

### Appendix I Data Submission Checklist

<b>Patient Name/Initials:</b>	<b>Patient ID #:</b>	<b>Date Completed</b>
<b>Site Name:</b>	<b>Visit (e.g., baseline, 4wk, 10 wk)</b>	<b>CRA Name:</b>
<b>CTSU SITES ONLY:</b>		
<input type="checkbox"/> CTEP Assigned Site Code _____ <input type="checkbox"/> Investigator Associate Code _____		

Date Submitted

- Signed Consent Form (Required from all RB members and CTSU members included with Baseline Study Documents submitted directly to DMC) \_\_\_\_\_
- Eligibility Checklist/Registration Form \_\_\_\_\_
- Flow sheet
  - Baseline \_\_\_\_\_
  - 4 Week Evaluation \_\_\_\_\_
  - 10 Week Evaluation \_\_\_\_\_
  - EOS Week Evaluation \_\_\_\_\_
- Toxicity Assessment Sheet
  - Baseline \_\_\_\_\_
  - 4 Week Evaluation \_\_\_\_\_
  - 10 Week Evaluation \_\_\_\_\_
  - EOS Week Evaluation \_\_\_\_\_
  - 4 Weeks Post-Treatment \_\_\_\_\_
- Blood Lab Reports
  - Baseline \_\_\_\_\_
  - 4 Week Evaluation \_\_\_\_\_
  - 10 Week Evaluation \_\_\_\_\_
  - EOS Week Evaluation \_\_\_\_\_
- Diary Card
  - ARI Diary
    - Baseline \_\_\_\_\_
    - 4 Week Evaluation \_\_\_\_\_
    - 10 Week Evaluation \_\_\_\_\_
    - EOS WeekEvaluation \_\_\_\_\_
  - Antibiotic Use Diary
    - 4 Week Evaluation \_\_\_\_\_
    - 10 Week Evaluation \_\_\_\_\_
    - EOS Week Evaluation \_\_\_\_\_
    - 4 Weeks Post-Treatment \_\_\_\_\_
- Current Medication Form
  - 4 Weeks \_\_\_\_\_
  - 10 Weeks \_\_\_\_\_
  - EOS \_\_\_\_\_
- Telephone Contact Form
  - 4 Weeks Post-Treatment \_\_\_\_\_