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.

<table>
<thead>
<tr>
<th>Bronze service</th>
<th>Silver service</th>
<th>Gold service</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single site study, UK based</td>
<td>Multicentre study, UK based</td>
<td>Multinational trial, EU based – quotes available on a case by case basis following discussion with KCTU</td>
</tr>
<tr>
<td>Single data entry user assigned</td>
<td>Multiple data entry users assigned</td>
<td>Multinational trial, beyond EU – quotes available on a case by case basis following discussion with KCTU</td>
</tr>
<tr>
<td>Single monitor assigned</td>
<td>Multiple monitors assigned</td>
<td>– quotes available on a case by case basis following discussion with KCTU</td>
</tr>
<tr>
<td>Database live for up to 24 months</td>
<td>Up to 500 unique variables programmed</td>
<td>– quotes available on a case by case basis following discussion with KCTU</td>
</tr>
<tr>
<td>Single database programmed</td>
<td>Study site to enter their data online</td>
<td>– quotes available on a case by case basis following discussion with KCTU</td>
</tr>
<tr>
<td>Pre-programmed adverse event form used</td>
<td>£3,500 database setup (max. 100 unique variables)</td>
<td>– quotes available on a case by case basis following discussion with KCTU</td>
</tr>
<tr>
<td>Pre-programmed concomitant medication form used</td>
<td>£1,100 server storage space x 2 years</td>
<td>– quotes available on a case by case basis following discussion with KCTU</td>
</tr>
<tr>
<td>Pre-programmed medical history form used</td>
<td>£600 administration of passwords annually X 2 years</td>
<td>– quotes available on a case by case basis following discussion with KCTU</td>
</tr>
<tr>
<td>Template inclusion / exclusion form used</td>
<td>£110 per export X4</td>
<td>– quotes available on a case by case basis following discussion with KCTU</td>
</tr>
</tbody>
</table>

Total cost = £7,340

Typically £18,000 - £40,000

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

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

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](http://www.ctu.co.uk).