| DEBUT Phsase 2B Product Development Timeline | | | Creator | Andrew D'Onofrio | |
|---|---|---|---|---|---|
| | | | Date | 6/25/2025 | |
| **Checkpoint** | | | **Components** | | *Ideal Date* |
| *Term* | *Title* | *Description* | *Goal* | *Title* | *Est. End* |
| C0 | Clinical & Engineering Reasoning (CER) | Completed SPR from the Phase One Development (Previously Referred to as Early Feasibilty Technical Report). Includes basic components to dive into early feasibilty studies and defining goals for long term verification / validation (usability) testing. This includes the following components<br>1. Project Scope (Clinical Background, Mechanisms, Users)<br>2. Research Index of Predicate Devices/ Experiments<br>3. Benchtop Components Bill of Materials<br>4. Procedural for Biomechanics/ Biological Algorithms<br>5. Device Concept Art and Due Diligence Reports<br>6. Customer Discovery Questions and Interviewees | G1 | Project Scope | |
| | | | G2 | Research of Predicate Devices/ Experiments | |
| | | | G3 | Benchtop | |
| | | | G4 | Algorithms | |
| | | | G5 | Customer Discovery | 08/26/25* |
| C1_D (Design) | Minimum Viable Product (MVP) | Initial Working Prototype with "Unofficial" Dataset proving viability of the individual components and integrated system. Concentrated R&D efforts (mechanical, computational, electrical) to create feasible and characterized parts. This process is progressive and includes the following:<br>1. Testing Isolated to Individual Components<br>2. Testing of Components Integrated onto a Benchtop Model<br>3. Testing of Components Integrated with a Participant (internal DEBUT member)<br>4. Testing of Components Integrated (+SWE) with Participant (internal DEBUT member)<br>Following confirmation of design, product will udnergo extensive design documentation and a comprehensive design freeze | G1 | Design Ideation | |
| | | | G2 | Prototype V1.0 | 10/31/25 |
| | | | G3 | Isolated Testing | |
| | | | G4 | Integrated Benchtop Testing | |
| | | | G5 | Integrated Simulated Testing | |
| | | | G6 | Integrated Simulated Testing with GUI | 2/1/26 |
| | | | G7 | Design Freeze | 2/1/26 |
| | | | G8 | Up-Scale | 3/1/26 |
| C1_Q (Regulatory) | Structuring Good Manufacturing Practices (GMP) | Creating the overall structure for proper documentation to ensure meeting the regulatory guidelines for the FDA and any regulatory submission, ranging from compiling a complete regulatory submission strategy that incorporates speicfic predicessor devices, creates strategies for risk mitigation, and integrates clinical feedback into design practices | G1 | Review FDA Regulatory Guidelines | |
| | | | G2 | Design History File (DHF) | 10/31/25 |
| | | | G3 | Risk Management File | |
| | | | G4 | Device Classification | |
| | | | G5 | ISO Standard Evaluation | 2/1/26 |
| C1_T (Testing) | IRB Testing Preparation | Evaluating the necessary benchmarks for affirming early validation testing and constructing testing worflows (equipment, measuring parameters, control variables, etc.) to create consistent dataset. The general step by steps includes:<br>1. Identifying resources for testing<br>2. Evaluating the Stakeholder Requirments (i.e. what convinces specialists of viability, investors to invest; x% reduction means y patients are saved)<br>3. Create a testing workflow that details the equipment requirements, personel requirements, experiemtnal components, testing equipment<br>4. Compiling information into a clear SOP for team to utilize during IRB writings/ clinical study | G1 | Testing Ideation | 10/31/25 |
| | | | G2 | IRB Testing Team | |
| | | | G3 | IRB Application | 11/15/25 |
| | | | G4 | Clinical Trainings | 2/1/26 |
| | | | G5 | Testing Equipment Completion | 2/1/26 |
| C2 | Early Feasibility Study/ IRB Mock Run | Confirm Results from C1_D and C1_T to affirm testing viability prior to official IRB dataset | G1 | Conduct Mock Test | 2/15/26 |
| **COMPLETED AFTER EARLY FEASIBILITY STUDY** | | | | | 3/15/25 |
| C3_D (Design) | Communication of Engineering and Clinical Learnings | Compile the IRB/ Clinical Data with workflow defined through C1_T, meeting statistical guidelines pre-established by project manager and FDA requirements. Additionally, compile data in accordance with legal guidelines that is clear to non-technical members of DEBUT | G1 | Post-Processing Data | |
| | | | G2 | Technical Writing Report | |
| | | | G3 | Engineering Communication | 4/15/25 |
| C3_Q (Quality) | 510(k) Premarket Notification | Meet the regulatory guidelines (or in place) identify areas where investment is needed in order to meet various regulatory guidelines established by the FDA, ISO, and CE regulations. Involves meeting with FDA staff members, MBDA/MS members for submission suggestions, and refining our scope to set-up direct areas of investment. Additionally, ensure that all design history files and design risk files are up-to-date | G1 | 510(k) Premarket Notification | |
| | | | G2 | IP Development | 5/1/25 |
| **COMPLETED ALL DATA CONSOLIDATION** | | | | | 5/1/25 |
| C4 | Commercialization | Compile manufacturing/BOM reports from the R&D phase, create slidedecks/ basic marketing materials (brand identity, name, color sheme), finalize into wholistic pitch report. Cap development with discussion about future potentials for IP, liscensing, etc. | G1 | DEBUT VentureWell Report (NIH/NBIB) | 5/1/25 |
| | | | G2 | Team Evaluation for Entrepreneurial Venture | 5/1/25 |

| DEBUT Phase 2B Next Steps | | | | Creator | Andrew D'Onofrio |
|---|---|---|---|---|---|
| | | | | Date | 7/21/2025 |
| **Role** | **Next Steps** | **Major Goal** | **Specific** | | **Date** |
| Electrical Engineers | Block Diagram for Sensor Data | G1/G2 (Design Ideation and Prototype V1.0) | Create Usable Sensors with Understood/ Clean Data Outputs | | 10/5/2025 |
| | Collect Datasheets for Sensors | | Create a BASIC Circuit and Arduino Processing System for Collecting Data | | 10/5/2025 |
| | Arduino Tutorial (Online/ Andrew) | | | | |
| | Electrical Equipment Training (Reading Datasheets) | | | | |
| Mechanical Engineers | List Expected Design Constraints from Usability and Sensors | G1/G2 (Design Ideation and Prototype V1.0) | Hand-Drawn Sketches with Specific Dimensions (Dimension Database) | | 9/21/2025 |
| | Find "Dummies" for Mechanical Benchtop Testing (Mock Arm) | | Low-Fidelity CAD Designs for ALL Mechanical Components | | 10/12/2025 |
| | Create Measurement Database ("Muscles are __ in from the elbow") | | Prototype V1.0 | | 10/26/2025 |
| Computational Engineer | In-Depth Understanding of Physiologic System | G1/G2 (Design Ideation and Prototype V1.0) | Create the Framework Code for Post-Processing | | 10/5/2025 |
| | Block Diagram for Data Processing Strategy | | Functional Script | | 10/26/2025 |
| | MATLAB/ Python Tutorial | | | | |
| | Find Ope-Source Codes for Modelling Similar Physiological Systems (uses similar inputs, gives CORRECT outputs) | | | | |
| Testing Engineer | Understand Verification Requirements | G1 (Testing Ideation) | Create a Verification Testing Suite of Methods for R&D | | 10/5/2025 |
| | Create List of Tests for Verifying Results (pre-IRB Testing) | | | | |
| Software Engineer | Block Diagram for GUI | G1/G2 (Design Ideation and Prototype V1.0) | Hand-Drawn GUI Interface/ Final Specified Block Diagram | | 10/5/2025 |
| | App Dev./ Website Building Tutorial | | BASIC Infrastructure for GUI (End-to-End) | | 11/16/2025 |
| | Research Data Streaming Strategies (BLE) | | | | |
| Quality Engineer | Read FDA/CFR Written Strategy Recommendations | G1/G2/G3 (Review FDA Regulatory Guidelines, Design History File (DHF), Risk Management File) | Create Basics Regulatory Strategy (Device Type, CFRs, Classifications) | | 10/5/2015 |
| | Regulatory Tutorial | | Evaluate Business Strategy User/Clincial Report Requirements | | 12/07/2025 |
| | Update Business Strategy Questionarre to include risk maangement/ usability questions | | | | |
| | Patent Inquiry/ IP Management | | | | |
| Business Strategists | Continue User/Clinical Interviews | N/A | Compile User/Clincial Report Requirements from Interviews | | 12/07/2025 |
| | Compile Risk Managemnt/ Usbaility Questionarre | | Create a Regulatory Strategy with Quality Team and Evaluate Business Feasibility | | 10/5/2025 |
| | Read FDA/CFR Written Strategy Recommendations | | | | |