TRUE PATIENT ENGAGEMENT: FROM CONTRIBUTORS TO CO-CREATORS



"BREAKING THE MOULD: REIMAGINING THE ROLE OF ADVOCACY FOLLOWING A REGULATORY DECISION **"**





The Healthcare Communications Association (HCA) and AXON recently co-hosted an insightful expert panel discussion "Breaking the Mould: Reimagining the role of advocacy following a regulatory decision". The discussion explored how we can optimize relationships and ways of working between patient advocates and the pharmaceutical industry following a regulatory decision.

In recent years, collaboration between pharma and patient advocates during clinical trials and regulatory reviews has become increasingly recognized as an integral part of the drug development process, with the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) setting out clear guidance on how patients' experiences, needs, and perspectives can be captured and meaningfully incorporated into drug development and evaluation. However, the role of patient advocates after a regulatory decision is less well-defined...

Those working in the pharmaceutical industry and broader healthcare community know first-hand the importance of early patient engagement. This engagement spans across various activities, including contributing to the development of clinical trials and ensuring that the process is inclusive and accessible.

SO WHY IS THIS NOT HAPPENING IN PRACTICE? AND WHY IS IT BREAKING DOWN POST-REGULATORY DECISION?



MUTUALLY BENEFICIAL COLLABORATION





All stakeholders within industry share the common goal of bringing medicine innovations to market, to help those patients who need it and acknowledge that there is always room for improvement to address unmet needs. Meaningful and transparent collaboration is essential to achieving this goal.

So, with this shared goal and aspiration, where are the challenges?

As previously mentioned, in recent years, the approaches used by pharmaceutical and biotech companies to invest in and conduct early drug development have evolved. There is a paradigm shift from the traditional model to a more agile, collaborative, and consultative model. Patient advocates and organizations are becoming more involved in the co-creation of drug development programs, from clinical trial design and throughout the drug life cycle, to post-marketing studies and evaluation.

The industry is recognizing the value of this vital role

Although the involvement and engagement are occurring, they tend to be ad hoc and are still in their infancy. Many companies know that they should become more collaborative and consultative, but they are deterred by the complexities within compliance, legal issues, and overall misunderstandings and bureaucracy. This means that they are reverting "back to the traditional approach," as this is more comfortable and familiar.

Therefore, in order to transform our healthcare industry and embrace the patient voice and be led by the people who are experiencing the illnesses and diseases first-hand, it is imperative that industry overcomes these challenges and consciously starts to weave patient engagement into their plans.



OVERCOMING CHALLENGES TO MEANINGFUL ENGAGEMENTS





While there is an abundance of evidence demonstrating the value of early and effective patient engagement, there are challenges that need to be addressed in order to progress.

The following is a summary of broad topics that were discussed and debated during the "breaking the mould" session, and multiple strategies that could be taken to overcome challenges and combat the supposed "apathy" in industry:



1. ETHOS AND INTEGRITY

"Now is always the right time to do the right thing."

Even when early and meaningful engagement is sought, it is not always possible to continue to engage throughout the many ups and downs in a product lifecycle. Ongoing collaboration should focus on specific challenges or issues related to the medicine or supply chain disruptions, in which the patient's voice would best resonate.

ACTION:

Embedding this principle into all strategies and fostering meaningful, authentic relationships is crucial. Be sure to keep the patient engagement plan on track and to consider engaging with the relevant organizations and people, not just in good times, but also in challenging times.







2. NO STATUS QUO

The challenge for the industry is to overcome the barriers to effective patient engagement, and to shift the corporate mindset away from the status quo of "we've always done it this way, therefore we will continue this way" to "how do we build trust with this patient community and how will our decisions affect the patient?". It is important to understand that some questions can only be answered by patients themselves. Research shows us that healthcare professionals are sometimes asked about patient emotions or the unmet needs of patient communities, but these are often just perceptions. These perceptions are not necessarily aligned with those of an actual patient living with a particular disease or condition. Patients are better able to articulate accurate insights and their personal experiences.

ACTION:

Avoid shortcuts and the mindset of "we've always done it this way." Early, meaningful engagement with patient advocacy groups can lead to better trial designs and improved chances of regulatory and health technology assessment (HTA) approval. Collaborating with in-house patient advocacy leads or expert agency partners can help to map out a definitive plan to incorporate the patient voice into the organization early on and maintain that engagement throughout the patient journey.





The pharmaceutical industry is dynamic, ever-changing, and turbulent. In order to thrive, patient organizations are starting to equip themselves with different resources and knowledge to understand and identify the various funding opportunities.

ACTION:

Pharma and physicians do not have all the answers. If we are saying "I think this is right for patients" rather than "what we know is...", then we are not doing our jobs. True co-creation requires being frank, open, transparent, and flexible.

4. INDUSTRY RED TAPE

The pharmaceutical industry is slow to change, and transparent patient engagement brings additional compliance and legal challenges. The complexities of the regulatory and legal landscape can blur the lines between what is and is not appropriate engagement.

ACTION:

In-house teams to develop a comprehensive patient engagement action plan, which will address these challenges with proposed solutions as an internal Operational Principle document or Standard Operating Procedure.





5. DEMONSTRATING THE VALUE OF PATIENTS

While industry partners look to engage with patients and organizations, there also needs to be an "impact measurement" or similar, which outlines the impact that meaningful engagement has had on the business; this should capture the value of the patient insights, the value of the strategic counsel, and the overall value to the business goals and success.

ACTION:

In-house teams to develop an evaluation framework including metrics and impact measurement as part of the overall measurement of these types of initiatives.

"If patients are involved, they should see how their input shapes the outcome. It's not enough to listen—we need to act, reflect, and return. Patients want to know if what they've provided has been taken on board and if not, have a true understanding of why. They don't just want a thank you email; they want to understand the impact they've had. As we rethink how we collect, apply, and return insights, one message stands out: Patients are not just contributors, they are co-creators."

Sam Robinson, Communications and Advocacy Practice Lead, AXON



PROPOSED GUIDING PRINCIPLES OF ENGAGEMENT





The following guiding principles will ensure successful early patient engagement and ongoing mutually beneficial interactions for industry and patient organizations.



1. SETTING A CLEAR ENTRY STRATEGY

While there is a growing trend in the pharma industry to publish values or principles for engaging with patient communities, more work is needed to ensure that these principles follow through into a comprehensive engagement strategy. There are many points of entry when establishing relationships—the earlier the better.

From a patient advocate and patient organization perspective, having a clear entry strategy is equally important and links back to the need to build resilience. Transparent and direct engagement can lead to more meaningful outcomes for both industry and patients.

2. IT GOES BEYOND REGULATORY APPROVAL

Early engagement and counsel will help to shape a robust clinical development program. This counsel may propose ways in which realworld evidence can be sought and collated, or strategies to understand the true cost-effectiveness of a medicine. These can be based on real-life information and data, rather than modelling.





3. REDEFINING LANGUAGE

The terms "engagement" and "collaboration" tend to be used interchangeably (incorrectly!). A narrative and definition of what is meant by engagement and collaboration should be created and aligned with patient organizations to set expectations and common ground around these phrases to ensure expectations are met—on both sides.

- Collaboration involves working together with others to achieve a common goal. It emphasizes teamwork, shared responsibilities, and collective problem-solving.
- Engagement is the deep emotional and intellectual connection that drives individuals to actively participate with enthusiasm and a sense of purpose, leading to higher productivity and satisfaction.



It goes without saying that true and valuable patient engagement must go beyond a "box-tick" exercise. Patient organizations and patient advocates should be confident that their counsel and input can drive real change–using patient experiences to enhance patient outcomes. It is also important, as patient groups become more involved, to demonstrate the true impact of these engagements internally to support further business strategies and decisions. The metrics matter!



THE FUTURE





These guiding principles are only the tip of the iceberg in redefining and optimizing patient engagement. The process and their value will continue to evolve and strengthen.

However, applying these with *HOPE*, Honesty, Open mindedness, Patient centricity and **Ensuring** every stakeholder, including patient organizations, and regulatory and ethics committees is part of the decision-making process, is a powerful and purposeful recipe for meaningful engagement.

Attributed to Robert Mitchell-Thain, Chief Executive Officer, PBC Foundation

As we continue to see this area grow in importance, it comes back to demonstrating real value. So next, let us unpick how to measure meaningful patient engagement and demonstrate its value.

