

DSI UPDATES GLOBAL NAME SAFETY RESEARCH MODEL

Drug Safety Institute (DSI) has revised our name safety research methodology based on newly discovered review procedures, and insight gained from recently hired naming officials from FDA, EMA and Health Canada.

Drug Safety Institute welcomed Carol Holquist to our team in late 2017. As former Director of the FDA's Division of Medication Errors and Prevention Analysis (DMEPA), Carol's first initiative with DSI was refining our name safety methodology to be in accordance with current FDA best practices. Among other changes, our new and optimized methodology considers the 2017 FDA changes in POCA and new learnings on how FDA is utilizing POCA.

Also in 2017, DSI welcomed José Ángel Ferrero, formerly with the EMA Name Review Group (NRG), and Scott Sawler, formerly with Health Canada's Marketed Health Products Directorate (MHPD). José and Scott have worked closely with our DSI Staff to modify our name safety research model to be in accordance with the current methodology employed by their respective former agencies.

Carol, José and Scott's methodology updates are intended to produce better outcomes for our clients and strengthen our market leadership role as the premier drug name development and safety testing agency.

For research conducted prior to January of 2018, please contact your account representative to discuss how these changes may affect your project. As always, Brand Institute is 100% committed to staying with our clients until they get a great name approved!



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