# Clinical Trial Management System

## Background

The speed at which Imperial College Healthcare NHS Trust sets up and initiates clinical research studies is an important metric. It is imperative that the Trust has the ability and capability to set studies up quickly in order to facilitate the large volume of world-leading clinical research being carried out across the Trust, as well as to make us academically and commercially competitive. This will allow us to demonstrate that NIHR infrastructure awards (BRC, CRF and CRN) are best placed to be hosted with Imperial College Healthcare NHS Trust, and to attract more commercial studies and subsequently increase our commercial research income.

It is imperative that ICHT has a ‘fit for purpose’ research database, which can also act as a Local Portfolio Management System (LPMS) that enables us to monitor, manage and facilitate study set up efficiently.

## Expectations

Imperial College Healthcare NHS Trust requires a Clinical Trial Management System (CTMS), which can also act as a Local Portfolio Management System (LPMS) that enables us to monitor, manage and facilitate study set up efficiently.

In order for the Trust to select the best possible CTMS to support our R&D operations, we expect the Supplier to be able to provide the Trust value for money, quality (ability to meet technical requirements), and social value. This will be reflected in the scoring of the bids.

## Details of Competition

### Dates and Timeline

* We open the submissions for expressions of interest on 12th April 2023.
* The submissions for expressions of interest will close on 24th May 2023.
* We will ask follow-up questions/clarifications from suppliers between 25th May and 8th June.
* The Suppliers, who have been shortlisted will be invited to give a demonstration of the system to Imperial College Healthcare NHS Trust between the period of 12th June and 3rd July 2023.
* The unsuccessful suppliers will be informed by 10th July 2023.
* Standstill period until 24th July 2023
* The outcome announced 25th July 2023
* 5-year contract (beginning pre-procurement activities in 2027)

### 3.2 Submissions

* Submission for expressions of interest should be emailed to the following email address: [Heidi.saunders@nhs.net](mailto:Heidi.saunders@nhs.net)
* Submissions should be sent to us utilising the template tables provided in Appendix A and B. Screenshots and appendices can be submitted in addition to the template tables.
* Potential Suppliers should send questions or requests to the following email address: [Heidi.saunders@nhs.net](mailto:Heidi.saunders@nhs.net)
* Answers to any questions will be circulated to all potential Suppliers via email.

### 3.3 Scoring

The expressions of interests will be scored based on quality-price-social value ratio model.

* 70% - Technical Requirements. See Appendix A for technical requirement and Score Rating Percentage for each section of the technical requirements document.
* 20% - Commercial scoring (Cost). Please provide fully itemised cost breakdown for annual costs, as well as ad hoc costs for professional services day rate.
* 10% - social value. See Appendix B for questions and Score Rating Percentage for each question.

**3.3.1 Technical Requirement Scoring**

Technical requirements (see Appendix A) have been classified using MoSCow principles: M = Must, S = Should and C = Could.

All requirements/questions which have been marked as M (Must) are pass/fail questions. Suppliers are expected to be able to meet all of the requirements marked as M.

All requirements/questions marked as S (Should) or C (Could) will be scored and will count towards the score rating percentage for the relevant section.

Questions will be scored from 0-5

* 0 - being failed to answer the question
* 1 - Indicates a poor answer lacking detail,
* 2 - indicates a below average answer, the supplier was below expectations one or more area on this answer
* 3 - Indicates a medium answer all basic criteria met, the answer did not exceed the panels expectations
* 4 - the answer exceeded the panels expectations
* 5 - the answer is exemplary and provided insights the panel would not ordinarily have considered

Where an answer is 5 the full amount of the technical marks for that question will be apportioned, where the answer is 3 60% of the total marks for that answer will be apportioned, 2 = 40% 1 =20%, 0 =0%

**3.3.2. Commercial scoring**

The Trust will not consider any Bids in excess of £50K (inc VAT) per annum for license and hosting fees (basic costs). Please provide fully itemised cost breakdown for annual costs, as well as ad hoc costs for professional services day rate. The basic costs will account for 90% of the commercial scoring, and the ad hoc costs will account for 10%.

* The lowest price Bid will receive 100% of the commercial Marks and will be used as a benchmark for all other pricing fulfilling the mandatory criteria. If a supplier fails to fulfil all mandatory requirements, they will not be qualified to be used as the Benchmark.
* A supplier costing 200% of the Baseline shall receive 0% of the commercial score.
* A supplier costing 150% of the Baseline will score 50% of the commercial score.
* This formula is Mandated for public sector contracts in the NHS.

**3.3.3. Social value scoring**

* Scoring will be done on the above 0-5 scale.
* Please indicate where you will deploy resources or sponsor initiatives specific to this engagement and tender exercise.
* Please avoid answers referring to Corporate Social Responsibility Policy in your organisation. Generally, such general vague statements may in all probability attract the score of 0.
* Answers must be specific to outcomes as a direct result of award of the contract following this exercise.

## **APPENDIX A – TECHNICAL REQUIREMENTS**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **1** | **Technology** | **MoSCoW** | **%** | **Score Rating Percentage** |
|  | Web based system | M |  | 5% |
| Answer |  |  |  |
|  | Ability to access the system through mobile technology | S | 2.5% |
| Answer |  |  |  |
|  | App version of the system available | S | 2.5% |
| Answer |  |  |  |
|  | Web browser independent design | M |  |
| Answer |  |  |  |
|  | Transport Layer Security (describe approach) | M |  |
| Answer |  |  |  |  |
| **2** | **Interfaces** | | |  |
|  | Ability to import/export patient and trial data to and from Cerner Millenium using Healthcare data standards that include HL7 v2 messages and HL7 FHIR. | M |  | 10% |
| Answer |  |  |  |
|  | Ability to receive data from the NIHR Central Portfolio Management System (CPMS) compliant with interface standards as supplied by NIHR. | M |  |
| Answer |  |  |  |
|  | Ability to send data to the CPMS compliant with interface standards as supplied by NIHR | M |  |
| Answer |  |  |  |
|  | Ability to interact with the Trust Website. Please describe the architecture you would use. | S | 2.5% |
| Answer |  |  |  |
|  | Ability to share reference and terminology data with NIHR Reference Data Services (RDS) | C | 2.5% |
| Answer |  |  |  |
|  | Ability to integrate with NIHR Identity Management solution to support single user sign-on function | C | 2.5% |
| Answer |  |  |  |
|  | Ability for other Trust database (e.g. MS SQL server/ADF) and reporting (e.g. QLIK) systems to access data (e.g. ODBC) from the system. | M |  |
| Answer |  |  |  |
|  | Open API to enable the system to link with other systems | C | 2.5% |
| Answer |  |  |  |  |
| **3** | **Study Management** | | |  |
|  | Ability to create a study record. Please provide screenshots. | M |  | 15% |
|  | Ability to add short title and long study title. Please provide screenshots. | M |  |
|  | Ability to search for a study based on multiple criteria; including CPMS ID, IRAS ID, Study Acronym, Study title etc. Please provide screenshots. | M |  |
|  | Dashboard function to give a visual presentation on the relevant studies and their status/progress as per individual/role/team. Please provide screenshots. | M |  |
|  | Dashboard function to give visual presentation to Sponsors/PIs/study teams on the status of their study. Please provide screenshots. | S | 1% |
|  | Functionality to see (in a visual way) how many days study set up has taken so far. Please provide screenshots. | S | 1% |
|  | Functionality to see different study/project statuses. Please provide screenshots. | M |  |
|  | Functionality to see the speed of study set up against a set target (a date). Please provide screenshots. | S | 1% |
|  | Functionality to create calculations against set fields. Please provide screenshots. | S | 1% |
|  | Functionality to allocate tasks to different teams/individuals. Please provide screenshots. | M |  |
|  | Functionality to send messages/emails to individuals via the system | S | 1% |
| Answer |  |  |  |
|  | Functionality to receive notifications when action complete. Please provide screenshots. | M |  |
|  | Functionality to track progress of amendments. Please provide screenshots. | S | 1% |
|  | Functionality to have a user-facing electronic form with relevant data fields, which feed into a specific study record. | S | 1% |
| Answer |  |  |  |
|  | Ability to add/modify/delete fields by the users (admin role). Please provide details how this is done. | M |  |
| Answer |  |  |  |
|  | Ability to design own fields, fields groups or tabs and associated user interface. | S | 1% |
| Answer |  |  |  |
|  | Reporting functions for recruitment numbers over various years as per study type and sponsor type, reports for RTT. Please provide example reports | M |  |
|  | Ability to track the speed and tasks for sponsorship reviews. Please provide screenshots. | M |  |
|  | Ability to have sponsor oversight of all study sites (contracts and costs/payments) and their status. Please provide screenshots. | M |  |
|  | Contact details for individuals visible in the system | S | 1% |
| Answer |  |  |  |
|  | Functionality to allow recruitment milestones to be entered and performance tracked based on these. Please provide screenshots. | S | 1% |
|  | Ability to record more than one PI for a study and map them to sites | S | 1% |
| Answer |  |  |  |
|  | Ability to send auto reminders with study reference number and IRAS number and full study title for Annual Progress reports, declaration of end of study form submission and final report submission (eg 4 weeks before due date, 2 weeks before due date and 3 days before due date | S | 1% |
| Answer |  |  |  |
|  | Notification to key contacts when certain information is updated. Please articulate the information flow. | S | 1% |
| Answer |  |  |  |
|  | When a person working on many studies leaves trust, the option should be available to put finish date for multiple studies to be recorded in whole batch instead of logging individually to put finish date | S | 1% |
| Answer |  |  |  |
|  | Notification duplicate study (title, IRAS ID, REC ref, or CPMS ID) is entered to prevent duplication of study records. Please provide screenshots. | S | 1% |
| **4** | **Patient management** | | |  |
|  | Ability to search patients based on multiple criteria; including Name, or Trial ID. Please provide screenshots. | S | 2.5% | 15% |
|  | Ability to add patient level research activity data to assigned studies against sites (including different activity types (e.g. Participant Identification, Screening, Screen failures, Recruitment, Follow-up). Please provide screenshots. | M |  |
|  | Ability to track patient status. Please provide screenshots. | M |  |
|  | Ability to collect aggregated research activity data where applicable types (e.g. Participant Identification, Screening, Screen failures, Recruitment, Follow-up). Please provide screenshots. | S | 2.5% |
|  | Ability to batch import patient data | M |  |
| Answer |  |  |  |
|  | Ability to append local data items to research activity record per study | C | 2.5% |
|  | Ability to record patient appointments | C | 2.5% |
| Answer |  |  |  |
|  | Ability to manage staff calendars | C | 2.5% |
| Answer |  |  |  |
|  | Ability to apply workflow to patient pathway, including multiple options (e.g. Study Arms) | M |  |
| Answer |  |  |  |
|  | Automatic link to study division/department, dependent on CI/PI details input | S | 2.5% |
| Asnwer |  |  |  |  |
| **5** | **Document management** | | |  |
|  | Ability to store relevant documents at a study level | M |  | 2.5% |
| Answer |  |  |  |
|  | Ability to store relevant documents at a site level | M |  |
| Answer |  |  |  |
|  | Ability to store relevant documents at a contact level (CVs, GCP certificates etc) | M |  |
| Answer |  |  |  |
|  | Ability to store relevant documents at a patient level | C | 1.25% |
| Answer |  |  |  |
|  | Ability to store documents at a general level (not linked to a particular study) | M |  |
| Answer |  |  |  |
|  | Document controls and restrictions | M |  |
| Answer |  |  |  |
|  | Drag and drop option for uploading files. Version control. Must be easy to upload document sets | S | 1.25% |
| Answer |  |  |  |  |
| **6** | **Site management** | | |  |
|  | Ability to add/create new sites. Please provide screenshots | M |  | 2.5% |
|  | Ability to edit site information | M |  |
| Answer |  |  |  |
|  | Ability to link many Sites at a time to a Study including supporting information | M |  |
| Answer |  |  |  |
|  | Ability to link people to sites | C | 2.5% |
| Answer |  |  |  |  |
| **7** | **System reporting** | | |  |
|  | Ability to create tailored reports using user definable criteria. Please provide information on how this is done | M |  | 10% |
| Answer |  |  |  |
|  | Ability to create research activity based reports using multiple criteria. Please provide information on how this is done | M |  |
| Answer |  |  |  |
|  | Ability to create site level based reports using multiple criteria | M |  |
| Answer |  |  |  |
|  | Ability to create PI/role based reports using multiple criteria | S | 1.67% |
| Answer |  |  |  |
|  | Ability to create study visit activity reports for patients recruited to particular studies | S | 1.67% |
| Answer |  |  |  |
|  | Ability to share reports with other users within system. Please provide information on how this is done | M |  |
| Answer |  |  |  |
|  | Ability to filter results of reports by rules. Please provide information on how this is done | M |  |
| Answer |  |  |  |
|  | Ability to control user access of reports available | S | 1.67% |
| Answer |  |  |  |
|  | Ability to output reports in multiple formats (including but not limited to PDF, XLS, XML). Please provide details of formats together with example reports | M |  |
| Answer |  |  |  |
|  | Provision of a standard suite of system reports, pre-built and available to users as standard | S | 1.67% |
| Answer |  |  |  |
|  | Ability to download templates for specific areas, such as grant costing information | C | 1.67% |
| Answer |  |  |  |
|  | Ability to upload templates for specific areas, such as grant costing information | C | 1.67% |
| Answer |  |  |  |  |
| **8** | **Finance** | | |  |
|  | Ability to track financial values of contracts | S | 0.6% | 5% |
| Answer |  |  |  |
|  | Ability to create costing templates for sites | S | 0.6% |
| Answer |  |  |  |
|  | Ability to create costing templates for studies | S | 0.6% |
| Answer |  |  |  |
|  | Ability to import but not limited to, existing standard costing templates | S | 0.6% |
| Answer |  |  |  |
|  | Ability to track study visit activity and associated costs | S | 0.6% |
| Answer |  |  |  |
|  | Ability to produce an invoice based on the patient activity/study visit information | S | 0.6% |
| Answer |  |  |  |
|  | Ability to enter "due dates" and reminders for payment of invoices | S | 0.6% |
| Answer |  |  |  |
|  | Ability to create income shares | S | 0.6% |
| Answer |  |  |  |  |
| **9** | **Grants** | | |  |
|  | Ability to record and report on grants: |  |  |  |
|  | Value of grants. Please provide screenshots | M |  |  |
|  | Main applicant grants. Please provide screenshots | M |  |
|  | Co-applicant grants. Please provide screenshots | M |  |
|  | Duration. Please provide screenshots | M |  |
|  | Funder. Please provide screenshots | M |  |
|  | Outcome. Please provide screenshots | M |  |
|  | Expenditure against budget. Please provide screenshots | M |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **10** | **Users and security model** | | |  |
|  | Ability to create user accounts through the application. Please provide information on how this is done | M |  | 5% |
|  | Ability to deactivate users through the application. Please provide information on how this is done | M |  |
|  | Expire Passwords by a number of failed attempts to login to the system. Please provide details | M |  |
|  | Expire Password by date. Please provide details | M |  |
|  | Single user logon | M |  |
|  | Ability to store and manage user contact information | M |  |
|  | System audit |  |  |
|  | Entire system | S | 0.7% |
|  | Study Record | M |  |
|  | User logon | M |  |
|  | Updating of data field definitions (Should) | S | 0.7% |
|  | Data capture (Should) | S | 0.7% |
|  | Reporting (Should) | S | 0.7% |
|  | Export (Should) | S | 0.7% |
|  | Creating fields | S | 0.7% |
|  | Amending field entries | S | 0.7% |
|  | Security |  |  |
|  | System level security model (independent security model that is not associated to the client operating system) | M |  |
|  | Closed system | M |  |
|  | Suitable controls and security to allow patient identifiable data to be stored and used within the application | M |  |
|  | access controls to enable appropriate access to patient identfiable data | M |  |
|  | Ability to set user permissions within the system at role and user level | M |  |
| **11** | **System training** | | |  |
|  | Supplier to provide a structured approach to system training for all relevant Trust staff in conjunction with nominated Trust trainers. Please provide details | M |  |  |
|  | Supplier to provide system training materials, as a minimum this should include user training manuals and associated training materials. Please provide details | M |  |
|  | Provision of a test training environment of the system. Please provide details | M |  |
| **12** | **System Support** | | |  |
|  | Helpline during routine working hours Mon-Fri | M |  | 5% |
|  | Technical support | M |  |
|  | Defined escalation and response routes and points of contact | M |  |
|  | General support |  |  |
|  | In-system help available | M |  |
|  | System user guides provided | M |  |
|  | FAQs /common issues log | C | 0.83% |
|  | Ability for users to feedback to system provider | S | 0.83% |
|  | Robust system change request process | M |  |
|  | Quick start guides for specific users (e.g. Research Nurses) | C | 0.83% |
|  | Online video tutorials | C | 0.83% |
|  | System accreditation |  |  |
|  | ISO 27001 Information security Management | S | 0.83% |
|  | ISO 9001 | S | 0.83% |

## **APPENDIX B – SOCIAL VALUE QUESTIONS**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Question** | **Maximum word count** | **Score Rating Percentage** |
| **1** | How would you deliver apprenticeships or employment to the local community in relation to this project? | 200 | 1.70% |
| Answer | (you may attach and refer to an appendix here) |  |  |
| **2** | How would you ensure that any products or service provided are sustainable and contribute to reducing carbon emissions as a result of this contract? | 200 | 1.70% |
| Answer | (you may attach and refer to an appendix here) |  |  |
| **3** | How would you support one of the community organisations or charities financially as a result of this contract? | 200 | 1.70% |
| Answer | (you may attach and refer to an appendix here) |  |  |
| **4** | How would you support the local community in terms of training, administration or publicity as a result of this contract? | 200 | 1.70% |
| Answer | (you may attach and refer to an appendix here) |  |  |
| **5** | How would you support local community organisations in terms of volunteering or pro-bon work as a result of this contract? | 200 | 1.70% |
| Answer | (you may attach and refer to an appendix here) |  |  |
| **6** | Are there any suggestions or innovations you have delivered before which you think would benefit the local community? | 200 | 1.70% |
| Answer | (you may attach and refer to an appendix here) |  |  |