

UKCRN Portfolio and Accrual System
Standard Accrual Data Format

Version 1.7

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Introduction

This document describes the UKCRN standard accrual data format. The list of data items given below is based on those which have been collected for the last five years for NCRN Portfolio Studies (the NCRN format is also shown at the end of this document). However, some additional items have been added in order to be able to report against the UKCRN's performance measures.

As the technical expertise and infrastructure of organisations and individuals supplying accrual data may vary, the data format has been designed to be relatively simple to generate, whilst providing the basic raw data which are required to support the reporting requirements of the UKCRN. As an aid to your understanding of the required format, the second part of this document is an explanation of the error messages which may be generated by the system as it attempts to validate your data.

The format of the data we require is shown below and an example is given. Because the data are intended to be read by a computer it will be essential that the format is followed precisely, for example:

- It is important that the column headings are as shown in below, and that all columns are present, even if they contain no information.
- The specified formats (e.g. for Dates and Investigator Names) must be as requested.
- The data should be in either Excel or .CSV format.
- All columns must be present even if the data may be absent
- All column names must be as specified, with no spaces and not as in the current (NCRN) format.
- Each file should contain only one table of data, although this may include more than one study. This table should not contain unnecessary blank rows or columns or hidden rows or columns. The column headings should appear only once at the top of the table and no additional 'heading' information should be present. See example below.
- Data for studies which are not in the UKCRN Portfolio must not be included in your submissions.
- In addition to the monthly accrual data we also need to know the total accrual into each study to date, this is a useful indication as to the level of completeness of a study, particularly where a study is recruiting both within and outside the UK, and assists the Topic Research Networks in planning their own portfolios; this is shown in the RunningTotal column.

- Data must be submitted for the whole of the current financial year and not just individual months. By providing this annual cumulative dataset the system will be able to check for retrospective changes to the data ensuring that the data on the UKCRN system are properly synchronised with the study data.
- The RecruitType field provides a means for reporting on accrual of subjects which fall outside of the scope of the main reported Network figures but which are nevertheless important for accurately representing network activity. For example in the case of the Cancer portfolio, overall accrual data is expressed as a percentage of cancer incidence and it is therefore appropriate only to include patients with a confirmed cancer diagnosis in this overall figure.

At present, RecruitType should be 1, except for non-cancer patient participants in Cancer portfolio studies which should be given a RecruitType of 0, for example all subjects recruited to primary screening or prevention studies and any unaffected individuals in control arms of some studies who should be given a RecruitType of 0.

StudyID	Acronym	InvestigatorName	InvestigatorID	SiteName	SiteID	StudyPatientID	StudyEntryDate	EntryEvent	EntryEventNo	RecruitType	RunningTotal	Gender	DOB	Ethnicity	Postcode
1356	Study1	Brown Dr P		Southern Hospital Atown	N0000111	TS001	13/01/2004	Registration	1	1	1	M	1960-11-01	1	LS99 9FF
1356	Study1	Brown Dr P		Southern Hospital Atown	N0000111	TS002	04/03/2004	Registration	1	1	2	M	1960-08-09	2	BD00 9PI
1356	Study1	Green Dr J		Southern Hospital Atown	N0000111	TS003	01/03/2004	Registration	1	1	3	F	1970-06-15	3	LS01 0XY
1356	Study1	Brown Dr P		Southern Hospital Atown	N0000111	TS004	12/02/2004	Registration	1	1	4	F	1954-10-06	4	LS01 0XY
1412	AStudy	Grey Dr R		Western Infirmary Btown	N0000056	AS346	22/03/2004	Randomisation	1	1	1	M	1955-08-21	5	LS01 0XY
1412	AStudy	Grey Dr R		Western Infirmary Btown	N0000056	AS347	30/01/2004	Randomisation	1	1	2	F	1951-01-10	1	LS01 0XY
1412	AStudy	Brown Dr P		Southern Hospital Atown	N0000111	AS348	03/02/2004	Randomisation	1	1	3	M	1952-09-30	2	LS01 0XY

UKCRN Standard Accrual Data Format

Column Heading (fields in bold are mandatory)*	Description	Required Format	Comments
StudyID	Identifier for a UKCRN Study (provided by the UKCRN Coordinating Centre).	Number	This will be supplied to you by the UKCRN or Topic Coordinating Centre once the study has been initialised on the system (i.e. the initial record has been created). If you are submitting data for more than one study they may all be included in the same spreadsheet.
Acronym	Short name or Acronym of study.	Free text	Must be the same as the current acronym stored in the UKCRN database (which will have been input by the Topic data manager).
InvestigatorName	Name of a randomising/registering Consultant/Doctor.	Surname Title Forename(s)/Initial(s), e.g. "Brown Dr Charles".	Please note that if you are submitting .CSV files and your data for this field contains commas (e.g. Jones, Dr K) you should enclose the data in double quotes " ".
InvestigatorID	Identifier for a randomising/registering Consultant/Doctor.		Not in use at present as there is no code list available for Investigators, please leave this column blank.
SiteName	Name of Site of study entry.	If you are using the standard UKCRN site codes you should use the site names as listed in the Site Codes file (see below). If you are not using the standard codes then you should give Site Name and the name of the appropriate Town or City, e.g. "Derriford Hospital Plymouth".	A site may be any location at which study participants may be recruited. Please note that if you are submitting .CSV files and your data for this field contains commas (e.g. Derriford Hospital, Plymouth) you should enclose the data in double quotes " "
SiteID	Identifier for Site of study entry	UKCRN provide a list of Site Codes - See note below on Hospital/Accrual Site Codes).	MUST NOT BE the patient's Hospital Record Number.
StudyPatientID	Pseudo-anonymised identifier for a patient within a study.	As recorded in study database	MUST NOT BE the patient's Hospital Record Number.

StudyEntryDate	Date on which a patient was either registered or randomised into a study.	dd/mm/yyyy, e.g. 14/02/2004	
EntryEvent**	Type of study entry.	'Randomisation' or 'Registration'	Registration is the default option to use if the study is not randomised. NB please see note ** below
EntryEventNo	Used for studies with multiple randomisations, e.g. if a patient is randomised 3 times, their third randomisation will be EntryEventNo 3.	Numeric	Default value = 1. If participant is registered, not randomised the value in this field should be 1 Usually, if your study has multiple randomisations, only the first randomisation will count for accrual purposes. You should assume that this is the case and only submit data for first randomisations unless the appropriate Topic Coordinating Centre requests otherwise.
RecruitType	Indicates whether the individual can be included in the incidence-based target (if appropriate).	Options are 1 (recruit included) or 0 (recruit not included). Default is 1.	At present, RecruitType should be 1, except for non-cancer patient participants in Cancer portfolio studies which should be given a RecruitType of 0 (for further information see above).
RunningTotal	The total accrual into the study since it opened to recruitment, including non-UK centres if appropriate - used by UKCRN as an indicator of the completeness of the study.	Numeric	May appear in one row only (per study in the file) or as a running total against each row.
Gender***	Gender of person recruited to a study.	'M' = Male, 'F' = Female	
DOB***	Date of birth of person recruited to a study.	Text, using ISO date format, i.e. YYYY-MM-DD.	This allows for varying degrees of detail as appropriate. The data supplier only needs to send the full date if that level of detail is required by the specific Topic
Ethnicity***	Ethnicity of person recruited to a study	Number	A list of codes to be used are available for download from the UKCRN web site at: http://www.ukcrn.org.uk/index/library/info_sys.html
Postcode***	The postcode of the participant	Will be used for analysis of the	The left hand part of the postcode and the

	at the time that they joined the study.	socio-economic groupings of study recruits.	numeric part of the right side only will be used, however it makes for a simpler process if the whole code is sent and the unwanted part removed by UKCRN.
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* Whilst all columns MUST be present in your data, mandatory columns must contain data.

**EntryEvent: Please note, we only require subject information once. Where there is a two-step process to recruitment (e.g. for studies with a registration and subsequent randomization) please provide a single record for each subject, depending on whether the Registration or the Randomisation is the point at which they officially join the study.

***It is acknowledged by the UKCRN that, in most cases, information on Gender, Date of Birth, Ethnicity and Postcode may not be available for current studies. These items are not mandatory and may be omitted from your upload (however you must leave the empty columns in place).

Hospital/Accrual Site Codes

As a means of facilitating data exchange, the UKCRN provide a set of codes which uniquely identify those locations (or accrual sites) where studies recruit subjects. These codes will be supplied by the UKCRN such that they can be integrated directly into users' own systems or mapped against users' own coding schemes. At present the code list identifies most UK hospitals. This list however, is not intended to be definitive and will continue to grow as new accrual sites are identified.

The list of codes is available for download from the Library section of the UKCRN at:

http://www.ukcrn.org.uk/index/library/info_sys.html

It is the intention of the UKCRN that, over time, all studies will use these codes when reporting accrual data to the Coordinating Centre.

Investigator Codes

The InvestigatorID column in the file structure shown above is present as future-proofing in case a standard set of codes for Investigators, which could be integrated into the system, becomes available. As there is currently no such code list this field should be left blank.

Feedback and Error Messages from Accrual System

If the data you have submitted differ from to the required specification, the system will generate either Warnings or Errors. Warnings are intended to draw your attention to aspects of the data which may be incorrect, however they do not prevent the data from being uploaded to the system. Errors, on the other hand indicate more serious issues with the data and require that you cancel the upload and modify your data file before attempting the upload again. When the system generates either an Error or a Warning, you will be able to identify the row(s) in the data file which must be corrected by viewing the details of the error. Further details of this process will be given in a more detailed User Guide which is currently in preparation and will be circulated shortly.

As an aid to your understanding of the required format, the table below is an explanation of the error or warning messages which may be generated by the system as it attempts to validate your data.

<u>Ref No</u>	<u>Message</u>	<u>Meaning</u>	<u>Action Required</u>
24	AccrualSite details cannot be empty.	At least one row in the file you are uploading has no value in the AccrualSiteName and AccrualSiteID fields	Check the original file and ensure that there is at least AccrualSiteName for each row before attempting the upload again.
26	AccrualSiteID and AccrualSiteName are inconsistent.	At least one row in the file you are uploading has values in the AccrualSiteName and AccrualSiteID fields which do not refer to the same site.	Check the original file and ensure that all AccrualSiteIDs present correspond to the correct AccrualSiteNames before attempting the upload again. If there is no AccrualSiteID for one of your sites, please contact UKCRN for a number, via the UKCRN Helpdesk (see below).
5	AccrualSiteName cannot be empty.	At least one row in the file you are uploading has no value in the AccrualSiteName field.	Check the original file and ensure that an AccrualSiteName is present for each row in the file before attempting the upload again.
28	Invalid AccrualSiteID.	At least one row in the file you are uploading has a value in the AccrualSiteID field which is invalid.	Correct the data file so that all AccrualSiteIDs are valid before attempting the upload again. Valid IDs are 8 characters in length beginning with 'N'. If you do not know the ID for a site, leave this field empty.
27	AccrualSiteName is unrecognised.	At least one row in the file you are uploading has a value in the AccrualSiteName field which does not match a known site for the study concerned.	This message is a <u>warning only</u> and will not prevent your data from being uploaded. It may have occurred because you have added a new AccrualSite to your data and this is not currently associated with your study in the system.

			<p>You should view the details of the warning in order to determine whether the AccrualSiteName is correct and, if not, correct the accrual file before attempting the upload again.</p> <p>If the AccrualSiteName is correct you may ignore this warning and the data will be accepted into the system and the new site associated with your study.</p>
3	Acronym cannot be empty.	At least one row in the file you are uploading has no value in the Acronym field.	Check the original file and ensure that an Acronym is present for each row in the file before attempting the upload again.
37	DOB cannot be in the future. Invalid values will be ignored.	At least one row in the file you are uploading has a value in the DOB field which is in the future.	This message is a <u>warning only</u> and will not prevent your data package from being uploaded, however you should view the details of the warning in order to determine whether the data in the original file should be corrected before attempting the upload again. If you proceed with the upload, any invalid data in this field will be ignored by the system.
19	Invalid DOB. Date of birth should be formatted as either a four digit year (e.g. 1970), a year and month (e.g. 1970-12) or a year month and day (e.g. 1970-12-15).	At least one row in the file you are uploading has a value in the DOB field which is not in the correct ISO format, as described in the warning message.	<p>This message is a <u>warning only</u> and will not prevent your data from being uploaded if it uses an alternative date format from that specified, however you should view the details of the warning in order to determine whether the data in the original file should be corrected before attempting the upload again. If you proceed with the upload, any data in this field which is not in a valid date format or in ISO Date format as described will be ignored</p> <p>NB we have encountered some issues with importing dates from Excel spreadsheets. This warning may be displayed even if you have input your DOB data in the correct ISO format. If this is the case then you need to take no action regarding this issue.</p>
11	EntryEvent cannot be empty.	At least one row in the file you are uploading has no value in the EntryEvent field.	Check the original file and ensure that an EntryEvent is present for each row in the file before attempting the upload again.
12	Unrecognised EntryEvent. Only Registration and Randomisation are valid.	At least one row in the file you are uploading has a value in the EntryEvent field which is not either 'Registration' or 'Randomisation'.	Check the original file and ensure that an EntryEvent of either 'Registration' or 'Randomisation' is present for each row in the file before attempting the upload again.
13	EntryEventNo cannot be empty.	At least one row in the file you are uploading has no value in the EntryEventNo field.	Check the original file and ensure that an EntryEventNo is present for each row in the file before attempting the upload

			again.
22	Invalid EntryEventNo. Entry event number must be whole numbers greater than zero.	At least one row in the file you are uploading has a value in the EntryEventNo field which is outside the acceptable range.	Check the original file and ensure that all EntryEventNo values are whole numbers greater than zero.
20	Unrecognised Ethnicity. Invalid values will be ignored.	At least one row in the file you are uploading has a value in the Ethnicity field which is not a valid Ethnicity code.	This message is a <u>warning only</u> and will not prevent your data from being uploaded, however you should view the details of the warning in order to determine whether the Ethnicity data in the original file should be corrected before attempting the upload again. If you proceed with the upload, any invalid data in this field will be ignored by the system.
18	Unrecognised Gender. Values accepted are M or F. Invalid values will be ignored.	At least one row in the file you are uploading has a value in the Gender field which is not M or F and is therefore invalid.	This message is a <u>warning only</u> and will not prevent your data from being uploaded, however you should view the details of the warning in order to determine whether the Gender data in the original file should be corrected before attempting the upload again. If you proceed with the upload, any invalid data in this field will be ignored by the system.
34	Invalid InvestigatorName.	At least one row in the file you are uploading has either a blank or a numeric values in the InvestigatorName field.	Ensure that an InvestigatorName is present for each row in the data file before attempting the upload again. If the Investigator name is unknown, then use the word 'unknown'.
4	InvestigatorName cannot be empty.	At least one row in the file you are uploading has no value in the InvestigatorName field.	Check the original file and ensure that an InvestigatorName is present for each row in the file before attempting the upload again. If the Investigator name is unknown, then use the word 'unknown'.
21	Invalid Postcode. Invalid values will be ignored.	At least one row in the file you are uploading has a value in the Postcode field which is not a valid Postcode.	This message is a <u>warning only</u> and will not prevent your data from being uploaded, however you should view the details of the warning in order to determine whether the Postcode data in the original file should be corrected before attempting the upload again. If you proceed with the upload, any invalid data in this field will be ignored by the system.
17	Invalid RecruitType. Values accepted are 0 or 1.	At least one row in the file you are uploading has a value in the RecruitType field which is not 1 or 0 and is therefore invalid.	Check the original file and ensure that a RecruitType of 1 or 0 is present for each row in the file before attempting the upload again.
16	Recruit Type cannot be empty.	At least one row in the file you are uploading has no value in the RecruitType field.	Check the original file and ensure that a RecruitType is present for each row in the file before attempting the upload again.
15	Invalid RunningTotal. RunningTotal values must be whole numbers greater than	At least one RunningTotal value in your file is not a whole number greater than zero.	Check the original file and ensure that all RunningTotal values given are whole numbers greater than zero.

	zero.		
14	RunningTotal cannot be empty.	There is no RunningTotal value for one or more of the studies in your file.	Check the original file and ensure that for each study, at least one row contains a RunningTotal value before attempting the upload again.
8	StudyEntryDate cannot be empty.	At least one row in the file you are uploading has no value in the StudyEntryDate field.	Check the original file and ensure that a StudyEntryDate is present for each row in the file before attempting the upload again.
9	StudyEntryDate is not a valid date.	At least one row in the file you are uploading has a value in the StudyEntryDate field which is not a valid date in the format 'dd/mm/yyyy'.	Check the original file and ensure that a valid StudyEntryDate, in the format dd/mm/yyyy is present for each row in the file before attempting the upload again.
10	StudyEntryDate is out of range. The date must fall between the study opening date and today's date.	At least one row in the file you are uploading has a value in the StudyEntryDate field which is outside the acceptable range, i.e. between the date that the study opened to recruitment and today.	Check the original file and ensure that all StudyEntryDates fall within the acceptable range before attempting the upload again.. If, having done this, the error is still present, please check with the Study Coordinator that the date that the study opened to recruitment is correctly recorded in the UKCRN Portfolio system.
36	StudyID and Acronym are inconsistent.	At least one row in the file you are uploading has values in the Acronym and StudyID fields which do not refer to the same Study.	Check the original file and ensure that all StudyIDs present correspond to the correct Acronym before attempting the upload again.
1	StudyID cannot be empty.	At least one row in the file you are uploading has no value in the StudyID field.	Check the original file and ensure that a Study ID is present for each row in the file before attempting the upload again.
2	StudyID is not recognised or is not valid for this Data Package.	At least one row in the file you are uploading has a Study ID which the system does not recognise as being associated with your data.	Check the original file and ensure that all Study IDs are correct for your studies. If you have recently added a new study to your data, please contact the UKCRN CC using the UKCRN Helpdesk (see below) to have this study registered for you on the accrual system.
7	StudyPatientID cannot be empty.	At least one row in the file you are uploading has no value in the StudyPatientID field.	Check the original file and ensure that a StudyPatientID is present for each row in the file before attempting the upload again.
32	InvestigatorID and InvestigatorName are inconsistent.	At least one row in the file you are uploading has values in the InvestigatorID and InvestigatorName fields which do not refer to the same Investigator.	The system is not currently using a standard set of InvestigatorIDs. This message should not be displayed as the validation check is therefore not appropriate.
35	Invalid InvestigatorID (in this version this value should be empty).	At least one row in the file you are uploading has a value in the InvestigatorID field which is invalid.	This message is displayed if you have written data into the InvestigatorID field. As the system is not currently using a standard set of InvestigatorIDs this column should be present but left empty.
38	Duplicate StudyRecruitID - This StudyRecruitID exists	The combination of StudyRecruitID and EntryEventNo appears more than once in the file	The system does not allow a StudyRecruit to be registered more than once or, if randomised, to be randomised more than

	more than once in this file for the same EntryEventNo.	with the same.	once with the same EntryEventNo. Please remove any rows from your data where the combinations of StudyRecruitID, EntryEvent and EntryEventNo are not unique.
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The UKCRN Helpdesk

Using the Helpdesk will allow us to make sure that requests are passed to the appropriate people and dealt with as quickly as possible. Also it gives us an audit trail of requests which have been made and problems which have been resolved.

At the moment there are links to the Helpdesk from the Portfolio search pages, in the bottom right corner of the login page of the UKCRN Web Site (you don't have to be logged-in), and on every page in the system once you have logged-in so you can use any of these to submit a request should you need to do so. The link is labelled "If you experience problems using the application, please click here".

NB: Issues logged on the helpdesk will be given priority over those raised by 'phone or email unless they constitute an emergency.