

## **Working with ICR-CTSU Information for Chief Investigators**

### **What is ICR-CTSU?**

The ICR Clinical Trials & Statistics Unit (ICR-CTSU) is a research lead, academic trials unit embedded within the Division of Clinical Studies at The Institute of Cancer Research (ICR), a College of the University of London, and has been established since the 1980s. Our objective is to design, coordinate and analyse cancer trials which will directly influence routine clinical practice within the NHS and worldwide. We are a UKCRC registered CTU and a NCRI Cancer Group CTU, recognised for our professional specialism in the development and delivery of cancer trials.

### **What does ICR-CTSU do?**

We lead the design, central coordination and analysis of national and international multi-centre trials of cancer treatments. Our experienced cancer trials staff, with specialist disease site and methodological knowledge, provide specialist input at all stages of trial development and conduct including statistical design and sample size calculation; preparation of funding applications; protocol development; case report form design; specialist clinical trial IT systems; data collection and management; central trial management and monitoring; regulatory affairs and quality assurance; and statistical analysis and reporting.

### **What type of trials does ICR-CTSU design and run?**

Our trials form an important component of the national portfolio of randomised phase III trials in breast, urological and head and neck cancers and trials evaluating new radiotherapy techniques and we have an expanding portfolio of early phase trials including exploratory phase II targeted treatment trials, trials in rarer tumour groups and trials in the surgical setting. Integrated translational research is fundamental to our scientific strategy. All our trials are multi-centre and will have been endorsed by the relevant NCRI Clinical Study Group.

### **How are ICR-CTSU trials managed?**

All ICR-CTSU trials fall under the scientific leadership of either the Director, the Deputy Director (Research) and other ICR-CTSU Faculty. Clinical Trial Programme Managers, working under the direction of the scientific lead, are each responsible for overseeing a component of the trials portfolio. Each trial has a named statistician and a dedicated trial manager, with data management, database programming and administrative support. The trial manager is responsible for the central coordination of the trial including initiating new sites, monitoring data and sample flow, monitoring data quality and site conduct, managing pharmacovigilance activities, maintaining trial approvals, and reporting trial conduct to the trial oversight committees, sponsors and funders. Central statistical monitoring and data analyses are conducted by the trial statistician under the direction of the scientific lead (see also 'How ICR-CTSU Manages Clinical Trials' diagram at the end of this document).

### **Who does ICR-CTSU work with?**

In addition to clinical colleagues at the Royal Marsden/ICR, ICR-CTSU works with key opinion leading clinicians and scientists located throughout the UK and in close collaboration with NCRI Clinical Studies Groups to help formulate and drive the national clinical research portfolios. Close collaborations exist with national and internationally located cooperative groups, trials units and academic laboratories.

### **How does ICR-CTSU prioritise trials?**

When prioritising trials, we take into account whether the trial aims are consistent with ICR-CTSU scientific strategy; the relevance and priority of the trial as assessed by the respective NCRI CSG; recruitment feasibility

based on expected incidence and competing trials; and the potential for the development or expansion of a sustainable and systematic programme of research.

#### **How are ICR-CTSUs trials sponsored?**

Trials managed by ICR-CTSUs are usually sponsored by ICR. Occasionally trials may be sponsored by a 3<sup>rd</sup> party academic collaborator (potentially international) or, in exceptional circumstances, a commercial partner (usually large, complex, international trials).

#### **How are ICR-CTSUs trials funded?**

Individual trials are funded via projects grants from NCRI partner organisations including CR UK, by NIHR project grants and by educational grants from industry. We have considerable expertise in costing clinical trial activity (including central trial management and local site participation costs), and work in partnership with CIs to ensure that research, service support and excess treatment costs are accurately attributed.

#### **How are ICR-CTSUs trial grants administered?**

The CI and ICR-CTSUs Scientific Lead are usually co-lead applicants on grant applications. This enables ICR to administer the grant and for the trial to contribute to the REF of both the CI's host institution and ICR. ICR usually holds and administers the grant as the majority of the research costs relate to the central trial management and statistical analyses. Any payments to cover research costs at participating sites are usually coordinated by ICR-CTSUs who are also responsible for implementing the required contracts between academic partners and with participating sites.

#### **Why does ICR-CTSUs require that industry funded studies are endorsed by CR UK's Clinical Research Committee (CRC)?**

Endorsement of industry funded trials by CRC facilitates NIHR portfolio adoption enabling access to NHS service support and excess treatment costs for participating sites. CRC endorsement also enables access to core support from our CR UK programme grant which provides high level scientific and operational oversight and budget and contracts management.

#### **What would my responsibilities be as a Chief Investigator?**

You would be expected to work in close collaboration with ICR-CTSUs on all aspects of study design and conduct from concept development through to final analysis and reporting. A detailed explanation is provided in a CI Responsibilities document which as a CI of an ICR-CTSUs trial you would be expected to sign.

## How ICR-CTSU Manages Clinical Trials:

