



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

## DOOR Data Collection Tool for Acute Bacterial Skin and Skin Structure Infection (ABSSSI) 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:** *Resolution or improvement of signs and symptoms of original infection to the extent that further antibacterial therapy is not needed.*
  - b. Absence of clinical success
    - i. **Definition:** *Any response that does not meet the definition of clinical success*
  
3. 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 ABSSSI, although this list is not exhaustive.<sup>1,2</sup>*

  - a. Yes
    - i. If Yes, select which infectious complication occurred and the **date it started**:
      - Bacteremia due to the same bacteria identified in the ABSSSI enrollment culture
      - Osteomyelitis
      - Septic shock
      - Progression (e.g. worsening or not improving) of original ABSSSI (wound infection, abscess, cellulitis)
      - New ABSSSI (wound infection, abscess, cellulitis)
      - 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.*

