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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: | | |