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Project Proposal

For the Degree Program in Sustainability Studies

Enhancing Drug Safety and Vigilance for Rare Diseases, an Empirical Analysis

Duration: 5-6 Months (27,5 ECTS = 825 h)
Location: Sigmaringen (Innocamp (Biophysicslab)) and remote

Possibilities for a follow-up Master's Thesis: yes
Potential Cooperation Partners (if applicable)**:** to be determined
Supervisor / Contact: Prof. Dr. Clemens Möller

Aim of the project:
This project aims to systematically review and enhance the theoretical frameworks and methodologies underpinning drug safety and pharmacovigilance databases, particularly focusing on rare diseases. By identifying gaps and inconsistencies in current systems, and leveraging advanced analytical techniques, this proposal seeks to improve the reliability and effectiveness of drug safety monitoring, contributing to better healthcare outcomes for patients with rare diseases.

Project description:
Background: Rare diseases affect a small percentage of the population, yet the complexity and variability of these conditions pose significant challenges in drug safety monitoring. Current pharmacovigilance systems are often not equipped to detect rare adverse events due to limited patient exposure and fragmented data reporting. This project will focus on enhancing the pharmacovigilance frameworks to address these challenges effectively.

Methodology: Literature Review, Data Analysis, **Qualitative Research (**e.g., Conduct interviews and focus groups with stakeholders to gather insights on practical challenges and opportunities in pharmacovigilance).

Expected Outcomes: A detailed report outlining current methodologies, gaps, and potential improvements in drug safety for rare diseases. Potentially, development of improved algorithms and frameworks for ADR detection and reporting, as well as

recommendations for policy changes and implementation strategies for better pharmacovigilance practices.

The outcomes will aim to reduce the occurrence of adverse drug reactions and improve patient safety and treatment outcomes.
This project addresses a critical gap in the field of pharmacovigilance by focusing on rare diseases, which are often overlooked in existing larger drug safety databases. By enhancing theoretical and empirical understanding and improving methodologies, this initiative will pave the way for significant advancements in the field of drug safety.

Suitable for / Requirements for the student: Students with strong background and research interest in pharmacology, drug discovery and development, epidemiology, data management or related fields.