Investigator’s Brochure [IB]

The Investigator’s Brochure (IB) is a comprehensive document that summarises all the relevant clinical and non-clinical information about the medicine being studied in humans.

An IB contains a ‘Summary of Data and Guidance for the Investigator’ section, the aim of which is ‘to provide the investigator with a clear understanding of the possible risks and adverse reactions, and of the specific tests, observations, and precautions that may be needed for a clinical trial.’

The IB also provides information to help with the clinical management of participants taking part in the clinical trial.

The sponsor (the organisation running and overseeing the trial) is responsible for keeping the information in the IB up-to-date. The IB is of critical importance. It should be reviewed annually and must be updated when any new and important information becomes available, such as when a medicine has received marketing approval and can be prescribed for use commercially.

Owing to the importance of the IB for the safety of participants in clinical trials, the International Conference on Harmonisation (ICH) has prepared a detailed guidance document for the authoring of the IB in the European Union, Japan, and the United States.