

Clinical Outcome Assessments (COA) Qualification Program
DDT COA #000071: Pneumonia Patient-Reported Outcome Measure
(PNEUMO-PRO)
May 4, 2017 Update

I. Administrative Information

Date: May 3, 2017

Attention: CDER Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Subject: **DDT QUALIFICATION SUBMISSION**

DDT Type: **CLINICAL OUTCOME ASSESSMENT- PATIENT REPORTED OUTCOME (PRO)**

DDT Tracking Record Number: **DDT COA 071**

Submission Type: **INITIAL BRIEFING PACKAGE**

DDT Name(s): **HOSPITAL-ACQUIRED BACTERIAL PNEUMONIA (HABP) PATIENT-REPORTED OUTCOME INSTRUMENT**

Context of Use: The Foundation for the National Institutes of Health Biomarkers Consortium (FNIH BC) is proposing to develop a patient-reported outcome (PRO) instrument to assess symptoms of HABP and their impact on how patients with HABP feel and function. Based on research conducted by FNIH BC it is clear that current clinical trial endpoints do not directly capture patient-reported benefits of treatment in HABP and do not meet the definition of well defined and reliable as specified in FDA regulations;† therefore, the development of a PRO in this specific patient population is needed.

Question for CDER:

1. Does the CDER committee agree that the methodology used to develop the HABP PRO measure, as described in this IBP, was appropriate?
2. Based on the completed and ongoing development procedures and findings detailed in this IBP, does the CDER committee agree there is good content validity of the draft HABP PRO measure?
3. The qualitative data support the use of items from the CABP PRO instrument in HABP patients. This finding suggests the use of a unified PRO instrument for both types of pneumonia. Does the CDER committee agree?

† Foundation for the National Institutes of Health Biomarkers Consortium–HABP/ VABP Working Group. Interim considerations for clinical trial design for the study of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia. July 15, 2013. Submission to Docket FDA-2013-N-0556.

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*A complete list of FNIH BC working group members can be found in Appendix A.

Appendix A

Contact Group Name:

HABP VABP Project Team

Members:

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