# Annex 1

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

|  |  |
| --- | --- |
| Protocol No.: |  |
| Study Title:………………………………………………………. |  |
| Name of the study medicine/device………………………..………………… | Report Date :…………  ⬜ initial ⬜ follow-up  Onset 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 |  |