

Site Number: _____

Screening ID: _____ - _____

Participant Letters: _____

Complete this form any time BEFORE RANDOMIZATION. Use this form to record a Subject's ineligibility or withdrawal from the study.

A. DATE

1. Date screening discontinued:

____/____/____
DAY MONTH YEAR

B. REASON FOR STUDY INELIGIBILITY

Mark the reason(s) for discontinuing the screening process: (*check all that apply*)

- | | |
|---|---|
| 1. <input type="checkbox"/> ₁ Subject does not have at least one diabetes-related autoantibody present | 14. <input type="checkbox"/> ₁ Subject has history of malignancies |
| 2. <input type="checkbox"/> ₁ Subject is not within 3-months (100 days) of diagnosis of type 1 diabetes | 15. <input type="checkbox"/> ₁ Subject requires use of non-insulin pharmaceuticals that affect glycemic control or influence glucose tolerance |
| 3. <input type="checkbox"/> ₁ Subject is not between the ages of 6 and 45 years | 16. <input type="checkbox"/> ₁ Subject has serologic evidence of HIV, Hep B, or Hep C infection |
| 4. <input type="checkbox"/> ₁ Subject has complicating medical issues that would interfere with the study conduct or cause increased risk | 17. <input type="checkbox"/> ₁ Subject has history of immunodeficiency or lymphopenia |
| 5. <input type="checkbox"/> ₁ Subject does not have stimulated C-peptide levels ≥ 0.2 pmol/ml | 18. <input type="checkbox"/> ₁ Subject withdrew consent |
| 6. <input type="checkbox"/> ₁ Subject is female with reproductive potential and is not willing to avoid pregnancy. | 19. <input type="checkbox"/> ₁ Subject is currently participating in another type 1 diabetes treatment study |
| 7. <input type="checkbox"/> ₁ Subject weighs less than 20 kg (44 lb) | 20. <input type="checkbox"/> ₁ Other |
| 8. <input type="checkbox"/> ₁ Subject is not willing to forgo live vaccinations during treatment and for at least 3 months after the last dose of study medication | If OTHER, a. Specify:

_____ |
| 9. <input type="checkbox"/> ₁ Subject is not at least three months from last live immunization received | |
| 10. <input type="checkbox"/> ₁ Subject is currently pregnant or lactating | |
| 11. <input type="checkbox"/> ₁ Subject has an active infection or positive PPD test | |
| 12. <input type="checkbox"/> ₁ Subject is not willing to comply with intensive diabetes management | |
| 13. <input type="checkbox"/> ₁ Subject requires use of other immunosuppressive agents | |

Initials (first, middle, last) of person completing this form:

F M L

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).



CTLA-4 Ig Study
PRE-RANDOMIZATION EXIT FORM

Form CTL01E

01 JAN 2008

Version 1.0

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Date form completed:

____/____/____
DAY MONTH YEAR

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Top Copy – Send to TrialNet Coordinating Center

Bottom Copy – Retain at site