## Perspectives in post marketing research

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Post marketing research includes Post Marketing Surveillance (PMS) studies and Drug Utilization Studies (DUS). PMS involves systematic monitoring of medications while they are used in clinical practice. Monitoring of medications while used in routine clinical practice is way different from the controlled settings of premarketing trials, in which study conditions are rigorously controlled. While, randomized clinical trials, which minimize variability, are useful for assessing the efficacy of a drug, they may not inform on the effects of a drug after it has been released for use in the general population. PMS studies can also provide valuable information on the use of drugs in special patient populations. Usually it's not possible to obtain such information from premarketing studies. Requirement for planned post marketing research provides an opportunity for the continued focus on the benefit risk profile of an approved drug, as well as conduct well planned studies in special populations. Although the importance of DUS has been well recognized, still DUS studies are not being planned as extensively as they should be. This presentation will focus on the importance of post marketing research, the value that it adds, the areas where improvisation is desired and regulatory authority and pharmaceutical industries perspective.

### Recent Publications

1. Haque A, Daniel S, Maxwell T, Boerstoel M (2017). Postmarketing Surveillance Studies-An Industry Perspective on Changing Global Requirements and Implications. Clin Ther. 2017 Apr;39(4):675-685.
2. Spelsberg Angela, Prugger Christof, Doshi Peter, Ostrowski Kerstin, Witte Thomas, Hüsgen Dieter *et al.* Contribution of industry funded post-marketing studies to drug safety: survey of notifications submitted to regulatory agencies *BMJ* 2017; 356 :j337
3. Real-World Evidence from https://www.evidera.com/wp-content/uploads/2018/10/09-New-Trends-in-Drug-Safety_Fall2018.pdf
4. Engel, P., Almas, M. F., De Bruin, M. L., Starzyk, K., Blackburn, S., and Dreyer, N. A. (2017) Lessons learned on the design and the conduct of Post-Authorization Safety Studies: review of 3 years of PRAC oversight. *Br J Clin Pharmacol,* 83: 884– 893. doi: 10.1111/bcp.13165.
5. Harugeri, A., Shastri, V., & Patel, C. (2017). Deriving meaningful insights from clinical trial and postmarketing safety data: Perspectives from India. *Perspectives in clinical research*, 8(2), 68-72.

### Biography

Deepa Arora is a Pharmacovigilance expert. She set-up integrated, regulatory compliant and cost-efficient end to end Pharmacovigilance systems for two Indian MNCs. Under her able leadership, teams successfully cleared PADE and GVP inspections conducted by various regulatory authorities. She's authored book- *Pharmacovigilance- An Industry Perspective.* Her forte is a clear understanding of regulations and expectations of regulatory authorities required for compliant PV systems. She also ensures compliance with safety aspects scrutinized during GMP and GCP inspections. Dr. Arora successfully led a consortium of companies for conducting post authorization safety studies and drug utilization studies in Europe to meet post authorization conditions imposed as an outcome of EMA referral. After the studies were conducted and conditions of marketing authorization were removed, these studies were also published in peer reviewed journals. Her passion is to continue strategic planning of the design, outcomes, endpoint(s) of observational studies with good methodological rigor and data quality to facilitate decision making by regulators, market access and HTA decision-making.