

ANNOUNCEMENT

SUMMER SCHOOL

24.-28.06.2019 in Halle (Saale)/Germany

e:Med Summer School:

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

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.

Haifa Kathrin Al-Ali

Eva Johanna Kantelhardt



with kind permission acknowledging
Shewangzaw Tamerat, Makush Galery Ethiopia

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Organisation

- ✓ **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
- ✓ **ORGANIZATION:** Krukenberg Cancer Center Halle; University Hospital Halle (Saale); Ernst-Grube-Straße 40; 06120 Halle (Saale); Germany

www.medizin.uni-halle.de/krukenberg-krebszentrum
- ✓ **CONTACT:** email: 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.

Program

Monday 24.06.2019				
	Duration	Format	Title	Speaker
13:00-14:00	Arrival of participants/lunch			
Chair: H. K. Al-Ali / E. Kantelhardt				
14:00-15:30	10		Welcome	H.K. Al-Ali/ E. Kantelhardt
	10		Introduction to the Summer School	E. Kantelhardt
	40	Discussion	Introduction of participants/ Expectations and personal view about Systems Medicine	All
	15	Talk	The pathway from traditional to stratified cancer medicine	H.K. Al-Ali
	15	"Use-case"	Introduction to myeloid leukemia as 'Use case' accompanying the course	H.K. Al-Ali
15:30-16:00	30		Coffee break	
Chair: P. Michl/ C. Wickenhauser				
16:00-18:15	20	Talk	What is personalized cancer medicine?	P. Michl
	20	"Use-case"	Introduction to pancreatic cancer as 'Use case' accompanying the course	P. Michl,
	20	Talk	Emerging developments in Omics	C. Wickenhauser
	20	Talk	Emerging developments in Big Data Analytics in the Life Sciences	I. Grosse
	40	Round table	Why do we need Systems Medicine for clinical trials in oncology today?	All
	15		Summary of day one	E. Kantelhardt
19:00	City Tour (discover the highlights of Halle (Saale), the more than 1.200 -years-old Handel City, conveniently by foot; 1 hour) and dinner (Osteria da Salvatore)			

Program

Tuesday 25.06.2019		Omics and Bioinformatics		
	Duration	Format	Title	Speaker
Genomics		Chair: C. Wickenhauser/ S. Feller		
08:00-10:00	30	Talk	"PCR-based and deep sequencing technologies"	U. Siebolts
	30	Talk	Analysis and integration of deep sequencing readouts (ex. healthy vs.disease, treated vs. untreated) to identify regulatory networks and establish genomic libraries in cancer	F. Heidel
	20	"Use-case"	Translation of deep sequencing results into (pre)clinical studies and clinical applications in pancreatic cancer	P. Michl
	20	"Use-case"	Translation of deep sequencing results into (pre)clinical studies and clinical applications in myeloid leukemias	H. K. Al-Ali
	20	Round table	Do we need tissue banking in clinical trials?	All
10:00-10:30	Coffee break			
Epigenomic		Chair: J-H. Klusmann/ M. Cross		
10:30:12:30	25	Talk	DNA methylation in cancer	M. Cross
	25	Talk	Epigenetic modification in chromatin machinery and its deregulation in cancer	C. Lobry
	25	Talk	RNA splicing in cancer	J-H. Klusmann
	15	"Use-case"	Translation of epigenetics into (pre)clinical studies and clinical applications in pancreatic cancer	P. Michl
	15	"Use-case"	Translation of epigenetics into (pre)clinical studies and clinical applications in myeloid leukemias	M. Cross
	15	Round table	The impact of genomics and epigenomics in clinical trials	All
12:30-13:15	Lunch			

Program

Tuesday 25.06.2019		Omics and Bioinformatics		
	Duration	Format	Title	Speaker
13:15-14:00	Refreshments and Posterwalk I			
Proteomics		Chair: M. Fuszard/ C. Thomssen		
14:00-15:00	15	Talk	Introduction to proteomics	M. Fuszard
	30	Talk	The role of proteomics in cancer	M Herling
	15	"Use-case"	Translation of results into (pre)clinical studies and clinical applications in breast cancer	C. Thomssen
Bioinformatics				
15:00-15:45	30	Talk	Predicting the sequence specificities of DNA- and RNA-binding proteins by deep learning	Matthew T. Weirauch
	10	Discussion	Proteomics and bioinformatics in cancer	All
	5		Summary of day two	Kandelhardt
15:45-16:15	Departure to the Workshops			
16:15-18:00	Workshop I: Molecular Pathology			Institute of Pathology
	Workshop II: Proteomics			Charles Tanford Protein Center
19:00	Guided tour through the famous Meckel anatomical collection; 1,5 hours and dinner (Lözius)			

Program

Wednesday 26.06.2019		Big Data		
	Duration	Format	Title	Speaker
Bioinformatics		Chair: R. Mikolajczyk/F. Klawonn		
08:00-10:00	30	Talk	Watchdog – a workflow management system to analyse large-scale experimental data	R. Zimmer
	30	Talk	Artificial neural network	F. Klawonn
	30	Talk	Medical Informatics Initiative: Challenges and Opportunities	R. Mikolajczyk
	30	Round table	Physicians versus computational biology !	All
	20	Round table	Do we need tissue banking in clinical trials?	All
10:00-10:30	Coffee break			
Modeling and Simulation (M&S)		Chair: R. Mikolajczyk/H. Gufler		
10:30-12:30	25	Talk	Modelling cancer at population level	R. Mikolajczyk
	25	Talk	The traditional RECIST-based approach in clinical oncology	H. Gufler
	25	Talk	Statistical modeling and image analysis in cancer	T. Bocklitz
	25	Talk	Could liquid biopsy data be used for modeling in cancer?	M. Binder
	20	Round table	Physicians versus computational modeling!	All
	15	Round table	The impact of genomics and epigenomics in clinical trials	All
12:30-13:15	Lunch			

Program

Wednesday 26.06.2019		Big Data		
	Duration	Format	Title	Speaker
13:15-14:00	Refreshments and Posterwalk II			
Real world Data and more		Chair: S. Saussele/ Pfirrmann		
14:00-16:00	30	Talk & "Use-case"	Could data from registries be translated into clinical applications and trials	S. Saussele
	30	Talk	Could registries be used to create models for cancer management?	M. Pfirrmann
	30	Talk	What is the benefit of a meta-analysis?	A. Wienke
	30	Round table	Advances in the management of cancer: Do they come from real world data or clinical trials?	All
16:00-16:30	Coffee break			
Real world data & clinical applications		Chair: E. Kantelhardt/ H. K. Al-Ali		
16:30-18:15	30	"Use-case"	Status and impact of cancer registries globally	E. Kantelhardt
	30	"Use-case"	Translations of results of registries for breast cancer into clinical applications and trials	E. Kantelhardt
	30	Round table	The future of oncology: computational biology, computational modeling, real world data, or clinical trials?	All
	15		Summary of day three	H. K. Al-Ali
19:00	Dinner (Taparazzi Restaurant)			

Program

Thursday 27.06.2019		Clinical trials in the era of „big data“		
	Duration	Format	Title	Speaker
Planing and designing a clinical trial		Chair: C. Roellig/ D. Hasenclever		
08:00-10:00	25	Talk	How to translate an idea into a clinical trial	C. Roellig
	15	Talk	Phases of clinical trials	H. K. Al-Ali
	35	Talk	Project design considerations: biometry, statistics and more	D. Hasenclever
	30	Talk	The impact of omics and "big data" on the design of clinical trials in cancer	C. Junghanss
	15	Round table	Pitfalls when designing clinical trials	All
10:00-10:30	Coffee break			
Preparing a clinical trial		Chair: J Steighardt/ P. Kelly		
10:30-12:30	30	Talk	Why do we need a coordinating center for clinical trials?	J. Steighardt
	30	Talk	Sponsoring and funding of a clinical trial	P. Kelly
	30	Talk	Regulatory requirements of a scientific project / clinical trial: ICH-GCP and Clinical Trials European Directive	M. Richter
	30	Talk	How informed are our patients? Do biomarkers help identify the right trial population?	B. Leplow
	20	Round table	Physicians versus computational modeling!	All
	15	Round table	The impact of genomics and epigenomics in clinical trials	All
12:30-13:15	Lunch			

Program

Thursday 27.06.2019		Clinical trials in the era of „big data“		
	Duration	Format	Title	Speaker
13:15-14:00	Refreshments and Posterwalk III			
Science versus regulations		Chair: D. Niederwieser/ P. Kelly		
14:00-15:25	25	Talk	EMA and FDA filing of clinical trials	P. Kelly
	25	"Use-case"	Planing and conducting an investigator initiated trial in acute myeloid leukemia	H. K. Al-Ali
	20	Round table	Planing a study in reality: How difficult is an investigator initiated trial (IIT)?	All
	15		Summary of day four	E. Kantelhardt
15:25-16:00	Departure to the Workshops			
16:00-18:00			Workshop I: Epidemiology - NAKO	Institute of Medical Epidemiology, Biometry and Informatic
			Workshop II: clinical trials	Coordination Center for Clinical Studies/Trials
19:00	Education and its Significance for the World -Visit the Franckeschen Stiftungen (Discover one of the most important educational institutions of the 18th and 19th century in Europe and the remarkable life and work of August Hermann Francke; 2 hours) and dinner (Pizza & Pasta- San Marco)			

Program

Friday 28.06.2019		Engaging, protecting, and communicating with patients		
	Duration	Format	Title	Speaker
Ethical & legal considerations		Chair: J. Schildmann/ T. Faltus		
08:00-10:00	30	Talk	Ethical requirements of a clinical trial	J. Schildmann
	30	Talk	Legal concerns in the era of big data	T. Faltus (tbc)
	30	Talk	The informed consent: What must be considered?	J. Schildmann
	30	Round table	Ethical and legal challenges in oncology today	All
	15	Round table	Pitfalls when designing clinical trials	All
10:00-10:30	Coffee break			
Patients' perspectives		Chair: Koffmann/ P. Jahn		
10:30-12:40	25	Talk	Symptom management and patient-reported outcome in clinical trials	P. Jahn
	25	Talk	Clinical trials in the genomic era from a patient's perspective	B. Koffman
	25	Round table	Where is the patient in systems medicine in oncology today?	All
	40	Discussion	Personal view of the participants about Systems Medicine at the end of the summer school	All
	15		Summary of the results of the summer school	H. K. Al-Ali
12:40	Lunch and farewell			

Application Requirements

SUBMISSION TIMELINE: 01.02.19-20.03.2019



A) ABSTRACT

- 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' perspective
- Full name, academic degree(s), institution, address, and email address should be provided in the abstract.
- 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.
- The body of the abstract should describe the background, methods, results, and conclusions.
- 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.

Application Requirements

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B) CURRICULUM VITAE (CV)

- The CV should contain information to:
 - 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 meet-ings
 - research grants and experience in funding

The language of the abstract & 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 organizer regarding the application by 30 April, 2019.

Reviewers

Cross, Michael	Universitätsklinikum Leipzig, Leipzig, Germany
Feller, Stephan Michael	Martin-Luther-Universität Halle-Wittenberg, Halle (Saale), Germany
Mueller, Lutz	Universitätsklinikum Halle, Halle (Saale), Germany
Niederwieser, Dietger	Universität Leipzig, Leipzig, Germany
Roellig, Christoph	Universitätsklinikum der Technischen Universität Dresden, Dresden, Germany
Saußeke, Susanne	Universitätsmedizin Mannheim, Mannheim, Germany
Schmoll, Hans-Joachim	Martin-Luther-Universität Halle-Wittenberg, Halle (Saale), Germany
Sunderkoetter, Cord	Universitätsklinikum Halle, Halle (Saale), Germany
Wienke, Andreas	Martin-Luther-Universität Halle-Wittenberg, Halle (Saale), Germany
Witzel, Isabell	Universitätsklinikum Hamburg-Eppendorf, Hamburg, Germany

Speakers and Session Chairs

Al-Ali, Haifa Kathrin	Krukenberg Cancer Center	Universitätsklinikum Halle, Halle (Saale), Germany
Binder, Mascha	University Clinic and Polyclinic of Internal Medicine IV	Universitätsklinikum Halle, Halle (Saale), Germany
Bocklitz, Thomas	Institute of Physical Chemistry	Jena Universität, Jena, Germany
Cross, Michael	Medical Clinic and Polyclinic I	Universitätsklinikum Leipzig, Leipzig, Germany
Faltus, Timo	Faculty of Law, Economics and Business	Martin-Luther-Universität Halle-Wittenberg, Halle (Saale), Germany
Feller, Stephan Michael	Institute of Molecular Medicine	Martin-Luther-Universität Halle-Wittenberg, Halle (Saale), Germany
Fuszard, Matt	Core Facility — Proteomic Mass Spectrometry	Martin-Luther-Universität Halle-Wittenberg, Halle (Saale), Germany
Grosse, Ivo	Institute of Informatic	Martin-Luther-Universität Halle-Wittenberg, Halle (Saale), Germany
Gufler, Hubert	Department of Radiology	Universitätsklinikum Halle, Halle (Saale), Germany
Hasenclever, Dirk	Institute for Medical Informatics, Statistics and Epidemiology	Universität Leipzig, Leipzig, Germany
Heidel, Florian	Department of Hematology and Internal Oncology	Universitätsklinikum Jena, Jena, Germany
Herling, Marco	Dept. of Medicine I, CECAD and CMMC	Universität zu Köln, Cologne, Germany
Jahn, Patrick	Health and Nursing Science	Universitätsklinikum Halle, Halle (Saale), Germany
Junghanss, Christian	Medical Clinic III	Universität Rostock, Rostock, Germany
Kantelhardt, Eva	Institute of Medical Epidemiology, Biometry and Informatic	Martin-Luther-Universität Halle-Wittenberg, Halle (Saale), Germany
Kelly, Patrick		Forma Therapeutics, Inc., Watertown, USA
Klawonn, Frank	Bioinformatics and Statistics	Helmholtz Centre for Infection Research, Braunschweig, Germany
Klusmann, Jan-Henning	University Clinic and Polyclinic of Pediatrics I	Universitätsklinikum Halle, Halle (Saale), Germany
Koffman, Brian		CLL Society Inc.; Claremont, USA
Leplow, Bernd	Institute of Psychology	Martin-Luther-Universität Halle-Wittenberg, Halle (Saale), Germany
Lobry, Camille	INSERM U1170	Institute Gustave Roussy, Villejuif Cedex, France
Michl, Patrick	University Clinic and Polyclinic of Internal Medicine I	Universitätsklinikum Halle, Halle (Saale), Germany
Mikolajczyk, Rafael	Institute of Medical Epidemiology, Biometry and Informatic	Martin-Luther-Universität Halle-Wittenberg, Halle (Saale), Germany
Niederwieser, Dietger		Universität Leipzig, Leipzig, Germany
Pfirmsmann, Markus	Institute for Medical Information Processing, Biometry, Epidemiology	Ludwig-Maximilians-Universität München; Munich, Germany
Richter, Michael	Coordination Center for Clinical Studies/Trials	Martin-Luther-Universität Halle-Wittenberg, Halle (Saale), Germany
Roellig, Christoph	Medical Clinic and Polyclinic I	Universitätsklinikum der Technischen Universität Dresden, Dresden, Germany
Saußele, Susanne	III. Medical Clinic	Universitätsmedizin Mannheim, Mannheim, Germany
Schildmann, Jan	Institute of History and Ethics of Medicine	Martin-Luther-Universität Halle-Wittenberg, Halle (Saale), Germany
Siebolts, Udo	Institute of Pathology	Universitätsklinikum Halle, Halle (Saale), Germany
Steighardt, Joerg	Coordination Center for Clinical Studies/Trials	Martin-Luther-Universität Halle-Wittenberg, Halle (Saale), Germany
Thomssen, Christoph	University Clinic and Polyclinic of Gynecology	Universitätsklinikum Halle, Halle (Saale), Germany
Weirauch, Mathew	The Center for Autoimmune Genomics and Etiology (CAGE)	Cincinnati Children's, Cincinnati, USA
Wickenhauser, Claudia	Institute of Pathology	Universitätsklinikum Halle, Halle (Saale), Germany
Wienke, Andreas	Institute of Medical Epidemiology, Biometry and Informatic	Martin-Luther-Universität Halle-Wittenberg, Halle (Saale), Germany
Zimmer, Ralf	Institute of Informatic	Ludwig-Maximilians-Universität München; Munich, Germany