



International Society for CNS Clinical Trials and Methodology

# **Impact of War in Ukraine on Clinical Trials: Lessons Learned from a Phase 3 Program in Schizophrenia**

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# Disclosures

**The contents of this presentation and the commentary provided reflect the presenter's individual opinions and do not represent the opinions of Sunovion Pharmaceuticals Inc.**

# Invasion of Ukraine- Impact on clinical trials

- Before the Russian invasion, Ukraine was a desirable destination for clinical trial sites
- Hundreds of clinical trials were ongoing at start of war
- Many pharma companies stopped recruiting patients and/or put new trials on hold (e.g. GSK & Pfizer)

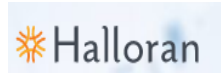
GRACE BROWNE SCIENCE MAR 14, 2022 7:00 AM

WIRED

## The War Puts Ukraine's Clinical Trials—and Patients—in Jeopardy

Hundreds of trials have been disrupted in the medical research hub. Some patients are at risk of losing their last chance at survival.

## Current State of Clinical Trials Impacted by the War in Ukraine



BY TYLER HOEY, CORTNEY MILLER AND SHAWN ROACH  
THU, MAY 12TH 2022

Medical News & Perspectives

## Clinical Trials Disrupted During War in Ukraine

JAMA April 26, 2022 Volume 327, Number 16 1535

Rita Rubin, MA

## War in Ukraine Impacts Clinical Research Industry

May 18, 2022 By [QPS](#)

# Preparation for impending war

Signs of impending conflict several months ahead of time allowed for some preparation

## New York Times Headlines

Nov 10, 2021

POLITICS

Blinken Warns Russia Against Making a 'Serious Mistake' in Ukraine

Dec 6, 2021

EUROPE

On Ukrainian Front, Grinding War and Weary Anticipation of Invasion

Jan 7, 2022

EUROPE

How Russia's Military Is Currently Positioned

Jan 25, 2022

EUROPE

As West Warns of Russian Attack, Ukraine Sends Different Message

Feb 23, 2022

BRIEFING

Will Russia invade Ukraine?

The Pentagon says troops are in place to attack.

By Carole Landry

Proactively sent IP and other supplies in anticipation of worst-case scenario

Data warehouse location moved

Evaluation of additional sites / countries

# Initial Response

## Define Key Priorities

- Priority #1: Human Safety
- Priority #2: Data integrity & quality
- Priority #3: Project delivery on schedule

## Develop Immediate Action Plan Based on Key Priorities

- Pause enrollment in Ukraine
- Pause on-site monitoring
- Allow active subjects to continue, where safe and feasible

## Continuous Impact Assessment

- Progress of war in relation to clinical trial sites
- Changing logistical issues (e.g. transport of supplies, IT connectivity)
- Monitoring effects on data
- Evolving regulatory guidance

Feb 24, 2022

BRIEFING

## War in Ukraine

Russia has launched a major invasion. Here's the latest.

By David Leonhardt



# Issue: Restrictions on Getting People (Subjects and CRAs) and Supplies On-site

## Potential Challenges

- Travel restrictions, site closures, safety considerations prevented on-site study visits
- Site-to-site variation
- IP re-supply, study supply inventories, SDV review

## Potential Mitigations

- Remote patient visit plan established for each study
- Engaged specialty couriers
- Extra supplies shipped to sites and weekly review of all study supplies to reduce risk of stock out and potential future shipping delays
- Pre-existing monitoring procedures enhanced to support remote monitoring
- Remote SDV implemented when critical

# Issue: Use of local labs due to inability / delay in shipment of lab samples to central lab

## Potential challenges

- Ensuring safety of subjects
- Collection and standardization of local lab data
- Ensuring blinded lab data remains blinded

## Potential mitigations

- By-subject monitoring of missing central lab data
- By-subject monitoring of local lab data for safety
- Forgo blinded lab assessments or develop special data handling conventions for them, if done at local lab
- Contracting with in-country lab vendors to help reduce number of local labs used

# Issue: Study Enrollment Pause in Ukraine

## Potential Challenges

- Potential timeline impacts
- Increased competition in other regions (e.g., many Sponsors utilizing US sites more as a result of enrollment pauses in Ukraine and Russia)

## Potential Mitigations and Tools

- Add sites in current countries
- Add new countries
- Efforts to increase site engagement: refresher investigator meetings, site calls, additional site budget for recruitment initiatives
- Continuously evaluate country-specific factors informing viability of re-opening Ukraine sites
- Detailed, contemporaneous enrollment tracking and reprojecting



# Issue: Ensuring Data Quality

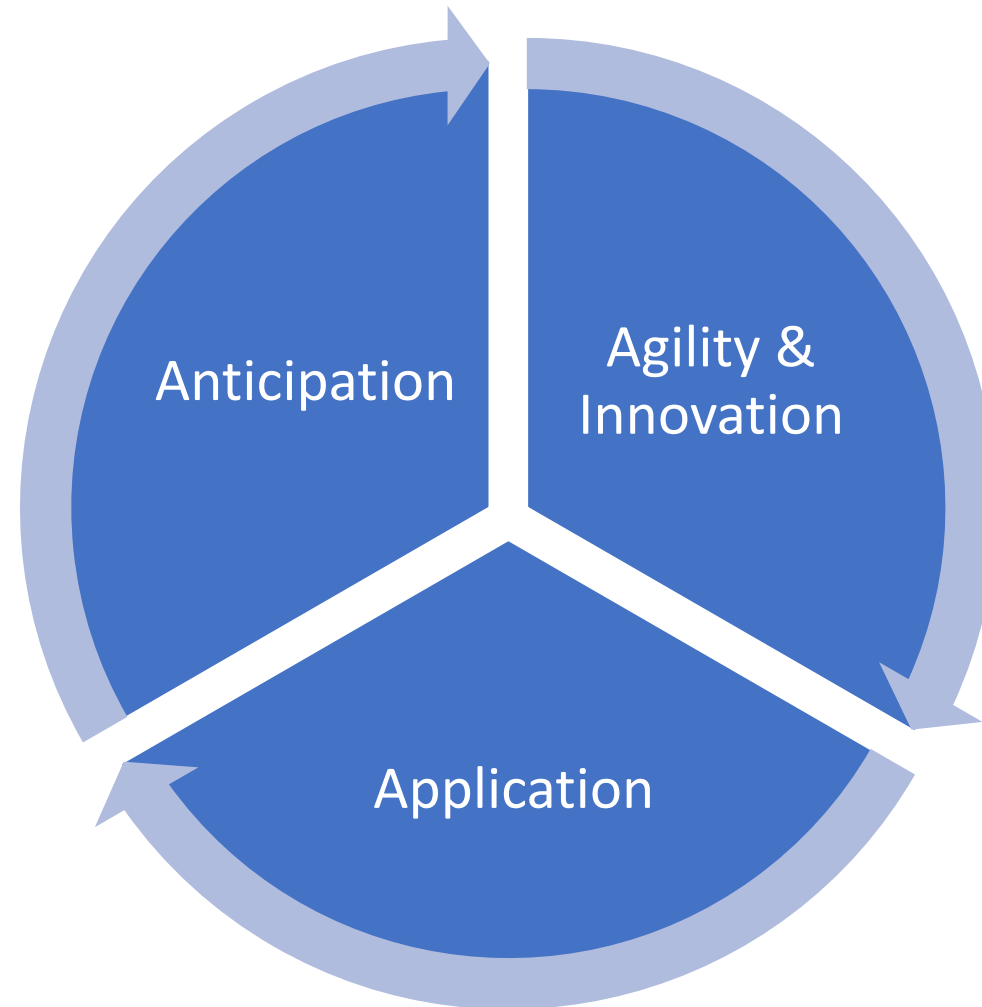
## Potential challenges

- Increased missing data (e.g., subjects not returning for visits; inability to ship lab samples)
- Impact of war on symptomatology (e.g., increased anxiety, paranoia) and treatment responsiveness
- Increased variability due to additional sites/countries
- Regional redistribution of trial subjects

## Potential mitigations to consider

- Increased remote data monitoring
- Review of blinded efficacy data collected before vs after the invasion
- Blinded or unblinded interim analysis
- Prespecified sensitivity analyses and data reporting/recording conventions- consider discussing approach/impact on overall assessments with regulators

# Looking Ahead: Enhancing Resiliency of Clinical Trials



Thank you!