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The Impact of Simulation-Based Learning on Study Acceleration:

Spoken from the Sponsor who Converted

Brad Stefanovic

VP, Head of Clinical Innovation

What I was doing

Vice President of Clinical Operations

- **Phase III Diabetic Foot Ulcer Trial**
  - Wagner Grade III & IV (There is no Grade V)
  - World Leading Academic Clinical Sites and KOL/Pis
  - Program Involvement since inception
  - Contributors to protocol development
  - Well Educated, trained and problem-solving ability for a complex program

**Simulations Plus acquired Pro-ficiency in 2024 and has retained all functionality and capabilities as part of the acquisition*

What happened in 2020

COVID-19 Lockdown

- **What we lost**
  - KOL and key academic sites
  - Historically high enrolling sites
  - Program and product knowledge
  - Problem-Solving and protocol complexity expertise
  - Clinical Infrastructure
    - Human
    - Equipment
    - Technology

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When reality set in

We need new sites

- **Identify Sites**
  - Do they have the patient population
  - Did they have clinical trial expertise in DFU?
  - Did they have clinical trial expertise at all?
  - Did we need to start clinical trial education from Scratch?

- **How can we train them?**
  - We could not travel to the sites (Lockdown)
  - We were not confident in Naïve sites being left to execute such a complex phase III protocol from just a slide deck
  - How do we assess competency?
  - How do we ensure Operational Quality and compliance?

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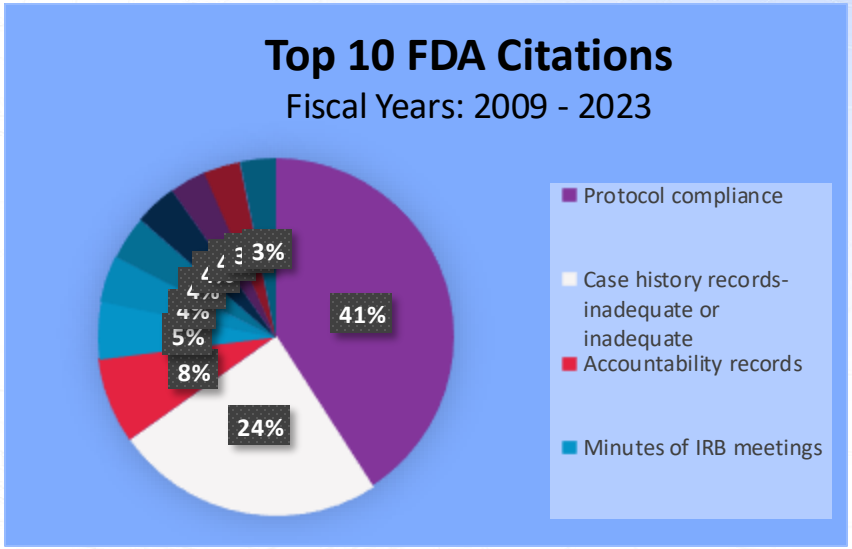
The Challenge

- **Gaps Caused by Traditional Learning (Powerpoint, Presentation, eLearning)**
  - Low Engagement & Retention
  - Unnecessary Time Burden on Sites
  - Lack of Evidence of Understanding
  - No Actionable Outcomes
  - Redundant Remediation
  - Persistent Human Error



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The suggestion

Simulation-Based Training and Learning

- **Pro-ficiency**
  - Enhancing clinical trial success through immersive, adaptive learning and actionable behavior-based insights

- **The Promise:** Achieve measurable understanding that improves:
  - Patient Safety
  - Operational Quality
  - Compliance

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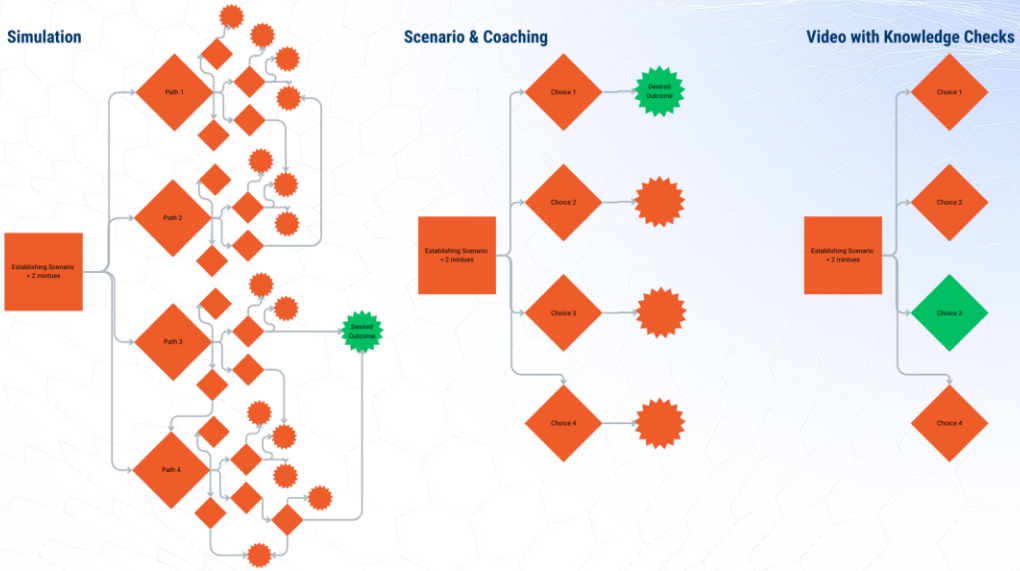
Our Solution – Best-in-Class Training

The Pro-ficiency Adaptive Learning Methodology

Interactive Simulations for Drastically Improved Competency

- Real world scenarios allow practice in a risk-free environment
- Targeted in-module coaching tailored to individual learning need
- Adaptability reduces training time and personalizes in-the-moment remediation
- Patient education that allows patients to explore their interest areas in an engaging environment
- Scientifically proven to be effective



And we develop the content, saving your team time!

The realization

Transforming Learning, Transforming Outcomes

- Pro-Active Risk Remediation
- Rehearsing on Patient Zero (Virtual Patients)
- Live, directly representative metrics and analytics
- Training no longer a “Check-Box” item
- Leverage training to strategically align the business of clinical operations
  - Risk Based Monitoring
  - Resource planning
  - Logistical efficiency identification
  - Global Scalability

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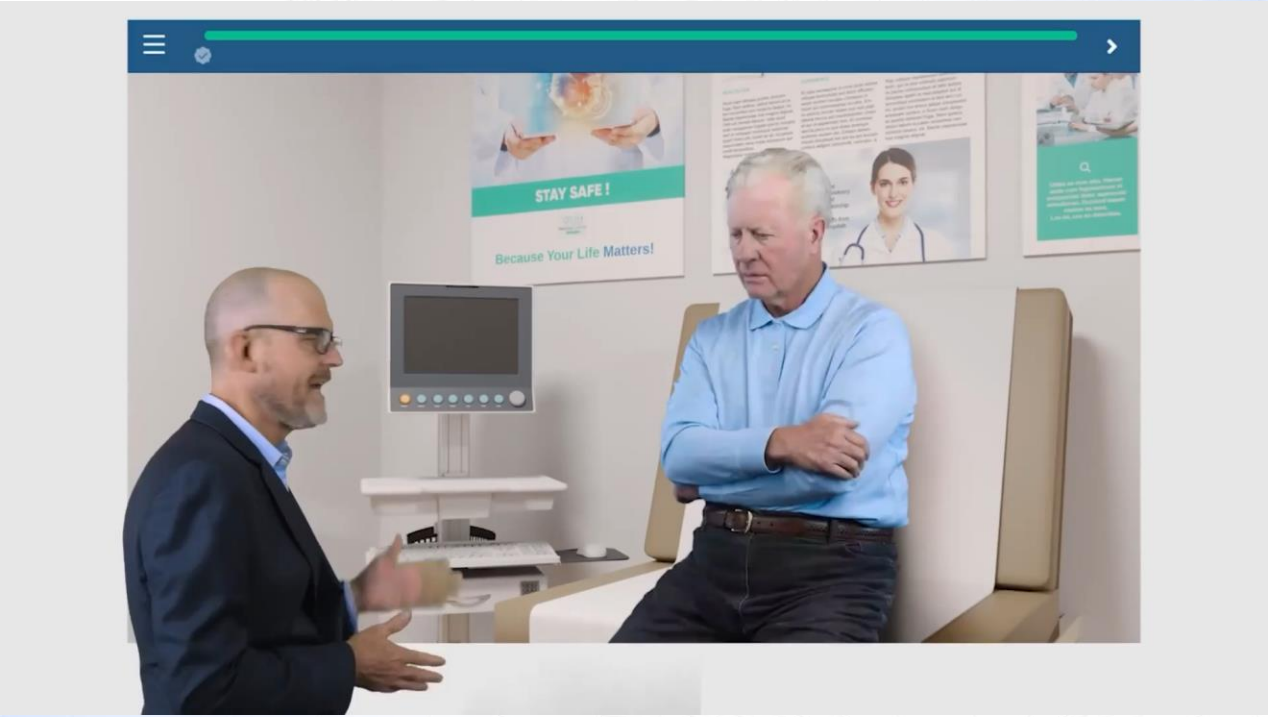
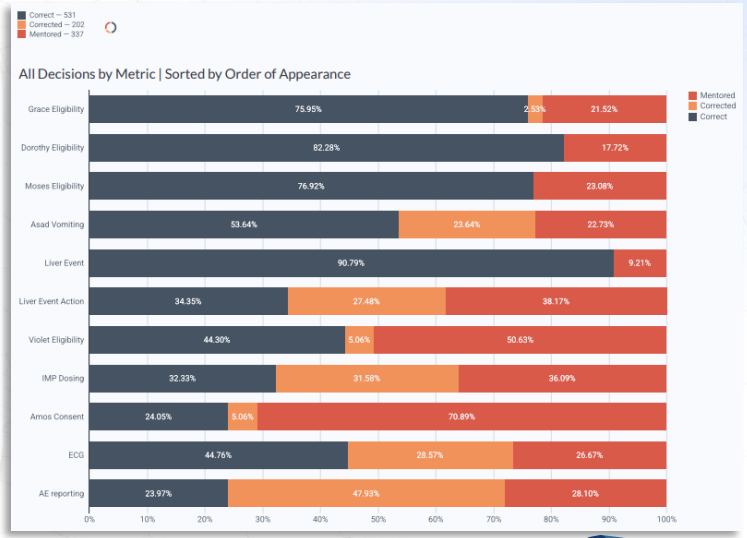
A Mock Scenario



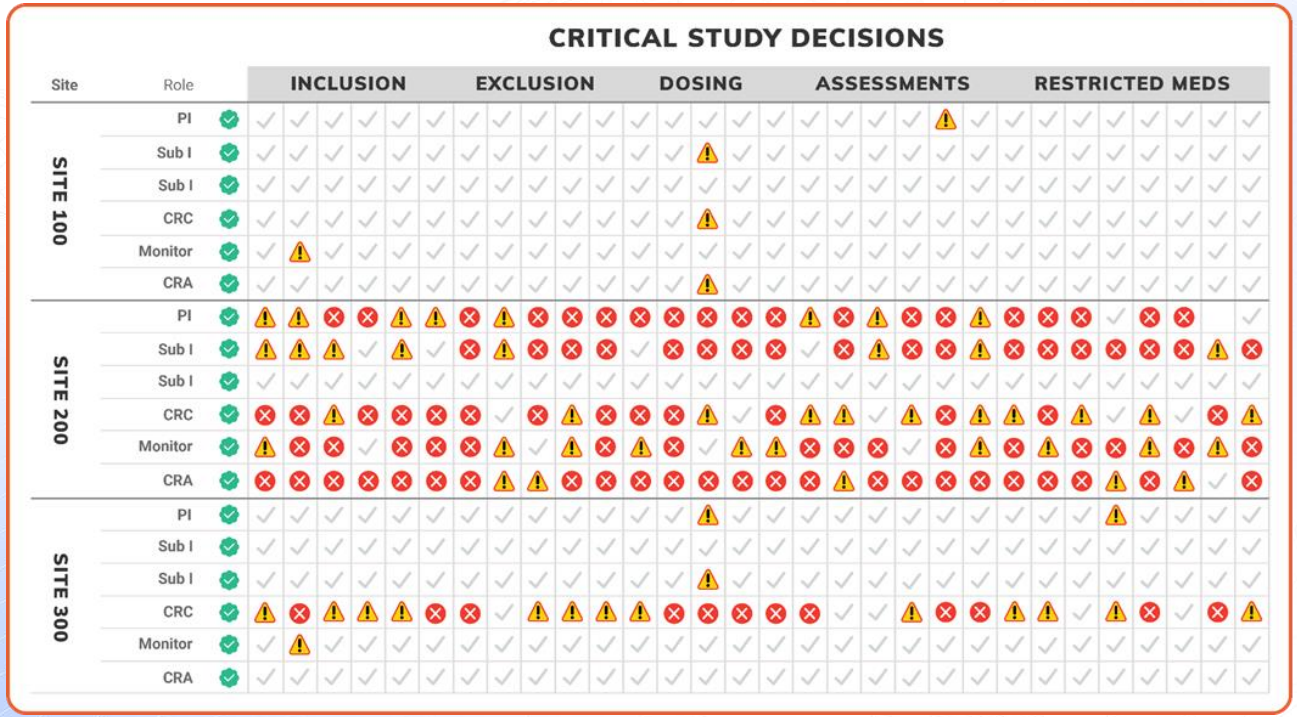
Our Solution – Measurable Competency

The Pro-ficiency Adaptive Learning Methodology

- **Behavioral Insights**
  - Track patterns of action for individuals, sites and across your study
- **Proactive Remediation**
  - Analytics visually illustrate remediation needs
  - IMs and SIVs can be focused on risk areas, serving as remediation BEFORE any patient interaction



Metric Driven Risk-Based Monitoring



✓ Indicates mastery of subject

⚠ Indicates that 1 corrective action was delivered

⊗ Indicates significant risk based on knowledge gap

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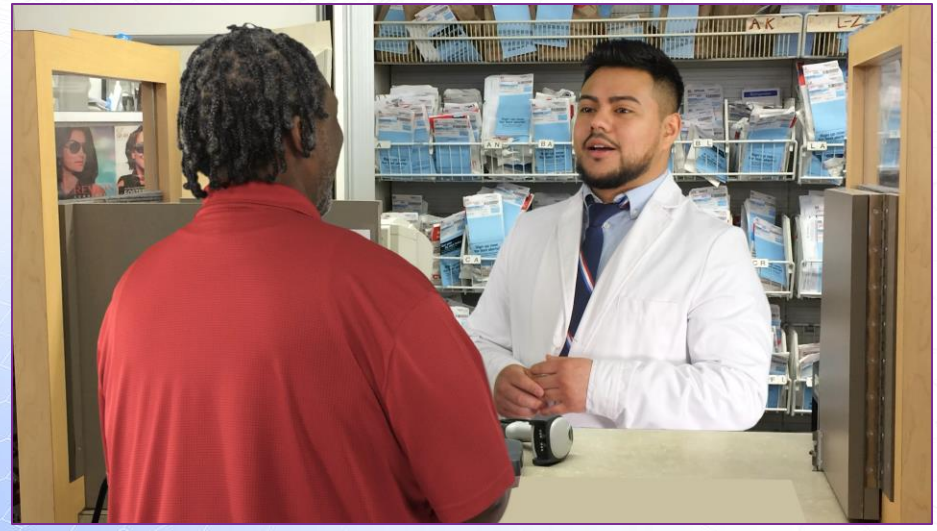
AI Translation Services

Our Ability to Engage and Drive Global Competency Standards using AI



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Tangible Results

Reduced Site Burden

- 30% reduction in training time
- 97% site satisfaction scores
- Selective SIVs reduce time and focus discussion
- SSOs and APIs smooth tech burden

Improved Study Quality

- 20% fewer deviations in critical risk areas
- Improved enrollment accuracy & speed to FPI

Long-term Savings

- $360k average savings per study*
- Improved speed to LPI
- 6 monitoring hours saved on average per site
- Calculated ROI of 250-300% on average

* Derived from an analysis of 12 global phase 3 studies

Global Standardization

- AI avatar & translation capabilities improve cultural competency
- Virtual training ensures competency regardless of location, and TIME a site team member joins the study

Testimonials

"There are many training solutions available out there, but I don't think any of them offer simulation-based training."
–Investigator

'As a PI, I have had the privilege of working closely with Pro-ficiency, and can say with confidence they have been **my gold standard** for the onboarding process since I started as a sub-investigator in 2018. I have used their comprehensive training modules across multiple sponsors and CROs since then and they are by far the most user friendly. Their adaptive learning technology and interactive simulation model keeps me, and my team engaged throughout the entire training process and their platform is by far the easiest to navigate from a site staff perspective. Because they make what is so often a tedious part of running a clinical trial less onerous, **I wholeheartedly recommend** Pro-ficiency, and do so often, to any research team, sponsor, or CRO looking to enhance their study start up and onboarding process in a site-centric way.'

- Dyanna Phillips Domilici, MD, Copley Clinical

"Having someone engaged in problem-based learning scenarios is a much better way to change behavior."
– Investigator

"Pro-ficiency is significantly better than other platforms I have used for training. The simulation training enables our staff to deeply internalize the critical parts of the protocol."
– Site Admin User

Dedicated to Clinical Trials

Adapts to the Study

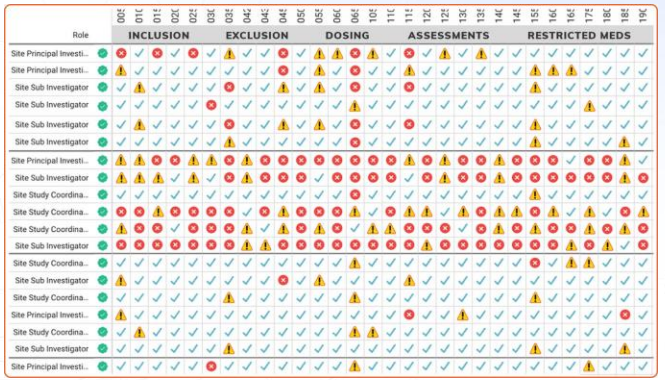
- Sites remember: Case study-based practice leads to improved application and retention
- Deviations are reduced: Errors are made in the module, NOT with patients
- Amendments are handled seamlessly: No more redundant training

System built for you

- Fully compliant solution created for clinical trials
  - 21 CFR Part 11 & 820, ISO 13485:2016, GDPR, ICH Q10, CCPA, GxP
  - Fully functioning LMS (for those who need one)
  - SSO and API ready (for those who don't)

You Are In Control

- We create content, you provide guidance & approval
- Analytics **validate CRA performance** as well as site
- 24/7 access to real-time compliance and competency reports



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The Conversion

Enhancing Training to be a personalized, representative and interactive strategic asset

- **Institute simulation training as early in study start up as possible**
  - Protocol Optimization
  - Site Feasibility confirmation
  - Streamline Investigator Meeting and/or SIV process
    - Leverage metrics on remote, in-person or hybrid approaches
    - Preserving budget and resources

- **Action Knowledge/Competency Gaps before they impact your Study Data**
  - Immediately improve data quality
  - Compliance/Operation Quality
  - Patient Safety

- **Invest now in Global Scalability and Cultural Competency, don't pay from a quality perspective later**
  - Leverage best-in-class AI and Content generation technology for engaging training
  - Addresses needs and learning goals for all target audiences
  - Build once use often for program level therapeutics

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