

Date: 2020JUL30

To: Collaborating Groups & Partners  
Qualified Investigators  
Principal Clinical Research Associates  
Centre Representatives  
Centre Clinical Research Associates

## CCTG and COVID-19 – Collection of COVID-19 Test Results

The COVID-19 Test Result eCRF has been included in the COVID-19 Protocol Deviation Report folder that has been added to most CCTG led trials. We would like to clarify the circumstances under which it is expected that COVID-19 test result data are reported, including completion of the COVID-19 Test Result / Screening eCRF.

Currently no CCTG led trial other than IC8 (*COV-IMMUNO - A Randomized, Phase III Trial of Immunization with IMM-101 versus Observation for the Prevention of Severe Respiratory and COVID-19 Related Infections in Cancer Patients at Increased Risk of Exposure*) mandates COVID-19 testing or is using COVID-19 testing for research purposes.

Thus for all CCTG led trials other than IC8, infection data is only being requested to allow for appropriate oversight and evaluation of safety and adverse events in order to be compliant with Good Clinical Practice and Health Canada regulations.

All of the following must be reported:

- Confirmed COVID-19 infections (whether an AE or SAE) on the AE eCRF as well as the result of the COVID-19 test on the COVID-19 Screening eCRF
- Suspected COVID-19 infection (whether an AE or SAE) on the AE eCRF as well as result of the COVID-19 test on the COVID-19 Screening eCRF
- Any AE which could be due to COVID-19 infection for which patient undergoes a COVID-19 test even if negative (please refer to CDC and government of Canada lists below) – report the AE (whether an AE or SAE) on the AE eCRF as well as result of the COVID-19 test on the COVID-19 Test Result /Screening eCRF
- COVID-19 swab/antigen positive test result – this indicates a viral infection and must be reported as an AE of COVID-19 infection and the COVID-19 test result must be reported (even if patient is asymptomatic)

If the patient has no symptoms that could be COVID-19 related and the test is negative, testing results should also be reported if permitted by your local REB. If not permitted in this instance, the COVID-19 Testing Question form can be left blank.

**CDC /Government of Canada COVID-19 Symptoms:**

- Fever or chills
- new or worsening cough
- Shortness of breath or difficulty breathing
- Fatigue or weakness
- Muscle or body aches
- Headache
- New loss of taste or smell
- Sore throat
- Congestion or runny nose
- gastrointestinal symptoms (nausea, abdominal pain, diarrhea, vomiting)
- feeling very unwell

If your local REB refuses to allow any COVID-19 test results to be reported, even if relevant to evaluation of an AE/SAE then this must be reported to CCTG in writing.

Sincerely,

A handwritten signature in black ink, appearing to read 'PBW', enclosed within a large, loopy oval shape.

Pamela Brown-Walker  
Quality Leader, Canadian Cancer Trials Group