**DDT COA #000018** **COMMENTS ON SUBMISSION**

Kellee Howard, MA, MSc
Senior Principal
ICON Commercialisation & Outcomes
Phone: 226-647-0629
Email: Kellee.Howard@iconplc.com

**Regarding: DDT COA #000018 Revised psychometric protocol and SAP for the Pneumonia Patient Reported Outcome Measure (PNEUMO-PRO©) for the measurement of community-acquired bacterial pneumonia (CABP) symptoms.**

Dear Ms. Howard,

Please refer to your June 6, 2018 submission for PNEUMO-PRO© (DDT COA #000018). After reviewing your responses and associated documents, we have the following comments and suggestions.

As stated in our letter dated June 20, 2018, we believe that it is not appropriate to expand the enrollment criteria window from 24 to 48 hours. Based on our teleconference held on October 18, 2018 and your most recent submission, the data did not support the extension of this enrollment window. If patients do not begin completing the instrument until the second day of treatment, this may jeopardize the instrument's ability to detect symptom improvement at day 3-5. We continue to encourage you to enroll patients within the first 24 hours as this is reflective of the population expected to be enrolled in clinical trials. With the recruitment challenges you outlined in your June 6, 2018, you may want to consider a smaller sample size of 125 CABP patients.

Please contact the COA Staff at COADDTQualification@fda.hhs.gov should you have any questions (refer to DDT COA #000018).

Sincerely,

Elektra J. Papadopoulos -S
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Date: 2019.01.18 11:38:43 -05'00'

Elektra Papadopoulos, MD, MPH
Associate Director
Clinical Outcome Assessments Staff
Office of New Drugs
Center for Drug Evaluation and Research

Sumathi Nambiar, MD, MPH
Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov