Prior Work

**Characterising the background incidence rates of adverse events of special interest for covid-19 vaccines in eight countries: multinational network cohort study**

Xintong Li,1 Anna Ostropolets,2 Rupa Makadia,3 Azza Shoaiib,3 Gowtham Rao,3 Anthony G Sena,3,6 Eugenia Martinez-Hernandez,4 Antonella Delmestri,1 Katia Verhamme,6,7 Peter R Rijnbeek,6 Talita Duarte-Salles,5 Marc A Suchard,8,9 Patrick B Ryan,2,3 George Hripcsak,2 Daniel Prieto-Alhambra1,6

https://github.com/ohdsi-studies/Covid19VaccineAesiIncidenceCharacterization

**Adverse Events of Special Interest**

- Pulmonary Embolism
- Hemorrhagic Stroke
- Non-Hemorrhagic Stroke
- Deep Vein Thrombosis (DVT)
- Appendicitis
- Disseminated Intravascular Coagulation
- Transverse Myelitis
- Anaphylaxis
- Bell’s Palsy
- Encephalomyelitis
- Narcolepsy
- Guillain Barre syndrome
- Acute Myocardial Infarction
- Myocarditis Pericarditis
- Immune Thrombocytopenia (ITP)
Proposed Work

Adverse Events of Special Interest within COVID-19 Subjects

- **Objective:** Quantify how often AESIs occur in subjects post COVID-19 disease overall and across specific age and sex groups.

- It is relevant to know how often these AESIs occur amongst patients who suffer the condition vaccines aim to prevent to provide a counterfactual for risk evaluation.

Methods

Adverse Events of Special Interest within COVID-19 Subjects

• Retrospective cohort study

• Target Cohorts:
  – First COVID-19 Event (positive test)
  – First COVID-19 Event (positive test OR diagnosis)

• Outcome Cohorts:
  – 15 previous AESIs + Thrombosis with Thrombocytopenia (TWT)

• Population Subgroups: age and sex

• 7 Time-at-Risks (between 0-365 days)

• Outputs: Counts, Incidence Rates and Incidence Proportions of Outcomes
Data Sources

Adverse Events of Special Interest within COVID-19 Subjects

- Highlighted Data Partners
  - Columbia University Irving Medical Center (CUIMC) Electronic Health Record (EHR)
  - Stanford
  - IBM MarketScan® Commercial Claims and Encounters (CCAE)
  - IBM MarketScan® Medicare Supplemental Beneficiaries (MDCR)
  - IBM MarketScan® Multi-state Medicaid (MDCD)
  - IQVIA® Disease Analyzer (DA) Germany (IQVIA_GERMANY_DA)
  - IQVIA® Disease Analyzer (DA) France (IQVIA_FRANCE_DA)
  - IQVIA® Australia Longitudinal Patient Data (IQVIA_AUSTRALIA_LPD)
  - Japan Medical Data Center (JMDC)
  - Optum® de-identified Electronic Health Record Dataset (OPTUM_EHR)
  - Optum® de-identified Clinformatics® Data Mart Database – Date of Death (OPTUM_DOD)
  - Clinical Practice Research Datalink (CPRD) – GOLD / Aurum
  - Various European Health Data & Evidence Network (EHDEN) Data Partners (particularly from the COVID19 call)
  - Other data sources from prospective data partners
Current Status

• Protocol built and testing package now

• Plan to share analysis within the week and collect results by the end of December

• If you would like to participate, please email Erica Voss at evoss3@its.jnj.com