**In Home Closed Loop**

Link to public websites:

PSO3: <http://jdrfconsortium.jaeb.org/Studies.aspx?RecID=458>

PSO4: <http://jdrfconsortium.jaeb.org/Studies.aspx?RecID=459>

Protocol Synopsis:

PSO3: Reduction Of Nocturnal Hypoglycemia By Using Predictive Algorithms And Pump Suspension - An Outpatient Pilot Feasibility and Safety Study.

PSO4: Pump Shut Off – In Children. Outpatient Reduction of Nocturnal Hypoglycemia by Using Predictive Algorithms and Pump Suspension in Children

Data Glossary:

This document provides a description of the nights dataset. The nights dataset combines many PSO3 and PSO4 public datasets, and creates several variables. The datasets used includes enrollment, session, CGM, pump, metered, and session glucose data. Other variables not included in the nights dataset may be found in the respective PSO3 and PSO4 folders. The following table provides a description of all the variables in the nights dataset.

nights – One record per night

|  |  |  |
| --- | --- | --- |
| Column Name | Description | Possible\_Values |
| DeidentID | Patient ID | PSO3\_0001, ..., PSO4\_0093 |
| SysStartDtTm | Datetime the subject started the session |  |
| SysEndDtTm | Datetime the session was concluded by either the user or the PSO3 system - This means that the PSO system stopped controlling the pump and calling the algorithm module |  |
| sessionID | RecID from session |  |
| psoPtPhase | Protocol phase in which the data was collected | B)Home Run-in, C)Clinical Trial Phase |
| EndSessionCompleteDtTm | Datetime when the user completed the PSO controller end session form |  |
| currentDt | Date of the night when the session started. A system starting after midnight would correspond to the previous date. |  |
| AlgoActive | Whether the predictive low-glucose suspend module was randomized to be active (intervention night) or not (control night) |  |
| exer\_Intensity | Exercise intensity | 1. No Exercise, 2. Low Exercise, 3. Med/High Exercise |
| Snack | Bedtime snack | Yes, No |
| bedtimeBGDtTm | Datetime of the bedtime blood glucose |  |
| bedtimeBG | Bedtime blood glucose value |  |
| morningBGDtTm | Datetime of the morning blood glucose |  |
| morningBG | Morning blood glucose value |  |
| nReadings | Number of CGM readings |  |
| numBelow60 | Number of CGM readings below 60 mg/dL |  |
| numAbove250 | Number of CGM readings above 250 mg/dL |  |
| iob | Insulin on board at the start of the session |  |
| cgmRateChg | CGM rate of change at the start of the session |  |
| nCGMHypo60\_Daytime | Number of CGM readings below 60 mg/dL during the preceding daytime |  |
| nCGM\_Daytime | Number of CGM readings during the preceding daytime |  |
| cgmRateChgGrp | CGM rate of change at the start of the session category | 1.<=-0.5 mg/dl/min, 2.(-0.5,+0.5) mg/dl/min, 3.>=+0.5 mg/dl/min, 4. Unknown |
| weekendNight | Indicator for whether night is on weekend (Friday or Saturday night) | 1)Yes, 2)No |
| sysStartTmGrp | Time the subject started the session category | A)12:00-21:00, B)21:00-23:00,  C)23:00-01:00,  D)01:00-12:00 |
| valid6Hrs | Indicator whether night had 6 hours of CGM data (72 measurements) |  |
| Ethnicity | Ethnicity | Hispanic or Latino, Not Hispanic or Latino, Unknown/not reported |
| Race | Race | White, Black/African American, Asian, Native Hawaiian/Other Pacific Islander, American Indian/Alaskan Native, More than one race, Unknown/not reported |
| DeidentEnrollDt | Deidentified Date of enrollment to the study |  |
| DeidentBirthDt | The Deidentified birth date |  |
| DeidentDiabetesDt | The Deidentified date of diabetes diagnosis |  |
| DailyIns | Total daily insulin (U/day) |  |
| Dailybasal | Total daily basal (U/day) |  |
| NumFingerstick | Average number of fingerstick readings done over the last seven days |  |
| Weight | Weight (kg) |  |
| Height | Height (cm) |  |
| HbA1CTest | HbA1C Test |  |
| ageAtEnroll | Age of subject upon enrolling in study |  |
| diabDuration | Diabetes duration upon enrolling in study |  |
| dailyBasal\_Ins | Total daily basal over total daily insulin |  |
| dailyIns\_U\_kg\_d | Total daily insulin over weight |  |
| iob\_dailyIns | Insulin on board over total daily insulin |  |