



# Helpful Hints: Data Management

## Acknowledgement

These Hints were generated from discussion by members of our Coordinators Network and other participants in PC4 workshops who were willing to share their experience.

### Databases

- Consider using an Access database: Access is easy to use, can generate versatile reports, and can set alerts for reminders and data settings or 'flags'.
- Online databases are good for larger studies with multiple sites. Advantages include randomisation and data checking capabilities, and access to reports.
  - Freeware, such as Redcap<sup>1</sup> and Oracle<sup>2</sup>, is available
  - If considering purchasing an online database, approach multiple companies for quotes and compare advantages and disadvantages. Ask for a timeline for database setup, as well as examples of other trials they have previously set-up, and for a live demonstration. Costs will vary depending on the length of the study, and the number of sites – more expensive is not necessarily better*Examples: <http://www.sealedenvelope.com/>,  
<http://bio-optronics.com/clinical-conductor/>*
- Speak to a Biostatistician to see how they would like the data presented to enable them to draw out assumptions during database design

### Recording data

- Ensure accurate record keeping:
  - Use charts to be able to track progress
  - Have a process for Acceptance of Minutes so you can prove decisions: especially important when dealing with multiple committees)
  - have good version control by using agreed filing conventions
- Use electronic forms (i.e. online surveys) whenever possible: this eliminates the need to transcribe data and minimises human error

### Quality control

- Consciously perform regular visual checks, i.e. deliberately scanning your data for 'outliers' – numbers or variables different to others in the data set
- If possible, ask a second person to randomly check at least 10% of the data
- Implement and document rules for quality control
- De-identifying data: programs such as 'Bit Locker'<sup>3</sup> are available to de-identify and secure data (Bit Locker is compatible with Access)
- If using an Access database, activate the data settings - red and yellow 'flags' to catch missing or inconsistent data
- Talk to your statistician early: they will tell you how to best manage missing data, and which will enable them to use appropriate statistical methods during analysis
- The use of Checklists & Guidelines can be useful to ensure adherence to protocols and data management plans
  - See PoCoG's (Psycho-Oncology Cooperative Research Group) Standard Operating Procedures<sup>4</sup>

1. <http://project-redcap.org/>

2. <https://www.oracle.com/database/index.html>

3. <http://windows.microsoft.com/en-au/windows-vista/bitlocker-drive-encryptionoverview>

4. [http://www.pocog.org.au/content.aspx?page=sop\\_datamgt](http://www.pocog.org.au/content.aspx?page=sop_datamgt)

### Contact us

[info@pc4tg.com.au](mailto:info@pc4tg.com.au)

[www.pc4tg.com.au](http://www.pc4tg.com.au)