Electronic data capture and database system for Clinical Trials

Selection process

The aim of the process was to provide the Board with a shortlist of 3 products that would provide electronic data capture, database design and management, and clinical trials management to the EBMT Clinical Trials group.

The first part of the selection process was performed by Sunil de Souza (SS) and Carmen Ruiz de Elvira (CR). The first screening involved looking at websites and, as necessary, sending e-mails seeking further information from those websites; the second screening involved organising demonstrations of the selected software.

The second part of the selection process was performed with the participation of Zoe Doran (ZD) and Georgia Bullock (GB); Kim Champion (KC) also participated occasionally.

The names of the sites to screen were gathered from different sources:
- internet searches
- the Applied Clinical Trials Directory & Buyer's Guide
- suggestions provided by:
  - Ronald Brand
  - Per Ljungam
  - Marleen van Os *
  - UK Cancer Research employees *

* Also listed in the Applied Clinical Trials Directory & Buyer's Guide

First screening

Points being looked at for first screening were mostly technical; attention was paid to features that would make it possible to use the system for the registry. The main points are listed below:
- regulatory compliance for clinical trials
- no client software necessary
- data entry validation
- fast screen turnover
- project control to remain in the hands of the EBMT
- clinical trials specific querying and monitoring system
- possibility of accessing the underlying database directly
- flexible and controllable user and access rights

A finer structure is described at the end of the document.

Over 50 web sites were visited. On first screening, sites were excluded because:
- information on the website defined them as CRO's
- information on the website defined them as consultancy firms
- description of software / services did not match our requirements

Follow up e-mails were sent to about 30 companies. On follow up, companies were excluded because:
- they did not reply to e-mail (poor customer support and/or website maintenance if e-mail was out of date)
- further information, as provided by company, defined them as Software Application Providers only (no technology transfer possible)

The final list was made of 12.

Second screening
Between March and May, SS and CR participated in demonstrations of 12 products. The demonstrations took place in the EBMT office, other organisation offices, the headquarter of the company, or, in most cases, through the web (see Table at end of document).

Five softwares were excluded after the demonstration (see Table). All other companies were sent a questionnaire which is included with this document, in which we asked for further clarifications and also requested an idea of the costing. In addition to the questionnaires, we engaged in e-mails correspondence with some of the vendors for specific issues (example Medidata, see Table).

Six questionnaires were returned; on this information, and other information gathered through e-mails, we excluded a further 3 companies (see Table).

Third screening
Demonstrations were requested from the 4 companies that made the short list. ZD participated in all of them, together with either GB or KC. SS and CR were also present. Vendors were asked to concentrate more on the user part (rather than the technical part), particularly on those aspects that would facilitate clinical trial management.

Further to these demonstrations it was felt that 2 companies were better placed to offer the service the EBMT were looking for. However, and following the initial guidelines provided by the Board, a 3rd company was also selected in the final shortlist. Steps taken are as follows:

1) A further meeting was arranged with eResearch, at their request, to discuss financial issues. The meeting took place on the 2nd August. The company took in the constraints and information provided and will come back to us with a proposal. They are also going to send in a technical expert to estimate the cost of implementing a first trial in their system.

2) A further demonstration will be requested of StudyBuilder. Its demonstration during the second screening was a PowerPoint led explanation of the working of the system. We agreed this was insufficient to get a good feeling on how things are really done and how difficult / slow would it be to actually implement clinical trials with it.

3) A financial plan will be requested from Velos. Its demonstration was done through the Web, this may have positioned them in a 3rd place through no fault of the software itself.
<table>
<thead>
<tr>
<th>Software considered and first demonstration performed</th>
<th>Contact Name 1</th>
<th>Contact Name 2</th>
<th>Contact email 1</th>
<th>Contact email 2</th>
<th>Date first demo</th>
<th>Demo location</th>
<th>Short list?</th>
<th>Reason not shortlisted</th>
<th>Sent questionnaire</th>
<th>Questionnaire returned</th>
<th>Requested questionnaire clarification</th>
<th>Follow up demo requested</th>
<th>Reason follow up demo not requested</th>
<th>Date second demo</th>
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<tr>
<td>Datatrak-clinical</td>
<td>Martin Hansen</td>
<td></td>
<td><a href="mailto:Martin.Hansen@datatrak.com">Martin.Hansen@datatrak.com</a></td>
<td></td>
<td>09/03/2007</td>
<td>Web demo</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>No</td>
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<td>Study Builder</td>
<td>Michael Jennings</td>
<td></td>
<td><a href="mailto:Michael.Jennings@studybuilder.com">Michael.Jennings@studybuilder.com</a></td>
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<tr>
<td>Volley</td>
<td>Allison Gray,</td>
<td>John Mclaren</td>
<td><a href="mailto:Allison.Gray@volley.com">Allison.Gray@volley.com</a>, <a href="mailto:John.Mclaren@volley.com">John.Mclaren@volley.com</a></td>
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<td>Yes</td>
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<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Clinical Trials net</td>
<td>Wes Darbashi</td>
<td></td>
<td><a href="mailto:Wes.Darbashi@clinicaltrials.net">Wes.Darbashi@clinicaltrials.net</a></td>
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<tr>
<td>MedNet Solutions</td>
<td>Timothy Frith, John Sweeney</td>
<td></td>
<td><a href="mailto:Timothy.Frith@mednet.com">Timothy.Frith@mednet.com</a>, <a href="mailto:John.Sweeney@mednet.com">John.Sweeney@mednet.com</a></td>
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<td>Dendrite</td>
<td>Peter Watson</td>
<td></td>
<td><a href="mailto:Peter.Watson@dendrite.com">Peter.Watson@dendrite.com</a></td>
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<td>26/03/2007</td>
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<td>No</td>
<td>Not compliant</td>
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<tr>
<td>eResearch</td>
<td>Simon Howells</td>
<td></td>
<td><a href="mailto:Simon.Howells@eresearch.com">Simon.Howells@eresearch.com</a></td>
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<tr>
<td>Oracle Clinical</td>
<td>Roger</td>
<td></td>
<td><a href="mailto:Roger@oracle.com">Roger@oracle.com</a></td>
<td></td>
<td>20/03/2007</td>
<td>Argen offices</td>
<td>No</td>
<td>Too expensive, requires intense system maintenance</td>
<td>No</td>
<td></td>
<td></td>
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<td>Very expensive. Company recommended we went through a consortium, but even that was too expensive</td>
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<td>Medidata Rave</td>
<td>Roger</td>
<td></td>
<td><a href="mailto:Roger@medidata.com">Roger@medidata.com</a></td>
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<td>Macro</td>
<td>Leanne Bernard</td>
<td></td>
<td><a href="mailto:Leanne.Bernard@macro.com">Leanne.Bernard@macro.com</a></td>
<td></td>
<td>02/05/2007</td>
<td>UCL Office - Headquarters</td>
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<td>Premasys</td>
<td>Matt O'Driscoll</td>
<td></td>
<td>Matt.O'<a href="mailto:Driscoll@premasys.com">Driscoll@premasys.com</a></td>
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<td>Web demo</td>
<td>No</td>
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<tr>
<td>MediScinet</td>
<td>Elaine</td>
<td>Judkins</td>
<td><a href="mailto:Elaine.Judkins@mediscinet.com">Elaine.Judkins@mediscinet.com</a></td>
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Points for screening softwares:

- FDA compliant (21 CFR part 11)
- GCP compliant
- Validated system
- Clinical Trials management (tracking status, setup, timelines, protocols, sites, sop’s, version control of documents, etc)
- Electronic Data capture (EDC) web based.
- Automated screen design (no programming required)
- Double data entry
- Conditional Navigation/Branching, Edit checks (Data validation).
- Entry of different unit values (where unit of measurements differs amongst different centres/countries.)
- Query resolution tracking up to item level (comments on each item), Source Data verification (SDV).
- Allows creation of calculated fields and customised functions (eg. Randomisation/minimisation)
- Allows upload/creation of libraries (customised/medical coding, MedDRA, WHO Drug, CTCAE, etc)
- Labelsets and reduced labelsets (allows creation of drop down lists)
- Locking of records
- User friendly
- User management/administration (access control).
- Audit Trail of Data with reason for change
- Audit trail of Design changes
- ODBC to database (Have access to database and can fire SQL queries on db)
- Download/Export to Excel, SAS/Strata, XML (E2B compliance required for Pharmacovigilance).
- Writing/creating Reports, pre defined status reports.
- System Hosted physically in the EU (as existing consent form does not allow data to be stored outside of the EU)
- Technology transfer (We will be trained to create/implement trials)
- Test environment for training
- Help/tips/notes
- Batch loading
- Any other significant capability (Different Language versions, Unacceptable delay in secs).
- Possibility to store data at different levels, allowing amalgamation or not of the information.