



Pharmacovigilance using Multiple Data Sources

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Postmarketing Pharmacovigilance

- GSK has a proactive, holistic approach to all safety information – literature, clinical trials, epidemiology studies, etc.
- Traditionally, Pharmacovigilance has focused on individual cases from spontaneous reports
- Newer, systems based tools for routine, proactive signal detection have been implemented (disproportionality analysis)
 - Sources: OCEANS (GSK) or AERS (FDA) databases
 - Methods: Multi-item Gamma Poisson Shrinker (MGPS), Proportional Reporting Rates (PRR)
- However, continued challenges exist
 - Reporting is voluntary – Underreporting – No numerator
 - Unknown exposure - No denominator
 - No comparison group
 - Bias in reporting



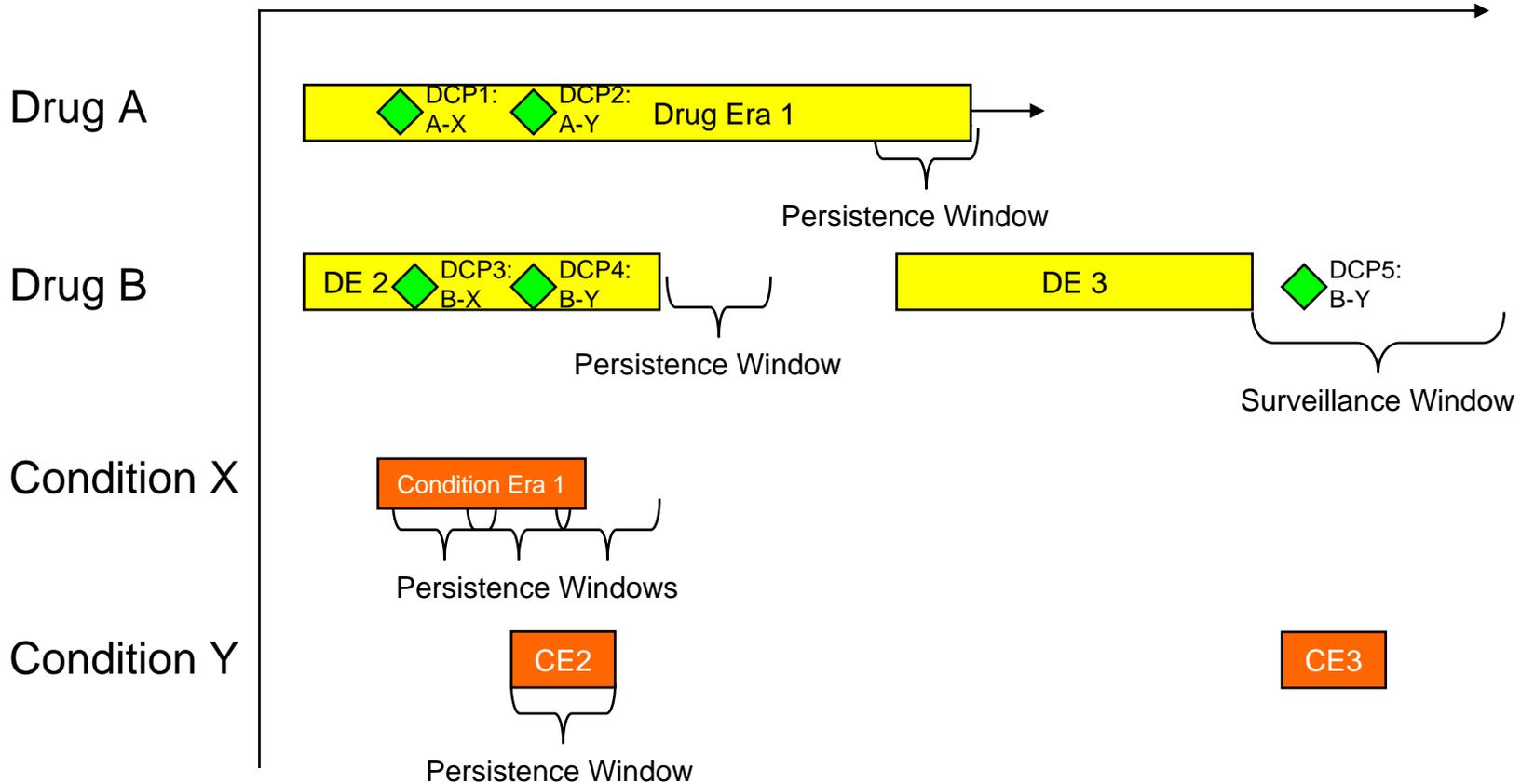
How can we improve?

- Supplement current process by leveraging observational data
 - Insurance claims:
 - e.g. Integrated Healthcare Information System (IHCIS), ~40 million lives, 22 months exposure
 - Electronic medical records:
 - e.g. GE Medical, ~5 million lives, 22 months exposure
- Establish context for evaluation of drug by exploring background of large population 'in the real world'
 - Demographics
 - Comorbidities
 - Concomitant medications
- Evaluate temporal relations
 - Symptoms and Diagnoses after prescription: drug-condition pairs
 - Changes in drug use before and after new prescription: drug-drug pairs
 - Doctor visits, procedures, laboratory values

Using Observational Data: A single patient example

Drug and Condition “eras” provide normalization across data sources

Person Timeline



Prescription



Diagnosis



Drug-Condition Pair

Future Vision

- Continue to develop methods to utilize observational data
 - Use ontologies to link concepts between disparate data sources
 - Develop analytics that minimize false positives and reduce bias
- Proactively use information during drug development to set the stage for post marketing surveillance
 - Use observational data to guide safety expectations of new treatments
 - Utilize new data types
 - New Biomarkers: e.g. pharmacogenetics, metabolomics
 - Develop classifiers/prognostics
 - Develop expected rates for patient subclasses

Backup

Hypoglycemia rates using Observational Data

