**Investigator’s brochures for medical device clinical trials**

A sponsor’s guide to the expectations for the contents of an Investigator’s Brochure

**Last updated**

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All trials that investigate medical devices, regardless of device classification, should have an Investigator’s Brochure (IB), or equivalent documentation.

The IB compiles all available clinical and non-clinical data to inform on the safety of the investigational device that is to be studied in humans.

#### What to include

A brochure should inform the reader and help them make an unbiased benefit-risk assessment of the proposed trial.

Information in the brochure should be:

* written in English (other languages not accepted);
* in language the reader understands;
* up to date; and
* presented in a concise, simple and non-promotional way.

A medically qualified person is expected to participate in the editing of your IB.

**Recommended structure**

We recommend that you present the information under the following headings:

* General
  + Identification of the IB
  + Sponsor of the trial/manufacturer
* Investigational device information
* Preclinical testing
* Existing clinical data
* Risk management
* Regulatory and other references

#### Ensuring completeness of your IB

You should pay particular attention to the following:

* Adequate characterisation/description of the device and its operation, including:
  + Design/engineering drawing and electronic models of device
  + Rationale for device design
  + Device and performance specifications
  + Description of materials (including biocompatibility information)
  + Description of function - how does the device and/or its components/subsystems work together to achieve the desired function
  + Verifications and validations reports for device, subsystems and main system
  + Usability studies, where applicable
* Adequate description of the manufacturing controls used to ensure that the devices are produced consistently and as designed (for example, compliance with [ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes](https://www.iso.org/obp/ui/#iso:std:iso:13485:ed-3:v1:en)).
* Include data-driven laboratory studies with detailed descriptions of methods and conclusions.
* Animal studies with validation of animal selection, scientific justification for the number of animals selected, and appropriate follow-up duration.
* A summary of prior publications, including copies of relevant publications (positive and negative) and relevant information.

**More information**

[ISO 14155:2020 Clinical investigation of medical devices for human subjects – Good clinical practice](https://www.iso.org/standard/71690.html)

[Clinical trials](https://www.tga.gov.au/clinical-trials)

[LINK] Review of first-in-human high-risk implantable or cardiac invasive medical device clinical trials