAST, MUMBAI – 400 097, INDIA, Mobile: +91 84549 45070 | BSL/BCS/23-24/308 dated 10.01.2024 | 12,57,502.40 |
| 9 | Bio-eVap DP Nitrogen Evaporator(Dual Press 144 Position) one set plus speX Series 144 Position Solid Phase Extraction one set plus Multitube Vortexer Main Unit two sets | Takahe Analytical Instruments, Navi Mumbai | S000478 Dated 10.01.2024 | 18,23,100.00 |
| 10 | Price for 5702 R with  A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors | Eppendorf India Private Limited Jasola Vihar, New Delhi | Email dated 16.01.2024  Qty. 5      2250000 Rs. Plus GST Extra with One year Warranty. | 26,55,000.00 |
| 11 | Micropipettes ( Volume range 10-100 ul, 20-200 ul , 100-1000 ul  and 500-5000 ul  ) each Volume range | Eppendorf India Private Limited Jasola Vihar, New Delhi | Email dated 16.01.2024  Qty. 5        300000 Rs. Plus GST Extra with Three year warranty. | 3,54,000.00 |
| 12 | Multipette M4 Starter kit , 1- channel, incl. Combitips advance rack, Combitips advance assortment pack | Eppendorf India Private Limited Jasola Vihar, New Delhi | Email dated 16.01.2024  Qty.5          157500 Rs. plus GST extra with One year warranty. | 1,85,850.00 |
| 13 | Techno-Commercial Offer for MEP & Interior work | ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 | APC/MRC/OFFER/ 23-24/752 dated 03.01.2024 quoted price @ Rs. 2000/- per Sq Ft for 30000 sq. ft carpet area | 7,08,00,000.00 |
| 14 | Kirloskar 125 KVA water cooled Genset three phase | Kirloskar |  | 33,51,200.00 |
| 15 | Interior Designs & Drawings | ARCHITECTS ATELIER H-123, Delta-2,  Greater Noida.  +91-9811399639 | Dated 02.01.2024 | 53,10,000.00 |
| 16 | Entris II Analytical balance and Cubis II Micro Analytical balance | SB Bio Chem | SB0123/2024/240124 dated 24.01.2024 | 29,78,320.00 |
| 17 | Agilent ICPMS – 7850 • PC and Printer are included • Microwave Digestion Included • IQ/OQ included • Autosampler Included • Gases supplies are not Included | Agilent Technologies, Agilent Technologies India Pvt. Ltd. Block C, RMZ Centennial, Plot Nos. 8A, 8B, 8C & 8D, Doddanakundi Industrial Area, ITPL Road, Mahadevapura Post, Bangalore- 560048 | Quotation Number: IN-J9VE24-124-095 dated 06.02.2024 | 1,07,38,000.00 |
| 18 | Non Agilent Product Microwave Digestion system | Agilent Technologies, Agilent Technologies India Pvt. Ltd. Block C, RMZ Centennial, Plot Nos. 8A, 8B, 8C & 8D, Doddanakundi Industrial Area, ITPL Road, Mahadevapura Post, Bangalore- 560048 | Quotation Number: IN-J9VE24-124-095 dated 06.02.2024 | 17,70,000.00 |
| 19 | Agilent 600 Bar HPLC – 1260 Infinity II with UV detector and Autosampler • IQ/OQ included | Agilent Technologies, Agilent Technologies India Pvt. Ltd. Block C, RMZ Centennial, Plot Nos. 8A, 8B, 8C & 8D, Doddanakundi Industrial Area, ITPL Road, Mahadevapura Post, Bangalore- 560048 | Quotation Number: IN-J9VE24-124-095 dated 06.02.2024 | 35,40,000.00 |
| 20 | Agilent ECM – XT Server to connect HPLC/LCMS and ICPMS   IQ/OQ included | Agilent Technologies, Agilent Technologies India Pvt. Ltd. Block C, RMZ Centennial, Plot Nos. 8A, 8B, 8C & 8D, Doddanakundi Industrial Area, ITPL Road, Mahadevapura Post, Bangalore- 560048 | Quotation Number: IN-J9VE24-124-095 dated 06.02.2024 | 59,00,000.00 |
| 21 | Agilent 1260 Infinity II HPLC system with 800 bar pressure,  Autosampler with chiller, Multicolumn compartment with  thermostat and UV Detector.   PC and Printer are not included | Agilent Technologies, Agilent Technologies India Pvt. Ltd. Block C, RMZ Centennial, Plot Nos. 8A, 8B, 8C & 8D, Doddanakundi Industrial Area, ITPL Road, Mahadevapura Post, Bangalore- 560048 | Quotation Number: IN-J9VE24-124-095 dated 06.02.2024 | 2,36,00,000.00 |
| 22 | Agilent 6475 LCMSMS system   PC and Printer are included   Nitrogen Generator included | Agilent Technologies, Agilent Technologies India Pvt. Ltd. Block C, RMZ Centennial, Plot Nos. 8A, 8B, 8C & 8D, Doddanakundi Industrial Area, ITPL Road, Mahadevapura Post, Bangalore- 560048 | Quotation Number: IN-J9VE24-124-095 dated 06.02.2024 | 8,26,00,000.00 |
| 23 | Supply of DAIKIN Make Ductable /Cassette Type/ Split Type  Air conditioners and Installation Work | Uniaer Engineering Company, Noida | Invoice Ref no. AS/DSU/UEC/102/23-24  Dated :-05-02-2024, | 49,30,375.00 |
| 24 | Mahindra Scorpio Classic S 75 TR | Shiva Auto Cat (India) Pvt Ltd, Patparganj Indstrial Area, Delhi-92 | Invoice dated 02.03.2024 | 15,83,332.00 |
| 25 | Mahindra Bolero Power Plus 86 | Shiva Auto Cat (India) Pvt Ltd, Patparganj Indstrial Area, Delhi-92 | Invoice dated 02.03.2024 | 11,05,911.00 |
|  | **TOTAL** |  |  | **40,19,07,316.60** |

**Manpower requirement**

Human capital is likely to be the highest cost as a proportion of the budget of a CRO. Human capital costs include the cost of the existing staff spending time on, or any new team members hired, to meet the CRO objectives. It also includes fees for external consultants or agency teams, if using them. To effectively manage 100 beds and 2 LC-MS/MS, the required personnel are detailed as follows:

**Clinical Department:**

**1. Head Clinical:**

Experience: Above 10 years

Quantity: 1 Approximate salary Rs. 25.00 lacs per annum per head

**Principal Investigator:**

Experience: Above 5 years

Quantity: 2 Approximate salary Rs. 15.00 lacs per annum per head

**Research Associate:**

Experience: Above 5 years

Quantity: 4 Approximate salary Rs. 4.00 lacs per annum per head

**Phlebotomist:**

Experience: Above 5 years

Quantity: 5 Approximate salary Rs. 2.50 lacs per annum per head

**Pharmacist:**

Experience: 2-3 years

Quantity: 2 Approximate salary Rs. 2.50 lacs per annum per head

**Trainee:**

Experience: 1-2 years

Quantity: 4 Approximate salary Rs. 2.00 lacs per annum per head

**Custodian and Recruiter:**

Experience: Above 5 years

Quantity: 2 Approximate salary Rs. 7.50 lacs per annum per head

|  |  |  |
| --- | --- | --- |
| **Total (Clinical): 20** |  | |
|  | | |
| **Bioanalytical Department:** | |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. | **Head Bioanalytical:** | | | | |  |
|  | | * Experience: Above 10 years * Quantity: 1 Approximate salary Rs. 15.00 lacs per annum per head | | | | |
| 2. | **Team Leader:** | | | |  | |
|  | | * Experience: Above 7 years * Quantity: 3 Approximate salary Rs. 12.00 lacs per annum per head | | | | |
| 3. | **Research Associate:** | | | | |  |
|  | | * Experience: Above 5 years * Quantity: 4 Approximate salary Rs. 5.00 lacs per annum per head | | | | |
| 4. | **Trainee:** | |  | | | |
|  | | * Experience: 1-2 years * Quantity: 4 Approximate salary Rs. 2.50 lacs per annum per head | | | | |
| 5. | **Custodian:** | | |  | | |
|  | | * Experience: Above 5 years * Quantity: 1 Approximate salary Rs. 7.50 lacs per annum per head | | | | |

|  |  |  |
| --- | --- | --- |
| **Total (Bioanalytical): 13** | |  |
|  | | |
| **Quality Assurance:** |  | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 1. | **Head Quality Assurance:** | | | | |  | |
|  | | * Experience: Above 10 years * Quantity: 1 Approximate salary Rs. 15.00 lacs per annum per head | | | | | |
| 2. | **Clinical QA:** | |  | | | | |
|  | | * Experience: Above 7 years * Quantity: 1 Approximate salary Rs. 10.00 lacs per annum per head | | | | | |
| 3. | **Clinical QA Associate:** | | | |  | | |
|  | | * Experience: 3-5 years * Quantity: 2 Approximate salary Rs. 5.00 lacs per annum per head | | | | | |
| 4. | **Bioanalytical QA:** | | |  | | | |
|  | | * Experience: Above 7 years * Quantity: 1 Approximate salary Rs. 10.00 lacs per annum per head | | | | | |
| 5. | **Bioanalytical QA Associate:** | | | | | |  |
|  | | * Experience: 3-5 years * Quantity: 2 Approximate salary Rs. 5.00 lacs per annum per head | | | | | |

**Total (Quality Assurance): 7**

**Statistical:**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. | **Statistician:** | |  |
|  | | * Experience: Above 5 years * Quantity: 1 Approximate salary Rs. 6.00 lacs per annum per head | |

|  |  |  |
| --- | --- | --- |
| **Total (Statistical): 1** | |  |
|  | | |
| **Report Writing:** |  | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. | **Team Leader:** | |  | |
|  | | * Experience: Above 7 years * Quantity: 1 Approximate salary Rs. 7.50 lacs per annum per head | | |
| 2. | **Research Associate:** | | |  |
|  | | * Experience: Above 5 years * Quantity: 2 Approximate salary Rs. 6.00 lacs per annum per head | | |

|  |  |  |
| --- | --- | --- |
| **Total (Report Writing): 3** | |  |
|  | | |
| **HR:** |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| 1. | **HR Manager:** | |  |
|  | | * Experience: Above 7 years * Quantity: 1 Approximate salary Rs. 7.50 lacs per annum per head | |

|  |  |
| --- | --- |
| **Overall Total: 45** |  |

**Manpower cost/Total annual salary bill during the 1st year:**

|  |  |  |  |
| --- | --- | --- | --- |
| S.No. | Designation of staff | No. of staff | Total annual salary |
| 1 | **Head Clinical** | 1 | 25,00,000.00 |
| 2 | **Principal Investigators** | 2 | 30,00,000.00 |
| 3 | **Research Associates for clinical department** | 4 | 16,00,000.00 |
| 4 | **Phlebotomists** | 5 | 12,50,000.00 |
| 5 | **Pharmacists** | 2 | 5,00,000.00 |
| 6 | **Trainee** | 4 | 8,00,000.00 |
| 7 | **Custodian and Recruiter** | 2 | 15,00,000.00 |
| 8 | **Head Bioanalytical** | 1 | 15,00,000.00 |
| 9 | **Team Leader** | 3 | 36,00,000.00 |
| 10 | **Research Associate** | 4 | 20,00,000.00 |
| 11 | **Trainee** | 4 | 10,00,000.00 |
| 12 | **Custodian** | 1 | 7,50,000.00 |
| 13 | **Clinical QA Associate** | 2 | 10,00,000.00 |
| 14 | **Bioanalytical QA** | 1 | 10,00,000.00 |
| 15 | **Bioanalytical QA Associate** | 2 | 10,00,000.00 |
| 16 | **Statistician** | 1 | 6,00,000.00 |
| 17 | **Report Writing team leader** | 1 | 7,50,000.00 |
| 18 | **Report Writing Research Associate** | 2 | 12,00,000.00 |
| 19 | **HR Manager** | 1 | 7,50,000.00 |
| 20 | **Head Quality Assurance** | 1 | 15,00,000.00 |
| 21 | **Clinical QA** | 1 | 10,00,000.00 |
|  | **Total** | **45** | **2,88,00,000.00** |

**Expenses on Regulatory approvals incurred during 1st year:**

The regulatory landscape in the pharmaceutical industry is complex and constantly continuously evolving. CROs need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally must navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines.

The clinical development is a most regulated segment of drug development process because it deals with humans. ICH-GCP norms are globally followed while conducting the clinical trials to ensure the safety, rights and wellbeing of the clinical trial participants. In addition, country specifical applicable rules and regulations are also applicable of the pharmaceutical companies conducting the clinical trials.

Regulatory agencies often require extensive documentation, data analysis, and review processes before granting approval for clinical trials or new drug applications. These approval delays can have substantial financial implications for CROs and sponsors, as they lead to extended timelines, increased costs, and potential loss of market opportunities. This has paved a way for the pharmaceutical companies to move to other attractive destinations in Asia Pacific regions like China and Australia.

Regulatory timelines for clinical trials in India are non-starter for foreign companies exploring India as destination for clinical trial in recent past. Delays in the approval process for clinical trials and drug development have significantly impacted the CRO industry. Central Drugs Standards Control Organisation (CDSCO), the top most regulator of clinical trials in India, has been at loggerheads with Indian pharma and CROs over the unprecedented delays in approval of clinical trials in past.

Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The below mentioned table represents some of the regulatory approvals, registration, accretions and the certifications the different kind of CROs need to maintain in order to be complaint to the applicable quality and regulatory requirements.

|  |  |
| --- | --- |
| **Service Area** | **Applicable Regulatory Approvals, Accreditations & Certifications** |
| **Discovery CROs** | GLP certification by National GLP Compliance Monitoring Authority, DST, GoI  Department of scientific and industrial research (DSIR) Certification  GMP certification by state FDA  ISO 9001:2015 (Quality Management System)  ISO 17025:2017 (Laboratory Management System) Testing and Calibration Labs |
| **Pre-Clinical CROs** | GLP certification by National GLP Compliance Monitoring Authority, DST, GoI, India  Committee for the Purpose of Control & Supervision of Experiments on Animals  (CPCSEA)  AAALAC accreditation.  ISO 9001:2015 (Quality Management System) |
| **Bioequivalence**  **Bioavailability**  **CROs** | BE center approval from Central Drug Standards Control Organization (CDSCO),  India  Independent Ethics committee (IEC) registration with Central Drug Standards  Control Organization (CDSCO), India  Foreign Regulatory Approvals like USFDA, EMEA, UKMHRA, ANVISA, TGA etc.  NABL certification as per ISO 15189:2016 or College of American Pathologists (CAP)  certification for Safety Testing Laboratory  GLP compliance of Bioanalytical Section of Bioequivalence centre  ICH-GCP compliance  ISO 9001:2015 (Quality Management System) |
| **Clinical Trials**  **(Phase I-IV) CROs** | CRO registration with CDSCO is not mandatory yet. CDSCO is going to make it  mandatory very soon.  Institutional Ethics committee (IEC) or Institution Review Board registration with  Central Drug Standards Control Organization (CDSCO), India  ICH-GCP compliance  ISO 9001:2015 (Quality Management System) |

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months’ time and another 06 months’ time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

**Lease Rentals during the Implementation period:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida , which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease. As such the company has incurred/will incur total pre-operative expenses of Rs. 89,60,000.00 under this head.

**Interest on term loan during the Implementation period:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

**General miscellaneous/operational expenses of the CRO during the 1st year:**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period.

**Project Cost**

The total project cost of the CRO is the fixed cost incurred for purchase of the equipment’s, plant/machineries, creation of infrastructure and also the intangible assets being the preliminary expenses being the manpower cost, expenses for getting the regulatory approvals, lease rentals, repayment of interest/other financials expenses on term loan/credit facilities, other general expenses to be incurred during the stipulated implementation period s under:

**Summary of the cost of project and means of finance**

**TOTAL PROJECT COST:**

**(Amount Rs. in lacs)**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | | **Particulars** | **Total (Amount)** | | Plant & Machinery at the prices on quotations held with  all expenses on taxes, freight, installation, and insurance | 40,19,07,316.60 | | Preliminary/Pre-operative Expenses on Manpower cost/  Regulatory approvals/Lease Rentals/ Interest on term  loan/ General miscellaneous/operational expenses of  the CRO during Implementation period | 3,88,80,000.00 | | **Total** | **44,07,87,326.60** | |  |

**Means of Finance:**

**(Rs. in lacs)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Particulars | Total Cost | Margin | Promoter's share | Term Loan |
| Plant Machinery, Equipment’s and misc assets. | 40,19,07,316.60 | 25% | 10,19,07,316.60 | 30,00,00,000.00 |
| **Total** Preliminary/Pre-operative Expenses during Implementation period | 3,88,80,000.00 | 100% | 3,88,80,000.00 | 0.00 |
|  | 44,07,87,326.60 |  | 14,07,87,326.60 | 30,00,00,000.00 |
| **Term Loan** | **Rs**. **3000.00** **lacs** | | | |

**Permissible Term Loan: Rs.** **3000.00 lacs**

DER of the unit is proposed at 2.14 as at 31.03.2024 which is well within acceptable limits of the bank. Average DSCR is projected to be at 1.73 as on 31.03.2025 and 1.80 as on 31.03.2026 which is reasonable.

**Breakeven point**

According to the proposed plan for the Clinical Research Organization setup, a tentative profit margin of 35% is anticipated. The company is expected to book net profit in the 1st full year of operations.

# **FACILITIES AND INFRASTRUCTURE**

M/S Skylimit Research Private Limited will have state-of-the-art facilities and infrastructure to facilitate quality execution of studies. The main components of infrastructure at M/S Skylimit Research Private Limited are well equipped Clinical, Bio-analytical and In-vitro study setup. We have state-of-the-art equipment, regulatory compliant software, hardware and secured networks.

M/S Skylimit Research Private Limited will have a well-designed, custom-built, compliant facility to conduct various activities of Clinical Research in Noida. It will spread over a total floor area of 32,000 sq.ft., which will cover the Clinical Units, Analytical Laboratory area, Volunteer screening area, Volunteer Information centers and external archives.

### **Clinical Facilities:**

All the clinical activities will be conducted in compliance with Global Regulatory Standards and the clinical unit meets world-class specifications.

**Noida Clinical Facility:**

* Facility having more than 32,000 sq. ft. of carpet area
* Clinical unit with 100 beds facilitating simultaneous conduction of multiple studies resulting in quick turnaround time
* Ease of conducting mix population studies with separate housing areas for Male and Female Subjects
* Clinical pathology lab accredited by the College of American Pathologists (CAP) and National Accreditation Board for Testing and Calibration Laboratories (NABL) equipped to carry out tests for biochemistry, haematology, urine chemistry and serology as per study requirements
* The clinical facility will be approved by DCGI (INDIA) and will be fully compliant with ICH GCP and other International Regulations like USFDA, WHO, UK MHRA, TGA (Australia), Canada, etc



Indicative photograph of the proposed CRO-1



Indicative photograph of the proposed CRO-2

### **Bio-Analytical Facility:**

We will have a fully GLP-compliant analytical facility with state-of-the-art laboratories spread over 8,000 sq ft and managed by highly skilled and experienced scientific professionals and support personnel.

This team is competent to develop and validate a minimum of 4-6 methods every month. Thus, we have a faster turnaround time for developing the molecule as well as testing it.

**State-of-the-art laboratory facilities for bio-analysis:**

* Latest Instrumentation and technology to ensure project completion with quick-turnaround time
* We will offer – Electronic documentation (paperless) and are working on Scientific Data Management System (SDMS), Laboratory Information Management System (LIMS) and eLab (electronic Lab) notebook
* Sample storage in controlled and limited access Deep freezer room with power back up and 24\*7 temperature Monitoring and alarm system
* Access controlled entry and exit facility
* Separate sample processing laboratory
* Validated and regulatory compliant software at M/S Skylimit Research Private Limited Research ensures movement of data from the analytical lab to documentation within a CFR Part 11 compliant environment
* Major equipment under annual maintenance contracts to minimize down time



Indicative photograph of the proposed CRO-3

### In-Vitro Study Setup:

M/S Skylimit Research Private Limited Research, proposes to be a leader in In-vitro Release Testing (IVRT) and In-vitro Permeation Testing (IVPT) analytical method development, validation, and testing services, to meet the fast-growing demand for these types of topical and transdermal drug analytical services with the most up to date regulatory requirement.

Through the use of appropriately selected In Vitro and In Vivo surrogate tests, we can accomplish the assessment of the BE of topical drug products. For most products IVRT, IVPT, and additional testing would be essential to establish BE along with Q1/Q2 testing.



Indicative photograph of the proposed CRO-4



Indicative photograph of the proposed CRO-5

**Salient Features of Facilities:**

* Clinical Research facility with attached Analytical, Support, and Ancillary Functions
* State-of-the-art Analytical, In-vitro study setup, and NABL Accredited clinical Lab
* Designated to International safety standard
* Access Control to all crucial labs to support confidentiality
* Ample storage facility for retaining samples at -20 ̊C and -70 ̊C
* Pool of latest and highly sensitive mass spectrophotometers and allied instruments
* Regulatory compliant archiving facility spread over 5,000 sq ft
* Systems with validated software that is CFR 21 Part 11 compliant

## M/S Skylimit Research Private Limited: Regulatory Services Included But will not be Limited To:

* To achieve the regulatory goal, we can suggest a concrete regulatory strategy to give you a competitive advantage
* Provide detailed feasibility before study execution to get real-time information and expected timelines.
* Preparation & submission of regulatory documents for obtaining:
* Approval to conduct a clinical trial in India
* Approval to import Investigational Products
* Central Bureau of Narcotics (CBN) and State FDA permit to import Narcotic and Psychotropic substances
* Liaising and Obtaining registration documents in the interest of clients
* Continuous follow-up post submission with regulatory authorities
* Safety reporting
* Preparation of regulatory submissions in CTD and eCTD format
* Preparation of summaries required for generic submission
* Executing regulatory submission
* Responding to the health authorities’ queries during the approval phases of the product

**Future projections of the company- Key financials**

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Particulars | 31.03.25 | 31.03.26 | 31.03.27 | 31.03.28 | 31.03.29 | 31.03.30 | 31.03.31 | 31.03.32 | 31.03.33 |
|  | Projected | Projected | Projected | Projected | Projected | Projected | Projected | Projected | Projected |
| Gross Revenue | 4.00 | 22.00 | 35.00 | 42.00 | 50.00 | 59.50 | 66.35 | 79.62 | 95.55 |
| % wise rise/fall in total sales | NA | 450.00 | 59.09 | 20.00 | 19.04 | 19.00 | 11.51 | 20.00 | 20.00 |
| PBDIT | 1.85 | 8.30 | 10.15 | 11.90 | 11.55 | 12.20 | 13.10 | 19.99 | 30.64 |
| PBT | 0.55 | 1.30 | 3.45 | 5.50 | 5.45 | 6.60 | 8.00 | 15.29 | 26.34 |
| PAT | 0.41 | 0.98 | 2.58 | 4.12 | 4.09 | 4.95 | 6.00 | 11.47 | 19.75 |
| Cash Accruals | 1.41 | 4.97 | 6.58 | 8.12 | 8.09 | 8.95 | 10.00 | 15.47 | 23.75 |
| Paid up capital | 10.00 | 10.00 | 10.00 | 10.00 | 10.00 | 10.00 | 10.00 | 10.00 | 10.00 |
| Tangible Net worth | 10.41 | 10.97 | 12.59 | 14.12 | 14.08 | 14.95 | 16.00 | 21.47 | 29.75 |
| Unsecured loans by promoters/relatives | 2.00 | 4.00 | 2.00 | 1.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Current Ratio | 1.57 | 1.33 | 1.59 | 1.15 | 1.28 | 1.17 | 1.48 | 2.22 | 2.38 |
| NWC | 1.98 | 1.20 | 2.48 | 0.69 | 1.32 | 0.85 | 2.57 | 8.70 | 13.65 |
| DSCR | 1.73 | 1.80 | 2.05 | 2.71 | 2.70 | 2.98 | 3.31 | 5.06 | 7.71 |
| Average DSCR | 2.20 | | | | | | | | |

**Justification for the consistent growth in performance:**

**1. Revenues:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies and based on the proposed Clinical Research Organization setup and the above assumptions, the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No.** | **Content** | **Actual Study Subject Cost (INR)** | **Vendor Industry Cost /Revenues expected (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 |
| **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 number of 60 subjects in each Pivotal study) in a year @ 65000/- per study | **Rs. 32,50,000** | **Rs. 32,50,000** |
| **11.Overall Cost** | Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year | **10,00,00,000** | **15,06,25,000** |

The company expects to achieve total revenue generation of Rs. 4.00 crores in the 1st year of operations i.e. FY 2024-25 which is expected to increase to Rs. 22.00 crores, Rs. 35.00 crores and Rs. 42.00 crores during the FY 2025-26, FY 2026-27 & FY 2027-28 respectively which is a reasonable estimation.

**2.Profitability:** The company will be able to turn into net/cash profit in the 1st year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**3.Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores by the end of FY 2023-24. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**4. Current Ratio:**  The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**5. NWC:**  The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores , Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**6. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

We attach herewith copies of the following documents/copies:

1. CMA data of the company for the FY 2023-24 to 2032-33

2. GST Registration certificate of the company

3. PAN/Aadhar of Sri Karan Pratap Rawat.

4. PAN/Aadhar of Ms. Sandeepika Sharma

5. PAN/Aadhar of Smt. Poonam Rawat.

6. PAN/Aadhar of Sri Arjun Singh Rawat.

7. PAN/Aadhar of Sri Yash Pratap Singh

8. PAN/Aadhar of Sri Ashish Vijaysinh Prabhugaokar

9. PAN/Aadhar of Smt. Vijaya Prabhugaokar

10. ITRs of Sri Karan Pratap Rawat for the AY 2023-24.

11. ITRs of Ms. Sandeepika Sharma for the AY 2023-24.

12. ITRs of Smt. Poonam Rawat for the AY 2023-24.

13. ITRs of Sri Arjun Singh Rawat for the AY 2023-24.

14. ITRs of Sri Yash Pratap Singh for the AY 2023-24.

15. ITRs of Sri Ashish Vijaysinh Prabhugaokar for the AY 2023-24.

16. ITRs of Smt. Vijaya Prabhugaokar for the AY 2023-24.

17. Memorandum & Article of Association of the Company

18. UDYAM certificate of the Company

19. Lease deed of the company registered at bahi no. 1, Sl. No. 520 at Sub-Registry, Noida on 29.-1.2024

20. Copy of Invoice No.- CBS/ srpl/2024/01 dated 12.01.2024 of Care Biosystems India Pvt. Ltd Mumbai for supply of Haier make Freezer, 230V/50 Hz

21. Copy of Invoice No.- IN-J9AB1S-124- 10522553 dated 12.01.2024of Agilent Technologies I Pvt Ltd for supply of 600 bar HPLC with DAD

22. Copy of Invoice No.- IN-J9AB1S-124- 10522553 dated 12.01.2024of Agilent Technologies I Pvt Ltd for supply of 600 bar HPLC with UV detector

23. Copy of Invoice No.- IN-J9AB1S-124- 10522553 dated 12.01.2024of Agilent Technologies I Pvt Ltd for supply of FLD single wavelength

24. Copy of Invoice No.- SCIEX-Delhi/HT/Skylimit/174282/24 dated 12.01.2024 of SCIEX India Pvt. Limited for supply of SCIEX Triple Quad 4500 System

Upgradeable to QTRAP

25. Copy of Invoice No.- SCIEX-Delhi/HT/Skylimit/174281/24 dated 12.01.2024 of SCIEX India Pvt. Limited for supply of SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer

26. Copy of Invoice No.- SBI/LGN/SKY/91324/186/2023-24 dated 11.01.2024 of SANGUINE BIO INSTUMENTS, Hyderabad for supply of Logan Water Jacketed Automated Transdermal Diffusion Cell System(24Cell System)

27. Copy of Invoice No.- BSL/BCS/23-24/308 dated 10.01.2024 of BLUE COOL SOLUTIONS, MUMBAI for Supply & Installation of Walk in Freezer Room with Ante Room

28. Copy of Invoice Email dated 16.01.2024 of Takahe Analytical Instruments, Navi Mumbai for Supply of Bio-eVap DP Nitrogen Evaporator(Dual Press 144 Position)

29. Copy of Invoice No.- S000478 Dated 10.01.2024 of Eppendorf India Private Limited Jasola Vihar, New Delhi for Supply of 5702 R with  A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes

30. Copy of Invoice No.- Email dated 16.01.2024 of Eppendorf India Private Limited Jasola Vihar, New Delhi for Supply of Micropipettes ( Volume range 10-100 ul, 20-200 ul , 100-1000 ul  and 500-5000 ul  ) each Volume range

31. Copy of Invoice No.- Email dated 16.01.2024 of Eppendorf India Private Limited Jasola Vihar, New Delhi for Supply of Multipette M4 Starter kit , 1- channel, incl. Combitips advance rack, Combitips advance assortment pack

32. Copy of Invoice No.- APC/MRC/OFFER/ 23-24/752 dated 03.01.2024 of ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida for Techno-Commercial Offer for MEP & Interior work

33. Copy of Invoice No.- of Kirloskar for supply of Kirloskar 125 KVA water cooled Genset three phase

34. Copy of Invoice No.- SB0123/2024/240124 dated 24.01.2024 of SB Bio Chem for supply of Entris II Analytical balance and Cubis II Micro Analytical balance

35. Copy of Invoice No.- IN-J9VE24-124-095 dated 06.02.2024 of Agilent Technologies, Agilent Technologies India Pvt. Ltd. for supply of Agilent ICPMS – 7850 • PC and Printer including accessories

36. Copy of Invoice No.- IN-J9VE24-124-095 dated 06.02.2024 of Agilent Technologies India Pvt. Ltd. for supply of Non Agilent Product Microwave Digestion system

37. Copy of Invoice No.- IN-J9VE24-124-095 dated 06.02.2024 of Agilent Technologies India Pvt. Ltd. for supply of Agilent 600 Bar HPLC – 1260 Infinity II with UV detector and Autosampler

38. Copy of Invoice No.- IN-J9VE24-124-095 dated 06.02.2024of Agilent Technologies India Pvt. Ltd. for supply of Agilent ECM – XT Server to connect HPLC/LCMS and ICPMS

39. Copy of Invoice No.- IN-J9VE24-124-095 dated 06.02.2024 of Agilent Technologies India Pvt. Ltd. for supply of Agilent 1260 Infinity II HPLC system with 800 bar pressure, Autosampler with chiller, Multicolumn compartment with thermostat and UV Detector

40. Copy of Invoice No.- IN-J9VE24-124-095 dated 06.02.2024 of Agilent Technologies India Pvt. Ltd. for supply of Agilent 6475 LCMSMS system PC and Printer included,

41. Copy of Invoice No.- AS/DSU/UEC/102/23-24 Dated :-05-02-2024 of Uniaer Engineering Company, Noida for supply of DAIKIN Make Ductable /Cassette Type/ Split Type

42. Copy of Invoice dated 02.03.2024 of Shiva Auto Cat (India) Pvt Ltd, Patparganj Indstrial Area, Delhi-92 for purchase of Mahindra Scorpio Classic S 75 TR

43. Copy of Invoice dated 02.03.2024 of Shiva Auto Cat (India) Pvt Ltd, Patparganj Indstrial Area, Delhi-92 for purchase of Mahindra Bolero Power Plus 86

Thanks,

Yours faithfully

Karan Pratap Rawat Yash Pratap Singh Sandeepika Sharma

Director Director Director