NCCCP HCIT DCT Technical Requirements Document

| Requirement | Tool currently Supports | Development Time in Plan | Can Support with addt’l budget | Cannot Support | Resolution | Phase 1(Nov 14th) | Phase2 **(Jan 15th)** | Phase 2 Est. (Days) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| (*Requirements included in these columns will be implemented before the Nov 1st deadline)* | |
| **Data Collection Tool Features** | | | | | | | | |
| 1. System will require that users have a user ID and password (list of existing user ID will be provided [by NCI Application Support] along with their LDAP association) and will provide the following functionality: | X |  |  |  |  |  |  |  |
| * 1. System will have the ability to authenticate user names and passwords against the NCI LDAP. | X |  |  |  |  |  |  |  |
| * 1. System will generate a temporary system generated password |  |  |  |  | Not Necessary - user IDs and passwords will be authenticated from NCI LDAP |  |  |  |
| * 1. System will e-mail the user with their user ID |  |  |  |  | Not Necessary - user IDs and passwords will be authenticated from NCI LDAP |  |  |  |
| * 1. System will e-mail the user in a separate e-mail their temporary system generated password |  |  |  |  | Not Necessary - user IDs and passwords will be authenticated from NCI LDAP |  |  |  |
| * 1. System will require the user, upon first entry into the system, to assign a new password and to confirm that password. |  |  |  |  | Not Necessary - user IDs and passwords will be authenticated from NCI LDAP |  |  |  |
| 1. System will require a ***Site Level Configuration Page*** to be enabled / or not enabled prior to launch of tool (in this case quarterly) or any data entry by the site’s users |  | | | | **Agreed Process -**  **PI Privileges page**, will be available in Phase 2 and will require the PI to assign one and only one user per form to be the designated submitter for each form and as such will be the user who submits the form as “Complete”; will require the PI to assign which pages the other users have default privileges to; the default privileges for all users will be: read, edit, enter, and save.  In all cases, all PIs should have the ability to do the following:   1. Assign only one user to each form as the only user who will get the “Complete” button to submit form as ready for PI approval. 2. Assign each user for the site to one or more forms as basic users. 3. Assign themselves (the site PI) as an assigned user to complete one or more forms and submit as ready for PI approval.   **Additional Budget:** as per call 9/15/2011 with Brenda/Dorie/Bill, we may be able to complete the following if we leverage another contract -   1. Select a form as a “PI Only” form, meaning no users from the site can access the page except the PI (ie to any other user other than the PI the page is non-viewable and no users other than the PI can read, edit, enter and save. |  |  | 15  (Including sub-sections) |
| * 1. When the tool has a Site Level Configuration Page enabled: |  |  |  |  |  |  |  |  |
| * + 1. System will provide the ability to assign one person responsible for maintaining access rights to site, forms, and modules |  |  | X |  | See 2.0 |  |  |  |
| * + 1. System will require Site Level Configuration Page for every site associated with the tool |  |  | X |  | See 2.0 |  |  |  |
| * + 1. System will provide the ability to complete the configuration page prior to launch date of each data collection period by allowing authorized users to assign users to forms or to select the previous quarter’s associations: |  |  | X |  | See 2.0 |  |  |  |
| * + - 1. System will provide the ability to review and enable the previous quarter’s assignments or create new assignments |  |  | X |  | See 2.0 |  |  |  |
| * + - 1. System will present a list of user IDs associated with each site. |  | X |  |  | The first release will include the ability to maintain users for a site. |  |  |  |
| * + 1. System will provide the ability to assign the users to a form or forms within a module |  |  | X |  | See 2.0 |  |  | Section 24 addresses this |
| * + - 1. System will provide the ability for authorized users to disable any assigned privilege for a user. |  |  | X |  | See 2.0 |  |  |  |
| * + - 1. System will provide the ability for authorized users to assign data entry privileges to a user for a specific form or set of forms. |  |  | X |  | See 2.0 |  |  |  |
| * + 1. System will provide the ability for authorized users to review the list of users and the forms they have been assigned before enabling data entry for that site every quarter. |  |  | X |  | See 2.0 |  |  |  |
| 1. System will require users to enter the tool by displaying a ***customizable Welcome Page*** that contains instructions ( such as directions on how to use the tool and how the tool data will be used): | X |  |  |  |  |  |  |  |
| * 1. System will provide the ability for authorized users to provide Welcome Page content | X |  |  |  |  |  |  |  |
| * 1. System will allow for addition of logo’s and ability to define these logo’s (in accordance with 508 compliance regulations) | X |  |  |  | We will use NCCCP logo and NCI banner. |  |  |  |
| * 1. System will provide the ability to indicate multiple contact roles and associated contact information (such as, for user ID and password issues contact XXX at XXX.com; for technology support contact XXX at XXX.com; for overall tool questions contact XXX at XXX.com); etc…) |  | X |  |  |  |  |  | 3 |
| * 1. System will present a list of links for each form of the tool that will allow entry into that form by each user for data collection | X |  |  |  | The tool will present a menu listing all of the forms. |  |  |  |
| * 1. Would like but does not require system to provide an alert box that notifies in a broadcast fashion to all users a customizable message that can be enabled or disabled by authorized users (such as a message about a deadline for submission being pushed out another week; etc…) |  | X |  |  | Messages can be displayed on the home page or on the first page users see after they log into the system. |  |  |  |
| 1. System will allow all ***questions and table formats*** to be displayed on multiple pages where each page corresponds to a form of the data collection, (i.e. the Advocacy Form, the Biospecimen Form, the Clinical Trials Form, etc.). | X |  |  |  |  |  |  |  |
| * 1. Each of the pages can contain headers which sub-divide the page into sub-forms. These sub-forms may be used to delineate questions that have a specific set of instructions or which may be arranged by topics. Each header should be clearly mapped to specific questions. | X |  |  |  |  |  |  |  |
| 1. System will allow for tool ***custom configuration***: |  |  |  |  |  |  |  |  |
| * 1. System will provide the ability to easily create, insert and remove new questions and tables within multiple forms without disturbing the structure of other forms. | X |  |  |  |  |  |  |  |
| * 1. Each question and table should have both: |  |  |  |  |  |  |  |  |
| * + 1. a unique id that is for the internal use of developers | X |  |  |  |  |  |  |  |
| * + 1. a displayed number or identifier for use by the end user in navigating their location within a form. | Not required as stated, can use form headers. Also, can use short name in data analysis | | | | **Not Required -** will reference form and question text when referring to questions in FAQ. |  |  |  |
| * + - 1. The numbers should be generated automatically, but the configurer should be able to set the tool to automatically label the questions with Scheme A: 1, 2, 3… n or Scheme B: 1-A, 1-B, 1-C… 2, 3… The configurer should be able to choose when to use scheme A or scheme B and when to number a question or table with a new integer. | **Not Required -** will reference form and question text when referring to questions in FAQ. |  |  |  |
| * + 1. System will provide the ability for authorized users to flag questions as read-only. |  | X |  |  | Related to QOPI reporting which is required every 6 months, Some questions are not required to be filled out for each quarter, questions/answers should be read-only |  |  | 3 |
| * + 1. System will provide the ability to disable forms or individual questions in a form. |  | X |  |  |  |  |  | 5 |
| * + - 1. Selection to make material read-only by the user, made inactive to data entry. | X |  |  |  | We are able to grey out a field or make a field viewable not editable at a question level, form level, and table level. NOT at a cell level. |  |  |  |
| 1. System will allow complex forms with a mixed use of questions and tables in mixed configuration that allows for multi person data uploads on a semi frequent data (quarterly). *Reference Clinical Trials Table*. |  |  |  |  | **DECISION PENDING:**  ***Clinical Trials Table – CRITICAL REQUIREMENT***  Clinical Trials Table will be built as a form within the Quarterly Report Module and submitted at the same time as the entire module.  The clinical Trials Table will consist of 2 tables, one with CTEP data from the previous quarter that is read-only and one with Self Reported data that is read, enter, edit, and save.  A capability for uploading data will be provided by HCIT. There are two providers of data:   * CTEP (Troy Bud) providing accrual data for the NCI trials for: 28 of 30 sites; generally 2 months after a quarter ends but with no consistent and reliable expected delivery date due to internal process variances; provided in a reliable and consistent format. * SAIC-F (Angela Carrigan) providing the NCI accrual data for 2 of 30 sites, St. Joseph – Mercy and Queens; provided 1-2 weeks after the CTEP data is uploaded; results from working with St. Joseph – Mercy to eliminate non-qualifying sites data from final numbers and working with Hawaii Co-operative Grp to cleanse the non-Queens data from the file.   CTEP table will NEVER be editable but always will be readable; always will be one quarter behind (due to the internal CTEP cleansing of the accrual data before it is considered final); must have a way to visually identify the date range for the represented data, as it will always be from the previous quarter but the second table, the Self Reported Trials, will be submitted as the existing quarter trials.  Self Reported Trials table will include the same fields as the CTEP data but will be provided by the users. The Self Reported Trials table will always be pre-populated with the same data that was submitted in the previous quarter but allowing the users to read, write, edit, save. The user must be able to add new trials. The user must be able to indicate a trial is closed in one quarter and have the system understand that that cell’s data will not be pulled over into the tables data next quarter. The user must be able to delete a trial and have the data removed from the table visually and not be included as part of the overall data for that quarter going forward.  SO, the form will have two tables, a form called CTEP data that is grayed out, then have a second form that represents additional trials that is editable.  A validation feature will be applied in the background so that if either CTEP/SAIC-F or the users at the sites try to enter a trial that is already entered in the other data set, a validation message will notify them that the form cannot accept duplicate trial data. The user at the site level will then be required to edit their data accordingly, as if it is present in the CTEP data that data is always the default accept for input. System will either notify user that the data is replicative or that it was deleted due to the accounting of it in the CTEP data.  Once the data is reviewed by the PI and approved as final so it is locked, the SAIC-F admins (Angela and team) must be able to run reports to determine any inconsistent data so they can alert HCIT to unlock that form for that user and notify the user that the data needs to be edited and resubmitted for approval…cleansing process.  NCI/SAIC-F will provide a visual work flow and an associated document that outlines the above process. |  |  |  |
| 1. System will provide for ***data submission functionality*** so that the user can indicate data is considered final in a validated manner by: |  |  |  |  |  |  |  |  |
| * 1. System will require the user to validate submission upon selecting a submit feature by: | X |  |  |  |  |  |  |  |
| * + 1. Requiring the system to validate that required questions have been completed and with the correct type of data (i.e. integer between 0 to 100 for a percentage) before the system submits data as final to the database | X |  |  |  |  |  |  |  |
| * + 1. Requiring the user to review the questions and user-input answers displayed by the system and allowing the user to review data before submission | X |  |  |  |  |  |  |  |
| * + - 1. System will allow user to edit data if a mistake is noted by presenting the user with an edit functionality | X |  |  |  |  |  |  |  |
| * + - 1. System will allow the user to print their input before submitting data as final | X |  |  |  | The user can print the input at any time in the data entry process. |  |  |  |
| * + - 1. System will allow the user to submit data as final and therefore submit data as final to the database | X |  |  |  | There will be a user submission and then the PI will validate and approve data. For the first quarter, ANY user can submit data, but only the PI can approve it. For following quarters, only one person per site can submit each form to the PI, but as many as the PI allows privileges to do so can read, write, edit, and save. |  |  |  |
| * + - 1. Once a form is submitted as final by the Form Submitter the system will consider the form complete and only allow the form to be accessed in read-only by users, including all Basic Users | X |  |  |  |  |  |  |  |
| * 1. System will present a validation message to the Form Submitter after data is submitted as final by presenting a message to the user: | X |  |  |  |  |  |  |  |
| * + 1. A customizable thank you message is displayed after submitting every form and upon final submission | X |  |  |  |  |  |  |  |
| * + 1. After displaying the thank you message, the data collection tool will return to the data collection tool home page after saving/ submitting data as final | X |  |  |  |  |  |  |  |
| 1. System will provide the ability for authorized users to indicate content as open to edit or not open to edit |  | X |  |  |  |  |  | 15-20 |
| * 1. The ability to assign content open for edit or to constrain content from editing must be configurable as follows: |  |  |  |  |  |  |  |  |
| * + 1. As a Module | X |  |  |  |  |  |  |  |
| * + 1. As a user |  |  | X |  |  |  |  |  |
| * + 1. As a Form within a Module |  |  | X |  |  |  |  |  |
| * + 1. As a set of question/answers within a Form |  |  | X |  |  |  |  |  |
| * + 1. As a Table within a Form |  |  | X |  |  |  |  |  |
| * + 1. As a line item within the Table |  |  | X |  |  |  |  |  |
| * + 1. As a column within a Table |  |  | X |  |  |  |  |  |
| * + 1. As a cell within a Table |  |  |  | X |  |  |  |  |
| * + 1. At a user action level (such as upon submitting validated data as final) | X |  |  |  |  |  |  |  |
| * + 1. As a time point (such as a date that quarterly report data is no longer being accepted) |  | X |  |  | We will use a field for due date at the module level. The collector tool currently has a reminder API which can be used to figure out which sites still need to complete data entry, *possibly send email to PI as reminder.* |  |  |  |
| 1. System must allow the System Administrator(s) to assign or flag content as an exclusion to what the system will consider a final submission | **Not required as stated.** Can be resolved through skip patterns. Are you a CCOP site? If yes, then ask questions specific to CCOP….. | | | |  |  |  |  |
| * 1. The ability to assign or flag content as an exclusion must be able to be applied at: |  |  |  |  |
| * + 1. Question level |  |  |  |  |
| * + 1. Answer level |  |  |  |  |
| * + 1. Table level |  |  |  |  |
| * + 1. Line items within a table |  |  |  |  |
| * + 1. Columns within a table |  |  |  |  |
| * + 1. Cell within a table |  |  |  |  |
| 1. System must be able to upload legacy data in batches using the following file formats: | Assuming this is legacy data migration; we have allocated time and budget for uploading data in one format. | | | | **Clarification –** legacy data will be provided in tab-delineated format by NCI/SAIC-F support staff. |  |  |  |
| * 1. Excel |  |  |  | X |  |  |  |  |
| * 1. CSV |  |  |  | X |  |  |  |  |
| * 1. Xml |  |  |  | X |  |  |  |  |
| 1. System must be able to accept data in batches from the following EHRs (if these EHRs do not support exporting of CSV or xml files): | Our recommendation would be to design a standard input file for the data to be submitted from any EHR. We would then design a conversion and validation process from any of the following EHRs (Cerner, Varian, Allscripts, Impac) to this standard format. | | | | HCIT will make available an open API and create the instructions for any system (including EHRs) to exchange data electronically.  HCIT will not do any work toward custom interfaces necessary for individual vendor engagement without further contractual financial discussions agreements with sites. If the site would like to electronically integrate with this tool and submit the data via an electronic interface, those interfacing costs would be paid by the site (HCITs costs and the selected vendors cost). If the vendor is one of the four indicated EHRs that is indicated for the planned conversion and validation process, the site would still be responsible for the interfacing costs of HCITs mapping efforts and the vendor’s associated costs. |  |  | 20  (This is to define a standard input format and to develop open APIs to integreate)  Individual HER intergration is not included. |
| * 1. Cerner |  |  | X |  | See above. |  |  |  |
| * 1. Varian |  |  | X |  | See above. |  |  |  |
| * 1. Allscripts |  |  | X |  | See above. |  |  |  |
| * 1. Impac |  |  | X |  | See above. |  |  |  |
| * 1. Eclypsis |  |  | X |  | See above. |  |  |  |
| * 1. Epic |  |  | X |  | See above. |  |  |  |
| * 1. Meditech |  |  | X |  | See above. |  |  |  |
| * 1. caEHR |  |  | X |  | See above. |  |  |  |
| * 1. iKnowmed |  |  | X |  | See above. |  |  |  |
| * 1. MDLand |  |  | X |  | See above. |  |  |  |
| * 1. Altos |  |  | X |  | See above. |  |  |  |
| * 1. GeniusDoc |  |  | X |  | See above. |  |  |  |
| * 1. Rabbit Healthcare |  |  | X |  | See above. |  |  |  |
| 1. System should be able to integrate with other information technology systems to allow for data consumption as well as data retrieval where interfaces have been built | X |  |  |  |  |  |  |  |
| 1. System will allow a user to submit ***attachments*** to a site data submission for the purpose of illustration or proof of action by: |  |  | X |  | **Bell and Whistle –** it was decided that NCI/SAIC-F would do our best to ask questions in the module and forms to support the data we would need from attachment documents so that the information is computable and reportable. Data cannot be mined from attachments so they would not be useable in analysis. If a site feels they need to submit an attachment as an example, it would be received via e-mail to the SAIC-F program mgt team and they would file it for future reference.  ***Should we decide it is a necessary function it could be provided but at additional cost and time for development that would need to be estimated by HCIT and approved by Rod and Dwayne.*** |  |  |  |
| * 1. System will allow user to submit supporting documents as attachments (could be Word, Excel, pdf) meant as example documents and are not added as data for Analysis |  |  | X |  | See above. |  |  |  |
| * + 1. System will allow user to add attachments with the ability for the user to associate tags to identify the document in searches |  |  | X |  | See above. |  |  |  |
| 1. System will provide the ability to review and either approve or edit data prior to submitting sites data as final through a ***final submission validation*** page, activated once all forms from a module are completed and data is submitted as final by all Form Submitters | X | X |  |  | **Agreed Process:**  ***Phase 1:*** all users associated with a site will have the following privileges: read, edit, enter, and save. Only the PI will be shown the “Submit” button. Sites will need to have an internal SOP to guide who is responsible for considering each form final and then notifying the PI that the form is ready to be reviewed and approved. Once the PI reviews the data, if he/she feels data needs to be edited, an e-mail will be sent to the user responsible for the form, as determined by internal SOP, and ask them t correct the data. Once the PI is satisfied the data is complete and as accurate as feasible, the PI will select “Submit” and the system will lock the data.  **Phase 2:** per a PI Privileges page, the PI will assign one user per page as the responsible party for submitting the data as complete for approval. All users will be able to read, edit, enter, and save. The user who has the responsibility to make the data complete will have an extra button called “Complete” (or something else as decided later). A site will define the SOPs for who completes what data entry for what form. The assigned user for each form will determine when the data is complete and ready for submission to the PI for approval. The assigned user for each form will then notify the PI (via internal SOP) that the form is complete and ready for review and approval. PI will approve data and submit it as final OR will decline the data and notify the user that they need to update the form and resubmit it as final (via internal SOP).  System will however supply the assigned user for each form a validation message when they submit the form as “Complete” that reads, “Please notify PI, as per internal SOP, that the form is ready for review and approval”. System will also provide the PI a reminder to notify the assigned user for a form when they decline a form and expect a user to edit specific data within that form (per internal SOP), with a validation message of, “Please notify the assigned user for this form that the form was declined and they need to edit specific data and resubmit the form as complete”.  **PI Privileges page**, will be available in Phase 2 and will require the PI to assign one and only one user per form to be the designated submitter for each form and as such will be the user who submits the form as “Complete”; will require the PI to assign which pages the other users have default privileges to; the default privileges for all users will be: read, edit, enter, and save.  In all cases, all PIs should have the ability to do the following:   1. Assign only one user to each form as the only user who will get the “Complete” button to submit form as ready for PI approval. 2. Assign each user for the site to one or more forms as basic users. 3. Assign themselves (the site PI) as an assigned user to complete one or more forms and submit as ready for PI approval.   **Additional Budget:** as per call 9/15/2011 with Brenda/Dorie/Bill, we may be able to complete the following if we leverage another contract -   1. Select a form as a “PI Only” form, meaning no users from the site can access the page except the PI (ie to any other user other than the PI the page is non-viewable and no users other than the PI can read, edit, enter and save. |  |  | 10 |
| * 1. System will provide the ability for authorized users to review all questions within each form so that they can edit or approve data and submit it as final |  | X |  |  | Site Administrator = PI |  |  |  |
| * + 1. System will provide the ability for authorized users to review the questions and user-input answers displayed by the system and allowing the user to review data before submission |  | X |  |  | Site Administrator = PI |  |  |  |
| * + 1. System will provide the ability for authorized users to edit data if a mistake is noted by presenting the user with an edit functionality |  | X |  |  | **Agreed Process:** in the first quarter of the tool, all users, including the PI, will be able to: read, edit, enter, and save. In Quarter 2, users will be constrained by the PI privileges page.  It is not OK for PI to make changes to data instead of kicking it back to the user who entered the data. PI will indicate the data has been “Declined” and the form will be kicked back to the user who submitted the data, the form will be unlocked by the action of the PI selecting “Decline”, and the PI will notify the user about the specific data they need to edit and resubmit. SOPs at a site level outline: how a user communicates with the PI that a form is ready for review and approval; and how a PI communicates with users associated with that form when data needs to be edited. |  |  |  |
| * + 1. System will provide the ability to print each form before submitting data as final | X |  |  |  |  |  |  |  |
| * + 1. System will provide the ability for authorized users to submit data as final and therefore submit data as final to the database |  | X |  |  |  |  |  |  |
| * + 1. Once a form is submitted as final by an authorized user, the system will consider the data for the site complete and only allow the form to be accessed in read-only by all users. | X |  |  |  |  |  |  |  |
| * 1. System will present a validation message after data is submitted as final: | X |  |  |  |  |  |  |  |
| * + 1. A customizable thank you message is displayed after submitting every form and upon final submission | X |  |  |  |  |  |  |  |
| * + 1. After displaying the thank you message, the data collection tool will return to the data collection tool home page after saving/ submitting data as final | X |  |  |  |  |  |  |  |
| 1. System will provide a ***robust database*** with the following capability at minimum and with the ability to support a flexible and extensive analysis of the data within in a number of manners: | X |  |  |  |  |  |  |  |
| * 1. System will store data in a database that is easily parse-able, preferably tab delimited | X |  |  |  |  |  |  |  |
| * 1. System will store data in a manner that allows data sets to be defined in units of time (such as monthly, quarterly, annually, etc…) | X |  |  |  |  |  |  |  |
| * 1. System will store data in a manner that captures who entered the data by user name, a time stamp, the questions that the user responded to, and the answers that the user saved or submitted |  |  | X |  | Although it is not a clinical database, it is a program management database, therefore is tied to contract dollars. As such, at minimum, date, time, and user validation must be applied to data changed. We need to know who, what, and when. Minimum expectation = from the time a PI submits module as approved, any changes will be auditable.  We currently only track who last saved a form and when, but not what data was changed. In the future, we can add a history of all users who saved a form. Would be difficult to track what questions were changed. |  |  | 10 |
| * 1. System will allow the data associated with a module and specific Site user from a previous time period (such as the previous quarter) to populate a new module/form in the next time period (quarter) in accordance with the Program’s SOP’s. | X |  |  |  |  |  |  |  |
| * + 1. This allows data from one time period (such as one quarter) to re-populate the next time period in order that the users do not need to re-enter data that has not changed from one time period to the next. | X |  |  |  |  |  |  |  |
| * + 1. This also allows data from one user associated with a Site who might have left the organization to be utilized by the next user to be assigned the same role and privilege when the data has not changed. | X |  |  |  |  |  |  |  |
| * 1. System will allow data to be segregated by quarter so reports can be run by quarter and allow for comparison from quarter to quarter to show trending | X |  |  |  |  |  |  |  |
| * 1. All data needs to be exportable in CSV or Excel | X |  |  |  | The tool currently supports bulk data exports in XML and JSON. The Analytics tool supports export to Excel and CSV. |  |  |  |
| * 1. Flexible report creation as well as canned report ability. | X |  |  |  |  |  |  |  |
| * 1. Ability to send reports to identified roles based on dates. |  |  | X |  | **Bell and Whistle** - not necessary. We will have report templates that we can run and distribute as necessary.  ***Should we decide it is a necessary function it could be provided but at additional cost and time for development that would need to be estimated by HCIT and approved by Rod and Dwayne.*** |  |  |  |
| 1. System will provide refresh functionality allowing data from one time period (such as one quarter) to be presented to the users based on the previous time quarter’s responses. |  |  |  |  |  |  |  |  |
| * 1. Prior to launching a new quarter, the tool will need to refresh the data previously accepted as final by the Site Administrator. | X |  |  |  | HCIT will conduct the data pre-population in the backend. We currently do not have a user interface for this. |  |  |  |
| * 1. System will cleanse the User Interface according to a pre-configured tag that determines fields that must be removed based on a user selection in the previous quarter, such as: |  |  |  |  |  |  |  |  |
| * + 1. Where the site selects a pre-identified selection from a question/answer deck or a table (such as the Clinical Trial table) that indicates conclusion (such as a Clinical Trial ended) in the previous quarter, the system will not present the data in the question/answer deck or the associated table UI in the launch of the next quarter’s data   *(i.e. when a trial is indicated as closed, the system should not pre-populate this data for the next quarter)* |  | X |  |  | It was decided that sites would delete the closed trials for the first quarter the tool is launched (July-Sept 2011), then HCIT will implement the ability for the system to automatically delete closed trials. |  |  | 5 |
| **Questions and Answers Formatting** | | | | | | | |  |
| 1. System will allow the following types of question/answer decks: |  |  |  |  |  |  |  |  |
| * 1. Select a single answer using either: | X |  |  |  |  |  |  |  |
| * + 1. radio buttons | X |  |  |  |  |  |  |  |
| * + 1. pull down select menu (no selection will be recorded unless the user chooses an answer) | X |  |  |  |  |  |  |  |
| * 1. Select all answers that apply using either: | X |  |  |  |  |  |  |  |
| * + 1. check boxes | X |  |  |  |  |  |  |  |
| * + 1. pull down select menu that allows for multiple selections when using the crtl key and clicking on answer choices |  |  | X |  | **Bell and Whistle** – deemed not necessary by the NCI/SAIC-F team.  Multi-select pull-downs are not standard and not advised. We recommend multi-select windows but have not implemented them in the tool yet.  ***Should we decide it is a necessary function it could be provided but at additional cost and time for development that would need to be estimated by HCIT and approved by Rod and Dwayne.*** |  |  |  |
| * 1. Select text answers that can be configured to use either a text field or a text area box: | X |  |  |  |  |  |  |  |
| * + 1. System will allow System Administrator(s) to select either text field or text area box | X |  |  |  |  |  |  |  |
| * + - 1. System will require System Administrator(s) to indicate text field or text area box size | X |  |  |  |  |  |  |  |
| * + - 1. System will require System Administrator(s) to indicate whether text field or text area box will be constrained to alpha-numeric entries | X |  |  |  |  |  |  |  |
| * 1. Select mixed type questions where user may select all that apply, including an “Other” selection that would then expand to allow for text entry that can be configured according to size and character limitations | X |  |  |  |  |  |  |  |
| 1. System will provide the ability to add custom styles to words or sentences within text-only content fields.   (i.e. “Please select all that apply | X |  |  |  |  |  |  |  |
| * 1. System will allow a question or answer to be customized to call attention to a detail, such as allowing for italicizes, bolding, underlining, or any combination of the three. | X |  |  |  | The forms are coded in XML for portability. Embedding HTML markup in XML hampers portability and makes the forms fragile. In cases where such markup is required, we do have a workaround but suggest that you use it sparingly. |  |  |  |
| **Tables (as in graphic user interface similar to Excel where data builds visually according to data entry)** | | | | | | | |  |
| 1. System will provide a graphical user interface similar to Excel, where data can be built in cells and columns and allowing for data entry that can be changed in format and style in every cell. | X |  |  |  | We allow for different formats in each column of the table (text, number, date, etc). We style the table as a whole. We do not support variations in style for each cell in a table. |  |  |  |
| 1. System will allow tables to appear within the same form as question/answer decks and also allow tables to be separate and complete forms of a module. This will allow users to go back and forth between entering data in tables and entering data as the answer to a question easily within a form which is usually domain specific (such as Clinical Trials or Disparities). Some data is better captured through constrained question/answer decks and others require the flexibility and ability to build on itself that a table provides. | X |  |  |  |  |  |  |  |
| 1. System will require the following formats for user input into tables, assigned by the System Administrator(s) when building the table: |  |  |  |  |  |  |  |  |
| * 1. Radio buttons | X |  |  |  |  |  |  |  |
| * 1. Pull down menu with a single selection | X |  |  |  |  |  |  |  |
| * 1. Pull down menu with multiple selections |  |  | X |  | **Bell and Whistle**, as described in 16.2.2, the HCIT caCURE tool does not support this.  ***Should we decide it is a necessary function it could be provided but at additional cost and time for development that would need to be estimated by HCIT and approved by Rod and Dwayne.*** |  |  |  |
| * 1. Check boxes | X |  |  |  |  |  |  |  |
| * 1. Text | X |  |  |  |  |  |  |  |
| * 1. When input is text system will apply validation rules (see form on validation below) | X |  |  |  |  |  |  |  |
| * 1. Mixed use selection, where a user might select several selections from a “select all that apply” answer type and within the question will be able to select other and add a text answer to describe selection, that can be configured to be character and size limited | X |  |  |  | The tool enforces type at the data model level. |  |  |  |
| 1. System will provide ability to enter text-only content fields that contain information displayed for the users benefit to give guidance on how they should answer the question; “Ex. use no hyphens in phone number, XXXXXXXXXX” or “Ex. format is XX/XX/XXXX”) | X |  |  |  |  |  |  |  |
| * 1. System will allow for italicizing, bolding, underlining, font size and style changes | X |  |  |  |  |  |  |  |
| **Validation** | | | | | | | |  |
| 1. Date validation |  |  |  |  |  |  |  |  |
| * 1. To make sure survey is not submitted twice. | X |  |  |  |  |  |  |  |
| * + 1. However, if the user contacts the Data Collection Tool Support POC after submitting their data, the tool could be “unlocked” to make edits to the data submitted. | X |  |  |  |  |  |  |  |
| 1. Text validation |  |  |  |  |  |  |  |  |
| * 1. The System should provide the ability for authorized users to choose whether input to each question or cell in a table is validated using any of the below strategies: |  |  |  |  |  |  |  |  |
| * + 1. Validate if a number is within limits. For instance, percentage entered is always between 0 and 100 | X |  |  |  |  |  |  |  |
| * + 1. Validate if a number is a positive integer | X |  |  |  |  |  |  |  |
| * + 1. Validate that an input is text with no special characters | X |  |  |  | **Exception:** the system does not accept dollar signs in a text field. |  |  |  |
| * + 1. Validate dates |  |  |  | X | We currently do not have the functionality to restrict dates based on other dates. |  |  |  |
| * + 1. Validate that required questions or cells in table are answered | X |  |  |  |  |  |  |  |
| **Security and Access Levels** | | | | | | | |  |
| 1. System will provide the ability to define security and access levels. Access levels (privileges) can be assigned at the form or module level. |  |  |  |  |  |  |  | 10 |
| * 1. System will provide the ability to assign the following set of privileges to users: |  |  |  |  |  |  |  |  |
| * + 1. **Read** – a user assigned this privilege on a form has the ability to read the questions. No data entry is allowed. |  |  |  |  |  |  |  |  |
| * + 1. **Read/Write** – a user assigned this privilege on a form has the ability to read, enter, and update questions. |  |  |  |  |  |  |  |  |
| * + 1. **Complete** - a user assigned this privilege on a form has the ability to mark the form as complete. This indicates that the form is ready for review and final submission. |  |  |  |  |  |  |  |  |
| * + 1. **Approve** – a user assigned this privilege on a form has the ability to mark the form as approved. This indicates that the form has been reviewed and is ready for final submission; no changes to the data are required. Once this action has been performed, the form becomes read-only. |  |  |  |  |  |  |  |  |
| * + 1. **Submit** - a user assigned this privilege on a module has the ability to submit the module for final submission. Once this action has been taken, the module is locked. |  |  |  |  |  |  |  |  |
| * + 1. **Decline** – a user assigned this privilege on a form has the ability to mark the form as declined. This indicates that the form contains data that needs to be modified before final submission. |  |  |  |  |  |  |  |  |
| 1. System will provide the ability for authorized users to assign one user’s form to another user so that when a new user comes on board they will not have to start with a blank slate. The old user’s data will be visible to the new user. |  | X |  |  | In the **second release**, there will be a comprehensive administration page that allows re-assignment of users to forms. Multiple users can be assigned to the same form. |  |  | 5 |
| 1. System should provide the ability for authorized users to reopen a form or an entire survey to allow user to make changes directed by the PI during the review and approval process | X |  |  |  | **Agreed Process:** PI selects “Declined” and that form is reopened for editing. Then the site will develop an SOP on how to notify the user that he/she needs to reenter data. The system will have a ***validation message*** displayed to notify the PI they must notify the user that the data has been reopened for editing. The same ***validation message*** will be given to the user when they complete a form and submit it to the PI for approval, that they will need to inform the PI - that they have completed the form and it is ready for the PI to approve.  If an entire module needs to be reopened, HCIT will do this on the backend.  If a form needs to be re-opened for editing after the PI submits the data as final, NCI/SAIC-F will submit a request via e-mail to Dorie who will have Leonid re-open that form for the specified user. |  |  |  |
| 1. System should provide the ability to build separate and distinct instances to enable different uses of the tool by the NCI agency within the NIH branch of the DHHS, if so required in the future. | X |  |  |  |  |  |  |  |
| 1. System will provide the ability to create and maintain separate and distinct modules to accommodate future support of multiple NCI Programs and those Program’s Projects. | X |  |  |  |  |  |  |  |
| **Data Migration (PILOT with NCCCP Data Collection Tool)** | | | | |  |  |  |  |
| 1. Data must be imported from the existing Plone NCCCP Data Collection Tool (DCT) and segregate this data by quarter for analysis but also allow for comparison analysis from one quarter to the next and allow for trending analysis or aggregation analysis. |  | X |  |  |  |  |  |  |
| 1. Data must be imported from pre-Plone quarterly reports dating back to pre-pilot launch 2006-2007. This data is currently in multiple formats but will be organized and delivered in one format (likely Excel). |  |  | X |  | **Data to be migrated:** Quarterly Report data, July 2010-June 2011; all BAS, IAS, FAS data; RTI Outcomes Survey; Disparities Dashboard data; Screening and Barrier Log data.  9/15/2011 (Brenda/Dorie/Bill) Discussed the need to make sure this data is migrated, even if we need to scope other efforts and increase our engagement in this project. Brenda and Angela to provide a list of the essential data files that still need to be migrated and the timelines associated. **We will assume the responsibility to provide the following:** reformatting of the files for each in the format we have worked to provide in the quarterly report data; providing the short name file associated with each for mapping; building the forms for each project; validating all data once HCIT maps and pre-validates data migration; user testing of interfaces; training materials and training of users.  ***Additional migration will have an additional cost associated and will need to be estimated and approved through Rod and Dwayne first.*** |  |  |  |
| 1. All migrated data must undergo extensive testing by pilot team to ensure data imported correctly prior to client testing. |  | X |  |  |  |  |  |  |
| **Roll Out** | | | | | | | |  |
| 1. Series of web-based, virtual training sessions that allow users at least 2 possible training times in each of the time zones. | X |  |  |  | HCIT will provide the training environment necessary to conduct the series of 6-8 web-based trainings with users, but the training will be conducted by the NCI/SAIC-F support staff. |  |  |  |
| 1. Developer should deliver training manual, detailed training PowerPoint for consumption by new users after launch, and a building set of FAQ like capture for all questions |  | X |  |  | Angela and Kathleen will share the current FAQ document to help populate the “Learn More” field. Kathleen Igo already forwarded the existing training docs as a template for the HCIT docs. |  |  |  |
| 1. Require alpha and beta test by NCCCP leadership initially (alpha) and by NCCCP NPAC leads (beta); expectation is that the developer will deliver a near final product that requires simple edits and functionality testing (extensive testing would have been done prior to this release by developer and project team). |  |  |  |  |  |  |  |  |
| 1. System needs to be able to deliver both a printable form of all the forms questions and an electronic form that allows the site to collect data in that form. The users will use it to collect the data from multiple sources and review it with PI before entering into the web-based tool.   [DO] We can implement blank printable forms for additional budget. |  |  | X |  | **Bell and Whistle - s**ystem can provide a data dump of all questions and answers, but not formatted. SAIC-F and NCI will create a “CRF” of all the questions and answer choices in a more user friendly format (such as the CRF format we currently use for the PLONE DCT and the Screening Log).  ***Should we decide it is a necessary function it could be provided but at additional cost and time for development that would need to be estimated by HCIT and approved by Rod and Dwayne.*** |  |  |  |
| Approximate Total Estimated days | | | | | | | | 100 -105 |