**Introduction**

The Clinical Study Plan will be prepared after the clinical study alignment between key stakeholders with agreement to proceed with the clinical study. The Clinical Study Manager/ Lead will prepare this Clinical Study Plan. The Clinical Study Plan will be updated as required according to Good Clinical Documentation Practices and version control standards. If the Clinical Study Plan is revised, it is the responsibility of the Clinical Study Managr/Lead to notify appropriate stakeholders, per the Study Request Form as well as the Clinical Study Team and associated Vendors and study sites about the potential impact resulting from the change.

**BG Stakeholders**

|  |  |
| --- | --- |
| **Primary Point of Contact** | Monica Bush |
| **Project Manager** | Matt Hogan |
| **Marketing Lead** | Monica Bush |
| **Claims Lead** | Monica Bush |
| **Clinical/Science Lead** | Beth Galaska |
| **Medical Monitor** | N/A |
| **Regulatory Affairs Lead** | Alex Friedman |
| **Legal Representative** | Tess Harper |
| **Privacy Officer** | Monica Sanches |
| **Other Key Project Team Members** | Benjamin Shelly, Tony Aquino |

|  |  |
| --- | --- |
| **Clinical Study Alignment & Agreement to Proceed** | Study Request Form - |
| Please refer to CTMS for study alignment and progress dates. |

### Clinical Study Scope

Describe and/or provide a short summary on the following study elements:

|  |  |
| --- | --- |
| **Philips Sponsor** | SRC-AI |
| **Protocol Title** | A Pilot Study Assessing Heart Rate Decay during Exercise Recovery in a Healthy Population with Vibratory Stimulation |
| **Protocol ID** | SRC-AI-MoonshotExerc-2019-10712 |
| **Study Objectives** | Cell 1 - Primary Objectives:  * To gather formulative participant preference data on the amplitude, oscillation frequency, and duty period for wristworn tactile vibratory system development * To gather initial physiological responses to the effects of amplitude, oscillation frequency, and duty period   Cell 2 – Primary Objective:   * To evaluate the impact of a wrist-worn tactile vibratory device when a paced auditory serial addition test (PASAT) is applied   Cell 3 - Primary Objective:   * Evaluate the ability of a tactile vibratory system to aid in faster heart rate recovery following exercise. |
| **Subjects** | Cell 1= Up to 100 participants  Cell 2= Up to 50 participants  Cell 3= Approximately 34 participants will consent to trial participation. |
| **Characteristics**: Healthy adults; aged ≥20 and ≤65 years (Cell 1 and 2); aged ≥20 and ≤50 years (Cell 3); who meet the inclusion/exclusion criteria |
| **Sites** | Philips (Pittsburgh, PA) |
| **Countries** | U.S.A |
| **Product Description** | The primary trial product in this study is a Philips wrist-worn prototype device. This device is capable of providing vibratory stimulation of predefined amplitude, duration, frequency, as well as no vibratory stimulation. This device will be labeled as investigational. A second product to be used in this study is Touchpoint (The Touchpoint Solution, 14269 N. 87th St., Suite 203, Scottsdale, Arizona). |

**Risks & Mitigation Strategy**

|  |  |  |  |
| --- | --- | --- | --- |
| **Anticipated Risks** | | **Anticipated Risk Level** | **Mitigations** |
| Recruitment | | Med | Initially the trial did not have a marketing agency to aid in recruitment. Following the second amendment, the protocol was modified to allow for the use of Campos. |
| Retention | | Low | Participants will be compensated. Only two visits required with online surveys at different timepoints throughout the study. |
| IEC/IRB approval | | Low | This is a minimal risk study. No anticipated any issues with IRB approval |
| Unique system or testing requirements | | Low- Med | Before human use, device will go through CPDR process to document prepardedness. |
| Protocol and/or GCP compliance | | Low | Plan to follow processes aligned with Clinical Research SRC QMS |
| Device risks to subject, malfunction, failure | | Low | This is a non-significant risk device. Risks to subject are minimal; Device defects will be tracked. Before human use, device will go through CPDR process to document the product’s readiness. |
| Prior experience with PI/site | | Low | Philips is the site and sponsor. The PI is a Philips employee and has extensive experience conducting clinical studies. |
| **Site Training Requirements** | Philips is the site and the sponsor. Key Study Personnel will be trained on protocol and GCP training on file (job requirement). | | |

### Clinical Study Timeline

Please see updated dates in CTMS.

The following are key timeline milestones, and will be reported as KPIs in CTMS.

|  |  |  |
| --- | --- | --- |
| **Key Milestones** | **Planned Start** | **Planned End** |
| Protocol Development Version 1.0 | 22JUL2019 | 7AUG2019 |
| Protocol Development Version 2.0 | 9OCT2019 | 15OCT2019 |
| Protocol Development Version 3.0 | 12DEC2019 | 13DEC2019 |
| EDC/Data Collection Tool Development | 28OCT2019 | 11NOV2019 |
| Site Activation | 21OCT2019 | 21OCT2019 |
| Study Duration  (FSFV-LSLV) | 21OCT2019 | 20DEC2019 |
| Database Lock | 20DEC2019 | 1JAN2020 |
| Contract Approval- Campos | 9DEC2019 | 10DEC2019  N/A |
| Product Release and Delivery to Study Site(s) | 21OCT2019 | 21OCT2019 |

|  |  |  |
| --- | --- | --- |
| **Milestones, other** | **Planned Start** | **Planned End** |
| Data Monitoring and Query Resolution | 6JAN2020 | 16JAN2020 |
| Study Closure Activities | 16JAN2020 | 01MAR2020 |

**Key Performance Indicators (KPIs)**

Information related to the clinical study shall be captured in CTMS including the unique protocol ID, study objectives, number of study subjects, and clinical sites among other relevant study elements.

During the study the following performance metrics (e.g. on target; performance meets requirements,) will be tracked as Study milestones in CTMS:

|  |
| --- |
| **KPIs** (include, as applicable)**:** |
| **Study Start-up:** |
| Protocol Development on target? |
| Database Build/Release on target? |
| Site Activation; study start (FSFV) on target? |
| **Mid-Study Performance:** |
| Study Recruitment on target? |
| Study Enrollment (LSFV) on target? |
| Completion of Study Procedures/Visits on target? |
| Monitoring Visits and Reports on target? |
| CRO Performance meets contract requirements? |
| Vendor Performance meets contract requirements? |
| **End-Study/Final Performance:** |
| Study Duration (FSFV-LSLV) on target, per study timeline? |
| Did the study meet the Primary Objective? |
| Did the study meet the Publication Strategy? |
| Did the study generate a new/updated Claim(s) as planned? |
| Did the study result in ‘no’ CAPAs? |
| Did the study result in ‘no’ SAEs or USADEs? |
| Did the study meet the target Enrollment? |
| Database Locked on target, per study timeline? |
| Results Communicated to stakeholders on target? |
| Clinical Study Report on target, per study timeline? |

### Study Resources / Outsourcing

Following are the key roles for this study, including any outsourced vendors:

| **Role** | **Name and FTE # Required** (e.g., 0.25, 0.5, 0.75, 1.0, etc) | **Planned Training** |
| --- | --- | --- |
| Clinical Study Manager (CSM) | Beth Galaska / 0.5 | Self-paced protocol review |
| Clinical Development Scientist (CDS) | Beth Galaska / 0.5 | N/A – protocol author (BG);  Subject Matter Expert (BS) |
| Clinical Operations Lead (COL) | Kelli Davis /0.10 | Self-paced protocol review |
| Clinical Research Associate(s)/ Study Monitor (CRA) | Beth Galaska/ 0.5  Melissa Weiner 0.25 | GCP on file- Philips U  GCP on file- Philips U  GCP on file |
| Clinical Research Coordinator (CRC) | Barb Griffith/0.20 | Attend Study Training; GCP on file- Philips U |
| Data Manager (DM) | Lindsey Heffernan/ 0.10 | Self-paced protocol review |
| Biostatistician(s) | Jeff Jasko / 0.10 | N/A - Protocol author- Version 1.0-3.0 |
| Medical Monitor | This is a minimal risk study and does not require a medical monitor | This is a minimal risk study and does not require a medical monitor |
| Privacy Officer | Monica Sanches 0.05 | N/A – will review study documents for privacy assessment |
| Medical Writer | This is a minimal risk study and does not require a medical writer. | This is a minimal risk study and does not require a medical writer. |
| Principal Investigator | Dr. David White (0.25) | Self-paced protocol review |
| Product Researchers | Monica Bush (0.25) | Self-paced protocol review (protocol collaborators); GCP/HSP training on file |

|  |  |  |
| --- | --- | --- |
| **Vendor** | **Name** | **Outsourced Activities** |
| Market Research  Facility | Campos | * Recruiting/Scheduling the last 17 participants |
| IRB/IEC | Allendale IRB | * Document Review & Approval for use w/ human subjects |

### Responsibilities, Accountabilities, Consulted & Informed (RACI)

The following individuals/roles are responsible, accountable, consulted and informed on the study documentation preparation, review and approval, as applicable:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Document(s)/Activity** | **(R)esponsible** (Owner/Executor) | **(A)ccountable** (Reviewer/Approver) | **(C)onsulted** (Informs/ Reviews/ Contributes) | **(I)nformed** (Notified of Results) |
| Study Request Form | CDS | CSM/CRA | COL | CRC |
| Study Start-up Checklist | CSM | CRA/COL | CDS | CRC |
| CTMS Study Registration | CSM | CRA/COL | CDS | CRC |
| Clinical Study Design | CDS | CSM/COL | CRA | CRC |
| Risk Assessment Document(s) | CSM/CDS | COL | CRA | IRB |
| Clinical Study Plan | CSM/CDS | COL | CRA | CRC |
| CTMS Updating | CSM/CDS | COL | CRA | CRC |
| Investigator Brochure (IB) | N/A – U.S. study and NSR device, so IB is not required | N/A – U.S. study and NSR device, so IB is not required | N/A – U.S. study and NSR device, so IB is not required | N/A – U.S. study and NSR device, so IB is not required |
| Clinical Study Protocol | CDS | Biostats/CSM/COL | CRA | CRC |
| Statisticial Analysis Plan | DM | CDS | CSM/CRA/COL | CRC |
| Site Selection & Qualification Report | N/A – Philips is the site | N/A – Philips is the site | N/A – Philips is the site | N/A – Philips is the site |
| Vendor Qualification Report | Product Researcher/CSM | CSM/CDS | CRA | CRC |
| Vendor Oversight & Delegation Plan | Product Researcher/CSM | CSM/CDS | CRA | CRC |
| Site Contracts (Vendor) | N/A – executed vendor contract on file | N/A – executed vendor contract on file | N/A – executed vendor contract on file | N/A – executed vendor contract on file |
| Budget and Resource Administration | COL | CDS | CSM/CRA | CRC |
| Site Regualtory File Development, Shipment | N/A-Philips is the site | N/A-Philips is the site | N/A-Philips is the site | N/A-Philips is the site |
| Trial Master File Maintenance & Reconciliation | CSM | CRA/CRC | COL | CDS |
| Subject Consent Document | CSM | CDS/COL | CRA | CRC |
| Informed Consent Form Checklist | CSM | COL/CRA | CDS | CRC |
| Privacy Impact Assessment | CSM | COL/CDS | CRA | CRC |
| Regulatory Agency Submissions & Reports | N/A – no regulatory submissions | N/A – no regulatory submissions | N/A – no regulatory submissions | N/A – no regulatory submissions |
| IRB/IEC Submission Documentation & Reports | CSM/CDS | COL | CRA | CRC |
| Clinical Study Registration Determination Document | CSM | CDS | CRA | CRC |
| Source Document Templates | CSM | DM/CRA/CDS | COL | CRC |
| Data Management Plan | DM/CSM/CDS | CRA | COL | CRC |
| User Acceptance Testing of Online Surveys | Product Researcher/DM | CDS/CSM | CRA | CRC |
| Product Release Document(s) | CDS/CSM | COL | CRA | CRC |
| Product Shipment | CSM | CDS/COL | CRA | CDS |
| Site Readiness Checklist | CSM | COL/CRA | CDS | CRC |
| Investigational Product Accountability Document(s) | CRC | CSM | COL/CRA | CDS |
| Clinical Study Monitoring Plan | CSM | COL/CRA | CDS | CRC |
| Site Training Documents | CSM/CRA | COL | CDS | CRC |
| Monitoring Reports | CSM | COL/CRA | CDS | CRC |
| Query Issue & Resolution | CSM | COL/CRA | CDS | CRC |
| Trial Master File/Site Regulatory File Audit Checklist(s) | CSM | COL/CRA | CDS | CRC |
| Adverse Event Assessment & Reporting Documentation | CSM | COL/CRA | CDS | CRC |
| Product Deficiency Assessment & Reporting Documentation | CSM/Product Researcher | COL/CRA | CDS | CRC |
| Clinical Study Database Lock/Unlock Form(s) | DM | Biostats | CSM | COL/CDS |
| Clinical Study Evidence Dissemination | CDS/Product Researcher | CDS, Biostats | COL | CRA |
| Clinical Study Report | CDS | CSM, Biostats | COL | CRA |
| Study Closure Checklist | CSM/CRA | COL | CDS | CRC |
| End Study Documentation Reconciliation & Archiving Documentation | CRC | CSM | COL | CDS |

### Applicable Regulations and Guidances.

|  |
| --- |
| FDA 21 CFR 21 CFR Parts 50, 54, 56 and 812.2b, Abbreviated Requirements |
| Good Clinical Practice |
| FDA Guidance for Industry; Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring |
| Declaration of Helsinki |

### Applicable Operating Procedures

The following 16.2.6 Manage Clinical Studies Operating Procedures shall be followed for this clinical study:

|  |  |  |  |
| --- | --- | --- | --- |
| **Operating Procedure Short Name** | **Yes** (input local QMS Doc ID) | **No** (x) | **Explain Rationale if No is Selected** |
| Philips PQMS Standard: Pre-Clinical / Clinical Studies Controls | PBMS-QMS-S-0003 |  |  |
| Philips Global Clinical Studies Quality Procedure (CSQP) | QSP 7.9.4-2004 Rev 00 |  |  |
| Clinical Study Plan Procedure | QSP 7.9.4-2012 Rev 00 |  |  |
| CRO/Vendor Qualification and Management Procedure | QSP 7.9.4-2013 Rev 00 |  |  |
| Investigator Initiated Study Management Procedure |  | X | This is not an investigator intiated study. |
| Site Regulatory File and Trial Master File Procedure | QSP 7.9.4-2010 Rev 01 |  |  |
| Investigational Product Management Procedure | QSP 7.9.4-2006 Rev 00 |  |  |
| Protocol Procedure | QSP 7.9.4-2007 Rev 00 |  |  |
| Investigator Brochure Procedure |  | X | This clinical study takes place in the U.S. using a NSR device, so an IB is not required. The device is classified as a wellness medical device. |
| Informed Consent Procedure | QSP 7.9.4-2014 Rev 00 |  |  |
| IRB/IEC Submission and Approval Procedure | QSP 7.9.4-2009 Rev 00 |  |  |
| Monitoring Procedure | QSP 7.9.4-2005 Rev 00 |  |  |
| Monitoring Plan Procedure | QSP 7.9.4-2018 Rev 00 |  |  |
| Data Management Plan Procedure |  | X | Due to deficiencies in new data management procedures, original procedure will be followed: 7.9-801 Data Management for Clinical Research. |
| Statistical Analysis Plan Procedure | QSP 7.9.4-2016 Rev 00 |  | Note: Located within the protocol |
| Database Lock Procedure | QSP 7.9.4-2023 Rev 00 |  |  |
| Clinical Study Registration Procedure | QSP 7.9.4-2017 Rev 01 |  |  |
| Adverse Event Monitoring Procedure | QSP 7.9.4-2019 Rev 00 |  |  |
| Product Deficiency Procedure | QSP 7.9.4-2020 Rev 00 |  |  |
| Risk Assessment Procedure | QSP 7.9.4-2021 Rev 00 |  |  |
| Clinical Study Report Procedure | QSP 7.9.4-2008 Rev 00 |  |  |
| Study Start-Up CHECKLIST | Form 4705 |  |  |
| Informed Consent Form CHECKLIST | Form 4706 |  |  |
| Trial Master File/Site Regulatory File Documents CHECKLIST | Form 4707 |  |  |
| Study Closure CHECKLIST | Form 4708 |  |  |
| Site Readiness CHECKLIST | Form 4709 |  |  |
| Clinical Study Request FORM | Form 4710 |  |  |
| CTMS Registration and Updating WI | SRC WI v 1.0 |  |  |

# Appendices

# Document Revision History

| **Version** | **Date** | **Author** | **Description of Change** | **Reason for Change** |
| --- | --- | --- | --- | --- |
| 1.0 | 11 October 2019 | Beth Galaska | Draft | N/A |
| 2.0 | 9 January 2019 | Beth Galaska | Initial Release | Updated to incorporate Amendment 1 and 2 |

# Document Approval History

| **Approved by** | **Role / Function** | **Signature & Date** |
| --- | --- | --- |
| Kelli Davis | COL |  |