# Demographics:

The Demographics form captures important information about the patient's age, sex, reproductive status, ethnicity, and race. This information is essential for understanding the patient's background and potential risk factors that may affect the trial results. It also helps to ensure that the trial is conducted in an ethical and equitable manner.

The Demographics form appears in the EDC at the Screening visit only. Its visibility is controlled by completion of the Study Visit form.

Enter the patient's date of birth.

The age in years at the time of consent will be automatically completed by the system based on the date the patient signed the main study consent and the date of birth.

Enter the patient's sex [Male | Female]. If 'Female', see items at (1).

(1) Enter whether the patient is of child-bearing potential [Yes | No]. If 'Yes', see items at (2). If 'No', see items at (3).

(2) Enter the contraception method(s) used by this patient.

(3) Enter the reason for non-child-bearing potential.

Enter the patient's ethnicity [Hispanic or Latino | Not Hispanic or Latino | Unknown | etc.].

Enter the patient's race [White | Aboriginal and Torres Strait Islander | Black or African American | etc.]. If 'Other', see items at (4).

(4) Enter the other race.

# Electrocardiogram:

The Electrocardiogram form captures information about the electrical activity of the heart, such as heart rate, PR interval, QRS duration, and QT interval. This information is used to assess the health of the heart and detect any abnormalities, which can be clinically significant. The form also records any other notable ECG findings, as well as an overall assessment of the ECG.

The Electrocardiogram form appears in the EDC at the Screening, Day 2 - Discharge, Day 14 - Follow-Up, Day 90 - Follow-Up, Day 120 - Sub-Study Procedure, Day 121 - Sub-Study Discharge, Day 134 - Sub-Study Follow-Up, Day 180 - Follow-Up, Day 230 - Follow-Up, Day 300 - Follow-Up, and Unscheduled visits. Its visibility is controlled by completion of the Study Visit, Eligibility Review, and Informed Consent forms.

Enter whether an ECG was performed [Yes | No]. If 'Yes', see items at (1). If 'No', see items at (2).

(2) Enter the reason why the Electrocardiogram was not performed.

(1) Enter the date the Electrocardiogram was performed.

(1) Enter the time the electrocardiogram was taken.

(1) Enter the heart rate in bpm.

(1) Enter the PR Interval in msec.

(1) Enter the QRS Duration in msec.

(1) Enter the QT Interval in msec.

(1) Enter the QTcF Interval in msec.

(1) Enter whether there were any other notable ECG findings [Yes | No]. If 'Yes', see items at (3).

(3) Enter any other notable electrocardiogram findings.

(1) Enter the overall assessment of the ECG [Normal | Abnormal]. If 'Abnormal', see items at (4).

(4) Enter whether the abnormality(s) were clinically significant [Yes | No].

# Eligibility Review:

The Eligibility Review form is used to assess whether a patient is suitable to participate in the trial. It captures information such as whether the review was performed, the date of the review, and whether the patient was eligible for the study. It also records the eligibility criteria and the specific criterion category and number that the patient failed on, if applicable. This form is important for ensuring that only suitable patients are enrolled in the trial.

The Eligibility Review form appears in the EDC at the Screening visit only. Its visibility is controlled by completion of the Study Visit form.

Enter whether eligibility review was performed [Yes | No]. If 'Yes', see items at (1). If 'No', see items at (2).

(2) Enter the reason eligibility review was not performed.

(1) Enter the date of review.

(1) Enter whether the patient was eligible for the study [Yes | No]. If 'No', see items at (3).

*(3) Eligibility Log - Add Occurrences or Complete the Pre-Filled Lines as Applicable:*

Enter the criterion category patient failed on [Inclusion | Exclusion].

Enter the criterion number patient failed on [INC 01 | EXC 01 | INC 02 | etc.].

# Height, Weight & BMI:

The Height, Weight & BMI form captures important information about a participant's physical measurements, such as their height, weight and body mass index (BMI). This data is essential for understanding the participant's health and progress throughout the trial. The form also records any reasons why measurements were not taken, as well as the date and time of the measurements.

The Height, Weight & BMI form appears in the EDC at the Screening and Unscheduled visits. Its visibility is controlled by completion of the Study Visit and Eligibility Review forms.

Enter whether height and weight measurements were performed for BMI calculation [Yes | No]. If 'Yes', see items at (1). If 'No', see items at (2).

(1) Enter the date of measurement.

(1) Enter the time of measurement.

(2) Enter the reason height and weight were not measured.

(1) Enter the height in metres.

(1) Enter the weight in kilograms.

(1) The BMI in kg/m2 will be automatically completed by the system based on the height and weight.

# Protocol Deviations:

The Protocol Deviations form captures information about any deviations from the trial protocol that occur during the trial. It records whether a deviation occurred, the related visit and assessment, the date of the deviation, and whether patient safety was compromised. It also records whether Sponsor and HREC notifications were required, and the dates of those notifications. Finally, it captures a summary and narrative of the deviation, the deviation category, and the outcome/corrective action taken. The form is important for ensuring that the trial is conducted in accordance with the protocol and that any deviations are properly documented and addressed.

The Protocol Deviations form appears in the EDC at the Common Forms visit only. Its visibility is controlled by completion of the Study Visit and Eligibility Review forms.

Enter whether a protocol deviation occurred [Yes | No]. If 'Yes', see items at (1).

(1) The Protocol Deviation Number will be automatically completed by the system based on the Form Occurrence Number.

(1) Enter the related visit [Inclusion Visit | Screening | Day 1 - Procedure | etc.].

(1) Enter the related assessment [Electrocardiogram | Pregnancy Test | Neurological Examination].

(1) Enter the date of the deviation.

(1) Enter whether patient safety was compromised [Yes | No].

(1) Enter whether Sponsor notification was required [Yes | No]. If 'Yes', see items at (2).

(2) Enter the date the sponsor was notified of the protocol deviation.

(1) Enter whether HREC notification was required [Yes | No]. If 'Yes', see items at (3).

(3) Enter the date of notification to the Human Research Ethics Committee.

(1) Enter a brief summary of the protocol deviation.

(1) Enter a detailed narrative of the deviation, including the source, its impact on the study, and the immediate action taken.

(1) Enter the deviation category [Out window|Missed|Not as per|etc.]. If 'Other', see items at (4).

(4) Enter the other category of protocol deviation.

(1) Enter the outcome or corrective action taken.