Principal Investigator: Prof. Marcin Waligóra, Jagiellonian University Medical College

Title of the project: Ethics of clinical trials during the COVID-19 pandemic

The aim of the project is to provide data and evidence for decision-makers involved in clinical trials to perform ethical research in the time of the COVID-19 pandemic.

Clinical trials are biomedical research with human subjects. The COVID-19 pandemic created unprecedented pressures for clinical trial regulators, ethics committees, researchers and other stakeholders to invent and register medicines and vaccines as quickly as possible. About 1300 COVID-19 clinical trials are underway. These include investigating more than 100 substances as vaccine candidates.

Traditional research procedures are now revolutionized: Some vaccines are tested with human subjects without pre-clinical (laboratory and animal) evidence. Others deliberately expose patients to controlled COVID-19 infection. Research paths are proposed to be shortened. Medicines are authorized by agencies without proof of efficacy (e.g. hydroxychloroquine authorized by the Food and Drug Administration to use on hospitalized patients with COVID-19).

I call these endeavors “organizational and methodological accelerators”. Some of these accelerators raise serious ethical concerns.

In the first stage of this project, my team would systematically collect these organizational and methodological accelerators of clinical trials in the time of the COVID-19 pandemic. In the second stage we would perform an ethical analysis of these accelerators. We will assess the risk and benefit level for participants of selected COVID-19 trials. We will also measure some indicators of the social value of these trials.