

13 March 2020

Dear Sponsor or CRO,

We understand the concern that is being expressed by Sponsors and Clinical Research Organisations (CROs) over the potential effects of the COVID-19 on trial activities.

We are following all guidelines provided by the Department of Health and these have been disseminated to all Icon Cancer Centre clinic staff and Icon Research staff at Icon Cancer Centre clinics and our Cordelia Street office. Staff have been educated on preventative and management guidelines of COVID-19 and there are appropriate plans in place for Icon Research to continue to operate as business as usual in the unlikely event of a quarantine. Hand sanitisation and general hygiene measures are in place and adopted at all Icon facilities as part of our general practice and all staff have reviewed our Personal Protective Equipment (PPE) video which provides guidance on donning and doffing.

The current situation is evolving and our plans will also evolve, but as of today Icon Research has undertaken risk mitigation measures to minimise transmission of COVID-19 and the risk to the conduct of research at Icon as per the following:

- Staff have been educated on how to manage suspected COVID-19 patients and a triage flow chart has been developed to guide staff on the management of suspected cases.
- Any trial patients who need to be quarantined for possible COVID-19 exposure in the community will be discussed with the Sponsor or CRO to arrange the appropriate clinical trial management.
- The Sponsor or CRO will be informed of any trial patient who needs admission for suspected COVID-19 infection via the normal SAE reporting mechanisms, but a discussion between the PI and the medical monitor would also be arranged.
- There are no plans to alter patient attendance at Icon Cancer Centre for clinical trial activities at this stage and patients who self-isolate will be assessed on a case by case basis.
- It may be recommended that for specific clinics and for specific clinical trials that limitations be placed on the research activity such as only new and urgent patients attending the centre (with the exception of patients on treatment) and all follow up consultations conducted via telephone or telehealth. The conduct of clinical trials under these arrangements will be negotiated between the Sponsor or CRO and the team from icon Research.
- CRAs can monitor at site as usual as long as they haven't travelled to China, Korea, Italy or Iran within the last 14 days. Other countries may be added to this list as the situation evolves.
- CRAs and any visitors attending Icon Research, the pharmacy or sites will need to confirm in writing 24 hours prior to attendance that they are not unwell with fever, sore throat, shortness of breath. Visitors presenting to Icon with any of these symptoms will be turned away.
- Whilst Icon Research will still facilitate any planned site visits or audits, Sponsors and CROs should strongly consider delaying any visits that involve overseas auditors travelling to Australia. This would also apply to regulatory inspections.
- Icon Research staff will not be travelling overseas to attend investigator meetings and Icon is also restricting domestic and cross-site travel to essential movement. In view of this, Icon is encouraging the utilisation of remote meetings via WebEx, Microsoft Teams or Skype as applicable.

- There are no recommendations from Icon currently to postpone or cancel initiation meetings for new research provided that the risk mitigation measures listed above are met.
- If Sponsors and CROs know of any possible effect on the continuance of IMP supplies, Icon should be notified as soon as possible.
- If Sponsors know of any effect on central lab kit supplies, we should be notified as soon as possible.

As an organisation Icon has implemented specific measures across the Australia cancer care division to keep employees and our patients safe.

Icon Frontline Screening Measures

- Screening prior to arrival – Icon is continuing to contact all patients before their appointment, asking all patients and companions to self-screen for travel, exposure to COVID-19 and symptoms before arrival. Many patients are responding to this and calling before arrival if they meet any of the criteria.
- Restriction on unwell visitors – Visitors have been asked not to enter our centres if they have any symptoms of a respiratory infection.
- Hand hygiene - Centres are provided with additional hand hygiene stations to support good hand hygiene amongst our visitor population.

Updated advice for Healthcare Workers

Any healthcare worker who has either of the following:

- Fever
OR
- Acute respiratory infection (e.g. Shortness of breath, cough or sore throat) with or without fever

must attend to the following:

- Exclude themselves from the workplace
- Seek medical advice (e.g. GP, local fever clinic or an Emergency Department) including:
 - Inform the doctor that they are a Healthcare Worker, working directly with cancer patients in a treatment facility
 - Ask whether they require testing for COVID-19
 - Clarify when they are able to return to work
- Keep their manager informed as to their situation and the outcome of their medical review

We will keep Sponsors and CROs updated should any changes occur.

Kind regards,

Adam Stoneley
Research Operations Manager, Icon Research