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CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

CIBMTR Data Reporting Requirements for CIBMTR SC21-07/BMT CTN 2101: COVID-19 Vaccine study

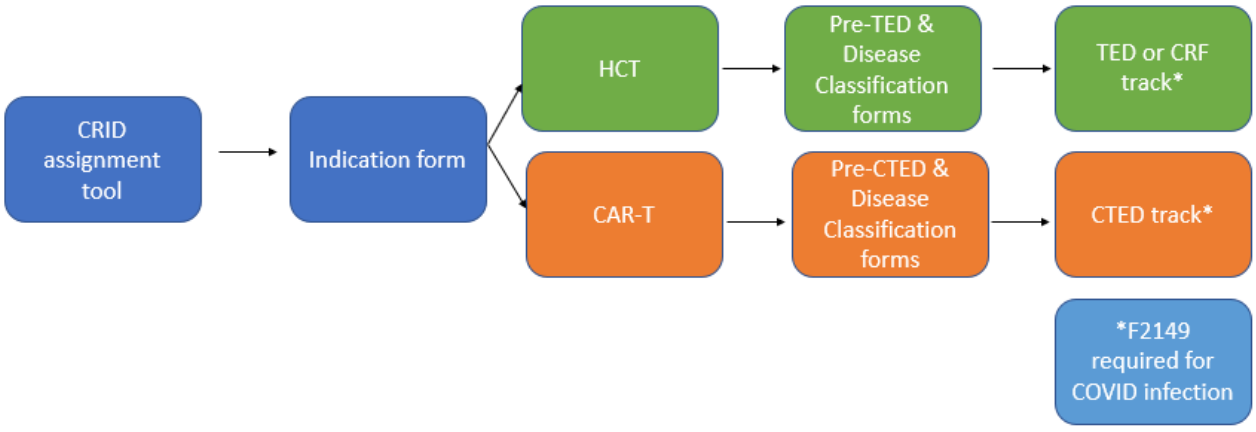
This document must be reviewed by

- Study Coordinator for CIBMTR SC21-07/BMT CTN 2101,
- CIBMTR Primary Data Manager and
- Staff responsible for completing CIBMTR (FormsNet3) and Emmes (e-clinical) Forms.

This is an Observational Study of HCT/CAR-T recipients receiving a COVID vaccine as part of SOC.

- Patient(s) enrolled to this study must consent to CIBMTR Research Database Protocol.
  - Enrollment in the CIBMTR SC21-07/BMT CTN 2101 study is expected to be after transplant.
  - If the patient did not consent to the CIBMTR Research Database Protocol prior to HCT/CAR-T therapy, they would be required to consent to the CIBMTR Research Database Protocol prior to consenting to this study.
- A CIBMTR Research ID (CRID) is assigned to every enrolled recipient using CRID assignment tool in FormsNet3
  - Your center's CIBMTR Primary Data Manager will provide the CRID to you. The CRID is the key element that links data collected by CIBMTR and BMT CTN for any protocol.
- The CRID should then be entered in e-clinical via Enrollment Form: Segment A [2101A (ENRA) COVID Vaccination Study]
- A Pre-TED **Form 2400 and Disease Classification Form 2402** must be completed for the HCT or a Pre-CTED **Form 4000 and Disease Classification Form 2402** must be completed for the CAR-T.
  - Confirm with your centers CIBMTR Primary Data Manager that these forms have been completed
- CIBMTR Form 2149 must be completed for COVID-19 infection.

CIBMTR Form Completion Flow for this study:



CIBMTR® is a research collaboration between the National Marrow Donor Program® (NMDP)/ Be The Match® and the Medical College of Wisconsin

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Milwaukee Campus
Medical College of Wisconsin
9200 W. Wisconsin Ave., Suite C5500
Milwaukee, WI 53226 USA
(414) 805-0700

Minneapolis Campus
National Marrow Donor Program/
Be The Match
3001 Broadway Street N.E., Suite 100
Minneapolis, MN 55413-1753 USA
(612) 884-8600

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Important Consent Related Information

- Patients providing consent for BMT CTN clinical protocols are consenting to the treatment specified and the data collection necessary for the clinical protocol, including CIBMTR data. Data for BMT CTN clinical trials are supplemented by data collected through the CIBMTR CRF forms. Thus, CIBMTR CRF data is needed for any patient that is enrolled in a BMT CTN clinical trial.

- Centers participating in BMT CTN trials must provide TED-level data to the CIBMTR on **all** consecutive hematopoietic stem cell transplants (HCT) performed at their institution during the period they are actively enrolling patients.

CIBMTR Forms: http://www.cibmtr.org/DataManagement/DataCollectionForms/index.html