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Pharmacovigilance & Drug Safety Summit

JULY 06-07, 2017   KUALA LUMPUR, MALAYSIA

Open access pharmacovigilance databases: Analysis of 11 databases

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The concept of transparency regarding scientific data is more and more obvious, this work aims at describing and analyzing what kind of safety data can be obtained from Pharmacovigilance (PV) databases that offer public access. Nine national pharmacovigilance databases (Australia, Canada, Denmark, Germany, Netherlands, New-Zealand, Japan, United Kingdom, USA) plus the World Health Organization (Vigibase) and the European Pharmacovigilance databases were compared according to the type of data provided, the possible requests (by drug, by adverse reaction) and the format of the safety data. Public access to PV databases is thus classified as high, medium or low. The results show that six databases grant case-level access, the others only provide aggregated data. In terms of general case information, the USA and Canada come first by sharing case ID, the type of report, the reporter and their qualification, whereas Vigibase does not provide any general information. Other databases mostly provide only one of these three items: Source, case ID, or type of report. Overall, the databases from Denmark, Japan, Netherlands, UK and VigiBase were classified as providing a low level of access to available safety information; those from Australia, Eudra Vigilance, Germany and New Zealand as providing a medium level of access; and those from the USA and Canada, as providing a high level of access. The 11 PV databases were analyzed, except for those in North America, provide limited information. This may be acceptable for patient use but not for research purposes.

Biography

Delphine Bertram, PharmD, PhD, has more than 12 years of experience in managing the safety of clinical trials. She has built and managed the Vigilance Unit of the Second Public French Hospital. She has hosted and managed European and French Health Authorities inspections (preparation, conduct and CAPA management), planned and executed internal/external audits. She has extensive knowledge in the international regulatory (ICH, FDA guidance's, GVP, MEDDEV) environment, for both pre- and post-marketing products, e-Health and social media monitoring. She has co-developed a free application to allow patients and healthcare professionals to report drug adverse effects to the health authority. She has a particular interest in e-Health precisely in the use of social data to improve drug surveillance.

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Notes:

J Clin Trial
ISSN: 2167-0870 JCTR, an open access journal

Global Pharmacovigilance 2017
July 06-07, 2017

Volume 7, Issue 4 (Suppl)

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