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

Form 6

Articles L. 1123-10 and R. 1123-39 to 1123- 44, R. 1123-48 and R. 1123-54 of the public health code

Date of initial report to the ANSM: //

Suspected unexpected serious adverse effect

Serious adverse event possibly related to the procedure for implementation of the medical device

To be sent

By email *(preferred)to:*	EC.DM-COS@ansm.sante.fr *(in the subject line, type in "VIGILANCE" and the number assigned by the ANSM (French Health Product Safety Agency) during registration of the application for marketing authorization and opinion)*
Par courrier à :	**Agence nationale de sécurité du médicament et des produits de santé (ANSM)** **Direction des dispositifs médicaux thérapeutiques et des cosmétiques** **Essais cliniques** **143-147 Boulevard Anatole France** **93285 Saint-Denis cedex**
Par fax :	01.55.87.37.17 (Spécifier à l'attention de l'ANSM/DMTCOS)

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: Quality: