

# SOLVE Trial: COVID-19 Guidance for sites

Due to the rapidly changing situation regarding COVID-19, we anticipate difficulties with restricted travel for staff and participants, and redeployment of research staff to NHS frontline roles. We are working under these unprecedented circumstances to ensure participant safety, maintain the integrity of the trial, and collect primary outcome data.

## **Temporary Pause to Recruitment**

As part of our response to the COVID-19 pandemic, it has been necessary to implement a **temporary pause on the recruitment of new patients into SOLVE until further notice.**

## **Participants still in Follow-Up (FU)**

**Where possible, participants already enrolled in SOLVE and yet to complete FU should be continue in the trial as per protocol.** This includes:

- Receiving the allocated trial intervention and provision of any follow-up (FU) data including safety reporting. Where the participant is unable to receive the allocated trial intervention, please ensure this is recorded so that it can be captured on the relevant CRF.
- That said, we recognise that in some instances, this may not be possible. Should you have to prioritise FU activities, **please ensure that safety reporting is the top priority.**
- Any other FU data can be provided at a later date when resources allow, though please ensure that any participant contact is documented in the clinical notes as normal.

## **Regarding safety reporting:**

- Please continue to report SAEs as per protocol (ie within 24 hours of awareness).
- However please **email** SAEs to the [SOLVE@trials.bham.ac.uk](mailto:SOLVE@trials.bham.ac.uk) mailbox.
- When emailing SAEs, please ensure the subject title includes 'SAE' and the participant's trial number.

## **Sending of hard-copy documentation**

- For the moment, please retain any hard-copy documentation that you would usually post/fax to the SOLVE Trial Office.
- Unless you are able to email it to the [SOLVE@trials.bham.ac.uk](mailto:SOLVE@trials.bham.ac.uk) mailbox

- Though please remember, if you are **emailing consent forms, these should be sent via encrypted email**. If you are unsure how to send an encrypted email, please contact the Trials Office, as they will be able to provide guidance on this.

### **Deviations**

- Please document all protocol deviations locally. The SOLVE Trial Office will provide guidance on how these should be reported when the COVID-19 crisis is over.

### **SOLVE Trial Team Contacts**

**Email:** [SOLVE@Trials.bham.ac.uk](mailto:SOLVE@Trials.bham.ac.uk)

**Phone:** 07866312007 (please only ring between the hours of **9am - 6pm Mon-Fri** (unless urgent), as this is my personal number)

All latest updates could also be found via our website:

<https://www.birmingham.ac.uk/research/bctu/trials/womens/solve/index.aspx>

### **Guidance documents**

HRA:

<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/covid-19-guidance-sponsors-sites-and-researchers/>

NIHR:

<https://www.nihr.ac.uk/news/dhsc-issues-guidance-on-the-impact-on-covid-19-on-research-funded-or-supported-by-nihr/24469>

### **Please Note:**

This document is correct as of 26<sup>th</sup> March 2020, and further changes may follow in the coming days. We will try to offer as much practical advice as we can to help you with the running of the SOLVE trial under the current circumstances.

Thank you, and all the very best to everyone your end,

SOLVE Trial Management Group