

## Summary of Changes | COVID-19

In an effort to collect data on the impact of the COVID-19 pandemic on our transplant and cell therapy recipients, CIBMTR is making a number of alterations to our data collection forms to facilitate the collection of these data.

### Effective Friday, March 27th:

- The Post-HCT Follow-up Data Form (2100) and Cellular Therapy Essential Data Follow-up Data Form (4100) have been updated to include a new organism option for COVID-19 (SARS-CoV-2). The updated option is located in the “Infection” section of each of these forms; F2100 R5 (Q429) and F4100 R5 (Q181)
  - The current option value “Coronavirus” has been updated to “Coronavirus (excluding COVID-19 (SARS-CoV-2))”. The additional instructional text was added to further clarify this option should NOT be selected if the organism is COVID-19.

### Effective Friday, May 8th:

- The Pre-TED Form (2400) has been modified to add three additional questions to capture COVID-19 (SARS-CoV-2) infection prior to the start of the preparative regimen / infusion; F2400 R7 (questions 88- 90).
- The Cellular Therapy Essential Data Pre-Infusion Form (4000) has also been modified to add three additional questions to capture COVID-19 (SARS-CoV-2) infection at any time prior to the start of the preparative regimen / infusion; F4000 R6 (questions 111- 113)
  - If a form 4000 was completed prior to the release, and updates are made to them, then the new COVID-19 (SARS-CoV-2) questions will be required to answer.
- The Post-TED Form (2450) has been updated to add:
  - Option for COVID-19 (SARS-CoV-2) as both a primary and contributing cause of death; F2450 R5 (questions 3 and 5).
  - Question to capture if the recipient developed COVID-19 (SARS-CoV-2) since the date of last report; F2450 (question 50).
  - If a form 2450 was completed prior to the release, and updates are made to them, then the new COVID-19 (SARS-CoV-2) questions will be required to answer.
- The Death Data Form (2900) has been modified to capture COVID-19 (SARS-CoV-2) as both a primary and contributing cause of death; F2900 R4 (questions 4 and 6).
  - If a death was reported for COVID -19, centers may now update the reason of death to list COVID-19 (SARS-CoV-2).

In order to collect more detailed data regarding the diagnosis, treatment and outcomes of COVID-19 infections, a new form, **Respiratory Virus Post-Infusion Data Form (2149)** has been created.

- Respiratory Virus Post-Infusion Form (2149) released in FormsNet3.
  - The form will automatically be generated in FormsNet3 when:
    - COVID-19 (SARS-CoV-2) is captured as an infection on the Post-HCT Form (2100), Post-TED (2450), or Post-CT (4100)
    - COVID-19 (SARS-CoV-2) is captured as a primary or contributing cause of death on either the Post-TED Form (2450) or Death Data Form (2900).
- Prior to the release, the ability to submit a fillable PDF version of the form 2149 to the Center Support, was available to report when a recipient was either diagnosed with or died from COVID-19 (SARS-CoV-2). **This will no longer be available** as a fillable PDF form and should now be submitted via FormsNet3.
  - Forms submitted to Service Now will be manually entered by May 15<sup>th</sup>. Centers will be contacted if there are any outstanding issues.
- We are encouraging centers to generate this form **on-demand** as soon as it is known when a recipient has been diagnosed with or died from COVID-19 (SARS-CoV-2). The “Initial” form should be submitted within 14 days after diagnosis.
  - There is no need to complete a post-infusion form (2100, 2450, or 4100) prior to its DUE date to generate the 2149.
- The 2149 has two timepoints, “Initial” and “Follow-up”.
- If the infection is captured as “improved” or “ongoing” in question 41 on “Initial” submission, an additional “Follow-up” 2149 will be made due to capture infection resolution. This form should be submitted, when the infection resolved, or death occurred.

**Centers will be reimbursed for completion of this form.**

The blank forms will be made available on the [Data Collection Forms Page](#) of the CIBMTR website.

**If you have any questions or concerns, please contact CIBMTR Center Support (<https://nmdp.service-now.com/csm>).**

## Frequently Asked Questions

**Q: Is the date of infection diagnosis the first test that is positive?**

**A:** Yes, this is the date that the first diagnostic test was positive. We still ask that you report ALL positive diagnostic tests conducted to determine the COVID-19 diagnosis (in question 2). An example is if the recipient had a nasal swab done 4/2/20 that was tested positive and later had a BAL 4/10/20 that also tested positive. The date of diagnosis would be 4/2/20.

**Q: What is infection resolution?**

**A:** Infection resolution is the first confirmatory negative test or the recipient death. If the status of the infection is captured as “improved” or “ongoing” on the “Initial” submission of the 2149, the infection resolution should be reported on a “Follow-up” 2149.

**Q: What is the date of evaluation?**

**A:** The date of evaluation should be the date the status of the infection was most recently assessed. If this is a “Follow-up” submission, the date should be captured as either the most recent assessment or date of death.

**Q: What if I submitted the “Initial” 2149 and the status of infection was resolved?**

**A:** If the “Initial” submission captures the resolution of the infection, the “Follow-up” 2149 will not come due in FormsNet3. If the “Initial” submission does NOT capture infection resolution, a “Follow-up” 2149 will come due for completion.