Optimising Phase IV communications

Communications around clinical trials have always been a critical part of pharma stakeholder engagement. Increased regulation and the plethora of competing studies have made it even more critical to develop and execute comprehensive study communication strategies. Phase IV studies are growing at an annual rate of around 20%, compared with about 7% growth for Phase II-III studies, according to data from Tufts University in the US.

Phase IV studies can represent a greater challenge for communications. These studies seek to solidify and expand the scientific basis and safety claims of their products beyond that required for registration purposes, assess the products in larger and/or different patient populations, and to evaluate the brand value in the real world through quality of life and health economic information.

As a result, Phase IV studies can assist market access stakeholders such as payers, policy makers and patient organisations with reimbursement decisions. It may be harder to recruit study site staff and patients for these studies, though, as some question their scientific merit while others see little monetary incentive. So how can companies effectively engage investigators and participating patients, as well as the range of stakeholders who need to understand and value the results?

Engage and align all internal stakeholders

Multi-stakeholder involvement is critical to the success of these studies. This includes working with medical affairs, marketing, market access and affiliates, clinical operations, health economics/outcomes research, regulatory and legal to ensure alignment around goals, desired outcomes and communications.

Plan and harness communications early

The combined team should plan all aspects of communications within and around the study from an early stage. Central to the success of study communications are: recruitment and retention of site staff and patients, integration into ongoing medical communications initiatives as well as the publications plan for the study. These form the backbone of milestones and communications opportunities for the study.

Accessing the right expertise at the right time.

All too often communications experts are brought in when a study is not achieving its intended objectives (eg, in the case of study recruitment targets) and/or in preparation for the first major data milestone. But it is important to plan communications early, especially given the challenges around Institutional Review Board/Ethics Committee approvals, in the case of patient recruitment initiatives, and time needed to deliver peer-review publications.

Study branding and messaging

Study branding has become a consistent part of trial communications. It is important that the branding does link back to the meaning of the study and is reinforced through the communications messages. The optimum study messaging takes into account the product label including environmental messages and how each study milestone contributes to the study end goal.

Integrating communications across disciplines and audiences

Phase IV studies in particular require targeting a variety of different channels and audiences. Integrating the messaging across all channels and aligning different tactics is key – from investigator communications and meetings, patient retentions activities, publications, to media relations, and patient advocacy group engagement.

Motivating and retaining site staff and patients

Investigators and study coordinators are the most important audience from a number of perspectives – in their role in recruiting and retaining patients, and also as advocates for the value of the study both during and upon its completion. Within Phase IV studies, gaining their buy-in to the scientific and clinical value of the study is crucial. Motivated study site staff can help overcome challenges in recruiting and retaining patients for Phase IV studies.

Harnessing advocates

Within any communications activity, harnessing external advocates is central to success. Around a clinical study, this means thought leaders, principle investigators and local site staff to champion the role and value of the study to colleagues. In addition patient advocacy groups need to be informed as studies are often listed on their websites and discussed on forums.

Making the most of opportunities and channels to engage

In Phase IV studies there are a number of opportunities to communicate the rationale, potential role of the study and its milestones. Building on existing conference activities around a stand, for example, or creating opportunities to meet with investigators and the study steering committee – all represent ways to deliver and reinforce messages around the study. Congresses also represent points to alert specialist trade media and involve patient advocacy groups. In an era of information overload, there is a role for online platforms – to educate participants around the study and disease area (aligned with compliance standards), and to create a community for investigators to interact.

Managing communications around milestones

Given the regulations around data milestones, it is critical that these communications are optimised and managed appropriately. This comes down to carefully mapping out who says what and when; but also the ability to plan for and anticipate any issues and the responses to them.

Maintaining momentum

Lastly, but not least, consider the length of the study in your communication plans. Keeping study sites and participants engaged and external stakeholders interested can be a challenge with longer term studies. Clearly it is important not to oversell the promise of a study too early. However, it is also important to have something new to say across the study timeframe and to deliver it in new ways.

the author: **Chuck Johnston,** Partner, and **Sam Barnes,** Director, are from Axon Communications. They can be contacted at cjohnston@axon-com.com and sbarnes@axon-com.com