F: Termination of clinical investigations involving the use of medical devices

It is obligatory for the manufacturer to notify the Inspectorate of the termination of a clinical investigation. If a clinical investigation is ended prematurely, the manufacturer must report this within two working days and not later than four calendar days, stating the reasons.

On termination of the clinical investigation, the Inspectorate will examine matters including whether all SAEs were reported correctly and within the prescribed periods of time.

If the investigation is ended prematurely, the Inspectorate will request submission of the following information:

1. Which SAEs gave rise to premature termination of the clinical investigation, how the medical device was involved in these SAEs, when the SAEs occurred, where they occurred (whether this was in the Netherlands or not), and the consequences of the events for the patients concerned;
2. The status of the inclusion in the Netherlands and/or other countries: details of how many of the planned patients had already been included in the Netherlands and elsewhere;
3. The current status regarding the reporting of SAEs and the status prior to termination of the investigation;
4. The action the manufacturer is taking in relation to patients for whom the medical device has already been used (is it desirable to remove the medical device, insofar as such is possible?) or to patients already included in the investigation (will the patients be informed of the findings?);
5. The consequences of premature termination of the investigation for the objective of obtaining CE certification;
6. Whether the registration form of the Inspectorate has already been filled in: if not, it must as yet be filled in and sent to the Inspectorate; the form will be used to record the premature ending of the clinical investigation in the European Eudamed database.