07/18/2022

**Petition for organization —Cell and Gene Therapy (CGT) Special Interest Group (SIG)**

**Overview and Mission**

The evolution of medicines from small molecules to proteins was a paradigm shift. The next leap on to cell and gene therapies (CGT) holds tremendous promise for patients, particularly with rare genetic conditions with no or minimal existing traditional therapeutic options. The patient, product, and system journeys for CGT are fundamentally different from traditional medicines and require new approaches in pharmacoepidemiology as well.

The Cell and Gene TherapySpecial Interest Group (CGT-SIG) serves as a collaborative community of ISPE members to discuss, develop, and improve study design, analytical methods, data elements, and quality for pharmacoepidemiologic studies focusing on the various aspects of CGT, including but not limited to safety and effectiveness.

**Objectives**

* To share knowledge and experience among members in the field of CGT
* To increase awareness of and discuss issues/challenges in pharmacoepidemiologic research on CGT
* To foster collaboration among the SIG members using novel real-world data sources and pharmacoepidemiologic methods to study CGT
* To develop and advance pharmacoepidemiologic methods (e.g., multi-database methods, data linkage (e.g. use of tokenization) and design-based approach to address bias) in the field of CGT
* To educate the general ISPE membership and external stakeholders on the role of pharmacoepidemiology in CGT
* To serve as a resource to ISPE membership by providing pharmacoepidemiologic research and training in CGT
* To increase participation, communication, and cooperation between ISPE members and other groups in academia, industry, and regulatory agencies that are focused on CGT

**Meetings**

We will hold quarterly, all-member teleconferences with agendas developed by committee leadership with input from SIG members. We will hold an annual, in-person meeting at the International Conference on Pharmaco­epidemiology & Therapeutic Risk Management (ICPE). ICPE-oriented SIG activities may include teaching pre-conference educational sessions, organizing symposia, workshops, and poster walks at the ICPE as well as stand-alone webinars on relevant topics.

**Committee Leadership**

Co-Chairs:

* Kui Huang | Pfizer

Vice-Chair: Quazi Ataher| CSL Behring

Secretary: TBD

**SIG Members**

Jamie Geier | Novartis

Darren Toh | Harvard Pilgrim

Niki Palmetto | Novartis

Yun Gu | Pfizer

Huifeng Wang |GSK

Sherry Xiao | Pfizer

Shilpa Viswanathan | Pfizer