

Summary Document for 2013-004526-28

- The trial was never opened or accrued in any EEA country.
- See Page 2 for Project Closure Numbered Memo 1101-056.



February 17, 2021

MEMORANDUM #1101-056

via E-mail

TO: Principal Investigators, Regulatory, Data, Clinic Coordinators and Laboratory Personnel for BMT CTN Protocol #1101

FROM: Elle Noel
Protocol Coordinator

SUBJECT: BMT CTN 1101 Study Closure

The BMT CTN DCC is pleased to announce the permanent closure of the BMT CTN 1101 study, "A Multi-Center, Phase III, Randomized Trial of Reduced Intensity (RIC) Conditioning and Transplantation of Double Unrelated Umbilical Cord Blood (dUCB) versus HLA-Haploidentical Related Bone Marrow (Haplo) for Patients with Hematologic Malignancies". All study participants have completed their 2-year post-transplant follow-up visits per the study design, and all data collection and analysis are complete. The primary manuscript was published in Blood on August 31, 2020 under the title, "*Double unrelated umbilical cord blood versus HLA-haploidentical bone marrow transplantation (BMT CTN 1101).*"

It is no longer necessary for sites to maintain IRB approval for the BMT CTN 1101 protocol. If your center has not already closed this study with your IRB, this memo may be submitted as documentation of formal closure of this study. Once you have received your IRB closure letter, please file the closure letter in your study files.

The BMT CTN DCC records retention requirement policy is for sites to maintain patients' research charts for 5 years after publication of the trial's primary manuscript (August 31, 2025). Site's institutional records retention policies should be followed if they exceed the requirements of the BMT CTN DCC.

In addition, the BMT CTN DCC, NHLBI, NCI and the BMT CTN 1101 Protocol Team would like to thank each participating center for their contributions to the trial. We greatly appreciate your efforts and your commitment to making this a successful study.

If you have any questions, please contact me at bmtctn1101@emmes.com or at 301-251-1161.

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BMT CTN Data Coordinating Center

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