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Open access literature databases for mandatory drug safety literature screening during clinical development and post market – equal access to new science for pharmaceutical companies.

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Statement of the Problem:
It is difficult and expensive to meet the regulatory requirements in Europe and USA using existing commercial providers. Regulatory agencies mandate frequent often weekly literature searches using widely used reference databases. In addition, the European Union require literature searches in local language in member states. For many small or midsize pharmaceutical companies, the current costs for access to commercial reference databases and articles is prohibitive.
Methodology & Theoretical Orientation:
To conduct the required literature searches normally a subscription is required to access to commercial databases where the cost can run tens of thousands annually. Access to the full text articles must be paid separately which typically cost between $20-100 to access pr. article. Most existing library databases are not designed to support the specialized type of search that is required for drug safety to produce expedited single case reports and aggregate reports where searches are in date sequence and articles should be presented in a tabular format to quickly review the relevance of the article and access the full text as needed.

Dr Steen Ottosen is a physician with a medical degree from the University of Southern Denmark and clinical experience from general surgery as well as family medicine and specialization in public health medicine from the University of Oslo, Norway. He has 20 years of experience in drug safety, medical and regulatory affairs and quality management. He is founder of the drug safety consultancy company Steen Ottosen ApS with consultants and clients in the US and Europe.

1. FDA Draft Guidance for Industry: Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines
2. EMA Guideline on good pharmacovigilance practices (GVP) Module VI – Management and reporting of adverse reactions to medicinal products
3. CIOMS V: Current Challenges in Pharmacovigilance: A Pragmatic Approach
4. ICH E2D: Post-approval safety data management
5. ICH E2A: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting

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