	-	_	 _	 RCT	-	•		-	-	 #001	-	I	Ι	I	I	-	 it #0	-	Ι	Ι	Ι	Ι	
Patient ID	[

ELIGIBILITY CRITERIA FORM 1.1 (page 1 of 2)

Eligibility Criteria: Must meet both inclusion criteria, and none of exclusion criteria

Inclusion Criteria

		YES	NO
1.	Patient is in ICU or under the care of an ICU physician at time the blood culture is drawn or reported as positive AND	P	
2.	Patient has a positive blood culture with pathogenic bacteria (Please refer to case report form instructions for details, organism codes table).		
Exc	clusion Criteria		
1.	Patient already enrolled in the trial		Ť
2.	Patient has severe immune system compromise, as defined by: absolute neutrophil count <0.5x109/L or is receiving immunosuppressive treatment for solid organ or cell transplant		ф Т
3.	Patient has a prosthetic heart valve or synthetic endovascular graft		þ
4.	Patient has documented or strong suspicion of syndrome with well-defined requirement for prolonged treatment:		ф
	infective endocarditis osteomyelitis/septic arthritis undrainable/undrained abscess unremovable/unremoved prospthetic material		
5.	Patient has a single positive blood culture with a common contaminant organism according to Clinical Laboratory & Standards Institute (CLSI) Guidelines:		ф Т
	Coagulase negative staphylococciBacillus spp.Corynebacterium spp. ("diptheroids")Propionobacterium spp.Aerococcus spp.Micrococcus spp.		
6.	Patient has a positive blood culture with Staphylococcus aureus or Staphylococcus lugdunensis		ц Ц
7.	Patient has a positive blood culture with Candida spp. or other fungal species.		ф
	PROCEED TO NEXT PAGE	•	

		te #002		Visit #00	, 		
Pati ID							
		EENING FC	<u>)RM 1.2 (pa</u>	<u>ge 2 of 2)</u>			
1.	Eligible Non-Randomized Patients					YES	NO
	1. Patient or substitute decision m	aker (SDM)	declined consei	nt			
	2. Patient unable to give consent	and SDM not	available				
	3. ICU physician declined conser						
	3. Too physician declined conser	n, reason.					
	4. Consent not obtained due to ot	her reason, pl	ease specify:				
2. F	Patient status (please check ONE box o			Eligible	, non-randomize	d	
3.	Who provided consent?	Patient	SDM	N/A (co	nsent not obtaine	d)	
4.	Patient co-enrolled in another trial?	Yes	🗌 No				
5.	Research Associate Initials						
6.	Date of Randomization (dd/mm/yyyy)		20				
7.	Time of Randomization (24 hr format)						
8.	Randomization arm	7 D	🗌 14 D				

Pati		#010 Visit #000)								
IC	D DEMOGRAPHICS AND COMORBIDITIES FORM 2.1 (page 1 of 3)										
1	Patient's age	5. S ex	c female male								
	Hospital admit date										
	dd/mm/yyyy		ght cm inches								
	ICU admit date dd/mm/yyyy		· · · · · · · · · · · · · · · · · · ·								
4.	ICU admit time 24hh:mm		ual weight I I I I I I I I I I I I I I I I I I I								
8.	Baseline APACHE II Score:	Already available									
	(First 24 hours in ICU & for randomized pts of	nly) Calculated using worksheet (pl	ease keep copy)								
9.	Admission category to ICU (for patient		_								
10	Medical Surgical Trauma		_ Other (specify): dd/mmyyyy								
10.	Location immediately prior to this ICL Emergency room of this hospital	ICU (other hospital), adm date:									
	Hospital ward	Other hospital's ER or ward									
	Operating room	adm date:									
	Step down / intermediate care unit	Other (specify):									
11.	Diagnosis that Patient Was Admitted	to ICU (check ALL that apply):									
	Bloodstream infection Conges	stive heart failure	ancreatitis COPD								
		dial infarction/angina Hepatic d									
	Urinary infection										
	Abdominal infection Periphe	eral vascular disease									
	Soft tissue infection Cerebro	ovascular disease	Specify								
		ntestinal bleeding Other: Sp	ecify								
10	— —	ectrolyte disoder									
12.	Comorbidities (History of in past or p		_								
	Angina/myocardial infarction		Gastrointestinal disease								
	Congestive heart failure	Asthma	Solid cancer, non-metastatic								
	Congestive heart failure NYHA IV	Other Severe lung disease	Solid cancer, metastatic								
	Arrhythmia	Specify:	Leukemia/Lymphoma								
	Valvular heart disease	Alcohol abuse									
	Congenital heart disease	IV drug abuse	Solid organ transplantation								
	Peripheral vascular disease	Obesity (BMI >30kg/m)	Neutropenia								
	Cerebrovascular disease	Liver disease (no portal HTN)	Corticosteroid use >15mg/d								
	Diabetes with end-organ damage	Liver disease (cirrhosis/portal HTN)									
	Diabetes without organ damage	Dementia	Other immunosuppression								
	Renal insufficiency (Cr>1.5x norm)	Other neurologic disorder	Specify:								
	Dialysis dependency	Specify:	NONE OF THE ABOVE								

-	BALANCE RCT #067 Plate #011 Visit #000 Itient Itient ID Itient
	DEMOGRAPHICS AND COMORBIDITIES FORM 2.2 (page 2 of 3)
12.	Date & time first positive blood culture (index blood culture) dd/mmyyyy 24hh : mm 'collected' for which patient enrolled in study 20 i
13.	Date & time first positive blood culture (index blood culture)
14.	Where was the positive sample drawn from (check ALL that apply):
15.	Number of positive blood culture "sets" within 24 hrs of index blood culture set (see case report instructions for what constitutes a blood cutlure set)
16.	Number of unique organisms isolated within 24 hrs of index blood culture set: 1 (monomicrobial) ≥ 2 (polymicrobial)
17.	Name(s) of organism(s) isolated within 24 hrs of index blood culture set (organism codes available in instruction booklet) organism 1 code
	organism 2 code
	organism 3 code
	organism 4 code
	organism 5 code

BALANCE RCT #067	Plate #012	Visit #000

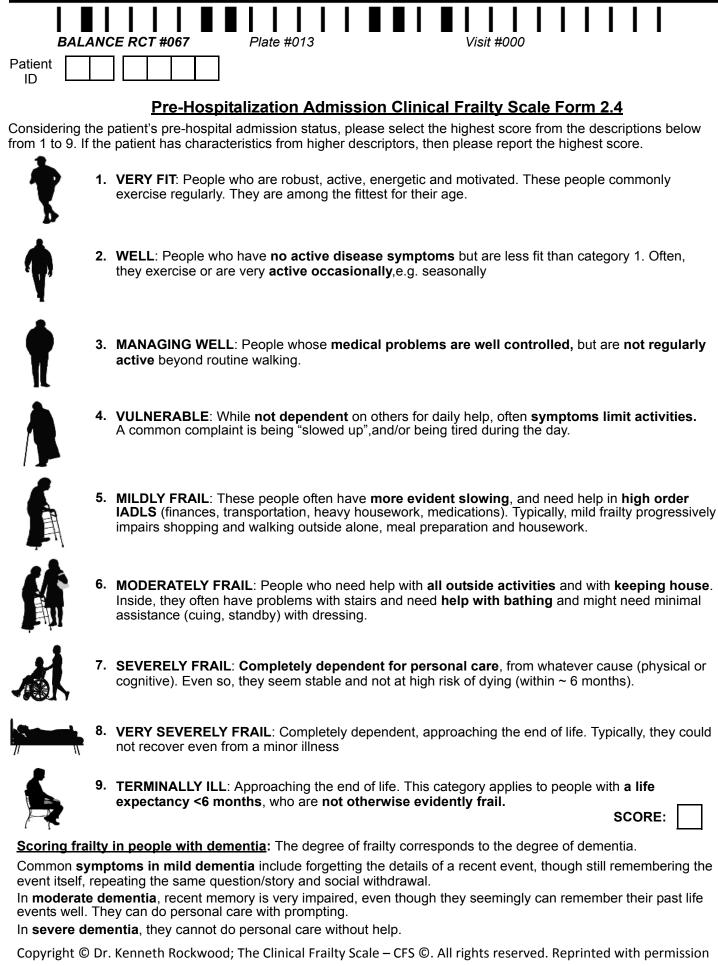
Patient ID

INDEX CULTURE AND POTENTIAL SOURCE OF INFECTION FORM 2.3 (page 3 of 3)

Physician diagnosis for possible source of infection (CHECK ALL THAT APPLY)

	not a possible source	unlikely source	possible source	probable source	most likely source
1. vascular catheter					
2. pneumonia/ lung/ respiratory					
3. urinary tract infection/pyelonephritis					
4. intra-abdominal/ hepato-biliary					
5. skin and/or soft tissue					
6. undefined/unknown (primary bacteremia	a)				
7. other infection; specify:					

not a possible source: no documentation/mention of this source in physician's notes unlikely source: documented as not likely or a query in physician's notes possible source: documented as likely a possible source in physician's notes probable source: documented as highly likely but not certain source of infection most likely source: documented as source of infection in physician's notes



2016 September 12 (ADDED 2018 Jul 09)

	BALANCE RCT #067 Plate #120 Visit #000									
	Datient DUTCOME FORM 3.1									
1.										
	Start Date End Date 1. 2.0 2.0									
	3.									
	4. 20 20									
	Outcome: Survival and Lengths of Stay									
2.	Was the patient discharged from the ICU alive?									
3.	Date of death or discharge from the ICU (dd/mm/yyyy)									
4.	Was patient re-admitted to ICU?									
	Re-admission Date Discharge Date									
	1st episode									
	2nd episode 20 20									
	3rd episode 2 0 2 0									
5.	Was the patient discharged from the hospital alive ?									
6.	Date of death or live hospital discharge (dd/mm/yyyy)									
7.	Discharged to: Home Rehabilitation facility Acute care facility									
	Long term care facility Chronic care facility Other, specify:									
8.	90 day outcome assessment date (dd/mm/yyyy) (90 days from positive (index) blood culture collection date) 2 0 2 0									
9.	Outcome at day 90? (Death on day 90 should be documented as "Dead")									
	□ Dead □ Alive in hospital □ Alive in acute care facility □ Alive at home □ Dead □ Rehabilitation facility □ Long term care facility □ Other. spedify:									
	Rehabilitation facility Long term care facility Other, spedify: Not known, reason:									
10.	Subjective Comments about patient, infection, course of illness or treatment that you believe are important to convey									
	that you believe are important to convey									

BALANCE RCT #067 P	Plate #020	Visit #000	
Patient	Tale #020	VISIL #000	
			CODES:
		TIBILITIES OF ORGANISM(S)	S = Susceptible
<u>IN /N</u>	DEX BLOOD	CULTURE FORM 4.1	I = Intermediate
ORGANISM #1 Organis	m code [.]	— ——	R = Resistant
- - - - - - -			CODE
ANTIMICROBIAL (check ALL that	CODE	meropenem	
ampicillin / amoxicillin		gentamicin	
amoxicillin-clavulanate		tobramycin	
cloxacillin/oxacillin		amikacin	
penicillin		vancomycin	
piperacillin		tigecycline	
piperacillin-tazobactam		colistin/colistemethate	
ticarcillin-clavulanate		polymyxin B	
cefazolin		erythro/azithro/clarithro	
ceftriaxone/cefotaxime		linezolid	
ceftazidime		other:	
clindamycin		other:	
tetracycline/doxycycline		other	
tmp-smx (septra)		other	🗌
ciprofloxacin		other	
levofloxacin		other:	
moxifloxacin		other:	
ertapenem		other:	
imipenem		other:	

BALANCE RCT #067 P	late #021	Visit #000	
Patient			
			CODES:
		TIBILITIES OF ORGANISM(S)	S = Susceptible I = Intermediate
		CULTURE FORM 4.2	R = R esistant
ORGANISM #2 Organis	m code:		CODE
ANTIMICROBIAL (check ALL that		meropenem	
ampicillin / amoxicillin		gentamicin	
amoxicillin-clavulanate		tobramycin	
cloxacillin/oxacillin		amikacin	
penicillin		vancomycin	
piperacillin		tigecycline	
piperacillin-tazobactam		colistin/colistemethate	
ticarcillin-clavulanate		polymyxin B	
cefazolin		erythro/azithro/clarithro	
ceftriaxone/cefotaxime		linezolid	
ceftazidime		other:	
clindamycin		other:	
tetracycline/doxycycline		other	
tmp-smx (septra)		other	
ciprofloxacin		other	
levofloxacin		other:	
moxifloxacin		other:	
ertapenem		other:	
imipenem		other:	

BALANCE RCT #067 P	Plate #022	Visit #000	
Patient			
			CODES:
		TIBILITIES OF ORGANISM(S) CULTURE FORM 4.3	S = Susceptible I = Intermediate
ORGANISM # 3 Organis			R = Resistant
ANTIMICROBIAL (check ALL that			CODE
_			
ampicillin / amoxicillin		gentamicin	
amoxicillin-clavulanate		tobramycin	
cloxacillin/oxacillin		amikacin	
penicillin		vancomycin	
piperacillin		tigecycline	
piperacillin-tazobactam		colistin/colistemethate	
ticarcillin-clavulanate		polymyxin B	
cefazolin		erythro/azithro/clarithro	
ceftriaxone/cefotaxime		linezolid	
ceftazidime		other:	
clindamycin		other:	
tetracycline/doxycycline		other	
tmp-smx (septra)		other	[]
ciprofloxacin		other	
levofloxacin		other:	
moxifloxacin		other:	
ertapenem		other:	
imipenem		other:	

BALANCE RCT #067	late #023	Visit #000	
Patient			1
<u>IN ///</u>		TIBILITIES OF ORGANISM(S) CULTURE FORM 4.4	CODES: S = Susceptible I = Intermediate R = Resistant
ORGANISM # 4 Organis			CODE
ANTIMICROBIAL (check ALL that	apply) CODE	meropenem	
ampicillin / amoxicillin		gentamicin	
amoxicillin-clavulanate		tobramycin	
cloxacillin/oxacillin		amikacin	
penicillin		vancomycin	
piperacillin		tigecycline	
piperacillin-tazobactam		colistin/colistemethate	
ticarcillin-clavulanate		polymyxin B	
cefazolin		erythro/azithro/clarithro	
ceftriaxone/cefotaxime		linezolid	
ceftazidime		other:	
clindamycin		other:	
tetracycline/doxycycline		other	🗌
tmp-smx (septra)		other	
ciprofloxacin		other	
levofloxacin		other:	
moxifloxacin		other:	
ertapenem		other:	
imipenem		other:	

BALANCE RCT #067	late #024	₩ ┃ ┃ ┃ 	
Patient D			[]
ANTIMICROB IN <i>IN</i>	DEX BLOOD	TIBILITIES OF ORGANISM(S) CULTURE FORM 4.5	CODES: S = Susceptible I = Intermediate R = Resistant
ORGANISM # 5 Organis			CODE
ANTIMICROBIAL (check ALL that	apply) CODE	meropenem	
ampicillin / amoxicillin		gentamicin	
amoxicillin-clavulanate		tobramycin	
cloxacillin/oxacillin		amikacin	
penicillin		vancomycin	
piperacillin		tigecycline	
piperacillin-tazobactam		colistin/colistemethate	
ticarcillin-clavulanate		polymyxin B	
cefazolin		erythro/azithro/clarithro	
ceftriaxone/cefotaxime		linezolid	
ceftazidime		other:	
clindamycin		other:	
tetracycline/doxycycline		other	_ 🗌
tmp-smx (septra)		other	_ 🗌
ciprofloxacin		other	_
levofloxacin		other:	
moxifloxacin		other:	
ertapenem		other:	
imipenem		other:	

BALANCE Patient		#030	Visit #000			
<u>(any tin</u>		IICROBIAL TREATMI re to 30d after index	ENT FORM 5.1 blood culture collection	on date)	<u>)</u>	
Antimicrobial Code	Start Date dd/mm/yyyy	Start Time	Stop Date dd/mm/yyyy		Dose (mg)	
1. Route	(other, specify)	/:/ ncy	2_0	/	 Yes	
2.				/		
Route	(other, specify)	ncy (other, spec	ify) Continued after dis	scharge	□ Yes	□ No
3.	20			/		
Route	(other, specify)	ncy (other, spec	ify) Continued after dis	scharge	□ Yes	□ No
4.	20			/		
Route	(other, specify)	ncy (other, spec	ify) Continued after dis	scharge	□ Yes	□ No
5.	20		20	/		
Route	(other, specify)	ncy (other, spec	ify) Continued after dis	scharge	□ Yes	□ No
6.	20			/		
Route	(other, specify)	ncy (other, spec	ify) Continued after dis	scharge	□ Yes	□ No
7.				/		
Route	(other, specify)	ncy (other, spec	ify) Continued after dis	scharge	□ Yes	
8.	20			/		
Route	(other, specify)	ncy (other, spec	ify) Continued after dis	scharge	□ Yes	□ No
	Please che	eck if additional forms re	quired for reporting			

	RCT #067 Plate	#031	Visit #000	1111	I	
Patient		#031	VISIL #000			
ID L		CROBIAL TREATM		-		
<u>(any tin</u>	ne from 3 days befor	<u>e to 30d after index</u>	<u>x blood culture</u>	collection dat	<u>te)</u>	
Antimicrobial Code	Start Date dd/mm/yyyy	Start Time	Stop Dat dd/mm/yy	te /yy	Dos (mg)	-
9.			2	0 /		
Route	(other, specify)	cy (other, spec	cify) Continue	d after discharge	, □ Yes	□ No
10.	20		2	0 /		
Route	(other, specify)	cy (other, spec	cify) Continue	d after discharge	y □ Yes	□ No
11.	20		2	0 /		
Route	(other, specify)	cy (other, spec	cify) Continue	d after discharge	y Yes	□ No
12.	20		2	0 /		
Route	(other, specify)	cy (other, spec	cify) Continue	d after discharge	, □ Yes	□ No
13.	20		2	0 /		
Route	(other, specify)	cy (other, spec	cify) Continue	d after discharge	, □ Yes	□ No
14.			2	0 /		
Route	(other, specify)	cy (other, spec	cify) Continue	d after discharge	y □ Yes	□ No
15.	20		2	0 /		
Route	(other, specify)	cy (other, spec	cify) Continue	d after discharge	y □ Yes	□ No
16.			2	0 /		
Route	(other, specify)	cy (other, spec	cify) Continue	d after discharge	, D Yes	
	Please chec	ck if additional forms re	equired for reporti	ng		

BALANCE		#032	Visit #000		
			NT FORM 5.3		
<u>(any tir</u>			lood culture collection	<u>date)</u>	
Antimicrobial Code	Start Date dd/mm/yyyy	Start Time	Stop Date dd/mm/yyyy	Dos (mg	
17.				/	
Route	(other, specify)	cy (other, specify	Continued after discha	arge 🗌 Yes	□ No
18.	20			/	
Route	(other, specify)	cy (other, specify	Continued after discha	arge 🛛 Yes	□ No
19.	20			/	
Route	(other, specify)	cy (other, specify	Continued after discha	arge 🗌 Yes	□ No
20.				/	
Route	(other, specify)	cy (other, specify	Continued after discha	irge 🗌 Yes	□ No
21.	20			/	
Route	(other, specify)	cy (other, specify	Continued after discha	arge 🗌 Yes	□ No
22.	20			/	
Route	(other, specify)	cy (other, specify	Continued after discha	ırge 🗍 Yes	
23.	20			/	
Route	(other, specify)	cy (other, specify	Continued after discha	arge 🗌 Yes	□ No
24.	20			/	
Route	(other, specify)	cy (other, specify	Continued after discha	arge 🗌 Yes	
	Please chec	k if additional forms requ	uired for reporting		

	RCT #067 Plate	#033	Visit #000				
Patient							
ID L		ICROBIAL TREATM					
<u>(any tii</u>	<u>me from 3 days befor</u>	<u>e to 30d after index</u>	blood culture coll	ection date	<u>e)</u>		
Antimicrobial Code	Start Date dd/mm/yyyy	Start Time	Stop Date dd/mm/yyyy		Dose (mg)	-	
25.	20		20	/			
Route	(other, specify)	cy (other, spec	ify) Continued aft	er discharge	□ Yes	□ No	
26.	20		20	/			
Route	(other, specify)	cy (other, spec	ify) Continued aft	er discharge	□ Yes	□ No	
27.	20		20	/			
Route	(other, specify)	cy (other, spec	ify) Continued aft	er discharge	□ Yes	□ No	
28.				/			
Route	(other, specify)	cy (other, spec	ify) Continued aft	er discharge	□ Yes	□ No	
29.	20		20	/			
Route	(other, specify)	cy (other, spec	ify) Continued aft	er discharge	□ Yes	□ No	
30.	20			/			
Route	(other, specify)	cy (other, spec	ify) Continued aft	er discharge	☐ Yes	□ No	
31.	20			/			
Route	(other, specify)	cy (other, spec	ify) Continued aft	er discharge	☐ Yes	□ No	
32.	20		20				
Route	(other, specify)	cy (other, spec	ify) Continued aft	er discharge	☐ Yes	□ No	
Please check if additional forms required for reporting							

BALANCE RCT #067 Plate #040	I I
Patient	
SOURCE CONTROL PR	OCEDURES FORM 6.1
(From 48h prior to 30d after first in NO SOURCE CONTROL PROCEDURES TO REPORT	dex blood culture collection date)
Source Control Procedure(s) Check All that Apply	Date Source Control Procedure First Performed dd/mm/yyyy
central vascular catheter removal	
central vascular catheter exchange over guidewire	
peripheral vascular catheter removal/exchange	
peripheral arterial catheter removal/exchange	
relief of ureteric obstruction or bladder obstruction	
change or removal of Foley catheter	
change or removal of nephrostomy tube	
relief of biliary duct obstruction via ERCP	
relief of biliary duct obstruction via surgery	
abscess drainage at bedside	
abscess drainage in operating room	
abscess drainage in radiology department	
wound debridement at bedside	
wound debridement in operating room	
thoracentesis without leaving drain in situ	
thoracostomy (chest tube) insertion	
paracentesis	
other; specify:	
—	

BALANCE RCT #067	Plate #050		Visit #	000			
Patient							
	BLOOD CULTU						
NO BLOOD CULTURES AFTE	index culture				<u>.er)</u>		
Date and time of blood cultur		Positive?					
dd/mm/yyyy	24hh : mm	YES NO	(Organism	Code(s)	 	
Index Culture:							
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9. 20							
10.							
11.							
12.] [
13.][
14.							
15.							
16.							
17.		- –]					
	check if additiona	_ I forms require	ed for repo	orting			

Pat	BALANCE RCT #067	Plate #051		Visit #000				
	BLOOD CULTURE RESULTS_FORM 7.2 (From index culture collection date to 30 days later)							
Date	e and time of blood cultur				~			
	dd/mm/yyyy	24hh : mm	Positive? YES NO	Organism Co	ode(s)			
18.	20							
19.								
20.								
21.								
22.								
23.								
24.								
25.								
26.								
27.								
28.								
29.								
30.								
31.								
32.		┘└─┴─┘└─┬─ ┐┌─┬─┐┌─┬─						
33.		┘└─┴─┘└──┬─						
34.								

BALANCE RCT #067	late #150	Visit #000	
Patient D			
ANTIMICROB IN BLC		TIBILITIES OF ORGANISM(S) RE RESULTS FORM 7.3	CODES: S = Susceptible I = Intermediate R = Resistant
ORGANISM #1 Organis			CODE
ANTIMICROBIAL (check ALL that	CODE	meropenem	
ampicillin / amoxicillin		gentamicin	
amoxicillin-clavulanate		tobramycin	
cloxacillin/oxacillin		amikacin	
penicillin		vancomycin	
piperacillin		tigecycline	
piperacillin-tazobactam		colistin/colistemethate	
ticarcillin-clavulanate		polymyxin B	
cefazolin		erythro/azithro/clarithro	
ceftriaxone/cefotaxime		linezolid	
ceftazidime		other:	
clindamycin		other:	
tetracycline/doxycycline		other	_ 🗌
tmp-smx (septra)		other	_
ciprofloxacin		other	_
levofloxacin		other:	_
moxifloxacin		other:	
ertapenem		other:	_
imipenem		other:	

BALANCE RCT #067	late #151	Visit #000	
Patient			
IN BLC		TIBILITIES OF ORGANISM(S) RE RESULTS FORM 7.4	CODES: S = Susceptible I = Intermediate R = Resistant
ORGANISM # 2 Organis			CODE
ANTIMICROBIAL (check ALL that	CODE		
ampicillin / amoxicillin		gentamicin	
amoxicillin-clavulanate		tobramycin	
cloxacillin/oxacillin		amikacin	
penicillin		vancomycin	
piperacillin		tigecycline	
piperacillin-tazobactam		colistin/colistemethate	
ticarcillin-clavulanate		polymyxin B	
cefazolin		erythro/azithro/clarithro	
ceftriaxone/cefotaxime		linezolid	
ceftazidime		other:	_
clindamycin		other:	
tetracycline/doxycycline		other	_ 🗌
tmp-smx (septra)		other	_
ciprofloxacin		other	_
levofloxacin		other:	
moxifloxacin		other:	
ertapenem		other:	
imipenem		other:	

BALANCE RCT #067	late #152	Visit #000	
Patient D			00050
ANTIMICROB IN BLC		TIBILITIES OF ORGANISM(S) RE RESULTS FORM 7.5	CODES: S = Susceptible I = Intermediate R = Resistant
ORGANISM # 3 Organis			CODE
ANTIMICROBIAL (check ALL that	CODE	meropenem	
ampicillin / amoxicillin		gentamicin	
amoxicillin-clavulanate		tobramycin	
cloxacillin/oxacillin		amikacin	
penicillin		vancomycin	
piperacillin		tigecycline	
piperacillin-tazobactam		colistin/colistemethate	
ticarcillin-clavulanate		polymyxin B	
cefazolin		erythro/azithro/clarithro	
ceftriaxone/cefotaxime		linezolid	
ceftazidime		other:	— 🗌
Clindamycin		other:	—
tetracycline/doxycycline		other	_ 🗌
tmp-smx (septra)		other	_ []
ciprofloxacin		other	_ []
levofloxacin		other:	
moxifloxacin		other:	
ertapenem		other:	
imipenem		other:	

BALANCE RCT #067	late #153	Visit #000	
Patient D			
ANTIMICROB IN BLC		TIBILITIES OF ORGANISM(S) RE RESULTS FORM 7.6	CODES: S = Susceptible I = Intermediate R = Resistant
ORGANISM # 4 Organis			CODE
ANTIMICROBIAL (check ALL that	CODE	meropenem	
ampicillin / amoxicillin		gentamicin	
amoxicillin-clavulanate		tobramycin	
cloxacillin/oxacillin		amikacin	
penicillin		vancomycin	
piperacillin		tigecycline	
piperacillin-tazobactam		colistin/colistemethate	
ticarcillin-clavulanate		polymyxin B	
cefazolin		erythro/azithro/clarithro	
ceftriaxone/cefotaxime		linezolid	
ceftazidime		other:	— 🗌
Clindamycin		other:	—
tetracycline/doxycycline		other	$-\Box$
tmp-smx (septra)		other	_ 🗌
ciprofloxacin		other	_
levofloxacin		other:	
moxifloxacin		other:	
ertapenem		other:	
imipenem		other:	

BALANCE RCT #067	late #154	Visit #000	
Patient D			
ANTIMICROB IN BLC		TIBILITIES OF ORGANISM(S) RE RESULTS FORM 7.7	CODES: S = Susceptible I = Intermediate R = Resistant
ORGANISM # 5 Organis			CODE
ANTIMICROBIAL (check ALL that	CODE	meropenem	
ampicillin / amoxicillin		gentamicin	
amoxicillin-clavulanate		tobramycin	
cloxacillin/oxacillin		amikacin	
penicillin		vancomycin	
piperacillin		tigecycline	
piperacillin-tazobactam		colistin/colistemethate	
ticarcillin-clavulanate		polymyxin B	
cefazolin		erythro/azithro/clarithro	
ceftriaxone/cefotaxime		linezolid	
ceftazidime		other:	
clindamycin		other:	— 🗌
tetracycline/doxycycline		other	_ 🗌
tmp-smx (septra)		other	_
ciprofloxacin		other	_
levofloxacin		other:	$-\Box$
moxifloxacin		other:	
ertapenem		other:	
imipenem		other:	

BALANCE RCT #067	late #155	Visit #000	
Patient D			[]
ANTIMICROB IN BLC		TIBILITIES OF ORGANISM(S) RE RESULTS FORM 7.8	<u>CODES:</u> S = Susceptible I = Intermediate R = Resistant
ORGANISM # 6 Organis			CODE
ANTIMICROBIAL (check ALL that	CODE	meropenem	
ampicillin / amoxicillin		gentamicin	
amoxicillin-clavulanate		tobramycin	
cloxacillin/oxacillin		amikacin	
penicillin		vancomycin	
piperacillin		tigecycline	
piperacillin-tazobactam		colistin/colistemethate	
ticarcillin-clavulanate		polymyxin B	
cefazolin		erythro/azithro/clarithro	
ceftriaxone/cefotaxime		linezolid	
ceftazidime		other:	— 🗌
clindamycin		other:	
tetracycline/doxycycline		other	_ 🗌
tmp-smx (septra)		other	_ 🗌
ciprofloxacin		other	_
levofloxacin		other:	
moxifloxacin		other:	
ertapenem		other:	
imipenem		other:	

BALANCE RCT #067	late #156	Visit #000	
Patient D			
ANTIMICROB IN BLC		TIBILITIES OF ORGANISM(S) RE RESULTS FORM 7.9	<u>CODES:</u> S = Susceptible I = Intermediate R = Resistant
ORGANISM # 7 Organis			CODE
ANTIMICROBIAL (check ALL that	CODE	meropenem	
ampicillin / amoxicillin		gentamicin	
amoxicillin-clavulanate		tobramycin	
cloxacillin/oxacillin		amikacin	
penicillin		vancomycin	
piperacillin		tigecycline	
piperacillin-tazobactam		colistin/colistemethate	
ticarcillin-clavulanate		polymyxin B	
cefazolin		erythro/azithro/clarithro	
ceftriaxone/cefotaxime		linezolid	
ceftazidime		other:	—
clindamycin		other:	—
tetracycline/doxycycline		other	_ 🗌
tmp-smx (septra)		other	_ 🗌
ciprofloxacin		other	_
levofloxacin		other:	
moxifloxacin		other:	
ertapenem		other:	
imipenem		other:	

BALANCE RCT #067	late #157	Visit #000	
Patient D			[]
ANTIMICROB IN BLO		TIBILITIES OF ORGANISM(S) E RESULTS FORM 7.10	<u>CODES:</u> S = Susceptible I = Intermediate R = Resistant
ORGANISM # 8 Organis			CODE
ANTIMICROBIAL (check ALL that	apply) CODE	meropenem	
ampicillin / amoxicillin		gentamicin	
amoxicillin-clavulanate		tobramycin	
cloxacillin/oxacillin		amikacin	
penicillin		vancomycin	
piperacillin		tigecycline	
piperacillin-tazobactam		colistin/colistemethate	
ticarcillin-clavulanate		polymyxin B	
cefazolin		erythro/azithro/clarithro	
ceftriaxone/cefotaxime		linezolid	
ceftazidime		other:	
clindamycin		other:	
tetracycline/doxycycline		other	_
tmp-smx (septra)		other	_ 🗌
ciprofloxacin		other	
levofloxacin		other:	
moxifloxacin		other:	
ertapenem		other:	
imipenem		other:	

BALANCE RCT #067	late #158	Visit #000	
Patient D			
ANTIMICROB IN BLO		TIBILITIES OF ORGANISM(S) E RESULTS FORM 7.11	<u>CODES:</u> S = Susceptible I = Intermediate R = Resistant
ORGANISM # 9 Organis			CODE
ANTIMICROBIAL (check ALL that	apply) CODE	meropenem	
ampicillin / amoxicillin		gentamicin	
amoxicillin-clavulanate		tobramycin	
cloxacillin/oxacillin		amikacin	
penicillin		vancomycin	
piperacillin		tigecycline	
piperacillin-tazobactam		colistin/colistemethate	
ticarcillin-clavulanate		polymyxin B	
cefazolin		erythro/azithro/clarithro	
ceftriaxone/cefotaxime		linezolid	
ceftazidime		other:	
clindamycin		other:	
tetracycline/doxycycline		other	_
tmp-smx (septra)		other	_
ciprofloxacin		other	[]
levofloxacin		other:	
moxifloxacin		other:	
ertapenem		other:	
imipenem		other:	

BALANCE RCT #067 P	late #159	Visit #000	
Patient D			00050
ANTIMICROB IN BLO		TIBILITIES OF ORGANISM(S) E RESULTS FORM 7.12	<u>CODES:</u> S = Susceptible I = Intermediate R = Resistant
-	sm code:		CODE
ANTIMICROBIAL (check ALL that	CODE	meropenem	
ampicillin / amoxicillin		gentamicin	
amoxicillin-clavulanate		tobramycin	
cloxacillin/oxacillin		amikacin	
penicillin		vancomycin	
piperacillin		tigecycline	
piperacillin-tazobactam		colistin/colistemethate	
ticarcillin-clavulanate		polymyxin B	
cefazolin		erythro/azithro/clarithro	
ceftriaxone/cefotaxime		linezolid	
ceftazidime		other:	
clindamycin		other:	
tetracycline/doxycycline		other	_ 🗌
tmp-smx (septra)		other	_ 🗌
ciprofloxacin		other	_ 🗌
levofloxacin		other:	
moxifloxacin		other:	
ertapenem		other:	
imipenem		other:	

B I
ANY OTHER POSITIVE CULTURE RESULTS FORM 8.1
(From_index culture collection date to 30 days later)
Specimen Type Urine Bronchial brush/wash/lavage Endotracheal tube aspirate Dissue biopsy
Abscess Burn Wound CSF Stool Body fluids
Other (specify)
Organism Code(s)
2. Date of collection
Specimen Type 🔲 Urine 🔲 Bronchial brush/wash/lavage 🗌 Endotracheal tube aspirate 🔲 Tissue biopsy
Abscess Burn Wound CSF Stool Body fluids
Other (specify)
Organism Code(s)
3. Date of collection 20 Time of collection (24 hh:mm)
Specimen Type 🔲 Urine 🔲 Bronchial brush/wash/lavage 🗌 Endotracheal tube aspirate 🔲 Tissue biopsy
Abscess Burn Wound CSF Stool Body fluids
Other (specify)
Organism Code(s)
4. Date of collection 20 Time of collection (24 hh:mm)
Specimen Type 🔲 Urine 🔲 Bronchial brush/wash/lavage 🗌 Endotracheal tube aspirate 🔲 Tissue biopsy
Abscess Burn Wound CSF Stool Body fluids
Other (specify) Pleural
Organism Code(s)
5. Date of collection 20 Time of collection (24 hh:mm)
Specimen Type 🔲 Urine 🔲 Bronchial brush/wash/lavage 🗌 Endotracheal tube aspirate 🔲 Tissue biopsy
Abscess Burn Wound CSF Stool Body fluids
Other (specify) Pleural
Organism Code(s)
2016 September 12 Please check if additional forms required for another organism

B B
Patient ID
ANY OTHER POSITIVE CULTURE RESULTS FORM 8.2
(From index culture collection date to 30 days later)
6. Date of collection 20 Time of collection (24 hh:mm)
Specimen Type Urine Bronchial brush/wash/lavage Endotracheal tube aspirate Tissue biopsy
Abscess Burn Wound CSF Stool Body fluids
Other (specify)
Organism Code(s)
7. Date of collection 20 Time of collection : (24 hh:mm)
Specimen Type 🔲 Urine 🔲 Bronchial brush/wash/lavage 🗌 Endotracheal tube aspirate Tissue biopsy
Abscess Burn Wound CSF Stool Body fluids
Other (specify)
Organism Code(s)
8. Date of collection 20 Time of collection (24 hh:mm)
Specimen Type 🔲 Urine 🔲 Bronchial brush/wash/lavage 🗌 Endotracheal tube aspirate 🔲 Tissue biopsy
Abscess Burn Wound CSF Stool Body fluids
Other (specify)
Organism Code(s)
9. Date of collection 20 Time of collection (24 hh:mm)
Specimen Type Urine Bronchial brush/wash/lavage Endotracheal tube aspirate Fissue biopsy
Abscess Burn Wound CSF Stool Body fluids
Other (specify)
Organism Code(s)
10. Date of collection 2 0 Time of collection : (24 hh:mm)
Specimen Type 🔲 Urine 🔲 Bronchial brush/wash/lavage 🗌 Endotracheal tube aspirate 🛄 Tissue biopsy
Abscess Burn Wound CSF Stool Body fluids
Other (specify)
Organism Code(s)

2016 September 12	Please check if additional forms required for another of	organism
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BALANCE RCT #067 F	Plate #070	Visit #000	
Patient			
OTHER POSITIVE CULTURE RESU		SUSCEPTIBILITIES OF ORGANISM	<u>S) FORM 9.1</u>
	m INDEX CULTURE TO	D 30 DAYS LATER) S = Susceptible I = Intermediate R = Resistant	
ANTIMICROBIAL (check ALL that	apply) CODE	meropenem	
ampicillin / amoxicillin		gentamicin	
amoxicillin-clavulanate		tobramycin	
cloxacillin/oxacillin		amikacin	
penicillin		vancomycin	
piperacillin		tigecycline tigecycline	
piperacillin-tazobactam		colistin/colistemethate	
ticarcillin-clavulanate		polymyxin B	
cefazolin		erythro/azithro/clarithro	
ceftriaxone/cefotaxime		fluconazole	
ceftazidime		voriconazole	
clindamycin		caspofungin	
tetracycline/doxycycline		micafungin	
tmp-smx (septra)		anidulafungin	
ciprofloxacin		amphotericin	
levofloxacin		other:	-
moxifloxacin		other:	- 🗌
ertapenem		other:	- 🗌
imipenem		other:	- 🗌

BALANCE RCT #067 F	Plate #071	Visit #000	
Patient			
OTHER POSITIVE CULTURE RESU		SUSCEPTIBILITIES OF ORGANISM	<u>S) FORM 9.2</u>
	m index culture to	D 30 DAYS LATER) CODES: S = Susceptible I = Intermediate R = Resistant R = Resistant	
ANTIMICROBIAL (check ALL that	apply) CODE	meropenem	
ampicillin / amoxicillin		gentamicin	
amoxicillin-clavulanate		tobramycin	
cloxacillin/oxacillin		amikacin	
penicillin		vancomycin	
piperacillin		tigecycline tigecycline	
piperacillin-tazobactam		colistin/colistemethate	
ticarcillin-clavulanate		polymyxin B	
cefazolin		erythro/azithro/clarithro	
ceftriaxone/cefotaxime		fluconazole	
ceftazidime		voriconazole	
clindamycin		caspofungin	
tetracycline/doxycycline		micafungin	
tmp-smx (septra)		anidulafungin	
ciprofloxacin		amphotericin	
levofloxacin		other:	-
moxifloxacin		other:	-
ertapenem		other:	-
imipenem		other:	- 🗌

BALANCE RCT #067 F	Plate #072	Visit #000	
Patient			
OTHER POSITIVE CULTURE RESUL			<u>S) FORM 9.3</u>
		S = Susceptible	
ORGANISM # 3 Organis	m code:	I = Intermediate R = Resistant	
ANTIMICROBIAL (check ALL that		meropenem	
ampicillin / amoxicillin		gentamicin	
amoxicillin-clavulanate		tobramycin	
cloxacillin/oxacillin		amikacin	
penicillin		vancomycin	
piperacillin		tigecycline tigecycline	
piperacillin-tazobactam		colistin/colistemethate	
ticarcillin-clavulanate		polymyxin B	
cefazolin		erythro/azithro/clarithro	
ceftriaxone/cefotaxime		fluconazole	
ceftazidime		voriconazole	
clindamycin		caspofungin	
tetracycline/doxycycline		micafungin	
tmp-smx (septra)		anidulafungin	
ciprofloxacin		amphotericin	
levofloxacin		other:	-
moxifloxacin		other:	-
ertapenem		other:	-
imipenem		other:	-

BALANCE RCT #067 P	late #073	┃ ■ Visit #000	
Patient			
OTHER POSITIVE CULTURE RESUL			<u>S) FORM 9.4</u>
(FRO ORGANISM #4 Organis	M INDEX CULTURE TO	0 30 DAYS LATER) CODES: S = Susceptible I = Intermediate R = Resistant R = Resistant	
ANTIMICROBIAL (check ALL that	apply) CODE	meropenem	
ampicillin / amoxicillin		gentamicin	
amoxicillin-clavulanate		tobramycin	
cloxacillin/oxacillin		amikacin	
penicillin		vancomycin	
piperacillin		tigecycline tigecycline	
piperacillin-tazobactam		colistin/colistemethate	
ticarcillin-clavulanate		polymyxin B	
cefazolin		erythro/azithro/clarithro	
ceftriaxone/cefotaxime		fluconazole	
ceftazidime		voriconazole	
clindamycin		caspofungin	
tetracycline/doxycycline		micafungin	
tmp-smx (septra)		anidulafungin	
ciprofloxacin		amphotericin	
levofloxacin		other:	- 🗌
moxifloxacin		other:	- 🗌
ertapenem		other:	-
imipenem		other:	-

BALANCE RCT #067 P	late #074	Visit #000	
Patient			
OTHER POSITIVE CULTURE RESUL			<u>S) FORM 9.5</u>
ORGANISM # 5 Organis	M INDEX CULTURE TO	0 30 DAYS LATER) CODES: S = Susceptible I = Intermediate R = Resistant R = Resistant	
ANTIMICROBIAL (check ALL that	apply) CODE	meropenem	
ampicillin / amoxicillin		gentamicin	
amoxicillin-clavulanate		tobramycin	
cloxacillin/oxacillin		amikacin	
penicillin		vancomycin	
piperacillin		tigecycline tigecycline	
piperacillin-tazobactam		colistin/colistemethate	
ticarcillin-clavulanate		polymyxin B	
cefazolin		erythro/azithro/clarithro	
ceftriaxone/cefotaxime		fluconazole	
ceftazidime		voriconazole	
clindamycin		caspofungin	
tetracycline/doxycycline		micafungin	
tmp-smx (septra)		anidulafungin	
ciprofloxacin		amphotericin	
levofloxacin		other:	-
moxifloxacin		other:	-
ertapenem		other:	-
imipenem		other:	-

BALANCE RCT #067 F	Plate #075	Visit #000	
Patient			
OTHER POSITIVE CULTURE RESU		SUSCEPTIBILITIES OF ORGANISM	<u>S) FORM 9.6</u>
		S = Susceptible	
ORGANISM #6 Organisi	n code:	I = Intermediate R = Resistant	
ANTIMICROBIAL (check ALL that	apply) CODE	meropenem	
ampicillin / amoxicillin		gentamicin	
amoxicillin-clavulanate		tobramycin	
cloxacillin/oxacillin		amikacin	
penicillin		vancomycin	
piperacillin		tigecycline tigecycline	
piperacillin-tazobactam		colistin/colistemethate	
ticarcillin-clavulanate		polymyxin B	
cefazolin		erythro/azithro/clarithro	
ceftriaxone/cefotaxime		fluconazole	
ceftazidime		voriconazole	
clindamycin		Caspofungin	
tetracycline/doxycycline		micafungin	
tmp-smx (septra)		anidulafungin	
ciprofloxacin		amphotericin	
levofloxacin		other:	-
moxifloxacin		other:	- 🗌
ertapenem		other:	-
imipenem		other:	- 🗌

Please check if additional forms required for another organism

BALANCE RCT #067 P	late #076	Visit #000	
Patient			
OTHER POSITIVE CULTURE RESUL			<u>S) FORM 9.7</u>
(FRO ORGANISM # 7 Organis	M INDEX CULTURE TO	30 DAYS LATER) CODES: S = Susceptible I = Intermediate R = Resistant R = Resistant	
ANTIMICROBIAL (check ALL that	apply) CODE	meropenem	
ampicillin / amoxicillin		gentamicin	
amoxicillin-clavulanate		tobramycin	
cloxacillin/oxacillin		amikacin	
penicillin		vancomycin	
piperacillin		tigecycline tigecycline	
piperacillin-tazobactam		colistin/colistemethate	
ticarcillin-clavulanate		polymyxin B	
cefazolin		erythro/azithro/clarithro	
ceftriaxone/cefotaxime		fluconazole	
ceftazidime		voriconazole	
clindamycin		caspofungin	
tetracycline/doxycycline		micafungin	
tmp-smx (septra)		anidulafungin	
ciprofloxacin		amphotericin	
levofloxacin		other:	
moxifloxacin		other:	
ertapenem		other:	
imipenem		other:	

Please check if additional forms required for another organism

<u>SM(S) FORM 9.8</u>
le
ate

Please check if additional forms required for another organism

BALANCE RCT #067 Plate #080 Visit #000
ID
WITHDRAWAL FORM 10.1 (page 1 of 1)
1. Did the patient withdraw from the study at any point? Yes No
2. Was daily data collection continued?
3. Reason for withdrawal from study
1. Patient had relevent exclusion criteria present prior to randomization
Please specify exclusion criteria:
2. Consent withdrawn
patient physician
Ilegal SDM Other family member
other (specify):
3. Duplicate randomization, specify first actual patient ID:
4. One day of study drug administered only
4. Date of withdrawal

P	BALANCE RCT #067	Plate #090	Visit #000	
			VERSE EVENTS FORM 11	. <u>.1</u>
	(Please refer to definitions)			
	Date First Diagnosed dd/mm/yyyy	during prescribed antibiotion treatment period	c after prescribed antibiotic treatment period but pt still receiving ABX for initial bacteremia	after prescribed antibiotic treatment period and pt not receiving ABX for initial bacteremia
1.	allergy]		
2.	anaphylaxis]		
3.	kidney injury]		
4.	☐ liver injury]		
5.	other related organ toxicity]		
6.	C. difficile]		

8. **NONE OF THE ABOVE**

BALANCE RCT #067 Plate #100 Visit #000
Patient D
TIME COURSE: DAILY DATA COLLECTION FORM 12.0
(note: day 0 means day of first positive (index) blood culture collection for which patient is included)
DAY 0 is: 20 (dd/mm/yyyy)
*Record the most extreme abnormal value from study day (between 08:00 this day and 07:59 the following day)
Respiratory support with mechanical ventilation? Yes No (defined as invasive positive pressure ventilation through an endotracheal tube or tracheostomy tube)
If patient receiving O ₂ via nasal prongs, specify highest value received ,
Dialysis (any mode)?
Any vasopressor/inotropic support?
- Dopamine <5ug/kg/min OR Dobutamine OR milrinone OR levosimendan any dose?
- Dopamine 5-15ug/kg/min OR Epi/Norpepi < 0.1ug/kg/min OR vasopressin OR metaraminol OR phenylephrine?
- Dopamine >15ug/k/min OR Epi/Norepi ≥ 0.1ug/kg/min
FiO ₂ (0.21-1.0) PaO ₂ (mmHg) Resp rate/min Platelet count (x10 9 /L) Bilirubin White blood cell Use the same ABG reading for FiO ₂ and PaO ₂ to get the worst P/F ratio) $x10^{9}$ /L
Creatinine (umol/L) Urine output (mL) Yes umol/L umol/L Is this a 24h urinecollection? No mg/dL Is this a 24h urinecollection? No hrs:
Central venous pressure C- reactive protein Glasgow Coma Score Patient intubated? Yes No Patient sedated? Yes No
Mean arterial pressure Systolic BP Diastolic BP Heart rate Core temperature mmHg mmHg mmHg deg C
Will there be collection of any more time points for this patient? Yes No

B I	0 1
Patient D	Study Day
TIME COURSE: DAILY DATA COLLECTION FORM 12.1	
(note: day 1 means 1 day after collection of first positive blood culture for which patient	<u>t is included)</u>
DAY 1 is:	
*Record the most extreme abnormal value from study day (between 08:00 this day and 07:59 the followi	ng day)
Respiratory support with mechanical ventilation? Yes No	
(defined as invasive positive pressure ventilation through an endotracheal tube or tracheostomy tube) If patient receiving O_2 via nasal prongs,	
specify highest value received ,	
Dialysis (any mode)?	
Any vasopressor/inotropic support?	No
- Dopamine <5ug/kg/min OR Dobutamine OR milrinone OR levosimendan any dose?	
- Dopamine 5-15ug/kg/min OR Epi/Norpepi < 0.1ug/kg/min OR vasopressin OR metaraminol OR phenylephrine?	
- Dopamine >15ug/k/min OR Epi/Norepi ≥ 0.1ug/kg/min	
FiO ₂ (0.21-1.0) PaO ₂ (mmHg) Resp rate/min Platelet count (x10 ⁹ /L) Bilirubin White	blood cell
	• x10 ⁹ /L
(Use the same ABG reading for FiO_2 and PaO_2 to get the worst P/F ratio)	
Creatinine (umol/L) Urine output (mL) Yes	u []
	arest
Central venous pressure C- reactive protein Glasgow Coma Score Patient intubated? Yes	No No
Patient sedated? Yes	No
Mean arterial pressure Systolic BP Diastolic BP Heart rate Core temp	erature
mmHg mmHg mmHg bpm .	deg C
Will there be collection of any more time points for this patient? Yes No	

B B	02
Patient ID	Study Day
TIME COURSE: DAILY DATA COLLECTION FORM 12.2	
(note: day 2 means 2 days after collection of first positive blood culture for which patien	t is included)
DAY 2 is: 20 (dd/mm/yyyy)	
*Record the most extreme abnormal value from study day (between 08:00 this day and 07:59 the following	ng day)
Respiratory support with mechanical ventilation? Yes No (defined as invasive positive pressure ventilation through an endotracheal tube or tracheostomy tube)	
If patient receiving O ₂ via nasal prongs, specify highest value received ,	
Dialysis (any mode)?	
Any vasopressor/inotropic support?	No
- Dopamine <5ug/kg/min OR Dobutamine OR milrinone OR levosimendan any dose?	No
- Dopamine 5-15ug/kg/min OR Epi/Norpepi ≤ 0.1ug/kg/min OR vasopressin □	
- Dopamine >15ug/k/min OR Epi/Norepi \geq 0.1ug/kg/min	
	blood cell
Use the same ABG reading for FiO ₂ and PaO ₂ to get the worst P/F ratio)] •[] X 10°/L
Creatinine (umol/L) Urine output (mL)	
tota inea	rest
Central venous pressure C- reactive protein Glasgow Coma Score Patient intubated?	
Patient sedated? Yes	No No
Mean arterial pressure Systolic BP Diastolic BP Heart rate Core temp	erature
mmHg mmHg bpm .	deg C
Will there be collection of any more time points for this patient? Yes No	

BALANCE RCT #067 Plate #101	03
Patient D	Study Day
TIME COURSE: DAILY DATA COLLECTION FORM 12.3	
(note: day 3 means 3 days after collection of first positive blood culture for which patier	<u>nt is included)</u>
DAY 3 is:	
*Record the most extreme abnormal value from study day (between 08:00 this day and 07:59 the follow	ing day)
Respiratory support with mechanical ventilation?	
(defined as invasive positive pressure ventilation through an endotracheal tube or tracheostomy tube) If patient receiving O_2 via nasal prongs,	
specify highest value received,	
Dialysis (any mode)?	
Any vasopressor/inotropic support?	No
- Dopamine <5ug/kg/min OR Dobutamine OR milrinone OR levosimendan any dose?	
- Dopamine 5-15ug/kg/min OR Epi/Norpepi < 0.1ug/kg/min OR vasopressin OR metaraminol OR phenylephrine?	
- Dopamine >15ug/k/min OR Epi/Norepi ≥ 0.1ug/kg/min	
FiO ₂ (0.21-1.0) PaO ₂ (mmHg) Resp rate/min Platelet count (x10 ⁹ /L) Bilirubin White	blood cell
	x10 ⁹ /L
(Use the same ABG reading for FiO ₂ and PaO ₂ to get the worst P/F ratio)	
Creatinine (umol/L) Urine output (mL)	
Image: Image	arest
	_
Central venous pressure C- reactive protein Glasgow Coma Score Patient intubated? Yes Patient sedated? Yes	No No
Patient sedated? Yes	
Mean arterial pressure Systolic BP Diastolic BP Heart rate Core temp	
mmHg mmHg bpm .	deg C
Will there be collection of any more time points for this patient? Yes No	

BALANCE RCT #067 Plate #101	04
Patient D	Study Day
TIME COURSE: DAILY DATA COLLECTION FORM 12.4	
(note: day 4 means 4 days after collection of first positive blood culture for which patien	nt is included)
DAY 4 is: 2 0 (dd/mm/yyyy)	
*Record the most extreme abnormal value from study day (between 08:00 this day and 07:59 the follow	ing day)
Respiratory support with mechanical ventilation? Yes No	
(defined as invasive positive pressure ventilation through an endotracheal tube or tracheostomy tube) If patient receiving O_2 via nasal prongs,	
specify highest value received ,	
Dialysis (any mode)?	
Any vasopressor/inotropic support?	No
+ - Dopamine <5ug/kg/min OR Dobutamine OR milrinone OR levosimendan any dose? □	
- Dopamine 5-15ug/kg/min OR Epi/Norpepi < 0.1ug/kg/min OR vasopressin OR metaraminol OR phenylephrine?	
- Dopamine >15ug/k/min OR Epi/Norepi > 0.1ug/kg/min	
FiO ₂ (0.21-1.0) PaO ₂ (mmHg) Resp rate/min Platelet count (x10 ⁹ /L) Bilirubin White	blood cell
(Use the same ABG reading for FiO ₂ and PaO ₂ to get the worst P/F ratio)	■ x10 ⁹ /L
(Use the same ABG reading for 1102 and PaO2 to get the worst F/T fatto)	
Creatinine (umol/L) Urine output (mL) Yes	al
Is this a 24h urinecollection? □ No → ne hrs	arest S:
Central venous pressure C- reactive protein Glasgow Coma Score Patient intubated?	No No
Patient sedated? Yes	No
Mean arterial pressure Systolic BP Diastolic BP Heart rate Core tem	perature
mmHg mmHg bpm .	deg C
Will there be collection of any more time points for this patient? Yes No	

BALANCE RCT #067 Plate #101	05
Patient ID	Study Day
TIME COURSE: DAILY DATA COLLECTION FORM 12.5	
(note: day 5 means 5 days after collection of first positive blood culture for which patien	<u>it is included)</u>
DAY 5 is:	
*Record the most extreme abnormal value from study day (between 08:00 this day and 07:59 the follow	ng day)
Respiratory support with mechanical ventilation?	
(defined as invasive positive pressure ventilation through an endotracheal tube or tracheostomy tube) If patient receiving O_2 via nasal prongs,	
specify highest value received ,	
Dialysis (any mode)?	
Any vasopressor/inotropic support?	No
- Dopamine <5ug/kg/min OR Dobutamine OR milrinone OR levosimendan any dose? □	
- Dopamine 5-15ug/kg/min OR Epi/Norpepi < 0.1ug/kg/min OR vasopressin OR metaraminol OR phenylephrine?	
- Dopamine >15ug/k/min OR Epi/Norepi ≥ 0.1ug/kg/min	
FiO ₂ (0.21-1.0) PaO ₂ (mmHg) Resp rate/min Platelet count (x10 ⁹ /L) Bilirubin White	blood cell
	x10 ⁹ /L
(Use the same ABG reading for FiO ₂ and PaO ₂ to get the worst P/F ratio)	
Creatinine (umol/L) Urine output (mL) Yes	
□ umol/L □ umol/L Is this a 24h urinecollection? □ No nea hrs □ mg/dL □ hrs hrs	arest
Central venous pressure C- reactive protein Glasgow Coma Score Patient intubated? Yes Patient sedated? Yes	No No
Mean arterial pressure Systolic BP Diastolic BP Heart rate Core temp	
mmHg mmHg bpm .	L deg C
Will there be collection of any more time points for this patient? Yes No	

BALANCE RCT #067 Plate #101	06
Patient ID	Study Day
TIME COURSE: DAILY DATA COLLECTION FORM 12.6	
(note: day 6 means 6 days after collection of first positive blood culture for which patien	<u>it is included)</u>
DAY 6 is:	
*Record the most extreme abnormal value from study day (between 08:00 this day and 07:59 the follow	ng day)
Respiratory support with mechanical ventilation?	
(defined as invasive positive pressure ventilation through an endotracheal tube or tracheostomy tube) If patient receiving O_2 via nasal prongs,	
specify highest value received,	
Dialysis (any mode)?	
Any vasopressor/inotropic support?	No
- Dopamine <5ug/kg/min OR Dobutamine OR milrinone OR levosimendan any dose? □	
- Dopamine 5-15ug/kg/min OR Epi/Norpepi < 0.1ug/kg/min OR vasopressin OR metaraminol OR phenylephrine?	
- Dopamine >15ug/k/min OR Epi/Norepi ≥ 0.1ug/kg/min	
FiO ₂ (0.21-1.0) PaO ₂ (mmHg) Resp rate/min Platelet count (x10 ⁹ /L) Bilirubin White	blood cell
FiO2 (0.21-1.0) PaO2 (mmHg) Resp rate/min Platelet count (x10 ⁹ /L) Bilirubin White Image: Second s	x10 ⁹ /L
(Use the same ABG reading for FiO ₂ and PaO ₂ to get the worst P/F ratio)	
Creatinine (umol/L) Urine output (mL)	
tota near tota n	arest
	_
Central venous pressure C- reactive protein Glasgow Coma Score Patient intubated? Yes Patient sedated? Yes	No □_ No
Patient sedated?	
Mean arterial pressure Systolic BP Diastolic BP Heart rate Core temp	
mmHg mmHg bpm .	deg C
Will there be collection of any more time points for this patient? Yes No	

BALANCE RCT #067 Plate #101	07
Patient ID	Study Day
TIME COURSE: DAILY DATA COLLECTION FORM 12.7	
(note: day 7 means 7 days after collection of first positive blood culture for which patien	<u>nt is included)</u>
DAY 7 is: 20 (dd/mm/yyyy)	
*Record the most extreme abnormal value from study day (between 08:00 this day and 07:59 the follow	ing day)
Respiratory support with mechanical ventilation? Yes No	
(defined as invasive positive pressure ventilation through an endotracheal tube or tracheostomy tube) If patient receiving O_2 via nasal prongs,	
specify highest value received,	
Dialysis (any mode)?	
Any vasopressor/inotropic support?	No
- Dopamine <5ug/kg/min OR Dobutamine OR milrinone OR levosimendan any dose?	
- Dopamine 5-15ug/kg/min OR Epi/Norpepi ≤ 0.1ug/kg/min OR vasopressin OR metaraminol OR phenylephrine?	
- Dopamine >15ug/k/min OR Epi/Norepi \geq 0.1ug/kg/min	
	blood cell
Use the same ABG reading for FiO ₂ and PaO ₂ to get the worst P/F ratio)] •[] X 10°/L
Creatinine (umol/L) Urine output (mL)	
tot Is this a 24h urinecollection?	arest
hrs	S:
Central venous pressure C- reactive protein Glasgow Coma Score Patient intubated? Yes	No
Patient sedated? Yes	No No
Mean arterial pressure Systolic BP Diastolic BP Heart rate Core temp	
mmHg mmHg bpm bpm	deg C
Will there be collection of any more time points for this patient? Yes No	

BALANCE RCT #067 Plate #101	08
Patient D	Study Day
TIME COURSE: DAILY DATA COLLECTION FORM 12.8	
(note: day 8 means 8 days after collection of first positive blood culture for which patier	<u>nt is included)</u>
DAY 8 is:	
*Record the most extreme abnormal value from study day (between 08:00 this day and 07:59 the follow	ing day)
Respiratory support with mechanical ventilation?	
(defined as invasive positive pressure ventilation through an endotracheal tube or tracheostomy tube) If patient receiving O_2 via nasal prongs,	
specify highest value received ,	
Dialysis (any mode)?	
Any vasopressor/inotropic support?	No
- Dopamine <5ug/kg/min OR Dobutamine OR milrinone OR levosimendan any dose?	
- Dopamine 5-15ug/kg/min OR Epi/Norpepi < 0.1ug/kg/min OR vasopressin OR metaraminol OR phenylephrine?	
- Dopamine >15ug/k/min OR Epi/Norepi ≥ 0.1ug/kg/min	
FiO ₂ (0.21-1.0) PaO ₂ (mmHg) Resp rate/min Platelet count (x10 ⁹ /L) Bilirubin White	blood cell
	x10 ⁹ /L
(Use the same ABG reading for FiO ₂ and PaO ₂ to get the worst P/F ratio)	
Creatinine (umol/L) Urine output (mL) Yes	
Image: Image	arest
Central venous pressure C- reactive protein Glasgow Coma Score Patient intubated?	□ No
Patient sedated? Yes	
Mean arterial pressure Systolic BP Diastolic BP Heart rate Core temp mmHg mmHg mmHg mmHg mmHg mmHg	deg C
	<u> </u>
Will there be collection of any more time points for this patient? Yes No	

BALANCE RCT #067 Plate #101	09
Patient D	Study Day
TIME COURSE: DAILY DATA COLLECTION FORM 12.9	
(note: day 9 means 9 days after collection of first positive blood culture for which patien	<u>nt is included)</u>
DAY 9 is:	
*Record the most extreme abnormal value from study day (between 08:00 this day and 07:59 the followi	ing day)
Respiratory support with mechanical ventilation? Yes No	
(defined as invasive positive pressure ventilation through an endotracheal tube or tracheostomy tube) If patient receiving O_2 via nasal prongs,	
specify highest value received ,	
Dialysis (any mode)?	
Any vasopressor/inotropic support?	No
- Dopamine <5ug/kg/min OR Dobutamine OR milrinone OR levosimendan any dose?	
- Dopamine 5-15ug/kg/min OR Epi/Norpepi < 0.1ug/kg/min OR vasopressin OR metaraminol OR phenylephrine?	
- Dopamine >15ug/k/min OR Epi/Norepi \geq 0.1ug/kg/min	
	blood cell
Use the same ABG reading for FiO ₂ and PaO ₂ to get the worst P/F ratio)	
Creatinine (umol/L) Urine output (mL)	
\Box	arest
	_
Central venous pressure C- reactive protein Glasgow Coma Score Patient intubated?	No
Patient sedated? Yes	No No
Mean arterial pressure Systolic BP Diastolic BP Heart rate Core temp	berature
mmHg mmHg bpm · · · · ·	deg C
Will there be collection of any more time points for this patient? Yes No	

BALANCE RCT #067 Plate #101	
Patient ID	Study Day
TIME COURSE: DAILY DATA COLLECTION FORM 12.10	
(note: day 10 means 10 days after collection of first positive blood culture for which patie	<u>ent is included)</u>
DAY 10 is:	
*Record the most extreme abnormal value from study day (between 08:00 this day and 07:59 the followi	ng day)
Respiratory support with mechanical ventilation? Yes No (defined as invasive positive pressure ventilation through an endotracheal tube or tracheostomy tube)	
If patient receiving O_2 via nasal prongs, specify highest value received ,	
Dialysis (any mode)?	
Any vasopressor/inotropic support? Yes No	No
- Dopamine <5ug/kg/min OR Dobutamine OR milrinone OR levosimendan any dose?	
- Dopamine 5-15ug/kg/min OR Epi/Norpepi < 0.1ug/kg/min OR vasopressin OR metaraminol OR phenylephrine?	
- Dopamine >15ug/k/min OR Epi/Norepi ≥ 0.1ug/kg/min	
FiO ₂ (0.21-1.0) PaO ₂ (mmHg) Resp rate/min Platelet count (x10 $^{9}/L$) Bilirubin White	blood cell
	x10 ⁹ /L
(Use the same ABG reading for FiO ₂ and PaO ₂ to get the worst P/F ratio)	
Creatinine (umol/L) Urine output (mL) Yes	al 🔲
	arest
Central venous pressure C- reactive protein Glasgow Coma Score Patient intubated?	No No
Patient sedated? Yes	No No
Mean arterial pressure Systolic BP Diastolic BP Heart rate Core temp	erature
mmHg mmHg mmHg bpm	deg C
Will there be collection of any more time points for this patient? Yes No	

BALANCE RCT #067 Plate #101	1 1 Study Day
Patient ID	
TIME COURSE: DAILY DATA COLLECTION FORM 12.11	
(note: day 11 means 11 days after collection of first positive blood culture for which patie	<u>ent is included)</u>
DAY 11 is: 20 (dd/mm/yyyy)	
*Record the most extreme abnormal value from study day (between 08:00 this day and 07:59 the follow	ing day)
Respiratory support with mechanical ventilation? Yes No (defined as invasive positive pressure ventilation through an endotracheal tube or tracheostomy tube)	
If patient receiving O ₂ via nasal prongs, specify highest value received ,	
Dialysis (any mode)?	
Any vasopressor/inotropic support?	No
- Dopamine <5ug/kg/min OR Dobutamine OR milrinone OR levosimendan any dose?	
- Dopamine 5-15ug/kg/min OR Epi/Norpepi < 0.1ug/kg/min OR vasopressin OR metaraminol OR phenylephrine?	
- Dopamine >15ug/k/min OR Epi/Norepi > 0.1ug/kg/min	
FiO2 (0.21-1.0) PaO2 (mmHg) Resp rate/min Platelet count (x10 ⁹ /L) Bilirubin White Image: Comparison of the same ABG reading for FiO2 and PaO2 to get the worst P/F ratio) Image: Comparison of the same ABG reading for FiO2 and PaO2 to get the worst P/F ratio) Image: Comparison of the same ABG reading for FiO2 and PaO2 to get the worst P/F ratio) Image: Comparison of the same ABG reading for FiO2 and PaO2 to get the worst P/F ratio)	blood cell
Creatinine (umol/L) Urine output (mL) Yes	arest
Central venous pressure C- reactive protein Glasgow Coma Score Patient intubated? Yes Patient sedated? Yes	No No
Mean arterial pressure Systolic BP Diastolic BP Heart rate Core temp mmHg mmHg mmHg bpm imm	deg C
Will there be collection of any more time points for this patient? Yes No	

BALANCE RCT #067 Plate #101 Patient Image: Comparison of the second	12 Study Day
TIME COURSE: DAILY DATA COLLECTION FORM 12.12	
(note: day 12 means 12 days after collection of first positive blood culture for which patie	<u>ent is included)</u>
DAY 12 is: 2 0 (dd/mm/yyyy)	
*Record the most extreme abnormal value from study day (between 08:00 this day and 07:59 the follow	ing day)
Respiratory support with mechanical ventilation? Yes No (defined as invasive positive pressure ventilation through an endotracheal tube or tracheostomy tube)	
If patient receiving O ₂ via nasal prongs, specify highest value received ,	
Dialysis (any mode)?	
Any vasopressor/inotropic support?	No
◆ Dopamine <5ug/kg/min OR Dobutamine OR milrinone OR levosimendan any dose?	
- Dopamine 5-15ug/kg/min OR Epi/Norpepi < 0.1ug/kg/min OR vasopressin OR metaraminol OR phenylephrine?	
- Dopamine >15ug/k/min OR Epi/Norepi ≥ 0.1ug/kg/min	
FiO2 (0.21-1.0) PaO2 (mmHg) Resp rate/min Platelet count (x10 ⁹ /L) Bilirubin White Image: Comparison of the same ABG reading for FiO2 and PaO2 to get the worst P/F ratio) Image: Comparison of the same ABG reading for FiO2 and PaO2 to get the worst P/F ratio) Image: Comparison of the same ABG reading for FiO2 and PaO2 to get the worst P/F ratio) Image: Comparison of the same ABG reading for FiO2 and PaO2 to get the worst P/F ratio)	blood cell
Creatinine (umol/L) Urine output (mL) Yes	arest
Central venous pressure C- reactive protein Glasgow Coma Score Patient intubated? Yes Patient sedated? Yes	No No
Mean arterial pressure Systolic BP Diastolic BP Heart rate Core temp mmHg mmHg mmHg bpm mmHg	deg C
Will there be collection of any more time points for this patient? Yes No	

B B	13
Patient ID	Study Day
TIME COURSE: DAILY DATA COLLECTION FORM 12.13	
(note: day 13 means 13 days after collection of first positive blood culture for which pati	<u>ient is included)</u>
DAY 13 is: 2 0 (dd/mm/yyyy)	
*Record the most extreme abnormal value from study day (between 08:00 this day and 07:59 the follow	ving day)
Respiratory support with mechanical ventilation? Yes No (defined as invasive positive pressure ventilation through an endotracheal tube or tracheostomy tube)	
If patient receiving O ₂ via nasal prongs, specify highest value received ,	
Dialysis (any mode)?	
Any vasopressor/inotropic support?	No
- Dopamine <5ug/kg/min OR Dobutamine OR milrinone OR levosimendan any dose?	
- Dopamine 5-15ug/kg/min OR Epi/Norpepi ≤ 0.1ug/kg/min OR vasopressin OR metaraminol OR phenylephrine?	
- Dopamine >15ug/k/min OR Epi/Norepi ≥ 0.1ug/kg/min	
FiO ₂ (0.21-1.0) PaO ₂ (mmHg) Resp rate/min Platelet count (x10 ⁹ /L) Bilirubin White	blood cell
(Use the same ABG reading for FiO ₂ and PaO ₂ to get the worst P/F ratio)	• x10 ⁹ /L
	tal
	earest s:
Central venous pressure C- reactive protein Glasgow Coma Score Patient intubated? Yes	No No
Patient sedated? Yes	No No
Mean arterial pressure Systolic BP Diastolic BP Heart rate Core tem	perature
mmHg mmHg bpm bpm	deg C
Will there be collection of any more time points for this patient? Yes No	

BALANCE RCT #067 Plate #101 I<
<u>TIME COURSE: DAILY DATA COLLECTION FORM 12.14</u> (note: day 14 means 14 days after collection of first positive blood culture for which patient is included DAY 14 is:
*Record the most extreme abnormal value from study day (between 08:00 this day and 07:59 the following day)
Respiratory support with mechanical ventilation? Yes No (defined as invasive positive pressure ventilation through an endotracheal tube or tracheostomy tube) If patient receiving O ₂ via nasal prongs, specify highest value received ,
Dialysis (any mode)?
Any vasopressor/inotropic support? - Dopamine <5ug/kg/min OR Dobutamine OR milrinone OR levosimendan any dose? - Dopamine <5ug/kg/min OR Dobutamine OR milrinone OR levosimendan any dose?
- Dopamine 5-15ug/kg/min OR Epi/Norpepi ≤ 0.1ug/kg/min OR vasopressin □ □ OR metaraminol OR phenylephrine? □ □ - Dopamine >15ug/k/min OR Epi/Norepi ≥ 0.1ug/kg/min □ □
$\begin{array}{c c} FiO_2 \ (0.21-1.0) & PaO_2 \ (mmHg) & Resp \ rate/min \\ \hline \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \$
Creatinine (umol/L) Urine output (mL) Yes Urine output (mL) Is this a 24h urinecollection?
Central venous pressure C- reactive protein Glasgow Coma Score Patient intubated? Yes No Patient sedated? Yes No
Mean arterial pressure Systolic BP Diastolic BP Heart rate Core temperature mmHg mmHg mmHg deg C
Will there be collection of any more time points for this patient? Yes No

BALANCE RCT #067 Study Drug #20 ⁻ Patient	1 Visit #000
	RELATED DAILY DATA FORM 13.1
	ent daily (each AM) for 16 days after Randomization)
Current date:	2 0 (dd/mm/yyyy)
- Research Coordinator to Assess Patient Daily for 16	Days after Randomization.
- Research Coordinator with Site Investigator to Ensu Duration Protocol.	re Clinical Team Adheres to Study Treatment
 If The Clinical Team Stops Antibiotics Earlier Or Conti Research Coordinator And/or Site Investigator Should 	nues Them Longer Than Dictated by Protocol Then the I Clarify The Reasons With The Clinical Team.
- If Clinical Team Deviates from Study Treatment Durat Follow Below Algorithm:	tion Protocol, Research Coordinator to
Is patient supposed to be on adequat	e treatment today?
Yes	
Is the patient actually still on adequate treatment?	Is the patient actually still on adequate treatment?
Yes	No
No	Yes Ask clinical team for reason for continuation or restarting of antibiotics:
antibiotics stopped due to adverse effects/side effects	recurrence of index infection and knowingly deviated from protocol
treating team thinks index infection no longer requires antibiotics and knowingly deviated from protocol	persistence of index infection and knowingly deviated from protocol
other reason(s):	clinical reasons for extended treatment that were not present at time of enrollment, specify:
	<pre>clinical reasons for extended treatment that were unrecognized at time of enrollment, specify:</pre>
	antibiotics re-started due to new infection unrelated to index infection, specify:
	other reason(s):
Was patient randomized to?	
7 D Discontinue the antibiotic on Day	7 14 D → Continue antibiotic until day 14
Will there be collection of any more time point	s for this patient? Yes No
2016 September 12 (UPDATED AUG 01 2017)	

BALANCE RCT #067 Study Drug #202	2 Visit #000
	RELATED DAILY DATA FORM 13.2
	ent daily (each AM) for 16 days after Randomization)
Current date:	20 (dd/mm/yyyy)
- Research Coordinator to Assess Patient Daily for 16	Days after Randomization.
- Research Coordinator with Site Investigator to Ensu Duration Protocol.	re Clinical Team Adheres to Study Treatment
 If The Clinical Team Stops Antibiotics Earlier Or Conti Research Coordinator And/or Site Investigator Should 	nues Them Longer Than Dictated by Protocol Then the I Clarify The Reasons With The Clinical Team.
 If Clinical Team Deviates from Study Treatment Durat Follow Below Algorithm: 	tion Protocol, Research Coordinator to
Is patient supposed to be on adequat	e treatment today?
Yes	
Is the patient actually still on adequate treatment?	Is the patient actually still on adequate treatment?
Yes	Νο
No ☐ → Ask clinical team for reason for premature discontinuation:	Yes ► Ask clinical team for reason for continuation or restarting of antibiotics: ↓
antibiotics stopped due to adverse effects/side effects	recurrence of index infection and knowingly deviated from protocol
treating team thinks index infection no longer requires antibiotics and knowingly deviated from protocol	persistence of index infection and knowingly deviated from protocol
other reason(s):	clinical reasons for extended treatment that were not present at time of enrollment, specify:
	clinical reasons for extended treatment that were unrecognized at time of enrollment, specify:
	antibiotics re-started due to new infection unrelated to index infection, specify:
	other reason(s):
Was patient randomized to?	
7 D Discontinue the antibiotic on Day	7 14 D → Continue antibiotic until day 14
Will there be collection of any more time point	s for this patient? Yes No
2016 September 12 (UPDATED AUG 01 2017)	

BALANCE RCT #067 Study Drug #203	3 Visit #000
	RELATED DAILY DATA FORM 13.3
	ent daily (each AM) for 16 days after Randomization)
Current date:	20 (dd/mm/yyyy)
- Research Coordinator to Assess Patient Daily for 16	Days after Randomization.
- Research Coordinator with Site Investigator to Ensu Duration Protocol.	re Clinical Team Adheres to Study Treatment
 If The Clinical Team Stops Antibiotics Earlier Or Conti Research Coordinator And/or Site Investigator Should 	nues Them Longer Than Dictated by Protocol Then the I Clarify The Reasons With The Clinical Team.
- If Clinical Team Deviates from Study Treatment Durat Follow Below Algorithm:	tion Protocol, Research Coordinator to
Is patient supposed to be on adequat	e treatment today?
Yes	
Is the patient actually still on adequate treatment?	Is the patient actually still on adequate treatment?
Yes	Νο
No ☐ → Ask clinical team for reason for premature discontinuation:	Yes ► Ask clinical team for reason for continuation or restarting of antibiotics: ↓
antibiotics stopped due to adverse effects/side effects	recurrence of index infection and knowingly deviated from protocol
treating team thinks index infection no longer requires antibiotics and knowingly deviated from protocol	persistence of index infection and knowingly deviated from protocol
other reason(s):	clinical reasons for extended treatment that were not present at time of enrollment, specify:
	clinical reasons for extended treatment that were unrecognized at time of enrollment, specify:
	antibiotics re-started due to new infection unrelated to index infection, specify:
	other reason(s):
Was patient randomized to?	
7 D Discontinue the antibiotic on Day	7 14 D Continue antibiotic until day 14
Will there be collection of any more time point	s for this patient? Yes No
2016 September 12 (UPDATED AUG 01 2017)	

BALANCE RCT #067 Study Drug #204 Patient	4 Visit #000
	RELATED DAILY DATA FORM 13.4
	ent daily (each AM) for 16 days after Randomization)
Current date:	2 0 (dd/mm/yyyy)
- Research Coordinator to Assess Patient Daily for 16	Days after Randomization.
- Research Coordinator with Site Investigator to Ensu Duration Protocol.	re Clinical Team Adheres to Study Treatment
 If The Clinical Team Stops Antibiotics Earlier Or Conti Research Coordinator And/or Site Investigator Should 	nues Them Longer Than Dictated by Protocol Then the I Clarify The Reasons With The Clinical Team.
- If Clinical Team Deviates from Study Treatment Durat Follow Below Algorithm:	tion Protocol, Research Coordinator to
Is patient supposed to be on adequat	e treatment today?
Yes	
Is the patient actually still on adequate treatment?	Is the patient actually still on adequate treatment?
Yes	No 🗌
No	Yes Ask clinical team for reason for continuation or restarting of antibiotics:
antibiotics stopped due to adverse effects/side effects	recurrence of index infection and knowingly deviated from protocol
treating team thinks index infection no longer requires antibiotics and knowingly deviated from protocol	persistence of index infection and knowingly deviated from protocol
other reason(s):	clinical reasons for extended treatment that were not present at time of enrollment, specify:
	<pre>clinical reasons for extended treatment that were unrecognized at time of enrollment, specify:</pre>
	antibiotics re-started due to new infection unrelated to index infection, specify:
	other reason(s):
Was patient randomized to?	
7 D Discontinue the antibiotic on Day	7 14 D → Continue antibiotic until day 14
Will there be collection of any more time point	s for this patient? Yes No
2016 September 12 (UPDATED AUG 01 2017)	

BALANCE RCT #067 Study Drug #203	5 Visit #000
	RELATED DAILY DATA FORM 13.5
	ent daily (each AM) for 16 days after Randomization)
Current date:	20 (dd/mm/yyyy)
- Research Coordinator to Assess Patient Daily for 16	Days after Randomization.
- Research Coordinator with Site Investigator to Ensu Duration Protocol.	re Clinical Team Adheres to Study Treatment
 If The Clinical Team Stops Antibiotics Earlier Or Conti Research Coordinator And/or Site Investigator Should 	nues Them Longer Than Dictated by Protocol Then the I Clarify The Reasons With The Clinical Team.
 If Clinical Team Deviates from Study Treatment Durat Follow Below Algorithm: 	tion Protocol, Research Coordinator to
Is patient supposed to be on adequat	e treatment today?
Yes	
Is the patient actually still on adequate treatment?	Is the patient actually still on adequate treatment?
Yes	No 🗌
No	Yes Ask clinical team for reason for continuation or restarting of antibiotics:
antibiotics stopped due to adverse effects/side effects	recurrence of index infection and knowingly deviated from protocol
treating team thinks index infection no longer requires antibiotics and knowingly deviated from protocol	persistence of index infection and knowingly deviated from protocol
other reason(s):	clinical reasons for extended treatment that were not present at time of enrollment, specify:
	clinical reasons for extended treatment that were unrecognized at time of enrollment, specify:
	antibiotics re-started due to new infection unrelated to index infection, specify:
	other reason(s):
Was patient randomized to?	
7 D Discontinue the antibiotic on Day	7 14 D Continue antibiotic until day 14
Will there be collection of any more time point	s for this patient? Yes No
2016 September 12 (UPDATED AUG 01 2017)	

BALANCE RCT #067 Study Drug #200	6 Visit #000
	RELATED DAILY DATA FORM 13.6
	ent daily (each AM) for 16 days after Randomization)
Current date:	20 (dd/mm/yyyy)
- Research Coordinator to Assess Patient Daily for 16	
- Research Coordinator with Site Investigator to Ensu Duration Protocol.	re Clinical Team Adheres to Study Treatment
 If The Clinical Team Stops Antibiotics Earlier Or Conti Research Coordinator And/or Site Investigator Should 	nues Them Longer Than Dictated by Protocol Then the I Clarify The Reasons With The Clinical Team.
- If Clinical Team Deviates from Study Treatment Durat Follow Below Algorithm:	tion Protocol, Research Coordinator to
Is patient supposed to be on adequat	e treatment today?
Yes	
Is the patient actually still on adequate treatment?	Is the patient actually still on adequate treatment?
Yes	Νο
No Ask clinical team for reason for premature discontinuation:	Yes ► Ask clinical team for reason for continuation or restarting of antibiotics: ↓
antibiotics stopped due to adverse effects/side effects	recurrence of index infection and knowingly deviated from protocol
treating team thinks index infection no longer requires antibiotics and knowingly deviated from protocol	persistence of index infection and knowingly deviated from protocol
other reason(s):	clinical reasons for extended treatment that were not present at time of enrollment, specify:
	clinical reasons for extended treatment that were unrecognized at time of enrollment, specify:
	antibiotics re-started due to new infection unrelated to index infection, specify:
	other reason(s):
Was patient randomized to?	
7 D Discontinue the antibiotic on Day	7 14 D → Continue antibiotic until day 14
Will there be collection of any more time point	s for this patient? Yes No
2016 September 12 (UPDATED AUG 01 2017)	

BALANCE RCT #067 Study Drug #203	7 Visit #000
	RELATED DAILY DATA FORM 13.7
	ent daily (each AM) for 16 days after Randomization)
Current date:	20 (dd/mm/yyyy)
- Research Coordinator to Assess Patient Daily for 16	Days after Randomization.
- Research Coordinator with Site Investigator to Ensu Duration Protocol.	re Clinical Team Adheres to Study Treatment
 If The Clinical Team Stops Antibiotics Earlier Or Conti Research Coordinator And/or Site Investigator Should 	nues Them Longer Than Dictated by Protocol Then the I Clarify The Reasons With The Clinical Team.
- If Clinical Team Deviates from Study Treatment Durat Follow Below Algorithm:	tion Protocol, Research Coordinator to
Is patient supposed to be on adequat	e treatment today?
Yes	
Is the patient actually still on adequate treatment?	Is the patient actually still on adequate treatment?
Yes	No 🗌
No	Yes ► Ask clinical team for reason for continuation or restarting of antibiotics: ↓
antibiotics stopped due to adverse effects/side effects	recurrence of index infection and knowingly deviated from protocol
treating team thinks index infection no longer requires antibiotics and knowingly deviated from protocol	persistence of index infection and knowingly deviated from protocol
other reason(s):	clinical reasons for extended treatment that were not present at time of enrollment, specify:
	<pre>clinical reasons for extended treatment that were unrecognized at time of enrollment, specify:</pre>
	antibiotics re-started due to new infection unrelated to index infection, specify:
	other reason(s):
Was patient randomized to?	
7 D Discontinue the antibiotic on Day	7 14 D Continue antibiotic until day 14
Will there be collection of any more time point	s for this patient? Yes No
2016 September 12 (UPDATED AUG 01 2017)	

BALANCE RCT #067 Study Drug #208 Patient	8 Visit #000
	RELATED DAILY DATA FORM 13.8
	ent daily (each AM) for 16 days after Randomization)
Current date:	20 (dd/mm/yyyy)
- Research Coordinator to Assess Patient Daily for 16	Days after Randomization.
- Research Coordinator with Site Investigator to Ensu Duration Protocol.	re Clinical Team Adheres to Study Treatment
 If The Clinical Team Stops Antibiotics Earlier Or Conti Research Coordinator And/or Site Investigator Should 	nues Them Longer Than Dictated by Protocol Then the I Clarify The Reasons With The Clinical Team.
- If Clinical Team Deviates from Study Treatment Durat Follow Below Algorithm:	tion Protocol, Research Coordinator to
Is patient supposed to be on adequat	e treatment today?
Yes	
Is the patient actually still on adequate treatment?	Is the patient actually still on adequate treatment?
Yes	No 🗌
No	Yes
antibiotics stopped due to adverse effects/side effects	recurrence of index infection and knowingly deviated from protocol
treating team thinks index infection no longer requires antibiotics and knowingly deviated from protocol	persistence of index infection and knowingly deviated from protocol
other reason(s):	clinical reasons for extended treatment that were not present at time of enrollment, specify:
	clinical reasons for extended treatment that were unrecognized at time of enrollment, specify:
	antibiotics re-started due to new infection unrelated to index infection, specify:
	other reason(s):
Was patient randomized to?	
7 D Discontinue the antibiotic on Day	7 14 D → Continue antibiotic until day 14
Will there be collection of any more time point	s for this patient? Yes No
2016 September 12 (UPDATED AUG 01 2017)	

BALANCE RCT #067 Study Drug #209	9 Visit #000
	RELATED DAILY DATA FORM 13.9
	ent daily (each AM) for 16 days after Randomization)
Current date:	2 0 (dd/mm/yyyy)
- Research Coordinator to Assess Patient Daily for 16	Days after Randomization.
- Research Coordinator with Site Investigator to Ensu Duration Protocol.	re Clinical Team Adheres to Study Treatment
 If The Clinical Team Stops Antibiotics Earlier Or Conti Research Coordinator And/or Site Investigator Should 	• •
 If Clinical Team Deviates from Study Treatment Durat Follow Below Algorithm: 	ion Protocol, Research Coordinator to
Is patient supposed to be on adequat	e treatment today?
Yes	
Is the patient actually still on adequate treatment?	Is the patient actually still on adequate treatment?
Yes	No 🗌
No Ask clinical team for reason for premature discontinuation:	Yes Ask clinical team for reason for continuation or restarting of antibiotics:
antibiotics stopped due to adverse effects/side effects	recurrence of index infection and knowingly deviated from protocol
treating team thinks index infection no longer requires antibiotics and knowingly deviated from protocol	persistence of index infection and knowingly deviated from protocol
other reason(s):	clinical reasons for extended treatment that were not present at time of enrollment, specify:
	<pre> clinical reasons for extended treatment that were unrecognized at time of enrollment, specify:</pre>
	antibiotics re-started due to new infection unrelated to index infection, specify:
	other reason(s):
Was patient randomized to?	
7 D Discontinue the antibiotic on Day	7 14 D Continue antibiotic until day 14
Will there be collection of any more time point	s for this patient? Yes No
2016 September 12 (UPDATED AUG 01 2017)	

BALANCE RCT #067 Study Drug #210	0 Visit #000
	RELATED DAILY DATA FORM 13.10
	ent daily (each AM) for 16 days after Randomization)
Current date:	20 (dd/mm/yyyy)
- Research Coordinator to Assess Patient Daily for 16	Days after Randomization.
- Research Coordinator with Site Investigator to Ensu Duration Protocol.	re Clinical Team Adheres to Study Treatment
 If The Clinical Team Stops Antibiotics Earlier Or Conti Research Coordinator And/or Site Investigator Should 	nues Them Longer Than Dictated by Protocol Then the I Clarify The Reasons With The Clinical Team.
 If Clinical Team Deviates from Study Treatment Durat Follow Below Algorithm: 	tion Protocol, Research Coordinator to
Is patient supposed to be on adequat	e treatment today?
Yes	
Is the patient actually still on adequate treatment?	Is the patient actually still on adequate treatment?
Yes	Νο
No ☐ → Ask clinical team for reason for premature discontinuation:	Yes ► Ask clinical team for reason for continuation or restarting of antibiotics: ↓
antibiotics stopped due to adverse effects/side effects	recurrence of index infection and knowingly deviated from protocol
treating team thinks index infection no longer requires antibiotics and knowingly deviated from protocol	persistence of index infection and knowingly deviated from protocol
other reason(s):	clinical reasons for extended treatment that were not present at time of enrollment, specify:
	clinical reasons for extended treatment that were unrecognized at time of enrollment, specify:
	antibiotics re-started due to new infection unrelated to index infection, specify:
	other reason(s):
Was patient randomized to?	
7 D Discontinue the antibiotic on Day	7 14 D → Continue antibiotic until day 14
Will there be collection of any more time point	s for this patient? Yes No
2016 September 12 (UPDATED AUG 01 2017)	

BALANCE RCT #067 Study Drug #217	1 Visit #000
	RELATED DAILY DATA FORM 13.11
	ent daily (each AM) for 16 days after Randomization)
Current date:	20 (dd/mm/yyyy)
- Research Coordinator to Assess Patient Daily for 16	Days after Randomization.
- Research Coordinator with Site Investigator to Ensu Duration Protocol.	re Clinical Team Adheres to Study Treatment
 If The Clinical Team Stops Antibiotics Earlier Or Conti Research Coordinator And/or Site Investigator Should 	nues Them Longer Than Dictated by Protocol Then the I Clarify The Reasons With The Clinical Team.
 If Clinical Team Deviates from Study Treatment Durat Follow Below Algorithm: 	tion Protocol, Research Coordinator to
Is patient supposed to be on adequat	e treatment today?
Yes	
▼ Is the patient actually still on adequate treatment?	Is the patient actually still on adequate treatment?
Yes	No 🗌
No	Yes Ask clinical team for reason for continuation or restarting of antibiotics: ↓
antibiotics stopped due to adverse effects/side effects	recurrence of index infection and knowingly deviated from protocol
treating team thinks index infection no longer requires antibiotics and knowingly deviated from protocol	persistence of index infection and knowingly deviated from protocol
other reason(s):	clinical reasons for extended treatment that were not present at time of enrollment, specify:
	clinical reasons for extended treatment that were unrecognized at time of enrollment, specify:
	antibiotics re-started due to new infection unrelated to index infection, specify:
	other reason(s):
Was patient randomized to?	
7 D Discontinue the antibiotic on Day	7 14 D Continue antibiotic until day 14
Will there be collection of any more time point	s for this patient? Yes No
2016 September 12 (UPDATED AUG 01 2017)	

BALANCE RCT #067 Study Drug #212 Patient	2 Visit #000
	RELATED DAILY DATA FORM 13.12
	ent daily (each AM) for 16 days after Randomization)
Current date:	20 (dd/mm/yyyy)
- Research Coordinator to Assess Patient Daily for 16	Days after Randomization.
- Research Coordinator with Site Investigator to Ensu Duration Protocol.	re Clinical Team Adheres to Study Treatment
 If The Clinical Team Stops Antibiotics Earlier Or Conti Research Coordinator And/or Site Investigator Should 	nues Them Longer Than Dictated by Protocol Then the I Clarify The Reasons With The Clinical Team.
- If Clinical Team Deviates from Study Treatment Durat Follow Below Algorithm:	tion Protocol, Research Coordinator to
Is patient supposed to be on adequat	e treatment today?
Yes	
Is the patient actually still on adequate treatment?	Is the patient actually still on adequate treatment?
Yes	Νο
No Ask clinical team for reason for premature discontinuation:	Yes ► Ask clinical team for reason for continuation or restarting of antibiotics:
antibiotics stopped due to adverse effects/side effects	recurrence of index infection and knowingly deviated from protocol
treating team thinks index infection no longer requires antibiotics and knowingly deviated from protocol	persistence of index infection and knowingly deviated from protocol
other reason(s):	clinical reasons for extended treatment that were not present at time of enrollment, specify:
	<pre>clinical reasons for extended treatment that were unrecognized at time of enrollment, specify:</pre>
	antibiotics re-started due to new infection unrelated to index infection, specify:
	other reason(s):
Was patient randomized to?	
7 D Discontinue the antibiotic on Day	7 14 D → Continue antibiotic until day 14
Will there be collection of any more time point	s for this patient? Yes No
2016 September 12 (UPDATED AUG 01 2017)	

BALANCE RCT #067 Study Drug #213	3 Visit #000
	RELATED DAILY DATA FORM 13.13
	ent daily (each AM) for 16 days after Randomization)
Current date:	20 (dd/mm/yyyy)
- Research Coordinator to Assess Patient Daily for 16	Days after Randomization.
- Research Coordinator with Site Investigator to Ensu Duration Protocol.	re Clinical Team Adheres to Study Treatment
 If The Clinical Team Stops Antibiotics Earlier Or Conti Research Coordinator And/or Site Investigator Should 	nues Them Longer Than Dictated by Protocol Then the I Clarify The Reasons With The Clinical Team.
- If Clinical Team Deviates from Study Treatment Durat Follow Below Algorithm:	tion Protocol, Research Coordinator to
Is patient supposed to be on adequat	e treatment today?
Yes	
Is the patient actually still on adequate treatment?	Is the patient actually still on adequate treatment?
Yes	No 🗌
No Ask clinical team for reason for premature discontinuation:	Yes
antibiotics stopped due to adverse effects/side effects	recurrence of index infection and knowingly deviated from protocol
treating team thinks index infection no longer requires antibiotics and knowingly deviated from protocol	persistence of index infection and knowingly deviated from protocol
other reason(s):	clinical reasons for extended treatment that were not present at time of enrollment, specify:
	clinical reasons for extended treatment that were unrecognized at time of enrollment, specify:
	antibiotics re-started due to new infection unrelated to index infection, specify:
	other reason(s):
Was patient randomized to?	
7 D Discontinue the antibiotic on Day	7 14 D Continue antibiotic until day 14
Will there be collection of any more time point	s for this patient? Yes No
2016 September 12 (UPDATED AUG 01 2017)	

BALANCE RCT #067 Study Drug #214 Patient	4 Visit #000
	RELATED DAILY DATA FORM 13.14
	ent daily (each AM) for 16 days after Randomization)
Current date:	20 (dd/mm/yyyy)
ا لــــــــــــــــــــــــــــــــــــ	
- Research Coordinator with Site Investigator to Ensu Duration Protocol.	-
 If The Clinical Team Stops Antibiotics Earlier Or Conti Research Coordinator And/or Site Investigator Should 	nues Them Longer Than Dictated by Protocol Then the I Clarify The Reasons With The Clinical Team.
- If Clinical Team Deviates from Study Treatment Durat Follow Below Algorithm:	tion Protocol, Research Coordinator to
Is patient supposed to be on adequat	e treatment today?
Yes	
Is the patient actually still on adequate treatment?	Is the patient actually still on adequate treatment?
Yes	No 🗌
No Ask clinical team for reason for premature discontinuation:	Yes Ask clinical team for reason for continuation or restarting of antibiotics: ↓
antibiotics stopped due to adverse effects/side effects	recurrence of index infection and knowingly deviated from protocol
treating team thinks index infection no longer requires antibiotics and knowingly deviated from protocol	persistence of index infection and knowingly deviated from protocol
other reason(s):	clinical reasons for extended treatment that were not present at time of enrollment, specify:
	clinical reasons for extended treatment that were unrecognized at time of enrollment, specify:
	antibiotics re-started due to new infection unrelated to index infection, specify:
	other reason(s):
Was patient randomized to?	
7 D Discontinue the antibiotic on Day	7 14 D Continue antibiotic until day 14
Will there be collection of any more time point	s for this patient? Yes No
2016 September 12 (UPDATED AUG 01 2017)	

BALANCE RCT #067 Study Drug	#215 Visit #000
Patient	
STUDY DRUG	RELATED DAILY DATA FORM 13.15
(This form is to be used to assess pat	ient daily (each AM) for 16 days after Randomization)
Current date:	20 (dd/mm/yyyy)
- Research Coordinator to Assess Patient Daily for 16	Days after Randomization.
 Research Coordinator with Site Investigator to Ensu Duration Protocol. 	re Clinical Team Adheres to Study Treatment
- If The Clinical Team Stops Antibiotics Earlier Or Cont Research Coordinator And/or Site Investigator Should	inues Them Longer Than Dictated by Protocol Then the d Clarify The Reasons With The Clinical Team.
- If Clinical Team Deviates from Study Treatment Dura Follow Below Algorithm:	tion Protocol, Research Coordinator to
Is patient supposed to be on adequa	te treatment today?
Yes	No 🛄
▼	
Is the patient actually still on adequate treatment?	Is the patient actually still on adequate treatment?
Yes	No 🗌
No Ask clinical team for reason for premature discontinuation:	Yes Ask clinical team for reason for continuation or restarting of antibiotics:
antibiotics stopped due to adverse effects/side effects	recurrence of index infection and knowingly deviated from protocol
treating team thinks index infection no longer requires antibiotics and knowingly deviated from protocol	persistence of index infection and knowingly deviated from protocol
other reason(s):	clinical reasons for extended treatment that were not present at time of enrollment, specify:
	clinical reasons for extended treatment that were unrecognized at time of enrollment, specify:
	antibiotics re-started due to new infection unrelated to index infection, specify:
	other reason(s):
Was patient randomized to?	
7 D Discontinue the antibiotic on Day	7 14 D Continue antibiotic until day 14
Will there be collection of any more time point	ts for this patient? Yes No
2016 September 12 (UPDATED AUG 01 2017)	

BALANCE RCT #067 Study Drug	#216 Visit #000
Patient	
STUDY DRUG	RELATED DAILY DATA FORM 13.16
(This form is to be used to assess pati	ient daily (each AM) for 16 days after Randomization)
Current date:	20 (dd/mm/yyyy)
- Research Coordinator to Assess Patient Daily for 16	Days after Randomization.
 Research Coordinator with Site Investigator to Ensu Duration Protocol. 	re Clinical Team Adheres to Study Treatment
- If The Clinical Team Stops Antibiotics Earlier Or Cont Research Coordinator And/or Site Investigator Should	inues Them Longer Than Dictated by Protocol Then the d Clarify The Reasons With The Clinical Team.
- If Clinical Team Deviates from Study Treatment Dura Follow Below Algorithm:	tion Protocol, Research Coordinator to
Is patient supposed to be on adequa	te treatment today?
Yes	No 🛄
▼	
Is the patient actually still on adequate treatment?	Is the patient actually still on adequate treatment?
Yes	No 🗌
No Ask clinical team for reason for premature discontinuation:	Yes Ask clinical team for reason for continuation or restarting of antibiotics:
antibiotics stopped due to adverse effects/side effects	recurrence of index infection and knowingly deviated from protocol
treating team thinks index infection no longer requires antibiotics and knowingly deviated from protocol	persistence of index infection and knowingly deviated from protocol
other reason(s):	clinical reasons for extended treatment that were not present at time of enrollment, specify:
	clinical reasons for extended treatment that were unrecognized at time of enrollment, specify:
	antibiotics re-started due to new infection unrelated to index infection, specify:
	other reason(s):
Was patient randomized to?	
7 D Discontinue the antibiotic on Day	y 7 14 D Continue antibiotic until day 14
Will there be collection of any more time point	ts for this patient? Yes No
2016 September 12 (UPDATED AUG 01 2017)	