National Institute for Health Research

NIHR Clinical Research Network Accrual FAQs
For Non-Commercial Eligible Studies on the Portfolio

What is accrual?

Accrual is an individual incidence of recruitment to a study on the UKCRN Portfolio.

Why do I need to provide accrual data?

The NIHR Clinical Research Network (CRN) is committed to improving clinical research infrastructure/service support and to make this more accessible so that more patients can benefit from being part of a research study. Accrual data are part of the key performance indicators which are being used to demonstrate the success of the Networks. These data will also feed into the process of allocating future funding to the NIHR Comprehensive Local Research Networks (CLRNs) to ensure that infrastructure resources/service support are directed to where they are required. A list of CLRNs and information on which Network you will be part of can be found on our website at:
http://www.ukcrn.org.uk/index/networks/comprehensive/clrns.html

What forms can accrual information take and how is it recorded?

Accrual can exist in many forms including:

- patients recruited to a treatment regime
- staff members who have completed questionnaire(s)
- individual members of focus groups
- the collection of tissue or blood samples during research
- participants who have answered questions during research

In each of these situations a line of data should be provided for each accrual examined during the study.

Where an accrual event occurs twice in the same study, e.g. a staff member completes 2 questionnaires or a sample is tested twice, the accrual is only normally counted once.

For reasons of confidentiality we do not hold the dates of birth/genders/postcode of our participants is this information required?

No. This is not mandatory information; it is only those columns in red that are mandatory. The other/non-mandatory columns can be left blank on the spreadsheet.

We have not gained consent from our participants to pass their information onto a third party. Does this mean that we are unable to pass the information onto the UKCRN?

You are able to pass information to us. Security of information pertaining to participants in the studies registered on the Portfolio is extremely important to us. The fields on the spreadsheet that provide information which could identify the patient directly are not mandatory. We also ask that you ensure your StudyPatientNumber is not a hospital or NHS number or any other type of data that could be traced back directly to the patient. You will therefore not be providing us with any data which could directly identify the patient. We do not publish the detailed accrual data you provide us with; only total numbers of study participants are made publicly available.

For which time period(s) is data required?

As activity-based funding allocations to CLRNs will be based on activity from **1 April 2008**, a line of data is required for every study participant recruited after 31 March 2008. We encourage study coordinators to provide a line of data for each participant recruited prior to April 2008 in order to provide baseline data. Where this is not possible we request that total numbers of recruits are submitted wherever possible. When providing total numbers these should be submitted to the accrual team as two figures; recruitment for April 2007 to March 2008 and recruitment prior to April 2007. Totals should include ***all*** recruitment, including international recruits. (see below)

Should I provide information on study participants from the Devolved Nations or from other countries?

Data for participants recruited in the Devolved Nations (Scotland, Wales and Northern Ireland) should be included. The Portfolio database will allocate data to the appropriate Clinical Research Networks for resource allocation purposes. Recruits from outside the UK should not have a row of data listed, but should be included in the running total. As you may have seen on the Portfolio database, entries for non-commercial studies that are open have a percentage bar to indicate how far forward they are with recruiting their planned sample size. This bar is calculated from the running total column in your spreadsheet. Therefore if you omit patients recruited from outside the UK from your running total it will appear as if you are underachieving against your planned sample size.

I have a number of control subjects and healthy volunteers as well as those suffering from the disease I am studying. Is there anyway to record this in the accrual data?

Yes. The spreadsheet has a column entitled “RecruitType”, this column uses ones and zeros to denote whether the subject is a control or healthy volunteer (0) or a sufferer of the disease in question (1).

Our study is open to recruitment, but we have not recruited anyone. Can we record this?

Yes, there is a specific process for logging the fact that there has not been any recruitment. This is outlined in the Accrual Upload User Guide available at:
http://www.ukcrn.org.uk/index/library/ info_sys.html

The research question which my study is addressing is part of a larger programme of research work which is already registered on the Portfolio and is submitting accrual. Should I submit my study for inclusion on the Portfolio as a study in its own right and then report accrual separately for this sub-study?

For the purposes of the Portfolio, a study is generally defined as a structured research activity which is the subject of a single ethics approval. Therefore, if the research question being addressed in the sub-study, or “nested study” is covered by the ethics approval which covers the main study, the sub-study would not be viewed as a separate study in its own right and accrual would not be submitted for this study as it will already be being collected for the main study. However, if the sub-study or “nested” study is the subject of a separate ethics approval and patients who have previously consented into the main study were required to additionally consent into the sub-study, then the sub-study would be considered as a study in its own right, would need to be registered onto the Portfolio and would report accrual.

The general principal is that the process of obtaining consent should be counted as the accrual event as this requires the provision of the necessary clinical infrastructure and should therefore underpin resource allocation models.

My study does not involve the recruitment of patients but is addressing a "Service Delivery, Organisation" type of research question which involves the collection and analysis of information relating to organisations, e.g. GP practices/nursing homes/hospital wards, how do I record this?

Where a study involves individuals, e.g. interviews with GP Practice Managers/NHS staff to research the outcomes of changes to the pattern of service delivery, then each individual who takes part in the study should be recorded as a single accrual. If however, the study is pitched at the level of whole organisations and does not involve individuals in any way, then the number of organisations (e.g. GP practices) which are contributing in some way to the study should be reported as the accrual.

The patients participating in my study are being recruited at their local GP practice, however the research project which they are involved in is taking place in a hospital, should I report the accrual site name as the GP practice or the hospital?

In general, the site where the patient is consented should be listed as the accrual site. This is on the assumption that, in general, the site where the patient is recruited is the site where most of the NHS infrastructure support is required. If however, this is not the case, then discretion should be used, and the local CLRN should decide which is the most appropriate site to be linked to the accrual.

My study team is under resourced and therefore cannot complete this request for accrual data. Can I obtain resources elsewhere to support this?

The Comprehensive Clinical Research Network (CCRN) was set up to provide infrastructure support to clinical research in the NHS. The support provided by the CCRN can include appropriate staff costs, such as Data Managers and Research Management staff and other service support. You should therefore direct queries of this nature to your Topic or Comprehensive Local Research Network. Contact details of the management teams can be found at the web address below:
http://www.ukcrn.org.uk/index/networks/comprehensive/clrns.html

If I have further queries about collating and uploading accrual who should I contact?

Please contact the UKCRN Accrual Team on 0113 3430354 or at accrual@ukcrn.org.uk