Contracting InferMed MACRO web based data entry system

Data Entry System Services:

The KCTU has hosted a commercial data entry system (InferMed MACRO) since 2005. The system is compliant with FDA 21 CFR part 11 and Good Clinical Practice (GCP). It is an appropriate system to use for medicinal trials falling under the Medicines for Human Use (Clinical Trials) Regulations 2004 and its subsequent amendments, and has also been used for other complex intervention trials. The web based system can be accessed 24 hours a day.

Functionality

Roles can be assigned to users, giving the ability to enter data relating to participants or to view data and raise discrepancies, but not amend data. Roles can also be tailored to be blind to treatment allocation where appropriate, with a secondary database being programmed to collect information about therapy sessions or surgical interventions, for example.

The system can be programmed to perform validation checks, such as range checks to prevent data entry errors. Missing data codes are routinely programmed into all fields, for ease of analysis. The system can also be programmed to flag up when a missing data code is entered, to aid monitoring. E-signatures may be programmed where required. The system can also be programmed to include e-signatures, where this is required. A standard feature of InferMed MACRO data entry system is the built in audit trail on all data fields, the automatic saving of data as you leave a form, and the ability to maintain a record of 'source data verification' checks. The system also has formal database lock functionality.

Package Costs:

The cost calculation of programming and hosting a data entry system for a study depends on the number of unique data variables to be programmed, the number of study sites, the number of users and variety of access required, the duration of time the system needs to be 'live' and the expected number of data extract requests required for data cleaning, data monitoring committee and trial steering committee reports during the study. *The average RCT requires 500 unique variables and **at least 2 data extracts per year.

Bronze service:

Single site study, UK based
Single data entry user assigned
Single monitor assigned
Database live for up to 24 months
Single database programmed
Pre-programmed adverse event form used
Pre-programmed concomitant medication form used
Pre-programmed medical history form used
Template inclusion / exclusion form used

Up to 100 additional unique variables programmed
Study site to enter their data online

£3,500 database setup (max. 100 unique variables)
£1,100 server storage space x 2 years
£600 administration of passwords annually X 2 years
£110 per export X4

Total cost = £7,340

Silver service:

Multicentre study, UK based
Multiple data entry users assigned
Multiple monitors assigned
Up to 500 unique variables programmed
Non-commercial data entry license fees apply
Study sites to enter their data online
Up to three databases programmed

- Database 1, baseline and outcome data
- Database 2, intervention details
- Database 3, therapist details

£35 per unique variable programmed*
£150 annual data entry site license
£1,100 server storage space annually

£600 administration of passwords annually
£600 surcharge per database beyond database 1
£110 per data extract**
S = Number of study sites
V = Number of unique variables to be programmed
Y = Number of years study to be 'live'
D = Number of databases to be programmed
E = Number of data extracts required

Total cost = (£35 x V) + (£150 x S x Y) + (£1,100 x Y) + (£600 x Y) + (£600 x (D-1)) + (£110 x E)

Typically £18,000 - £40,000

Gold service:
Multinational trial, EU based – quotes available on a case by case basis following discussion with KCTU

Platinum service:
Multinational trial, beyond EU – quotes available on a case by case basis following discussion with KCTU

To request a formal quote (including Gold and Platinum services) please complete support request form online www.ctu.co.uk.