Request For Information

Clinical Trials Management System

RFI #15-562879-cs

Date Issued: 4/9/15

Due Date: Thursday, May 7, 2015

Submitted by the University of California
Davis Health System

This RFI is also available at: http://www.ucdmc.ucdavis.edu/matmgt

All questions regarding this RFI should be by email only and directed to:

Connie Stewart
UCDHS Purchasing Department
Email: cjstewart@ucdavis.edu

Questions should not be directed to any other University departments or staff. Material or substantive information provided to any Responder, as a result of questions received, will be provided to all Responders via an addendum to this RFI.
Proposed Schedule of Events

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Release of Request for Information</td>
<td>April 9, 2015</td>
</tr>
<tr>
<td>Receipt of Responders’ E-Mailed Questions by noon PST</td>
<td>April 16, 2015</td>
</tr>
<tr>
<td>UCDHS Response to Vendors’ Questions by 4pm PST</td>
<td>April 21, 2015</td>
</tr>
<tr>
<td>Receipt of Responders’ Reply to this RFI by 3pm PST</td>
<td>May 7, 2015</td>
</tr>
<tr>
<td>On-site demos (if requested)</td>
<td>To be determined</td>
</tr>
</tbody>
</table>

Vendor Inquiries

Inquiries regarding this RFI process and the functional or technical requirements of the proposed systems must be emailed by noon PST on 4/16/15. The ONLY UCDHS contact person and address are listed below. Questions must be submitted via email.

Connie Stewart  
UCDHS Purchasing Department  
E-mail: cjstewart@ucdavis.edu  
All questions/inquiries by email

NOTE: DO NOT EMAIL ANY OTHER EMPLOYEE AT UCDHS REGARDING THIS RFI.

Proposal Submittal Instructions

Each Responder is required to submit their response via e-mail to: cjstewart@ucdavis.edu

All Responder replies must be emailed and the email posted and received in the UCDHS Purchasing Department no later than 3:00 p.m. PST on May 7, 2015. UCDHS Purchasing Department will not accept any response after the due date and time.

Following evaluation of this RFI, UCDHS may release a formal Request for Proposal. Requests for demonstrations or presentations from vendors may be requested and you may be contacted accordingly.
GOAL OF REQUEST FOR INFORMATION

1. To obtain detailed information from Responders regarding their experience and capabilities in successfully delivering Clinical Trials Management System that meets the requirements of the UC Davis Health System.

2. To obtain information, pricing structures, approximate budgetary costs, work plans, estimated implementation schedules, proposed methodologies and approaches to be utilized.

3. To solicit information that will enable UCDHS to compare and evaluate Responders’ Clinical Trials Management System offerings to determine the optimum direction for the Health System.

4. To complete the required UCDHS IT Evaluation Process for the proposed Clinical Trials Management System (attachments on Page 9).
Scope of Work
The UC Davis Health System (UCDHS) desires to purchase a Clinical Trials Management System to support management of the clinical trial enterprise including research subject tracking, accurate cost determination and recovery for clinical trials conducted within the UC Davis Health System. To this end, this RFI will be used to identify potential applications to meet the need. The application will be judged on features and integration in the following areas:

- Security: Authentication and access controls
- Interoperability & flexibility: Ability to connect with other applications, and availability of user tools to design and customize forms and configure workflows
- Quality Control: Process completion checks, versioning, notifications
- Calendaring: Create, manage and customize study calendars
- Coverage Analysis (CA): Construct and/or customize a coverage analysis model for determining the cost elements of conducting a clinical trial
- Budgeting: Assign trial-specific costs to the elements as per sponsor budget, conduct break-even analysis
- Invoicing: Invoice creation based on various criteria, and Accounts Receivable reconciliation
- Reporting: Extensive, customizable data extraction and results export
- Support and Training: Avenues for both full-service, urgent support and self-service troubleshooting. Options for training including updated user manuals, administrative manuals, videos or other modes of training.

Responses to this RFI must be formatted in the order presented above. Responses that do not follow this format will not be considered. It is strongly preferred that RFI responses are relatively brief, containing the minimum necessary verbiage to convey salient features and capabilities.

Minimum Requirements
Features are classified as required and optional. Requirements are mandatory; applications which do not fulfill all of the requirements will not be considered. Optional features are not mandatory but are highly desirable.

1. **Security**
   a. Required:
      i. Role-based authentication & authorization
      ii. Ability to control access to all components and functionality via user roles
      iii. e-signature authority
      iv. Ability to integrate/use CAS protocol (Kerberos) or Active Directory for authentication
      v. Support encryption of stored data at rest using recognized, standard, and secure algorithms
      vi. The system must be capable of 21 CFR Part 11 compliance
   b. Optional:
      i. Ability to create groups of users using any data fields
      ii. Ability to support both an internal authentication store (internal to the application) and external authentication store (e.g., Active Directory)

2. **Interoperability & flexibility**
   a. Required:
      i. Ability to interface with Epic Electronic Medical Record research functionality contained in the Epic 2012 release or later
      ii. Intuitive, easy to use interface
      iii. Ability to do bidirectional interfacing in real-time with the following applications:
         1. Epic Electronic Medical Record Research functionality contained in the Epic 2012 release or later
         2. REDCap (Research Electronic Data Capture)
         3. IRB system – specify
      iv. Ability to run multiple instances of software for (at minimum): Development, Testing, Production
   b. Optional
      i. Ability to access a demo system in a sandbox environment for new feature testing
      ii. Ability to manually change administrative information based on permission.
iii. Ability to easily design custom forms to support administrative and other functions without an expert programmer.
iv. Must be able to add fields to existing forms on demand without an expert programmer
v. Ability to create custom “Study Status”
vi. Ability to access the backend of the database via an administrative interface to manipulate the elements of the system (i.e. menus)
vii. Interface with the National Cancer Institute CTRP module (reporting system)
viii. Able to accept uploaded files (Excel, Word and PDF), with version control to store multiple versions of the same document.

1. Multiple versions of an uploaded file must be clearly delineated and accessible to user.

3. Quality Control
   a. Required:
      i. Versioning of study calendars, billing grids and budgets. A billing grid is defined as a schedule of events with indicators of who pays for procedures and services indicated per protocol
         Ability to compare versions to see what has changed.
      ii. Ability to selectively apply changes in a study to user-selectable sets or sub-sets of study subjects:
         1. Future study subjects
         2. Study subjects on treatment
         3. Past study subjects
      iii. Provide electronic notification of new or changed information to appropriate users.
      iv. Ability to support workflows for financial management and administrative processes (i.e. provide informational statuses when the work is in progress, complete, etc.).
      v. Ability to create an audit trail to track who has added/change/deleted a record.
   b. Optional:
      i. Document (upload) version capability
      ii. Customizable dashboard features for administration of studies

4. Calendaring
   a. Required:
      i. Ability for users to create general study calendars formatted with the following characteristics:
         1. Horizontal format with visits in columns across the top and procedures, services and other activities in rows down the left side.
         2. Ability to create a minimum of 500 number of rows and columns.
      ii. Ability to record user-defined events. Examples:
         1. Dates study subjects seen, for what
         2. Visit window violations
         3. Cancelled appointments
         4. Unplanned visits & procedures
         5. Justification why service was not performed
      iii. Ability to add procedures/visits at will.
      iv. Ability to create a record using an existing similar trial.
      v. Ability to create multiple arms for a study.
      vi. Multiple calendars for single trial
   b. Optional:
      i. Multiple or unlimited treatment cycles and follow-up visits
      ii. Calendar versions with effective dates (in the event of amendments)
      iii. Allow patient to transfer from one calendar to another during participation in trial
      iv. Ability to re-schedule a user-selected subset of an individual study subject’s events.
5. **Coverage Analysis (CA)**
   a. **Required:**
      i. Ability to create custom QCT form, and record and track qualifying status.
      ii. Ability to create billing grid based on a schedule of events, modifiable at any time and tightly integrated with calendaring and budgets.
      iii. Billing grid must have the following characteristics:
          1. Horizontal format with visits in columns across the top and procedures, services and other activities in rows down the left side.
          2. Ability to create an adequate number of rows and columns – specify limits
          3. Ability to include separately CPT Codes, Modifiers, Service Codes and description of procedures.
          4. Ability to provide visual delineation of billable to insurance vs. billable to study for each line item.
          5. Ability to add or record billing justification for each procedure.
   b. **Optional:**
      i. Ability to maintain versions of the CA (which consists of the QCT form AND the billing grid) based on changes made to any component.
          1. Ability to map colloquial description of procedures/service onto the actual billing codes in the billing grid.
          2. Ability to reference procedures from Rate Master (Excel) document based on any data field in Rate Master.
          3. Ability to create bundles of codes such that selecting the key for a bundle will display its contents and use them to populate the billing grid.
          4. Reconcile Epic EMR billing with anticipated charges based on billing grid.

6. **Budget**
   a. **Required:**
      i. Ability to create budgets with the following characteristics:
          1. Horizontal format with visits in columns across the top and procedures, services and other activities in rows down the left side.
          2. Unlimited number of rows and columns.
          3. Ability to include start up, close out and billable items as separate parts of the budget.
          4. Ability to express budget as cost per study subject.
      ii. Ability to separate patient care services from other expenses.
      iii. Ability to trigger changes in the CA and budgets with relevant protocol changes.
   b. **Optional:**
      1. Ability to automatically populate budget with costs in bundles of procedures.
      2. Ability to create external (negotiated) budgets by applying user-defined markups.
      3. Ability to draw costs from the Rate Master based on CPT codes or any other characteristics (name of the procedure, facility/ GL code etc.)
      4. Ability to provide labor costs in dollars per hour format in addition to percent effort
      5. Ability to do automatic break-even (enrollment ) analysis

7. **Invoicing**
   a. **Required:**
      i. Ability to aggregate current accounts receivables based on but not limited to completed events in calendar
      ii. Extensive, flexible and configurable invoicing capabilities, including:
          1. Ability to generate invoices based on negotiated rates (as opposed to internal budget rates), payment milestones, completed procedures or visits, past due notices and/or other data points as needed.
          2. Reconciliation of cash received with accounts receivable and invoices.
   b. **Optional:**
      i. Ability to generate automatic notifications to users for invoices past due.
8. Reporting
   a. Required:
      i. Ability to create ad-hoc queries using any data points in the system without an expert programmer
      ii. Ability to roll in all completed activities per study, per department, per PI and overall for the Health System.
      iii. Provide easy comparison of accounts receivable vs. income.
      iv. Ability to generate a list of enrolled subjects including any user-selected data points as needed.
      v. Ability to enumerate anticipated subjects and compare with actual enrollments, including screen failures
      vi. Ability to customize reports without an expert programmer.
      vii. Ability to export reports as Excel, Word and PDF files.
      viii. Ability to report qualifying and non-qualifying studies by their qualifying status
      ix. Ability to report on groups of users using any data points
      x. Ability to report on custom “Study Status” and other customized menu options
      xi. Ability to track and report each study patient individually from the study inception to any user-defined point in time
      xii. Ability to report on activities in the system using “user roles” (i.e. what a user did and when)
   b. Optional:
      i. Ability to facilitate Adverse Events (AE)/ Serious Adverse Events (SAE) and deviations reporting. Reconcile Epic EMR billing with anticipated charges based on billing grid.
      ii. Ability to customize AE/SAE features for individual studies
      iii. Reporting on patient accruals, deviations, studies.
      iv. Dashboard format of reports
      v. Export to statistical tools, technical database management requirements, regulatory DB auditing requirements

9. Case Report Forms (CRFs)
   a. Optional:
      i. Ability to create custom Case Report Forms without an expert programmer
      ii. Custom eCRF development, flexible data quality controls, change management, branching logic, ability to interact across forms
         a. Ability to generate printed representations of eCRFs including multiple choice options, for documentation/training/etc.
         b. Ability to keep version control of eCRFs
      iii. Ability to report on any data point in a CRF or a user-defined group of CRFs
      iv. Should include ability to manage longitudinal studies
Response Conditions

1. Notwithstanding any other provision of the RFI, Responders are hereby advised that this RFI is a solicitation for information only and is not to be construed as an offer to enter into any contract or agreement.

2. UCDHS shall have the unconditional and unqualified right to withdraw, cancel, or amend this RFI at any time. Responders shall bear all costs associated with the preparation and furnishing of responses to this RFI. All replies shall be firm for a period of 180 days following the reply submission due date.

3. Responses to this RFI should be made according to the instructions contained herein.

4. UCDHS reserves the right to interpret or change any provision of this RFI at any time prior to the submission date. Such interpretation or change shall be in the form of a written addendum to this RFI. Such addendum will become part of this RFI and any resultant contract. Such addendum shall be made available to each company that has received an RFI.

5. UCDHS has, at its sole discretion, the unconditional and unqualified right to determine that a time extension is required for submission of replies, in which case, a written RFI addendum issued by UCDHS shall indicate the new submission date for replies.

6. Prior to the final submission date, any Responder may retrieve its information to make additions or alterations. Such retrieval, however, shall not extend the final submission date.

7. Responders wishing to submit information in response to this request do so entirely at their own expense, and submission of a reply indicates acceptance of the conditions contained in the RFI unless clearly and specifically noted otherwise.

8. PUBLIC INFORMATION AND TRADE SECRETS—The California Public Records Act limits UCDHS’s ability to withhold pre-qualification and bid data to trade secrets or records, the disclosure of which is exempt or prohibited pursuant to federal or state law. If a submittal contains any trade secrets that Responder does not want disclosed to the public or used by UCDHS for any purpose other than evaluation of the Responder’s eligibility, each sheet of such information must be marked with the designation “Confidential.” UCDHS will notify the Responder of any request, by another party, to inspect such confidential information. Responder will have an opportunity to establish that such information is exempt from inspection in any proceeding to compel inspection.

9. All computer programs and data made available by UCDHS to Responders hereunder shall remain the property of the UCDHS and shall be maintained, used, and disseminated in accordance with the California Information Practices Act of 1911, Civil code Sections 1798 through 1798.76, and the California Public Records Act, Government Code Section 6250 through 6260. All listings and all copies of listings that reveal names or identification numbers of individuals, (i.e., employees, patients, etc.) shall be destroyed or returned to UCDHS.
TECHNOLOGY EVALUATION

The UCDHS IT Evaluation Process is a set of activities and procedures referring to the acquisition of new applications, technology, or technology devices. It is the goal of the UC Davis Health System to ensure new applications, technology, and devices adhere to current Information Technology, Clinical Engineering, and Security standards to safeguard patient privacy, enable organizational efficiencies, and provide overall protection of health systems assets.

Please complete the following questionnaires included with the RFI:

- Preliminary Checklist
- Technology Questions
- Security Questions

These documents should be submitted as separate attachments. If a question does not apply to your product, enter N/A. Certain IT functional areas may request a conference call to receive clarification on answers if necessary.
Contract Terms and Conditions

The University of California Terms and Conditions for Goods and Services shall apply to this Request for Information and will be attached as a separate document.

No form of the University’s name shall be used in promotional materials, signs, announcements, or other forms of communication or advertising originated by Responder unless the University’s express written permission for such use has been obtained in advance.

Under existing campus policy (P & P Manual #260-15) a gift or donation to the University may not be coupled with the expectation of tangible compensation or with the imposition of contract or grant requirements. Each purchasing transaction, business contract, research contract, affiliation agreement, and grant shall be considered as separate and whole in itself. As such, it is the policy of the University of California Health System that no gift or donation to the University, nor any of its business contracts, purchasing transactions, research contracts, affiliation agreements, or grants shall be used as partial consideration for any other transaction, contract, agreement, grant or gift/donation.

As referenced herein, contracted equipment shall refer to all equipment contracted under this agreement. The title to Contracted Equipment shall at all times remain with the vendor, and the risk of loss arising due to UCDHS’s fault or negligence, or due to theft or disappearance, shall pass to UCDHS upon the date the Contracted Equipment is delivered and installed at the site. The risk of loss due to all other causes shall remain with the vendor.

Vendor’s equipment shall conform to manufacturer published specifications or as otherwise agreed by both parties.

PIGGYBACK CLAUSE

The University of California Davis Health System (UCDHS) grants other University of California (UC) entities the right to acquire the properties and/or services from a resulting contract based on this competitively bid Request for Proposal (RFP). By submitting an RFP that results in a contract, the Contractor agrees to make the same bid terms and price, exclusive of freight and transportation fees, available to other University of California entities. UCDHS will not be responsible for any problems, which may arise between UC entities and the Contractor as a result of any sales and/or purchases made.