

CLINICAL TRAILS - 28 and 29 May 2026
MAY 28, 29 2026 - 2 DAY TRAINING COURSE
In person
"St. Ekaterina" Hospital (Hall 2),
52A Pencho Slaveykov Blvd, 1431 Sofia, Bulgaria
Faculty Team



Dr. Georgi Mihaylov Georgiev



Dr. Georgi Mihaylov Georgiev is a senior medical professional with extensive expertise in clinical research, pharmaceutical medicine, and healthcare management. He currently serves as Senior Medical Director at IQVIA, following a long-standing career in the clinical research sector. Dr. Georgiev has held key leadership roles at AstraZeneca, including Clinical Research Manager, Head of Office, and Country Head, before advancing to Medical Director roles within IQVIA. His early career includes academic and clinical positions at Alexandrovska Hospital, where he specialized in internal medicine and gastroenterology.

His educational background combines medical training with advanced qualifications in healthcare and corporate management. Dr. Georgiev is a recognized contributor to the development of clinical research in Bulgaria. He is the founder of the Bulgarian Association of Clinical Research and served as its Deputy Chairman. He has also participated in a Ministry of Health working group responsible for the development of Bulgaria's Drug Law prior to EU accession. His professional expertise spans clinical trial methodology, study design and protocol development, medical monitoring, clinical operations, and medical statistics, positioning him as a highly respected expert in evidence-based medicine and clinical drug development.

Dr. Rossitsa Vassileva



Dr. Rossitsa Vassileva is a highly experienced professional in regulatory affairs, clinical research, and healthcare policy, with a distinguished international career spanning over two decades. She currently serves as Head of Regulatory & Matrix Services Country/Region at PSI CRO, overseeing regulatory, ethics, translation, clinical supplies, and document management activities across Bulgaria, Greece, and Turkey. Her career includes senior roles at leading global organizations such as Bristol-Myers Squibb, Aventis Pharma, and Quintiles, as well as executive leadership in the CRO sector. She also served as Managing Director at the National Council for Pricing and Reimbursement in Bulgaria, where she was responsible for pricing, health technology assessment, and reimbursement decisions.

Since 2008, Dr. Vassileva has been a registered expert with the European Commission, contributing as an evaluator of research projects in fields such as oncology, immunology, nephrology, and transplantation. She is an active member of the Bulgarian Association for Drug Information, Bulgarian Medical Doctor Union, and Bulgarian Association of Clinical Research. In addition, she serves as a legal medical expert in clinical trials in Bulgaria. Fluent in multiple languages and combining strong academic training with extensive practical expertise, Dr. Vassileva is recognized as a leading authority in the regulatory and clinical research field.

Julia Kovacheva-Palahanova



Over 25 years of experience in the clinical research field, including 6 years as Research Nurse / Site Coordinator, 7 years as Clinical Research Associate, and 13 years as People Manager. Over 16 years of service in PPD / Thermo Fisher Scientific, including FSO and FSP models. Experienced in managing different roles and functions, including feasibility, start-up, contracts, on-site and remote monitoring, and line management. Participated in the PPD EMEA Quality Forum Steering Committee, PPD EMEA Quality Champions, Regional EMEA Critical Thinking Champion – Clinical Operations, Local Quality and Patient Recruitment Lead, and PPD Select Partnership Manager. Key focus areas include quality in monitoring, quality improvement, cross-functional and cross-border expansion, patient enrollment, team retention and growth, training, and knowledge sharing.

Bachelor of Science in Nursing, with experience in reanimation and psychiatry. Master of Science in Health and Social Management. Holds postgraduate certifications in Project Management and Quality Assurance. As of June 2025, Chairperson of the Management Board of the Bulgarian Association of Clinical Research (BACR), and Lead of the Trainings and Professional Affiliations Working Groups.

Ivaylo Ivanov



Ivaylo Ivanov is working at ICON Clinical Research since Oct 2021 with current position as Senior Project Manager. Ivaylo is experienced professional with extensive experience in regulatory affairs, clinical trials, project management, and start-up clinical activities, holding a Master of Pharmacy degree and a PhD. Having more than 16 years' experience in the Pharmaceutical and CRO industry occupied multiple positions like regulatory specialist, senior CRA, Affiliate Clinical Study Manager, Clinical Study Unit Lead, Clinical Trial Application Regulatory Manager and Project Manager. Participated in numerous workshops and training sessions covering SOPs, GCP-ICH, regulatory challenges, project management, leadership, and people management. Authored multiple articles and posters on drug legislation, regulatory analysis, and clinical trials in Bulgaria and Eastern Europe. Possessing strong communication and organizational skills, flexible to fast changing environment and problem-solving attitude.

Maria Veleva



Maria Veleva is a highly experienced clinical research professional with over 25 years of expertise in clinical trials, quality management, and regulatory compliance. She has held senior global and regional roles, including at IQVIA, where she managed cross-country teams and led quality-driven initiatives. Her core competencies include GCP audits, inspection readiness, quality management systems, and the successful delivery of Phase I–III international clinical studies across oncology, internal medicine, and rare diseases.

As the Founder and Principal Consultant of Velev Consulting Ltd., she provides strategic consultancy services to pharmaceutical companies, CROs, and clinical service providers, focusing on improving efficiency, quality, and risk management. She is also an active trainer, speaker, and contributor to international professional organizations, playing a key role in advancing best practices in clinical research and promoting innovative approaches, including the integration of artificial intelligence in clinical trials.

Margarita Strokova



Margarita Strokova, MD has master's degree in Medicine from Medical University, Sofia and Master of Business Administration from New Bulgarian University, Sofia.

Joined Pharma Industry in 1997 and has extensive experience in pharmaceutical marketing, scientific communication, Medical Governance and Pharmacovigilance (for products both under clinical trials and marketed). Worked for over 13 years as local person responsible for Pharmacovigilance in GSK Bulgaria and 3 years as Local Country Medical Head.

Margarita has experience in safety operations (MI and PV) and from September 2021 is part of PharmaLex team and later Cencora/Pharmalex company.

Radoslava Naydenova



Radoslava holds a master's degree in Strategic management of the Pharmaceutical Industry from Medical University, Sofia as well as Bachelor's degree in Linguistics and International relations from Sofia University. She has extensive experience in different areas of pharmaceutical industry gained over the last 15 years in the fields of manufacturing and importation planning, pricing and reimbursement, sales analysis, and pipeline project management.

As a Regulatory Affairs professional she has in-depth knowledge of the local Bulgarian and EU legislation procedures and guidelines governing pharmaceutical products, GMP, GDP, food supplements, medical devices, and cosmetics. For the period of 14 years starting from 2008 until beginning of 2023, she has taken different expert and management positions at Nobel Pharma Bulgaria, last of which Regulatory Affairs Project manager.

Since February 2023 she has joined the pharmaceutical consultancy field as a Senior Manager Regulatory Affairs at PharmaLex with broad span of regulatory interactions with EMA, CMDh and EU national competent health authorities as well as Swissmedic.

Prof. Tatyana Benisheva - Dimitrova



Prof. Tatyana Benisheva - Dimitrova, MD DSc., President of BADI is a medical doctor and professor in the Faculty of Public Health at Medical University, Sofia, Bulgaria. After receiving an EC-CADREAC scholarship she completed master's degree in Drug Regulatory Affairs (2004/2005) at the University of Bonn and later in 2010 a Master degree in "Public Health" at the Medical University of Sofia, Bulgaria.

She was a Director of the "Drug Policy" Department at the Ministry of Health (2000-2005) and has over 10 years of experience at the Bulgarian Drug Agency (BDA). As the first president of the National Council on Prices and Reimbursement of Medicinal Products 2013-2014 (pricing and reimbursement competent authority in Bulgaria) she started an EU-project-OPAC for establishing of electronic database of medicinal product. As a managing director of consulting in Bulgaria Betaconsult Pharma Ltd. (2007-2013) she developed drug regulatory activities at the global regulatory database IDRAC of the Thompson Reuters (2006-2012) In 2010 she established a NGO - Bulgarian Association for Drug Information (www.badibg.org) for postgraduate education in the field of medicine and medical devices. Prof. Benisheva was a member of the German society DGRA and Board member of the EAMEA at DIA, and Advisory council at the DIA in Europe and board member of IFFAP.

Since 2023 she is a member of the Ethical Committee for clinical trials at the Ministry of Health in Bulgaria. Her over 25 years of experience in clinical drug regulatory affairs (life cycle management and market access of medicinal product) is complemented by more than 100 publications in the regulatory science field of medicines.