

STUDY HANDBOOK

CERTIFICATE OF ADVANCED STUDIES IN PERSONALIZED MOLECULAR ONCOLOGY

02. February 2023



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1. GENERAL DESCRIPTION

Cutting-edge technologies, like next-generation-sequencing (NGS), combined with the development of targeted therapies are now revolutionizing clinical practice, bringing new complexity to the field of oncology. The Certificate of Advanced Studies (CAS) in Personalized Molecular Oncology aims at providing a comprehensive and integrative view of the field, by covering (i) tumor biology and genetics, (ii) molecular pathology, (iii) clinical bioinformatics, and (iv) clinical oncology. First of its kind in Switzerland, it will focus on the methodologies used to generate, analyze and interpret patients' molecular profiles, also touching upon the associated technical, regulatory and ethical challenges. As an important outcome, it will establish a common language between the wide range of professionals involved in the personalized oncology process, from biologists, bioinformaticians, pathologists to clinicians, enabling an efficient and better informed use of e.g. genomic data for both routine clinical practice and clinical research. Moreover, it should empower professionals to develop a vision for their own institution, by critically evaluating the potential benefits and limitations of current and future developments in personalized oncology.

2. TARGET AUDIENCE

The Certificate of Advanced Studies (CAS) in Personalized Molecular Oncology targets an interdisciplinary audience of professionals involved in personalized molecular oncology, including laboratory managers, biologists, bioinformaticians, pathologists, geneticists, clinicians and pharmaceutical company employees. Applicants will be selected on the basis of their CV and demonstrated interest and experience in personalized oncology, and are expected to hold a university degree.

3. PROGRAM STRUCTURE AND CURRICULUM

- a. Teaching and Learning Modes
 - Lectures
 - Group discussions
 - Hands-on
 - On-site lab visits

b. Curriculum page 3

- Module 1: Tumor biology and genetics
- Module 2: Molecular pathology
- Module 3: Clinical bioinformatics
- Module 4: Clinical oncology

c. Degree

Certificate of Advanced Studies (CAS) in Personalized Molecular Oncology

4. ASSESSMENT FORMATS

Modules evaluation

Modules are evaluated individually. Exams are graded from 0 to 6, 6 being the best grade and 4 the minimum to pass the module.



What - Each exam consists of 30-50 multiple-choice questions (60-100% of the questions) and/or open questions (0-40% of the questions). The questions are related to topics covered during the class and homework assignments. In particular, considering that each module is spit in 8 major topics (see Curriculum), each topic of a module should be addressed by at least 5% of the questions of the corresponding exam.

How - The exam consists of an online questionnaire, powered by SIB-hosted Moodle platform. Participants complete the exam at home, with course material allowed. Completion time is recorded, but no time limit is set a priori. The aim is that participants can successfully complete the exam within 2h. Each student can access the exam form using unique credentials specific to him/her.

When - Students should complete the online exam between 2-4 weeks after the end of each module. As such, the exam only becomes available online 2 weeks after the end of the module, to ensure that students take sufficient time to study and integrate the module program. After the 4 weeks deadline, the exam is no longer accessible and students who did not take the exam are considered as having failed the module (grade: 0/6).

CAS mini-thesis

In addition, after successfully passing the four modules exams, students complete the program by writing a mini-thesis on a study case in small multi-disciplinary groups.

What - The Program Board proposes several study cases and literature review topics to the students. In addition, students may submit proposals of study cases or literature review topics to the Program Board, before two weeks after the end of the fourth module. All topics proposed by students must be accepted by majority vote within the Program Board.

Working through the study case may involve using free, open-source bioinformatics tools.

The mini-thesis is the final written report (20-50 pages) that presents the study case, discusses all the analyses performed (or that would need to be undertaken and for what reason) and provides some conclusions on the case. A review of literature on a particular topic may also be part of a minithesis.

How - The students form small multi-disciplinary groups of 3-5 people. As much as possible, expertise should be distributed across the various groups (if possible, try having a bioinformatician, a pathologist, an oncologist, and a geneticist in each group). The students complete the mini-thesis at home, and may contact the Program Board in case of questions (if needed, a phone/on-site meeting may be planned).

When - The students have 8-12 weeks to complete the mini-thesis, starting after the exam of the last module (i.e. starting 4 weeks after the end of the last module).



5. QUALITY ASSURANCE / QUALITY DEVELOPMENT

Quality is assured on the student's side with an anonymous online questionnaire of about 20 questions with the following topic blocks: content, organization, teaching & interaction, relevance and satisfaction. This questionnaire is sent after the end of each module. It also asks participants if they would agree to provide us with a private email to contact them again in the future to answer a long-term feedback form and thereby keep track of alumni. This is important to assess to what extent the Certificate of Advanced Studies (CAS) in Personalized Molecular Oncology has an impact on their professional life.

An online questionnaire is also sent to teachers/speakers after their respective module, with the following blocks: organization, level and participation of the students.

The results of the questionnaires are communicated to the module coordinators and discussed with the Program Board before the start of every new session, thereby ensuring that content and format can be adjusted in due time as needed.

6. Institutions

The Certificate of Advanced Studies (CAS) in Personalized Molecular Oncology is organized jointly by (i) the University Hospital of Basel, which is the Swiss hospital sequencing the largest number of samples in oncology (~1500/year), (ii) the University Hospital of Lausanne, a major onco-hematology sequencing center in Switzerland, and (iii) the SIB Swiss Institute of Bioinformatics, an internationally recognized leader in bioinformatics.

7. PROGRAM BOARD

The program board is composed as follows:

• Prof. Dr. Christian Ruiz (Chair of Programme Board)

CSO of Moonlight Al

Titular professor of the Medical Faculty

University of Basel

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• Prof. Dr. Andreas Wicki

Senior Consultant in Oncology, Deputy Head Oncology Medical Oncology and Hematology University Hospital Zurich andreas.wicki@usz.ch| +41 (0)44 255 21 54

• Dr. Salvatore Piscuoglio

Research group leader, Co-Director Research Department Pathology Institute of Medical Genetics and Pathology, University Hospital Basel Visceral Surgery Research Laboratory (Clarunis), Department of Biomedicine, University of Basel salvatore.piscuoglio@usb.ch | +41 (0)61 328 68 74

PD Dr. Matthias Matter

Head of Molecular Pathology Unit Institute of Medical Genetics and Pathology, University Hospital Basel matthias.matter@usb.ch | +41 (0)61 328 64 71



• PD Dr.med. Dr.phil. Benjamin Kasenda

Specialist in Medical Oncology (FMH)

Specialist in Internal Medicine and Haematology and Oncology (D)

Senior physician, Medical Oncology

University Hospital Basel
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• Dr. Aitana Neves

Team Lead Data Science
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• Prof. Dr. Jacqueline Schoumans Pouw

FAMH specialist in medical genetics, Director of the Cancer Genetic Unit Clinical Hematology Service/Laboratory Dpt, Lausanne University Hospital jacqueline.schoumans@chuv.ch | +41 (0)21 314 33 87

• Director of Studies (see below; no right to vote)

8. DIRECTOR OF STUDIES / PROGRAM COORDINATOR

The CAS leadership is shared between a Director of Studies and a Program Coordinator.

Director of Studies

Prof. Dr. Dr. Sacha Rothschild

Director Oncology/Haematology
Cantonal Hospital Baden
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Program Coordinator

Miriam Tesfai

Clinical Bioinformatics
SIB Swiss Institute of Bioinformatics
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9. TEACHING FACULTY

Members of the program board are the main teachers of modules 1, 2 and 4. For module 3, SIB appoints teachers within its pool of scientists. For each module, external lecturers may also be invited as required, to present state-of-the-art techniques/methods/research.

Module 1: Tumor biology and genetics; Prof. Dr. Jacqueline Schoumans Pouw, internal/external lecturer(s)

Module 2: Molecular pathology; PD Dr. Matthias Matter, Dr. Salvatore Piscuoglio, PD Dr. Christian Ruiz, internal/external lecturer(s)

Module 3: Clinical bioinformatics; Dr. Aitana Neves, Mrs. Valérie Barbié, SIB scientists (NN), external lecturer(s)

Module 4: Clinical oncology; Prof. Dr. Andreas Wicki, PD Dr. Sacha Rothschild, PD Dr. Benjamin Kasenda, internal/external lecturer(s)



10. DEREGISTRATION AND FINANCES

- Cancellation prior to the enrollment closing date is not subject to any charge.
- Cancellation between the enrollment closing date and start of the Certificate of Advanced Studies (CAS) in Personalized Molecular Oncology is charged CHF 600.- to account for administrative fees.
- From the first day of training, the whole registration fee is due.

Requests for postponing or cancellation must be submitted by email to the Program Coordinator. Incomplete records will not be processed.

The minimum-maximum number of participants to run the Certificate of Advanced Studies (CAS) in Personalized Molecular Oncology is set to 15-25 per session.

11. ORGANIZATION

The tasks of the Director of Studies are shared with the Program Coordinator, as follows:

- The Director of Studies submits proposals to the Program Board, signs certificates, and is responsible for the cost coverage of the CAS.
- The Program coordinator has the operational responsibility of the CAS in cooperation with Advanced Studies, submits proposals to the Program Board, and implements quality assurance measures.

A secretary provides support for logistics.

12. CONTACT

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13. ATTACHMENTS

N/A



3B CURRICULUM

Certificate of Adva	anced Studies (CAS) in Personalized Mole	ecular Oncology				
Modules	CONTENT - LECTURER	LEARNING OBJECTIVES	DURATION	CONTACT HOURS (OPTIONAL)	WORKLOAD	ECTS
Module 1: Tumor biology and genetics	1) Basic cytogenetics and molecular genetics 2) Heriditary vs acquired genetics 3) Genetic recombination, DNA damage and repair 4) Solid tumors and hematological malignancies 5) Genetic predisposition to cancer 6) Diagnostic genetic testing 7) Tumor cell proliferation 8) Clonal evolution & tumor heterogeneity Module coordinator/teachers: Prof. Dr. Schoumans, NN	 Describe the mechanisms yielding to genetic variation, and be familiar with the various types of genetic variants Distinguish hereditary genetic anomalies from acquired genetic anomalies Discuss the advantages and limitations of different genetic laboratory methodologies for diagnostic testing Demonstrate how to interpret nonhotspot mutations using public databases and taking into account overall genomic aberrations and clonal evolution. Be aware of ethical implications of incidental genetic findings 	8 weeks	28h	60h	2
Module 2: Molecular pathology	 Sample classification and preparation Principles of nucleic acids extraction Sequencing platforms and setup 	 Understand the basics (procedures and rules) of an accredited clinical laboratory Gain knowledge about the different types of specimens (e.g. tissue biopsy, cytology, resections) 	8 weeks	28h	60h	2



	4) Understanding gene panels 5) Internal/External Quality controls 6) Laboratory accreditation 7) Reporting genomic variants 8) Interpreting a molecular profile Module coordinators/teachers: PD. Dr. Matter, Dr Piscuoglio, Prof. Dr Ruiz, NN	- Get familiar with all the steps that lead from samples collection to final molecular report generation along with all possible bottlenecks - Have an overview about the currently used technological platforms in molecular diagnostics (comparison with the research setting) - Get familiar with the most common clinically relevant variants along with their interpretation and classification system				
Module 3: Clinical bioinformatics	1) Data pre-processing 2) Read mapping 3) Variant calling 4) Quality control 5) Variant annotation 6) Hardware, security, privacy 7) Artificial intelligence (AI) basics 8) AI current and future applications Module coordinators/teachers: Dr Lebrand, Mrs Barbié, SIB Trainers, NN	 Communicate efficiently with bioinformaticians. Describe a bioinformatics analysis pipeline to call mutations from NGS data. Perform quality control at the run, read and variant levels. Use off-the-shelf bioinformatics tools to annotate and support the interpretation of variants. Consider hardware, security and privacy issues when managing omics data. Understand how artificial intelligence contributes to and will further impact personalized oncology. 	8 weeks	28h	60h	2



			32 WEEKS	112н	240н	
_			TOTAL	TOTAL	TOTAL	TOTAL
	NN					
	PD Dr Rothschild, Prof. Dr Wicki,					
	Module coordinators/teachers:					
	cussion of clinical cases					
	8) Molecular Tumor Board – Dis-					
	Oncology – How to improve evidence	implications for patients and families				
	7) Clinical Trials in Molecular	- Learn about genetic counseling and its implications for patients and families				
	tical exercises	and routinely used targeted therapies				
	sion of example cases and prac-	molecular aberrations in solid tumors				
	and genetic counseling - Discus-	- Get familiar with the most frequent				
	interpretation of genetic results	tive markers in molecular oncology				
	6) Risks and probabilities for the	- Understand the importance of predic-				
	Oncology	of clinical trials in oncology				
	5) Targeted Therapies in Clinical	ciples underlying the design and analysis				
	Markers	- Get a basic understanding of the prin-				
	4) Prognostic and Predictive	proaches				
	miology	used to optimize therapeutic ap-				
	3) Cancer Statistics and Epide-	ical mechanisms and how these may be				
5 9	2) Tumor Immunology	- Get detailed knowledge of immunolog-				
Sy	aberrations in solid tumors	aberrations hampering this signaling				
odule 4: nical onco-	1) Tumor Physiology – Key sig- naling pathways and molecular	- Describe main intracellular signaling pathways in solid tumors and molecular	8 weeks	28h	60h	2

ECTS=European Credit Transfer and Accumulation System



Assessment Formats	DURATION	CONACT HOURS (OPTIONAL)	WORKLOAD	ECTS
Modules evaluation (exam at the end of each module)	32		240	8
CAS mini-thesis (in small multi-disciplinary groups)	8		60	2
	TOTAL	TOTAL	TOTAL	TOTAL
			Н	
Certificate of Advanced Studies (CAS) in Personalized Molecular Oncology	DURATION	CONTACT HOURS (OPTIONAL)	WORKLOAD	ECTS
TOTAL	40 WEEKS	112н	300н	10