# ANNEX 2

**AF/02-019/01**

Unexpected Adverse Event Summary Report

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| --- | --- |
| Principal Investigator: …………………………………………………………………………. |  |
| Study Title: ……………………………………………………………………………………... | Protocol No.: |
| Name of the studied medicine/device………………………..…………………………….. | This report covers the period : |
| Sponsor: ………………………………………………………………………………………... | From…………………To………………. |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **#** | **Description of Unexpected Adverse Events** | **Date of Event**  **(D/M/Y)** | **Date start and end of Tx (D/M/Y)** | **F or M** | **Age**  **(Y)** | SERIOUSYes No | **RELATED TO STUDY** Yes No | **Concomitant medication** | **Intervention** |
|  |  |  |  |  |  | **⬜ ⬜** | **⬜ ⬜** |  |  |
|  |  |  |  |  |  | **⬜ ⬜** | **⬜ ⬜** |  |  |
|  |  |  |  |  |  | **⬜ ⬜** | **⬜ ⬜** |  |  |
|  |  |  |  |  |  | **⬜ ⬜** | **⬜ ⬜** |  |  |

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| --- | --- |
| **Comment:** |  |
| **Reviewed by**: ………………………………….…………………………………………………………………… | **Date** (D/M/Y): ……………………………………. |