Bb Bellberry Limited
supporting research and ethics

COVID-19: Considerations for Clinical Trials

As the COVID-19 situation escalates in a number of jurisdictions around the world and within Australia, many Clinical Trial Sites and Sponsors are considering actions to be taken to protect the welfare of trial Participants, and to support the continuation of on-going trials.

The following are suggested topics for planning purposes. This list should not be considered to be complete, and additional considerations are likely to emerge as the situation continues to develop. Not every topic will be relevant to every trial. They are however intended to be a helpful starting point when considering planning for individual sites and trial situations.

Participant Communication

Your participants may be reluctant to attend trial visits in a hospital setting, or to a busy clinical practice, or to use public transport to reach you. Your participants may have questions about how their trial will continue in light of any local outbreak. In time, you are likely to have participants placed in self-isolation or quarantine. Participants will undoubtedly have questions about what the emerging pandemic means for their trial participation. Consider proactively supporting your participants with an FAQ or a helpline contact. Establishing lines of communication will assist if further pandemic developments trigger additional changes in the coming weeks.

Access and Continuity of Supply

Consider how to assure ongoing access to trial products and any other items required for delivery of the trial protocol. Consider whether participants might need a larger supply of investigational product to cover any period of uncertain access. Consider whether and how that might be dispensed and delivered in a way that minimises risk to participants. Many sites will hear from Sponsors in the coming days and weeks, as they deploy their pandemic planning. Please speak to the HREC for support with amendments, violations or safety reports.

Protocol Amendments or Deviations

Where changes are anticipated, reach out early and proactively to discuss these with the HREC. Some Investigators are exploring a reduction in protocol-mandated study visits, use of remote consultations and alternative dispensing. These can be documented proactively in an Amendment for the HREC to review or may be submitted as a Protocol Violation if more urgent changes are required for the safety of participants. Consider submitting a 'Plan B' amendment now so that you're pre-approved to move to new processes if and when you need to.

Possible Amendments

As the situation is still developing, it may be appropriate to consider substantial changes for a “what if” scenario that might never occur. In these circumstances, the HREC will consider scenario planning with anticipated changes, and articulation of when and how you would choose to deploy that amendment. Bellberry HRECs will work with you to ensure sites can make changes in this volatile and rapidly changing environment. Consider submitting a 'Plan B' amendment now so that you're pre-approved to move to new processes if and when you need to.

Participant Monitoring

Consider the continuation of participant monitoring if quarantine or isolation measures are required. Some sites already make use of remote technologies, which are likely to see broader use in the coming weeks. If you are considering remote technologies you should check whether that method is appropriate and accessible to all participants. Speak to the HREC about any amendments required.

123 Glen Osmond Road Eastwood South Australia 5063
P 08 8361 3222 E bellberry@bellberry.com.au www.bellberry.com.au
ABN 16 109 019 730

Health System Reprioritisation

Consider whether any location changes might be needed to support the ongoing monitoring of participants. As an example, in some cases, alternative pathology pathways are being explored, along with alternative pharmacy arrangements.

Site Screening and Travel Restrictions

Daily updates on countries considered at risk can be found at health.gov.au, along with advice for travel screening and access restrictions. This list is changing frequently, so please ensure that you check in with it often. As the situation develops, travel risks are likely to apply to locations within Australia as well as overseas.

Signatures

As the use of remote working takes hold, we are likely to see delays in getting hold of wet ink signatures. Bellberry supports the use of electronic signatures and would encourage you to consider using them even if you haven't before.

Pandemic Planning

In rapidly-changing scenarios such as the one facing Australia right now, decisions you make today may be out of date by tomorrow. Consider putting aside time on an on-going basis to manage changes required as the situation develops.

Quality of Documentation and Reporting

We anticipate a large number of changes to current practice and approved protocols as this situation evolves. Bellberry HRECs will support you to process amendments, violations and safety reports as they arise. In such a rapidly-changing situation, it is critical that you keep good records to support compliant reporting.

Safety of Trial Participants

Participant safety is always our prime focus. At a time like this, sites should be prepared to re-evaluate trial activities and discuss individual trial participation if the risk profile changes.

Sites running trials approved by Bellberry HRECs are encouraged to reach out early for support.