Guideline number	**57.016G**	Version	**1.0**
Title	**EDGE Minimum Dataset**		

The tables below detail the minimum EDGE data to be entered to achieve meaningful output. There are 2 data levels within EDGE; **Project** = P and **Site** = S.

Data Level	Field	Description and example of source
P	Local Project Reference	NHS GG&C R&I reference number from correspondence or SReDA
P	Sites	OID Form/Form 57.010A
P	Project Forms/Study Type	IRAS R&I Form/Form 57.010A
P	Project Forms/Specialty	GCRF Planning Meeting/Form 57.010A
P	IRAS Number	IRAS R&I Form first batch of digits
P	MREC Number	REC Correspondence
S	Status	**Feasibility/Concept/Project Site in Setup** = Form 57.010A/Planning Meeting **Open** = Regulatory Green Light, study open to recruitment **Closed to recruitment in follow-up** = Study finished recruiting **Completed** = Last patient last visit **Archived** = Study paperwork archived
S	Principal Investigator	Form 57.010A
S	Site target recruitment	Form 57.010A /OID Form
S	Patient data collection plan/Patient	All GCRF studies should default to patient
S	Patient identifier type/CHI Number	All GCRF studies should default to CHI Number
S	Approval process/NHS Permissions	All GCRF studies should use the NHS permissions process
S	Start date (NHS Permission)	Date of R&I permission/approval
S	SIV date	Date of SIV
S	Open to recruitment	Regulatory Green Light
S	Recruitment end date (Planned)	Form 57.010A/Protocol/OID Form/Sponsor representative
S	Recruitment end date (Actual)	Study Team/Sponsor representative
S	Planned Closing Date	Form 57.010A/Protocol/OID Form/Sponsor representative
S	Closed Date	Last patient last visit
S	Project Site Forms/Project Team	Form 57.010A
S	Project Site Forms/GCRF Support	Details of level of GCRF support/ Form 57.010A
S	Project Site Forms/Overall Score	Risk Assessment Score Form 17.048
S	Project Site Forms/Exceptional	Exceptional Risk Score Form 17.048
S	Project Site Forms/Score Status	Score Status Form 17.048

S	Project Site Forms/Date Score Completed	Date of Form 17.048
S	Project Site Forms/Score Complete By	Name of manager/senior research nurse completing Form 17.048
S	Set-up costs	Signed Contract with Sponsor/Costing Template
S	Patients	All patients consented, screened, recruited and randomised to each study must be recorded Minimum patient level data: • Name • DOB • CHI • Address • Email • Telephone • GP/Surgery • GP Telephone • Next of Kin All patients consented and recruited to studies must have subject ID recorded in 'Randomisation Number' field.
S	Patient/Appointments	All patient appointments must be recorded
S	Patient costs	All patient costs must be recorded as per contract this includes all visit costs (nursing/pharmacy/imaging)

Guideline signatories

Prepared by Signature	Kirsty McAinsh Date
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Document history

Version	Date	Description
1.0	02/08/2023	New release under SOP 57.016 – Guide was previously behind SOP 57.011

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