The New Face of Informed Consent: IT'S MORE THAN A SIGNATURE

Informed patients make for compliant participants, compliant participants deliver verifiable data. This equation leads to the delivery of a product ready for market approval and ultimately market launch.

Contributed by

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Patient-centered care is driving the focus of healthcare delivery today — from quality and access to information-based care with improved health outcomes. That model, promoted by the Institute of Medicine, applies to clinical trials as well, particularly when it comes to informed consent. A responsive informed consent process mindful of patients' rights, concerns, and ongoing educational needs can go a long way towards recruitment and, importantly, retention of study volunteers. And that leads to reliable, validated data and study success.

Seeing Informed Consent Through an Information Lens

Let's first take a moment to analyze the situation. Approximately 165,000 clinical trials throughout the world, including 10,974 in the United States, are seeking to enroll 2.8 million participants. Of those clinical trials, 90% will fail to meet their enrollment requirement. One CenterWatch report has also estimated that the average dropout rate in a clinical trial is 25%, and rates as high as 40% have been reported.

The financial costs associated with these trial delays and dropouts are also considerable. Each day that a drug is withheld from the market means a loss of sales amounting to $4 million to $5 million a day.

Clearly, the need for clear, actionable, relevant, and engaging educational solutions supporting informed consent and ultimately recruitment and retention objectives has never been greater.

Informed patients make for cooperative and compliant participants. Without participants, you wouldn't have a trial; without compliant participants, you wouldn't have verifiable data; and without participants or data, you would not have the ability to submit for approval. We will revisit this later.

When initiating informed consent, it's important to understand that the mandatory signing of a document is just the beginning of a continuous process. Our experience and research confirms that approaching informed consent from the patient's perspective drives successful outcomes. Clinical trial stakeholders ultimately benefit from study participants who understand all aspects of what a study entails: from acknowledging a study drug's risks and benefits to adhering to a dosing regimen. Each of these is a piece of the total equation for a successful trial, which starts with a solid foundation, the informed consent.

Start at the Beginning

The typical informed consent form ranges from 20 pages to 30 pages and is filled with medical terms meant for a clinical scientist. In the United States, almost half of the population reads at or below an eighth-grade level. So how do you bridge the gap, set expectations, and lay the foundation for success?

What emerged at Artcraft Health was a patient resource guide, an 8-page to 16-page booklet that explains the fundamental learning principles and key information from the informed consent form and couples them with engaging design and clear medical illustrations. In each case, a question-and-answer format is used to explain on a sixth-grade reading level the following topics to a patient and his or her caregiver:

- What is a clinical trial?
- What is informed consent?
- What is the eligibility criteria?
- What are the study's objectives?
- What is a placebo?
- What are the risks and benefits of the study drug?

This content is then integrated into other print formats or digital tools that can be used for ensuring retention throughout a trial, such as instructional video brochures, game apps (for pediatric studies), and informational websites.

Formula for Success

It's a fairly straightforward formula:

- Improved communication = enhanced recruitment and retention and patient satisfaction
- Increased patient compliance = verifiable outcomes
- Verifiable outcomes = the potential to go to market

In today's competitive market landscape there is no room for increased costs associated with participant dropout or recruitment delays that end in an extended launch to market. The need for clear communication and setting expectations early on is crucial in reaching clinical trial objectives; and that is just what our patient resource guides accomplish. As earlier discussed, informed patients make for compliant participants, compliant participants deliver verifiable data. This equation leads to the delivery of a product ready for market approval and ultimately market launch. PV

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