Future of patient recruitment lies in strategic, supportable engagement

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Revolutionising patient recruitment in India with a site-centric and tech-enabled model for sponsors

I'll start the article by introducing the '**Recruitment Drift Syndrome**'. What does it signify?

Patients drift away before the site is ready to recruit. But what about commitments we (Site team) were given while filling feasibility and during site selection visit?

India is experiencing a significant change in the clinical research landscape. The nation is becoming a considerable location for international clinical trials due to its fast expanding pharmaceutical industry, rising disease load, and advancements in digital healthcare. A major problem, nevertheless, even with the large patient base and expanding infrastructure i.e. **Patient recruitment**.

More than 80% of trial delays worldwide are caused by delayed patient recruitment, and socio-cultural complexity, ignorance, and low interaction between sponsors and investigators create additional obstacles in India. With more than 20 years of experience as a clinical research professional, I have seen firsthand both the problems and the solutions that can change this story.

A site-centric, technology-enabled paradigm designed specifically for India is presented in this paper. It enhances patient recruitment while fostering long-lasting relationships between sponsors and clinical sites.

The Actual Situation; Difficulties in Recruiting Patients:

1. **Insufficient Patient Knowledge**
   The majority of patients in India are not aware that clinical trials are a viable therapeutic option, despite the country's high disease burden. Few people think about taking part, mostly because they are afraid, feel stigmatized, or don't know enough about it.
2. **Overworked Sites and Investigators**
   Site staff frequently handle several studies with little assistance, which restricts their ability to successfully recruit, interact with patients and search patient outside the site. We should not forget that oversee the clinical study is not a primary job of Investigators involved in this, they have other tasks as Clinician, Academician, Member of different

committees and vice versa.

3. **Issues with Eligibility and Protocol Complexity**
   A high screen failure rate is caused by strict inclusion/exclusion criteria and inadequately localized methods.
4. **Fewer Referrals to Doctors**
   Private practitioners and trial locations are not in communication. The majority of doctors are neither encouraged nor trained to refer qualified patients to the trial site.
5. **Insufficient Technology Use**
   Digital technologies that facilitate recruitment, engagement, and data flow are frequently lacking for sites and investigators especially in tier-2/3 cities.

Presenting the Tech-Enabled and Site-Centric Model:

Sponsors need to reconsider their recruitment approach in order to overcome these obstacles. A successful model needs to be:

- Adaptable to the local environment (Plan A might work for Site X but not for Site Y).
- Digitally connected (referral & outreach dashboards, digital pre-screening tools, and EMR/OPD data integration).
- Focused on the referral network and location (e.g., feedback loops, doctor education programs, referral mapping, feedback loops, ethical honoraria, certificates, or acknowledgments).

This is a model that has worked well in many studies although providing outcome seen in Ophthalmology and Paediatrics.

1. **Using Sites as Strategic Centres**

When equipped with the appropriate tools and ecosystem, sites become more than just places to conduct trials; they are also recruitment engines.

Sponsors ought to:

- Work together to determine viability with site input on reasonable schedules
- Co-create recruitment objectives and metrics
- Assign coordinators specifically for site recruitment.

2. **Making Use of the PICs Framework**

Presenting the PICs Framework, a strategy model for locating and enlisting physicians to refer patients to trials:

PICs = Potential + **I**nterested + **C**omfortable doctor**s**

Impact on Sponsors:

- Increases referral rates and site-level enrollment forecasts.
- Targeted engagement results in fewer screen failures.

3. **Online Promotion and Pre-Screening**

- To lessen the workload for coordinators, sponsors ought to invest on e-consent, chatbot-assisted patient education, and pre-screening systems that are coupled with EMR/EHR tools.
- Employ geo-targeted advertisements to inform particular patient groups.
- To assess interest, use mobile-friendly pre-screeners. Use dashboards to share pre-screening data with websites.

4. **Content for Localized Patient Education**

- Convert recruitment brochures, trial summaries, and other site or study specific material into local languages.
- Culturally relevant content increases engagement delivered via SMS or WhatsApp,.

5. **Honoraria and Referral Partnerships Openness** (Under guidelines of Ethics Committee or Regulatory Body).

- Through fair recognition, referral acknowledgment, and MOU-based referral systems, promote moral and open doctor collaboration.
- Arrange referral summits every three months with involved HCPs.
- Provide documentation of every referral touch points that is audit-safe.

Real-World Application:

Ophthalmology study in Lucknow:

Using the PICs model including tech-enabled support, our team activated over 100 referral doctors (Government Hospitals/Private centres/Clinics/Diagnostics centres especially doing OCT) in around 6 months across same city and periphery of 300 km. Within 30 days:

- Referral-to-consent ratio improved by **41%**
- Completed enrolment **22 days ahead of schedule**
- Doctor engagement satisfaction increased
- Site had finished at 2nd in global ranking

Paediatric study in Delhi and Lucknow:

Our team actively approached more than 120 referral physicians in the same city over the course of about six months (Government Hospitals, Private Centres, Clinics, and particularly Paediatricians, including Mohalla Clinics). In ten days, we started getting referrals and finally came to conclusion:

- 450 subjects were enrolled at 3 sites in 2 cities in around 6 months
- **100 subjects** were enrolled in just **4 weeks** at Lucknow site
- Referral-to-consent ratio improved by **85%**
- Trial completed enrollment **10 days ahead of schedule**

Strategic Recommendations:

1. Create referral-ready procedures while taking Indian site constraints into account.
2. The study startup phase budget for digital pre-screening tools.
3. Include the PICs model in the outreach and site viability plan.
4. Assist sites undergoing digital transformation, from EMR integration to WhatsApp outreach.
5. Create a site-sponsor-doctor triangle that encourages cooperation rather than only observation.
6. Small budget for recruitment leads to substantial impact to the clinical trial cycle.

Conclusion:

India has enormous potential for patient recruitment, but sponsors need to think beyond the box. In addition to expediting their deadlines, sponsors can establish credibility within the local clinical research ecosystem by developing site-centric, digitally enabled, and referral-smart models, such as the PICs framework designed by the author.

The future of patient recruitment lies in strategic, supportable engagement — and the time to act is now.

A well-crafted and practical recruitment strategy, tailored to the real-world challenges of the site, facilitates faster link with the right patients and drives the accomplishment of research goals.

"In research, time isn't just money — it's medication, momentum, and meaningful outcomes."
Every delayed enrolment in any clinical study is a step away from hope — for the patient, the doctor, and the data.

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