# ANNEX 1

**AF/01-019/01**

**Serious Adverse Event Report**

|  |  |  |
| --- | --- | --- |
| Principal Investigator: …………………………………….. | | Study Site: |
| Protocol Title: ………………………………………………………. | | Protocol No.: |
| Sponsor (if applicable)…………………………… | | |
| Name of the study drug / medical device: | | |
| Report Type  ⬜ Initial ⬜ follow-up  ⬜ Final | Report Source:  ⬜ Investigator ⬜ Sponsor  ⬜ DSMB ⬜ IRB member  ⬜ Others, specify: | |

|  |  |  |  |
| --- | --- | --- | --- |
| Subject’s initial/number: | Age: | | **⬜** Male **⬜** Female |
| Describe Reactions (onset date, signs, symptoms, including relevant tests/ lab data) | | | |
| Medical treatment | | | |
| Progression of the SAE | | | |
| Seriousness:  ⬜ Death  ⬜ Life Threatening  ⬜ Hospitalization –⭘ initial ⭘ prolong  ⬜ Disability / Incapacity  ⬜ Congenital Anomaly  ⬜ Other………………………………… | | Relation to ⭘ Drug ⭘ Device ⭘ study  ⬜ Not related  ⬜ Possibly  ⬜ Probably  ⬜ Definitely related  ⬜ Unknown | |
| Changes to the protocol recommended? | | ⬜ No ⬜ Yes , attach proposal | |
| Changes to the informed consent form recommended? | | ⬜ No ⬜ Yes , attach proposal | |
| Reported by: …………………………………………………  Report Date: | | | |