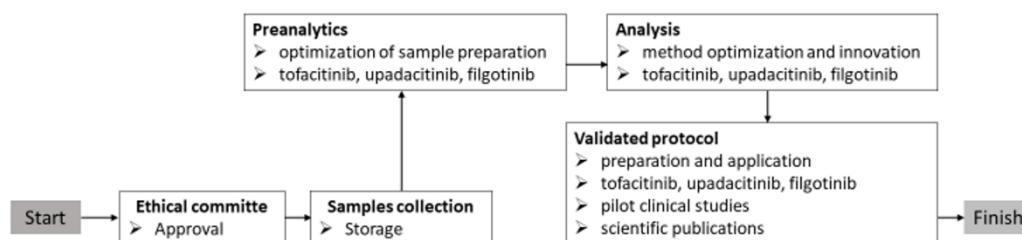
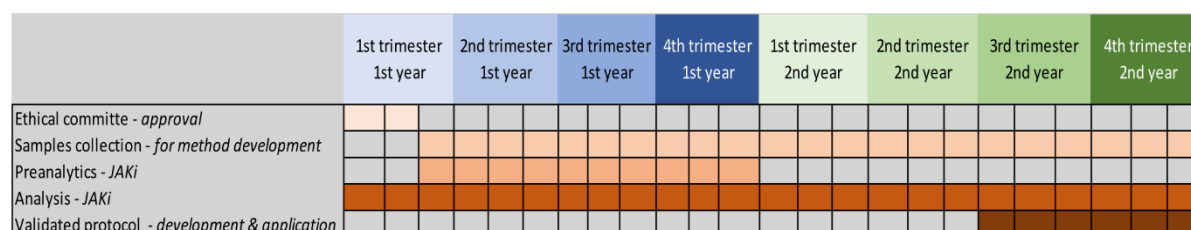


PROJECT PLAN AND DELIVERABLES

Pert diagram for individual work packages and their interconnectedness and logical and time sequence:



Timeline of the project (Gantt diagram):



WORK PACKAGES

Work package number	1
Title of the work package	Ethical committee
Start of implementation of the work package (Mx Month¹)	M1
End of implementation of the work package (Mx month)	M2
Involvement (expressed in Person Months)²	R4 Key researcher 2 Person Months
Objectives	
To obtain the approval of the medical ethical committee according to the basic rules of medical research	
Description of the work package	
The standard procedure of the clinical institution will be followed, i.e., the application, together with the study protocol specifying the burden for the patients, inclusion and exclusion criteria and the informed consent will be presented to the local medical ethical committee. A part of this package is also the project management and administration.	
Deliverables	
1 - approval of the medical ethical committee	

¹ The months are indicated ascending from the start of the project, i.e., the month in which the project started is M1.

² In case of involvement of the research team in the project implementation, it is necessary to identify the individual positions, identify the category of researcher R1-R4 for researchers and determine the level of involvement for all members of the research team.

Work package number	2
Title of the work package	Samples collection
Start of implementation of the work package (Mx Month³)	M3
End of implementation of the work package (Mx month)	M24
Involvement (expressed in Person Months)⁴	R4 Key researcher 16 Person Months
Objectives	
To collect samples of patients on IBD treatment for the method development	
Description of the work package	
During this phase, the samples derived from patients with IBD on stable treatment with respective drugs will be taken and stored until further processing (preanalytical treatment, analysis). For all samples informed consent of the patients + GDPR will be obtained. A part of this package is also the project management and administration.	
Deliverables	
1 – samples collection from patients treated with respective drugs	

Work package number	3
Title of the work package	Preanalytics
Start of implementation of the work package (Mx Month⁵)	M3
End of implementation of the work package (Mx month)	M12
Involvement (expressed in Person Months)⁶	R4 Team leader 7 Person Months R4 Key researcher 2 Person Months R3 Key researcher 5 Person Months R3 Key researcher 5 Person Months R3 Key researcher 5 Person Months R1 Key researcher 5 Person Months
Objectives	
To develop the protocol of the preanalytical sample preparation for respective IBD drugs - JAKi.	
Description of the work package	
During this phase, the samples derived from patients with IBD on stable treatment with respective drugs will be taken and current preanalytical procedures will be tested. The clinical samples (as processed in the hospital) will be additionally treated before the analytical measurements (dilution, extraction, protein precipitation, filtration, etc., applying one or more preparation steps depending on the analytical method used). A part of this package is also the project management and administration.	
Deliverables	
3 – protocols for the preanalytical sample preparation for JAK inhibitors (tofacitinib, upadacitinib, filgotinib).	

Work package number	4
Title of the work package	Analysis

³ The months are indicated ascending from the start of the project, i.e., the month in which the project started is M1.

⁴ In case of involvement of the research team in the project implementation, it is necessary to identify the individual positions, identify the category of researcher R1-R4 for researchers and determine the level of involvement for all members of the research team.

⁵ The months are indicated ascending from the start of the project, i.e., the month in which the project started is M1.

⁶ In case of involvement of the research team in the project implementation, it is necessary to identify the individual positions, identify the category of researcher R1-R4 for researchers and determine the level of involvement for all members of the research team.

Start of implementation of the work package (Mx Month⁷)	M1
End of implementation of the work package (Mx month)	M24
Involvement (expressed in Person Months)⁸	R4 Team leader 12 Person Months R3 Key researcher 15 Person Months R3 Key researcher 15 Person Months R3 Key researcher 15 Person Months R1 Key researcher 15 Person Months
Objectives	
To develop the analytical procedure to assess levels of JAK inhibitors.	
Description of the work package	
During this phase, model samples (starting from M1) and the samples derived from patients with IBD on stable treatment with JAKi drugs (starting from M3) will be analysed for JAKi levels. The analytical method optimization (testing various operation parameters, implementing innovative technologies and analytical approaches) will be carried out employing the clinical samples processed in the hospital and additionally treated before the analytical measurements. A part of this package is also the project management and administration.	
Deliverables	
3 - optimized/innovative analytical methods in the IBD drugs monitoring (JAKi: tofacitinib, upadacitinib, filgotinib)	

Work package number	5
Title of the work package	Validated protocol
Start of implementation of the work package (Mx Month⁹)	M19
End of implementation of the work package (Mx month)	M24
Involvement (expressed in Person Months)¹⁰	R4 Team leader 5 Person Months R4 Key researcher 4 Person Months R3 Key researcher 4 Person Months R3 Key researcher 4 Person Months R3 Key researcher 4 Person Months R1 Key researcher 4 Person Months
Objectives	
To formulate the validated protocol of analytical procedure to assess levels of JAKi for pilot clinical studies (therapeutic drug monitoring, pharmacokinetics)	
Description of the work package	
The protocol will be formulated based on the results from the previous work packages – preanalytics (whole sample preparation) and analysis (optimization/innovation), plus full validation. Thus, the validated protocol for JAKi will include defined steps and conditions of sampling, sample preparation, sample storage, instrumental and operating analysis parameters, and validation parameters according to the FDA, ICH or EMA guidelines (including also accuracy from comparative study using two independent methods). A part of this package is also the project management and administration.	
Deliverables	
3 – validated protocol for each JAK inhibitor (tofacitinib, upadacitinib, filgotinib) 3 – pilot clinical studies (levels examined in the three JAKi: tofacitinib, upadacitinib, filgotinib) 3 – scientific papers describing the fully validated protocols and resulting clinical studies aimed at therapeutic drug monitoring and pharmacokinetics of the respective medications (tofacitinib, upadacitinib, filgotinib) involved in a key group of the IBD drugs – JAK inhibitors.	

⁷ The months are indicated ascending from the start of the project, i.e., the month in which the project started is M1.

⁸ In case of involvement of the research team in the project implementation, it is necessary to identify the individual positions, identify the category of researcher R1-R4 for researchers and determine the level of involvement for all members of the research team.

⁹ The months are indicated ascending from the start of the project, i.e., the month in which the project started is M1.

¹⁰ In case of involvement of the research team in the project implementation, it is necessary to identify the individual positions, identify the category of researcher R1-R4 for researchers and determine the level of involvement for all members of the research team.

3 – abstracts from international scientific conference presentations of methodical advances (analytical innovations) and clinical findings and proposals achieved as part of the project

LIST OF MILESTONES:

Mile sto ne nu mb er	Milestone	Wo rk pa cka ge nu mb er	Method of verification	Expected time to reach the milestone (project month)
1	Creating an excellent team	1 - 5	addendum to the employment contract	M1 -M12
2	Public procurement and delivery of project infrastructure	3 - 5	Signed and published project infrastructure agreement (supplier agreement)	M1 – M12
3	Ethical committee approval	1	registered institutional documents (approvals)	M1 – M2
4.	Sample collection, for method development,	2	documented biological material (institutional documents), informed consent of the patient + GDPR	M3 – M24
5	Preamalytical sample preparation protocols, for JAKi	3	methodical reports (protocols), a part of open-access publications	M3 – M12
6	Optimized/innovative analytical methods and determined JAKi levels	4	methodical reports (protocols), a part of open-access publications	M1 – M24
7	Validated protocols and pilot clinical studies	4,5	methodical reports (protocols), open-access publications (papers, abstracts)	M19 – M24
8	Scientific papers, conference abstracts	4,5	open access publications registered at the publisher, WoS, Scopus	M19 – M24
9.	Interim report on the implementation and achievements of the project	1 - 5	the report, available on the institution's web	M12 (mid-term of project implementation)
10	Final report on the achievements of the project presented	1 - 5	the report, available on the institution's web	M24 (end of project implementation)
11	Collaborations (national, international)	1-5	institutional documents, contracts, affiliation in published papers	M1 - M24
14	Doctoral student inclusion	3-5	institutional documents, contracts, affiliation in published papers	M1 - M24