

# Antibiotics Form—Follow-up

Participant Trial Number:

   

Participant Initials:

 

Randomising Site:

**Antibiotics administered** — Complete this form if antibiotics are re-introduced in the follow-up period and up to 28 days post randomisation.

Antibiotics delivered for suspected sepsis episode *	Date and time started	Dose	Unit *	Frequency *	Route *	Given for reason other than infection?	Stopped/ Changed (please circle)	If antibiotic has stopped/ changed, indicate reason *	Date and time stopped
	dd - mon - yyyy hh : mm					No/Yes	No/Yes		dd - mon - yyyy hh : mm If patient discharged on antibiotics, please specify expected end date: dd - mon - yyyy hh : mm
						<b>If yes were these used for:</b> <input type="checkbox"/> Anti-inflammatory and immunomodulatory effects <input type="checkbox"/> Gastro-intestinal stasis <input type="checkbox"/> Other, please specify _____			
	dd - mon - yyyy hh : mm					No/Yes	No/Yes		dd - mon - yyyy hh : mm If patient discharged on antibiotics, please specify expected end date: dd - mon - yyyy hh : mm
						<b>If yes were these used for:</b> <input type="checkbox"/> Anti-inflammatory and immunomodulatory effects <input type="checkbox"/> Gastro-intestinal stasis <input type="checkbox"/> Other, please specify _____			

\* complete using coded lists on instructions page

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

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

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

Date signed:

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# Antibiotics Form—Follow-up

Participant Trial Number:

Participant Initials:

Randomising Site:

**Continuation Page** — Complete this form if antibiotics are re-introduced in the follow-up period and up to 28 days post randomisation.

Antibiotics delivered for suspected sepsis episode *	Date and time started	Dose	Unit *	Frequency *	Route *	Given for reason other than infection?	Stopped/ Changed (please circle)	If antibiotic has stopped/ changed, indicate reason *	Date and time stopped
	<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="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>					No/Yes	No/Yes		<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="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>
						<b>If yes were these used for:</b> <input type="checkbox"/> Anti-inflammatory and immunomodulatory effects <input type="checkbox"/> Gastro-intestinal stasis <input type="checkbox"/> Other, please specify _____			
	<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="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>					No/Yes	No/Yes		<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="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>
						<b>If yes were these used for:</b> <input type="checkbox"/> Anti-inflammatory and immunomodulatory effects <input type="checkbox"/> Gastro-intestinal stasis <input type="checkbox"/> Other, please specify _____			

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

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

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

Date signed:

-     -

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Participant Trial Number:

   

Participant Initials:

 

Randomising Site:

**Continuation Page** — Complete this form if antibiotics are re-introduced in the follow-up period and up to 28 days post randomisation.

Antibiotics delivered for suspected sepsis episode *	Date and time started	Dose	Unit *	Frequency *	Route *	Given for reason other than infection?	Stopped/ Changed (please circle)	If antibiotic has stopped/ changed, indicate reason *	Date and time stopped
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						<b>If yes were these used for:</b> <input type="checkbox"/> Anti-inflammatory and immunomodulatory effects <input type="checkbox"/> Gastro-intestinal stasis <input type="checkbox"/> Other, please specify _____			

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

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

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

Date signed:

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**Completion Guidelines for CRF 7: Antibiotics Form—Follow-up**

This is a rolling CRF to be updated as antibiotics prescribed change during a patient's care, therefore ensure this is signed off as each page is completed or at the end of the intervention period, whichever is first.

- 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.
- Times:** Please record all times in the 24-hour format.

**Completion Guidelines for CRF 7: Antibiotics Form—Follow-up**

- When completing the table please enter the numerical code corresponding to the following antibiotics as applicable:

Code	Antibiotic	Code	Antibiotic	Code	Antibiotic
1	AMIKACIN	32	DEMECLOCYCLINE HYDROCHLORIDE	63	TEDIZOLID
2	AMOXICILLIN	33	DOXYCYCLINE	64	TEICOPLANIN
3	AMPICILLIN	34	ERTAPENEM	65	TELAVANCIN
4	AMPICILLIN WITH FLUCLOXACILLIN	35	ERYTHROMYCIN	66	TEMOCILLIN
5	AZITHROMYCIN	36	FIDAXOMICIN	67	TETRACYCLINE
6	AZTREONAM	37	FLUCLOXACILLIN	68	TICARCILLIN WITH CLAVULANIC ACID
7	BENZYL PENICILLIN SODIUM (Penicillin G)	38	FOSFOMYCIN	69	TIGECYCLINE
8	CEFACLOR	39	GENTAMICIN	70	TINIDAZOLE
9	CEFADROXIL	40	IMIPENEM WITH CILASTATIN	71	TOBRAMYCIN
10	CEFALEXIN	41	LEVOFLOXACIN	72	TRIMETHOPRIM
11	CEFIXIME	42	LINEZOLID	73	VANCOMYCIN
12	CEFOTAXIME	43	LYMECYCLINE	74	OTHER
13	CEFRADINE	44	MEROPENEM		
14	CEFTAROLINE FOSAMIL	45	METHENAMINE HIPPURATE (Hexamine hippurate)		
15	CEFTAZIDIME	46	METRONIDAZOLE		
16	CEFTAZIDIME WITH AVIBACTAM	47	MINOCYCLINE		
17	CEFTOBIPROLE	48	MOXIFLOXACIN		
18	CEFTOZOZANE WITH TAZOBACTAM	49	NALIDIXIC ACID		
19	CEFTRIAZONE	50	NEOMYCIN SULFATE		
20	CEFUROXIME	51	NITROFURANTOIN		
21	CHLORAMPHENICOL	52	NORFLOXACIN		
22	CIPROFLOXACIN	53	OFLOXACIN		
23	CLARITHROMYCIN	54	OXYTETRACYCLINE		
24	CLINDAMYCIN	55	PHENOXYMETHYLPENICILLIN (Penicillin V)		
25	CO-AMOXICLAV	56	PIPERACILLIN WITH TAZOBACTAM		
26	CO-FLUAMPICIL	57	PIVMECILLINAM HYDROCHLORIDE		
27	COLISTIMETHATE SODIUM	58	RIFAMPICIN		
28	CO-TRIMOXAZOLE	59	RIFAXIMIN		
29	DALBAVANCIN	60	SODIUM FUSIDATE (Fusidic acid)		
30	DAPSONE	61	STREPTOMYCIN		
31	DAPTOMYCIN	62	SULFADIAZINE		

**Completion Guidelines for CRF 7: Antibiotics Form—Follow-up**

- When completing section A, please enter the numerical codes corresponding to the following units, frequency, routes and reasons as applicable:

Code	Unit
1	g
2	mg
3	other

Code	Frequency
1	Once daily—Od
2	Twice daily—Bd
3	Three times daily—Tds
4	Four times daily—Qds
5	One off
6	Continuous infusion

Code	Route
1	IV
2	Oral
3	Rectal
4	Nebuliser

Code	Reason for change
1	Antibiotic escalation
2	Antibiotic de-escalation
3	Re-infection/recurrence
4	New infection/superinfection
5	Clinical relevant suspected antibiotic associated adverse reaction (complete Antibiotic Adverse reaction CRF)
6	Antibiotics stopped
7	Other, please specify

- For antibiotics given at regular intervals (e.g. antibiotic X three times a day), record the value of an individual dose and then complete relevant frequency.
- For antibiotics given as continuous infusions, record the total dose given over the last 24 hours based on the patient prescription and the recorded units and complete the frequency column with code 7 for continuous infusion.

**Completion Guidelines for CRF 7: Antibiotics Form—Follow-up****Guidance on Macrolide drugs: Erythromycin, Azithromycin and Clarithromycin**

These drugs can sometimes be used for their effects other than for treating infection.

1. Used long term (many months) for their anti-inflammatory and immunomodulatory effects in patients with chronic lung diseases (e.g. COPD, bronchiectasis and asthma). It is likely that if a patient is admitted to critical care with sepsis, these drugs will not be continued for this purpose. However, they may be reintroduced later (perhaps within 28-days) or commenced as new therapy in a patient with chronic lung disease. If these drugs are given in this way, they need to be indicated as such in the antibiotic forms (intervention and follow up).
2. Erythromycin is sometimes used in an attempt to treat gastro-intestinal stasis in critical illness. It is an unlicensed use for this purpose and we do not recommend its use in this way. However, if it is used for this purpose and not for the treatment of infection, this will need indicating on the antibiotic forms (intervention and follow-up)

**For any use of a macrolide antibiotic in ADAPT-Sepsis, it is important that the research team discuss with the clinical team why they are being given within the intervention and follow up periods.**