



BUSINESS PLAN · INDIA

# Contract Research Organisation (CRO)

*Clinical and bio-analytical research services*

PHARMA

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This document is confidential and prepared for planning purposes. All financial figures are illustrative model assumptions for an Indian MSME context and must be validated against live quotes, local rates and professional advice before any investment or borrowing decision.

## 1. Executive Summary

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This plan sets out a **Contract Research Organisation (CRO)** in India — a research-services firm providing clinical trials, bioavailability/bioequivalence (BA/BE) studies, bioanalytical, clinical-data-management, regulatory & related research to pharma/biotech sponsors under contract. It earns **project/service fees on scientific expertise & capability**, monetising India's cost-competitive, skilled clinical-research ecosystem & global outsourcing of drug development — a largely **expertise- & lab-capability-driven, GCP-/regulatory-/data-integrity-critical, project-based** professional-services business (asset-lighter than manufacturing, but lab/quality-intensive).

Global & Indian pharma/biotech outsource drug-development research to CROs for cost, speed, skill & regulatory capability; India offers a large patient pool, skilled scientists & cost advantage. A CRO is an **expertise + regulated-capability business**: moderate capital (labs/facilities), driven by scientific expertise, GCP/regulatory compliance, data integrity, sponsor relationships & project execution. It is **GCP-, ethics-committee-, CDSCO/DCGI-regulated**, with data integrity & quality as the reputation-critical core. Revenue is **project/service fees (clinical trials, BA/BE, bioanalytical, data-management, regulatory)**; success rests on scientific expertise, GCP/quality/data-integrity, regulatory capability, sponsor relationships & project execution — it is expertise-, quality- & project-flow-driven.

This is a research-services business — funded by promoter equity plus term debt (labs/facility) & working capital. This plan models a CRO requiring **₹6 crore** (₹2.2 crore promoter + ₹3.8 crore bank finance), targeting **₹10 crore** revenue in Year 1 scaling to **₹26 crore** by Year 3. (CRO; project/service fees on expertise, GCP/quality/data-integrity/project-driven — figures illustrative; GCP & regulatory compliance prerequisites.)

## 2. Business Description, Vision & Legal Structure

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**Concept:** A contract research organisation - clinical trials, BA/BE, bioanalytical, data-management & regulatory research for pharma/biotech sponsors under contract, earning project/service fees.

**Vision:** To accelerate safe, quality drug development with world-class, cost-effective research.

**Mission:** Deliver GCP-compliant, data-integrity-driven research - rigorous, ethical, on-time - that sponsors & regulators trust.

### Legal structure options

- **Private Limited** — recommended for sponsors, labs/capex, regulatory & funding.
- **LLP** — possible for a focused/bioanalytical CRO.

**Regulatory anchor:** a CRO is regulated — CDSCO/DCGI (clinical-trial/BA-BE approvals), Good Clinical Practice (GCP/ICH-GCP), ethics committee (registered), New Drugs & Clinical Trials Rules, data integrity/ALCOA, lab accreditation (NABL/GLP for bioanalytical), consent/ethics. Scientific expertise, GCP/quality/data-integrity, regulatory capability, sponsor relationships & project execution determine success; it is expertise-, quality- & project-flow-driven — data integrity & ethics are reputation-critical.

## 3. Promoter & Ownership

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Led by a promoter with clinical-research, pharmacology, bioanalytical or CRO expertise. The team includes clinical/medical (investigators/coordinators), bioanalytical scientists, clinical-data-management & biostatistics, QA/regulatory (GCP), & BD (sponsors). Scientific expertise, GCP/quality/data-integrity & sponsor relationships are the differentiators. Ownership & stakes are editable inputs; GCP/ethics/regulatory prerequisites.

## 4. Market Analysis — India

India is a growing global clinical-research & BA/BE hub — cost-competitive, skilled scientists, large patient pool & improving regulatory framework — with pharma/biotech (domestic & global) outsourcing development. Demand is drug-development-/outsourcing-/generics-driven. The market rewards scientific expertise, GCP/quality/data-integrity, regulatory capability, sponsor relationships & execution; it is expertise-, quality-, regulatory- & project-flow-sensitive, met with expertise, GCP/quality, capability & BD.

### Demand drivers

- **Global & Indian pharma/biotech** outsourcing.
- **Generics BA/BE** (large demand).
- **Cost/skill/patient-pool** advantage.
- **Clinical trials & new-drug** development.
- **Regulatory/data-management** services.

### Market sizing (illustrative framing)

| Layer        | Definition                     | Indicative scale |
|--------------|--------------------------------|------------------|
| TAM          | Clinical research/CRO in India | Large & growing  |
| SAM          | Service line & therapy         | Substantial      |
| SOM (Yr 1-3) | Projects / sponsors            | Scaling          |

### Target segments

- Generic pharma (BA/BE — core).
- Pharma/biotech (clinical trials).
- Bioanalytical & data-management.
- Global sponsors (cost/skill).

## 5. Competition & Competitive Advantage

**Landscape:** global CROs, large Indian CROs, bioanalytical/BA-BE specialists & academic sites. The CRO competes on scientific expertise, GCP/quality/data-integrity, regulatory track record, turnaround, cost & sponsor relationships.

### The business's edge

- **Scientific expertise & capability.**
- **GCP/quality & data-integrity (reputation).**
- **Regulatory track record (audits/inspections).**
- **Turnaround & cost.**
- **Sponsor relationships & repeat.**

## 6. Products & Revenue Model

| Stream | Model | Basis |
|--------|-------|-------|
|--------|-------|-------|

|                                          |                                     |                  |
|------------------------------------------|-------------------------------------|------------------|
| BA/BE studies (generics)                 | Per-study fee                       | Core             |
| Clinical trials (phases)                 | Project fee (per-patient/milestone) | Core/scale       |
| Bioanalytical services                   | Per-sample/project                  | Recurring/volume |
| Clinical-data-management & biostatistics | Project/service fee                 | Margin           |
| Regulatory / consulting                  | Fee                                 | Ancillary        |

Revenue is **project/service fees** — BA/BE (core generics volume), clinical trials (larger/milestone), bioanalytical (volume), data-management/biostats & regulatory. Economics = projects × fee × utilisation (net of study/lab cost); scientific expertise, GCP/quality/data-integrity, capability, sponsor relationships & execution drive it — the decisive CRO levers (expertise/quality/project-driven).

## 7. Go-to-Market — Sponsors & Projects

- **Sponsor BD** (generic/pharma/biotech, domestic + global).
- **GCP/quality & regulatory** credentials (audits/track record).
- **Service-line focus** (BA/BE/bioanalytical/trials).
- **Turnaround, cost & capability** pitch.
- **Repeat & relationships** (sponsor trust).

### Sales approach

Build GCP/quality/regulatory credentials → win sponsor projects (BA/BE/trials/bioanalytical) → execute with data integrity & on-time → pass audits/inspections → build track record, repeat & relationships. Expertise, GCP/quality/data-integrity, capability & sponsor relationships build the CRO; reputation (audits/data-integrity) is the moat.

## 8. Operations Plan (regulated research)

- **Facilities:** clinical unit (beds for BA/BE), bioanalytical lab (NABL/GLP), data-management & IT — moderate capex, quality-critical.
- **Conduct:** protocol/ethics approval, subject recruitment/consent, study conduct (GCP), sampling/analysis, data management/biostatistics, reporting.
- **Quality & data integrity:** QA, SOPs, ALCOA data integrity, audit-readiness — reputation-critical.
- **Regulatory:** CDSCO/DCGI, ethics committee, GCP, inspections (incl. global — USFDA/EMA for regulated work).
- **Talent:** skilled scientists/clinicians — the core asset.

### Project workflow

| Stage   | Activity           | Metric           |
|---------|--------------------|------------------|
| Win     | Sponsor/proposal   | Project-flow     |
| Approve | Ethics/CDSCO       | Compliance       |
| Conduct | Study/GCP          | Quality/timeline |
| Analyse | Bioanalytical/data | Data integrity   |

|        |              |                   |
|--------|--------------|-------------------|
| Report | Report/audit | Acceptance/repeat |
|--------|--------------|-------------------|

## 9. Regulatory, Licences & Compliance (India)

- **CDSCO/DCGI:** clinical-trial/BA-BE approvals; New Drugs & Clinical Trials Rules.
- **GCP & ethics:** ICH-GCP; registered ethics committee; informed consent.
- **Lab/data:** NABL/GLP (bioanalytical); ALCOA data integrity; SOPs.
- **Global (regulated work):** USFDA/EMA inspection-readiness; company; GST.

## 10. Organisation & Manpower Plan

| Role                                        | Yr 1      | Yr 2      | Yr 3      |
|---------------------------------------------|-----------|-----------|-----------|
| Promoter / leadership                       | 1         | 2         | 3         |
| Clinical & bioanalytical scientists         | 15        | 28        | 45        |
| Data management, biostatistics & regulatory | 6         | 12        | 20        |
| QA/quality (GCP) & clinical ops             | 5         | 9         | 15        |
| BD, admin & support                         | 3         | 6         | 10        |
| <b>Total</b>                                | <b>30</b> | <b>57</b> | <b>93</b> |

## 11. Implementation Timeline & Milestones

| Phase | Timeline   | Milestone                                                    |
|-------|------------|--------------------------------------------------------------|
| Setup | Month 0-6  | Entity, labs/clinical unit, NABL/GCP, ethics, first sponsors |
| Ramp  | Month 6-12 | First studies, data integrity/quality, ₹10cr                 |
| Build | Year 2     | More sponsors/service-lines, audits, ₹18cr                   |
| Scale | Year 3     | ₹26cr revenue; track record & (global) capability            |

## 12. Financial Plan (Illustrative)

All figures are illustrative model assumptions for an Indian context, shown so the promoter can replace them with live rates. They are not projections of guaranteed results.  $CRO\ economics = projects \times fee \times utilisation$  (net of study/lab cost); expertise/talent & quality/data-integrity are core; GCP/regulatory prerequisites.

### 12.1 Project cost & means of finance

| Capital requirement                          | ₹           |
|----------------------------------------------|-------------|
| Clinical unit, bioanalytical lab & equipment | 3,20,00,000 |
| IT/data-management, QA & setup               | 80,00,000   |
| Working capital (project + receivables)      | 1,50,00,000 |

|                                          |                    |
|------------------------------------------|--------------------|
| Accreditation, licensing & pre-operative | 50,00,000          |
| <b>Total project cost</b>                | <b>6,00,00,000</b> |
| Promoter contribution                    | 2,20,00,000        |
| Bank finance (term + WC)                 | 3,80,00,000        |

## 12.2 Projected Profit & Loss (3 years)

| Particulars                            | Year 1              | Year 2              | Year 3              |
|----------------------------------------|---------------------|---------------------|---------------------|
| BA/BE & clinical studies               | 6,50,00,000         | 11,50,00,000        | 16,50,00,000        |
| Bioanalytical & data-management        | 2,80,00,000         | 5,50,00,000         | 8,00,00,000         |
| Regulatory / consulting & other        | 70,00,000           | 1,50,00,000         | 1,50,00,000         |
| <b>Total revenue</b>                   | <b>10,00,00,000</b> | <b>18,50,00,000</b> | <b>26,00,00,000</b> |
| Scientist/staff salaries (core cost)   | 4,50,00,000         | 8,20,00,000         | 11,40,00,000        |
| Study, lab, consumables & subject cost | 2,40,00,000         | 4,40,00,000         | 6,20,00,000         |
| Overheads, QA & compliance             | 1,80,00,000         | 3,20,00,000         | 4,40,00,000         |
| Interest & depreciation                | 70,00,000           | 90,00,000           | 1,00,00,000         |
| <b>Total expenses</b>                  | <b>9,40,00,000</b>  | <b>16,70,00,000</b> | <b>23,00,00,000</b> |
| <b>Net profit (before tax)</b>         | <b>60,00,000</b>    | <b>1,80,00,000</b>  | <b>3,00,00,000</b>  |
| Net margin                             | 6%                  | 9.7%                | 11.5%               |

## 12.3 Unit economics & break-even

- **Projects × fee × utilisation:** revenue per scientist/study; BA/BE is core volume, clinical trials larger; bioanalytical/data-management add recurring; utilisation (project flow) & talent productivity drive it.
- **Quality & data integrity:** GCP/quality/data-integrity & audit/inspection track record are reputation-critical & the moat — a data-integrity failure (regulatory action) is existential; quality is a cost of trust.
- **Break-even:** at a project/utilisation threshold covering talent & lab/fixed cost; margins improve with utilisation, service-mix, (global) capability & scale.

## 12.4 Projected Cash Flow — Year 1 (quarterly, illustrative)

| Particulars (₹)                 | Q1               | Q2               | Q3               | Q4               |
|---------------------------------|------------------|------------------|------------------|------------------|
| Opening balance                 | 15,00,000        | 13,00,000        | 13,50,000        | 14,00,000        |
| Project collections             | 2,00,00,000      | 2,45,00,000      | 2,75,00,000      | 2,90,00,000      |
| Salaries, study/lab & operating | 2,02,00,000      | 2,44,50,000      | 2,74,50,000      | 2,88,50,000      |
| <b>Closing balance</b>          | <b>13,00,000</b> | <b>13,50,000</b> | <b>14,00,000</b> | <b>15,50,000</b> |

CRO carries project WC (study cost before milestone/collection) + receivables & heavy talent/lab fixed cost; utilisation/project-flow drives cash. Milestone billing, project flow, utilisation, quality (avoiding costly failures), CC & the WC line manage cash; the key risks are project-flow gaps, data-integrity/quality/regulatory failure (existential), talent attrition &

receivable timing — met with BD, quality/data-integrity, retention & milestone billing.

## 12.5 Key Performance Indicators to Monitor

- **Delivery:** project flow; utilisation; on-time; study success.
- **Quality:** GCP/data-integrity; audit/inspection outcomes; deviations.
- **Revenue:** service-mix (BA-BE/trials/bioanalytical); repeat; global share.
- **Finance:** revenue/scientist; utilisation; net margin; receivable days.

## 13. Funding Requirement & Bankability

Total ask: **₹3.8 crore bank finance** against ₹2.2 crore promoter contribution — term for the clinical unit/bioanalytical lab/IT plus working capital (project + receivables). Bankability rests on GCP/quality/regulatory credentials, sponsor relationships, project flow & utilisation; India's cost/skill/patient-pool advantage & generics BA/BE demand support it. Year-1 profit ~₹60 lakh growing to ₹3 crore supports servicing; utilisation, quality & project flow are key. Expertise, GCP/quality/data-integrity, capability & sponsor relationships underpin the model. (*GCP & regulatory compliance are prerequisites.*)

### 13.1 Funding utilisation

| Use of funds                                 | ₹                  | % of total  |
|----------------------------------------------|--------------------|-------------|
| Clinical unit, bioanalytical lab & equipment | 3,20,00,000        | 53.3%       |
| Working capital (project + receivables)      | 1,50,00,000        | 25%         |
| IT/data-management, QA & setup               | 80,00,000          | 13.3%       |
| Accreditation, licensing & pre-operative     | 50,00,000          | 8.3%        |
| <b>Total</b>                                 | <b>6,00,00,000</b> | <b>100%</b> |

## 14. Risk Analysis & Mitigation

| Risk                                                    | Mitigation                                              |
|---------------------------------------------------------|---------------------------------------------------------|
| Data-integrity/quality/regulatory failure (existential) | GCP, QA, ALCOA data integrity, audit-readiness, culture |
| Project-flow gaps / utilisation                         | Sponsor BD, service-mix, repeat, global sponsors        |
| Talent attrition                                        | Retention, culture, training, scientist development     |
| Regulatory / ethics / trial risk                        | Ethics committee, GCP, consent, compliance, oversight   |
| Receivable / project WC                                 | Milestone billing, WC line, credit discipline           |

## 15. SWOT Analysis

|                                                                                                                                                             |                                                                                                                                                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Strengths</b><br>India cost/skill/patient-pool advantage; generics BA/BE & outsourcing demand; expertise moat; asset-lighter than mfg; global potential. | <b>Weaknesses</b><br>Quality/data-integrity-critical (existential); talent-dependent; project-flow-sensitive; regulatory/ethics risk; utilisation-driven. |
| <b>Opportunities</b><br>Global outsourcing; generics BA/BE; bioanalytical/data-management; clinical trials; (global) inspection-ready capability.           | <b>Threats</b><br>Regulatory/data-integrity action; competition (global/large CROs); talent war; ethics/trial scrutiny; project cyclicity.                |

## 16. Recommended AiSevak Tools for This Business

This CRO would use AiSevak's Pharma vertical tools in delivery:

- **Research ops:** project/utilisation & study-conduct/GCP, bioanalytical/data-management & data-integrity/QA, sponsor-CRM tools.
- **Regulatory & compliance:** CDSCO/DCGI & ethics/GCP, NABL/GLP & audit-readiness tools (with Legal & Finance verticals).
- **Practice:** Business Plan, utilisation/service-mix and Break-even tools to model the CRO.

## 17. Key Assumptions & Notes

- CRO: clinical trials, BA/BE, bioanalytical, data-management & regulatory research for pharma/biotech sponsors under contract; project/service fees on expertise; asset-lighter than mfg but lab/quality-intensive.
- Projects × fee × utilisation decisive; scientific expertise, GCP/quality/data-integrity (reputation-critical; failure existential), regulatory capability, sponsor relationships & execution are the levers.
- Term (labs/clinical unit) + WC; CDSCO/DCGI, ICH-GCP, ethics committee, NABL/GLP, ALCOA data integrity prerequisites.
- Utilisation, quality/data-integrity, service-mix & talent drive economics; figures illustrative, exclude GST; GCP & regulatory compliance prerequisites.

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