Data Collection Study

Cionic-01-001

March 29, 2021

Background

Cionic Inc., is a San Francisco based for-profit company specializing in developing a platform technology that enables hardware and software to enhance human mobility and improve overall quality of life. The Cionic-Apollo System is the first product under development, consisting of sensors that measures how muscles behave and how the body moves, and allows for targeted augmentation through electrical stimulation.

The purpose of this data collection study is to capture information about how the body moves using the Apollo System's sensor system in order to build algorithms for providing targeted external electrical muscle stimulation to individuals with impacted mobility. In addition, Cionic will use this data collection study as an opportunity to further inform design changes and reinforce safety and efficacy of the product.

Cionic is preparing for a 510(k) submission of it's Apollo System, and while there is no requirement from the FDA for any testing on human participants, Cionic recognizes the need to conduct this data collection on both adult and pediatric impacted populations.

Organizational Relationships

Cionic is working closely with Edge Analytics, a consulting firm who has been contracting for Cionic for over a year. They are primarily responsible for algorithm development, and are working closely on this data collection study. Lina Colucci, PhD is a cofounder of Edge Analytics and a sub-investigator on this study.

Starfish Therapies is a physical therapy clinic in Burlingame, CA owned by Stacy Menz where pediatric data collection will take place. Starfish is not being compensated in any way to allow Cionic to use their clinic as a data collection site. The data collection process and study administrators will be identical for all sessions completed at Starfish

Specific Aims

This protocol describes a data collection study intended to inform the development and refinement of the Apollo system. This device has been designed to collect raw movement data from the participant, convert this data into clinically relevant measures such as limb orientation and muscle activation, and to deliver functional electrical stimulation (FES) to support and augment muscle activation in order to account for movement deficits. The study consists of three independent data collection Sessions (Table 1), each accomplishing one of the Study Aims.

AIM 1 - Movement measurement

Session A of the study is designed to collect physiological data on impacted participant populations in order to record and characterize movement from people with lower body deficits. This will be accomplished by recording kinematic data (movement velocity, range of motion) and functional data (muscle activation signals via electromyography (EMG). The output of this session will be data recorded from the system which is de-identified and used for internal Cionic engineering and software development. This Session does not involve electrical stimulation.

AIM 2 - Muscle Activation and Usability

The Apollo System consists of a wearable leg strap with sensors, designed for accurate, repeatable, and comfortable use by participants irrespective of movement deficits. The leg strap includes an array of adhesive stimulation electrodes that must be positioned accurately over target nerves and muscles. Session B of the study will test different electrode placements on the leg to determine which positions result in the optimal muscle activation. This session will also evaluate the comfort of stimulation using these electrodes during extended use as a measure of usability.

AIM 3 - FES for Gait Assistance

Session C is to characterize and collect data on the impact of electrical stimulation on impacted participants' gait. This study involves placement of electrodes onto participants and delivering patterns of stimulation optimized to allow the participant to have an improved gait, as characterized by increased range of movement, speed, and self-reported assessment of their assisted walking.

Table 1. Summary of protocol session

	Session A	**Session B**	**Session C**
Specific Aim	Movement measurement	Muscle activation & usability	FES for Gait Assistance
Involves data collection?	Yes	Yes	Yes
Involves stimulation?	No	Yes	Yes
Approximate # of adult participants	20	20	10
Approximate # of pediatric participants	10	10	10
Activity	Measure movement during walking without any intervention.	Measure muscle activity and effect of FES on muscles only (no movement).	Measure effect of FES on gait.

Participant Selection

This data collection study is looking to recruit up to a total of 50 different adult participants and 30 different pediatric participants. There are three independent sessions in the study, with a decreased number of participants needed for Session C (Figure 1). There are no gender-based or ethnicity restrictions. Adult participants between the age of 18-70 and pediatric participants may be between the ages of 6-17.

Inclusion criteria

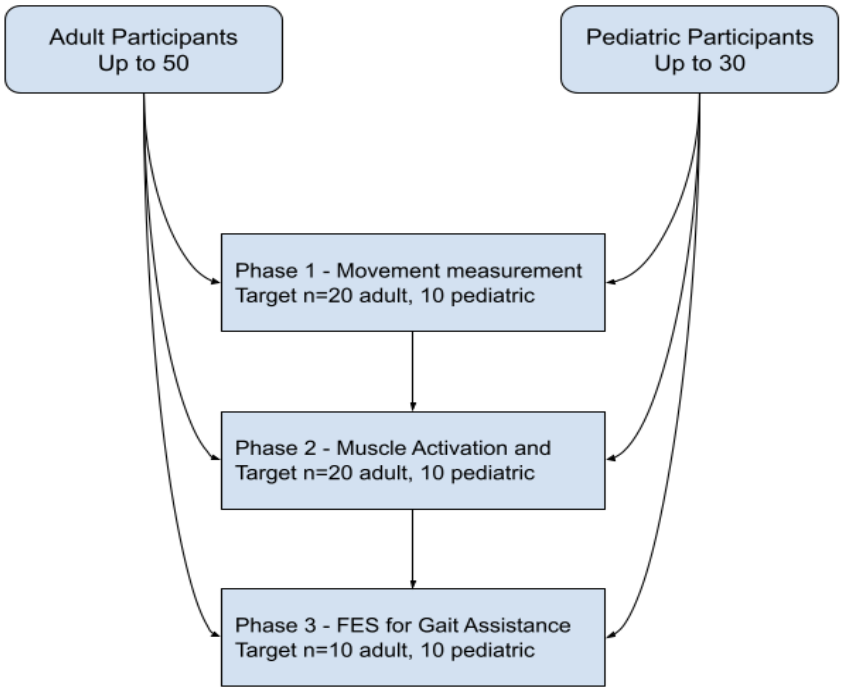
- Are living with lower extremity impairment that makes walking difficult and/or uncomfortable
- Capable of sitting, standing and walking with or without assistance
- Ability to walk at least 10 meters with minimal assistance

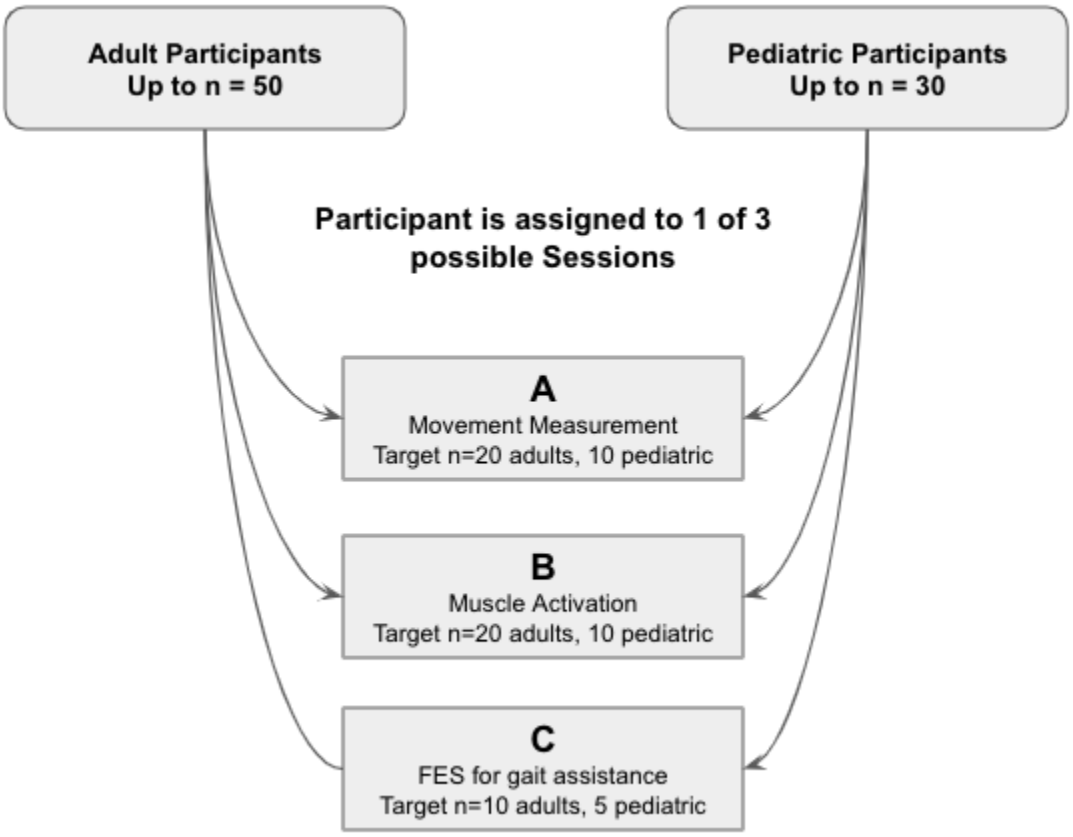
- Ability to understand and follow the basic instructions in English
- Parent/guardian must be accompany and be present with pediatric participants

Exclusion criteria

- Having non-reversal damage to the central and peripheral body's system
- Underlying pre-existing conditions like thrombosis/hemorrhage, severe epilepsy or other seizure disorder, severe atrophy or history of implanted electrical devices
- Cognitive impairment that would prevent the participant from fully understanding the study and ability to provide informed consent
- Lower motor neuron disease or injury that may impair response to stimulation
- Pregnant woman
- Skin conditions of the affected lower limb, including cuts, burns or lesions
- Latex allergy

Figure 1. Participant distribution by Session





Methods

The Cionic wearable devices measure information about leg and muscle activity that enable mobility. The system consists of four leg straps, two foot sensors, and two foot insoles (or pressure aray of pressure sensors), connected by insulated wires to a battery-powered control box worn on the thigh. The device can also be (optionally) configured to attach sticky electrode pads to the body, which are connected to an integrated battery powered control box worn at the hip, capable of stimulating muscle contractions.

The Cionic sensing devices are made up of sensors that are either part of compression-type wearable garments held snugly in place with velcro and sticky electrode gel, or attached to the shoes. This system will measure what the body, i.e., pelvis and legs, are doing while the participant. It also has sensors that measure what some of the body's muscles are doing during movement. When muscles are working,

they produce a small electric current that can be measured with sensors on the skin over the muscle.

Each participant will be asked to wear:

- Two elastic leg straps (Figure 2), containing multiple sensors, will be secured to each leg with Velcro. One strap will be secured around each thigh and one around each shank (lower leg). These straps will measure two things: (1) the activity levels of the muscles underneath the straps, and (2) the physical orientation of the legs.
- One foot sensor will also attach to the top of the participant's shoes to measure the physical orientation of the feet. The straps and foot sensors will be connected by stretchable wires.
- Lastly, thin pressure-sensing pressure pads (Figure 3) will be inserted inside each of the shoes. The pressure sensors measure where the foot is applying downward pressure inside the shoes at all times.

Participants in sessions B and C will wear the Cionic stimulation device (Figure 4), which includes all of the above, as well as sticky electrode pads connected to a battery powered control box worn at the hip, capable of stimulating muscle contractions (manually or algorithmically).

- One Functional Electrical Stimulation (FES) control box clipped to the hip.
- Maximum of eight pairs (16 total) sticky electrode pads worn at one time on the shins, calves, quadriceps, and/or hamstrings. These electrodes will connect to the FES control box via insulated wires.

These devices connect wirelessly via Bluetooth to an application running on a smartphone. The smartphone's camera will also record video of the lower body only. We will not record the participant's face. The content of the data will be uploaded to a secure server and used to develop product algorithms and inform product design.

The Apollo system utilizes a battery-powered, body-worn electronic controller that generates stimulation waveforms and receives EMG signals. The magnitude, frequency and duration of the stimulation waveforms are controlled by a smartphone application

operated by the study coordinator. Software, hardware, and user controls all limit the maximum energy that can be delivered to a subject. The controller's maximum output parameters (current of 100 mA, pulse duration of 400 microseconds) enable a maximum per-pulse charge of 40 microcoulombs, which is equivalent to our predicate device (Otto Bock, Stilwell Med4, K080950) which are cleared for the same indications intended for the Apollo system.

Each stimulation session starts with current amplitude at 0 mA and is increased manually by the study coordinator in small increments, preventing sudden, uncontrolled increases in energy. Recording of electromyography (EMG) signals from muscle in the Apollo system does not involve delivery of energy to the patient. Pain can occur when EMG is utilized for nerve conduction studies with needle electrodes, however this is not the paradigm used in our study.

The electronic controller is being developed in conformity with IEC 60601-2-10 (Medical Electrical Equipment - Particular requirements for the basic safety and essential performance of nerve and muscle stimulators).

While used for a different indication for use, an over-the-counter transcutaneous electrical nerve stimulator, commonly referred to as a TENS Device, is well adopted therapy that can be used as a commonly recognized example of how the electrical stimulation will feel on the study participant.

Figure 2. Apollo system leg straps

Figure 3. Representative foot sensors (image source: TekScan.com

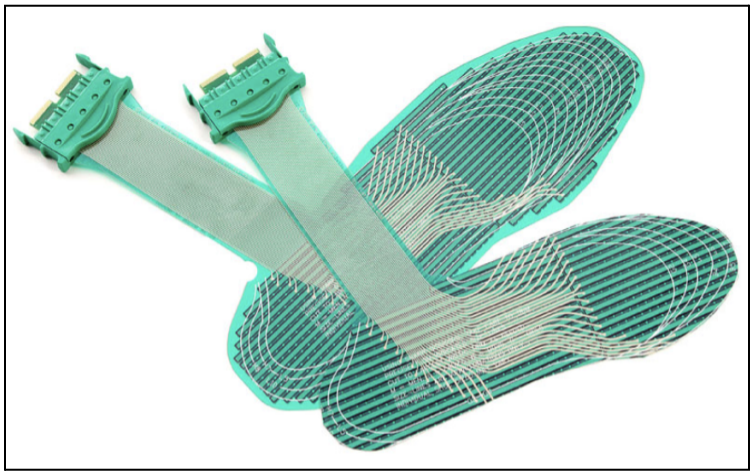


Figure 4. Apollo system control unit

Data Collection and Movement Tasks by Session

Each independent session of the study involves directing the participant to perform a series of movement tasks in order to elicit different types of data. Each session is subdivided into tasks. Instruction will be provided to the participant before entering a new task, and the study coordinator will also use these opportunities to gauge participant pain, need for breaks and understanding of the task. For pediatric participants, their parent or guardian will also be consulted between tasks.

Session A - Sensor Data Collection

Session A will consist of approximately 2 hours of sensor data collection. The participant will be outfitted with a Cionic leg straps on the thigh and shank of both legs and foot pressure sensors taped under both shoes. The leg straps consist of EMG (non-invasive muscle electrical signals) sensors and IMU (accelerometry/movement signals) sensors. Participants will be asked to wear clothing amenable to sensor placement and movement such as shorts.

Task 1: Introduction and anatomical measurements

- Introductions to all Cionic team members and review study activities.
- Confirm signed informed consent.
- Provide opportunity for participants to change clothes if necessary.
- Measure anatomical features using a flexible tape including thigh and calf circumference and leg length.

Task 2: Equipment setup

- Secure leg straps to the participant's body and confirm comfort.
- Initiate data collection device and ensure connection to Smartphone app.
- Record non-personally identifiable participant information within the app.
- Validate system operation by confirming communication between app and all data collection channels.
- Sensors will be calibrated by guiding the participant through specific limb movements both standing and sitting.

Task 3: Treadmill

- Participant will be guided onto a treadmill with side handles.
- An overhead safety harness will be fitted to any participant who requires or requests a harness.
- Walking will be initiated on the treadmill at a rate no more than the participant’s comfort level for up to 5 minutes while movement data is collected.
- The process will then be repeated up to 5 times for walking intervals of up to 2 minutes while data is collected and reviewed.
- Verbal check-in with participants for pain, understanding and need for a break.

Task 4: Overground Gait

- Participant will be guided to an open area with at least 20 feet of walking area without any physical obstructions.
- Participant will be asked to walk unaided in the walking area for up to 5 minutes while data is collected.
- The process will then be repeated up to 5 times for walking intervals of up to 2 minutes while data is collected and reviewed.
- Verbal check-in with participant for pain, understanding and need for a break.

Task 5: Seated Exercises

- Participant will be seated comfortably.
- Participants will be asked to perform isolated leg movements. Movements will include knee flexion and extension, hip abduction and adduction, thigh flexion and extension
- Each movement may be repeated up to 5 times.
- Verbal check-in with participant for pain, understanding and need for a break.

After completion of all tasks, equipment will be removed from the participant and sanitized with isopropyl alcohol. A brief post-study survey will be administered verbally or via computer by the study coordinator.

Session B - FES Pad Calibration

Session B will consist of ~2 hours of FES stimulation on the participant's muscles while sensor measurements are made. The goal is to test the placement of our FES pads on each of the 4 main muscle groups: quadriceps, hamstrings, calf, and tibialis anterior (front of lower leg). The participant will wear sensorized leg straps equipped with FES and two foot pressure sensors inside each shoe. Surface muscle stimulation will be applied gently at first, increasing slowly as directed by the participant. Several electrode pad locations will be tested for each muscle.

Task 1: Introduction and anatomical measurements

- Introductions to all Cionic team members and review study activities
- Confirm signed informed consent
- Provide opportunity for participants to change clothes if necessary
- Measure anatomical features using a flexible tape including thigh and calf circumference and leg length.

Task 2: Equipment setup

- Secure leg straps to participant's body and confirm comfort.
- Initiate data collection device and ensure connection to Smartphone app.
- Record non-personally identifiable participant information within the app.

- Validate system operation by confirming communication between app and all data collection channels.
- Sensors will be calibrated by guiding the participant through specific limb movements both standing and sitting.

Task 4: Isolated muscle group data collection

- An array of 2” x 2” adhesive electrodes (typical of TENS therapy system) will be applied to a muscle group of interest.
- Sensors will be calibrated by guiding the participant through specific limb movements both standing and sitting.
- Participants will be asked to move their feet and legs to access their range of motion
- Stimulation will be delivered to different combinations of electrodes on the muscle group. At each instance stimulation will be started at the lowest setting (0mA) and increased slowly until either a sufficient muscle response is achieved or the participant reports discomfort. If any discomfort is felt, stimulation will be immediately stopped, and a new combination of electrodes will be selected.
- Verbal check-in with participant for pain, understanding and need for a break.

Muscle Group	**Tibialis Anterior**	**Quadriceps**	**Gastrocnemius**	**Hamstrings**
Participant position	Supine	Seated	Prone	Prone
Intended Movement	Foot dorsiflexion	Lower leg extension	Foot plantar flexion	Lower leg flexion

After completion of all tasks, equipment will be removed from the participant and sanitized with isopropyl alcohol. A brief post-study survey will be administered verbally or via computer by the study coordinator.

Session C - FES Gait Assist

Session C will consist of approximately 2 hours of periodic FES stimulation while the participant walks. The goal is to test Cionic's gait augmentation stimulation algorithms. The participant will wear sensorized leg straps equipped with FES and foot pressure sensors inside each shoe. Surface muscle stimulation will be applied gently at first, increasing slowly as directed by the participant.

Task 1: Introduction and anatomical measurements

- Introductions to all Cionic team members and review study activities.
- Confirm signed informed consent.
- Provide opportunity for participants to change clothes if necessary.
- Measure anatomical features using a flexible tape including thigh and calf circumference and leg length.

Task 2: Equipment setup

- Secure leg straps to the participant's body and confirm comfort.
- Initiate data collection device and ensure connection to Smartphone app.
- Record non-personally identifiable participant information within the app.
- Validate system operation by confirming communication between app and all data collection channels.
- Sensors will be calibrated by guiding the participant through specific limb movements both standing and sitting.

Task 3: Treadmill trial

- Participant will be guided onto a treadmill with side handles.
- An overhead safety harness will be fitted to the participant.
- Walking will be initiated on the treadmill at a rate no more than the participant's comfort level at a participant-reported speed for up to 5 minutes while movement data is collected.
  Data will be reviewed to confirm readiness for treadmill gait protocol.
- The process will then be repeated up to 5 times for walking intervals of up to 2 minutes while data is collected and reviewed.
- Verbal check-in with participant for pain, understanding and need for a break.

Task 4: Treadmill trial with stimulation assist

- Participant remains on the treadmill with side handles.
- An overhead safety harness remains fitted to the participant.
- A gait assist algorithm will be entered into the Apollo system.
- Walking will be initiated on the treadmill at a rate no more than the participant's comfort level
- After notifying participant, the electrical stimulation algorithm will be applied to the leg electrodes, starting at 0mA and slowly increased until effective gait is achieved or the participant reports discomfort. If pain or discomfort is reported the stimulation and treadmill will be stopped immediately.
- The process may be repeated up to 10 times with different gait assist algorithms.
- Verbal check-in with participant for pain, understanding and need for a break.

Task 5: Stimulated Assisted Exercise

- The participant will choose 1-3 exercises that they already do regularly as part of their physical therapy. If none are identified, seated toe raises, half raises, and leg extensions will be suggested
- Participant will complete 1-10 reps of each to calibrate the Apollo device
- Participant will repeat this process with low stimulation turned on
- Based on participant feedback, stimulation parameters will be tuned as much as needed to maximize comfort and utility

After completion of all tasks, equipment will be removed from the participant and sanitized with isopropyl alcohol. A brief post-study survey will be administered verbally or via computer by the study coordinator.

Pediatric Accommodations

All sessions were designed to accommodate children by aiming for a total time of < 1.5 hours. In addition, entertainment activities like books, coloring pens and paper, and an ipad with childrens games will be available for children to play during setup times (as long as parents approve). Children will also be addressed directly to ensure they fully

comprehend their study rights and to confirm that they are in full control of their participation.

Risk & Benefit Assessment

The Apollo System represents minimal risk to the participants participating in each session of the data collection study. Like with any study of this kind, there are some known risks, that although rare, are associated with participation:

- Some participants may experience slight pain or discomfort from the electrical stimulation
- Minor skin irritation at the site of sensor/electrode placement
- Some participants my experience anxiety or anxiousness due to the anticipation of receiving an electrical stimulation
- Injury caused by unintended falls
- Exposure to COVID-19 or other communicable disease

It is not always possible to know all of the risks associated with a study like this one. If any new risks are reported for this study, someone from the study team will let the participant know so that they can decide if they would like to continue taking part.

<u>Risk Mitigation Strategies</u>

Cionic has done the following things to reduce the risks to participants.

- Have done internal experiments and made design modifications to increase safety
- Cionic team is well trained and to strictly follow the study protocols
- Participants will have the option to wear a safety harness secured overhead to protect them from falls. Session C will require all participants to be in harness.
- The testing area will be safe, well lit and clear of all obstacles
- Any actions will be discussed with the participant prior and their comfort will be monitored throughout the study
- participants will self manage a walking speed and control their level of electrical stimulation for their own comfort level
- A COVID safety protocol will be strictly adhered to, requiring all people who visit the site to check temperatures, practice social distancing, require mask

wearing and follow all other CDC guidelines to prevent the spread of COVID-19

Benefits

This study is intended to benefit future participants, should it prove to provide great knowledge to clinicians and therapists of possible targeted treatments for neurological injuries or conditions that impact the lower extremities and limit mobility.

Participant Identification, Recruitment & Informed Consent

Method

Cionic will be working directly with physical therapy providers and participant advocacy groups to identify an impacted population. Starfish Therapies will identify existing physical therapy patients and will refer them by email to Cionic. In addition, Cionic will be utilizing the services of a third-party recruiter, User Interviews, to recruit participants in the adult study. User Interviews will serve as our primary recruiting tool for adults, but may also contribute toward pediatrics as well. User Interviews is an online platform that will email our recruitment flyer to individuals who have registered with the site expressing desire to participate in research. Interested candidates will complete the short screener survey.

The PI will reach out candidates who qualify for the study to set up a Zoom meeting to introduce candidates to the study and further screen participation based on the candidate's ability to walk safely and grasp basic compression. All the discussion and dialogue will follow a script. There will also be a short slide deck that will be shared with all potential participants that shares information about Cionic and the study.

Candidates that qualify and are interested in participating will be sent the digital Informed Consent form and virtually walked through it. Candidates do not need to sign the consent prior to arriving for data collection. After the Zoom meeting, candidates who qualify will be notified to schedule a time slot to participate using Google calendar. When they arrive, the Consent doc will be reviewed and signed if it has not already been done. After the data collection is completed, User Interviews disburses the Amazon gift card compensation to participants digitally.

We will also post recruitment pages on our website (one for pediatrics and one for adults). Interested candidates who click through the website or email research@cionic.com will be contacted via email to begin the same screening process outlined above.

Physical copies of the recruitment flyer may also be posted at local physical therapy clinics if they agree to allow us to post them. The screening and intake process will be identical to what is identified above.

Consent Process

Selected participants, and/or parents of pediatric participants, will be provided an PDF electronic consent form for their review. A member of the Cionic team will walk the participant through the informed consent form and encourage them to take time to review and reach out with any questions at all. The participants will be sent a DocuSign link to provide consent signature. Alternatively, they can bring the signed paper informed consent form to their first visit. In addition, basic assent forms will be shared with pediatric participants. All forms will be stored on a secure server, paper forms will be digitized and destroyed.

Participant Capacity and Comprehension

The study's inclusion criteria and recruitment plan may include individuals with impairments that are sometimes associated with decision making impairments and/or language impairments. The pre-screening video conference call is in place to determine if the severity of these impairments will require additional safeguards or if the interested party will need to be excluded from the study.

Study Withdrawal

During the consent process participants will be informed that they may withdraw from the study at any time. We will confirm that they understand that they have this option. Participants will be entitled to financial compensation if they withdraw from the study for each session that they physically attend. Participants will not be compensated for data collection sessions that they cancel or miss.

Data Storage, Monitoring and HIPAA

This study involves the collection of data from sensors on the Apollo system as well as possible external kinematic data collection systems for validation. No data collected includes personally identifiable information. The devices comprising the system connect wirelessly via Bluetooth to an application running on a smartphone.

The smartphone's camera will also record video of the lower body only. The participant's face and voice will not be recorded. The content of the data will be uploaded to a secure server. Each set of data will be organized using a unique numerical identifier that does not include PHI (e.g., initials) such as date of testing and study Session. This unique identifier will be recorded separately in a participant tracking file which will include demographic data such as gender and age, diagnosis, time since onset and qualitative rating of their mobility. Adverse events and protocol deviations will be recorded for each participant. This data will also be stored on a secure server.

Primary Investigator Dean Achelis will be responsible for ensuring participants' safety on a daily basis. Data collected from this study will be reviewed on a weekly basis by the PI and Sponsor for each week there are study participants. All data collected on paper and entered into electronic format will be verified by a second individual and discrepancies will be reviewed by the PI for resolution. Resolution can include correction of the entry, leaving the entered data in place, or removal of the specific data. There is no DSMB for this study.

All Adverse Events (AEs) will be reviewed by the PI within one business day of occurrence. AEs determined to be Serious Adverse Events related to subject safety will be reported to Ethical & Independent Review Services IRB within one business day of review by the PI. Adverse Events and Unanticipated Problems will be reviewed on a monthly basis in order to ensure good practice and identify any emerging issues of concern. The PI will determine whether the study should be modified based on these findings.

Quality assurance activities include following written and consistent procedures. Data collection pages will be reviewed monthly to ensure the quality of the data collection, management and analysis

The study sponsors recognize the requirement to adhere to the Health Insurance Portability and Accountability Act (HIPAA). As stated, we will not be recording PHI and data will be stored on a secure server. Additionally, individual data will not be publicly disclosed. In the future, aggregate data from the study (mean, variance, demographic data) may be disclosed to the FDA to support regulatory submissions.

Data Storage and Contact for Future Studies

In the screening questionnaire and Informed Consent doc, participants will indicate whether they would like their information to be saved for future studies. If they select "Yes", their information will be saved. If they select "No," their information will be destroyed from all databases.

Statistical Analysis

This is a broad study intended to collect data on individual participants. Key measurements such as walking speed, range of motion and muscle activation may be pooled for determination of average values and deviation. This study is not intended to generate statistically significant data intended to infer any clinical diagnosis or recommendation.

Debriefing Procedures

After each session of the study there will be a post-study debriefing with the participant where they will be encouraged to give feedback and complete the Exit Interview.

Costs to participants

No charges will be made to any participants or parental guardians.

Payment for Participation

Participants will be given a $50- $100 Amazon gift card for each session of the study in which they participate, given at the time of the visit. We will start by offering a $50 gift

card, but if we struggle to recruit will apply for a revision to increase the compensation up to $100.