

Beyond Familiar Sites: Rethinking Site Selection to Bridge Clinical Research and Routine Care

Despite the rise of decentralised trial models, clinical research delivery remains fundamentally dependent on sites. Yet the current U.S. site network is overburdened, under-resourced and increasingly strained by growing demand. To address unmet health needs and keep pace with advances in discovery science, the U.S. must expand and modernise its site ecosystem to increase capacity, accelerate patient recruitment and ensure patient representation better reflects real-world U.S. populations, in line with FDA FDORA requirements.¹

Thought leaders have long argued that achieving these goals will require broader participation from community-based care facilities ('non-traditional' sites) that can extend research into a wider geographic and demographic cross-section of the population.²⁻⁴ The authors of a landmark paper in JAMA expressed a broader recognition that clinical research and routine healthcare currently function as 'a house divided,' limiting both the generation of evidence and its application to patient care.⁵ Yet, while many sponsors recognise the need for change, pressing timelines, delivery risk and operational status quo continue to push site selection toward familiar sites.² The result is a self-reinforcing cycle in which prospective new sites struggle to gain entry.

Listening to the Ecosystem

To gain a deeper understanding of this predicament, the Association of Clinical Research Professionals (ACRP), with expert input from Altura and support from Genentech, Duke Clinical Research Institute and the National Medical Fellowships, conducted a qualitative research initiative involving in-depth interviews with five sponsors and ten research sites, spanning the spectrum of 'research-centric,' to 'care-centric,' (Figure 1). A full report is available on the ACRP website.⁶

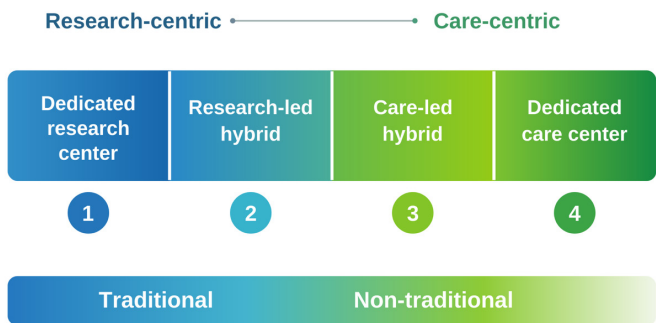


Figure 1. Overarching Classification of Site Types, Where 'care-centric,' Denotes Community-based Care (primary and preventive) for Large, Local Patient Populations

Although not intended to be representative of the entire industry, the interviews revealed consistent themes. Most notably, sponsors described a lack of practical mechanisms for broadening site networks beyond familiar sites without taking on what they perceived to be disproportionate operational risk. At the same time, aspiring

sites, particularly those with non-traditional care-centric models, described a formidable path into research, with a high bar to entry. Together, these insights point to a system that's unwelcoming to new entrants and fails to give sponsors the necessary level of confidence in engaging them.

Sponsors' Perspectives

Two factors weigh particularly heavily in sponsors' risk calculations: the experience of the Principal Investigator (PI) – both overall research pedigree and therapeutic area expertise – and the familiarity of the site's model. Lack of experience is often a non-negotiable barrier, while community-based sites, where research is not the dominant activity, are generally perceived as operationally riskier. Yet many sponsors also recognise that, for common chronic conditions, these settings may offer the greatest opportunity: access to large and diverse patient populations, often supported by pre-existing trusted relationships between patients and healthcare providers. Three barriers to change emerged clearly: a lack of practical frameworks for evaluating new and unfamiliar sites; operational pressures (including start-up and enrolment deadlines) that encourage site selection teams to default to familiar options; and reluctance to shoulder the burden of 'de-risking,' aspiring new sites alone.

Sites' Perspectives

Across site interviews, experience was confirmed as the dominant currency of credibility, imposing a 'Catch-22' for aspiring sites. Interviewees observed that sponsors often place unduly heavy emphasis on the credentials of the PI and on highly specific research and therapeutic area experience. They countered that site capability depends on more than a single CV: experienced PIs can help anchor newer sites; conversely, less experienced PIs can be ably supported by a strong sub-I and competent study staff. Similarly, expertise acquired in adjacent therapeutic areas may often be transferable. A broader and more far-sighted assessment of competence and capability could expand the site base without materially increasing risk. With regard to the feasibility process itself, interviewees were unanimous that this remains geared primarily toward traditional academic research environments and added that no useful feedback is ever given to unsuccessful applicants.

Matching Site Models to Research Needs

Site selection needs a strategic framework that aligns therapy area and protocol requirements with fit-for-purpose site model(s). Research-centric sites remain essential for complex, specialist studies – particularly in areas such as oncology and rare disease – where concentrated expertise, infrastructure and experience are critical. On the other hand, care-centric, community-embedded sites offer distinct advantages for common chronic conditions, namely direct access to rich reserves of patients. Some care-centric organisations already possess mature governance structures, experienced clinicians and proven experience with industry-sponsored interventional clinical trials. Figure 2 shows a prototype decision framework.

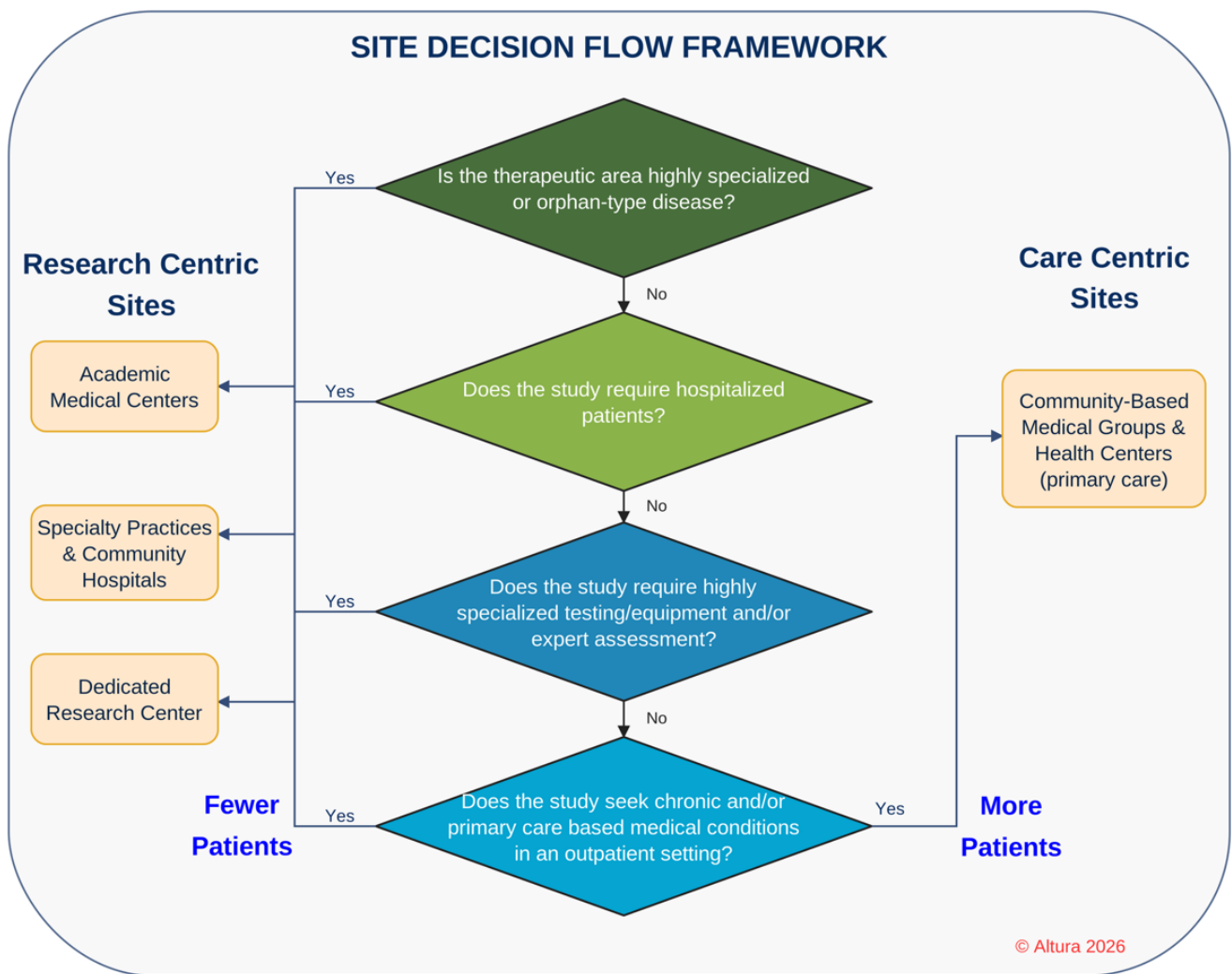


Figure 2. Decision Framework for Matching Site Models to Study Types

From Intent to Action: Practical Pathways for Sponsors

While many sponsors recognise the need to broaden their site base, translating intent into action requires a more deliberate approach to site development and engagement (Figure 3). Different site models face different barriers and therefore require different strategies. Some emerging research-centric sites may simply need opportunities to demonstrate their capability. Certain care-centric organisations may already be viable research sites but overlooked because of their unfamiliar model. Others will require longer-term cultivation and partnership before they can participate effectively in research. In essence, sponsors need to become partners in building the site ecosystem, rather than simply consumers of site performance.

The following workstreams represent practical steps that could begin now while broader changes in strategy, operating models and collaboration start to take shape:

- **Evolve the Feasibility Process:** Introduce greater flexibility within site assessment, create opportunities for direct dialogue with prospective sites and provide constructive feedback to unsuccessful applicants.
- **Aim to Pilot Non-traditional Sites in Appropriate Studies:** For studies in common chronic conditions, consider including a small proportion of appropriately vetted care-centric sites, supported by additional oversight and modest initial enrolment targets.

- **Strengthen Institutional Memory:** High staff turnover within sponsors and CROs can cause non-traditional sites to slip off the radar even if they have been previously engaged successfully. Robust, consistently utilised tracking systems are needed to avoid this.
- **Align Incentives with Strategy:** Operational teams will continue to default to familiar sites unless incentives and accountability mechanisms (which may involve a combination of federal government and industry stakeholders) explicitly support broader site engagement.

Conclusion

The findings of this qualitative inquiry largely confirmed the premise that prompted it: that current site selection practices are limiting the industry's ability to expand capacity, accelerate recruitment and improve participant representation. Our interviews illuminated several of the practical barriers that sustain this pattern.

There is an evident supply/ demand imbalance in clinical research: the industry's demand for research capacity continues to grow, while the mechanisms through which new capacity enters the system remain weak. Engaging with and investing in aspiring and emerging sites of all types brings much needed capacity expansion. Leveraging non-traditional, care-centric sites brings access to untapped reserves of prospective participants in the numbers and demographic diversity that research really needs. Ultimately, site selection should no longer be viewed as a routine operational exercise, but as a strategic

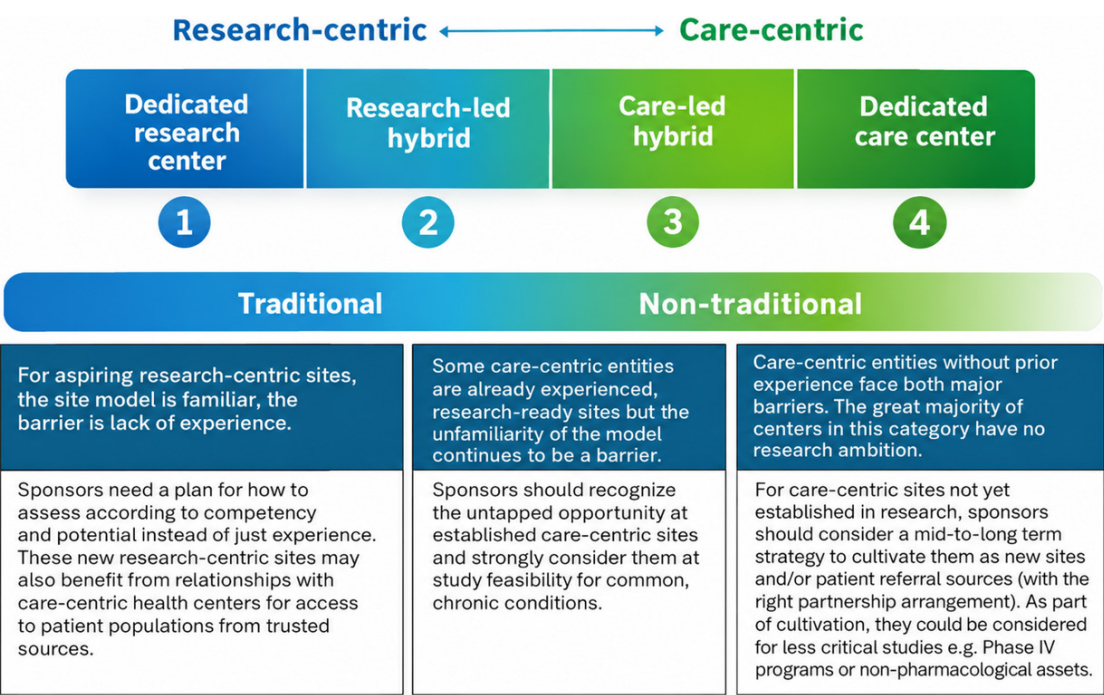


Figure 3. Strategies for Engaging with Less Experienced and Less Traditional Sites

determinant of whether clinical trials can achieve their scientific, commercial and societal goals.

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