




**Navigating Requirements Ambiguity and Volatility**  
**One Step at a Time**  
**-or-**  
**Why Culture Matters**

**Culture** is the base on which success is built.





The image shows the lower legs and feet of two people walking on a cobblestone path. The scene is captured in a low-angle, silhouette style against a bright, hazy background. A dark, semi-transparent overlay covers the entire image, and the text is centered in white. The overall mood is professional and focused on health and movement.

Orpyx delivers wearable medical and health tools that quantify biometrics and provide decision support to optimize health outcomes







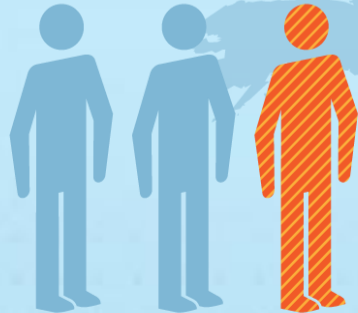


# The Problem

## Epidemic of Diabetes & Diabetic Foot Care



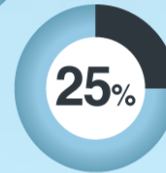
**Over 30%** (24% pre-diabetic  
or 9.4% diabetic)  
**1 in 3** North Americans  
136 million people are  
diabetic or pre-diabetic.



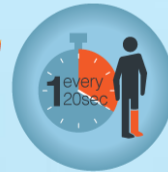
## Diabetic Peripheral Neuropathy



**1M** ulcers per year in the US



**25%** of people with diabetes  
develop ulcers during  
their lifetime.



**120,000** lower extremity  
amputations / year



Leading cause of  
hospitalization related  
to diabetes.

# The Problem

## Cost of Diabetic Foot Ulcers



Foot ulcers requiring acute care can result in treatment costs of up to **US\$70,000 per event**, varying with the severity of the wound.

*Journal - Advanced Skin Wound Care 14: 297-301*



# A Priority Solution

## Management of Diabetic Foot Ulcers



### SurroSense Rx® (V1)

International patent coverage

Registered medical device with  
FDA, Health Canada

First peripheral neuropathy  
compliance monitor



Replaces plantar protective  
sensation.

Designed to work in standard running  
or walking shoes. Sized to fit full  
complement of shoe sizes.

Flexible. <0.7mm thin.

Patient portal collects and  
interprets uploaded plantar  
pressure data.

Plantar pressure and foot  
movement measured in real-time  
via sensors.

Alerts and feedback provided via  
mobile app or smartwatch.

# A Digital Health Solution

Orpyx → Actionable Data → Reduced Ulceration



**COMPLETE**

## Pre-Clinical Studies

- Safety testing, ISO13485, US FDA 21CFR820 design control systems in place since 2013.
- Extensive third party external validation of sensor performance against gold-standard lab instruments.

**COMPLETE**

## Pilot & Case Studies

- Demonstrated **83%** relative risk reduction in callus and ulcer formation in high-risk patients
- Economics studies showed **70% cost savings**
- Case studies examine SSRx's utility in non-diabetic neuropathy

**COMPLETE**

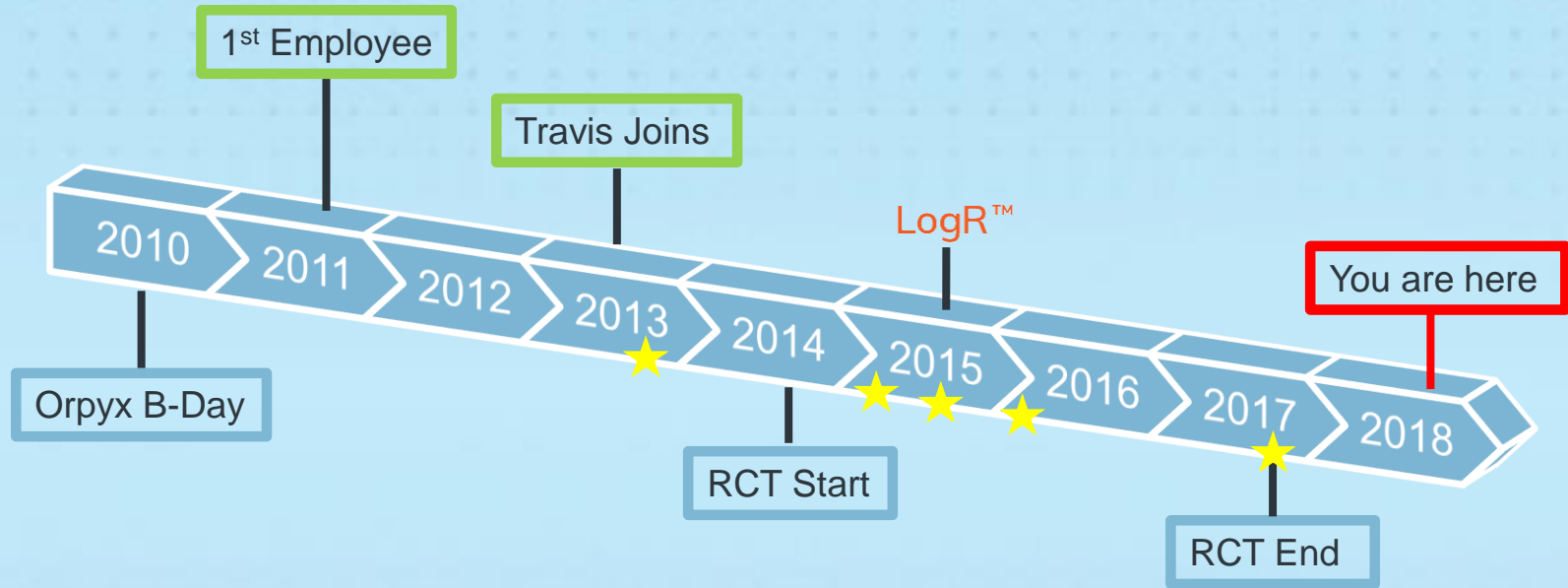
## Multi-Site RCT

- 3-year multi-site RCT (UK-based)
- Preparation of multiple publications underway

**IMPACT: Reduction**  
in ulceration



# Timeline – Key Events



★ - Trial End

# LogR™

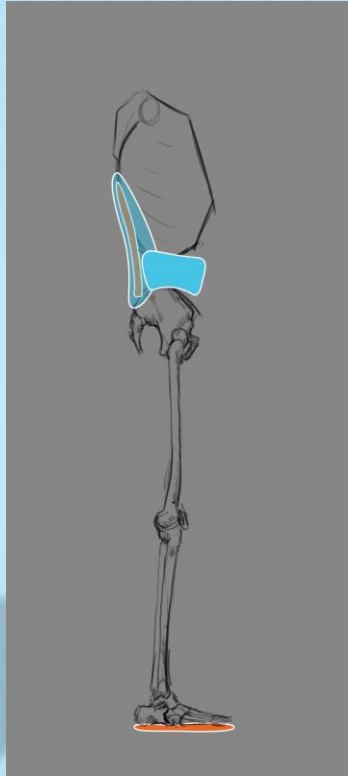
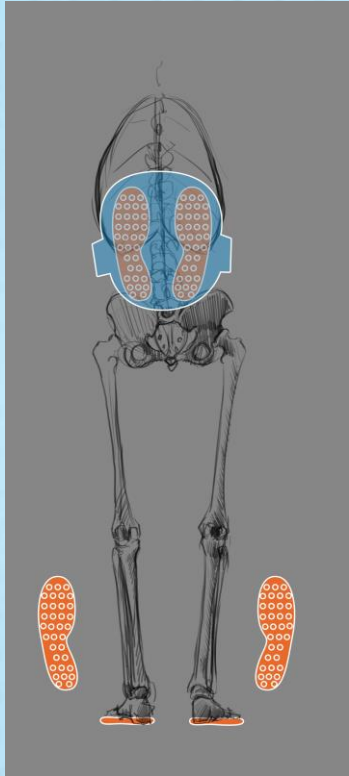
# ORPYX®





# SurroGait Rx™

ORPYX®



# Key Challenges



- First Mover – No predicate device
- Preventative – System is treatment based
- Evidence Based Medicine
- Regulatory & Reimbursement Hurdles

# Navigating Uncertainty



- Accept it - you're wrong about everything.
- Be system – not goal oriented
- Measure what matters
- Get the right people at the right time
- Build and evolve the culture



# Process

- Accept it - you're wrong about everything.
  - Identify and validate assumptions ASAP and continuously.
- MVP - Minimum Viable Process
  - What are your process/business requirements?
  - Constantly evaluate and evolve
  - Beware the downside risks
  - Must fit people and culture
- Process matters when the stakes are high.

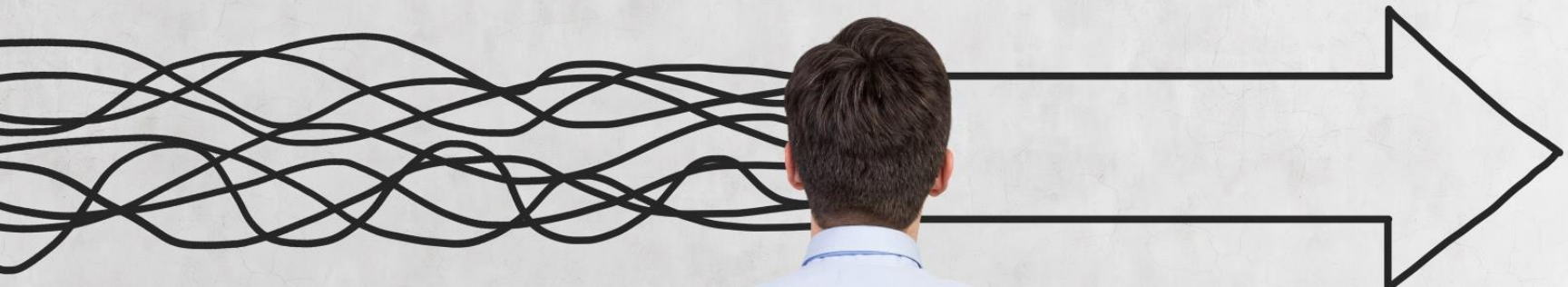




# Example – Orpyx Product Dev



- SCRUM Like Process
  - System oriented
  - Cross-functional
  - Weekly Iterations - Low Churn, Effective, Transparent
  - Integrated into our QMS System
- Focus on rapid/cost effective prototyping
- Built for uncertainty



# Example – Orpyx IP Process



- “Quantitative” Methodology For Evaluating IP
- IP are scored across 6 categories by a group.
- IP is ranked and prioritized based on score.
- Process is repeated for new and old items regularly.
- Outcomes are fed back into the process.

**FEELS QUANTITATIVE**



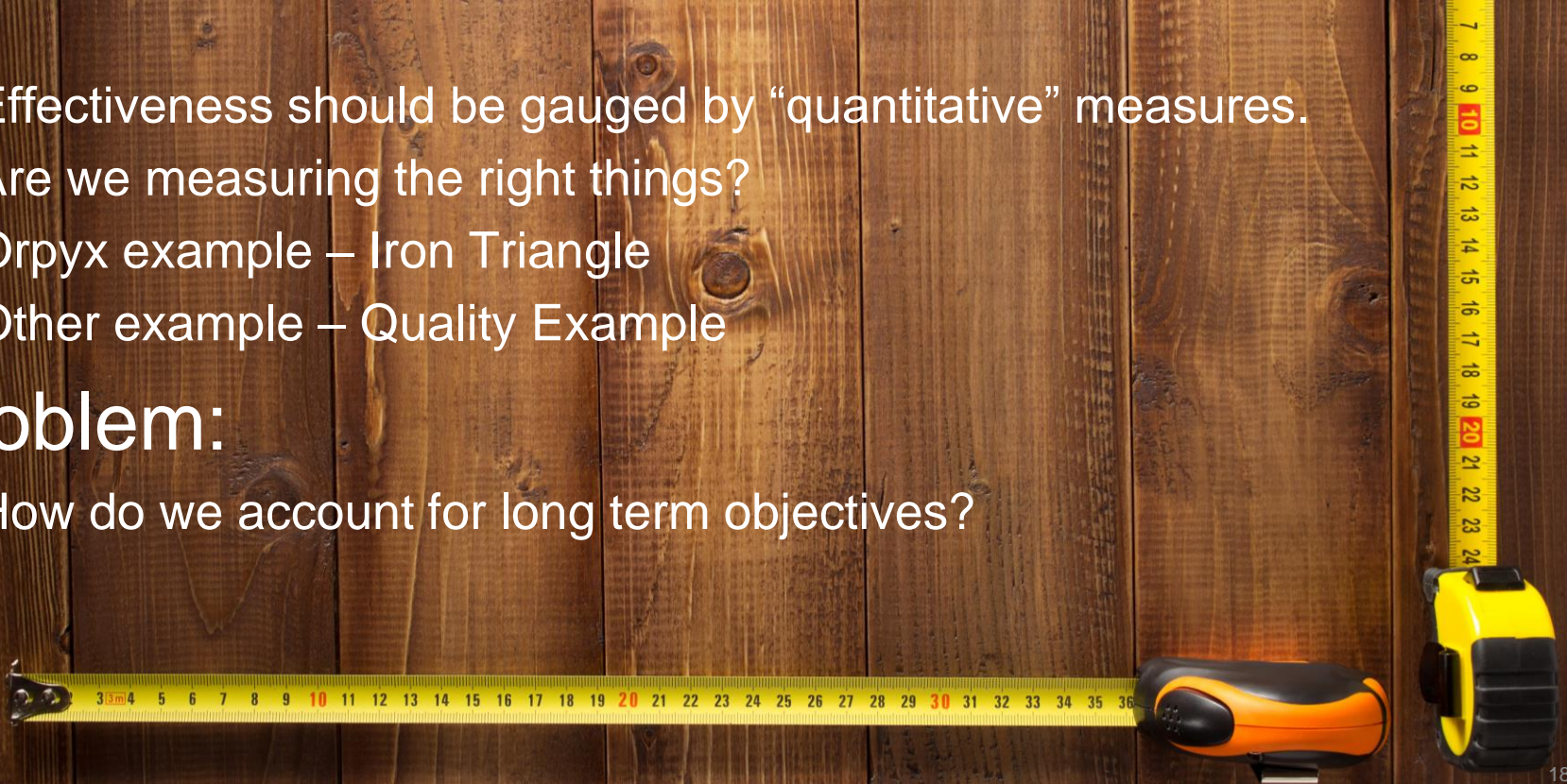


# Measure What Matters

- Effectiveness should be gauged by “quantitative” measures.
- Are we measuring the right things?
- Orpyx example – Iron Triangle
- Other example – Quality Example

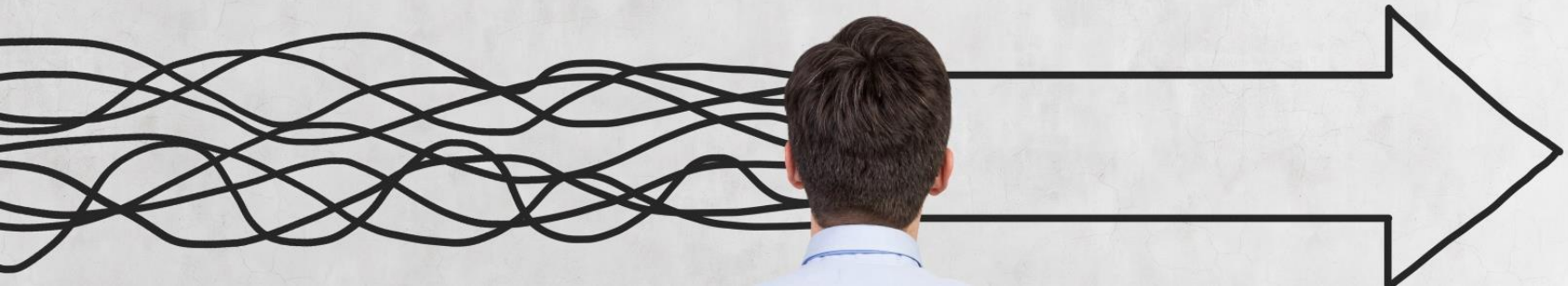
## Problem:

- How do we account for long term objectives?



# Process Conclusions

- You are probably wrong – your process should help with this.
- Process matters when the stakes are high.
- Never stop evolving your process – feedback loops and incrementalism are great.
- Process and metrics should long and short term focused.





# The People

- People Over Process
  - Agile Manifesto
  - Toyota
- People can make all the difference
  - Jimmy Garoppolo, Steve Jobs
- Culture and People are linked.
  - Every person is a culture microcosm.
  - Vibe Tribe



# The People

- Get the right people at the right time
  - The Alliance – Reid Hoffman
  - Cultural fit is critical
- People are “Predictably Irrational”
  - Behavioral Economics
  - This should/does affect your requirements
  - Know thy bias
- The Orpyx Example



# The People Conclusions



- Build systems to optimize for your people
- Never underestimate the power of the individual
- Cultural fit is critical
- Beware of your bias



# The Importance of Culture



- “Culture Eats Strategy for ...”
- Culture is your organizations guiding light.
- Values matter – but you have to live them.
- Employees shape the Culture and Vice Versa
- Culture can be explicit or implicit
  - Example - Orpyx is “Sciencey”
- Culture affects everything





# Culture Over Time

- 1<sup>st</sup> Law - A culture in motion tends to stay in motion acted upon by an unbalanced force (Inertia).
- 2<sup>nd</sup> – Culture equals people multiplied by time.
- 3<sup>rd</sup> – For every action there is likely an opposite over reaction.

# Culture and Requirements

- Requirements and Values Alignment/Misalignment
- Fossilized Requirements – “We’ve always done ...”
- Requirements gathering and validation.
- Requirements and prioritization.

# Conclusion

- Culture Eats Everything.
  - Be aware of this.
- People, Culture and Process are interdependent and reinforcing
  - Understanding is critical to exploiting it.
- Be explicit about your culture
  - Live your values
- Accept it - you're now a little less wrong about everything.
  - Identify and validate assumptions ASAP



THANK YOU