Instructions: Copy/paste the below tables into an email and enter all details

To: eu-seriousbreachescommittee@amgen.com

Subject line: Potentially Reportable Serious Breach

|  |  |
| --- | --- |
| **SUBMITTER DETAILS** | |
| Name |  |
| Job Title |  |
| Email |  |
| Phone |  |
| **ALTERNATE CONTACT DETAILS** (ie somebody who can respond to queries if submitter is not available) | |
| Name |  |
| Job Title |  |
| Email |  |
| Phone |  |

|  |  |
| --- | --- |
| **STUDY DETAILS** *(list all, separated by ;)* | |
| Product(s) |  |
| Protocol number(s) |  |
| Sponsor |  |
| Countries where the event occurred |  |
| **SITE DETAILS** *(list all, separated by ;)* | |
| Investigator |  |
| Site number (for this study) |  |
| Amgen Clinical Monitor |  |
| **Supplier or OTHER DETAILS** *(list all, separated by ;)* | |
| Supplier name |  |
| Supplier address |  |

| **POTENTIAL IMPACT (Select all that apply)** | | |
| --- | --- | --- |
| Is the event likely to impact to a significant degree the safety or physical or mental integrity of a study participant? | | ☐ Yes  ☐ No |
| Is the event likely to impact to a significant degree the rights of a study participant? | | ☐ Yes  ☐ No |
| Is the event likely to affect to a significant degree the reliability and robustness of the data and the scientific value of the study? | | ☐ Yes  ☐ No |
| Is the event likely to impact to a significant degree other Amgen studies? | | ☐ Yes  ☐ No |
| Is the event a Potentially Reportable Serious Breach for other reasons not listed above, including local reporting requirements in other countries?  If Yes provide details including impacted countries in the next row. | | ☐ Yes  ☐ No |
| *Provide details of the background and impacted countries in this row:* | | |
| Date of awareness of issue | DD MMM YYYY | |
| Date of the issue (date issue occurred) | DD MMM YYYY | |

|  |
| --- |
| **GIVE DETAILS OF THE POTENTIALLY REPORTABLE SERIOUS BREACH**  Explain the potentially reportable serious breach and what has happened.   * Do not include unnecessary personal information or commercially confidential information * Do not include any potentially unblinding information * Use tables and text as needed * Do not use acronyms |
| *Enter Information here including:*  *Context required to support understanding of the event:*  *How the event was discovered, when and by whom:*  *Timeline including decision process leading to submission to Amgen.* |