Home Trial Support

Q1: We have seen the industry adopt the term "patient-centricity" in an effort to increase patient engagement. What impact do you think the patient-centric movement has had?

A: Patient-centricity has been at the core of MRN since its inception in 2006 so I believe its impact is substantial. However, the term "patient-centricity" can have different meanings depending on how you engage with patients. Therefore, it may be difficult to measure the true impact of "patient-centricity". For MRN, patient-centricity means we put the patient at the centre of what we do – by bringing the trial to the patient, in their own community. The patient-centric movement in the industry is in response to a chronic, long-term reduction in patient recruitment and retention. For many years, access to the study IMP was considered sufficient to attract patients to trials, coupled with a willingness to do whatever their doctor advised them. Over the last two decades we have seen a cultural shift away from blind trust in doctors as well as a broadening of therapeutic areas under research – embracing many more mild and moderate conditions as well as more rare but serious conditions. All of these changes mean we have to be more aware of the patient's needs in order to enrol them in studies. The patient-centric movement recognises patient need and has introduced patient involvement, from how we assess their condition medically (making it more relevant) to how we manage the logistics of the trial with the patient in mind (reducing the impact on their lives). MRN works in the latter part of this scope. In our hands, recruitment will increase in a site operating Home Trial Support anywhere from 60% to 600% (we have seen all of these) and retention levels hit around 98%.

Q2: Companies today are more open and do not view patients as simply subjects who generate data – but as informed collaborators whose participation is core to the overall success of trials. Can you talk us through the current trends and new, innovative opportunities in the industry that you think of as patient-centric?

A: We know that 85% of clinical trials fail to recruit enough patients and 30% of patients drop out of studies once they enrol. Because of this, CROs and sponsors are focusing on innovating to improve trial design and implementation in collaboration with their patients. While there are many innovations in clinical trials today, more so than I have seen at any other time in my 30 years in the industry, only some of these are patient-centric; others are focused on sites or sponsors.

Firstly, we've seen innovation in community-based trial services. Each of these can operate separately but the best results will come from a combination in any given trial.

- Home Trial Support. Our own core service, allowing patients two key freedoms – to be seen **where** they want, and to be seen **when** they want. This reduces the impact of the trial on a patient's life and is profound if they don't have frequent travel to a site. This service has seen exponential growth over the last decade.

- Telemedicine. This service is much newer, is sweeping through the mainstream health sector and is finally getting traction in trials. It will be a critical way of keeping patients in the community, again reducing the impact of the trial.

- Concierge services. This has been available for several years now and is best suited for very long travel and overnight stays for patients and families when they still have to go into the site.

We've seen an increase in the patient voice.

- There is a new approach of many specific condition charities to focus on their own investment in trial sponsorship, turning their advocacy into investment – a huge benefit in focusing the patient voice. Organising patients into effective advocates improves the way we listen to and address the needs of patients in trials.

- Digital endpoints are now more relevant to patient outcomes, more sensitive than traditional assessments and simpler to do. This is already adding value and will accelerate dramatically in my view in the next few years.

- FDA requirements for patient-orientated endpoints are now starting to penetrate requirements for endpoints in draft labels and in dossier reviews. Other regulatory authorities are behind but starting to catch up.

Lastly, we've seen innovative approaches to data collection.

- Sensors in the home and in wearable devices are now able to gather data about a patient on a continuous basis. These are likely to be strongly outcome-based at present – measuring activities of daily living, for example.

- As we see various methods of measuring simple but powerful parameters, we can combine them into complex algorithms to predict changes in illness, leading to earlier diagnosis and awareness of disease progression.

- Data capture techniques have extended to more patient-friendly devices such as their own phones and watches, and further integration with traditional data collection systems is simplifying the approach and reducing costs, as well as making data easier to report for patients.

Q3: Putting the patient first is at the forefront of MRN's Home Trial Support (HTS), a service that is designed to positively impact the patient experience. Can you tell JCS how MRN seeks to make participation easier for patients in clinical trials?

A: Some of the biggest challenges of delivering a successful clinical trial are identifying, recruiting and retaining patients. A patient-centric approach asks the question "How do we meet the needs of patients to make it easier for them to take part in our trial?" Although there is limited publication in this area, what does exist, along with expert opinion, is clear. Patients want to travel less, to be at a site visit for less time and to be able to have visits out of hours and any day of the week. They want reduced time costs and incidental costs for them and their partners, carers and families.

Patients want the freedom to be seen where they want. Given the chance to be seen at home, patients will take it. Not offering it to them because they CAN get to the site misses the point. By not having to travel to the site, they can get on with their lives. An hour-long visit takes all afternoon in a clinic, and incurs travel costs (a pain, even if they are reimbursed).

Patients also want the freedom to be seen when they want – not just on the day the clinic is open. They may need to go to school, go to work, look after family and a host of other things they want to fill their lives with. They want to be people first and patients second, but the system rarely allows that.

The convenience that a community trial solution like Home Trial Support (HTS) offers patients makes trials with these services more attractive to patients and keeps them in trials once enrolled. It's important to note that we don't replace the site or the oversight of the principal investigator, we simply relocate a number of visits. The simple step of seeing a patient at home for perhaps two-thirds of their visits allows for a much better experience for the patient. We encourage drug developers to offer innovative services allowing patients to participate from their community, not only to retain patients, speeding up the trial, but also to give patients a better opportunity to care for their families and maintain their everyday lives.

Q4: The relationships between sponsors, contract research organisations (CROs) study sites, and vendors can present many challenges in clinical trial planning and execution. How does MRN work to engage with all stakeholders to ensure the success of the trial? How do you forge and maintain strong relationships with the site study team?

A: It's important that all stakeholders have clear pathways of communication with each other. We know from working with all parties that when open communication is hampered, it leads to silos, creating a lack of transparency of workflows. Ultimately, this type of organisation will lead to unnecessary and costly delays. Workflow transparency allows service providers to have access to each other's systems when necessary; this is especially important when implementing in-home and remote solutions. In addition to clear communication, it's important that we all understand we have shared patient-centric values and goals.

Patient-centricity is not something that should exclude any given stakeholder. Sites and sponsors are critical to trial success and their needs also need to be met. What we should aim for is balance. We all benefit from a successful trial and that can only happen when all stakeholders communicate and collaborate. Sites and sponsors are incredibly important to MRN and we work hard to ensure they feel comfortable using our services and confident in the quality of care we are providing their patients.

Q5: What are your thoughts on the growing trend in the use of technology and telemedicine in clinical trials and how is MRN responding? Do support organisations like MRN have the ability to work with technology providers as the digitisation of clinical trials increases?

A: MRN have always valued innovation in clinical trials and we feel that telemedicine is a significant step in the right direction for the industry's drug developers and for patients. It has clear synergies with Home Trial Support. Some visits need a physician assessment that does not require an examination. In other cases, a nurse may be concerned about a patient and need a medical opinion, which can be accessed on the spot through a telehealth service. We can imagine several other scenarios where nurses and technology work together. We have an R&D function within our business, dedicated to finding new ways to work and new ways to offer our existing services. Telemedicine has been part of this exploration as we strive to continue building a patient-centric service and innovate to keep up with the growing trends in the market. As a result, we have successfully delivered our services alongside telemedicine for several studies. We have also worked with the extended eCOA solutions, BYOD solutions and internet-enabled devices for specific data collection.

Q6: We've seen MRN listed as one of the UK's top 1000 companies on the London Stock Exchange, with MRN having a reported 30% + CAGR year after year. What has made MRN so successful in the clinical trial support organisation sector?

A: MRN was founded by and is currently run by experts with decades of experience running trials in project management, nursing and pharmacy. Our experienced team focuses on structure, quality, resource management and financial control which has given us the ability to be an ultra-high growth business (defined as over 25% per annum) since 2006. This way of operating has allowed us to scale consistently to meet our customer needs whilst maintaining our quality mantra. Within MRN, we have almost 1000 years combined experience in clinical trials and we partner with other sector-leading services providers when required. We've performed over 40,000 visits and continue to evolve our services in response to trends in the market, securing MRN's growth as a leading provider for the foreseeable future. Our success is not only a result of our experience and quality delivery but it's also because of our people. Teamwork, engagement and creativity are our core values that we started the business with and continue to guide us today. We focus heavily on employee engagement within our business. We have unusually high scores using the Gallup 12 engagement scoring system (a de facto corporate gold standard), meaning our people like working at MRN and work hard for everyone's mutual benefit – not just for MRN, but also for each other, for patients and for customers.

Q7: There is a lot changing in the industry and there are a lot of potential solutions to trial challenges. How do all the innovations we've spoken about fit together and how do you think these innovations will shape the future of clinical trial design?

A: Clinical trial designs are going to start to change. Data collection will move out of visit structures and start to be designed into streaming data collection tools. Nursing in the home will be for 'high touch' trial designs – blood sampling, drug administration, targeted examinations, complex operator assessments (ECG, spirometry) etc. Technology will focus on automated measurements, questionnaires and self-assessments. Yet all IMP is inherently dangerous, and technology cannot yet replace an experienced professional meeting a patient face to face and assessing their morbidity – face-to-face elements are likely to remain, some in the home and some at the site. Phase IV trials are more likely to be 'low touch', requiring less, sometimes zero, face-to-face contact. We will see visit schedules determined only by medical need and patient psychology, rather than simply being the only way to collect data. Some visits might be suitable for telemedicine, some might be better face to face with a physician, some can be done by a nurse. Each innovation we've discussed has a different and complex rationale; improvements in quality, changes in data types, increases in speed of recruitment and improved (endpoint) relevance to the patient.

If patient-centricity works, more patients will recruit per month and be retained. That must ultimately decrease recruitment times and probably reduce site numbers. MRN has complex models that show the improvements we see in recruitment lead to cost-neutral budgets. The optimal solution will depend on the style of trial being designed, the therapeutic area, the development phase, and more. Protocol designers are going to have to get their heads around these changes to unlock the true value of the solutions – as of today, we have barely scratched the surface.

Graham Wylie

Dr. Graham Wylie, CEO of MRN, has worked in the pharmaceutical industry for over 30 years and has been an agent of change throughout. His career started at Pfizer, spanning clinical trial management, development of global technology platforms and global change management and continued at PAREXEL as a Medica l Director and then Vice President of Account Management. He formed MRN as CEO in 2006, which has since become the leader of the community based Clinical Trials Support Organisation sector and has been one of the fastest growing companies in the UK throughout the last 13 years.