

Early Phase Trials Best Practice Toolkit INSTRUCTIONS

1. This first edition of the checklist has been created in Excel

If you are not familiar with how Excel works, here is an online beginners guide: https://www.youtube.com/watch?v=rwbho0CgEAE

2. The spreadsheet requires you to enter into certain cells

You will need to "Enable Editing" by clicking on the "Enable Editing" or "Enable Content" box that may display at the top of the spreadsheet.

3. The spreadsheet consists of 12 tabs

- a. The first tab is the homepage; you can navigate to all the other tabs from the homepage by clicking on coloured boxes that provide the titles of each category/tab of the checklist. You can also access these Instructions and other FAQ's from the homepage.
- b. Tabs 2-11 shown at the bottom of the spreadsheet contain the individual sheets for each of the 10 checklist categories. You can navigate between tabs either by clicking on the "Home" button in the top right corner of each tab or you can move through each tab at the bottom of the check list.
- c. The last tab is a summary page.

4. How to use each tab

- a. The only columns that you can enter into are highlighted in the heading in Orange:
 - i. Trial Type Filter (column B)
 - ii. Answer (column E)
 - iii. Site Comments (column J)
- b. Filters First determine if you want to filter out the questions that you see to only show those relevant to IP or DEVICE. To do this go to Column B, Trial Filter Type. In the highlighted Orange Cell in Cell B3 you can choose the filter option: IP to show IP questions only, DEVICE to show Device questions only or SELECT ALL to show both.
- c. Question structure
- There is a high level question classification that relates to a category of questions (Column C)
- There are specific numbered individual questions that each require an input answer (Column D)
- There is a rationale/description for each question to give more information. This is shown in a text box when you click on the question in Column D.

4. How to use each tab

- d. Answer each question via a drop down list in Column E. Click on the cell with "INPUT" and select the relevant Responses Yes, No, In Progress or Not Applicable (NA)
- e. The What if No column (column I) is defaulted as being blank. If you select NO to answer a Question, the WHAT IF NO column will change from being blank to display a message saying what you need to do to move this question from No to Yes. For some No responses it is not applicable to have a response to the What if No so this shows as NA for not applicable.
- f. Resources are provide in Column G, these are links to resources to help provide guidance on certain questions. The intent of this checklist is to have all the relevant resources relating to the conduct of trials contained within the checklist to save site staff time in having to search for them.
- g. Adding a comment in each tab you can add a comment in Column J, it is suggested that you write a comment for those questions that you answer as No or In Progress to indicate what your action is. The site comments will feed through to the summary page. The site comments can only be edited within each tab and not from the summary page.

5. How to use the Summary Page

- a. Filters You can choose how you view the summary page. You can choose to filter by "ANSWER" (Column D) ie show all those questions answered No or In Progress (filter out all the Yes or NA responses). This then becomes an action list of what you need to work on. To filter by Answer, click on the "Filter Answer" orange cell in D3 on the Summary Page and select which answers you wish to see.
 - If you go back and make any changes in any tabs after you have filtered the summary page you will need to refresh the summary page to be the changes you have made, to do this click on the FILTER ANSWER again and reselect what you want to filter on. This will pull through any changes that you have made.
- b. Site Comments if you wish to add or amend a site comment from the Summary page, you will need to go back to the question in the relevant tab. To do this, click on the question number in column A on the summary page, this is a hyperlink back to that question in the relevant tab. The comment can be amended here. You can then navigate back to the summary tab.

6. We hope the checklist provides a useful tool for site staff

We welcome your feedback on this first version of the checklist, please send it to info@ctiq.com.au