

June 1, 2022

TO: ALL NATIONAL CLINICAL TRIALS NETWORK (NCTN) MEMBERS AND NCI COMMUNITY ONCOLOGY RESEARCH PROGRAM (NCORP) AFFILIATES AND SUBAFFILIATES; CTSU

FROM: SWOG Operations Office (E-mail: protocols@swog.org)

RE: SWOG COVID-19 Deviation and Diagnosis Guidance

MEMORANDUM – SWOG COVID-19 Deviation and Diagnosis Guidance

The purpose of this memorandum is to notify sites of changes to the COVID-19 diagnosis and deviation data collection.

The NCI has removed the requirement to report COVID-19 minor protocol deviations to NCI CIRB at time of Continuing Review (CR) as follows:

- This requirement started for all trials with CR date on or after July 1, 2020 and will end **for all trials on June 30, 2022.**
- **The requirement to collect date of initial Covid diagnoses will end for most trials* on June 30, 2022.**

SWOG COVID-19 Data Collection

In response to this change in requirement, Rave will be modified to remove the Covid Diagnosis and Deviation Form, as is appropriate. The following data submission requirements must still be observed:

- For any COVID-19 infection, an Adverse Event also must be reported on the Adverse Event or Late Effects form as “Infections and Infestations – Other, Specify” using the text “COVID-19” in the specify field.
- If a participant goes off protocol treatment or study intervention due to a COVID-19 diagnosis or other pandemic related reason, submit the Off Treatment/Protocol Notice and document the COVID-19 details in the Comments including the text “COVID-19” in the text.
- If a participant permanently withdraws consent for further follow-up due to a COVID-19 diagnosis or other pandemic reason submit the Consent Withdrawal form details in the Comments including the text “COVID-19” in the text.

*Exceptions

The trials that must continue to report COVID-19 Diagnoses are: S1418, S1501, S1826, S1918, and S1925.

These trials need to continue to report COVID-19 diagnoses on the Covid Diagnosis and Deviation Form. To access the form in Rave, utilize the ‘Add Event’ drop-down located on the Subject Home Page for each participant. For a participant with a COVID-19 diagnosis, provide the date of the first positive test on this form. It is not necessary to report if they test positive again. If the participant has a positive diagnosis of COVID-19, please use the existing Covid Diagnosis and Deviation Form, recording only the diagnosis until a revised shortened COVID-19 Diagnosis form can be included into Rave. No deviations need to be reported on these trials after June 30, 2022.

This memorandum serves to notify the NCI, CIRB, and SWOG Statistics and Data Management Center.

cc: PROTOCOL & INFORMATION OFFICE