Form number: 3

Baseline Form—Part 1

sepsis adapt
Biomarker-guided antibiotic duration for sepsis

Participant Trial Number: ☐☐☐☐ **Participant Initials:** ☐☐

Randomising Site:

A. Baseline characteristics

Please enter the date & time of the following:

1) Hospital Admission: d d - m o n - y y y y h h : m m

2) ICU/HDU admission: d d - m o n - y y y y h h : m m

3) First diagnosis of suspected sepsis or suspected septic shock:

d d - m o n - y y y y h h : m m

Additional clinical information:

4) Core body temperature (°C): ☐☐.☐

5) White cell count: (x10^9/L): ☐☐.☐

B. Critical Care Admission and Origin:

1) Critical Care Admission Category:

☐ Medical
☐ Elective surgical
☐ Emergency surgical
☐ Other, please specify_____

2) Origin:

☐ Emergency Department
☐ Emergency Admissions Unit
☐ Medical ward
☐ Surgical ward
☐ Another Critical Care Unit
☐ Other, please specify _____

Completion Guidelines for CRF 3: Baseline Form

This CRF should be completed after a patient has been randomised into the ADAPT-Sepsis trial.

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.

Part 1:

The baseline form is formed by Part 1 and Part 2. Part 1 should be completed as soon as possible and should be signed off on page 6 of the form (the last page of the Part 1).

Part 2:

Information required to complete Part 2 may not be available when Part 1 is completed. Please ensure that this information is entered when available. Part 2 requires an additional sign off at the end of page 10 (last page of Part 2).

Baseline Characteristics Guidance:

- Section 1 Part A4 & A5: Core body temperature and White cell counts should be recorded approximately at the time of diagnosis.

Critical Care Admission and Origin Guidance:

- Section 1 Part B1: Critical care admission category refers to the reason for initial hospital admission. This may not relate to sepsis.
- Section 1 Part B2: Origin refers to the hospital department which the patient was initially admitted via.

Baseline Form—Part 1

Participant Trial Number: ☐☐☐☐ Participant Initials: ☐☐

Randomising Site: _____

C. Initial Care Bundle

Within 3 hours of presentation*:

1. Was lactate level measured: No ☐ Yes ☐
2. Were blood cultures obtained prior to first antibiotics: No ☐ Yes ☐
3. Was intravenous crystalloid fluid administered for hypotension or raised lactate: No ☐ Yes ☐
4. Were broad spectrum antibiotics administered: No ☐ Yes ☐

If yes please complete the antibiotic form.

5. Was anti-fungal treatment used as part of the 3-hour treatment bundle? No ☐ Yes ☐
6. Was anti-viral treatment used as part of the 3-hour treatment bundle? No ☐ Yes ☐

Within 12 hours of presentation*:

7. Source control (e.g. surgical/radiological abscess drainage, vascular line removal) No ☐ Yes ☐ Not Relevant ☐

Within 24 hours of presentation*:

8. Was the patient started on systemic steroids (IV or oral) No ☐ Yes ☐
9. Was the patient put on renal replacement therapy No ☐ Yes ☐

D. Trial specific procedures:

1) Date and time first research blood sample taken for the ADAPT-Sepsis trial:

d d - m o n - y y y y h h : m m

2) Date and time first research blood sample delivered to the laboratory:

d d - m o n - y y y y h h : m m

Completion Guidelines for CRF 3: Baseline Form

Initial Care Bundle:

- *"Time of presentation" is defined as the time of triage in the emergency department or, if presenting from another care venue, from the earliest chart annotation consistent with all elements of sepsis or septic shock ascertained through chart review.

sepsis adapt
Biomarker-guided antibiotic duration for sepsis

Baseline Form—Part 1

Participant Trial Number: ☐☐☐☐ **Participant Initials:** ☐☐

Randomising Site:

E. qSOFA, SOFA and APACHE II Scores

1) Please complete the following table for qSOFA and SOFA:

qSOFA and SOFA Score		
Organ system	Test	Baseline value
Respiration	Lowest PaO_2 / FiO_2 Ratio (kPa) (see reverse for conversion from mmHg to kPa#)	☐☐.☐☐
	Assisted Ventilation?	No ☐ Yes ☐ If yes was this: Invasive ☐ Non-invasive ☐
	qSOFA— Respiratory Rate ≥ 22/min	No ☐ Yes ☐
Coagulation	Lowest platelets (x 10^9/L)	☐☐☐.☐☐
Liver	Highest bilirubin (µmol/L)	☐☐☐.☐☐
Cardiovascular	Lowest Mean Arterial Pressure (MAP) (mmHg)	☐☐☐
	Inotrope (µg/kg/min)	Dopamine: No ☐ Yes ☐ Dose: ☐☐☐.☐☐ Dobutamine: No ☐ Yes ☐ Adrenaline (Epinephrine): No ☐ Yes ☐ Dose: ☐☐☐.☐☐ Noradrenaline (Norepinephrine): No ☐ Yes ☐ Dose: ☐☐☐.☐☐ Vasopressin: No ☐ Yes ☐ Milrinone: No ☐ Yes ☐ Levosimendan: No ☐ Yes ☐
	qSOFA— Systolic blood pressure ≤ 100mmHg	No ☐ Yes ☐

Baseline Form—Part 1

Participant Trial Number: ☐☐☐☐ **Participant Initials:** ☐☐

Randomising Site:

E. qSOFA, SOFA and APACHE II Scores continued

1) Please complete the following table for qSOFA and SOFA:

qSOFA and SOFA Score		
Organ system	Test	Baseline value
Renal	Highest creatinine (µmol/L)	☐☐☐.☐☐
	Urine Output (mL/24 hours)	☐☐☐☐
Neurological	Glasgow Coma Score (GCS)	*If not possible to complete GCS complete the following questions:* *A) Is patient sedated?* No ☐ Yes ☐ *B) Does patient have an endotracheal tube for ventilation?* No ☐ Yes ☐
	qSOFA— Altered mentation—is the patient confused/delirious?	No ☐ Yes ☐ N/A—patient sedated ☐

APACHE II Score: ☐☐ **OR** CMP Number: ☐☐☐☐☐☐☐☐

If your unit does not contribute to CMP and does not calculate APACHE II scores locally, please complete APACHE II calculation in the APACHE II booklet supplied.

Completion Guidelines for CRF 3: Baseline Form

SOFA Score Guidelines:

- For the purposes of the ADAPT-Sepsis trial the following SOFA and qSOFA assessments will be calculated:

Table 1. Sequential [Sepsis-Related] Organ Failure Assessment Score[a]

	Score				
System	0	1	2	3	4
Respiration					
Pao_2/Fio_2, mm Hg (kPa)	≥400 (53.3)	<400 (53.3)	<300 (40)	<200 (26.7) with respiratory support	<100 (13.3) with respiratory support
Coagulation					
Platelets, $\times 10^3/\mu L$	≥150	<150	<100	<50	<20
Liver					
Bilirubin, mg/dL (μmol/L)	<1.2 (20)	1.2-1.9 (20-32)	2.0-5.9 (33-101)	6.0-11.9 (102-204)	>12.0 (204)
Cardiovascular	MAP ≥70 mm Hg	MAP <70 mm Hg	Dopamine <5 or dobutamine (any dose)[b]	Dopamine 5.1-15 or epinephrine ≤0.1 or norepinephrine ≤0.1[b]	Dopamine >15 or epinephrine >0.1 or norepinephrine >0.1[b]
Central nervous system					
Glasgow Coma Scale score[c]	15	13-14	10-12	6-9	<6
Renal					
Creatinine, mg/dL (μmol/L)	<1.2 (110)	1.2-1.9 (110-170)	2.0-3.4 (171-299)	3.5-4.9 (300-440)	>5.0 (440)
Urine output, mL/d				<500	<200

Abbreviations: Fio_2, fraction of inspired oxygen; MAP, mean arterial pressure; Pao_2, partial pressure of oxygen.

[a] Adapted from Vincent et al.[27]

[b] Catecholamine doses are given as μg/kg/min for at least 1 hour.

[c] Glasgow Coma Scale scores range from 3-15; higher score indicates better neurological function.

Box 4. qSOFA (Quick SOFA) Criteria

Respiratory rate ≥22/min

Altered mentation

Systolic blood pressure ≤100 mm Hg

- Please note, the international name for Adrenaline is Epinephrine. The international name for Noradrenaline is Norepinephrine.

- Tick 'Yes' or 'No' to indicate whether the participant was receiving each inotrope. If 'Yes' is ticked for Noradrenaline, Adrenaline or Dopamine, provide the highest dose of that inotrope over the 24 hour period.

[#]**Conversion of mmHg to kPa** = mmHg × 0.13332

qSOFA should be recorded as close to the first clinical decision of suspected sepsis/septic shock as possible.

Baseline Form—Part 1

Participant Trial Number: ☐☐☐☐ **Participant Initials:** ☐☐

Randomising Site:

F. Co-enrolment

1) Is participant co-enrolled in any other trial? No ☐ Yes ☐

If yes, which trial(s)

_____

_____

_____

Form completed by (print name): _____

Signature: _____ **Date signed:**

Form number: 3

Baseline Form—Part 2

sepsis adapt
Biomarker-guided antibiotic duration for sepsis

Participant Trial Number: ☐☐☐☐ **Participant Initials:** ☐☐

Randomising Site:

A. Infection: Please complete this part when information becomes available

1) Is it a community or hospital acquired infection causing sepsis?

☐ Community acquired
☐ Hospital acquired

2) Presumed site of infection causing sepsis (as determined by the treating clinical team):

Site	Yes/No	Additional information
Respiratory tract	No ☐ Yes ☐	If yes, was it pneumonia? ☐ No ☐ Yes, was it ventilator associated? ☐ No ☐ Yes
Central nervous system	No ☐ Yes ☐	
Skin and soft tissue	No ☐ Yes ☐	If yes, was it a surgical site infection? No ☐ Yes ☐
Central line related infection	No ☐ Yes ☐	
Intra-abdominal	No ☐ Yes ☐	
Urinary tract	No ☐ Yes ☐	If yes, was it associated with a urinary catheter? No ☐ Yes ☐
Ear, nose and throat	No ☐ Yes ☐	
Blood stream	No ☐ Yes ☐	If yes, was it primary? No ☐ Yes ☐ (i.e. not associated with another site)
Unknown focus	No ☐ Yes ☐	
Other	No ☐ Yes ☐	Specify:

Baseline Form—Part 2

sepsis adapt
Biomarker-guided antibiotic duration for sepsis

Participant Trial Number: ☐☐☐☐ **Participant Initials:** ☐☐

Randomising Site:

A. Infection (continued):

3) Is there a causative microorganism identified for the infection causing sepsis?

☐ No → *If no, skip the remaining question and sign off this CRF.*

☐ Yes → *If yes, complete part i below.*

i) What sample was each pathogen detected in? (see reverse for list of pathogens, record all pathogens thought to cause the sepsis episode)

Pathogen: _____

☐ Blood
☐ Urine
☐ Urine (pathogen antigen test)
☐ Respiratory tract
☐ ENT
☐ Cerebrospinal fluid
☐ Intra-abdominal
☐ Central line trip
☐ Wound swab
☐ Other, specify_____

Pathogen: _____

☐ Blood
☐ Urine
☐ Urine (pathogen antigen test)
☐ Respiratory tract
☐ ENT
☐ Cerebrospinal fluid
☐ Intra-abdominal
☐ Central line trip
☐ Wound swab
☐ Other, specify_____

If more than 2 pathogens identified please use continuation page.

Form completed by (print name): _____ *(Please note: your name must be on the trial delegation log)*

Signature: _____ **Date signed:** d d – m o n – y y y y

sepsis adapt
Biomarker-guided antibiotic duration for sepsis

Baseline Form—Part 2

Participant Trial Number: ☐☐☐☐ **Participant Initials:** ☐☐

Randomising Site:

A. Continuation Page:

i) What sample was each pathogen detected in? (see reverse for list of pathogens, record all pathogens thought to cause the sepsis episode)

Pathogen: _____

- ☐ Blood
- ☐ Urine
- ☐ Urine (pathogen antigen test)
- ☐ Respiratory tract
- ☐ ENT
- ☐ Cerebrospinal fluid
- ☐ Intra-abdominal
- ☐ Central line trip
- ☐ Wound swab
- ☐ Other, specify_____

Pathogen:_____

- ☐ Blood
- ☐ Urine
- ☐ Urine (pathogen antigen test)
- ☐ Respiratory tract
- ☐ ENT
- ☐ Cerebrospinal fluid
- ☐ Intra-abdominal
- ☐ Central line trip
- ☐ Wound swab
- ☐ Other, specify_____

Pathogen: _____

- ☐ Blood
- ☐ Urine
- ☐ Urine (pathogen antigen test)
- ☐ Respiratory tract
- ☐ ENT
- ☐ Cerebrospinal fluid
- ☐ Intra-abdominal
- ☐ Central line trip
- ☐ Wound swab
- ☐ Other, specify_____

Pathogen:_____

- ☐ Blood
- ☐ Urine
- ☐ Urine (pathogen antigen test)
- ☐ Respiratory tract
- ☐ ENT
- ☐ Cerebrospinal fluid
- ☐ Intra-abdominal
- ☐ Central line trip
- ☐ Wound swab
- ☐ Other, specify_____

Form completed by (print name): _____ *(Please note: your name must be on the trial delegation log)*

Signature: _____ **Date signed:** d d – m o n – y y y y

Completion Guidelines for CRF 3: Baseline Form

Definition of hospital/community acquired infections:

- Hospital acquired/associated infection occurs at least 48 hours after hospital admission or recent exposure to hospital care.
- Community acquired/associated infection is anything that is not hospital acquired.

Pathogen list:

- When completing question 3, please enter the numerical code corresponding to the following pathogens as applicable:

Code	Pathogen
1	Acinetobacter baumannii
2	Acinetobacter Iwoffii
3	Aerococcus viridans
4	Aeromonas hydrophilia
5	Arcanobacterium haemolyticum
6	Bacillus cereus
7	Bacteroides fragilis
8	Bartonella heselae
9	Bartonella quintana
10	Bordetella pertussis
11	Brucella neotomae
12	Burkholderia cepacia
13	Campylobacter coli
14	Campylobacter jejuni
15	Candida (any species)
16	Citrobacter freundii
17	Clostridium difficile
18	Clostridium perfringens
19	Corynebacterium diphteriae
20	Corynebacterium jeikeium
21	Corynebacterium urealyticum
22	Eikenella corrodens
23	Enterococcus faecalis
24	Enterococcus faecium
25	Enterobacter aerogenes
26	Enterobacter cloacae
27	Escherichia coli
28	Fusobacterium nucleatum
29	Haemophilus influenzae
30	Helicobacter pylori
31	Influenza virus A
32	Klebsiella oxytoca
33	Klebsiella pneumoniae
34	Lactobacillus acidophilus
35	Legionella pneumophilia
36	Listeria monocytogenes
37	Microbacterium sp.
38	Micrococcus luteus
39	Moraxella catarrhalis
40	Morganella morganii
41	Mycobacterium chelonae
42	Mycoplasma bovis
43	Neisseria meningitidis
44	Nocardia nova
45	Pasteurella multocida
46	Propionibacterium acnes
47	Proteus mirabilis
48	Proteus vulgaris
49	Providencia stuartii
50	Pseudomonas aeruginosa
51	Rothia dentocariosa
52	Salmonella enterica
53	SARS-CoV-2
54	Serratia marcescens
55	Shigella sonnei
56	Staphylococcus aureus (MRSA)
57	Staphylococcus aureus (MSSA)
58	Staphylococcus epidermidis
59	Staphylococcus haemolyticus
60	Staphylococcus lugdunensis
61	Staphylococcus saprophyticus
62	Stenotrophomonas maltophilia
63	Streptococcus agalactiae
64	Streptococcus gordonii
65	Streptococcus mutans
66	Streptococcus pneumoniae
67	Streptococcus pyogenes
68	Veillonella dispar
69	Vibrio parahaemolyticus
70	Yersinia pseudotuberculosis
71	Other, specify

Please note that this pathogen list is a comprehensive list of bacteria associated with sepsis and also includes Candidia (no. 15) species which are fungi and Influenza virus A (no.31) and SARS-Cov-2 which are viruses, which can also be associated with sepsis.