ID CARD of **optYmAb** project



**Title**: Improving Clinical **O**utcomes with **P**recision Dosing in Patients with Inflammatory Bowel Disease **T**hrough **I**nvestigating Variability of **M**onoclonal **A**ntibodies **B**ased on Population Pharmacokinetic-Pharmacodynamic Modeling ​

**Acronym**: optYmAb

**Duration**: 01.01.2024. – 31.12.2026.

**Sub-program**: biomedical sciences

**Budget**: 289,389.39 EURO

**Funding**: Science Fund of the Republic of Serbia, Prisma call

**Consortium**: Faculty of Pharmacy; University of Belgrade - ; Faculty of Medicine (School of Medicine); University of Belgrade – partner.

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**Abstract:** Crohn’s disease and ulcerative colitis, with an increasing prevalence, are characterized by chronic gastrointestinal inflammation in a protracted relapsing and remitting course. Biological therapy revolutionized inflammatory bowel disease (IBD) treatment. While being effective, monoclonal antibodies (mAb) are well-tolerated in inducing and maintaining the remission. Nevertheless, up to 50% of patients do not adequately respond or experience relapse. Hence, their quality-of-life decreases, while healthcare systems encounter greater costs. Currently, it is unclear if the response could be improved with intensified dosing. Great, and still unexplainable, variability in mAb concentrations among patients exists, with high uncertainty how it contributes to the response-to-treatment over time. optYmAb aims to investigate and quantify the sources of variability and dynamic interplay between anti-TNFα (infliximab, adalimumab) and anti-integrin (vedolizumab) concentrations - pharmacokinetics (PK), levels of inflammatory biomarkers - pharmacodynamics (PD), clinical response and quality-of-life of adult IBD patients from the beginning and on maintenance of biologic treatment. Utilizing comprehensive pharmacostatistical methodology on big data will result in multi-level PK-PD-response models, leading to the answers to specific clinically related questions, as contemporary pharmacotherapy supports model-informed personalized dosing approach. Pharmacoeconomic model will be developed. This is not only up to date but also aspiring as it is aiming towards comprehensive quantification of mAb-patient bidirectional relationship, both on individual and population level, being the first research that links all the points between mAbs dose and clinical response over the time. Combined knowledge will provide further prognostic information regarding the risk of relapse at earlier time points and allow preventive interventions in the clinical practice at rational costs.

**Instagram**: optymab

**LinkedIn**: optYmAb project [linkedin.com/in/optymab-project-5538632ab](https://www.linkedin.com/in/optymab-project-5538632ab)

**Webite**: [www.optymab.com](http://www.optymab.com)