Cancer Research UK Clinical Trials Unit Glasgow and Beatson Clinical Research Facility

Quality System

Description of the Cancer Research UK Clinical Trials Unit Glasgow and Beatson Clinical Research Facility

The Cancer Research UK Clinical Trials Unit (CTU) Glasgow and the Beatson Clinical Research Facility (BCRF) are co-located in the Beatson West of Scotland Cancer Centre (BWoSCC) in Glasgow with a small number of staff housed within other NHS/UoG accommodation in Glasgow. Although the CTU and the BCRF work closely together, and some staff have responsibilities and oversight in both activities, the activities of both functions are entirely separate. This document provides a description of both activities.

With respect to the Quality System for the CTU and BCRF, there is one Quality System in place which encompasses both activities. Within this, there are Quality Documents and Standard Operating Procedures (SOP) which are overarching across both activities as well as clearly defined SOPs that are specific to only one activity. The SOP prefix within the SOP name identifies which SOPs are overarching and which are specific:

- SOP-CTU-GEN (general) are SOPs that cover both activities and could be applicable to staff within the CTU and BCRF
- SOP-CTU-TCC (trial coordinating centre) are SOPs for the CTU activity and are only applicable to staff within the CTU
- SOP-CTU-PTS (participating trial site) are SOPs for the BCRF activity and are only applicable to staff within the BCRF

The CTU Quality Assurance Manager (QAM) is responsible for the management and oversight of the Quality System and all documents are managed within Q-Pulse. Please refer to the SOP on SOPs for further information regarding the entire SOP process (CTU-GEN-GEN-002).

Cancer Research UK Clinical Trials Unit (CTU) Glasgow

The CTU is a UK Clinical Research Collaboration (UKCRC) Registered CTU with responsibility for the development and coordination of academic-led cancer clinical trials. All administrative aspects of the clinical trial are co-ordinated by the CTU. Key tasks involve funding applications, development of clinical trial protocols, preparation of regulatory and ethical documentation, collection, processing and analysis of data, and preparation of reports and publications.

Trials can be developed locally by Chief Investigators (CIs) employed by either the University of Glasgow (UoG) or Greater Glasgow Health Board (GGHB) or by CIs employed by other Institutions. Sponsorship (legal oversight and indemnity) for CTU trials is provided by NHS Greater Glasgow and Clyde Health Board with or without University of Glasgow as Co-sponsor (a collaboration overseen by Glasgow Biomedicine).

Cancer Research UK fund many CTU personnel via a Core CTU Programme Grant that is renewed every 5 years subject to external scientific peer review. Project grants fund other CTU personnel for the duration of the project. Research personnel include project managers, trial coordinators, statisticians, IT, pharmacovigilance and QA staff.

The UKCRC Registration of the CTU is part of a collaboration known as Cancer Clinical Trials Unit Scotland (CaCTUS) which is a partnership between the CTU and the NHS Cancer Clinical Trials Services in Edinburgh. As an organisation, CaCTUS is committed to working with investigators to develop and manage new cancer clinical trials. CaCTUS have a small number of overarching SOPs which apply only to the working of the collaboration itself which are not part of the CTU Quality System and not managed by the QAM.

All new trials taken on by the CTU require to be reviewed and approved by the In-House Trials Advisory Board (IHTAB) – please refer to the IHTAB Quality Document for more information on this process.

Beatson Clinical Research Facility (BCRF)

Participating site activity can be viewed as the NHS delivery end of clinical trials: putting patients and their data into clinical studies. The BWoSCC is the largest participating site in the Scottish Cancer Research Network (SCRN). All administrative aspects of trials in which the BWoSCC participate are performed by the BCRF. The majority of these trials are multicentre clinical drug trials (Clinical Trials of an Investigational Medicinal Product CTIMPs). Between 45-50% of these trials are pharma/industry funded trials that are commercially-sponsored. The rest are academically-sponsored trials (non-commercial), the majority of which are eligibly funded (for instance by cancer research charities). These include those trials that are co-ordinated by the CTU.

Early phase trials, which require close monitoring of patients during treatment, run through the Clinical Research Unit (CRU) within the BWoSCC. Late phase trials generally need larger patient numbers to participate and patients usually receive their study treatment through standard care routes.

For both early and late phase trials, the research infrastructure (for instance clinical trial coordinators, research nurses, pharmacist, radiographer, lab technician) is funded by commercial income, NHS R&D (CSO), SCRN, Experimental Cancer Medicines Centre (ECMC), and some project-specific grant monies.

The CRU and SCRN have their own Quality Systems that are completely independent to the BCRF Quality System.

All new trials taken on by the BCRF require to be reviewed and approved by the Clinical Trials Executive Committee (CTEC) – please refer to the CTEC Quality Document for more information on this process.

Document History

Version	Approved	Effective	Reviewed	Comments
Version 1	05 Aug 2002	05 Aug 2002	19 Jul 2007	New Reference Document
Version 2	10 Aug 2007	10 Aug 2007	17 Apr 2018	Significant changes throughout document. (Revision author: Andrea Harkin)
Version 3				