



The Key for Turning Data into Knowledge to
Improve Treatments for Patients

DOOR Data Collection Tool for Hospital-Acquired and Ventilator-Associated Bacterial Pneumonia Trials: Investigator Assessment of Clinical Success and Complications

This DOOR data collection tool is provided to help prospectively obtain data needed to use the ARLG-proposed DOOR endpoints. This DOOR tool should be used only in addition to a trial's standard data collection forms.

Participant ID: _____

Date of assessment (could be used at multiple assessments): _____

1. Has the participant died?
 - a. No
 - b. Yes → *if this option is selected, complete the study mortality CRF questions. No further questions are required*
 - c. Unknown/lost to follow-up → *if this option is selected, no further questions are required*
 - i. Date of last contact:

2. What is the participant's current clinical response?
 - a. Clinical success
 - i. **Definition:** *Complete resolution or significant improvement in the presenting signs and symptoms of the original infection, without any new symptoms of pneumonia or need for additional antimicrobial therapy for pneumonia*
 - b. Absence of clinical success
 - i. **Definition:** *Any response that does not meet the definition of clinical success*

3. Has the participant required new mechanical ventilation (not present at study enrollment) since enrollment or since last completion of this form?
 - a. Yes
 - i. If yes, provide date of intubation/initiation of mechanical ventilation:
 - ii. **OPTIONAL:** If yes, did they have any of the following complications since being mechanically ventilated?
 - Barotrauma complication (e.g. pneumothorax, pneumomediastinum, subcutaneous emphysema)
 - Positioning-related complication (e.g. decubitus ulcer)
 - Device-related complication (e.g. endotracheal tube complication, tracheostomy, tracheostomy malfunction, tracheal ulcer)
 - Other (e.g. tracheoesophageal fistula, critical illness myopathy)
 - b. No

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4. Has the participant had an **infectious complication** since study enrollment?

Definition: Any newly identified event (not present at study enrollment) that represents a progression or a direct complication of the original infection under study. Listed below are common examples for HABP/VABP, although this list is not exhaustive.^{1,2}

a. Yes

i. If Yes, select which infectious complication occurred and the **date it started**:

- Complicated pleural effusion
- Necrotizing lung infection
- Acute respiratory distress syndrome (ARDS)
- Bacteremia due to the same bacteria identified in the enrollment respiratory culture
- Meningitis or osteomyelitis due to the same bacteria identified in the enrollment respiratory culture
- Septic shock
- Other (describe): _____

b. No

1. The investigator may attribute events that discovered near to study enrollment as occurring prior to enrollment if the event clearly started before enrollment, even if it did not conclude or become culture-proven until after enrollment.
2. If the study is unblinded, we recommend utilizing a blinded adjudication committee to ensure agreement for each infectious complication identified.