KING'S HEALTH PARTNERS | Clinical Trials Office

CI Responsibility:

International Trial Considerations

Are you thinking of taking your trial outside the UK?

This document outlines some of the regulatory, operational, and logistical considerations for conducting clinical trials across multiple countries. This is not an exhaustive list. Other countries may use different regulatory submissions systems (e.g. CTIS in the EU) and different templates. **Work closely with your KHP-CTO CRA to explore additional requirements.**

- **Legal Representation outside UK**

All clinical trials conducted outside the UK must have a Legal Representative in that region *unless co-sponsored in the region.* The appointment and costs must be included in the contract and trial budget. This representative acts on behalf of the Sponsor in regulatory communications and must be clearly documented in the IRAS Form and TMF.

- **Checklist:**

☐ Appoint a Legal Representative

☐ Include representative contract/trial budget ☐ Document details in the TMF and IRAS Form

- **Translation of Participant-Facing Documents**

All documents intended for participants must be translated into the local language(s) of the trial site. Some countries will have their own templates that must be used. A back-translation should be done to ensure accuracy and consistency. Use of certified translators is recommended. Retain documentation of the translation process.

- **Checklist:**

☐ Translate participant-facing documents into local languages

☐ Perform back-translation to verify accuracy ☐ Use certified translators and retain documentation of the process

- **IMP Movement Across Borders**

IMP shipments across borders require customs declarations and may be subject to import/export controls. IMPs should be released by a local Qualified Person (QP) before use.

Use of GxP-compliant couriers is mandatory, and IMP should be shipped under validated temperature- controlled conditions with continuous monitoring. Other countries may have local labelling requirements and different standard practices (e.g. IMP prep /administration)

- **Checklist:**

☐ Prepare export/import declarations

☐ Ensure local QP release before site use

☐ Use GxP-compliant courier services

☐ Maintain validated temperature control and monitoring

- **Pharmacovigilance (PV) Requirements**

Different countries may approve different versions of the RSI at different times, which can affect adverse event reporting. All SARs of a global trial must be assessed against the UK RSI to determine if they are SUSAR in the UK. All UK relevant SUSARs must be reported to the MHRA within regulatory timelines: 7 days for fatal/life-threatening events, 15 days for others. Requirements in other countries should be reviewed.

- **Checklist:**

☐ Report UK relevant SUSARs within 7/15-days ☐ Track RSI versions approved in each country ☐ Ensure investigators use correct RSI version ☐ Confirm local PV requirements for other countries

- **Operational Considerations**

Time zone differences between the UK and other countries may delay trial support. Establish clear communication protocols to mitigate delays. Healthcare systems and referral pathways may differ from the UK, so confirm that standard of care and treatment availability align with the trial protocol.

- **Checklist:**

☐ Establish communication protocols for time zone differences.

☐ Assess referral pathways and treatment access at each site.

☐ Confirm feasibility of protocol implementation at each site.