



CT:IQ
Clinical Trials:
Thinking Smarter

Early Phase Trials Best Practice Toolkit FAQs

1. Who are the intended users of the checklist?

Sites either conducting or looking to commence conducting (early phase) studies.

2. Can this checklist apply to other phases or trials, not only early phase?

Absolutely, the checklist can be more broadly utilized by sites that conduct any phase of research studies. The checklist's intention is to guide best practice at sites.

3. What level of detail is in the checklist?

The best practice recommendation checklist is intended to provide a high level overview of best practice recommendations given the variability amongst sites in their capabilities and practices. While completing the checklist sites are encouraged to review the question rationales and resource links for further information from the source of the recommendation.

4. Why are some questions repeated in other tabs of the checklist?

There are not many questions that are repeated. Repetition is necessary in these cases as some users may not complete the checklist in its entirety and it was important that these questions were covered.

5. What resources have been provided in the checklist?

The resources we have provided are publicly available ones and are to be used as a guide. Modification to tools and resources will be required in many cases to suit your specific site requirements. As these are external third party resources some links may become obsolete. We will do our best to keep all links current.

6. Why is the checklist in Excel?

The project did not have a budget to develop a bespoke online checklist. We hope to secure funding to develop a Version 2 in an online format that would be more intuitive and user friendly. Excel was the best free platform available that had the required functionality. It was also an application that most people are familiar with. If you are not familiar with Excel we have provided a link to a "how to use excel" video in the written instructions.

7. What does IP stand for?

IP stands for Investigational Product which is any therapeutic good (including placebos) being tested or used as reference in a clinical trial. This checklist can be conducted for Investigational Products or Devices. Some sites may conduct trials in both so all questions are relevant. For those sites that do trials in one or the other, the checklist can be filtered by clicking on cell B3 in each of the tabs and selecting either "IP" or "DEVICE".

8. Why are some cells highlighted in Orange?

The orange cells indicate those cells or columns that you can input into.

In each of the 10 section tabs these input cells are:

- Cell B3 "Select Trial Type Filter" allows you to filter by either IP or DEVICE.
- Column E is the "Answer" column where you can input an answer for each question via a drop down list with responses of :

Yes

No

In Progress

NA (not applicable)

- Column J is for "Site Comments". This allows you to enter free text comments or notes to create an action plan of what you need to do to move any No's to Yes responses.
- Cell J1 "HOME", this allows you to return easily to the main homepage.

On the SUMMARY page the input cells are :

- Cell D3 "Filter Answer", allows you to filter the summary to show only the No responses, or the No's and In Progress, or you may want to see just the Yes's. You can select how you view the summary page.
- Cell G1 "HOME", this allows you to easily return to the main homepage.

9. Why does the Summary page not always show any changes I have made?

You should refresh the summary page after you have made any changes within any of the sheets in the checklist. To do this, click on Cell D3 "Filter Answer" and reselect your preferred filter method eg No. This will refresh the Summary page.

10. How can I provide feedback?

We would love feedback on this version 1 of the checklist. Currently feedback can be provided by sending an email to info@ctiq.com.au. We plan to develop a feedback email template during 1Q 2019 and will load this once complete. The more this checklist is used and feedback provided the better we can make version 2 so please take the time to give us feedback.