Fellow	FRANCESCO DE PRETIS

Host Organisation	VTT

Scientific coordinator	MARKUS FORSBERG MARK VAN GILS

I – SCIENTIFIC ACTIVITY DURING YOUR FELLOWSHIP

Hosted at VTT Technical Research Centre of Finland, the fellowship research project was aligned with the focus of the hosting institution, whose Smart Health team aimed to transform health data into knowledge by data-driven technologies, applications, and processes and enable personalized, preventive, and predictive health. With the rise of precision and personalized medicine, drug safety assessment is one of the main topics that has to be aligned with these developments. The main perspective of the research project was to develop novel concepts of drug safety assessment in smart hospital setting, capable of collecting, analysing, and providing tailored information for drug safety.

This project researched in depth the potential benefits of using a smart hospital as a data source for precision drug safety assessment. Hospitals were suggested as a good laboratory for studying adverse drug events (ADEs) because the most severe events occur there. In addition, the quality of data in hospitals electronic health records (EHRs) was usually superior to data from other sources due to more comprehensive data on drug administration. The use of computerized systems, sensors, and the Internet of Things (IoT) in smart hospitals was identified as a key-feature to lead to a much more robust and widespread data collection, which could improve the selection of treatments for patients.

As part of a feasibility study on smart hospital-driven precision pharmacovigilance, three key deliverables were identified:

Data Collection: The study explored methods for data collection, drawing on approaches from health informatics and hospital pharmacoepidemiology. The goal was to design a data management system capable of tracking a patient from admission to discharge, integrating data from the hospital pharmacy, patient EHRs, and reports of ADRs entered by physicians. Smart data collection methods, such as IoT devices for physicians, nurses, and patients, were identified as crucial. Data privacy and security were also considered, with the aim of including enough cases and patients to validate the system in line with current approaches in digital medicine.

Data Analysis: The feasibility study explored the potential of more fine-grained statistics to advance pharmacovigilance. Along with standard computational methods, such as Bayesian inference, knowledge engineering, and artificial intelligence (AI), new methods better suited to this precision framework were identified. These methods could be validated through combinations to standard pharmacovigilance practices, in accordance with existing literature.

Data Exploitation: The study identified the creation of a personalized information leaflet as a key deliverable of precision pharmacovigilance. The leaflet would be based on individual pharmacogenomic information and a patient stratification approach, using supervised and unsupervised machine learning techniques to compare individual data with a sample of patients. The leaflet would be released in a digital format, following advances in dematerializing medication information. Validation of these methods would take place in accordance with recent research work carried out in developing and validating information leaflets. Ultimately, clinicians would be responsible for the validation and retesting of such tools, in line with protocols applied in decision-support systems in healthcare.

II – PUBLICATION(S) DURING YOUR FELLOWSHIP

Francesco De Pretis, Mark van Gils, and Markus M. Forsberg. A smart hospital-driven approach to precision pharmacovigilance. Trends in Pharmacological Sciences, 43(6):473–481, June 2022.

Francesco De Pretis, Marjo Kervinen, Kaisa Haatainen, Miia Tiihonen, Anna-Maija Tolppanen, and Markus M. Forsberg. Collection of Data for Detecting Adverse Drug Events in Smart Hospitals via Electronic Health Records, the GTT, Sensors and IoMT. In 21st ISoP Annual Meeting "A New Era of Pharmacovigilance: Challenges and Opportunities" 20–23 September 2022 Verona, Italy, Drug Safety, 45(10):1111–1327, August 2022.

Yaman Abdin, Francesco De Pretis, and Jürgen Landes. Fast Methods for Drug Approval: Research Perspectives for Pandemic Preparedness. International Journal of Environmental Research and Public Health, 20(3):2404, January 2023.

Hilkka Liedes, Juha Pajula, Anna-Leena Vuorinen, Francesco De Pretis, Mark van Gils, Kari Harno, Mika Lehto, Mikko Niemi, Jaakko Lähteenmäki. "CYP3A4*22 May Increase Bleeding Risk in Ticagrelor Users". Basic & Clinical Pharmacology & Toxicology, under review.

Francesco De Pretis, Markus Varheenmaa, Marjo Kervinen, Miia Tiihonen, Mark van Gils and Markus M. Forsberg. Collection of adverse drug events in smart hospitals: Perspectives on harvesting signals through the Global Trigger Tool, sensors and Internet of Medical Things. In preparation.

III – ATTENDED SEMINARS, WORKHOPS, CONFERENCES

6th PreMed project workshop and steering group, VTT, Espoo, Finland, April 22, 2021.

21st International Society of Pharmacovigilance Annual Meeting "A New Era of Pharmacovigilance: Challenges and Opportunities" Verona, Italy, 20–23 September 2022.

IV – RESEARCH EXCHANGE PROGRAMME (REP)

During the Research Exchange Program (REP) in June 2021, the participant had the opportunity to visit the HeKa research group at INRIA in France, where the initial idea for a smart hospital-driven approach to precision pharmacovigilance was presented. The visit proved to be a valuable experience as it was possible to receive feedback from other researchers and learn about the ongoing projects being handled at INRIA.

The REP provided a unique platform to engage with researchers from different backgrounds, allowing the participant to learn from their experiences and collaborate on ideas. Overall, it was a great opportunity for the participant to expand his network, gain valuable insights, and explore potential collaborations.