

Pricing Document

- This document is used to provide an illustration of the cost drivers associated with pricing a clinical trial for EDC deployment and Data management. Illustrations are made based upon average elements of a simple/ moderate and complex study.
- Actual costs will be assessed based on study specifications and a protocol of requirements.

eCRF and EDC Design, Build and testing	Basis	Simple Study	Moderate Study	Complex Study
eCRF and EDC system build oversight and project management				
eCRF design and build	Modules	25	32	40
eCRF translations				
CRF printing				
Study Data Management documentation generation	Trial complexity	1	1.5	2
EDC system database build, analytics, reporting and testing	Trial complexity	1	1.5	2
EDC data integrations and incoming 3rd party data set-up (i.e Safety Labs)	Data types	1	2	3
EDC edit check specification, programming and testing	Checks	125	160	250
SAE form design, data capture and reporting module				
Randomisation and notifications module				
Data Management and EDC				
Project start up activities, project kick off, communication and risk planning etc.	Trial complexity	1	1.5	2
EDC system training and provision of eLearning software	Trial	1	1	1
Study EDC database hosting and licensing	Months	14	20	36
EDC Help Desk provision and contact support	Months/Sites	14	60	360
Project Management oversight, timelines, TCs, reporting, project reviews and project close out etc.	Months	14	20	36
Data entry, data processing and query management (paper elements)				
Data management of electronic 3 rd party data	Data Types	1	2	3
Data Management, data validation, correspondence, database locking	Months	14	20	36
Completed assessments		2500	5000	25000
Query Management	Queries	300	600	3000
Query Management (Paper)				
Medical coding of terms (MedDRA/WHO DD)	Terms	450	900	4500
SAE reconciliation	SAEs	5	10	50
Additional reporting requirements (Specify DSMB, IND/Patient profiles etc)				
Preparations and return of TMF elements including eCRF media direct to investigational site(s)	Sites	1	2	10
	Trial	1	1	1
Total Range cost:		Simple unique £70,223.40 - £85,828.60	Moderate unique £111,785.08 - £136,626.20	Complex unique £282,977.82 - £345,861.78