**ICON**

Enhancements to DDAS Web Application

**Brief Business Requirements**

Rev 2

30 Nov, 2017

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# Revision History

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Revision** | **Date** | **Sections Changed** | **Summary/Description of Change** | **Author(s) of Change** |
| 1 | Nov/13 | All | First Release | Patrick/Pradeep |
| 2 | Nov/30 | Requirements/Input Template | Additional Protocal Number required in Input Template | Patrick/Pradeep |
| 2 | Nov/30 | Proposed Solution/ Input Template | Input Template Enhancements | Patrick/Pradeep |

# Requirements

The existing DDAS Web application needs to be enhanced with the following additions.

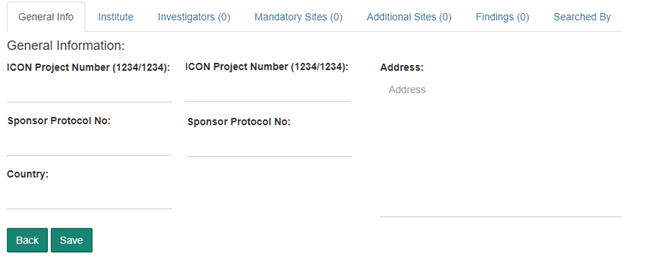
1. Input Template Enhancement
   1. Capability of the tool to be modified to include 2 study numbers as the Due Diligence checks are requested for investigators who would be participating in 2 studies at once.
   2. Input template as well as tool should accept 2 study numbers at once so 1 compliance search form should be generated for investigators with 2 studies in it.
   3. Capability of the tool to be modified to include 2 Protocol Numbers.
   4. Input template as well as tool should accept 2 Protocal Numbers at once so 1 compliance search form should be generated for investigators with 2 Protocol Numbers in it.
2. QC Work Flow
   1. Arrangement to allow the junior resource to pass on their works to senior resource for review along with any comments and similarly, senior resource allowed to review as well as pass this back on junior resource with any review comments
3. Admin Dashboard
   1. A new dashboard to be incorporated into tool for all Admins.
   2. Include the admin related results in table formats
   3. Include the graphical representation or any presentable form for management purpose.
4. Advanced Reports
   1. A detailed report on all investigators based on the findings status (after review) for a Specified Period / Resource / Studies
   2. Report listing investigators with No Findings
   3. Report listing investigators with Findings.
   4. Reassignment report to understand how many investigators were reassigned for Specified Period / Resource
   5. Study Specific report with all investigators completed along with the Date of Review Completed, Findings status with Resource Names
   6. A report with details of all investigators completed for a specific period of time along with time taken for each review for each investigator. This report is to be available for all Users as well.
5. Minor Corrections
   1. Corrections in Search Filters
      1. Currently tool is searching based on the full name of the investigators, but would need the individual filters as First and Last name.
   2. Automated Text inclusion in ICSF
      1. Tool to automatically add text “NA” in final ICSF for Medical License Number field if there were no Medical license provided by User.
   3. Reset keyword in filter
      1. When User uses any keyword on the review page to filter matches, currently tool retains the keyword typed by User earlier even after user moves & comes back to same later. This should be reset by tool so the User doesn’t get confused on the filter search.
   4. Bright Highlights
      1. The provided highlights on the matches are mild and User facing difficulties viewing on screen. The highlight needs to be improved further to make it more bright or dark to improve this.
   5. Increased Page Size
      1. Currently, tool provides the matches in quite smaller page which leads User to scroll down quite lot or more to different page to find all matches. So this page layout or page needs to be increased to incorporate larger no. of matches to help user review more stress-free.

1. Download facility for Data Files downloaded from Search Sites.

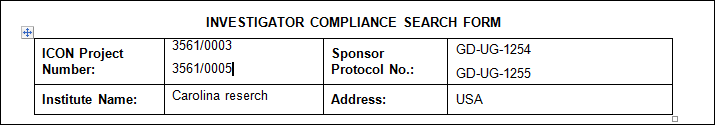
# Proposed Solution

## Input Template Enhancement

* 1. The Investigator Compliance Search Form will include an additional field ‘ICON Project Number’ and an additional field ‘Sponsor Protocol No.’ as shown below:



* 1. Input template as well as the tool will accept one or two ICON Project Numbers (study numbers).
  2. Input template as well as the tool will accept one or two Sponsor Protocol Nos. and the same will be displayed in the fields shown above.
  3. The generated Compliance Form will display both ICON Project Numbers wherever two ICON Project Numbers are available.
  4. The generated Compliance Form will display both Sponsor Protocol No. wherever two Sponsor Protocol Nos. are available.
  5. ICON Project number and Sponsor Protocol Number should be displayed in the below format in compliance search format



## QC Work Flow

1. The ‘Search Resource’ (auditee) will be able to assign a Compliance Form for audit and identify an Auditor. Working
2. If possible tool should allow to attach any supporting documents(ML copies etc) for the review
3. The application will send an email alert informing the Auditor to take up the Audit. – not working
4. The Auditor can login and open the Compliance Form for Audit not working, auditor is not able to find the compliance search form to be audited
5. The Auditor will not be permitted to modify the contents of the Compliance Form created by the Auditee.
6. The following fields will be provided for the Auditor to provide observations.
   * 1. Comments
     2. Accepted / Rejected

These fields will be available at Compliance Form level and Investigator level against each finding.

*Auditor should be able to view the whole ICSF*

*Auditor should be able to view the review page to check if there were any findings missed by the Auditee*

1. The Auditor will mark the Audit as completed and an email alert will inform the Auditee about the status.
2. *Auditee and auditor should only be able to view the forms related to them but admin should have access to all. Also, Auditee and Admin should be allowed to change the auditor name/ reassign to different auditor if required*
3. *All comments from auditee and auditor should be stored in the tool for internal purposes and should be archived after 6 months along with the ICSF*

## Admin Dashboard

1. A dashboard with current status will be available for the Admin.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **User** | **Opening Balance** | **Compliance forms uploaded** | **Compliance forms completed** | **Closing Balance** |
| David | 5 | 9 | 7 | 7 |
| Naveen | 2 | 6 | 3 | 5 |
| Maya | 3 | 7 | 8 | 2 |

1. Include the graphical representation or any presentable form for management purpose.

## Advanced Reports

1. A detailed report on all investigators based on the findings status (after review) for a Specified Period / Resource / Studies
2. Filters
   * + 1. Review Completed On – From and To
       2. Resource Name
       3. Study Number
       4. Finding Status (No Findings, Findings)
3. Columns
4. Name of the Investigator
5. Study Number
6. Review Completed On
7. Findings Status (Issues Identified / Issues Not Identified)
8. Investigated by (Resource Name)
9. Reassignment report to understand how many investigators were reassigned for Specified Period / Resource
10. The application workflow will be arranged to record Date and Time of Assignment of the Compliance form to a Resource.
11. When the Compliance Form is uploaded the Resource is automatically assigned to the uploaded Compliance Form
12. The Date and Time when the Compliance form is taken out from the current Resource will be recorded.
13. A report will be generated with the following columns.
14. Project Number
15. Principal Investigator
16. Resource
17. Resource Assigned on – Date and Time
18. Resource Removed on – Date and Time

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Project Number | Principal Investigator | Resource | Assigned on | Assignment Removed On |
| 1234/5678 | David Jones | Ram | 1-Jan-2017, 2:30 PM | 5-Jan-2017, 7:00 AM |
| 1234/5678 | David Jones | Shyam | 5-Jan-2017, 7:00 AM |  |

1. Study Specific report with all investigators completed along with the Date of Review Completed, Findings status with Resource Names

Study Number[ 1111/2222 ]

|  |  |  |  |
| --- | --- | --- | --- |
| Investigator Name | Date Review Completed | Findings Status | Resource Name |
| David Jones | 5-Sep-2017 | Issues Identified | Ram |
| William Joseph | 12-Oct-2017 | Issues Not identified | Shyam |

1. A report with details of all investigators completed for a specific period of time along with time taken for each review for each investigator. This report is to be available for all Users as well.

Review completed during [ from date ] and [ to date ]

|  |  |  |  |
| --- | --- | --- | --- |
| Investigator Name | Review Completed On | Status | Time Taken (in minutes) |
|  |  |  |  |
|  |  |  |  |

* + - * Time Taken is the time duration between Date and Time the Compliance Form is uploaded and searched AND the Date and Time when the Investigator Review is completed.
      * The above computation does not take into consideration the actual time used by the Resource to carry out the review of that specified Investigator.
      * A Compliance Form that is carried over to the next day will result in a inaccurate result.

## Minor Corrections

1. Corrections in Search Filters
2. Currently tool is searching based on the full name of the investigators, but would need the individual filters as First and Last name.

This facility is currently available. The application user can paste any part of the name, First Name or Last Name to get filtered records.

1. Automated Text inclusion in ICSF
2. Tool to automatically add text “NA” in final ICSF for Medical License Number field if there were no Medical license provided by User.

This will be provided.

1. Reset keyword in filter
2. When User uses any keyword on the review page to filter matches, currently tool retains the keyword typed by User earlier even after user moves & comes back to same later. This should be reset by tool so the User doesn’t get confused on the filter search.
3. This will be corrected.
4. Bright Highlights
5. The provided highlights on the matches are mild and User facing difficulties viewing on screen. The highlight needs to be improved further to make it more bright or dark to improve this.

This will be provided.

1. Increased Page Size

Currently, tool provides the matches in quite smaller page which leads User to scroll down quite lot or more to different page to find all matches. So this page layout or page needs to be increased to incorporate larger no. of matches to help user review more stress-free.

An option to select the number of items per page (5, 10, 25, 50, 100) will be provided.

## Download facility for Data Files downloaded from Search Sites.

Archive data files from all Search Sites and make them available for download.