November 2016

NEW Perspectives

Patient- centricity issue

Putting patients at the centre of the clinical programme

In June 2016, members of Ashfield Healthcare Communications joined more than 100 delegates gathered at Canary Wharf in London for eyeforpharma's second annual Clinical Excellence EU Summit.

This 2 day event brought pharma, pharma service providers, patients and academics together on an equal footing, to discuss how to better inform and motivate potential trial participants, provide a better patient experience, and encourage long-term engagement. The key issues discussed at the meeting are outlined below, providing an overview of different perspectives from the summit.

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Why involve patients?

For a tool that has patients at its heart, the typical clinical trial has been 'remarkably unfriendly' for patients in the past. As the pharmaceutical industry is now focusing more attention on patients – their raison d'être – most companies have realised that they should consider patients' views when designing and running clinical trials.

This was an opinion strongly endorsed by patients and their representatives at the summit, and "No research without us" was a quote from the summit that summed it up nicely. But beyond the moral imperative, there are practical advantages to be gained by companies that involve patients in clinical development planning and trial design. At the summit, we heard that trials designed with the patient in mind recruit quicker and retain a higher proportion of participants. These trials often focus on meeting the needs of potential participants so that they can make an informed decision to enrol. If patients are involved in planning studies, the design will be more accessible and the endpoints more relevant to them. Small practical changes, such as concierge service and providing refreshments, can make a big difference when patients have travelled long distances and are unfamiliar with the study centre.

An important opinion discussed at the summit proposed that improved trial recruitment and retention, together with a reduction in protocol amends and deviations, may likely result in shorter trial duration and quicker regulatory approval of the drug in question, consequently leading to lower overall costs for the sponsor company as well as improved outcomes for patients.

Delegates all agreed that developing an environment where trial sponsors and patients work together to drive the development of new therapies should be the ultimate goal.

Trials designed with the needs of patients in mind recruit quicker and retain a higher proportion of their participants

When to involve patients?

There was a clear and simple message from the patient summit – involve patients **as early as possible**. By engaging patients early on in trial development, many of the challenges around clinical trial recruitment and retention can be addressed before they become an "issue management" matter. The feedback was clear – patient engagement should not be treated as a box-ticking exercise, but a true attempt to involve patients and their families in the decision-making process and improve the patient experience. Patient groups can even be involved as early as drug discovery – for example, Pfizer in partnership with Ataxia UK, and researchers from three major universities have initiated a collaborative drug discovery programme in Friedreich's ataxia.

Patients should be involved as early as possible in trial development

How to involve patients?

Th oughout the meeting, a number of perceived challenges to engaging patients were discussed. A lack of understanding of drug research and development processes mean that many patients struggle to see the contribution they could make by participating in a clinical trial. The efore, there should be a focused discussion on the importance of helping patients to understand what a clinical trial is and how to address patient attitudes of "So what?", "Who cares?" and "What do I get?".

One key insight from the meeting was that many patients view trials as a last resort, so being offered the opportunity to enrol in a clinical trial may actually scare some people, making them believe that there is no hope for them. It was clear from the discussions that clinical trial sponsors should not make assumptions but instead understand how best to inform and support patients before, during and after a clinical trial. It is also important to appreciate the burden of participation for patients and study sites in order to transform clinical trials into simpler, patient-centred, clinician-friendly interactions. For example, thinking through what participants, their families and study sites have to do? How far do participants have to travel? How much additional work is created for clinicians? It was the opinion of the delegates that by appreciating an individual's needs, what a parent/carer thinks, or understanding the sites' and clinicians' processes, a new paradigm can be developed for clinical trials. But how can this be achieved? By listening.

To involve patients we need to listen to them

Listening

Regulatory framework

The regulatory landscape is changing and both the FDA and EMA are exploring ways in which to ensure the 'patient voice' is captured. For example, patients are already involved at the EMA in a variety of different ways throughout the regulatory procedure.

Patient profiling

Existing online communities such as Raremark™ or PatientsLikeMe® are being utilised to gather patient insights through online focus groups, surveys and data-sharing. Information gained from such sources can be used to create patient profiles, informing companies about what motivates individuals to participate in clinical trials, what barriers exist to recruitment and retention, and what outcome measures are important to patients.

Direct patient input

It was clear from the delegates at the summit that nothing beats directly talking to patients and study site personnel about a study! It can provide real insight into the design and the best ways to run it. Some approaches were discussed that are already being used including:

- **Patient advisory boards** – Merck has used patient advisory boards to gain patient input into clinical trial design and development. For these to be successful, patients must have the freedom to express themselves in a safe environment
- **Trial simulations** – In partnership with the study team in dry age-related macular degeneration, Janssen Pharmaceuticals piloted an interactive trial simulation workshop that included investigators/ study coordinators and patients. Participants provided feedback on a mock-up of a trial site before protocol approval. This provided the study team with the opportunity to make practical changes to the protocol that would improve the experience for both patients and study site personnel
- **Study nurse committee** – Novo Nordisk has been working to improve the experience for study sites and patients on their haemophilia trials. As part of their approach they have established a committee of nurses (7–8) from across the globe who review protocols from a practical point of view, participate in the training of other nurses and coordinators, provide advice on recruitment and retention, and actively participate in investigator meetings.

As highlighted at the summit, one important factor to bear in mind is that it can take a lot of time to prepare before talking to patients, as there is a need to establish a clear framework, gain approvals and many other steps. Therefore, the advice from those already implementing these activities outlined at the meeting is to start patient engagement early, at disease/ programme level and refine individual trials. This will almost certainly save time in the long-run.

Communicating with patients

Patient understanding of what a clinical trial really involves will help enrolment and retention, while feedback on patients' experience of a trial will help improve future protocols. It was highlighted at the summit that a simple "thank you" and summary of the study results will do wonders for patients' perceptions of the trial; perceptions which may spread far via social media and patient groups. This in turn will help with recruitment to other trials.

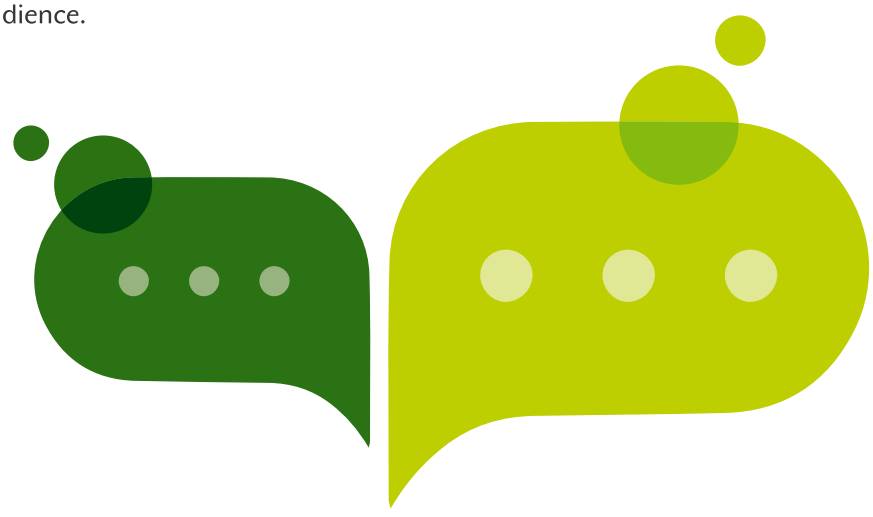
However, how sponsors communicate trial information is important, as language and literacy can be a barrier. Anything with visual impact will successfully counter such barriers, for example infographics and videos:

- **Patient videos** – Lilly has been using videos to aid recruitment of patients to their clinical trials. During the meeting they shared compelling videos of individuals sharing their experiences of participating in a migraine trial
- **Comics** – UCB's creative lab has developed a comic book that explains what a clinical trial is, using characters developed by children for children.

The summit highlighted that a key challenge facing most patients is gaining access to information that is clear, understandable and visible. Providing easy access to trial information in a suitable format across multiple channels can only improve patient experience. For example, programmatic advertising can be utilised to raise awareness of a particular trial via social media. However, patients must be directed to alternative sites and support if they discover they do not fit the criteria for a specific trial. Such support might include access to a call centre, the opportunity to receive updates on future trials, and alternative trial sites to explore.

Involving patients, patient families and patient groups in the development of any materials developed will ensure that the final output is suitable for its target audience.

A simple "thank you" and summary of the study results will do wonders for patients' perceptions of the trial



Patients as consultants

As the healthcare industry starts to engage more fully with patients as consultants, there needs to be a wider discussion about fair market value for their input.

Patients are being asked to relay their experience, which takes time and preparation. Currently, there is no legislation or industry standards in place, and ethics committees are not used to this approach. Furthermore, as patients become more educated around clinical trials and develop into 'expert patients', we need to be mindful of which patients should be consulted and when. For example, a newly diagnosed patient may offer a different perspective to that of a patient well-educated in speaking with pharma and other stakeholders.

In summary

The patient summit highlighted that patient insights has the power to influence the efficiency of clinical trials and develop a new paradigm, but there has to be complete stakeholder engagement involving patients, patient families, pharma, pharma service providers, regulatory bodies, healthcare professionals and payers.

So what does the healthcare industry need to do? First of all, engage with patients and their advocates; explain to them what they want to do and why, listen to what they think, and ask them for advice. Then use that information to improve understanding and experience of the whole trial process. Finally, inform patients how their input has improved the trial design and what the trial has shown. Most importantly, make sure that patients and their caregivers are thanked for their input at every appropriate opportunity. Improving patients' lives is the reason we do clinical trials – put them at the centre of the process not on the side lines.

Patients are the reason we do clinical trials – put them at the centre of the process not on the side lines

At Ashfield Healthcare Communications we are passionate about involving patients in every aspect of clinical drug development. For further information about how our multidisciplinary team of patient experts can help you with any aspect of patient engagement, contact Jo Fearnhead-Wymbs, Patient Engagement Director (J.Fearnhead-Wymbs@ashfieldhealthcare.com).

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