

May 23, 2018

Summary of January 2018 Teleconferences

DDT #000099 Feasibility Study Protocol for the Child Asthma Diary (CAD)

FDA's Clinical Outcome Assessments (COA) Staff held teleconferences with the Critical Path Institute's (C-Path) Patient Reported Outcome (PRO) Consortium on January 10, 2018 and January 19, 2018. The following is a summary of our current recommendations, as discussed during the January 2018 teleconferences, for your consideration.

- As previously communicated in our request for an Initial Briefing Package (dated June 9, 2017), we continue to believe that child asthma symptoms would be more reliably assessed through an appropriately designed interviewer-administered PRO (for children with difficulty reading), self-reported PRO and observer-reported (ObsRO) instrument and we continue to recommend that you only proceed with development of these three versions of the PASD.
 - a. We do not agree with proceeding with further development of the co-completed, PRO/ObsRO version of the PASD. Specifically, as written, it is unclear who is providing responses (i.e., separate responses based on self-report and observations are not indicated), and we are not sure about the utility of the co-completed version above and beyond the interviewer-administered PRO version.
 - b. In light of the above recommendation, we do not recommend that you proceed with the current feasibility study but instead, make any recommended changes to the draft instrument(s) and conduct a small number of traditional cognitive interviews (whether in person or via web or video) to test as it will provide better standardization of procedures across study subjects.
- As discussed during our January 19, 2018 teleconference, after reviewing the original work completed for the Pediatric Asthma Diary - Observer (PAD-O; 5-11 years) and Pediatric Asthma Diary - Child (PAD -C; 8-11 years) as well as the revised PASD, we recommend the following modifications to the revised PASD:
 - c. PASD – Observer
 - i. **Instructions:** We recommend that you revise the instructions as follows:
 1. **Morning Diary:** “Based on what you observed or what your child told you, think about your child’s asthma from when he/she went to bed last night until he/she woke up this morning.”
 2. **Evening Diary:** “Based on what you observed or what your child told you, think about your child’s asthma from when he/she woke up this morning until now.”
 3. **Both the Morning and Evening Diary:**

- a. Rater standardization: In both the instructions and the parent FAQ, specify that the same parent should be rating the child for the duration of the study.
 - b. Recall period: revise definition of last night and today to read
 - i. Last night: “from the time your child went to bed last night until he or she woke up for the day.”
 - ii. Today: “from the time your child woke up this morning until now.”
4. Additional item(s) (not to be included in the scoring):
- a. Global severity item:
 - i. Morning Diary: we recommend you add the following item to capture a global rating of severity – “Based on what you observed or what your child told you, how bad was your child’s worst asthma symptoms (wheezing, coughing, difficulty breathing) since he/she went to bed last night?”
 - ii. Evening Diary: we recommend you add the following item to capture a global rating of severity – “Based on what you observed or what your child told you, how bad was your child’s worst asthma symptoms (wheezing, coughing, difficulty breathing) today?”
 - b. Sleep Monitoring:
 - i. Did you check on your child while they slept last night due to their asthma?
Yes/No
 - ii. **User Manual and Training Materials**: Please submit a final, revised user manual, along with training materials, for Agency review and comment. These materials should be tested during the planned cognitive interviews.
- d. PASD - Child
- i. **Instructions**: We recommend that you revise the instructions as follows:
 - 1. **Morning Diary**: “For each question, think about your asthma from when you went to bed last night until you woke up this morning.”
 - 2. **Evening Diary**: “For each question, think about your asthma from when you woke up this morning until now.”
 - 3. **Both the Morning and Evening Diary**:
 - a. Recall period: revise definition of last night and today to read:
 - i. Last night: “from the time you went to bed last night until you woke up for the day.”
 - ii. Today: “from the time you woke up this morning until now.”
4. Additional item(s) (not to be included in the scoring):
- a. Global severity item:
 - i. Morning Diary: we recommend you add the following item to capture a global rating of severity – “How bad was worst asthma symptom(s) (wheezing, coughing,

- hard time breathing, chest tightness) from the time you went to bed to the time you woke up for the day?”
 - ii. Evening Diary: we recommend you add the following item to capture a global rating of severity – “How bad was worst asthma symptom(s) (wheezing, coughing, hard time breathing, chest tightness) today?”
- b. Activity limitations:
 - i. We recommend that you add the following item back into the evening diary: “Because of your asthma, how hard was it to run around, play or do sports today?”
- ii. **User Manual and Training Materials**: Please submit a final, revised user manual, along with training materials, for Agency review and comment. These materials should be tested during the planned cognitive interviews.