# Annex 2

Form AF/AS/02-019/2022/01.2

# Suspected Unexpected Serious Adverse Reaction Report

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Principal Investigator:…………………………………………………………………………. | | | | | | | | | | Application No: | | | |
| Study Title:……………………………………………………………………………………... | | | | | | | | | | Protocol No.: | | | |
| Name of the studied medicine/device………………………..…………………………….. | | | | | | | | | | This report covers the period : | | | |
| Sponsor:………………………………………………………………………………………... | | | | | | | | | | From…………………To………………. | | | |
| # | Description of SuspectedUnexpected Serious Adverse Reaction | Date of Event  (D/M/Y) | Date start and end of Tx (D/M/Y) | No. of Animals | No. of age | F or M | Initial | Age  (Y) | Serious  Yes No | | Related to Study  Yes No | Concomitant medication | Intervention | |
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**Annex 3**

Form AF/AS/03-019/2022/01.2

Document History

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| **Autho**r | **Version** | **Date** | **Description** |
| EC Members | 01.0 | 2 January 2019 |  |
| MW, | 01.1 | 2 January 2020 |  |
| MW, | 01.2 | 1. January 2022 | 1. Item 5.1.2 : add box 2 “On site SAE should go to Fullboard and Offsite SAE should go to expedited 2. Annex 1 : modified template Annex 1 3. Annex 2 : Modified template Annex 2 4. References : Declaration of Helsinki, 2013 & Council for International Organizations of Medical Sciences *(***CIOMS***),***2016** |