CITY Device Deficiency or Issue Worksheet

Participant ID:

Namecode:

All UADEs, ADEs, device complaints, and device malfunctions will be reported irrespective of whether an adverse event occurred, except in the following circumstances.

The following device issues are anticipated and will not be reported on a Device Issue Form but will reported as an Adverse Event if the criteria for AE reporting described above are met:

- *Component disconnections*
- *CGM sensors lasting fewer than 7 days or longer per the approved duration of sensor use per the manufacturer*
- *CGM tape adherence issues*
- *Battery lifespan deficiency due to inadequate charging or extensive wireless communication*
- *Intermittent device component disconnections/communication failures not leading to system replacement*
- *Device issues clearly addressed in the user guide manual that do not require additional troubleshooting*
- *Skin reactions from CGM sensor placement or pump infusion set placement that don't meet criteria for AE reporting*

DEVICE DEFICIENCY OR ISSUE INFORMATION

1. Investigated device: *[List of devices updated per protocol]*

☐ Dexcom G4 Platinum Professional Receiver
☐ Dexcom G4 Platinum Professional Transmitter
☐ Dexcom G4/G5 Sensor
☐ Dexcom G5 MOBILE Receiver
☐ Dexcom G5 MOBILE Transmitter
☐ Dexcom G6 Receiver
☐ Dexcom G6 Sensor
☐ Dexcom G6 Transmitter
☐ Other

If *Other*, please describe: _____

1a. Serial number:

_____

☐ Unknown ☐ N/A

2. Type of device deficiency or issue:

- ☐ Device malfunction
- ☐ User error
- ☐ Inadequate instructions/training
- ☐ Inadequate labeling
- ☐ Other

If *Other*, please describe:

_____

3. Description of device deficiency or issue:

_____

_____

_____

4. Date problem first occurred/was identified:

_____ _____ / _____ _____ / _____ _____ _____ _____
(mm/dd/yyyy)

5. Location of Occurrence:

- ☐ Home
- ☐ Inpatient
- ☐ Clinic (outpatient)
- ☐ Other

If *Other*, please describe:

_____

6. Frequency:

- ☐ Single Event
- ☐ Intermittent
- ☐ Continuous

7. Effect on study device:

- ☐ No change
- ☐ Study device modified/adjusted
- ☐ Study device replaced
- ☐ Discontinued temporarily
- ☐ Discontinued permanently

8. Date device replaced or modified and first used by participant (leave empty if not applicable or not yet used by subject):

_____ _____ / _____ _____ / _____ _____ _____ _____
(mm/dd/yyyy)

RELATED ADVERSE EVENT OR ADVERSE DEVICE EFFECT

1. Did an adverse event or adverse device effect that requires reporting according to the protocol occur in association with this device deficiency or issue?

☐ Yes ☐ No

(If Yes, complete an Adverse Event Form. If No, complete question 1a.)

1a. If not associated with a reportable adverse event or adverse device effect, please describe the likelihood that the device deficiency or issue could have led to an adverse event or adverse device effect:

☐ Not assessable
☐ Not possible
☐ Unlikely
☐ Possibly
☐ Probably
☐ Certainly

1ai. If you answered Possibly, Probably, or Certainly related, what adverse event could have occurred? Check all that apply:

☐ Hypoglycemia

☐ Hyperglycemia

☐ Other (indicate below)

_____

2. Does the device deficiency or issue meet the definition of an Unanticipated Adverse Device Effect (UADE)?

Unanticipated adverse device effect *(21 CRF 812) means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.*

☐ Yes ☐ No

(If yes, complete question 1a.)

2a. if Yes, please describe the reason for classifying the device deficiency or issue as an UADE:

_____

_____