

## Clario Ukraine Response Update

March 22nd, 2022

---

Dear Client,

Further to the ongoing events unfolding in Ukraine and the subsequent impacts of the conflict, we would like to provide you with the following updates. Because the situation is evolving so rapidly, we encourage you to engage directly with your Clario Project Manager to understand how your studies in Ukraine and neighbouring/impacted regions may be affected.

### **Logistics**

We continue to monitor the impact to supply chain continuity within the affected countries. Below is an updated summary of import/export capabilities across the impacted countries.

#### **Ukraine**

- Order Creation: Administration Possible
- Proforma Invoice Creation: Suspended
- Inbound Shipments: Suspended
- Outbound Shipments: Suspended

#### **Russia**

- Order Creation: Administration possible
- Proforma Invoice Creation: Possible with risk of delay
- Inbound Shipments: Test shipments into Russia are in progress
- Outbound Shipments: Suspended

#### **Belarus**

- Order Creation: Administration suspended
- Proforma Invoice Creation: Suspended
- Inbound Shipments: Suspended
- Outbound Shipments: Suspended

Following the receipt of guidance from the European Council, EU 2022/328, Clinical Trial Supplies are exempt from the trade sanctions. We are still exploring supply chain routes that can safely enable your clinical trial supplies to be shipped to sites in Russia. We currently have shipments in process and we are prepared to react to any challenges we may face during transit. We will proceed with caution and closely monitor these shipments to ensure they clear customs before we can be confident about supply chain continuity. We will share our experience and capabilities post completion.

Freight charges for Russian imports are expected to be more expensive than usual at this time. We have little advance notice of this and ask for your patience and understanding as our carriers attempt to regain continuity of the supply chain.

Our carriers continue to alert us of the potential for delays in transit to the APAC region. As of today, we have not yet observed any significant impacts but will continue to monitor the situation. Our Project Management team will share visibility at the study level and work with you as best possible to manage your shipments. We encourage you to proactively engage with your Clario Project Manager to prepare and manage impacts or potential changes to your trial strategy.

## **Data Transmission & Trial Management**

It is expected that internet and telecommunication services may be subject to disruption during this crisis. However, Clario's ability to receive and process data remains intact. Across all our service lines, our Project Management teams will support you through operational strategies in the event of temporary or permanent loss of connectivity. Additionally, our eCOA platform operates with offline capabilities, enabling data to be stored on devices until an internet connection is established, at which point it will be transmitted.

Currently, we see decreased telecoms activity from within Ukraine, indicating less study level activity, due either to disruption to in-country telecoms services or from patients being unable to complete their assessments. We encourage you to engage with your Clario Project Manager and keep us informed on how you intend to manage affected patients.

We have established internal triage groups across our product lines to enable our Project Managers to get quick assessments on technical options/feasibility of any requests you may have. These groups are already proactively identifying methods to best support client requests regarding limitations on shipping capabilities, patient site migrations or alternative data collection methods. Please reach out to your Clario Project Manager if you need consultative support.

Any study with ongoing changes to software for devices in the field will be impacted if there is no access to the internet. Consequently, if your study includes Ukraine, there is a heightened risk that devices may not be running on the latest software release. Therefore, any patient using offline capabilities may be using an old version in error. Should your study have ongoing updates, your Project Manager will discuss this with you so that we can collectively monitor active sites/patients to mitigate this risk.

## **Trial Continuity**

Given that many of our customers have had to freeze enrolment within the affected countries, we do expect that Sponsors will look to other countries to make up the required patient populations necessary for their protocol. Doing this through active countries on the trial will be the most efficient solution. However, if you decide to open a new country in your trial, Clario can support you through our current change management practices. We ask that you communicate with us early on regarding any potential strategies you are considering so that we can proactively advise on solutions and any experiences we are seeing across other active trials.

## Trade Compliance

We are continuously analysing this situation with respect to regulations and are cooperating with our partners, banks and insurance companies to ensure that we meet trade and financial compliance requirements. With the exemption of clinical trial materials being supported by regulations, we anticipate that customs services for our shipments will resume in Russia. We will closely manage the first few shipments to understand if there are additional difficulties to overcome. As more information is provided regarding sanctions and financial consequences with affected banks, we will evaluate our position relevant to clinical trial management and proactively engage with you where needed.

## Cyber Security

Our Cyber Security operations team fully aligns to US Cybersecurity and infrastructure Security Agency (CISA) recommendations, including a “Shields Up” program that recommends four steps to strengthen security posture. To date, this program has been effective and no concerns relating to our services and infrastructure have materialized.

### 1. Identify and catalogue all internet-exposed assets

- Clario maintains applications service catalogues that identify clinical and business operations, who can access the applications and how they are connected on the network - whether external or internal.
- Infrastructure for all internet-facing clinical applications is monitored 24x7x365 by Clario’s security platform and Security Operations Centre (SOC). The SOC receives weekly threat intelligence reports from our security partner, Mandiant Managed Defence.

### 2. Detect, prioritize, and remediate known exploitable vulnerabilities

- Our continuous 24x7x365 network and server endpoint monitoring system captures all security events in a Security and Event Monitoring (SIEM) platform. From this system, our security operations team identifies and evaluates risks and develops and executes appropriate remediation steps.
- As a result of the crisis in Ukraine, the Clario SOC has applied a heightened focus on cybersecurity events/intrusions. Our Security Operations Team generates and reviews daily reports on these events/intrusions, particularly those sourced from Russian IP address space.

### 3. Protect all cloud-based services

- Clario provides continuous Security Impact Assessments for all internet-facing applications, applying remediation where necessary.
- For all endpoints, user laptops, workstations and servers integrated with cloud-based services, Clario continuously monitors infrastructure and captures security events in a SIEM platform.

### 4. Continuously alert, triage and remediate on detected intrusions

- This is the primary function of the Clario SOC.



CLARIO.

### **Next Steps**

Our Project Management team is fully aware of all active studies impacted by the current events and will coordinate with you on recommended actions. We encourage you to collaborate closely with your Clario Project Manager and support team to ensure that we are aligned on how you wish to manage your patients.

This is an evolving situation to which our critical response team will continue to observe and respond. It is important that we remain fully aligned with our clients, so we will endeavour to maintain the appropriate level of outbound communication. Meanwhile, should you have any questions, please do not hesitate to contact your Project Manager.

Kind Regards,

**Clario Executive Leadership**