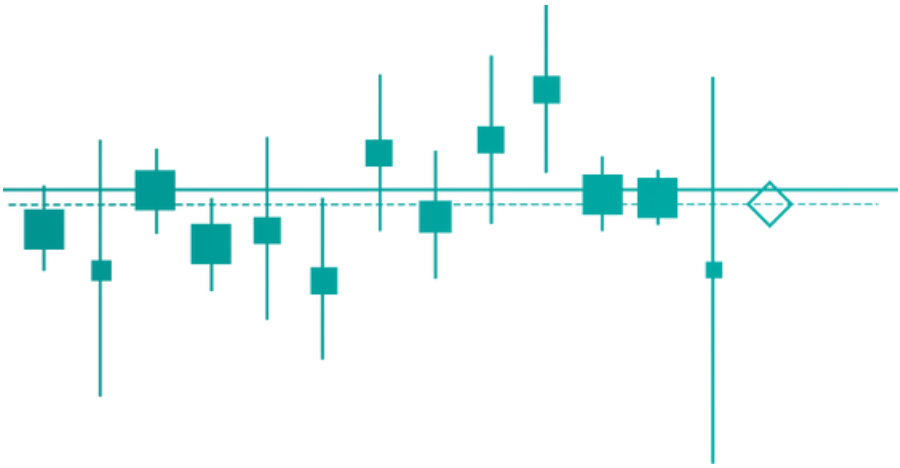
# RESEARCH SERVICES

Professional planning and guidance of clinical research for your needs

SEMMELWEIS UNIVERSITY
**CENTRE FOR TRANSLATIONAL MEDICINE**

# INTRODUCTION
# TO OUR SERVICES



## I. SYSTEMATIC REVIEW AND META-ANALYSIS

We are delighted to offer you our comprehensive systematic review and meta-analysis service. With over 200 published meta-analyses in various fields of healthcare, our center has established itself as a leading authority in evidence synthesis.

Our dedicated team of statisticians and methodology experts work diligently to ensure that your systematic reviews and meta-analyses are conducted with the highest level of rigor and accuracy. We follow internationally recognized guidelines, such as PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses), to ensure that our findings are transparent and reliable.

As part of our service, we offer:

1. **Thorough Literature Search:** Our experienced team helps you to conduct a comprehensive and systematic search of the literature to identify relevant studies from various sources, including databases, grey literature, and unpublished data.
2. **Robust Data Analysis:** Our dedicated statisticians utilize advanced statistical methods to analyze the data extracted from the included studies. We conduct meta-analyses using state-of-the-art software to synthesize the findings and provide meaningful insights.
3. **Methodological Expertise:** Our methodology team ensures that your systematic reviews and meta-analyses are conducted in accordance with the highest standards of research methodology. We help you to carefully assess the quality of included studies, evaluate risk of bias, and perform sensitivity analyses to ensure the reliability of our findings.
4. **Comprehensive Reporting:** We will help you to provide a detailed and transparent report of your findings, including forest plots, summary measures, subgroup analyses, and interpretation of results. The resulted manuscripts are tailored to meet the specific needs of our clients and are ready for submission to leading journals.

## II. CLINICAL RESEARCH PLANNING

Randomized controlled trials or prospective observational trials initiation

We are excited to introduce our comprehensive clinical trial planning service. With our extensive experience in conducting randomized trials and prospective observational trials, we are well-equipped to guide you through the entire process of planning a successful clinical trial.

Our center has initiated over 20 randomized trials and prospective observational trials in various fields of healthcare, adhering to internationally recognized guidelines, such as the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) statement, to ensure the highest standards of trial design and methodology.

Our service includes:

1. **Expert Methodological Guidance:** Our experienced methodology experts provide thorough guidance throughout the planning phase of your clinical trial. From study design to sample size calculation, randomization methods, and blinding strategies, our team ensures that your trial is designed with robust methodology and statistical considerations.
2. **Statistical Expertise:** Our dedicated statisticians provide valuable insights on statistical analysis plans, outcome measures, and data management strategies. We utilize advanced statistical methods to ensure that your trial is powered to detect meaningful results and minimize bias.
3. **Protocol Development:** We work closely with your team to develop a comprehensive and detailed protocol that outlines the study objectives, methodology, inclusion and exclusion criteria, study procedures, and statistical analysis plan. Your protocols are tailored to meet the specific requirements of your team and are ready for submission to regulatory agencies or ethical review boards.
4. **Risk Assessment and Mitigation:** Our team conducts thorough risk assessments to identify potential risks and challenges in your trial. We work with you to develop strategies to mitigate these risks, ensuring that your trial is conducted in a safe and ethical manner.
5. **Collaboration and Communication:** We believe in close collaboration with our clients, and our team is readily available to provide ongoing support and address any questions or concerns throughout the trial planning process. We maintain open communication channels to ensure that your input and feedback are incorporated into the trial design.

## III. CLINICAL RESEARCH ANALYSIS

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## IV. PATIENT REGISTRY PLANNING AND INITIATION

We are delighted to introduce our patient registry initiation service. With our expert methodology group and statisticians, we can assist you in establishing well-structured patient registries that capture meaningful data for research and clinical purposes.

Our service includes:

1. **Patient Population Formulation:** Our methodology experts work closely with you to define the appropriate patient population for your registry. We help you identify the relevant inclusion and exclusion criteria, ensuring that your registry captures data from patients who meet the specific characteristics of your research or clinical objectives.
2. **Variable and Outcome Selection:** Our team provides guidance on selecting the appropriate variables and outcomes to collect in your registry. We help you define the data elements that are most relevant to your research question or clinical outcome of interest, ensuring that your registry collects high-quality and meaningful data.
3. **Registry Design and Methodology:** Our experts assist you in designing the registry with robust methodology, including data collection forms, data management processes, and quality assurance measures. We ensure that your registry is designed to capture accurate and reliable data that can be analyzed and interpreted effectively.
4. **Expert Statistical Support:** Our dedicated statisticians provide valuable insights on statistical analysis plans, sample size calculation, and data analysis strategies. We utilize advanced statistical methods to analyze the data from your registry, generating meaningful findings that contribute to your research objectives.
5. **ECDMS System:** Additionally, we offer our unique Electronic Case Report Form (eCRF) and Data Management System (ECDMS) that enables efficient and secure data collection and management. This system allows for seamless data sharing and collaboration with other centers, facilitating multi-center studies and enhancing the overall impact and generalizability of your research findings.

In summary, our center offers extensive experience and expertise in systematic reviews and meta-analyses, clinical trial planning, trial data analysis, patient registry initiation, and data management. We are confident in our ability to provide evidence-based insights, guide you towards well-designed trials, conduct robust data analysis, and help you establish meaningful registries. Our goal is to generate impactful research findings that contribute to the advancement of scientific knowledge in your field.

## V. PATIENT REGISTRY ANALYSIS

We are thrilled to offer our expertise in analyzing existing datasets. Our experienced methodology team and biostatisticians are skilled in utilizing the latest tools and techniques to conduct comprehensive data analysis, helping you derive meaningful insights from your existing datasets.

Our service includes:

1. **Data Analysis:** Our expert biostatisticians are proficient in a wide range of statistical methods and software, enabling us to conduct rigorous data analysis on your existing datasets. Whether it's a retrospective study, a database analysis, or a secondary data analysis, we utilize advanced statistical techniques to analyze your data and provide you with accurate and reliable results.
2. **Interpretation of Results:** Our methodology team works closely with you to interpret the results of the data analysis in the context of your research question or objective. We provide valuable insights and explanations, helping you understand the implications of the findings and their relevance to your research or clinical practice.
3. **Reporting for Journals:** Our experts are well-versed in the reporting guidelines of scientific journals, including CONSORT, STROBE, and PRISMA, among others. We assist you in preparing high-quality manuscripts that adhere to these guidelines, ensuring that your results are presented in a clear, concise, and scientifically rigorous manner.
4. **Comprehensive Results Presentation:** We understand the importance of presenting results in a comprehensive way. Our team helps you to generate easy-to-interpret visualizations and tables, summarizing the findings of the data analysis in a manner that is accessible to both researchers and clinicians. We strive to provide you with results that are visually appealing, meaningful, and suitable for dissemination in various scientific forums.

# SYSTEMATIC REVIEW & META-ANALYSIS

Step by step guide on how to perform and publish high quality registry analyses

## WHAT DO WE OFFER

Guidance through the mandatory steps of a meta-analysis. Statistical analysis. Review of manuscript.

**Included consultations:**
**3-5** consultations (30 minute) with meta-analysis experts
**1-2** consultation (30 minute) with statisticians

## EXPERIENCE

Over **200** published meta-analyses with a cumulative **IF above 1000**

## PRICING

For non Semmelweis University clients *
**2000** €

For Semmelweis University clients *
**1000** €

For Semmelweis University clients within the CTM PhD programme
**Free of charge**

** Possibility of individual pricing, additional fees may apply*

## OUR STAFF

Meta-analysis experts, statisticians

## REFERENCES


**Nagy R**, et al., Association of body mass index with clinical outcomes in patients with cystic fibrosis: a systematic review and meta-analysis. **JAMA Netw Open. 2022**; IF 13.353, SJR D1

**Ocskay K**, et al., Uncertainty in the impact of liver support systems in acute-on-chronic liver failure: a systematic review and network meta-analysis. **Ann Intensive Care. 2021**; IF 10.318, SJR D1

**Kelava L**, et al., Dietary supplementation of transient receptor potential vanilloid-1 channel agonists reduces serum total cholesterol level: a meta-analysis of controlled human trials. **Crit Rev Food Sci Nutr. 2021**; IF 11.208, SJR D1

**Garami A**, et al., Hyperthermia induced by transient receptor potential vanilloid-1 (TRPV1) antagonists in human clinical trials: Insights from mathematical modeling and meta-analysis. **Pharmacol Ther. 2020**; IF 13.4, SJR D1

# THE PROCESS OF OUR SERVICE

## STEP 1 INITIAL CONSULTATION, ACCESS TO UNIQUE ELEARNING MATERIALS

After discussing what we may offer and coming to a consensus, our unique e-learning materials help introduce the concept of meta-analysis.

## STEP 2 QUESTION DEVELOPMENT

At the core of every great research lies the question itself. Our meta-analysis experts help you decide on the question, how it must be posed to be able to answer it by meta-analysis and guide you through the preliminary searches and assessment of published literature.

## STEP 3 FEASIBILITY CHECK

At this point a strategy for the project is laid clear, aided by our meta-analysis experts and expert statisticians.

## STEP 4 SEARCH KEY DEVELOPMENT

The search key is one of the most vital parts of a systematic review – as the systematic nature depends on it. Our experienced meta-analysis experts will help you balance the feasibility (number of results) with the exhaustiveness of the project.

## STEP 5 PROTOCOL DEVELOPMENT

Based on our extensive experience in planning meta-analyses, meta-analysis experts and statisticians help develop the protocol, making the registration process as smooth as possible – and improving chances of acceptance later.

## STEP 6 SELECTION PROTOCOL DEVELOPMENT, DATA COLLECTION PLAN

Quality reviews depend on a reproducible selection and correct and exhaustive data collection. We help you avoid the most important pitfalls, and together with the statistical team help plan the data collection to ensure maximum yield for your efforts.

## STEP 7 POOLING STRATEGY

Common errors in meta-analyses include pooling data that cannot be compared or refraining from analysing data based on minor differences observed. We know the line, and we show you where it is!

## STEP 8 STATISTICAL ANALYSIS

Our experienced statistical team performs all necessary analyses (including sensitivity and bias analyses), in the way required by top journals everywhere.

## STEP 9 ROB/GRADE GUIDANCE

Assessing the quality of the included articles and the strength of evidence of the own project is often subjective and the results criticized by reviewers.

## STEP 10 MANUSCRIPT REVIEW

Our experts perform a review of the completed manuscript, pre-empting potential issues that may arise during peer review and bringing the manuscript to the highest quality.

# CLINICAL TRIAL ESTABLISHMENT

Step by step guide on how to perform and publish high quality registry analyses

## WHAT DO WE OFFER

Support during each step of the establishment, individual consultations, practical advices, unique electronic case report form system, help with the preparation of necessary documents, access to elearning materials.

## OUR STAFF

Clinical trial and data management experts, statisticians, IT team, ethical coordinator, clinical research administrators

## EXPERIENCE

We have **19** active registries currently, with more than **17100** enrolled patients.

## REFERENCES


**Szakács Z** et al. Haemorheological and haemostatic alterations in coeliac disease and inflammatory bowel disease in comparison with non-coeliac, non-IBD subjects (HERMES): a case-control study protocol.
**BMJ Open**. 2019. IF: 3.006

**Juhász MF** et al. The EFFect of dietary fat content on the recurrence of pancreaTitis (EFFORT): Protocol of a multicenter randomized controlled trial.
**Pancreatology**. 2022. IF: 3.977

**Kui B**, et al. EASY-APP: An artificial intelligence model and application for early and easy prediction of severity in acute pancreatitis.
**Clin Transl Med**. 2022. IF: 8.554

**Nagy R**. et al. In-Hospital Patient Education Markedly Reduces Alcohol Consumption after Alcohol-Induced Acute Pancreatitis.
**Nutrients**. 2022. IF: 6.706


## PRICING

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**2000** €, with ECDMS: ~ **4000** €

For Semmelweis University clients *
**1000** €, with ECDMS: ~ **3000** €

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# THE PROCESS OF OUR SERVICE

## STEP 1 CONSULTATION

We would like to offer the opportunity to discuss your research team's topic of interest with Clinical Research Experts (CRE). During this meeting we would introduce you to all steps of the clinical trial establishment, protocol writing and questionnaires, followed by a discussion about the strategic and financial plan. After agreement, we will provide access to our eLearning materials.

## STEP 2 RESEARCH QUESTION DISCUSSION, PROTOCOL AND QUESTIONNAIRE DEVELOPMENT

The second meeting will cover a more detailed discussion about the planned registry, high-quality data collection and thorough literature search. We will lend all necessary materials, templates and questionnaire samples.

## STEP 3 STUDY PROTOCOL PREPARATION

You will need to prepare the protocol based on the provided template. During this meeting, you would be introduced to the importance of a multidisciplinary review phase. When the protocol is ready, the CRE will propose two rounds of corrections with statistical expert (SE) involvement. Additional consultations and reviews can be required during this step.

## STEP 4 CASE REPORT FORM DISCUSSION

With the help of the CRE, your research team will start the preparation of the questionnaires. When the data collection forms are ready, the CRE will propose two rounds of corrections with statistical expert (SE) involvement.

## STEP 5 INTERNAL AND EXTERNAL REVIEW OF THE PROTOCOL AND QUESTIONNAIRE

Based on the suggestions, the protocol and questionnaires need to be updated. Additional consultations and reviews can be required during this step.

## STEP 6 FINALIZATION OF THE PROTOCOL

When the pre-study protocol is finalized, the CRE will propose two rounds of corrections with the involvement of SE.

## STEP 7 DISCUSSION ABOUT ETHICAL APPROVAL AND USER GUIDE

The ethical coordinator will present you the needed forms for ethical approval. The CRE will demonstrate the importance of user guide. The ethical coordinator and CRE will offer help in two rounds to review the prepared documents.

## STEP 8 STUDY PROTOCOL REGISTRATION

After receiving the ethical approval, we will register your protocol to an internationally recognised database.

## STEP 9 OPTIONAL: STUDY PROTOCOL PUBLICATION *

We will discuss in details the requirements of journals, how to choose the most suitable journal and provide templates to write a high-quality manuscript. The CRE will propose two rounds of corrections with statistical expert (SE) involvement.

## STEP 10 CASE REPORT FORM TESTING

When the questionnaires are ready, it is strongly suggested that to be tested next to the bedside. If corrections are needed, the questionnaire needs to be updated.

## STEP 11 FINALIZATION OF THE QUESTIONNAIRE

Final step of the data collection form development. When the data collection forms are finalized, the CRE will propose two rounds of corrections with the involvement of SE.

## STEP 12 ONLINE PLATFORM DEVELOPMENT

Discussion with the IT team about the forms. Based on the finalized questionnaires, the electronic case report forms will be prepared. Once the platform is finalized, a test phase needs to be included

## STEP 13 TEACHING PARTICIPANTS INVOLVED IN PATIENT ENROLMENT

Our clinical research administrators will give advices for the teaching on the personnel. All involved participants must be familiar with the structure and the questionnaires of the trial.

## STEP 14 PATIENT ENROLMENT

When the electronic case report forms, user guide and participants as ready, the patient enrolment can be started.

# CLINICAL TRIAL ANALYSIS

Step by step guide on how to perform and publish high quality registry analyses

## WHAT DO WE OFFER

Support during each step of the establishment, individual consultations, practical advices, unique electronic case report form system, help with the preparation of necessary documents, access to eLearning materials.

## OUR STAFF

Support during each step of the analysis, individual consultations, practical advices, help with the preparation of necessary documents, access to e-learning materials

## EXPERIENCE

We have **7** ongoing trials currently, with more than **5800** enrolled patients.

## REFERENCES


**Szakács Z** et al. Haemorheological and haemostatic alterations in coeliac disease and inflammatory bowel disease in comparison with non-coeliac, non-IBD subjects (HERMES): a case-control study protocol.
**BMJ Open**. 2019. IF: 3.006

**Juhász MF** et al. The EFFect of dietary fat content on the recurrence of pancreaTitis (EFFORT): Protocol of a multicenter randomized controlled trial.
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# THE PROCESS OF OUR SERVICE

## STEP 1 CONSULTATION

We would like to offer the opportunity to discuss your research team's topic of interest with Clinical Research Experts (CRE). During this meeting we would assess the feasibility of the project, introduce you to all steps of the clinical trial analysis, followed by a discussion about the strategic and financial plan. After agreement, we will provide access to our eLearning materials.

## STEP 2 DATA CLEANSING DISCUSSION

The next step, is to introduce you to the steps of data cleansing. The statistical experts (SE) will guide the process. They will send materials and templates for this tasks.

## STEP 3 DISCUSSION ABOUT ETHICAL APPROVAL

If needed, the ethical coordinator will present you the needed forms for ethical approval. The completed documents will be checked in a two round review phase.

## STEP 4 ANALYSIS PLAN DISCUSSION

The CRE will explain how to complete the statistical analysis plan, based on which the SE will perform the analysis. External reviewing of the planned is highly recommended.

## STEP 5 FINALIZATION OF THE ANALYSIS PLAN

When finalized, the CRE will propose two rounds of corrections with statistical expert (SE) involvement. Additional consultations and reviews can be required during this step.

## STEP 6 DESCRIPTIVE STATISTICS

First, we will show you the descriptive statistics. If needed, additional groupings can be performed with the update of the analysis plan. Additional consultations can be required during this step.

## STEP 7 COMPARATIVE STATISTICS AND ADDITIONAL ANALYSES

Next, you will receive the comparative statistics and the additional analyses. If needed, additional groupings can be performed with the update of the analysis plan. Additional consultations can be required during this step.

## STEP 8 ARTICLE PREPARATION DISCUSSION *

We will discuss in details the requirements of journals, how to choose the most suitable journal and provide templates to write a high-quality manuscript. The CRE will propose two rounds of corrections with statistical expert (SE) involvement. Additional consultations and reviews can be required during this step.

# REGISTRY ESTABLISHMENT

Step by step guide on how to establish high quality prospective patient registries

## WHAT DO WE OFFER

Support during each step of the establishment, individual consultations, practical advices, unique electronic case report form system, help with the preparation of necessary documents, access to eLearning materials.

## OUR STAFF

Registry establishment and data management experts, statisticians, IT team, ethical coordinator, clinical research administrators.

## EXPERIENCE

We have **19** active registries currently, with more than **17100** enrolled patients.

## REFERENCES


**1. Szentesi A** et al. Alcohol consumption and smoking dose-dependently and synergistically worsen local pancreas damage.
**Gut.** 2022. IF: 31.793

**2. Juhász MF** et al. Pancreatic family history does not predict disease progression but connotes alcohol consumption in adolescents and young adults with acute pancreatitis: Analysis of an international cohort of 2,335 patients.
**Front Med (Lausanne)**. 2022. IF: 5.058

**3. Kiss S** et al. Early prediction of acute necrotizing pancreatitis by artificial intelligence: a prospective cohort-analysis of 2387 cases.
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# THE PROCESS OF OUR SERVICE

## STEP 1 CONSULTATION

We would like to offer the opportunity to discuss your research team's topic of interest with Patient Registry Experts (PRE). During this meeting we would introduce you to all steps of the registry establishment, followed by a discussion about the strategic and financial plan. After agreement, we will provide access to our eLearning materials.

## STEP 2 RESEARCH QUESTION DISCUSSION, QUESTIONNAIRE DEVELOPMENT

The second meeting will cover a more detailed discussion about the planned registry, high-quality data collection and thorough literature search. We will lend all necessary materials, templates and questionnaire samples.

## STEP 3 CASE REPORT FORM DISCUSSION

With the help of the PRE, your research team will start the preparation of the questionnaires. During this meeting, you would be introduced to the importance of a multidisciplinary review phase. When the data collection forms are ready, the PRE will propose two rounds of corrections with statistical expert (SE) involvement.

## STEP 4 INTERNAL AND EXTERNAL REVIEW OF THE QUESTIONNAIRE

Based on the suggestions, the questionnaires need to be updated. Additional consultations and reviews can be required during this step.

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# ADDITIONAL CONSULTATIONS

**APPLIES FOR ALL SERVICES**

- **3-5** optional consultations with CRE (30 min)
- **1-2** optional consultation with SE (30 min)

Additional consultation: **100** € / 1 hour

Additional rounds of document corrections: **100** € / round

* **1-1** authorships are expected for clinical trial and statistical experts, respectively; publication process is the responsibility of the research team

SEMMELWEIS UNIVERSITY
**CENTRE FOR TRANSLATIONAL MEDICINE**

# RESEARCH SERVICES

## GET IN TOUCH!

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tmk@semmelweis.hu