Call to Action: Harmonisation of Pharmacovigilance Regulations for Post-marketing Pregnancy and Breastfeeding Safety Studies

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Abstract

Globally, more than 200 million women become pregnant each year, most of whom receive medications despite limited information on their safe use during pregnancy. The paucity of drug safety data on pregnant and breastfeeding women stems from the routine exclusion of this population from clinical trials due to scientific, ethical, regulatory and legal concerns. Consequently, at the time of initial drug approval, there may be scant safety data to inform the drug benefit-risk balance to the mother, foetus, or infant. Although momentum is growing to include this underrepresented population in clinical trials, most information on drug exposure outcomes comes from data collected in the post-marketing setting. Regulatory guidance and legislation on medication use in pregnancy and breastfeeding were reviewed globally by TransCelerate IGR PV Pregnancy and Breastfeeding Team. ICH standards and CIOMS guidelines served as benchmarks for national safety regulations and guidance. The landscape assessment identified a lack of harmonisation of global regulations on research in pregnant and breastfeeding women. This editorial focuses on the ambiguities and lack of harmonisation in global regulations on post-marketing pregnancy and breastfeeding safety studies. There is currently no ICH standard to guide these types of safety studies and, in most regions reviewed, there are no clear regulations or guidance on when and how to conduct them. While a challenging undertaking, greater clarity and harmonisation would facilitate more timely completion of post-marketing pregnancy safety studies that would ultimately generate the critical data needed to optimize benefit-risk decisions for pregnant and breastfeeding women.

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