



Participant ID

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Nickname

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Date of visit

month	day	year					

C. Blood Pressure

1. Seated Arm Blood Pressure

- a. Blood Pressure Reading 1 (after sitting 5 minutes) JISBP1

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JIDBP1 mmHg
- b. Blood Pressure Reading 2 (after waiting 30 seconds) JISBP2

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JIDBP2 mmHg

Inform participant and PCP via letter if

- The participant is NON-DIABETIC and if systolic BP  $\geq$  140 or diastolic BP  $\geq$  90 on the mean of 1a and 1b.
- OR
- The participant is DIABETIC and if systolic BP  $\geq$  130 or diastolic BP  $\geq$  80 on the mean of 1a and 1b.

**PART II / HISTORY**

This section must be completed for all participants.

D. Events and Procedures

1. Since the last contact or visit, has the participant experienced any of the following?  
*CHECK ALL THAT APPLY*

- |   |                          |                 |               |  |
|---|--------------------------|-----------------|---------------|--|
| a. Any acute life threatening event?.....                                   | <input type="checkbox"/> |                 | <b>JIACTT</b> |  |
| b. Permanent or severe disability?.....                                     | <input type="checkbox"/> |                 | <b>JIDISA</b> |  |
| c. Required or prolonged hospitalization?.....                              | <input type="checkbox"/> |                 | <b>JIHOSP</b> |  |
| d. Overdose of any medication?.....   | <input type="checkbox"/> |                 | <b>JIOVDO</b> |  |
| e. Pregnancy resulting in congenital abnormality or birth defect?.....      | <input type="checkbox"/> | <b>JICONG</b>   |               | If checked, complete E08 for each event. |
| f. Required intervention or treatment to prevent serious adverse event?.... | <input type="checkbox"/> |                 | <b>JITSAE</b> |  |
| g. Possible CVD event?.....   | <input type="checkbox"/> |                 | JIPCVD        |  |
| h. Renal failure?.....  | <input type="checkbox"/> |                 | JIRENFL       |  |
| i. Kidney transplant?.....  | <input type="checkbox"/> |                 | JIKIDTRNS     |  |
| j. Eye procedure?.....  | <input type="checkbox"/> | <b>JIRETINA</b> |               | → Complete E09                           |
| k. Gastric reduction surgery?.....  | <input type="checkbox"/> | <b>JIGAS</b>    |               | → Complete E11                           |

If any of options a. – i. are checked, complete a separate E08 for each event. For multiple CVD events that may occur during the same hospitalization, complete an E08 for the first CVD diagnosis and report subsequent events (from the same hospitalization) on the same E08 form.

If option j is checked, complete an E09 form. If option k is checked, complete an E11 form.

Participant ID  

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Nickname  

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Date of visit  

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**PART III/ MLS PARTICIPANT SECTION**

**Complete sections E and F for all MLS participants.**

E. Metformin Status

1. Has the participant taken any STUDY METFORMIN since the last visit? Yes  1 No  2 **JITAKMT**

**IF YES, complete the F08 Metformin Safety & Adherence Form for this participant.**

F. Dispensing of Metformin

**Complete the Metformin Safety Assessment Checklist for all participants receiving study metformin before metformin is dispensed.**

1. How many months of metformin was dispensed (0, 3, 6)?.....  **JIDISP**

METFORMIN LABEL 

Remove label from metformin before dispensing and affix here.
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METFORMIN LABEL 

Remove label from metformin before dispensing and affix here.
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