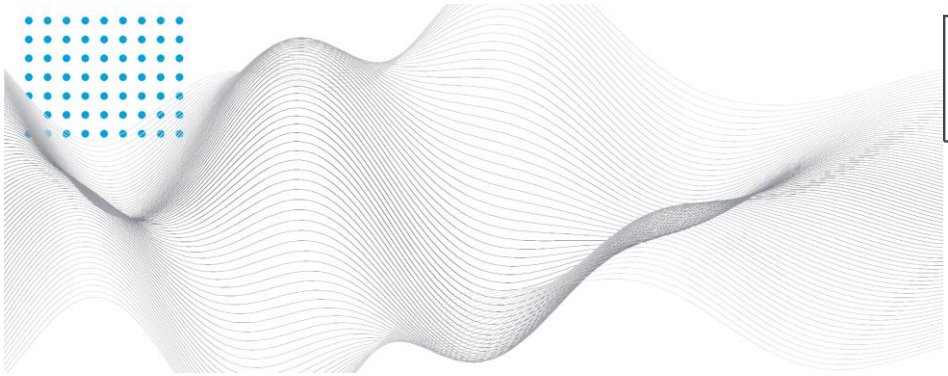


PRAVEG Consultancy Services

ENHANCING POTENTIAL, ACCELERATING GROWTH

WHITE PAPER

SETTING UP BIOMETRICS IN INDIA

EXTENDING A GLOBAL FUNCTION, OR BUILDING ONE FROM ZERO

A practitioner's guide for CROs and pharma and biotech sponsors: extending an existing Biometrics function to India, and standing one up from zero. Why India, the four layers in build order, two case tracks, inspection readiness, and a readiness checklist for each case. A Praveg white paper by Sagar Kalantre, Founder Director & CEO.

CASE A

Established CROs and sponsors headquartered outside India that want a second Biometrics site in India without diluting the first.

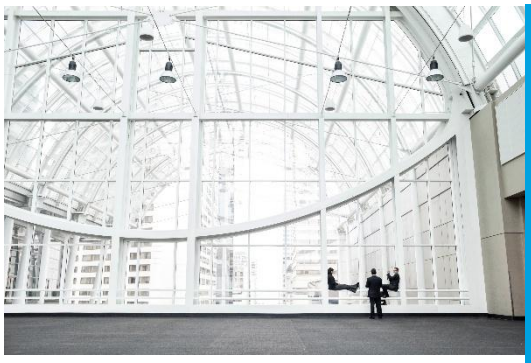
CASE B

India-based CROs and sponsors that currently outsource Clinical Data Management, Statistical Programming and Biostatistics and want to internalise them.

FROM THE FOUNDER

A note from the founder

Trials rarely get stuck on the science. They get stuck on data, and the data gets stuck when the function behind it was set up in the wrong order, or governed from the wrong place.



Over twenty years I have set up Clinical Data Management processes from scratch, headed a Biometrics division of fifty associates, sat on both sides of sponsor audits, and spent a good part of that time inside global organisations that ran India delivery sites: first as the person in India receiving work allocated from headquarters, later as the person at headquarters deciding what to allocate. More recently, Praveg has helped Indian CROs stand up their own CDM, programming and statistics functions, and global organisations establish Biometrics teams in India.

Two different starting points, one pattern. The organisations that struggle are not short of talent or ambition. Those building from zero buy a system before deciding what it is for, hire a team before the environment is validated, and discover the gaps in month eleven in front of a sponsor auditor. Those extending from abroad treat the India site as a place to put work, measure it on hours, govern it by email, and lose the people who could have made it a second hub.

This paper covers both cases in one place, because the foundations are shared even where the decisions differ. It is practitioner guidance, not theory, and it is deliberately frank about cost, dual running and sequence. The timelines are indicative; the order is not negotiable.

Sagar Kalantre
Founder Director & CEO
Praveg Consultancy Services LLP

SECTION 1

Executive summary

Biometrics functions in India rarely fail on talent. India has the talent. They fail on sequence and on governance: the order in which the function is built, and the decision rights it is given once it exists.

This paper is written for two readers who share a destination and start from different places. **Case A** is the established CRO or pharma or biotech sponsor headquartered outside India that already runs Clinical Data Management (CDM), Statistical Programming and Biostatistics and wants a second site in India that does not dilute the first. **Case B** is the India-based CRO or sponsor that currently outsources Biometrics and wants to internalise it, building the function for the first time. Both draw on Praveg's own experience setting up Biometrics functions for CROs and establishing teams in India for global organisations [P1][P3], the author's twenty years inside sponsor, CRO and IT services organisations [P2], and published regulatory and market sources cited throughout.

The shared argument is simple. **You are not buying a team. You are building a quality system that happens to employ people.** It has four layers, built in order: governance and scope, then process and quality system, then systems and validation, and only then people and volume. Case A inherits the first three layers from headquarters and must transfer them without losing the evidence behind them; Case B must build all four. The two case tracks in Sections 4 and 5 set out what is specific to each. The sections around them (why India, the four layers, inspection readiness and the readiness checklists) apply to both.

A note on time. Timelines in this paper are given in months because that is how budgets are set, but a Biometrics function matures in studies, not months. Treat the first six to twelve months, or the first one to four studies taken through set-up, conduct and close-out, as the establishment period, whichever comes later: the window in which the quality system is proven, the first sponsor audit is passed and the team earns the right to run without supervision.

7–12 months

to a first live study (Case B, 7–9) or to independent operation of an India site (Case A, 9–12) when the layers are built in order. Built out of order, the second year is spent repairing the first.

Case A, in one line: choose the route to the site on control, time and risk, not on cost alone; write down the site's decision rights before you write down its headcount; and plan for dual running, because the saving is real but it does not start in month one.

Case B, in one line: decide scope before you buy a system, validate the environment before you hire the team, and build for the first sponsor audit from day one.

Three things to take from this paper

1. Decide before you buy or hire. Scope and decision rights come first; systems and headcount follow. This holds whether the function is new or a second site of an existing one.

2. Documents transfer; evidence does not. SOPs can be adopted on day one. Training records, validation evidence for a shared system instance and quality culture have to be generated afresh, by a named owner, on a dated plan.

3. Build for the first sponsor audit from day one. It usually arrives between month seven and month eleven, and inspection readiness retrofitted then costs a multiple of inspection readiness designed in month one.

SECTION 2

Why India, and why now

2,117 global capability centres in India, employing 2.36 million people [10]	**23 of 50** of the world's largest life-sciences companies have India centres [9]	**480+** mid-market GCCs; 35% set up in just two years [11]	**40–60%** clinical research cost advantage vs North America and Europe [12]

The case for an India Biometrics site has moved beyond cost. Cost remains real: industry estimates put India's clinical research cost advantage at roughly 40–60% against North America and Europe [12]. But the more durable argument is the scale and depth of the talent base, and the fact that the world's largest life-sciences companies have already made the move.

- India hosts 2,117 global capability centres across 3,728 units, employing 2.36 million people, according to the nasscom-Zinnov India GCC Landscape Report 2026 [10].
- Twenty-three of the world's fifty largest life-sciences companies have set up capability centres in India, which has become a global life-sciences GCC hub over the past five years, and India has more than 2.7 million professionals in the life-sciences sector [9].
- The move is no longer only for the largest companies. More than 480 mid-market GCCs now operate in India, employing over 210,000 people, and 35% of them were set up in just two years [11].
- India's own trial activity is growing: 94,730 trials on the Clinical Trials Registry of India by 2025, with about 18,000 registered in 2024 alone, and 1,641 Phase I trials between 2019 and 2024 [1], and expanding early-phase trial capacity is now a stated national priority for ICMR and the regulator [2]. The New Drugs and Clinical Trials Rules, 2019 set 90-working-day timelines for trials of drugs developed outside India [3]. A sponsor with an India site is better placed to run India in its global programmes.
- Regulatory direction favours organisations that own their data governance. ICH E6(R3), adopted in January 2025 and effective in the EU from 23 July 2025 with FDA final guidance following in September 2025 [4][5], adds a dedicated data governance section and makes risk-based quality management the organising principle for every party in a trial [5]. A captive site that follows the same quality system as HQ is easier to defend under E6(R3) than a chain of subcontractors.

Why own the function at all

For a CRO or sponsor that has been outsourcing Biometrics, the reasons to own the function usually come down to four:

- **Margin.** Data management, programming and statistics are a recurring, high-skill line that a CRO currently pays a vendor for. Owned well, it becomes a profit centre rather than a pass-through.
- **Sponsor confidence.** Global sponsors increasingly want to see the data team, not a subcontract. An in-house function with its own SOPs and audit history is easier to qualify.
- **Control of the critical path.** Database lock is where trials may get stuck. Owning the function means owning the timeline.

- **Regulatory direction.** ICH E6(R3), adopted in January 2025 and in force in the EU from 23 July 2025 [4][5], introduces a dedicated data governance section and makes risk-based quality management the organising principle for every party in a trial [5]. That expectation lands on whoever holds the data. It is easier to meet with a function you control.

When a second site adds risk, not capacity (Case A)

Not every organisation should do this, and the counter-case is worth stating plainly:

- If the HQ function is itself under strain (audit findings open, lead roles vacant, SOPs mid-revision), a second site will import the strain, not relieve it. Fix home first.
- If the business case is cost alone, with no plan for the site to own work end to end, the site will be staffed by people who know they are a cost line, and they will leave for employers who treat them as a capability.
- If no one at HQ will spend a meaningful share of their time in India at least for the first year, the site will be governed by email, and just email is not governance.

When owning it is wrong (Case B)

Owning Biometrics is wrong for some organisations, and it is better to say so early than to discover it in month nine. Keep outsourcing if any of these hold:

- Your study volume cannot keep a minimum viable team busy. A function that runs two studies a year will lose its people to boredom before it loses them to competitors.
- Your therapeutic focus is too narrow to justify fixed cost, and your pipeline is uncertain beyond the next twelve months.
- No one at executive level will own the build. A Biometrics set-up without an executive sponsor becomes an IT project with a hiring plan attached, and it stalls at the first budget review.

The volume threshold is discussed with figures in the Case B track (Section 5). If you are below it, a hybrid model (a small in-house oversight core with vendor overflow) is often the right answer, and the four layers below still apply to the core.

> *India has the talent. Success depends on the set-up.*
>
> Sagar Kalantre, Praveg [P3]

AT A GLANCE

Highlights

The numbers that frame the decision, and where year-one money goes. Market figures are cited in the references; cost shares and break-even are Praveg planning ranges.

India GCCs
global capability centres employing 2.36 million people (FY26) [10]

2,117

Trials on CTRI
registered trials in India by 2025, about 18,000 added in 2024 alone [1]

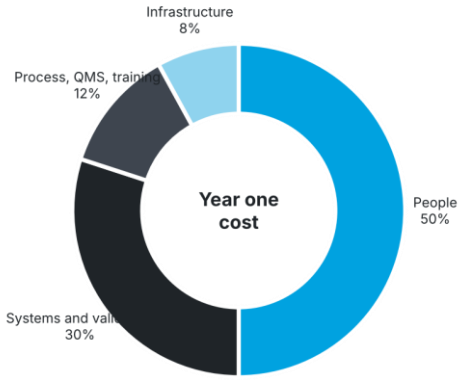
94,730

Cost position
clinical research cost advantage against North America and Europe [12]

40–60%

Time to establish
first live study (Case B) or independent operation (Case A), indicative

7–12 months



50%

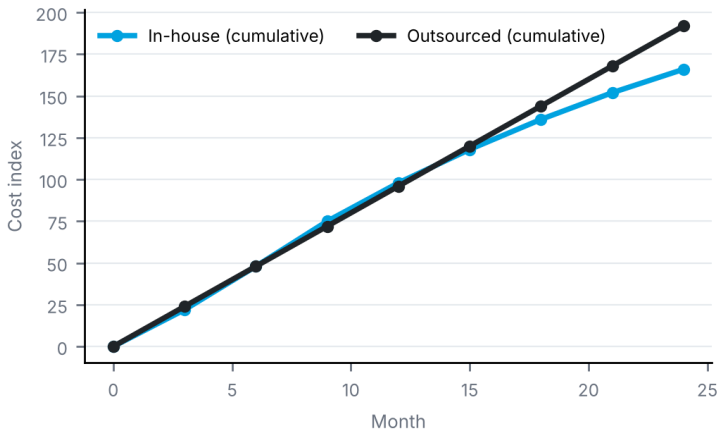
People, including recruitment and first-year attrition replacement (Case B); 45% in Case A, where the site-lead premium replaces some recruitment cost

25–30%

Systems and validation (Case B) or entity, facilities and infrastructure (Case A), front-loaded

12%

Dual running and HQ time in Case A, the line most plans omit; process, QMS and training in Case B



Break-even arrives in year two

Illustrative cumulative cost of an in-house function against continued outsourcing (Case B) or of an India site against carrying the work at headquarters (Case A). The fixed cost of the quality system, the validated environment and the dual-running period is carried first; the crossover typically lands in the second year, and the business case should say so.

SECTION 3

The four layers, in the order they must be built

Praveg's approach to any organisational build starts from a simple principle: diagnose before you act, then design, implement and govern [P2]. The diagnostic Praveg uses, the Praveg OPTIC Maturity Model™, reads an organisation across five pillars: Organisation and People, Process, Technology, Improvement and Context (its capability to read and calibrate to its environment), and then sequences the work by a written rule rather than by instinct [P2][P4]. Applied to a Biometrics build, that sequencing almost always lands on the same conclusion: the function has four layers, and each one only works if the one beneath it is in place. In Case B all four are built. In Case A the first three exist at headquarters and the work is to transfer them with their evidence intact; the layers below are written from the builder's point of view, and the Case A track in Section 4 sets out what changes in transfer.

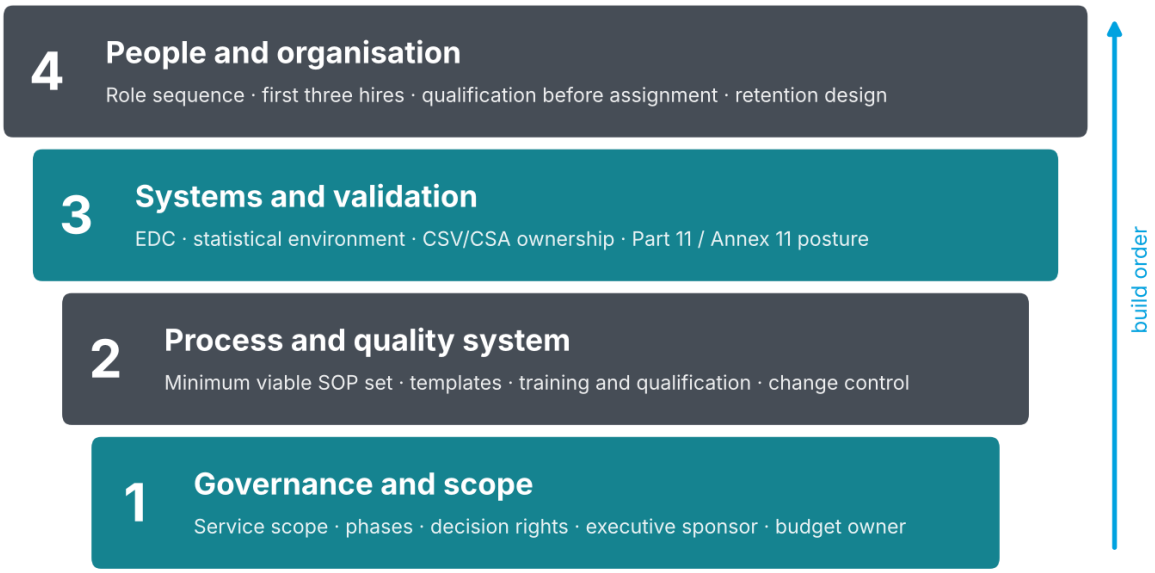


Figure 1. The four layers of a Biometrics function, in build order.

Layer	What it contains	What breaks when it is skipped
1. Governance and scope	Service scope, phases, sponsor types, decision rights, executive sponsor, budget owner, target operating model	Systems bought for the wrong workload; SOP set either bloated or incomplete; hiring profile wrong
2. Process and quality system	SOP architecture, templates (DMP, SAP, edit checks, reconciliation plans), QMS, training and qualification, change control	Each study invents its own process; audits find version-control and training gaps first
3. Systems and validation	EDC, statistical environment, CDISC tooling, document management; CSV/CSA scope and ownership; Part 11 posture	People hired into an unvalidated environment; first sponsor audit finds the system, not the data

Layer	What it contains	What breaks when it is skipped
4. People and organisation	Role sequence, first three hires, India talent realities, onboarding and qualification, retention design	Culture set by whoever arrived first; attrition in year two; knowledge concentrated in one person

Layer 1: Governance and scope

The single most consequential decision in a Biometrics build is made before anything is bought or anyone is hired: **what, exactly, will this function do?** The honest answer is usually narrower than the ambition. Three sub-decisions matter most.

- **Service scope.** CDM only; CDM plus statistical programming; or full Biometrics including biostatistics and SAP authorship. Each step up roughly doubles the SOP set, changes the system footprint (a statistical computing environment is a validation project of its own) and changes the seniority of the first hires.
- **Phase and study type.** Phase I and bioequivalence studies have short cycles and high repetition, which suits a new team. Late-phase oncology does not. Starting with the study types your sponsors actually bring, rather than the ones in the brochure, keeps year one survivable.
- **Full-service or data-only.** If the CRO offers monitoring and site management too, Biometrics must integrate with those processes (query turnaround, SDV expectations, SAE reconciliation with pharmacovigilance). If it is data-only, the interfaces are with sponsor teams instead. These are different operating models and different SOP sets.

Alongside scope, name the executive sponsor and the budget owner. In Praveg's experience these are often different people, and the build needs both: one to protect it in the leadership room, the other to release money at the points where the plan says money is needed. Decision rights between Biometrics and Clinical Operations (who signs off eCRF design, who owns the lock date, who escalates a sponsor dispute) should be written down at this stage, not negotiated study by study later.

> *Trials rarely get stuck on the science. They get stuck on data.*
>
> Sagar Kalantre, Praveg [P3]

Layer 2: Process and quality system

This is the layer most first-time builders either skip or over-build. Both failures are expensive.

Skipping it produces a team that invents process per study. Praveg's diagnostic work has found this pattern repeatedly: one contract research unit came to Praveg after a difficult inspection with a data-integrity finding, and the underlying problem turned out to be that three teams were running three versions of the same SOP, each believing theirs was current. The organisation had grown from twelve people to ninety in four years without a governance mechanism for SOP version control. A process governance board, a single SOP repository and a quarterly compliance review took eight weeks to put in place, and the next inspection outcome was materially different (Chapter 1, Praveg OPTIC Maturity Model™, First Edition 2026) [P1][P4].

Over-building it produces the sixty-SOP trap: a large-CRO procedure set imported wholesale, which no one in a twelve-person function can follow, and which an auditor will hold you to anyway. An auditor does not care whether an SOP was aspirational. If it exists and you did not follow it, that is a finding.

The minimum viable quality system for a new Biometrics function is smaller than most people expect. Praveg has developed exactly this kind of system-agnostic SOP set for clients, covering eCRF design through archival [P2]. In outline:

Area	Minimum documents	Why it is on the list
Data management	DM plan template; eCRF design and edit-check specification; data review and query management; medical coding; SAE reconciliation; database lock	Every sponsor audit walks this chain
Programming	Programming standards; validation (double programming or independent review); SDTM/ADaM mapping conventions; output QC	The first question a sponsor statistician asks is "how do you QC?"
Statistics	SAP authorship and review; randomisation and blinding; interim analysis governance	Only if biostatistics is in scope
Quality and governance	Document control and version management; training and qualification records; change control; deviation and CAPA; vendor qualification	These are where young functions are found wanting first
Infrastructure	User access management; backup and restore; audit trail review	Part 11 and Annex 11 expectations sit here

Two points on standards. Align the CDM procedures to the Good Clinical Data Management Practices (GCDMP) published by the Society for Clinical Data Management; sponsors recognise it and it gives new staff a shared vocabulary. And write the procedures against ICH E6(R3), not E6(R2). The revision's data governance section and its risk-based quality management framing [4][5] are what sponsor quality teams will be auditing against from now on.

Vendor qualification deserves a specific mention because new functions usually have vendors before they have a vendor-qualification SOP. In one 2026 remote vendor-qualification audit of a young biometrics CRO that the author supported, two of the three findings were exactly this: vendors engaged before the qualification procedure existed, and annexure forms without version control. Neither was a data problem. Both were avoidable in week one.

Layer 3: Systems and validation

A first-time buyer of an EDC and a statistical environment is in a weak position: the vendors know the market and the buyer does not. Three rules keep the decision sound.

1. **Decide scope first (Layer 1), then buy.** The system footprint for CDM-only is one validated EDC plus document management. Full Biometrics adds a statistical computing environment, CDISC tooling and output management, each with its own validation effort.
2. **Evaluate on validation burden and sponsor compatibility, not feature count.** The questions that matter: Does the vendor supply a validation package and audit-trail documentation that your sponsors' QA teams have accepted before? Can the platform produce the exports and Define.xml your sponsors expect? What is the vendor's own inspection history? Dashboards and AI features are sold hard and rarely decide an audit.
3. **Name a validation owner and give the work a budget line.** Computer system validation is not an IT afterthought. ISPE's GAMP 5 Second Edition (July 2022) and the FDA's Computer Software

Assurance guidance, finalised in September 2025, both push towards risk-based, critical-thinking assurance rather than document volume [7]. That is good news for a small function, because proportionate validation is now defensible. But "proportionate" is a judgement someone has to own and document.

The sequencing consequence is the one most often ignored: **do not hire the delivery team until the environment is validated and the first study configuration has been dry-run.** Praveg has seen teams of six sitting idle for weeks because the EDC validation slipped. They are billable, they are bored, and the best of them start taking calls from recruiters.

One further lesson from Praveg's assessment work: revalidation after change is as important as initial validation. In an assessment six weeks before a sponsor audit at a mid-sized CRO, one of the four material gaps was an EDC system that had not been revalidated after a system update. The model's Priority Lens put Process first, with Organisation worked to its enabling floor [P1][P4]. Change control for systems belongs in Layer 2 so that it is already a habit when Layer 3 goes live.

Layer 4: People and organisation

Only now does hiring start, and the order of hires matters more than the number.

The first three hires set the culture. A Biometrics lead with hands-on CDM depth and sponsor-facing credibility; a senior statistical programmer who can set the programming standards and the QC discipline; and a data management lead who will own study start-up. All three should have audited and been audited. Everything that follows is shaped by their habits. Volume hires come after the first study is configured and the SOPs have been used in anger at least once.

India talent realities. The experienced-but-not-expensive layer in Indian Biometrics sits in the six-to-ten-year band: people who have run studies end to end at a CRO or a global sponsor's captive, who understand audits, and who have not yet moved into people management. They are the backbone of a new function and the hardest to retain in year two, when larger employers notice them. Retention is designed, not hoped for: a visible path to lead roles, exposure to sponsor interaction, and a training budget that is actually spent.

Qualification before assignment. GCP, SOP and system training must be documented and complete before a person touches live study data. This is both a regulatory expectation and a practical one: a training matrix with missing due dates is a routine audit observation, and it is the kind of finding that makes an auditor look harder at everything else.

Avoid single points of failure from the start. In the mid-sized CRO assessment described above, the Data Management Lead role had been vacant for eleven weeks when the sponsor audit was six weeks away [P1]. The fix in that case was an interim appointment in week one. The better fix is a deputy for every critical role from the moment the function has more than one study.

> *Passed not because the organisation was perfect, but because it could see itself clearly.*
>
> Chapter 11, Praveg OPTIC Maturity Model™ (First Edition 2026), field vignette [P1][P4]

SECTION 4

Case A: Extending an existing Biometrics function to India

For the established CRO or sponsor outside India. The SOPs exist. The systems are validated. The quality culture has an audit history. The question is harder than building from zero: how do you replicate a function you already run well, in a country where you have never operated, without turning it into a cheaper and worse copy of itself?

Three ways to establish the site

There are three broadly distinct routes to an India Biometrics site. Each has a different profile of speed, control, cost and risk, and each suits a different starting position.

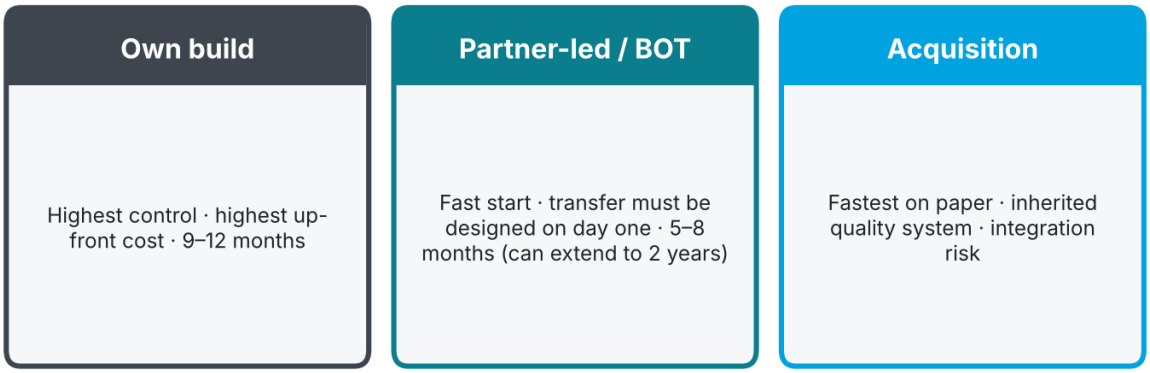


Figure 1. Three routes to an India Biometrics site.

	Own build	Partner-led / build-operate-transfer	Acquisition
What it is	You set up the entity, hire the team, extend your systems and quality system directly	A partner establishes and runs the site to your SOPs and systems, then transfers it to you at an agreed point	You buy an existing Indian Biometrics capability and integrate it
Time to first live study	Typically 9–12 months (indicative)	Typically 5–8 months, but can extend up to 2 years (indicative)	Fastest on paper; integration can take longer than a build
Control	Full from day one	Full over standards; operational control transfers at hand-over	Full ownership; limited control over inherited culture and systems
Cost profile	Highest up-front; lowest run-rate	Lower up-front; partner margin during the operate phase	Capital outlay; integration cost; retention payments
Main risk	HQ bandwidth; India-specific logistics done for the first time	Partner dependence; transfer design; staff loyalty at hand-over	Inherited quality system; validation debt; key-person loss post-deal

	Own build	Partner-led / build-operate-transfer	Acquisition
Best fit	Organisations with strong HQ bandwidth and a long-term India commitment	Organisations that want the site but not the first-year learning curve	Organisations that need scale fast and have integration muscle

Three observations from practice. First, **most mid-sized CROs and sponsors land on a hybrid of the first two**: an own build with an on-ground partner for the first twelve to twenty-four months, covering entity set-up, logistics, early hiring and local compliance, while HQ concentrates on transferring the quality system and the first studies. That is the model Praveg supports most often, because it keeps control with the client while removing the first-year learning curve [P3]. Second, **build-operate-transfer only works if the transfer is designed on day one**: who moves across, on what terms, with which systems, and when. A BOT with a vague transfer clause becomes a long-term outsourcing contract with extra steps. Third, **acquisition is the route most likely to disappoint on quality**, because the thing you are buying is a quality system you did not build, and a validated environment you did not validate. Due diligence on an Indian Biometrics acquisition should be led by QA and validation, not just by finance.

What transfers from headquarters, and what does not

This is the section where HQ assumptions most often break. The instinct is to treat the India site as a mirror: same SOPs, same systems, same training, same quality. Some of that is right. Some of it is not, and the differences are where the first audit findings come from.

Element	Transfers as-is?	What actually has to happen
Global SOPs	Mostly	Adopt as the controlling documents. Add local annexes where Indian law, local vendors or the site's scope differ. Do not fork the SOP set; a forked set is three versions of the truth within two years.
Templates (DMP, SAP, edit checks, lock checklist)	Yes	Transfer unchanged. The site must be auditable to the same artefacts as HQ.
Shared system instance (EDC, statistical environment)	Partly	The system is validated; the site's use of it is not. User-access provisioning, role configuration, local infrastructure qualification and site-specific training records all need their own evidence.
Training and qualification records	No	Every India hire starts at zero. A qualification-before-assignment rule with a training matrix is non-negotiable, and it is the first thing a sponsor auditor will open.
Quality culture	No	Culture is carried by people, not documents. It transfers through the site lead, through HQ staff on the ground in year one, and through the first three or four studies run jointly.
Vendor relationships	Partly	Global vendors may serve India; local vendors (recruitment, IT, facilities, local labs) must be qualified under your vendor-qualification SOP before use, not after.

Element	Transfers as-is?	What actually has to happen
Data-handling and privacy policies	No	Must be rewritten for India's Digital Personal Data Protection Rules, 2025 and their interface with GDPR or other home regimes (see the logistics table below).
Employment and labour compliance	No	Indian employment contracts, statutory benefits and labour-law obligations replace HQ templates; several policies are mandated in specific forms (see the logistics table below).
Entity finance and statutory compliance	No	Indian books of account, statutory audit, GST and withholding-tax compliance and annual filings are new obligations that sit with the Indian entity (see the logistics table below).
Intercompany charging and transfer pricing	No	How HQ pays the India entity for its services (typically a cost-plus intercompany agreement) and the transfer-pricing documentation behind it must be designed before the first invoice (see the logistics table below).

The pattern behind this table is a simple one. **Documents transfer. Evidence does not.** A quality system is only as good as the evidence that people were trained on it, that the systems were qualified for its use and that deviations were handled under it. All of that evidence has to be generated afresh in India, and the plan should say who generates it, by when.

Praveg's diagnostic work shows what happens when the evidence layer is neglected. In one assessment six weeks before a sponsor quality audit at a mid-sized CRO, the gaps were not in the SOPs but in the evidence around them: a Data Management Lead role vacant for eleven weeks, a database lock checklist in two versions, an EDC not revalidated after a system update, and query timelines tracked by study but not by site. The lead role was filled on an interim basis in week one; the audit closed with four observations, none critical, and the sponsor's quality team noted the CRO's structured response to its own gaps as a positive indicator of quality culture (Chapter 11, Praveg OPTIC Maturity Model™, First Edition 2026) [P1][P4]. A new India site is the same kind of young organisation, under the same kind of scrutiny.

The governance model

The decision that determines everything else about an India site is not where it is, how big it is or what it costs. It is **who decides what**. Two models dominate, and the choice between them should be explicit.

Hub-and-spoke

The India site reports functionally into the HQ Biometrics leadership; study allocation, standards, hiring approvals and sponsor interaction are controlled from HQ; the site lead runs delivery. This is the natural starting point and it is the right model for the first six to twelve months or the first few studies, while the quality system is being transferred and the first studies are run jointly. It is the wrong model to stay in. A site that is only ever told what to do loses its best people to employers that let them decide.

Autonomous unit with shared standards

The India site owns its studies end to end, hires against an approved plan without case-by-case HQ approval, interacts directly with sponsors on its studies, and is measured on outcomes (lock timeliness, audit results, retention, margin) rather than on hours. HQ owns the standards, the quality system and

the audit programme. This is where a successful site should be by month eighteen to twenty-four, and the transition should be written into the plan with a date, not left to happen.

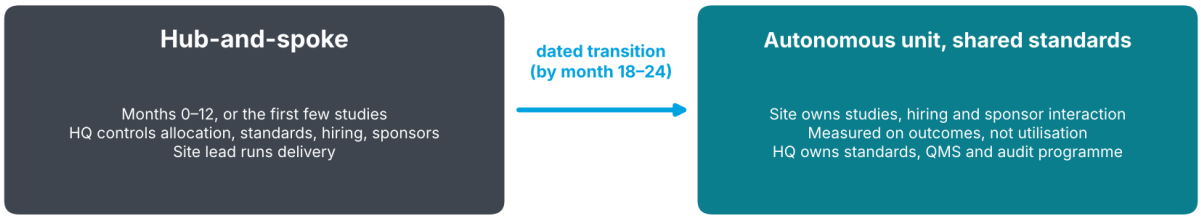


Figure 2. The governance transition, with a date attached.

The cost-centre trap

A site set up purely as a cost centre, with decision rights retained at HQ and performance measured on utilisation, produces a predictable cycle. The strongest hires, who joined to build something, discover that they are executing someone else's decisions. They leave. Their replacements are hired for cost. Quality drifts. HQ concludes that India is difficult, and either shrinks the site or outsources it. The site did not fail; the governance did. The remedy is the same as it is for any organisation Praveg works with: decide what the unit is for, write down the rule by which it will be governed, and let the people who run it own the outcome. That is the logic of the Praveg OPTIC Maturity Model™: diagnose across Organisation and People, Process, Technology, Improvement and Context, then sequence by a written rule [P2][P4].

Oversight cadence

Whichever model applies, the oversight rhythm should be explicit and proportionate. A pattern that works in Praveg's experience:

- **Weekly:** study-level delivery review between HQ and site study leads, by exception, for the first six months; fortnightly thereafter
- **Monthly:** site scorecard reviewed by the HQ Biometrics head: lock timeliness, query cycle time by site, open deviations, training completeness, attrition and pipeline
- **Quarterly:** quality review including internal audit findings, CAPA status and the site's own assessment of its gaps
- **Annually:** an independent assessment of the site against the global quality system, ideally before the heaviest sponsor audit of the year

The logistics headquarters underestimates

None of the items below are difficult individually. Collectively, they are where own-build timelines slip by three to six months, because each is being done for the first time by someone whose main job is something else. This is the work an on-ground partner takes off the HQ team's desk [P3].

Area	What has to be done	Common surprise
Legal entity and registrations	Entity formation (commonly a private limited company or LLP), tax registrations, statutory registrations for employment, bank account, registered office	Sequential dependencies mean this is a 10–16 week critical path, not a form
Employment and labour compliance	Employment contracts under Indian law, statutory benefits (provident fund, gratuity, insurance), leave and working-time rules, grievance and prevention-of-harassment policies, background verification; state-level shops-and-establishments registration	Policies cannot simply be translated from HQ; several are mandated in specific forms, and some registrations are state-specific
Data privacy	Policies and processing records under the DPDP Rules, 2025; cross-border transfer conditions; breach notification; interface with GDPR for EU sponsors	The Rules were notified on 13 November 2025 with phased commencement over 18 months [6]; a site set up now must be designed for full compliance in 2027
IT and infrastructure	Network qualification, secure access to HQ systems, endpoint control, backup; local infrastructure qualification evidence for the shared validated instance	Infrastructure qualification is a validation deliverable, not an IT ticket
Facilities	Office selection, fit-out, access control, business continuity	Access control and visitor logs are audit items
Entity finance and statutory compliance	Indian books of account and statutory audit, GST registration and returns, withholding tax (TDS) on vendor and salary payments, annual filings with the Registrar of Companies and the tax authorities, and a local finance controller or outsourced accountant	These obligations are continuous from day one of the entity, not from the first study; a missed statutory filing is a director-level liability in India
Intercompany charging and transfer pricing	An intercompany services agreement under which HQ pays the India entity, usually on a cost-plus basis; transfer-pricing documentation and an arm's-length margin. India's safe-harbour regime for IT-enabled and knowledge-process captives sets a single consolidated margin of 15.5% on operating expenses for eligible entities from the 2026–27 tax year, under the Income Tax Act, 2025 [13]	Revenue cannot simply be "transferred"; the margin, the agreement and the documentation are examined by the Indian tax authority, and opting into safe harbour is a decision to take with Indian tax counsel
Shift and overlap design	Working hours that overlap meaningfully with HQ and sponsor time zones without burning out the team	A permanent late or early shift is the single most reliable driver of attrition in India Biometrics teams
Local vendors	Recruitment agencies, IT support, facilities, local laboratories or printers where relevant	All must be qualified under your vendor-qualification SOP before first use

One further point on data. A site that handles subject-level data for EU sponsors will be audited against GDPR expectations as well as Indian law. The DPDP Rules permit cross-border transfer subject to conditions the central government may specify under Rule 15 [6]; the transfer mechanisms, the data-

processing agreements and the breach-notification procedures should be settled before the first study, because the first EU sponsor will ask for them in qualification.

Hiring in India from outside India

The Indian Biometrics talent market is deep, competitive and layered. Knowing where to hire from matters as much as how many to hire.

The site lead is the hire that decides the site. The profile that works is someone with fifteen to twenty years in Biometrics, who has led delivery at a CRO or a global sponsor's India captive, who has been audited and has audited others, and who is known in the Indian market well enough to attract the next ten hires. The temptation is to send an HQ expatriate. That can work for a transition year, but a site led by an outsider for longer than that is a site that the Indian market reads as a branch office, and it hires accordingly. The better pattern, in Praveg's experience, is an Indian site lead paired with an HQ counterpart who spends real time on the ground in year one.

The experienced-but-not-expensive layer sits in the six-to-ten-year band: people who have run studies end to end, understand audits and have not yet moved into people management. They are the backbone of a new site and the hardest to retain in year two, when the large employers that trained them notice they have left. Retention is designed, not hoped for: a visible route to lead roles, direct sponsor exposure, and a training budget that is actually spent.

Qualification before assignment is non-negotiable and is the first thing a sponsor auditor opens. Every hire starts at zero on your quality system, however experienced they are. A training matrix with due dates, maintained from the first hire, is both a regulatory expectation and the cheapest audit finding to avoid.

Deputies for critical roles from the moment the site has more than one study. A lead role vacant for weeks before an audit is a recurring pattern in young functions [P1], and in a site twelve time zones from HQ it is the kind of gap no one notices until the auditor does.

The role of an on-ground partner in year one

An on-ground partner is most valuable in the first twelve to twenty-four months and should be designed to become less necessary thereafter. The work it takes on, in Praveg's model: entity and compliance set-up, the first wave of hiring against HQ-defined profiles, local vendor qualification, policy localisation (HR, IT, data privacy), site-level process set-up alongside the HQ quality system, and running the first studies alongside the new team until they can run alone [P1][P3]. The partner should have no interest in staying: the measure of success is a site that no longer needs it.

> *Praveg provided valuable strategic direction while helping us establish scalable biometrics processes. Their understanding of both operations and technology ecosystems significantly accelerated our setup activities.*
>
> Founder, clinical research services company, client testimonial [P1]

Timeline and cost model (Case A)

The figures below are Praveg's indicative ranges for an own-build with on-ground partner support. They are planning guidance, not quotations; the right numbers depend on scope, headcount and the HQ team's available bandwidth.

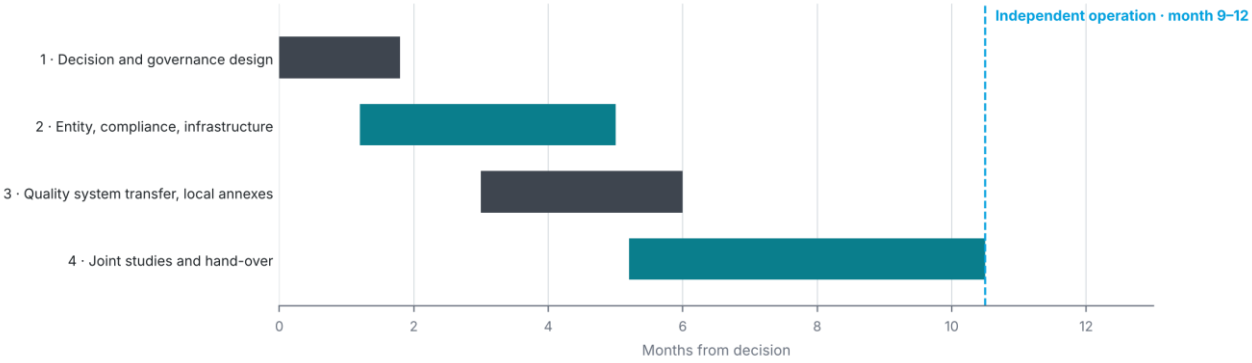


Figure 3. Indicative phasing, with overlaps, from decision to independent operation.

Phase	Indicative duration	Runs alongside	Exit criterion
1. Decision and governance design	4–8 weeks	Nothing; this is the gate	Model chosen; decision rights and operating model written; executive sponsor and budget owner named
2. Entity, compliance and infrastructure	10–16 weeks	Site lead search; policy localisation	Entity live; bank, registrations and office in place; IT qualified
3. Quality system transfer and local annexes	8–12 weeks	Site lead onboarded; first-wave hiring	Controlling SOPs adopted; local annexes approved; training matrix live
4. Joint studies and hand-over to site ownership	12–20 weeks	Volume hiring; sponsor qualification visits	Three or four studies run jointly; first internal audit complete; site owns its studies
Total to independent operation	**9–12 months**		Partner-led routes typically 5–8 months to first live study, longer to full transfer

Months or studies? The month figures describe the set-up. The site is established only once it has taken studies through the full cycle on its own. Praveg treats the establishment period as the first six to twelve months or the first one to four studies, each covering set-up, conduct and close-out, whichever is later. A site that reaches month ten with its joint studies still in conduct has not yet proven its database lock process in India, and its transition to autonomy should be judged on studies closed, not on the calendar.

The dual-running period

The cost line most often missing from an India business case is dual running: the period, usually three to nine months, in which HQ staff are spending time on India set-up and joint studies while still carrying their own workload, and in which the India team is salaried but not yet independently productive. Plans that show cost savings from month one are not wrong about the eventual saving; they are wrong about when it starts. In Praveg's experience the cost crossover for a well-run site typically arrives in the second year, and the business case should say so.

Where the money goes in year one

- **People:** 40–50%, including recruitment, the site lead premium and first-year attrition replacement
- **Entity, facilities and infrastructure:** 20–30%, front-loaded
- **Quality system transfer, localisation, validation evidence and training:** 10–15%
- **Dual running and HQ time:** 10–20%, the line most plans omit
- **On-ground partner support:** 5–10%, declining through the year

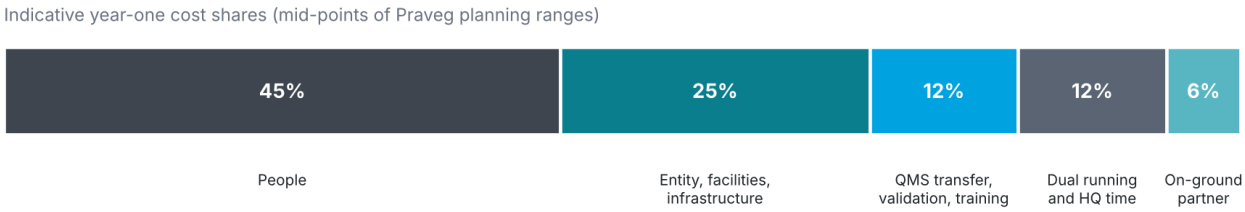


Figure 4. Indicative year-one cost shares (mid-points of Praveg planning ranges).

Five mistakes that are expensive to undo (Case A)

1. **Shipping the global SOP set unchanged and calling it done.** Symptom: local practice diverges silently; the first audit finds Indian employment, privacy or vendor practices that no SOP covers. Fix: controlling global SOPs plus local annexes, approved through HQ change control.
2. **Hiring the site head from the HQ expatriate pool for the long term.** Symptom: the Indian market reads the site as a branch office; senior Indian talent does not apply. Fix: an Indian site lead with an HQ counterpart on the ground in year one.
3. **Measuring the site on utilisation.** Symptom: the strongest hires leave within eighteen months; quality drifts. Fix: measure on outcomes (lock timeliness, audit results, retention, margin) and give the site the decision rights that go with them.
4. **Treating the shared system instance as "already validated".** Symptom: the first sponsor audit finds no evidence that India users, roles and infrastructure were qualified. Fix: a site-level validation evidence plan with an owner.
5. **A permanent late or early shift to match HQ hours.** Symptom: attrition concentrated in the six-to-ten-year band. Fix: design overlap windows, rotate them, and move work rather than people where the process allows.

From the field: a composite case (Case A)

The following is a composite drawn from Praveg's experience with India Biometrics set-ups and from the author's years inside global organisations with India delivery sites [P2][P3]. Details have been altered and combined; no single organisation is described.

A mid-sized European CRO with a forty-person Biometrics function decided to open an India site after losing quite a few bids on price. The initial plan was a hub-and-spoke model: twelve data managers and programmers in India, allocated work from headquarters, measured on billable hours, reporting to the HQ head of data management. The business case showed cost savings from month eight.

Praveg's first intervention was on governance, not logistics. The plan was reframed around a site lead with her own decision rights over study start-up and hiring, a dated transition from hub-and-spoke to an autonomous unit at month twenty-four, and a scorecard built on lock timeliness, audit results and retention rather than utilisation. The HQ head of data management committed to one to two continuous weeks per quarter in India for the first year.

Entity formation, registrations and office took fourteen weeks, running in parallel with the site-lead search. The global SOP set was adopted unchanged as the controlling documents, with six local annexes covering employment, data privacy under the DPDP Rules, local vendor qualification, infrastructure qualification for the shared EDC instance, business continuity and site-level training. Four smaller studies were run jointly with HQ study leads over the first six to nine months of operation.

The first sponsor qualification audit came in month ten. The auditor's focus was exactly where this paper says it would be: training records, infrastructure qualification evidence for the India users of the shared system, and the data-transfer agreements with EU sponsors. All three had been built in. The audit closed with two minor observations.

Cost crossover arrived in month fifteen, not month eight. At month twenty-four the site had grown to twenty-two people, had taken on its first directly won sponsor, and had lost three people, none from the original leadership group. The CRO's subsequent description of the site, in its own bids, was not "our India delivery centre" but "our second Biometrics hub".

SECTION 5

Case B: Standing up Biometrics from zero

For the India-based CRO or sponsor building Biometrics for the first time. You are not buying a team. You are building a quality system that happens to employ people, and the order in which you build it decides whether year two is spent growing or repairing.

The scope decision, in detail

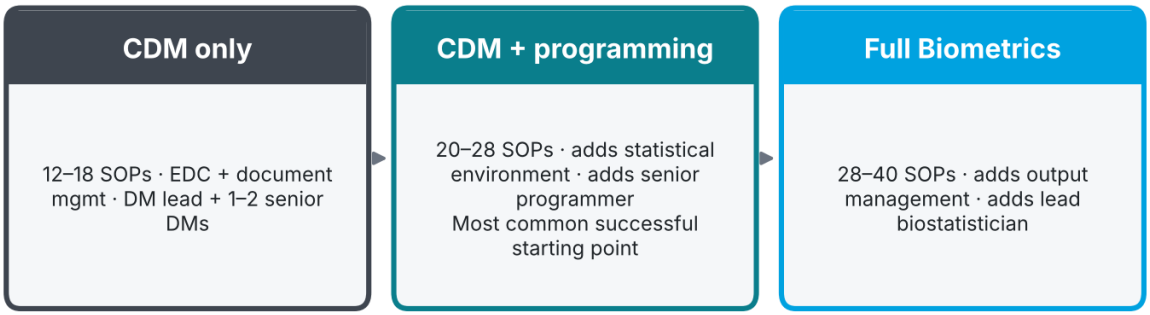


Figure 2. Three scope options and what each implies.

Because scope drives everything, it is worth being explicit about what each option implies. The table below reflects the pattern Praveg sees across set-ups; the figures are indicative ranges from engagement experience, not benchmarks.

Scope option	Core SOP count (approx.)	Validated systems	First hires	Typical fit
CDM only	12–18	EDC; document management	Biometrics/DM lead; 1–2 senior DMs	CRO adding data management to monitoring services; sponsor wanting data oversight
CDM + programming	20–28	EDC; statistical environment; CDISC tools	Add a senior programmer with QC ownership	CRO targeting submission-ready SDTM/ADaM; sponsor with in-house statisticians elsewhere
Full Biometrics	28–40	All of the above plus output management	Add a lead biostatistician	CRO positioning as full-service; sponsor with no external statistics

Two observations from practice. First, **CDM plus programming is the most common successful starting point** for an Indian CRO: it captures the recurring revenue and the submission-ready deliverables sponsors value, without the regulatory exposure of signing off a statistical analysis plan on day one. Biostatistics is usually added once the programming group has delivered three or four

studies cleanly. Second, **phase matters as much as service line.** A function that starts on Phase I and bioequivalence work builds repetition and audit history fast; one that starts on a late-phase oncology study learns everything at once, under a sponsor's most demanding quality team.

Timeline and cost model (Case B)

The figures below are Praveg's indicative ranges from Biometrics set-up engagements for Indian CROs. They are planning guidance, not quotations; the right numbers for a specific organisation depend on scope, the systems chosen and the starting state of the quality system.

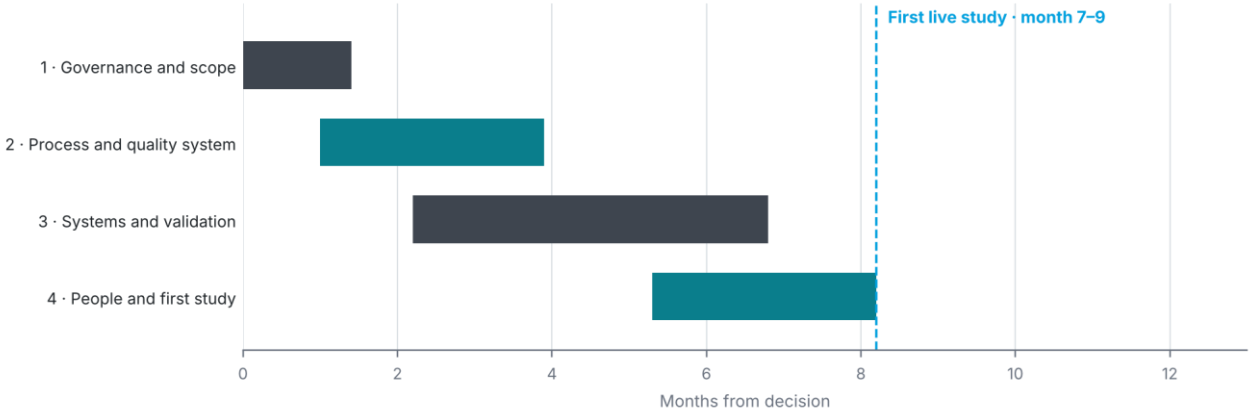


Figure 3. Indicative phasing, with overlaps, from decision to first live study.

Phase	Indicative duration	Runs alongside	Exit criterion
1. Governance and scope	4–6 weeks	Nothing; this is the gate	Scope, operating model, executive sponsor and budget signed off
2. Process and quality system	8–12 weeks	System evaluation can start in week 4	Core SOP set approved; templates ready; training plan defined
3. Systems and validation	12–20 weeks	First three hires recruited in the second half	Validation summary signed; first study configuration dry-run complete
4. People and first study	8–12 weeks to first live study	Volume hiring; sponsor qualification visits	First study live; first internal audit complete
Total to first live study	**7–9 months**		With overlaps; longer where biostatistics is in scope from the start

Months or studies? The month figures above describe the build. The function is established only once it has taken studies through the full cycle. Praveg treats the establishment period as the first six to twelve months or the first one to four studies, each covering set-up, conduct and close-out, whichever is later. A function that reaches month nine with one study still in conduct has not yet proven its database lock process, and it should not be described to sponsors as established until it has.

Where the money goes

First-time builders consistently budget for people and under-budget for everything else. As a share of year-one cost, in Praveg's experience, the pattern is roughly:

- **People:** 45–55%, including recruitment cost and the first-year attrition replacement that most plans omit
- **Systems and validation:** 25–35%, including licences, the validation effort itself and the vendor audits sponsors will expect
- **Process, quality system and training:** 10–15%, including external SOP development or review, GCP and system training, and the first internal audit
- **Infrastructure and overhead:** 5–10%

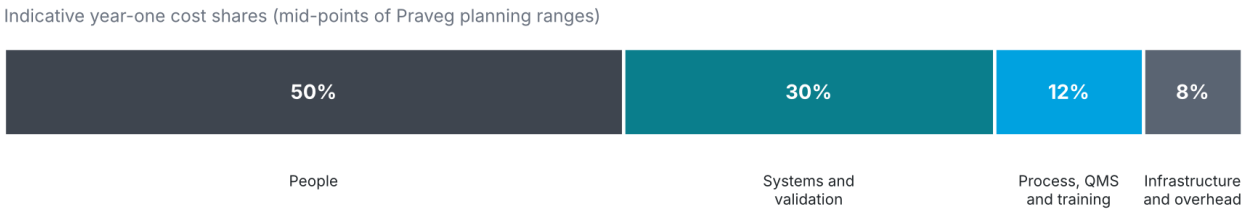


Figure 4. Indicative year-one cost shares (mid-points of Praveg planning ranges).

Three hidden lines deserve their own row in the budget: validation rework after the first protocol amendment; dual-running cost while studies transition from the outgoing vendor; and inspection-readiness work before the first sponsor audit.

Break-even against outsourcing

Whether owning the function pays depends on volume. A rule of thumb from Praveg's engagements: an in-house CDM-plus-programming function of eight to twelve people typically overtakes the outsourced cost once it is sustaining five to seven concurrent studies of moderate complexity, usually in the second year. Below three or four concurrent studies, the fixed cost of the quality system and the validated environment is rarely recovered, and a hybrid model (small in-house core, vendor overflow) is the better answer. These are directional figures; the break-even for a specific organisation should be modelled on its own pipeline before the decision is taken.

Five mistakes that are expensive to undo (Case B)

1. **Buying the EDC before deciding the service scope.** Symptom: a system licensed for a workload the function never runs, or one that cannot produce the deliverables the first real sponsor needs. Fix: Layer 1 before Layer 3, always.
2. **Hiring the team before the environment is validated.** Symptom: idle billable staff; early resignations. Fix: recruit the first three hires during validation, volume hires after the dry-run.
3. **Copying a large-CRO SOP set wholesale.** Symptom: procedures no one follows, which auditors hold you to anyway. Fix: a minimum viable set written for a function of your size, aligned to GCDMP and E6(R3), expanded as scope grows.
4. **No sponsor-facing QA voice in the first six months.** Symptom: the first sponsor audit is the first time anyone looks at the function the way an auditor would. Fix: an internal audit before the first sponsor audit, by someone who has sat on the sponsor side.

5. **Underestimating training time.** Symptom: training records that lag live work; an auditor's first observation. Fix: qualification before assignment, tracked in a matrix with due dates, from the first hire.

From the field: a composite case (Case B)

The following is a composite drawn from Praveg's Biometrics set-up engagements for Indian CROs [P3]. Details have been altered and combined; no single client is described.

A mid-sized Indian CRO with established monitoring and site-management services decided to bring Clinical Data Management and statistical programming in-house after two of their biggest sponsors asked, in the same quarter, who was handling their data. The founder's first instinct was to hire a data manager and buy an EDC. Praveg's first recommendation was to do neither for six weeks.

Those six weeks went on scope. The CRO settled on CDM plus programming, Phase II and III, with biostatistics to follow once the programming group had a track record. That decision cut the candidate system list in half and set the SOP count at twenty-four. The SOPs were written as system-agnostic procedures, so that the later EDC choice did not force a rewrite, and were aligned to GCDMP.

System evaluation started in week four of the process phase. The CRO chose an EDC on the strength of its validation package and the fact that two of its target sponsors already accepted that platform. Validation took fourteen weeks and was owned by the newly hired Biometrics lead, which meant the person who would defend the system in the first audit was the person who had validated it. The senior programmer joined in week eight of validation and built the programming standards while the environment was being tested.

The first live study started in month eight. The first sponsor audit came in month eleven and closed with observations on training-record completeness and one deviation record; none were major. The founder's later comment, that Praveg's understanding of both operations and technology "significantly accelerated our setup activities" [P1], reflects what the sequencing bought: not speed in any single phase, but the absence of rework between phases.

At twenty-four months the function was running nine studies with a team of fourteen, had added a lead biostatistician, and had lost two people to larger employers, both from the six-to-ten-year band, both replaced from a pipeline the CRO had deliberately kept warm.

SECTION 6

Inspection readiness from day one

The stakes of getting data quality wrong in India are not theoretical. In December 2023, confirmed on re-examination in 2024, the European Medicines Agency's human medicines committee recommended suspending the marketing authorisations of a large number of generic medicines after serious concerns about the validity and reliability of bioequivalence data from a Pune-based CRO. Of more than 400 medicines the CRO had tested for EU companies, only around 35 had sufficient supporting data from other sources to keep their authorisations [8]. The CRO's clients, not only the CRO, paid for the data-integrity failure.

A new Biometrics function, or a new India site of an existing one, will be audited by sponsors well before any regulator sees it. The practical consequence is that the function should be built as if the first sponsor audit were in month seven, because it often is. Praveg's assessment experience suggests the following are the areas a sponsor quality team examines first in a young function:

- SOP version control and the training records that prove staff were trained on the current version
- System validation evidence and change control, including revalidation after protocol amendments
- Role coverage: vacant or interim critical roles, and whether a deputy exists
- Study-level artefacts: data management plan, edit-check specification, database lock checklist, each in exactly one current version
- Query and data-review metrics tracked at the level the sponsor cares about (by site, not only by study)

Each of these is cheap to design in and expensive to retrofit. The lesson from the vignettes in Section 3 is not that the organisations were poor; it is that the ones that could see their own gaps before the auditor arrived came through, and in one case the sponsor noted the structured response to its own gaps as a positive indicator of quality culture [P1].

Data privacy is now part of inspection readiness

India's Digital Personal Data Protection Rules, 2025 were notified on 13 November 2025, with phased commencement: some provisions immediate, consent-manager obligations within twelve months, and the substantive obligations (including breach notification and cross-border transfer conditions under Rule 15) at eighteen months, in May 2027 [6]. A Biometrics function handling subject-level data for global sponsors will need its data-handling and transfer procedures written against these rules as well as against GDPR where EU sponsors are involved. Build the policy in Layer 2, not after the first EU sponsor asks for it.

SECTION 7

Readiness checklists

Fourteen questions for each case, one line each. Mostly "no" on a theme means that theme is where the work starts.

Case A: for headquarters leadership

Theme	Question	Yes / No
Decision	Have you chosen between own build, partner-led/BOT and acquisition on an explicit comparison of control, time and risk, not cost alone?	
Decision	Is there a named executive sponsor and a separate budget owner for the India site?	
Governance	Are the site's decision rights (study start-up, hiring, sponsor interaction) written down?	
Governance	Is there a dated transition from hub-and-spoke to an autonomous unit?	
Governance	Is the site measured on outcomes rather than utilisation?	
Transfer	Are global SOPs adopted as controlling documents with local annexes, rather than a forked set?	
Transfer	Is there a site-level validation evidence plan for the shared system instance, with an owner?	
Transfer	Is there a qualification-before-assignment rule with a training matrix from the first hire?	
Compliance	Are data-handling policies written against the DPDP Rules, 2025 and the home regime (GDPR or other)?	
Compliance	Are local vendors qualified under your vendor-qualification SOP before first use?	
Compliance	Are the intercompany services agreement, transfer-pricing position and Indian statutory-finance set-up designed before the first invoice?	
People	Is the site lead an Indian-market-credible hire with an HQ counterpart committed to time on the ground?	
People	Is the shift and overlap design sustainable for the six-to-ten-year band?	
People	Does every critical role have a named deputy once there is more than one study?	
Business case	Does the business case show the dual-running period and a realistic crossover in year two?	

Case B: for the first-time builder

Layer	Question	Yes / No
Governance	Is the service scope (services, phases, full-service or data-only) written down and signed off?	
Governance	Is there a named executive sponsor and a separate budget owner?	
Governance	Are decision rights between Biometrics, Clinical Operations and other functions documented?	
Governance	Has the break-even been modelled on your actual pipeline?	
Process	Is there a minimum viable SOP set sized for the function, aligned to GCDMP and ICH E6(R3)?	
Process	Do vendor qualification, change control and training procedures exist before vendors and systems do?	
Process	Is there a single document repository with version control?	
Process	Are data-privacy procedures written against the DPDP Rules, 2025 (and GDPR where relevant)?	
Systems	Does the EDC shortlist include validation package and sponsor acceptance as selection criteria?	
Systems	Is validation owned by a named person with a budget line?	
Systems	Is there a revalidation trigger for protocol amendments?	
People	Are the first three hires defined, with audit experience as a requirement?	
People	Is there a qualification-before-assignment rule with a training matrix?	
People	Does every critical role have a named deputy once there is more than one study?	

Praveg offers this checklist as a self-assessment. The fuller diagnostic behind Praveg's set-up engagements is the Praveg OPTIC Maturity Model™: a thirty-five-item instrument across the five pillars, scored on a 1–5 scale from Reactive to Optimising, calibrated to a Target Maturity Profile for the organisation rather than to an abstract level five, and sequenced by its Priority Lens so that the work starts where it will move the function most [P4]. Details at opticmm.com.

SECTION 8

Conclusion

Two starting points, one conclusion. A Biometrics function in India, whether built from zero or extended from headquarters, succeeds on sequence and governance, not on talent or money. Built in the right order (governance, process, systems, people) and given the decision rights that go with ownership, it reaches its first live study or independent operation in seven to twelve months, passes its first sponsor audit on the evidence it built in from day one, crosses cost in year two, and keeps the people who built it. Built out of order, or governed as a place to put work, it spends its second year repairing its first.

India has the talent. The set-up is the variable, and the set-up is a decision the leadership team makes before anyone is hired and before the first flight is booked.

Field vignettes and the composite cases are drawn from real engagements and have been anonymised, compressed and in places composited. Figures are as reported by the people involved, not audited. Indicative timelines, cost shares, break-even and crossover figures are Praveg planning ranges from engagement experience and should be validated against a specific organisation's scope and plan before use. Nothing in this paper is legal advice; entity, employment, tax and data-privacy decisions should be taken with qualified Indian counsel.

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ABOUT PRAVEG

About Praveg Consultancy Services LLP

Praveg Consultancy Services LLP is a boutique consulting and training firm, ISO 9001:2015 certified, with two practices: industry-agnostic PM and PMO consulting, and Biometrics with life-sciences AI for pharma, biotech, CROs and medical device companies [P2]. Praveg has set up Biometrics functions (Clinical Data Management, Statistical Programming and Biostatistics) for CROs, covering process, systems, teams and policies, and now offers Biometrics set-up as a defined service, including the establishment of Biometrics teams in India for global sponsors and CROs [P3]. Praveg also delivers clinical data management, biostatistics and programming, CDISC and submission deliverables, vendor oversight and inspection readiness, and practitioner-led CDM training [P1].

Sagar Kalantre, Founder Director & CEO, has more than twenty years across pharma, CRO and IT. He has spent part of that time inside global sponsor and CRO organisations with India delivery sites, has headed a Biometrics division of up to fifty associates spanning CDM, statistical programming and biostatistics; was one of two lead data managers who set up the CDM process, including EDC and systems, for a Switzerland-based pharma company; and has managed portfolios of around thirty-five clinical data projects for a Germany-based pharma company. He holds PMP®, PMO-CP®, CSM®, Lean Six Sigma Black Belt and SAS® certifications, is an ISO 9001 Lead Auditor, serves as an expert on an ICMR data management committee and as an Independent Director, has twice served as a PMI PMO Global Awards judge, and speaks at national and international forums. He is the author of *Primer to Project Management* and of the Praveg OPTIC Maturity Model™ (First Edition 2026) [P2][P4].

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