OMOP Mini Symposium プログラム

日時：平成 25 年 10 月 21 日（月）13 時 00 分～15 時 00 分

場所：日本製薬工業協会　5F 3AB 会議室

12:30	開場
13:00-13:05	開会の挨拶 データサイエンス部会　副部会長　　田辺三菱製薬㈱　酒井弘憲
13:05-13:50	An Overview of US Databases and the OMOP Program of Research Paul Stang　Janssen Research & Development, LLC
13:50-14:35	Review of the Key Research Findings of OMOP to Date Patrick Ryan　Janssen Research & Development, LLC
14:35-15-00	質疑応答

OMOP とは？

OMOP は PhRMA と FDA が提携して、国立衛生研究所の財団として設立した官民パートナーシップで、医薬品とアウトカムの関係を観察研究で検出し評価するための様々な研究を行う学際的な研究グループで common data model や各種アルゴリズムなどすべての研究成果を無料で公開しています(http://omop.org/)。例えば最近では、複数の医療データソースからなるネットワーク全体から、効率的に医薬品とアウトカムとの関係に関するエビデンスを生成する研究を行い、その結果セルフ・コントロールデザインが全体に安定したパフォーマンスを示したこと、急性腎障害、急性心筋梗塞、消化管出血に比べて急性肝障害は一貫して予測精度が低かったこと、相対リスク比が 2 以上の場合には確実に正の相関を検出できるが、それより小さい効果では困難であったこと、データソース間のばらつきが大きく、どの研究デザインでも、効果の推定値がかなり異なる可能性があることなどを見出しています。すべての結果を日本のデータベースにも一般化できるわけではありませんが、それぞれのデータベースの特徴を明らかにし、特定のアウトカムのための最適な解析戦略を構築するための体系的で再現可能な手順は、近い将来日本でも大いに参考になることでしょう。

講演抄録

An Overview of US Databases and the OMOP Program of Research

Paul Stang

Vice-President: Global R&D Epidemiology, Janssen Research & Development, LLC

This presentation will briefly review the databases available and how they are used to answer critical questions. The fundamental goal of OMOP's research will be reviewed: that is to develop and evaluate standardized algorithms that can reliably discriminate the positive controls from the negative controls, and to understand how an estimated effect from an observational study relates to the true relationship between medical product exposure and adverse events. We studied performance and variation across databases, definitions, and methods.

Review of the Key Research Findings of OMOP to Date

Patrick Ryan

Head, Epidemiology Analytics, Janssen Research and Development

OMOP's latest experiment, the team evaluated the performance of a risk identification system for four health outcomes of interest: acute myocardial infarction, acute liver injury, acute renal failure, and gastrointestinal bleeding. For these outcomes, OMOP established a reference set of 399 test cases: 165 'positive controls' that represent medical product exposures for which there is evidence to suspect an association with the outcome, and 234 'negative controls' that are drugs for which there is no evidence that they are associated with the outcome. Several insights were gained about expected behavior of a risk identification system. We observed that self-controlled designs are optimal across all outcomes and all sources, but the specific settings are different in each scenario. All sources achieve good performance (Area under ROC curve > 0.80) for acute kidney injury, acute MI, and GI bleed, while acute liver injury has consistently lower predictive accuracy. A risk identification system should confidently discriminate positive effects with relative risk>2 from negative controls, but smaller effect sizes will be more difficult to detect. The results underscore the importance of transparency and complete specification and reporting of analyses, as all study design choices were shown to have the potential to substantially shift effect estimates.

以上