

Literature Settings for 2011-2012 OMOP Research

Literature	Analytical design choice
<p>Lit: Self-controlled case series design similar to Tata 2005 study of SSRIs-GI bleed [29]</p>	<p>Self-controlled case series SCCS: 1928010 Outcomes to include: First occurrence Prior distribution: normal Variance of the prior: Determined through cross-validation Time-at-risk: Length of exposure Include index date in time-at-risk: No Apply multivariate adjustment on all drugs: No Required observation time: 180d</p>
<p>Lit: New user cohort design similar to Smith 2011 study of isoniazid-acute liver injury [30]</p>	<p>New user cohort CM: 21000211 Required observation time prior to exposure: 180d Nesting within indicated population: No Comparator population: Patients with a diagnosis for the indication of the target drug and at least one exposure to a drug known to be not associated with the outcome Time-at-risk: Length of exposure + 30d Propensity score covariate selection strategy: Bayesian logistic regression using all available covariates Covariate eligibility window: 180d prior to exposure Dimensions to include as potential covariates: Drugs conditions and procedures Additional covariates include in the propensity score model: Age and sex and index year and Charlson index and number of drugs and number of visits and number of procedures Covariate selection algorithm additional parameters: Normal prior distribution with variance = 1 Propensity score trimming: None Metric: Propensity score stratification using Mantel Haenszel adjustment over 20 strata</p>
<p>Lit: Temporal pattern discovery design similar to Norén 2010 [13]</p>	<p>Temporal pattern discovery ICTPD: 3020001 Control period: -1080d to -361d before exposure start Time-at-risk: 30d from exposure start Use control period in expected calculation: Yes Use 1mo prior to exposure in expected calculation: Yes Use 1d prior to exposure in expected calculation: Yes</p>
<p>Lit: Observational screening design similar to Ryan 2009 [1]</p>	<p>Observational screening OS: 409002 Study design: Self-controlled cohort Exposures to include: First occurrence Outcomes to include: First occurrence Time-at-risk: Length of exposure + 30d Include index date in time-at-risk: No Control period: Length of exposure + 30d Include index date in control period: No</p>
<p>Lit: New user cohort design similar to Schneeweiss 2009 study of NSAIDs-GI Bleed [16]</p>	<p>New user cohort CM: 21000055 Required observation time prior to exposure: 180d Nesting within indicated population: No Comparator population: Patients with exposure to most prevalent comparator drug which shares the same indication as the target drug but is not in the same pharmacologic class Time-at-risk: Length of exposure + 30d Propensity score covariate selection strategy: High-dimensional propensity score covariate selection algorithm by Schneeweiss et al Covariate eligibility window: 180d prior to exposure Dimensions to include as potential covariates: Drugs conditions and procedures Additional covariates include in the propensity score model: Age and sex and index year and Charlson index and number of drugs and number of visits and number of procedures Covariate selection algorithm additional parameters: 500 top confounders from among 500 most prevalent covariates in each dimension that occur in at least 100 persons Propensity score trimming: None Metric: Propensity score adjustment using 5 strata as indicator variables in logistic regression outcome model</p>

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Literature	Analytical design choice
<p>Lit: Case-control design similar to Griffin 2000 study of ibuprofen-acute renal failure [31]</p>	<p>Case control CC: 2000241 Controls per case: up to 10 controls per case Required observation time prior to outcome: 180d Time-at-risk: Length of exposure Include index date in time-at-risk: No Case-control matching strategy: Age and sex Nesting within indicated population: No Exposures to include: All occurrences Metric: Odds ratio with Mantel Haenszel adjustment by age and gender</p>
<p>Lit: Case-control design similar to Opatrny 2008 study of clopidogrel-GI bleed [32]</p>	<p>Case control CC: 2000314 Controls per case: up to 10 controls per case Required observation time prior to outcome: 180d Time-at-risk: Length of exposure + 30d Include index date in time-at-risk: No Case-control matching strategy: Age and sex Nesting within indicated population: Yes Exposures to include: All occurrences Metric: Unadjusted odds ratio</p>
<p>Lit: Case-control design similar to Fischer 2005 study of indomethacin-acute myocardial infarction [33]</p>	<p>Case control CC: 2000241 Controls per case: up to 10 controls per case Required observation time prior to outcome: 180d Time-at-risk: Length of exposure Include index date in time-at-risk: No Case-control matching strategy: Age and sex Nesting within indicated population: No Exposures to include: All occurrences Metric: Odds ratio with Mantel Haenszel adjustment by age and gender</p>