

Clario Ukraine Response Update

April 13th 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 Devices: Currently not possible (under review by the Federal Office for Economic Affairs and Export Control)
- Inbound Shipments Re-Supplies*: Currently only possible for Cardiac Safety
- Outbound Shipments: Suspended

Belarus

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

* Re-Supplies

- **Respiratory (pulmonary testing):** Accessories used for clinical trials, including bacterial filters for respiratory devices, ink cartridges and other products are on the sanctions list, which means Clario cannot ship until further notice. The Federal Office for Economic Affairs and Export Control did not give permission to export electronics and filters. Our application for exemption is pending approval.
- **Cardiac Safety:** Electrodes, ECG-paper and related items were successfully shipped in the last 2 weeks. For existing protocols, Clario will continue to ship re-supply orders for items which are not on the sanction list.

Following the receipt of guidance from the European Council, EU 2022/328, Clinical Trial Supplies are exempt from the trade sanctions. However, in order to ensure compliance of Russia-bound shipments that include materials on the sanction list, under harmonization tariff code 8471, such as laptops, smartphones and tablets, a 3-step exemption process must be followed:

1. The importer must approve the shipment
2. The Federal Office for Economic Affairs and Export Control must approve the exception permission to ship
3. Approvals must be coordinated with the transport carrier

Regarding medical devices, we have requested a statement from the Federal Office for Economic Affairs and Export Control to fully understand what approval process is required for shipment to Russia. Feedback is not expected before **mid-May**.

Freight charges for Russian imports are expected to be higher 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. Additionally, whilst we have seen carrier cost fluctuations in neighbouring countries such as Georgia, no further impacts have been identified.

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.

We had previously reported 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. Following analysis of transmission data, we have observed a 47% decline in transmittals in Ukraine and 17% decline in Russia. Whilst there is speculation on Russia's withdrawal from the global internet, there has yet to be any confirmation on what access there may or may not be for outside countries. We are closely monitoring this and will develop appropriate mitigations where possible as the visibility of the situation improves. 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 allow 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 on your trials, Clario can support this through our current change management practices, and we ask that you communicate with us early on 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.

Updated sanction lists also include names of individuals who may be working at hospital/research institutes in Russia. Our response team is currently cross-referencing this list with a master list of all site contacts in Russia. Should we identify any individuals on the sanction list who may be involved in any of your studies, our Project Management team will contact you to determine the appropriate course of action. We will continue to monitor any further sanctions of this nature and advise you accordingly.

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.

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