Medicines & Healthcare products Regulatory Agency

Where a trial is notifiable but also meets one of the additional criteria in the table below, applicants should make this clear in the cover letter. The licensing authority will use this information to determine whether to exercise its right to undertake a full review of a notifiable trial before issuing a decision.

Additional criteria
Any of the IMPs used in a trial that is eligible for automatic approval under Condition A are placebos. This is a potential safety concern because use of a placebo in these trials (but not trials eligible for automatic authorisation under Condition B or C) can change the risk-benefit profile, as there is no benefit for participants on a placebo and there is the potential for increased risk through exposure to excipients
For a trial eligible for automatic approval under Condition C, the application uses a different version of one or more of the: • protocol • Investigator's Brochure (IB) • IMP dossier (for EU or EEA approvals) • IMP manufacturing process and controls (for USA approvals) compared to the trial that was already approved in the USA, EU or EEA state. This is a potential safety concern because in this scenario, the document(s) being used for the trial will not have been approved by any authority
The applicant considers that the application may require the licensing authority or ethics committee to consult with a relevant committee or specialist group before issuing a decision
The application is for a trial that combines both an IMP and an investigational medical device or investigational in-vitro diagnostic device
The sponsor is requesting to disapply or vary the standard labelling requirements for at least one IMP involved in the trial that is not exclusively administered in a hospital or healthcare setting
The sponsor is intending to deviate from standard reporting of suspected unexpected serious adverse reactions