biolinq

ClinicalTrials.gov Protocol with SAP Cover Page

For Submission of Study Documents

Study Title:	Safety and Effectiveness Study of the Biolinq MicroArray Intradermal Continuous Glucose Biowearable System (CP-011)
NCT Number:	NCT06229743
Document Type:	Clinical Protocol with SAP
Version/Revision Number:	V1(February 03, 2025) with redactions for PII, trade secret, or confidential commercial information.

Safety and Effectiveness Study of the Biolinq MicroArray Intradermal Continuous Glucose Biowearable System

Protocol Number: CP-011

Investigational Device: The Biolinq MicroArray Intradermal Continuous Glucose Biowearable System

Study Sponsor: Biolinq, Inc.

Study Contacts:

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[redacted]

Version Number: 1

Version Date: February 03, 2025

DCO-2025-0014

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2 PROTOCOL SIGNATURE PAGE

Protocol Title: Safety and Effectiveness Study of the Biolinq MicroArray Intradermal Continuous Glucose Biowearable System

Protocol Number-Version: CP-011, Version 1

Protocol Date: February 03, 2025

Sponsor: Biolinq, Inc.

The undersigned have read and understand the Protocol specified above and agree on its content. I/we agree to conduct this study in accordance with applicable FDA regulations, including parts 11 (Electronic records; electronic signatures), 50 (Protection of human subjects), 54 (Financial disclosure by clinical Investigators), and 56 (Institutional Review Boards), of CFR Title 21. Investigators shall also conduct this study in accordance with any IRB requirements and local laws.

_____ _____

Investigator Signature Date

_____

Investigator Name

_____

Name of Institution

3 ABBREVIATIONS

Table 1 Abbreviations

ADE	Adverse Device Effect
AE	Adverse Event
AFE	Analog Front End
ARD	Absolute Relative Difference
BMI	Body Mass Index
CFR	Code of Federal Regulations
CGM	Continuous Glucose Monitor/Monitoring
CRF	Case Report Form
DKA	Diabetic Ketoacidosis
EDC	Electronic Data Capture
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HbA1c	Glycosylated Hemoglobin
HIV	Human Immunodeficiency Virus
ICH	International Conference on Harmonisation
IDE	Investigational Device Exemption
IRB	Institutional Review Board
ISO	International Organization for Standardization
IIT	Intensive Insulin Therapy
IMU	Inertial Measurement Unit
IV	Intra Venous
LA	Laboratory Analyzer
MARD	Mean Absolute Relative Difference
mg/dL	Milligrams per deciliter
NFC	Near Field Communication
NIIT	Non-Intensive Insulin Therapy
OCT	Optical Coherence Tomography
PCB	Printed Circuit Board
PI	Principal Investigator
POC	Point of Care
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SMBG	Self-Monitoring Blood Glucose
SOA	Schedule of Activities
YSI	YSI 2300 STAT PLUS Analyzer
UADE	Unanticipated Adverse Device Effect
US	United States

4 PROTOCOL SYNOPSIS

Table 2 Protocol Synopsis

Title:	Safety and Effectiveness Study of the Biolinq MicroArray Intradermal Continuous Glucose Biowearable System
Study Sponsor:	Biolinq, Incorporated
Investigational Device:	Biolinq System: Biolinq MicroArray Intradermal Continuous Glucose Biowearable System.
Reference Device:	FDA-cleared Laboratory Analyzer (LA) [YSI STAT PLUS 2300 Glucose and L-Lactate Analyzer (Yellow Springs, Ohio)]
Comparator Devices:	The following commercially available comparator devices will be used to collect glucose data for reference analysis: • Self-monitoring blood glucose (SMBG) meter: [redacted] • Continuous Glucose Monitor (CGM): [redacted]
Design:	Clinical safety and effectiveness study – open label, prospective, multi-center, single arm
Objectives:	The primary objective of the study is to evaluate the safety and effectiveness of the Biolinq MicroArray Intradermal Continuous Glucose Biowearable System, which is intended to be worn for up to five (5) days (up to 120 hours) in adults with diabetes mellitus (DM). Data collected from this study is intended to be used to support commercial marketing application(s) for the intended commercial patient population of non-insulin-users.
Study Population	To attain sufficient hypoglycemic and hyperglycemic values in the study in conjunction and ensure that underrepresented populations are included in the evaluation, the study will enroll subjects outside the device's intended population and include persons requiring insulin for management of their disease. [redacted]
Number of Subjects:	Enroll up to 247 subjects to ensure at least 206 subjects are treated allowing for up to 18.2% screen failures.

Number of Centers:	A minimum of five (5) and up to eight (8) centers in the United States will participate in the study.
Estimated Duration:	[redacted]
Randomization	The study will utilize three (3) independent randomization assignments with 1:1 ratio for the location of the biowearable (left vs. right volar forearm), 7:3 ratio for the number of biowearables (one vs. two), and the 1:1 ratio for the primary biowearable determination (proximal vs. distal) for subjects who were randomized to wear two biowearables.
Co-Primary Endpoints:	1. For all available matched pair data points when the Biowearable displays BLUE ("in target" color indicator), the percentage of reference blood glucose values between 55-207 mg/dL must be calculated, [redacted] 2. For all available matched pair points when the Biowearable displays YELLOW ("above target" color indicator), the percentage of reference blood glucose values between 154-460 mg/dL must be calculated, [redacted] [redacted]
Safety Analyses:	1. Overall adverse device effect rate 2. Individual adverse device effect rates 3. Distribution of Draize assessments for erythema and edema for Bioliq Biowearable
Observational Analyses:	[redacted]
Device Precision:	Precision of the Bioliq Biowearables from subjects who wore two biowearables will be assessed [redacted]

Sample Size Statistical Rationale:	[redacted]
Inclusion Criteria:	Individuals may be included in the study if they satisfy all the following: General 1. ≥ 22 years old. 2. Willing and able to provide written signed and dated informed consent. 3. Access to phone or computer with internet to complete subject log. Diabetes History and Health 4. Diagnosis of type 1 diabetes (T1D)/ LADA or type 2 diabetes (T2D) and on intensive insulin therapy (IIT) with known dosing parameters for at least three (3) months prior to the Screening Visit with an A1c of 5.5%-10% or diagnosis of type 2 diabetes (T2D) and on non-intensive insulin therapy (NIIT) or T2D not using insulin with an A1c of 7.5% to 11%. 5. Weigh at least 110 lbs (50 kilograms). 6. Be otherwise in good health, as determined by a medical care professional. 7. Willing to refrain from Acetaminophen use for the duration of study enrollment. 8. If using an automated insulin delivery (AID) system, willing to disable automated features and go into open loop mode during the duration of in-clinic days. Device and Glucose Assessments – Willing to: 9. Wear one (1) commercial CGM system [redacted] on the abdomen per approved labeling and have up to 1 replacement. 10. Wear up to two (2) Biolinq Biowearables simultaneously following the application procedures on the volar forearm for up to 7 days. 11. Participate in two (2) In-Clinic sessions lasting up to 11.5 hours of blood draws (anticipated up to 13 hours on site per visit) each. 12. Perform up to five (5) fingersticks a day with the SMBG device provided during non-in-clinic days. 13. Avoid immersing study devices into water (e.g., no hot tub, SCUBA diving). 14. Wear an activity tracker or record activity levels on a daily log.

Exclusion Criteria:	Individuals with any of the following will be excluded: General 1. Current participation in another investigational study protocol. (If a subject has recently completed participation in another drug study, the subject must have completed that study at least 30 days prior to being enrolled in this study.) *Note*: Subjects will not be excluded if enrolled in another observational trial, wherein the subject is in the follow-up phase and no tests/procedures impacting the subject's health are required. Subjects will be excluded if they have been previously enrolled in this study. 2. Work for, are family members with, or live with someone that works for the sponsor or competitor diabetes-related company (includes social media influencers or bloggers). 3. In the investigator's opinion, any reason that may lead to subject non-compliance with study requirements or confound study data. Health 4. Currently taking Hydroxyurea. 5. Known allergy to medical grade adhesives, acrylic, latex, or isopropyl alcohol. 6. Have dermatological conditions that preclude wearing Biolinq Biowearables (e.g., extensive psoriasis, recent burns, severe sunburn, extensive eczema, extensive scarring, dermatitis herpetiformis, skin lesions, erythema, infection, or other conditions at the discretion of the investigator). 7. For subjects of child-bearing potential, pregnant or not practicing an acceptable form of birth control during the study. 8. Hematocrit measurement via point-of-care (POC) or laboratory testing that is less than the applicable below-mentioned value: a. Male: 36.0% b. Female: 33.0% 9. Have donated blood, had significant blood loss, or participated in a study with significant blood sampling (340 cc or more) within 56 days prior to study enrollment or plan to participate in such activities during study wear. 10. Required or scheduled to have diathermy, X-ray, MRI, or CT during study wear. 11. In the investigator's opinion, the subject has a history of concomitant medical condition that could interfere with the study participation or present a risk to the safety and welfare of the subject or study staff. Such historical conditions include but are not limited to: a. Syncope in past 6 months b. Severe hypoglycemia (loss of consciousness, seizure, or emergency medical technician assistance within the past 6 months) c. Diabetic ketoacidosis (DKA) requiring hospital admission in the past 6 months d. Coagulopathy e. Chronic infectious disease (e.g., HIV/AIDS, Hepatitis B or C) f. End stage renal disease and currently managed by dialysis or anticipating initiating dialysis during the study wear period g. History of congestive heart failure

Methodology:	This is an open label, single arm, multi-center study conducted in 5-8 investigational sites in the United States. Enroll up to 247 subjects to yield at least 206 treated subjects assuming up to 18.2 % screen failures. **Consent and Screening:** Subjects are considered enrolled after signing and dating an Institutional Review Board (IRB) approved informed consent form (ICF). activities must be completed within 30 days prior to the Biolinq application and include eligibility criteria, vitals, demographics, medical history review, Fitzpatrick Skin assessment, pregnancy testing (as applicable), A1c and hematocrit tests. Subjects who meet the study eligibility criteria will be scheduled for Biolinq Biowearable application. Screen failures must exit the study and reasons for exit are documented. Subjects who do not complete screening activities within 30 days are still eligible to participate in the study but must be reconsented and re-screened. Subjects who passed the screening activities will be randomized [redacted]

[redacted]

[redacted]

The YSI STAT PLUS 2300 Glucose and L-Lactate Analyzer will be used to measure glucose values (reference data) for all blood draws during in-clinic sessions. Four active venous blood draws will be done every hour (one blood draw every 15 ± 7 minutes). A matching SMBG fingerstick on the same arm as the Biolinq Biowearable will be taken simultaneously with the draw for three (3) out of every four (4) blood draws for comparative purposes.

Using glucose measurements taken under close direction and observation of the investigator staff, insulin dosing (for subjects on insulin) and meal composition/timing may be manipulated during the in-clinic session to obtain sufficient data variation between 40-400 mg/dL and attain sample sizes required for performance evaluation to support device commercial application.

Investigators or designated staff will monitor subjects for safety during an in-clinic session. In-Clinic Guidelines (Appendix 1 – In-Clinic Guidelines) will be provided as guidance, but the investigator or designee will maintain final discretion for any in-clinic procedures and methods used based on their medical expertise and training. A “crash cart” will be prepared and easily accessible for potential emergency situations. At a minimum, this cart should include vial(s) of insulin, normal saline, blood pressure cuff, defibrillator, a bag-valve mask, carbohydrate snacks, glucose tabs or gel, glucagon, and dextrose solutions. Subjects will be discharged at the end of the in-clinic day according to investigator discretion per Appendix 1 – In-Clinic Guidelines.

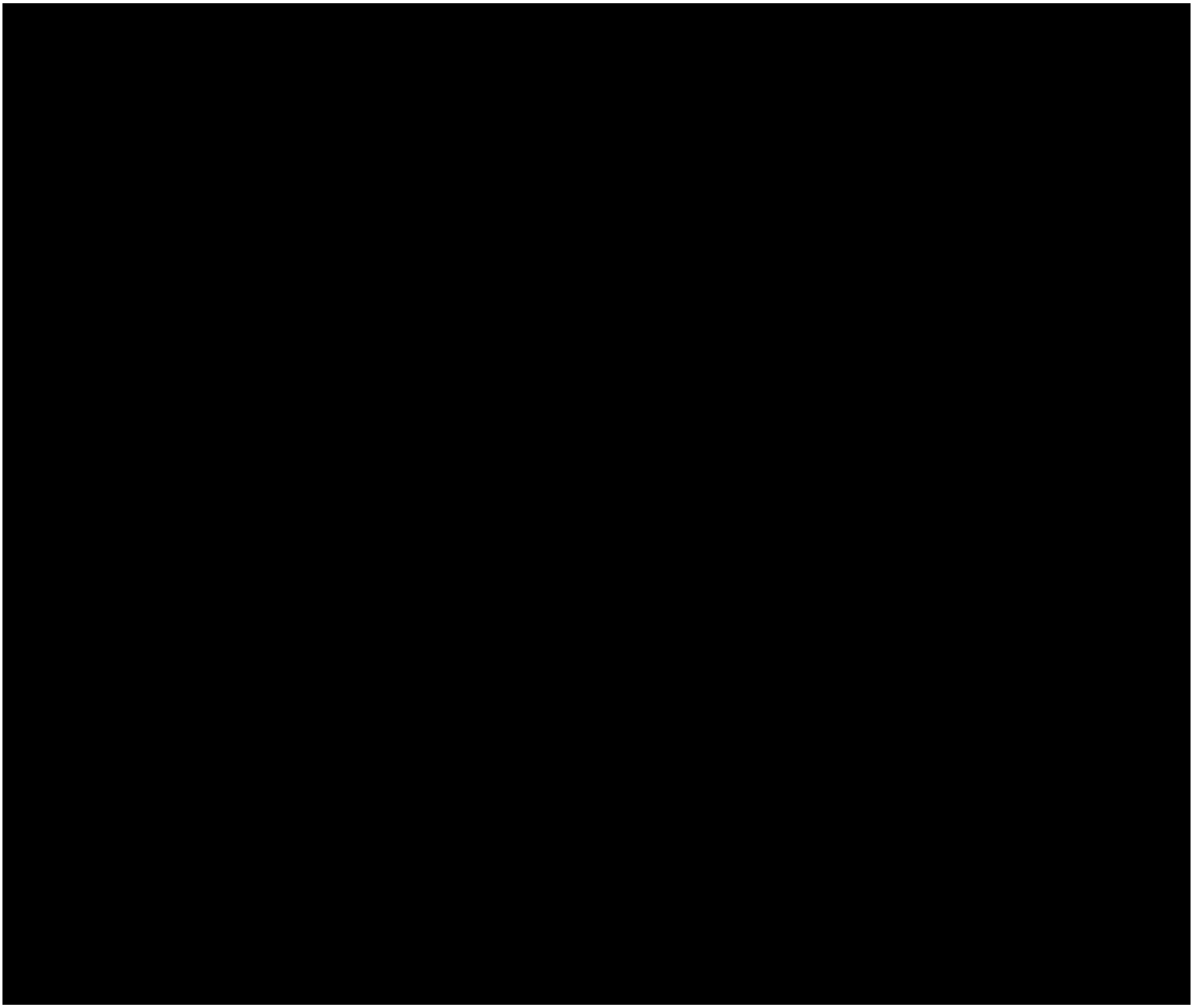
[redacted]

Adverse Event, Protocol Deviation and Device Observation Assessments:

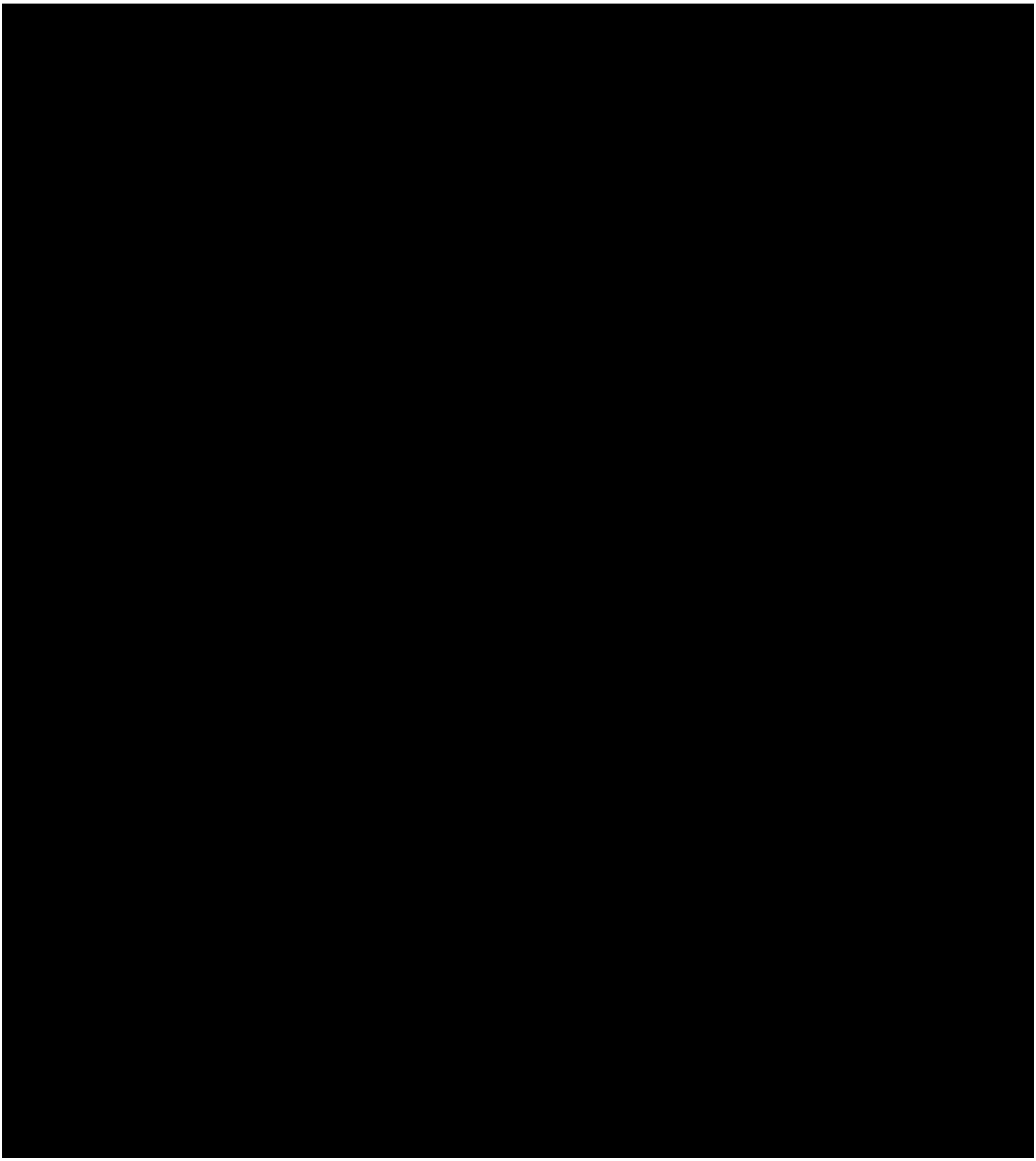
After consent and through study exit, each subject will be monitored for any new onset and/or worsening of adverse events regardless of the relatedness to the investigational device, procedure, protocol deviations, or device observations. Adverse events will be followed through resolution. If the investigator deemed the event is stable and requires no additional

	follow-up, then the subject may exit the study. Protocol Deviations and Device Observations will be documented and reported as applicable. **Study Exit:** Subjects may exit the study after screen failure, if all devices fail prior to end of wear period, or at subject completion of protocol after device removal and resolution of any ongoing adverse events. Subjects lost-to-follow-up may exit after at least three (3) attempts to contact the subject have been documented. Subjects may also exit study at any time with their withdrawal of consent or an investigator decision to withdraw the subject for cause. Reason for study exit for each subject must be documented.
Sponsor and Contact Information:	Biolinq, Incorporated 10260 Sorrento Valley Road San Diego, California 92121 

5 SCHEMA



6 SCHEDULE OF ACTIVITIES (SOA)



[redacted]

7 INTRODUCTION

There are 27 million people in the US with Type 2 diabetes on non-insulin therapies and three million with Type 2 diabetes requiring basal insulin only.[1,2,3] At a population level, glycemic control in people with diabetes has worsened over the past 10-15 years despite the introduction of six new drug therapeutic categories, as published in the New England Journal of Medicine.[4] Recent studies have demonstrated CGM's effectiveness in people with Type 2 diabetes, including those not using insulin,[5,6,7] and the American Diabetes Association recommends CGM use in persons with Type 2 diabetes. ADA recommends intermittent use of CGM to aid in evaluating periods of hyperglycemia to make medication dose adjustments.[8] Despite these recommendations, less than 1% of the Type 2 non-insulin using population are estimated to be using conventional CGM. Commonly cited barriers to conventional CGM adoption for all diabetes populations include cost, discomfort/pain on insertion, skin/adhesive problems, size/form factor, disruptive alerts, and difficulty interpreting CGM data.[9,10]

The absence of a device specifically designed to support disease management for people with Type 2 diabetes leaves these individuals with inadequate options to improve metabolic health. Currently, people with Type 2 diabetes are required to make the choice between using CGMs designed and optimized for people with Type 1 diabetes or continuing to rely on discrete blood glucose measurements produced by test strips. These blood glucose measurements can be painful and inconvenient to use and provide limited context on personal health trends and patterns, including the impact of food, medications, and activity on glycemic variability. Given the rising rates of Type 2 diabetes and prediabetes globally, as well as the increased risk for diabetes diagnoses following COVID-19 infection, there is a clear and growing need for more accessible, less invasive, and easier-to-use CGM devices designed specifically for people with Type 2 diabetes.

[redacted]

The primary objective of the study is to evaluate the safety and effectiveness of the Biolinq MicroArray Intradermal Continuous Glucose Biowearable System over a 5-day period in adults with diabetes mellitus. Data collected from this study is intended to be used to support commercial marketing application(s) for the intended commercial patient population of non-insulin-users.

8 STUDY MATERIALS

8.1 BIOLINQ MICROARRAY INTRADERMAL CONTINUOUS GLUCOSE BIOWEARABLE SYSTEM

[redacted]

[redacted]

The reportable glucose range for the sensor is between 70 mg/dL and 400 mg/dL. BLINQ does not provide glucose information below 70 mg/dL to mitigate the risk of off-label use by those who need more information about hypoglycemia, such as persons requiring multiple daily insulin injections. Additionally, the device does not have any audible or vibratory alerts or alarms.

A summary of clinical studies conducted by Biolinq with the current version Biolinq MicroArray Intradermal Continuous Glucose System is provided in a Report of Prior Investigations.

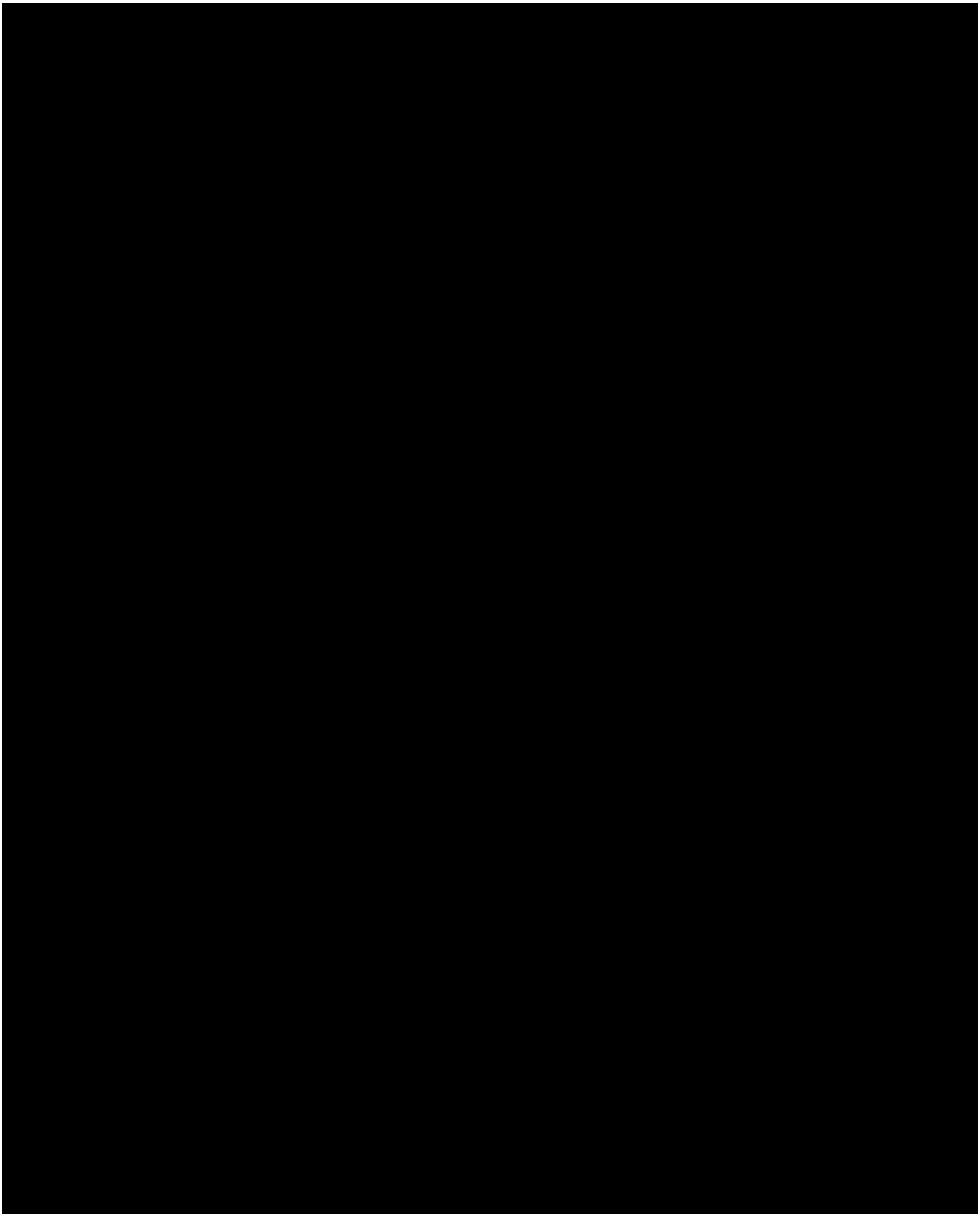
8.1.1 SYSTEM OVERVIEW

The Biolinq MicroArray Intradermal Continuous Glucose Biowearable System consists of multiple components broadly categorized as follows:

i. Biolinq Microarray Sensor
ii. Biolinq wearable
iii. Biolinq applicator

The Biolinq sensor consists of a sterile microarray sensor stack assembly that resides in the upper strata of the reticular dermis to measure interstitial glucose. The sensor is directly connected to a wearable that is adhered to the skin and is applied using the Applicator assembly. The Biolinq System measures and reports glucose information for up to five (5) days. The Biolinq System is designed to measure glucose levels for up to five (5) days. The wearable applied may also contain non-medical device designated off the shelf-components that capture actigraphy and environmental information to transfer to secondary display [redacted]

[redacted]



[redacted]

8.2 OTHER STUDY DEVICE/MATERIALS

8.2.1 COMMERCIAL CGM

[redacted]

8.2.2 SELF-MONITORING BLOOD GLUCOSE (SMBG)

[redacted]

8.2.3 ACTIVITY TRACKER AND ELECTRONIC SUBJECT LOG

Subjects will be provided with an activity tracker device to wear throughout the study to capture subject activity levels. [redacted]

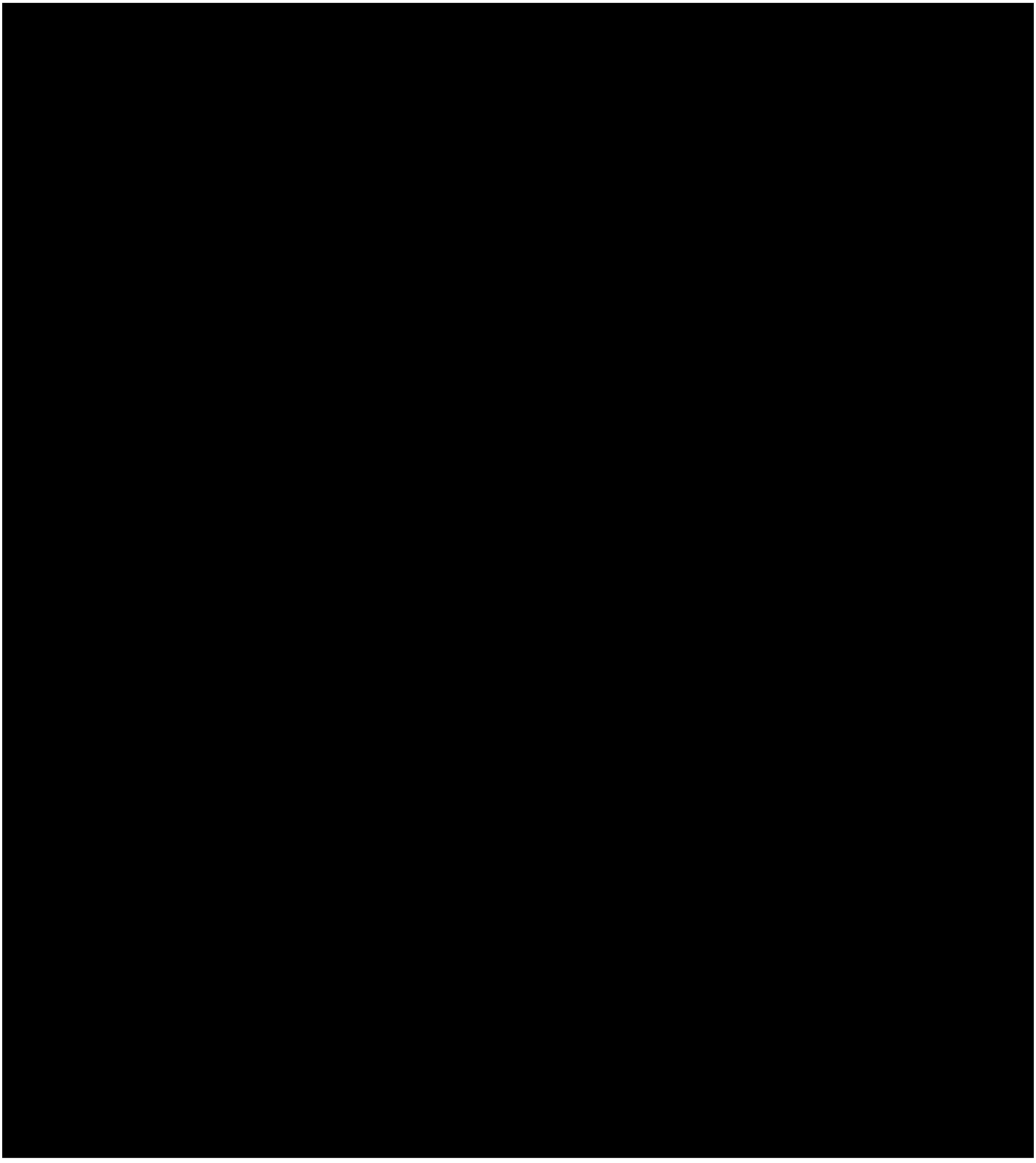
8.2.4 LABORATORY ANALYZER

During In-Clinic Days, the FDA-cleared laboratory analyzer (LA) [YSI 2300 STAT PLUS Analyzer (Yellow Springs, Ohio)] will be used to measure venous sample glucose concentrations. Venous samples will be drawn according to a pre-specified protocol schedule and per the In-Clinic Guidelines located in Appendix 1 – In-Clinic Guidelines.

9 POTENTIAL RISKS AND BENEFITS

9.1 STUDY DEVICE RISKS

[redacted]



[redacted]

10 RATIONALE FOR THE STUDY DESIGN

[redacted]

[redacted]

All subjects will wear a minimum of one Biolinq wearable each; a random subset of subjects will wear two wearables simultaneously for precision analysis. The study enrollment is designed to ensure a diverse population is evaluated when establishing a potentially new commercial product in the United States and other countries where the data may also be accepted to support marketing authorization.

11 STUDY OBJECTIVES

11.1 PURPOSE OF STUDY

The primary objective of the study is to evaluate the safety and effectiveness of the Biolinq MicroArray Intradermal Continuous Glucose Biowearable System, which is intended to be worn for up to five (5) days (up to 120 hours) in adults with diabetes mellitus (DM). Data collected from this study is intended to be used to support commercial marketing application(s) for the intended commercial patient population of non-insulin-users.

11.2 CO-PRIMARY PERFORMANCE ENDPOINTS

Biolinq System performance will be characterized with respect to laboratory reference venous measurements. The primary endpoint, matched paired (Sensor-YSI) measurements, will be collected during multiple in-clinic sessions on days 1, 3, and/or 5 of wear.

- For all available matched pair data points when the Biowearable displays BLUE (“in target” color indicator), the percentage of reference blood glucose values between 55-207 mg/dL must be calculated, and the lower one-sided 95% confidence bound [redacted]
- For all available matched pair points when the Biowearable displays YELLOW (“above target” color indicator), the percentage of reference blood glucose values between 154-460 mg/dL must be calculated, and the lower one-sided 95% confidence bound [redacted]

[redacted]

11.3 DEVICE SAFETY

Safety of the Biolinq System will be characterized by the:

1. Overall adverse device effect rate
2. Individual adverse device effect rates
3. Distribution of Draize assessments for erythema and edema for Biolinq Biowearable by Adverse Device Effects (ADEs) and Serious Adverse Device Effects (SADEs) experience by study participants.

11.4 DEVICE PRECISION

Randomization for 30% of subjects treated will receive a second Biolinq Biowearable to analyze device precision. Randomization scheme will ensure equally weighted assignments obtained from all participating clinical sites.

12 STUDY POPULATION

To attain sufficient hypoglycemia and hyperglycemia values in the study, the study will enroll subjects outside the intended commercial population of non-insulin-users. Enrollment efforts should attempt to include a 1:1 ratio of male to female subjects. Each site will be provided with a Site Enrollment Plan for diabetes type by the Sponsor to ensure target study population goals are met study wide.

[redacted]

12.1 DIVERSITY PLAN

In addition, the Site Enrollment Plan will include a Diversity Plan to attain the desired distribution of traditionally underrepresented populations. [redacted]

12.2 INCLUSION CRITERIA

Individuals may be included in the study if they satisfy all the following:

<u>General</u>

1. ≥ 22 years old.
2. Willing and able to provide written signed and dated informed consent.
3. Access to phone or computer with internet to complete subject log.

<u>Diabetes History and Health</u>

4. Diagnosis of type 1 diabetes (T1D)/ LADA or type 2 diabetes (T2D) and on intensive insulin therapy (IIT) with known dosing parameters for at least three (3) months prior to the Screening Visit with an A1c of 5.5%-10% or diagnosis of type 2 diabetes (T2D) and on non-intensive insulin therapy (NIIT) or T2D not using insulin with an A1c of 7.5% to 11%.
5. Weigh at least 110 lbs (50 kilograms).
6. Be otherwise in good health, as determined by a medical care professional.
7. Willing to refrain from Acetaminophen use for the duration of study enrollment.
8. If using an automated insulin delivery (AID) system, willing to disable automated features and go into open loop mode during the duration of in-clinic days.

<u>Device and Glucose Assessments – Willing to:</u>

9. Wear one (1) commercial CGM system ([redacted] on the abdomen per approved labeling and have up to 1 replacement.
10. Wear up to two (2) Biolinq Biowearables simultaneously following the application procedures on the volar forearm for up to 7 days.

11. Participate in two (2) In-Clinic sessions lasting up to 11.5 hours of blood draws (anticipated up to 13 hours on site per visit) each.
12. Perform up to five (5) fingersticks a day with the SMBG device provided during non-in-clinic days.
13. Avoid immersing study devices into water (e.g., no hot tub, SCUBA diving).
14. Wear an activity tracker or record activity levels on a daily log.

12.3 EXCLUSION CRITERIA

Individuals with any of the following will be excluded:

General

1. Current participation in another investigational study protocol. (If a subject has recently completed participation in another drug study, the subject must have completed that study at least 30 days prior to being enrolled in this study.) *Note*: Subjects will not be excluded if enrolled in another observational trial, wherein the subject is in the follow-up phase and no tests/procedures impacting the subject's health are required. Subjects will be excluded if they have been previously enrolled in this study.
2. Work for, are family members with, or live with someone that works for the sponsor or competitor diabetes-related company (includes social media influencers or bloggers).
3. In the investigator's opinion, any reason that may lead to subject non-compliance with study requirements or confound study data.

Health

4. Currently taking Hydroxyurea.
5. Known allergy to medical grade adhesives, acrylic, latex, or isopropyl alcohol.
6. Have dermatological conditions that preclude wearing Biolinq Biowearables (e.g., extensive psoriasis, recent burns, severe sunburn, extensive eczema, extensive scarring, dermatitis herpetiformis, skin lesions, erythema, infection, or other conditions at the discretion of the investigator).
7. For subjects of child-bearing potential, pregnant or not practicing an acceptable form of birth control during the study.
8. Hematocrit measurement via point-of-care (POC) or laboratory testing that is less than the applicable below-mentioned value:
    a. Male: 36.0%
    b. Female: 33.0%
9. Have donated blood, had significant blood loss, or participated in a study with significant blood sampling (340 cc or more) within 56 days prior to study enrollment or plan to participate in such activities during study wear.
10. Required or scheduled to have diathermy, X-ray, MRI, or CT during study wear.
11. In the investigator's opinion, the subject has a history of concomitant medical condition that could interfere with the study participation or present a risk to the safety and welfare of the subject or study staff. Such historical conditions include but are not limited to:
    a. Syncope in past 6 months
    b. Severe hypoglycemia (loss of consciousness, seizure, or emergency medical technician assistance within the past 6 months)
    c. Diabetic ketoacidosis (DKA) requiring hospital admission in the past 6 months
    d. Coagulopathy
    e. Chronic infectious disease (e.g., HIV/AIDS, Hepatitis B or C)
    f. End stage renal disease and currently managed by dialysis or anticipating initiating dialysis during the study wear period
    g. History of congestive heart failure

13 STUDY DESIGN

13.1 DESIGN SUMMARY

This study will be a clinical safety and effectiveness study of the Biolinq System. The study will be an open label, prospective, multi-center, single arm study conducted in the United States.

13.2 DURATION OF PARTICIPATION

[redacted]

13.3 ESTIMATED STUDY DURATION

[redacted]

13.4 STUDY CENTERS

A minimum of five (5) and up to eight (8) centers in the United States will participate in the study.

14 STUDY ENROLLMENT

14.1 STRATEGIES FOR RECRUITMENT AND RETENTION

Subjects will be recruited through various IRB-approved advertising methods including but not limited to digital campaigns, available Investigator treatment databases, print, radio, or the like. All advertising materials will be pre-approved by the reviewing IRB prior to implementation.

14.2 INFORMED CONSENT

To protect the rights, safety, and welfare of subjects, the study is conducted in accordance with the 21 CFR 50, Protection of Human Subjects. The Principal Investigator or designee, as delegated by Principal Investigator on site delegation of authority log, will explain the study nature, overview, purpose, objectives, expected participation duration, study activities, risks of study participation, alternative treatment, participation benefit, study sponsor, cost for participation, new information sharing, medical cost coverage if he/she gets hurt, stipend amounts, confidentiality, and IRB contact information. Subjects will be given ample time to consider their voluntary participation in the study and to ask questions. Potential subjects may take a copy of the IRB Approved Informed Consent Form (ICF) home to review with family and friends prior to deciding on whether to participate in the study.

Participants must be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. A copy of the Informed Consent Form will be offered to the participants for their records. The informed consent process will be conducted and documented within the IRB approved Informed Consent Document, with required signatures obtained, before the participant participates in any study activities. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

14.3 ENROLLMENT

Subjects who sign the IRB approved ICF will be considered “Enrolled” in this study.

14.4 SCREENING

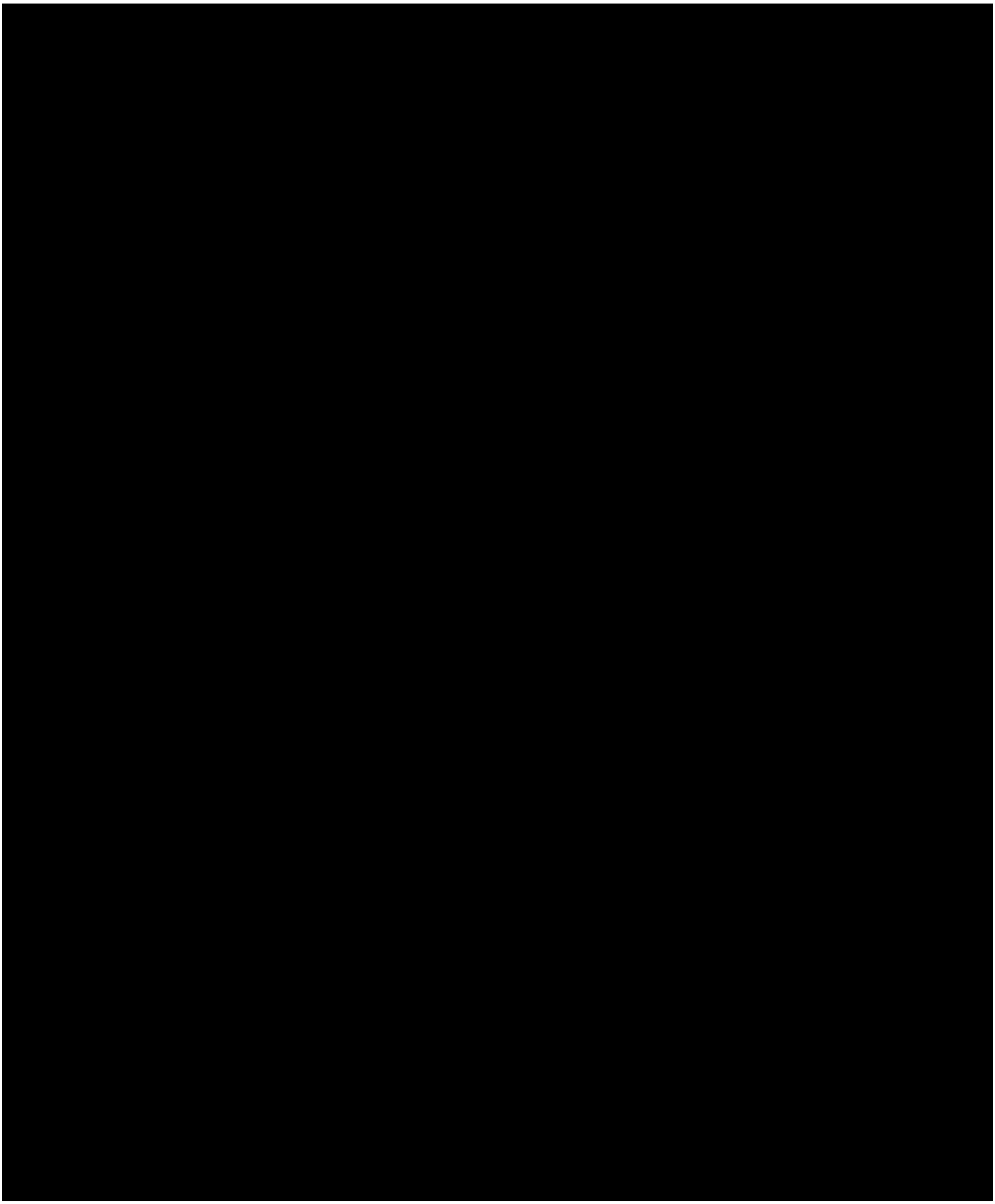
[redacted]

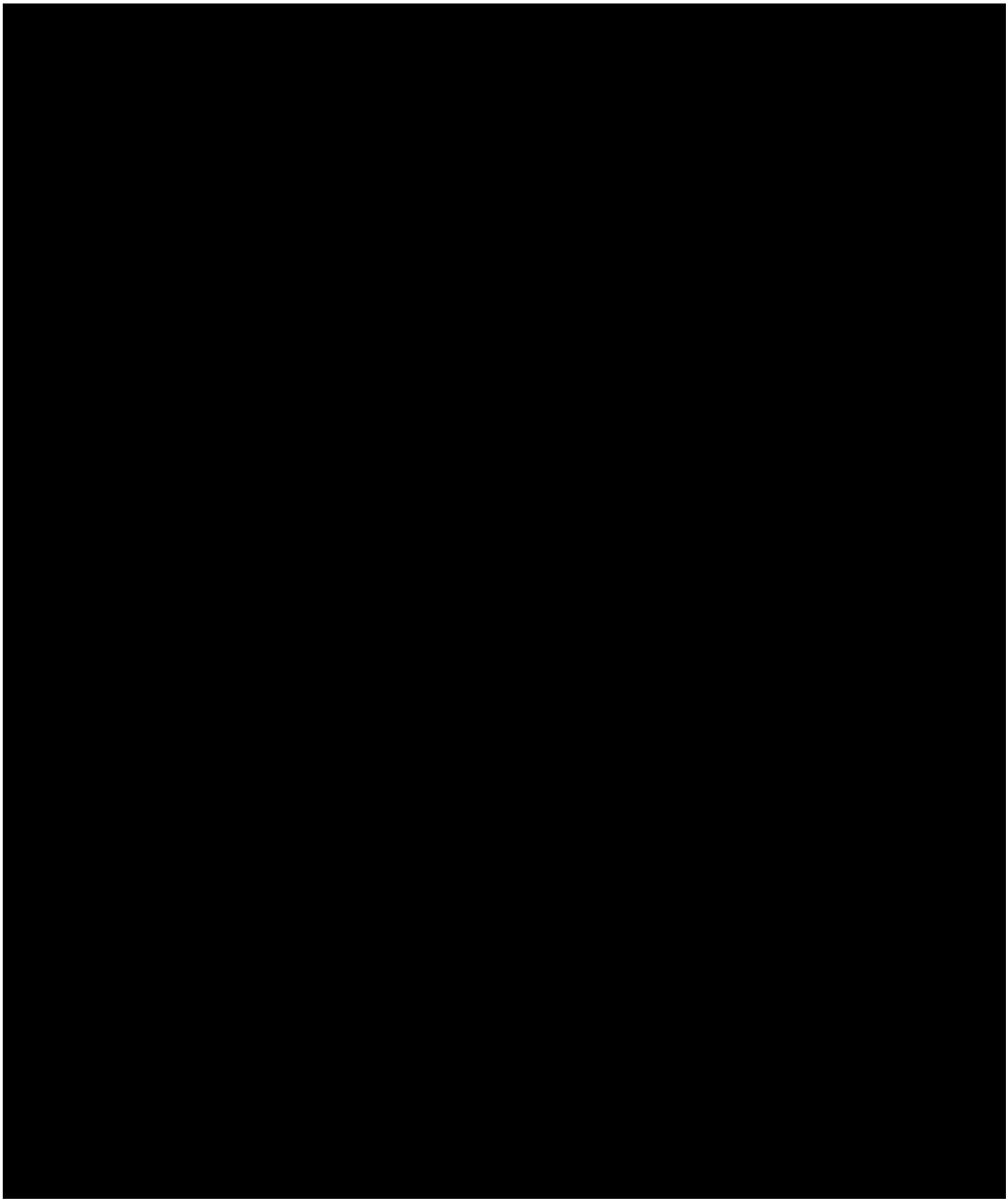
14.5 DEVICE ASSIGNMENT

[redacted]

15 STUDY PROCEDURES

[redacted]





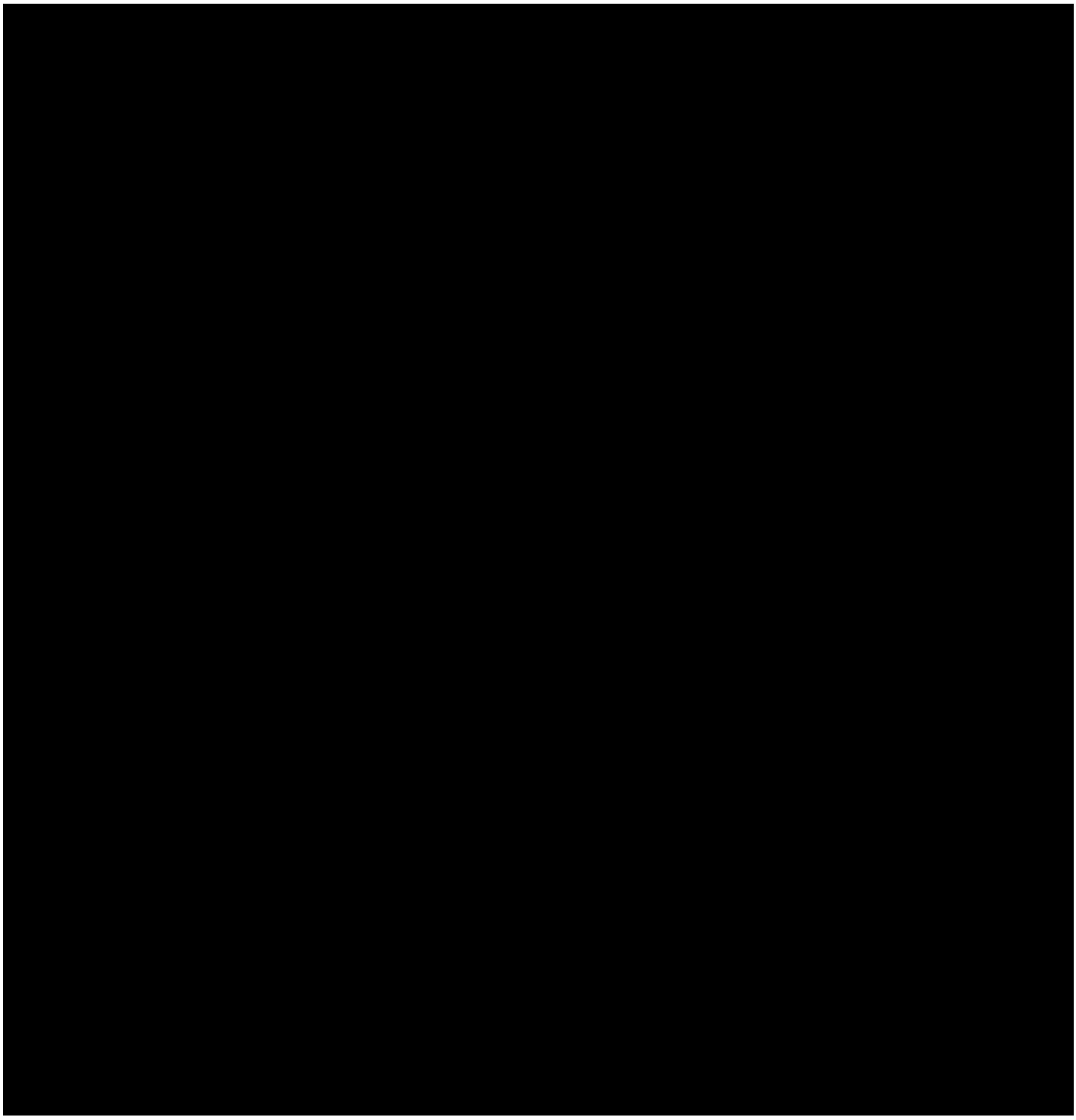


Table 6. Draize Assessment for Erythema and Edema Severity

Value	Erythema	Value	Edema
0	No erythema	0	No edema
1	Very slight erythema *(barely perceptible)*	1	Very slight edema *(barely perceptible)*
2	Well-defined erythema	2	Slight edema *(edges of area well defined by definite raising)*
3	Moderate-to-severe erythema	3	Moderate edema *(raised ~ 1 mm)*
4	Severe erythema *(beet to crimson red)*	4	Severe edema *(raised more than 1 mm and extending beyond area of exposure)*

16 DESCRIPTION OF SAFETY EVALUATION

16.1 DEFINITIONS OF ADVERSE EVENTS (AE)

An adverse event means any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the Biolinq MicroArray System. This definition includes events related to the Biolinq MicroArray System, or the commercially available CGMs as well as events related to the procedures involved. All suspected adverse events will be assessed and monitored by the Principal Investigator, or designee, and recorded in the appropriate source worksheet and transcribed to Case Report Form.

16.1.1 ADVERSE DEVICE EFFECT (ADE)

An adverse device effect is an adverse event related to the use of the Biolinq MicroArray System.

16.1.2 SERIOUS ADVERSE EVENTS (SAE)

An adverse event (AE) is considered "serious" if, in the view of either the investigator or Biolinq, it results in any of the following outcomes:

a) Death
b) Serious deterioration in the health of the subject, that either resulted in:
    a. A life-threatening illness or injury, or
    b. A permanent impairment of a body structure or a body function, or
    c. In-patient or prolonged hospitalization, or
    d. Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function

c) Led to fetal distress, fetal death or a congenital abnormality or birth defect

16.1.3 UNANTICIPATED ADVERSE DEVICE EFFECT (UADE)

An UADE is not expected to occur; however, an unanticipated adverse device effect (UADE) is defined as any serious adverse effect on health or safety or any life-threatening problem or death caused by – or associated with – the device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan (including documents such as the protocol, the Informed Consent Form, and other study-related documents), or any other unanticipated serious problem associated with the device that relates to the rights, safety, or welfare of subjects.

An Unanticipated Adverse Device Effect (UADE) is a serious adverse device effect that has not been previously identified in nature, severity or degree of incidence in the investigational plan (including documents such as the protocol, the informed consent form, and other study-related documents).

16.2 SEVERITY OF ADVERSE EVENTS

All adverse events will be classified by the Principal Investigator or designee. The following guidelines will be used to describe severity.

- **Mild** – Awareness of signs or symptoms, but easily tolerated; are of minor irritant type; causing no loss of time from normal activities; symptoms would not require medication or a medical evaluation; signs and symptoms are transient.
- **Moderate** – Discomfort severe enough to cause interference with usual activities, requiring treatment but not extended hospitalization or intensive care for the subject.
- **Severe** – Incapacitating, causing inability to do work or usual activities; signs and symptoms may be of systemic nature or require medical evaluation and/or treatment, requiring additional hospitalization or intensive care (prolonged hospitalization).

16.3 RELATIONSHIP OF ADVERSE EVENT TO THE STUDY DEVICE

The Principal Investigator, or designee, will assess all adverse events (AEs) and determine their relation to the Biolinq MicroArray System. The Principal Investigator, or designee, will use his/her clinical judgment to examine and evaluate the adverse event based on an examination of the subject and the temporal relationship with the use of the device. The degree of certainty about causality will be graded using the categories below.

- **Definitely Related** – There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out. The clinical event occurs in a plausible time relationship to administration of the study device and cannot be explained otherwise.
- **Probably Related** –The AE has a strong temporal relationship to use of the investigational device and another etiology is unlikely.
- **Potentially Related** – The AE has a strong temporal relationship to the use of the investigational device and an alternative etiology is equally or less likely compared to the potential relationship to the investigational device.
- **Unlikely to be related** – The AE has minimum or no temporal relationship to use of the investigational device and/or a more likely alternative etiology exists.
- **Not Related** – The AE is completely independent of the investigational device and is due to an underlying disease state or concomitant medication or therapy not related to the study device.

All device-related irritation will be recorded. Post-removal follow-up may be requested until resolution in the case of any ongoing adverse events.

16.4 ADVERSE EVENT REPORTING

Any AE not considered an SAE, occurring during the study will be documented by the Principal Investigator or designee on the appropriate source worksheet, entered into the Electronic Data Capture system, and reported to the Sponsor within 30 days of the occurrence of the adverse event. All adverse events (mild, moderate, and severe) will be reported in the final Clinical Study Report.

16.4.1 SERIOUS ADVERSE EVENT (SAE) REPORTING

Any SAE, including death, that may occur during a clinical study must be reported immediately (within 24 hours of awareness) to Biolinq, Inc. Clinical Affairs personnel will document details and Clinical Affairs management's assessment of the SAE in a timely manner. The Sponsor contacts are listed on the protocol title page.

16.4.2 UNANTICIPATED ADVERSE DEVICE EFFECT (UADE) REPORTING

During the review of a reported SAE, if the PI, or designee, determines the severity or extent of the event was not cited in this protocol or the report of prior investigations, and the event was classified as at a minimum, possibly related to the device, the event will be documented as an UADE.

If the event is classified as an UADE, the PI or designee must notify their IRB and Biolinq will notify the FDA, reviewing IRBs, and other participating Investigators, as applicable, within ten (10) working days of the original SAE notification.

If it is determined that the UADE presents an unreasonable risk to subjects, Biolinq will terminate all investigations or parts of investigations presenting that risk as soon as possible, but not later than 5 working days after such determination is made and not later than 15 working days after Biolinq first receives notice of the original SAE. Biolinq will not resume a terminated study without IRB and FDA approval, as applicable.

16.5 DEVICE OBSERVATION REPORTING

A Device Observation (DO) is defined as any suspected inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device, including malfunction, misuse or use errors, or inadequacy in information supplied by the Sponsor.

Site will document Device Observations on source documents and CRFs at each occurrence and notify sponsor. All applicable DOs will be recorded on the Investigational Product Accountability log.

17 STATISTICAL ANALYSIS & METHODS

17.1 ANALYSIS COHORTS

Analysis cohorts for the study are prospectively defined and are described in the following subsections. To ensure that the calculated percentage of points is representative across all glucose ranges (i.e. data from each of the glucose range should be adequately represented and not heavily weighted toward the midrange at the expense of the high and low range glucose values), glucose levels will be manipulated during the in-clinic sessions (Table 5).

Information pertaining to the statistical analysis methods using these cohorts is provided in the subsequent sections.

17.1.1 ENROLLED COHORT

The Enrolled Cohort includes all subjects who sign the study IRB approved informed consent. Analyses pertaining to screening eligibility, safety, and protocol compliance prior to the Biolinq application, and study exit will be performed using the Enrolled Cohort.

17.1.2 TREATED COHORT (ANALYSIS POPULATION)

All enrolled subjects who have undergone device application will be included in all analyses. All data that is collected during the study will be included in the analysis. [redacted]

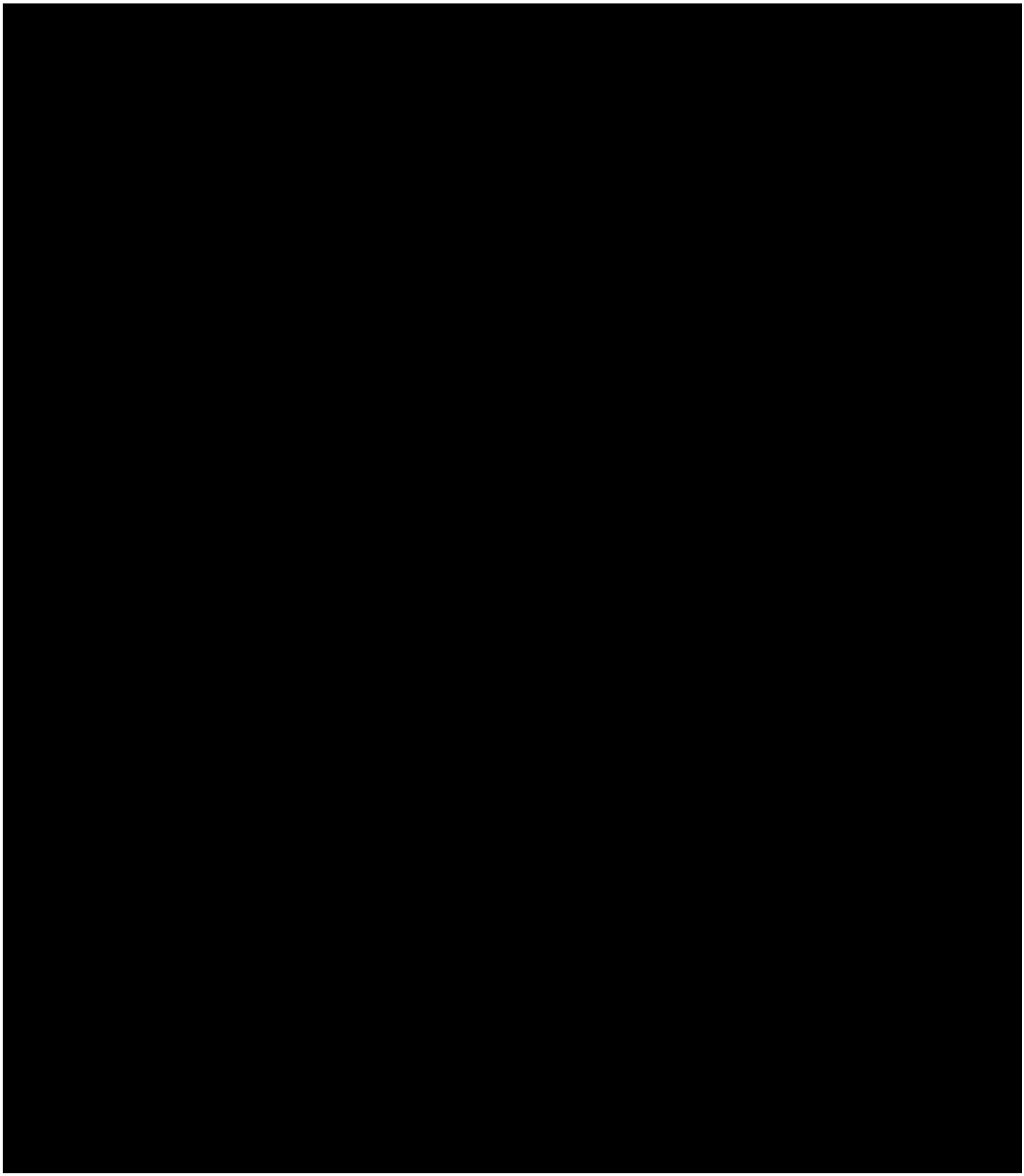
17.2 STATISTICAL METHODS FOR SAFETY OUTCOME

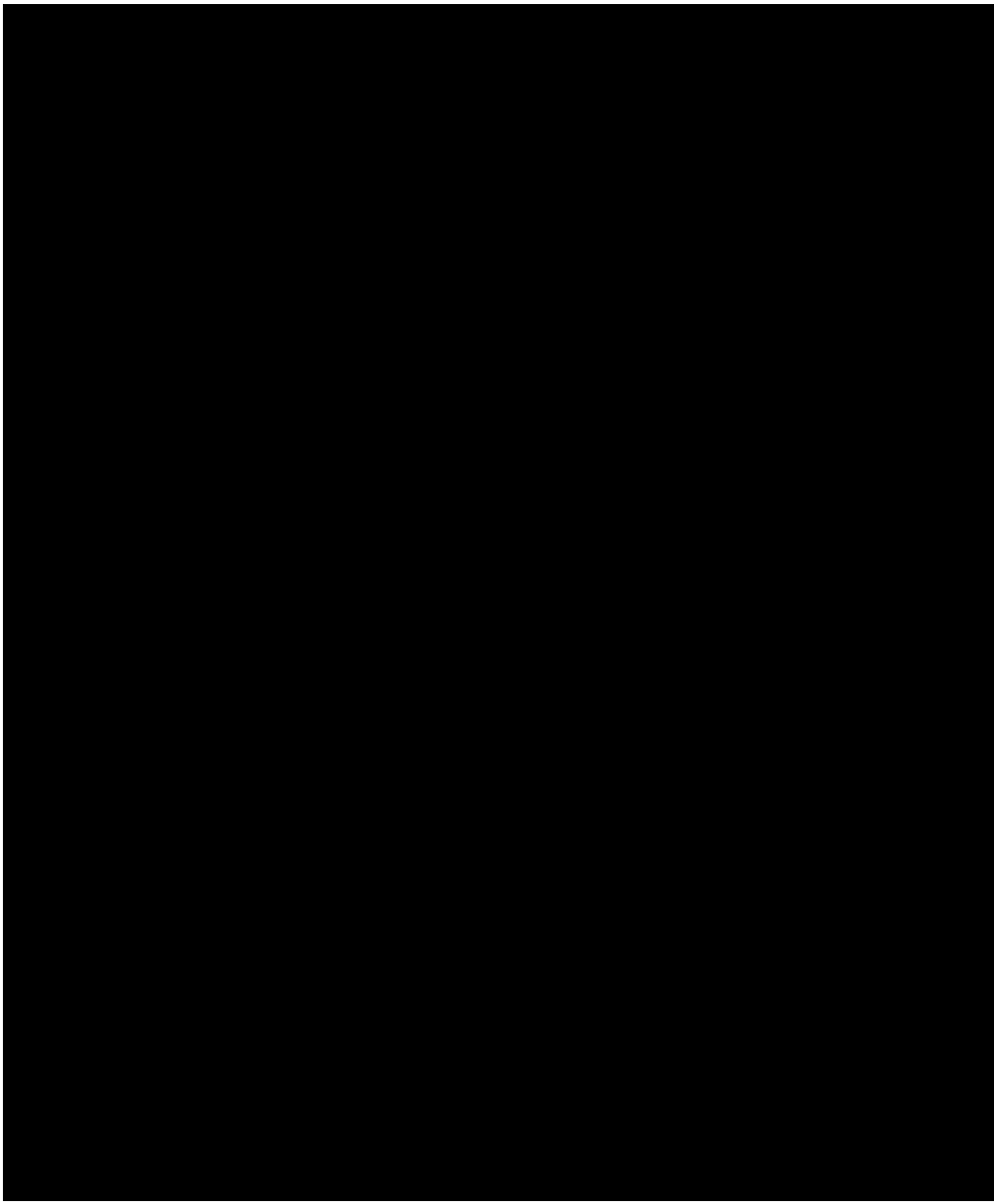
Overall and individual adverse events are summarized for safety outcome by frequency and percentage. In addition, the number of AEs, ADEs, SAEs, SADEs, and UADE and percentage of Subjects with events are summarized. A by-Subject listing of adverse events will also be provided in the study report.

The erythema and edema Draize assessment at each biowearable wear location is another safety outcome that will be analyzed and reported. [redacted]s.

17.3 METHOD DEFINITIONS FOR PERFORMANCE METRICS

[redacted]





18 DATA MANAGEMENT PLAN

18.1 CASE REPORT FORMS (CRFS)

Investigators are responsible for delegating personnel to complete the appropriate case report forms for each subject enrolled in the study. The CRFs should be completed within 5 working days of study visit or the day data is received. The Investigator must sign for data accuracy and completeness contained on each CRF. Biolinq will provide training and instructions to each investigational site on how to properly complete these CRFs.

18.2 SOURCE DOCUMENTS

Source documents refer to the records on which clinical observations are first recorded. Original source documentation must be maintained at the investigational site to substantiate data entered on the CRFs. Source documentation must be made available by the investigational site so that information entered on CRFs is verified

and facilitates monitoring by Biolinq or its authorized representative. Source documents must also be made available to any regulatory agency in the event of an inspection so that the integrity of study data may be verified.

The Sponsor will provide sample source worksheets to help with the collection of information for transfer to the EDC System. Sample source worksheets may be revised by site to match workflow or site requirements provided that all required data is collected. In cases where no original source data otherwise exists, a source document worksheet provided by the site or sponsor may be used to establish a source record. To minimize data-related errors, considerations should be taken to avoid duplicative generation of source documentation. All source documents must be signed and dated by the qualified individual generating the record and/or investigator when applicable.

18.3 DATA MANAGEMENT

A 21 CFR Part 11 compliant electronic data capture (EDC) system will be used for data collection in the study. User Acceptance Testing will be performed to validate each eCRFs utilized in the study prior to its use and all subsequent updates. Data is entered into the EDC system by trained delegated personnel as indicated on the Delegation of Responsibilities Log and on its appropriate electronic case report forms (eCRFs). The eCRFs must be completed or updated to reflect the latest data on each Subject participating in the study. The Investigator or authorized Sub-investigator electronically signs the eCRFs testifying data entry accuracy and completeness.

No study document should be destroyed without prior written agreement between Biolinq and the investigational site. If an investigational site is no longer enrolling Subjects or following any enrolled Subjects, an investigator may transfer custody of study records to Biolinq providing a notice of such transfer is given within 10 working days.

The investigational site must maintain study documentation on paper or electronic file for each Subject file. If additional study documentation is required for submission to Biolinq, it must be redacted to remove the Subject's name or other Subject identification, and the Subject's unique identification code inserted prior to being sent to Biolinq.

In the Subject file, information should include corresponding follow-up dates, data noted on Table 8, and reasons for early withdrawal from the study if applicable or study exit after activity completion per protocol. It must be possible to verify subject consent to participate in the study, inclusion, and exclusion criteria in the study from the Subject file. These documents should identify the Subject. Evaluation of these records should be documented as necessary, signed, and dated by the Investigator. All data recorded on the eCRFs must be in the Subject's source data.

18.4 DEVICE DATA DOWNLOAD

[redacted]

18.5 DATA COLLECTION

[redacted]

19 ETHICAL CONSIDERATIONS

19.1 STATEMENT OF COMPLIANCE

The trial will be carried out in accordance with ISO 14155:2020 Clinical Investigation of medical devices for human subjects – Good clinical practice, International Conference on Harmonization Good Clinical Practice (ICH GCP) and the following: United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, and/or 21 CFR Part 812).

The study will also be conducted in accordance with the Declaration of Helsinki (1964).

19.2 PROTOCOL APPROVAL AND AMENDMENTS

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the Institutional Review Board (IRB)/ Ethics Committee (EC) for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled.

All revisions and/or amendments to the protocol and informed consent must be approved in writing by the Sponsor, the appropriate IRB, and regulatory body, as appropriate.

20 REPORTS

The Investigator or designee is responsible for completing the Case Report Forms (CRFs) or Electronic Data Capture (EDC), as applicable. The Sponsor and Investigator will submit any progress or safety reports that the IRB or applicable regulatory authorities may require, including any final close-out reports.

21 MONITORING

Monitoring will be conducted by trained and experienced clinical professionals in accordance with Biolinq's standard operating procedures. Monitors will evaluate study conduct and documentation on an ongoing basis to ensure that the rights and well-being of trial participants are protected, that the reported trial data are accurate, complete, and verifiable, and that the conduct of the trial is in compliance with the currently approved protocol/amendment(s), with International Conference on Harmonisation Good Clinical Practice (ICH GCP), and with applicable regulatory requirement(s).

21.1.1 PROTOCOL DEVIATIONS

The Investigator or designee is required to conduct the study in accordance with the protocol, the Study Agreement, and all applicable local and national regulations. A protocol deviation exists when a requirement in the protocol is not followed. All protocol deviations must be reported to the Sponsor using the appropriate source worksheet and entered into the Electronic Data Capture (EDC) system.

All protocol deviations that have the potential to affect the reliability or integrity of the study data will be reported to the sponsor and evaluated by the Principal Investigator, or designee, and Sponsor. Any protocol deviations that have the potential to adversely affect the health and safety of study subjects, adversely affect the reliability and integrity of the data, constitute a breach of subject confidential information, constitute a deviation from the IRB requirements for the study or constitute a failure to adhere to local, state, or federal regulations must be reported to the IRB and the FDA as required.

22 STUDY TERMINATION

Each subject's participation in the study will be terminated following the completion skin site evaluations after device removal, or when all adverse events have been resolved or deemed as ongoing but stable. The study will be terminated for a subject if they become acutely ill during the study.

Prior to sensor removal, the subject may voluntarily withdraw at any point in the study or the investigator and/or Sponsor may determine it is in the best interest of the subject to be terminated from the study. The reason for participant discontinuation or withdrawal from the study will be recorded on the appropriate source worksheet and entered into the Electronic Data Capture (EDC) system

The clinical study in its entirety will be considered complete upon completion of a final Clinical Study Report and per Biolinq's standard operating procedures.

23 INVESTIGATOR RESPONSIBILITES

The Investigator's signature on this protocol confirms that Investigator is familiar with all sections of the protocol and agrees to conduct this study in accordance with the provisions of the protocol and applicable regulations. The Investigator must sign this protocol prior to commencement of any study-related activities (e.g., screening).

Investigator and designees are responsible for protecting the rights, safety, and welfare of subjects under the Investigator's care. The Investigator and designees are also responsible for obtaining IRB approval prior to study

start and the written informed consent of each subject before he/she participates in this study. The informed consent must comply with FDA regulations and be approved by the IRB.

Other Investigator and designee responsibilities include ensuring completion of appropriate source worksheets, and entry into the Electronic Data Capture (EDC) system per the study timelines discussed in this protocol, the site initiation visit and subsequent monitoring visits. In certain circumstances Investigators or designee must report serious adverse events to the Sponsor and reviewing IRB as soon as made aware (without a delay that cannot be justified).

Investigator or designee will retain study records until the latter of the following: 2 years after the last approval of a marketing application and until there are no pending or contemplated marketing applications or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. No records will be destroyed without the written consent of the sponsor. It is the responsibility of the sponsor to inform the investigator or designee when these documents no longer need to be retained.

24 SPONSOR RESPONSIBILITES

Biolinq, Inc. is the Sponsor of this study. The Sponsor is responsible for selecting qualified Investigators and providing them with the information needed to conduct the investigation properly. The Sponsor will ensure proper monitoring of the investigation and that IRB and FDA approvals have been obtained prior to the Investigator or designee commencing study-related activities. The Sponsor is also responsible for ensuring that the reviewing IRBs and FDA, if applicable, are promptly informed of significant new information.

24.1 CONFLICT OF INTEREST POLICY

This study is sponsored by Biolinq as part of the commercial development of the Biolinq MicroArray System. The Principal Investigator(s) is not an employee of Biolinq and any disclosable financial arrangement will be documented as appropriate on a financial disclosure form and reported to IRB as required. The Informed Consent process will be conducted by the Principal Investigator(s) or designee.

24.2 STUDY RECORDS

This study will be conducted in accordance with Biolinq's standard operating procedures. All clinical study sites will provide direct access to all trial related source data/documents, and reports for the purpose of monitoring and auditing by the sponsor, and inspection by local and regulatory authorities.

24.3 INVESTIGATIONAL DEVICE ACCOUNTABILITY

Designated staff will maintain appropriate records of each device intended for the clinical study. (e.g., record of the subject device assignments, such as serial number of the device, subject ID, expiration dates, and date which the device was applied to/removed from subjects). At the conclusion of the study, the devices may undergo post-study investigation, as applicable. After processing, the devices will be cleaned, disposed of, and/or documented per appropriate regulations. The commercially available CGM used for the study will be transported, stored, and disposed of according to the instructions for use provided with the packaging. Designated staff will keep records of the serial and/or lot numbers, subject ID, and dates of insertion and removal of study-assigned devices.

24.4 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection is the responsibility of the clinical study staff at the site under the supervision of the Principal Investigator, or designee, at that site. The Principal Investigator, or designee, is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data. Study data collection may be through paper source and/or electronic data capture (EDC) format, per current Sponsor processes. As applicable, hard copies of the study visit Case Report Forms may be provided for use as source document worksheets for recording data for each participant enrolled in the study. In addition, electronic data will be downloaded from the Biolinq System, the

commercial CGM and glucometers, and the activity trackers and will be maintained per sponsor guidelines. Clinical data (including adverse events (AEs), concomitant medications, and expected adverse reactions data) and clinical laboratory data, if applicable, will be entered into the subject-specific study binders or EDC system, as applicable.

24.5 CONFIDENTIALITY AND PRIVACY

The Sponsor and Investigator must treat Subjects' identity as confidential. Subjects must not be identified in any publicly released reports of the study. All records are kept confidential to the extent provided by national or local law. The study monitors and other authorized representatives of the Sponsor may inspect all documents and records that are required to be maintained by the Investigator, including but not limited to, medical records. Regulatory agencies also maintain the right to review records pertinent to the study. Unless required by law, the sponsor and investigator must report de-identified data to secure subject confidentiality.

25 REFERENCES

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26 APPENDICES

26.1 APPENDIX 1 – IN-CLINIC GUIDELINES

26.1.1 PURPOSE

To outline guidelines for performing an In-Clinic Day to assess performance of the Biolinq System relative to an FDA-cleared glucose laboratory analyzer (YSI 2300 STAT PLUS Analyzer).

26.1.2 IN-CLINIC OBJECTIVE

The primary objective of an In-Clinic Day is to safely obtain sufficient data variation between 60-400 mg/dL to evaluate the performance of the Biolinq Biowearable in and around its measuring range of 70-400 mg/dL. Commercially available comparator devices (SMBG, CGM) will also be evaluated for reference analysis during an In-Clinic Day.

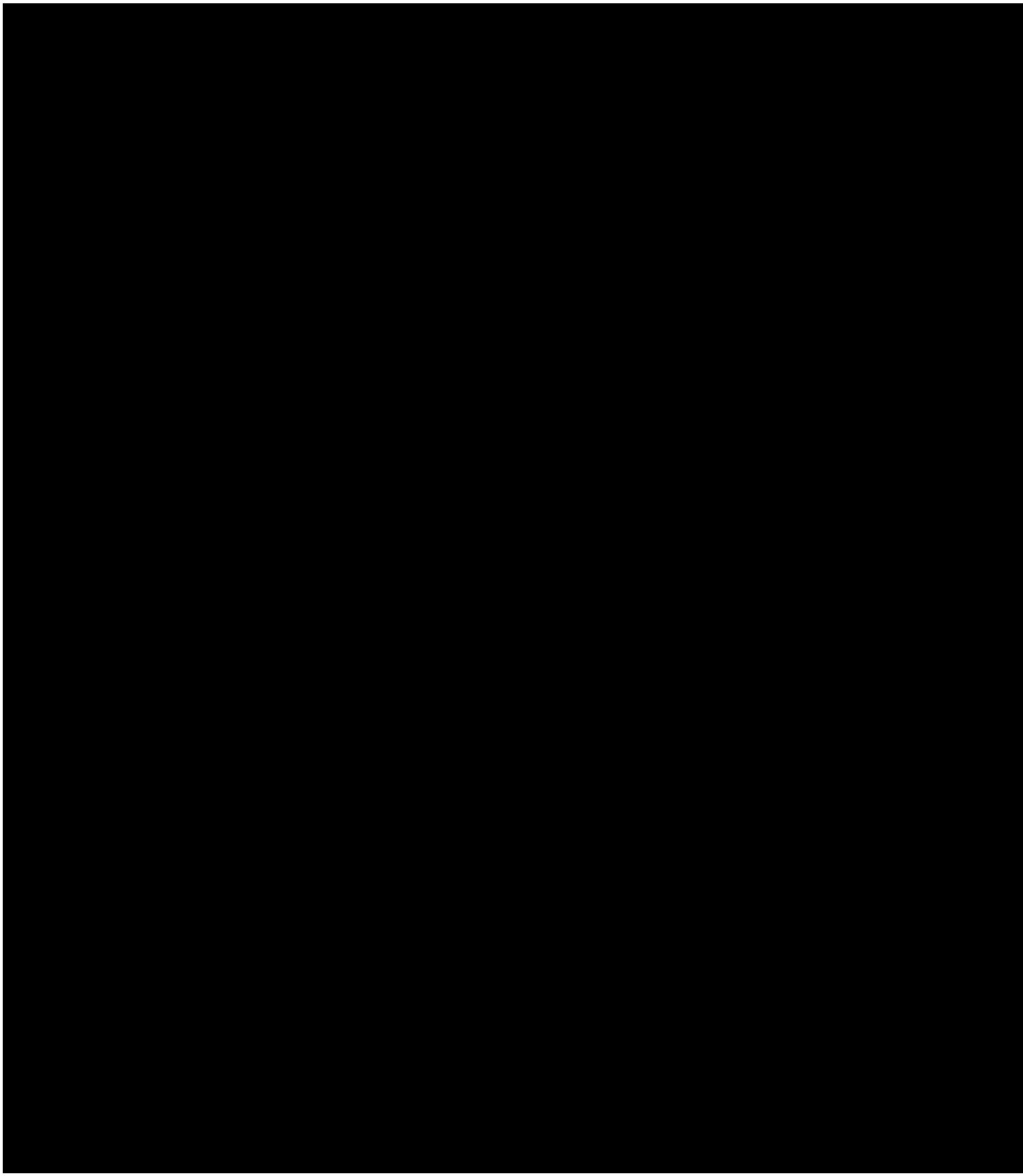
26.1.3 RESPONSIBILITIES

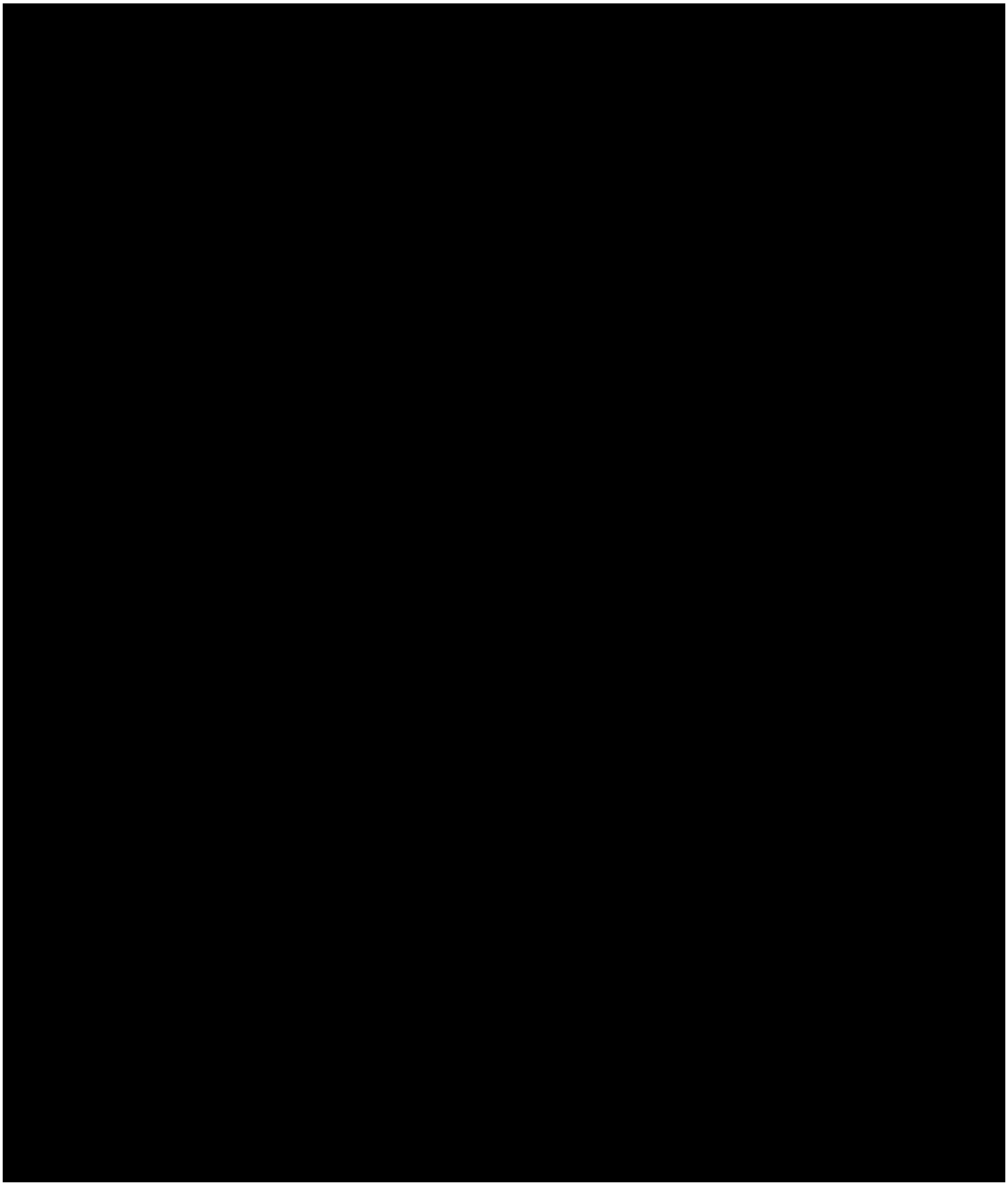
The investigator and investigator's staff or qualified designees are responsible for:

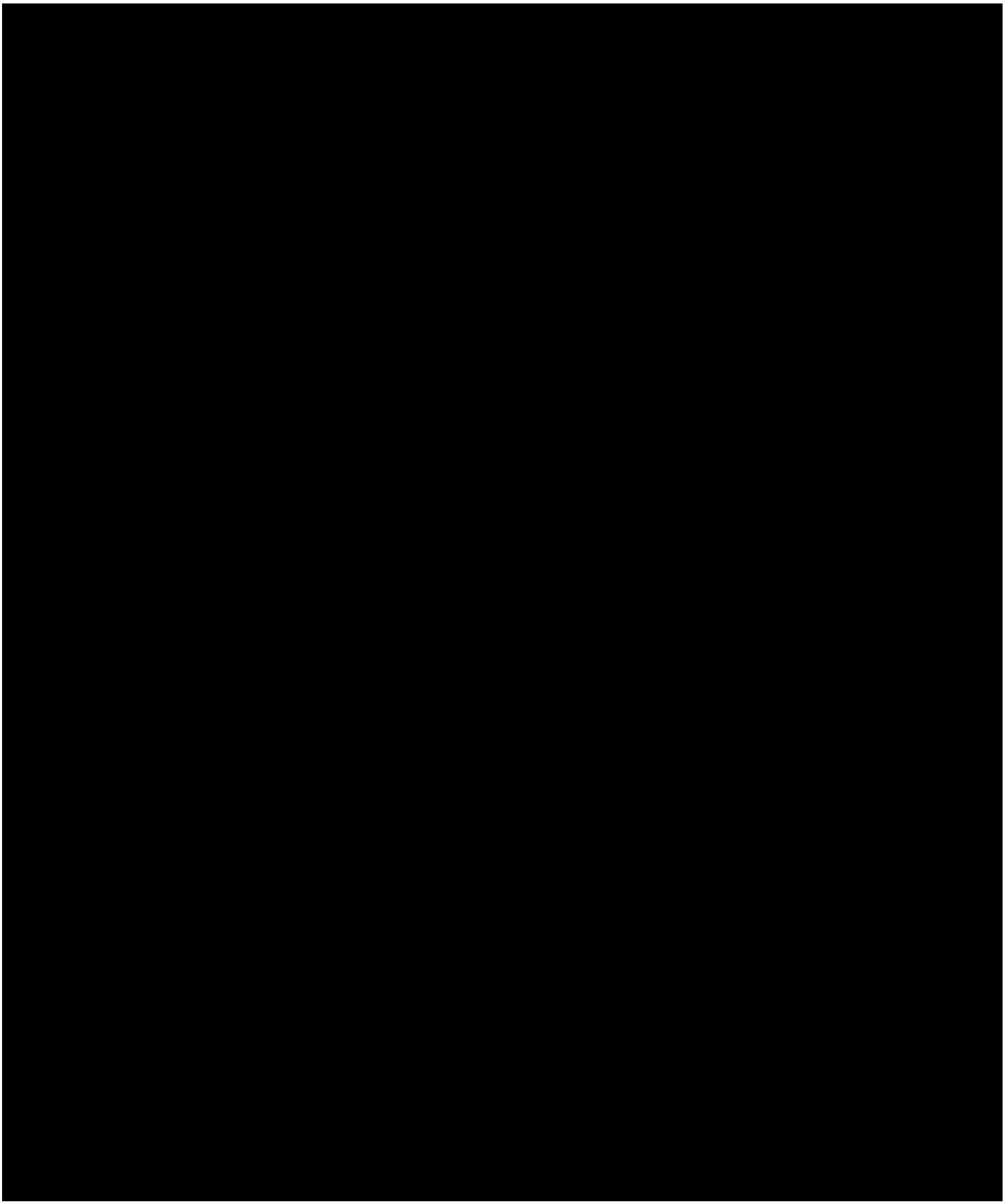
- Inserting intravenous catheter(s) for each subject
- Monitoring subjects for safety, including blood glucose levels
- Obtaining blood samples and target glucose ranges, as outlined in this document

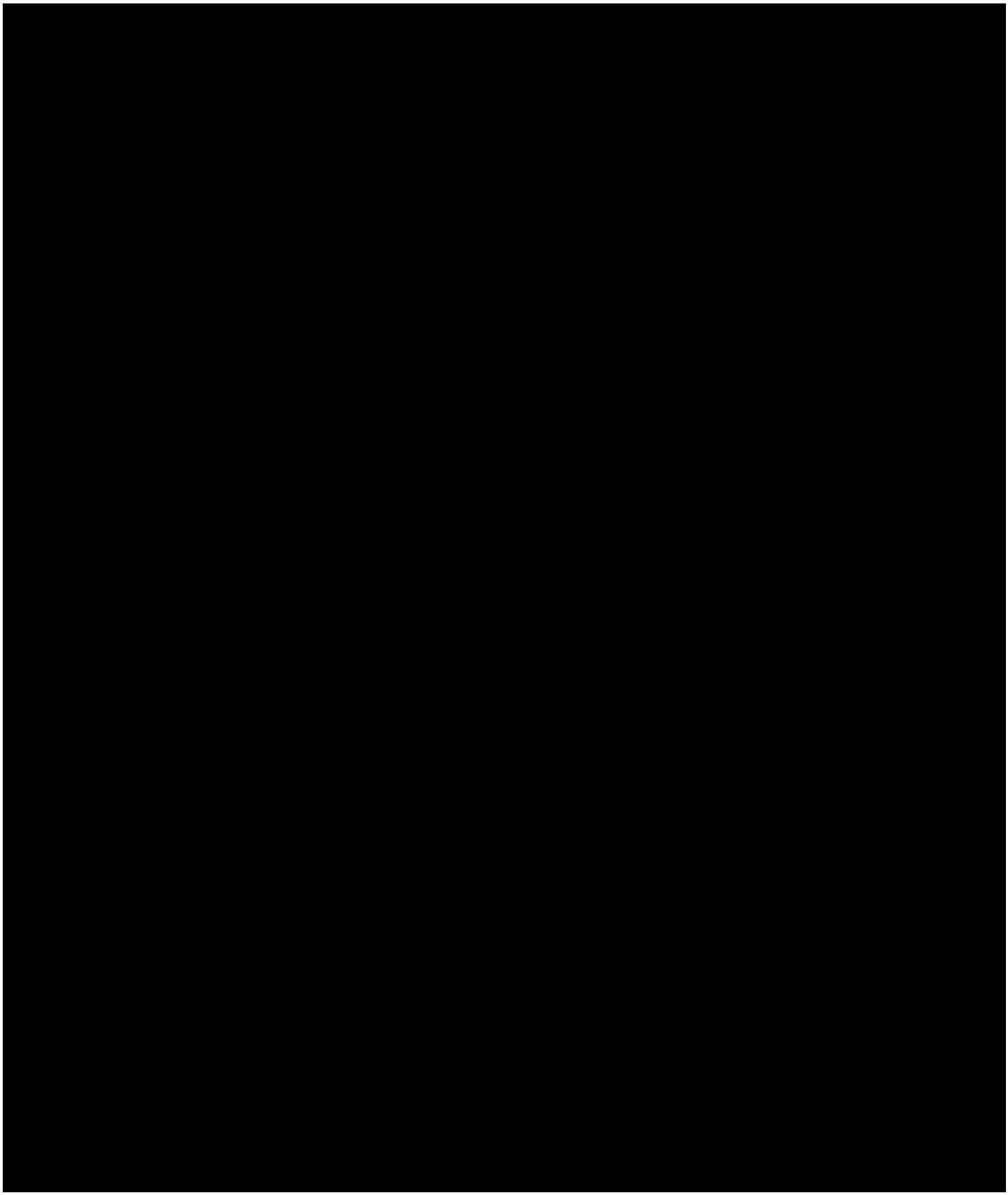
The Principal investigator shall maintain final discretion for any In-Clinic procedures and methods used based on their medical expertise and/or training.

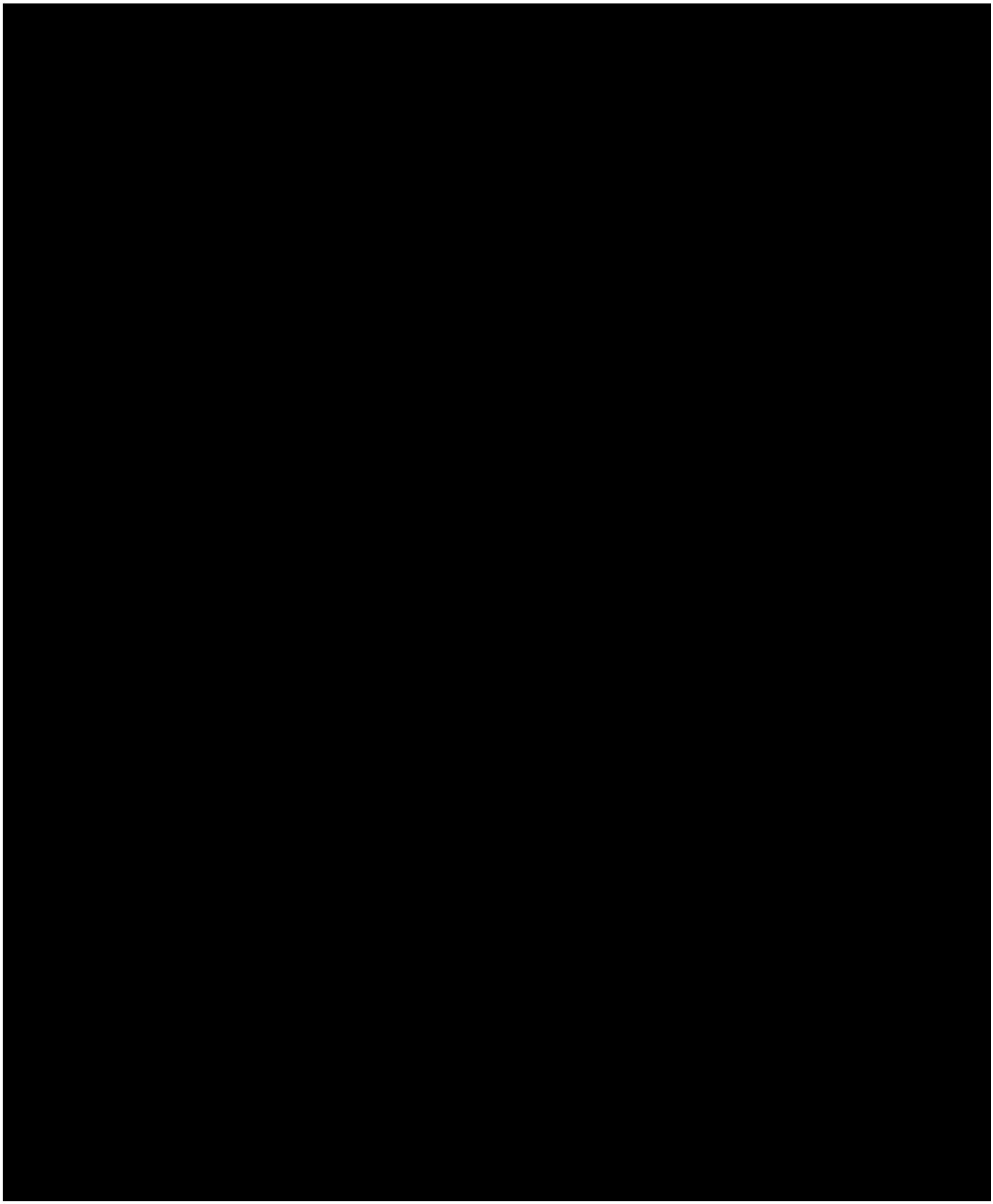
26.1.4 SAFETY MEASURES











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