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| ANSM - Agence nationale de sécurité du médicament et des produits de santé | **Form 6** |
| **Clinical investigation involving a medical device or an in vitro diagnostic medical device.**  **Vigilance report : additional information, follow-up data** |
| *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](mailto: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: | |