Reports of adverse events that occur during clinical trials help identify issues with treatment safety and efficacy, and allow for better education of health practitioners and the general public, ultimately allowing us to learn from our mistakes to increase patient safety. In order to enable more effective sharing of such reports, this workshop will address the question of what the ontological basis for adverse events is.

This one-day workshop is divided into two parts. The first half will be presentations of accepted papers. The second half will be discussions centered around the construction of an adverse event representation within the OBO Foundry framework, motivated by the use case of vaccination clinical trials.

We will start with a proposal prototype for how the representation could be based on the Ontology for General Medical Science (OGMS) and the Information Artifact Ontology (IAO), and, together, aim to establish building blocks for reuse and expansion by the larger biomedical ontologies community. It is expected that discussion of adverse events will force more general issues to be addressed, such as relations between signs, symptoms and diseases or how to encode diagnoses and hypotheses. Conclusions of such discussions will be incorporated into the OGMS and the IAO.

Presentations will include:

- **AEO: A Realism-Based Biomedical Ontology for the Representation of Adverse Events**
  Yongqun He, Zuoshuang Xiang, Sirarat Sarntivijai, Luca Toldo, Werner Ceusters

- **Reporting Adverse Events: Basis for a Common Representation**
  Mélanie Courtot, Ryan Brinkman, Alan Ruttenberg

- **QUEST Adverse Event Database**
  Pia Emilsson, Kerstin Forsberg

- **Classifying Adverse Events from Clinical Trials**
  Bernard Lasalle

- **An Ontological Representation of Adverse Drug Events**
  Guoqian Jiang, Jon Duke, Jyotishman Pathak, Christopher Chute

- **Toward Answering Time-Related Questions from Adverse Event Reports Using Ontology-based Approaches**
  Cui Tao, Guoqian Jiang, Kimberly Clark, Deepak Sharma, Christopher Chute

- **Supporting Medical Device Adverse Event Analysis in an Interoperable Clinical Environment: Design of a Data Logging and Playback System**
  David Arney, Sandy Weininger, Terrie Reed, Susan Whitehead, Julian Goldman

- **Using Failure Modes, Mechanisms, and Effects Analysis in Medical Device Adverse Event Investigations**
  Shunfeng Deng, Diganta Das, Michael Pecht

- **Assessing Surgical Adverse Events Using Administrative Data**
  Tina Hernandez-Boussard, Catherine Curtin, Kathryn McDonald

  *In addition, short overviews of some existing resources will be presented:*

- **IAO: The Information Artifact Ontology**
  Alan Ruttenberg

- **OGMS: The Ontology of General Medical Science**
  Albert Goldfain

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