Developing Recommended Language on Patient Engagement for FDA Consideration

OVERVIEW

The Issue
Many stakeholders in the health care community, including the U.S. Food and Drug Administration (FDA) have expressed a need for the FDA to provide guidance to encourage product sponsors (e.g., biopharmaceutical companies) and others to engage patients throughout the drug-development lifecycle and ensure the information collected is useful to the regulatory review process. The Prescription Drug User Fee Act (PDUFA) VI commitment letter (not yet enacted) outlines the need for such guidance.

Background
The National Health Council (NHC) has been dedicated to furthering patient engagement in drug development and hosted three multi-stakeholder events to inform the development of recommended language, language that could be offered to the FDA to help advance its work in this area:

1) March 2015 -- The NHC and the Genetic Alliance (GA) co-hosted a forum for stakeholders to establish a common vision to drive meaningful integration of the patient voice in medical product research, development, and approval as part of patient-focused drug development (PFDD). The product of this meeting was a white paper entitled, "Dialogue /Advancing Meaningful Patient Engagement in Research, Development, and Review of Drugs."
2) December 2015 -- The NHC and the GA convened a meeting to inform the scope and contents of proposed FDA guidance document language intended to guide industry, patient organizations, and other stakeholders in collecting input and information from patients to help inform drug development. The product of this meeting was a summary and outline of the topics that should be included in FDA guidance.
3) October 2016 -- The NHC and the GA convened a third stakeholder meeting to revisit topic areas previously considered for FDA guidance in light of the PDUFA VI commitment letter and on next steps for advancing guidance language in those areas.

The Approach
As a result of multi-stakeholder input, the NHC and GA refined its strategy and will produce a series of documents to align with the guidance requirements under the PDUFA VI commitment letter. The NHC and GA have developed the first document and are currently forming working groups to tackle the remaining topics of interest. This initiative will result in a series of documents with recommended language on patient engagement to be submitted to FDA for its consideration.

Timeline for Documents

1) The first document defines key terms and concepts related to patient engagement and encourages patient-focused drug development efforts.

   Expected completion: Completed

2) Additional documents will be completed in parallel fashion over the next one to two years.

   Expected completion: Two draft documents released by August 2017