

CRF Application Details:

For further
information about
applying to use the
CRF, please
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You can also visit
our website at:
www.wtcrf.ed.ac.uk

Phase I Accreditation Scheme

MHRA

In November 2007, the Medicines and Healthcare products Regulatory Agency (MHRA), introduced a voluntary accreditation scheme for units conducting Phase I clinical trials. Accredited units must meet stringent standards for avoiding harm to trial subjects and for handling medical emergencies should they arise. Integrated within NHS hospitals that offer immediate access to critical care facilities, CRFs provide an optimal environment in which to undertake Phase I clinical trials.

In November 2010, Edinburgh CRF became the first non-commercial clinical research facility in the UK to be considered for Phase I Accreditation with the MHRA. We applied for supplementary accreditation and underwent a full GCP and Phase I inspection. During the course of our inspection, we worked with the MHRA to demonstrate the key differences between hospital-based CRFs and commercial research units. After a final follow up visit in May 2011, we were informed that we can expect to be accepted into the scheme within the next few weeks. We eagerly await formal confirmation of our achievement and the receipt of our accreditation certificate!

NEW Gene Therapy Facilities at the CRF!

Since February 2008, Edinburgh WT-CRF has supported a consortium led observational run-in study aimed at defining levels of CF disease activity in individual patients. Information from the study is guiding the selection of effective methods for measuring changes in the lung.

The run-in study has been done in preparation for a clinical trial of cystic fibrosis transmembrane receptor (CFTR) gene therapy.

Building work began on the 30th of May 2011 to develop pressure controlled dosing cubicles in the WT-CRF. The new facilities are expected to be ready for use by the end of July.

The UK CF Gene Therapy Consortium recently won two prestigious Medical Futures Innovation Awards for this programme of work:

The Best Therapeutic Innovation (Respiratory) and the MRC Translational Research Award.

<http://www.ed.ac.uk/news/staff-bulletin/medical-futures-070611>

Publication Highlight!

Lowering the Troponin I assay diagnostic threshold improves outcomes in Acute Coronary Syndrome

Mills NL, Churchhouse AM, Lee KK, Anand A, Gamble D, Shah AS, Paterson E, MacLeod M, Graham C, Walker S, Denvir MA, Fox KA, Newby DE (2011)

Implementation of a sensitive troponin I assay and risk of recurrent myocardial infarction and death in patients with suspected acute coronary syndrome.

Journal of the American Medical Association
2011 Mar 23;305(12):1210-6.

Abstract:

<http://jama.ama-assn.org/content/305/12/1210.short>

CRF Study Information

CRF Application Forms

The CRF is developing an online application system for users.

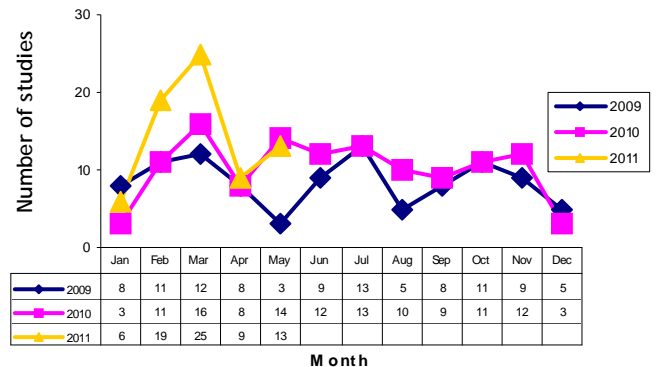
Annual Metrics Report

The yearly metrics report (1st April 2010 - 31st March 2011) is now complete! The CRF is required to report on the number of studies, subject visits, and publications. Our activity continues to increase year on year.



Development of an online CRF application system! Watch this space!

Number of CRF applications submitted - new studies



“CRF IT development highlights”

CRF IT Developments

Forms Manager System for study data capture (eCRFs)

Do you need to add a new field to an eCRF? IT have developed a system called **‘Forms Manager’**, which can be used to capture study data!

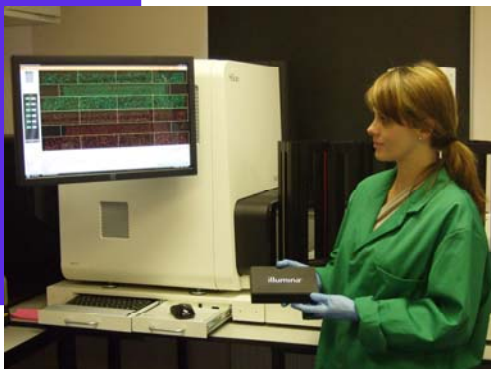
This allows the user to add, modify and delete fields. The CRF have already used the system for 4 studies and have more in line for the rest of the year, having received good feedback!

NHS R&D Trial Recruitment Register

Patient recruitment numbers are a key metric for funders. To make this data easier to collect for NHS R&D, our IT team has developed a website where investigators or trial data managers can quickly enter in patient recruitment for each trial they are running. This system is to now available to use!

Illumina HiScan Microarray Platform

Louise Evenden (Technician) using the ‘Illumina HiScan’



The Genetics Core has been running an Illumina Microarray platform for the past 5 years to investigate genetic variation, gene expression levels and methylation levels. The laboratory is the first in Scotland to purchase the latest platform, the ‘Illumina HiScan’ that is able to process the new generation of high density genotyping arrays utilising data from the 1,000 genome project.

This investment in new technology will ensure that researchers continue to get access to these top-of-the-range genetic platforms for their clinical research!

BRIC Launch!



The research Magnetic Resonance Imaging (MRI) facility at the WTCRF Imaging Core based at the Western General Hospital will be re-launched as the Brain Research Imaging Centre (BRIC) in Spring 2011. The Centre has a new logo (see above) to go with its new name, and a new website will be launched in the next few weeks (which will be at www.bric.ed.ac.uk).

The Centre has been functioning for over 12 years, and has carried out almost 20,000 research and related scans since

it opened.

The Centre houses a wealth of experience and knowledge surrounding a research-focused MRI scanner, allowing study of the brain in terms of disease states and also brain function, with notable studies carried out into: Stroke, Aging, Psychiatric Disorders, Multiple Sclerosis, Oncology and also a wide range of functional MRI studies plus MR method development studies.

HAIST Study

(Hypothermia Against Ischaemic Stroke Trial (check out <http://www.bbc.co.uk/news/health-12267140>) aka WTCRF study EI0802

This is a study being conducted at the BRIC. BRIC has been involved in a number of studies investigating "brain-cooling" as a tool to tackle stroke. The HAIST trial is a high profile pilot study (featured on Reporting Scotland and on the BBC website) led by Dr Malcolm Macleod from the Centre for Clinical Brain Sciences (CCBS), investigating how to cool and then maintain cooling of the brains of stroke sufferers using cold saline administration followed by use of "cooling blankets".

CRF Patient & Public Involvement

Public Open Day!

The CRF opened its doors to the public on the 20th May as part of a UK wide event involving members of the UK CRF Network. Visitors were able to learn more about research into various health conditions, including, stroke, cancer, diabetes, mental health and more.

Professor Ian Deary and Dr Mark Strachan presented talks on the importance of patients and the public getting involved in clinical research.

Visitors enjoyed some very interactive stands provided by the local research networks including; being a cancer detective and seeing cancer cells under the microscope and building a DNA molecule using jelly beans and cocktail sticks! The day was a great success and gave the public an opportunity to come and find out what happens in a Clinical Research Facility.

VITATOPS Participant Meeting!

On the 11th February 2011, the VITamins TO Prevent Stroke (VITATOPS) trial invited their participants to the Scottish Health Services Centre at the WGH, to listen to a talk from Professor Dennis Martin. This was an opportunity to feedback the results of the study and for the participants to have a chance to ask questions and network with other trial participants. The afternoon was a great success and it received very good feedback.

"What do professional cancer detectives do?"

"What's new in managing Diabetes and its complications?"

Editors

This is the first edition of the new CRF Newsletter. The newsletter aims to update everyone on any news, developments, events, study information, publications, new equipment or laboratory services that are available for use. You name it and we will distribute all the relevant

information you need to know! Please send any relevant information or feedback to: wtcrf.education@ed.ac.uk

Thank you
Michelle Evans and
Louise McKay
(CRF Education Programme)

