Krukenberg Krebszentrum Halle

DKG KREBSGESELLSCHAFT Zertifiziertes Onkologisches Zentrum

Medizinische Fakultät der Martin-Luther-Universität Halle-Wittenberg

UKH Universitätsklinikum Halle (Saale)

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Federal Ministry of Education and Research

First Announcement

e:Med Summer School

24.-28.6.2019 in Halle (Saale)/Germany

CLONE – Clinical Trials in Oncology in the New Era of Omics, Big Data, and Modeling

(with kind permission acknowledging Shewangzaw Tamerat,

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Dear colleagues,

the wealth of innovative data emerging from cancer biology, bioinformatics, and epidemiology is revolutionizing our understanding of cancer. These advances have profound implications for the design and conduct of clinical trials in oncology with new ethical and legal challenges arising. The Summer School of the Krukenberg Cancer Center Halle (KKH) with its talks, round table discussions, workshops, and poster walks will bring physicians and researchers from various disciplines in Systems Medicine together to illuminate personalized medicine in oncology. The interdisciplinary programs needed for the analysis of vast amounts of data from multiple research platforms and how to translate these results into prognostic biomarkers and tailored clinical studies with targeted therapies will be discussed**.**

Ass. Professor Haifa Kathrin Al-Ali

Dr. Eva Johanna Kantelhardt

Date:	**24.06.2019-28.06.2019**
Location:	DORMERO Hotel Halle, Leipziger Straße 76, 06108 Halle (Saale), Germany
Language:	English
Costs:	travel, accommodation, and meals are covered by the Summer School
Organisation:	Krukenberg Cancer Center Halle; University Hospital Halle (Saale); Ernst-Grube-Straße 40; 06120 Halle (Saale); Germany
Contact:	E-mail: kkhalle@uk-halle.de; Telefon: +49 (0)345 557-7712
Participants:	Around 20 physicians and researchers from different disciplines of Systems Medicine from Germany and abroad will be competitively selected by a panel of experts based on a submitted abstract along with a curriculum vitae per mail to kkhalle@uk-halle.de
Submission timeline:	**01.02.19-20.03.2019**
	Application requirements are listed after the program.

Preliminary Program

Monday 24.6.		
13:00-14:00		Arrival of participants/lunch
	Format	**Title**
14:00-15:30		Welcome
		Introduction to the Summer School
	Discussion	Introduction of participants/ Expectations and personal view about Systems Medicine
	"Use-case"	Introduction to myeloid leukemias (acute and chronic) as 'Use case' accompanying the course
	"Use-case"	Introduction to pancreatic cancer as 'Use case' accompanying the course
15:30-16:00		Coffee break
16:00-18:15	Talk	The pathway from traditional to stratified cancer medicine
	Talk	What is personalized cancer medicine?
	Talk	Emerging developments in Omics
	Talk	Emerging developments in Big Data Analytics in the Life Sciences
	Round table	Why do we need Systems Medicine for clinical trials in oncology today?
		Summary of day one
19:00		**Evening programm and dinner**

Tuesday 25.06		Omics & Bioinformatics
Genomics		
	Talk	PCR-based and deep sequencing technologies
08:00-10:00		
	Talk	Analysis and integration of deep sequencing readouts to identify regulatory networks and establish genomic libraries in cancer
	"Use-case"	Translation of deep sequencing results into (pre)clinical studies and clinical applications in pancreatic cancer
	"Use-case"	Translation of deep sequencing results into (pre)clinical studies and clinical applications in myeloid leukemias
	Round table	Do we need tissue banking in clinical trials?
10:00-10:30		Coffee break
Epigenomics		
10:30:12:30	Talk	DNA methylation in cancer
	Talk	Chromatin modification in cancer
	Talk	RNA splicing in cancer
	"Use-case"	Translation of epigenetics into (pre)clinical studies and clinical applications in pancreatic cancer
	"Use-case"	Translation of epigenetics into (pre)clinical studies and clinical applications in myeloid leukemias
	Round table	The impact of genomics and epigenomics in clincal trials
12:30-13:15		Lunch
13:15-14:00		Refreshments & Posterwalk I
Proteomics		
14:00-15:00	Talk	Introduction to proteomics
	Talk	Proteomics, post-translational modifications in cancer
	"Use-case"	Translation of results into (pre)clinical studies and clinical applications in breast cancer
Bioinformatics		
15:00-15:45	Talk	Predicting the sequence specificities of DNA- and RNA-binding proteins by deep learning
	Discussion	Proteomics and bioinformatics in cancer
		Summary of day two
15:45-16:15		Departure to the Workshops
16:15-18:00		Workshop I: Molecular Pathology
		Workshop II: Proteomics
19:00		Cultural evening program & dinner

Wednesday 26.06		Big Data
Bioinformatics		
08:00-10:00	Talk	Watchdog – a workflow management system to analyse large-scale experimental data
	Talk	Artificial neural network
	Talk	Smart Medical Information Technology for Healthcare (SMITH)
	Round table	Physicians versus computational biology !
10:00-10:30		Coffee break
Modeling and Simulation (M&S)		
10:30-12:30	Talk	Introduction to M&S
	Talk	The traditional RECIST-based approach in clinical oncology
	Talk	Statistical modeling and image analysis in cancer
	Talk	Could liquid biopsy data be used for modeling in cancer?
	Round table	Physicians versus computational modeling !
12:30-13:15		Lunch
13:15-14:00		Refreshments & Posterwalk II
Real world Data & more		
14:00-16:00	Talk & "Use-case"	Could data from registries be translated into clinical applications and trials
	Talk	Could registries be used to create models for cancer management?
	Talk	What is the benefit of a meta-analysis?
	Round table	Advances in the management of cancer: Do they come from real world data or clinical trials?
16:00-16:30		Coffee break
Real world data & clinical applications		
16:30-18:15	Talk	Status and impact of cancer registries globally
	"Use-case"	Translations of results of registries for breast cancer into clinical applications and trials
	Round table	The future of oncology: computational biology, real world data, or clinical trials?
		Summary of day three
19:00		Dinner

Thursday 27.06		Clinical trials in the era of „big data“
Planing and designing a clinical trial		
08:00-10:00	Talk	How to translate an idea into a clinical trial
	Talk	Phases of clinical trials
	Talk	Project design considerations: biometry, statistics and more
	Talk	The impact of omics and "big data" on the design of clinical trials in cancer
	Round table	Pitfalls when designing clinical trials
10:00-10:30		Coffee break
Preparing a clinical trial		
10:30-12:30	Talk	Why do we need a coordinating center for clinical trials?
	Talk	Sponsoring and funding of a clinical trial
	Talk	Regulatory requirements of a scientific project / clinical trial: ICH-GCP and Clinical Trials European Directive
	Talk	How informed are our patients? Do biomarkers help idenify the right trial population?
12:30-13:15		Lunch
13:15-14:00		Refreshments and Posterwalk III
Science & regulations		
14:00-15:25	Talk	EMA and FDA filing of clinical trials
	"Use-case"	Planing and conducting an investigator initiated trial in acute myeloid leukemia
	Round table	Planing a study in reality: How difficult is an investigator initiated trial (IIT)?
		Summary of day four
15:25-16:00		Departure to the Workshops
16:00-18:00		Workshop I: Epidemiology - NAKO
		Workshop II: clinical trials
19:00		Cultural evening program & dinner

Friday 28.06.2019		Engaging, protecting, and communicating with patients
	Format	**Title**
Ethical & legal considerations		
08:00-10:00	Talk	Ethical requirements of a clincal trial
	Talk	Legal concerns in the era of big data
	Talk	The informed consent: What must be considered?
	Round table	Ethical and legal challenges in oncology today
10:00-10:30		Coffee break
Patients' perspectives		
10:30-12:40	Talk	Symptom management and patient-reported outcome in clinical trials
	Talk	Clinical trials in the genomic era from a patient`s perspective
	Round table	Where is the patient in systeme medicine in oncology today?
	Discussion	Personal view of the participants about Systems Medicine at the end of the summer school
		Summary of the results of the summer school
12:40		Lunch & farewell

Application Requirements

Submission timeline: **01.02.19-20.03.2019**

A) **Abstract (background, methods, results, and conclusions) 2,000 characters**

- All types of **oncology-related research** (not older than two years) are eligible for submission. Abstracts should address scientific questions, clinical observations, or contain primary scientific data in one of the following areas:
  - Omics (genomics, epigenomics, proteomics)
  - Bioinformatics and big data analytics
  - Epidemiology and registries
  - Themes related to clinical trials such as results, biometry, informatics, statistics, regulation, funding..etc.
  - Ethical and legal considerations in oncology research
  - Themes related to patient reported outcomes and patients' perspectives
- The abstract should not exceed 2,000 characters for the title and body including section titles, and tables. The character count does not include spaces or author name, address, institutions, disclosures, and funding information. A maximum of one illustration, one data table, and/or two figures are permitted.

B) Cover page

- Full name, academic degree(s), institution, address, and email address should be provided.
- The information provided upon submission must belong to the applicant.
- Disclosure information for all authors & funding source (if present) at the end of the abstract are required.

C) Curriculum vitae (CV)

The CV should contain information to:

- available publications with impact factors (those related to oncology should be bold)
- experience in the conduct and design of research projects
- experience in the conduct and design of clinical trials
- available national and international co-operations
- active participation (oral presentation/poster) in national and international meetings
- research grants and experience in funding

The language of the abstract and CV is English.

Abstract & CV should be submitted per email to kkhalle@uk-halle.de. Each applicant will receive a letter of notification via email from the organisor regarding the application by 30 April, 2019.