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

To: eu-seriousbreachescommittee@amgen.com

Subject line: Potentially Reportable Serious Breach

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| --- |
| **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 |  |

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| **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  |

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| **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.* |