The following discussion applies 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 are more structured than the voluntary system of reporting.

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

This Guidance discussion refers only to the company sponsored studies whether initiated by regulatory authorities or not.

The merits of post-marketing collection of safety data are many. Whereas clinical trials provide safety data from a narrowly defined group of participants, post-marketing data comes from a wider range of patients who can have co-morbidities and concomitant medication not allowed in the clinical trial setting. They can also collect data over longer periods than in a clinical trial.

The studies are observational and not interventional. 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 patients who have already had the device implanted or are taking the drug, or will be those who have at least made the decision to have the device implanted 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, it is failure to specify this starting point that is a common problem with submissions to the Research Ethics Committee.

Interventional vs Observational

The Inclusion Criteria often specifies participants as those who would be suitable for the device or drug. This indicates that they are not using the drug or device and also no decision has been made to commence using the drug or device. This is a different starting point. When a patient agrees to enter such a study, it can no longer be considered a post-marketing or Phase IV study. The protocol mandates the use of the drug or device in which case it is interventional and not observational. It becomes a vehicle for use of the device or drug rather than a vehicle for data collection only.

If the Inclusion Criteria **do not** specify the device is implanted or the drug has commenced, or a decision has been made to have the device implanted or to commence the drug, the protocol will be considered to involve an intervention. In that case the following will need to be addressed.

- There will need to be a 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 contain this support and will need a full discussion of the marketed alternatives.
- This may require an Investigator's Brochure or Product Information

By contrast, if the decision has already been made outside of the study framework, that is a treatment decision reached between doctor and patient, the Protocol and the PICF need only describe the data gathering exercise.

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