# 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)  | SeriousYes No | Related to StudyYes No   | Concomitant medication | Intervention |
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**Annex 3**

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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**
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