Optum

# Advance public health and safety with our trusted epidemiologists

The lifecycle of medications and vaccines often comes with regulatory requests requiring a response, including the need to evaluate potential safety signals and satisfy post-marketing commitments. Additionally, there may be opportunities to address forward-thinking research questions, such as label expansion.

Optum® Epidemiology brings unparalleled experience and expertise to improve real-world understanding of the safety and effectiveness of drugs and biologics. The Optum Epidemiology team has been conducting post-marketing drug safety research to address FDA and EMA requirements or commitments since our founding in 1980. These decades of pharmacoepidemiology experience allow our research team to employ academic rigor and broad-based experience to transform real-world data into evidence that can be used for regulatory decision-making.

### Post-marketing safety and effectiveness

Evaluate the safety profile of newly approved products in the context of existing therapies, including confirming safety outcomes through medical record adjudication after necessary approvals.

### Optum Dynamic Assessment of Pregnancies and Infants (DAPI)

Investigate pre- and post-natal exposures and their effect on pregnancy and infant outcomes using a systematic approach and out unique data asset linking mothers and babies.

### External control arms

Tap into our expertise to assess drug safety and effectiveness using external comparators, which expands the scope of questions that may be addressed beyond traditional single arm or randomized trials.

## One of the largest and most trusted real-world data repositories

**Medical claims data** (commercial claims, Medicare)

**Electronic health record (EHR) data**

**Proprietary data linkages**

## Capabilities that leverage proprietary Optum data

**Linkage to external data sources:** Optum can link external data sources to the claims database for select patients after necessary approvals. These include:

- **Medical record review:** This allows confirmation of exposures, outcomes, and covariates initially identified from the claims, an essential element for post-marketing safety studies.
- **National Death Index (NDI):** NDI may be linked to a subset of patients in the claims database to identify deaths and causes of death.

**Survey capabilities:** Optum can survey eligible patients and/or physicians following appropriate approvals.

**Machine learning and natural language processing (NLP):** Access information stored within free-text clinical notes to extract insight not available in traditional database studies.

## Connect with our team:

**John D. Seeger, PharmD, DrPH**
Chief Scientific Officer, Epidemiology
john.seeger@optum.com

**Florence T. Wang, ScD**
Vice President, Epidemiology
florence.wang@optum.com

To learn more, visit:
**optum.com/epidemiology**

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