2542: Mogamulizumab Supplemental Data Collection

The Mogamulizumab Supplemental Data Collection Form (Form 2542) is designed to support a retrospective and prospective, multicenter, observational registry of patients treated with mogamulizumab alone or in combination, within one year prior to allogeneic hematopoietic cell transplantation (allo HCT) or treated with mogamulizumab, alone or combination, within 18 months after HCT.

The Mogamulizumab Supplemental Data Collection Form will come due for all recipients enrolled on the study irrespective of Mogamulizumab administration status. This includes recipients on the Case arm, those who received Mogamulizumab one year prior to or 18 months post allo HCT and recipients on the Control arm, those who satisfy the study eligibility criteria except Mogamulizumab administration. The 2400 and 2402 will confirm eligibility, this includes event date, age at event, disease subtype, and type of infusion. Once eligibility is confirmed, the 2500 and 2542 will come due for all recipients.

The 2118 will capture if Mogamulizumab was used post-transplant at 100 days, 6 months, 12 months and 2 years post-transplant. If the use of Mogamulizumab post-transplant is indicated on any 2118, the 2542 will become due.

Links to Pages of Mogamulizumab Supplemental Data Collection Section of Forms Instruction Manual
Q1-3: Complications of Interest
Q4-9: Post-Infusion Critical Illness

Manual Updates:
Sections of the Forms Instruction Manual are frequently updated. The most recent updates to the manual can be found below. For additional information, select the manual section and review the updated text.

If you need to reference the historical Manual Change History for this form, please reference the retired manual section on the Retired Forms Manuals webpage.

Date	Manual Section	Add/ Remove/ Modify	Description
7/19/2023	2542: Mogamulizumab Supplemental Data Collection	Modify	Clarified when the 2542 will come due above: *The Mogamulizumab Supplemental Data Collection Form will come due for all recipients enrolled on the study, irrespective of Mogmulizumab administration status. This includes recipients on the Case arm, those ~~each patient~~ who received Mogamulizumab one year prior to or 18 months post allo HCT and recipients on the Control arm, those who satisfy the study eligibility criteria except Mogamulizumab administration. The 2400 and 2402 will confirm eligibility, this includes event date, age at event, disease subtype, and type of infusion. Once eligibility is confirmed, the 2500 and 2542 will come due.*

			~~*The 2500 will confirm use of Mogamulizumab pre-transplant, triggering the 2542*~~.
1/24/2020	2542: Mogamulizumab Supplemental Data Collection	Add	Version 1 of the 2542: Mogamuluizumab Supplemental Data Collection section of the Forms Instruction Manual released. Version 1 corresponds to revision 1 of the Form 2542.

Last modified: Jul 19, 2023

Q1-3: Complications of Interest

Question 1: Were there any Grade ≥ 3 potentially immune-mediated complications of interest?

Indicate whether the recipient experienced a Grade ≥ 3 potentially immune-mediated complication of interest during the timeframe captured by the specific visit ID of form 2542 . Only report the following Grade ≥3 immune-mediated complications of interest:

- Polymyositis
- Autoimmune Thyroiditis
- Autoimmune Hepatitis
- Myositis
- Pneumonitis/Interstitial Lung Disease
- Myocarditis
- Polyneuropathy (Guillain-Barre Syndrome and its variants)
- Dermatitis/rash (not considered GVHD)
- Encephalitis.

If no Grade ≥ 3 potentially immune-mediated complications of interest occurred (timeframe), report “no” for question 1 and go to question 4.Please use the referenced table here for grading criteria.

Complete questions 2-3 for each specific complication of interest.

Questions 2-3: Specify Grade ≥ 3 potentially immune- mediated complication of interest.

Specify each Grade ≥3 potentially immune-mediated complications of interest that occurred (in the reporting timeframe) in question 2 and report the date (YYYY-MM-DD) when the complication initially occurred in question 3.

Copy and complete questions 2-3 to report more than one Grade ≥3 potentially immune-mediated complication of interest.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
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Last modified: Dec 22, 2020

Q4-9: Post-Infusion Critical Illness

Questions 4-5: Did the recipient experience a complication of infusion requiring a transfer to an intensive care unit?

Report whether the recipient required a transfer to the intensive care unit due to a complication directly related to the infusion. If “yes” report the date of transfer to the intensive care unit in question 5. Otherwise, report “no” and continue to question 6.

Question 6: Did the patient develop sepsis requiring pressor support?

Report whether the patient developed sepsis and required pressor support. If “yes” report the date pressor support started in question 7. Otherwise, report “no” and continue to question 8.

Question 7: Date pressor support required:

Indicate date pressor support was required.

Question 8: Did the recipient die as a result of organ failure?

If the recipient died as a result of organ failure, select “yes” and submit the form.

If the recipient did not die as a result of organ failure, select “no” and submit the form.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
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Last modified: Dec 22, 2020