Requirement Specification Document

Clinical Trials Outcome Database (CTOD)

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Document Revision History

Ver #	Date	Author	Reviewer	Description of Changes	Comments
1	26th Aug 2013	GVKBIO	Group Review		Initial Draft
2	06th Sep 2013	GVKBIO		Removed "Tracking Versions of the data" since this functionality is not in the scope of application development	Section 1.1- Overview
		GVKBIO		Removed "Data Development(Curation/Review/QC)" and "Task Management" as they are not in the scope of this SRS	Section 2.1
		GVKBIO		Updated High level system context diagram & Application work flow diagram	Section 2.1.1
		GVKBIO		Updated Technology overview diagram: colored in yellow the items which are	Section 2.1.2

				not in scope of this SRS	
		GVKBIO		Added the ER diagrams	Section 2.1.4
		GVKBIO		Added requirements from URS-A-28 to URS-A-36	Section 3
		GVKBIO		Updated the text in application scope	Section 3.1
		GVKBIO		Added another role as "Search Admin"	Section 3.2
		GVKBIO		Updated responsibilities for Quality Check role	Section 3.2
		GVKBIO		Removed sections for Task management & Data development as they are out of scope for this SRS	Section 4
		GVKBIO		Added section User management	Section 4.1
		GVKBIO		Added section User creation	Section 4.1.1
		GVKBIO		✓ In screen field details, changed field Role to Position ✓	Section 4.1.1
		GVKBIO		✓ In Screen field details, added Action items for the controls present in the form.	Common to all screen field details table.
		GVKBIO		✓ Added View users section	Section 4.1.2
		GVKBIO		Added User Editing section	Section 4.1.3
		GVKBIO		Added User Deleting section	Section 4.1.4
		GVKBIO		Added View users section	Section 4.1.2
		GVKBIO		Added user editing section	Section 4.1.3
		GVKBIO		Added User deleting section	Section 4.1.4
		GVKBIO		Updated the text in search	Section 4.2.2

			GVKBIO		page section	
			GVKBIO		Updated search flow diagram ✓ Mentioned error message ✓ Changed Admin to Search Admin	Section 4.2.2
			GVKBIO		Updated mock screen Removed "And" selection box between sections	Section 4.2.2
			GVKBIO		Updated Summary view section text	Section 4.2.3
			GVKBIO		Updated the text in Results view section	Section 4.2.5
			GVKBIO		Added Trial design section with mock screen and field details	Section 4.2.5.2
			GVKBIO		Added Treatment arms section with details and mock screen	Section 4.2.5.3
			GVKBIO		Added Patient characteristics section with mock screen and screen field details	Section 4.2.5.4
			GVKBIO		Added Outcomes section with mock screen and screen field details	Section 4.2.5.5
			GVKBIO		Updated text in view saved queries	Section 4.2.6
			GVKBIO		Updated view template section along with the screen. In screen provided two tabs for public & private templates	Section 4.2.8
			GVKBIO		Updated text in view specification sections	Section 4.2.10
			GVKBIO		Updated text in specification details	Section 4.2.10.1

3	14th Sep 2013	GVKBIO		Updated document as per the comments provided for CTOD prototype.	✓ Section 4.1 – Mockscreen ✓ Added section 4.1.5,4.1.6,4.1.7,4.1.8 ✓ Updated 4.2.4 – Mock screen: added control treatment secondary filter ✓ Section 4.2.5.1- updated mock screen: removed data extractor name & data extraction date ✓ Section 4.2.5.2- updated mock screen: Added expand check box and Trial data navigation ✓ Section 4.2.5.3-Upated mock screen: Added Arm Ids filter option ✓ Section 4.2.5.4-Updated mock screen: added Arm ids filter option ✓ Section 4.2.5.5 – Updated mock screen: added Arm ids filter option ✓ Section 4.2.5.5 – Updated mock screen: added Arm Ids filter option ✓ Section 4.2.6 – Update mock screen : In private queries, added Indication column and total reference column and changed column name from Created date to Saved date ✓ Section 4.2.6 – View saved queries – Public: updated columns as private. ✓ Section 4.2.7 - Updated mock screen: changed the table action buttons ✓ Section 4.2.10 – updated mock screen: Changed display as suggested in UI prototype review

					comments

REQUIREMENTS SPECIFICATIONS

1   INTRODUCTION

1.1   Overview

As there is high attrition rate, high development costs and time involve in the process of drug discovery, there is a need to have efficient drug discovery process. In order to achieve the effective drug development there should be ability to access the data

- ✓ *Quickly*
- ✓ *Securely*
- ✓ *Share & Explore*
- ✓ *Analyze comprehensive*
- ✓ *Integrated*
- ✓ *Up-to-date clinical efficacy and safety data*

There is abundant clinical trial outcomes information available in public domain. This data can be leveraged to address the high attrition rate involved in and expedite the drug development process with the help of quantitative development techniques like Model-based meta-analysis (MBMA)

In order to have the information to hand when required, published literature data needs to be extracted, normalized and stored in a meaningful way. It must be possible to query the data in a variety of ways when required. Furthermore, it is very important that the users of the data have confidence in that data and that time is not lost verifying that data.

The simplest approach is to record the data in an excel spreadsheet. While this is straight forward to implement, there are some limitations like

- ✓ *Querying the data*
- ✓ *Preventing duplication of data*
- ✓ *Automating the validation of the input data*
- ✓ *Quality control*
- ✓ *Data loading*
- ✓ *Relational search*

To overcome the above said limitations as well as providing a much better platform for searching, extracting, exchanging and using the data, the data has to be stored in a relational database structure, which can provide more effective and extendible platform for querying

*and extracting the data. Such a solution being offered is **Clinical Trial Outcomes Database (CTOD)** application*

1.2   Purpose

Purpose is to develop a web application that facilitates efficient retrieval and usage of the data by user groups (Pharmacometricians, Clinical trial protocol development groups, Health outcome research groups etc.) and subsequently support quantitative decision making.

Modules that constitute a comprehensive application are

 a) *Admin and Meta data management*
 b) *Data Development life cycle (Extraction/Rev/QC)*
 c) *Querying platform to retrieve the data and export in multiple formats*
 d) *View and generate exportable standard and customized Reports*
 e) *Graphical data visualizations*

While all the above modules are essential, a modular approach can be adapted to develop the comprehensive platform. This version of the document covers the development of below mentioned modules:

 a) ***Search :*** *Querying platform to retrieve the data and export in multiple formats*
 b) ***Reporting :*** *View and generate exportable standard and customized Reports*
 c) ***Visualization:*** *Graphical data visualizations*
 d) ***User Management:*** *Managing the user & roles*

1.3   Intended audience

The objective of this tool is to support Pharmacometricians, Clinical trial protocol development groups, Health outcome research groups etc. to search, retrieve and use the data.

2   BUSINESS PROCESS UNDERSTANDING

In the CTOD application the key entity is the clinical trial assessment time course data or study endpoint. The database should store the information of clinical trial outcomes at a summary level extracted from external published literature.

There can be several publications for the same clinical trial. Trials in a particular disease area of interest e.g. diabetes, should be clustered together and be searchable using the appropriate search terms.

2.1 System Functional Overview

- *User management*
- *Search on complete data*
- *Reporting & VisualizationExport*
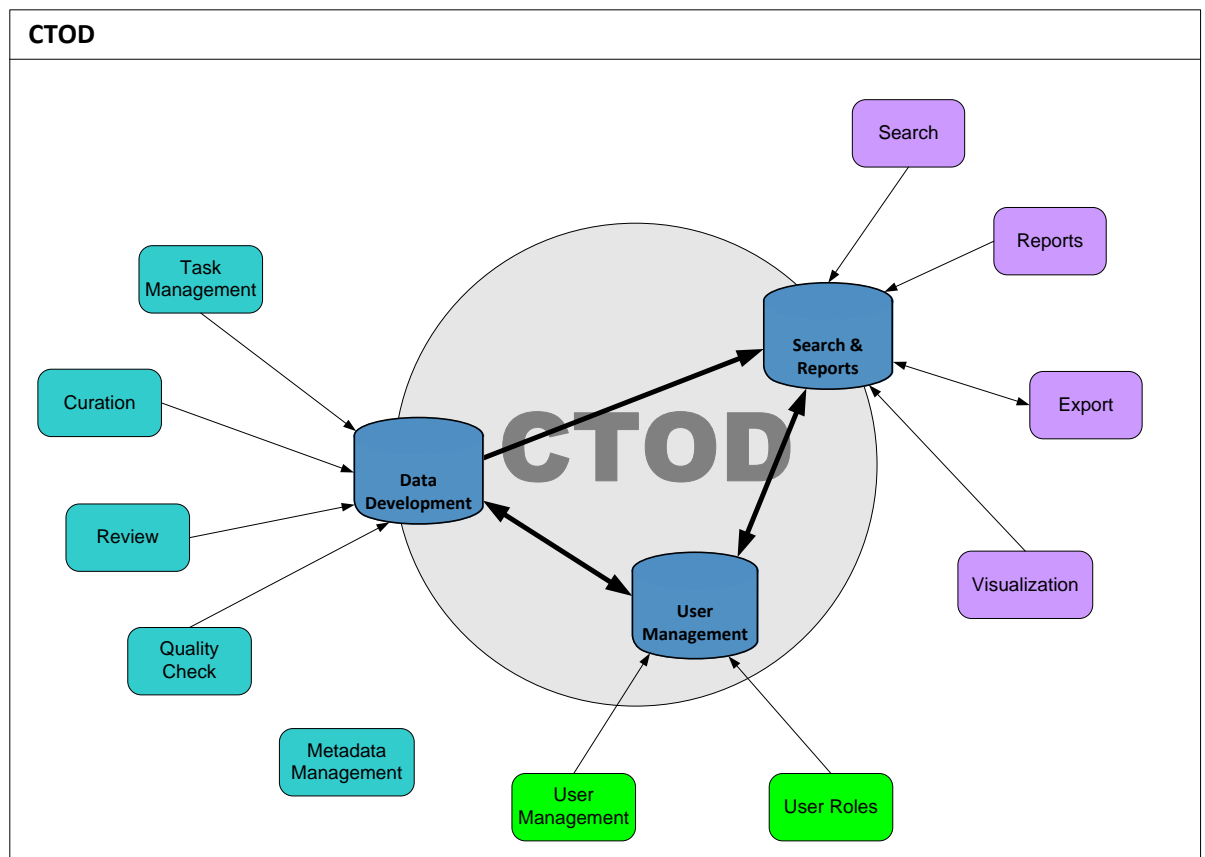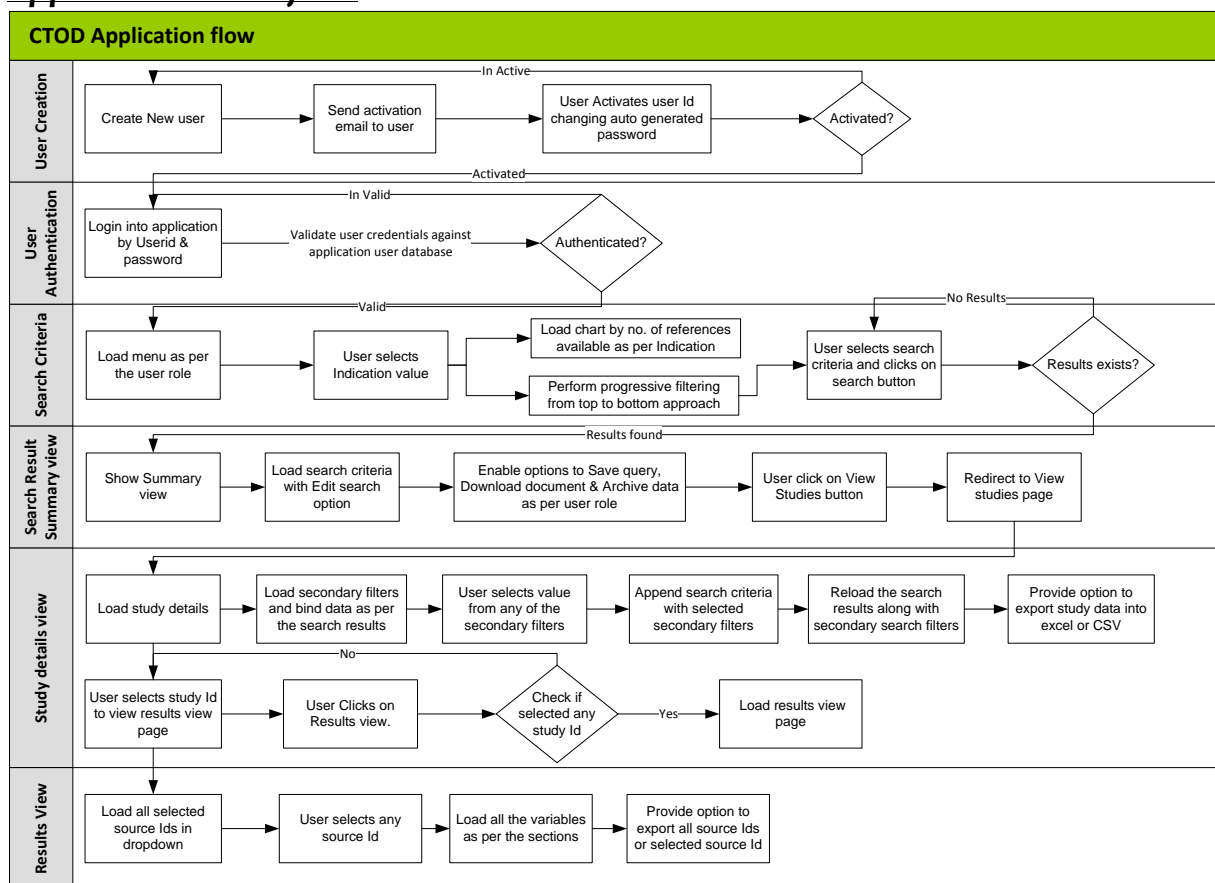
2.1.1 *High Level System Context*

Figure 1

Application Work flow

CTOD Application flow	

User Creation	Create New user → Send activation email to user → User Activates user Id changing auto generated password → Activated? (In Active loops back)

(Activated ↓)

User Authentication	Login into application by Userid & password → Validate user credentials against application user database → Authenticated? (In Valid loops back)

(Valid ↓)

Search Criteria	Load menu as per the user role → User selects Indication value → Load chart by no. of references available as per Indication / Perform progressive filtering from top to bottom approach → User selects search criteria and clicks on search button → Results exists? (No Results loops back)

(Results found ↓)

Search Result Summary view	Show Summary view → Load search criteria with Edit search option → Enable options to Save query, Download document & Archive data as per user role → User click on View Studies button → Redirect to View studies page

| Study details view | Load study details → Load secondary filters and bind data as per the search results → User selects value from any of the secondary filters → Append search criteria with selected secondary filters → Reload the search results along with secondary search filters → Provide option to export study data into excel or CSV |
| | User selects study Id to view results view page → User Clicks on Results view. → Check if selected any study Id → (Yes) Load results view page (No loops back) |

Results View	Load all selected source Ids in dropdown → User selects any source Id → Load all the variables as per the sections → Provide option to export all source Ids or selected source Id

Flow Diagram 1

2.1.2   Technology Overview
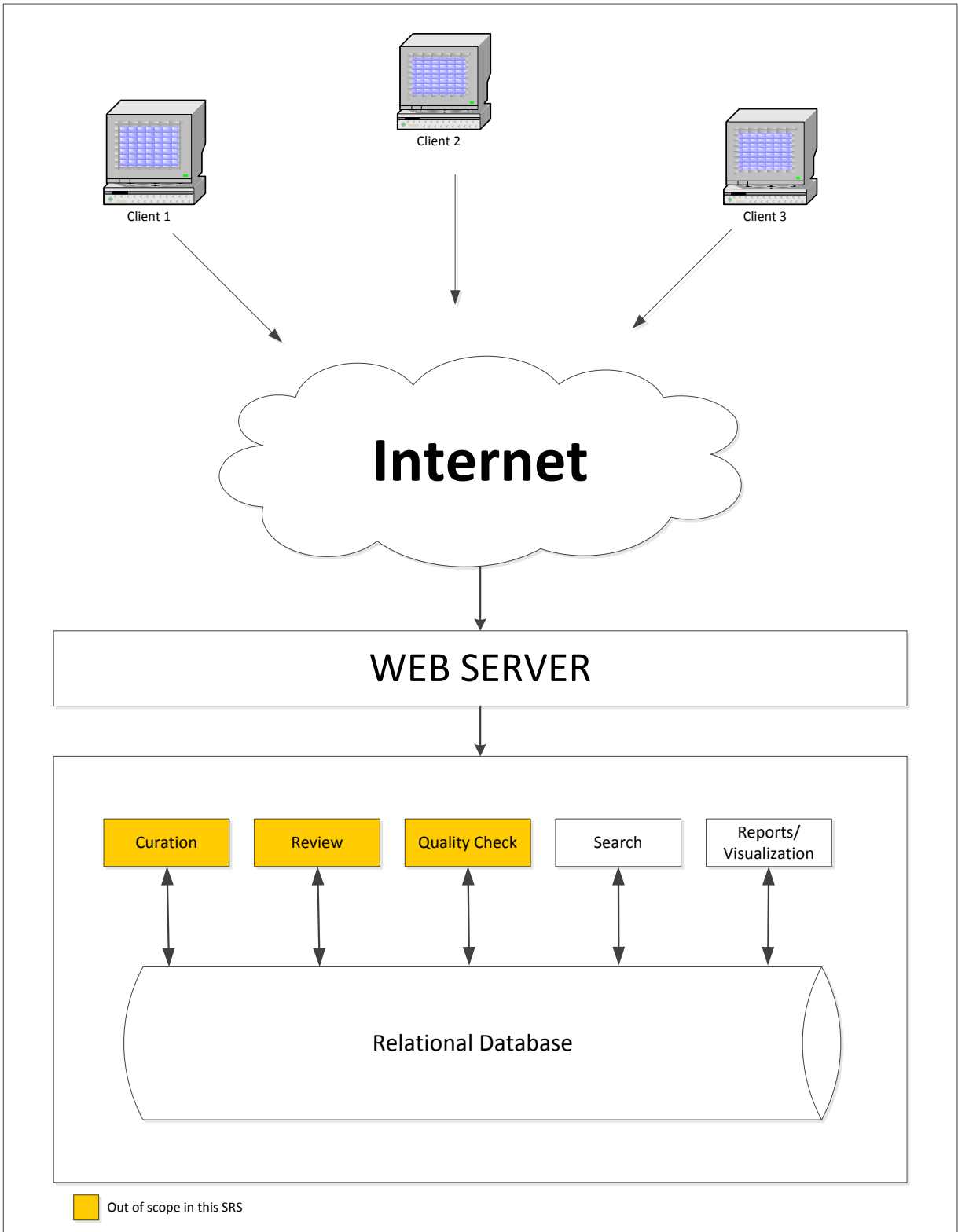
Figure 2

2.1.3   System interfaces Overview

There will be no interaction with external systems.

2.1.4 **Data Model**

The Below figure depicts high level illustration of the data model.
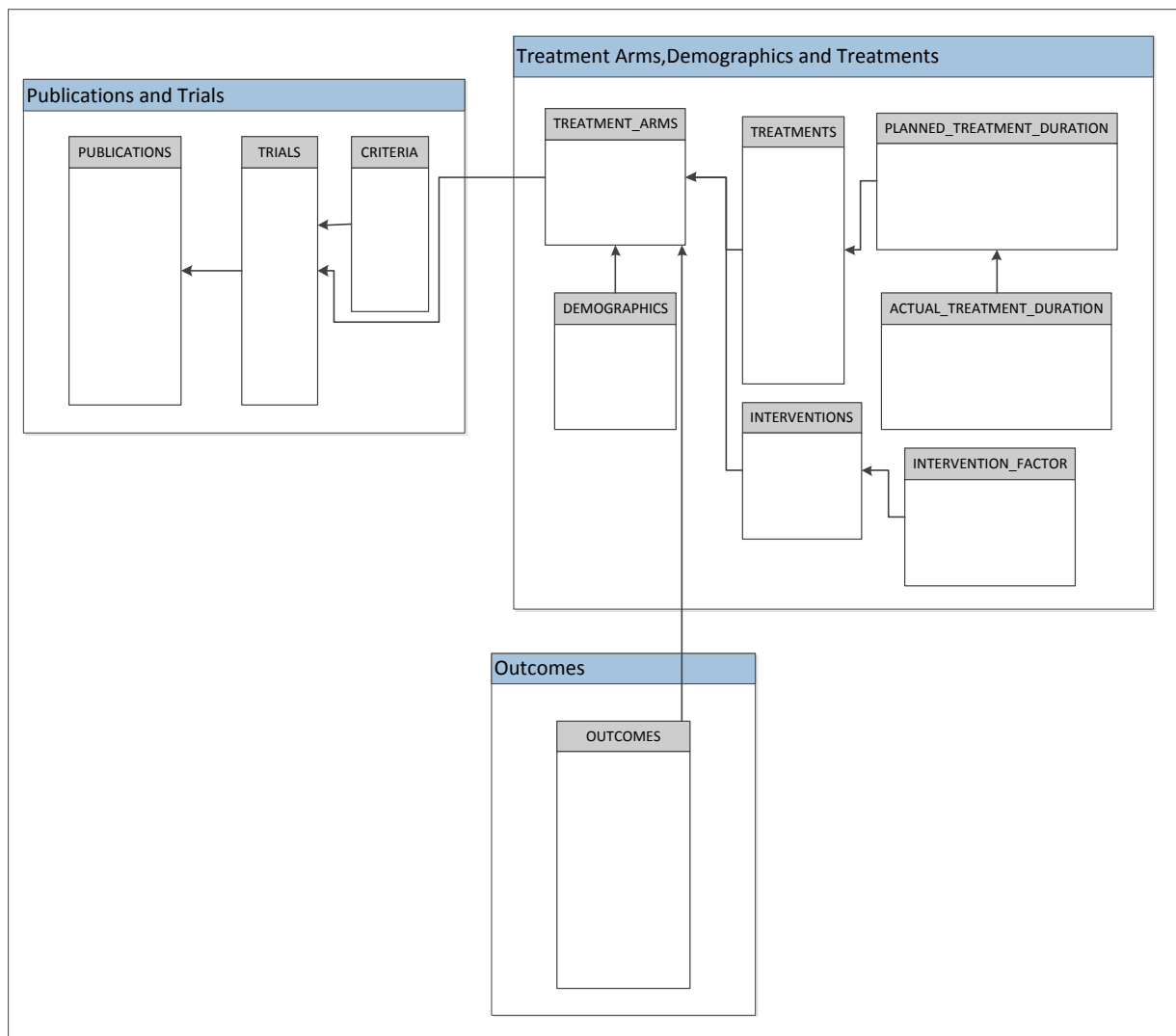
Figure 3

CTOD_ER-Diagram_2
013-08-30.jpg

CTOD_Search_ER-Di
agram_2013-08-30.jp

Note: The flow and design may change based on the final SRS document.

➢ ***Treatment Arms, Demographics & Treatments:*** *This section will have tables related to patient treatment details.*
- o ***Treatment***
- o ***Treatment Arms***
- o ***Planned Treatment Duration***
- o ***Actual Treatment Duration***
- o ***Intervention***
- o ***Intervention Factor***
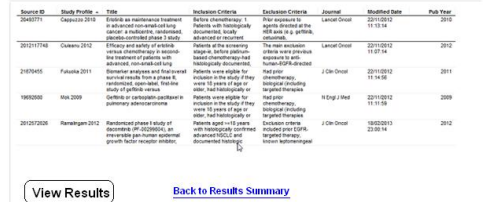
        o   *Demographics*
- **Publications & Trials:** *This section will have tables related publications and trials information*
  - *Publications*
  - *Trials*
  - *Criteria*
- **Outcomes:** *This section will have tables related to outcomes.*
  - *Outcomes*
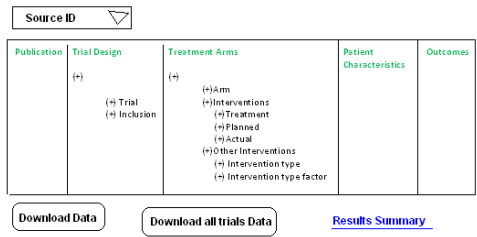
3   BUSINESS REQUIREMENTS

Below are the list of requirements, these requirements are categorized as per the business criticality like:

- P1 : High

- P2: Medium

- P3: Low
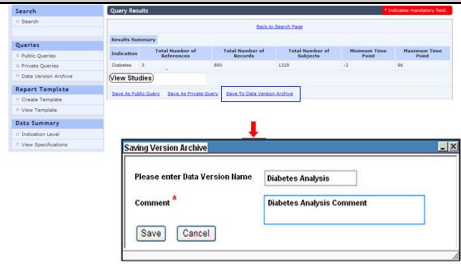
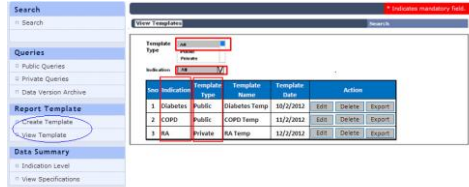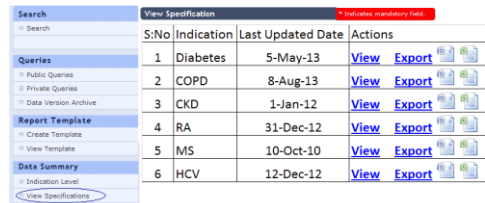| Req. ID	Requirement Description	Business Criticality	Comment
URS-A-1	The user must be able to run the required query at two levels • Primary filters • Secondary filters	P1	The user once landing into the search page should view the Disease Area for selection. A graphical overview of the Disease areas and no of trials present should be shown to the user.
URS-A-2	The Search filters should adapt progressive filtering wherever applicable. The selected Indication in the above screen should be again shown in the Disease Area filter of this page along with the other sections for selection to perform the search.	P1	The progressive filters follow a defined hierarchy. Please refer the inserted sheet on the search variables, hierarchy and their anticipated behavior indicated. \\infwd194\Global CTOD\scoping\Search\Search Page model_v2.0.xlsx Also refer to the respective variables and attributes for the search page

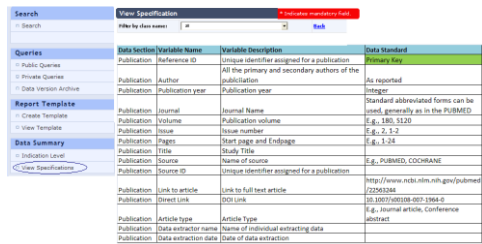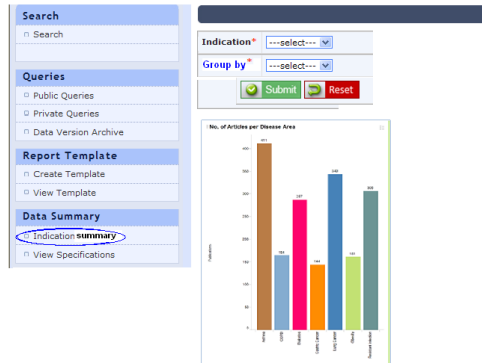| Req. ID	Requirement Description	Business Criticality	Comment
			[\\infwd194\Global CTOD\scoping\Search\Search Variables and Values_V1.1.xlsx](#)
URS-A-3	The user should be able to efficiently perform the search. Since each search variable might have multiple values to be selected, a box that displays possible values and allows multiple selections should be possible. Also, in order to make the search efficient some options like Select all, deselect all would help	P1	Based on the selection of the values in the parent hierarchy, only those relevant values for the child hierarchies should be shown for selection. LitDB is the best example
URS-A-4	The user should be able to efficiently alter the search selections and re-perform the search if required (something like reset variable, select all, deselect all should be helpful)	P1	
URS-A-5	Once the search is submitted, user should be directed to a page with "Results Summary" that shows a summary table of the results	P1	
URS-A-6	Upon clicking the "View Studies" user should be directed to a page that displays a table with high level information of the trials. The user should be able to export the studies table. Towards this an option to export upon right click on the table or a link to export the table may be provided. This file is referred to as "Reference file" in the Key concepts table in Section 4 above	P1	Please refer to the file in the path below for the format and the respective variables to be displayed [\\infwd194\rajasekhar\inp34\Global CTOD\scoping\Search\View Studies Format.xlsx](#) A link that takes the user back to "Results Summary" will be very useful
URS-A-7	The user should be able to select single or multiple studies (rows) in the table above for viewing the	P1	Towards this result view, the data classes are grouped into few high level section for

Req. ID	Requirement Description	Business Criticality	Comment
	entire trial data in html page		displaying the results as shown below

In order to make the results (entire trial data for selected studies) display meaningful for the user a filter (a Drop down, default value is 1st Study) that lists all the resulted studies should be provided and upon selection of the respective study the trail data should be shown

A link that takes the user back to "Results Summary" will be very useful so that user can save the search if required |
| URS-A-8 | User should be able to export the trial data (excel or csv) to his local disk. User may export the trial data of the current study he is viewing or all the studies. Hence, respective options are to be provided. | P1 | To this end, two buttons like, "Download data" or "Download All trials data" should be provided

(As shown above) |
| URS-A-9 | User should be able to export the data in a flat file format or relational file format | P1 | To this end, upon clicking on the "Download Data" or "Download All Trials data" in the above screen (URS-A-7), user should be directed back to the "results summary" page. The respective check box in the Results summary page should be checked as shown in the screen below

 |
| URS-A-10 | User should have an option to export the data for all fields or for customized fields | P1 | As shown in the above screen.

The pre-requisite is that a customized template should be created or a pre-saved list |
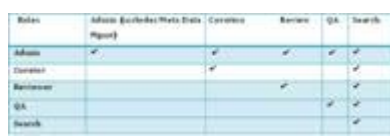
Req. ID	Requirement Description	Business Criticality	Comment
			available for selection in the dropdown as shown above
			This is pretty much similar to how we dealt in LitDB.
URS-A-11	Only the relevant fields for that specific indication should be displayed or exported	P1	Shall provide such table with the indication specific variables.
			All fields are relevant to all indications, except for the Demographics and inclusion sections where the values pertaining to vertical tables vary based on an indication. The value lists specific to each indication shall be provided
URS-A-12	User should be able to create a customized template with the fields of his interest for the respective data sections	P1	Please note that, though user can customize the fields for export, there would be a mandatory set of fields (shall provide them) that are selected by default (and cannot be altered).
			Upon selection of the Disease in the dropdown, the respective indication specific variables for the respective sections should be shown as collapse/expand. Very similar to the way how we dealt in LitDB.
			\\infwd194\Global CTOD\scoping\Search\Customized Template.xlsx
URS-A-13	User should be able to save and share the created custom template	P1	While the user is a non-admin he will be able to save only a private template (Template accessible only to his login), while the user is an admin he can either save as a private template or public template (as shown in above screen)
			Again same as how we dealt this is LitDB

Req. ID	Requirement Description	Business Criticality	Comment
URS-A-14	User should be able to save the search query as a private or public query	P1	While the user is a non-admin he will be able to save only a private query (query accessible only to his login), while the user is an admin he can either save as a private or public query (a query that once saved appears in all user login) as shown in above screen Again same as how we dealt this is LitDB
URS-A-15	There should be a link for the user to view all the list of saved queries.	P1	Again same as how we dealt this is LitDB As the list may run into numbers after some time, user should be able to filter the queries based on an indication
URS-A-16	User should be able to Run/Delete/Rename/Modify the existing private/public query. When User tries to modify the query, he should be directed to the search page with search variables populated for the respective query values. The objective is to provide the existing query as a starting point for building a complex query or modifying the existing query filters	P1	Again same as how we dealt this is LitDB Upon clicking the View link in the screen shot, user should be able to see the search criteria as a pop-up (as we dealt in LitDB) If user is a normal user, then he can modify either Public or Private query, but shall be able to save as only Private query If user is an Admin, then he can modify either Public or Private query and shall be able to save as either Public or Private query A normal user can not delete a public query and similarly when Admin deletes a public query it is deleted from all the user logins under public queries list
URS-A-17	User should be able to save the version of the search results (fetched on that particular date) as a "Data version archive" As the data is continuously updated in the data base, it is important to maintain the record	P1	Again same as how we dealt this is LitDB

Req. ID	Requirement Description	Business Criticality	Comment
	of the older version of the data that is used for analysis. Version Archiving enables the user to archive the version of the data that is being used for analysis as a reference at a future point of time. **As discussed on 23-Aug-2013:** There will be no data versioning. User can save the search results in an excel file and save it as achieve in the application under his account		 Upon clicking the "Save to Data version Archive" user will be prompted for providing a Archive name and a mandatory comment At this point user can view the search criteria of the archived data version and also can re-run the search, but one has to be aware that the re-run search fetches the results on the latest version of the production data available and may not always match with the archived version of the data set. This would match only in case when the production version available is same as the archived version.
URS-A-18	There should be link for the user to view/Retrieve/Export the Archive data versions under his login	P1	Again same as how we dealt this is LitDB A table with Indication Name, Version Archive Name, its Query Date and Comment is displayed (by default the table is sorted by the order of time as saved in the database) There are filters to view the version archives specific to a period (duration) or an indication or both At this point user can view the search criteria by clicking on the button (a pop-up window is shown with the search criteria) Upon clicking the Run query, latest version of the result set is retrieved but not the archived version of the data Upon clicking "view data/export" user is directed to the Page in URS-A-5 and the navigation continues
URS-A-19	There should be a link for the user	P1	Again same as how we dealt this is LitDB

Req. ID	Requirement Description	Business Criticality	Comment
	to view the list of existing templates.		As the list may run into numbers after some time, user should be able to filter the Templates based on an indication and type (public or private)
URS-A-20	User should be able to Edit/Delete/Export the private or public template. When User tries to modify the template, he should be directed to the create template page (URS-A-12) where the user can modify (check or uncheck new or existing fields) and save the template as a new template or overwrite the existing template. The objective is to make the existing template as a starting point for creating a new template	P1	Again same as how we dealt this is LitDB If user is a normal user, then he can modify either Public or Private template, but shall be able to save only as Private template If user is an Admin, then he can modify either Public or Private template and shall be able to save as either Public or Private template A normal user can not delete a public template and similarly when Admin deletes a public template it is deleted from all the user logins under public templates list
URS-A-21	After viewing the search results if user goes back to the search page the selected values of the earlier search should be retained for efficient modification of the search parameters Solution: Edit search	P1	It is very useful to provide a link in all the pages that Take back to the "Search Results page" Upon doing so, the previous search criteria for that login should be retained
URS-A-22	User should be able to access the specifications of the data variables for the respective indication	P1	A link to be provided to access the Disease specific spec files as shown below By default all the Indications and the respective Specs shall be shown.

Req. ID	Requirement Description	Business Criticality	Comment
			Over the time as the indication list grows and in order to efficiently find the specification for a respective indication a drop down to filter the specs would be very useful
URS-A-23	User should be able to view the Specification for a selected Indication within the application (html view)	P1	Upon clicking the View action, user should be able to view the specification in the html page As there could be many data sections with multiple variables, in order make the view more convenient and efficient, a drop down to filter the Specs for a respective section would be useful. By default all the sections are shown. We shall provide the respective source files in this regards
URS-A-24	User should be able to export the Specification to an Excel or Word document	P1	Upon clicking the Export action, user should be able to export the specification to word doc or Excel file as shown above in the screen
URS-A-25	Application should provide quick summary of the existing indication database upon selection	P1	Towards this, a link to Indication summary should be provided with a Dropdown to select the respective indication and a Drop down to select the grouping variable for summarizing the indication database. Upon Submit, user should be directed to a

Req. ID	Requirement Description	Business Criticality	Comment
			page to view with summary format as attached in the excel CTOD Summary reports.xlsx The file can be accessed at \\infwd194\Global CTOD\scoping\Reports\CTOD Summary reports.xlsx
URS-A-26	User should be able to export the generated report as an Excel or Word doc	P1	
URS-A-27	The generated report apart from just a table should provide a histogram as shown in the excel object in URS-A-25	P1	
URS-A-28	Admin module would be accessible only through admin log	P1	
URS-A-29	Admin should be able to efficiently manage the application access by being able to control the access of relevant modules to the relevant users	P1	Find below the matrix with the module accessibility for the respective roles Admin can be either GVK or Client side
URS-A-30	Admin should be able to add/delete/Edit users and control the respective module access to the users	P1	as we dealt in LitDB Up on Admin login, the landing page should show the existing users in a table as shown below. There should also be a link called "View

Req. ID	Requirement Description	Business Criticality	Comment
			Users" such that Admin can navigate to this page from any other page (as shown above) Please note that Admin has access to all modules and by default he should be landed into the Metadata management module
URS-A-31	To create a new user, admin should be prompted for a form to define a new user with a set of fields required	P1	 Admin should be able to define the respective roles for the user. One user can have multiple roles
URS-A-32	Once admin creates the user, the login credentials should be sent through a system generated email.	P1	
URS-A-33	The user upon receiving the system generated email with the application url and credential details would be expected to login into the system and change the password and other profile information if required within a span of 15 days	P1	If the user does not login within 15 days and change the default password provided by the system, the account is subjected to expiry
URS-A-34	Apart from Admin creating a user, any scientific user upon accessing the url should also be able to register and create his own login upon providing the required profile details. Such users shall be granted access only to the search module upon online registration	P1	There should be a link in the application using which any user can register, provide required details and create a login. Such online registered accounts cannot be inactive for more than 15 days and are subjected to expiry.
URS-A-35	Application should have the provision to manage the "Forgot	P1	

Req. ID	Requirement Description	Business Criticality	Comment
	Password" situation		
URS-A-36	In case the account becomes inactive, there should be efficient way to reactivate the account	P1	

3.1 Application Scope and Boundary

Scope of the application is to provide search and visualization as mentioned below. CTOD data development (Curation/Review/QC) is out of scope for this version of application.

CTOD Search & Visualization:

➢ *Data Model: Create data model that can be easily scalable to multiple diseases areas.*

➢ *Admin: Purpose of Admin is to manage all the admin related activities like user management, metadata management, definition & maintenance of data group & task management.*

➢ *Search: Search the database by the selecting the defined fields and user inputs.*

➢ *Reporting: Retrieving the data from the database as per the selected criteria.*

➢ *Visualization: Display the search results data in graphical representation*

3.2 Users of the Application

Below are the users of the CTOD Application:

Role	Responsibilities
Role Manager	• Administrator will assign users access rights on the application • Manages definition & maintenance of data groups • Manages the user of data curation, reviewers & quality check
Administrator	• Administrator manages meta data management • Manages the user tasks • Application admin will have option to save public queries • Manages public templates
Search User	• Will have access to search functionality
Curator	• Curates the assigned article in the curation module of CTOD application

Role	Responsibilities
Reviewer	• Reviews the curated data
Quality Check	• Checks the reviewed data • Transfer reviewed data to production server

4 APPLICATION FLOW

Application flow is categorized into different modules as below

- ✓ **User Management**

    - ➢ *User Creation, Editing & Delete*

    - ➢ *View Users*

    - ➢ *Role Creation, Editing & Deleting*

    - ➢ *View Roles*

    - ➢ *Assigning user roles*

    - ➢ *Role based application access privileges*

    - ➢ *Problem in sign in*

- ✓ **Search**

    - ➢ *Login into application*

    - ➢ *Select search criteria to search*

    - ➢ *View summary of search results*

    - ➢ *View/Export studies of search results*

    - ➢ *View/Export results for selected studies*

    - ➢ *View saved queries – Private or Public*

    - ➢ *Save to/Download Archived data*

    - ➢ *Create user templates*

    - ➢ *Export results in user templates*

    - ➢ *View user templates*

    - ➢ *View specification*

- ✓ **Reports & Visualization**

    - ➢ *Summary reports*

    - ➢ *Data visualization*

    - ➢ *Archive search results*

4.1 User Management

User management is an authentication feature that provides administrators with the ability to identify and control the state of the user logged into the application. Any new users must register to get access to the application modules and each user will have one or multiple roles to access the application.

4.1.1 User Creation

In order to access the CTOD application, user must be registered with the application. User creation can be done in two different ways like:

User Registration: Steps for user registration
- ✓ User has to click "Create new account" link in the home page
- ✓ Provide all the required information in this screen
- ✓ Click on create account button
- ✓ On successful registration an auto email will be sent to user email id
- ✓ Email contains user name, system generated password and application URL
- ✓ User has to click on application URL
- ✓ User will be redirected to Change password screen
- ✓ User has to change application generated password and set new password
- ✓ On successful change of the password, account will be activated and user can access the search module
- ✓ Default role will be "Search" use
- ✓ After use has registered and If the user hasn't activated his account more than 15 days, then account will be expired

Admin Registration: Steps for user registration by admin

- ✓ Go to User management page
- ✓ Click "Create New User"
- ✓ Provide all the required information in this screen
- ✓ Click on create account button
- ✓ On successful registration an auto email will be sent to user email id
- ✓ Email contains user password and application URL
- ✓ Admin has to inform the user about registration
- ✓ User has go to his email Id and click on application URL
- ✓ User will be redirected to Change password screen
- ✓ User has to change application generated password and set new password
- ✓ On successful change password, account will be activated and user can access the search module
- ✓ Default role will be "Search" use
- ✓ After user is registered and if the user hasn't activated his account for more than 15 days, then account will be expired

Flow diagram:

Create New User

```
Open CTOD URL
      │
      ▼
Click Create new account
      │
      ▼
User: Fill the form details  ◄──────────────────┐
      │                                          │
      ▼                                          │
Click Create Account                             │
     button                                      │
      │                                          │
      ▼                                          │
Check Unique User name ──Duplicate found──► Show error message ──┐
      │                                                          │
   Unique                                                        │
      ▼                                                          │
Check Unique Email Id ──Duplicate found──► Show error message ───┘
      │
   Unique
      ▼
Send auto email with
credentials & appl. URL
to user email Id
      │
      ▼
User: Click appl. URL
      │
      ▼
If activating <15 days from creation date ──► User account Inactive
      │
      ▼
Show Change password screen
      │
      ▼
If Successfully changed password
      │
      ▼
Login into application
```

Flow Diagram 2

Mock Screen:

Screen 1

Screen field details:

*FT = Field Type
*DT= Data Type

Field	Type	Validation/Restrictions	Description
First Name	FT: Textbox DT: NVarchar	Mandatory Length: 50	Uses first name
Middle Name	FT: Textbox DT: NVarchar	Optional Length: 50	User middle name
Last Name	FT: Textbox DT: NVarchar	Mandatory Length: 50	User last name
User Name	FT: Textbox DT: NVarchar	Mandatory Length: 15 Special characters allowed: "_"(underscore) and	User name required to login into the application

		".”(dot)	
Date of Birth	FT: DD-Textbox, MM-Dropdown, YY-Dropdown DT: Date	Mandatory Length:12	User date of birth
Gender	FT: Dropdown DT: Varchar	Mandatory Length:6	User gender
Email Address	FT: Textbox DT: NVarchar	Mandatory/Unique Length:50	User valid email id, activation email will be sent to this email Id
Area of Interest	FT: Dropdown DT: Varchar	Mandatory Length:50	Users area of interest
Title	FT: Textbox DT: NVarchar	Optional Length:100	Users title
Organization Category	FT: Dropdown DT: NVarchar	Optional Length:100	Users organization category in which he is working
Organization Name	FT: Textbox DT: NVarchar	Optional Length:100	Users current organization name
Address	FT: TextArea DT: Nvarchar	Optional Length:500	User address details
City	FT: Textbox DT: Varchar	Mandatory Length:50	User residing city
State	FT: Textbox DT: Varchar	Mandatory Length:50	User residing state
Country	FT: Dropdown DT: Varchar	Mandatory Length:50	User residing country
Phone	FT: Textbox DT: NVarchar	Mandatory Length:25	User phone number for communication Prefix the phone number with selected country code
Captcha	FT: Textbox DT: Nvarchar	Mandatory	Captcha image to make sure that user is entering and it is not auto filling. **Note:** this field is used for validation, value will not be saved in database.
Agreement	FT: Checkbox	Mandatory	Option to accept the agreement. **Note:** this field is used for validation, value will not be saved in database.
Action Items			

Control Name	Control Type	Event	Action
Create New Account	Button	Click	**Actions:** ✓ Do Client side validation ✓ Do Server side validation ✓ Save data ✓ Send auto email to users email id **Client Side Validations:** ✓ Mandatory fields ✓ Validate captcha text ✓ Validate proper email Id ✓ Validate user name with min length should be 3 ✓ Validate user name format (check field details) ✓ Show proper error messages **Server Side Validations:** ✓ Check for unique user name ✓ Check for unique email id ✓ Generate random password ✓ Save user details with password ✓ Send auto email to Id activation ✓ Show success message and inform user to check email and activate his account
Reset	Button	Click	**Actions:** ✓ Clear all the values in the form

4.1.2 View Users

View users option can be accessed only by the Admin user. User has to click on "User Management" to view the all the users.

Screen 2

4.1.3 User Editing

User details can be edited either by user or by the admin user

Editing by User: User can edit his profile by visiting "Edit Profile" section. User will have an option to change all the details except the user name.

Editing by Admin: Admin user will have all the privileges to change the user details by visiting User management page as shown in Screen 2.

- ✓ Visit user management
- ✓ Search for the user
- ✓ Click on "Edit" button
- ✓ Update & Save the details
- ✓ Email will be sent to user about the changes made

4.1.4 User Deleting

User deletion can be done only by Admin user. User management page has option to delete the user. Deletion of any user will be a SOFT delete.

SOFT deletion: User will not be deleted from the database but user will be made In-Active.

Steps for deletion:

- ✓ Visit user management

- ✓ Search for the user

- ✓ Click on "Delete" button

- ✓ Show alert message for deletion

- ✓ Do Soft delete in the database

- ✓ Show confirmation message

4.1.5 Create & View Role:

Create role option will be available only to the user having "Role Manager" role. Using this option user can create any new roles which will be used in the application.

Screen field details:

*FT = Field Type
*DT= Data Type

Field	Type	Validation/Restrictions	Description
RoleName	FT: Textbox DT: NVarchar	Mandatory	Role name
Description	FT: Textarea DT: NVarchar	Optional	Description of the role
Action Items			

Control Name	Control Type	Event	Action
Create Role	Button	Click	**Actions:** ✓ Client side validation: Check is role is entered ✓ Check for duplicate role

			✓ Save role **Client Side Validations:** ✓ Mandatory fields ✓ Show proper error messages **Server Side Validations:** ✓ Validate Duplicate role name
Reset	Button	Click	**Actions:** ✓ Clears the values from input fields
View Roles : Edit	Button	Click	**Actions:** ✓ Show the values in create role controls ✓ Change "Create role" button to "Update Role"
View Roles: Delete	Button	Click	**Actions:** ✓ Show confirmation message for deletion like "Are you sure you want to delete the role?" ✓ If user accepts then delete the role ✓ Perform SOFT delete for the role

4.1.6 Assign User Roles:

Assign user roles option will be accessible only to the user having "Role Manager" role. Using this functionality role manager can assign multiple roles for selected user. This functionality will be available in create user functionality as highlighted in below screen shot.

4.1.7 Role based application access:

Role wise application access functionality is used to define the list of all functionalities in the application and assign the privilege of accessing to each role. Each application role will have one or more functionalities assigned.

4.1.8 **Problem in sign in**

Problem in sign in option will be used when any user forgets his password or if any user has registered in the application but did not activate his account with in 15 days of registration.

Steps of problem in sign in:

- ✓ User has to provide his user id, date of birth and email ids which was used when registering the account.
- ✓ Submit the form
- ✓ Application will validate the details
- ✓ If provide details match with each other
- ✓ Application will send new auto generated password to the user's email id
- ✓ User must go to his email id, which has new auto generated password and application URL
- ✓ User clicks the URL, that redirects to the application change password functionality
- ✓ User must provide auto generated password, new password and re-enter new password and submit the request
- ✓ Validate the new password as per the password format
- ✓ Update the user password

Flow Diagram:

Problem in Sign In Flow

User	Application

(Open Application URL)

↓

Click Problem in sign in link

↓

Enter User Id, Date of Birth & Email id

↓

Click Submit → ⬦ Valid details?

⬦ → Send email with new password and URL → Open email and click appl. URL

Open email → Redirect to change password page → Enter auto generated password & new paaword

↓

Click Submit → ⬦ Valid details?

⬦ → Redirect to application login → Enter user id & new password

→ ⬦ Valid credentials?

⬦ → (Login to application)

Mock Screen:

Screen field details:

*FT = Field Type
*DT= Data Type

Field	Type	Validation/Restrictions	Description
User Name	FT: Textbox DT: NVarchar	Mandatory	Enter registered user name
Date of birth	FT: Textbox DT: NVarchar	Mandatory	Enter registered date of birth
Email Id	FT: Textbox DT: NVarchar	Mandatory	Enter registered email id

Action Items			
Control Name	**Control Type**	**Event**	**Action**
Submit	Button	Click	**Actions:** ✓ Do Client side validation ✓ Validate User name, date of birth and email ✓ If invalid, show message "Invalid details" ✓ If Valid, send new auto generated password along with application URL to user email id ✓ Show message, "New password sent to your registered email id, please change the password using the URL sent in email" **Client Side Validations:** ✓ Mandatory fields ✓ Show proper error messages

			Server Side Validations:
			✓ Validate User name, date of birth and email

4.2 Search

CTOD search is performed as per user selected preference. Search can be performed under 2 filter criteria's like Primary filters & Secondary filters. Initial search will be performed using primary filter fields. Secondary search filtering will be done on the primary search filter results.

4.2.1 Login:
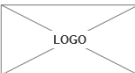
In order to perform search functionality user has to login into the application using the registered username and password.

Flow Diagram:

Flow Diagram 3

Mock Screen:

Screen 3

Screen field details:

*FT = Field Type
*DT= Data Type

Field	Type	Validation/Restrictions	Description
User Name	FT: Textbox DT: NVarchar	Mandatory	Enter registered user name
Password	FT: Textbox DT: NVarchar	Mandatory	Enter password

Action Items			
Control Name	**Control Type**	**Event**	**Action**
Sign In	Button	Click	**Actions:** ✓ Do Client side validation ✓ Validate user with username & password ✓ If invalid, show message "Invalid username or password" ✓ If Valid, redirect to search page **Client Side Validations:** ✓ Mandatory fields ✓ Show proper error messages **Server Side Validations:**

			✓ Validate user with username & password
Create New User	Hyper Link	Click	**Actions:** ✓ Redirects to "Create new account" page
Problem in Signing In	Hyper Link	Click	**Actions:** ✓ Redirects to "problem in signing" page

4.2.2 **Search Page:**

After successful login into the application user can perform the search by selecting the required criteria. The fields available in the search screen are the primary search fields to perform the initial data search. There are other secondary search fields available to search on the primary fields search results. Details about the secondary search fields are explained in below sections.
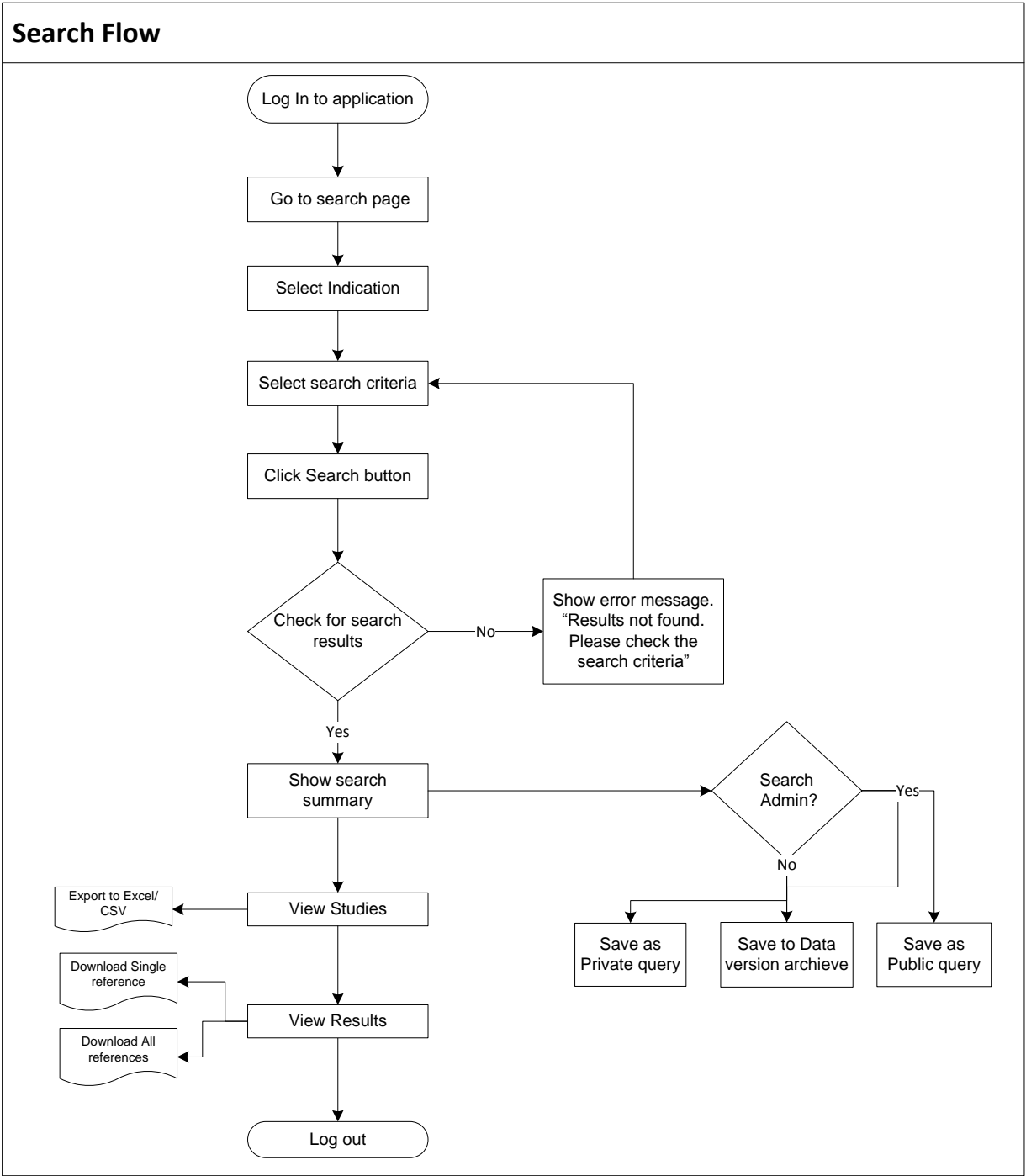
Steps to search:

✓ User has to first select "Indication" field value which is mandatory

✓ Upon selecting the indication value, data in the other search fields will be loaded as per the selected indication.

✓ Data for each control in the form will be loaded on the basis of Top to Bottom Progressive filtering approach.

✓ If user selects/un-selects values in the search fields, then the data in other fields is loaded as per the selected search values

✓ User has to select the required search criteria values

✓ **Search criteria:** The search criteria conditions when searching the data would be as follows

  o In between the sections the condition for searching the data would be "AND" operator.
    For Ex: Between "Treatment Class" & "Treatment Values" when searching data "AND" is performed

  o Within each section if there are multiple values search will be performed as

    ▪ By default "OR" operator is performed for all selected values.
      For Ex: If there are multiple values in "Treatment Class" then for those selected values "OR" criteria is performed when searching.

    ▪ If user selects "**Combination/All Selected**" check box then "AND" operator is performed for all selected values.
      For Ex: If there are multiple values for in "Treatment Name" then for those selected values "AND" criteria is performed when searching.

Progressive filtering: Search will start by selecting Indication value

- ✓ Indication: On selecting Indication value, the relevant data w.r.t. selected indication will be filled in the below controls

    - o Trial filters: Load Trial design, Trial phase, Randomization and control as per selected indication

    - o Treatment Class: Load treatment class as per selected indication

    - o Treatment Name: Load treatment name as per indication

    - o Inclusion Criteria: Load inclusion criteria's as per selected indication

    - o Assessment Filters: Load assessment filters as per selected indication

    - o Publication Start year:

        - • Get minimum start date year of all references filtered as per selected indication.

        - • Get maximum end date year of all references filtered as per selected indication

        - • Load years range between minimum start date year and maximum end date year.

    - o Publication End year: Same as publication start year

    - o Literature Type: Load list of distinct literature types filtered as per indication

- ✓ Upon selecting the field values, then the top to bottom progressive filtering will be applied.

Flow Diagram:

Search Flow

```
                        ┌─────────────────────────┐
                        │   Log In to application  │
                        └─────────────────────────┘
                                    │
                                    ▼
                        ┌─────────────────────────┐
                        │    Go to search page     │
                        └─────────────────────────┘
                                    │
                                    ▼
                        ┌─────────────────────────┐
                        │     Select Indication    │
                        └─────────────────────────┘
                                    │
                                    ▼
                        ┌─────────────────────────┐
                        │   Select search criteria │◄──────────────┐
                        └─────────────────────────┘                │
                                    │                              │
                                    ▼                              │
                        ┌─────────────────────────┐                │
                        │    Click Search button   │                │
                        └─────────────────────────┘                │
                                    │                              │
                                    ▼                    ┌──────────────────────┐
                              ◇ Check for ◇    No   │  Show error message. │
                              ◇ search     ◇────────►│  "Results not found. │
                              ◇ results    ◇         │  Please check the    │
                                    │                │   search criteria"   │
                                   Yes               └──────────────────────┘
                                    ▼
```

Search Admin? — Yes
No

Save as Private query

Save to Data version archieve

Save as Public query

Show search summary

View Studies — Export to Excel/ CSV

Download Single reference

View Results — Download All references

Log out

Flow Diagram 4

Mock Screen:

Screen 4

Screen field details:

*FT = Field Type
*DT= Data Type

Field	Type	Validation/Restrictions	Description
Diseases Section			
Indication	FT: Dropdown List DT: NVarchar	Mandatory Length: 50	List of indications. User has to select indication to perform search
Trial Filters Section			
Trial Design	FT: Dropdown List	Optional	List of trial designs

	DT: Varchar	Length:50	
Trial Phase	FT: Dropdown List DT: NVarchar	Optional Length:50	List of all phases
Randomisation	FT:Dropdown List DT:Nvarchar	Optional Length:50	List of randomization values
Control	FT: Dropdown List DT: Nvarchar	Optional Length:50	List of control values
Treatment Filters Section			
Treatment Class	FT: List box DT: Nvarchar	Optional Length:100	List of treatment class values as per selected indication Validation: ✓ If user clicks "Select All" option then disable "Combination" check box
Treatment Name	FT: List box DT: Nvarchar	Optional Length:50	List of treatment names as per selected indication or as per selected treatment class Validation: ✓ If user clicks "Select All" option then disable "Combination" check box
Inclusion Criteria Section			
Inclusion criteria *(Max only 6 criteria)*	FT: Dropdown List DT: Nvarchar	Optional Length:50	List of available inclusion criteria s. By default 3 values will be displayed and user can add more three if required
Inclusion value	FT: Textarea – Multiple values DT: Nvarchar	Optional Length:250	Textbox with popup window to select multiple values
Assessment Filter section			
Assessment Filter	FT: List box DT: Nvarchar	Optional Length:100	List of assessments displayed as per the above selected criteria Validation: ✓ If user clicks "Select All" option then disable "Combination" check box
Additional Limits Section			

Publication start year	FT: Dropdown List DT: Numeric	Optional Length:4	Display list of start years as per the above selected criteria
Publication end year	FT: Dropdown List DT: Numeric	Optional Length:4	Display list of end years as per the above selected criteria
Sample size	FT: Textbox DT: NVarchar	Optional Length: 1000	Enter sample size
Literature Type	Textbox DT: Nvarchar	Optional Length: 100	Enter literature type
Chart visualization	Column Chart	Dynamic	Displays number of references available as per selected indication

<div align="center">

Action Items

</div>

Control Name	Control Type	Event	Action
Select All	Checkbox	Click	**Actions:** ✓ Marks as selected for all the values in the below list box and show the values in "Selected" list ✓ Remove all the values from the main list box
De-Select All	Checkbox	Click	**Actions:** ✓ De-selects all the selected from the list view ✓ Remove all the values from the selected list box
Combination	Checkbox	Click	**Actions:** ✓ If combination is checked then when searching the data, all the selected values will be searched as "AND" operator in the database.
All Selected	Checkbox	Click	**Actions:** ✓ If combination is checked then when searching the data, all the selected values will be searched as "AND" operator in the database.
Search	Button	Click	**Actions:** ✓ Validate form ✓ If combination is checked then when searching the data, all the selected values will be searched as "AND" operator in the database.
Reset	Button	Click	**Actions:** ✓ Clears all selected value

4.2.3 Summary View

Upon selecting the search criteria and clicking the search button, user will be redirected to search summary page. Search summary view page contains the below details.

- ✓ Search Criteria: This section displays the searched parameters selected by the user in search screen (on what basis results are retrieved) in hierarchical fashion

   For Ex: Disease name = Diabetics; Trail Design= X-over; Trail Name= All....

- ✓ Edit Search: If user wants to modify the search criteria clicking on 'Edit Search' link will redirect to search screen with the selected search criteria values.   User can change the query selections and can re submit the search.

- ✓ Results summary: This section displays the summary information of the results retrieved as per the selected criteria like total numbers of records retrieved with indication, references etc.

- ✓ View studies: When user clicks on "View Studies" button, user will be redirected to view studies page where details of the search data is displayed.

- ✓ Save Query: User can save the searched query for future reference. Search queries can be saved in two formats as:
   - o Private query: Private queries can be saved by all the users. Queries saved as private can be viewed only the user in this login and they cannot be shared with other users.
   - o Public query: Only Admin user can save the query as public. Queries saved as public can be viewed to all the users in their login.

- ✓ Down Load Query Data: User can download the search results (Retrieved record) in CSV or Excel formats. User has option to download the data as complete data or user defined custom templates.

- ✓ Archive data to excel: Using archive option user can save the data of the search results in his account. Search results will be saved in excel format, in future if user want to view the data, user can download the view the data.

Mock Screen

Screen 5

Screen field details:

*FT = Field Type
*DT= Data Type

Field	Type	Control	Description
Search criteria	Display	Label	Displays the complete criteria as per the user selection in search screen
Edit search	Display	Hyperlink	Link to go back to search screen to edit the search criteria
Results Summary	Display	Table	Displays the summary details of selected search criteria
Results Summary Table Fields			
Indication	Display	Label	Indication selected by the user in search screen
Total References	Display	Label	Total number of references found in the database as per the selected search criteria
Total Records	Display	Label	Displays the total records found in the database for selected search criteria
Total Subjects	Display	Label	Displays total number of subjects

Minimum Time Point	Display	Label	Displays minimum time point of all the search results found
Maximum Time Point	Display	Label	Displays maximum time point of all the search results found.
Save query	Display	Hyper link	Links to save the search criteria as private or public query
Download query data – Complete	Display	Button	Export search results data in excel or CSV file as relational format or flat file format
Download query data – Custom	Display	Button	Export search results data in excel or CSV file as relational format or flat file format for custom templates
Custom	Mandatory	Dropdown List	Select the saved template to export the data
Archive search data	Display	Hyperlink	Archive the search results data to excel for future references

Action Items

Control Name	Control Type	Event	Action
View Studies	Button	Click	**Actions:** ✓ Redirects to View studies page
Save as Private query	Hyper Link	Click	**Actions:** ✓ Pop up window appears ✓ User has to enter query name & description ✓ Click on Save query to save the query
Save as Public query	Hyper Link	Click	**Actions:** ✓ Pop up window appears ✓ User has to enter query name & description ✓ Click on Save query to save the query

- **Save as private query:** Users can save the searched query for future purpose by clicking on 'Save as private query' link. A popup window appears in which user has to enter the query name and query description and click on "Save Query" button to save the selected query. User can view all this saved queries in "View Saved queries" option.

Screen 6

Screen field details:

*FT = Field Type
*DT= Data Type

Field	Type	Validation/Restrictions	Description
Query name	FT: Textbox DT: NVarchar	Mandatory Length: 15 Special characters allowed: "_" (underscore) and "."(dot)	Enter the query name to save the search query as public
Description	FT: Texarea DT: Nvarchar	Text Optional	Enter the description of the selected query
Action Items			

Control Name	Control Type	Event	Action
Save Query	Button	Click	**Actions:** ✓ Validate the query name and description which are mandatory ✓ Save the query as private to user account
Cancel	Button	Click	**Actions:** ✓ Close the window

- **Save as public query:** This option will be available only to the Admin user of the application. Admin user can create a query, and if the admin user feels that this query will be helpful to all the users, then he can save the query as Public query. All queries saved as public by the admin user can be viewed by all the application users in View Saved queries option. Users can "Run" & "Edit" the public queries

Screen 7

Screen field details:

*FT = Field Type
*DT= Data Type

Field	Type	Validation/Restrictions	Description
Query name	FT: Textbox DT: NVarchar	Mandatory Length: 15 Special characters allowed: "_" (underscore) and "."(dot)	Enter the query name to save the search query as public
Description	FT: Texarea DT: Nvarchar	Text Optional	Enter the description of the selected query

Action Items			
Control Name	**Control Type**	**Event**	**Action**
Save Query	Button	Click	**Actions:** ✓ Validate the query name and description which are mandatory ✓ Save the query as public to user account
Cancel	Button	Click	**Actions:** ✓ Close the window

- **Archive query data:** Using this option user can save the searched results data in an excel format in his application account for future reference. When he clicks 'Archive query-data' link a pop up

window appears with 'Enter data file name', 'Description' fields and 'Archive Data & 'Cancel' buttons. User has to enter excel file name & its description and click on "Archive Data" button. User can view this data in View archive data option and download the saved data to his desktop.

Screen 8

Screen field details:
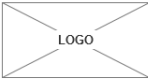
*FT = Field Type
*DT= Data Type

Field	Type	Validation/Restrictions	Description
Data file name	FT: Textbox DT: NVarchar	Mandatory Length: 15 Special characters allowed: "_" (underscore) and "."(dot)	Enter file name to save the search query results data to archive excel file for future reference.
Description	FT: Texarea DT: Nvarchar	Text Optional	Enter the description of the archived data file

Action Items			
Control Name	**Control Type**	**Event**	**Action**
Archive Data	Button	Click	**Actions:** ✓ Validate the file name field and description field which are mandatory ✓ Save the selected query along with the archive data ✓ Create excel file with the search data ✓ Save the file with the given name into user accoungt
Cancel	Button	Click	**Actions:** ✓ Close the window

4.2.4 **View Studies**

When user clicks on "View Studies" in summary page, then user will be redirected to view studies page. This page displays the study details of the search results data along with the secondary filters. All the secondary filters will be populated with the data as per the search results. When user selects any secondary criteria then the main search criteria will be appended with the secondary filter and search data will be filtered as per the selected secondary filters.

Mock Screen:

Screen 9

Screen field details:

Field	Type	Control	Description
Search criteria	Display	Label	Displays the complete criteria as per the user selection in search screen
Study details	Display	Table	Search results are displayed for some fields, with option to select the source ids to view the results in next screen
Study Details table fields			
Select	Select	Checkbox	Option to select one or more source ids to view the results view. **Validation:** ✓ At least one check box to be selected when moving to Results view.
Source ID	Display	Label	Unique identifier assigned for a publication
Title	Display	Label	Study Title
Author	Display	Label	All the primary and secondary authors of the publication
Sponsor	Display	Label	Name of Sponsor
Trial.Design.ID	Display	Label	Unique identifier assigned for a trial. Generally one to one relation between publication to trial. Many to Many relationship can also be handled with this structure
Number of patients	Display	Label	Total number of patients recruited
Number of treatment arms	Display	Label	Number of treatment arms
Trial start year	Display	Label	Year of first patient entered
Trial end year	Display	Label	Year of trial closure
Phase	Display	Label	Phase of clinical development
Inclusion criteria	Display	Label	Description of inclusion criteria
Exclusion criteria	Display	Label	Exclusion description text as given in the literature
Countries	Display	Label	Geographical location where the

				study is conducted
Trial design	Display	Label		Design adapted for the trial
Publication year	Display	Label		Publication year
Journal	Display	Label		Journal Name
Volume	Display	Label		Publication volume
Issue	Display	Label		Issue number
Pages	Display	Label		Start page and End page
Secondary Filters	FT: List box DT: Nvarchar	Optional		Option to perform secondary search on primary search results. Select the required values for the fields to further filter the data.
Secondary Filters				
Subgroup	Select	List box		List of subgroup values as per the search results data
Outcome Stat.	Select	List box		List of outcome statistics as per the search results data
Outcome Category	Select	List box		List of outcome categories as per search results data
Statistical Population	Select	List box		List of statistical population values as per search results data
Imputation Method	Select	List box		List of Imputation method values as per search results data

Action Items

Control Name	Control Type	Event	Action
Secondary filters	List box	Select	**Actions:** ✓ Select any value from secondary filter control ✓ Filter the study details data as per selected filter
View Results	Button	Click	**Actions:** ✓ Redirect user to results view page
Export to Excel	Image Button	Click	**Actions:** ✓ Export the results data into excel format
Export to CSV	Image Button	Click	**Actions:** ✓ Export the results data into CSV format

4.2.5 Results View

Upon clicking on "View Results" button in study details page, user will be redirected to results view page. User has to select required studies to view data in results view. In results view the data is grouped into high level sections and displayed in different tabs categorized as

- ✓ Publication

- ✓ Trial Design

- ✓ Treatment Arms

- ✓ Patient Characteristics

- ✓ Outcomes

4.2.5.1 Publication: Publication tab has the details of the selected source Id publication details.

Mock Screen:

Screen 10

Screen field details:

*FT = Field Type
*DT= Data Type

Field	Type	Control	Description
Search criteria	Display	FT: Label DT: Nvarchar	Displays the complete criteria as per the user selection in search screen

Results view	Display	FT: Tabs DT: NVarchar	Display the result fields in their respective tab sections in structured format.
Export	Display	FT: Button DT: NVarchar	Export the data to excel or CSV for selected source id or all source ids
Publication View Field Details			
Reference ID	Display	FT: Label DT: Number	Unique identifier assigned for a publication
Author	Display	FT: Label DT: Nvarchar	All the primary and secondary authors of the publication
Publication Year	Display	FT: Label DT: Number	Publication year
Journal	Display	FT: Label DT: Nvarchar	Journal Name
Title	Display	FT: Label DT: Nvarchar	Study Title
Source	Display	FT: Label DT: Nvarchar	Name of source
Source ID	Display	FT: Label DT: Nvarchar	Unique identifier assigned for a publication
Link to article	Display	FT: Label DT: Nvarchar	Link to full text article
Direct Link	Display	FT: Label DT: Nvarchar	DOI Link
Article type	Display	FT: Label DT: Nvarchar	Article Type

4.2.5.2   Trial Design: This section will have the Trial design details which are categorized into Trial and Inclusion

Mock Screen:

Source Id:

14990632 ▼

| Publication | Trial Design | Treatment Arms | Patient Characteristics | Outcomes |

☐ Expand all

Trial Level Information

First Previous Trials 1 of 2 Next Last

Trial Acronym	LEAD-6
Trial AcronymDerived	N
Sponsor	Novo Nordisk
Number of patients	464
Number of treatment arms	2
Trial start year	2007
Trial end year	2008
Phase	III
Randomisation	Y
Controlled trial	Y
Blinding	open label
Trial registry name	ClinicalTrials.gov
Trial registry number	NCT00518882
Inclusion criteria	Participants aged 18–80 years with type 2 diabetes were eligible if their HbA1c value was 7–11% and if they had a body-mass index (BMI) of 45·0 kg/m2 or less on stable treatment with maximally tolerated doses of metformin, sulphonylurea, or both, for 3 months or more
Exclusion criteria	Exclusion criteria included previous insulin treatment (except short-term treatment for intercurrent illness), previous exposure to exenatide or liraglutide, impaired liver or renal function, clinically significant cardiovascular disease, retinopathy or maculopathy requiring acute treatment, uncontrolled hypertension (>=180/100 mmHg), or cancer
Sample size calculation details	163 individuals in each group were needed for 85% power to detect a difference of 0·4% between groups (assuming a SD of 1·2%), a clinically meaningful margin for non-inferiority. Assuming a 25% drop-out rate, 434 participants (217 per group) were needed at randomisation

Analysis method details	The primary endpoint was the difference between treatment groups in HbA1c values from baseline to week 26. 163 individuals in each group were needed for 85% power to detect a difference of 0·4% between groups (assuming a SD of 1·2%), a clinically meaningful margin for non-inferiority. Assuming a 25% drop-out rate, 434 participants (217 per group) were needed at randomisation. Analyses of efficacy outcomes were based on the intention-to-treat population. The primary endpoint was also analysed for the per-protocol population. We analysed most endpoints with the analysis of covariance (ANCOVA) with treatment, country, and current antidiabetic drug as explanatory variables, and baseline HbA1c values as covariate. We imputed missing values by carrying the last observation forward. We did hierarchical tests for non-inferiority and superiority of liraglutide and background oral antidiabetic drugs versus exenatide and background oral antidiabetic drugs. We first established non-inferiority and then tested superiority, each at 2·5% significance level. We assumed non-inferiority if the upper limit of the two-sided 95% CI for treatment difference was less than 0·4%, and superiority if the upper limit was less than 0. We compared the proportions of patients achieving HbA1c target values using logistic regression with treatment, country, and background oral antidiabetic drug as explanatory variables, and baseline HbA1c values as covariate. We developed estimates of overall treatment satisfaction from an ANCOVA model with treatment, country, and background oral antidiabetic drug as fixed effects, and baseline Diabetes Treatment Satisfaction Questionnaire summary score as covariate. Missing data were not imputed. We analysed hypoglycaemic episodes using a generalised linear model with treatment, background oral antidiabetic drug, and country as fixed effects. We compared other safety data with descriptive statistics. Significance level was set at p<0·05, and data are expressed as least square means (SE) unless stated otherwise
Countries	US, AT, DK, FI, FR, DE, IE, MK, NO, PL, PR, RO, SI, ES, SE, CH
COUNTRY CODES	840, 40, 208, 246, 250, 276, 372, 807, 578, 616, 630, 642, 705, 724, 752, 756
Trial design	Parallel group
Multicentre study	Y
Trial Comments	In article it is given as 15 countries, but according to NCT it was 16, we have captured the data fron NCT. For HBA1C, FPG, And BW the SE values from Graph were captured according to Mean (1.96 SE) which was given in the article.

Screen field details:

*FT = Field Type
*DT= Data Type

Field	Type	Control	Description
Trial Design			
Trial Level Information Fields			
Trial Acronym	Display	FT: Label DT: Nvarchar	Numeric code for the geographical location where the study is conducted
Trial Acronym Derived	Display	FT: Label DT: Nvarchar	Derived Unique identifier for trial when trial acronym does not exist
Sponsor	Display	FT: Label DT: Nvarchar	Name of Sponsor
Number of patients	Display	FT: Label DT: Number	Total number of patients recruited
Number of treatment arms	Display	FT: Label DT: Number	Number of treatment arms
Trial start year	Display	FT: Label DT: Number	Year of first patient entered

Trial end year	Display	FT: Label DT: Number	Year of trial closure
Phase	Display	FT: Label DT: Nvarchar	Phase of clinical development
Randomization	Display	FT: Label DT: Nvarchar	Is the trial randomized
Controlled trial	Display	FT: Label DT: Nvarchar	Does the trial have a control arm(s)
Trial Control	Display	FT: Label DT: Nvarchar	
Blinding	Display	FT: Label DT: Nvarchar	What kind of blinding is adapted in the trial
Trial registry name	Display	FT: Label DT: Nvarchar	Registry name of trial
Trial registry number	Display	FT: Label DT: Nvarchar	Unique registry identifier for the trial. Essential to link the multiple publications pertaining to the same trial
Inclusion criteria	Display	FT: Label DT: Nvarchar	Inclusion description text as given in the literature
Exclusion criteria	Display	FT: Label DT: Nvarchar	Exclusion description text as given in the literature
Sample size calculation details	Display	FT: Label DT: Nvarchar	Textual description for sample size calculation as given in the literature
Analysis method details	Display	FT: Label DT: Nvarchar	Textual description for analysis method details as given in the literature
Countries	Display	FT: Label DT: Nvarchar	Geographical location where the study is conducted
COUNTRY CODES	Display	FT: Label DT: Number	Numeric code for the geographical location where the study is conducted
Trial design	Display	FT: Label DT: Nvarchar	Design adapted for the trial
Multicentre study	Display	FT: Label DT: Nvarchar	Was this a multi-centre study
Trial Comments	Display	FT: Label DT: Nvarchar	Overall trial comments if any

Screen field details:

*FT = Field Type
*DT= Data Type

Field	Type	Control	Description
Trial Design			
Inclusion Fields			
Inclusion Criteria	Display	FT: Label DT: Nvarchar	Description of inclusion criteria
Value	Display	FT: Label DT: Nvarchar	value of criteria, supplements description

4.2.5.3   Treatment Arms: This section will have the Treatment Arms details, they are categorized into

- ✓ Arms
- ✓ Interventions
  - o Treatment
  - o Planned
  - o Actual
- ✓ Other Interventions
  - o Intervention Types
  - o Intervention Type factors

Treatment Arms:

Arm: Mock screen

Screen field details:

**FT = Field Type
**DT= Data Type

Field	Type	Control	Description
Treatment Arms			
Arm Fields			
Arm.ID	Display	FT: Label DT: Number	Numerical identifier assigned to the randomized arm in the trial. This is a grouping variable to identify the group of patients in whom the outcome is assessed.
Re-randomised arm id	Display	FT: Label DT: Number	Numerical identifier used to differentiate re-randomized arms from the main groups (randomized arms)
Reference ID	Display	FT: Label DT: Number	Unique identifier assigned for a publication
Trial.Design.ID	Display	FT: Label DT: Number	Unique identifier assigned for a trial. Generally one to one relation between publication to trial. Many to Many relationship can also be handled with this structure
Treatment Arm	Display	FT: Label DT: Nvarchar	Treatment (top level description)
Washout details	Display	FT: Label DT: Nvarchar	Description of washout
Arm.Control	Display	FT: Label DT: Nvarchar	Indicator of control Arm in the trial

Treatment.Naive	Display	FT: Label DT: Nvarchar	Whether patients are naïve to that specific treatment or not (their first time to be exposed to that drug)
Randomized.N	Display	FT: Label DT: Number	Number of patients Randomized to a treatment arm
Completed.N	Display	FT: Label DT: Number	Number of patients Completed the treatment
Results from PRO	Display	FT: Label DT: Nvarchar	Whether results available for patient related outcomes or not
PRO INSTRUMENT	Display	FT: Label DT: Nvarchar	Instrument used to measure patient related outcomes
Treated.N	Display	FT: Label DT: Nvarchar	Number of patients treated with the respective treatment

Screen field details:

*FT = Field Type
*DT= Data Type

Field	Type	Control	Description
Treatment Arms - Intervention			
Treatment Fields			
Arm.ID	Display	FT: Label DT: Number	Numerical identifier assigned to the randomized arm in the trial. This is a grouping variable to identify the group of patients in whom the

			outcome is assessed.
Re-randomised arm id	Display	FT: Label DT: Number	Numerical identifier used to differentiate re-randomized arms from the main groups (ranomized arms)
Phase	Display	FT: Label DT: Nvarchar	Description of the specific phase within the overall study from which the data is derived
Phase Duration	Display	FT: Label DT: Number	length of time of the study phase from which the data is derived
Phase Duration unit	Display	FT: Label DT: Nvarchar	time unit for Phase Duration
Phase Description	Display	FT: Label DT: Nvarchar	Comment concerning the study phase
Titration	Display	FT: Label DT: Nvarchar	Forced titration is a trial in which dose was escalated (changed) in everybody according to a specific schedule. Titration to target means that the dose was adjusted according to a certain efficacy or tolerability outcome. In several trials the dose was changed during the trial.
Titration.Duration	Display	FT: Label DT: Numner	Duration of titration period
Titration.Duration Unit	Display	FT: Label DT: NVarchar	Duration units for titration period
Titration.Target	Display	FT: Label DT: Nvarchar	E.g., Name of lipid biomarker used for titration to target (LDL, etc.). Use "dose" for forced titration studies
Titration.Value	Display	FT: Label DT: Number	Target value for titration to target; target LDL or target dose in a forced titration setting
Titration.unit	Display	FT: Label DT: Nvarchar	Unit of target value for titration to target
treatment.name	Display	FT: Label DT: Nvarchar	Generic name of the treatment
Treatment.Class	Display	FT: Label DT: Nvarchar	Class of treatment

Treatment.Description	Display	FT: Label DT: Nvarchar	Additional information available regarding the treatment

Screen field details:

*FT = Field Type
*DT= Data Type

Field	Type	Control	Description
Treatment Arms - Intervention			
Planned Fields			
Arm.ID	Display	FT: Label DT: Number	Numerical identifier assigned to the randomized arm in the trial. This is a grouping variable to identify the group of patients in whom the outcome is assessed.
Re-randomized arm id	Display	FT: Label DT: Number	Numerical identifier used to differentiate re-randomized arms from the main groups (randomized arms)
Period ID	Display	FT: Label DT: Number	Numeric identifier assigned for Study period. E.g., In X-over trails where the treatment switch happens, the assignment of the period numbers would be 1, 2 etc.,
Period	Display	FT: Label DT: Nvarchar	Used to qualify the "Period" field with any additional information deemed necessary or helpful
Period Duration	Display	FT: Label DT: Nvarchar	Length of time of the period in a study phase from which the data is derived
Period Duration Unit	Display	FT: Label DT: Nvarchar	time unit for Period Duration
Period Description	Display	FT: Label DT: Nvarchar	Comment concerning the period

Treatment.Start.Time	Display	FT: Label DT: Number	Start time of the specific dose of the drug
Treatment.End.Time	Display	FT: Label DT: Number	End time of the specific dose of the drug. This will be useful for the titration trials, Xover or indicate switch-in. Also useful to relate the data from multiple tabs if the dose changes with time
Treatment.Time.Unit	Display	FT: Label DT: Nvarchar	Units used to record treatment time
Treatment.Dose	Display	FT: Label DT: Nvarchar	Planned Dose of Active Treatment
Treatment.Dose.Units	Display	FT: Label DT: Nvarchar	Units used for the measurement of Dose
Treatment.Frequency	Display	FT: Label DT: Nvarchar	Dose regimen
Treatment.ROA	Display	FT: Label DT: Nvarchar	Route of Administration for treatment
Treatment.Formulation	Display	FT: Label DT: Nvarchar	Formulation of the treatment
Treatment.Brand	Display	FT: Label DT: Nvarchar	The drug brand name
Treatment.Prior	Display	FT: Label DT: Nvarchar	Patients taking same treatment prior to this treatment (Y/N).
Treatment.Administration days	Display	FT: Label DT: Nvarchar	No. of days of treatment administration
Treatment.Administration duration(hours)	Display	FT: Label DT: Nvarchar	Duration of treatment administration e.g; 30 min iv infusion
Treatment.Administration per cycle	Display	FT: Label DT: Nvarchar	Number of drug administration's per cycle
Treatment.Cycle length (weeks)	Display	FT: Label DT: Nvarchar	Duration of the treatment cycle
Treatment.max No of Cycles	Display	FT: Label DT: Nvarchar	Maximum number of treatment cycles allowed

Screen field details:

Field	Type	Control	Description
Treatment Arms - Intervention			
Actual Fields			
Arm.ID	Display	FT: Label DT: Number	Numerical identifier assigned to the randomized arm in the trial. This is a grouping variable to identify the group of patients in whom the outcome is assessed.
Period ID	Display	FT: Label DT: Number	Numeric identifier assigned for Study period. E.g., In X-over trails where the treatment switch happens, the assignment of the period numbers would be 1, 2 etc.,
Treatment.Dose.Avg	Display	FT: Label DT: Number	Average drug administered
Treatment.Dose.Avg unit	Display	FT: Label DT: Nvarchar	Units used for the measurement of average dose
Treatment.Dose.Avg type	Display	FT: Label DT: Nvarchar	To record if this is Mean or Median
Treatment.median no of cylces	Display	FT: Label DT: Number	Median number of treatment cycles administered
Treatment.mean no of cycles	Display	FT: Label DT: Number	Mean number of treatment cycles administered

Treatment.Administration days	Display	FT: Label DT: Nvarchar	Drug administration days e.g; day1, day8
Mean Duration of Treatment	Display	FT: Label DT: Number	Mean duration of treatment
Median Duration of Treatment	Display	FT: Label DT: Number	Median duration of treatment
Treatment Duration Units	Display	FT: Label DT: Nvarchar	Duration units for treatment

Screen field details:

*FT = Field Type
*DT= Data Type

Field	Type	Control	Description
Treatment Arms – Other Interventions **Intervention Type Fields**			
Intervention ID	Display	FT: Label DT: Number	Numeric identifier assigned for each non-pharm intervention in an Arm
Arm.ID	Display	FT: Label DT: Number	Numerical identifier assigned to the randomized arm in the trial. This is a grouping variable to identify the group of patients in whom the outcome is assessed

Re-randomized arm id	Display	FT: Label DT: Number	Numerical identifier used to differentiate re-randomized arms from the main groups (ranomized arms)
Intervention type	Display	FT: Label DT: Nvarchar	Type of intervention
Intervention type description	Display	FT: Label DT: Nvarchar	Description of intervention type
Intervention Start Time	Display	FT: Label DT: Number	Time at which intervention was first applied
Intervention End Time	Display	FT: Label DT: Number	Time at which intervention was withdrawn
Intervention Time Unit	Display	FT: Label DT: Nvarchar	Units used to record intervention time

Screen field details:

*FT = Field Type
***DT= Data Type

Field	Type	Control	Description
Treatment Arms – Other Interventions **Intervention Type Factor Fields**			
Intervention ID	Display	FT: Label DT: Number	Numeric identifier assigned for each non-pharm intervention in an Arm
Arm.ID	Display	FT: Label DT: Number	Numerical identifier assigned to the randomized arm in the trial. This is a grouping variable to identify the group of patients in whom the

			outcome is assessed.
Re-randomized arm id	Display	FT: Label DT: Number	Numerical identifier used to differentiate re-randomized arms from the main groups (randomized arms)
Intervention type factor/Concomitant Rx	Display	FT: Label DT: Nvarchar	Intervention type factor
Intervention type value/CM Dose	Display	FT: Label DT: Nvarchar	Data for intervention type or Dose of the Concomitant
Intervention type value unit/CM Dose unit	Display	FT: Label DT: Nvarchar	Units used to record intervention type value or Concomitant dose
Other Interventions Comments	Display	FT: Label DT: Nvarchar	Overall interventions comments if any

4.2.5.4 Patient Characteristics: This section will have details of patient characteristics.

Mock Screen

Screen field details:

*FT = Field Type
*DT= Data Type

Field	Type	Control	Description
Patient Characteristics			
Patient Characteristics Fields			

Arm.ID	Display	FT: Label DT: Number	Numerical identifier assigned to the randomized arm in the trial. This is a grouping variable to identify the group of patients in whom the outcome is assessed.
Re-randomized arm id	Display	FT: Label DT: Number	Numerical identifier used to differentiate re-randomized arms from the main groups (ranomized arms)
SubArm Number	Display	FT: Label DT: Number	Sub group identifier used to differentiate sub group analysis from the main groups (ranomized arms)
Sub group	Display	FT: Label DT: Nvarchar	Specific charachter of the sub group used, like Male, Female, Ethni origin, Baseline covartoate level or a specific strata (pre-randomization variable)
Patient characteristic	Display	FT: Label DT: Nvarchar	Name of patient characteristic
Patient characteristic unit	Display	FT: Label DT: Nvarchar	Unit for patient characteristic
Patient characteristic Summary stat	Display	FT: Label DT: Nvarchar	Type of summary stat
Patient characteristic value	Display	FT: Label DT: Number	Data for patient characteristic
N patients	Display	FT: Label DT: Number	Number of patients in the treatment arm with that particular characteristic
Variability measure	Display	FT: Label DT: Nvarchar	Measurement of variability used
Variability measure value	Display	FT: Label DT: Number	Value of variability measurement
Norm.variability measure value	Display	FT: Label DT: Number	Normalization value of variability measurement
N Patients in Arm/Subarm	Display	FT: Label DT: Number	Total number of patients in an Arm or Subarm
Demographic Comments	Display	FT: Label DT: Nvarchar	Overall demographic comments if any

4.2.5.5 Outcomes: This section will have details of outcome details

Screen field details:

*FT = Field Type
*DT= Data Type

Field	Type	Validation	Description
Outcomes			
Outcomes Fields			
Arm.ID	Display	FT: Label DT: Number	Numerical identifier assigned to the randomized arm in the trial. This is a grouping variable to identify the group of patients in whom the outcome is assessed.
Re-randomized arm id	Display	FT: Label DT: Number	Numerical identifier used to differentiate re-randomized arms from the main groups (ranomized arms)
Period ID	Display	FT: Label DT: Number	Numeric identifier assigned for Study period. E.g., In X-over trails where the treatment switch happens, the assignment of the period numbers would be 1, 2 etc.,
SubArm Number	Display	FT: Label DT: Number	Sub group identifier used to differentiate sub group analysis from the main groups (ranomized arms)

Location	Display	FT: Label DT: Nvarchar	Location of the outcome value data in the manuscript.
Outcome Full form	Display	FT: Label DT: Nvarchar	Name of outcome measure
Outcome Short form	Display	FT: Label DT: Nvarchar	
Outcome Subscale	Display	FT: Label DT: Nvarchar	Description of the Endpoint subscale
Outcome class	Display	FT: Label DT: Nvarchar	
Outcome statistic	Display	FT: Label DT: Nvarchar	Statistic type
Outcome category	Display	FT: Label DT: Number	Absolute/CFB/PCFB/etc..
Outcome measurement time	Display	FT: Label DT: Number	time since randomization
Outcome measurement time 2	Display	FT: Label DT: Nvarchar	time since last dose - useful for tracking switchover, Titration and x-over to a new treatment or dose
Outcome time of the day	Display	FT: Label DT: Nvarchar	Hours post dose
Outcome measurement time unit	Display	FT: Label DT: Nvarchar	Unit used to record outcome measurement time
Outcome observation duration	Display	FT: Label DT: Nvarchar	Duration for which the outcome is measured
Outcome observation duration units	Display	FT: Label DT: Nvarchar	Units for the duration of the outcome measured
Outcome point estimate	Display	FT: Label DT: Nvarchar	outcome Value
Outcome point estimate unit	Display	FT: Label DT: Nvarchar	outcome Value unit
Outcome variability measure	Display	FT: Label DT: Number	Type of variance
Outcome variability	Display	FT: Label DT: Number	Estimate of variability

Outcome variability lower limit	Display	FT: Label DT: Number	Variability lower limit
Outcome varibility upper limit	Display	FT: Label DT: Nvarchar	Variability upper limit
Outcome p-value	Display	FT: Label DT: Nvarchar	P-value for treatment vs comparator
Outcome p-value type	Display	FT: Label DT: Nvarchar	P-value type for treatment vs comparator
Scale Lower Bound	Display	FT: Label DT: Number	Catagorical Scale Lower bound
Scale Upper Bound	Display	FT: Label DT: Number	Categorical Scale Upper bound
Outcome Scale Range, Categories or Words	Display	FT: Label DT: Nvarchar	Category Description
Outcome definition	Display	FT: Label DT: Nvarchar	Detailed description of outcome derivation
Outcome analysis objective	Display	FT: Label DT: Nvarchar	Objective of the statistical analysis of the outcome
Non-inferiority margin	Display	FT: Label DT: Nvarchar	Margin applied if outcome analysis type is non-inferiority
N pts in analysis	Display	FT: Label DT: Nvarchar	Number of patients in analysis of the outcome
N events in analysis	Display	FT: Label DT: Nvarchar	Number of events in analysis of the outcome
N at risk	Display	FT: Label DT: Nvarchar	The no of patients at risk for the respective event, especialy in the survival estimates (KM curve) this will be available.
Outcome type	Display	FT: Label DT: Number	Hierarchical outcome type
Comparator	Display	FT: Label DT: Number	Record Arm ID instead of Treatment details in text as mapping can be easily established using numeric data rather than text data
Re-Randomized Comparator id	Display	FT: Label DT: Number	Record re-randomized ID instead of Treatment details in text as mapping can be easily established using numeric data rather than text data

	Display	FT: Label DT: Nvarchar	Record Sub-arm ID instead of Treatment details in text as mapping can be easily established using numeric data rather than text data
Comparator subgroup id			
Statistical population	Display	FT: Label DT: Nvarchar	Statistical population used in analysis of the outcome
Imputation method	Display	FT: Label DT: Nvarchar	Technique used for dealing missing data
Statistical population definition	Display	FT: Label DT: Nvarchar	Detailed description of the analysis population
Outcome analysis stage	Display	FT: Label DT: Nvarchar	Final/Interim
Assessment Comments	Display	FT: Label DT: Nvarchar	Overall outcome comments if any

4.2.6 View saved queries

This feature is used to view the queries saved by the user and queries saved by admin. Queries saved by user are shown in "Private Queries" and queries saved by Admin user are shown in "Public Queries" tabs.

Private queries: The queries saved by the user himself will be view in "Private Queries" tab. These queries are visible only to the user. User has an option to 'RUN', 'EDIT', 'RENAME' & 'DELETE' the queries.

Mock Screen:

Screen 11

Screen field details:

Field	Type	Validaton/ Restrictions	Description
Indication	FT: Dropdown List DT: Nvarchar	Mandatory	List of indications
Private queries	FT: Table DT: NVarchar	Display	Display list of private saved queries with query name, description.
Action	FT: Button	Optional	Display different action buttons like Run, Edit, Rename & delete

Action Items			
Control Name	**Control Type**	**Event**	**Action**
Run	Button	Click	**Actions:** ✓ Runs the selected query and redirects the user to summary page.
Edit	Button	Click	**Actions:** ✓ Redirects to the search page ✓ Loads all the query parameters as per the saved query
Rename	Button	Click	**Actions:** ✓ Show pop up window , same as save query ✓ Display already saved query name and description ✓ Click Save query to update the query name and description
Delete	Button	Click	**Actions:** ✓ Prompt for user confirmation about deletion ✓ If user chooses to delete then delete the query ✓ Deletion will be hard delete

Public queries: Only "Admin" user will have an option to save the query as "Public". Any query saved as public can be viewed by all users in their "Public Queries" tab. User will have option to 'RUN', 'EDIT' options. "Admin" user will have option to "Rename" and "Delete" the saved query.

Screen 12

Screen field details:

Field	Type	Validation/Restrictions	Description
Indication	FT: Dropdown List DT: Nvarchar	Mandatory	List of indications
Private queries	FT: Table DT: NVarchar	Display	Display list of public saved queries with query name, description.
Action	FT: Button	Optional	Display different action buttons like Run, Edit, Rename & delete

Action Items			
Control Name	**Control Type**	**Event**	**Action**
Run	Button	Click	**Actions:** ✓ Runs the selected query and redirects the user to summary page.
Edit	Button	Click	**Actions:** ✓ Redirects to the search page ✓ Loads all the query parameters as per the saved query

4.2.7 **View Archived data:**

View archive data will display the list of archive files saved by the users for the future reference. Data can be viewed by downloading the file to the user's local system. User will have option to View, Run, Edit, Rename & Delete the saved results.

Screen 13

Screen field details:

Field	Type	Validations/Restrictions	Description
Indication	FT: Dropdown List DT: NVarchar	Mandatory	List of indications
Range Start year	FT: Textbox DT: Numeric	Optional Length: 4	Option to enter the start date to filter the archived data
Range End year	FT: Textbox DT:Numeric	Optional Length:4	Option to enter the end date to filter the archived data
Archived Data	FT: Table	Display	Displays the list of user saved archived files
Action	FT: Button	Optional	Display different action buttons like View, Run, Edit, Rename & Delete
Action Items			
Control Name	**Control Type**	**Event**	**Action**
Run			**Actions:** ✓ Runs the selected query and redirects the user to

			summary page.
Edit	Button	Click	**Actions:** ✓ Redirects to the search page ✓ Loads all the query parameters as per the saved query
Rename	Button	Click	**Actions:** ✓ Show pop up window , same as save archive data ✓ Display already saved name and description ✓ Click Save to update the name and description
Delete	Button	Click	**Actions:** ✓ Prompt for user confirmation about deletion ✓ If user chooses to delete then delete the data ✓ Deletion will be hard delete

4.2.8 Create Template

Create template option helps the user to select his required preference fields when exporting the search results data. User templates will be created as per the selected indication.   So for each indication user can create multiple templates as per his requirement.

Templates can be created as public and private.

Private Template: Templates saved by the search users are saved as private, which are accessible to the user himself. This option will be available for both search users and admin users.

Public Template: Public template saving option will be available only to the search admin user. Templates saved as public will be available to all users of the application.

Steps to create template:

- ✓ Select the indication
- ✓ Select the required fields listed in each section
- ✓ Click Save as public/private template.

Mock Screen:

Screen 14

Screen field details:

Field	Control	Validations/ Restrictions	Description
Indication	FT: Dropdown List DT: NVarchar	Mandatory	List of indications
Publication & Trial Data	FT: Select List View DT:NVarchar	Optional	Option to select multiple fields as per the main section to create a template
Publication Fields			
Reference ID	Check box	Mandatory	-

	Value: Checked		
Author	Check box Value: Checked	Mandatory	-
Publication	Check box Value: Checked	Mandatory	-
year	Check box Value: Checked	Mandatory	-
Journal	Check box Value: Checked	Mandatory	-
Title	Check box Value: Checked	Mandatory	-
Source	Check box Value: Checked	Mandatory	-
Source ID	Check box Value: Checked	Mandatory	-
Link to article	Check box Value: Un-Checked	Optional	-
Direct Link	Check box Value: Un-Checked	Optional	-
Article type	Check box Value: Un-Checked	Optional	-
Data extractor name	Check box Value: Un-Checked	Optional	-
Data extraction date	Check box Value: Un-Checked	Optional	-
Trial Data Fields			
Trial.Design.ID	Check box Value: Checked	Mandatory	-
Reference ID	Check box Value: Checked	Mandatory	
Trial Acronym	Check box Value: Un-Checked	Optional	
Trial Acronym Derived	Check box Value: Un-Checked	Optional	
Sponsor	Check box Value: Un-Checked	Optional	

Number of patients	Check box Value: Checked	Mandatory	
Number of treatment arms	Check box Value: Checked	Mandatory	
Trial start year	Check box Value: Un-Checked	Optional	
Trial end year	Check box Value: Un-Checked	Optional	
Phase	Check box Value: Checked	Mandatory	
Randomisation	Check box Value: Checked	Mandatory	
Controlled trial	Check box Value: Checked	Mandatory	
Trial Control	Check box Value: Checked	Mandatory	
Blinding	Check box Value: Checked	Mandatory	
Trial registry name	Check box Value: Checked	Mandatory	
Trial registry number	Check box Value: Checked	Mandatory	
Inclusion criteria	Check box Value: Checked	Mandatory	
Exclusion criteria	Check box Value: Checked	Mandatory	
Sample size calculation details	Check box Value: Un-Checked	Optional	
Analysis method details	Check box Value: Un-Checked	Optional	
Countries	Check box Value: Un-Checked	Optional	
COUNTRY CODES	Check box Value: Un-Checked	Optional	
Trial design	Check box Value: Checked	Mandatory	

Multicentre study	Check box Value: Checked	Mandatory	
Trial Comments	Check box Value: Un-Checked	Optional	
Trial Inclusion Data	FT: Select List View DT:NVarchar	Optional	Option to select multiple fields as per the main section to create a template
Trial Inclusion Data Fields			
Trial.Design.ID	Check box Value: Checked	Mandatory	
Reference ID	Check box Value: Checked	Mandatory	
Inclusion Criteria	Check box Value: Checked	Mandatory	
Value	Check box Value: Checked	Mandatory	
Arm Data	FT: Select List View DT:NVarchar	Optional	Option to select multiple fields as per the main section to create a template
Arm Data Fields			
Arm.ID	Check box Value: Checked	Mandatory	
Re-randomised arm id	Check box Value: Checked	Mandatory	
Reference ID	Check box Value: Checked	Mandatory	
Trial.Design.ID	Check box Value: Checked	Mandatory	
Treatment Arm	Check box Value: Checked	Mandatory	
Washout details	Check box Value: Un-Checked	Optional	
Arm.Control	Check box Value: Checked	Mandatory	
Treatment.Naive	Check box	Mandatory	

	Value: Checked		
Randomized.N	Check box Value: Checked	Mandatory	
Completed.N	Check box Value: Checked	Mandatory	
Results from PRO	Check box Value: Un-Checked	Optional	
PRO INSTRUMENT	Check box Value: Un-Checked	Optional	
Treated.N	Check box Value: Un-Checked	Optional	
Treatment Data	FT: Select List View DT:NVarchar	Optional	Option to select multiple fields as per the main section to create a template
Treatment Data Fields			
Treatment ID	Check box Value: Checked	Mandatory	
Arm.ID	Check box Value: Checked	Mandatory	
Re-randomised arm id	Check box Value: Checked	Mandatory	
Reference ID	Check box Value: Checked	Mandatory	
Trial.Design.ID	Check box Value: Checked	Mandatory	
Phase ID	Check box Value: Checked	Mandatory	
Phase	Check box Value: Checked	Mandatory	
Phase Duration	Check box Value: Checked	Mandatory	
Phase Duration unit	Check box Value: Un-Checked	Optional	
Phase Description	Check box Value: Un-Checked	Optional	

Titration	Check box Value: Un-Checked	Optional	
Titration.Duration	Check box Value: Un-Checked	Optional	
Titration.Duration Unit	Check box Value: Un-Checked	Optional	
Titration.Target	Check box Value: Un-Checked	Optional	
Titration.Value	Check box Value: Un-Checked	Optional	
Titration.unit	Check box Value: Un-Checked	Optional	
treatment.name	Check box Value: Checked	Mandatory	
Treatment.Class	Check box Value: Checked	Mandatory	
Treatment.Description	Check box Value: Checked	Mandatory	
Patient Data	FT: Select List View DT:NVarchar	Optional	Option to select multiple fields as per the main section to create a template
Patient Data Fields			
PatChar.Record.ID	Check box Value: Checked	Mandatory	
Reference ID	Check box Value: Checked	Mandatory	
Trial.Design.ID	Check box Value: Checked	Mandatory	
Arm.ID	Check box Value: Checked	Mandatory	
Re-randomised arm id	Check box Value: Checked	Mandatory	
SubArm Number	Check box Value: Checked	Mandatory	
Sub group	Check box Value: Checked	Mandatory	

Patient characteristic	Check box Value: Checked	Mandatory	
Patient characteristic unit	Check box Value: Checked	Mandatory	
Patient characteristic Summary stat	Check box Value: Checked	Mandatory	
Patient characteristic value	Check box Value: Checked	Mandatory	
Norm.Patient characteristic unit	Check box Value: Checked	Mandatory	
Norm.Patient characteristic value	Check box Value: Checked	Mandatory	
N patients	Check box Value: Checked	Mandatory	
Variability measure	Check box Value: Un-Checked	Optional	
Variability measure value	Check box Value: Un-Checked	Optional	
Norm.variability measure value	Check box Value: Un-Checked	Optional	
N Patients in Arm/Subarm	Check box Value: Un-Checked	Optional	
Demographic Comments	Check box Value: Un-Checked	Optional	
Outcome Data	FT: Select List View DT:NVarchar	Optional	Option to select multiple fields as per the main section to create a template
Outcome Data Fields			
Assessment.record.ID	Check box Value: Checked	Mandatory	
Reference ID	Check box Value: Checked	Mandatory	
Trial.Design.ID	Check box Value: Checked	Mandatory	
Arm.ID	Check box Value: Checked	Mandatory	

Re-randomised arm id	Check box Value: Checked	Mandatory	
Phase ID	Check box Value: Checked	Mandatory	
Period ID	Check box Value: Checked	Mandatory	
SubArm Number	Check box Value: Checked	Mandatory	
Location	FT: Select List View DT:NVarchar	Optional	
Outcome Full Form	Check box Value: Checked	Mandatory	
Outcome Short Form	Check box Value: Checked	Mandatory	
Outcome Subscale	FT: Select List View DT:NVarchar	Optional	
Outcome class	FT: Select List View DT:NVarchar	Optional	
Outcome statistic	Check box Value: Checked	Mandatory	
Outcome category	Check box Value: Checked	Mandatory	
Outcome measurement time	Check box Value: Checked	Mandatory	
Outcome measurement time 2	Check box Value: Checked	Mandatory	
Outcome time of the day	FT: Select List View DT:NVarchar	Optional	
Outcome measurement time unit	Check box Value: Checked	Mandatory	
Outcome observation duration	FT: Select List View DT:NVarchar	Optional	
Outcome observation duration units	FT: Select List View DT:NVarchar	Optional	
Outcome point estimate	Check box Value: Checked	Mandatory	

Outcome point estimate unit	Check box Value: Checked	Mandatory	
Outcome variability measure	Check box Value: Checked	Mandatory	
Outcome variability	Check box Value: Checked	Mandatory	
Outcome variability lower limit	Check box Value: Checked	Mandatory	
Outcome variability upper limit	Check box Value: Checked	Mandatory	
Norm.Outcome point estimate	Check box Value: Checked	Mandatory	
Norm.Outcome point estimate unit	Check box Value: Checked	Mandatory	
Norm.Outcome variability measure	Check box Value: Checked	Mandatory	
Norm.Outcome variability	Check box Value: Checked	Mandatory	
Norm.Outcome variability lower limit	Check box Value: Checked	Mandatory	
Norm.Outcome varibility upper limit	Check box Value: Checked	Mandatory	
Outcome p-value	FT: Select List View DT:NVarchar	Optional	
Outcome p-value type	FT: Select List View DT:NVarchar	Optional	
Scale Lower Bound	FT: Select List View DT:NVarchar	Optional	
Scale Upper Bound	FT: Select List View DT:NVarchar	Optional	
Outcome Scale Range, Categories or Words	FT: Select List View DT:NVarchar	Optional	
Outcome definition	FT: Select List View DT:NVarchar	Optional	
Outcome analysis objective	FT: Select List View DT:NVarchar	Optional	

Non-inferiority margin	FT: Select List View DT:NVarchar	Optional	
N pts in analysis	Check box Value: Checked	Mandatory	
N events in analysis	Check box Value: Checked	Mandatory	
N at risk	Check box Value: Checked	Mandatory	
Outcome type			
Comparator	Check box Value: Checked	Mandatory	
Re-Randomised Comparator id	FT: Select List View DT:NVarchar	Optional	
Comparator subgroup id	FT: Select List View DT:NVarchar	Optional	
Statistical population	Check box Value: Checked	Mandatory	
Imputation method	Check box Value: Checked	Mandatory	
Statistical population definition	FT: Select List View DT:NVarchar	Optional	
Outcome analysis stage	FT: Select List View DT:NVarchar	Optional	
Assessment Comments	FT: Select List View DT:NVarchar	Optional	

Action Items			
Control Name	**Control Type**	**Event**	**Action**
Select Indication	Dropdown list	Select	**Actions:** ✓ Select Indication ✓ Get all fields as per indication ✓ Display fields as per section
Save as private Template	Button	Click	**Actions:** ✓ Validate the form ✓ Show popup asking for template name and description ✓ Save template details as Private
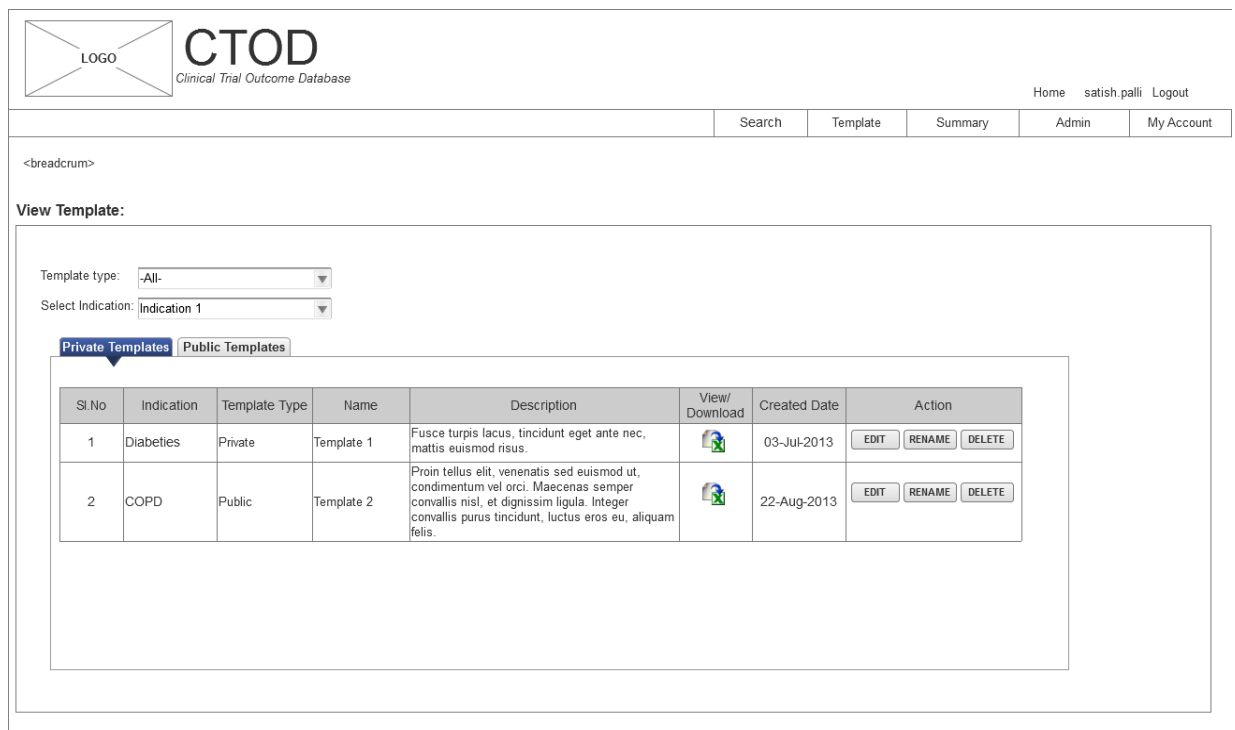
Save as Public Template(Available to search admin user)	Button	Click	**Actions:** ✓ Validate the form ✓ Show popup asking for template name and description ✓ Save template details as Public	
Reset	Button	Click	**Actions:** ✓ Clear all user selected queries	

4.2.9 View Templates

View templates will display two types of templates to the user like Private and Public templates. Private templates are those saved by the user and public templates are those saved by the Admin user. Any template saved as public by the admin user can be viewed by all users in public template tab.

Template Types:

4.2.9.1 Private Template: Templates saved by the user are viewed in private template tab. Logged in user templates

Screen 15

Screen field details:

Field	Control	Validation/ Restrictions	Description
Indication	FT: Dropdown List	Mandatory	List of indications

Private Templates	FT: Table	Display	Display list of queries saved by the user as per the Indication.
Private template table fields			
Sl.No	Label	Display	Serial number of the record
Indication	Label	Display	Indication under which the template is created
Name	Label	Display	Name of template provided at the time of saving the template
Description	Label	Display	Description of the template provided when saving the template
Export	Image Button	Click	Option to export the template details in excel format
Created date	Label	Display	Create date of the template
Action	FT: Button	Optional	Display different action buttons like Edit, Rename & Delete
Action Items			

Control Name	Control Type	Event	Action
Export	Image button	Click	**Actions:** ✓ Export the template fields into excel file
Edit	Button	Click	**Actions:** ✓ Redirect to Create template page ✓ Select all the fields saved in the template in create template page ✓ Update template details
Rename	Button	Click	**Actions:** ✓ Show popup of create template ✓ Display already saved template name and description
Delete	Button		**Actions:** ✓ Prompt for user confirmation ✓ Delete the template from the database.

4.2.9.2 **Public Template:** Templates saved as Public by the Admin user will be shown in public template tab. User can edit those templates and save them as private templates.

Screen field details:

Field	Control	Validation/ Restrictions	Description
Indication	FT: Dropdown List	Mandatory	List of indications
Public Templates	FT: Table	Display	Display list of queries saved as public by admin
Private template table fields			
Sl.No	Label	Display	Serial number of the record
Indication	Label	Display	Indication under which the template is created
Name	Label	Display	Name of template provided at the time of saving the template
Description	Label	Display	Description of the template provided when saving the template
Export	Image Button	Click	Option to export the template details in excel format
Created date	Label	Display	Create date of the template
Action	FT: Button	Optional	Display different action button Edit

<div align="center">

Action Items

</div>

Control Name	Control Type	Event	Action
Export	Image button	Click	**Actions:** ✓ Export the template fields into excel file
Edit	Button	Click	**Actions:** ✓ Redirect to Create template page ✓ Select all the fields saved in the template in create template page ✓ Update template details

4.2.10 View Specification:

View specification will have details of the data variables categorized into multiple main sections like Publication, Trial design, Treatment arms, Patient characteristics and Outcomes.

Mock Screen:

Screen 16

Screen field details:

Field	Control	Validation/Restrictions	Description
View Specification Data	FT: Table	Display	Display list of indication with last updated date and export as excel & CSV format

View Specification Table fields			
Sl.No	Label	Display	Serial number of the record
Indication	Label	Display	Indication name
Last Updated	Label	Display	Last updated date for any change of variable in the indications
Export	Image Button	Click	Option to export specification list in word or excel
Action	FT: Button	Optional	Display different action buttons like View

Action Items				
Control Name	**Control Type**	**Event**	**Action**	
View	Button	Click	**Actions:** ✓ Redirect to view specification details page	

4.2.10.1**Specification Details:**

Specification details will show the complete list of variable for the selected indication in view specification page. The list can be filtered as per the class/data section

from the table.

CTOD
Clinical Trial Outcome Database

Home   satish.palli   Logout

| Search | Template | Summary | Admin | My Account |

<breadcrum>

Specification Details:

| Specification | Inclusion | Patient Characteristics | Outcome |

Add Specification

Data Section: ▾   Variable Name: enter text…   Variable Description: enter text…   Data Standard: enter text…   [Add]   [Reset]

Filter by data section: All ▾   Search: enter text…

S.No.	Data Section	Variable Name	Variable Description	Data Standard	Action
1	Publication	Reference ID	Unique identifier assigned for a publication	Primary Key	Edit
2	Publication	Author	All the primary and secondary authors of the publciiation	As reported	Edit
3	Publication	Publication year	Publication year	Integer	Edit
4	Publication	Journal	Journal Name	Standard abbreviated forms can be used, generally as in the PUBMED	Edit
5	Publication	Volume	Publication volume	E.g., 180, S120	Edit
6	Publication	Issue	Issue number	E.g., 2, 1-2	Edit
7	Publication	Pages	Start page and Endpage	E.g., 1-24	Edit
8	Publication	Title	Study Title		Edit
9	Publication	Source	Name of source	E.g., PUBMED, COCHRANE	Edit
10	Publication	Source ID	Unique identifier assigned for a publication		Edit
11	Publication	Link to article	Link to full text article	http://www.ncbi.nlm.nih.gov/pubmed/22563244	Edit
12	Publication	Direct Link	DOI Link	10.1007/s00108-007-1964-0	Edit
13	Publication	Article type	Article Type	E.g., Journal article, Conference abstract	Edit
14	Publication	Data extractor name	Name of individual extracting data		Edit
15	Publication	Data extraction date	Date of data extraction		Edit
16	Trial level	Trial.Design.ID	Unique identifier assigned for a trial. Generally one to one relation between publication to trial. Many to Many relationship can also be handled with this structure	Primary Key	Edit
17	Trial level	Reference ID	Unique identifier assigned for a publication	Foreign Key	Edit
18	Trial level	Trial Acronym	Unique identifier for trial	This answers the question of linking same trial in multiple publications. E.g. primary endpoint in one, sub grups in another.	Edit
19	Trial level	Trial AcronymDerived	Derived Unique identifier for trial when trial acronym does not exist	This answers the question of linking same trial in multiple publications. E.g. primary endpoint in one, sub grups in another.	Edit

Specification Details:

| Specification | Inclusion | Patient Characteristics | Outcome |

Add Inclusion criteria

Indication: Diabeties   Indication Criteria: enter text…   [Add]   [Reset]

Filter by Indication: All ▾   Search: enter text…

Indication	Inclusion Criteria	Action
All	Minimum age	Edit
All	Maximum age	Edit
All	Navie Patients	Edit
Asthma	Minimum age	Edit
Asthma	Maximum age	Edit
Asthma	WHO performance status	Edit
Asthma	Karnofsky performance status	Edit
Asthma	Number of prior therapies	Edit
Asthma	EGFR mutation status	Edit
Asthma	ALK mutation status	Edit
Asthma	KRAS mutation status	Edit
Asthma	FGFR mutation status	Edit
Asthma	EGFR expression	Edit
Asthma	ECOG performance status	Edit
Asthma	Staging	Edit
Asthma	Prior treatment with EGFR-TKI	Edit
Asthma	Prior treatment with platinum-based chemotherapy	Edit
Asthma	Prior treatment with bevacizumab	Edit
Asthma	FGFR amplifaction	Edit
Asthma	staging system	Edit
Asthma	EGFR expression status	Edit
Asthma	WHO performance status	Edit

Specification Details:

| Specification | Inclusion | **Patient Characteristics** | Outcome |

Add Patient Characteristic

Indication: Diabeties

Patient Characteristic: enter text...   [Add] [Reset]

Filter by Indication: All ▼   Search: enter text...

Indication	Patient characteristic	Action
All	AgeRange lower limit	Edit
All	AgeRange upper limit	Edit
All	Age	Edit
All	%Male	Edit
All	%Female	Edit
All	%Caucasian	Edit
All	%Black	Edit
All	%Hispanic	Edit
All	%Asian	Edit
All	%other	Edit
All	%Never smoker	Edit
All	%Past smoker	Edit
All	%Current smoker	Edit
All	%Ever smoker	Edit
All	%Smoker Unknown	Edit
All	Mean body weight	Edit
All	Mean BMI	Edit
All	%Non Smoker	Edit
All	Patient Characteristic Not Reported	Edit
Asthma	Exacerbation last year	Edit
Asthma	Exacerbation treated with antibiotics	Edit
Asthma	FEV1	Edit

Specification Details:

| Specification | Inclusion | Patient Characteristics | **Outcome** |

Add Outcomes

Indication: Diabeties

Outcome Short form: enter text...   Outcome Full form: enter text...   [Add] [Reset]

Filter by Indication: All ▼   Search: enter text...

Indication	Outcome Short Form	Outcome Full Form	Action
All	PAELD	Patients with an adverse event leading to discontinuation	Edit
All	AERASH	Adverse event of rash	Edit
All	AEDIARRHOEA	Adverse event of diarrhoea	Edit
All	AEFATIGUE	Adverse event of fatigue	Edit
All	AENAUSEA	Adverse event of nausea	Edit
All	AEVOMITING	Adverse event of vomiting	Edit
All	AEINFECTION	Adverse event of infection	Edit
All	AENEUTROPENIA	Adverse event of neutropenia	Edit
All	AEFEBNEUT	Adverse event of febrile neutropenia	Edit
All	AETHROMBO	Adverse event of thrombocytopenia	Edit
All	AEANEMIA	Adverse event of anemia	Edit
All	OFPRDR	outcome for patients requiring dose reductions	Edit
All	PWALOAE	Patients with at least one adverse event	Edit
All	PWALOSAE	Patients with at least one serious adverse event	Edit
All	PLELD	Discontinuations for lack of efficacy	Edit
All	PLD	Patients discontinuing	Edit
All	MSD	Medicaiton: study drug	Edit
All	MR	Mortality	Edit
All	PLDOR	Patients discontinuing for Other reasons	Edit
Asthma	TTF	Time to treatment failure	Edit
Asthma	EQ5D	EQ5D	Edit
Asthma	COMP	Complience	Edit
Asthma	DISU	Disutility for exacerbation	Edit
Asthma	EXACTand EXACT-RS	Exacerbations of chronic pulmonarydisease tool and EXACT-Respiratory symptoms	Edit
Asthma	FEV1RPPN	FEV1 reversibility, %PN	Edit

Screen 17

Screen field details:

Field	Control	Validation/Restrictions	Description
Filter by class	FT: Dropdown	Optional	List of class names to filter the

name	List		specification data
Specification Details	FT: Table	Display	Display the details of specification
Specification Details Field			
Sl.No	Label	Display	Serial number of the record
Data Section	Label	Display	Indication under which the template is created
Variable Name	Label	Display	Name of the variable
Variable Description	Label	Display	Description of the variable
Data Standard	Label	Display	Type of data shown in the variable value

4.2.11 Indication Summary

Indication summary provide the complete summary details for the selected indication.

Screen 18

Screen field details:

Field	Control	Validation/Restrictions	Description
Select Indication	FT: Dropdown List DT: NVarchar	Mandatory	List of indications
Group by	FT: Dropdown List DT: NVarchar	Mandatory	List of fields to do group by on the indication to display the summary details
Articles Chart	FT: Column Chart	Dynamic	Column chart to display the number of articles present in the database for the selected indication.

Summary data	FT: Data Table	Dynamic	Table to show the summary chart as per the selected indication and group by field
Summary chart	FT: Column chart	Dynamic	Column Chart displaying the summary details

5 SYSTEM REQUIREMENTS

GVK will use the current infrastructure to host and maintain the Application and Database server, no equipment will be purchased under the work order. (*Ref: WO 1 - Signature Pending.pdf*)

5.1 Application Architecture
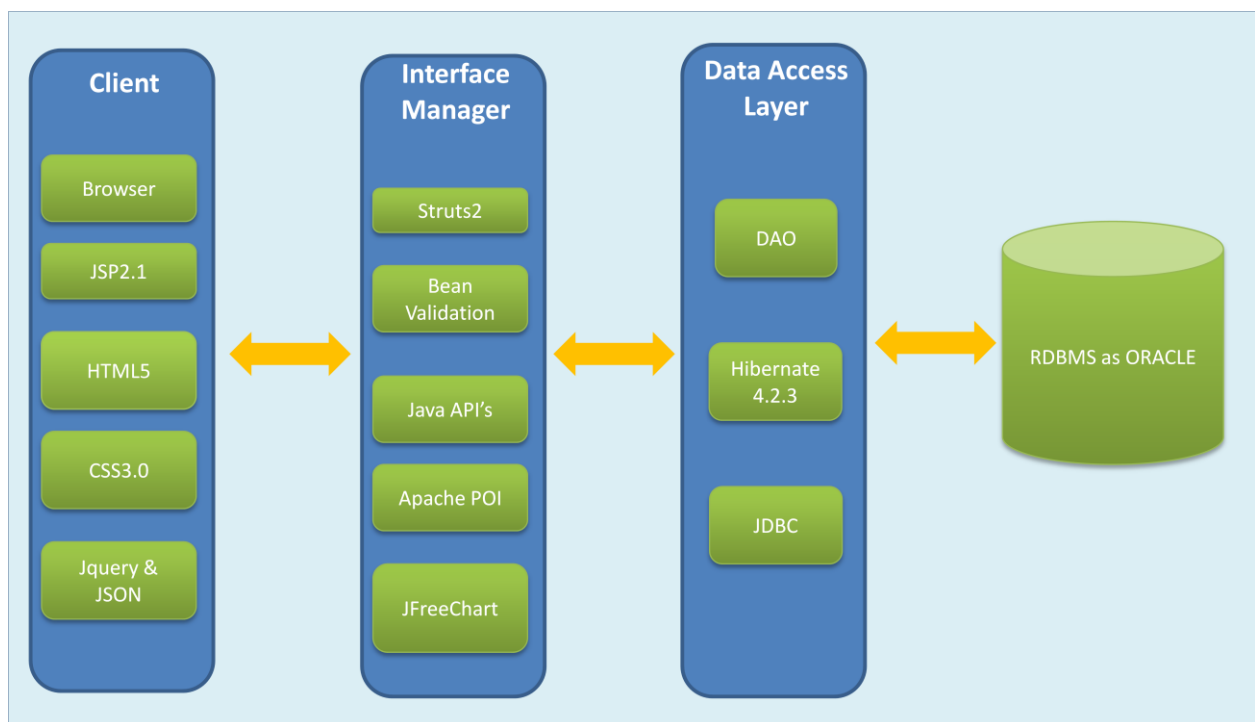
5.2 Architecture Requirements

- *The application should be hosted by GVK and used the clients thru internet network.*

- *Database server will be Oracle version 11r2 standard database engine.*

- *Application server will be Apache Tomcat 7 running on a Linux Server (Red Hat Enterprise 6)*

- *Web application will be developed with browser compatibility of IE9 & Chrome.*

- *Application should be developed using Java EE 6 standards with backend Oracle11r2.*

5.2.1 Miscellaneous System Requirements

- ✓ **Operating System**: LINUX
- ✓ **Database:** Oracle 11r2 is the standard database engine that has to be used.
- ✓ **Browser Compatibility**:
  - **Primary:** IE 9 and Google Chrome
- ✓ **Web Server:** Apache tomcat 7 as web server on Linux(RHEL 6) OS
- ✓ **Logs:** CTOD Application
  - **User Log:** User log(user login activities) is implemented at backend level
  - **System Log:** System log (Error log) is implemented at application level.

5.2.2 Pending decisions and Risks

- *Registering the public domain name*
- *Server on which application and database will be hosted and maintained*

6 DATA MIGRATION REQUIREMENTS

Data migration would be required under the below scenarios:

- ✓ ***Data developed in excel sheet:*** *If data developed in excel sheet then that data has to be imported into CTOD search database thru automated scripts. This importing of data will be done whenever the data is developed in excel.*

- ✓ ***Data developed in curation tool:*** *If data developed in curation tool then that data will be migrated to CTOD search database using database scripts.*

7 BACKUP & DATA RECOVERY REQUIREMENTS

Data backup will be taken regularly on periodic intervals as mentioned below. There will be automation system to take the backups.

- ✓ *Daily*
- ✓ *Weekly*
- ✓ *Monthly*

8 SPECIAL USER REQUIREMENTS

8.1 Security

- ✓ *User Authentication: User authentication will be done in application level.*
- ✓ *Access will be restricted as per the role assigned to user when creating new user.*

8.2 Reliability

No Reliability requirements are defined

8.3   Audit Trial

No Audit Trial Requirements are defined.

8.4   User Training

Training will be provided thru Web-Ex for a team of 8 to 10 members, and will be done by GVK SME team.

8.5   User Manual & Help

User manual will be prepared as per the application flow.

9   RISK

Below are few risks identified

Sl.no	Risk	Proba bility	Impact	Mitigation	Comments
1	Requirements still in progress	TBD	TBD	TBD	
2	Deadline already fixed – refer BMGF SOW	TBD	TBD	TBD	
3	Staffing of Resources to execute the project with JEE6 skills	TBD	TBD	TBD	
4	Initial scope was for only Search interface, now Curation is also being suggested by Product Owner- Requirements yet to start for the same.	TBD	TBD	TBD	
5	Late changes in requirements	TBD	TBD	TBD	

*

10   DOCUMENT REFERENCES

Referred to the following Documents for Requirements

- ✓ CTOD application v0.1.pdf
- ✓ Queries_CTOD_0.4.xlsx`
- ✓ ClinPharm Data models comparision 27Nov12.xlsx
- ✓ Search Page model_v2.0.xlsx
- ✓ Customized Template.xlsx
- ✓ WO 1 - Signature Pending.pdf

11   OPEN ISSUES

NA

12   REVIEW AND SIGN OFF