ANSM - Agence nationale de sécurité du médicament et des produits de santé

Clinical investigation involving a medical device or an in vitro diagnostic medical device.

Vigilance report : Initial report

Articles L. 1123-10 et R. 1123-46, R. 1123-49, R. 1123- 55, R. 1123-60 du code de la santé publique

Suspected unexpected serious adverse effect	☐

To be sent	
By e-mail	EC.DM-COS@ansm.sante.fr
By mail	**Agence nationale de sécurité du médicament et des produits de santé (ANSM)** **Direction médicale des dispositifs médicaux, des cosmétiques et des dispositifs de diagnostic in vitro** **143-147 Boulevard Anatole France** **93285 Saint-Denis cedex**

THIS SECTION FOR ANSM ONLY

Date initial report was received: **/ /**

Registration number: **/ / /ei**

Clinical investigation identification

Clinical investigation registration number from the ANSM:
Code number of the clinical investigation protocol assigned by the sponsor, version and date:

Full title of the clinical investigation :

Code number identifying the investigation participant:

Patient Initials : Surname initial: First name initial:
Gender: F: ☐ M: ☐ Birthday: / / and/or Age: years

In vitro diagnostic medical device used :

Common device name:
Trade name (if CE marked) :
Model : Version (including software) :
Serial number : Batch number :
Reason for wich this device was used in this patient :
How was this device used :

Starting date of this device utilization : / /

Termination date of this device utilisation : / /
Was there « unblinded » ? Yes ☐ No ☐ Non applicable ☐
If yes, results :

Other treatments :

Concomitant drug therapy and non-drug treatment (dosage, date treatment began, …) :

Information about the suspicion of serious adverse event or reaction :

Complet description including signs and/or symptoms, organe affected,severity, and the criteria that qualifies the effect of serious. If necessary, explain the diagnosis:

Description of the adverse effect or event :

Date of 1st onset / /

End date / / or Duration (specify time period) :

What were the consequences when the device was suspended, and if applicable, when the device was reintroduced :

Place of occurence (research centre, hospital, day hospital, home, nursing home…)

Follow-up will be mentioned (information related to recovery and possible after-effects (sequels) additional tests and if necessary, specific treatments required and their results:

Death ☐ Give the cause :

Any additional information about a possible effect relationship including any information resulting from an eventual autopsy or other post-mortem tests (including the medical examiner report) when they are available:

Important detailed factors that can help in the evaluation of the case, related pathologies (that can have a causal relationship with the serious adverse event – SAE), medical and family histories, results obtained from special investigation :

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Possible cause-effect relationship

Imputability estimate

- ***by the sponsor :***

- to the device : certain : ☐ likely : ☐ possibly : ☐ not likely : ☐

- ***by the investigator (only in the case of discrepancy between the*** **investigator and the sponsor)*** **:**

- to the device : certain : ☐ likely : ☐ possibly : ☐ not likely : ☐

Important comments :

Identification of the reporter

- Name of person to be contacted :
- Address :
- Phone number :

Administrative and sponsor information

Date of report by the sponsor : / /
Origin of the effect /event :

a) Clinical investigation : ☐
b) Scientific literature provide a copy) : ☐
c) Spontaneous notification: ☐
d) Othe health/registry authority: ☐

Date on which the sponsor first became aware of the adverse event :
/ /
Country in which the event occurs :
Sponsor name :
Sponsor address :

Person delegated by the sponsor to submit the report
- Name of the person :
- Adress :
- Phone number :

Case ID number assigned by the sponsor :

Attach a copy of the serious adverse event (SAE) form filled out by the investigator
Attach a copy of the hospital report, if available

Date : / / Sponsor signature :

Name: Title :