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|  **Report details** |
| EudraCT number: |  |
| Sponsor number: |  |
| Protocol title: |  |
| Centre number: |  |
| Country deficiency occurred:(if applicable) |  |
| Participant number: |  |
| Device: |  |
| Type of report: | Initial Supplementary Follow-up |
| **Device details** |
| Describe the nature of the device, its normal (label) applications and its application in the Clinical Investigation if different: |
| **SAE/SADE details** |
| Date of event: |  |
| Date of onset: |  |
| Diagnosis: |  |
| Description of deficiency: |
| **Seriousness criteria:** |
|  | * Death
* Life threatening illness or injury
* Permanent impairment of a body structure or body function
* Hospitalisation or prolongation of existing hospitalisation
* Medical or surgical intervention to prevent life threatening illness , injury or impairment to a body structure or body function
* Foetal distress, death or congenital anomaly or birth defect
* Recommendation of DMC
* New event/reaction likely to affect the safety of participants
* Post study USADE
 |
| Severity of event: | Mild Moderate Severe |
| **Action taken** |
|   |
| **Additional information** |
| Name and contact details of person reporting and role (ie PI): |  |
| Date of report: |  |
| PI signature: |  |
| Date received by Sponsor: |  |
| Action: |