

Hemalibrium



A new way forward
through early diagnosis

The Problem

Over **5 million** people in the United States suffer from heart failure with a projection of **8 million** by 2030

With more than **26,000** people obtaining mechanical circulatory support (MCS) systems in the United States each year, more people are developing acquired von Willebrand syndrome (aVWS)

Acquired von Willebrand syndrome occurs when the von Willebrand protein in the blood is at low concentrations or becomes deformed and ineffective for clotting

The current standard test (PTT) is not accurate for this unique patient population, resulting in misdiagnosis of aVWS

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The Problem

A reliable screening tool for patients who have aVWS and who use MCS systems is **not** available on the market



Current Method

Patient blood is collected in a vacutainer and sent to a large hematology laboratory for analysis

Blood has to be isolated and then analyzed using a partial thromboplastin time (PTT) test

The first line test does not always confirm the diagnosis of aVWS when MCS devices are used



Solution

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Innovative

Easy-To-Use

Novel

Practical

A focused diagnostic tool geared towards acquired von Willebrand Syndrome for people using MCS systems

Solution

- Identify MCS users who are at higher risk of internal bleeding
- Provide a test that can accurately screen for vWF and the probability of future bleeding events
- Reduce the cost needed for an effective tool used by patients and providers
- Ensure rapid analysis during a point-of-care visit

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Competitive Landscape

				
Point-Of-Care				
Targeted				
Reliable				
Easy-To-Use				

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Market Opportunity



Targeting the diagnostic side of MCS users with aVWS enables our company to focus on a **specific** customer base

Our product will save over **100 million** in avoidable hospital visits each year from the already strained healthcare system

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Business Model

Value creation

Our product will revolutionize the diagnostic capacity for these patients, while limiting the unnecessary pain incurred when current methods are not effective

Value delivery

Our team will go from benchtop to bedside using the most cutting edge technology and unbridled fruition

Value extraction

Deliverables will be given to providers on a planned schedule, and our product will be consumable

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Reimbursement

Coverage

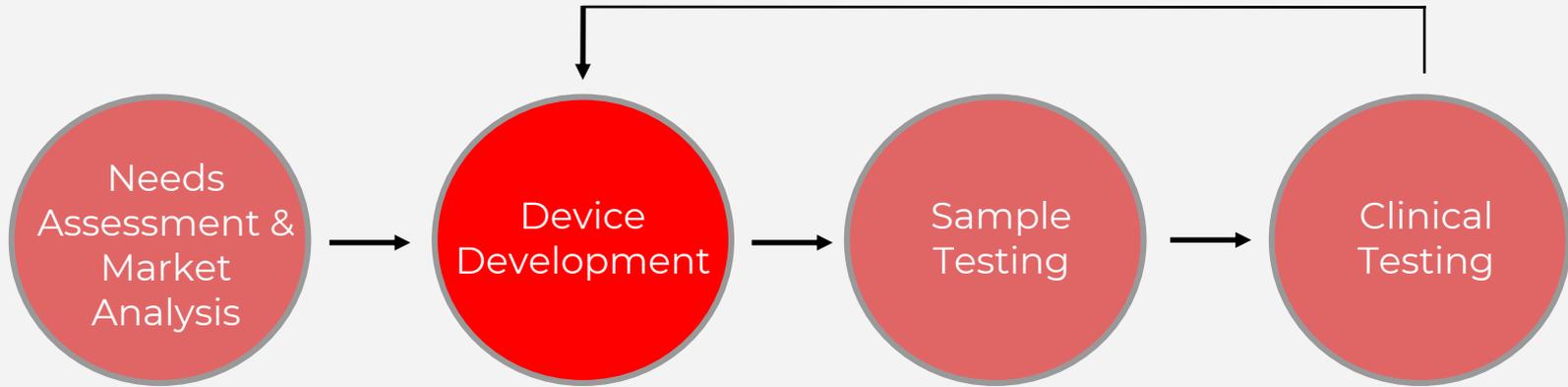
Our product will be eligible for reimbursement rates similar to other diagnostic products on the market as a laboratory expense

Savings

- 5 million people in the United States have heart failure
- 26,000 patients require mechanical circulatory support (MCS)
- Testing this subset of patients can eliminate the need for ED visits prior to complications
- Potential savings from ED visits alone
 - 150 million



Technology Validation



Customer Validation

Internist

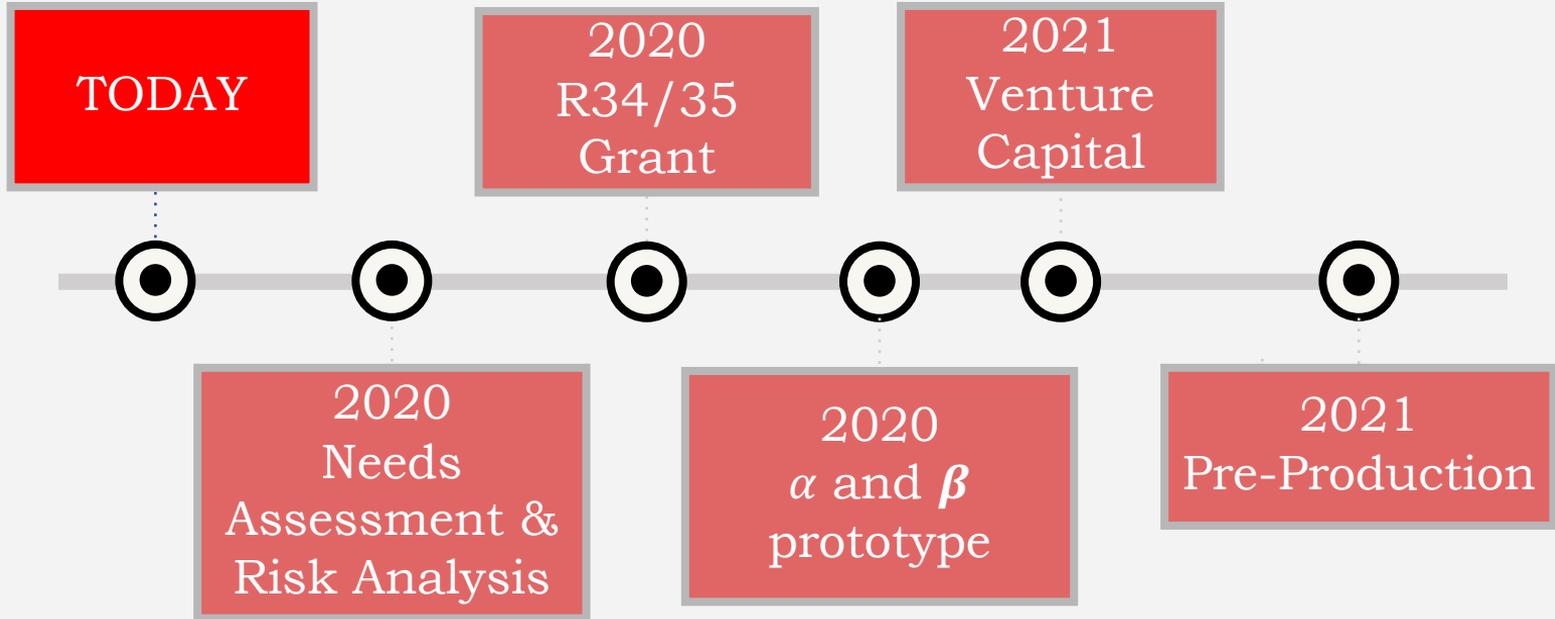
I think this is a really important problem for a lot of patients waiting for transplants and who have them.

As our company grows, we will conduct broader market research of our targeted patient population and consumers that will purchase our innovative device

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Timeline



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Regulation

FDA Classification

Class 2 device based upon current medical devices

Filing Method

510(k) premarket submission

Timeline

2-3 years

New Search		Back to Search Results
Device	Coagulation System For The Measurement Of Whole Blood Viscoelastic Properties	
Definition	A coagulation system for the measurement of whole blood viscoelastic properties is an in vitro diagnostic device used to evaluate blood coagulation, fibrinolysis, or both, in patients.	
Physical State	Automated or semi-automated instrument with ultrasound-based technology. Cartridges with reagents.	
Technical Method	Ultrasound technology to assess coagulation characteristics of blood.	
Target Area	Blood	
Regulation Medical Specialty	Hematology	
Review Panel	Hematology	
Product Code	QFR	
Premarket Review	Office of In Vitro Diagnostics and Radiological Health (OIR)	
Submission Type	510(k)	
Regulation Number	864.5430	
Device Class	2	
Total Product Life Cycle (TPLC)	TPLC Product Code Report	
GMP Exempt?	No	
Summary Malfunction Reporting	Ineligible	
Implanted Device?	No	
Life-Sustain/Support Device?	No	
Third Party Review	Not Third Party Eligible	

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Regulation

International Markets

Europe

European Medicines Agency (EMA)

Canada

Health Canada

China

National Medical Products Administration

Timeline

2-3 years after FDA approval



Leadership Team



Sana Syed

St. Louis
University PhD

Biomedical
Engineering



Kaitlyn Ammann

University of
Arizona PhD

Biomedical
Engineering



Avery Witting

Mayo Clinic
Research Fellow

Biomedical
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We are an up-in-coming, talented team looking to improve the lives of patients through focused diagnostic devices



Exit Strategy

Acquisition by multi-national company to become subsidiary

- Roche
- Abbott
- Beckman Coulter

Licencing or assign intellectual property to outside party

Potential Value: 20 million



Risk Mitigation

Risk Factor	Risk Mitigation Strategy
Market not supporting the device and associated costs	<ul style="list-style-type: none">● Perform market validation assessment with potential customers● Evaluate cost-benefit analysis of change within corporate structure
Operations management inhibiting aims of company	<ul style="list-style-type: none">● Implement specially crafted vetting process for new talent● Institute a strong culture built upon trust and dedication to vision
Financial solvency of company throughout the first 5 years of existing	<ul style="list-style-type: none">● Establish liquid channels of capital before expending resources● Form a diverse investment vehicle for continuous funding opportunities



Use of Funds

Specific Activity	Funds Required	Deliverable	Deliver By
Economic Viability Study	\$15,000	Report highlighting the viability of our product in its intended market	2/15/2020
Research Staff	\$150,000	Workforce able to find solutions to problems	3/1/2020
Marketing and Finance Team	\$130,000	Comprehensive reports on expenditures of capital and focused advertising proposals	3/1/2020
Laboratory Space and Equipment	\$200,000	Functional prototype	12/31/2020

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Thank you for this
opportunity to
grow, learn, and
innovate

