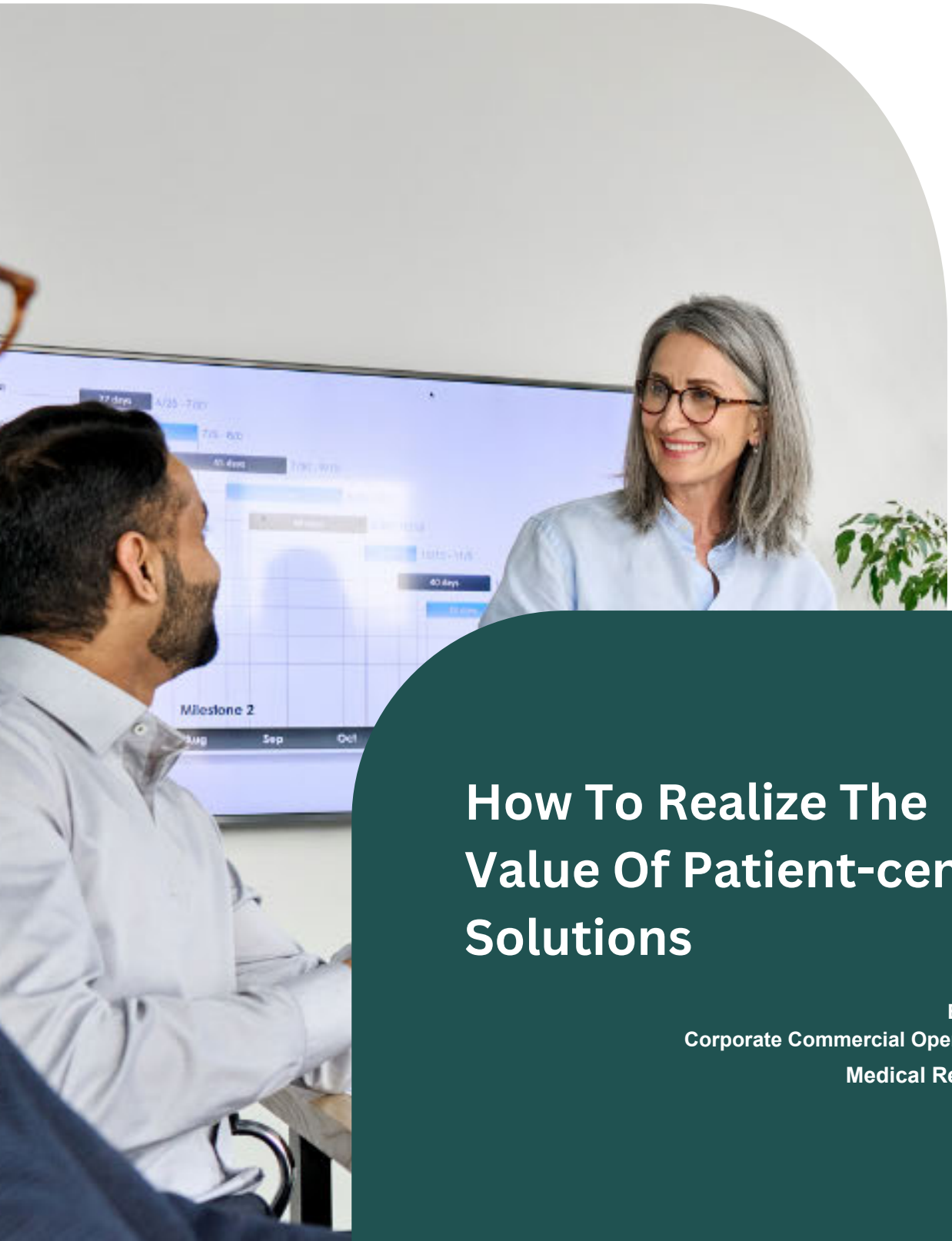

How To Realize The Value Of Patient-centric Solutions

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The way clinical trials are conducted is and always will be an evolution, adapting to the constant developments and advancements in healthcare, technology, and patient requirements.

Hybrid, remote, virtual, and decentralized are all terms used extensively in recent years to describe an array of solutions that Sponsors can put in place to run trials, but what solution gets implemented depends on what Sponsors are trying to achieve. Is the objective more diverse and inclusive trials and representative patient populations? Engaged research facilities? Holistic support for participants? More geographically dispersed trials? Effective and efficient data collection and management? Overall faster timelines? All of the above?

While these solutions aim to create more efficient and successful trials for all stakeholders, it is the consideration of each individual trial's unique challenges that should determine the most viable trial design and solution options. Often, one standalone service or product won't be the answer, but rather a combination of solutions, designed to be implemented and coordinated together to best serve each individual trial.

The adoption of innovative trial design and patient-centric solutions has had a slow climb over the last two decades. While these solutions, when embedded in drug portfolios can drive improved recruitment and retention, stakeholder engagement, and ultimately return for patients and sponsors, their widespread utilization remains far from mainstream.

Often, it's not the vision of the future preventing the adoption but the practicalities of integrating new solutions into a trial design. Sponsors have the challenge of balancing the cost of implementing hybrid, remote, virtual, decentralized and technology elements to deliver measurable benefits while navigating a backdrop of under resourced and over-stretched healthcare facilities globally.

It's important that the Sponsor strikes the right balance between trial and patient considerations and works closely with vendors to fully understand the solutions available and the possible return. This transparent discussion is required to indicate which solutions can have the greatest impact.

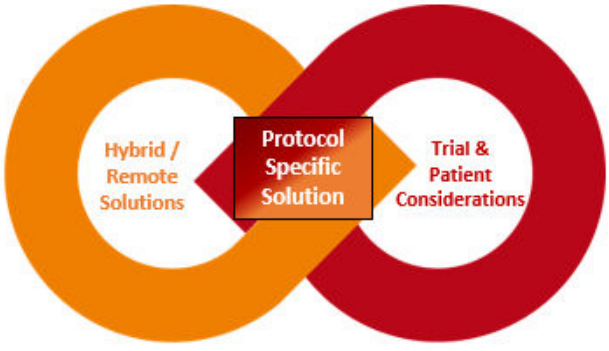
The decision of which solutions to utilize is not only impacted by a Sponsor's budget, types of products under study, clinical trial phase, geographic location of trial sites, and patient population, including interactions with patient advocacy or other patient support[1], but also the Sponsor's willingness and ability to incorporate hybrid and remote trial solutions or technology platforms.

The right mix of solutions for a trial should address the most considerable challenges for that protocol and will have shared objectives between the Sponsor, sites and patients.

The design of this ecosystem is paramount and can be thought of as a synergy between solutions and objectives for each individual protocol.

Hybrid/ Remote solutions include;

- Healthcare Professional conducting in-home clinical visit
- IMP administration
- IMP & Sample logistics
- Sample collection & processing
- Data collection through eSource direct into EDC system
- Site & Pharmacy relationship management
- Equipment & supplies management
- Quality & risk management
- Patient safety oversight
- Telemedicine, eDiary, eConsent
- Sensors & wearables



Implementation considerations for Patients & the trial

- Sponsor size and budget
- Clinical study phase
- Patient Population
- Indication
- Geographic location of study sites
- Types of drugs/devices under study
- Site/Investigator/Patient perspectives

Delivering outcomes for patients, achieves goals for all stakeholders.

The relationship between the Sponsor, site, and solution provider / vendor should be working towards the shared goal of making it easier for patients, sites and healthcare professionals to engage in and deliver clinical trials.

Up to 85% of clinical trials fail to recruit or retain a sufficient sample size, leading to failures to meet recruitment timelines in four out of every five trials, even though nearly $1.9 billion is spent on recruitment annually. Planning and implementing a flexible recruitment infrastructure and a comprehensive approach to recruitment is necessary for studies with challenges in recruitment. By optimizing strategies, trials can be more cost-effective and diverse[2].

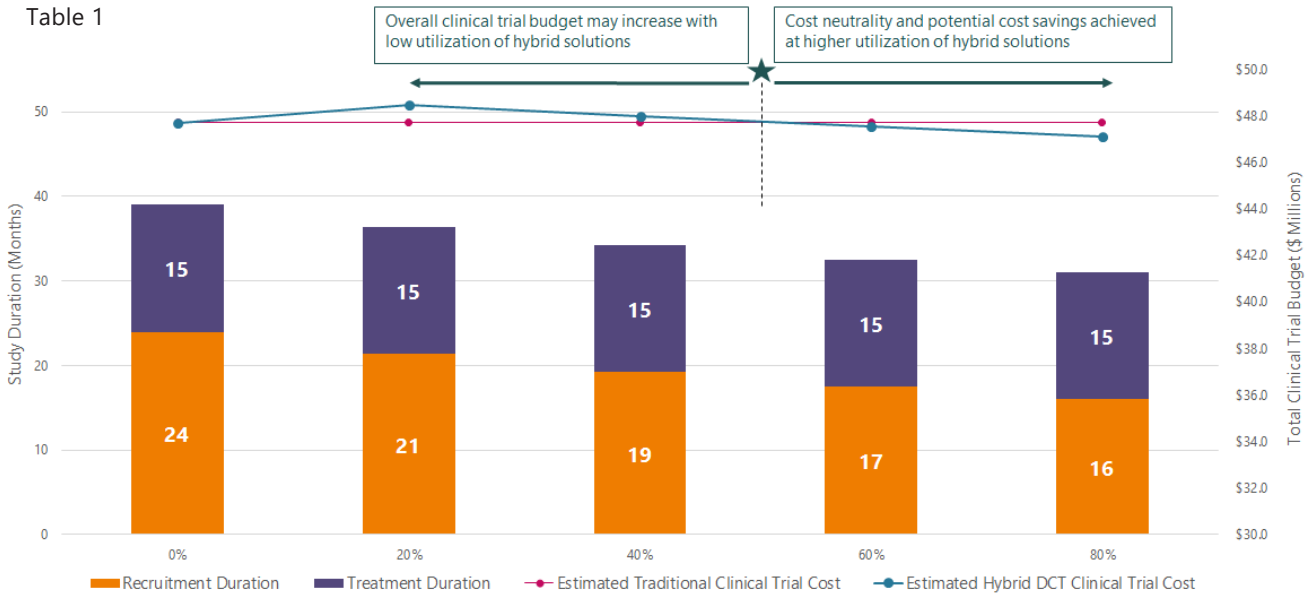
Hybrid and remote solutions can lead to more successful recruitment and improved patient retention by creating a trial design, focused on the patient experience, that reduces the burden on the patient. A hybrid strategy can also help trials meet timelines, potentially preventing the delays often experienced in the traditional model, protecting targeted trial milestones and recruitment rates.

By providing support to sites, either resource constrained sites or on-boarding and training trial naive sites, trials can be run more efficiently and in locations that may not have previously been able to offer patients the opportunity of participation. This can increase recruitment by expanding the patient pool but it's not just about widening the net, it's about being efficient with the wider net -finding, engaging and supporting people willing to participate in research.

Another method, that goes hand-in-hand with creating greater access to trials through fully supported sites, is creating more flexible trials for patients, allowing them to take part in a clinical trial from their home at a time convenient to them either through the use of technology or through in-home clinical care provided by remote healthcare professionals.

Sponsors, sites and patient cannot realize the full benefit these solutions offer if they are not continually integrated from concept to trial completion. If the solutions are integrated into the protocol and underutilized, little impact can be realized. However, as seen in Table 1, increased utilization from 20% of patients using the hybrid model to 80 % can save a Sponsor up to 5 months of recruitment time[1].

Table 1



Feedback from a global pharmaceutical company implementing in-home visits with direct-to-patient investigational product shipments for a rare disease study demonstrated that Home Trial Support can address the high burden experienced by both patients and care-givers while keeping overall trial costs approximately net neutral.

In Summary

The integration of hybrid, remote, virtual, and decentralized patient and site solutions can have a substantial impact when utilized together with traditional methods to achieve overall Sponsor objectives. This alignment of solutions can deliver improved recruitment and retention which in turn leads to financial return. However, the only way financial return can be delivered is when all stakeholders are fully engaged in the adoption and implementation, if not, we will continue to see these solutions as optional add-ons that end up being more expensive to the overall trial. Sites need to be empowered to run trials through vendor and Sponsor support and patients need the option to have a more flexible trial schedule -making it more likely they remain engaged in the trial. Finally, vendors need to have transparent discussions with Sponsors on the design and application of innovative solutions to create the most value, without this we will never truly move the needle to deliver more efficient clinical trials.

About MRN

MRN accelerates patient recruitment and improves patient engagement and retention through site-centric and patient-centric solutions. As an innovative market-leader, MRN provides customized solutions to optimize each individual protocol and creates more flexible, efficient and accessible clinical trials that deliver accelerated timelines. Through integrated in-home visit delivery and a vast global network of trained, research ready sites, all empowered by MRN's digital solutions, MRN engages with and empowers diverse communities around the world to participate in and advance medical research.

Sources:
1: "Uptake! Where patient centricity meets financial return for DCT solutions", MRN, March 2021. https://themrn.io/newsroom/resources_posts/where-patient-centricity-meets-financial-return-for-dct-solutions-whitepaper/

2: "Uncovering key clinical trial features influencing recruitment", Journal of Clinical and Translational Sciences, September 2023, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10565197/#:~:text=Further%2C%20up%20to%2085%25%20of,on%20recruitment%20annually%20%5B2%5D.

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