From Protocol to Patient Implementing a Clinical Interventional Trial in an Active Combat Zone –

Lessons from Ukraine

HERO

Healing Electroceutical Dressing for the Recovery of Open Wounds

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on behalf of the HERO study team

University of Pittsburgh

and

***Partners**: U Colorado, UKR Coordinating hub and Pharmaxi (CRO)*

University of Pittsburgh | McGOWAN INSTITUTE FOR REGENERATIVE MEDICINE
Regeneration Through Innovation™

Disclosures

- Education consultant for Arthrex, Inc (*current manufacturers of Bioelectric Bandage being tested in Ukraine*)

- This effort was awarded through MTEC solicitation MTEC-24-01-MPAI and is funded by Combat Casualty Research Program (CCCRP) in accordance with Congressional direction to establish medical partnering with the Ukraine specified in Sec 736 NDAA 2023 and Sec 721 NDAA 2024.

- The views and conclusions contained herein are those of the author(s) and should not be interpreted as representing the official policies or endorsements, either expressed or implied, of the U.S. Government”.

Two Studies. One Mission.

HERO

Healing Electroceutical Dressing for the Recovery of Open Wounds

University of Pittsburgh |
4 UKR clinical sites

ARROW Platform

Antimicrobial Resistance Research to Improve Outcomes of Traumatic Wounds

University of Colorado ·
4 UKR clinical sites

Brief Study Overview

HERO

Healing Electroceutical Dressing for the Recovery of Open Wounds

***Objective**: To evaluate the efficacy of a wireless electroceutical dressing (WED) (PowerHeal™ Bioelectric Bandage), in managing infected traumatic wounds.*

***Main methodology**: Randomized, unblinded, controlled study on 150 subjects with traumatic wounds, ratio 1:1 (PowerHeal™ Bioelectric Bandage+ SOC : SOC)*

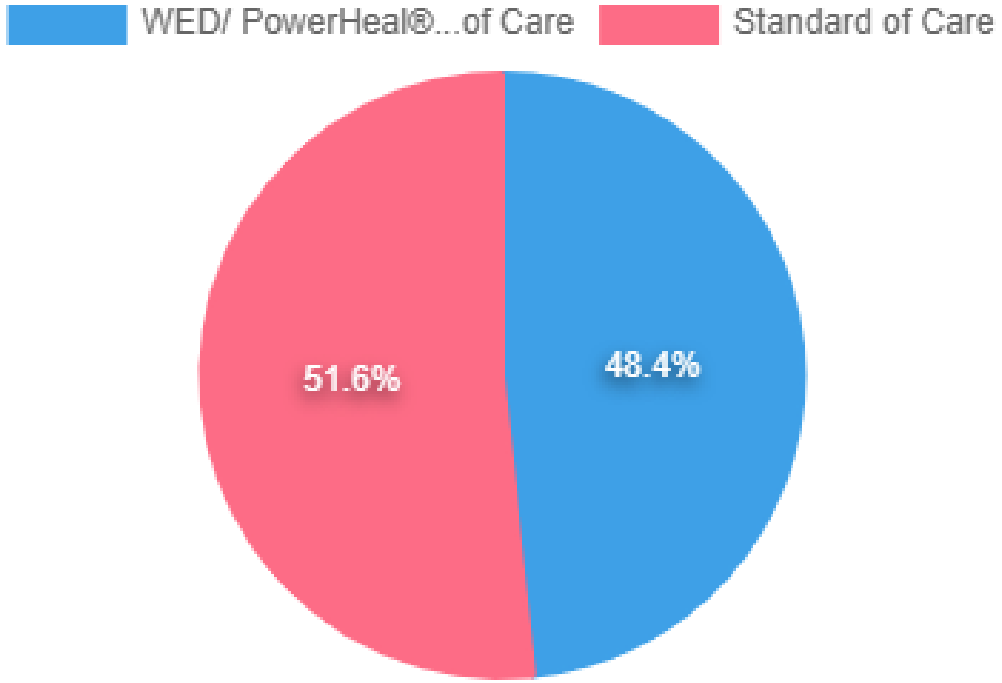
***Expected outcomes**:*

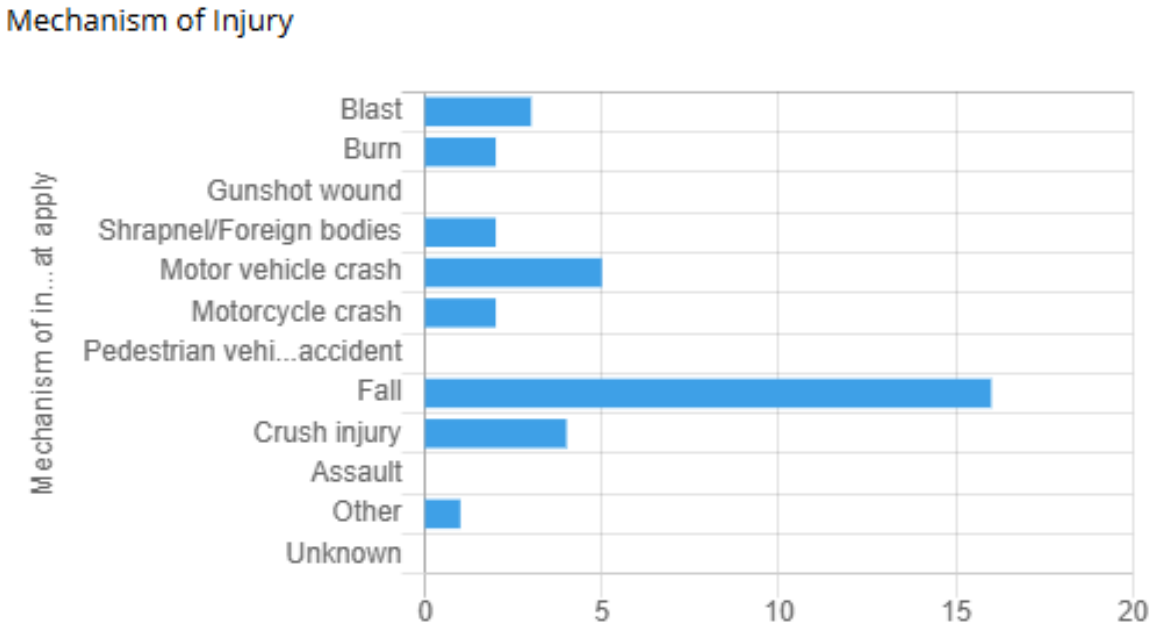
In PowerHeal™+SOC compared to SOC alone

- *accelerates wound closure*
- *decreases infection*

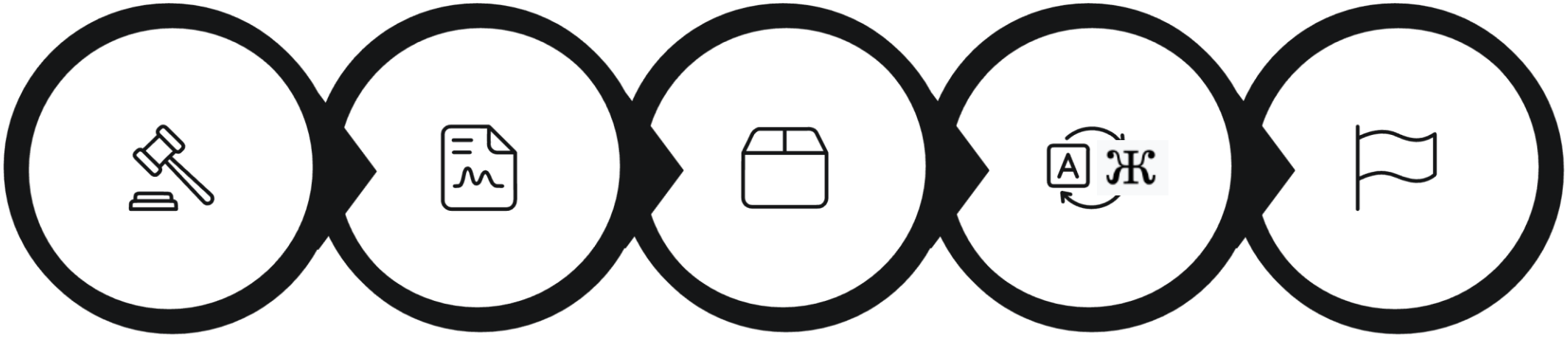
Current Status (as of June 22, 2026)

Current enrollment (from one site): 42
Remaining to be enrolled: 108
3 additional sites activated





Five Phases of Implementation



Regulatory & Ethics

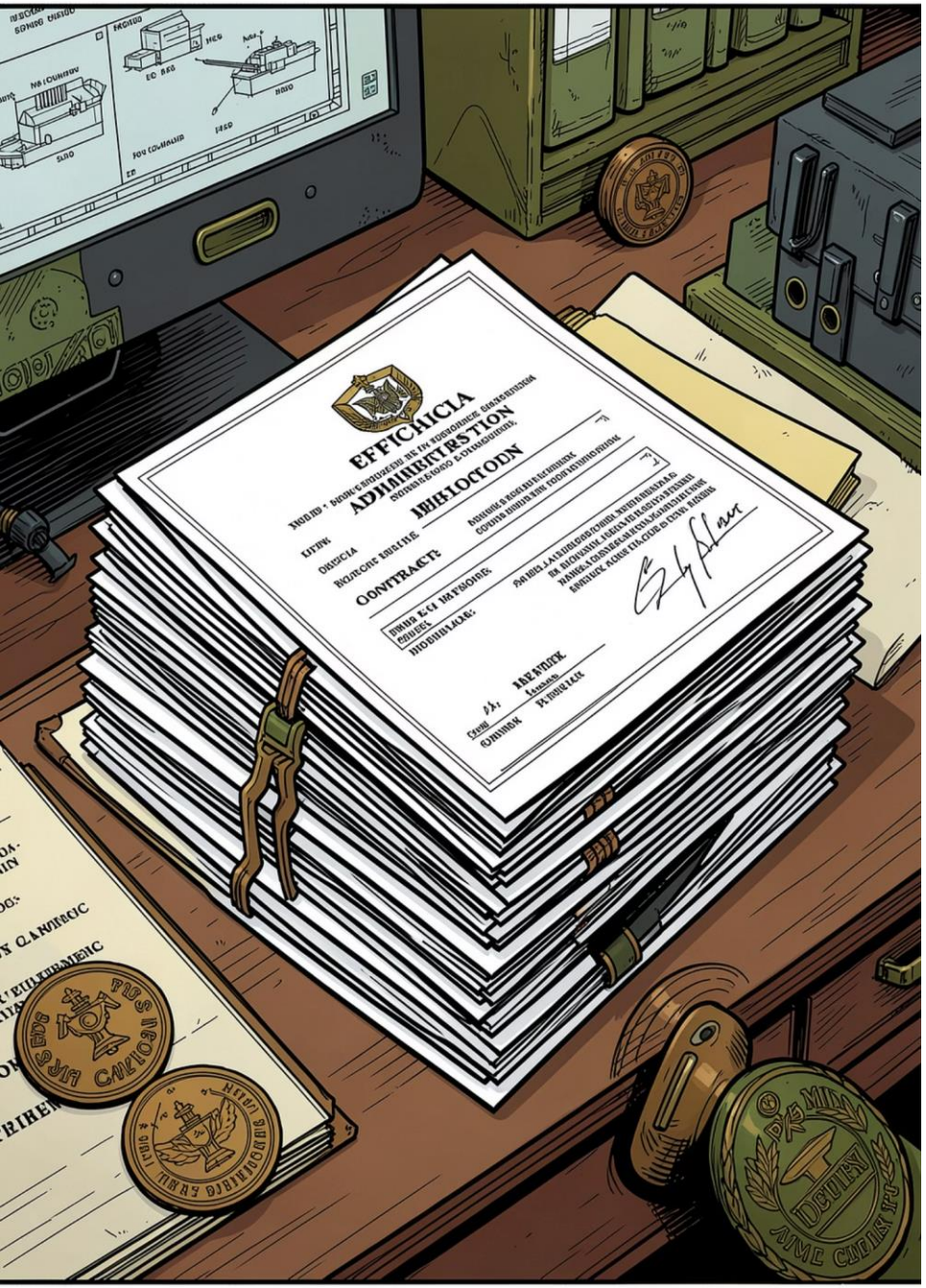
Institutional Contracting

Device Procurement

Document Translation

Site Activation

Each phase introduced complexities rarely encountered in peacetime research.



Contracting: A Binational Network

Concurrent Execution

Contracts across US institutions, Ukrainian sites, and the CRO had to be finalized simultaneously — delays cascaded instantly

Rebuilt Core Documents

Standard US protocol documents were entirely reconstructed to meet Ukrainian regulatory standards

Translation requirements

All documents needed translation to Ukrainian – in many cases regulatory requirements need certified translation

No Precedent

No existing template existed for binational, wartime clinical trial contracting

Regulatory Approval: Three Layers, Not One

Conventional US Multisite Trial

Typically requires a **single IRB** for all sites.

HERO in Ukraine

Simultaneous engagement at **four distinct levels across two countries** —

UKR: local sites and national regulator

US: university and federal

Importation & Translation

1 Device Import Permits

Dedicated permits required for investigational device entry into Ukraine.

2 Certified Translation

All protocol documents required certified Ukrainian translation — introducing critical timeline dependencies.

3 Wartime Logistics

Supply chains disrupted by active conflict required contingency routing and buffer timelines.

4 Cross-Continent Interactions

With partnership spread across two countries, the network required constant coordination, rapid recalibration, and shared oversight across every partnering organization.

A Multinational Research Network

Snapshot of tasks

US Partners

- Overall oversight
- Development of regulatory material
- Translation of documents
- Coordinating meetings
- Dressing source (industry partner) & shipment
- Study progress

Ukraine Partners

- Site documentation (Local Ethics Committees)
- State Service of Ukraine on Medicines and Drug Control (SMDC)
- Site Initiation Visit
- Inventories
- Sample & Data Collection and Upload (REDCap)
- Local oversight on study

Study Timeline: From Award to Enrollment

← DATE	MILESTONE
Nov 2024	**Award received**
Feb 2025	**Contracting with partners** University of Colorado • Pharmaxi (Ukraine CRO)
Mar 2025	Regulatory process begins • Pharmaxi Power of Attorney
Jun 2025	DoW-OHRO preapproval
Jul–Aug 2025	LEC submission (Jul) → LEC approval (Aug) SMDC submission (Aug)
★ Oct 2025	**SMDC approval • SIV conducted** Dressings manufactured & quality checked
Nov 2025	**Pitt cede/Reliance • COMIRB • DoW-OHRO approvals**
★ Dec 2025	Dressings shipped from Vomaris Customs cleared • Dressings received at central coordinating hub
★ Feb 2026	**First participant enrolled (Site 1)**
Mar–Jun 2026	**Amendment: 3 additional sites activated** LEC (Mar) • SMDC sub (Apr) • SMDC approv (May) • COMIRB/OHRO/SIV (Jun)
Dec 2026	*Target: Study completion*

⚠ Key Complications

Regulatory phase (Mar–Nov 2025)

- limited clarity on Pharmaxi's actual role;
- changes in translation cost coverage;
- insufficient communication;
- complete IRB protocol overhaul required.

Study start / enrollment

- changes in patient flow to site driven by active combat activity
- variable access to eligible wounded service members.

Amendment — 3-site expansion

Access to site LECs and documentation impacted by changes in frontline combat activity; proximity to active conflict disrupted site operations and scheduling.

- Contracting/Regulatory
- Device
- Enrollment/Expansion

What has Made It Work so far

Strong & Resilient Partnerships

- Pharmaxi's on-the-ground expertise was irreplaceable
- Central partner coordinating between sites
- Excellent support from CU

Agility in pivoting

- Rapid communication
- Quick decision changes

Lessons for Future DoW-Funded Research

Engage Local Partners Early

Local CROs navigate pathways no US team can anticipate

Build Redundancy Into Every Phase

Conflict zones demand parallel pathways, not sequential ones

Design for Volatility

Protocols must assume timelines will shift — build flexibility in from day one.

Prepare for remote involvement

Potential limitation – inability to embed US investigators in UKR -

Bottom Line: Innovation in conflict zones requires a fundamentally restructured approach where stakes are high, timelines are volatile, in person involvement is limited and care delivery is the mission.

Collaborators

Pittsburgh: *Chandan K. Sen (PI), Ronald Poropatich, Sashwati Roy, Vasyl Pastukh*

Colorado: *Corey Bills, Adit Ginde, Samantha Simon, Jennifer Peers, Margaret Howard, Vikhyat Bebarta*

Site 1: *Roman Fishchuk, Ivanna Kirieieva, Khrystyna Levandovska, Stanislav Salii, Oleksii Diachok*

Sites 2-4 teams

UKR coordinator team visit to Pittsburgh, November 2025

Pharmaxi: *Yurii Lebid, Iryna Derecha, Olga Goryacha*

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