



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

## DOOR Data Collection Tool for Complicated Intra-Abdominal Infection (cIAI) 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 of the baseline signs and symptoms of cIAI and without any of the following: surgical site wound infection, unplanned surgical or percutaneous drainage procedures for complication or recurrence of cIAI<sup>1</sup> or initiation of non-trial antibacterial therapy for cIAI treatment*
  - b. Absence of clinical success
    - i. **Definition:** *Any response that does not meet the definition of clinical success*
    - ii. **Optional:** *If did not have clinical success, free-text the reason they did not meet clinical success criteria:* \_\_\_\_\_
  
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 cIAI, although this list is not exhaustive.<sup>2,3</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 enrollment culture
      - Peritonitis with or without abscess
      - Septic shock
      - Surgical site wound infection
      - New intra-abdominal abscess
      - Other (describe): \_\_\_\_\_
  - b. No
    1. *This would NOT include routine adjustments of percutaneous drain to help with original source control including drain repositioning, exchange, or upsizing. If a new drain was required in a new or enlarging intraabdominal abscess this would meet criteria for clinical failure.*
    2. *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.*
    3. *If the study is unblinded, we recommend utilizing a blinded adjudication committee to ensure agreement for each infectious complication identified.*