

MHSRS-26-2536 COMBAT CASUALTY CARE • ADVANCES IN FAR-FORWARD (ROLES 1/2) CLINICAL CARE PROVISION



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Dual-Chamber Intranasal Drug Delivery for Rapid Field Care: Human Pharmacokinetic Proof-of-Concept Using EMRX-101 Naloxone

Rapid, needle-free drug delivery for prolonged field care — no IV access or advanced training required.

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01 INTRODUCTION

In combat casualty care and austere settings, rescue medications must be **portable, rugged, and usable with little training**. Intranasal (IN) delivery is needle-free and ideal for self- and buddy-aid—but combining rapid absorption with long-term stability in a single product is difficult.

ExiVex is developing a **modular, universal IN platform**: one pocket-sized device—small enough for an IFAK or cargo pocket, comparable to a standard IN spray—that accepts **interchangeable, pre-filled drug cartridges**. One form factor, many indications. The lead program, EMRX-101 (naloxone), demonstrates feasibility.

02 WHY TWO CHAMBERS

The active drug is stored **separately** from the absorption-enhancing excipients and buffer, combining only at actuation:

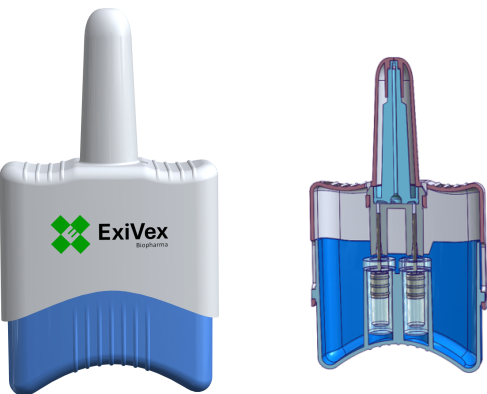
- **Stability.** Excipients that speed nasal uptake also degrade the drug if stored together—separation preserves potency over long field storage.
- **Field-ready.** Withstands the temperature swings and multi-year pre-positioning of military stockpiles.
- **Universal buffer.** The same Vial 2 chemistry enhances absorption across many drugs—enabling the platform.

STABILITY

Vial 1 holds the same naloxone active as Narcan[®], so its established shelf-life applies; Vial 2 buffer is stored separately for stability.

DUAL-CHAMBER DEVICE

NEEDLE-FREE, ATRAUMATIC SINGLE-SPRAY DELIVERY



- **MIXING CHAMBER**
Combines drug + buffer at the moment of use.
- **VIAL 1 • DRUG**
Interchangeable, mission-specific cartridge.
- **VIAL 2 • BUFFER**
Universal absorption enhancer, kept separate for stability.

03 METHODS

IRB-approved, single-site, **randomized, double-blind, four-treatment crossover** study comparing EMRX-101 with Narcan[®] and IM naloxone.

- **Design:** four-period crossover, randomized sequence, washout between periods.
- **Consent:** written informed consent obtained before any procedures.
- **Data collection:** serial venous draws to 90 min; plasma naloxone by validated LC-MS/MS.
- **Participants:** 13 healthy adults; mean age 45.1 y; 53% male (7/13).
- **Interventions:** single dose per period — EMRX-101 4 mg IN, EMRX-101 3 mg IN, Narcan[®] 4 mg IN, naloxone 2 mg IM.
- **Endpoints:** C_{max}, T_{max}, early-interval AUC & relative bioavailability; safety and nasal tolerability.

04 RESULTS — PK PROFILE

EMRX-101 produced faster absorption, higher early concentrations, and greater overall exposure than Narcan[®] at the same nominal dose.

Faster T_{max} than Narcan[®]

7× plasma naloxone at 2 min vs Narcan[®]

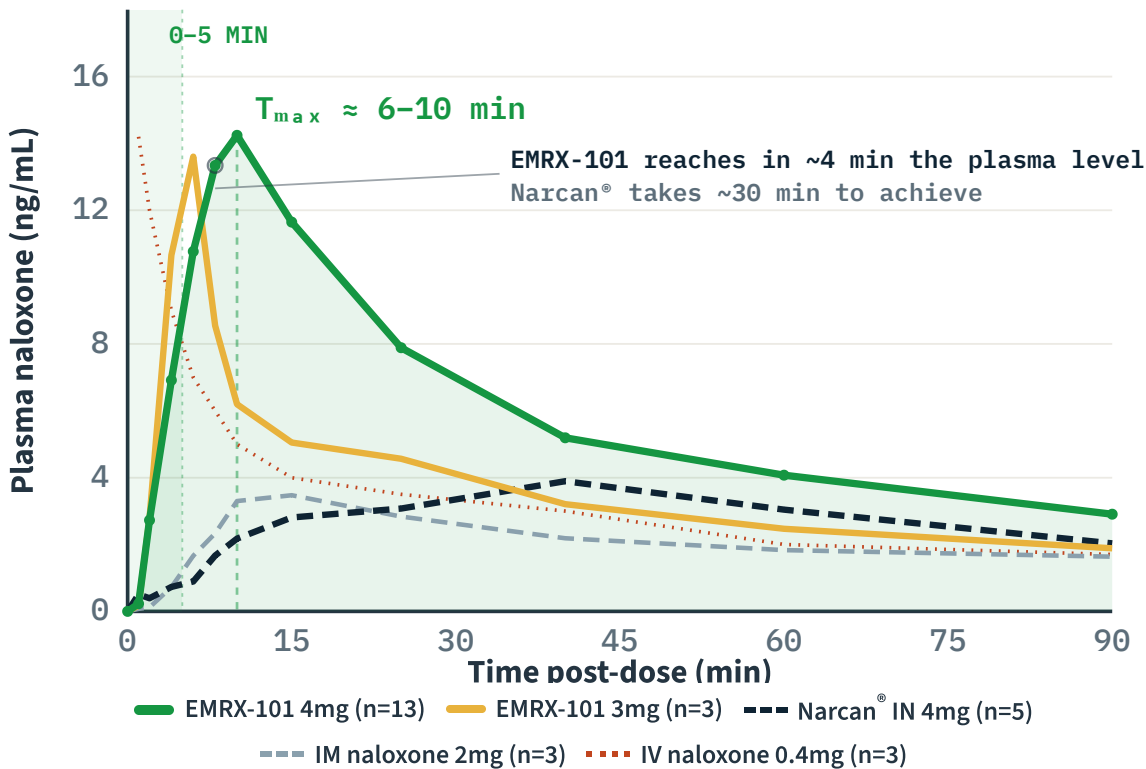


Fig 2. Mean plasma naloxone concentration-time profiles, ExiVex clinical PK dataset.

05 KEY FINDINGS

7–9x

higher mean plasma **naloxone** at 2–4 min vs Narcan[®]

6-10 min

mean T_{max} compared to 17-60min for Narcan[®]

215–817%

relative **bioavailability** across AUC intervals

TRL-6

safety & PK demonstrated for EMRX-101

Rapid, consistent absorption across subjects indicates reliable early exposure—the parameter that matters most in acute opioid reversal. Nasal tolerability was comparable to Narcan[®].

06 POTENTIAL USES OF THE PLATFORM

The same device and universal buffer accept many payloads—**swap the pre-filled cartridge, not the device**. This cuts logistics burden and medic training to a single form factor. Candidate payloads under evaluation:

PAYLOAD	FIELD INDICATION	STAGE
Naloxone (EMRX-101)	Opioid overdose reversal	LEAD • TRL-6
Ketamine	Acute pain / procedural sedation	PRE-CLINICAL • TRL-4
Ketamine + Ketorolac	Multimodal acute battlefield pain	PRE-CLINICAL • TRL-4
Ketorolac + Sumatriptan	Migraine / headache	PRE-CLINICAL • TRL-4
Atropine	Nerve-agent / organophosphate exposure	PRE-CLINICAL • TRL-4
Midazolam	Seizure control	PRE-CLINICAL • TRL-4

07 IMPACT TO THE WARFIGHTER

A **modular intranasal platform** delivering multiple life-saving therapies from **point of injury through prolonged field care**—without needles, IV access, or advanced training.

- ◆ **Faster reversal** where seconds decide survival
- ◆ **Any hand**—buddy-aid and self-aid ready, minimal training
- ◆ **Lighter load**—one device, many missions, fewer SKUs