

Principal Investigator & Project Team

RE: Guidance and Support for ROKC Managed Studies

version 2.0 dated 27th APRIL 2020 with updates to: IMP Supply and Diagnostics sections.

Thank you for your professional and dedicated management of your patients and their safety on NEAT ID and ROKC Studies during this exceptionally difficult time. We will continue to support you and your colleagues over the coming months.

We have compiled a checklist of actions and solutions to address the practical aspects of managing patients safely on clinical trials, which we hope you will find helpful. Following our discussions with clinical sites over the past two weeks, we believe many are already implementing some or all of this guidance.

This guidance has been produced in line with the guidance provided by your National Regulatory Authority and has been reviewed and approved by the Chief Investigators of our Studies and the NEAT ID Executive committee.

IMP Supply

- We recommend that you regularly check stock levels of IMP. Please contact your local Monitor or the study Project Manager if you have any problems.
- Patients (or a relative/friend) should collect study medication from Pharmacy. If this is not possible, then home delivery should be considered. If you have any difficulty in arranging delivery of trial drug to a patient's home via your Pharmacy, please contact your local Monitor or the study Project Manager for further support.
- Conduct a risk assessment for home delivery and record locally, including delivery mechanism, confirmation of receipt of Study drug by patient and home storage arrangements. Where study drugs can be transported and stored ambiently, there is no requirement for temperature monitoring or special storage arrangements.
- You will be able to supply up to 6 months of Study medication. *Note: Currently not applicable in Italy.*

Patient Visits

- Where face to face appointments are not permitted, replace visits with telephone calls and document in the patient's medical record.
- Any appointment visit deviations must be documented locally. Your local Monitor or the study Project Manager can help with this.

Monitoring Visits

- ROKC uses remote, risk-based monitoring for our Studies, which is supported by your National Regulatory Authority.
- We recognise that scheduled on site visits will need to be reduced or cancelled during COVID-19 pandemic.
- Appropriate risk assessments and rationale for any reduction in visits should be properly documented.
- Your local Monitor will work with you to continue the remote monitoring of your site as per the Monitoring Plan. Where on-site visits will fall outside the visit window, these will be recorded by

your Study Monitor.

Signing Documents

- Where wet ink signatures are required for Study documentation, ROKC will move to digital signatures using **DocuSign**. Your local Monitor or the study Project Manager will provide guidance and support on how to use **DocuSign**.
- There is no cost to clinical sites to use **DocuSign**.

Diagnostics (Blood tests and other assessments)

- Patients unable to attend clinic for blood tests or other assessments should have their appointment performed by telephone and diagnostic visits rescheduled to a later date. Patient visits should be managed in line with your local protocol for returning to normal services after COVID-19.
- Where blood tests are deemed necessary as part of maintaining patient safety, a risk vs. benefit assessment (contracting COVID-19 when visiting the site vs. performing safety tests) must be conducted on a case-by-case basis, and documented in the patient's medical records. This should be a clinical decision based on the individual patient's situation and trial specifics. The assessment should determine if the patient is required to attend an on-site visit.
- Any blood test deviations must be documented locally.

Managing deviations and serious breaches

- General guidance from Regulatory Authorities in all countries has been consistent, pragmatic and supportive on managing deviations.
- Please ensure all deviations are documented, to enable appropriate evaluation of the trial, including, visit dates, bloods and other diagnostics, assessments and IMP dispensing.

SAE and DSUR reporting

- Please submit reports as soon as possible and notify your local Monitor or the study Project Manager.

SUSAR reporting

- Particular attention should be paid to timely reporting of a SUSAR where patient safety is at risk. Every effort should be made to notify your Regulatory Authority via your local Monitor or the study Project Manager.

New patients

- Please note that all Studies are still open to recruitment, subject to appropriate local risk assessment and prioritisation of patient safety.
- Please contact your local Monitor or the study Project Manager for further guidance and support.

Regular communication

- Please maintain regular contact with your local Monitor or the study Project Manager. Should you have any questions relating to a Study you are managing do not hesitate to contact a member of the study team.
- We will maintain appropriate levels of communication and contact with you during the COVID-19 pandemic, taking into consideration the clinical service pressures being experienced by your clinical site.
- Please ensure that you are familiar with the current guidance from the applicable Regulatory Authority and Ethics Committee in your country and frequently monitor updates from them.

Thank you again for your continued support of our Studies and the safe management of your patients. We trust this guidance will be helpful to you in your daily management of patients and please contact your local Monitor or study Project Manager for further advice and support whenever required.

Kind regards,

ROKC Study Team