**Appendix**

**Full description of criteria for selection of potential post-IGIV acute ischemic stroke (AIS) cases.**

The study population consisted of new IGIV users who initiated treatment from January 1, 2006, through December 31, 2012. New IGIV users were defined as those with an IGIV treatment preceded by a period of 183 days of medical and pharmaceutical insurance coverage, during which no Ig treatments were observed. The first such IGIV treatment date was designated the patient’s new use date. For the parent study on IGIV and thromboembolic event (TEE) risk, the arterial TEE endpoint included cases of acute myocardial infarction (AMI) and acute ischemic stroke (AIS).

Patients were followed from the IGIV new use date until the first occurrence of an inpatient arterial TEE diagnosis during a post-IGIV risk or control period, loss of health plan enrollment, or the end of the study period (December 31, 2012). For the arterial TEE endpoint, the risk period was defined as days 0-2 following an IGIV treatment, and the control period as days 14-27 following an IGIV treatment.

After identifying patients with a qualifying post-IGIV inpatient arterial TEE diagnosis, we applied the following exclusion criteria. A patient was excluded if (a) an inpatient encounter with an arterial TEE diagnosis was observed in the prior 30 days, (b) no medical procedure or diagnosis constituting a potential IGIV indication was observed in the prior 183 days, (c) the patient received IGIV within 20 days of a prior or subsequent IGIV treatment episode, or the end of the study period (to ensure that a control period was observable for the patient), or (d) the proximate IGIV treatment episode included an administration of a subcutaneous or intramuscular IG product or multiple branded IGIV products on or before the TEE admission date.

In this manuscript we report on the positive predictive value (PPV) associated with AIS diagnoses. PPVs for AMI diagnoses codes are reported separately.

For additional details, please see the protocol for the parent study, available online at <https://www.sentinelsystem.org/sites/default/files/Drugs/Assessments/Mini-Sentinel_Thromboembolic-Events-After-Immunoglobulin-Administration-Protocol_0.pdf> .

**Appendix Table A1. Reasons charts could not be obtained for review.**

| **Reason** | **Frequency** |
| --- | --- |
| Chart not obtained, or obtained after deadline for chart review | 3 |
| Chart not retrieved due to high cost | 4 |
| Data partner or vendor unable to locate chart corresponding to requested encounter | 13 |
| Data partner unable to identify patient | 1 |
| Data partner unable to map treatment record in SDD to provider name/identifiers needed for chart request | 14 |
| Insufficient information in chart | 1 |
| Provider did not reply | 5 |
| Provider refused to participate | 9 |
| Provider refused to participate due to legal/compliance/HIPAA concerns | 13 |
| Total | 63 |