COVID-19: Cross Cancer Institute Clinical Trial Unit FAQ for Sponsors

March 19, 2020

This is a living document, and is subject to change at any time. We encourage sponsors to check the Alberta Health Services (AHS) Website for ongoing updates to response plan. In addition, sponsors may discuss study specific action plans with the local Investigator and Study team.

1. Is CCI allowing on-site monitoring visits at this time?

Currently we are not able to accommodate on-site monitoring visits at the Cross Cancer Institute. External monitors often travel from institution to institution and from city to city. To safeguard our patients and staff, and to safeguard external monitors, no monitoring/site selection/feasibility/initiation or close-out visits will take place on site until further notice. This is a measure to prevent the possibility of spread of the coronavirus disease to a particularly vulnerable patient population, and to the staff that provide care, conduct and collect research data.

2. Is remote monitoring available at CCI?

At CCI remote access to the Electronic Medical Record is not possible. Transmission of redacted source documents will be limited to key eligibility criteria and Serious Adverse Drug Reactions (SADRs) only. There is a risk of Personal Health Information (PHI) being released when source documents are sent off site, and it is extremely resource intensive. Sponsors are encouraged to perform data management review in lieu of on-site visits, e-mail or telephone communication with staff regarding essential information during regular business hours may be possible.

3. Does your site have any plans of stopping recruitment activities?

For essential **therapeutic clinical trials**, recruitment may continue based on clinical Investigator judgement, taking into consideration what is best for their patient. In addition, in cases where recruitment remains active, sponsors should anticipate a reduction in overall rate of enrollment. HREBA-CC and sponsors will be notified if recruitment is suspended.

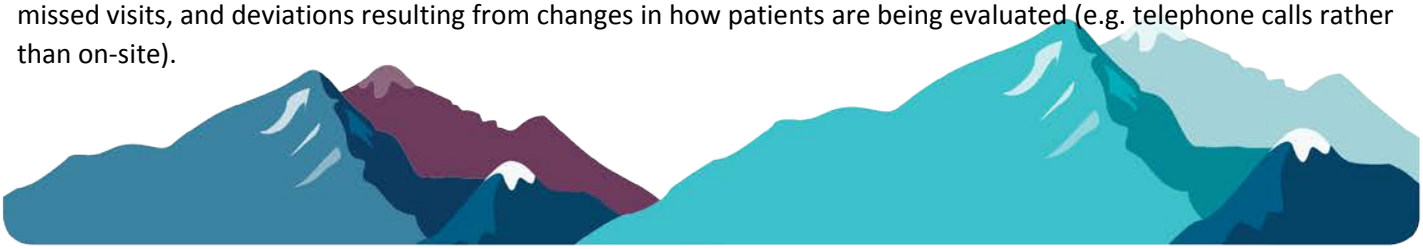
4. What should be expected for any patients currently in screening?

For any patient currently in screening for essential treatments, the patient may continue to be screened/enrolled, based on the Investigator's judgement for what is best for the patient.

5. Does your site have any plans that will affect active patients and their study visits?

Patients currently receiving treatment on an active trial will continue to be treated in accordance with AHS and CCI guidelines and pandemic instructions

Investigators will use all reasonable efforts to manage the patient according to the protocol, but patient safety will supersede protocol compliance. It is possible, and probable, that select study visits may be completed remotely, or if necessary, omitted. In cases where all protocol requirements cannot be reasonably completed, priority will be placed on collecting the protocol elements for safety, and end point measures. Sponsors should expect missed data due to missed visits, and deviations resulting from changes in how patients are being evaluated (e.g. telephone calls rather than on-site).



Studies using specialists (e.g. ophthalmology) located outside the Cross Cancer Institute may be affected.

6. Is there an increased possibility that patients will not be able to travel to the hospital for their visits?

Yes. We serve patients from across Northern Alberta and the Territories, and a number of patients commute a considerable distance for their care at Cross Cancer Institute. It is possible that patients may be unable to commute to the hospital due to their own illness, a caregiver's illness, or generalized concerns about entering the hospital, or a large urban area. The Investigator and study team will make all efforts to support the patient with coming to CCI where appropriate, and will source alternative solutions to complete the protocol requirements where appropriate. However, sponsors should expect missed data due to missed visits, and deviations resulting from changes in how patients are being evaluated (e.g. telephone calls rather than on-site).

7. What are some of the possible contingency plans your site has in cases where a patient is unable/should not come into the hospital for a research visit?

While not limited to the points below, in cases where a patient can not/should not be coming to the hospital, with sponsor consultation, the following options may be appropriate to ensure completion of clinical trial protocol requirements:

1. **Pharmacy**: Given the current global situation Pharmacy, in consultation with management, the Clinical Trial Unit, and Investigators will manage Investigational Product in the best interest of our patients.
2. **Oral Accountability**: May include phone calls with the patient for verbal confirmation of accountability, pill diaries, with reconciliation once the patient is able to return to the site.
3. **Safety Labs:** In cases where lab tests are typically completed at CCI, tests may be completed at a community lab where test results are available in NetCare. Central Labs for CCI clinical trials can only be collected at the CCI site at this time. Central lab kit collection may be affected.
4. **Medical Imaging:** CT, MRIs, PET Scans will continue to solely be provided at CCI for clinical trial purposes.
5. **Quality of Life Questionnaires:** In cases where a patient does not require additional onsite activities, QoL assessments may be collected remotely if reasonable, either on paper, provided at an earlier onsite visit, via mail, or electronically or phone. Tablet use may be affected, depending on Infection control precautions.

8. Do you anticipate any delays with initiating new studies?

There may be delays in activating new studies at CCI. Start-up activities on new and incoming studies will continue according to the direction of management and guidance of clinical investigators. Planned timelines and targeted deadlines may be adjusted given the fluid situation. This will be challenging, as we value research and realise the overarching benefit to all our patients; however, during this period we will be focusing on clinical trials that deliver essential treatment options for patients with an unmet need. Non-essential trials or studies will not be activated. Affected studies will be activated as efficiently as possible once resources are available.

In addition, to manage available resources, activation efforts are to be allocated to studies currently in review, and on studies focusing on COVID-19 research.

9. Will there be any impact on submitting Protocol Amendments to your REBs?

We are not aware of any at this time. As a reduction in available human resources due to COVID-19 infection, isolation, or redeployment to support hospital operations is expected there may be additional impact.