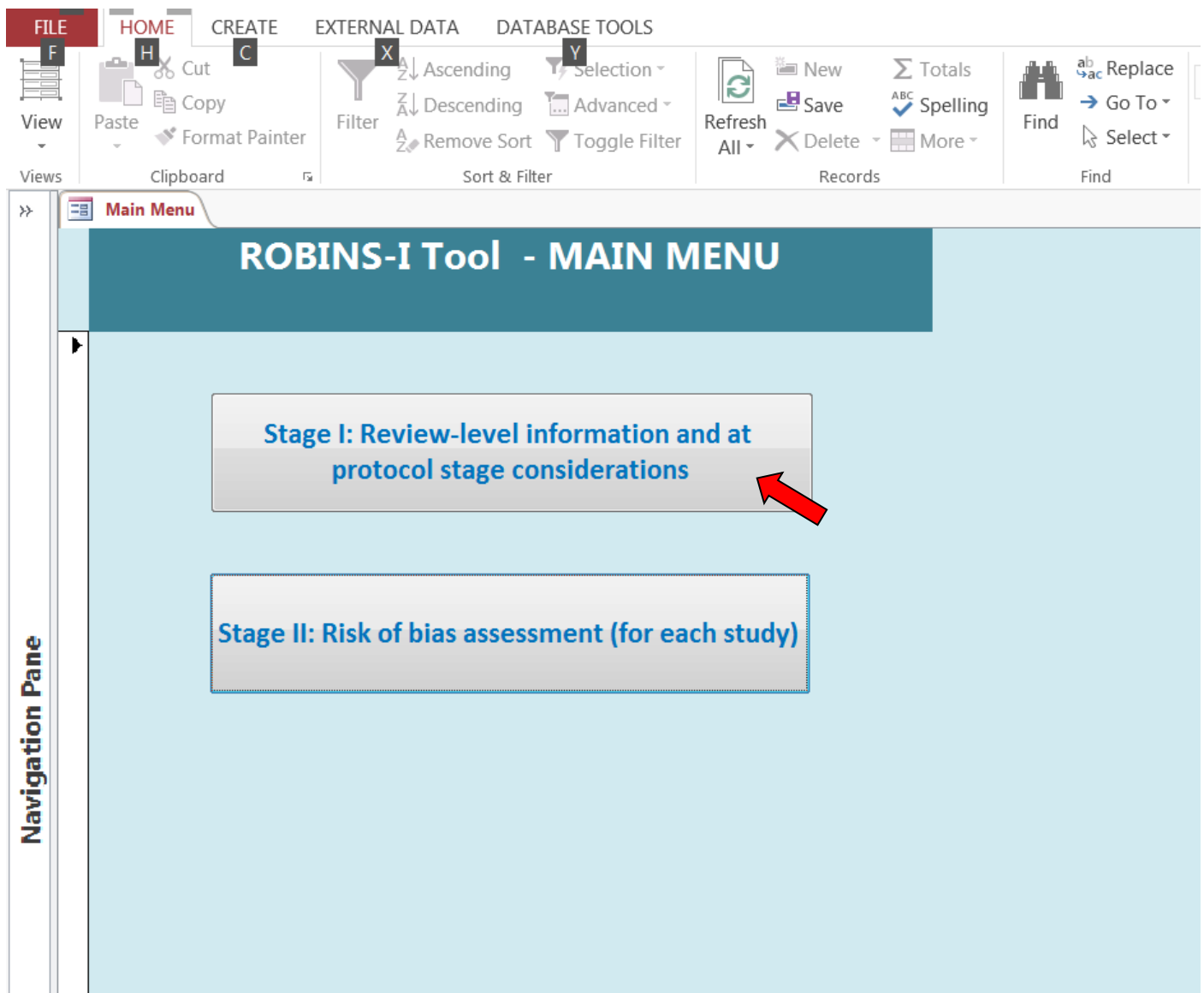


## Brief user guide for the Access database for ROBINS-I

1. Download the Access database to your computer and save it on your computer.

It may not be possible for two assessors to use the same copy of the database at the same time. You may resolve this by creating one copy for each assessor for their sole use (there are other options but they require some Access skills). You could rename each copy according to the sole assessor using it, for example: “ROBINS-I\_Vaccines\_review\_John” and “ROBINS-I\_Vaccines\_review\_Janet”. However, if the two (or more) assessors never intend to use the database simultaneously and a single copy of the database can be accessed by all assessors (at different times), then keeping a single copy of the database may be the preferred option.

2. On opening the database you should see the main menu:



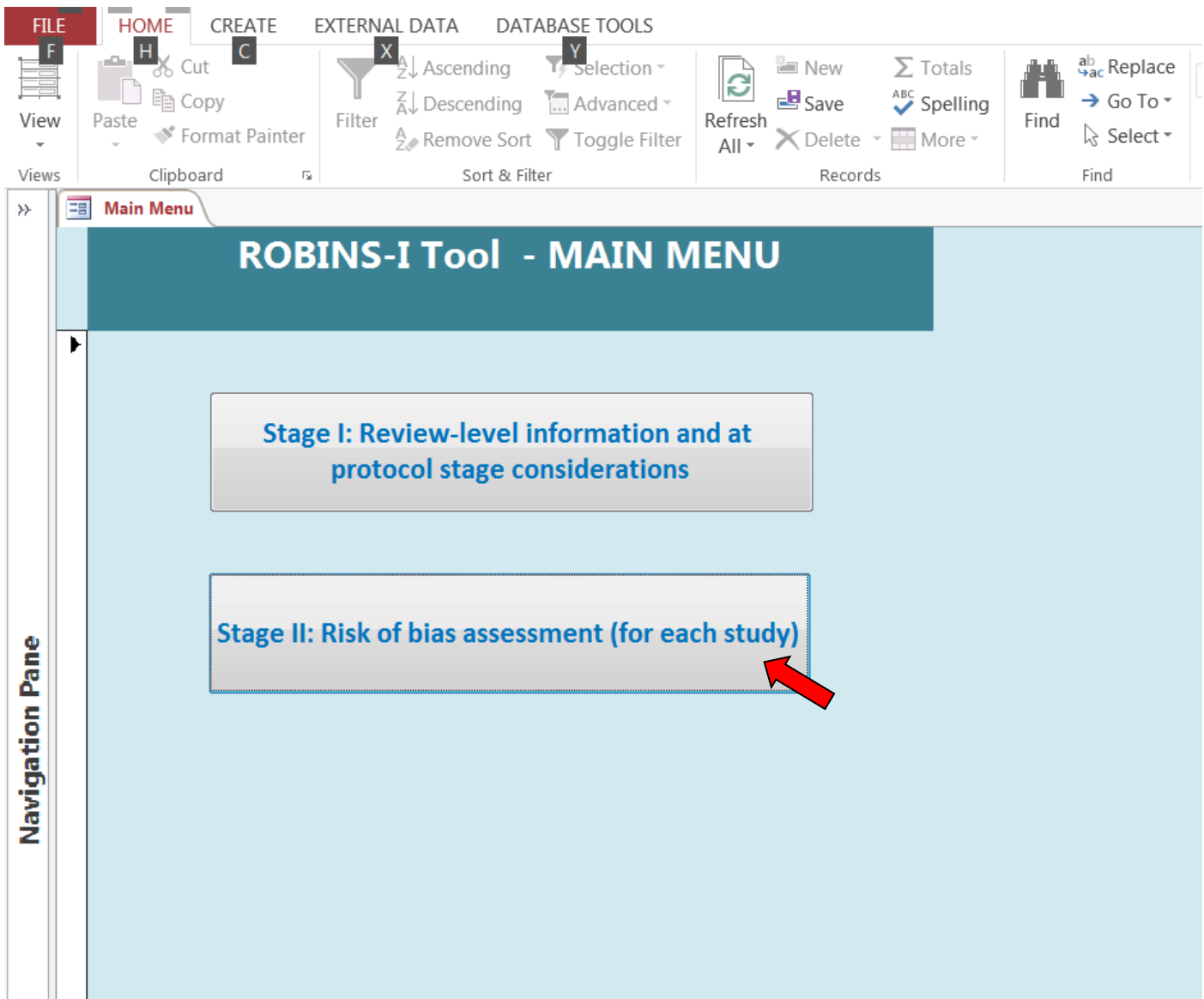
3. Click on “Stage I: Review-level information and protocol-stage considerations”. This will open the Review information form.

4. Enter review information and protocol-level considerations. You will only need to enter review details once for the whole review.

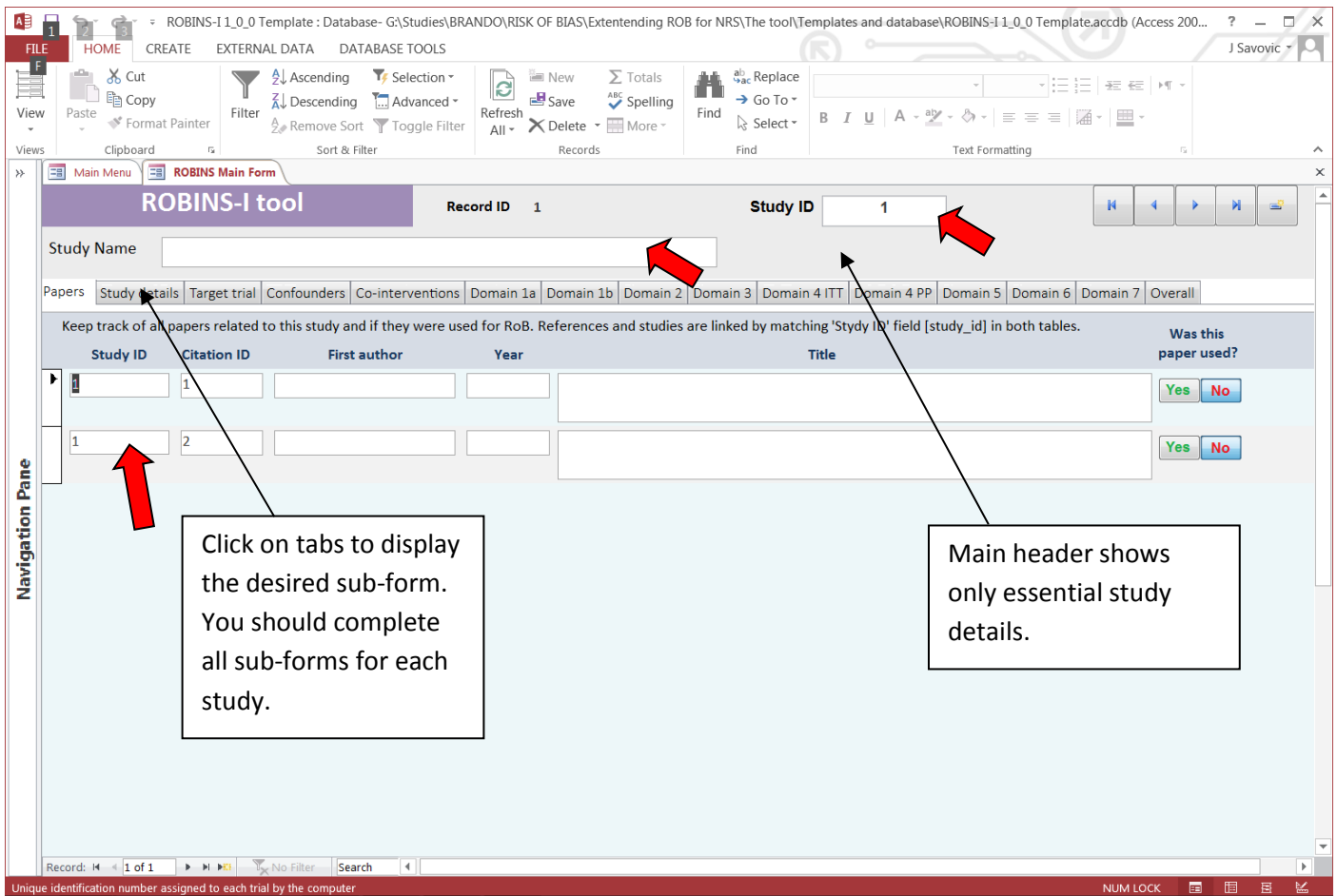
*Please note that all text boxes, except those where you are asked to list confounders and co-interventions are limited to 255 characters, so you will need to be concise. This is the maximum allowed for text fields in Access. The boxes for listing confounders and co-interventions are memo fields which allow a lot of text to be stored, but it is not possible to process this data later.*

The screenshot shows the Microsoft Access interface with the 'ROBINS-I tool (Stage I): At protocol stage' form open. The form has a yellow header bar and a light blue background. It contains several text input fields for 'Review title', 'Authors / assessors', 'Participants', 'Experimental Intervention', 'Comparator', and 'Control'. There are also two larger memo fields for 'List the confounding domains relevant to all or most studies' and 'List co-interventions that could be different between intervention groups and that could impact on outcomes'. A red arrow points to the 'X' button in the top right corner of the form. The Access ribbon and navigation pane are visible.

5. Once you complete this form, close it by clicking on “X” in the top right corner **of the form** (not the “X” of the very top right corner of the entire Access window as this will close the entire database, see the red arrow on the snapshot above for closing the form).
6. When you close the form the Main Menu will become visible again. To start a risk of bias (ROB) assessment for a new study, click on the “Risk of bias assessment (study-level)” button.



7. The ROB form will open. This form has the main header at the top and 15 sub-forms or pages: Papers, Study details, Target trial, Confounders, Co-interventions, Domains 1a and 1b (this domain is split to fit better on the form), Domains 2 and 3, Domain 4 ITT, Domain 4 PP, Domains 5 to 7, and Overall bias.

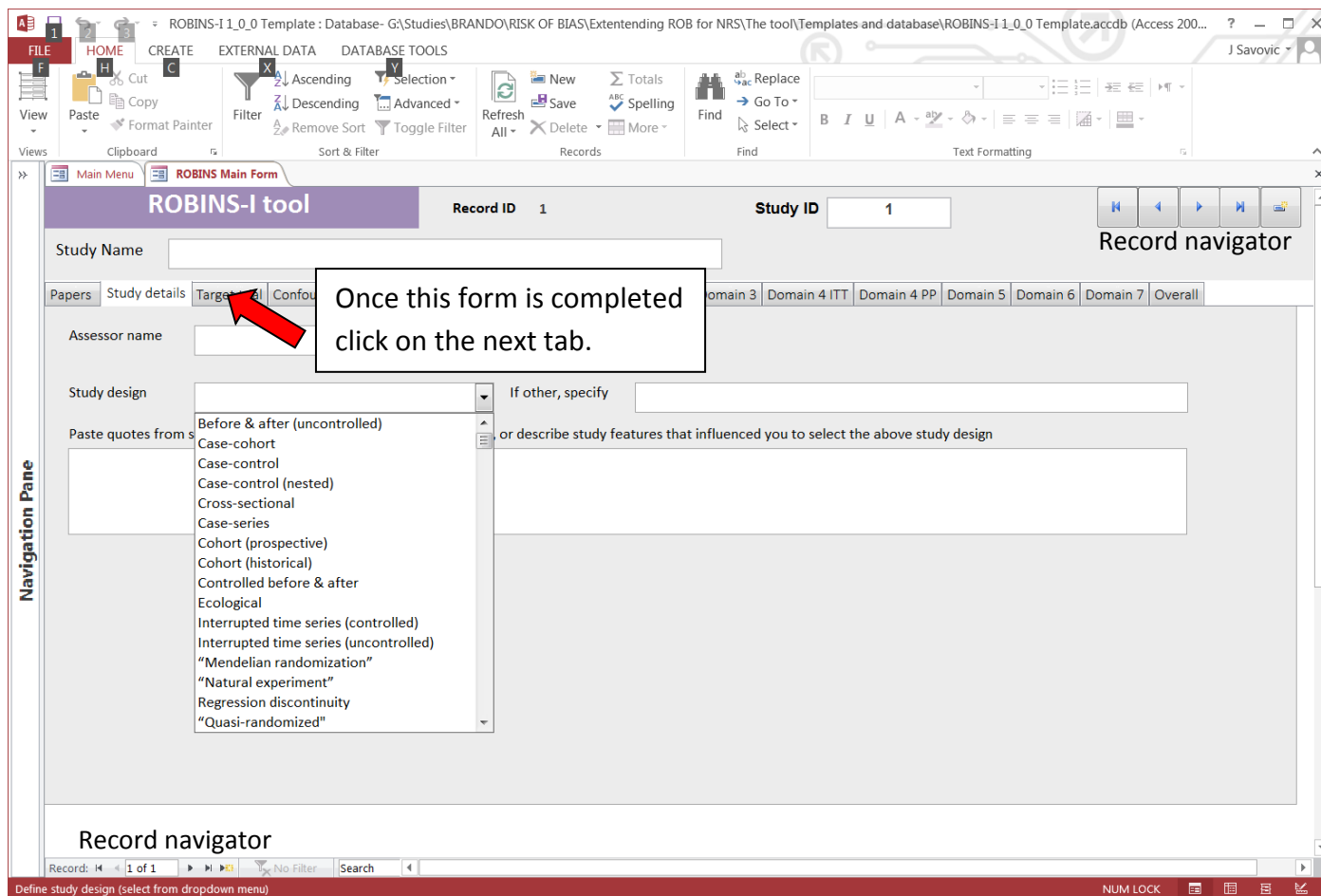


8. The first page “Papers” is displayed by default on loading the ROB assessment form. Each page (sub-form) has its own tab. The page tabs are located just under the main header at the top of the form. You can go through all 15 pages by clicking on the tabs.

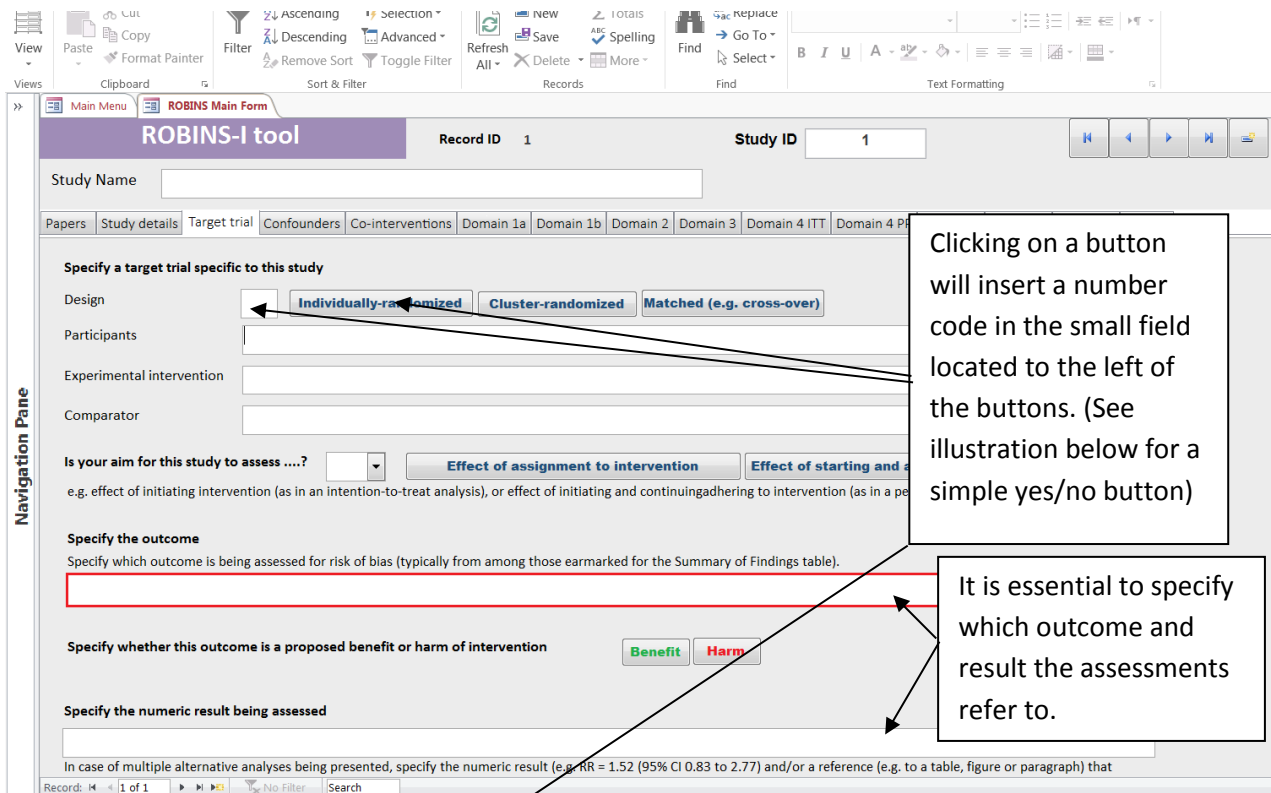
- In the main header you only need to enter the study name (a study name that is unique, but meaningful is usually most convenient) and the study ID number. Study ID number is a mandatory field and has to be a number. Duplicate study IDs are allowed so that you are able to complete multiple ROB assessments for several outcomes from the same study. Record ID is unique for each assessment (e.g. for each study-outcome combination) and is assigned automatically when you add a new record.

9. The first page (“Papers”) is optional, but it can be very useful. It allows you to keep track of all papers reporting on the same study and which of those have been used for assessing risk of bias (or for general data extraction). In order for it to work properly, all citations/references in Access table “References and Screening” need to have assigned a “Study ID” (which allows multiple records with different “citation-id” field to have the common “Study ID” field. “Study ID” field is then matched with the identical field in the Access Table “ROBINS\_ROB assessments”. “Study ID” provides a link between the “References and Screening” and “ROBINS\_ROB assessments”, thus linking multiple papers reporting on the same study via the same “Study ID”. Using this feature requires a bit of Access knowledge, but it is optional. If you don’t need it, you can ignore this form and click onto the next tab, “Study details”.

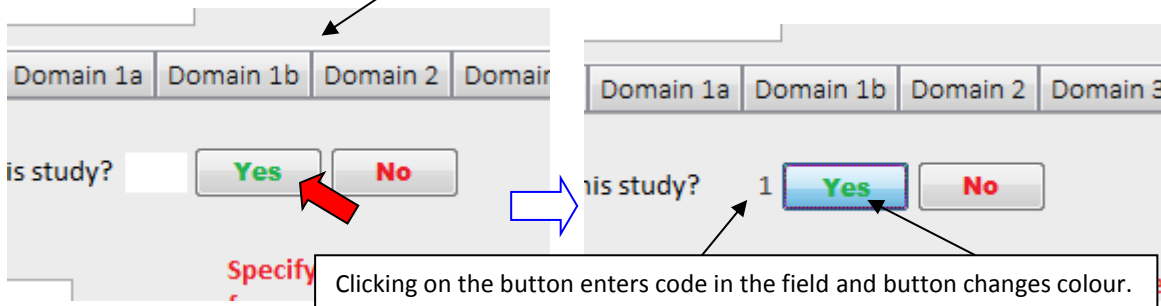
**Important:** Some of the pages may be longer than the size of the Access window (this will depend on your screen size). Access tends to load these longer pages somewhat scrolled down, so that the top of the sub-form is just below the header. This results in tabs being hidden. All you need to do to see the tabs is to scroll up a bit and the tabs will be visible again. You will also need to scroll down to complete the bottom parts of the form.



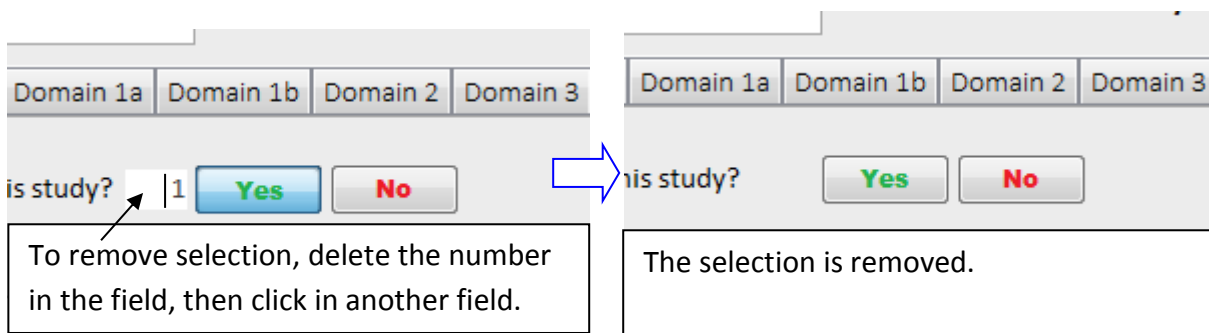
10. The second page “Study details” has a field for Assessor’s name and to select the study design from the drop-down menu, with a free-text field available if the study design in question is not available in the drop-down. Since study design labels are often unreliable and inconsistent, it is recommended that the brief description of study design/methods is recorded - a larger text-box allows for this (this field allows longer size of text). Complete the “Study details” sub-form first. Then click on the “Target trial” tab to open next page (sub-form).
11. In the Target trial sub-form, it is essential that you specify the outcome of interest, define the target trial etc. The below screen-shot shows the Target trial form and explains how the option buttons work.



How buttons work:



To change your selection, click on the other button options, this will change the code in the field. To completely remove your selection, place the cursor in the field with the inserted code and delete it, then click on another field. Your previous selection will be removed. **This applies to all buttons in the database.**



12. After completing all of the study details and target trial information, click on the “Confounders” tab. Follow the instructions in the main ROBINS-I guidance document on how to complete this. It is not essential to complete these 2 pages in Access. If you prefer, you can do this part in Excel or in a Word document (these alternative forms are also available at [www.riskofbias.info](http://www.riskofbias.info)).

The screenshot shows the ROBINS-I tool interface. At the top, there is a navigation pane on the left and a main menu. The main area displays a table with the following columns: Record ID, Confounding domain, Measured variable, and three sets of response buttons (Yes, No, No info). The first row has Record ID 1, Confounding domain 'Socio-economic status', and Measured variable 'Eligibility for state benefits'. The second row has Record ID 1, Confounding domain 'Age', and Measured variable '5-year age groups'. A third row is partially visible below. Annotations include a box pointing to the Record ID '1' in the second row stating 'Record ID is automatically created and linked to the correct study.' and another box stating 'A new row is automatically created as soon as you enter something in the row above.'

Record ID	Confounding domain	Measured variable	Is there evidence that controlling for this variable is unnecessary?			Is the confounding domain measured validly and reliably by this variable(s)?			OPTIONAL: Is failure to adjust for this variable (alone) expected to favour experim. intervention or comparator?					
1	Socio-economic status	Eligibility for state benefits	2	Yes	No	No info	2	Yes	No	No info	0	Experim.	Comparator	No info
1	Age	5-year age groups	2	Yes	No	No info	1	Yes	No	No info	2	Experim.	Comparator	No info
				Yes	No	No info		Yes	No	No info		Experim.	Comparator	No info

13. After completing the Confounders page, repeat the process for the Co-interventions page.

14. Now click on “Domain 1a” which will allow you to complete the first part of the Confounding domain.

**Navigation Pane**

**ROBINS-I tool** Record ID 1 Study ID 1

Study Name

**DOMAIN 1: BIAS DUE TO CONFOUNDING - Preliminary Signalling Questions 1.1 to 1.3** Descriptions of what was done in the study

1.1 Is there potential for confounding of the effect of intervention in this study? **Yes** **Probably Yes** **Probably No** **No**

If N/PN to 1.1: the study can be considered to be at low risk of bias due to confounding and no further signalling questions need to be considered. (Go to next tab "Domain 1b", skip all other SQs and go to the Risk of bias judgement for Confounding and select LOW risk of bias)

If Y/PY to 1.1: determine whether there is a need to assess time-varying confounding:

1.2. Was the analysis based on splitting participants' follow up time according to intervention received? **Yes** **Probably Yes** **Probably No** **No**   
**No information** **Not applicable**

If N/PN to 1.2, answer questions relating to baseline confounding (Skip SQ 1.3 and go to next tab "Domain 1b" and answer 1.4 to 1.6)  
If Y/PY, proceed to question 1.3.

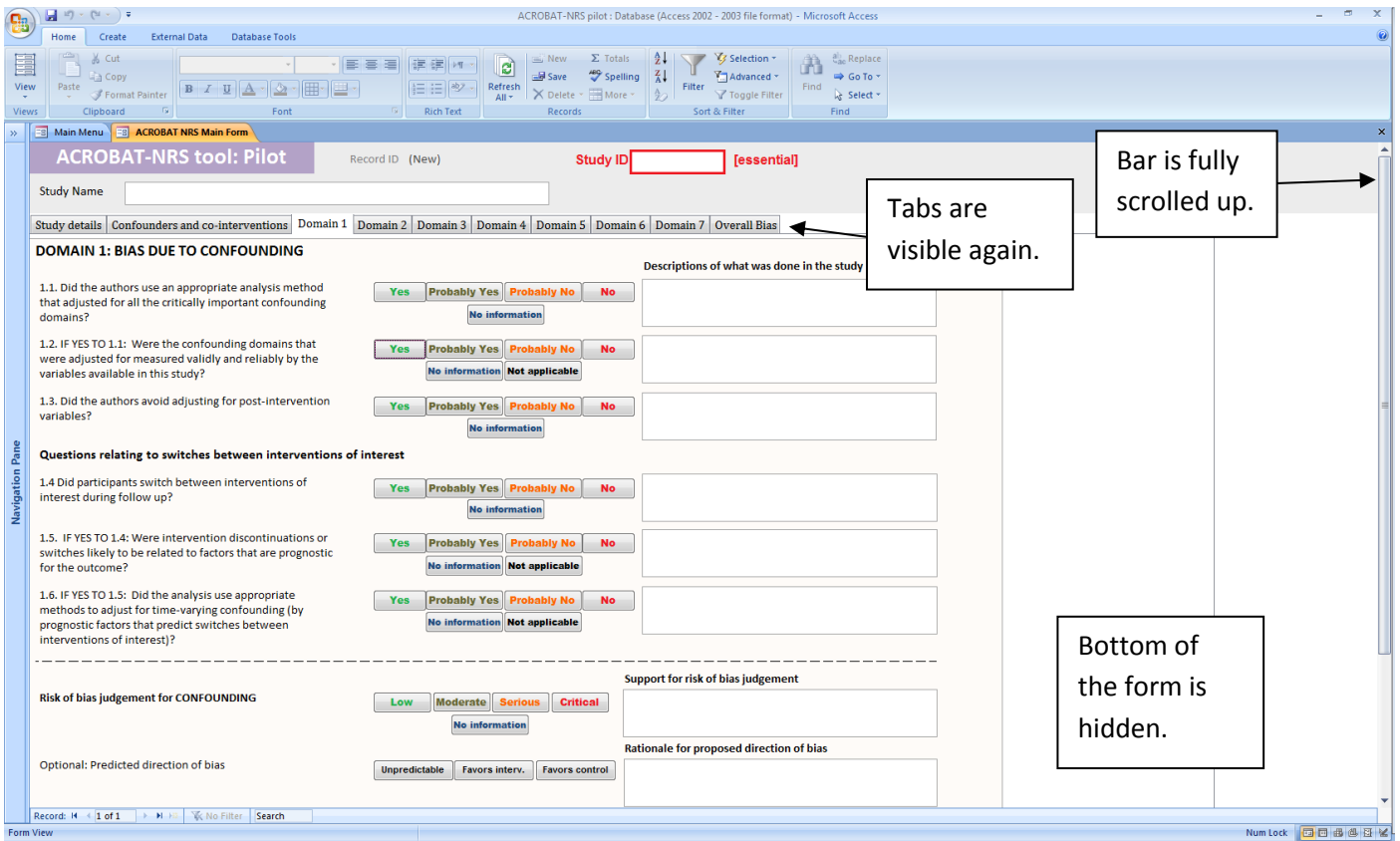
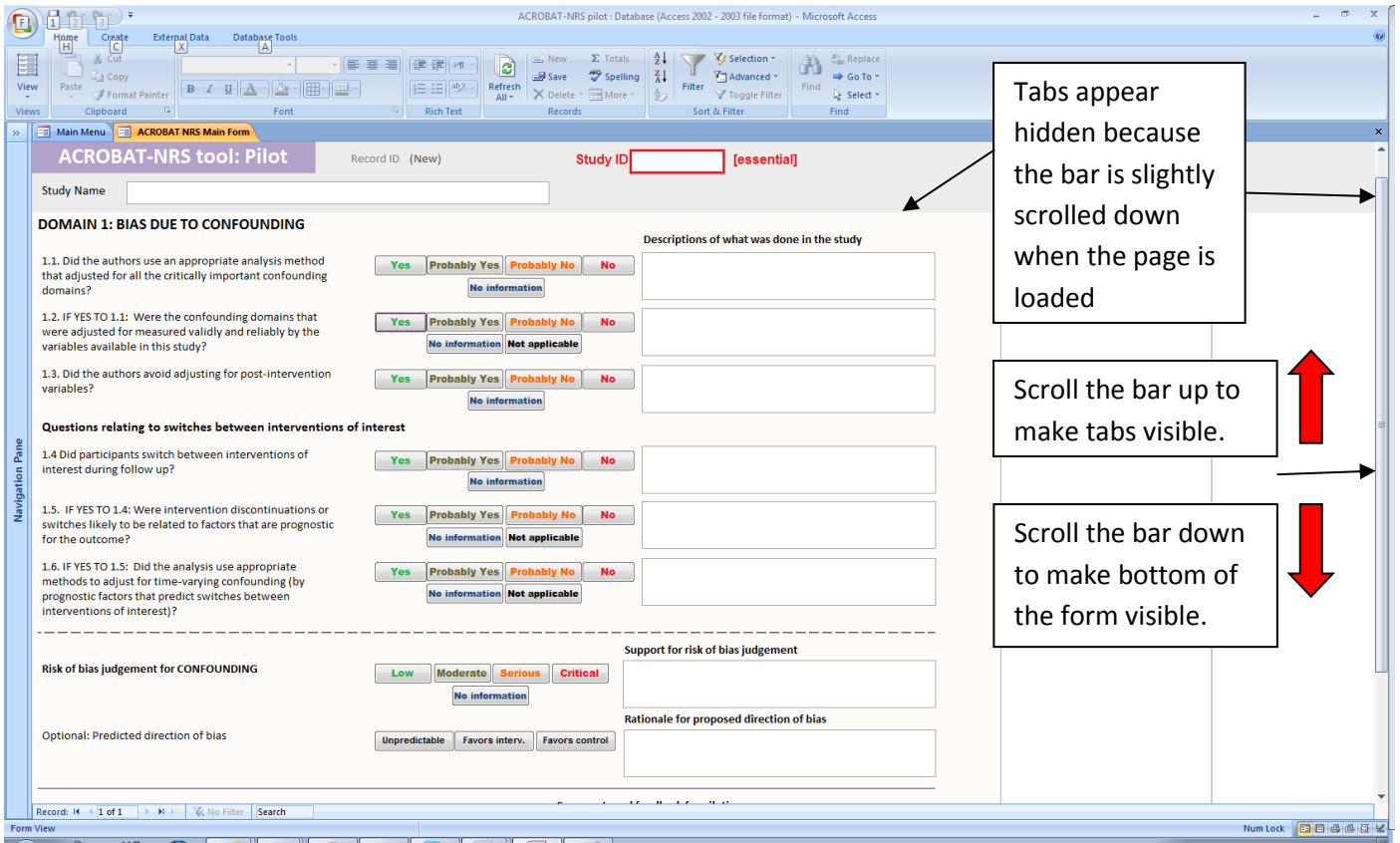
1.3. Were intervention discontinuations or switches likely to be related to factors that are prognostic for the outcome? **Yes** **Probably Yes** **Probably No** **No**   
**No information** **Not applicable**

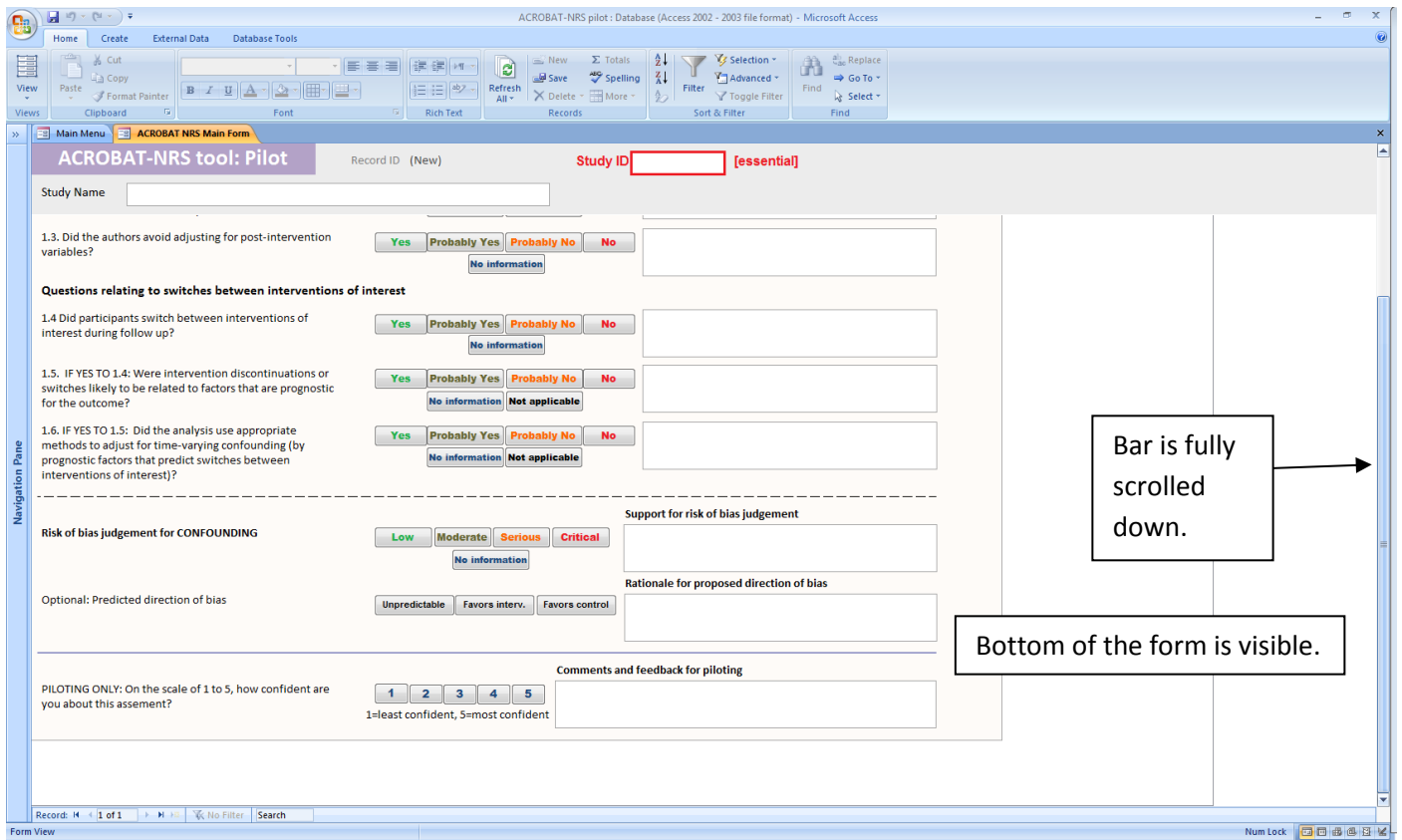
If N/PN, answer questions relating to baseline confounding (Go to next tab "Domain 1b" and answer 1.4 to 1.6 only)  
If Y/PY, answer questions relating to both baseline and time-varying confounding (Go to next tab "Domain 1b", skip questions 1.4 to 1.6 and answer questions 1.7 and 1.8)

15. On clicking on "Domain 1b" tab, the second part of the Confounding domain page will open.

This is one of the longest pages (sub-forms), so depending on the length of your screen Access may display it slightly scrolled down. You will need to scroll up to make tabs visible again and you will need to scroll down to see and complete the bottom part of the form (see next 3 snapshots). [Note: An older version of the form is used in these diagrams, which slightly differs from the current version, but the explanation of the scrolling issue is identical].







16. Answer the signalling questions and the risk of bias judgement by clicking on one of the answer option buttons and provide descriptions / support for judgment in the free-text boxes ('Description', 'Support for judgement' and 'Rationale') on the right of each question. It is really important to complete the 'Description', 'Support for judgement' and 'Rationale' text-boxes to provide transparency and justification for your decisions, as these can be subjective. Adding quotes from study reports which influenced how you answered signalling questions or reached a risk of bias judgment will be particularly useful. These will provide a useful insight into what information from the report you are using to answer questions, whether different assessors identify the same information from study reports and whether the same information from study reports generates the same answers/judgements.
17. After completing assessments for confounding, click on "Domain 2" tab to do assessments for selection bias. Then go through all the remaining tabs/domains until you have answered all questions.
18. In the final tab "Overall" you will see all your previous domain level judgements displayed to help you reach the overall (across all domains) judgment of the risk of bias for this outcome. [Illustration shown is from the previous version of the tool, but the form hasn't changed since that version.]
19. When you have finished with one study and want to start the next you will need to click either on the next record icon or the new record icon in the record navigator sections, located in the top right and the bottom left corner of the form (see snapshot below).

Views | Clipboard | Font | Rich Text | Records | Sort & Filter | Find

Main Menu | ACROBAT NRS Main Form

## ACROBAT-NRSI tool

Record ID 1 | Study ID 1

Study Name Vermont 2001-2009 | Cardiovascular mortality

Study details | Target trial | Confounders 1 | Confounders 2 | Co-interv. 1 | Co-interv. 2 | Domain 1a | Domain 1b | Domain 2 | Domain 3 | Domain 4 | Domain 5 | Domain 6 | Domain 7 | Overall

### Review of your domain level judgements

Confounding | Selection bias | Measuring interventions | Reporting bias

Direction of bias | Direction of bias | Direction of bias

Departures from interventions | Misclassification

Direction of bias | Direction of bias | Direction of bias

Codes for risk of bias: 0=No information, 1=Low, 2=Moderate, 3=Serious, 4=Critical  
 Codes for direction of bias: - 1=Unpredictable, 2=Favours experimental, 3=Favours comparator, 4=Towards null, 5=Away from null

### OVERALL BIAS ASSESSMENT ACROSS ALL DOMAINS

OVERALL RISK OF BIAS JUDGEMENT (for this study and outcome)

Low | Moderate | Serious | Critical | No information

Optional: What is the overall predicted direction of bias for this outcome?

Unpredictable | Favours interv. | Favours control | Toward null | Away from null

Support for risk of bias judgement

Rationale for proposed direction of bias

Record navigator

Record: 1 of 1 | No Filter | Search

Top part of the form displays your domain level judgements (these are read only)

