CLINICAL TRIALS

1st Clinical Trial Conference

March 25-27, 2022

University Health Sciences Lahore

Prof. Javed Akram
Vice Chancellor, UHS
Chairman Conference Organizing Committee
President PSIM

Prof. Masood Sadiq
Vice Chancellor
University of Child Health Sciences, Lahore
Chairman Scientific Committee

Maj. Gen. Prof. Dr. Aamer Ikram
Principal Investigator CS-CTP-AD5NCOV-III
Executive Director,
National Institutes of Health, Islamabad
Keynote Speaker

Mr. Asim Rauf
Chief Executive Officer
Drug Regulatory Authority
Guest of Honor

Dr. Shehnoor Azhar
Secretary Conference Organizing Committee

Clinical trials explore whether a medical strategy, treatment, or device is safe and effective for humans. These studies also may show which medical approaches work best for certain illnesses or groups of people. They have historically represented the most authentic means of discovering of treatments against various diseases. Whether dietary interventions of mediaeval times aiming at longevity or accidental discovery of Penicillin in laboratory, the race to explore effective treatments has endured through centuries and millennia. Modern day clinical trial represents a multidisciplinary endeavor known for its quality standards and reproducibility in a variety of settings. While it resolved several longstanding ethical and methodological issues, many more keep propping up.

Academic institutions identify issues through education and research. University of Health Sciences Lahore is amouang the leading medical institutions that strives for solutions to local health problems. Since its inception, the university envisioned to train world class professionals capable to apply biopsychosocial perspectives towards patient care. Its expertise in conducting quality research is now well-known whether for the laboratory infrastructure or randomized clinical trials. From March 25 -27, 2022, 1st Clinical Trial Conference is being organized at the UHS City Campus. In line with the theme "Clinical trials – the way forward", the event gathers research partners to deliver and attend a series of workshops and interactive sessions. The organizers welcome all aspiring participants and hope to make this event promote continuous professional efforts to discover newer and better treatments in local setting.

Professor Khalid Saeed Khan

Professor Khalid Khan is Distinguished Investigator (Beatriz Galindo programme) at the University of Granada, Spain. With an h-index>70 he has published over 400 peer-reviewed papers and supervised 25 higher-degree theses. Professor Khalid Khan has contributed to many trials and meta-analyses. He is the lead author of 'Systematic Reviews to Support Evidence-Based Medicine', which won a BMA Medical Book award.

Transparency in Clinical Trials

Behind every medicine and intervention, there are thousands of patients who have volunteered to participate in clinical trials, which have led to many breakthroughs in disease prevention and treatment in the last few decades. Without the willingness of these individuals, many would have suffered. The current pandemic has itself seen how clinical trials have informed healthcare decision-making and public policies. In midst of the extraordinary focus on research COVID-19 over 2 years, there have been over 200 retracted papers. Of these, 6 have been randomized clinical trials, a high-validity study design which, according to the rules of evidence-based medicine, would have provided the most reliable evidence to inform practice. It is likely that not all retractions are the result of deliberate fraud and fabrication. Unintentional errors and faults in technique are bound to have played their part. The value of clinical trials depends fundamentally on the quality of information produced and the relevance of the data to address public health needs. There are many aspects of clinical trials starting from the ethical review and approval process as well as conducting trials such as data monitoring and patient safety. However, it all begins with prospective registration to declare publicly what is planned. There is a great demand for public documentation of all aspects throughout the lifecycle of a clinical trial. Education and training in prospective registration of clinical trials is an essential requirement.

Professor Sidrah Saleem

Professor / Head of Department
University of Health Sciences, Lahore
MBBS, M.Phil., PhD (Microbiology)

Professor Sidrah Saleem is a clinical microbiologist and contributed to Phase III COVID-19 vaccine trials at UHS. She remains interested in laboratory standards to complement high-impact clinical research.

Preparing laboratories as per GCP

Laboratories play a major role in biopharmaceutical innovations by providing a high-quality pre-clinical data. It requires both scientific equipment and expertise. Then the scope of work is further expanded during each of the phase of the clinical trial where protocols may necessitate collection, processing, storage, and transport of various biological samples and specimen. Therefore, laboratory staff must be well-trained and certified before clinical research begins. World Health Organization and Center for Disease Control (USA) issue guidelines in this regard, that could be applied in any context. It all comes to the updated Standard Operating Procedures of a lab that ultimately determine the success of clinical research in search of a new cure for a disease.

Dr. Masud ur Rehman

Dr. Masudur Rehman is a senior pharmacist having a PhD Degree in pharmacology. He has a professional experience of 32 years, of Hospital Pharmacy, Hospital Management, Drug Regulation and Health Management. He wielded positions of Hospital Pharmacists, Deputy Drug Controller, Assistant Chief (Planning Commission), Deputy Director General E&M (Drug Control Organization), Additional Director, Chairman Central Licensing Board, Drug Regulatory Authority of Pakistan. He currently holds portfolio of Director, Pharmacy Services and Chairman, Clinical Studies Committee.

Future prospects of clinical trials

Clinical trials are designed to evaluate new interventions for diagnosis, treatment and prevention. Randomized clinical trials are vital for determining of efficacy of an intervention. It's worth in global economy is over 70 billion US $ annually. Share of Pakistan is in few millions, which can be enhanced substantially. Several factors are already in favor such as potential to scale-up recruitment, genetic buildup, availability of infrastructure, and trained healthcare workforce.The local regulatory environment is also comparatively swift in the region that is known for being cost effective. All these strengths should attract the international trials to Pakistan. It's a good time to harness this opportunity for patient welfare through promoting high-quality clinical research in this country.

Dr. Ume Sughra

MBBS, MPH, FCPS, FRCP (Glasg), MRCP-HPE
Associate Professor of Public Health &
of Al-Shifa Clinical Trial Site
Principal Investigator for Phase III Clinical Trial ZF2001

She has teaching and mentoring experiences of more than 15 years and contributed to several researches. She is currently running a Phase III clinical trial of a COVID-19 Vaccine candidate at her institution.

COVID-19 Vaccination Trials in Pakistan:

Lessons learned in multicenter and multicultural settings

COVID-19 Vaccine Trials: Lessons learned in multi-center & multi-cultural settings

Research response during pandemics and emergencies required very careful contextualizing to collect high-quality data while protecting not just the study validity but also the well-being of researchers involved. It necessitates devising ethical as well as methodological solutions to develop timely evidence that informs clinical as well as public health scenarios.

While each of the phases of clinical trial represents a unique challenge, COVID-19 compelled running each of the phases, often running in parallel, under unique settings. Dealing with various unforeseen challenges requires teamwork not just within but also beyond the recruiting site. Nevertheless, it is encouraging to witness new clinical sites and teams that contributed in local testing of various vaccine candidates and once expects it to continue for other compounds so that evidence-based products are available locally. Finally, it provides an opportunity to discuss international research linkages and how teamwork varies with affiliations across sectors (public and private, local and foreign).

Dr. Sumayya Azam

Dr. Sumeyya Azam is a Gynecologic Surgeon and Clinical Research Specialist working as a Clinical Study Consultant (Medical Scientist) In CanSino Biologics Inc., China. She has served as an off-site supervisor of various research courses of NIH, USA. She has been awarded with "Certified Sentinel of Science Award Recipient" by Publons, recognized as one of the world's top 10% of researchers contributing to peer-review of the field of Medicine

Monitoring and Audits of Study Sites

Inspection and audits, intended to determine compliance and identify opportunities for improvement are quality assurance (QA) systems (planned and systematic) as part of quality management systems. The purpose of audit and inspection is to verify compliance with applicable regulations, protocol, Standard Operating Procedures and principles of Good Clinical Practices. The topic addresses preparation of research staff (Sponsors, Contract Research Organizations, and sites) for either inspection by regulatory authority or audit by sponsors/systematic or independent audit function. The topic further addresses documented ethical aspects from historic HIV/AIDS clinical studies.

Different perspectives of local CROs and expert advice

1. Ensuring Global Standards (DRK Pharma Solutions)
2. Analysing the status Quo (Metrics Research)
3. Preparing an Ideal Research Site (Dimensions Research)
4. Quality Assurance in Clinical Research (Mr. Asim Rana, UHS Adjunct Faculty)

Programme

Day	Date	Facilitators	Topic	Time
1	25-03-2022 Friday	Prof. Khalid Saeed Khan (University of Granada)	Transparency in clinical trials	10:00 to 12:30
		Prof. Sidrah Saleem (University of Health Sciences Lahore)	Preparing laboratories as per GCP	14:30 to 16:30
		Conference dinner		19:00
		Dr. Masud ur Rehman (Drug Regulatory Authority)	Future prospects of clinical Trials	9:30 to 11:00
2	26-03-2022 Saturday	Mr. Asim Munir (DRK Pharma Solutions) Mr. Murtaza Hussain (Metrics Research) Mr. Khurram Zaki (Dimensions Research) Mr. Asim Rana (UHS Adjunct Faculty)	Different perspectives of local CROs and expert advice	11:30 to 13:00
		Lunch		13:00 to 14:00
		Conference Opening	Welcome note by VC UHS	14:15 to 15:30
			Prof. Khalid Saeed Khan (Distinguished speaker)	
			Prof. Aamer Ikram (Keynote address)	
			Remarks from guest of honor & chief guest	
			Presentation of UHS momentos to guests	
3	27-03-2022 Sunday	Dr. Ume Sughra (Al-Shifa School of Public Health Rawalpindi)	COVID-19 Vaccine Trials: Lessons learned in multi-center & multi-cultural settings	10:30 to 12:30
		Dr. Sumayya Azam (CanSino BIO)	Monitoring & audits of study sites	10:30 to 12:30
		On behalf of organizing committee	Vote of thanks	12:30 to 12:45
		Lunch		13:00 to 14:00

Online Registration at
www.uhs.edu.pk

Now Open

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