

Adverse events

Date of adverse event _____

Hours from start of cooling _____

Date of discovering _____

Description of adverse event:

Consequences for the infant:

Outcome:

Serious adverse event* yes no

Did you stop cooling ? yes no

If yes, date of stopping _____

If yes, time of stopping _____

***Adverse Event (AE):** any untoward medical occurrence in a patient

***Serious Adverse Event (SAE):** any untoward and unexpected medical occurrence or effect that:

- Results in death,
 - Is life-threatening – refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe,
 - Requires prolongation of existing inpatients' hospitalisation,
 - Results in persistent or significant disability or incapacity,
- Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

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