

UKCRC
Registered
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Trials Units



UKCRC Registered CTU Network – Things to consider when working on trials outside the UK



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Things to consider when working on trials outside the UK

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1. Abbreviations

CTU – Clinical Trials Unit

CV – Curriculum Vitae

DEI – Diversity, Equity and Inclusion

EDI – Equality, Diversity and Inclusion

eTMF – Electronic Trial Master File

GCP – Good Clinical Practice

GBP – Great British Pound

GP – General Practitioner

IMP – Investigational Medicinal Product

NGO – Non-Governmental Organisation

PI – Principal Investigator

TMF – Trial Master File

USD – United States Dollar

WHO ERC – World Health Organisation Research Ethics Review Committee

2. Introduction

It is challenging to provide comprehensive guidance on how UK-based Clinical Trials Units (CTUs) might get involved in multi-national trials or trials in a single country outside the UK. The experiences of CTUs working on trials in specific countries have varied. They have encountered different facilitators and barriers and some of these issues might be different, no longer exist or have expanded.

Therefore, rather than try to produce formal guidance that could quickly become outdated, we have prepared this *Things to Consider* document. It highlights issues that you may need to think about in a range of areas and points to resources prepared by others. We welcome your feedback.

If you would like to talk with colleagues in another CTU with experience of working in a specific country, please contact regctus@leeds.ac.uk who will try to connect you with an appropriate person.

3. General Issues

3.1. Costing / Funding

- Consider currency fluctuations and exchange rates, and how these may impact the budget over the course of the project. What will happen if there are currency losses/gains?
- Consider the stability of the funding source. What will happen if the funding is withdrawn?
- Will the funding be agreed in the local currency or in a standard currency (e.g. USD or GBP)?
- Will you pay salaries etc. in local currency or in a standard currency (e.g. USD or GBP)?
- Are salaries in line with local institutional or government policies and do you have evidence for the relevant pay scale?
- What are the overheads policies of the overseas' institutions and to what extent will they be covered by the funder?
- Will there be differences between the trial activities that need to be funded in different countries (e.g. who will pay for standard procedures such as diagnosis, treatment and outcome assessment as the clinical pathways and funding of these may differ between countries)?
- Consider potential inflation when costing for equipment, materials etc.
- Obtain reliable, cost-effective quotes from (government) registered suppliers where possible.
- If staff employed by your institution will be working overseas for all or part of the project, consider the cost for their Overseas Allowances (including health care insurance, school fees, security, accommodation, family travel to the UK, etc).
- Consider identifying sites to take part and assessing their feasibility to be involved with criteria developed for the specific study (e.g. number of potential participants, experience of the PI, past international trial experience).

3.2. Culture and Local Setting

- Are there any local cultural and religious norms, context and sensitivities, that you need to be aware of (e.g. gender of researcher, practitioner and participant)?

- Are there ‘taboo’ topics which need to be approached with care (e.g. the position and hence willingness of women to question or challenge the *status quo*; stigma associated with any aspect of the trial)?
- Is there a local hierarchy of decision making among the people you will work with?
- Is there a local lack of willingness to say ‘no’?
- Are any incentives that will be used in the trial appropriate and acceptable?
- What are the most important equality, diversity and inclusion (EDI) (or ‘diversity, equity and inclusion’ (DEI) in some countries) issues for the setting and the trial, including for digital access?
- Will patient/personal and public involvement and engagement (PPIE) be similar or different to what you are used to?
- Will local legislation impact on the trial (e.g. for collection of data related to drug use or sexual behaviours)?
- Will local culture impact on which questionnaires would be answered?
- Permitted rescue medications may differ between countries – how will this be assessed and dealt with in the trial?
- Consider how political issues, civil unrest or war may impact on the ability to conduct trial activities (e.g. importation and transportation of materials, safety of staff and participants, disruption to recruitment).

3.3. Language and Literacy

- What will be the main languages for written and spoken communication with your collaborators?
- What level of literacy do you expect collaborators, practitioners and participants to have for English and for their native or other languages?
- What language will be needed for the main trial documents (e.g. collaboration agreement and protocols) and for documents that are practitioner or participant facing (e.g. posters, participant information leaflets, consent forms, outcome assessment forms)?
- Are non-English versions of the data collection instruments validated for use in the relevant language?
- How will documents be translated, what quality checks will be employed of the translations, and who will arrange and pay for this (e.g. is computer-based translation acceptable and sufficiently reliable)?

3.4. Confidentiality and Privacy

- What are the local regulations for data protection including data transfer and processing in potentially a different country?
- What are the local regulations for data protection?

3.5. Holidays

- Are there major holidays that could impact on trial activities, and are these fixed (e.g. Christmas, national holidays) or do they change from year to year (e.g. lunar new year in China, Tết in Vietnam, Easter)?

3.6. Working Patterns and Employment Law

- How much annual leave will in-country staff take and how is this arranged?
- What are the core working hours and days for in-country staff?

- What employment law operates in the country – for example in the USA notice periods are very short?

4. Oversight of the Trial

4.1. Sponsorship

- Will you need an in-country sponsor, or will a sponsor elsewhere be acceptable?
- Consider whether an organisation that can commit to sponsoring the trial in another country outside the UK can be identified and the impact of this on a collaboration agreement that delegates some responsibilities from the Trial Coordinating Centre to a National Coordinating Centre
- When do the sponsorship arrangements need to be in place (e.g. before funding application)?

4.2. Contracts

- Which country's laws will apply to the contract?
- Who will be responsible for signing the contract and/or collaboration agreement at the country or site level?
- What types of agreement are needed between sponsor and partner(s) (e.g. for data transfer)?
- What responsibilities will be delegated by the sponsor?
- Which partners and sub-partners are involved in the research and who will have contracts with them?
- Is there a single coordinating centre or site or multiple study sites?
- Will there be a central agreement with an in-country coordinating centre and/or agreements with each participating site?

4.3. Insurance and Indemnity

- Does the main sponsor's insurance cover trial activities in the country?
- Are special arrangements needed for insurance and indemnity in the country and for movement of people or items between countries?
- Will there be additional costs for insurance that need to be included in the trial's budget?

4.4. Finance

- Are there any regulations around the transfer of funds between countries?
- Will you need to follow due diligence steps in your host institution before money can be transferred?
- Are there any special arrangements for funding to the country (for example, if it is low- or middle-income country)?
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- Could there be issues with transfer of funds to government institutions (e.g. might funds be held by national/central bank and become unavailable to investigators for prolonged periods)?
- Will you need international collaborators to provide a financial audit trail for the trial's funder and what are the funder's requirements on this, including the level of detail required?
- Would it be worth involving a paying agent or grant financial administrator such as an NGO with affiliations to a partner organisation to avoid issues with accessing funds?

4.5. Ethics, Regulatory Approval, Research Governance and Oversight

- What is the process for applying to ethics and regulatory bodies?
- Is UK (institutional) ethical approval required in addition to local approvals?
- Will local ethical approval be needed or will central in-country approval suffice?
- If more than one ethics approval is needed, what order should they be obtained in and which should dominate if there is a difference of opinion?
- Can ethics and regulatory applications be made in parallel to save time or must they be made in sequence?
- How long might it take to obtain these approvals?
- Consider any fees associated with applying for ethics approval and subsequent modifications or ongoing annual fees within the country.
- Are guidance and the application forms available online or do they need to be requested?
- Can submission portals be accessed outside of country or will a local investigator need to complete the submission on sponsor's behalf?
- Would it be worth working with a specialist organisation that has experience of multinational trials or trials in the specific country?
- What documents are required for submissions to ethics and regulatory agencies and what language do these need to be (e.g. institutional letters of support, CV and GCP certificates of investigators, case report forms, participant information leaflets and consent forms, budget breakdown, etc.)?
- Will hard and/or soft copies of the submission be required?
- Are permissions needed from local gatekeepers (e.g. village chief, community leader, NGOs, Ministry of Health, director or oversight group for the site, etc.)?
- What approval is needed to conduct research at each site in the trial?
- What are the expectations of Good Clinical Practice certification?
- How will consent and assent be obtained?
- What are the local rules for age of majority and capacity to consent?
- What will be acceptable as proof of consent (e.g. thumb print or signature)?
- Are there local requirements for reporting to regulatory bodies?
- Are there local requirements for inspection and audit by regulatory bodies?
- Are there local requirements for Good Manufacturing Practice for trial interventions?
- Are there local requirements to pay or reimburse each participant?
- Will you need a local trial management group or steering group?
- What local representation will be needed on the trial's oversight groups, including the Data Monitoring Committee?
- Will the funder or sponsor require you to use a CTU, Contract Research Organisation or something similar in each country?

5. Running the Trial

5.1. Registration

- Will the trial be registered in an international or national registry or both?
- Who will be responsible for registering the trial?
- Do the ethics committees, regulatory bodies, funder or sponsor require any specific type of trial registration?

5.2. Protocol

- Will a single protocol cover all countries, or will there need to be local variations (e.g. for diagnosis, 'standard care', timing of clinic visits or outcome assessments, or routine data)?
- Will different routes to access potential participants be available (e.g. social media channels)?
- Are the potential harms and any 'rescue' activities similar in all countries?
- Will what happens for participants after the trial be the same in all countries?
- Are the estimates used for the sample size calculation valid in all countries?
- What will be classed as an adverse event?
- How will adverse events be reported to you?
- What are local requirements for reporting adverse events to the national regulatory bodies?
- How will any participant characteristics (e.g. eligibility, diagnosis and outcomes) be adjudicated?
- If WHO ERC approval is required, then country specific protocols will be needed, regardless of whether the procedures are the same across countries and an addendum outlining each country's context for the study may be needed.
- Will the protocol be published? If so, have you considered using the Trials protocol template?

5.3. Risks to Researchers and Participants

- Researchers travelling to high-risk countries should receive training before travel.
- Consider any UK guidance about travelling to the country and keep this under review because this guidance may change.
- Do members of the central team need to take any special precautions when travelling to the country (e.g. vaccinations)?
- Are there any safeguarding risks for researchers, practitioners or participants, and might this require additional staff or funding (e.g. for security or chaperones)?
- Be aware of the local and institutional safeguarding policies, which should form part of due diligence.

5.4. Training

- How will training of site staff be done (e.g. online or in person)?
- Are there any local leaflets about clinical trials that could be provided to those involved in the trial (e.g. participants, practitioners, outcome assessors)?

5.5. Trial Supplies

- Consider procurement law and timelines for any necessary tender process.
- Will you procure trial supplies in-country?
- Will the trial interventions (e.g. medications) vary between countries?
- Might a trial drug be standard of care in one country and not in others?
- Who will be responsible for contracts with and payment to in-country suppliers?
- Consider potential for stock-outs and timeline and costs for shipment and importation of trial supplies (sea or air freight).
- Are there any regulations relating to trial supplies crossing borders?
- Will taxes or duties need to be paid as trial supplies cross borders?
- Consider the need for an import license for the trial materials, interventions or equipment and keep this under review because regulatory requirements and restrictions may change.

- Are there any conditions on (non) national procurement (e.g. preventing the importing of Indian products into Pakistan)?
- Will importation require clearing agents, bill of lading and other documentation?
- Consider storage and management in country (e.g. how will materials be distributed, do you need cold chain storage or temperature monitoring, will you provide locked cabinets for storing materials, how will you track stock levels, who is responsible etc.)?

5.6. Data Collection

- Will the data be stored in-country, centrally in the UK, or in another country (e.g. a multinational study may require data to be stored centrally for cleaning and management)?
- What are the regulations for data transfer between countries?
- Is a data transfer agreement needed to move data between countries?
- Will ethical committees or regulatory bodies need to approve data transfer agreements?
- Where will paper-based data collection be stored, during and after the trial?
- Might paper case report forms be useful in countries with unreliable internet connection, or for trials in settings without remote internet access?
- Might you need to provide internet connection for data upload to database and general internet access?
- Consider if the outcome measures proposed are translated into the range of local languages required and if not, then how these will be validated for use.
- Consider whether there are any differences in the choice of language between countries that may affect data collection (e.g. GP, family doctor, family physician).

5.7. Sample Collection

- Will samples be tested at central (national or international) or site-level facilities?
- Do site-level facilities have the required certification or do samples need to be processed at a central, accredited laboratory?
- If samples need to cross borders, what regulations need to be followed?

5.8. Statistical Analysis

- Who will be responsible for the statistical analysis of the study overall?
- Will there need to be country specific statistical analysis plans?
- If there are multiple countries involved in the study, will the primary analysis be overall or within country?
- Will any country-specific analysis plans impact on the sample size calculation?
- Do you expect the same magnitude of effect across countries?
- Does any diversity of sites need to be considered within the analysis and if the trial is multi-country study, how site-specific analysis be incorporated alongside country?

5.9. Health Economic Analysis

- Will differences in resource costs between countries impact on the health economic analysis (e.g. staff or equipment costs for delivering the trial interventions)?
- Will there need to be country-specific health economic analysis?
- Will a country specific health economic analyses use trial data (effects and/or costs) that are country specific or from the trial as a whole?

5.10. Qualitative Interviews

- If qualitative interviews will be conducted in multiple languages, when will translation of transcripts occur, and how will context be preserved?
- Where will the consent forms and the qualitative data be stored and/or archived?
- Will you have a clear safeguarding protocol in place before data collection begins?

5.11. Monitoring

- Will a local risk assessment be needed to determine the level of monitoring?
- Will central or local monitoring be needed?
- Are there local regulations for monitoring?
- Will the monitoring be in-person or remote?
- Is IMP risk assessment required?
- Consider whether to use central statistical monitoring and source data verification.

5.12. Trial Master File

- Where will the contents of the Trial Master File (TMF) be stored?
- Will you use an electronic or paper-based TMF?
- If choosing eTMF, what system will you use?

6. After the Trial

6.1. Dissemination

- Will there be country-level reports or dissemination activities?
- Are there specific policies or regulations about informing trial participants of the results in the country?
- How will the central team be involved in those activities?
- Who will be an author and who will be acknowledged in reports?
- What will you do to ensure fair recognition of collaborators?
- Will dissemination products be produced in the local language?
- Consider publishing under the name of the trial collaborative group.

6.2. Data Archiving and Sharing

- Where will the trial materials be archived?
- Will data be archived as a whole or within countries?
- How will data be shared inside and outside the trial team after the trial?
- Who will be responsible for making decisions about data sharing?

7. Other Resources

These online documents provide additional guidance and information.

Global Health Trials Knowledge Hub produced by the Global Health Network

<https://globalhealthtrials.tghn.org>

Toolkit for international surgical trials (but relevant to non-surgical trials), prepared by the Clinical Trials Research Unit (CTRU) at the University of Leeds

<https://internationaltrialstoolkit.co.uk/considerations>

Ethics in global research, prepared by University of Edinburgh
<https://www.ethical-global-research.ed.ac.uk>

Public holidays in more than 200 countries
<https://www.timeanddate.com/holidays>

Development Assistance Committee List showing which countries and territories are eligible to receive official development assistance (ODA) from the UK
<https://www.oecd.org/dac/financing-sustainable-development/development-finance-standards/daclist.htm>

Trial registries that contribute to the WHO International Clinical Trials Registry Platform
<https://www.who.int/clinical-trials-registry-platform/network>

Advice from the UK government on international travel
<https://www.gov.uk/foreign-travel-advice>

WHO Guidance for Best Practice in Clinical Trials
<https://www.who.int/publications/i/item/9789240097711>

WHO guidance on research in the field in the context of health emergencies and disaster risk management
<https://wkc.who.int/our-work/health-emergencies/research-methods/sections-and-chapters/section-7/chapter-7-5-research-in-field>

Guidance for the UK Information Commissioner's Office on international data transfer
<https://ico.org.uk/for-organisations/data-protection-and-the-eu/data-protection-and-the-eu-in-detail/the-uk-gdpr/international-data-transfers>