



# 28 Day Follow-up

Participant Trial Number:

Participant Initials:

   
 

Randomising Site:

## A. Source of data

- 1) Confirm source of data: \_\_\_\_\_
- 2) Date information acquired:   -    -

## B. Patient mortality status

- 1) Is patient still alive? No  Yes  *If no, complete a death form.*

## C. Follow-up data

- 1) Was the patient readmitted to hospital following initial discharge and up to 28 days following randomisation?  
 No  Yes  *If no, move on to Section C Question 2.*
- i) Was this readmission unscheduled?  
 No  Yes  *If yes, complete a Readmission form.*
- 2) Has the patient received any systemic antibiotics following hospital discharge?  
 No  Yes  *If yes, update the antibiotic follow-up form.*

**Completion Guidelines for CRF 9: 28 Day Follow-Up Form**

**Participant Initials:** Write the initials of the participant's first/given name and surname/family name only. For double barrelled surnames/ family names use the initial from the first part of the surname/family name.

**Dates:** Please use the following formats for dates: 06-Jun-1956.

**Source of Data Guidance:**

- When completing section A1, please enter the applicable numerical code below:

1	GP
2	Patient
3	Relative
4	Other, specify

**Antibiotic Use Guidance:**

\* Systemic = Intravenous/oral/rectal



# 28 Day Follow-up

Participant Trial Number:      Participant Initials:

Randomising Site:

## D. Suspected Clinically Significant Antibiotic Related Events

1) Has the participant experienced any suspected clinically significant antibiotic related events from hospital discharge to 28 days following randomisation?    No     Yes

*If yes, complete the table below entering start and stop dates if known, if not known enter NK-MON-2017 or NK-NK-2017*

Event	Yes/No	Start date	Ongoing?	Stop date
Anaphylaxis	No <input type="checkbox"/> Yes <input type="checkbox"/>	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Gastrointestinal	No <input type="checkbox"/> Yes <input type="checkbox"/>	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Haematological	No <input type="checkbox"/> Yes <input type="checkbox"/>	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Hepatobiliary	No <input type="checkbox"/> Yes <input type="checkbox"/>	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Renal	No <input type="checkbox"/> Yes <input type="checkbox"/>	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Neurological	No <input type="checkbox"/> Yes <input type="checkbox"/>	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Dermatological	No <input type="checkbox"/> Yes <input type="checkbox"/>	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Cardiac	No <input type="checkbox"/> Yes <input type="checkbox"/>	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Muscular	No <input type="checkbox"/> Yes <input type="checkbox"/>	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Other	No <input type="checkbox"/> Yes <input type="checkbox"/> <i>If yes, specify:</i>  _____	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

2) Has the participant experienced Clostridium Difficile diarrhoeal infection from hospital discharge to 28 days following randomisation?

No     Yes

3) Has the participant experienced infection with a multi-drug resistant organism from hospital discharge to 28 days following randomisation?

No     Yes       If yes, specify \_\_\_\_\_

Form completed by (print name): \_\_\_\_\_

*(Please note: your name must be on the trial delegation log)*

Signature: \_\_\_\_\_

Date signed:   -     -

Completion Guidelines for CRF 9: 28 Day Follow-Up FormCenter for Disease Classification for Multi-Drug Resistant (MDR) bacteria:

Phenotype Name	Phenotype Code	Phenotype Definition
Methicillin-resistant <i>Staphylococcus aureus</i>	MRSA_HAI	<i>Staphylococcus aureus</i> that has tested Resistant (R) to at least 1 of the following: methicillin, oxacillin, or ceftazidime
Carbapenem-resistant Enterobacteriaceae	CREall_HAI	Any <i>Escherichia coli</i> , <i>Klebsiella oxytoca</i> , <i>Klebsiella pneumoniae</i> , or <i>Enterobacter</i> spp. that has tested Resistant (R) to at least 1 of the following: imipenem, meropenem, doripenem, or ertapenem
Carbapenem-resistant <i>E.coli</i>	CREcoli_HAI	Any <i>Escherichia coli</i> that has tested Resistant (R) to at least 1 of the following: imipenem, meropenem, doripenem, or ertapenem
Carbapenem-resistant <i>Enterobacter</i> spp.	CREenterobacter_HAI	Any <i>Enterobacter</i> spp. that has tested Resistant (R) to at least 1 of the following: imipenem, meropenem, doripenem, or ertapenem
Carbapenem-resistant <i>Klebsiella pneumoniae/oxytoca</i>	CREklebsiella_HAI	Any <i>Klebsiella oxytoca</i> or <i>Klebsiella pneumoniae</i> that has tested Resistant (R) to at least 1 of the following: imipenem, meropenem, doripenem, or ertapenem
Carbapenem-non-susceptible <i>Pseudomonas aeruginosa</i>	carbNS_PA_HAI	<i>Pseudomonas aeruginosa</i> that has tested either Intermediate (I) or Resistant (R) to at least 1 of the following: imipenem, meropenem, or doripenem
Extended-spectrum cephalosporin-resistant <i>E.coli</i>	ESCEcoli_HAI	Any <i>Escherichia coli</i> that has tested Resistant (R) to at least 1 of the following: cefepime, ceftriaxone, cefotaxime, or ceftazidime.
Extended-spectrum cephalosporin-resistant <i>Klebsiella pneumoniae/oxytoca</i>	ESCKlebsiella_HAI	Any <i>Klebsiella oxytoca</i> or <i>Klebsiella pneumoniae</i> that has tested Resistant (R) to at least 1 of the following: cefepime, ceftriaxone, cefotaxime, or ceftazidime.
Multidrug-resistant <i>Pseudomonas aeruginosa</i>	MDR_PA_HAI	<i>Pseudomonas aeruginosa</i> that has tested either Intermediate (I) or Resistant (R) to at least 1 drug in at least 3 of the following 5 categories: <ol style="list-style-type: none"> <li>1. Extended-spectrum cephalosporin (cefepime, ceftazidime)</li> <li>2. Fluoroquinolones (ciprofloxacin, levofloxacin)</li> <li>3. Aminoglycosides (amikacin, gentamicin, tobramycin)</li> <li>4. Carbapenems (imipenem, meropenem, doripenem)</li> <li>5. PIP/PIPTAZ (piperacillin, piperacillin/tazobactam)</li> </ol>
Carbapenem-non-susceptible <i>Acinetobacter</i> spp.	carbNS_Acine_HAI	Any <i>Acinetobacter</i> spp. that has tested either Intermediate (I) or Resistant (R) to at least 1 of the following: imipenem, meropenem, or doripenem
Multidrug-resistant <i>Acinetobacter</i> spp.	MDR_Acine_HAI	Any <i>Acinetobacter</i> spp. that has tested either Intermediate (I) or Resistant (R) to at least 1 drug in at least 3 of the following 6 categories: <ol style="list-style-type: none"> <li>1. Extended-spectrum cephalosporin (cefepime, ceftazidime, ceftriaxone, cefotaxime)</li> <li>2. Fluoroquinolones (ciprofloxacin, levofloxacin)</li> <li>3. Aminoglycosides (amikacin, gentamicin, tobramycin)</li> <li>4. Carbapenems (imipenem, meropenem, doripenem)</li> <li>5. PIP/PIPTAZ (piperacillin, piperacillin/tazobactam)</li> <li>6. Ampicillin/sulbactam</li> </ol>
Vancomycin-resistant <i>Enterococcus faecalis</i>	VREfaecalis_HAI	<i>Enterococcus faecalis</i> that has tested Resistant (R) to vancomycin
Vancomycin-resistant <i>Enterococcus faecium</i>	VREfaecium_HAI	<i>Enterococcus faecium</i> that has tested Resistant (R) to vancomycin