| Serious Adverse Event Notification | |
|---|---|
| Update Date | |
| Country where the AE occurred | |
| Adverse event notification for | |
| International case number | |
| Report number | |
| ANVISA considerations | |
| File number | |
| CE or CEE number | |
| Num. Clinical protocol | |
| Study blinding (Who is blinded in this study?) | |
| Chapter ICD 10 | |
| ICD 10 Group | |
| ICD 10 category | |
| ICD 10 sub-category | |
| Clinical indication | |
| Severity/Intensity of the disease under study | |
| Product development phase | |
| Does the sponsor in Brazil know the allocation of each research subject? | |
| CPF of the notifier | |
| Name | |
| Notifier category | |
| Specify another category | |
| Company name | |
| Contact email (Business) | |
| Contact email | |
| Commercial phone) | |
| Telephone | |
| Sex | |

| Serious Adverse Event Notification | |
|---|---|
| Age | |
| Date of birth | |
| Age Range | |
| Research subject code | |
| initials | |
| Allocation | |
| Description of the intervention procedure | |
| Type of adverse event notification | |
| Notification sequence | |
| Factors and other comorbidities | |
| Does the volunteer have or have had a concomitant illness or clinical condition? | |
| ICD10 sub-category (2) | |
| Start date (2) | |
| End date (2) | |
| ICD10 sub-category (3) | |
| Start date (3) | |
| End date (3) | |
| ICD10 sub-category (4) | |
| Start date (4) | |
| End date (4) | |
| ICD10 sub-category (5) | |
| Start date (5) | |
| End date (5) | |
| Institution that maintains the research center | |
| ORGAN/UNIT | |
| SERVICE/SUB-UNIT | |
| Principal investigator's phone number | |
| Principal investigator | |

| Serious Adverse Event Notification | |
|---|---|
| Number of subjects expected in the center | |
| Number of subjects admitted to the center | |
| Adverse Event | |
| MedDRA code | |
| WHOART for EA | |
| WHOART term for adverse event | |
| EA start date | |
| EA end date | |
| Narrative | |
| AE Severity | |
| Date of knowledge of the adverse event | |
| Cause of AE in the opinion of the investigator | |
| Type of adverse event | |
| CNES number of the service | |
| Institution that maintains the health service | |
| ORGAN/UNIT | |
| SERVICE/SUB-UNIT | |
| Federation Unit/State | |
| Postal code of the service location | |
| Was it supported with resources provided by the sponsor? | |
| Was any action necessary? | |
| Action taken | |
| AIH number (hospital admission authorization) | |
| Date of interruption of experimental or control treatment | |
| Another procedure | |
| Treatment | |
| Dose | |
| EA intervention start date | |

| Serious Adverse Event Notification | |
|---|---|
| Treatment end date for AE | |
| Unit in which there was hospitalization | |
| Postal code of the place of hospitalization | |
| CNES number of the service | |
| Date of admission | |
| Evolution in relation to EA | |
| Was it necessary to break the masking code? | |
| Description Medication A | |
| Dose of Medicine A | |
| pharmaceutical form | |
| route of administration | |
| Manufacturer of Medicine A | |
| Lot(s) of product A | |
| Product Category | |
| Description of Other Product Category | |
| Start date of use (A) | |
| End of use date (A) | |
| Causality WHO (A) | |
| Did the event occur again? | |
| Did/does the research subject use other products/medicines? | |
| Medicine B | |
| Dose of Medicine B | |
| pharmaceutical form (B) | |
| route of administration (B) | |
| Manufacturer of Medicine B | |
| Batch of Medicine B | |
| Product Category | |
| Description of Other Product Category | |

| Serious Adverse Event Notification | |
|---|---|
| Start date of use (B) | |
| End of use date (B) | |
| WHO Causality (B) | |
| Did the event occur again? | |
| Medicine C | |
| Dose of Medicine C | |
| pharmaceutical form (C) | |
| route of administration (C) | |
| Product Category | |
| Description of Other Product Category | |
| Start date of use (C) | |
| End of use date (C) | |
| WHO Causality (C) | |
| Did the event occur again? | |
| Medicine D | |
| Dose of Medicine D | |
| Product Category | |
| Description of Other Product Category | |
| Start date of use (D) | |
| End of use date (D) | |
| WHO Causality (D) | |
| Did the event occur again? | |
| Medicine E | |
| Medication Dose (E) | |
| Product Category | |
| Description of Other Product Category | |
| Start date of use (E) | |
| End of use date (E) | |

| Serious Adverse Event Notification | |
|---|---|
| WHO Causality (E) | |
| Did the event occur again? | |
| I assume civilly and criminally full responsibility for the data presented | |
| Notification sending date | |