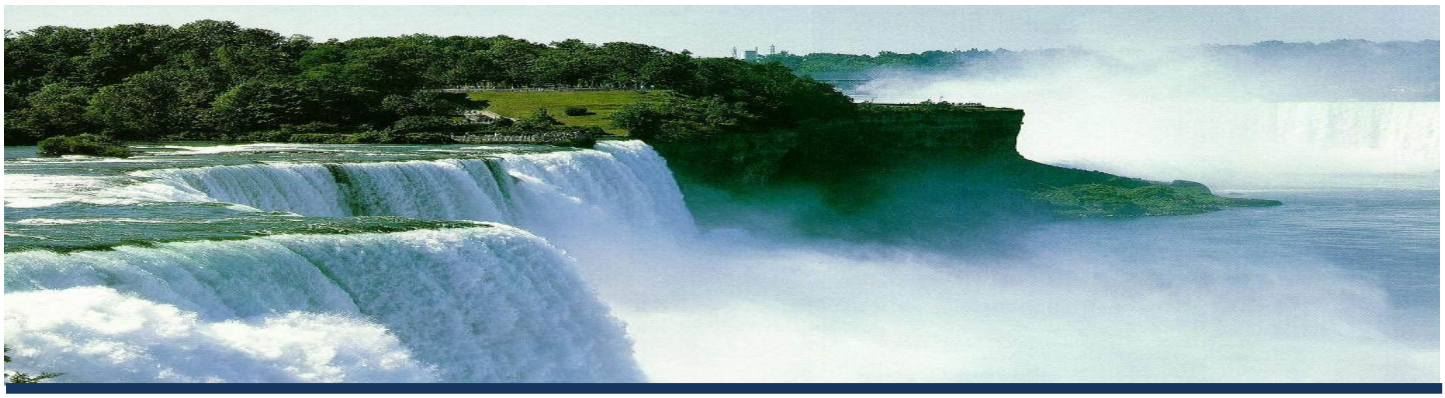

ICBO: International Conference on Biomedical Ontology

Representing Adverse Events

July 26, 2011 ▪ 9:00am - 6:00pm

Workshop Venue:

Marriott Buffalo Niagara, 1340 Millersport Highway ▪ Amherst, New York 14221

Room: Salon E / 2nd Floor

PROGRAM

8:30am **Registration**

9:00am **Introduction**
Barry Smith, University at Buffalo

9:10am **Session 1**
Chair: Albert Goldfain

Adverse Events Representation Frameworks

- **AEO: A Realism-Based Biomedical Ontology For the Representation of Adverse Events** (20 min)
  Yongqun He, Zuoshuang Xiang, Sirarat Sarntivijai, Luca Toldo, Werner Ceusters
- **Reporting Adverse Events: Basis For a Common Representation** (20 min)
  Mélanie Courtot, Ryan Brinkman, Alan Ruttenberg

9:50am **Adverse Events in Clinical Trials**

- **Reporting Adverse Events: Basis for a Common Representation** (15 min)
  Pia Emilsson, Kerstin Forsberg
- **Classifying Adverse Events from Clinical Trials** (20 min)
  Bernard LaSalle, Richard Bradshaw

10:25am **Adverse Drug Events**

- **An Ontological Representation of Adverse Drug Events** (15 min)
  Guoqian Jiang, Jon D. Duke, Jyotishman Pathak, Christopher G. Chute

10:40am **Break**

11:10am **Session 2**
Chair: Alan Ruttenberg

Medical Device Adverse Events

- **Toward Answering Time-Related Questions from Adverse Event Reports Using Ontology-Based Approaches** (20 min)
  Cui Tao, Guoqian Jiang, Kim Clark, Deepak Sharma, Christopher G. Chute
- **Supporting Medical Device Adverse Event Analysis in an Interoperable Clinical Environment: Design of a Data Logging and Playback System** (20 min)
  David Arney, Sandy Weininger, Susan F. Whitehead, Julian M. Goldman
- **Using Failure Modes, Mechanisms, and Effects Analysis in Medical Device Adverse Event Investigations** (20 min)
  Shunfeng Cheng, Diganta Das, Michael Pecht

Late submission

- **Assessing Surgical Adverse Events Using Administrative Data** (15 min)
  Tina Hernandez-Boussard, Catherine Curtin, Kathryn McDonald

12:30pm **Break**

1:30pm **Session 3: OBO Foundry Efforts**
Chair: Yongqun "Oliver" He

- **IAO: The Information Artifact Ontology** (20 min)
  Alan Ruttenberg
- **OGMS: The Ontology of General Medical Science** (20 min)
  Albert Goldfain

2:10pm **Session 4: General Discussion**

General Issues (65 min)
Moderated by William Hogan
- What is an adverse event?
- Minimum information to report an AE
- Time and causation
- AEs vs 'complications', AEs vs 'side effects', AEs vs 'device misuse'
- Application of AE reports

Medical Device Use Case (55 min)
Albert Goldfain
Several records from the FDA MAUDE database will be presented as illustrative use cases in medical device adverse event reporting. Each case will be described using terms and relations from OBO Foundry ontologies, with a specific focus on modeling the (free-text) event narratives described in the records. Through this exercise, we hope to assess OBO Foundry coverage and expressiveness for the medical device adverse event reporting task.

4:10pm **Break**

4:40pm **General Discussion** (cont.)

Clinical Trials Use Case (50 min)
Pia Emilsson and Kerstin Forsberg
A use case will be presented describing how a query from a regulatory authority is handled as part of the regular ongoing pharmacovigilance in pharmaceutical research and development. It will illustrate how databases and literature are being reviewed manually, exemplify how databases are structured and highlight some of issues in the coding of data. With this use case, we hope to provide a background to our interest in a more ontologically based approach to enable a more automatic way to access, structure and analyze patient safety related data.

Future Directions (30 min)
- How do we generate standards needed?
- How do we work collaboratively on such standards?

6:00pm Conclusion of Workshop

Organized by:

Mélanie Courtot, British Columbia Cancer Research Centre · Albert Goldfain, Blue Highway, LLC
Yongqun “Oliver” He, University of Michigan Medical School · Alan Ruttenberg, University at Buffalo