

Investigator SCRIPT Pneumonia and Viral Episode Assessment and Outcome Evaluation

Study ID: _____

Reviewer 1 2 3 CR: _____
Date

<input type="radio"/> N/A – go to page 2		Episode Category Assessment	
Is this for the initial pneumonia episode? Date of BAL in REDCap: _____	<input type="radio"/> Yes, this is the initial pneumonia episode (implies > 1 episodes) <input type="radio"/> Yes, this is the initial and also final pneumonia episode <input type="radio"/> No, multiple episodes		
If not initial, is this the final pneumonia episode?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A		
Patient Category: <input type="radio"/> Clinical CAP (not hospitalized within the last 7 days) <input type="radio"/> Clinical HAP (current admission >48 hours or discharged from a healthcare facility within the last 7 days where admission >24 hours) <input type="radio"/> Clinical VAP (on ventilator >48 hours or reintubated < 24 hours from extubation) <input type="radio"/> Non-pneumonia control* <input type="radio"/> Infection ^a <input type="radio"/> Known Condition ^b <input type="radio"/> Unknown	*If non-pneumonia control, cause of infiltrate: <input type="radio"/> ARDS <input type="radio"/> Aspiration <input type="radio"/> Atelectasis <input type="radio"/> Fibrosis <input type="radio"/> Fluid overload <input type="radio"/> Heart failure/pulmonary edema <input type="radio"/> Pleural effusion <input type="radio"/> Pulmonary hemorrhage <input type="radio"/> Other: _____ <input type="radio"/> Unknown		
^a <i>If infection:</i> <input type="radio"/> Cholangitis/cholecystitis <input type="radio"/> Colitis <input type="radio"/> Other intra-abdominal <input type="radio"/> Line infection <input type="radio"/> Tracheobronchitis <input type="radio"/> Urinary tract <input type="radio"/> Wound/skin <input type="radio"/> Other: _____	^b <i>If known condition, cause of fever/leukocytosis:</i> <input type="radio"/> Aspiration <input type="radio"/> Atelectasis <input type="radio"/> Drug fever <input type="radio"/> Pancreatitis <input type="radio"/> Other: _____ <input type="radio"/> None <input type="radio"/> Unknown		
STOP here for non-pneumonia control			
Choose one: (from Episode Category Assessment) <input type="radio"/> Viral* only <input type="radio"/> Bacterial/Viral* Co-Infection <input type="radio"/> Bacterial/Etiology defined <input type="radio"/> Culture-negative** (%PMNs ≥ 50%) <input type="radio"/> Culture-negative*** (%PMNs < 50%) <input type="radio"/> Indeterminate	[*] <i>If viral, select virus type: (select all that apply)</i> <input type="checkbox"/> Influenza <input type="checkbox"/> SARS-CoV-2 <input type="checkbox"/> Other: _____		
Demographics page immune status is <input type="radio"/> Immunocompromised <input type="radio"/> NON-Immunocompromised			
^{**} <i>If culture-negative (%PMNs ≥ 50%):</i> <input type="radio"/> Immunocompromised <input type="radio"/> Nonimmunocompromised	^{***} <i>If culture-negative (%PMNs < 50%):</i> <input type="radio"/> Neutropenic (ANC < 500/uL) <input type="radio"/> Immunocompromised <input type="radio"/> Nonimmunocompromised		

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If Viral Only <input type="radio"/> N/A	
Were appropriate antivirals administered?	<input type="radio"/> Yes* <input type="radio"/> No <input type="radio"/> N/A – no appropriate antivirals
<i>*If yes, select antiviral: (select all that apply)</i>	<input type="checkbox"/> Influenza – oseltamivir <input type="checkbox"/> Influenza-baloxavir <input type="checkbox"/> Influenza-peramivir <input type="checkbox"/> Influenza-other: _____ <input type="checkbox"/> SARS-CoV-2-remdesivir <input type="checkbox"/> SARS-Cov-2-other: _____ <input type="checkbox"/> Adenovirus-cidofovir <input type="checkbox"/> Herpes or Varicella-acyclovir <input type="checkbox"/> RSV-ribavirin only if immunocompromised <input type="checkbox"/> Other (please specify): _____
Were empirical antibiotics for this episode started prior to BAL?	<input type="radio"/> Yes* <input type="radio"/> No
<i>*If yes, number of days prior to BAL collection?</i>	<input type="radio"/> ≤ 48 hours before BAL <input type="radio"/> > 48 hours before BAL
Were empirical antibiotics started/continued after BAL collection?	<input type="radio"/> Yes* <input type="radio"/> No
<i>*If yes, select number of days antibiotics were given:</i>	<input type="radio"/> < 72 hours after BAL <input type="radio"/> 3-7 days after BAL <input type="radio"/> 8-10 days after BAL <input type="radio"/> 11-14 days after BAL <input type="radio"/> ≥ 15 days after BAL
Viral Pneumonia Clinical Impression	
Was viral retesting performed?	<input type="radio"/> Yes* <input type="radio"/> No (go to Global Viral Clinical Impression)
<i>*If yes, PCR cleared?</i>	<input type="radio"/> Yes by BAL Date of 1 st negative test with no subsequent positive: _____ <input type="radio"/> Yes by NP/OP (no BAL available or subsequently completed) Date of 1 st persistent negative test: _____ <input type="radio"/> Other viral procedure: _____ Date of repeat test: _____ <input type="radio"/> No Date of last positive test: _____
Global Viral Clinical Impression: (Go to PCT after)	Pneumonia (Check best answer) <input type="radio"/> Cure <input type="radio"/> Persistence (repeat positive PCR until death, transfer to LTAC, needs time interval from last testing [i.e. positive within 7 days]) <input type="radio"/> Superinfection pneumonia (N/A if single episode only) <input type="radio"/> Indeterminate (NP positive but BAL clear, no recent PCR prior to death or transfer to other facility) Other: (if applicable, all that apply) <input type="checkbox"/> Extrapulmonary infection (Single Viral) (<i>see extra question</i>)*

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If ***extrapulmonary infection**, choose site (**check all that apply**) and corresponding documentation:

Site (<i>check all that apply</i>)	Documentation (<i>check most appropriate – only one</i>)			
	Definitive with positive culture	Definitive without culture proof	Radiologic/imaging only	Clinical suspicion only
<input type="checkbox"/> Cholangitis/cholecystitis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Colitis /C. diff	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Other intra-abdominal (SBP, abcess, etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Line infection	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Tracheobronchitis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Urinary Tract	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Wound/skin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Empyema (unrelated to the index pna)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Other (<i>please specify</i>): _____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If Bacterial/Viral Co-Infection N/A (Viral Only)

Were appropriate antivirals administered?	<input type="radio"/> Yes* <input type="radio"/> No <input type="radio"/> N/A – no appropriate antivirals
<i>*If yes, select antiviral: (select all that apply)</i>	<input type="checkbox"/> Influenza – oseltamivir <input type="checkbox"/> Influenza-baloxavir <input type="checkbox"/> Influenza-peramivir <input type="checkbox"/> Influenza-other: _____ <input type="checkbox"/> SARS-CoV-2-remdesivir <input type="checkbox"/> SARS-CoV-2-other: _____ <input type="checkbox"/> Adenovirus-cidofovir <input type="checkbox"/> Herpes or Varicella-acyclovir <input type="checkbox"/> RSV-ribavirin only if immunocompromised <input type="checkbox"/> Other (please specify): _____
Was viral retesting performed?	<input type="radio"/> Yes* <input type="radio"/> No (go to <i>If initial sample, has the patient...</i>)
<i>*If yes, PCR cleared?</i>	<input type="radio"/> Yes by BAL Date of 1 st negative test with no subsequent positive: _____ <input type="radio"/> Yes by NP/OP (no BAL available or subsequently completed) Date of 1 st persistent negative test: _____ <input type="radio"/> Other viral procedure: _____ Date of repeat test: _____ <input type="radio"/> No Date of last positive test: _____

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Continue If Bacterial/Viral Co-Infection or Complete If Bacterial Only <input type="radio"/> N/A (Viral only)	
If initial sample, has the patient been actively treated for pneumonia for more than 24 hours prior to sample collection?	<input type="radio"/> Yes* <input type="radio"/> No <input type="radio"/> N/A BAL Collection Date/Time: _____ <i>(Obtain from EPIC - Microbiology)</i>
Starting antibiotics for pneumonia: _____ Start date for antibiotics for pneumonia: _____ <i>*If yes, how many calendar days has patient been treated? (Day BAL – Day abx started)</i>	_____ days <input type="radio"/> N/A
Appropriate initial antibiotics? <i>(in the 72 hrs. preceding culture results)</i> <i>*Refer to biofire results if applicable</i>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A – no bacterial pathogen
Were antibiotics for pneumonia discontinued on D 7-8?	<input type="radio"/> Yes* <input type="radio"/> No <input type="radio"/> N/A**(death/transfer to another institution) <i>*if Yes, finish following clinical impression and go to PCT</i> <i>**if N/A, skip “clinical impression” questions and go to PCT</i>
Clinical Impression	
Clinical Impression at <u>D7-8</u> : <i>*must be actively treated at this time point</i>	Pneumonia (Check best answers) <input type="radio"/> Cure <input type="checkbox"/> Persistence <i>(check all that apply)</i> <input type="checkbox"/> Positive Culture <input type="checkbox"/> Positive PCR <input type="checkbox"/> Abscess / Cavity <input type="checkbox"/> Empyema <input type="checkbox"/> Endocarditis <input type="checkbox"/> Other: _____ <input type="checkbox"/> Superinfection pneumonia <input type="checkbox"/> Indeterminate Other: (if applicable, all that apply) <input type="checkbox"/> Extrapulmonary infection <i>(see extra question)*</i> <input type="checkbox"/> Prophylaxis only

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If ***extrapulmonary infection**, choose site (**check all that apply**) and corresponding documentation:

Site (<i>check all that apply</i>)	Documentation (<i>check most appropriate – only one</i>)			
	Definitive with positive culture	Definitive without culture proof	Radiologic/imaging only	Clinical suspicion only
<input type="checkbox"/> Cholangitis/cholecystitis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Colitis /C. diff	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Other intra-abdominal (SBP, abcess, etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Line infection	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Tracheobronchitis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Urinary Tract	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Wound/skin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Empyema (unrelated to the index pna)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Other (<i>please specify</i>): _____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

<p>Were antibiotics for pneumonia discontinued on D10?</p>	<p> <input type="radio"/> Yes* <input type="radio"/> No <input type="radio"/> N/A**(death/transfer to another institution) </p> <p><i>*if Yes, finish following clinical impression and go to PCT</i> <i>**if N/A, skip "clinical impression" questions and go to PCT</i></p>
<p>Clinical Impression at D10:</p> <p><i>*must be actively treated at this time point</i></p>	<p>Pneumonia (Check best answers)</p> <p> <input type="radio"/> Cure <input type="checkbox"/> Persistence (<i>check all that apply</i>) </p> <ul style="list-style-type: none"> <input type="checkbox"/> Positive Culture <input type="checkbox"/> Positive PCR <input type="checkbox"/> Abscess / Cavity <input type="checkbox"/> Empyema <input type="checkbox"/> Endocarditis <input type="checkbox"/> Other: _____ <p> <input type="checkbox"/> Superinfection pneumonia <input type="checkbox"/> Indeterminate </p> <p>Other: (if applicable, all that apply)</p> <ul style="list-style-type: none"> <input type="checkbox"/> Extrapulmonary infection (<i>see extra question</i>)* <input type="checkbox"/> Prophylaxis only

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If ***extrapulmonary infection**, choose site (**check all that apply**) and corresponding documentation:

Site (<i>check all that apply</i>)	Documentation (<i>check most appropriate – only one</i>)			
	Definitive with positive culture	Definitive without culture proof	Radiologic/imaging only	Clinical suspicion only
<input type="checkbox"/> Cholangitis/cholecystitis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Colitis /C. diff	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Other intra-abdominal (SBP, abcess, etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Line infection	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Tracheobronchitis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Urinary Tract	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Wound/skin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Empyema (unrelated to the index pna)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Other (<i>please specify</i>): _____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Were antibiotics for pneumonia discontinued on D14?	<input type="radio"/> Yes* <input type="radio"/> No <input type="radio"/> N/A**(death/transfer to another institution) <i>*if Yes, finish following clinical impression and go to PCT</i> <i>**if N/A, skip "clinical impression" questions and go to PCT</i>
If no , what date were antibiotics for pneumonia stopped?	Stop date for antibiotics for PNA: _____ <input type="radio"/> Stop date unknown (patient was discharged on antibiotics for pneumonia)
Clinical Impression at D14 : *must be actively treated at this time point	<p>Pneumonia (Check best answers)</p> <input type="radio"/> Cure <input type="checkbox"/> Persistence (<i>check all that apply</i>) <ul style="list-style-type: none"> <input type="checkbox"/> Positive Culture <input type="checkbox"/> Positive PCR <input type="checkbox"/> Abscess / Cavity <input type="checkbox"/> Empyema <input type="checkbox"/> Endocarditis <input type="checkbox"/> Other: _____ <input type="checkbox"/> Superinfection pneumonia <input type="checkbox"/> Indeterminate <p>Other: (if applicable, all that apply)</p> <input type="checkbox"/> Extrapulmonary infection (<i>see extra question</i>)* <input type="checkbox"/> Prophylaxis only

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If ***extrapulmonary infection**, choose site (**check all that apply**) and corresponding documentation:

Site (<i>check all that apply</i>)	Documentation (<i>check most appropriate – only one</i>)			
	Definitive with positive culture	Definitive without culture proof	Radiologic/imaging only	Clinical suspicion only
<input type="checkbox"/> Cholangitis/cholecystitis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Colitis /C. diff	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Other intra-abdominal (SBP, abcess, etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Line infection	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Tracheobronchitis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Urinary Tract	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Wound/skin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Empyema (unrelated to the index pna)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Other (<i>please specify</i>): _____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

PROCALCITONIN: (within 72 hrs of BAL/NBBAL Collection) [All categories]

Are serial PCTs available? <i>Note: minimum of 2 measurements within this treatment episode</i>	<input type="radio"/> Yes* <input type="radio"/> No
*If yes , does the patient meet PCT criteria for cure?	<input type="radio"/> Yes, (check criteria below) <input type="radio"/> No <input type="checkbox"/> 80% change/decrease from baseline <input type="checkbox"/> Absolute value of ≤ 0.5 ng/mL

IF FINAL EPISODE: [All categories]

Overall Global Clinical Cure **please refer to guidelines*

Overall Success?	<input type="radio"/> Yes ↳ If Yes, all criteria? (see text box below) <input type="radio"/> Yes <input type="radio"/> No ↳ If No, was patient extubated before day 7 ? <input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> No ↳ Cause of failure: * <input type="checkbox"/> Antibiotics for another indication in addition to suspected/proven PNA <input type="checkbox"/> Persistence (<i>check all that apply</i>) <input type="checkbox"/> Positive Culture <input type="checkbox"/> Positive PCR <input type="checkbox"/> Abscess / Cavity <input type="checkbox"/> Empyema <input type="checkbox"/> Endocarditis <input type="checkbox"/> Other: _____ <input type="checkbox"/> Persistent inflammation only <input type="checkbox"/> Recurrence <input type="checkbox"/> Superinfection pneumonia
	<div style="border: 1px solid black; padding: 5px;"> 1. survive duration of treatment 2. able to stop antibiotics for pneumonia a. Continuation of same antibiotics > 14 days but signs/symptoms of pneumonia stable (WBC, secretions, oxygenation, radiograph) or improving? 3. causative pathogen disappears from respiratory secretions or no further samples a. %PMNs in repeat BAL < 50% in non-neutropenic 4. clinical manifestations of pneumonia improve/resolve (e.g., fever, secretions, WBC, hypoxemia, septic shock) 5. ability to wean from vent or at least initiate SBTs a. Drop in minute ventilation and/or improvement in oxygenation b. Patient returned to pre-pneumonia ventilator/ECMO status or weaning from vent </div>	* <i>Check best answers</i>