

Introduction:




- This application has been developed by UWA students as part of their CITS3200 Professional computing course. Thank you very much for using our application.
- The application has been developed on Visual Basic for Applications using a number of code snippets sourced from StackOverflow and other forums to augment user experience. Refer to code comments for purpose of each code module and links to reference code snippets in use.
- The application IP falls under Creative Commons (open source) <https://creativecommons.org.au/>
- The table of contents has been hyperlinked for ease of use. Click the description to be redirected to the appropriate section. **PLEASE NOTE THE USER GUIDE ISN'T DESIGNED TO BE PRINTED!** Use "Return to TOC" link found along the first column to redirect back to contents as needed.
- Throughout the guide there will be a number of symbols in use:
 -  Context adding content sourced externally
 -  Important information users need to be aware of
 -  Opportunities for error present; request users use extra caution in flagged activities

TABLE OF CONTENTS

	Contains
1 Application Environment required	 
2 Application Architecture	
2.1 Making of bulk changes	
2.2 Security Features provided by the application	 
2.3 Automatic Back-up option	 
2.4 Overview of report generation	 
2.5 Changes to Overview Report and Register worksheet	
3 Using Data-Entry User forms	
3.1 Standard Method for Accessing Data Entry Form	
3.2 Working with the Navigation / Initial form	
3.2.01 Register Navigation Buttons	
3.2.02 Applying Form Options	
3.2.02.1 Filter Only Pre-commencement	
3.2.02.2 Skip to Incomplete Entry	
3.2.02.3 Save via Navigation	
3.2.03 Changing Study Status	 
3.2.04 Reverting back to Default Values	
3.2.05 Searching for a Study Record	 
3.2.06 Creating a New Study Record	 
3.2.07 Delete a Study Record	
3.2.07.1 Permanent Record Deletion	 
3.2.07.2 Undo soft deletion of a record	
3.2.08 View Reminders and Activity Completion Status	
3.2.09 View Change Log	
3.2.10 Editing Study Records	 
3.3 Working with Activity Data Entry Forms	
3.3.01 Common Elements of Activity Data Entry Forms	 
3.3.02 Date Validation	 
3.3.03 Study Details Form	
3.3.04 CDA Form	
3.3.05 Feasibility	
3.3.06 Site Selection Form	
3.3.07 Recruitment Plan Form	
3.3.08 Ethics Review Form	
3.3.09 Governance Review Form	
3.3.10 Indemnity Review Form	
3.3.11 Budget Review Form	
3.3.12 CTRA Form	
3.3.13 Financial Disclosure Form	
3.3.14 SIV Form	
4 Overview Report	 
4.1 Special Circumstances Covered	
4.2 Colours Applied to the Report	
4.3 Using Excel Table filters in Overview Report or Register Table	
4.4 Quick Access to Study Records from Overview Report	 

1 Application Environment Needed

- The application is designed to work with MS Excel version 2010 or later. No additional plugins are needed to run the application.
 - Only standard MS Excel reference libraries have been invoked to reduce installation burden on the end user and enable the application to run on both Windows and Macintosh PCs.
 - The application will not work properly when stored in SharePoint or other cloud storage system due to restrictions imposed in those systems for using macro enabled content.
 - The application at minimum will cater for display resolution with 100% scaling of 1280 x 800 to be able to view data entry userforms in their entirety. Therefore use in mobiles or tablets is not advised.
- 🔗 To run the application, it is necessary to "Enable use of Macros". A good guide to applying the settings is found via link below:
<https://www.ablebits.com/office-addins-blog/2020/03/11/enable-disable-macros-excel/>

2 Application Architecture

- The application has been developed using Visual Basic for Applications and MS Excel formulae syntax. In addition, custom MS Excel userforms have been developed to support data entry.
- The application comprised of three interlinked parts:
 - Register table located in the "Register" worksheet that stores all entered data and other information needed for the application functionalities - Pseudo-database
 - Set of userforms to enable users to navigate the register table and make sure of functionalities developed to enhance interaction with the register table
 - VBA macro driven overview report that summarizes all data in the register table for easy review of study start-ups
- The user forms have been developed not only to enhance the data entry process but also augment the user experience through real time data validation, having a flow that matches the pre-commencement activity stages - displaying only pertinent information for an activity record, enables storing of reminders.

2.1 Making of Bulk Changes

- Users are able to make bulk changes to the register by directly editing the register table. However, doing so will bypass version controls and activity completion tracking in the application. Activity completion tracking can be reinitiated by navigating to the record after searching for it and editing the record.
- Standard Microsoft Undo functionality will be available in case you wish to revert any bulk changes made. Worst case refer to [section 2.3](#) below regarding where backup files could be accessed.

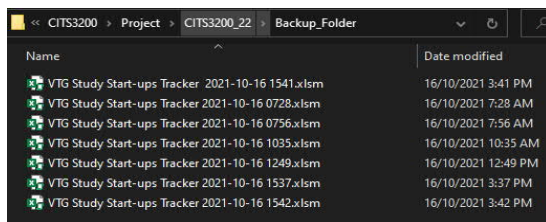
2.2 Security Features

- No security features have been incorporated into the application due to its use case for private use within a single department of the organisation and the occasional need to make bulk changes to studies. Thus, there is a risk of overwriting or losing data. Malicious access to the application will be managed via internal network cybersecurity protocols.
- No passwords have been incorporated into the application. The only protected worksheet is the "User Guide" - no password has been used. Implementing password protection in the "Overview Report" and "Register" worksheets will stop the application from writing new data.

- 🔗 If in future password protection becomes necessary it is recommended to use document level protection. Refer to guide found via link below:
<https://support.microsoft.com/en-us/office/protect-an-excel-file-7359d4ae-7213-4ac2-b058-f75e9311b599>

2.3 Automatic Back-up

- To better support reverting to earlier versions, the application has code applied to save a duplicate copy of the file each time it is saved. The copies are stored in a "Backup_Folder" that is created in the same file directory as the original file. Up to 7 recent saved versions of the excel file will be maintained via this approach. It is assumed users will have access to write into folders where they are storing files.
- Backup files will be named as "VTG Study Start-ups Tracker <Timestamp>" to ensure each file name is unique



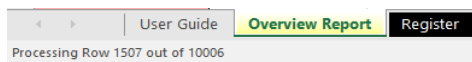
Name	Date modified
VTG Study Start-ups Tracker 2021-10-16 1541.xlsm	16/10/2021 3:41 PM
VTG Study Start-ups Tracker 2021-10-16 0728.xlsm	16/10/2021 7:28 AM
VTG Study Start-ups Tracker 2021-10-16 0756.xlsm	16/10/2021 7:56 AM
VTG Study Start-ups Tracker 2021-10-16 1035.xlsm	16/10/2021 10:35 AM
VTG Study Start-ups Tracker 2021-10-16 1249.xlsm	16/10/2021 12:49 PM
VTG Study Start-ups Tracker 2021-10-16 1537.xlsm	16/10/2021 3:37 PM
VTG Study Start-ups Tracker 2021-10-16 1542.xlsm	16/10/2021 3:42 PM

- Backup file saving will fail when the user lacks the permission to create a folder or add write to a folder in which the file is stored. Similarly, the backup save will fail if the file is stored on SharePoint or other cloud file repository due to inability to create a folder and store a backup file programmatically. In such scenarios where backup file fails to save, a pop-up will be displayed at the centre of the excel application window declaring the backup failed. It is only possible to do backup saves when the file is stored in a local or network (intranet) directory.

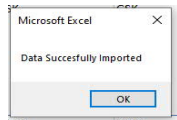


2.4 Overview report generation

- Due to the processing power required by Excel to summarize register data into an overview report, it is requested users be patient. Testing has shown delays of up to 1 min per 1000 study records could be incurred. During the time the report is being processed it is recommended to refrain from interacting with excel until a pop-up informing data has been imported activates.
- To offer users a guide of progress, the application status bar at the bottom left hand corner will display progress of processing. Interrupting the process may in the worst case cause excel to stall.

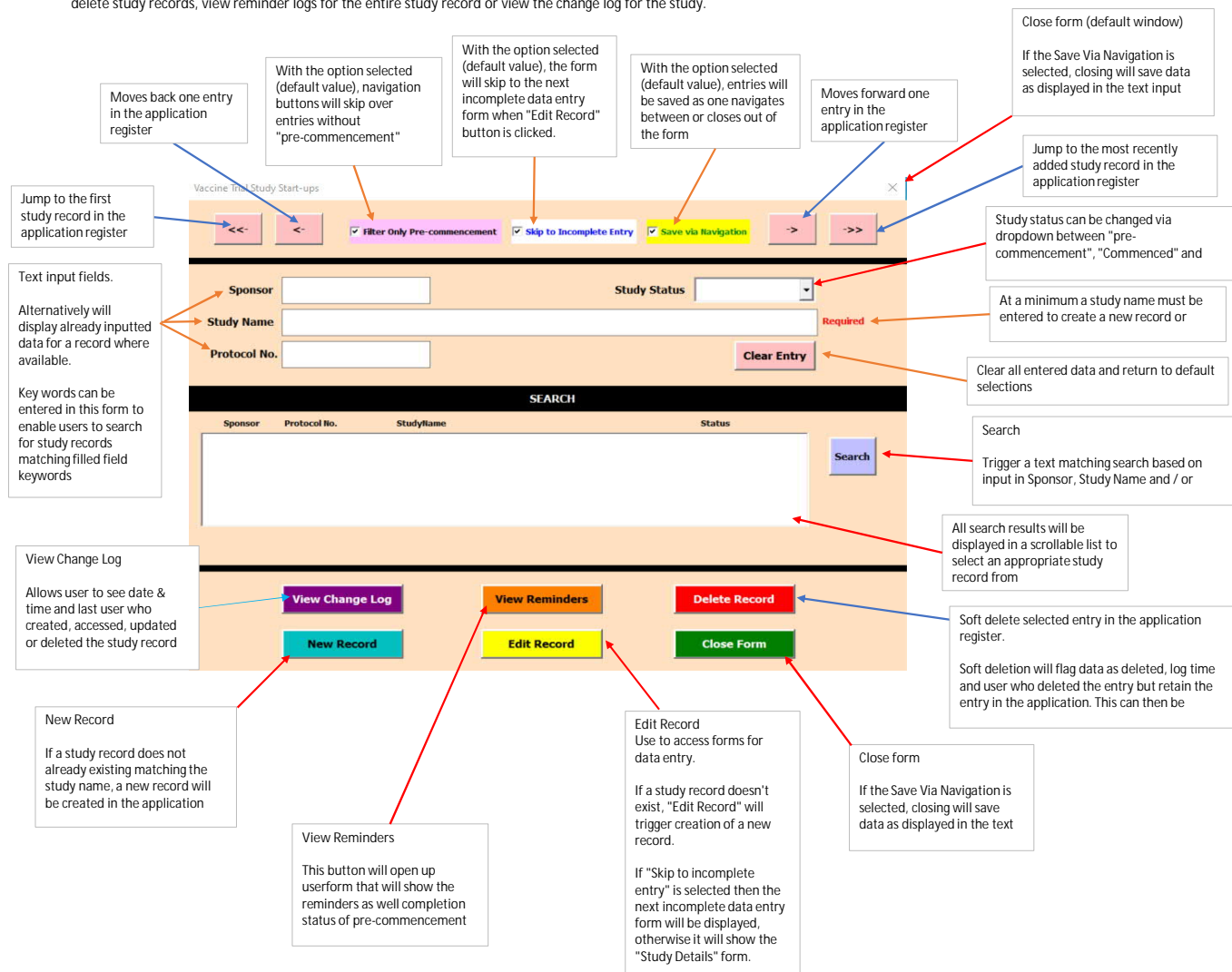


- Once all processing has been completed, all cells of the report coloured as required and data copied across, a pop-up will open at the centre of the excel application window.



2.5 Changes to Overview Report and Register worksheet tables

- It is strongly advised against editing the structure and positioning of tables located within these worksheets. Code in use in the application is associated with positions and column references of the tables displayed, thus changes may break the application functionality.



3.2.01 Register Navigation Buttons

- The form has four primary navigation options to enable users to scroll up or down the application register records.



Jump to the first record in the application register (oldest)



Jump to the last record in the application register (most recent)



Navigate to the previous record. If this is applied from the first (oldest) record, the button will cycle back to the last (most recent) record.



Navigate to the previous record. If this is applied from the last (most recent) record, the button will cycle back to the first (oldest) record.

3.2.02 Applying Form Options

- Three toggles are available to the user to alter the behaviour of the form. All toggles are selected by default when first loading a form or clearing a form via clear button:



3.2.01.1 Filter Only Pre-commencement

- When selected, a filter is implemented on form navigation so that records that do not have a pre-commencement study status (Refer to [Section 3.2.03](#)) are skipped.

Behaviour changes:



Jump to the first record in the application register with "Pre-commencement" study status



Jump to the last record in the application register with "Pre-commencement" study status



Navigate to the previous record with "Pre-commencement" study status



Navigate to the next record with "Pre-commencement" study status

3.2.01.2 Skip to Incomplete Entry

- When selected, the form will redirect the user to the next data entry form that hasn't been completed yet saving some time. Without the option selected, the first form shown on following the Navigation/Initial form will always be the "Study Details" form.
- Pre-commencement process activities are deemed complete if all input fields associated with them are filled and all date fields are filled with valid dates.

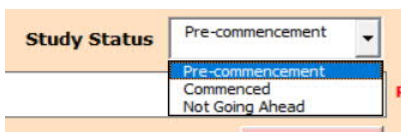
3.2.01.3 Save via Navigation

- When selected, the form will save all text field data when navigating between forms or closing out of the form.
- When "Save via Navigation" is active, there will be a slight lag introduced when shifting between forms due to data being saved when forms transition.
- Users cannot undo changes made once a form is navigated out of or closed!
- De-selecting the form will change the displayed text to be "Save via Button". Once deselected, data is only saved if "Apply Changes" button is clicked in associated activity data entry forms.



3.2.03 Changing Study Status

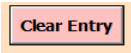
- Typically users are able to change the status of a study record between: "pre-commencement", "commenced" and "not going ahead".



- The study status toggle also plays a pivotal role in reverting soft deletion of records (Refer to [Section 3.2.07](#)).
- Completed study records with "Pre-commencement" study status will automatically be changed to "Commenced" when the record is viewed after SIV data has passed.
- To make it more obvious study status is different, a different font colour is used depending on the status as follows:
 - Pre-commencement
 - Commenced
 - Not Going Ahead
 - DELETED
- Records where the study status is pre-filled by the application are ones that the application has already found in the register and thus identified. These records can then be edited or deleted by the application. Moreover, only such records can have their reminder and change logs viewed by user. For the application to identify records, either a search has to be performed (refer to [Section 3.2.05](#)) or the record is navigated to via form navigation buttons (refer to [Section 3.2.01](#)).

3.2.04 Reverting back to Default Values

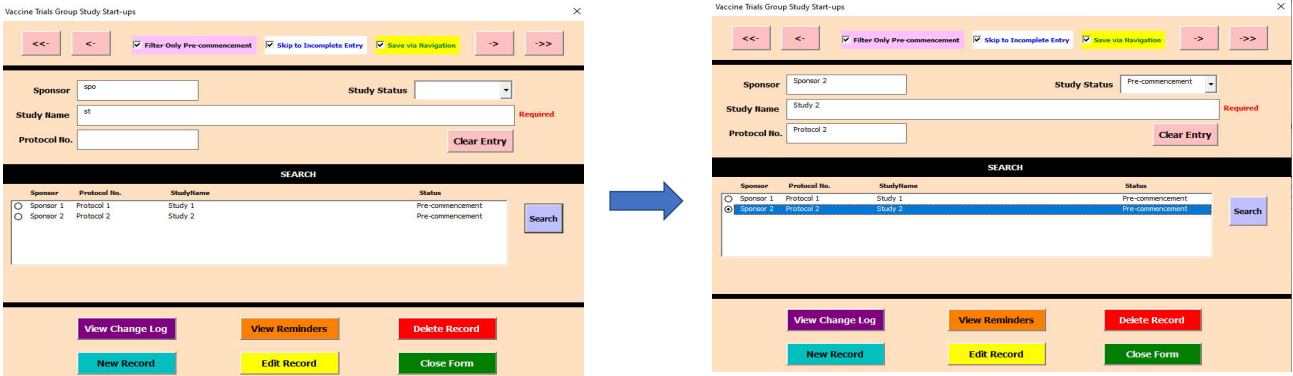
- The "Clear Entry" button provides an easy way for users to clear all text input fields and revert to default form options.



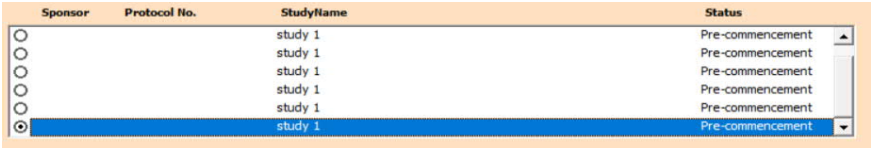
- Clearing will re-activate the following form options (refer to [Section 3.2.02](#) above):
 - ✓ Filter Only Pre-commencement
 - ✓ Skip to Incomplete Entry
 - ✓ Save via Navigation

3.2.05 Searching for a Study Record

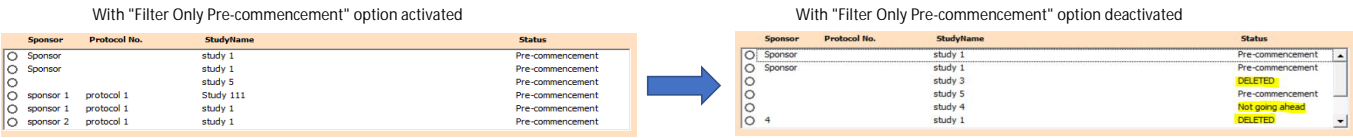
- The application provides a textual search that enables keyword matching across three fields: Sponsor, Study Name and Protocol Number.
- Textual search provides the simplest means for users to let the application know what record to pull from the register without having to cycle through records. Records the application has already identified will have Study Status pre-populated (refer to [Section 3.2.03](#)).
- By entering keywords in the Sponsor, Study Name and Protocol No. text input fields and clicking on the search button, records matching the search criteria will be displayed. Users can then select a record to load from the search results by clicking on it within the list box. This will cause the selected record to be highlighted.



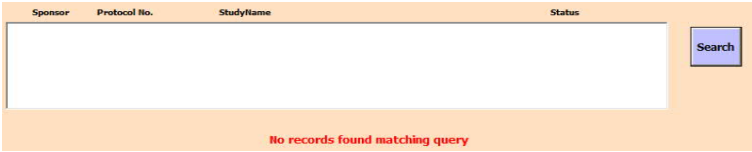
- A vertical scroll bar will appear if a search matches exceed what can be displayed in the list box. By default the most recent matching record will be shown at the bottom. To scroll the list of matching records, users can click the top and bottom arrow buttons in the vertical scroll bar with a mouse or trackbar. Alternatively, users can click on the list box to activate a record and navigate up and down using arrow keys on the keyboard.



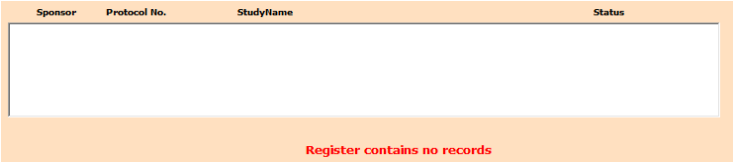
- ▲ ■ Search is also affected by option of "Filter Only Pre-commencement". Therefore, with this option selected only "pre-commencement" status entries will be retrieved by search.



- If search fails to locate any matching records then the following message is shown below the search list box.



- Attempting search on an empty register will cause the following error message to be displayed below the search list box.



3.2.06 Creating a New Study Record

- In order to create a new record, at minimum a study name has to be entered in the Navigation / Initial form.
- The application considers a study record to be new if it has a unique combination of study name, protocol number and sponsor name that doesn't exist in the register already.
- A genuine new record can then be created by clicking the "New Record" button will redirect the user to the data entry form with the new record details populated (Refer to [Section 3.3](#))



- When a new record is created, the change log (refer to [Section 3.2.09](#)) will store the timestamp when it was created and the username of the person who created it.

	Time Stamp	Change Agent
Created On	16-Oct-2021 05:21:09 PM	Valued Customer

- Attempting to create a record without a study name will result in the message below to be displayed under the search list box.

Sponsor	Protocol No.	StudyName	Status
Please enter a study name to create a new record			

- Attempting to create another study with the same study name, protocol number and sponsor as a pre-existing one will also cause the application to run its textual search (refer to [Section 3.2.05](#)) and a message will be displayed prompting further user action.
- If only a single record matching the sponsor, study name and protocol number combination is found then the corresponding entry will be loaded into the form and user prompted to use edit functionality (refer to [Section 3.2.10](#)) instead.

Vaccine Trials Group Study Start-ups

<<< < <<< Filter Only Pre-commencement Skip to Incomplete Entry Save via Navigation >>> >>

Sponsor

Study Status Pre-commencement

Study Name study 5 Required

Protocol No.

Clear Entry

SEARCH

Sponsor	Protocol No.	StudyName	Status
		study 5	Pre-commencement

Study already exists, consider edit instead

View Change Log

View Reminders

Delete Record

New Record

Edit Record

Close Form

- If multiple records are found by the textual search, the user will be prompted to select a record out of the list and proceed to use edit functionality instead.

Sponsor	Protocol No.	StudyName	Status
<input type="radio"/>		study 1	Pre-commencement
<input type="radio"/>		study 1	Pre-commencement
<input type="radio"/>		study 1	Pre-commencement
<input type="radio"/>		study 1	Pre-commencement
<input type="radio"/>		study 1	Pre-commencement
<input type="radio"/>		study 1	Pre-commencement

Study already exists, select from search list and consider edit instead

View Change Log

View Reminders

Delete Record

New Record

Edit Record

Close Form

3.2.07 Delete a Study Record

- Clicking the delete button will then trigger a pop-up message to appear at the centre of the excel application. This does not necessarily correspond to the centre of the form. Clicking OK will trigger soft deletion.



- To soft delete a record, click the "Delete Record" first ensure the form has identified the record to be deleted either via search or through the navigation toggles at the top (refer to [Section 3.2.03](#)). Attempting to delete an entry without a record identified by the application will result in the following message prompt to be displayed below the search list box.

Sponsor	Protocol No.	StudyName	Status

Need study entry identified (via search or navigation) to be able to delete it

- When a record is soft deleted, the following changes are applied:
 - The study status of the record is changed to "DELETED"

Study Status DELETED

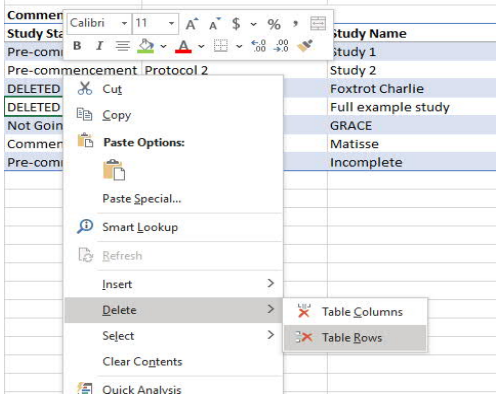
- The change log will display the timestamp and user name of individual that deleted the record

Change Log		
	Time Stamp	Change Agent
Created On	13-Sep-2021 09:09:52 AM	Valued Customer
Deleted On	14-Oct-2021 11:09:47 PM	Valued Customer
Last Accessed	14-Oct-2021 11:09:09 PM	Valued Customer

- Deleted records are filtered out of navigation when "Filter Only Pre-commencement" option has been selected.
- Deleted items will not appear in the "Overview Report"

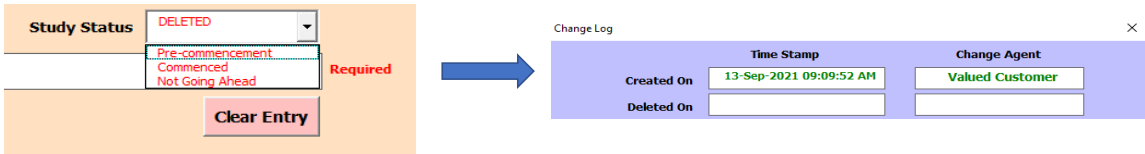
3.2.07.1 Permanent Record Deletion

- To **Permanently** delete a record from the register, you would have to locate the record row in the register and delete the row from the table. An option for doing this is to right click a cell in the table row to be deleted and selected delete Table Rows as shown.



3.2.07.2 Undo soft deletion of a record

- In the Navigation or initial form, ensure "Filter Pre-commencement Only" is deactivated.
- Search (refer to [Section 3.2.05](#)) or navigate to the record (refer to [Section 3.2.01](#)) you wish to undo deletion for.
- Change the study status (refer to [Section 3.2.03](#)) of the record from "DELETED" to any other option in the dropdown. This will remove the deletion timestamp in the change log and thus the record accessible to the overview report.



Sponsor	Protocol No.	StudyName	Status
<p>Need study entry identified (via search or navigation) to view Reminder Log</p>			

3.2.09 View Change Log

- The form will show time stamps associated with study record creation, deletion and access as well as the username associated with the MS Office installation.
- Because corporate profiles are tied to individuals, the name of the person applying the change to the register will be displayed.
- Changes made in this form are not saved. However, the information will be updated each time the form is activated (deselected and reselected).

Change Log

	Time Stamp	Change Agent
Created On	13-Sep-2021 09:09:52 AM	Valued Customer
Deleted On		
Last Accessed	14-Oct-2021 11:05:02 PM	Valued Customer

LAST CHANGED

Study Details	14-Oct-2021 04:02:54 PM	Windows
CDA	08-Oct-2021 10:09:40 AM	Valued Customer
Feasibility	08-Oct-2021 09:20:33 AM	Valued Customer
Site Selection	08-Oct-2021 09:20:36 AM	Valued Customer
Recruitment	08-Oct-2021 09:20:38 AM	Valued Customer
Ethics Review	09-Oct-2021 05:00:39 AM	Valued Customer
Governance Review	08-Oct-2021 09:20:52 AM	Valued Customer
Indemnity Review	08-Oct-2021 09:20:55 AM	Valued Customer
Budget Review	08-Oct-2021 09:21:06 AM	Valued Customer
CTRA	08-Oct-2021 09:21:01 AM	Valued Customer
Financial Disclosure	08-Oct-2021 09:21:09 AM	Valued Customer
STV	08-Oct-2021 09:21:15 AM	Valued Customer

Close Log

- Attempting to open the Change Log without having navigated to or searched for a study of interest will cause the form to display the message below.

SponsorProtocol No.StudyNameStatus

Need study entry identified (via search or navigation) to view Change Log

3.2.10 Editing Study Records

- For best results, edit records that have already been identified by the application (refer to [Section 3.2.03](#)) - this can be done by using search or navigation buttons to locate the record of interest.
- Clicking the "Edit Record" will initiate a search in the register for the pairing of study name, sponsor and protocol number. If a matching record is found in the register, the application will progress to the pre-commencement activity data entry forms (refer to [Section 3.3](#)).



- Prior to loading of pre-commencement activity data entry forms, as part of the edit process, the application will then evaluate the completion status of all entries in the record. This helps the application identify the first incomplete activity (as per order of pre-commencement study start-up work flow) and hence where next to redirect the user to if "Edit Record" is successful.
- If the option "Skip to Incomplete Entry" is active (refer to [Section 3.2.02.2](#)), when "Edit Record" is successful, it will redirect to the data entry form of the last incomplete pre-commencement activity. Otherwise, the first data entry form opened will be associated with entering further "Study Details (refer to [Section 3.3.03](#))".
- As a minimum, to edit an entry the study name must be entered otherwise a message prompting this will be displayed below the search list box.

Sponsor	Protocol No.	StudyName	Status

Need atleast study name entered to edit study record

- When attempting to Edit Records for study names that do not exist in the register, a message will appear prompting the user to use search in case part of the test was missed or to create a new record as the combination of study name, sponsor and protocol number as entered cannot be found in the application register.

Sponsor	Protocol No.	StudyName	Status

Record not found in the register, consider searching register or creating new record

- ▲ ■ If the user attempts to edit a record that has not been identified by the application, the search functionality (refer to [Section 3.2.05](#)) will be triggered.
 - If a single match is found via the search, then the application will progress with editing the record found
 - If multiple matches are found, the user is prompted to select a matching record and re-attempt "Edit Record"

Sponsor	Protocol No.	StudyName	Status
<input type="radio"/> Sponsor		study 1	Pre-commencement
<input type="radio"/> Sponsor		study 1	Pre-commencement
<input type="radio"/> sponsor 1	protocol 1	study 1	Pre-commencement
<input type="radio"/> sponsor 2	protocol 1	study 1	Pre-commencement

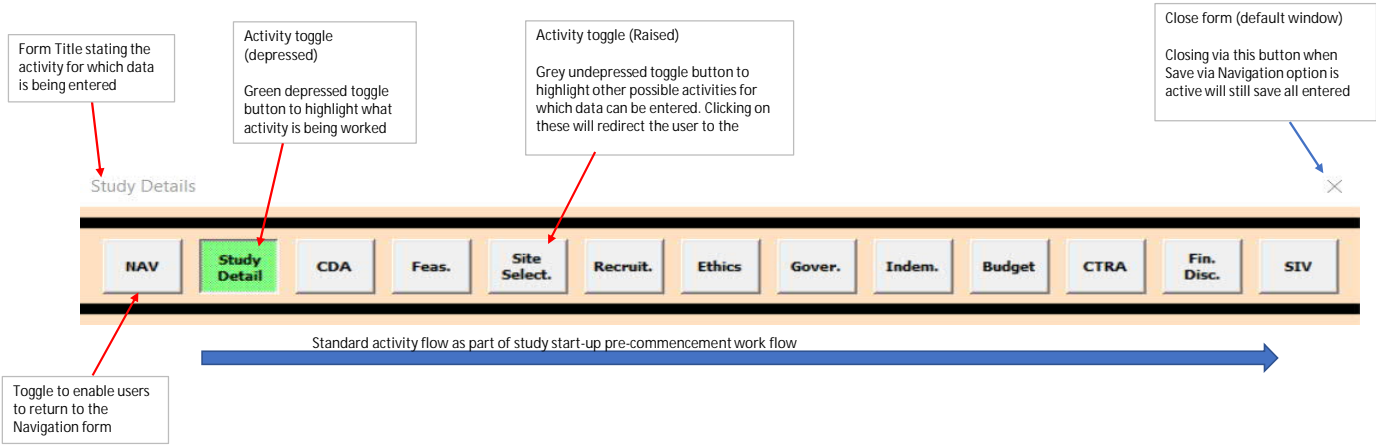
Select record from search list and re-attempt edit

3.3 Working with Activity Data Entry Forms

- After a New Record (refer to Section 3.2.06) or Edit Record is successful (refer to Section 3.2.10) are successful, the user will be redirect to the activity data entry forms.
- All activity data entry forms are designed to only collect data for a particular activity within the vaccine study start-up pre-commencement work flow.

3.3.01 Common Elements of Activity Data Entry Forms

- Unlike the Navigation form, all activity data elements share common header and footer sections.
- The common header section contains:
 - Form title matching the activity for which the data is being entered
 - A Navigation bar contain toggle buttons to redirect users to other forms that form part of the application. Only grey raised buttons will redirect the user.
 - The active activity is denoted by a depressed green coloured toggle button. Clicking on it will not redirect the user.
 - Every activity has its own form and thus activity toggle button. In addition, the Navigation form has a toggle button so users can return back to it as required and return back via "Edit Record" (refer to Section 3.2.10).
 - Standard windows close button on the top right hand corner to exit the userform.



- Study Name field is found below the navigation bar in all activity data entry forms except the "Study Details" form. This helps users recall what study they are entering data for if required.

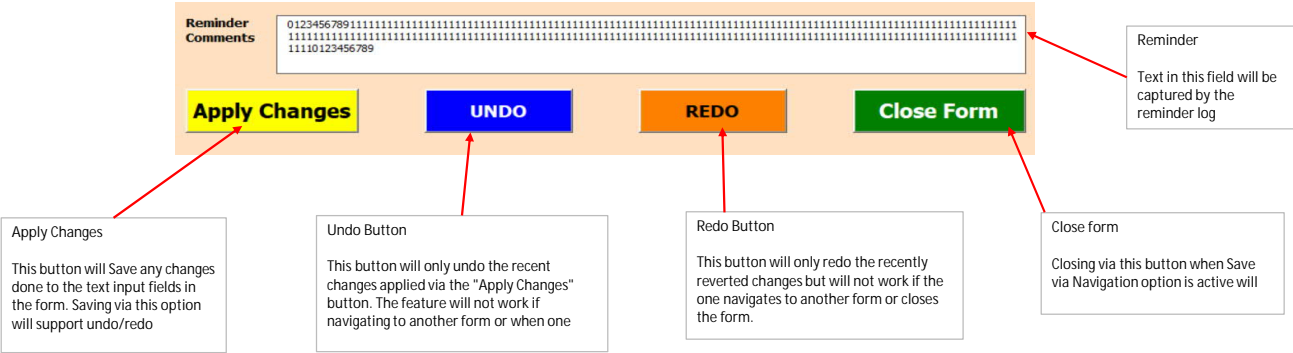
- ▲ ■ All activity data entry forms also contain the option to activate or deactivate the "Save via Navigation" option (refer to Section 3.2.02.3). Changes made to this toggle in one form will transfer over to other forms. The option is always located below the SIV toggle button as shown.



- With "Save via Navigation" active the update log within the "Change Log" (refer to Section 3.2.09) will update with each transition of the user form. With option deactivated, the update log will only be changed when "Apply changes" button in each activity data entry form is clicked.

LAST CHANGED		
Study Details	14-Oct-2021 04:02:54 PM	Windows
CDA	08-Oct-2021 10:09:40 AM	Valued Customer
Feasibility	08-Oct-2021 09:20:33 AM	Valued Customer
Site Selection	08-Oct-2021 09:20:36 AM	Valued Customer
Recruitment	08-Oct-2021 09:20:38 AM	Valued Customer
Ethics Review	09-Oct-2021 05:00:39 AM	Valued Customer
Governance Review	08-Oct-2021 09:20:52 AM	Valued Customer
Indemnity Review	08-Oct-2021 09:20:55 AM	Valued Customer
Budget Review	08-Oct-2021 09:21:06 AM	Valued Customer
CTRA	08-Oct-2021 09:21:01 AM	Valued Customer
Financial Disclosure	08-Oct-2021 09:21:09 AM	Valued Customer
SIV	08-Oct-2021 09:21:15 AM	Valued Customer

- The common footer section contains:
 - Reminder Text input field to add activity specific reminder details. Data entered in this field is viewable in the "Reminder Log" (refer to [Section 3.2.08](#)).
 - Apply Changes Button to manually save any changes made to the data entered. Moreover, using this option retains memory of what was loaded enabling undo/redo to function.
 - Undo Button will revert changes to those prior to apply settings was clicked. Consequently, you cannot undo after navigating out of a form and returning back to it.
 - Redo Button will return changes applied when apply setting was clicked.



- Whenever data is saved by the activity data entry form, the completion status of the form is also re-evaluated. This aids with future running of "Overview Report" and makes it easier for the application to determine the first incomplete section to be completed so the application can skip to it if option "Skip to Incomplete Entry" is active.

3.3.02 Date Validation

- All dates entered in the application date entry fields are expected to be in DD-MMM-YYYY. Use of this format will result in least errors.
- All date fields have a validation applied at point of changing focus away from the text field. Validation informs the user when data entered is not a valid date or fails to follow chronological order. The warning message will appear to the right of the text field as shown.

The screenshot shows a form with five date entry fields. The first field, 'Date CDA Received from Sponsor', contains '10-Jan-2020'. The second field, 'Date CDA Sent to Contracts', contains 'A' and has a red error message: 'Please enter a valid date: DD-MMM-YYYY'. The third field, 'Date CDA Received from Contracts', contains '02-Feb-2020'. The fourth field, 'Date CDA Sent to Sponsor', contains '01-Jan-2019' and has a red error message: 'Date entered earlier than date received from Contracts'. The fifth field, 'Date CDA Finalised', contains '31-Mar-2020'.

If a valid date is detected it will automatically be converted to DD-MMM-YYYY format

- If dates are not entered in the desired format, the application will make its best attempt at translating date data entered into DD-MMM-YYYY where possible. Formats the application can handle and ones to avoid include:

Date Format Entered	Use Recommendation	Example Input	Conversion outcome
D-M-YY, D/M/YY	OK to use	1/9/11	01-Sep-2011
D-M-YYYY, D/M/YYYY	OK to use	1/9/2011	01-Sep-2011
DD-MM-YYYY, DD/MM/YYYY	OK to use	01/09/2011	01-Sep-2011
YY-M-D, YY/M/D	REFRAIN	11/9/1	11-Sep-2001
YYYY-M-D, YYYY/M/D	OK to use	2011-9-1	01-Sep-2011
YYYY-MM-DD, YYYY/MM/DD	OK to use	2011-09-01	01-Sep-2011
D-M, D-MM, D-MMM	OK to use	1 Sep	01-Sep-2021
DD-M, DD-MM, DD-MMM	OK to use	01-09	01-Sep-2021
DD st/nd/rd/th MMM YYYY	REFRAIN	01st Sep 2011	01st Sep 2011
M-D-YY, M/D/YY	REFRAIN	9/1/11	09-Nov-2011
M-D-YYYY, M/D/YYYY	REFRAIN	09/01/2011	09-Nov-2011
MM-DD-YYYY, MM/DD/YYYY	REFRAIN	01/09/2011	09-Nov-2011

Overall, the application cannot handle dates with none month name text inside (e.g. 1st, 2nd, 3rd, 4th) as well as dates entered in American format.

- The main details required to be entered in this form are:

- The main detail required to be entered in this form is:

- The main details required to be entered in this form are:

[illegible]

- The main details required to be entered in this form are:

Enter appropriate date
when governance review
is approved

- The main details required to be entered in this form are:

Enter appropriate date
when indemnity review is
initiated

- The main details required to be entered in this form are:

[illegible]

- The main details required to be entered in this form are:

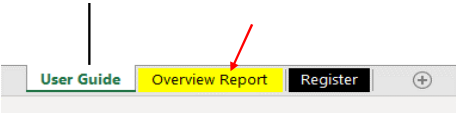
- The main detail required to be entered in this form are:

- The main detail required to be entered in this form are:

[illegible]

4 Overview Report

- The worksheet tabs at the bottom of the excel application can be used to navigate to the "Overview Report" worksheet as by clicking on the Yellow tab.



- The "Overview Report" worksheet has been pre-set to retain a convenient freeze pane view that ensures the section below is always visible.

Vaccine Trials Group Study Start-ups		Data retrieved 10-Oct-2021 10:08 PM	
Completed activity		Import Data into Report	
Incomplete activity			
Open Data Entry Form			
Please do not edit the structure of this table			
Study Status	Date Created	Study Name	Date La
Pre-commencement	13-Sep-2021	Study 1	10-Oct-21
Pre-commencement	13-Sep-2021	Study 2	10-Oct-21

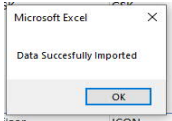
- Two shapes are available to trigger different functionality in the application:



- Performs same functionality as the one located in the Register worksheet tab.
- Clicking the shape will trigger opening of the Navigation/Initial form. Users can utilise the form to read, create, delete or edit records in the application register (refer to [Section 3.1](#))



- Clicking the shape will trigger a sub-routine that will extract out all records that have not been deleted from the register and summarize the data for review. The summary contains all information entered for each activity. Reminders are only included if an activity is deemed incomplete (refer to [Section 3.2.08](#)).
- When data import is successful a pop-up will appear at the centre of the excel application window (refer to [Section 2.5](#)).



Moreover, the timestamp when data was last retrieved will be updated in Cell "C1" of the "Overview Report" sheet.

	A	B	C
1	Vaccine Trials Group Study Start-ups		Data retrieved 16-Oct-2021 09:57 PM

- ⚠ □ The table data is erased each time data is imported to avoid inadvertent duplication of records from multiple runs of the sub-routine. Moreover, all auto-filters applied are removed to ensure duplicates are not created.
- ⚠ □ The imported data is disconnected from the application register. Changes made in the report table will NOT be transferred back into the application register.

4.1 Special Circumstances Covered

- If there are no records in the application register, a message will be displayed in cell C1 of the Register worksheet as shown below.

Vaccine Trials Group Study Start-ups		Register table only has deleted values
Completed activity		Import Data into Report
Incomplete activity		
Open Data Entry Form		

- If all records in the application register are deleted entries, then a message will be displayed in cell C1 of the Register worksheet as shown below.

Vaccine Trials Group Study Start-ups		Register table has no data
Completed activity		Import Data into Report
Incomplete activity		
Open Data Entry Form		

4.2 Colours Applied to the Report

- As described in the report legend, two colours are used to indicate whether an activity is in progress or is complete:

Completed activity	
Incomplete activity	

- Similar colouring is also applied for overall multiorganizational activities as follows:
 - Overall Ethics Reviews = Green if at least 1 of the Ethics Review Board has approved and all fields are filled, with only valid dates (i.e. ones MS Excel can interpret) entered. Summary information contains list of Ethics Review boards that have completed approving the study.

Overall Ethics Approval
CAHS Complete
NMA Complete
WNHS Complete
Others Complete

Light red if none of the Ethics Review boards have provided approval or if a lot of the data required is missing i.e. partially completed forms or dates entered are not valid. Summary information contains list of incomplete forms for review.

Overall Ethics Approval	CAHS Ethics Approval
CAHS Incomplete	Date Submitted = A Date Responded = A Date Resubmitted = A Date Approved = A Reminder: CAHS

- Overall Governance Reviews = Green if at least 1 of the Governance Review Board has approved and all fields are filled, with only valid dates (i.e. ones MS Excel can interpret) entered. Summary information contains list of Governance Review boards that have completed approving the study.

Overall Governance Approval
PCH Complete
TKI Complete

Light red if none of the Governance Review boards have provided approval or if a lot of the data required is missing i.e. partially completed forms or dates entered are not valid. Summary information contains list of incomplete forms for review.

Overall Governance Approval	PCH Governance Approval
PCH Incomplete	Date Submitted = A Date Responded = A Date Approved = A Reminder: PCH

Overall Budget Reviews = Green if at least all Budget Review processes are completed by VTG, TKI and Pharmacy. This requires all Budget review forms to have inputs of valid dates (i.e. ones MS Excel can interpret) entered. Summary information contains list of Budget review boards that have completed approving the study.

Overall Budget Approval	VTG Budget Approval
VTG Complete	Date Finalised = 01-Aug-20
TKI Complete	Date Submitted Finance = 15-Aug-20
Pharmacy Complete	Date Approved = 01-Sep-20

Light red if less than 3 Budget Reviews are completed. Summary information contains list of incomplete forms for review.

Overall Budget Approval	VTG Budget Approval
VTG Incomplete	Date Finalised = A
	Date Submitted Finance = A
	Date Approved = A
	Reminder: VTG

Overall Study Record = The overall study is deemed complete if all of the pre-commencement activities with filled records are evaluated by the application as complete (refer to [Section 3.2.10](#)). In such a scenario, the Study Status cell for the record (1st report column) is coloured green.

Study Status
Pre-commencement

If the overall study is evaluated to be incomplete, the study status cell for the record is coloured light red.

Study Status
Pre-commencement

Study Status Red if some of the sections are incomplete

Study Status	Date Created	Study Name	Date Last Updated	Protocol Number	Sponsor	CRO	Age Range / Reminder	CDA
Pre-commencement	13-Sep-2021	Study 1	15-Oct-2021 01:31			CRO 1	Age 1 Reminder: Reminder to call Person 1	
Pre-commencement	13-Sep-2021	Study 2	15-Oct-2021 01:32	Protocol 2	Sponsor 2		Reminder: Call Mr M to followup on 17th October	Date Recv. Sponsor = 01-Jan-11 Date Sent Contracts = Date Recv. Contracts = Date Sent Sponsor = Date Finalised =
Pre-commencement	13-Sep-2021	Full example study	15-Oct-2021 01:48	PNUM-12343	ABC	CRO	Children ages 1 to 5	Reminder: Confirm date Date Recv. Sponsor = 10-Jan-20 Date Sent Contracts = 01-Mar-20 Date Recv. Contracts = 02-Feb-20 Date Sent Sponsor = 01-Jan-19 Date Finalised = 31-Mar-20
Not Going Ahead	04-Oct-2021	GRACE	15-Oct-2021 01:31	212171	GSK	GSK	pregnant women 18-49 y/o	

Red due to Protocol No. missing

Red due to 4 empty input fields

Study Status Green only if the all filled pre-commencement activity entries are complete

Reminder text shown where available for incomplete sections

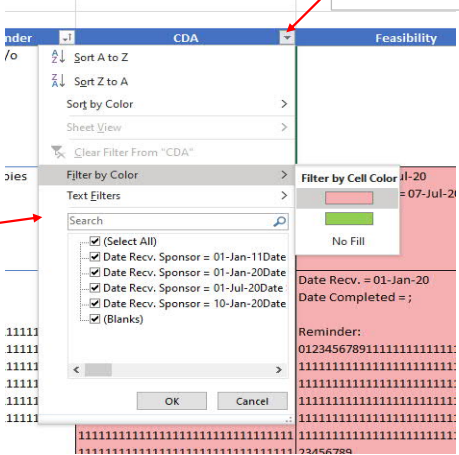
4.3 Using Excel Table filters in Overview Report or Register Table

Both the Overview Report Table and the core Register table are standard MS Excel tables. Consequently, the full suite of MS Excel auto-filtering is available for use. This enables one to filter using wildcards, cell colours, date ranges and keywords.

A decent guide on auto-filter basics can be found at: <https://www.contextures.com/xlautofilter01.html>

Standard excel auto-filter offer numerous options to filter data based on the type of data that is stored in the column e.g. by colour, text, date range, number

Auto-filter can be accessed via dropdowns on each cell of the table header row



4.4 Quick Access to Study Records from Overview Report

- Double clicking anywhere on a row in the overview report table will trigger opening of the data entry navigation form (refer to Section 3.2) with the study record associated with the table row pre-selected already. Users can then simple continue with editing the record as required (refer to Section 3.2.10).
- If a different row of the report table is double clicked after a data entry user form has already loaded, the first form will be closed and the new form loaded with the 2nd record identified instead.

als Group Study Start-ups

Data retrieved 15-Oct-2021 01:49 AM

Status	Date Created	Study Name
Lead	04-Oct-2021	GRACE
	04-Oct-2021	Matisse

Vaccine Trials Group Study Start-ups

<<< < ☒ Filter Only Pre-commencement ☒ Skip to Incomplete Entry ☒ Save via Navigation > >>>

Sponsor

GSK

Study Status

Not Going Ahead

Study Name

GRACE

Protocol No.

212171

Clear Entry

SEARCH

Sponsor

Protocol No.

StudyName

Status

Search

View Change Log

View Reminders

Delete Record

New Record

Edit Record

Close Form

Double clicking cell in Table Row opened up associated record as in the data entry form

