



ADAPT-Sepsis Trial

Biomarker-guided Duration of Antibiotic treatment in hospitalised Patients with Sepsis

[Frequently Asked Questions](#)

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What timeframe does the baseline sample need to be taken in?

The baseline sample should be taken after randomisation to the trial, and should still be within 24 hours of starting intravenous antibiotics for a suspicion of sepsis. If the sample cannot be taken within 24 hours of starting antibiotics, the patient should not be randomised on the trial.

What should we do if we haven't received any advice back by the afternoon, but we did send a sample in to the labs?

When troubleshooting for ADAPT-Sepsis, it's really important to remember that this a blinded trial, and therefore the allocation of each patient should be concealed during discussions. For this reason we suggest getting in touch with us, and we will then liaise with the lab team to see if there is a problem.

What happens when ADAPT-Sepsis participants are discharged to the ward?

When patients are discharged to the ward blood sampling will need to continue, either until antibiotics for the suspicion of sepsis are stopped or until the 28 Day Follow Up time point. This can mean identifying the treating team to pass the protocol stoppage advice onto.

What happens if we can't find the clinical team to hand the protocol stoppage advice over to?

If the treating team can't be found or identified, a protocol deviation needs to be completed in the unscheduled events on the database, with details as to why the advice couldn't be handed over.

How do we know which trials you are co-enrolling with?

We are constantly updating the trials we can co-enrol with, so if you have a patient who has participated in another trial, please get in touch with us to see if there is a co-enrolment agreement in place. Similarly we provide an up-to-date list on our site newsletters.

What should we do if the baseline sample is taken too late to analyse in the lab?

The sample can be placed in the fridge to be tested first thing the following morning. The lab team will need to ensure that the results are inputted prior to the results of the next day's sample to ensure the protocol advice is returned to the research team in the correct order.

Data Collection

A patient has been withdrawn from intervention but remains on follow up. A withdrawal CRF has been completed, but an intervention form keeps being generated on the daily data tracker, how can we stop this?

If the patient has withdrawn from the intervention but not from follow up, once the withdrawal CRF has been completed the "Stop" button can be pressed on the daily data tracker. This will stop daily intervention forms from being completed. Please continue to collect antibiotic data from the patient up until day 28.

If there is no urine output available at baseline, shall we leave this blank on the baseline SOFA Score CRF?

If a baseline urine output within 24 hours of randomisation, please use the closest available data possible prior to randomisation.

If a patient dies whilst still on antibiotics, what do I put as the end date and time on the antibiotic CRF?

Please put the date and time of death as the date and time of the end of antibiotics. Please also ensure a Death Notification Form has been completed.

If a patient isn't under assisted ventilation, what do I put for the P/F ratio?

If a patient isn't on any assisted ventilation, either invasive or non-invasive, the default to 21% oxygen (FiO₂ would be 0.21 in the P/F equation). The PaO₂ will be taken from the closest blood gas analysis. The P/F ratio can then be calculated.

Do we need to collect anti-fungals on the antibiotic form?

No, we do not need to collect any information about anti-fungals on ADAPT-Sepsis.

How do I record CMP number on the eCRF if I don't have the APACHE II score?

As you know, the CMP number is made up of an 11 digit number, which consists of the 8-digit patient admission number, and the site identifier. Please enter the 8-digit patient number onto the eCRF.

Eligibility/ Consent

What do you mean by severely immunocompromised?

This would have to be judged by the clinical team. Any patient who has had a bone marrow transplant would not be considered eligible for the trial. As an example of neutropenia; neutrophils <500/microliter has been provided, outside of this is down to clinician discretion.

Do you have a trial definition of acute organ dysfunction?

No, this would be assessed as per the discretion of the diagnosing team.

Does the eligibility have to be assessed by a clinician on the delegation log?

The eligibility does not have to be assessed by a clinician on the delegation log. Research nurses can confirm that patients fulfil all of the inclusion criteria, with the exception of confirming that the patient is likely to remain hospitalised and receiving antibiotics for the next 72 hours. This has to be confirmed by a clinician, but they do not have to be listed on the delegation log.

Do consultants receiving the stoppage advice have to have GCP training?

The protocol antibiotic stoppage advice must be sent initially to only members of staff who are listed on the delegation log. The email can then be forwarded on to other members of staff not related to the trial. However, consultants who are listed on the delegation log to receive the trial advice do not have to have GCP training.

Can we recruit a participant who has a DNAR in place?

There may be different reasons for a patient to have a DNAR in place, and therefore we ask you to use your discretion when determining whether it's appropriate to approach the patient/nominated consultee. If a DNAR is in place as it's felt that the patient would not survive a resuscitation attempt, then we would ask you to consider the patient for ADAPT-Sepsis.

How long do we keep trying to gain retrospective consent for, if the patient was discharged before we could discuss the trial with them?

If you are aware of the patient regaining capacity, then please phone ahead prior to sending the PIS/consent form out to them, regardless of whether they have reached the Day 28 time point. If a couple of attempts are made to contact the patient and no response is received, then we are confident that this would constitute 'best efforts', and we therefore feel that it would not be appropriate to continue to chase.

If the patient did not regain capacity prior to being discharged and prior to Day 28 Follow Up, then as per Section 2.7.1 of the protocol, patients will have been expected to give consent to those data collection points.

Sites open to recruitment – lab team

When speaking to the research team, please remember that they are blinded, so please ensure care is taken to maintain the allocation concealment.

Is there a button to press if the sample is haemolysed, or can't be processed?

Currently on the database there is no function to mark a sample as haemolysed. In this instance you would need to contact the trial team at Warwick CTU on 02476 151665 to confirm that no result will be entered, and therefore that no treatment advice will be generated. The trial team will then get in touch with the research team to advise standard care.

What should we do if a sample arrives too late to process?

If a sample arrives too late in the day to process, it can be put in the fridge to be run the next morning. However, the results of that sample must be uploaded onto the database before the results from that day's research sample. If you are required to do this, please get in touch with the research team to advise them that they will be receiving two pieces of advice that day, and that the first piece of advice will be from the previous day's sample.

I have received a sample in the lab but it is not visible on the tracker – why is this?

If the sample isn't visible on the tracker when you log onto the database, this is most likely to be because the 'send sample to lab' hasn't been pressed by the research team. This may be because the research team haven't come in to work yet, so firstly it may be worth putting the sample in the fridge, and waiting for an hour before trying again. Failing this, it might be necessary to get in touch with the research team to ask someone to press the button. Please remember [the research team are blinded](#), so please do not reveal which arm the patient is on.