



## IBM Clinical Development Subject PDF

|                   |   |
|-------------------|---|
| Study Name        | Training - NAPAS                                      |
| Study Status      | Demo / Sandbox (NOTE: STUDY NOT LIVE. PDF DRAFT ONLY) |
| Site/Organization | 12 -- Javara, Dr. Patel                               |
| Subject           | NAPAS12006  |
| Language          | English (United States)                               |
| Generated         | 01-NOV-21 14:18:33 GMT                                |

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## V1: Enrollment (Day 0)

Date of Visit

Page

|       |             | Page Summary   |
|-------|-------------|--|
| Date: | 01-JAN-2021 | <b>Current Status:</b><br>Data Entered<br><br><b>Last Page Status</b><br>Change<br>Mdingi, Colleen<br>(01-NOV-2021<br>13:37:22 GMT)<br><br><b>Last Page Data</b><br>Change<br>Mdingi, Colleen<br>(01-NOV-2021<br>13:37:22 GMT)<br><br>(0) All Page Queries<br>(0) Open Queries<br>(0) Answered Queries<br>(0) Closed Queries |

## Demographics

### Page

|                  |                        | Page Summary   |
|------------------|------------------------|--|
| Date of Birth:   | 01-MAY-2004            | Current Status:<br>Data Entered  |
| Age at Consent:  | 16                     | Last Page Status<br>Change<br>Mdingi, Colleen<br>(01-NOV-2021<br>13:39:12 GMT)         |
| Gender at Birth: | Female                 | Last Page Data<br>Change<br>Mdingi, Colleen<br>(01-NOV-2021<br>13:39:12 GMT)           |
| Race:            | Asian                  | (1) All Page Queries<br>(1) Open Queries<br>(0) Answered Queries<br>(0) Closed Queries |
| Ethnicity:       | Not Hispanic or Latino |  |

## Diabetes History

### Page

|  |                                 | Page Summary   |
|--|---------------------------------|--|
| Date of Diabetes Diagnosis:  | UNK-SEP-2020                    | <b>Current Status:</b><br>Data Entered<br><br><b>Last Page Status Change</b><br>Mdingi, Colleen<br>(01-NOV-2021 13:40:31 GMT)<br><br><b>Last Page Data Change</b><br>Mdingi, Colleen<br>(01-NOV-2021 13:40:31 GMT)<br><br>(0) All Page Queries<br>(0) Open Queries<br>(0) Answered Queries<br>(0) Closed Queries |
| Type of Diabetes:  | Type 1                          |  |
| Insulin Therapy followed:  | Multiple Daily Injections (MDI) |  |
| <i>Record the Type of Insulin and average total daily dose (use the last 3 days or if available from pump download) on the Concomitant Medication Log.</i> |                                 |  |
| Prior CGM use?   | NO                              |  |
| In the past 6 months, had subject experienced ketoacidosis (extremely high blood sugar levels) requiring emergency room visit or hospitalization?          | NO                              |  |
| In the past 6 months, had subject experienced extremely low blood sugar levels resulting in loss of consciousness or seizure?                              | NO                              |  |

## Medical History (1)

### Page

|   |                     | Page Summary  |
|---|---------------------|---|
| <b>List Medical History to include procedures/surgeries; if applicable also include diagnosis/reason.</b> |                     | <b>Current Status:</b><br>Data Entered  |
| <b>Include associated medications on the Concomitant Medications Form.</b>                                |                     | <b>Last Page Status Change</b><br>Mdingi, Colleen<br>(01-NOV-2021 13:41:19 GMT) |
| Body System:  | Cardiovascular      | <b>Last Page Data Change</b><br>Mdingi, Colleen<br>(01-NOV-2021 13:41:19 GMT)   |
| Diagnosis/Procedure/Prior Surgery:  | high blood pressure |   |
| Ongoing?  | YES                 | (0) All Page Queries  |
| Start Date:   | 13-NOV-2014         | (0) Open Queries  |
|   |                     | (0) Answered Queries  |
|   |                     | (0) Closed Queries  |

## Medical History (2)

Page

|  |                     | Page Summary   |
|--|---------------------|--|
| <p><b>List Medical History to include procedures/surgeries; if applicable also include diagnosis/reason.</b></p> <p><b>Include associated medications on the Concomitant Medications Form.</b></p> |                     | <p><b>Current Status:</b><br/>Data Entered</p>   |
| Body System:   | Endocrine           | <p><b>Last Page Status Change</b><br/>Mdingi, Colleen<br/>(01-NOV-2021 13:42:32 GMT)</p> |
| Diagnosis/Procedure/Prior Surgery:   | Hyperglycemic event | <p><b>Last Page Data Change</b><br/>Mdingi, Colleen<br/>(01-NOV-2021 13:42:32 GMT)</p>   |
| Ongoing?   | NO                  | <p>(0) All Page Queries</p>  |
| Start Date:  | 26-NOV-2020         | <p>(0) Open Queries</p>  |
| End Date:  | 27-NOV-2020         | <p>(0) Answered Queries</p>  |
|  |                     | <p>(0) Closed Queries</p>  |

## Medical History (3)

Page

|   |             | Page Summary  |
|---|-------------|---|
| <b>List Medical History to include procedures/surgeries; if applicable also include diagnosis/reason.</b><br><b>Include associated medications on the Concomitant Medications Form.</b> |             | <b>Current Status:</b><br>Data Entered  |
| Body System:  | Other       | <b>Last Page Status Change</b><br>Mdingi, Colleen<br>(01-NOV-2021 13:48:12 GMT) |
| If "Other", specify:  | anxiety     | <b>Last Page Data Change</b><br>Mdingi, Colleen<br>(01-NOV-2021 13:48:12 GMT)   |
| Diagnosis/Procedure/Prior Surgery:  | anxiety     |   |
| Ongoing?  | YES         | (0) All Page Queries<br>(0) Open Queries<br>(0) Answered Queries                |
| Start Date:   | 13-NOV-2018 | (0) Closed Queries  |



## Medical History (4)

### Page

|   |                    | Page Summary  |
|---|--------------------|---|
| <b>List Medical History to include procedures/surgeries; if applicable also include diagnosis/reason.</b> |                    | <b>Current Status:</b><br>Data Entered  |
| <b>Include associated medications on the Concomitant Medications Form.</b>                                |                    | <b>Last Page Status Change</b><br>Mdingi, Colleen<br>(01-NOV-2021 13:50:52 GMT) |
| Body System:  | Infectious Disease | <b>Last Page Data Change</b><br>Mdingi, Colleen<br>(01-NOV-2021 13:50:52 GMT)   |
| Diagnosis/Procedure/Prior Surgery:  | asthma             | (0) All Page Queries  |
| Ongoing?  | YES                | (0) Open Queries  |
| Start Date:   | 11-NOV-2003        | (0) Answered Queries  |
|   |                    | (0) Closed Queries  |

## Physical Exam

### Page

|  |                 | Page Summary   |
|--|-----------------|--|
| <b>Measurements:</b>   |                 | <b>Current Status:</b><br>Data Entered<br><br><b>Last Page Status Change</b><br>Mdingi, Colleen<br>(01-NOV-2021 13:43:33 GMT)<br><br><b>Last Page Data Change</b><br>Mdingi, Colleen<br>(01-NOV-2021 13:43:33 GMT)<br><br>(2) All Page Queries<br>(2) Open Queries<br>(0) Answered Queries<br>(0) Closed Queries |
| Height (record height to nearest inch):  | 59              |  |
| Weight (record weight to nearest pound):   | 68              |  |
| BMI:   | 14              |  |
| <b>Assessment:</b>   |                 |  |
| Does the subject have a condition preventing or complicating the placement, operation or removal of the Sensor or wearing of transmitter, including upper extremity deformities or skin condition? | YES             |  |
| Location of condition:   | Right Upper Arm |  |
| <b>Laboratory:</b>   |                 |  |
| HbA1c Results (%):   | 4.2             |  |
| Comments:  |                 |  |

## Inclusion & Exclusion Criteria

Page

|   |     | Page Summary  |
|---|-----|---|
| <b>INCLUSION CRITERIA:</b><br><b>Male and Female Subjects meeting all of the following inclusion criteria will be included in this study:</b>           |     | <b>Current Status:</b><br><b>Data Entered</b><br><br><b>Last Page Status Change</b><br>Mdingi, Colleen<br>(01-NOV-2021 13:44:21 GMT)  |
| 1. Subject has diabetes.  | YES | <b>Last Page Data Change</b><br>Mdingi, Colleen<br>(01-NOV-2021 13:44:21 GMT)<br><br>(1) All Page Queries<br>(1) Open Queries<br>(0) Answered Queries<br>(0) Closed Queries |
| 2. Subject is greater than 18 years of age.   | YES |   |
| 3. Subject has a smartphone that is internet enabled.   | YES |   |
| 4. Subject is able to comply with study protocol tasks and understand written and verbal instructions in the investigator's opinion.                    | YES |   |
| 5. Subject is willing and able to provide written signed and dated informed consent.  | YES |   |
| <b>EXCLUSION CRITERIA:</b><br><b>Subjects meeting any of the following exclusion criteria at the time of screening will be excluded from this study</b> |     |   |
| 1. Subject is critically ill or hospitalized.   | NO  |   |
| 2. Prior use of CGM defined as:   |     |   |
| More than 1 week of continuous CGM use in the last 6 months?  | NO  |   |
| More than 4 weeks of continuous CGM use in the last 12 months?  | NO  |   |
| More than 12 weeks total use in the last 3 years?   | NO  |   |
| 3. Subject has a known contraindication to dexamethasone or dexamethasone acetate.  | NO  |   |
| 4. Subjects requiring intravenous mannitol or mannitol irrigation solutions.  | NO  |   |
| 5. Subject is on dialysis at the time of enrollment.  | NO  |   |
| 6. Female subjects who are  | NO  |   |



pregnant, planning on becoming  
pregnant or nursing.

## Screening Outcome

### Page

|   |                    | Page Summary                    |
|---|--------------------|---------------------------------|
| Screening Outcome:  | Screening complete | Current Status:<br>Data Entered |
| If "Screen failure", specify reason in comments section.              |                    | Last Page Status<br>Change      |
| If "Physician decision", specify reason in comments section.          |                    | Mdingi, Colleen                 |
| If "Study terminated by sponsor", specify reason in comments section. |                    | (01-NOV-2021<br>13:44:30 GMT)   |
| If "Death", specify cause of Death in comments section.               |                    | Last Page Data<br>Change        |
| If "Withdrawal of subject", specify reason in comments section.       |                    | Mdingi, Colleen                 |
| Comments:   |                    | (01-NOV-2021<br>13:44:30 GMT)   |
|   |                    | (0) All Page Queries            |
|   |                    | (0) Open Queries                |
|   |                    | (0) Answered Queries            |
|   |                    | (0) Closed Queries              |

## Visit Assessments

### Page

|  |     | Page Summary   |
|--|-----|--|
| Quantity of BG Test Strip Vials Dispensed:   | 9   | <b>Current Status:</b><br><b>Data Entered</b>  |
| Was subject instructed to make diabetes care decisions based on BG meter values?   | YES | <b>Last Page Status Change</b><br>Mdingi, Colleen<br>(01-NOV-2021 13:45:27 GMT)        |
| Was subject instructed to keep a diary/log of hypoglycemic and hyperglycemic events and to contact site when severe or serious events occur? | YES | <b>Last Page Data Change</b><br>Mdingi, Colleen<br>(01-NOV-2021 13:45:27 GMT)          |
| Comments:  |     | (0) All Page Queries<br>(0) Open Queries<br>(0) Answered Queries<br>(0) Closed Queries |

## Interim Visit Assessment Call

### Page

|  |             | Page Summary  |
|--|-------------|---|
| <b>30 Day Call</b>   |             | <b>Current Status:</b><br>Data Entered  |
| Date of Call:  | 30-DEC-2020 |   |
| Are there any incidences of Adverse Events that need to be reported?   | YES         | <b>Last Page Status Change</b><br>Mdingi, Colleen<br>(01-NOV-2021 13:46:24 GMT) |
| <b>If "YES", document on Adverse Events and/or Concomitant Medications Form if applicable.</b>   |             |   |
| Was subject reminded to keep a diary/log of hypoglycemic and hyperglycemic events and to contact site when severe or serious events occur? | YES         | <b>Last Page Data Change</b><br>Mdingi, Colleen<br>(01-NOV-2021 13:46:24 GMT)   |
| Please include any additional Comments as necessary:   |             | (0) All Page Queries  |
|  |             | (0) Open Queries  |
|  |             | (0) Answered Queries  |
|  |             | (0) Closed Queries  |
| <b>60 Day Call</b>   |             |   |
| Date of Call:  | 30-JAN-2021 |   |
| Are there any incidences of Adverse Events during home use that need to be reported?   | NO          |   |
| <b>If "YES", document on Adverse Events and/or Concomitant Medications Form if applicable.</b>   |             |   |
| Was subject reminded to keep a diary/log of hypoglycemic and hyperglycemic events and to contact site when severe or serious events occur? | YES         |   |
| Please include any additional Comments as necessary:   |             |   |

## V2: Visit 2 (Day 90)

Date of Visit

Page

|       |             | Page Summary  |
|-------|-------------|---|
| Date: | 19-MAR-2021 | <b>Current Status:</b><br>Data Entered  |
|       |             | <b>Last Page Status</b><br>Change<br>Mdingi, Colleen<br>(01-NOV-2021<br>13:58:40 GMT) |
|       |             | <b>Last Page Data</b><br>Change<br>Mdingi, Colleen<br>(01-NOV-2021<br>13:58:40 GMT)   |
|       |             | (1) All Page Queries  |
|       |             | (1) Open Queries  |
|       |             | (0) Answered Queries  |
|       |             | (0) Closed Queries  |



## Visit Assessments

### Page

|  |                           | Page Summary   |
|--|---------------------------|--|
| Was BG data file downloaded?   | NO                        | Current Status:<br>Data Entered  |
| Why was file not downloaded?   | subject forgot SMBG meter | Last Page Status<br>Change<br>Mdingi, Colleen<br>(01-NOV-2021<br>13:59:06 GMT)         |
| Quantity of BG Test Strip Vials<br>Dispensed:  | 9                         | Last Page Data<br>Change<br>Mdingi, Colleen<br>(01-NOV-2021<br>13:59:06 GMT)           |
| Was subject instructed to make<br>diabetes care decisions based on<br>BG meter values?   | YES                       | (0) All Page Queries<br>(0) Open Queries<br>(0) Answered Queries<br>(0) Closed Queries |
| Was subject reminded to keep a<br>diary/log of hypoglycemic and<br>hyperglycemic events and to<br>contact site when severe or<br>serious events occur? | YES                       |  |
| Comments:  |                           |  |

## AE Assessment

### Page

|   |    | Page Summary   |
|---|----|--|
| Are there any incidences of Adverse Events that need to be reported?                    | NO | Current Status:<br>Data Entered  |
| If "YES", document on Adverse Events and/or Concomitant Medications Form if applicable. |    | Last Page Status Change<br>Mdingi, Colleen<br>(01-NOV-2021 13:59:20 GMT)               |
| Did subject record in their diary any Adverse Events that need to be reported?          | NO | Last Page Data Change<br>Mdingi, Colleen<br>(01-NOV-2021 13:59:20 GMT)                 |
| If "YES", document on Adverse Events and/or Concomitant Medications Form if applicable. |    |  |
| Please include any additional Comments as necessary:                                    |    | (0) All Page Queries<br>(0) Open Queries<br>(0) Answered Queries<br>(0) Closed Queries |

## Interim Visit Assessment Call

### Page

|  |             | Page Summary   |
|--|-------------|--|
| <b>30 Day Call</b>   |             | <b>Current Status:</b><br>Data Entered<br><br><b>Last Page Status Change</b><br>Mdingi, Colleen<br>(01-NOV-2021 14:00:01 GMT)<br><br><b>Last Page Data Change</b><br>Mdingi, Colleen<br>(01-NOV-2021 14:00:01 GMT)<br><br>(0) All Page Queries<br>(0) Open Queries<br>(0) Answered Queries<br>(0) Closed Queries |
| Date of Call:  | 21-APR-2021 |  |
| Are there any incidences of Adverse Events that need to be reported?   | NO          |  |
| <b>If "YES", document on Adverse Events and/or Concomitant Medications Form if applicable.</b>   |             |  |
| Was subject reminded to keep a diary/log of hypoglycemic and hyperglycemic events and to contact site when severe or serious events occur? | NO          |  |
| Please include any additional Comments as necessary:   |             |  |
| <b>60 Day Call</b>   |             |  |
| Date of Call:  | 21-MAY-2021 |  |
| Are there any incidences of Adverse Events during home use that need to be reported?   | YES         |  |
| <b>If "YES", document on Adverse Events and/or Concomitant Medications Form if applicable.</b>   |             |  |
| Was subject reminded to keep a diary/log of hypoglycemic and hyperglycemic events and to contact site when severe or serious events occur? | NO          |  |
| Please include any additional Comments as necessary:   |             |  |

## Adverse Events Form

### Adverse Events (1)

Page

|   |   | Page Summary                                  |
|---|---|---|
| Adverse Event Description:  | Failure to remove sensor on initial attempt | Current Status:<br>Data Entered               |
| Additional Description of Event:  |   | Last Page Status Change                       |
| Next Scheduled Removal Date:  | 02-JUN-2021                                 | Mdingi, Colleen<br>(01-NOV-2021 14:01:58 GMT) |
| Date Investigator/Study Staff Became Aware of Event:                              | 24-JUN-2021                                 | Last Page Data Change                         |
| Date of Onset:  | 23-JUN-2021                                 | Mdingi, Colleen<br>(01-NOV-2021 14:01:58 GMT) |
| Status:   | Ongoing                                     |   |
| Severity:   | Mild  | (1) All Page Queries                          |
| Action Taken:   | Other                                       | (1) Open Queries                              |
| If selected, specify:   | Plan to remove the sensor in 3 weeks.       | (0) Answered Queries                          |
| If Action Taken is "Concomitant Therapy", add to the Concomitant Medication Form. |   | (0) Closed Queries                            |
| Relationship to Study Device:   | Possibly Related                            |   |
| Relationship to Device-Insertion/Removal Procedure:                               | None  |   |
| Relationship to Study Procedure:  | None  |   |
| Meets Serious Adverse Event Criteria?   | NO  |   |
| <b>CEC INITIAL REVIEWER</b>   |   |   |
| Date Reviewed:  |   |   |
| Name of Reviewer:   |   |   |
| Relationship to Study Device:   |   |   |
| Relationship to Device-Insertion/Removal Procedure:                               |   |   |
| Relationship to Study Procedure:  |   |   |
| Severity:   |   |   |
| Is the Event Serious?   |   |   |

Adverse Event Physiological  
System:

Adverse Event Category:

Does event require immediate  
escalation to DSMB? (Causes  
such as death or serious  
deterioration of health or fetal  
distress, deemed related to the  
device.)

Is the Initial Review Complete?

**Action Required:**

Comments:

### CEC MEETING ADJUDICATION

Date Reviewed:

Reviewed By:

Is the CEC Adjudication  
Complete?

**Action Required:**

Comments:

## Concomitant Medications Form

### Concomitant Medications Form (1)

Page

|  |             | Page Summary   |
|--|-------------|--|
| <i>If medication is Insulin, include the average total daily dose (use last 3 days or if available from pump download) with the medication name.</i> |             | Current Status:<br>Data Entered  |
| Medication Name:   | Lisinopril  | Last Page Status<br>Change<br>Mdingi, Colleen<br>(01-NOV-2021<br>13:57:13 GMT) |
| Indication:  | asthma      | Last Page Data<br>Change<br>Mdingi, Colleen<br>(01-NOV-2021<br>13:57:13 GMT)   |
| Start Date:  | 08-OCT-2019 | (0) All Page Queries   |
| Ongoing?   | YES         | (0) Open Queries   |
|  |             | (0) Answered Queries   |
|  |             | (0) Closed Queries   |

## Concomitant Medications Form (2)

Page

|  |                       | Page Summary   |
|--|-----------------------|--|
| <i>If medication is Insulin, include the average total daily dose (use last 3 days or if available from pump download) with the medication name.</i> |                       | Current Status:<br>Data Entered  |
| Medication Name:   | Fluticasone - inhaler | Last Page Status<br>Change<br>Mdingi, Colleen<br>(01-NOV-2021<br>13:58:14 GMT) |
| Indication:  | high blood pressure   | Last Page Data<br>Change<br>Mdingi, Colleen<br>(01-NOV-2021<br>13:58:14 GMT)   |
| Start Date:  | 20-NOV-2007           | (0) All Page Queries   |
| Ongoing?   | YES                   | (0) Open Queries   |
|  |                       | (0) Answered Queries   |
|  |                       | (0) Closed Queries   |