

-
Participant ID

Nickname

RISE **RUNEND.2**

July 2014

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Restoring Insulin Secretion Study
RUNEND: End of Run-in Visit Inventory

1. Study Visit Number VISIT	<input type="text"/> REN
2. Visit date (mm/dd/yyyy) Replaced with DAYSRAND	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
3. Run-in start date (mm/dd/yyyy) Available on RUNSTART form	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
4. Total weeks of run-in REWEKS → Must be ≥3 weeks and ≤4 weeks for randomization	<input type="text"/>
5. Staff ID	<input type="text"/> <input type="text"/> <input type="text"/>

Instructions: This form is completed at the end of the run-in period.

Diabetes Management

6. Has the participant used any diabetes medication (other than metformin for pediatric participants) since the last visit? **REDIAMED**
- 1 Yes 2 No
- If YES, participant is ineligible.
7. **If PEDIATRIC**, is the participant on metformin? **REMET**
- 1 Yes 2 No
- a. **If YES**, what is the current dose? **REMETDOSE**
- mg/day
8. Is the participant taking any other new medications since start of run-in? **RENEWMED**
- 1 Yes 2 No
- a. **If YES**, are any of the new medications exclusionary (MOP v.1 Appendix 14.1.1)? **REMEDEXCL**
- 1 Yes 2 No
9. Was the participant diagnosed with any new illness since start of run-in? **RENEWILL**
- 1 Yes 2 No
- a. **If YES**, are any of the new illnesses exclusionary (MOP v.1 Appendix 14.1.2)? **REILLEXCL**
- 1 Yes 2 No

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Serious Adverse Events

10. Since the last visit, has the participant experienced any of the following?

Check All That Apply

- | | |
|--|----------------------------|
| a. Any acute life-threatening event? THREAT | <input type="checkbox"/> 1 |
| b. Required or prolonged hospitalization? HOSPITAL | <input type="checkbox"/> 1 |
| c. Permanent or severe disability? DISABILITY | <input type="checkbox"/> 1 |
| d. Pregnancy resulting in congenital anomaly or birth defect? BIRDEF | <input type="checkbox"/> 1 |
| e. Required intervention to prevent permanent impairment or damage? PREVENT | <input type="checkbox"/> 1 |
| f. Overdose of a <u>study</u> medication? OVERDOSE | <input type="checkbox"/> 1 |
| g. An episode of hypoglycemia that required help from someone else to bring the blood sugar back to normal? (e.g. due to loss of consciousness, confusion or severe lethargy) SEVHYPO | <input type="checkbox"/> 1 |
| h. Other serious medical event? OTHMED | <input type="checkbox"/> 1 |

For FEMALE participants with reproductive potential only: *If participant missed a period perform a pregnancy test.*

- | | |
|--------------------------|----------------------------|
| i. Pregnant? PREG | <input type="checkbox"/> 1 |
|--------------------------|----------------------------|

➔ *If any of the above are checked complete **SAE Form***

Symptom History

11. Since the last visit, did the participant experience any of the following?

- | | Yes | No |
|---|---|----------------------------|
| a. Episode(s) of low blood sugar? RELOWBS | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| If YES | | |
| i. Was this repeated mild hypoglycemia? (blood glucose <70 mg/dl more than twice/week or 5 times/month) REMILDHYP | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| ii. How many episodes of mild hypoglycemia have occurred since the last clinic visit? REHYPONUM (1-14) | <input type="text"/> <input type="text"/> time(s) | |
| b. Skin rashes? RESKINRASH | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| c. Frequent stomach pains, bloating, nausea, vomiting, diarrhea, or loss of appetite? RESTOMACH | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| d. Symptoms of diabetes out of control (nocturia more than once a night on a regular basis, enuresis, increased thirst, urinating more often than usual)? RESYMP | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |

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e. Other clinically important symptoms?

12

If "Other,"

i. Specify:

Run-in Medication Adherence

12. Has the participant taken run-in metformin/placebo during the run-in?

RERUNMET1 Yes2 No

IF YES,

a. Percent of expected pills taken **REMETADHERE** %13. **Adult Study:** Has the participant taken run-in injection placebo during the run-in?**RERUNINJCT**1 Yes2 No

IF YES,

a. Number of returned pens **RESYRINGE**1 0%2 1 - 49%3 50 - 79%

b. Calculated medication adherence

REINJCTADHR4 80 - 100%5 >100%14. **Pediatric Study:** Did the participant successfully demonstrate the ability to give him/herself an injection?**REDEMONST**1 Yes2 No15. Did the participant meet adherence criteria for taking medication as prescribed (**at least 80% adherence to both**)?**READHERE**1 Yes2 No