





GEFÖRDERT VOM





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,

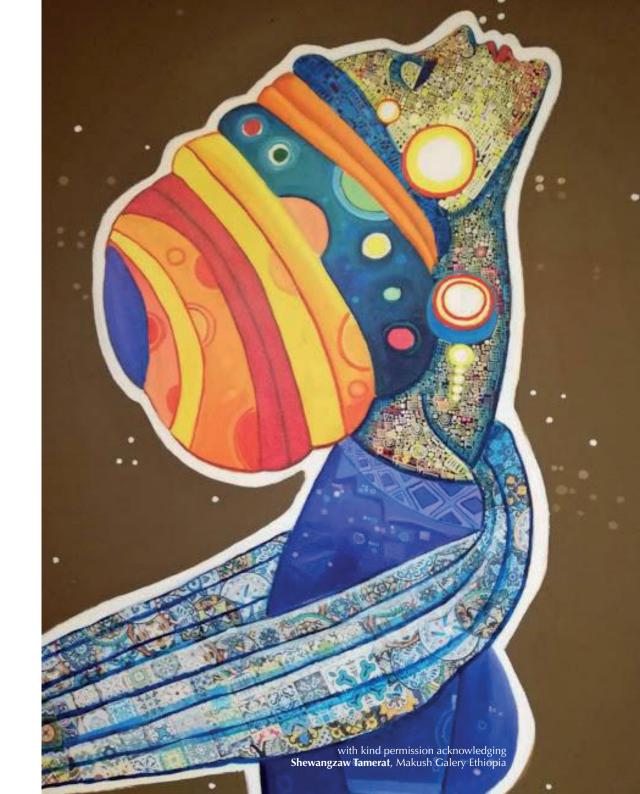
the wealth of innovative data emerging from cancer biology, bioinformatics, and epidemiology is revolutionizing our understanding of cancer. These advances have profound implications for the design and conduct of clinical trials in oncology with new ethical and legal challenges arising.

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



Contents

\odot	ORGANISATION	Page 4
\odot	PROGRAM	Page 5
\odot	APPLICATION REQUIREMENTS	Page 13
\bigcirc	REVIEWERS	Page 15
\bigcirc	SPEAKERS AND CHAIRS	Page 16

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.

Monday 24.06.2	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 t	he highlights of Halle (Saale), the more than 1.200 -years-old Handel City, conveniently b and dinner (Wenzel Prager Bierstuben Halle)	y foot; 1 hour)			

Tuesday 25.06.2	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 clincal trials	All	
12:30-13:15			Lunch		

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)					

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 S	imulation (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 clincal trials	All
12:30-13:15			Lunch	

Wednesday 26.0	06.2019		Big Data		
	Duration	Format	Title	Speaker	
13:15-14:00			Refreshments and Posterwalk II		
Real world Data	a 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 ap	plications	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)				

Thursday 27.06	Thursday 27.06.2019 Clinical trials in the era of "big data"				
	Duration	Format	Title	Speaker	
Planing and des	igning a clini	ical trial	Chair: C. Röllig/ D. Hasenclever		
08:00-10:00	25	Talk	How to translate an idea into a clinical trial	C. Röllig	
	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 clin	ical 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 idenify the right trial population?	B. Leplow	
	20	Round table	Physicians versus computational modeling!	All	
	15	Round table	The impact of genomics and epigenomics in clincal trials	All	
12:30-13:15			Lunch		

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 r	egulations		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 Medi- cal 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)				

Friday 28.06.20	19		Engaging, protecting, and communicating with patients		
	Duration	Format	Title	Speaker	
Ethical & legal o	consideration	S	Chair: J. Schildmann/ T. Faltus		
08:00-10:00	30	Talk	Ethical requirements of a clincal 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' perspec	ctives		Chair: B. Koffman/ 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 systeme 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

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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.

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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

Röllig, Christoph Universitätsklinikum der Technischen Universität Dresden, Dresden, Germany

Saußele, Susanne Universitätsmedizin Mannheim, Mannheim, Germany

Schmoll, Hans-Joachim Martin-Luther-Universität Halle-Wittenberg, Halle (Saale), Germany

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Witzel, Isabell Universitätsklinikum Hamburg-Eppendorf, Hamburg, Germany

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Al-Ali, Haifa Kathrin Krukenberg Cancer Center

Binder, Mascha University Clinic and Polyclinic of Internal Medicine IV

Bocklitz, Thomas Institute of Physical Chemistry Cross, Michael Medical Clinic and Polyclinic I

Faltus, Timo Faculty of Law, Economics and Business

Feller, Stephan Michael Institute of Molecular Medicine

Fuszard, Matt Core Facility — Proteomic Mass Spectrometry

Grosse, Ivo Institute of Informatic
Gufler, Hubert Department of Radiolgy

Hasenclever, Dirk Institute for Medical Informatics, Statistics and Epidemiology

Heidel, Florian Department of Hematology and Internal Oncology

Herling, Marco Dept. of Medicine I, CECAD and CMMC

Jahn, Patrick Health and Nursing Sience

Junghanss, Christian Medical Clinic III

Kantelhardt, Eva Institute of Medical Epidemiology, Biometry and Informatic

Kelly, Patrick

Klawonn, Frank Bioinformatics and Statistics

Klusmann, Jan-Henning University Clinic and Polyclinic of Pediatrics I

Koffman, Brian

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Pfirrmann, Markus Institute for Medical Information Processing, Biometry, Epidemiology

Richter, Michael Coordination Center for Clinical Studies/Trials

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Saußele, Susanne III. Medical Clinic

Schildmann, Jan Institute of History and Ethics of Medicine

Siebolts, Udo Institute of Pathology

Steighardt, Joerg Coordination Center for Clinical Studies/Trials Thomssen, Christoph University Clinic and Polyclinic of Gynecology

Weirauch, Mathew The Center for Autoimmune Genomics and Etiology (CAGE)

Wickenhauser, Claudia Institute of Pathology

Wienke, Andreas Institute of Medical Epidemiology, Biometry and Informatic

Zimmer, Ralf Institute of Informatic

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