



Expanded Access Program of CYT107 as Add on Immunotherapy in Patients with Refractory Bacterial and Fungal Infections in Ukraine

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Disclaimer

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Disclosure

- Kristen Pettrone has no conflicts to report

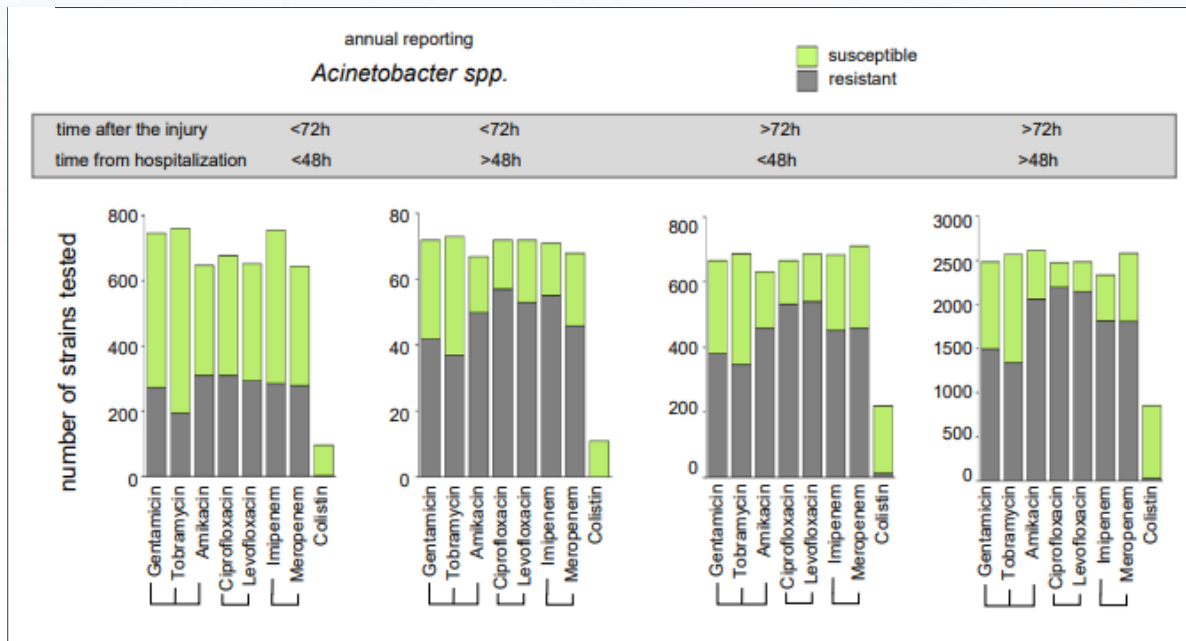
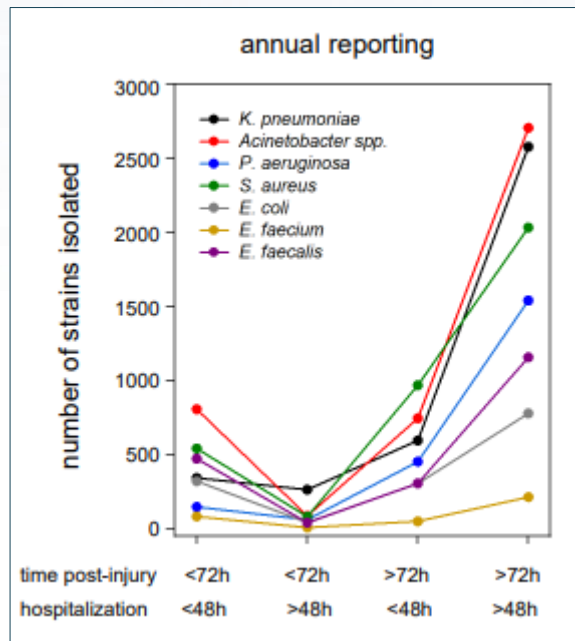
Learning Objectives

- 1) Understand the gaps in treatment options for complex infections in Ukraine
- 2) Describe the benefits of an expanded access framework for a host-directed therapeutic
- 3) Describe the challenges with EAP implementation in Ukraine

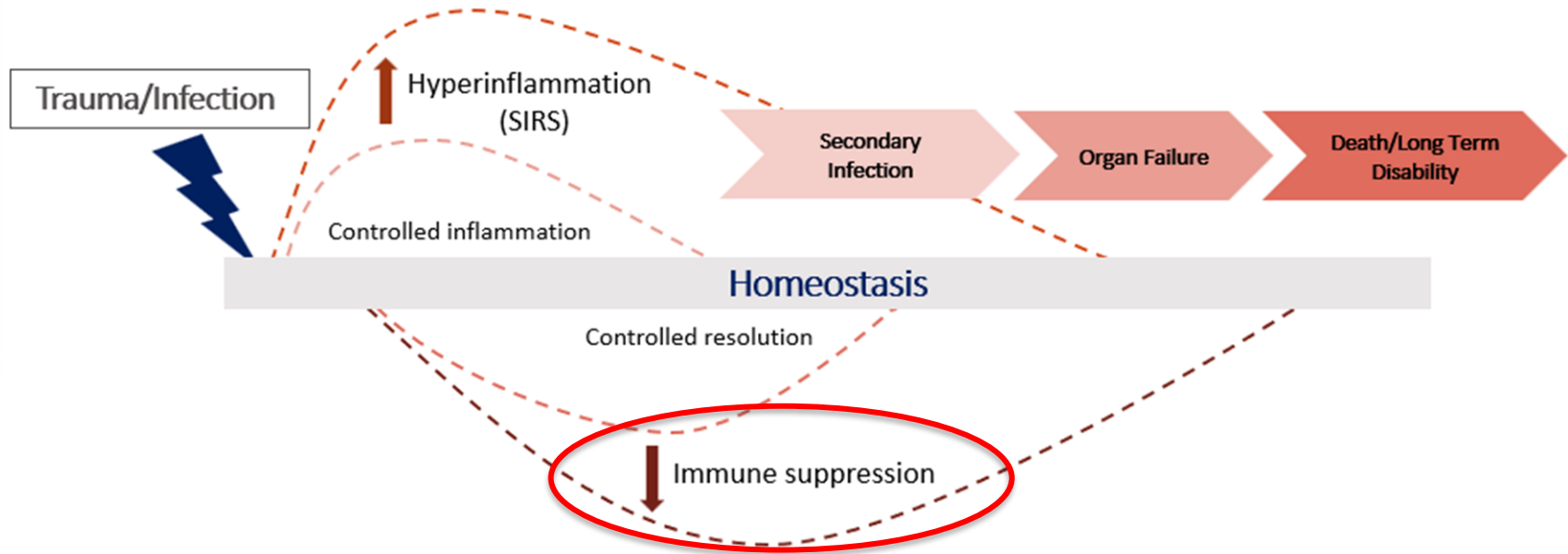
The Scope of the Problem

Antimicrobial resistance among clinical isolates associated with combat-related infections in Ukraine: first nationwide surveillance, 2023-2024.

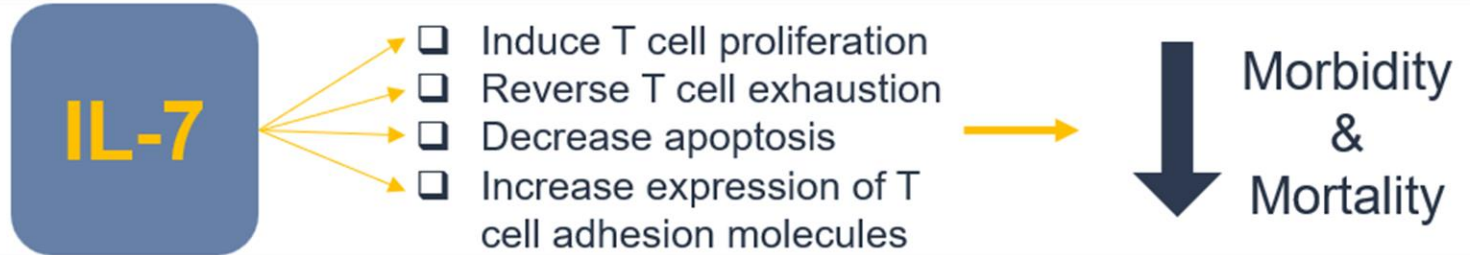
Kasatkina, L., Havrylov, I., Sboieva, A. et al. *npj Antimicrob Resist* (2026).



Adding to the Complexity



Recombinant Human Interleukin-7



CYT107

- Glycosylated recombinant human IL-7 (rhIL-7)
- Manufactured by RevImmune
- Administered to over 650 patients including phase II clinical trials for multiple indications.
- US military physicians have requested emergency use of CYT107 and successfully treated two military servicemen with traumatic wounds and refractory fungal infections

Case Report

Compassionate use of CYT-107 for intractable fungal wound sepsis following trauma

Day 11



Day 57



Day 65



Day 88



Turnbull IR, Mazer MB, Hoofnagle MH, Kirby JP, Leonard JM, Mejia-Chew C, Spec A, Blood J, Miles SM, Ransom EM, Potter RF, Gaut JP, Remy KE, Hotchkiss RS. IL-7 Immunotherapy in a Nonimmunocompromised Patient With Intractable Fungal Wound Sepsis. Open Forum Infect Dis. 2021 May 23;8(6)

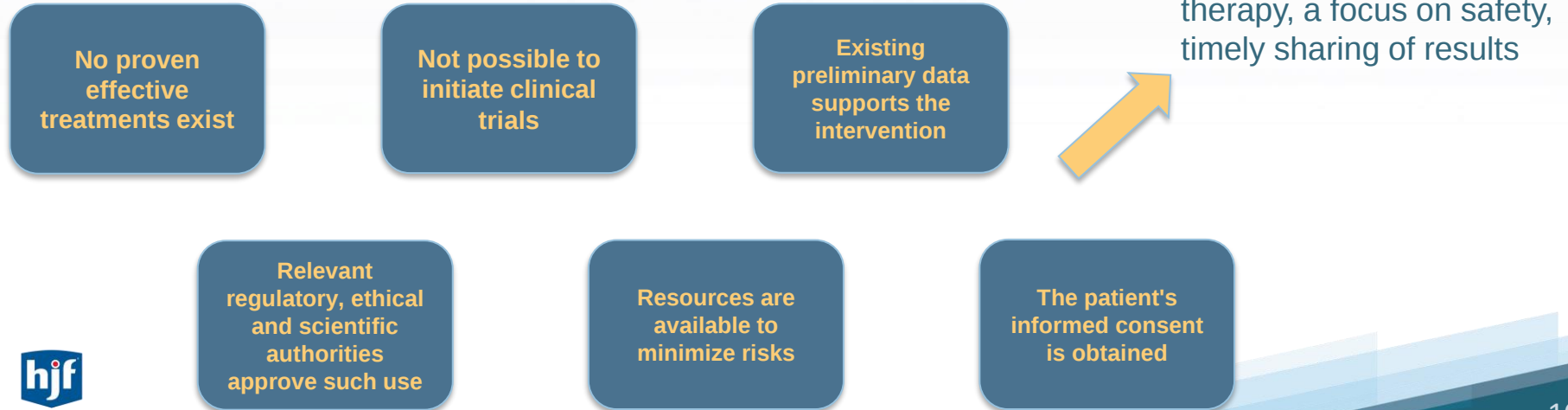
Program Aim

Provide recombinant IL-7 immunotherapy (CYT107) under an Expanded Access Program to up to 50 critical care patients with refractory bacterial or fungal infections in Ukraine.

Expanded Access Program (EAP)

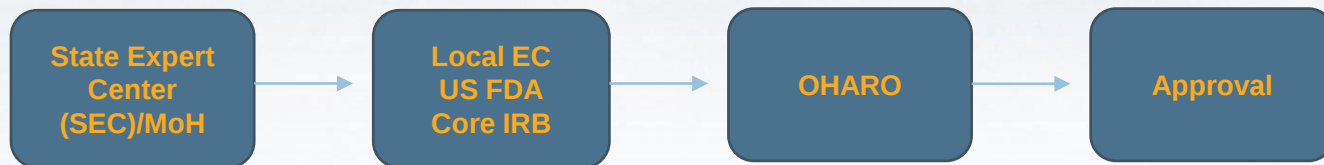
- Compassionate use, MEURI (Monitored Emergency Use of Unregistered and Experimental Interventions)
- Use of unproven interventions outside clinical trials in public health emergencies

Under the following conditions:



EAP Regulatory and Conduct

Regulatory

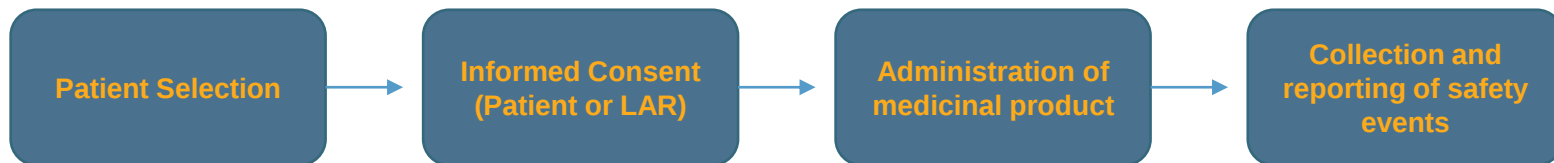


Ukraine MoH Order (2022) : Expanded patient access to unregistered medicinal product

FDA: Intermediate-size patient population expanded access protocol (under RevImmune IND)

Collaborators: RevImmune, Washington University, Culmen International, Pharmaxi, Dnipro Mechnikov Regional Hospital and Kyiv City Hospital No. 1

Expanded Access Program



EAP vs Clinical Trial in Ukraine

EAP

- Universal patient access (at the discretion of treating physician)
- Safety data collection only
- Less complex
- Facilitate clinical trial conduct (when feasible)

Clinical Trial

- Limitations on study population and study sites (military)
- Ability to collect structured data (outcomes) → Efficacy evaluation possible
- Complex to set up and implement

Implementation Challenges

- 100% Remote
 - Inability to conduct on site training and monitoring.
- Ongoing risk to program personnel and hospitals in country due to ongoing conflict
 - Required a shift in EAP sites (lead physician at one planned hospital killed in drone strike)
- Repeated internet and power outages
 - Delays in communication with key regulatory agencies

Implementation Challenges

- Logistics
 - IP/ supply movement
- Additional infrastructure requirements
 - support to maintain IP and data integrity
- Hospital and physician availability

Summary

Despite these challenges, EAPs provide a more efficient, consistent pathway for patients, including combat injured, with serious diseases to access investigational treatments when no alternatives exist

Acknowledgements

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