

T-1103 - Research Project Data Dictionary

Data Field Name	Location	Section	Definition	Data Type	Requirement Level	Project Stage (When Populated)	Data Quality G Cleansing Plan
Edge ID	Project Level	Identifiers	EDGE's Unique ID for project	Integer	System-Generated (S)	Automatically generated at project creation.	Validate uniqueness. Ensure no duplicates.
IRAS Number	Project Level	Identifiers	Integrated Research Application System (IRAS) approval systems generated number	Integer	Mandatory (M)	During project setup after IRAS submission.	Check format matches IRAS standard. Cross-verify with IRAS form.
Local Project Reference	Project Level	Identifiers	Pre-Edge / Old studies Project ID (Studies migrated from Reda to Edge)	String	Optional (O)	At project creation /migration of old studies.	Ensure consistency with old system.
Clinical trials gov number	Project Level	Identifiers	Project Identifier for non-UK countries. Used through-out US and Canada for trial identification.	String	Optional (O)	During regulatory registration prior to recruitment.	Validate against ClinicalTrials.gov. Ensure correct prefix (NCT).
CPMS ID	Project Level	Identifiers	Central Portfolio Management System Assigned Unique Identifier for portfolio adopted studies (AKA - UKCRN ID / NIHR ID)	Integer	Mandatory (M) if it is portfolio study	Upon NIHR portfolio adoption.	Cross-check with CPMS. Ensure numeric integrity.
EudraCT Number	Project Level	Identifiers	Unique Clinical Trials Database Registration and Identifier number issued by the European Union Drug Regulating Authorities Clinical Trials for all Clinical Trials taking place within the European Union	String	Optional (O)	During regulatory approvals before site setup.	Validate EU format. Ensure no missing digits.
ISRCTN	Project Level	Identifiers	The ISRCTN (International Standard Randomised Controlled Trial Number) is a numeric system for the unique identification of randomised controlled trials worldwide	String	Optional (O)	At trial registration stage.	Confirm with ISRCTN registry. Ensure correct numeric sequence.
Protocol ID	Project Level	Identifiers	The number on the protocol as issued by the project sponsor	String	Mandatory (M)	At protocol finalisation.	Validate against protocol. Ensure correct formatting.
REC Number	Project Level	Identifiers	Research Ethics Committees Unique identifier for the Project	String	Mandatory (M)	After ethics approval.	Validate against REC letter. Ensure correct formatting.
WHO Number	Project Level	Identifiers	The WHO (World Health Organisation) or UTN (Unique Trial Number) is provided by the World Health Organisation to facilitate the unambiguous identification of clinical trials. The WHO/UTN is not a registration number	String	Optional (O)	At WHO UTN registration.	Confirm with WHO UTN registry. Ensure correct mapping.
Additional IRAS Number and Additional REC Number	Project Level	Identifiers	Unique identifier for the Projects running in Scotland / Ireland	String	Optional (O)	During setup for Scotland/Ireland sites.	Validate region-specific numbering. Ensure no duplication.
Short Title	Project Level	Core Details	Project short title or acronym (If Applicable)	String	Mandatory (M)	At project creation.	Ensure exact match with IRAS. Remove trailing spaces.
Full Title	Project Level	Core Details	Project full title as per IRAS form	String	Mandatory (M)	At project creation using IRAS form.	Ensure exact match with IRAS. Remove trailing spaces.
Summary	Project Level	Core Details	Brief Summary of the project	String	Mandatory (M)	During project setup.	Ensure exact match with IRAS. Ensure <300 words.
Chief Investigator	Project Level	Core Details	The investigator with overall responsibility for the research. In a multi-site project, the CI has co-ordinating responsibility for research at all sites. The CI is usually based within the Sponsor Organisation	String	Mandatory (M)	During project setup.	Validate against sponsor documentation. Ensure correct spelling.
Visibility	Project Level	Core Details	(Public / Private) Public projects are visible to all users nationally of the EDGE system. Private projects are only visible to the organization locally which has created them	Boolean (Yes/No)	Mandatory (M)	At project creation.	Confirm correct setting (Public/Private).

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Status	Project Level	Core Details	The current status of the project nationally within its life cycle-Following status available from dropdown - Abandoned - COVID-19: The Project has been abandoned due to COVID-19 - Archived: The Project has been archived for future reference - Closed - COVID-19: The Project is closed due to COVID-19 - Closed - follow up complete: The Project is closed to further recruitment and the follow up of participants is complete - Closed to recruitment - in follow up: The Project is closed to further recruitment, and participants are in follow up - Closed to recruitment - no follow up: The Project is closed to further recruitment, and there are no participants in follow up - Completed: The Project is complete and published. - Concept: The Project is in the conception stage and is not in formal development - Destroyed: Project documentation has been destroyed - Development: The Project is in the development phase - Feasibility: The Project is at the feasibility phase - Follow up on hold - COVID-19: Participant follow up is on hold due to COVID-19 - Open: The Project is open, but it is not open to recruitment - Open to recruitment: The Project is open to recruitment - Project in setup: The Project is currently in the setup and pending approvals from regulatory authorities - Project setup suspended - COVID-19: The Project setup is suspended due to COVID-19 - Recruitment on hold - COVID-19: Participant recruitment is on hold due to COVID-19 - Suspended: The Project is currently suspended - Withdrawn: The Project been withdrawn from any further work at this time	String	Mandatory (M)	Updated throughout project lifecycle.	Ensure status aligns with milestones. No contradictory statuses.
Project Type	Project Level	Core Details	Whether the project has involvement from Industry or is Academic or a mix. If the study is also adopted onto the national register	String	Mandatory (M)	During setup.	Validate against sponsor classification. Ensure correct adoption flag.
Phase	Project Level	Core Details	In which stage of drug approvals process is the project investigating.	Integer	Optional (O)	During setup for CTIMPs.	Ensure numeric phase (I–IV). Cross-check protocol.
Planned Start Date	Project Level	Core Details	Proposed start date for the project across all participating sites	Date	Mandatory (M)	During setup.	Validate date format. Ensure before planned end date.
Planned End Date	Project Level	Core Details	Proposed end date for the project across all participating sites	Date	Mandatory (M)	During setup.	Check chronological order. Flag unrealistic durations.
Start Date	Project Level	Core Details	The date which the project starts as identified by the sponsor	Date	Optional (O)	At project activation.	Ensure matches sponsor confirmation.
End Date	Project Level	Core Details	End date for the project across all participating sites	Date	Optional (O)	At project closure.	Validate against closure documentation.
Disease Area	Project Level	Core Details	Classification of Disease Area e.g. Cancer	String	Mandatory (M)	During setup.	Standardise using controlled vocabulary (e.g., ICD categories).
Disease Site	Project Level	Core Details	Classification of specific site within disease area e.g. Melanoma	String	Mandatory (M)	During setup.	Validate against disease area.

CTIMP	Project Level	Core Details	Whether the project is a Clinical Trial of an Investigational Medicinal Product or not.	Boolean (Yes/No)	Mandatory (M)	During setup.	Cross-check with protocol. Ensure binary Yes/No.
Device	Project Level	Core Details	Whether the project is a medical device study or not.	Boolean (Yes/No)	Mandatory (M)	During setup.	Cross-check with protocol. Ensure binary Yes/No.
ATIMP	Project Level	Core Details	Whether the project is a Advanced Therapy Investigational Medicinal Product or not.	Boolean (Yes/No)	Mandatory (M)	During setup.	Cross-check with protocol. Ensure binary Yes/No.
Participant Scope	Project Level	Core Details	Whether the project recruit Adult / Paediatric participants	String	Mandatory (M)	During setup.	Ensure Adult/Paediatric/Both. cross-check inclusion criteria.
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Randomisation	Project Level	Core Details	Description of an interventional studies randomisation status, whether that be randomised or non-randomised. A randomised trial assigns participants to different groups entirely by chance, while a non-randomised trial assigns participants based on factors like researcher choice, patient preference, or geographical logistics.	String	Mandatory (M)	During setup.	Ensure matches protocol. standardise terms (Randomised/Non-randomised).
Participant Status Workflow	Project Level	Core Details	- Interventional trial: A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. - Observational study: A study in which the investigators do not seek to intervene, but simply observe the course of events.	String	Mandatory (M)	During setup.	Validate workflow type (Interventional/Observational)
Participant Data Collection Plan	Project Level	Core Details	The name of the workflow assigned by sponsor at the project level to denote the stages involved in the patient journey through the clinical trials. E.g. Pre-screened - Approached - Consented-Recruited. All NIHR adopted studies will be assigned a default workflow based on their design.	String	Optional (O)	During setup.	Ensure workflow matches protocol and sponsor requirements
Site Owner and Site Parent	Project Site Level	Core Details	The site's legal owning organisation	String	Mandatory (M)	During site setup.	Validate organisation names.

Project Site Status	Project Site Level	Core Details	The current status of the project at the site- Following status available from dropdown - Abandoned - COVID-19: The Project owning organisation, Site, or sponsor has chosen to abandon the Project due to COVID-19 at this Site - Accepted: The Site has been approached to gauge interest in running the Project and has accepted - Archived: The Site has been archived - Closed: The Site is closed, and no more participants can be recruited - Closed - COVID-19: The Site is closed due to COVID-19, and no more participants can be recruited - Closed - follow up complete: The Site is closed and follow up has finished - Closed to recruitment - in follow up: The Site is closed to recruitment, but in the follow up stage - Completed: The Site is completed and published - Concept: The Site is in a concept stage and is not in formal development - Declined: The Site has been approached to gauge interest in running the Project but has declined - Destroyed: Project Site documentation has been destroyed - Expression of Interest: The Site has been approached to gauge interest in running the Project - Feasibility: The Site is in a feasibility stage - Not Selected by Sponsor: The Sponsor has decided not to run the Project at this Site - Open: The Site is open and is actively recruiting participants - Project Site in setup: The Site is still being setup before it is ready to be opened - Project Site in setup suspended - COVID-19: The Site setup has been suspended due to COVID-19, before it is ready to be opened - Recruitment on hold - COVID-19: The Site recruitment is on	String	Mandatory (M)	Updated throughout site lifecycle.	Ensure status aligns with milestones. No conflicting statuses.
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Site Type	Project Site Level	Core Details	The definition of the sites recruitment focus as either a site for identifying patients (PIC) or to recruit and treat patients (Recruiting site) - Following types available from dropdown • All Site Activities: All types of Site activity take place at this Site • Continuing Care: This could be a Local Hospital • Follow-up Site: This is a follow up centre and participants are not screened, recruited, or treated here • Other: None of the Site types reflect these Sites activities ((Please select "Other" as the site type and enter "0" as the recruitment target if your study is recruiting without consent)) • PICSite: This is a participant identification centre and does not recruit participants • Promoting Site: This is where only Posters or similar promotional information is displayed • Recruiting Site: This is a participant recruitment centre • Sponsor Only: Where the sponsor is not a Site • Step-down Site: This is Respite care, Local Hospital, Convalescence home, or similar • Sub Site: A Sub-Site conducts contracted services for the sponsor but does not recruit participants. This can include services such as performance monitoring or governance	String	Mandatory (M)	During site setup.	Validate against dropdown list. Ensure correct classification.
Principal Investigator	Project Site Level	Core Details	The investigator responsible for conducting and overseeing the research at a specific site. The Principal Investigator (PI) is usually based within the host organisation.	String	Mandatory (M)	During site setup.	Validate spelling. Ensure PI is registered at site.
Target Recruitment	Project Site Level	Core Details	The recruitment target for the lifetime of the project for that specific project Site only.	Integer	Mandatory (M)	During site setup.	Ensure numeric. Check against site contract.
Actual Recruitment	Project Site Level	Core Details	Actual participant recruitment of the project for that specific project Site only.	Integer	System-Generated (S)	Throughout recruitment period.	Validate counts. Reconcile with participant logs.
Participant Data Collection Plan	Project Site Level	Core Details	The template of patient identifiable data to collect when recruiting a patient	String	Mandatory (M)	During site setup.	Ensure template matches project-level plan.
Participant Identifier Type	Project Site Level	Core Details	The local Organisations preferred Site Identifier for patients-Following types available from dropdown • CHI Number: Used in Scotland (identical to NHS Number but from a reserved range) • H&C Number: Used in Northern Ireland (identical to NHS Number but from a reserved range) • Local Number: A Site-specific identifier that has no validation • NHS Number: Used in England and Wales • Ontario Health Number: Used in Ontario, Canada	String	Mandatory (M)	During site setup.	Validate against region. Ensure correct identifier type.
Approval Process	Project Site Level	Approvals	Name of the Approval process- e.g. HRA Approval	String	Mandatory (M)	During site setup.	Validate against governance approval documentation.
Capacity & capability assessment required?	Project Site Level	Approvals	Whether the project need capacity & capability assessment or not	Boolean (Yes/No)	Mandatory (M)	During site setup.	Ensure Yes/No. Cross-check sponsor requirements.
Date site invited	Project Site Level	Approvals	The date on the sponsor email received by the site providing the protocol in the version to be submitted for regulatory review.	Date	Mandatory (M)	During feasibility stage.	Validate date. Ensure before site selected. Ensure chronological order.

Date site selected	Project Site Level	Approvals	The date on the sponsor email received by the site providing the minimum defined documents to enable site to commence arrangement and/or confirmation of local capacity and capability as applicable representing that the site has been selected to take part in the study.	Date	Mandatory (M)	During setup.	Ensure chronological order. cross-check sponsor email.
Date site confirmed by Sponsor	Project Site Level	Approvals	The date of the first contract signature of all the organisations involved (i.e., sponsor, site, third party) or date on the email received from the sponsor providing the final statement of activity ready for final agreement.	Date	Mandatory (M)	During setup.	Validate against contract signature. Ensure chronological order.
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Date site confirmed	Project Site Level	Approvals	The date of the last contract signature of all the organisations involved (i.e. sponsor, site, third party) or date of final written agreement of statement of activity, as applicable.	Date	Mandatory (M)	During setup.	Ensure matches final agreement date. Ensure chronological order.
Non-confirmation Status	Project Site Level	Approvals	The reason why the site was not confirmed, where applicable.	String	Optional (O)	If site not confirmed.	Ensure reason selected from dropdown.
SIV Date	Project Site Level	Milestones	Date of Site initiation visit (SIV).	Date	Mandatory (M)	During site setup.	Validate date. Ensure before open to recruitment.
Open To Recruitment (Planned)	Project Site Level	Milestones	The date the site is expected to be allowed to start recruiting	Date	Mandatory (M)	During setup.	Check chronological order. Ensure realistic timeline.
Open To Recruitment (Date Site Ready to Start)	Project Site Level	Milestones	The date the sponsor confirms green light to the site and the site is allowed to start recruiting	Date	Mandatory (M)	At site activation.	Validate against green light email.
Recruitment End Date (Planned)	Project Site Level	Milestones	The date recruitment is scheduled to end	Date	Mandatory (M)	During setup.	Ensure before site closure.
Recruitment End Date (Actual)	Project Site Level	Milestones	Actual date the site closed to recruitment	Date	Optional (O)	At recruitment closure.	Validate against site logs.
Closing Date (Planned)	Project Site Level	Milestones	The planned date this site will close	Date	Mandatory (M)	During setup.	Ensure after recruitment end date.
Closing Date (Actual)	Project Site Level	Milestones	The actual date this site closed	Date	Optional (O)	At site closure.	Validate against closure documentation.