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Short Communication

# Statement on education and scientific research in the field of therapeutic drug monitoring by the COST Action ENOTTA CA21147

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## Abstract

The present article discusses and highlights the need for education and scientific research in the field of therapeutic drug monitoring (TDM) through the prism of the COST Action on the European Network on Optimising Treatment with Therapeutic Antibodies in Chronic Inflammatory Diseases (ENOTTA). The overall hypothesis was that training schools and short-term scientific missions (STSM) would advance the field in areas with a high need for knowledge exchange.

Educational and research topics span the spectrum of the manufacturing of biological and personalized medicines, quality assurance, clinical research, regulatory approval, treatment evaluation, predicting therapeutic results via modeling, stratification of patients, assay of biologicals concentration in plasma, and cost-effectiveness of therapeutic drug monitoring.

In conclusion, we put forward that an educational program on TDM may be helpful in advancing the field and should include the aforementioned subjects. In addition, clinical application and interpretation in a variety of treatment areas should be presented in detail. Such a comprehensive educational program will respond to the requirements of best practices in TDM and future developments in the area.

## Keywords

COST program, education, scientific research, therapeutic drug monitoring

## Introduction

Therapeutic drug monitoring (TDM) aims at ensuring that the right drug is used at the right dose for the right patient (Spector et al. 1988). To achieve these goals, physicians and pharmacists need stratification of appropriate patients, standardization of assays, and individualized treatment guided by TDM (Gross 2001; Bluett et al. 2025; Eylenbosch

et al. 2025), performed in standardized laboratories (Skrede et al. 2024). Along this line, these are also the goals and objectives of the working groups (WG) of the European Network on Optimising Treatment with Therapeutic Antibodies in Chronic Inflammatory Diseases (ENOTTA), a European Cooperation in Science and Technology (COST) Action financed by the COST Association (www.cost-eu).

A COST Action provides a unique opportunity for junior and senior researchers and scientists to join networks engaging professionals from different scientific areas in European and neighboring countries. Part of these opportunities are the Short-Term Scientific Missions (STSM), training schools, webinars, and other forms of educational activities.

Within the COST Action ENOTTA, we previously assessed available educational programs on TDM and identified the need for a more structured education on TDM (Petrova et al. 2026).

The present article discusses and highlights the need for education and scientific research in the field of TDM through the prism of the COST Action ENOTTA. The overall hypothesis was that training schools and STSM would advance the field in areas with a high need for knowledge exchange.

## Results

STSMs are an important and very useful tool for researchers to visit other universities or research institutions for scientific research purposes that can be fulfilled in a short period of time, i.e., not less than 1 month for young researchers and innovators (YRI) and not less than 1 week, in general, for advanced researchers, and cannot be longer than 3 months in both cases. The mobility of YRI is particularly encouraged and actively supported. In ENOTTA, a procedure for STSM applications was created in line with the requirements of the COST Association. Usually, the host proposes a research project, and interested candidates apply. However, interested candidates could also express their interest in a research topic, which would then be announced on the ENOTTA website (https://enotta.eu/grants/open-calls/), along with those of the hosts.

During the first three grant periods of ENOTTA, 18 STSM took place (Table 1). As can be seen, the topics of the STSM vary from systematic reviews to assay methods, modeling studies, work with registries, and similar activities. Interest is oriented mostly toward biological medicines for inflammatory immune-mediated diseases and modeling techniques for therapeutic response prediction.

In addition to the STSM, in the same period, three training schools, 19 webinars, and two educational courses on the principles and practice of clinical and translational research, as well as on mathematical perspectives on immunobiology, took place. The training schools are organized primarily by the WG leaders and other main WG members and are hosted at leading institutions in Europe (Table 2). Furthermore, two 3-day courses were offered introducing clinical research processes and mathematical modeling (Table 2). The webinar series addressed gaps in knowledge, presenting a wealth of detailed information, in particular about TDM, related clinical procedures, and their practical application, in a live and on-demand manner, as all webinars were recorded and uploaded on the YouTube channel of ENOTTA (https://www.youtube.com/@Cost.enotta).

Collectively, Fig. 1 shows the educational activities within ENOTTA, organized by different institutions evenly distributed across participating countries.

## Discussion and conclusion

In this work, we summarized topics of educational activities under the scheme of STSM, training schools, educational courses, and webinars as part of the COST Action ENOTTA. These topics span the spectrum of the manufacturing of biological and personalized medicines, quality assurance, clinical research, regulatory approval, treatment evaluation, predicting therapeutic

**Table 1.** STSM research topics.

| Host country | Awardee country | Research topic |
|---|---|---|
| United Kingdom | Cyprus | Cost-effectiveness of TDM-guided vedolizumab treatment vs standard vedolizumab treatment for ulcerative colitis. |
| Bulgaria | Italy | A mechanistic mathematical model to describe the effect of methotrexate in reducing immunogenicity of adalimumab in axial spondyloarthritis. |
| Greece | Iceland | Sex-biased transcriptomic reprogramming in immune-related adverse events. |
| Italy | Iceland | Flow cytometric assessment of inflamed tissues in cardiovascular disease. |
| Sweden | Belgium | Population pharmacometrics model-based dose optimization of subcutaneous infliximab in inflammatory bowel disease. |
| Netherlands | Sweden | Collaboration with the Uppsala and Sanquin pharmacometrics team. |
| Netherlands | Belgium | Exploring the potential of a Belgian psoriasis registry: learnings from the BIOCAPTURE registry. |
| France | Czech Republic | The role of methotrexate metabolites in reducing immunogenicity of adalimumab in axial spondyloarthritis. |
| Iceland | Italy | Flow cytometric assessment of inflamed tissues in cardiovascular disease. |
| United Kingdom | Belgium | Towards individualized treatment in dermatology: a collaborative approach to model-informed precision dosing of therapeutic antibodies. |
| United Kingdom | Ireland | Leveraging bioinformatics for comprehensive analysis of patient data and sample availability in psoriasis research. |
| Türkiye | Tunisia | Systematic literature review of the differences between available therapeutic drug monitoring assays. |
| Belgium | Serbia | Characterization of exposure–response model for infliximab in patients with severe forms of inflammatory bowel diseases |
| Bulgaria | Poland | Systematic literature review of CEA analyses for TDM |

**Table 2.** Training schools and webinars by organizing institution, subject, and goals.

| Institution | Subject | Goals |
|---|---|---|
| | | **Training schools** |
| University of Manchester, United Kingdom | Biomarkers training school | Provide a comprehensive, multidisciplinary understanding of biomarkers; explore their role in precision diagnosis and therapy; and dive into bioinformatics tools, emerging technologies, and ethical considerations. |
| KU Leuven, Ghent, Belgium. | Model-informed precision dosing | Focus on monoclonal antibody dosing in chronic immune-mediated inflammatory diseases. |
| University of Porto, Spain | Health economics and outcomes research (HEOR) | Equip participants with essential skills in health economics and the interpretation of pharmacoeconomic data. |
| | | **Educational courses** |
| Greek Scientists Society | Introduction to the principles and practice of clinical and translational research | Provide participants with a comprehensive understanding of the clinical research process and the various roles and responsibilities involved in conducting successful and ethical clinical research studies. Explain the clinical use of TDM of biologics in different pathologies. |
| Bulgarian Academy of Sciences | Workshop on mathematical perspectives on immunobiology | Mathematical modeling and computational analysis applied to immunology, host–pathogen interactions, onset, and progression in human diseases. |
| | | **Webinars** |
| University Medical Centre in Ljubljana; Vrije Universiteit Brussel | Model-informed precision dosing (MIPD) of therapeutic antibodies in chronic inflammatory diseases | Overview of the available evidence for therapeutic drug monitoring in gastroenterology, an illustration of its current role in clinical practice, and an outline of potential future developments. |
| The University of Manchester, United Kingdom; University of Tours Hospital, France | Immune-mediated inflammatory diseases (IMIDs) (Pt. 2) and therapeutic antibodies vs. small molecules | Give a broad overview of the risk factors for developing IMIDs, their pathogenesis, advanced biologic therapies, and how immunogenicity affects response; explain how this variability can be studied by analyzing dose–concentration–effect relationships, the mechanisms of which are different from those of small molecules. |
| Medical University of Vienna, Austria; KU Leuven in Belgium | Therapeutic drug monitoring (TDM) | Explain the traditional concept of TDM, together with the opportunities and challenges of this approach. It additionally highlights new developments to enhance TDM and current scientific evidence on TDM. |
| University of Belgrade, Serbia; Polytechnic Institute of Porto, Lisbon | Dose stratification vs. therapeutic drug monitoring (TDM) | Exploring the advantages and challenges associated with proactive and reactive TDM; synthesize current evidence regarding the use of TDM for mAbs; and provide insights into the evolving landscape of personalized medicine in inflammatory bowel disease (IBD) management. |
| Jagiellonian University, Medical College, Poland; KU Leuven, Belgium | Pharmacoeconomics and patient preferences in chronic inflammatory diseases | Expand knowledge and understanding of how patients perceive and value the attributes associated with both current and emerging treatments. |
| University of Poitiers, France; Uppsala University, Sweden | Pharmacometrics and model-informed precision dosing (MIPD) | Introducing basic pharmacometrics principles and pharmacometric models for the purposes of precision dosing of medicines. |
| Pharmacy Faculty of Lisbon University; Clinical Bioanalytics Laboratories at Sandoz | Regulatory and industry perspective on TDM/MIPD | Outlining the regulatory approval process, emphasizing clinical pharmacology studies and dose optimization required for regulatory compliance, illustrated with case examples involving, e.g., infliximab. Discuss the pharmaceutical industry's role, focusing on the optimization of analytical assays for clinical studies and their possible application in TDM. |
| University of Hamburg, Germany; InsightRx, San Francisco, California, USA | Software tools for MIPD | Model-informed precision dosing (MIPD) software leverages pharmacokinetic (PK) and pharmacodynamic (PD) models to optimize individualized medication dosing. After the presentations, the audience will be familiar with the underlying concept of MIPD, have seen case examples, and be introduced to challenges when using MIPD software. |
| Bellvitge University Hospital, Barcelona (Spain); University of Bergen, Norway | Experience with MIPD and the role of analytics | Presentation of the principles of analytical methods currently employed for serum concentrations of therapeutic antibodies. Present experience on the implementation of TDM and MIPD of biologics in inflammatory bowel disease. |
| Faculty of Medicine, University of Niš; Dokuz Eylül University, Türkiye | Artificial intelligence in TDM/MIPD | Artificial intelligence and machine learning have gained increasing popularity across disciplines in the last decade, but their application in MIPD remains in early stages, holding promise for the future. |
| Nutrition and Drug Research Department of the Institute of Public Health, Jagiellonian University, Medical College | Introduction to pharmacoeconomics | Provide an introductory overview of pharmacoeconomics to raise awareness of the importance of cost-effectiveness in the treatment of IMIDs and how to interpret such analyses. Practical examples of published cost-effectiveness studies in TDM are presented. |
| Health Insurance Organization Cyprus (HIO) | Introduction to health economics and outcomes research (HEOR) | Introduces fundamental concepts such as opportunity costs, trade-offs, and health utility measurement, encompassing direct and indirect methods. Discuss economic evaluation techniques, including cost-effectiveness analysis (CEA), cost-utility analysis (CUA), and incremental cost-effectiveness ratios (ICERs). |
| University of Manchester, United Kingdom | Clinical efficacy vs. effectiveness: ideal results vs. real-world impact | Summarize efficacy and clinical effectiveness, their similarities, and how they differ in context and scope, with examples from rheumatology. |
| University of Manchester, United Kingdom | Systematic review and meta-analysis | Cover the process of conducting systematic reviews and meta-analyses, including the formulation of research questions, literature search strategies, data extraction methods, and established frameworks. |
| Jagiellonian University, Medical College in Cracow, Poland | Optimizing therapy and personalizing treatment | Explores the role of TDM in enhancing the efficacy and safety of clinical treatments. Emphasize how TDM supports personalized medicine. Outline challenges in fixed-dose strategies and introduce TDM methodologies, including sample collection, analytical techniques, and real-time data interpretation. |
| Ankara University, Türkiye | Cost of illness, budget impact analysis | Present two essential methodologies in health economics: cost of illness (COI) and budget impact analysis (BIA). |
| Jagiellonian University in Kraków Medical University Sofia, Faculty of Pharmacy | Basics of stochastic thinking and Markov models | Introduce core modeling approaches in health economics, focusing on decision trees, Markov models, and partitioned survival models. Emphasize relevance for long-term and complex disease modeling. |
| MabDesign, France | Biologics: Industrial production of biopharmaceuticals | Explore key steps and challenges in large-scale manufacturing of biopharmaceuticals—from upstream development to downstream purification. |
| University of Manchester, United Kingdom | Markov models, simple practical examples | Present a simple Markov model technique for TDM. |

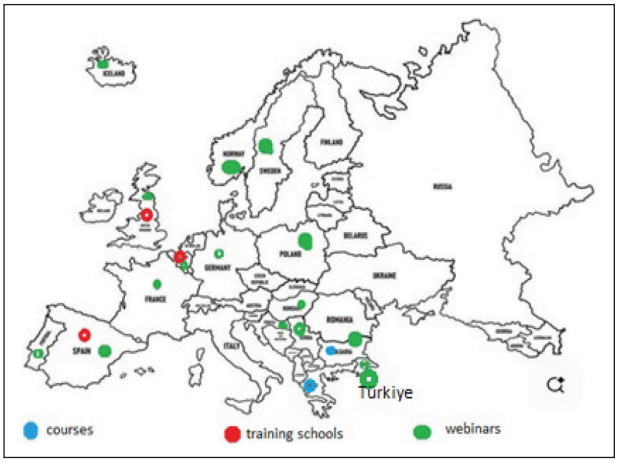


**Figure 1.** Map of the training schools, webinars, and courses.

results via modeling, stratification of patients, assay of biologicals concentration in plasma, and cost-effectiveness of therapeutic drug monitoring.

In conclusion, we put forward that an educational program on TDM may be helpful in advancing the field and should include the aforementioned subjects. In addition, clinical application and interpretation in a variety of treatment areas should be presented in detail. Such a comprehensive educational program will respond to the requirements of best practices in TDM and future developments in the area (D'Angio et al. 1990; Gross 2001; Shenfield 2001).

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## Additional information

### Conflict of interest

The authors have declared that no competing interests exist.

### Ethical statements

The authors declared that no clinical trials were used in the present study.

The authors declared that no experiments on humans or human tissues were performed for the present study.

The authors declared that no informed consent was obtained from the humans, donors or donors' representatives participating in the study.

The authors declared that no experiments on animals were performed for the present study.

The authors declared that no commercially available immortalised human and animal cell lines were used in the present study.

### Use of AI

No use of AI was reported.

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### Data availability

All of the data that support the findings of this study are available in the main.

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