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Mapping the Landscape of Patient-Centric Activities Within Clinical Research

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ABSTRACT

Purpose: Although there has been more involvement by patients in the drug-development process, there are not a lot of published data that quantify patient-centric activities or that document these activities across a large scale. In order to examine the patient-centricity landscape and to quantify the adoption and implementation of these initiatives, the Tufts Center for the Study of Drug Development and the Drug Information Association collaborated on a research study. The study examined patient-centric activities implemented by pharmaceutical, biotechnology, and contract research organizations, as well as activities being piloted or in the planning stages.

Methods: A global industry survey was conducted across pharmaceutical, biotechnology, and contract research organizations, assessing 25 patient-centric activities within clinical research. Some of these initiatives involve the use of social media to engage with patients, or the use of social listening to monitor study activity. Initiatives being implemented, planned, or piloted in addition to those not being considered were evaluated by respondents. Twenty-two unique companies responded to the survey, representing a mix of large, mid-sized, and small organizations.

Findings: The most widely adopted patient-centric initiatives, including activities both implemented and piloted across organizations, were patient advisory boards (17/22 companies), professional panels (16), lay-language clinical trial results summaries (13), assessment of the patient–organization landscape (10), and the use of home nursing networks (9).

Implications: The results of the study suggest that organizations have a varied approach to the adoption and implementation of patient-centric initiatives, with more activities occurring in the planning stages than are being piloted or implemented. Many factors affect implementation and adoption, including buy-in by senior management, organizational vision, resources, and level of investment. (*Clin Ther*. 2017;▮:▮▮▮–▮▮▮)

Key words: clinical research, drug-development process, patient-centric activities.

INTRODUCTION

A recent focus of the pharmaceutical industry is assessing the role of patient-centricity in clinical research, as reflected in the numerous publications, reports, and conferences examining the role of the patient within the drug-development process. Although there has been more patient involvement in drug development compared with a few years ago, there remains a lack of published data that quantify patient-centric activities or that document these activities across a large scale. Patient involvement in the clinical research process is significant, as it can potentially improve the research process, minimize the burden of participation, and improve clinical trial design and execution. Patients may also provide input into clinical trial protocols and study design that could lead to improved recruitment.[1]

Recent findings from studies suggest that best practices for patient involvement in drug development have not yet been established.[1–3] This research also reveals that the present frameworks are not sufficient to support more widespread patient involvement.[1,3] Data were gathered in these studies through various methodologies, including interviews with health care and patient thought leaders, and through case examples in the literature. Additional research indicates that no “master framework” for systematic patient involvement in drug development can be identified

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and that patient involvement is inconsistent and fragmented (although in some therapeutic areas it may be productive).[2] Other researchers acknowledge that guidance on patient engagement does not exist but that there is a need for it.[3]

Various definitions of *patient-centricity* are also offered in the published literature. Robbins et al[4] define *patient-centricity* as "a dynamic process through which the patient regulates the flow of information to and from him/her via multiple pathways to exercise choices consistent with his/her preferences, values and beliefs (p. 350)." Getz[5] described 4 core principles of patient-centricity, including relevance, pragmatism, feasibility, and interactivity. Through these principles, a methodology for measuring *return on investment* of patient-centricity initiatives is proposed. The return on investment of these initiatives can be measured in pharmaceutical, biotechnology, and contract research organizations through quantitative (internal and external reach) and qualitative measures. One example of an *internal reach* measure is the total number of initiatives being piloted or implemented within a particular time frame, while *external reach* may be the total number of patients or study volunteers reached by all patient-centric initiatives within a particular time frame.

Patient-centric initiatives are numerous and vary in their levels of uptake and adoption by the pharmaceutical industry. The range of initiatives include patient advisory boards, professional panels, advocacy group support and involvement, real-time data collection, direct-to-patient clinical trials, home nursing networks, telemedicine, wearables (*patient-reported outcomes,* which are patient self-reported data), and eConsent. Mobile nursing services in clinical trials have been broadening their reach, especially in North America and Western Europe.[6] *eConsent* manages patient consent using technology, but has not had much utilization.[7] Other uses of patient-centric initiatives can be seen in *crowdsourcing protocols,* defined as gathering input from patients, physicians, and other stakeholders via the World Wide Web, especially within oncology clinical trials.[8] Another patient-centric initiative is social listening which aggregates social media data such as patient posts or comments to gather information on patient insights or to identify unmet needs during treatment. *Telemedicine,* the use of electronic communication and remote technologies to treat patients, also has potential in patients within clinical research. However, its use can be costly and challenging both in terms of technology requirements and training or usability from the perspective of a patient.[9] In the United States, there have also been increases in patient wearables and other monitoring devices that transmit patient data to health care professionals. The use of remote monitoring technologies is expected to reach 4 million patients by 2020.[10] The use of electronic patient-reported outcomes in clinical trials is an application of wearables. There are a number of challenges with the use of mobile health applications, including data security and privacy, data qualification, and validation and regulatory acceptance.[10]

Smith et al[11] discussed the need for a common language, alignment, and best practices around patient engagement. The Patient-Centered Outcomes Research Institute (Washington, DC) has developed general guidance through their Engagement Rubric, which describes how input from patients and other stakeholders can be gathered throughout the research cycle.[12] The Clinical Trial Transformation Initiative has also developed recommendations and best practices for effective engagement with patients in clinical trials.[13] The European Patients Academy on Therapeutic Innovation (Brussels, Belgium) is a public–private partnership and consortium of 33 organizations that focuses on facilitating patient involvement in research and development. In addition, the US Food and Drug Administration recently hosted meetings that focused heavily on patient involvement, including panels representing different stakeholder groups such as patient advocacy groups, consumer advocacy groups, health care professionals, and other industry professionals.[14]

Despite many efforts to integrate various stakeholder input from patients, pharmaceutical companies, academic, and others, published data examining the adoption and implementation of specific patient-centric initiatives across pharmaceutical and biotechnology companies have been lacking. Some research highlights specific initiatives but is limited and does not evaluate activities being piloted or in the planning stages.[15] To date, no published data exist that quantify the adoption of specific patient-centric initiatives that can provide value and guide decision making among biopharmaceutical companies and other industry stakeholders.