Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ First 3 Letters of First Name: __ __ __

Complete this form for all regularly scheduled follow-up visits.

A. VISIT INFORMATION

1. Visit Date: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

2. For which visit, in the study sequence, is this form being completed? *(check one)*

☐ 3	Week 1	☐ 7	Month 2	☐ 17	Month 12	☐ 29	Month 24
☐ 4	Week 2	☐ 8	Month 3	☐ 20	Month 15	☐ 99	Other
☐ 5	Week 3	☐ 11	Month 6	☐ 23	Month 18		
☐ 6	Week 4	☐ 14	Month 9	☐ 26	Month 21		

IF OTHER,
a. Specify: _____

3. Did visit occur at a site other than the primary study site? Y N
IF YES,
a. Indicate Site Number for reimbursement: __ __ __ __
NOTE: *Site Number* ***must*** *correspond to a TrialNet Clinical Center, Affiliate, or Participating Physician*

B. PREGNANCY MONITORING

1. Does the participant have reproductive potential? Y N
IF YES, continue (otherwise, proceed to **Section C**)
a. Do you currently use a form of birth control? *(Females and males of reproductive age are expected to use a form of birth control, or practice abstinence)* Y N
b. Do you plan on becoming pregnant, or fathering a child, in the next 3 months? Y N

IF FEMALE, continue with Questions c and d (otherwise, proceed to **Section C**)
c. Are you currently taking birth control medication? Y N
d. Was a urine pregnancy test completed at this visit? Y N
IF YES,
1. Was the test result positive? Y N

If the participant answered YES to **Question b**, discontinue therapy and complete a Medication Withdrawal Form (**MMF08W**).

If the **pregnancy test** result was **positive**, discontinue therapy and complete a Pregnancy Confirmation Report (**MMF09**), Adverse Event Report (**MMF07**), and Medication Withdrawal Form (**MMF08W**). The Coordinating Center must be notified within 24 hours of clinic notification of an active pregnancy in a study participant. See **Chapter 10** of the MMF/DZB **Manual of Operations** for more details.

C. EBV MONITORING INFORMATION

1. Was the participant Epstein-Barr Virus (EBV) seropositive at Baseline? Y N
IF NO,
a. Has the participant attended **all** required monthly EBV serology-monitoring visits? Y N
2. Was blood drawn to monitor for EBV viral load (by PCR) at this clinic visit? Y N
3. Was blood drawn to monitor EBV serology (IgG and IgM anti-EBV) at this clinic visit (*only required for participants who were* ***EBV seronegative*** *at study entry)*? Y N
4. Since the last scheduled clinic visit, have results of a prior EBV test come back positive *(indicating a new infection or re-activation of an old infection)*? Y N

IF YES, discontinue therapy, complete a Medication Withdrawal Form (**MMF08W**)
AND complete an Adverse Event Report Form (**MMF07**)

Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ First 3 Letters of First Name: __ __ __

Date of Visit: __ __/__ __/__ __ __ __

D. CMV MONITORING INFORMATION

1. Was the participant Cytomegalovirus (CMV) seropositive at Baseline? Y N
2. Was blood drawn to monitor for CMV viral load (by PCR) at this scheduled clinic visit? Y N
3. Was blood drawn to monitor CMV serology (IgG and IgM anti-CMV) at this scheduled clinic visit (*only required for participants who were **CMV seronegative** at study entry)*? Y N
4. Since the last scheduled clinic visit, have the results of a prior CMV test come back positive *(indicating a new infection or re-activation of an old infection)*? Y N

IF YES, discontinue therapy, complete a Medication Withdrawal Form (**MMF08W**)
AND complete an Adverse Event Report Form (**MMF07**)

For a **CMV seropositive** participant, a positive CMV test is defined as a greater than 5-fold increase in CMV viral load, or a viral load that is greater than 10,000 copies/ml

For a **CMV seronegative** participant, a positive CMV test is defined as any increase in serology or in viral load

E. ADVERSE EVENT ASSESSMENT

1. During the interval since the last scheduled clinic visit, have you had any symptoms, injuries, illnesses or side effects, or worsening of pre-existing conditions? Y N
2. Since the last scheduled clinic visit, have you experienced 3 or more consecutive days of fever, sore throat, and/or lymphadenopathy (swollen glands)? Y N

IF YES to Question 1 or 2, complete an Adverse Event Report Form (**MMF07**)

IF YES to Question 2, answer Questions 2a and 2b

a. Did the participant have additional blood drawn for EBV genome and serology analysis? Y N
   IF YES,
   1. Was the result of the test positive (i.e. indicating infection or reactivation)? Y N

IF YES, discontinue therapy and complete a Medication Withdrawal Form (**MMF08W**)

b. Did the participant have additional blood drawn for a CMV-PCR to check for CMV reactivation? Y N
   IF YES,
   1. Was the result of the test positive (i.e. indicating reactivation)? Y N

IF YES, discontinue therapy and complete a Medication Withdrawal Form (**MMF08W**)

3. Since the last scheduled clinic visit, have you had any vaccinations? Y N
   IF YES,
   a. Specify: _____
4. Since the last scheduled clinic visit, have you had any allergies or allergic episodes? Y N
5. Since the last scheduled clinic visit, have you experienced any infections that have required a visit to your doctor's office and/or treatment with antibiotics or antiviral therapies? Y N
   IF YES,
   a. Indicate number of infections since last scheduled clinic visit: __ __

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "" if the desired information is permanently unavailable (i.e. will not be known in any future updates).*

Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ First 3 Letters of First Name: __ __ __

Date of Visit: __ __/__ __/__ __ __ __

F. GENERAL PHYSICAL EXAMINATION

1. Please collect the following physical assessments:
   Note: *Have the participant rest for 5 minutes before doing these assessments.*

   a. Temperature: __ __ . __ ºC or __ __ __ . __ ºF

   b. Seated arm blood pressure: __ __ __ mmHg / __ __ __ mmHg (Systolic / Diastolic)

   c. Seated heart rate: __ __ __ Beats/minute

   d. Seated respiratory rate: __ __ __ Breaths/minute

   e. Weight: __ __ __.__ kg or __ __ __. __ __ lbs

   f. Height: __ __ __.__ cm or __ __. __ __ in

Questions 2 and **3** do not need to be completed for **Week 1** and **Week 3** visits

2. Record whether the following systems are normal or abnormal for the physical exam:

System	Normal?	System	Normal?
a. HEENT *(Head, eyes, ears, neck, throat)*	Y N	g. Abdomen	Y N
b. Neck	Y N	h. Musculoskeletal	Y N
c. Thyroid	Y N	i. Neurologic	Y N
d. Lungs	Y N	j. Genitourinary	Y N
e. Chest/Breasts	Y N	k. Skin/Nails	Y N
f. Heart/Circulatory	Y N	l. Lymph nodes	Y N

Questions 4 is only completed for **Month 12** and **Month 24** visits

3. Was an ECG taken at this clinic visit (an ECG **must** be taken at Month 12 and 24 visits)? Y N
   IF YES,
   a. Was the ECG classified as normal? Y N

G. BLOOD SUGAR MONITORING

1. Do you regularly monitor your blood sugar levels? Y N
   IF YES,
   a. How many times (on average) during the day? __ __
      OF THESE,
      1. How many occur *before* meals (including snacks): __ __
      2. How many occur *after* meals (including snacks): __ __
2. Do you check your blood sugar:
   a. When you wake up in the morning? Y N
   b. Before bedtime? Y N
   c. At any time during the night (e.g. 3:00 AM)? Y N
3. Do you regularly have a snack before bedtime? Y N

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "" if the desired information is permanently unavailable (i.e. will not be known in any future updates).*

Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ First 3 Letters of First Name: __ __ __

Date of Visit: __ __/__ __/__ __ __ __

H. RECENT HYPOGLYCEMIC EVENTS

1. Have you had any low blood sugar events or periods since your last scheduled clinic visit *(defined as any blood sugar level < 50 mg/dl and/or symptoms of low blood sugar)*? Y N

   IF YES,

   a. Number of times __ __

   b. Of those, how many were major (loss of consciousness, seizure, or assistance required from another person)? __ __

If any *major* hypoglycemic events have occurred since the last scheduled clinic visit, complete the Major Hypoglycemic Event Form (**MMF04**) to record the details of these events.

I. INSULIN REQUIREMENTS

1. Indicate your daily insulin routine *(check one)*:

- ☐ 1 No insulin
- ☐ 2 1-2 Injections per day
- ☐ 3 3 + Injections per day (MDI)
- ☐ 4 Insulin Pump (CSII)

Answer the following questions regarding your daily insulin requirements *(on an average day)*:

Type of Insulin	Use this type?	IF YES, a. Average daily dose
2. Humalog (H)	Y N	__ __ __.__ units
3. NovoLog	Y N	__ __ __.__ units
4. Regular (R)	Y N	__ __ __.__ units
5. NPH (N)	Y N	__ __ __.__ units
6. Lente	Y N	__ __ __.__ units
7. Ultralente	Y N	__ __ __.__ units
8. Lantus/Glargine	Y N	__ __ __.__ units
9. Detemir	Y N	__ __ __.__ units
10. Other	Y N	__ __ __.__ units

Indicate (by circling Yes or No) at which point(s) in the day these insulin injections (or bolus administrations for pump users) take place:

11. Wake Up	12. Breakfast		13. Lunch		14. Dinner		15. Before Bed
	a. Before	b. After	a. Before	b. After	a. Before	b. After	
Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "" if the desired information is permanently unavailable (i.e. will not be known in any future updates).*

Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ First 3 Letters of First Name: __ __ __

Date of Visit: __ __/__ __/__ __ __ __

J. CONCOMITANT MEDICATION

1. Since the last scheduled clinic visit, have you had any changes in the medications (other than the study drug and insulin) or vitamin supplements that you are taking? Y N

   IF YES,

   a. Are you currently taking any prescription medications other than the study drug and insulin? Y N

   b. Are you currently taking vitamin supplements that contain Niacin or Vitamin E? Y N

   c. Are you currently taking steroid medications for the treatment of other conditions? Y N

Chronic use of **steroid-based medications**, regardless of form, is an exclusion criterion for this study. If the participant is taking steroid-based medications chronically, the participant's study medication must be withdrawn and the Medication Withdrawal Form (**MMF08W**) must be completed.

   d. Are you currently taking any antidepressant or antianxiety medications? Y N

   e. Are you currently taking any medications for the treatment of high blood pressure? Y N

2. Are you currently taking any antibiotics? Y N

   IF YES,

   a. For what? _____

K. COLLECTION OF ORAL MEDICATION (*NOTE: Bottle ID# = Randomization Number*)

	Bottle ID #	a. Number of Pills Remaining		Bottle ID #	a. Number of Pills Remaining
1.	__ __ __ __	__ __ __	4.	__ __ __ __	__ __ __
2.	__ __ __ __	__ __ __	5.	__ __ __ __	__ __ __
3.	__ __ __ __	__ __ __	6.	__ __ __ __	__ __ __

L. DACLIZUMAB ADMINISTRATION

This section needs to be completed at the **Week 2** visit **only**.

1. Was the participant given his/her second IV infusion (DZB or DZB placebo) at this study visit? Y N

   IF YES,

   a. Dose of DZB or DZB placebo infused: __ __ __ mg

   b. Affix second part of label from DZB or DZB placebo infusion kit administered to the participant:

Attach Second Part of Label From Vial 1 Here

NOTE: Check here ☐ if only one infusion kit required for both initial and subsequent infusion.

   IF NO,

   c. Explain: _____
   _____
   _____
   _____

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "" if the desired information is permanently unavailable (i.e. will not be known in any future updates).*

Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ First 3 Letters of First Name: __ __ __

Date of Visit: __ __/__ __/__ __ __ __

M. DISPENSATION OF MYCOPHENOLATE MOFETIL

1. Has new study medication been dispensed at this clinic visit, or at any time since the last scheduled clinic visit? Y N

   IF NO, **skip to Question 4**

Instructions:

(1) The participant should take the first dose of the study medication in the clinic before leaving.
(2) The Study Coordinator should write today's date on the label of the bottle (in the space provided).
(3) The participant should continue taking the study medication, per the instructions on the bottle, until it is empty (unless instructed differently by Study Coordinator).
(4) When the last capsule is taken from the bottle, the participant should write the date on the label of the bottle (in the space provided).
(5) The participant should begin taking capsules from the second bottle at the next dosing time after completing the first bottle.
(6) The participant will write the date on the label of the new capsule bottle (in the space provided).
(7) The participant should take medication as prescribed from this capsule bottle until he/she returns to the study clinic to receive refill bottles (unless instructed differently by the Study Coordinator).
(8) Have the participant write the date the last capsule was taken from this bottle (in the space provided).

2. Record the Randomization Number used to dispense study medication: __ __ __ __

3. Labels and dates of study medication bottles dispensed to the participant at this study visit:

	Attach Second Part of Bottle Label	**1. Date Bottle Given to Participant**
a.	 **Attach Second Part of Label From Bottle 1 Here**	__ __ / __ __ / __ __ __ __ MM DD YYYY
b.	 **Attach Second Part of Label From Bottle 2 Here**	__ __ / __ __ / __ __ __ __ MM DD YYYY
c.	 **Attach Second Part of Label From Bottle 3 Here**	__ __ / __ __ / __ __ __ __ MM DD YYYY
d.	 **Attach Second Part of Label From Bottle 4 Here**	__ __ / __ __ / __ __ __ __ MM DD YYYY

4. Indicate prescribed daily dose of study medication following this clinic visit: __ __ __ __ mg

5. Indicate frequency of dosing prescribed: ☐ 1 Once per day ☐ 2 BID ☐ 3 TID

6. Have there been any change(s) in the dose of study medication since the last scheduled clinic visit? Y N

   IF YES,

   a. Number of changes since the last scheduled clinic visit: __ __

7. Is the participant restarting study medication following a period of withdrawal? Y N

   IF YES,

   a. Date participant restarted study medication: __ __ / __ __ / __ __ __ __ MM DD YYYY

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "" if the desired information is permanently unavailable (i.e. will not be known in any future updates).*

Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ First 3 Letters of First Name: __ __ __

Date of Visit: __ __/__ __/__ __ __ __

N. LABORATORY ASSESSMENTS

Were blood samples taken during this visit for the following?

1. CBC with diff *Visits: All*	Y	N	10. PK Analysis *Visits: Week 4*	Y	N
2. Chemistries *Visits: Week 2 and 4, Month 2, 3, 6, 9, 12, 18, 24*	Y	N	11. EBV PCR/serology *Visits: Month 3, 6, 9, 12, 15, 18, 21, 24*	Y	N
3. Serum for autoantibodies *Visits: Week 4, Month 3, 6, 9, 12, 18, 24*	Y	N	12. CMV PCR/serology *Visits: Month 3, 6, 9, 12, 15, 18, 21, 24*	Y	N
4. HbA1c *Visits: Month 3, 6, 9, 12, 15, 18, 21, 24*	Y	N	13. Rubella titers *Visits: Week 4, Month 6, 12, 18, 24*	Y	N
5. Immune Testing *Visits: Week 1, 2, 4, Month 2, 3, 6, 12, 24*	Y	N	14. Viral flu titers *Visits: Week 4, Month 6, 12, 18, 24*	Y	N
6. MMTT – 2-hour *Visits: Month 3, 6, 12, 18*	Y	N	15. RNA (stored) *Visits: Week 3, Month 3, 6, 12, 18 and 24*	Y	N
7. MMTT – 4-hour *Visits: Month 24*	Y	N	16. T-cells (stored) *Visits: Month 3, 6, 12, 18 and 24*	Y	N
8. DZB levels *Visits: Week 2, 4*	Y	N	17. Serum (stored) *Visits: Week 4, Month 3, 6, 9, 12, 18 and 24*	Y	N
9. MMF levels *Visits: Week 2, Month 3, 6, 12, 18, 24*	Y	N	18. DNA (stored) *Visits: Any*	Y	N

19. Was blood drawn for immune testing or stored samples on a date other than the date of this visit? Y N

IF YES,

a. Date blood drawn for immune testing: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

b. Date blood drawn for stored samples: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

20. Was blood drawn for ELISPOT analysis at this study visit? Y N
Visits: Month 3, 6, 12, 18 and 24

Initials (first, middle, last) of person completing this form: __ __ __ (F M L)

Date form completed: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "" if the desired information is permanently unavailable (i.e. will not be known in any future updates).*