Investigator Sponsored Study (ISS)-Information Sheet

下記を英語にてご記入後メールでお送りください。

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| --- | --- |
| Submission Date (Year/Month/Date) |  |
| **Study Contact（申請者情報）** |
| **Sponsor** (研究責任医師あるいは代表者氏名) |  |
| Institution:   |  |
| Address |  |
| City |  |
| State/Province/Region/Prefecture |  |
| Postal Code: |  |
| Country: |  |
| Telephone:  |  |
| Fax:  |  |
| Email:  |  |
| **Primary Study Contact（主たる連絡先。上記Sponsorと異なる場合。）** |  |
| Institution:   |  |
| Address |  |
| City |  |
| State/Province/Region/Prefecture |  |
| Postal Code: |  |
| Country: |  |
| Telephone:  |  |
| Fax:  |  |
| Email:  |  |
| **Study Proposal** |
| Study title:   |  |
| Amgen product(s):  |  |
| Non Amgen product(s):  |  |
| Country information:  | □ Single country  □ Multi-country |
| If multi-country study, provide list of countries:    |  |
| Will Amgen study drug(s) be used off-label? If yes, in which country(ies)?  |  |
| Study phase:   | * 1   □　2    □ 3    □ 4    □ Other
 |
| Study Design:      | □Neoadjuvant   □Adjuvant  □Other:        □Open-label  □Placebo-control  □Single-blind  □Observational □Retrospective   □Double-blind  □Observational □Prospective  □Non-randomized  □Randomized 　Randomization Ratio:        □Comparator:   |
| Site Information:   | □Single site  □Multi-site 　Number of Sites:     |
| Study Objectives（Primary）:       |  |
| Study Endpoints (Primary):        |  |
| Sample size |  |
| **Subject Selection**  |
| Inclusion criteria:  |  |
| Exclusion criteria: |  |
| **Support Requested** |
|  □Drug and funding  □Drug only  □Funding only  □Other:  |
| Amount of Amgen funding requested (JPY):  |  |
| Estimated total study budget (JPY): |  |