



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

## DOOR Data Collection Tool for Complicated Urinary Tract Infection (cUTI) 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 signs and symptoms of the original infection under study (cUTI or acute pyelonephritis), without any new cUTI symptoms needing additional antimicrobial therapy*
  - b. Absence of clinical success
    - i. **Definition:** *Any response that does not meet the definition of clinical success*
3. Has the participant had a recurrent UTI since enrollment (or since last completion of this form)?
 

**Definition of recurrent UTI:** *After a period of significant improvement or resolution of UTI symptoms, there was a recurrence of UTI symptoms requiring a new start or extension of antibiotic therapy.*

  - a. Yes
    - i. If yes, provide date for the recurrent UTI (list first date of new symptoms): \_\_\_\_\_
  - b. No
4. Has the participant had an **infectious complication** since enrollment (or since last completion of this form)?
 

**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 cUTI, 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:
      - Renal or perinephric abscess
      - Septic shock
      - Bacteremia due to the same bacteria identified in original urine culture
      - Epididymo-orchitis
      - Prostatic abscess
      - Other (describe): \_\_\_\_\_
  - b. No
  1. *The investigator may attribute events that occur 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.*