

# Patient-centric strategies taking flight

## Widely embraced; tactics implemented throughout clinical research process

**P**atient-centered clinical research has the potential to profoundly change the way clinical research is conducted, and now leading sponsors and CROs have embraced the concept, implementing a variety of initiatives that engage patient communities in the development of better therapies that can improve their outcomes.

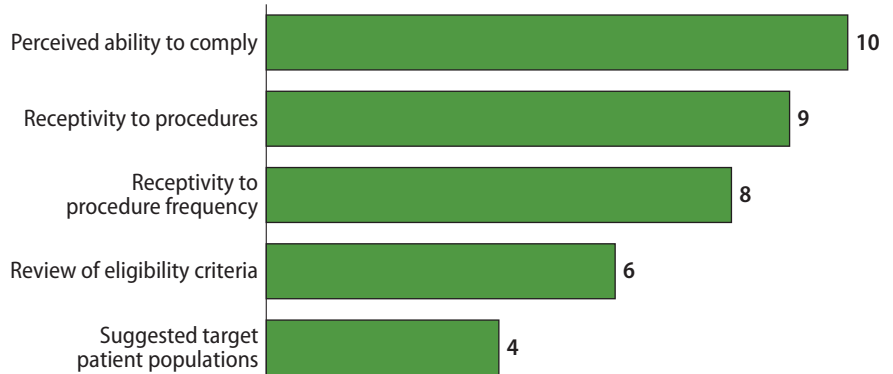
The movement has grown steadily, as companies have recognized the benefit of devoting resources to programs that gather patient perspectives and take their viewpoints into account during decision-making processes. Patient communities now help design protocols, recruit patients for studies, educate the public about the importance of clinical research, involve healthcare providers in supporting the enterprise and disseminate trial results.

These new patient-centered programs have offered a conceptual roadmap of how the industry should think about engaging patients and the public in clinical research going forward.

A patient-centered approach goes beyond seeing a study through the eyes of the patient, according to Ken Getz, director of Sponsored Research Programs and associate professor, Center for the Study of Drug Development, Tufts University School of Medicine. The ultimate goal, he said, is to engage patients, along with their support networks, as partners taking

### Where sponsors plan to seek input from patient panels

Number of sponsors mentioning these protocol design areas



Source: Tufts CSDD 2013 survey of 14 major pharmaceutical companies <csdd.tufts.edu>

an active role in developing products that better address their needs.

“At the end of the day, if we do different patient-centric activities correctly, we’ll eventually have the patient community committed and taking ownership for the success of the research enterprise, because they feel they have a vested interest in that success as an engaged partner in the process,” said Getz, who also is founder and board chair of the non-profit Center for Information & Study on Clinical Research Participation (CISCRP).

### Searching for new models

Although a few industry leaders and organizations have advocated for greater patient engagement in clinical research for decades, the concept has gathered steam as the industry

explores different models for innovation and collaboration. Most widely agree the current drug development model no longer works: studies have high failure rates and are slow and inefficient, and costs continue to rise. As industry has begun to forge new collaborative partnerships to lower development costs, reduce failure rates and improve efficiencies, many sponsors have begun to reexamine their relationships with the patient community.

“It was sort of the ‘aha moment’ in industry, when organizations realized, almost simultaneously, that this is a missing piece in development,” said Anthony Yanni, M.D., head of the Patient Value & Strategy Group, co-lead of the Sanofi Patient Engagement Initiative, Sanofi.

“Developmental processes are expensive and we all want the same thing: We want to make sure what we