Beyond Home Visits: A Site Perspective on the Future of Decentralised Clinical Trials

A comprehensive executive report analyzing the evolution, operational realities, site challenges, and hybrid future of decentralised trial execution.

Host:	**Nic Goatman** — VP Commercial, Medical Research Network
Panelists:	**Graham Wylie** — Founder, CEO & Chairman, MRN **Helen Marks** — Site Operations Director, MRN
Topic:	Decentralised Clinical Trials (DCTs), Site Burdens, and Hybrid Care Delivery

1. Executive Summary & Industry Context

Clinical trials face persistent systemic challenges in patient recruitment, retention, and geographic accessibility. Over the past six years—accelerated by the global COVID-19 pandemic—Decentralised Clinical Trials (DCTs) transitioned from an innovative niche concept into a central strategic imperative for clinical development.

However, as healthcare environments normalized post-pandemic, many trial protocols reverted to traditional site-centreed defaults despite proven remote operational capabilities. This executive report synthesizes key insights from the webinar discussion between Nic Goatman, Graham Wylie, and Helen Marks, providing a detailed examination of operational site burdens, investigator oversight, regulatory dynamics, and the sustainable future of hybrid clinical trial design.

2. The Pandemic Surge: Emergency Response to Operational Scale

Reflecting on the onset of the pandemic in 2020, Graham Wylie recalled the immediate uncertainty felt across the clinical research sector as traditional hospital operations faced unprecedented lockdowns. Initial disruption quickly evolved into a massive, industry-wide shift toward Home Trial Support (HTS) solutions.

- **Unprecedented Proposal Growth:** MRN experienced a 5x to 6x increase in proposal requests, escalating from a pre-pandemic average of 25–30 proposals per month to over 170 per month. Countless additional proposals were turned away due to immediate operational capacity.
- **Trial Disruption and Stoppages:** Approximately 80% of active clinical trials globally were forced to halt or pause during early lockdown phases, while trial cancellation rates tripled across the industry as sponsors evaluated shrinking market returns.
- **Emergency Continuity:** HTS provided the vital mechanism enabling clinical trials to maintain patient enrollment, ensuring participants received critical investigational medicinal products (IMP) safely at home.

> *"Any clinical trial that wanted to keep going, it was quite clear, would have to have some form of home therapy or home visits associated with it... We went from 25–30 proposals a month to 170."*
>
> **— Graham Wylie, CEO & Chairman**

3. Post-Pandemic Reality: Why Sites Reverted to Traditional Defaults

Despite the rapid adoption of remote care during the pandemic, trial designs frequently returned to traditional site-based models once restrictions eased. The panel explored the root operational causes behind this trend:

A. Vendor Oversaturation and Bad Operational Experiences

During the pandemic height, the competitive landscape surged from approximately six specialized vendors to over 170 companies offering DCT services. Many new entrants lacked clinical research depth, delivering poor operational experiences that left investigative sites "burned" and hesitant to re-engage with decentralised models. Following the pandemic, nearly all of these opportunistic entrants folded or exited the sector, requiring established pioneers to rebuild trust.

B. Technology Fatigue and System Proliferation

Helen Marks emphasized the severe administrative burden placed on clinical site personnel by disconnected software platforms. Every trial sponsor mandates its own preferred IRT, eCRF, lab portal, and electronic consent tools.

- Sites must complete unique training modules, manage individual logins, and navigate separate workflows for every study.
- Because HTS is often introduced as an *optional* protocol service (unlike mandatory IRT or EDC platforms), overwhelmed site staff frequently decline HTS upfront to avoid taking on additional system training—unaware that HTS ultimately reduces overall site visit workloads once active.

> *"Every sponsor and every trial has its own system that sites have to learn how to use... HTS is an optional piece that sites have the option to decline. And I can see why they do, until they experience the value."*
>
> **— Helen Marks, Site Operations Director**

4. Redefining DCT Value: Resource Expansion vs. Gadgets

Graham Wylie pointed out that many pure-technology DCT solutions—such as standalone wearables and remote tracking apps—failed to sustain momentum post-pandemic because they failed to address the core clinical problem.

Core Insight: HTS as a Capacity & Reach Enabler

Decentralisation is not simply sending a local nurse down the street; it is a strategic **resource expansion mechanism**. By deploying dedicated HTS nurses and remote care models, sponsors add clinical capacity and overcome geographic boundaries. This grants trials access to much wider patient populations, directly driving recruitment velocity and participant retention.

Overcoming Geographic Disadvantage & Expanding Diversity

Conventional trial recruitment is naturally constrained to narrow geographic radiuses around major academic medical centres. This restricts enrollment to affluent, highly mobile demographics who can afford frequent travel, excluding working parents, hourly workers, and rural populations.

By integrating home health visits and local community clinics, trials remove travel barriers, making participation accessible to underrepresented patient groups while maintaining protocol compliance.

5. Principal Investigator (PI) Oversight & Regulatory Dynamics

The panel addressed common sponsor misconceptions regarding PI oversight and regulatory compliance in decentralised settings:

- **PI Oversight in Practice:** PI oversight is governed by structured protocols, robust source documentation, and direct communication—not physical proximity. In standard hospital clinics, PIs do not physically oversee every procedure performed by junior clinicians. HTS nurses function as seamless extensions of the site team, executing thorough verbal handovers, immediate adverse event reporting, and prompt source document transfers.
- **Regulatory Alignment:** Major global health authorities (FDA, EMA, MHRA) maintain positive consensus around decentralised trial methods when GCP standards are strictly upheld. Internal sponsor risk aversion, rather than regulatory opposition, remains the main barrier to adoption.

6. Modernizing Operations: What to Ditch vs. What to Keep

To improve efficiency, the panel identified key traditional practices that should be eliminated alongside core clinical principles that must be protected:

Practices to Eliminate (To Be Ditched)	Essential Elements to Preserve (To Be Kept)
Superfluous Paperwork: Printing electronic records for physical signature during monitoring visits.	**Physician Relationship:** Maintaining core face-to-face physician contact to foster trust and rapport.
Duplicate Data Entry: Transcribing physical medical notes into electronic EDC systems manually.	**Patient-Centricity:** Ensuring participants feel valued, cared for, and supported throughout.
Rigid Protocol Language: Hardcoding fixed visit locations without accommodating patient choice.	**Dedicated Trial Focus:** Protecting research activities from competing clinical care duties.

7. The Future: A Flexible, Nuanced Hybrid Model

The future of clinical research lies in striking an optimal balance through a **flexible hybrid trial design**. Rather than forcing a binary choice between fully site-based or fully remote designs, protocol authors should evaluate scheduled assessments on a visit-by-visit basis.

Combining central site expertise for complex procedures with home visits and community clinics for routine care delivers maximum convenience to patients, reduces site burden, and accelerates trial completion. Engaging experienced HTS partners early in protocol development ensures robust execution and long-term trial success.

About Medical Research Network (MRN)

Medical Research Network (MRN) is the recognised global leader in Home Trial Support and Decentralised Clinical Trial solutions. With over 20 years of specialized experience, MRN partners with pharmaceutical sponsors and CROs to accelerate drug development, expand geographic recruitment, and optimise patient retention across complex clinical trials.