Level 1, 22 Cordelia Street
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31 March 2020

Dear Sponsor or CRO,

Keeping our patients and staff safe is our number one priority, and the Icon Group's management team are meeting daily to respond to the evolving environment to ensure that the measures we have in place across Australia are the strongest they can possibly be to keep our patients and staff safe.

As indicated on our previous correspondence, alongside with good hand hygiene, the most critical and rudimentary measure we have implemented is a strong and uncompromising social distancing policy. Since the prior updates to sponsors, there have been further developments that impact on the conduct of clinical trials at Icon. The first 10 points listed below are changes in policy that have been introduced that do not directly relate to the conduct of clinical trials but are relevant, whereas the subsequent points 11 to 20 are more closely related to Good Clinical Practice (GCP), protocol compliance and participant activities.

1. Telehealth

All investigators have been advised to consider whether their patients can be reviewed by telehealth. At this point in time, Icon Research is not planning on enforcing telehealth consultations, but Icon Research is in the process of identifying relevant clinical trials and suitable patients for telehealth, and subsequently notifying the research sponsors/Investigators accordingly.

2. Working from home

Icon has decided to implement a remote working model for our Brisbane head office which includes our data management team, our research implementation team, our research finance team, management staff and clinical trial coordinators (CTCs) when not required at clinic. Research staff will continue to be available via email and video conferencing platforms in line with current working hours. We expect remote working to remain in place for at least the next month and we will endeavour to minimise any changes to workload and disruptions to communication resulting from this change in work pattern.

3. Focussed but reduced clinical workforce

Icon Research has been working hard to investigate how we can mitigate the potential workforce impact of isolation requirements through time efficient scheduling of clinic attendance by research staff. Icon's significant front-line staff base of CTCs will be limiting time in clinic to patient visits and supporting the conduct of clinical trials and will be working from home for the remainder of the time. This reduced but focused capacity is necessary to reduce the risk of transmission and quarantine for the entire CTC team at each clinic. All CTCs will have their office phones forwarded to their mobile and will be available during working hours.

4. Social distancing in the clinic environment

There must now be no more than one visitor per patient. This is part of our efforts to support social distancing and hygiene practices within the centre. Social distancing measures are also in place within the centre waiting areas, including seat spacing and fast tracking of patients to ensure close contact periods are not exceeded.

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5. Heightened clinic screening

All patients and companions attending clinical sites will now be verbally screened for respiratory symptoms, signs of a fever, recent travel or contact with a COVID-19 case. This entry screening extends to patients, their visitors, suppliers and contractors before being allowed inside the facility, and is performed in addition to the patient and visitor screening message sent out prior to their appointment.

6. Contractor and supplier screening

Further to Icon's entry screening for visitors and patients, Icon has requested all service providers such as radiology to provide notification of their own screening measures to ensure their staff are appropriately screened in line with our own measures. Icon has also requested that all known contractors screen their workers before sending anyone out to the site.

7. Self-isolation travel changes

In accordance with the government's announcement and policy, that anyone returning from overseas travel must self-isolate for fourteen days, all staff, patients and visitors travelling overseas are required to follow the current government regulations such mandatory hotel isolation for returning overseas travellers. Anyone arriving in Australia is provided with a public health notice with self-isolation commencement date and clearance to return to work date fourteen days from the arrival or return to Australia. For staff, if COVID-19 symptoms develop during the self-isolation period, the team member must notify their manager and seek urgent medical attention and if symptoms are present medical clearance must be provided before requesting further direction from their manager.

8. Patients from northern New South Wales

A significant number of Icon and Icon Research patients reside in northern New South Wales and travel to Icon Cancer Centre clinics for treatment and trial appointments. As per advice from both the governments of Queensland and New South Wales, the closure of the border between Queensland and New South Wales will not affect patients travelling for medical treatment as this is deemed to be for essential purposes. These patients have been advised to apply for an exemption pass which will allow their treatment visits to continue.

9. New patient information and FAQ flyer

Icon understands that patients may have many questions about their treatment during COVID-19. To help address patients' concerns and anxiety, a patient information and FAQ sheet is provided to all patients when they visit. It is also accessible online at https://iconcancercentre.com.au/covid-19/ and is regularly updated as Icon's measures continue to evolve around the rapidly changing situation.

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10. Staff wellness acknowledgement log

Every member of staff is required to report on a daily basis their general health and wellbeing to their manager, specifically reporting presence or absence of any fever or acute respiratory symptoms. If any team member has to be excluded from work due to fever or respiratory symptoms, they need to seek medical advice and can only return to work with medical clearance. This may include being tested for COVID-19 and obtaining a negative test result, however Icon is aware that staff may currently not meet the criteria for testing. Medical clearance from the team member's GP would remain the correct criteria to return to work in that instance.

11. Activation of new trials

Icon Research is requesting Investigators to identify where there is an immediate need to commence their specific studies that are awaiting activation or initiation. If the Investigator indicates that there is no immediate need, we are requesting the Sponsor to delay activation of the trial. The determination of this immediate need is based upon whether there are patients who have limited treatment options and the trial opportunity allows this to be addressed.

12. Conduct of site qualification and initiation visits

All site qualifications must be virtual and using telephone or teleconferencing alternatives.

13. Restriction to participant visits

Patient visits and treatments may be impacted or restricted in accordance with the direction of the Investigator for reasons of patient safety. It is anticipated that trial participants of vulnerable populations may not wish to present to the clinic for research appointments. The Clinical Trial Coordinators will communicate with trial participants to limit this or seek alternatives including but not limited to tele-health or telephone consultations with investigators. It is expected that patients will need to utilise additional or unanticipated pathology or radiology service providers if they are not attending their regular clinic. We understand that these additional facilities will need to be added to the FDA 1572 and other documentation as necessary when identified.

14. Enrolment of trial participants

Icon is committed to continue offering research opportunities to patients but Investigators have been asked to enrol patients dependent upon whether there is a definite need to treat on a clinical trial regimen, or when there are no or limited treatment options for the patient or when the participation in the trial does not require any additional appointments for trial purposes.

15. Deviations from protocol and protocol amendments

It is anticipated that there may be a number of instances that will result in lack of adherence to the protocol related to social distancing, participant attendance, issues with the supply chain, reduction in the study team and others. When these changes or challenges arise Icon Research will be reaching out to the sponsor and relevant Human Research Ethics Committee (HREC) to discuss proactive solutions or document in preparation for subsequent reporting of protocol deviations.

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16. Impact of reduction in staff

As per the earlier points, our teams of research finance, data management and research implementation are all operating on a work from home model and the Clinical Trial Coordinators based are operating on split team capacity models to comply with social distancing policy and ensure continuity of operations if there is an exposure to COVID-19 and quarantining is required. There will be an expected decrease in response to communication and conduct of timely activities and we implore the sponsors to show patience and flexibility at this time.

17. Restriction to on-site monitoring visits

On site monitoring visits have been cancelled for the next month until the 27th of April 2020. It is not known whether the remote working model will continue beyond this date but updates and anticipated duration will be provided as the situation evolves. While monitoring visits will be cancelled, video/phone calls with Clinical Trial Coordinators and Data Managers can be arranged to discuss queries.

18. Authorisation of documents and signatures

Given that the operations of Icon and Icon Research are required to immediately comply with strict social distancing protocols, lack of contact tracing for external documents and reduction of staff due to shift splitting, the use of “wet ink” is no longer supported by the organisation. It is advised that where digital signatures replace wet ink signatures on regulatory documents and untraceable documents using applications such as DocuSign and Adobe Acrobat. For internal documents requiring signatures, scanned copies of the original signed document will suffice.

19. Remote data review by external monitors

As Icon Research currently use paper medical records for clinical trial source data records and Icon does not have an electronic medical record (EMR) system that allows secure, patient-limited, remote access with compliant audit trails, there is a current need to provide remote source data verification. Icon Research has explored the potential use of sending masked or redacted copies of scanned clinical trial source data but this is an exhaustive task and still would require follow-up source data verification post review and post pandemic to ensure authenticity.

The current solution which is expected to go live in early April 2020 is the provision of secure virtual monitoring “rooms” where monitors and CRAs would be provided access to a remote, secure and trial-specific data room via a ISO27001 certified and SOC2 compliant platform containing the pre-requested clinical trial source data documents and investigator site file documents.

This application would be managed by the Data Manager Team Lead and the Research Operations Manager and permission would only be granted by them after receiving a request from the Data Manager for the trial. The request would be prioritised according to endpoints of the clinical trial, schedule of data locks and other factors and would require at least 1 week’s notice for an appointment in the virtual motoring room.

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20. Investigational product delivery to patients

In the context of limiting the need for clinical trial participants attending clinics, Icon is considering the option of dispensing and dispatching oral investigational product directly to patients if there is a corresponding telehealth appointment and the sponsor has provided advice and approval for this arrangement to occur. Clinical Trial Coordinators and River City pharmacy staff will be in contact with the sponsors of relevant studies to see if this is possible and then seek approval for the relevant HREC to seek an amendment to the conduct of the protocol.

I would like to ask for your consideration and patience as we adhere to Icon policy, protocol compliance and care for patients and staff concurrently. Please contact me on (07) 3737 4558 or adam.stoneley@icon.team if you have any additional questions or concerns, or refer to updated Letters to Sponsors at https://iconcancercentre.com.au/research/#covid-19 .

Kind regards,

Adam Stoneley

Research Operations Manager, Icon Research