SHARING OF CLINICAL TRIAL DATA PRIOR TO 2000?
IMPACT Observatory Baseline Setting

Mersiha Mahmić-Kaknjo[1], Josip Šimić[2], Jelena Barbarić[3], Ana Utrobičić[4], Karmela Krleža-Jerić[5]

[1]Department of Clinical Pharmacology, Zenica Cantonal Hospital, Zenica, Bosnia and Herzegovina
[2]Health Sciences Library, Faculty of Health Studies, University of Mostar, Mostar, Bosnia and Herzegovina
[3]Department for Development, Research and Health Technology Assessment, Agency for Quality and Accreditation in Health Care and Social Welfare
[4]Central Medical Library, University of Split School of Medicine, Split, Croatia
[5]NewFelPro-IMPACT Observatory, University of Split School of Medicine, Split, Croatia

Introduction: A clinical trial is any research study that prospectively assigns human participants to one or more health-related interventions to evaluate the effects on health outcomes. Sharing of clinical trial data is expected to influence the research, knowledge creation and consequently patient outcomes. The IMPACT **(IMP**roving**A**ccess to **C**linical **T**rial data) Observatory is exploring the dynamics of the clinical trial data sharing over time, starting with the baseline set in 2000.

Objective: To present preliminary results of the scoping review of literature on exploring perceptions and practices of sharing and reuse of clinical trial data prior to and in the year 2000 and thus set a baseline situation of the IMPACT Observatory.

Methodology: Search, selection, and analysis of literature. Literature search was performed in MEDLINE/PubMed by 2 librarians using 8 different search strategies that were developed jointly with the investigators. The papers from previous direct discovery were added. After deduplication, two reviewers scoped papers' titles and abstracts. Eventual disagreements were solved by discussion. In the next stage the full papers have been analysed by three reviewers.

Results: Searches resulted in a total of 1204 records. After deduplication, exclusion of papers not meeting the criteria, and adding 8 previously identified publications, 129 papers were selected for the analysis. Evaluation of their full texts led to further exclusion of 35 papers. We based our analysis on the remaining 94 publications.

Preliminary results of the scoping review reveal limited data sharing prior to 2001. The initially vague notion of concept and benefits of data sharing led to a rich discussion and pioneer efforts which laid the ground for further development. We observed a dynamic that was sometimes led by specific patient groups (such as HIV/AIDS, cancer), triggered by media due to scandals, and a broad discussion about pros and cons of data sharing. Databases and registries were formed. However, the growing understanding of the importance and potential benefits of data sharing was matched with numerous obstacles.

Conclusion: Preliminary result indicate that at the end of 2000 there was a clear perception that data sharing was necessary, but it was not clear how to achieve it.