

Who Is Missing from Medication Safety Evidence? A Cross-National Assessment of Target-Trial Readiness in Pregnancy, Ageing, and Multimorbidity

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Abstract

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This study evaluates whether publicly available pharmacovigilance systems contain the information required for comparative medication-safety research using target-trial principles. It combines a secondary analysis of global VigiBase aggregates with a cross-national audit of public safety-data architectures from major regulatory systems.

The analysis included 15,069,370 sex-coded reports from 131 countries and assessed evidence visibility across pregnancy, ageing, and multimorbidity populations. The study found that numerical representation does not necessarily provide causal evidence because essential target-trial components such as treatment denominators, synchronized treatment initiation, comparator groups, baseline confounders, and longitudinal follow-up were unavailable.

The target-trial readiness assessment identified zero fully operationalizable components, three partially operationalizable components, and five absent components across the evaluated data systems. The study highlights the need for linked longitudinal healthcare databases, pregnancy registries, electronic health records, and mortality data for valid comparative medication-safety research.