Adverse Events of Special Interest within COVID-19 Subjects

OHDSI Open Studies Presentation

2021.11.16 Community Call

Vaccine Evidence Working Group

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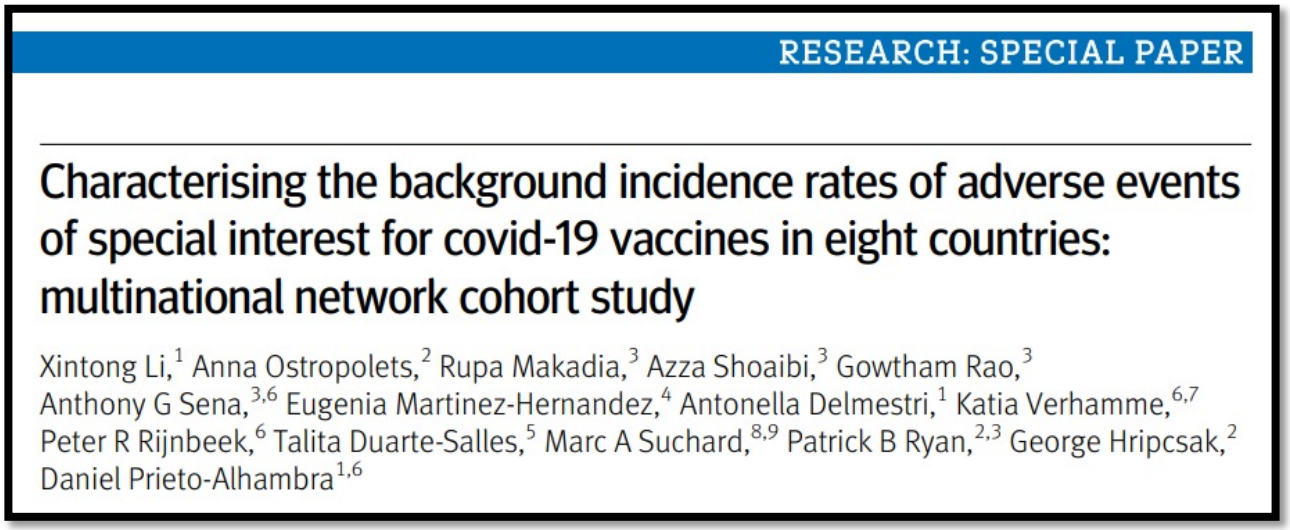
Azza Shoaibi, Anna Ostropolets, Fredrik Nyberg, Thamer Alshammary, Marc Suchard, Martijn Schuemie, Dani Prieto-Alhambra, Peter Rijnbeek, Patrick Ryan . . .

And in the future, many more!

Prior Work



RESEARCH: SPECIAL PAPER

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

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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)

Li, X., Ostropolets, A., Makadia, R., Shaoibi, A., Rao, G., Sena, A. G., Martinez-Hernandez, E., Delmestri, A., Verhamme, K., Rijnbeek, P. R., Duarte-Salles, T., Suchard, M., Ryan, P., Hripcsak, G., & Prieto-Alhambra, D. (2021). Characterizing the incidence of adverse events of special interest for COVID-19 vaccines across eight countries: a multinational network cohort study. *medRxiv : the preprint server for health sciences*, 2021.03.25.21254315. https://doi.org/10.1101/2021.03.25.21254315

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.

- Protocol: https://ohdsi-studies.github.io/Covid19SubjectsAesiIncidenceRate/Protocol.html

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

EHDEN
EUROPEAN HEALTH DATA & EVIDENCE NETWORK

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