

ISOP ISRAEL ACTIVITIES

2013-2018

After one year of activities and vision elaboration, ISOP ISRAEL Chapter was officially created in 2014 during the ISOP Annual Meeting in Tianjin, China.



A truly positive emotional experience for such an ancient civilisation to welcome our Israeli Chapter based on another ancient tradition. ISOP Annual Meeting, Tianjin 2014

HISTORY

2013: White Paper for the Israeli Ministry of Health (MOH), at the establishment of the Pharmacovigilance Department

The Israeli Ministry of Health established the Pharmacovigilance and Risk Management Department. A new Pharmacovigilance Regulation, the Procedure 6 (Noal 6), based on the European regulation and Good Pharmacovigilance Practices, was voted by the Israeli Parliament, the Knesset. At the request of Dr Dorit Dil Dahlieli, Head of the Pharmacovigilance department and Dr Eyal Schwartzberg, Head of the Pharmaceutical department, **ISOP ISRAEL draw up a White Paper**, to analyse the weaknesses and strengths of the Israeli Pharmacovigilance System and to propose recommendations of actions, for all stakeholders, nation-wide.

Analysis of the Israeli PV System was presented in the ISOP Annual meeting in Pisa 2013.

2013-2014: Hot Topics in Pharmacovigilance: Training on the new Regulation for Industry

The Industry has suddenly to face new requirements: nominating a QPPV, writing PSUR... for which they should be trained. We started a cycle of training on Procedure 6 in Teva and were hosted by several companies with the support of MOH; a Pharmacovigilance forum, born from these Hot Topics, is now handled directly by the Pharmacist association.

2014: Introduction of Pharmacovigilance & Risk Management in the International Intensive Course of Pharmaco-epidemiology at Tel Aviv University

The program in Pharmacovigilance was designed and taught by ISOP ISRAEL in the course organised by Prof Daniel Cohen, Head of Public Health in the Sackler Medicine Faculty in Tel Aviv University. The international Advanced Course is always held in collaboration with the most renowned universities worldwide: John Hopkins, University of Maryland, England & London School of Public

Health. In 2104, Prof Le Louet lectured on behalf of the University Paris-Est Creteil and ISOP. The participants were experienced epidemiologists and risk managers.

2013-2014: Design of Academic Programs on Pharmacovigilance and Risk Management

Design of two cursus with preliminary contacts with European academies for joint programs

- Introduction in the general courses: Basic Principles of Pharmacovigilance and Risk Management; role of the Healthcare Professionals as Public Health stakeholders;
- Master and Advanced Courses.

Since 2015, Innovative approach for a multidisciplinary, integrated methodology to decrease the risks of anticoagulants

We have identified several tools and set up a strong partnership with ISMP (The Institute for Safe Medication Practices) see below. Self-assessment questionnaires, on several high-risk medications, are available on their website and have been extensively used in hospitals and community. These tools are the backbone of our methodology. <https://www.ismp.org/assessments/antithrombotic-therapy>

Our Innovative Approach

1. Use one class of medication with known high morbidity/mortality: i.e. the anticoagulants
2. On a case study, apply tools and methods to build a safety culture and a multidisciplinary approach
3. Have pilot centres which will be able to show the efficacy of the methodology
4. Set up parallel tracks: projects on the field and organisation of an international conference

Actions which have been set up in this frame

- **Project Presentation** to congresses in Israel and abroad, to associations and hospital departments: (for congresses see below) Hospital Hadassah 2015 Jerusalem, Hospital Assaf Harofe, Clinical Pharmacology Annual meetings 2015, 2016 Tzrifin, Hospital Maayanei Hayeshua 2018 Bne Braq....
- **Position Paper for risk management of anticoagulants for the Ministry of Health** Patient's Safety Unit: Boaz Lev, Anat Ecka-Zohar Dana Arad, and Sharon Olsha
- **Launching of the 2019 international Symposium**, multidisciplinary and solution-oriented: **SAFETY FROM ALL ANGLES**, decreasing risks, improving communication, under the auspices of Prof Hervé le Louet, President of CIOMS. See below the details
- **Submission to Reboot forum of the multidisciplinary Risk Management Plan on anticoagulants in hospitals** in partnership with PSI (pharmacist association) and Data2Life (signal detection tool start-up). Reboot is a foundation who give grants for innovative initiatives and we have reached the semi-finals
- **Implementation in Hospital Maayanei HaYeshua of the ISOP ISRAEL methodology to decrease the risks or antithrombotics**

- **Organisation of a national campaign for Superpharm**, the national chain of community pharmacies to advise patients on the risks of anticoagulants;
- **A student from the Hebrew University of Jerusalem is now dedicating his PharmD thesis on ISOP ISRAEL projects on anticoagulants**
- **ISOP ISRAEL Chairman awarded** for its outstanding contribution to Israel as a new French immigrant 2016

CONGRESSES PARTICIPATION

(poster or oral communication)

- ❖ **ISOP annual meetings:** posters
 - Pisa Italy 2013
 - Tianjin China 2014 Chapter announcement
 - Prague 2015
 - Liverpool 2017
- ❖ **Pharmacovigilance conference Ministry of Health 2013** Jerusalem
- ❖ **MEDIF 2015** Jerusalem Oral Communication
- ❖ **Baltic Life Sciences International Conference 2016** Vilna Oral Communication
- ❖ **IMA International fellowship 2016** Haifa, Oral Communication
- ❖ **Israeli Society for Quality, 2017**, Beer Sheva, Oral Communication
- ❖ **Society for Patient Safety and Risk Management in Healthcare**, Oct2017, Petah Tikva, poster
- ❖ **Ministry of Health Meeting of the Risk Managers in Hospital**, July 2018, presentation of the Maayanei Hayeshua project, Tel Aviv
- ❖ **Chairman invited to provide lectures** in the advanced course for risk managers in Technion University and for Clinical Pharmacists specialisation course in Hebrew University of Jerusalem : 2018-2019

PARTNERSHIPS

- ❖ **ISMP: Institute for Safe Medication Practices** is a US organization, working closely with FDA, devoted, for 35 years, to medication error prevention and safe medication use; ISMP initiatives are built upon a non-punitive approach and system-based solutions. Represented in our Advisory Board by both its founder Dr Mike Cohen and its Medical Director. <https://www.ismp.org>
- ❖ **Center For Medicine in Public Interest, USA:** founded and headed by Peter Pitts former FDA Associate Commissioner, CMPI provides expert advices on health policies to Authorities all over the world and gives high level insights on health policies and initiatives www.cmpi.com
- ❖ **The King's College of London**, represented by the Director of The Center of Implementation Sciences and Patient Safety, Prof Nick Sevdalis
<https://www.kcl.ac.uk/ioppn/depts/hspr/research/cis/about.aspx>
- ❖ **BIOFORUM:** organising courses and congresses; Bioforum has been the first to introduce Pharmacovigilance courses in Israel, pioneering and advocating for ISOP ISRAEL and gave us the opportunity to train the majority of Pharmacovigilance managers of industry since 2008
<http://www.bioforum.org.il/en-US/Default.aspx>

- ❖ **PSI: The Pharmacists Association of Israel:** gathering clinical pharmacists and pharmacists from industry, hospitals and community; <http://www.psi.org.il/>
- ❖ **The Israeli Clinical Pharmacology Association** <https://pharmacology.doctoronly.co.il/>
- ❖ **The Alliance for Patients Safety:** a US and Israeli association advocating patients' rights and transparency of the patient electronic record; <http://www.allianceforpatientsafety.org/>
- ❖ **The Social Journey to Cure Medicine** launching initiatives at system level to improve patient safety and healthcare quality <http://www.cure-medicine.co.il/>
- ❖ **eVeDrug** : providing e-health solutions and offering to ISOP ISRAEL a smartphone application in Hebrew to report Adverse Drug Reaction and a Pharmacovigilance database <https://www.evedrug.eu/#>
- ❖ **Data2Life** : a data mining company, able to capture and make accessible “real-world” drug related effects intelligence from multi-sourced, cross-referenced data: e-Health records, regulatory databases, company or HMOs databases, social media posts, literature: <http://data2life.com/>
- ❖ **The Hebrew University of Jerusalem HUI, School of Pharmacy,** Clinical Pharmacologist course (the HUI is ranked among the 100 first universities of the world)