

-
Participant ID

Nickname



**Restoring Insulin Secretion Study
RUNSTART: Start of Run-in Visit Inventory**

1. Study Visit Number VISIT	<input type="text"/> RST <input type="text"/>
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. Staff ID	<input type="text"/> <input type="text"/> <input type="text"/>

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

Diabetes Management

4. Has the participant used any diabetes medication (other than metformin for pediatric participants) since the last visit? **RSDIAMED** 1 Yes 2 No
→ If YES, participant is ineligible.
5. **If PEDIATRIC**, is the participant on metformin? **RSMET** 1 Yes 2 No
a. **If YES**, what is the current dose? **RSMETDOSE** mg/day
6. Is the participant taking any other new medications since screening? **RSNEWMED** 1 Yes 2 No
a. **If YES**, are any of the new medications exclusionary (MOP v.1 Appendix 14.1.1)? **RSMEEXCL** 1 Yes 2 No
7. Was the participant diagnosed with any new illness since screening? **RSNEWILL** 1 Yes 2 No
a. **If YES**, are any of the new illnesses exclusionary (MOP v.1 Appendix 14.1.2)? **RSILLEXCL** 1 Yes 2 No

Serious Adverse Events

8. Since the screening visit, has the participant experienced any of the following?
- Check All That Apply**
- a. Any acute life-threatening event? **THREAT** 1
- b. Required or prolonged hospitalization? **HOSPITAL** 1
- c. Permanent or severe disability? **DISABILITY** 1
- d. Pregnancy resulting in congenital anomaly or birth defect? **BIRDEF** 1
- e. Required intervention to prevent permanent impairment or damage? **PREVENT** 1

<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>
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<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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- f. Overdose of a study medication? **OVERDOSE** 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** 1
- h. Other serious medical event? **OTHMED** 1

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

- i. Pregnant? **PREG** 1

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

Symptom History

9. Since the screening visit, did the participant experience any of the following?
- | | Yes | No |
|---|---|----------------------------|
| a. Episode(s) of low blood sugar? RSLOWBS | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| If YES | | |
| i. Was this repeated mild hypoglycemia? (blood glucose <70 more than twice/week or 5 times/month) RSMILDHYP | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| ii. How many episodes of mild hypoglycemia have occurred since the last clinic visit? RSHYPONUM | <input type="text"/> <input type="text"/> time(s) | |
| b. Skin rashes? RSSKINRASH | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| c. Frequent stomach pains, bloating, nausea, vomiting, diarrhea, or loss of appetite? RSSMOMACH | <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)? RSSYMP | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| e. Other clinically important symptoms? RSOTHER | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |

If "Other,"

i. Specify:

Medication Dispensing

10. Was run-in metformin placebo dispensed? **RSMETPLDISP** 1 Yes 2 No
11. **Pediatric Study Only:** Was run-in active metformin dispensed? **RSMETACDISP** 1 Yes 2 No
12. **Adult Study Only:** Was run-in injection placebo dispensed? **RSINJCTDISP** 1 Yes 2 No