**S1 Table.** Results from Multivariable Logistic Regression Models of Study Delay

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| --- | --- | --- | --- |
| **Characteristic** | **Adjusted Odds Ratio (aOR)** | **95% Confidence Interval (CI)** | *P value* |
| PIP opinion year |  |  |  |
| 2008 | 1 [Reference] |  |  |
| 2009 | 1.01 | (0.26-3.87) | 0.99 |
| 2010 | 0.90 | (0.19-4.28) | 0.89 |
| 2011 | 1.59 | (0.41-6.14) | 0.50 |
| 2012 | 0.42 | (0.09-1.92) | 0.27 |
| 2013 | –b | –b | –b |
| Therapeutic area a |  |  |  |
| Alimentary and metabolism | 1 [Reference] |  |  |
| Blood | 0.25 | (0.07-0.88) | 0.03 |
| Cardiovascular | 0.66 | (0.13-3.42) | 0.62 |
| Genitourinary | 0.05 | (0.00-0.72) | 0.03 |
| Anti-infective | 0.82 | (0.22-3.01) | 0.76 |
| Antineoplastic | 1.26 | (0.29-5.40) | 0.76 |
| Neurologic | 0.58 | (0.15-2.20) | 0.42 |
| Respiratory | 0.30 | (0.07-1.34) | 0.12 |
| Musculoskeletal and others | 1.14 | (0.26-5.08) | 0.86 |
| Planned completion after MA |  |  |  |
| Yes | 1.17 | (0.59-2.35) | 0.65 |
| No | 1 [Reference] |  |  |
| Orphan drug status |  |  |  |
| Yes | 0.44 | (0.18-1.05) | 0.06 |
| No | 1 [Reference] |  |  |
| Study type |  |  |  |
| PK/PD only | 1 [Reference] |  |  |
| Primarily efficacy | 1.14 | (0.50-2.60) | 0.75 |
| Efficacy and safety | 0.58 | (0.14-2.51) | 0.47 |
| Primarily safety | 0.95 | (0.40-2.28) | 0.91 |
| Total modifications | 2.31 | (1.18-4.51) | 0.02 |
| Modification type |  |  |  |
| Study size | 0.86 | (0.29-2.54) | 0.79 |
| Endpoints | 0.95 | (0.27-3.38) | 0.93 |
| Population | 0.59 | (0.21-1.63) | 0.31 |
| Statistical methods | 0.58 | (0.18-1.87) | 0.37 |
| Treatment duration | 0.29 | (0.11-0.76) | 0.01 |
| Other changes | –b | –b | –b |
| Planned study enrolment (N) | 1.00 | (1.00-1.00) | 0.91 |