Purpose

To outline the ethical aspects considered by Bellberry HRECs when reviewing observational post-marketing and Phase IV studies of drugs or devices.

Guidance

The following considerations apply to both drugs and devices. Post-marketing surveillance can refer to:

- Voluntary reporting of adverse events to the regulatory authorities of the country in which they arise.
- Company sponsored studies which often are established to answer a specific safety question. These studies are more structured than the voluntary system of reporting.

Regulatory authorities can require Post-Approval Studies that systemically gather safety data as a condition of approval.

These considerations refer only to company sponsored studies whether initiated by regulatory authorities or not.

The merits of post-marketing collection of safety data are many. Where clinical studies provide safety data from a narrowly defined group of participants, post-marketing data comes from a wider range of patients who may have co-morbidities and concomitant medication that is often not allowed in the clinical study setting. Post-marketing studies can also collect data over longer periods of time than in a clinical study.

Post-marketing studies are observational and not interventional in that they seek only to collect data. The device or drug which is the focus of the post-marketing study will have been approved by the TGA and will be listed on the Australian Register of Therapeutic Goods. The participants under observation will be those who are already using or had the device implanted, are taking the drug or those who have at least made the decision to use the device or commence using the drug. This should be reflected in the Inclusion Criteria, and it becomes the starting point for the observational study which involves only collection of data. However, failure to specify this starting point is a common issue with submissions to the HREC.

Interventional vs Observational

Study Inclusion Criteria often specifies participants as those who would be suitable for the device or drug. This indicates that the participants are not using the drug or device in addition to no decision having been made to commence using the drug or device. The inclusion of these criteria requires a different study design and can no longer be considered a post-marketing or Phase IV study. Where the protocol mandates the use of the drug or device, the study is considered interventional and not observational as the study becomes a vehicle for use of the device or drug rather than a vehicle for data collection only.

If the study is considered to involve an intervention in that the Inclusion Criteria **do not** specify the device is in use or implanted, the drug has commenced or a decision has been made to use or implant the device or to commence the drug, the study will need to address the following:

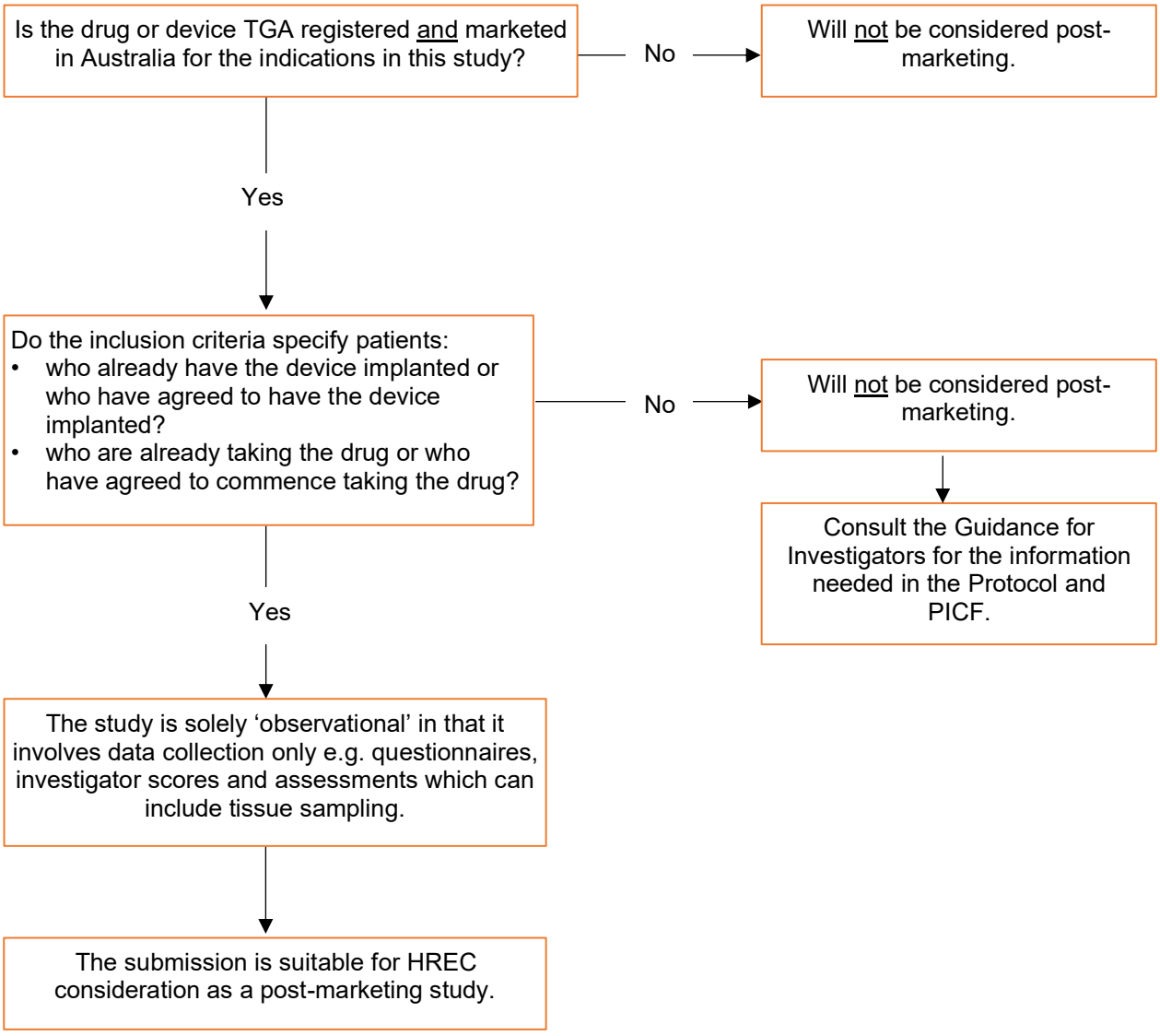
- Provide justification for using this particular device or drug, especially when others are marketed and available for use. This will require a full disclosure of the risks of the drug or device and they will need to be compared with the risks of alternative drugs or devices. It will also require support for efficacy compared with the alternatives.

- The Protocol and the Participant Information Sheet will need to clearly contain this supporting information and will need a full discussion of the marketed alternatives.

- This may require provision of an Investigator's Brochure or Product Information

By contrast, where a participant decision has already been made outside of the study framework, potentially as a treatment decision reached between doctor and patient, the Protocol and the PICF need only describe information relevant to the data gathering exercise.

Assessment of Suitability for HREC Consideration as a Post-Marketing Study



References

BA G3 Protocol Development – Clinical Study
BA G4 Protocol Development - Non-Clinical Study