CRITICAL PATH INSTITUTE

Critical Path Innovation Meeting

On September 14, 2017, Critical Path Institute's (C-Path) Patient-Reported Outcome (PRO) Consortium and Electronic Patient-Reported Outcome (ePRO) Consortium participated in a Critical Path Innovation Meeting (CPIM) at the U.S Food and Drug Administration's (FDA) White Oak campus in Silver Spring, MD. As stated on FDA's website, the goals for CPIMs are "to discuss a methodology or technology proposed by the meeting requester and for CDER to provide general advice on how this methodology or technology might enhance drug development."

The PRO Consortium and ePRO Consortium requested the meeting, titled "The Use of Wearable Devices to Collect Endpoint Data in Clinical Trials," to achieve the following objectives:

- Discuss activity monitor-based examples of proposed uses of wearable technology to measure patients' real-life physical functioning to inform or support endpoints in clinical trials
- Work toward a shared understanding of some of the open regulatory and scientific issues related to the use of wearable devices to collect endpoint (i.e., treatment benefit) data in clinical trials

For the purpose of this discussion, the term *wearable device* was defined as a small electronic device containing one or more sensors that are integrated into clothing or other accessories that can be worn on the body, such as on a wrist band, belt, headband, adhesive patch, contact lens or glasses. Common sensors used in wearable devices include those for measuring movement and position, such as accelerometers, gyroscopes, magnetometers, and global positioning systems (GPS), or sensors for assessing electrophysiological and chemophysiological function or other physiological properties such as body temperature.

Those participating in the CPIM in person included representatives from the PRO Consortium, ePRO Consortium, C-Path, and FDA; representatives from each of these organizations also joined by phone/WebEx. After a brief overview by FDA of CPIM "ground rules" and introductions of those in the room, the following foundational principles for the discussion were presented by C-Path:

We are not interested in the use of technology just for the sake of using technology (i.e., not advocating for technologies that are in search of an endpoint). We are interested in exploring how existing or emerging technologies could help us to…

- measure traditional efficacy endpoints more accurately or
- measure meaningful endpoints that were not previously feasible or easy to assess.

Prepared presentations included a summary of a manuscript (subsequently accepted for publication in *Value in Health*) titled "Selection of and Evidentiary Considerations for Wearable Devices and Their Measurements for Use in Regulatory Decision Making: Recommendations from the ePRO Consortium" and examples of the use of activity monitors in multiple sclerosis (MS) and chronic obstructive pulmonary disease (COPD). The MS example provided a published approach to determining a meaningful change in the number of daily steps taken and the COPD example used the Innovative Medicines Initiative's PROactive project to demonstrate the successful development of an outcome measure that combines results from an activity monitor with patient self-report to assess COPD treatment benefit.

Collaborative, constructive, and substantive discussion occurred throughout the 90-minute meeting. Although CPIMs are informal and no official meeting minutes will be prepared, participants agreed to

continue the dialog and to further explore ways of leveraging data generated by wearable devices to inform or support meaningful clinical trial endpoints.