Digital Self-Management and Health Coaching for Type 2 Diabetes - Impact on Diabetes clinical and wellness indicators

STUDY PROTOCOL

Protocol ID	CP-0010
Revision	A
Date	Mar 2018
Sponsor:	LabStyle Innovation (LSI) Contact: Yifat Hershcovitz Phone: 972.52.529.6979 E-mail: yifat@mydario.com

Protocol Signature Page

(To be signed after IRB approval and before study initiation)

The signatures below constitute the approval of this protocol and its attachments and provide the necessary assurances that this study will be conducted according to ethical principles, GCP compliance, and all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable U.S. Federal Regulations.

Principal Investigator:

Dr. Alan Schorr		9-July-18
Name	Signature	Date

Sponsor Representative:

Yifat Hershcovitz, PhD		9-July-18
Name	Signature	Date

List of Abbreviations

ADE	Adverse Device Effect
AE	Adverse Event
App	Software Application on smart mobile device
BGMS	Blood Glucose Monitoring System
BP	Blood Pressure
CDE	Certified Diabetes Expert
CRF	Case Report Form
HCT	Hematocrit
EC	Ethics Committee
GCP	Good Clinical Practice
FDA	Food and Drug Administration
IDE	Investigational Device Exemption
IRB	Institutional Review Board
PI	Principal Investigator
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SMD	Smart Mobile Device
SSF	Study Site File
USADE	Unanticipated Serious Adverse Device Effect
LSI	LabStyle Innovation Ltd.

Protocol Synopsis

Protocol Title:	Digital Self-Management and Health Coaching for Type 2 Diabetes - Impact on Diabetes clinical and wellbeing indicators
Protocol ID:	CP-0010
Principal Investigator:	Dr. Alan Schorr 380 Middletown Blvd Ste 710 Langhorne, PA 19047 Phone: (215) 750-1691 Email: Alan Schorr <abs@sugardoc.com>
Sponsor:	LabStyle Innovation (LSI) 8 Hatokhen St. North Industrial Park Caesarea 3088900, Israel
Sponsor Representative:	Yifat Hershcovitz Phone: 972.52.529.6979 E-mail: yifat@mydario.com
Product to be Evaluated:	Dario Blood Glucose Monitoring System (BGMS) and connected cloud platform
Research Center:	Diabetes and Endocrinology Consultants of Pennsylvania, LLC (Decpa LLC) 380 Middletown Blvd Suite 710, Oxford Square Langhorne, PA 19047-1845
Research Center Representative:	Dr. Alan Schorr
Data Management & Statistics:	LabStyle Innovation (LSI)
Study Objectives:	To evaluate the impact of the Dario digital self-monitoring platform provided with diabetes management coaching on: 1. Individual's Quality of Life for 2. Clinical parameters (HbA1C, weight, lipids profile, etc.) For people with Type 2 Diabetes at end of study vs. baseline.
Study Design:	single-arm
Study Type	Interventional, Behavioral

Study Specimen:	Lab test Venous blood - Blood glucose level and HbA1C Self-test Capillary whole blood - Blood glucose level
Study Procedures:	Each subject enrolled in the study will be requested to complete an intake questionnaire including diabetes quality of life questions. The subject will use Dario Blood glucose monitoring system and will be contacted by a Certified Diabetes Educator (CDE) two to three times a month as well as have a direct communication using other communication channels such as mail, chat and text messaging (SMS) for lifestyle and diabetes management coaching for a total duration of three months. In the end of study, the subject will complete a diabetes quality of life questionnaire and have a blood test to evaluate its clinical parameters.
Study Population:	Males and females with type 2 Diabetes, ages above 35 recruited through clinic, physician offices, and similar sources having HbA1c level of 8.5% or more, verified by last lab test performed during the last 60 days
Number of Visits	2 visits only
Sample Size:	25 subjects
Data to be Collected:	• QoL questions • Demographic (age, gender, ethnicity, education, etc.) • Diabetes profile: type, time since diagnosis and insulin treatment • Concomitant medications • Medical history • Dario measurement details (test strip lot #, smart mobile device type, Dario meter #) • Capillary whole blood Glucose levels • Venous blood test: HbA1C, Lipid profile, HCT results • Blood Pressure (BP)
Inclusion / Exclusion Criteria	**Inclusion Criteria** 1. Adults 35 years of age or older 2. Diagnosed type 2 Diabetes 3. HbA1C test taken less than 2 months ago and is equal to or above 8.5% 4. Able to read, write and understand English 5. Have supported smartphone (see appendix C for the full smartphone list) with internet package for their service provider 6. The subject is able and agrees to sign the informed consent form **Exclusion Criteria** 1. Adults with impaired cognition

	2. Cohabiting with a participant in the study 3. Have an underlying medical condition (such as kidney disease, hemoglobin variants, anemia) that may provide misleading A1C levels 4. Subject is critically ill 5. Subject has an impairment that prevents him/her from following the study procedures 6. Subject is not using medication that may interfere with the blood glucose measurement 7. HCT level which are outside Dario BGMS declared range (20%-60%)
Analyses & Reports:	Complete analysis and final report after enrolling up to 25 subjects and aiming to have 20 people running the full three months program (after withdrawal) to complete the coaching program that meet the inclusion/exclusion criteria

TABLE OF CONTENTS

1.0 Introduction

Diabetes is one of the prevailing epidemics of the century. The increasing global prevalence of diabetes is challenging traditional approaches towards diabetes management. Novel self-management tools, which aim to engage patients in daily diabetes care and optimize the role of health care professionals, may facilitate a more robust, scalable, and effective approach to the management of diabetes.

Self-monitoring of blood glucose is a valuable tool for helping patients achieve and maintain target blood glucose levels to reduce the risk of diabetes-related complications. Particularly, frequent self-monitoring of blood glucose is an essential requirement to adequately manage diabetes mellitus type 1 or type 2. When performed and utilized properly, blood glucose meters for self-measurement of blood glucose allow diabetic patients to determine their blood glucose level and to use the information as part of their treatment program.

Health coaching is defined as health education, promotion and support by a medical professional to enhance the well-being of individuals and facilitate the achievement of their health-related goals. Diabetes health coaching is provided by certified diabetes educator (CDE) giving overall guidance related to all aspects of diabetes to increase subject's knowledge and skills about the disease and to promote self-care behaviors for effective self-management and glycemic control.

A connected BGMS with a digital platform that enables real-time accessibility by the health coach to the patient's clinical data, provides an effective way to intervene on real clinical information. Intervention in close proximity to recorded clinical events (e.g. hyperglycemic events, continuous out of range (OOR), etc.) on easy to remember occurrences may lead to more effective life change activities by the patient.

The aim of this study is to evaluate the effect of digital self-monitoring blood glucose and diabetes health coaching, in adults with Type 2 Diabetes and its impact on diabetes clinical and wellness indicators over a period of 3 months.

2.0 Device Information

2.1 Device Name

Dario Blood Glucose Monitoring System (BGMS) with Dario digital platform providing access to patient's clinical information and logged behavior captured in the BGMS Application (app).

2.2 BGMS Intended Use

The Dario Blood Glucose Monitoring System consists of the Dario Blood Glucose Meter,

Dario Glucose Test Strips, Dario Glucose Control Solutions and the Dario App as the display component of the Dario Blood Glucose Monitoring System. The Dario Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip. The Dario Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The Dario Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home to monitor the effectiveness of diabetes control. The Dario Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The Dario Blood Glucose Test Strips are for use with the Dario Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip.

The Dario Control Solutions are for use with the Dario Blood Glucose Meter and the Dario Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

2.3 Device Description

The Dario Blood Glucose Monitoring System (BGMS) by LabStyle Innovation (LSI) is used for measuring blood glucose levels from fresh capillary whole blood samples taken from the fingertip. It consists of a blood glucose meter (dongle), which is connected to a smart mobile device for usage with a dedicated application, disposable test strips stored in a cartridge, a lancing device and lancets.

The Dario™ BGMS has a unique all-in-one feature allowing the holding of all relevant items for glucose self-testing in one small, easy to carry, simple to use lancing device enclosure, while enabling blood glucose measurement as is customary in other smart and non-smart mobile device-based blood glucose meter products on the market.

The Dario BGMS comprises the following components:

- Blood Glucose Meter (BGM) (attaches to a smart mobile)
- Smart Mobile Device Application Software (available on iTunes (Apple)/Google Play (Android))
- Disposable Glucose Test Strips (25 per cartridge)
- Disposable mobile device cover

- Control Solutions (Level 1 and Level 2)
- Lancing Device and Lancets. The Lancing Device provides storage enclosures for the Dario™ Blood Glucose Meter and for the Test Strip cartridge.

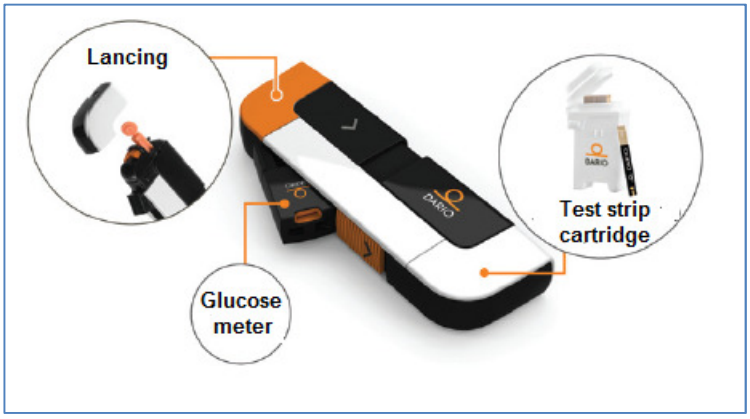


Figure 1: Dario Device

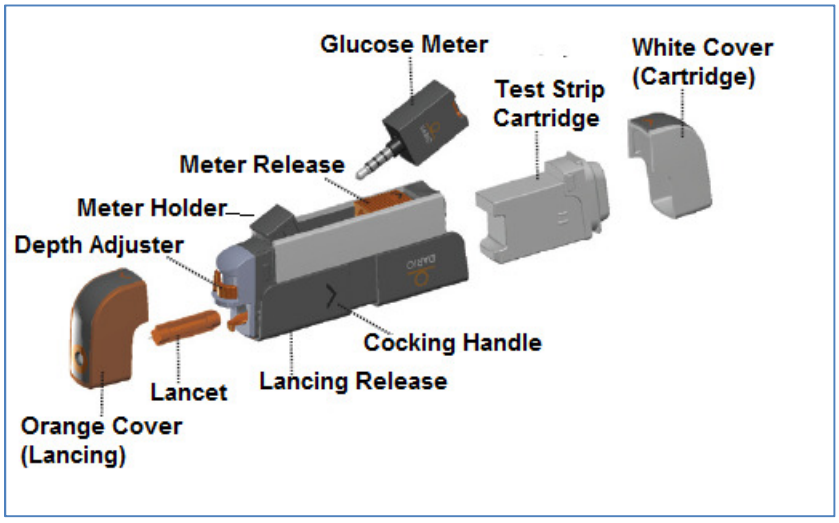


Figure 2: Dario Device Components

2.4 Device as Provided for Study

The below list of device and components will be provided by LSI for usage in the study.

- Dario BGMS Welcome Kits which include:
    - Dario Blood Glucose Meter (BGM) that attaches to a smart mobile device
    - Dario Lancing Device
    - Dario Lancets
    - Disposable mobile device cover
- Dario Blood Glucose Test Strip Cartridge packs
- Dario lancets
- Dario Control Solution

The subject will be handed with the following equipment and supplies:

- One Dario BGMS Welcome Kit
- Blood Glucose Test Strip Cartridge packs – total of 300 test strips
- 100 Lancets
- Control solutions

Subject will use their own smartphone. Only subjects with supported smartphones will participate in the study.

2.5 Device Labeling

The following labeling items are provided when the user receives the Dario:

- Dario™ Blood Glucose Monitoring System User Guide
- Dario™ Blood Glucose Monitoring System Quick Guide with Instructions for Use

All pieces of device labeling will be provided in English.

2.6 Dario Digital Platform

Dario digital platform (Dario Engage) provides visibility and reports on patient blood measurement and in the context of the measurement additional user inserted data, such as physical activity, mood, carbs counting, diabetes type, Insulin type etc. The system facilitates 100% data capture with near real-time data synchronization. All cloud stored information enables ubiquitous access of the coach to the system. The coach or any other healthcare provider can then intervene and follow-up the patient's diabetes monitoring to enhance patient motivation and compliance.

3.0 Study Objectives

To evaluate the impact of the digital self-monitoring platform provided with diabetes management coaching on:

1. Individual's Quality of life
2. Clinical parameters (HbA1C, weight, lipids profile, etc.)

For adults with Type 2 Diabetes at end of study vs. baseline

4.0 Study Design and Procedure

4.1 Study Description

This study is designed to assess the effect of digital self-monitoring platform used with the remote support of a Health coach on clinical outcomes and Diabetes quality of life. Study design will be an open-label randomized trial of adults with Type 2. Patients are recruited through the Diabetes and Endocrinology Consultants center setting. Upon randomization to the intervention group, study participants will receive three months diabetes health coaching comprising of:

1. Two scheduled phone sessions with a Diabetes health coach a month;
2. Ongoing dual communication with the coach using digital communication channels such as chat, SMS and emails
3. Diabetes education, behavior modification, goal setting and reinforcement.

The Dario App will record participant's glucose measurements and additional information captured by the patient such as medication intake, food and physical activity results. The coach will get access to the patients' App captured information and will intervene ad necessary in the context of the clinical information.

4.2 Study Outcome measures

The following outcomes will be evaluated on subjects that completed the three month coaching program at the end of study vs. baseline.

1. Wellness
    a. Quality of Life evaluation by questionnaires
2. Clinical outcome
    a. HbA1C taken in blood test
    b. Capillary Blood Glucose
    c. Weight and BMI
    d. Cardiovascular risk parameters, Lipid panel: Total Cholesterol, Triglyceride, LDL and HDL levels – Blood test
    e. Blood Pressure

4.3 Study Flow

- Upon arrival at the study site, potential candidate will be required to complete a CRF (Case Report Form) to verify subject eligibility. If found eligible, the subject

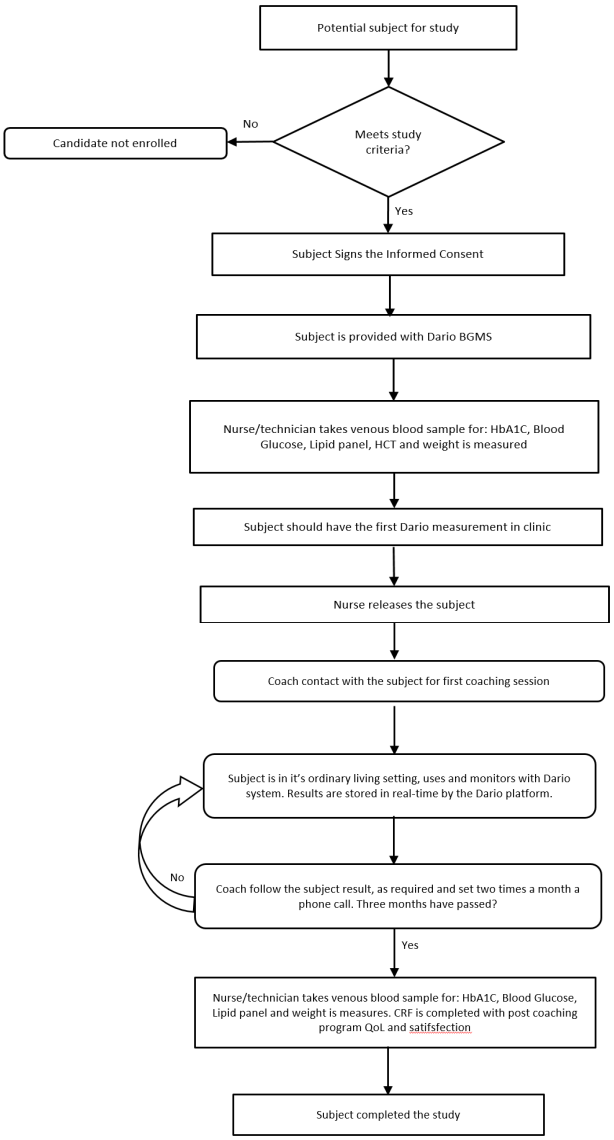
will be provided information about the study and consented to participate in the study.

- Subject will be provided with Dario BGMS Welcome Kit, Dario Test Strip Cartridges, lancets and Control Solutions.
- Subject will download the App and register and will conduct the first Dario measurement in the clinic
- Subject will be handed with Coach communication channels page (including coach name, phone number and email address_
- At this stage the subject has completed the first clinic visit of the study and can start the coaching program.
- The Diabetes health coach will be provided subject's information and will set up the first phone call coaching session with the subject.
- Before the first session the coach will receive a subset of the CRF with the subjects relevant information.
- During the first session, the Diabete health coach will complete an intake session which includes aspects in Diabetes quality of. The questions express the satisfaction of the patient with managing and controlling diabetes. The items were added according to specific quality of life module (*"Development of diabetes-specific quality of life module to be in conjunction with the World Health Organization quality of life scale brief version (WHOQOL-BREF)" Lin et al. Health and Quality of Life Outcomes (2017) 15:167).* The Diabetes health coach will set up phone calls with the subject on a basis of two times per month for a period of three months.
- During the entire coaching period of three months the Diabetes health coach will have two coaching sessions a months (a total of six session throughout the program) and also will communicate via various communication channels: chat, SMS, email and phone and will drive the coaching based on the data captured by Dario Application including: blood glucose measurements, physical activity, carbs etc. Each coaching session will be recorded in a dedicated coaching summary form as provided in appendix B.
- Following the three months coaching the coach will have a closing session with the subject which will include progress, satisfaction and quality of life questions.
- On day 91 to day 100 the subject will be required to arrive at the Name of Clinic for a venous blood sample administered by a nurse/technician for testing:
    - HbA1C

- Lipid panel: Total Cholesterol, Triglyceride, LDL and HDL levels
- HCT

The nurse will measure weigh Body Mass Index and Blood Pressure.

- The subject is then released from the study.
- The flowchart below illustrates the study flow:



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5.0 Study Population

5.1 Inclusion Criteria

To be eligible to participate in this study, a subject must meet all the following criteria:

7. Adults 35 years of age or older
8. Diagnosed type 2 Diabetes
9. HbA1C test taken less than 2 months ago and is equal to or above 8.5%
10. Able to read, write and understand English
11. Have supported smartphone (see appendix C for the full smartphone list) with internet package for their service provider
12. The subject is able and agrees to sign the informed consent form

5.2 Exclusion Criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

8. Adults with impaired cognition
9. Cohabiting with a participant in the study
10. Have an underlying medical condition (such as kidney disease, hemoglobin variants, anemia) that may provide misleading A1C levels
11. Subject is critically ill
12. Subject has an impairment that prevents him/her from following the study procedures
13. Subject is not using medication that may interfere with the blood glucose measurement
14. HCT level which are outside Dario BGMS declared range (20%-60%)

5.3 Recruitment

The study is aimed to recruit a total of 25 male and female subjects having Type 2 Diabetes between ages 35 years or older. The recruitment will be performed through the Diabetes and Endocrinology Consultants of Pennsylvania, LLC (Decpa LLC) center. The clinic will identify patients that have done HbA1C test during the last 60 days and has HbA1C level as indicated in the inclusion criteria. These subjects will be approached by the clinic to participate in the study.

Each subject completes the study in 2 visits to the diabetes and endocrinology consultants center. The subject will receive a Diabetes health coaching which will include 2 monthly coaching sessions for a period of three months. The total study duration depends on the ability to enroll 25 subjects and is planned for three to four months.

6.0 Consent process

6.1 Screening Questionnaire

Potential candidate arriving at the study site will complete a screening questionnaire to verify his/her eligibility to be included in the study and to collect basic information including but not limited to: type of diabetes, age, gender, ethnicity, level of education, previous experience using smart mobile device, previous experience using BGMS, etc.

The screening questionnaire is provided in the CRF in **Appendix A**.

6.2 Informed Consent

Candidates found eligible for the study will receive an explanation by the investigator or delegate regarding the research nature of the study, the scope and aims of the study, the procedures to be followed and any discomfort that he/she may experience. The candidate will then be asked to read the informed consent form, ask any questions he/she may have and sign the form to indicate consent to participate in the study. Written informed consent must be obtained from each study candidate. The form should be signed and dated by both the subject and the investigator or delegate. One copy of the signed consent will be given to the subject and the original will be retained by the site.

Subjects may withdraw their consent to participate in the study at any time without prejudice. The investigator may withdraw a subject if, in his clinical judgment, it is in the best interest of the subject or if the subject cannot comply with the protocol. Any withdrawal case should be fully documented in the CRF.

6.3 Medical Information

Demographic and medical information acquired verbally from the subject and through the screening questionnaire – including (but not limited to) age, gender, relevant medical information, concomitant medications, etc. – will be recorded in the CRF for all subjects participating in this study.

7.0 Study Conduct

7.1 Study Category

This clinical study is exempt from most provisions of the IDE regulation because it fits the category provided in 21 CFR 812.2(c)(3):

The Dario™ BGMS –

- *is properly labeled in accordance with 21 CFR 809.10(c);*
- *is noninvasive[1];*
- *does not require an invasive sampling procedure that presents significant risk[1];*
- *does not by design or intention introduce energy into a subject;*

and

- *is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.*

7.2 Duration of Study

Each subject completes the study in 2 visits to the diabetes and endocrinology consultants center.

The total study duration depends on the ability to enroll up to 25 subjects and is planned for three to four months.

7.3 Device Accountability

Complete traceability records of all devices and accessories will be kept throughout the study.
Dario meter serial number and strip lot numbers, will be documented in subject's CRF.
Additional material used during the study will also be recorded.
Subject will use their own smartphone. Only subjects with supported smartphones will participate in the study.

7.4 Protocol Deviation

Any deviation from the study protocol should be notified to the sponsor and fully documented on study deviation forms. Situations where the investigator anticipates, contemplates or makes a conscious decision to deviate from the protocol must be approved by the sponsor prior to deviation. Situations where unforeseen circumstances are beyond the control of the investigator's control (product failure, patient illness, etc.) and/or where the investigator needs to protect the subject's life or physical well-being in an emergency do not require prior sponsor approval.

7.5 Protocol Modification

An amendment to the protocol may be proposed to the sponsor by the clinical site staff. The amendment will be prepared and approved by the sponsor. The amendment must be

[1] According to 21 CFR 812.3(k), blood sampling that involves simple venipuncture is considered noninvasive.

submitted to the IRB. When applicable, the amendment's implementation will take place only once approved by the IRB.

7.6 Confidentiality

Each subject will be identified by his/ her initials and a unique subject identification number. Source data will be stored with source documents. The Study Site File (SSF) will be held in a secure area. The subject's name and personal data will remain confidential and will not be published in any way. However, the sponsor's representative and regulatory representatives, auditors and inspectors may have access to medical files in order to verify authenticity of the collected data.

7.7 Record Retention

It is the investigator's responsibility to retain study essential documents for at least 5 (five) years after the clinical study.

7.8 Case Report Forms

The study case report form (CRF) is the primary data collection instrument for the study. All data requested on the CRF must be recorded. All entries in the CRF should be printed legibly using ballpoint pen (no pencil). If any entry error has been made, such an error should be corrected by drawing a single straight line through the incorrect entry and entering the correct data above it. All such changes must be initialed and dated by the person making the change. Erasing or whiting-out errors is prohibited.

The following abbreviations should be used:

- If the answer to a question is unknown, write 'UNK' (Unknown)
- If a question is not applicable, write 'N/A' (Not Applicable)
- If a requested task has not been done, write 'ND' (Not Done)

Completed CRF must be signed and dated by Investigator confirming the accuracy and completeness of data entries.

7.9 Study Funding

The study is funded by LabStyle Innovation Ltd.

8.0 Adverse Events

All adverse events (AE) occurring during the study will be recorded on the appropriate case report form page by the nurse/technician. The nature, severity and relation of the

adverse event to the study device will be documented. The PI will sign the adverse event form.

8.1 Definitions

Adverse Event (AE) means any undesirable experiences (sign, symptom, illness, or other medical event) occurring to a subject, whether or not associated with the investigational product or related procedures.

Serious Adverse Event (SAE) means any adverse event experience that results in any of the following outcomes: death, a life-threatening adverse experience, inpatient hospitalization or prolongation of an existing hospitalization, a persistent or significant disability/incapacity, permanent impairment of a body function or permanent damage to a body structure, or necessitated medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

Unanticipated Adverse Device Effect (UADE) 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.[2]

8.2 Reporting Requirements

According to the study category (see **Error! Reference source not found.**), the reporting requirements appropriate for this study are provided in 21 CFR 812.150(b) (1):
"Unanticipated adverse device effects. A sponsor who conducts an evaluation of an unanticipated adverse device effect under § 812.46(b) shall report the results of such evaluation to FDA and to all reviewing IRB's and participating investigators within 10 working days after the sponsor first receives notice of the effect. Thereafter the sponsor shall submit such additional reports concerning the effect as FDA requests."
Additionally, the clinical site staff is required to report all possible device malfunctions or failures observed during the study. These incidents will be documented in the relevant page of the CRF.

[2] 21 CFR § 812.3(s)

8.3 Anticipated Adverse Events

Anticipated adverse events for the Dario™ BGMS include those that are reasonably expected to occur in association with any other type of commercially available BGMS intended for home use, which includes local pain at the finger prick site. Due to the fact that the device will be used only at the site and its results will not serve for treatment decisions, there are no other anticipated adverse events.

Additional anticipated adverse events that may occur in the study are these associated with obtaining capillary blood sample e.g., local pain at needle insertion site, small hematoma, etc.

8.4 Adverse Event Recording

All adverse events occurring during the study must be recorded by the investigator or delegate on the appropriate AE form in the subject's CRF within a reasonable time (up to 5 calendar days from being aware of the event).

8.5 Expedited Reporting of SAE

In the unlikely occurrence of a serious adverse event, such event must be reported to the sponsor within 24 hours of investigator's/delegate's knowledge of the event by calling or emailing the information to:

Yifat Hershcovitz
Phone: 972-525296979
E-mail: yifat@mydario.com

If applicable, the investigator should also inform the representative of the IRB within 24 hours of becoming aware of the event. A copy of the report cover letter should be filed in the SSF.

The sponsor is responsible for the ongoing safety evaluation of the device and, if applicable, communicating the information with the FDA.

9.0 Statistical Analysis

9.1 Sample Size

This study will include up to 25 subjects.

9.2 Data Analyses

Data will be analyzed comparing the quality of life and clinical outcome before and after the program.

To assess the outcome of the study, the effect of intervention along with digital self-monitoring will be evaluated. Paired group tests will be applied for comparing the results gathered on the same subjects after three months to the baseline values.

10.0 Study Monitoring, Auditing, and Inspecting

10.1 Study Monitoring

This study will be monitored by the sponsor's representatives. The investigator will allocate adequate time to accommodate such monitoring activities. The investigator will also ensure that the monitor or other compliance or quality assurance reviewer is given access to all study-related documents and study related facilities (e.g., clinic, laboratory, etc.).

The sponsor will monitor the study as follows:

- In the first week of the study
- Six weeks into the study
- In the end of the study

10.2 Study Auditing and Inspecting

The investigator will permit study-related monitoring, audits, and inspections by the IRB, the sponsor, and government regulatory bodies of all study related documents (e.g. CRF). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., clinic, laboratory, etc.).

Participation as an investigator in this study implies acceptance of potential inspection by government regulatory authorities and applicable compliance and quality assurance officers on behalf of the sponsor.

10.3 Data recording method

The CRF data will be inserted into an excel spreadsheets for analysis.

A double insertion method will be performed on the outcome data by the clinic personal (the before and after QoL and clinical data) to assure correctness.

11.0 Ethical Considerations

This study is to be conducted according to US and international standards of Good Clinical Practice (FDA Title 21 part 812 and ICH guidelines), applicable government regulations and institutional research policies and procedures.

This protocol and any amendments will be submitted to a properly constituted Institutional Review Board (IRB) for formal approval of the study conduct. The decision of the IRB concerning the conduct of the study will be made in writing to the investigator and a copy of this decision will be provided to the sponsor before commencement of this study.

All subjects for this study will be provided a consent form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. This consent form will be submitted with the protocol for review and approval by the IRB for the study. The formal consent of a subject, using the IRB-approved consent form, must be obtained before that subject is enrolled in the study.

Any changes in the study protocol and/or informed consent form that affect the safety and/or welfare of the subject must be re-approved by the IRB and the approval documented.

12.0 Publication Policy

All information concerning this study that was not previously published is considered confidential information. This confidential information shall remain the sole property of LabStyle Innovation; it shall not be disclosed to others without written consent from LabStyle Innovation and shall not be used except in the performance of this study.

Any investigator involved with this study is obligated to provide the Sponsor with all data derived from the study.
The investigator will be aloud, providing a written approval from the sponsor, to publish the study data and outcome.

13.0 Appendices

Appendix A – Case Report Form

Appendix A -
Coaching Pilot Case

Appendix B – Coaching Session Summary

Coach Initials | | | | **Subject ID** | | | |

Date: _____ **Session number**: 1 / 2 / 3 / 4 / 5 / 6 / __

Session main discussion points:

Set goals:

Session additional comments:

General satisfaction:

(very unhappy) 1 / 2 / 3 / 4 / 5 (very happy)

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Appendix C – Supported smart mobile devices

- iPhone 4S, 5, 5S, SE, 6, 6 Plus, 6S, 6S Plus
- LG G3, G4, G5, G6
- Samsung Galaxy S4, S5, S6, S6 Edge, S7, S7 Edge, S8, S8+
- Galaxy Note 4, 5, 8

Most up-to-date list can be found under https://mydario.com/support/getting-started/