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 : additional information, follow-up data

Articles L. 1123-10, R. 1123-46, R. 1123-49, R. 1123- 55, R. 1123-60 of the French Public Health Code

Date of initial report to the ANSM: **/ /**

Suspected unexpected serious adverse effect ☐

To be sent

By email *(preferred)* to: EC.DM-COS@ansm.sante.fr

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 additional 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 :

Date of the additional information report **/ /**

Code number identifying the investigation participant:

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

Follow-up of the previously reported serious adverse effect/event (the possible initiated treatments and the results will be listed):

Additional information obtained since the initial report:

_____

Do additional data change the assessment of the effect's or event's imputability to the device being studied?
yes: ☐ **no:** ☐
If yes, explain:

Comments:

Attach a copy of the Serious Adverse Event (SAE) report form filled out by the investigator.
Attach a copy of the hospital report if necessary

Date: **/ /** Sponsor signature:

Name: Title: