



# ISOP ISRAEL

## HOT TOPICS IN PV

#	Topic	Leader(s)	Date	Location	Comments
PVS	What is a Pharmacovigilance system : a holistic picture; + role and responsibilities of the QPPV + What do we still need in Israel to reach the international standards ?	Irene Fermont / Hedva Voliovitch	2 January 2014 16h-18h30	TEVA Bazel 16, Petah Tikva.	
PSUR	PSUR/ PBRER - A new format, A new approach main changes in content and format, link to other reports, results expected by authorities, and PV & Risk Assessment Committee (PRAC).	Irene Fermont	9 March 2014	Tel Aviv	ISOP ISRAEL is proud to be hosted by the Pharmaceutical Society of Israel for a joint session
SDB	Safety database : international standards , when, what data , electronic transmission to Eudravigilance & FDA	Delphine BERTRAM	7 May 2014	MSD Hod Hasharon	
SDSM	Signal detection, signal management : highlights		early July 2014	tbd	
QAPV	Quality in PV, audits, and readiness to inspection	to be confirmed	early September 2014	tbd	
LS	Literature search : databases, keywords, periodicity	to be confirmed	November 2014	tbd	
RMP	Risk Management Plan/ REMS : key to EU and US markets	Irene Fermont	end December 2014	tbd	
SDEA	How to secure the PV process with partners, providers, affiliates: Safety Data Exchange Agreement and audits	Tal Kleinfeld	January 2014	tbd	
Author : Irene Fermont					
23 October 2013- updated 27 April 2014					