DDT #000018 **COMMENTS ON SUBMISSION**

June 20, 2018

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Regarding: DDT #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 #000018). We offer the below comments after conducting a preliminary review of your responses and associated documents. Please note an additional response letter will be sent at a later date containing further comments and recommendations.

At this time, it is not appropriate to expand the enrollment criteria window from 24 to 48 hours. 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 change at day 3-5.

However, we offer the following suggestions for enhancing enrollment:

- Modify your inclusion criteria from "at least 3 symptoms" to "at least 2 symptoms". This is consistent with FDA's draft guidance *Community-Acquired Bacterial Pneumonia: Developing Drugs for Treatment*.
- Include hospital-acquired bacterial pneumonia (HABP) patients (ex. From screening log-respiratory diagnosis attributed to other source (HAP).

Additionally, it is acceptable to modify the inclusion criteria to reflect self-report of a fever.

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

Sincerely,

Elektra J. Papadopoulos -S

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Date: 2018.06.26 21:46:25 -04'00'

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