# Annex 1

 Form AF/AS/01-019/2022/01.2

|  |  |
| --- | --- |
| Protocol No.:  |  |
| Study Title:………………………………………………………. |  |
| Name of the study medicine/device………………………..………………… | Report Date :…………⬜ initial ⬜ follow-upOnset date:…………… |
| Sponsor:…………………………………………………Research Location :…………………………………….. | Date of first use:……………………….. |

|  |  |  |
| --- | --- | --- |
| Subject’s initial/number/identification: | Age: | **⬜** Male **⬜** Female |

|  |  |
| --- | --- |
| Subject’s history: | Laboratory findings: |

|  |  |
| --- | --- |
| SAE / SUSAR: | Treatment:Outcome: **⬜** resolved **⬜** on-going |

|  |  |
| --- | --- |
| Seriousness:⬜ No. of Death | Relation to ⭘ Drug ⭘ Device ⭘ study⬜ Not related⬜ Possibly⬜ Probably⬜ Definitely related⬜ Unknown |

|  |  |
| --- | --- |
| Seriousness: ⬜ Life Threatening an Euthanized | Relation to ⭘ Drug ⭘ Device ⭘ study⬜ Not related⬜ Possibly⬜ Probably⬜ Definitely related⬜ Unknown |

|  |  |
| --- | --- |
| Seriousness:⬜ No. of Disability / Incapacity / Euthanized | Relation to ⭘ Drug ⭘ Device ⭘ study⬜ Not related⬜ Possibly⬜ Probably⬜ Definitely related⬜ Unknown |

|  |  |
| --- | --- |
| Seriousness:⬜ 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 |

|  |  |
| --- | --- |
| **Signature of PI :**  | Date: |
| Reviewed by : ……………………… | Date:  |

|  |  |
| --- | --- |
| Comment : ……………………………………………….Action :* + - 1. Continue
			2. Continue with remark
			3. Discontinue /Terminate
 |  |