

Case study:

Celebrex and Peptic Ulcer/Bleeding

Challenge: Prove Safety of Celebrex for Peptic Ulcer and Bleeding

Celebrex and Vioxx belong to a common drug class, the cyclo-oxygenase-2 inhibitors (COX-2s). The high publicity accorded to an excess risk of myocardial infarction in Vioxx users and the withdrawal of Vioxx from the market was followed by a reduction in Celebrex sales, presumably because of new concerns over that drug's risk-benefit balance. i3 Drug Safety was asked to strengthen data on Celebrex's principal safety advantage: a reduced risk of serious gastrointestinal complications versus non-steroidal anti-inflammatory drugs (NSAIDs).

Solution: Case-control study

i3 Drug Safety performed a case-control study of patients hospitalized for peptic ulcer, bleeding, and perforation. A case-control study is a comparison of persons with an adverse effect to persons without, and can provide full information on determinants of risk. The i3 Drug Safety study was "nested" in a cohort of users of COX-2s and NSAIDs identified in health care claims data and involved medical chart confirmation of all cases. Nesting assures unbiased sampling of control patients—for comparison to cases—for highest quality assessment of the effects of study drugs and important confounders. Chart review confirms that idiosyncracies of insurance coding do not affect the results.

Result: Celebrex has Lower Risk of Hospitalization

Users of Celebrex had much lower rates of hospitalization for peptic ulcer, bleeding, and perforation than users of NSAIDs. They also had lower risks than users of Vioxx. i3 Drug Safety used the same analysis identified and controlled for many known risk factors, including age, concomitant drug use, and coexisting illnesses. These studies can be incorporated into ongoing regulatory evaluation and used in risk/benefit calculations to reduce burden of adverse effects in the population.