

# **UK Clinical Research Network (UKCRN) Portfolio Database User Guide**

Version 1.1

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This User Guide has been developed to explain what the UKCRN Portfolio Database is and how it should be populated. The User Guide is primarily intended for use by the Topic-Specific Research Network (TCRN) Coordinating Centres and the Study Coordinators of all UKCRN portfolio studies. The document may also be useful as background information for the Local Research Networks (LRNs) and the Clinical Studies/Research Groups.

## **1. Background**

UKCRN has been established to provide support for clinical research and to facilitate the conduct of high quality randomised prospective trials and other well-designed studies. It is tasked with developing a world class infrastructure to support clinical research in the UK. Its specific aims are to:

- improve the coordination of research
- improve the speed of research
- maintain and enhance the quality of research
- widen involvement in research
- strengthen links with industry
- improve the integration of research.

LRNs are being established to facilitate the delivery of UKCRN studies, enabling more studies to be developed and delivered on time and to high standards. The TCRN Coordinating Centres are responsible for overseeing the development of a national portfolio of clinical research studies for their topic. (A separate paper is being finalised that describes which studies are eligible to join the UKCRN portfolio, and will be available on the UKCRN website in the near future).

When a study is added to the UKCRN portfolio it means that UKCRN-funded staff within the LRNs can work on that study. This can range from publicity of the study, to R&D approval applications, to identification and recruitment of patients, to collection of data, etc, depending on the available resource within individual sites in the Clinical Research Network.

The Study Coordinators of UKCRN studies are key individuals for UKCRN and its LRNs, as they are involved in the day to day management and coordination of the studies. They are also the people who have the detailed knowledge and information about UKCRN studies. Some of this information will be collected and stored in a central database, the UKCRN Portfolio Database.

## **2. Why is study information required for a Portfolio Database?**

As described in detail below, the UKCRN Portfolio Database is a key central resource for UKCRN, the TCRN Coordinating Centres and the LRNs, in order to store information about each study to assist the LRNs in developing their local portfolio and also in providing a high quality and reliable central register of all UKCRN

studies. The information provided will assist the UKCRN, TCRN Coordinating Centres and the LRNs in the performance management of their activities. The information will also provide key reporting data to allow UKCRN to report on its activity to the Department of Health and also the UKCRC Board, against the set of performance measures being developed and agreed by the UKCRC Board.

Provision of the study information and accrual data is therefore an essential component of UKCRN's activity.

It should be noted that work is on-going through the National Institute for Health Research (NIHR) to develop a unified set of web-based systems that will hold the information required to manage health and social care research in England. The integrated system is being designed to make the processes of information input, retrieval and dissemination faster and easier for everyone involved. This means that although the current requests for study information for the UKCRN Portfolio Database may duplicate the provision of similar information to other bodies involved in research in the UK (for example, COREC or MHRA), systems are being developed to streamline the collection of such information, with the intention of Study Coordinators/Chief Investigators only having to provide such information once and for that information to be shared across relevant organisations. Your cooperation in providing the required data in the interim period whilst this system is available is much appreciated.

### **3. Overview of UKCRN Portfolio Database**

The UKCRN Portfolio Database has been developed by the UKCRN Coordinating Centre in collaboration with each TCRN Coordinating Centre, using the National Cancer Research Network Database as its core design. Additional functionality has been added for the purposes of UKCRN. The Portfolio Database was launched in spring 2006 and will be continually developed as the TCRNs begin to use the database. Some reporting functions have yet to be introduced.

The UKCRN Portfolio Database has a number of key functions:

- Central register of UKCRN studies (<http://pfsearch.ukcrn.org.uk/>) – this enables TCRNs and their LRNs to search for and access information about the studies in the TCRN portfolio and indicates which studies UKCRN staff are able to work on. The register also promotes the studies in the portfolio. A small set of information about studies in the database is accessible by anyone using the UKCRN web site. The database is kept up to date with newly-funded studies and with any new information about portfolio studies on a daily basis.
- Central database of accrual data for UKCRN studies – this stores UK-wide recruitment data collected on a monthly basis. An overall accrual figure is publicly available, but access to more detailed accrual data is password-protected and limited to staff working on UKCRN studies. Individual LRN staff can only access detailed accrual data for their LRN.
- Source of reports to support the management of UKCRN and its LRNs – these enable TCRNs to manage activity across and within its LRNs and for LRNs to manage activity across its sites. Reports are available that describe recruitment across sites within the LRNs and on accrual to different types of study within the

TCRN and LRN (for example, accrual to industry versus non-commercial trials). Reports are also available on portfolio activity, for example numbers of active studies and number of active sites per study. Report access is password-protected to staff working on UKCRN studies. See Section 5 for details on how to access the reports.

- Source of reports to enable performance management of the activity of UKCRN and its LRNs – the reports described above also allow the UKCRN to report on its activity against an agreed set of performance measures (currently being finalised).

The UKCRN Portfolio Database is accessible on the UKCRN web site. As noted, some information is publicly available, but many functions are limited to staff working on UKCRN studies.

#### **4. Population of the UKCRN Portfolio Database**

The UKCRN Coordinating Centre Information Systems team have overall responsibility for the development and management of the UKCRN Portfolio Database, including report definition (in discussion with TCRNs) and report design.

Each TCRN Coordinating Centre is responsible for identifying studies for its own TCRN portfolio. This includes identifying on-going studies to establish the initial TCRN portfolio and then identifying newly funded studies on an on-going basis. TCRN Coordinating Centres must seek confirmation of portfolio eligibility for individual studies from the UKCRN Coordinating Centre whilst the initial TCRN portfolio is being established.

Permission to add and approve UKCRN portfolio studies in the Portfolio Database is limited and password-protected. TCRN Assistant Directors are responsible for identifying which level of access different staff involved in TCRN studies should have. Permission can be given for the four tasks listed below. Suggestions are given for who might have access to each task. TCRN Coordinating Centre staff can have access to all studies and all tasks, at the discretion of the TCRN Assistant Director. Study Coordinators will only be able to access the studies for which they are responsible, even if they have access to more than one of the tasks listed below.

Population of the UKCRN Portfolio Database is via a web-based proforma (see Section 4 for details on how to access the database). Each stage of data entry (see below) includes a number of data entry pages, organised into grouped tasks (for example, when providing study information, data items relating to study design are grouped together on one page). It is recommended that the user clicks 'save' when data is added to each page. This will ensure that no work is lost if the user has to break off from data entry. It is also worth noting that users do not have to enter all data items on a page at the same time – individual items can be added as and when.

A summary of how and when information should be added to the UKCRN Portfolio Database is given in Appendix 1. Before any study information goes live on the UKCRN web site, the TCRN Coordinating Centre has to approve that information. This means that once a Study Coordinator adds any information it will not go live immediately.

Population of the database includes the following stages:

**a. Initialising a new study** – this involves adding a small core set of information about individual studies being added to the Portfolio Database, and should be carried out by TCRN Coordinating Centre staff. As soon as the TCRN Coordinating Centre becomes aware of an eligible study, it can be added to the UKCRN Portfolio Database. The database can flag if a study has been funded but is still in set-up. This can assist TCRNs and LRNs in developing the individual LRN portfolios and will assist in planning future portfolios.

The fields required to initialise a study are listed below:

| Field                     | Description   |
|---------------------------|---|
| Acronym/Short Name        | Short name or acronym of study  |
| Study Title               | Title of study as it appears on the protocol. An abridged title can also be added that will appear on the public searchable UKCRN Portfolio Database. |
| Primary Topic             | Main Topic in which the study belongs   |
| Sub-topic                 | Sub-topic(s) under whose remit a study falls.   |
| Portfolio Eligibility     | How the study qualifies to be part of the UKCRN portfolio   |
| Study Coordinator Details | Details of the main day-to-day contact for the study  |

Once studies are added to the Portfolio Database (initialised), they are stored on the system but not displayed on the public searchable database on the UKCRN web site until further study details are added (see point b).

**b. Providing study information** (add/amend details of existing studies) – this involves adding additional information about UKCRN studies and can be added either by TCRN Coordinating Centre staff or the individual Study Coordinators for the portfolio studies. Most of the information required needs to be added whilst the study is in set-up. Some fields are only required towards the end of the study (e.g. publications).

A minimum dataset has been included in this step. These data fields are:

| Field                        | Description   |
|------------------------------|---|
| Portfolio qualification date | Date when the study became eligible to be added to the TCRN Portfolio   |
| Active status                | Whether study is in set-up, open to recruitment or closed   |
| Clinical Studies Group       | Clinical Studies Group  |
| Disease/diagnosis            | Specific disease/diagnosis of the patient population for the study  |
| Is this a randomised study?  | Whether or not the study, or any part of it, is randomised  |
| Primary study design         | Design of the study (interventional, observational, both)   |
| Overall sample size          | Total number of subjects to be recruited to the study from all sites/countries  |
| Geographical scope           | Location of study sites (UK multi-centre, international multi-centre, single centre)  |
| Inclusion criteria           | Key inclusion criteria for participant selection  |
| Exclusion criteria           | Key exclusion criteria for participant selection  |
| Funder                       | Name(s) of funding body(ies)<br>date when outline grant application submitted, date when full application submitted, date of funding award, date when grant started, date of MREC, dates of patient entry |

|                                    |  |
|------------------------------------|--|
| Degree of commercial participation | Whether or not industry is supporting and/or sponsoring the study    |
| Planned start of recruitment       | Date when it is planned that the study will open to recruitment      |
| Planned end of recruitment         | Date on which it is planned that the study will close to recruitment |
| Is the study open to new centres?  | Whether or not the study is open to additional centres               |

The items in the minimum dataset have to be added before a study can go live in the UKCRN Portfolio Database, when it will appear on the search tool on the UKCRN web site. It is important that these data items are added as soon as possible once a study has been initialised so that the LRNs are aware of new studies. If the user inputs data into all the fields which make-up the minimum dataset the system will allow them to save the record as complete and ready for approval by the TCRN Coordinating Centre (meaning that it may be displayed on the web site once approved); otherwise the information may only be saved as incomplete.

The other fields required during the set-up phase should then be added as soon as those data are available. They do not have to be added together, but ideally all will be added before a study is open to recruitment. The fields required here are:

| Section             | Field                              | Description  |
|---------------------|------------------------------------|--|
| Basics              | ISRCTN                             | International Standard Randomised Controlled Trial Number (only applies to RCTs)   |
|                     | EudraCT number                     | Number given to a study when added to the EudraCT database (only applies to trials of medicinal products)  |
|                     | MREC number                        | Allocated MREC number  |
|                     | MREC date                          | Date on which MREC approval was first given for the study  |
| Topics              | Clinical Studies Group             | Name(s) of Clinical Studies/Research Group(s) associated with the study  |
| Study Design        | Observational                      | Specific design of an observational study  |
|                     | Interventional                     | Specific design of an interventional study   |
|                     | Interventional detail, if required | Specific treatment being investigated in an interventional study   |
|                     | UK sample size                     | Total number of subjects to be recruited to the study from UK centres  |
|                     | Description of sample size         | Free text to add information about the sample size, e.g. number of patients to be registered and number to be randomised   |
|                     | Phase                              | Phase of the study (I, II, III etc)  |
|                     | Length of follow up (months)       | Maximum length of follow-up (in months) for patients in the study  |
|                     | Planned date of primary analysis   | Estimated date when the primary analysis is planned to take place (1 <sup>st</sup> of the month can be added if exact date not yet known)                                    |
|                     | Planned date of presentation       | Estimated date when the presentation of the results of the primary analysis is planned to take place (1 <sup>st</sup> of the month can be added if exact date not yet known) |
| Eligibility         | Sample gender                      | Gender of patients eligible to be included in the study  |
|                     | Lower age limit                    | Lower age limit for patient selection in study   |
|                     | Lower age limit units              | Units of the lower age limit (days, months, years)   |
|                     | Upper age limit                    | Upper age limit for patient selection in study   |
|                     | Upper age limit units              | Units of the upper age limit (days, months, years)   |
| Support and Funding | Name of Sponsor                    | Name of organisation or individual sponsoring the study  |

|                         |   |   |
|-------------------------|---|---|
|                         | Subvention Criteria   | Criteria required for subvention to be awarded in study, if applicable  |
|                         | Subvention Amount   | Amount of subvention received, if any, with notes   |
|                         | Within scope of EU directive                                    | Whether or not the study falls within the scope of the EU Directive for Clinical Trials   |
|                         | Detail of commercial involvement, if applicable                 | If industry is involved in the study, details about how   |
|                         | Degree of Consumer Involvement                                  | Degree to which patients and the public/ consumers have been involved in the study development  |
|                         | Detail of consumer involvement, if applicable                   | If patients and the public/consumers have been involved in the study, details about how   |
| Recruitment             | Actual start of recruitment                                     | Date on which the study first opened to recruitment – i.e. when the first centre was ready to begin enrolling patients, not when the first patient was enrolled |
|                         | Date first UK site activated                                    | Date when the first patient in a UK site was enrolled   |
|                         | Actual end of recruitment                                       | Date when the study closed to recruitment   |
|                         | How do patients join the study                                  | Details on how patients join the study – whether they are Randomised, Registered etc  |
|                         | If other, please enter details                                  | If patients join the study by an 'other' route to one specified in the above field, details of how enrolled   |
|                         | Accrual note  | Any comments/notes about patient entry  |
|                         | Study Settings  | Whether the study is being carried out in primary care, secondary care, tertiary care or an other setting   |
|                         | Estimated recruitment in the first year                         | An estimate of the number of patients expected to be recruited in the first 12 months of the study  |
|                         | Estimated annual recruitment in subsequent years                | An estimate of the number of patients expected to be recruited in the second and subsequent years of the study  |
|                         | Planned number of UK sites                                      | Number of UK sites expected to participate in the study   |
| Management and Contacts | Is the primary Coordinating Centre for this study within the UK | Whether or not the unit/centre responsible for the central coordination of the study is based in the UK   |
|                         | Current protocol version  | Version number of the current version of the study protocol   |
|                         | Date of release for this protocol                               | Version date of the current version of the study protocol   |
|                         | Protocol web address (if available)                             | Web address of online version of protocol, if available   |
|                         | Study email address   | Specific email address for the study management team  |
|                         | Study web site (if available)                                   | Specific web address for the study management team or for study information   |
|                         | Accrual contact   | Name and contact details of the person who will be responsible for supplying accrual data to the UKCRN  |
|                         | Chief investigator  | Name and full contact details of the Chief Investigator   |
| Summary                 | Federal Wide Assurance  | Whether or not Federal Wide Assurance required for the study  |
|                         | Treatment schedule (if available)                               | Facility to upload a graphical view of the treatment schedule, if available   |
|                         | Treatment graphic   | Facility to upload a graphical view of the treatment flowchart, if available  |

|                   |   |  |
|-------------------|---|--|
| WHO Registration* | WHO number                                    | Once system established, WHO trial registration number   |
|                   | Interventions                                 | Once system established, specific name(s) of the intervention(s) and the comparator being studied  |
|                   | Outcomes                                      | Once system established, specific measurements or observations used to measure the effect of experimental variables in a study   |
| Notes             | Study Notes (not displayed on public website) | Comments/notes on the study that will not be displayed on the public website but which may be useful for the TCRNs to know about. This may refer to the background to the study or to changes to the design which have happened over time. |
|                   | Additional Notes (visible on public website)  | Comments/notes on the study that will be displayed on the public website. This may refer to the background to the study or to changes to the design which have happened over time.   |

\* Note that this process is under development by the WHO International Clinical Trials Registration Platform and no information is currently required on this page

As noted, some fields are only required towards the end of the study. These are listed on the Portfolio Database entry screen under 'Publications' and are:

| Field                           | Description   |
|---------------------------------|---|
| Actual date of primary analysis | The date when the primary analysis was completed            |
| Actual date of presentation     | The date when the study results were ready for presentation |
| Date of main study publication  | The date when the primary analysis was first published      |
| Citations for this study        | References for any publications arising from the study      |

It should be noted that work is on-going within the UKCRN Coordinating Centre to provide further guidance on the requirements for these data items, for example clarification on whether all presentations (oral and/or poster) should be included and whether all publications should be included. Further guidance will follow.

It is the TCRN Coordinating Centre's responsibility to ensure that study information is provided promptly, and for liaising with Study Coordinators to ensure that they are familiar with the database requirements and working. Support and advice can be provided by the UKCRN Coordinating Centre staff.

**c. Approving study information** (approve or reject changes to a study) - any information added to the Portfolio Database has to be approved before it goes live on the UKCRN web site. The TCRN Coordinating Centre staff are responsible for approving any new information or any updates to the study data. It is therefore recommended that TCRN Coordinating Centre staff regularly check the approvals screen to ensure that new information is approved promptly.

Once TCRN Coordinating Centre staff have approved new data/changes to study information, the new data will go live on the Portfolio Database.

**d. Provision of accrual data** – (process accrual data) accrual data is required on a monthly basis for recruitment at all UK sites involved in each UKCRN portfolio study. Each month an email requesting data will be sent to the individual identified as the accrual contact for that study (this may be the Trials Units, Study Coordinator or Investigator running UKCRN studies or the TCRN Coordinating Centres, if they are acting as a collection point for accrual data). Data should be uploaded to the system via a secure, encrypted web interface at which point it will be validated for both

format and content. Accrual data will be required in a standard format. Further details are available in the Data Collection Requirements (Accrual) document.

## 5. How to access the UKCRN Portfolio Database

A User account is needed in order to access the UKCRN Portfolio Database if you are adding details of new studies, modifying study information or uploading accrual data. Further details are available in the UKCRN Web Portal User Guide.

Please note that for security purposes the system will automatically log-out any user who has been inactive for 20mins or more. If you are working in the Portfolio for 20mins but do not save your work you will be prompted to log-in to the system again and at this point the data you have input will be lost. In order to avoid this situation you should save your work on a regular basis, perhaps every 5 mins. The system will then know that you are active and will not log you out.

## 6. Implications for NCRN

The UKCRN Portfolio Database must now be used to add study information and accrual data for NCRN studies.

The UKCRN Portfolio Database includes additional fields to the NCRN Portfolio Database, some of which are now minimum data items. This means that if any changes are made to NCRN studies, the database will flag if data items in the minimum dataset are to be added.

For data items not in the minimum dataset, it is not mandatory to add the additional fields for all NCRN studies. However, for relatively new studies, the NCRN Coordinating Centre may decide that these fields ought to be added and they will liaise with Study Coordinators to ask them to provide that data.

In particular, it would be useful to add all information regarding publications for all NCRN studies.

## 7. Further information

Further information can be obtained from the relevant TCRN Assistant Director or the UKCRN Coordinating Centre (Christopher Button, Research Network Lead, tel: 0113 392 4478, email: [c.button@ukcrn.org.uk](mailto:c.button@ukcrn.org.uk) or Maxine Stead, Assistant Director for Clinical Trials, tel: 0113 392 4046, email: [m.stead@ukcrn.org.uk](mailto:m.stead@ukcrn.org.uk)).

## Appendix 1. Summary of steps required to populate the UKCRN Portfolio Database

