|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Adverse Event [AE] | |  | | | | |
| Verbatim *[AE1]* | |  | | | | |
| Verbatim *[AETERM]* | |  | | | | |
| Coding *[AE2]* | |  | | | | |
| CTCAE SOC  *[AESOC]* | | **\*List of SOC from CTCAE V4.0** | | | | |
| CTCAE Term  *[AEPT]* | | **\*List of Terms (PT) from CTCAE V4.0** | | | | |
| Dates of event *[AE3]* | |  | | | | |
| Ongoing at the  beginning of treatment  *[AESGO]* | □ | | Start date  *[AESDT]* | |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_| DD/MM/YYYY | Cycle at which the event started  *[AECYCLE]* | |\_\_|\_\_| |
| Ongoing at  the end of treatment and/or  at the end of short-time follow up  *[AEEGO]* | □ | | End date  *[AEEDT]* | |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_| DD/MM/YYYY |  |  |
| Details on the case *[AE4]* | |  | | | | |
| Grade *[AEGR]* | | |\_\_| | | | | |
| DLT *[AEDLT]* | | 🌕 0-No 🌕 1-Yes | | | | |
| *SAE [AESER]* | | 🌕 0-No 🌕 1-Yes | | | | |
| SAE *[AE5]* | |  | | | | |
| Date of SAE reporting to PV  *[AESERDT]* | | |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_| DD/MM/YYYY | | | | |
| CIOMS Number  *[AECIOMS]* | | |\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_| | | | | |
| Additional information *[AE6]* | |  | | | | |
| Related to  *[AEREL]* | | 🌕 1-Drug 1  🌕 2-Drug 2  🌕 3-Drug 3  🌕 4-Cancer  🌕 99-Other | | | | |
| If other, specify *[AEREL\_S]* | |  | | | | |
| Action  *[AEACN]* | | 🌕 0-No action  🌕 1-Action 1  🌕 2-Action 2  🌕 99-Other | | | | |
| If other, specify *[AEACN\_S]* | |  | | | | |
| Treatment required  *[AETRTYN]* | | 🌕 0-No 🌕 1-Yes | | | | |