



## **ADAPT-Sepsis Trial**

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

### [Frequently Asked Questions](#)

### [Potential or New Sites](#)

#### **Why is this trial important?**

The ADAPT-Sepsis Trial is the result of a National Institute of Health Research (NIHR) Health Technology Assessment (HTA) commissioned call for high quality evidence in the field of antibiotic use in sepsis to benefit patients. It responds to evidence gaps and recent research recommendations from NICE (Diagnostic Guidance (DG 18) for Sepsis 2015).

#### **Who is the funder of this Trial?**

National Institute of Health Research (NIHR) Health Technology Assessment (HTA) Commission.

#### **Is the Trial eligible for NIHR Clinical Research Network (CRN) Portfolio adoption?**

Yes, NIHR HTA funded trials are automatically eligible for NIHR CRN Portfolio adoption and support.

#### **Is there any funding available for us as a site to be involved in the Trial?**

Yes – There is a per-patient payment of £50.

We have calculated NHS support costs of 2 hours nursing time per patient for recruitment and consent.

NHS Treatment (inc. excess treatment) costs have been included for laboratory analysis of any additional CRP and PCT tests within trial.

For PCT set-up and wastage – funding solutions are available. Please get in contact with the trial team at [adaptsepsistrial@warwick.ac.uk](mailto:adaptsepsistrial@warwick.ac.uk) for further details for your site.

#### **How many sites will participate in ADAPT-Sepsis?**

We are aiming for approximately 48 sites across the UK.

#### **What are the timelines for being open for recruitment?**

We are now working with sites for the main phase of the trial and will be opening sites until the end of April 2021.

#### **How long will the trial be open for and what is the recruitment target?**

The trial opened in January 2018 and is planned to continue until the end of April 2021 with the aim of recruiting 2760 patients.

### **What would be the per site recruitment target?**

To achieve our recruitment target, we need sites to recruit approximately 4 patients per month from the time they join the trial.

### **Can patients be co-enrolled to other critical care research trials?**

Please refer to [our website](#) for the list of trials (both observational and interventional) with which ADAPT-Sepsis can co-enrol. It is frequently revised and your response to our site selection questionnaire will assist us with this.

### **Can I still be involved in the trial if our site does not provide local laboratory PCT analysis?**

Yes – we can work with you and your team to facilitate NHS adoption of a laboratory PCT assay for your Clinical Biochemistry Department, which includes financial support.

### **Is the trial funded by a commercial partner?**

No – the trial is funded via the NIHR and with NHS support. Thermo Fisher Diagnostics Limited, by way of a memorandum of understanding, have agreed to assist the trial team with the adoption of new laboratory PCT assays into the NHS as required. Thermo Fisher have no involvement in the design and delivery of the trial, the trial data or its findings, and trial dissemination.

We have been working with commercial assay platform suppliers for help regarding the PCT wastage issues. This has been supported by NIHR HTA. The commercial suppliers have no involvement in the design and delivery of the trial, the trial data or its findings and dissemination.

### **We already use daily CRP though do not have a protocol for discontinuation of antibiotics. Should we be selected as a site would “standard care” be our current practice, with the “standard care + CRP” being use of a CRP based protocol, or would we have to stop measuring CRP routinely for patients in the “standard care” group?**

You can continue to measure CRP daily as per your standard practice. We use an extra trial blood sample in order to test either CRP or PCT levels, and you would be blinded to the result.

### **We already use PCT though do not have a protocol for discontinuation of antibiotics. Should we be selected as a site would “standard care” be our current practice, or would we have to stop measuring PCT routinely for patients in the “standard care” group?**

You will not be able to continue routinely measuring PCT for trial patients and must be able to ensure a position of equipoise. This is because the guidance for stopping antibiotics utilising PCT is better defined than the guidance for CRP.

**We don't have 24/7 research nurse cover, can we still take part?**

Yes – we can work with you and your team to establish how the intervention can be delivered in the absence of the team.