

ACTIVE Surveillance to improve the VALUE of Pharmacovigilance as a Public Health tool

Group II:
Identification of
Unanticipated Signals



Unanticipated (Events) Signals Working Definition

- Unlabeled, high unexpected frequency or serious off-label use in “new” subpopulation

UN-ANTICIPATED SIGNALS:

- Improve spontaneous reporting
- Improve bidirectional communication, e.g. physician query for like events, communication with reporters
- EMR support system for physicians, e.g. datamining by practitioners
- Discovery – linked to enhanced support systems to electronic health records
- Large simple clinical trials, especially for anticipated “blockbusters”

UN-ANTICIPATED SIGNALS:

- Develop early warning list with relationships to precursor events
- Develop reference set (+ and -)
- Standardize from clinical trial and other data (technical and value analysis)
- Gold standard of drug event combinations with high sensitivity
- Pilot projects (e.g. define domains that need to go into linked database, evaluate ability to pull useful data from multiple sources, overcome HIPAA challenges)

UN-ANTICIPATED SIGNALS:

- Set of de-identified EHR for datamining
- Orthogonal testing
- Develop guidelines and policies for signal management system to address transparency and create safe harbor; developed with input from federal, private sector, patient advocacy groups, media, academic, etc.
- Create registry of registries
- Identify multiple data sources

DAY TWO: UN-ANTICIPATED SIGNALS:

- Need to focus what we look for, even though causal relationship not known (e.g. potential target list)
- Use of meta analysis and update

DAY TWO: UN-ANTICIPATED SIGNALS:

- Data standards for data sets which are subject to meta analysis (data needs and quality)
- Standard for conducting meta analysis