

## UoB Position Paper: Clinical Research Registration

### Background

There are a number of drivers that necessitate registration of research on a publicly accessible database to ensure that knowledge of the research activity is available to a world-wide audience.

1. In 2008, the World Medical Association (WMA) General Assembly amended the Declaration of Helsinki and two new principles were added to reflect the need for prospective registration of a trial as well as making results of the trial public. This became a WHO requirement in 2013.

*“Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.”* The Helsinki Declaration also now states, *“Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties ... should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available.”*

For more information, see the WHO’s [International Standards for Clinical Trial Registries](#).

2. More recently the Health Research Authority (HRA) included these requirements in the [Make it Public strategy](#).

The requirement applies to all studies applying for/requiring NHS Research Ethics Approval involving clinical investigations of a medicinal product, clinical investigations of a medical device, combined trials of an investigational medicinal product and an investigational medical device and other clinical trials to study a novel intervention or randomised clinical trials comparing interventions in clinical practice. The requirement for registration is highlighted during pre-award and post-award research ethics and governance processes and needs to be in place before recruitment of the first subject.

3. Clinical research funded directly or indirectly by the US government e.g. NIH funded project must register on a US registry.
4. Journal requirements. Some journals also requiring registration of the study via a WHO-recognised registry prior to recruitment of the first participant before the paper can be accepted for publication.

### Aim of the position paper

This paper provides information for investigators to assist with selecting the most appropriate registry for their proposed research and takes into consideration the University’s legal, funder and publication requirements.

### Study registration options for UoB led clinical studies

1. There are several WHO-recognised registries and a complete list is available in Appendix 1.

2. UoB has formed a position in relation to preferred registry use and this decision is based on an assessment of legal, funder, publication as well as resource and reputational requirements. We have three preferred options:

2.1. **The ISRCTN registry:** was launched in 2000. Originally ISRCTN stood for 'International Standard Randomised Controlled Trial Number'; however, the scope of the registry has now widened beyond randomized controlled trials to include any study designed to assess the efficacy of health interventions in a human population. It registers both, observational and interventional trials and content is curated by a team of expert editors. The registry is recognised by WHO and the International Committee of Medical Journal Editors (ICMJE).

Investigators can manage their own activity on this database and, as such, there are no institutional administration costs. The registry is not directly government-funded. A single registration fee of £226 + VAT may be required for some registrations but UK funders of health research regard this fee as an allowable research cost. The Department of Health and Social Care, via the NIHR Clinical Research Network (CRN) Portfolio, provides free study registration with ISRCTN for non-commercial studies, with an interventional component. <http://www.isrctn.com/>

2.2. **EudraCT:** EudraCT is a database of all clinical trials conducted in the European Union from 1 May 2004 onward. Initially a non-public database, it was launched for the public as EU Clinical Trials Register in March 2011. Trials involving sites specifically in EU countries must be registered in the EU Clinical Trials Register (except adult Phase 1 studies). EudraCT is WHO-recognised. <https://www.clinicaltrialsregister.eu/ctr-search/search>.

2.3. **ClinicalTrials.gov:** This is the largest clinical trials registry. Clinical trials conducted in the United States or funded by NIH are required to be registered via this registry. Its registrations represent about 75% of what is available through the WHO Portal (ICTRP). The registry is run by the United States National Library of Medicine (NLM).

Historically researchers have used Clinicaltrials.gov as it is administered in the US, and is currently free of charge, being funded by the US Government. ClinicalTrials.gov are now strongly encouraging organisations to appoint a named administrator to ensure compliance with their terms of use. UoB has set-up a central account managed by members of the Research Governance Team.

There is a risk of potential financial penalties if results are not submitted (FDAAA801) [legal clarification on the scope of this has been requested from SECO (KF) in June 2015]. In discussion with CTOC it was agreed that researchers will be encouraged to use other publicly available databases and ensure that the fees for these are included within grant applications.

2.4. **Other study registration options.** Other registries are also set up and managed by governmental organizations, non-governmental organizations, universities, as well as commercial and non-profit entities. This includes pharmaceutical companies, international organizations, and health organizations. A list is available at [CIRCARE](#) and are summarised in Appendix 1.

For non-clinical health and social care research, registration may be satisfied by relying on the Health Research Authority's routinely published [summaries of research ethics committee applications](#).

## **RECOMMENDATION**

1. ISRCTN should be the default registry for UoB clinical research. The Research Governance Team will support Chief Investigators in maintaining their registry entries.
2. EudraCT and Clinicaltrials.gov should only be used for research studies being conducted in an EU or USA context, or funded by the EU or NIH. The RGT cannot guarantee to support CIs when the use of these registries has not mandated by the funder or regulatory agencies.
3. Chief investigators are responsible for ensuring that their registration entries are kept up to date, that the costs of registration (where required) are included in the grant application, and that they will take responsibility for avoiding financial penalties if these were to be applied by the Registry for non-compliance.

## Appendix 1: WHO-recognised registries

Information sourced from Wikipedia, checked, and edited Jan 2021.

### Africa

The Pan-African clinical trials registry ([PACTR](#)) is funded by the [European and Developing Countries Clinical Trials Partnership](#) (EDCTP) and operates out of the South African Cochrane Centre ([Cochrane Collaboration](#)) based at the South African Medical Research Council. PACTR is a primary member of the WHO's International Clinical Trials Registry Platform (ICTRP), and thus contributes data to the central search portal hosted by ICTRP.

### Australia and New Zealand

The [ANZCTR](#) is publicly owned and managed by a non-profit organizations. It is funded by an enabling grant from Australia's [National Health and Medical Research Council](#) (NHMRC).

### Brazil

Brazil has a registry (the Registro Brasileiro de Ensaios Clínicos, abbreviated [ReBEC](#)). ReBEC is a project of the Brazilian Ministry of Health, The [Panamerican Health Organization](#) (PAHO) and The Oswaldo Cruz Foundation (FIOCRUZ).

### Canada

The [Canadian Institutes of Health Research](#) (CIHR) participates with the ISRCTN.

### China

China's clinical trial registry is [ChiCTR](#). It is available both in Chinese (Mandarin) and English. ChiCTR was established in October 2005, and it participates in the [World Health Organization](#)'s International Clinical Trials Registry Platform.

### Cuba

Cuba's clinical registry is the RPCEC (Cuban Public Registry of Clinical Trials).

### Europe

The [EudraCT](#) is a database of all clinical trials conducted in the [European Union](#) from 1 May 2004 onward. Initially a non-public database, it was launched for the public as EU Clinical Trials Register in March 2011.

### Germany

The [DRKS](#) is an open access, free of charge online register for clinical trials and is available both in English and German. DRKS is part of the [ICTRP network](#) at [WHO](#). The DRKS works with two partner registries in Germany, DeReG - German Registry for Somatic Gene-Transfer Trials and Clinical Trial Registry of the University Medical Center Freiburg.

### India

India's clinical trials registry is [Clinical Trials Registry – India](#). CTRI is in English and it participates in the [World Health Organization](#)'s International Clinical Trials Registry Platform.

### Iran

Iran's registry, the [IRCT](#). It is run and funded by the Iranian Ministry of Health and Medical Education.

### Italy

[The Portal of the Clinical Research with Medicines of the Italian Medicines Agency](#) (AIFA). The Portal of the Clinical Research with Medicines of the Italian Medicines Agency (AIFA) is a public source of

information about the clinical trials with medicines conducted in Italy, the regulations and the ethical principles ruling the research, as well as the initiatives that AIFA promotes in the field of research.

### **Japan**

Japan has three networked registries [Japan Primary Registries Network \(JPRN\)](#). Its search portal is hosted by the Japanese National Institute of Public Health. While the search portal is only available in Japanese, the three registries' sites are also available in English.

### **Netherlands**

The [Netherlands' registry](#) participates with WHO. While the "About" sections of the website are only available in the Dutch language, clinical trial data are available in English.

### **South Africa**

[South African National Clinical Trials Register](#). Clinical trial guidelines for South Africa are available at the Department of Health's [official site](#).

### **South Korea**

South Korea's registry is [Clinical Research Information Service \(CRiS\)](#). It is managed by the Korea Centers for Disease Control and Prevention and funded by South Korea's Ministry of Health and Welfare.

### **Sri Lanka**

The [Sri Lanka Clinical Trials Registry \(SLCTR\)](#). It is funded by the Sri Lanka Medical Association and managed by the Sri Lanka Clinical Trials Registry Committee.

### **United Kingdom**

The [ISRCTN registry](#) was launched in 2000. Originally ISRCTN stood for 'International Standard Randomised Controlled Trial Number'; however, the scope of the registry has now widened beyond randomized controlled trials to include any study designed to assess the efficacy of health interventions in a human population. It registers both observational and interventional trials and content is curated by a team of expert editors.

### **United States**

Clinical trials in the US are registered on [clinicaltrials.gov](#). Clinicaltrials.gov is the largest clinical trials registry. Clinical trials conducted in the United States are required to be registered in the registry. Its registrations represent about 75% of what is available through the WHO Portal (ICTRP). The registry is run by the United States National Library of Medicine (NLM).

### **Other registries**

- Clinical trial registries are also set up and managed by governmental organizations, non-governmental organizations, universities, as well as commercial and non-profit entities. This includes pharmaceutical companies, international organizations, and health organizations. A list is available at [CIRCARE](#).
- The [IFPMA Clinical Trials Portal](#) is a major pharmaceutical industry initiative designed to increase the transparency of clinical trials by providing a convenient "one-stop-shop" for published clinical trial information. It helps to fulfil the commitment made by the research-based pharmaceutical industry in its [Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases](#).
- [WHO Clinical Trial Registry Platform Home](#).
- [WHO International Clinical Trials Registry Platform Search Portal](#).