

# STUDY HANDBOOK

# CERTIFICATE OF ADVANCED STUDIES IN PERSONALIZED MOLECULAR ONCOLOGY

30. October 2018



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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
  - Case working
  - On-site lab visits
  - Hands-on
  - Selfstudies and Homework

# b. Curriculum page 8FF

- 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

Online module exams

Homework

Written exam (CAS mini-thesis)

# 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. Participants and teachers are also encouraged to join the Certificate of Advanced Studies (CAS) in Personalized Molecular Oncology LinkedIn group to network with their peers. This group is a simple and efficient way of keeping track of student's career paths, as most professionals nowadays keep their LinkedIn profile up to date.

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 oncohematology 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:

# Manager:

#### PD Dr. Sacha Rothschild

Senior Consultant in Oncology, Head of Center for lung tumors, Co-Chair of the Network Molecular Tumor Therapy

Tumor Center and Medical Oncology, University Hospital Basel sacha.rothschild@usb.ch | +41 (0)61 265 50 74/59

#### Members:

#### Dr. Aitana Lebrand

Clinical Bioinformatics Project Manager



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# PD Dr. Andreas Wicki

Senior Consultant in Oncology, Deputy Head of Center for neuro-endocrine and endocrine tumors, Head of Phase 1 Oncology Unit, Co-Chair of the Network Molecular Tumor Therapy Tumor Center and Medical Oncology, University Hospital Basel

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# Dr. Luca Quagliata

Head of R&D Unit

Institute of Medical Genetics and Pathology, University Hospital Basel

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# Prof. Luigi Terracciano

Head of Molecular Pathology Unit Institute of Medical Genetics and Pathology, University Hospital Basel Luigi.Terracciano@usb.ch | +41 (0)61 328 78 49

#### PD Dr. Christian Ruiz

Head of Research Unit, Head of Laboratory Department Institute of Medical Genetics and Pathology, University Hospital Basel christian.ruiz@usb.ch| +41 (0)61 556 52 95

# Dr. Grégoire Rossier

Project Manager in Training
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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

# 8. Director of Studies / Program Coordinator

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

Director of Studies

# PD Dr. Sacha Rothschild

Senior Consultant in Oncology, Head of Center for lung tumors, Co-Chair of the Network Molecular Tumor Therapy
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Program Coordinator

#### Dr. Aitana Lebrand

Clinical Bioinformatics Project Manager
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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, Prof. Luigi Terracciano, Dr. Luca Quagliata, PD Dr. Christian Ruiz, internal/external lecturer(s).

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

Module 4: Clinical oncology, PD Dr. Andreas Wicki, PD Dr. Sacha Rothschild, 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

# Dr. Aitana Lebrand

Program coordinator
Clinical Bioinformatics Project Manager
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# 13. ATTACHMENTS

Online module exams

Homework

Written exam (CAS mini-thesis)



3B CURRICULUM

Certificate of Adva	Certificate of Advanced Studies (CAS) in Personalized Molecular Oncology	cular Oncology				
Modules	CONTENT - LECTURER	LEARNING OBJECTIVES	DURATION	CONTACT HOURS	Workload	ECTS
				(OPTIONAL)		
Module 1:	1) Basic cytogenetics and mo-	- Describe the mechanisms yielding to	8 weeks	28h	60h	2
and genetics	2) Heriditary vs acquired genet-	the various types of genetic variants				
	ics	- Distinguish hereditary genetic anoma-				
	3) Genetic recombination, DNA	lies from acquired genetic anomalies				
	damage and repair	- Discuss the advantages and limitations				
	4) Solid tumors and hematologi-	of different genetic laboratory method-				
	cal malignancies	ologies for diagnostic testing				
	5) Genetic predisposition to	- Demonstrate how to interpret non-				
	cancer	hotspot mutations using public data-				
	6) Diagnostic genetic testing	bases and taking into account overall				
	7) Tumor cell proliferation	genomic aberrations and clonal evolu-				
	8) Clonal evolution & tumor	tion.				
	heterogeneity	- Be aware of ethical implications of in-				
	9) Homework	cidental genetic findings				
	10) Online module exam					
	Module coordinator/teachers:					
Module 2:	1) Sample classification and	- Understand the basics (procedures and	8 weeks	28h	60h	2
Molecular	preparation - Terracciano /	rules) of an accredited clinical laborato-				
pathology	Quagliata	ΓY				
	2) Principles of nucleic acids	- Gain knowledge about the different				



Module 3: 1) Data Clinical 2) Read bioinformatics 3) Varia 4) Quali 5) Varia 6) Hard 7) Artifi sics 8) AI cu tions	extraction - R 3) Sequencing setup - Quagl 4) Understand Ruiz / Quaglia 5) Internal/Ex trols - Terracc 6) Laboratory Terracciano 7) Reporting g Quagliata 8) Interpretin file - Quagliat 9) Homework 10) Online mo Module coord Prof. Dr. Terra Dr Quagliata,
<ol> <li>Data pre-processing</li> <li>Read mapping</li> <li>Variant calling</li> <li>Quality control</li> <li>Variant annotation</li> <li>Hardware, security, privacy</li> <li>Artificial intelligence (AI) basics</li> <li>AI current and future applications</li> </ol>	extraction - Ruiz 3) Sequencing platforms and setup - Quagliata 4) Understanding gene panels - Ruiz / Quagliata 5) Internal/External Quality controls - Terracciano 6) Laboratory accreditation - Terracciano 7) Reporting genomic variants - Quagliata 8) Interpreting a molecular profile - Quagliata / Terracciano 9) Homework 10) Online module exam Module coordinators/teachers: Prof. Dr. Terracciano, Dr Quagliata, PD Dr Ruiz
- 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.	types of specimens (e.g. tissue biopsy, cytology, resections)  - 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
8 weeks	
28h	
60h	
2	



	10) Online module exam	cy issues when managing omics data.				
		- Understand how artificial intelligence				
	Module coordinators/teachers:	contributes to and will further impact				
	Dr Lebrand	personalized oncology.				
	Mrs Barbié					
	SIB Trainers					
Module 4:	1) Tumor Physiology – Key sig-	- Describe main intracellular signaling	8 weeks	28h	60h	2
Clinical	naling pathways and molecular	pathways in solid tumors and molecular				
oncology	aberrations in solid tumors	aberrations hampering this signaling				
	2) Tumor Immunology	- Get detailed knowledge of immunolog-				
	3) Cancer Statistics and Epide-	ical mechanisms and how these may be				
	miology	used to optimize therapeutic approach-				
	4) Prognostic and Predictive	es				
	Markers	- Get a basic understanding of the prin-				
	5) Targeted Therapies in Clinical	ciples underlying the design and analysis				
	Oncology	of clinical trials in oncology				
	6) Risks and probabilities for the	- Understand the importance of predic-				
	interpretation of genetic results	tive markers in molecular oncology				
	and genetic counseling - Discus-	- Get familiar with the most frequent				
	sion of example cases and prac-	molecular aberrations in solid tumors				
	tical exercises	and routinely used targeted therapies				
	7) Clinical Trials in Molecular	- Learn about genetic counseling and its				
	Oncology – How to improve ev-	implications for patients and families				
	idence					
	8) Molecular Tumor Board –					
	Discussion of clinical cases					
	9) Homework					
	10) Online module exam					



		Module coordinators/teachers: PD Dr Rothschild PD Dr Wicki	
32 WEEKS	TOTAL		
11	TOTAL		_
112н			_
2н 240н	TOTAL		•

ECTS=European Credit Transfer and Accumulation System

		Written exam (CAS mini-thesis)			ASSESSMENT FORMATS
8 WEEKS	TOTAL TOTAL	8 weeks			DURATION CONACT
9		0h	(OPTIONAL)	Hours	CONACT
60н	TOTAL	60h			WORKLOAD ECTS
	TOTAL	N			ECTS

Total			Certificate of Advanced Studies (CAS) in Personalized Molecular Oncology
40 WEEKS			DURATION CONTACT
112н	(OPTIONAL)	Hours	CONTACT
300н			WORKLOAD ECTS



# Homework

Homework will be done before and after each classroom event.

What – Homework will consist of, but is not limited to:

Reading of scientific articles; reading of professional guidelines; online tutorials; preparation of questions on a specific topic; viewing educational videos; identifying relevant literature. In total, preparation work should consist of ~20h/module.

When – Homework is performed before the start of the module, and/or in-between module sessions, and/or after the module.

How – Homework is performed by students on their free time and is due by a date fixed by the module coordinator.



#### Online module exams

After each module, proof of achievement is provided within 2-4 weeks in the form of a written online examination.

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 e.g. SIB-hosted Lime Survey 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 a unique token 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).



# Written exam (CAS mini-thesis)

Students write a written thesis at the end of their continuing education studies.

What – The Program Board proposes several study cases to the students. In addition, students may submit study cases proposals to the Program Board, before the end of the fourth module. All study cases must be endorsed by at least one member of 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 mini-thesis.

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 endorsing Program Board member 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).