



## **EARLY PHASE TRIALS BEST PRACTICE CHECKLIST**

The Early Phase Trials Best Practice Checklist has been developed by CT:IQ, a collaborative of Australian clinical trial stakeholders who aim to develop and implement recommendations that will improve the impact, quality and efficiency of clinical trials.

The checklist provides a summary of recommendations, considerations and resources for clinical research sites in the conduct of clinical trials, particularly those sites conducting early phase studies.

## **WHY WAS THE CHECKLIST DEVELOPED?**

There is currently no single source of best practice for the conduct of early phase trials in Australia, which presents a risk to the safe and effective operation of early phase trials. A need was identified for a practical tool that could be used by site staff to provide guidance for the set up and conduct of early phase trials in Australia.

The objective of the Early Phase Best Practice project was to identify best practice guidance that could be tested and shared to improve practices in early phase trials in Australia. The project team developed its recommendations in the form of a comprehensive checklist for research sites to utilise.

## **WHO WILL USE THE CHECKLIST?**

Throughout the project it was established that while the checklist is branded an early phase checklist, many of the practices are broadly applicable to other phases of clinical research and can therefore be used to verify the practices in any clinical trials unit.

## **HOW WILL THE CHECKLIST BE USED?**

The checklist is designed as a practical tool for site staff. For existing clinical trial sites, it will validate their current practices. For sites venturing into early phase research, it will guide them in their set up.

It will take approximately 30-60 minutes to complete the Excel checklist. The checklist can be saved by the user and completed over several sessions.

## **FEEDBACK IS WELCOME**

Given that this is a live and ongoing project, the team is very interested in user feedback on the usefulness and effectiveness of the checklist.

Provide Feedback.