

Trade and Co-operation Agreement Company Statement

Introduction

The UK and EU have now entered into the Trade and Co-operation Agreement (TCA) which became effective on 1 January 2021. We look forward to continuing our long experience of serving EU-based customers, clinicians and patients and have made a number of adjustments to ensure these relationships operate smoothly in the coming months and years some of which are outlined below.

EU Activities

✓ Supply Chain

Yourgene Health's products are manufactured in the UK and we have considerable experience of fulfilling customers' needs across the world with a wide variety of customs protocols. We are also investigating warehousing options within the EU to ensure ease of supply to our EU customers. In the meantime, shipments will be sent by air to avoid potential disruption and delays at ports. Due to the uncertainty surrounding the new Customs Clearance procedures, our ability to guarantee delivery dates may be affected in the short-term but rest assured we will manage the product journey up to your door.

For shipments to countries within the EU, to minimise any potential disruptions with the Customs clearance process, we kindly request that our customers include their EORI (or equivalent) on their purchase orders/instructions.

✓ Our Team

Yourgene Health is expanding its EU-based team to ensure customers have localized support. This is in addition to its multilingual support teams based in Manchester, UK.

✓ Regulatory

BSI Netherlands is Yourgene Health's notified body and its CE certificates have all been transferred to BSI Netherlands. As such, Yourgene's products and systems remain eligible for sale within the EEA after 1 January 2021.

✓ Data

From 1 January 2021, the Trade and Co-operation Agreement maintains GDPR equivalency between the EU and the UK for a period of 6 months. This period will hopefully allow mutual recognition to be agreed. We have GDPR compliant procedures and policies for the storage and archiving of data which is available on request to Sponsors. All data (both paper and electronic) and patient samples are stored securely in the UK in accordance with our standard operating procedures. Electronic data is maintained on UK servers with contingency plans if mutual recognition cannot be agreed within the permitted timeframe.

UK and Non-EU Activities

✓ UK Warehousing

Yourgene Health's warehouses are located in Manchester, UK. For UK and non-EU customers, product will continue to be shipped from this location.

✓ Product Stock

Our primary concern is to ensure that you, our valued customers do not experience any disruption to your product supply. We have a robust supply chain with products supplied from our inventory in Manchester, UK. Our products also have a substantial shelf life which further protects our customers from any unforeseen short-term disruptions to our supply chain.

Even with this buffer in place, we urge our customers to forward plan and place their orders in advance to minimise the impact of any potential delays to shipments.

✓ Shipping Arrangements

Yourgene Health are experienced in shipping via a range of methods and routes including air, sea, rail and road. Following the TCA, we anticipate UK deliveries will continue without any disruption. For international deliveries, we will continue to ship via air, however we have the necessary procedures in place to use alternative shipping methods.

✓ Services

Yourgene Genomic Services accept samples internationally and this will continue following the TCA. The patient consent forms provide an opt-in check box for patients within the European Economic Area (EEA) to agree to the transfer of data outside of this region which will enable the continuation of sample processing within our laboratories. Yourgene Genomic Services is working towards UKAS accreditation for ISO 15189:2012 which specifies the global requirements for quality and competence for medical laboratories. Yourgene Genomic Services are also an approved private test provider on the Test to Release for International Travel Scheme as per [gov.uk requirements](https://www.gov.uk/government/news/test-to-release-for-international-travel-scheme).

✓ The Team

Yourgene Health embraces its diverse workforce and will support any employees through any changes which occur as a result of the TCA, including providing support with applications for settled or pre-settled status.

✓ Regulatory

BSI Netherlands are Yourgene Health's notified body as of September 2019 – [view press release](#). This allows Yourgene Health to continue to sell its products and systems in the UK after 1 January 2021 as they are registered with the MHRA and the UK recognizes the current CE mark status until the end of the transition period to the UK CA mark.

✓ Data

After the end of the transition period, GDPR will be retained in UK law, of which Yourgene Health complies. Yourgene Health remain committed to high data protection standards. We

have set procedures and policies for the storage and archiving of data which is available on request to Sponsors. All data (both paper and electronic) and patient samples are stored securely in the UK in accordance with our standard operating procedures. Electronic data is maintained on UK servers.

✓ Our Suppliers

Yourgene Health maintains positive relationships with its critical suppliers and have had regular meetings to ensure it understands their preparation activities for the initial period following the TCA. Yourgene carries out rigorous selection and monitoring processes for its suppliers of materials which is managed from its Quality Management System. This includes Supplier Audits to ensure its requirements are being met and resolve any potential issues. Yourgene are also holding >3months of stock of some of its critical reagents to mitigate potential impacts on its customers.