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Patient Centricity: Exploring The Patient Perspective From Different Angles

ICON invited distinguished speakers to participate in a panel discussion on patient centricity, based on their global experience and varying stakeholder positions in the industry.

Patient Advocacy Representative: Avril Daly, Vice President, EURORDIS and CEO, Retina International

Clinical Investigator: Prof. Orla Hardiman, Consultant Neurologist, Professor of Neurology, Trinity College Dublin and Consultant Neurologist, Beaumont Hospital

Pharmaceutical Executive: Dr. Anthony Yanni, Senior Vice President, Patient Centricity, Astellas Pharma

Moderator: Dr Nuala Murphy, President, Clinical Research Services, ICON plc

GETTING TO GRIPS WITH PATIENT CENTRICITY

Patient centricity has been a hot topic at industry conferences and featured in trade publications for quite some time, but while it seems fairly obvious that drug development is centered on the patient, the truth is that patients were not always an integral part of the process.

Yes, pharma and biotech have always had the end game of improving patient lives by launching new and improved treatments on to the market but the patient wasn't necessarily seen as a key stakeholder in how the clinical trial was designed and perhaps more importantly involved in the conversation as to whether the drugs being developed would actually be beneficial and improve the patient's quality of life.

In a survey developed to help biopharma and medical device companies to transform their businesses from product centered to patient-centered, the 2nd Annual Patient-Centric Benchmark Survey, released April 2018, showed that 86% of pharmaceutical industry respondents ranked the importance of delivering on patient-focused missions as greater than 8 out of 10, but only 21% were confident in their own company's ability to deliver on these missions[1]. The overarching insight from the survey was that participants fully recognized the importance of the concept but are still struggling with integrating this into their operating models for the benefit of all stakeholders.

To open the discussion Dr. Murphy asked participants to comment on how they would define the term and what it meant to them in their work.

Definitions of the term varied, but panelists were, not surprisingly, still quite aligned on the general concept of patient centricity; considering the patient view and understanding the impact and burden of the protocol on patients throughout the trial but also engaging the patient for better outcomes for all.

Prof. Hardiman considered patient centricity democratization of what we do in drug development; the act of building a true partnership with the patient. It means aligning what is happening to the person, what should be happening, what they would like to be happening to them throughout the development of the treatment. Dr. Yanni noted that from a drug development perspective, there are two key aspects to patient centricity, cultural and operational. On the cultural side, it is about making each employee consciously aware of the importance of the patient in the organization's mission, and this involved education. On the operational side, he explained, it is more complicated; it is about uncovering accurate insights that can be collated and shared with decision-makers who can incorporate them into the development of each new therapy or device. Dr. Yanni explained how his appointment reflects Astellas' level of commitment and investment in this area. Astellas believes that putting the patient at the center of drug development is as critical as the many more "traditional" inputs.

LISTENING TO THE PATIENT IN THE EARLY STAGES FOR BETTER OUTCOMES

There was general agreement that consulting with the patient on aspects of the protocol is essential. Prof. Hardiman maintained that the patient holds the key to selecting the right endpoints. Using patient insight can provide important intelligence to inform study design, which in turn leads to more meaningful outcomes for all stakeholders. Dr. Yanni agreed and suggested that it isn't enough to engage patients pre-trial or when they are recruited. Rather, the conversation with the patient should be initiated at the discovery stage to determine if the drug has the potential to truly improve patient lives. "You wouldn't think it possible to bring a product to market without having regulatory input," he said. "In the same way, you shouldn't think about bringing a drug to development without integrating the patient piece."

Avril Daly suggested that we need to view patient centricity in the context of civil society because we are all patients at some

time or other. "Listening, and applying that insight across the lifecycle of development is critical to better outcomes," she said. "This process needs to begin at the earliest stage of development." As an example, Avril Daly recounted a situation in which a company was developing a very interesting molecule that held promise for a specific patient community. After talking with a group of patients, the developers discovered that the patient benefit was dramatically different from what they had expected. With that insight, they reconsidered their drug development plan, adapted their approach and the drug is now in the clinical trial phase. She suggested that gathering such input from patients may be easier for smaller, more flexible biotech companies and that she suspected larger organizations could struggle with adapting procedures in the early stages of drug development based on this type of input. Avril Daly noted that she is also aware of situations where patient organizations have influenced the selection of patient-reported outcomes or endpoints – and expects growth in this practice.

Asked whether he has seen the impact of patient insight on the course of clinical development, Dr. Yanni shared that he has seen instances in which programs have been altered, redirected on even stopped based on patient insights. He has also seen programs paused to better understand how newly understood characteristics of a molecule could better meet the specific patient need or opportunities refined based on discussion with a broader group of patients to understand the treatment continuum, the potential entry points, and how that aligns with a clinically meaningful benefit.

Prof. Hardiman raised the issue around representative input from patient advocacy groups, believing that its value can vary depending on the therapeutic area involved. The concern emerged from her experience with patients in neurology who are often too ill to provide meaningful input. In such situations, it can be difficult to know if the input is really representative of the average patient. She suggested that this can be the case especially if the advocacy network has become so professionalized and well-structured that its connection to patients with the condition is weaker. "We need to ensure," she said, "That we don't just tick the box because of a regulatory requirement or to complete a grant submission. It [patient input] shouldn't become just part of the institutionalized machine and thus part of the system to a point that is not representative of patients."

Dr. Yanni agreed with the complexity of gathering and assessing patient input. It requires the appropriate infrastructure and a specialized team that can interpret and make actionable the insight to better align with patient need. "True patient engagement," he said, "Happens not in a moment in time, but rather via an ongoing, parallel conversation." The goal is to have a very clear understanding of the reasons for the chosen molecule – the safety, efficacy, and most importantly the impact on the patient which is aligned to the science – when it comes time for approval. This conversation must begin in discovery and continue well after launch.

When it came to a wish list for the future, the panelists were all in agreement that a stronger, well-funded, clinical research infrastructure for clinical research was a priority. This infrastructure needs to be connected at a local, national and international level and to support sustainable repeatable processes. The panelists also agreed that a key component of this had to be interoperable patient registers. Although patient communities are willing to participate in registers and health care agencies, and pharma and regulators acknowledge the value of real-world evidence, there is disagreement among stakeholders of where obligation lies to conduct these.

Consequently, there is a lack of appropriate funding for long term research and analysis. According to Prof. Hardiman alignment across industry stakeholders is happening but there is more to be done so that outcomes can be translated into meaningful benefits for patients. She would like to see an increased focus on not just treating the primary molecule mechanism of the disease but a more holistic approach that would provide optional interventions to alleviate symptoms and ultimately the quality of life of the patient. After all, it's all about the patient...

This article is an extract from the report "Patient Centricity - Exploring the patient perspective from different angles". Download a full copy of the report.

[1]The 2nd Annual Aurora Project Patient-focused Benchmark Survey 2018