

## NCRI trials centre approval for Scotland

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In April we received the great news that a joint bid between ourselves and ISD (Information Services Division) to become an approved co-ordinating centre for National Cancer Research Institute (NCRI) clinical trials was approved. We are the only such centre in Scotland and we intend to act as a service for the whole Scottish oncological community – not just Glasgow and Edinburgh. There is a bit of history and some rather complex interactions in the clinical trials arena right now. Multiple acronyms do not help – so I will explain them as they appear. This short article is intended to throw some light on these arrangements as they stand at the moment – and since I am based in Glasgow the article will be particularly biased to that constituency. Since I chair a number of these organisations I find myself having to explain these interactions on a frequent basis – so here goes.

Cancer Research UK is the single biggest cancer charity in the UK and was formed by the merger of the Cancer Research Campaign (CRC) and the Imperial Cancer Research Fund (ICRF). It has supported the clinical trials unit (CTU) based in the Beatson Oncology Centre (BOC) for many years. This support is in the form of programme funding with quinquennial review. Happily at our last review we were alpha –star rated (the top bracket) and our funding was renewed in full. The CTU has built up an enviable reputation over the last 20 years. Particular strengths being the phase I (first in man) studies and the SCOTROC series of large scale randomised trials (Scottish Trials in Ovarian Cancer). All studies are performed to GCP (Good Clinical Practice) guidelines and we have in place written SOPs (Standard Operating Procedures) for all activities related to the conduct of the trial and data collection and handling. This all requires a small army of people who design the studies and case report forms (CRFs), look after the patients and collect and collate the data. Additional support for these staff comes from the commercial trials which we perform in the department under the umbrella organisation called Glasgow Biomedicine which is a Trust / University joint initiative.

The early phase trials are performed in a dedicated clinic and bed space known as the Clinical Research Unit (CRU) which is staffed by personnel who have specialist trials experience. In addition, as and when we do

studies with special assays applied to patient materials the samples are taken and processed according to GLP standards (Good Laboratory Practice) and trials specific SOPs. They are then shipped to our laboratories on the Garscube estate for analysis in a dedicated lab known as the ASU (Analytical Services Unit) which in turn has quality assurance processes in place. This may all seem like overkill – but imagine yourself trying to decide on the therapy of a patient without the confidence that all the relevant investigations had been done to a high quality standard. This actually goes on in all service labs (for example haematology), which are nationally certified, but we are just not so aware of its presence. In fact, this has been an area of immense change and extra investment in the last few years.

NTRAC ( National Translational Cancer Research) was set up as a joint initiative between the Department of Health in England and Wales and the CSO (Chief Scientists Office) in Scotland. We made a joint bid with colleagues in Dundee and became an NTRAC centre about 1 year ago. We used the extra funding awarded from this source kit out ASU and to employ specific staff with a remit to perform assays and associated Quality Assurance procedures. We also supported a part of the set up of the local biobank which aims to retrieve and store fresh tumour tissue from cancer patients with all the necessary consent needed to facilitate translational projects using these tissues.

England set up a National Cancer Research Network (NCRN) some 3 years ago with the remit to double accrual to cancer trials. This was initially limited to trials within the NCRN portfolio. In Scotland this was set up in 3 regional networks with support from the Scottish Executive. In the West of Scotland (WoSCRN) we elected to set this up in a decentralised way. So the majority of research staff are employed in regional health boards with service level agreements in place to ensure shared objectives. In the BOC we have 3 staff with responsibility of managing this network and developing information technology to support local trials set-up, screening of patients, randomisation and delivery of therapy. Many objectives of this organisation have big overlaps with CTU and we envisage these two parts becoming more seamlessly integrated in future.

The role of NCRI co-ordinating centres is to develop new studies usually in collaboration with specific NCRI cancer studies groups (for example the lung cancer sub-group). This involves involvement in study concept, design, statistical input, protocol development, funding requests and appropriate peer review. The ISD (in a previous guise know as the SCTN

– Scottish Cancer Therapy Network) in Scotland has particular strengths in this area and has been doing these tasks for many years. The major focus of this work has been in the field of breast cancer.

The NCRI Cancer Clinical Trials Unit for Scotland is a joint effort between us and ISD. The first steps towards adopting unified working arrangements and SOPs have been taken already. A steering group with representation from both organisations has already met and will soon issue a tender for a £50K contract to facilitate and accelerate this process. We have also put our first proposal to an NCRI disease specific sub-group to develop a trial with them to get this going. At the moment we have this unwieldy name – I think CACTUS sounds good – Cancer Clinical Trials Unit Scotland.