BiomArker-guided Duration of Antibiotic treatment in hospitalised PaTients with **Sepsis**

FAQs for Blood Sciences Laboratories

Q) Will the ADAPT-Sepsis trial take a lot of laboratory time and resource?

A) No. ADAPT-Sepsis samples can easily be worked into the lab's routine workflow, although booking in of an ADAPT-Sepsis sample may take slightly longer than a routine hospital or GP sample.

Q) Will it be difficult dealing with lots of ADAPT-Sepsis trial samples at once?

A) No. The target recruitment for a site is one patient per week into the trial. As the research nurse team will have a significant amount of work generated by each patient in the trial, the likelihood of multiple patients in the trial at once is low. The most I have personally handled at one time is 4.

Q) Running procalcitonin takes a long time compared to CRP. Will it not be obvious which test is being performed thereby negating the blinding?

A) No. There is an in-built delay in the ADAPT-Sepsis database that will delay the sending of advice to the clinical teams for patients in the CRP or No-Test arm based on the average time of PCT reporting.

Q) We have rapid turnover of staff, especially in our specimen reception team and are worried we will not be able to log into the database if staff have moved on. What do we do?

A) From my personal experience, it has been easier to not involve specimen reception in handling ADAPT-Sepsis samples and restricting it to BMS or Clinical Scientist staff to receive the samples and handle them. Although this can be an added pressure on time, particularly on weekends, once staff are familiar with the trial, it can easily be worked into a daily routine.

Q) This trial requires lab input which is different and a lot more than what we would do for other trials, so we're unsure we can accommodate it. Is there staff resource available?

A) There is no direct staff resource available as part of the trial, however the lab input is quite minimal. Although the lab staff are required to log into the ADAPT database to discover which test to perform and to report the results, this should realistically take no more than 2 minutes per sample per day.

Q) How will ADAPT-Sepsis sample analysis fit into our existing workflow of handling samples?

A) Whilst ADAPT-Sepsis samples require some careful handling that is different to routine samples, this should not adversely affect existing workflow. Having set the trial up in two labs, my own experience has shown that keeping the

ADAPT-Sepsis trial within the biochemistry staff and generally limiting it to qualified staff to handle has helped minimize the disruption to the service. Ensuring that the research teams know who to contact to hand samples over means that when samples arrive in the lab, they are handed over to the person who can deal with them there and then. This may be the duty BMS or duty biochemist, or another named individual with responsibility for dealing with ADAPT-Sepsis samples that day. Working it into routine practice within the laboratory daily routine seems to be the easiest way to ensure the trial works.

Q) How can ADAPT-Sepsis samples be integrated into our LIMS system?

A) At the labs where I set up ADAPT, we created a single dummy patient in the LIMS with, for example, the Surname ADAPT SEPSIS and the Forename RESEARCH or something similar. Every ADAPT-Sepsis sample was booked in using this patient and the patient's trial number was used as the clinical information so that it was easy to link each patient in the trial with the results produced. This dummy patient did not communicate with any other patient software so there was no risk of the results being returned to the requesting clinicians. In one of the labs, non-lab staff had access to a read-only version of the LIMS to look up results. In this instance, we made the ADAPT-Sepsis patient so that it could not be viewed through the read-only interface again so there was no chance of the result being received by the research or clinical teams.

Q) How does the lab communicate results to the research teams?

A) The lab does not (and in fact MUST NOT) communicate results directly to the research team. Results must only be entered into the database which translates the result into an advisory comment which is then relayed to the research teams by email.

If for any reason the laboratory system is down and, for example, PCT results cannot be reported, it is important that the research team are NOT informed of which test is unavailable as this may inadvertently unblind the research team.

Q) Who in the lab will work on ADAPT-Sepsis, who needs database access, and do they need GCP training?

A) In my personal experience, it has been best to restrict the ADAPT-Sepsis trial to qualified BMS and Clinical Scientist staff. All staff associated with the trial will need database access, and the local laboratory lead will need to have GCP training and will be the only person listed on the delegation log. All other BMS and clinical Scientist staff will be listed on the Lab read and acknowledgement form.

If there are any questions you have that aren't answered here, please get in touch either through the ADAPT-Sepsis team or by email and I will endeavor to answer.

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