

COST CLINIMARK TRAINING SCHOOL

Approaches for Biomarker Discovery and Validation



CA16113 - CliniMARK



Exact dates of the Training School:	September 23 rd to 27 th 2019
	Venue: Spetses Hotel, Greece
Number of working days (nights):	41/4 days (5 nights)
Deadline for applications	16 th June 2019

Participants

Instructors: 24 Senior Researchers from Academia, Industry and Regulatory Agencies

Trainees: 60 PhD/MSc students and scientists involved in biomarker research

Introduction

The quest for novel biomarkers is a popular research activity with high productivity. Thousands of studies are published claiming the discovery of biomarkers suitable for improving disease management. **The stark reality though indicates that very few potential biomarkers are approved for clinical use.** The application of omics approaches (Genomics, Transcriptomics, Proteomics, Metabolomics, etc.) in biomarker discovery has contributed significantly in increasing the number of publications reporting initial findings that are not validated. Major issues associated with this dire situation are the difficulty in analytical validation of robust biomarker assays, flawed study design, and the inability to exploit the full potential of high-throughput omics approaches. **Thus, there is a waste of research resources without tangible benefits to society.** Moreover, there are many unmet clinical needs that are not currently addressed by the available biomarkers in diseases of high prevalence and of high financial and social cost such as cancer, cardiovascular disease, chronic kidney disease, and chronic obstructive pulmonary disease. This situation is partly due to a lack of education resources dedicated to omics studies in biomarker research.

Teaching objectives and topics

The unique feature of the proposed workshop is that it will expose the problems associated with omics biomarker studies and train a new generation of scientists able to fix the flawed biomarker discovery and implementation paradigm. In order to achieve this ambitious goal **the following specific teaching objectives are set so that students can:**

- 1. obtain a global view of omics approaches and the biomarker life cycle from discovery to clinical implementation**
- 2. acquire skills relevant to biomarker data analysis (analytical assay validation, clinical performance)**
- 3. develop critical thinking by thorough evaluation of published biomarker studies, and improve writing and presentation skills**

The following topics be covered during the workshop:

- A) Introduction to the different **biomarker types** (diagnostic, prognostic, etc.)
- B) Introduction to the different **omics approaches** and their application in the context of biomarker research
- C) Emphasis on the importance of **defining the biomarker context of use** in the clinical setting before initiating a research protocol on biomarker discovery and validation
- D) Presentation of **good biomarker practice guidelines** on:
 - 1. study design** (number and type of samples, proper statistical analysis, reporting of all findings, etc.)
 - 2. analytical validation of assays** (reproducibility, LOD, linearity, etc.)
 - 3. clinical performance** (sensitivity, specificity, etc.), validation in an independent large set of samples (ideally multi-center study) by different researchers (external independent validation)
 4. comparison of the performance of the new biomarker with biomarkers already used in clinical practice (umbrella reviews)
 5. tools for assessing if biomarkers are effective in improving concrete patient clinical outcomes (randomized trials, etc.)
 6. implementation in sub-optimal conditions and different populations.

Daily Program

	Mon, Sep 23	Tue, Sep 24	Wed, Sep 25	Thu, Sep 26	Fri, Sep 27	
09:00	Arrival and Registration	Introduction to omics and Biomarkers Antonia Vlahou	Biomarkers for doping Sulev Kõks	Biomarkers in Screening for Obstructive Sleep Apnea Deborah Penque	Biomarkers for psychiatric disorders Chris Turck	
09:30						
10:00		Biomarker panels by CE-MS Harald Mischak	Biomarker clinical implementation Eva Caceres	Proteomics for anxiety disorders: mind the mitochondria Michaela Filiou	Predictive biomarkers for CVD Andreas Simm	
10:30						
11:00		Coffee break	Coffee break	Coffee break	Coffee break	
11:30		Targeted proteomics assays for biomarkers Virginie Brun	Quality control in biomarker research Andrea Wutte	Proteomics for biomarker discovery Michalis Aivaliotis	Biomarkers of healthy ageing Niki Chondrogianni	
12:00						
12.30		Student talks 1-13	Student talks 19-31	Student talks 36-48	Student talks 49-60	
13:00						
13.30						
14:00		Lunch Break Poster viewing Discussions Free time	Lunch Break Poster viewing Discussions Free time	Lunch Break Poster viewing Discussions Free time	Lunch Break Poster viewing Discussions Free time	
14:30						
15:00						
15.30		High sensitivity immunoassays Stanislav Kuula	Analytical validation of sRAGE MRM assay Rainer Bischoff	Cultural excursion	Meet the expert Biomarker assay validation Study design, MRM data analysis Eureka: something is rotten in the biomarker kingdom Makis Zoidakis	
16:00						
16:30		Student talks 14-18	Student talks 32-35			Coffee break
17:00		Changing the biomarker implementation paradigm Peter Groenen	Biomarkers used in clinical practice for monitoring biological drugs Begoña Oliver			Epigenetics and Redox Biomarkers Alexander Bürkle
17:30		Genomics biomarkers Lila Koumandou	Liquid biopsy preparation Chris Sutton			Oxidative stress and biomarkers Grune Tilman
18:00						
18:30	Molecular diagnostics: from bench to clinic Daria Ler	Antibody Quality Control Saara Wittfooth	Summing-Up Round Table			
19:00						
19:30	Biomarkers at the interphase of academia and industry Alain van Gool	Poster session discussions	Poster session discussions	Farewell reception /		
20:00						
20:30	Welcome reception	Dinner	Dinner	Dinner		

Instructions for applicants and selection criteria

The training school will target early stage researchers (ESRs) with a background on molecular biology, biochemistry, chemistry, and medicine, primarily experienced PhD students and post-doctoral level scientists within 5 years after completion of their doctorate. Trainees will be selected primarily based on their qualifications relevant for the course content, their potential to contribute to the breadth of science and the benefit they are likely to obtain with respect to their future careers, while ensuring a broad participation from different countries.

Applicants should send to izoidakis@bioacademy.gr the following documents:

- 1. A two-page CV**
- 2. A letter of intent that clearly states why she/he intends to participate in this training school (300 words maximum).**
- 3. An essay (300 words maximum) supporting or opposing the use of PSA in a specific clinical context.**

Deadline for applications: 16th of June 2019

The trainees whose application is approved will prepare a poster on their research and a 3 minute presentation of the main points of its content that will be followed by a 2 minute discussion. Thus, all trainees will have the opportunity to present themselves and their research before the poster sessions. Particular emphasis will be given to poster sessions since they allow trainees to present their work to their peers and to experienced researchers, get feedback on their projects, and eventually establish fruitful collaborations.

For additional information contact Makis Zoidakis (izoidakis@bioacademy.gr)

Venue information

The course will be held at Spetses Hotel in Greece (<https://spetses-hotel.gr/en/>)

The island of Spetses is easily accessible from and very well connected to Athens. Spetses is a well-established location for scientific training events and this hotel has successfully hosted many FEBS and IUBMB Advanced Courses in the past, with consistently positive experience and feedback. The hotel is easily accessible, but is in a quiet and secluded area of Spetses, allowing the participants to focus fully on the training course, and ensuring a perfect atmosphere for a relaxed but intensive interaction between the senior scientists and the trainees.

The hotel has full lecture facilities (the B. Clark lecture theatre with audio-visual aids, photocopiers, computers and free internet access) as well as ample space for poster sessions and informal meetings allowing direct interaction between participants, including the daily “meet the experts” sessions in the afternoons.

The meeting is on a full-board residential basis, so participants and lecturers will have all meals together, thus allowing additional informal discussions during these periods. The hotel has already confirmed reservation of the venue for the duration of the course and offers special group rates for the participants and lecturers of the course

Registration fee

Total all-inclusive registration fee for young scientists is (in €uro): **550** €

This all-inclusive registration fee **breaks down** into costs for the whole duration of the workshop:

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|---|------------|---|
| 1. Meals (breakfast, lunch & dinner) : | 229 | € |
| 2. Accommodation (double): | 290 | € |
| 3. Administrative part of registration fee: | 31 | € |

Course Organizers

Aivaliotis Michalis, Aristotle University of Thessaloniki, Greece

Chondrogianni Niki, National Hellenic Research Foundation, Greece

Filiou Michaela, University of Ioannina, Greece

Koumandou Lila, Agricultural University of Athens, Greece

Tilman Grune, German Institute of Human Nutrition Germany

Zoidakis Makis, Biomedical Research Foundation Academy of Athens, Greece

Speakers

Bischoff Rainer, University of Groningen, The Netherlands

Brun Virginie, Protein Dynamics Laboratory CEA, France

Bürkle Alexander, Department of Biology University of Konstanz, Germany

Caceres Eva, Immunology Division, Universitat Autònoma Barcelona, Spain

van Gool Alain, Radboud University Medical Center, The Netherlands

Groenen Peter, Idorsia Pharmaceuticals, Switzerland

Köks Sulev, Murdoch University, Australia

Stanislav Kuula, Merck Chemicals GmbH, Germany

Ler Daria, EUROFARM Centar Laboratory, Bosnia and Herzegovina

Mischak Harald, Mosaiques Diagnostics, Germany

Oliver Begona, Instituto de Investigacion Biomedica de Malaga, Spain

Penque Deborah, National Institute of Health Dr Ricardo Jorge, Portugal

Simm Andreas, Martin Luther University Halle-Wittenberg, Germany

Sutton Chris, University of Bradford, UK

Turck Chris, Max Planck Institute of Psychiatry Munich, Germany

Vlahou Antonia, Biomedical Research Foundation Academy of Athens, Greece

Wittfooth Saara, University of Turku, Finland

Wutte Andrea, Biobanking and BioMolecular Resources Research Infrastructure, Austria