



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







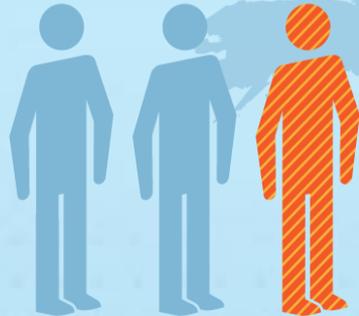
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The Problem

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

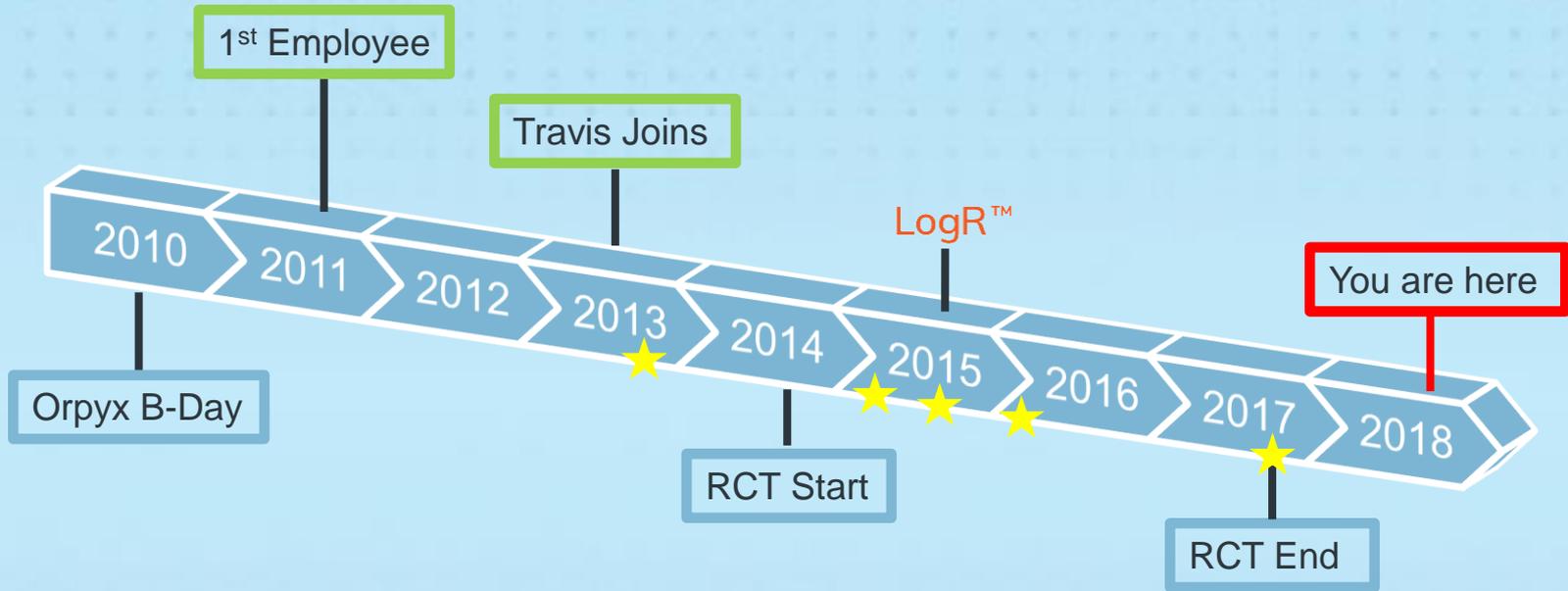
Multi-Site RCT

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

IMPACT: Reduction
in ulceration



Timeline – Key Events



★ - Trial End

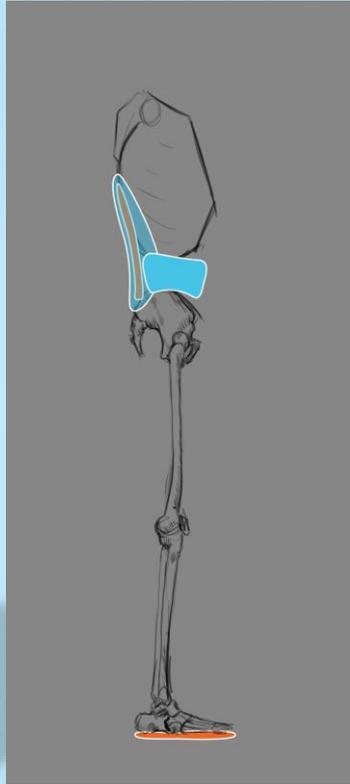
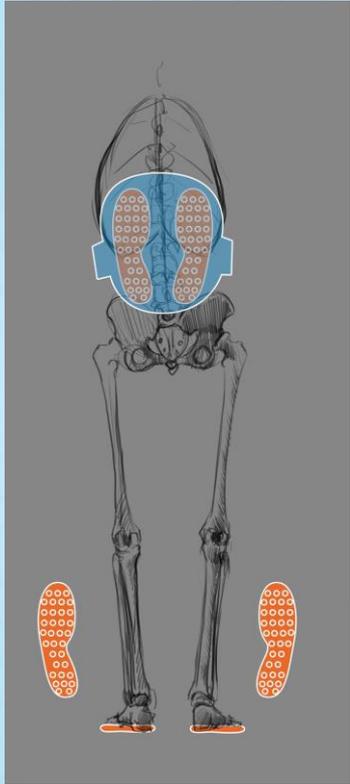
LogR™

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

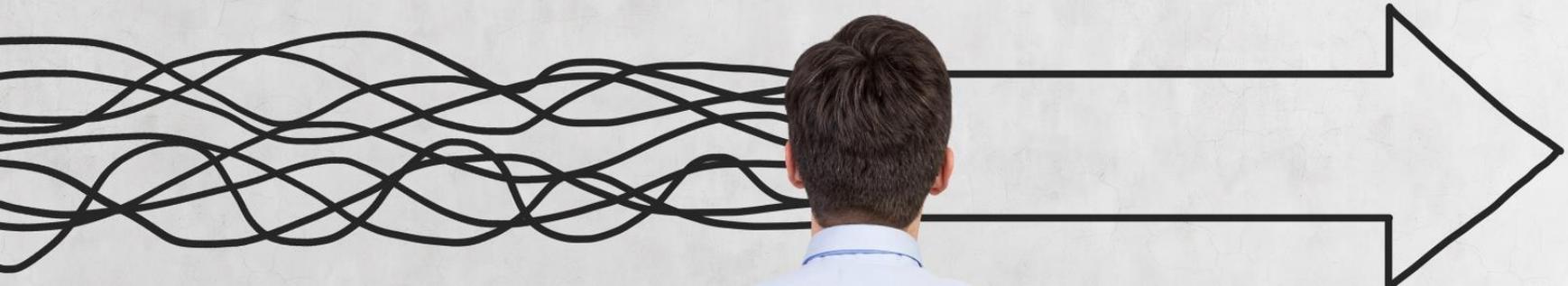
- Accept it - you're wrong about everything.
 - Identify and validate assumptions ASAP and continuously.
- MVP - Minimum Viable Process
 - What are your process/business requirements?
 - Constantly evaluate and evolve
 - Beware the downside risks
 - Must fit people and culture
- Process matters when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

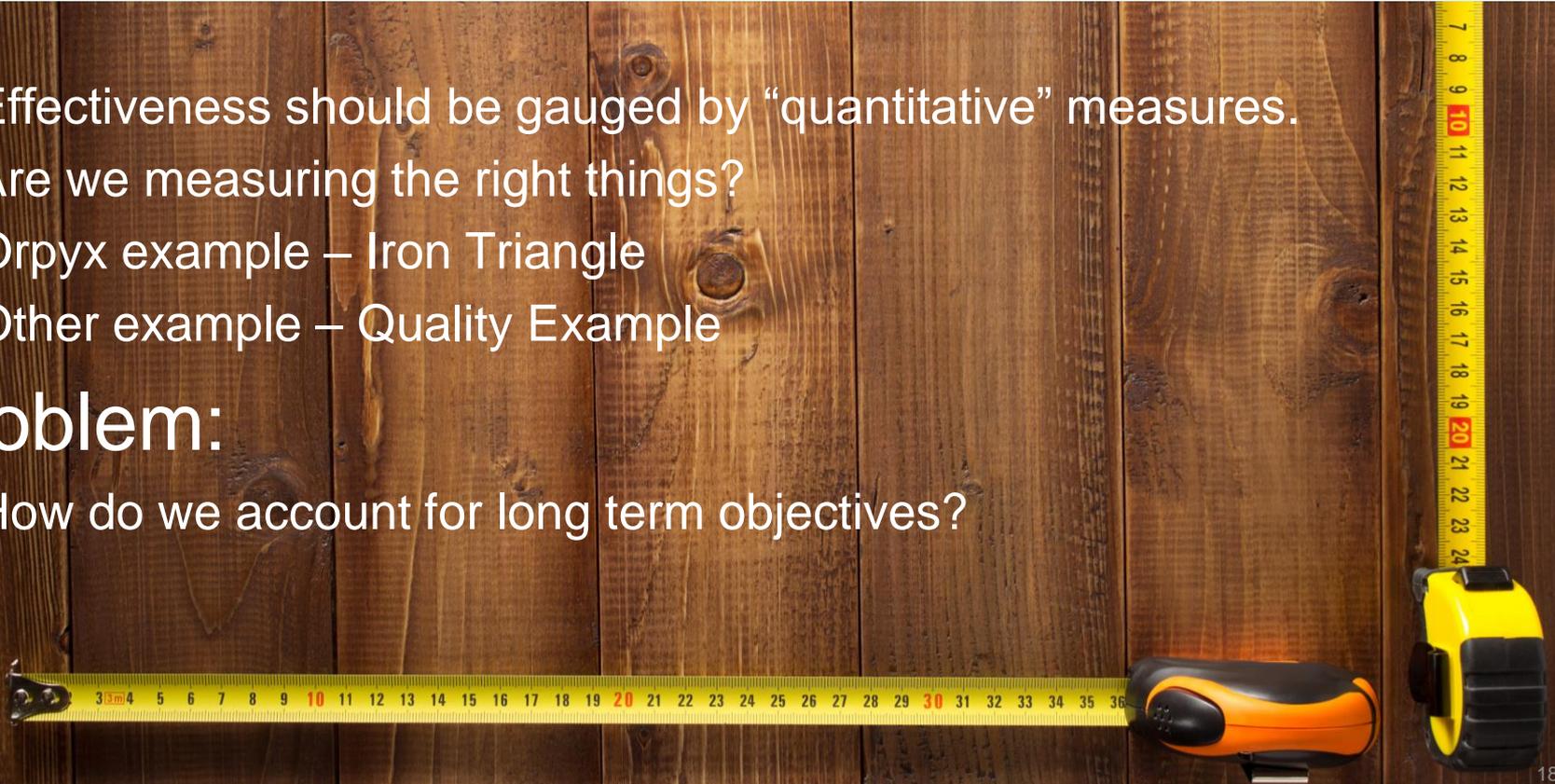


Measure What Matters

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

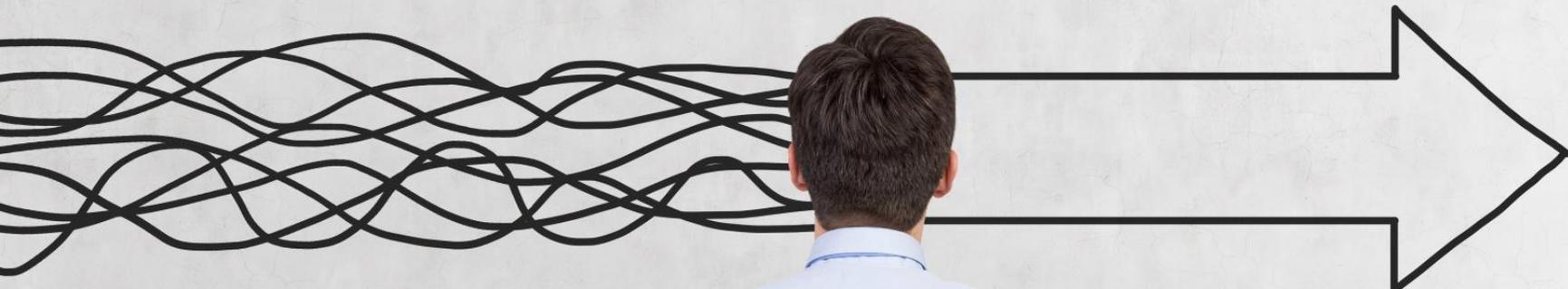
Problem:

- 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

- 1st Law - A culture in motion tends to stay in motion acted upon by an unbalanced force (Inertia).
- 2nd – Culture equals people multiplied by time.
- 3rd – 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