Level 1, 22 Cordelia Street
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25 May 2020

Dear Sponsor or CRO,

There is no doubt that the unprecedented challenges caused by COVID-19 have required a mammoth and sustained effort by our entire workforce. It has now been three months since Icon started SMS screening of patients, two months since the World Health Organisation declared COVID-19 a global pandemic and seven weeks since a number of Icon sites commenced treatment in PPE. Across all centres, staff have had to learn freshly developed protocols for treating patients at various levels of COVID risk and many people have had to work from home and find new ways to share information, have robust debate and make decisions without the normal non-verbal communication to assist.

In the coming weeks, when it is safe to do so based upon new and active cases in local catchment, sites will start to transition from Level 2 to Level 1 COVID-19 Safe Status and then to Preparedness. Under the move to Preparedness, the offsite workforce will return to sites. Icon will evaluate each sites ability to continue to segregate the teams on site and to implement working arrangements that limit cross infection. This transition will not be rushed, and every site will be assessed to ensure that they are equipped and ready to manage this new way of working before further changes are made.

With the easing of restrictions in the community due to a strong performance flattening the curve, Icon has reviewed the timeline for the return to the Cordelia Street head office under the model of Preparedness. Stage 1 involves an initial wave of staff to return on Monday 25 May 2020 with a maximum of 50% of the staff complement and conformity to social distancing protocols including the minimum distance of 1.5m between workstations or 1 staff member in a $4m^2$ space. The return to the office will be considered and conservative and further entry of staff will be delayed for several weeks as COVID-19 cases are tracked in the community and how people are maintaining social distancing within the office space. Should this continue to move along positively, Icon expects to have people continue to return to the office in two week intervals over the coming one to two months and an expected full complement of staff at June 22 2020.

Icon Research have implemented specific actions and changes to policy that to ensure trial participant safety, compliance with Icon's values and Icon's social distancing and infection control measures are followed. In addition to the changes documented on previous correspondence to Sponsors and CROs at https://iconcancercentre.com.au/research/#covid-19 , Icon Research have further updates to policies and work practices relating to the restriction to on-site monitoring visits, impact of reduction in staff and remote data review by external monitors.

1. Restriction to on-site monitoring visits

On site monitoring visits had been cancelled until the end of May 2020 and this will extend until at least June 22 2020 in accordance with Icon's operational model of Preparedness under the Icon Group COVIDSAFE Workplan. For all interstate visitors, including monitors, they need to apply for a border pass at the following website: https://www.qld.gov.au/border-pass/non-resident-travelling-to-queensland .

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For external visitors, such as monitors, based in Queensland and not requiring a border pass, will need to comply with the resection to external closure until June 22 2020. This restriction applies not only to Icon Head office but also research offices at Icon Cancer Centre clinics and Rivercity Pharmacy.

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 on-site visits and face to face contact is limited will be cancelled, there are a vast number of innovations still underway to support the conduct of research including but not limited to virtual pre-study meetings, dry site initiation visits, telehealth appointments for study participants, delivery of oral investigational drug to patients, video or phone calls to resolve queries, virtual secure data rooms for remote source data verification and use of digital signatures instead of hard copy wet-ink authorisations.

2. Impact of reduction in staff

Currently all Icon Research teams are all operating on split team capacity models to comply with social distancing policy and ensure continuity of operations.

As of May 25 2020, 50% of the combined Research Finance and Research Implementation Teams return to working from the Cordelia Street head office with a staggered return to 100% by the June 22 2020.

Clinical Trial Coordinators will continue working in a split team response for the foreseeable future, following the social distancing and infection control measures specified at Icon Cancer Centre clinics located at Chermside, Gold Coast University Hospital, Richmond, South Brisbane Southport and Wesley. . Workload management will continue to be evaluated on an ongoing basis including the prioritisation of accrual to clinical trials where there is a definite need to treat.

As of May 25 2020, the Data Management team will commence a return to office plan under 3 Stages.

Stage 1: Commencing on 25 May, 50% of the Data Management team will return to the office. Icon Human Resources Department have measured and assessed the area and social distancing rules are met with this number of returnees. Consideration and priority to be given based on employees that have found working from home difficult to manage. In Stage 1, a maximum of 3 Data Managers will be on site with the reminder of the team working from home.

Stage 2: Commencing on 8 June, 70% of the Data Management team will return to the office. In Stage 2, a maximum of 5 Data Managers will be on site with the remainder of the team working from home.

Stage 3: Commencing 22 June 2020, all Data Managers will return to head office as per their normal rostered working schedule. It is expected On-site monitoring can resume with locally based CRAs. Interstate CRA visits will be confirmed based on government's current COVID-19 travel restrictions.

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3. 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, the sponsor requirement and core business deliverable has not been achievable. 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 doubling or tripling the time and staffing to deliver the same result.

Icon Research has engaged TrialDocs to train staff during from May 25 2020 with a view to activating SiteDocs Portal managed secure data rooms by June 1 2020 and full implementation of the TrialDocs electronic investigator site file (eISF) and CoreDocs by July 1 2020. A primary advantage of using TrialDocs for both the eISF function and the secure data rooms are the containment of all relevant site-specific, trial-specific and patient-specific data within the one platform with training, compliance, security and oversight managed for one application or vendor rather than multiple.

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. Please approach your primary Data Manager for the respective clinical trial to request a room.

Icon's commitment to clinical trials, which underpins our delivery of the highest quality cancer care, is evident in the recent appointment and commencement of Dr Sophie Mepham as Executive Manager of Icon Research as of May 18 2020. Sophie's strong background in clinical research in both the United Kingdom and Australia is supported by obvious enthusiasm and energy for her role of leading a team of dedicated professionals to grow Icon's research footprint across all of our centres. Sophie would be very happy to be contacted about any of the activities and measures that Icon Research have undertaken in relation to the pandemic via her email of sophie.mepham@icongroup.global.

I would like to thank you for your flexibility, compassion 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