DEBUT Technical Workshop #1: **Documentation of Experimental Designs**

Andrew D'Onofrio
Phase 1B Project Manager
ajd323@cornell.edu

CORNELL DEBUT
BIOMEDICAL ENGINEERING PROJECT TEAM

Contents

CORNELL DEBUT
Biomedical Engineering Project Team

I.
What is the purpose of robust testing and documentation for MedTech in entrepreneurship?

CORNELL DEBUT
BIOMEDICAL ENGINEERING PROJECT TEAM

Stakeholders

Individuals with vested interest or impact on the development of a product

---

Customers

Ex.

Nurses
Doctors
Patients

Investors

Ex.

Venture Capital
Corporate Investors

Regulators

Ex.

FDA (Primary)
CDC
WHO

Stakeholders

Customers	Investors	Regulators
Is it worth the cost? Is it similar to other? Is it realistically usable? Is it necessary for me?	Are next steps realistic? How long until profit? How scalable?	Is there predicate? Are you legitimate? Is your product realistic?
Convince to Buy	**Convince to Invest**	**Convince to Sell**

CORNELL DEBUT
BIOMEDICAL ENGINEERING PROJECT TEAM

Types of Testing

User Needs (Usable, Necessity, Accessibility)	• Customer Discovery/ Needs Evaluation • Design Testing • Customer Surveying
Product Value (Manufacturability, Demand, ROI, Potential for Growth)	• **Robust** Manufacturing Procedural • Consult w/ Contract Manufacturers (CMs) • Investing Portfolios with Growth Areas
Efficacy (Reliability, Universality, Validity, Value to Market)	• Verification and Validation • Clinical Trials (MedTech specific)

Types of Testing

Specific Experimentation Required

Specific Documentation Required

Why?
Can't convince customers, investors, and regulators with bad documentation and testing

- Customer Discovery/ Needs Evaluation
- Design Testing
- Customer Surveying

- **Robust** Manufacturing Procedural
- Consult w/ Contract Manufacturers (CMs)
- Investing Portfolios with Growth Areas

- Verification and Validation Testing
- Clinical Trials (MedTech specific)

II.
What is DEBUT's specific process for the two-year product cycle and Why?

CORNELL DEBUT
BIOMEDICAL ENGINEERING PROJECT TEAM

Product Timeline

Cornerstone Ideas of Early MedTech Product Development

Ideation	Verification	Validation	Commercialization

These stages vary in length, depth, and complexity from project-to-project, company-to-company, and even country-to-country

Causes for Variations:

1. Novelty of Product
2. Complexity in Design
3. Complexity in Testing
4. Accessibility of End User

CORNELL DEBUT
BIOMEDICAL ENGINEERING PROJECT TEAM

DEBUT's Big Ideas

1. Compared to the typical MedTech start-up, Cornell DEBUT has a **compressed timeline** for R&D (for variety)
2. Our goal is to create a product that reaches **all three stakeholders** (customers, investors, regulators)
3. Our process covers the **first three major cornerstones** of MedTech development and creates a product with **commercial potential**

CORNELL DEBUT
Biomedical Engineering Project Team

DEBUT Timeline

Ideation	Verification	Validation	Protofacturing
~6 months (Sem 1)	~6 months (Sem 2)	~6 months (Sem 3)	~6 months (Sem 4)
What is the Idea? • Customer Discovery • ISRs • Establish Design Metrics	**Do we Meet Metrics?** • SPRs • Feasibility Testing • Characterization Testing • Report Design Constraints • Alpha Prototyping	**Does Device Work?** • Usability Testing • Experimentation with Use Cases (*ex. IRB testing*) • Beta Prototyping	**Is it Investable?** • Creating Manufacturing Procedurals • Compile Portfolio and Pitch • Design Freezes • Protofacturing

**Phase 1 Off schedule due to VentureWell Presentations/ Medtronic Competition*

CORNELL DEBUT
BIOMEDICAL ENGINEERING PROJECT TEAM

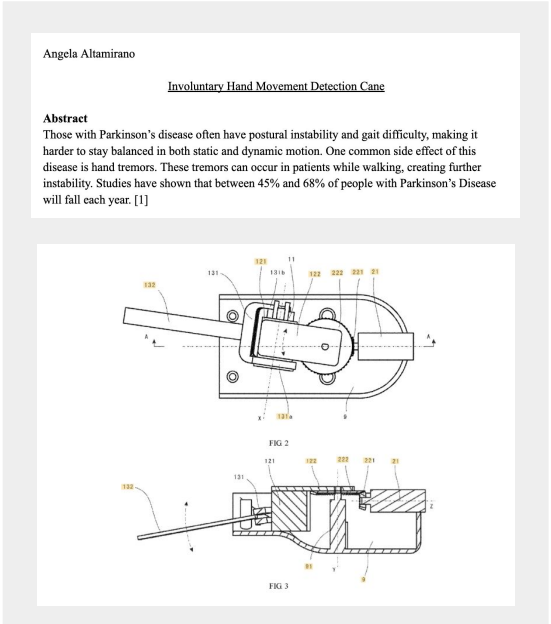
Timeline In Context

Example: Involuntary Hand Movement Detection Cane (*SteadyStride*)

- An R&D member (Angela) creates an ISR with the idea
  - General technology outlined
  - Basic Goals for Usage
  - Doesn't look like final product
- Some Customer Discovery is Conducted w/ Parkinson's patients
- Metrics for Success are Set

What are the Next Steps?

Ideation



Angela Altamirano

Involuntary Hand Movement Detection Cane

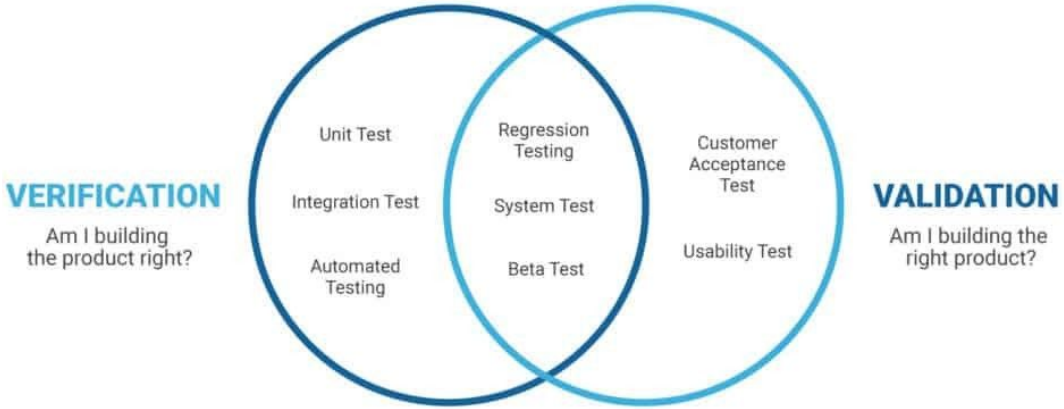
Abstract

Those with Parkinson's disease often have postural instability and gait difficulty, making it harder to stay balanced in both static and dynamic motion. One common side effect of this disease is hand tremors. These tremors can occur in patients while walking, creating further instability. Studies have shown that between 45% and 68% of people with Parkinson's Disease will fall each year. [1]

CORNELL DEBUT
BIOMEDICAL ENGINEERING PROJECT TEAM

Verification & Validation

All devices must undergo Verification and Validation (V&V)



<u>Verification</u> - Do we Meet Metrics?

Testing that a device operates to requirement correctly (Sem 2)

<u>Validation</u> - Does Device Work?

Testing that a device meets the users needs

CORNELL DEBUT
Biomedical Engineering Project Team

Verification & Validation

Verification - Testing that a device operates to requirement correctly

- *Feasibility Testing* - Testing the likelihood of success with set constraints (typically with predictive models, design reports, number crunching, etc.)
- *Alpha Prototyping* - The first iteration of a product that meets expectations by developers
- *Characterization Testing* - Testing the outcomes/characteristics of a products core features

Validation - Testing that a device meets the users needs

- *Usability Testing* - Testing how the intended users interact with the product for feedback
- *Beta Prototyping* (Minimum Viable Product) - The second iteration of a product that works as user's intend to use
- *Pre-Clinical Testing (pre-DV* Testing)* - Testing the functionality in context prior to investing resources towards official clinical testing

DEBUT Specific Timeline (Compressed compared to industry)

CORNELL DEBUT
BIOMEDICAL ENGINEERING PROJECT TEAM

Timeline In Context

Verification - Testing that a device operates to requirement correctly

- *Feasibility Testing* - **"How do we know this will work?"**
- *Alpha Prototyping* - **"Let's build this in whatever way will get this to be functional"**
- *Characterization Testing* - **"How will different parts of the alpha system perform"**

Validation - Testing that a device meets the users needs

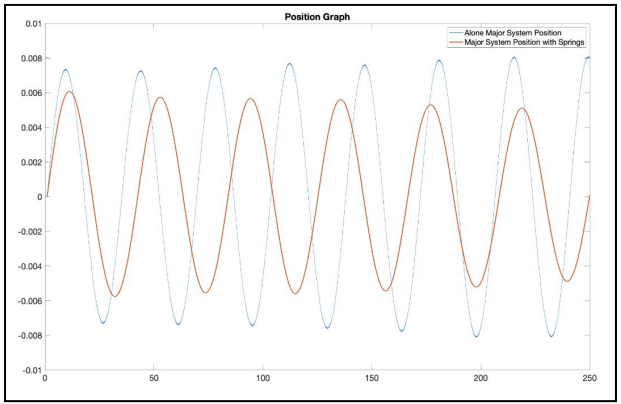
- *Usability Testing* - **"How will people interact and how do we improve these areas"**
- *Beta Prototyping* - **"Let's build a prototype similar to what people will use"**
- *Pre-Clinical Testing (pre-DV* Testing)* - **"What type/range of data will we expect from official clinical testing? Do we need to redesign due to unforeseen issues?"**

Let's go back to SteadyStride

SteadyStride Verification

Feasibility Testing

Affirmed tremors could realistically be dampened



Alpha Prototyping

Device that worked as intended for users

Characterization Testing

Checked the actual dampening effect

CORNELL DEBUT
BIOMEDICAL ENGINEERING PROJECT TEAM

SteadyStride Validation

Usability Testing
Discovered areas to improve the product and collect feedback/ data

Beta Prototyping
Device that both works and is close to intended (MVP)

Pre-Clinical Testing
Insight on clinical data to determine financial viability in clinical testing

***Product dependent**
(pre-clinical data was not conducted given more changes were made between the first round of testing and patent filling

CORNELL DEBUT
Biomedical Engineering Project Team

III.
What are the best practices for recording design/testing information prior to investment/FDA submission

CORNELL DEBUT
BIOMEDICAL ENGINEERING PROJECT TEAM

ALWAYS BE WRITING!!!

Something is always better than nothing,
prioritize recording EVERYTHING first!

Use weekly work summaries,
mid-semester and end-semester goals to
record everything that is possible

CORNELL DEBUT
BIOMEDICAL ENGINEERING PROJECT TEAM

Basic Documentation

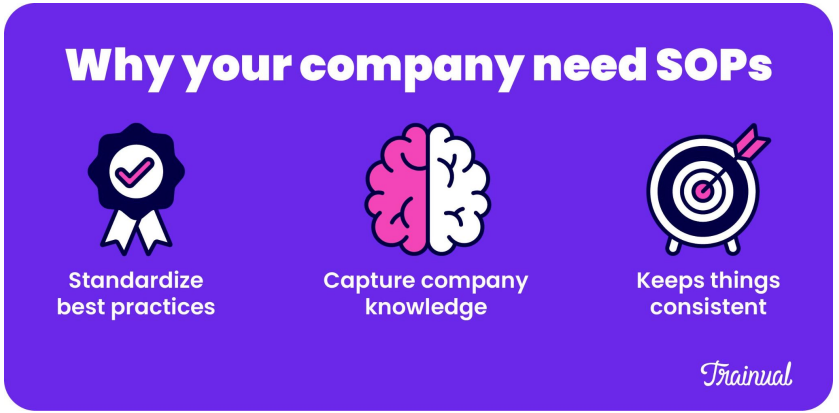
A majority of testing through each stage has an in-depth report describing the set-up and procedural of the experiment. This is necessary:

Regulatory Submission	Internal Reference
• Reproducibility • Transparency • Clarity • Cohesiveness **NO GAPS ARE PERMITTED**	• Cohesiveness between team members • Reduction in meetings • Ease for improving experimental design

CORNELL DEBUT
BIOMEDICAL ENGINEERING PROJECT TEAM

Standard Operating Procedure

1. **Standard Operating Procedure (SOP)** - A set of step-by-step instructions compiled to outline how to perform a task or process
    - Product Descriptions
    - Testing Procedures
    - Manufacturing Processes
    - **SOPs are major assignments, and typically are completed over the course of a project**



Standard Operating Procedure

A. **Purpose** - Describing the intent of the document/ project
B. **Scope** - The individuals intended to reference the document
C. **References/ Related Documents** - Other documents used
D. **Definitions** - Clarify terms, spell out acronyms/ abbreviations
E. **Roles and Responsibilities -** Members of the team involved
F. **Procedure**
    a. **Major Steps** -MAJOR Steps for accomplishing the objective
    b. **Action Steps** - Individual Action Items for completing steps
    c. **Notes** - Separate set of clarifying notes
G. **Appendices** - Additional notes from across the document
H. **Revision History** - List of times the documents been edited

Example Document Here

CORNELL DEBUT
BIOMEDICAL ENGINEERING PROJECT TEAM

Bill of Materials

2. Bill of Materials (BOM) - A set list of materials in a design to outline prototyping

- All prototype builds (alpha and beta)
- Protofacturing documentation
- Maintain a running list (besides internal accounting) on products that are purchased and implemented in our experimental designs

SteadyStride Team	***SteadyStride Bill of Materials***						Date Created:	September 16th, 2025	
							Contributors:	Andrew D'Onofrio & Emma Weiss	
Item	*Part Number*	*Description*	*Reason for Purchase*	*Package or Unit*	*Units Supplied*	*Supplier*	*Cane Unit Cost*	*Net Purchase Cost*	*Quantity*
1	41298013044	Base Cane	Overall Assembly	Unit	1 Unit	Amazon	14.99	14.99	1
2	1174N119	7 mm O-Rings	Overall Assembly	Package	1 Pack - 50 O-Rings	MacMaster-Carr	0.4268	21.34	6
3	A00-K0-1.75-1000-SPLFREE	Black Matte Plastic (PLA) Reel	Overall Assembly	Unit	1 Unit	3D Universe	25.99	25.99	1
4	700-001-1146	TPU Reel	TPU Base Assembly	Unit	1 Unit	Amazon	24.99	24.99	1
5	9262K875	110 mm O-Ring	TMD Assembly	Package	1 Pack - 5 O-Rings	MacMaster-Carr	1.546	7.73	1
6		Aluminum Mass	TMD Assembly						
7	92095A127	M5 x 20 mm Black Oxide Bolts	TMD Assembly	Package	1 Pack - 25 Bolts	MacMaster-Carr	0.3412	8.53	16
8	90593A004	M5 x 2.00 mm Black Oxide Nuts	TMD Assembly	Package	1 Pack - 100 Bolts	MacMaster-Carr	0.1345	13.45	16
9	9455K285	Specialty Gaskets	Bosu Assembly	Unit	1 Unit	MacMaster-Carr	13.83	13.83	1
10	97763A456	M3 x 16mm Black Oxide Bolts	Spring Interfaces	Package	1 Pack - 25 Bolts	MacMaster-Carr	0.44	11	4
11	9657K74	Compression Springs	Springs	Unit	1 Unit	MacMaster-Carr	0.7525	9.03	4
12	91290A438	M8 Bolts x 35 mm	Overall Assembly	Package	1 Pack - 50 Bolts	MacMaster-Carr	0.2986	14.93	9
13	9560T7	PlastiDip	TPU Base Assembly	Unit	1 Unit	MacMaster-Carr	4.61	18.44	1
14		Locrite Adhesive	TMD Assembly						
15		Graphite Lubricant	TMD Assembly						
16	K02754007	Black Spray Paint	TPU Base Assembly	Unit	1 Unit	Amazon	6.98	6.98	1
17	7610A37	Spray Adhesive	Overall Assembly	Unit	1 Unit	MacMaster-Carr	4.175	16.7	1
						Unit Cost	99.5046		

CORNELL DEBUT
BIOMEDICAL ENGINEERING PROJECT TEAM

Bill of Materials

A. **Part Number** - Supplier Part Number
B. **Description** - Basic Details about the component purchased
C. **Reason for Purchase** - Describe where the component will be use
D. **Package or Unit/ Units Supplied** - The amount that is purchased through the supplier link
E. **Supplier** - Company providing the component
F. **Unit Cost** - UNIT cost of each individual component purchased
G. **Net Purchase Cost** - Amount spent to obtain the minimum amount of the component required for build
H. **Quantity** - Number of units needed for the build

Example Document Here

CORNELL DEBUT
BIOMEDICAL ENGINEERING PROJECT TEAM

Thank You!

Any questions? Also can email Andrew with any questions as well

CORNELL DEBUT
Biomedical Engineering Project Team