

ANNUAL REPORT

2023



2022
2023

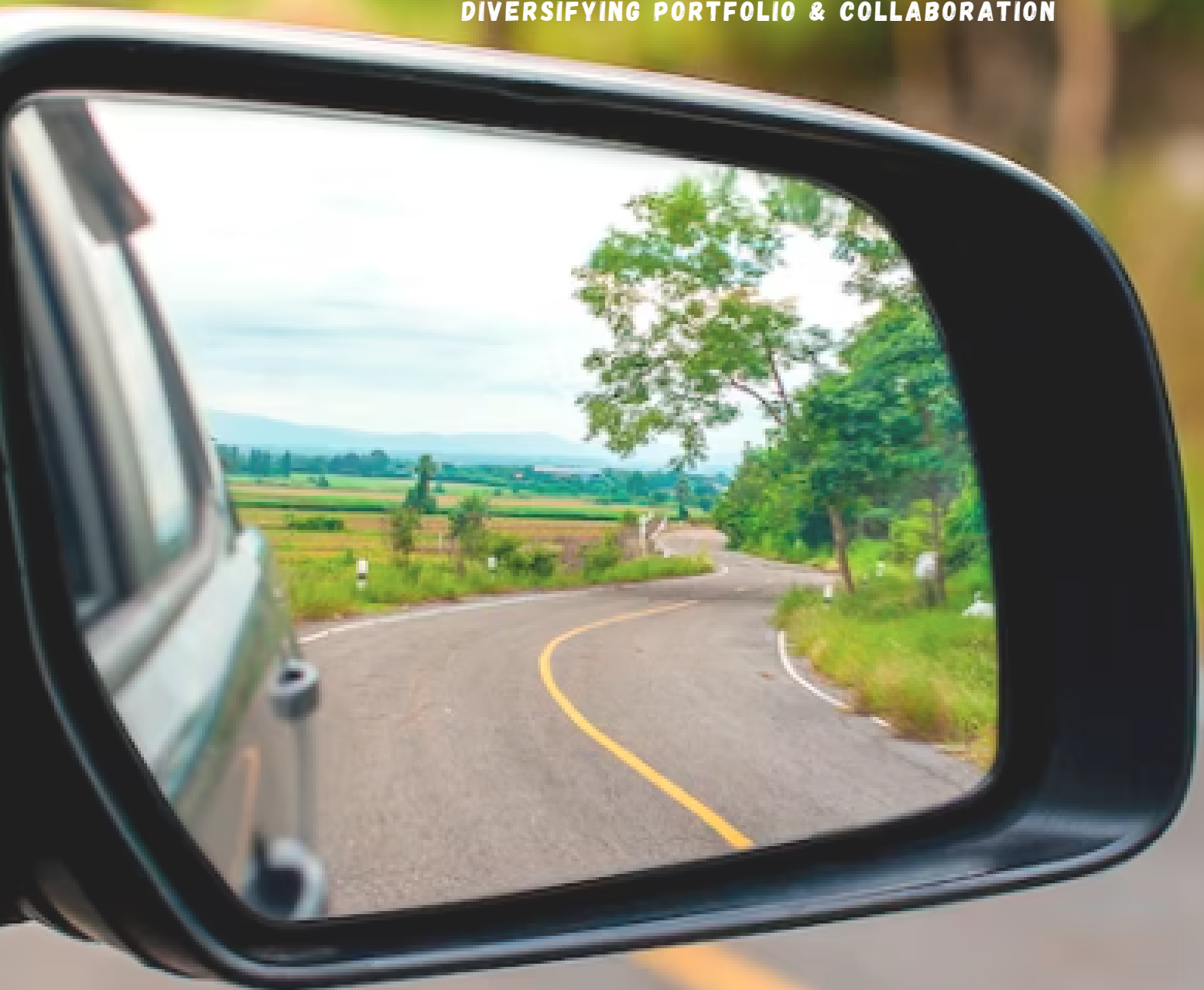
LOOKING BACK...

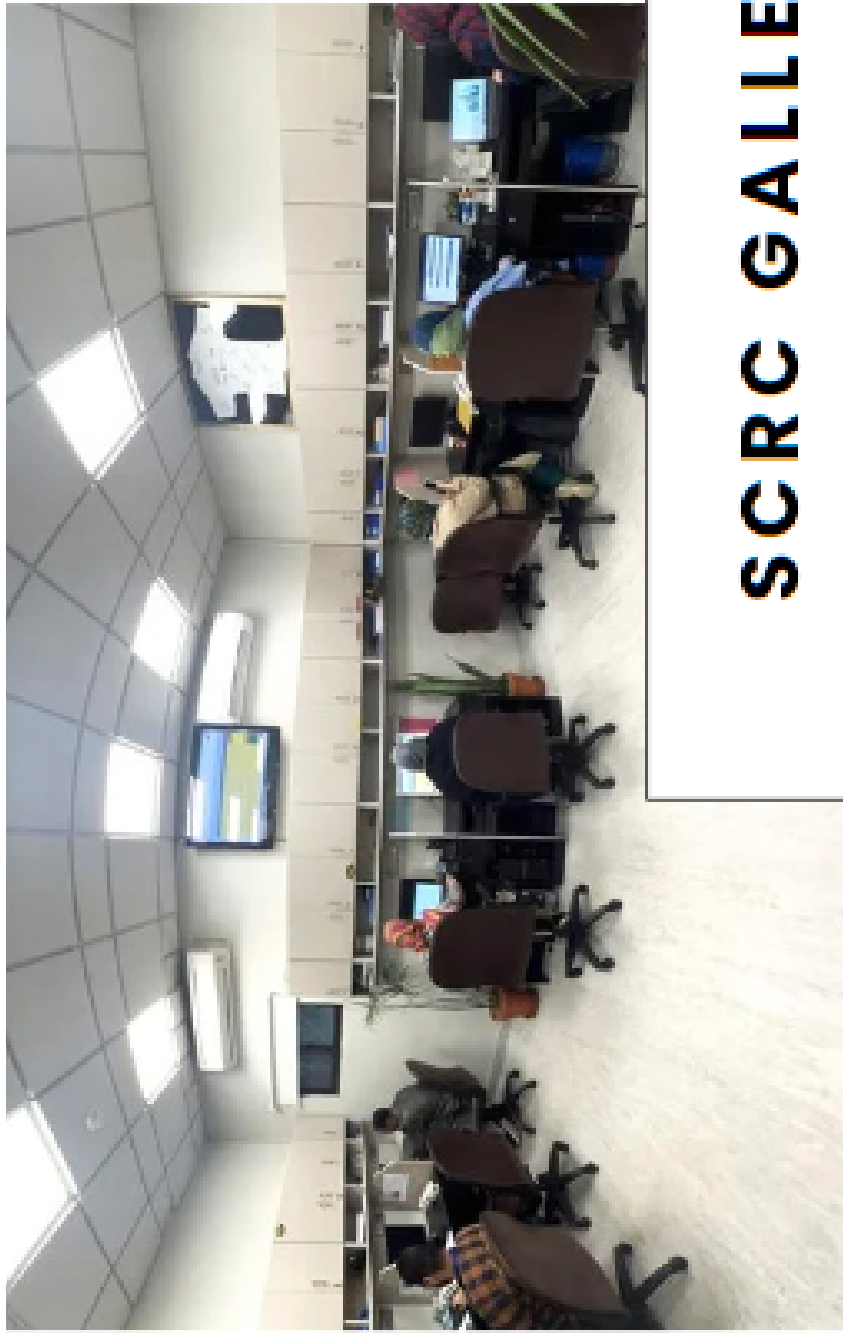
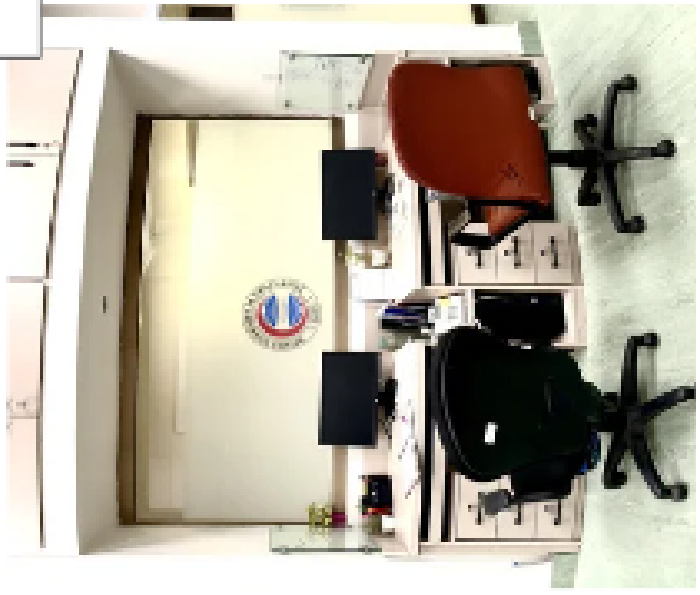
WINDING DOWN COVID VACCINE TRIALS

FORMATION OF CORE SCRC TEAM

DEFINING REGULATORY FRAMEWORKS

DIVERSIFYING PORTFOLIO & COLLABORATION





SCRC GALLERY

DIRECTOR'S MESSAGE

Asalamoalaikum

Running a CTU is like running a large kitchen.

There are raw vegetables and meat (ideas and feasibilities in the pipeline). There is stuff on the stove (hot, recruiting trials). There is stuff well cooked and ready to present (trials ready to submit and publish).

Like real-life kitchens, there is lots of waste and byproducts such as paperwork and catch-22 emails. There are over-cooked dishes (trials past their expected date of delivery awaiting regulatory approvals).

Like a kitchen, it takes a village – supply chain, meetings, and collective wisdom.

But in the end, the joy of cooking is to present what you have toiled for and see a hungry person i.e. patient– smile.

Clinical Research is the kitchen and everyone else practicing medicine is a mere consumer.

In our part of the world, attracting each trial and enrolling each patient is a challenge but the rewards are immense. You put your institution and your country on the map. You become a part of the Circuit. You matter!

Our superb team at SCRC works meticulously to make Shifa and Pakistan proud.

Our vision is to be more than worker bees one day, and come up with new recipes of our own (investigator-initiated trials) that will change the world for the better and take us where no one has gone before.

Until then,



DR. MUHAMMAD AYAZ MIR, FACP

Diplomate American Board of Medicine & Hematology

Director, SCRC

ayaz.mir@shifa.com.pk

MEET OUR *Exceptional* TEAM



Dr. Tehreem Zahid

Clinical Research
Associate



Dr. Sundus Dadan

Clinical Research
Associate



Dr. Sofia Khan

Clinical Research
Associate



Dr. Ammar Khalid

Clinical Research
Associate



Dr. Amna Khan

Clinical Research
Associate



Dr. Dua Rasool

Clinical Research
Associate



Dr. Fatima Khaliq

Medical Officer



Raja Waseem

Research Pharmacist



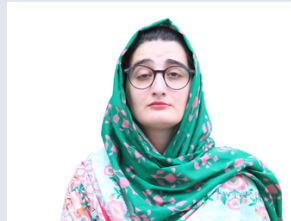
Anita Yaseen

Research Nurse



Mehwish Rafique

Senior Biostatistician



Maliha Aziz

Biostatistician



Sumaira Gulzar

Data Abstractor



Nimra Altaf

Assistant Data Manager



Zafar Iqbal

Cancer Registrar



Muhammad Irfan

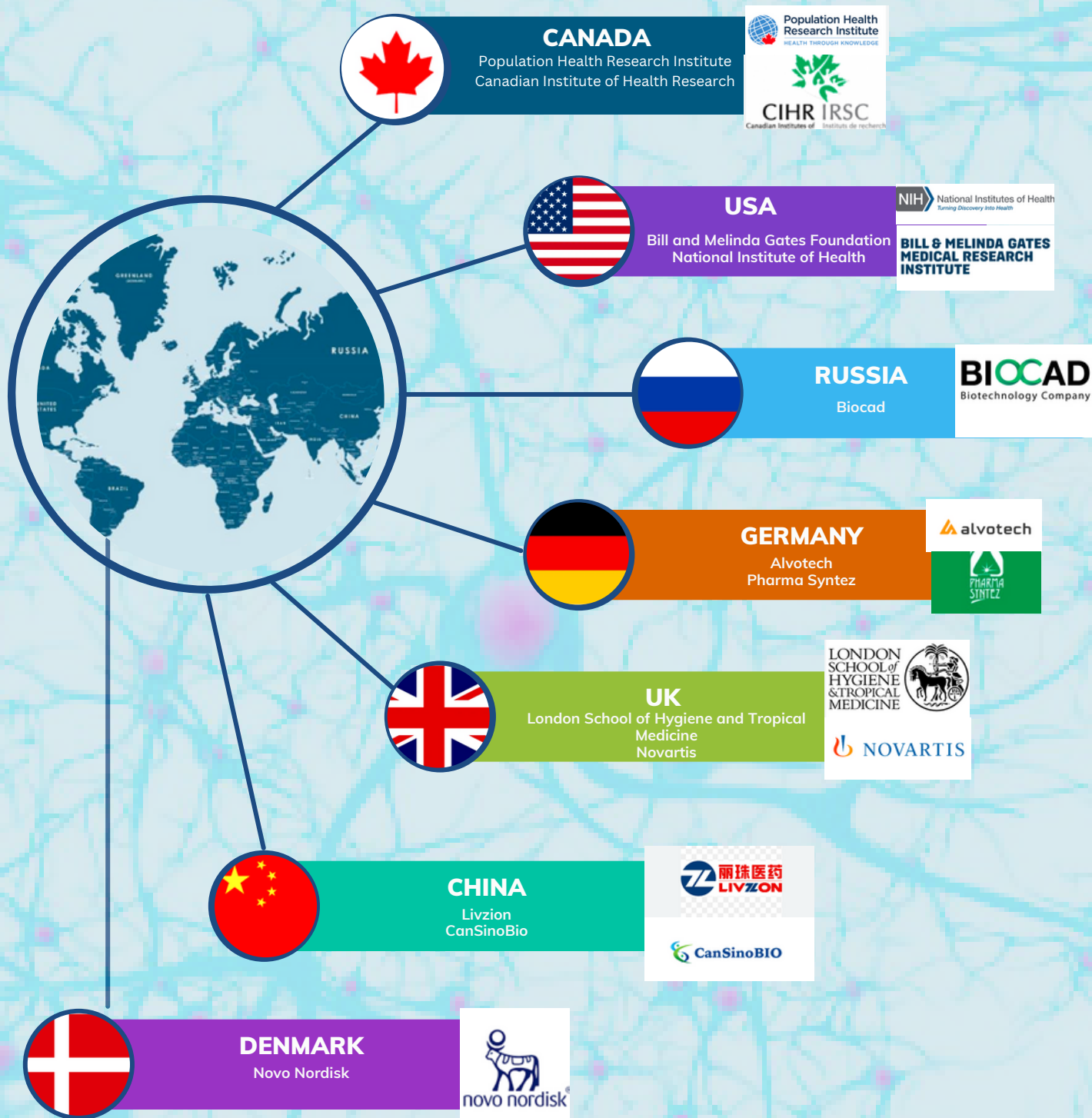
Office Assistant



Abdul Mannan

Research Coordinator

OUR COLLABORATORS



UPDATED SCRC POLICIES (2023)

Academic Research

Conflict of Interest Policy

Policy For MoU

Policy For Travel Grants

Policy for Internship

Policy for information to Patients

Policy for SCRC staff involvement as contributors

Clinical Trial

Policy for feasibility studies

Policy for Co-PI

Policy for third party Vendors

Policy for Archiving Clinical Trial Records

SCRC Investigational Product

Policy for Protocol Grants

Policy For ICU admission for Clinical Trial Participants

Cancer Registry

Cancer Registry Data Sharing Policy

Manual and Procedure Cancer Registry Policy

2023

DATA SAFETY AND MONITORING BOARD ▲ AND CLINICAL TRIALS APPRAISAL COMMITTEE MEETING ○ CALENDAR

JANUARY						
SUN	MON	TUE	WED	THU	FRI	SAT
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FEBRUARY						
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MAY						
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JUNE						
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JULY						
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AUGUST						
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SEPTEMBER						
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OCTOBER						
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NOVEMBER						
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DECEMBER						
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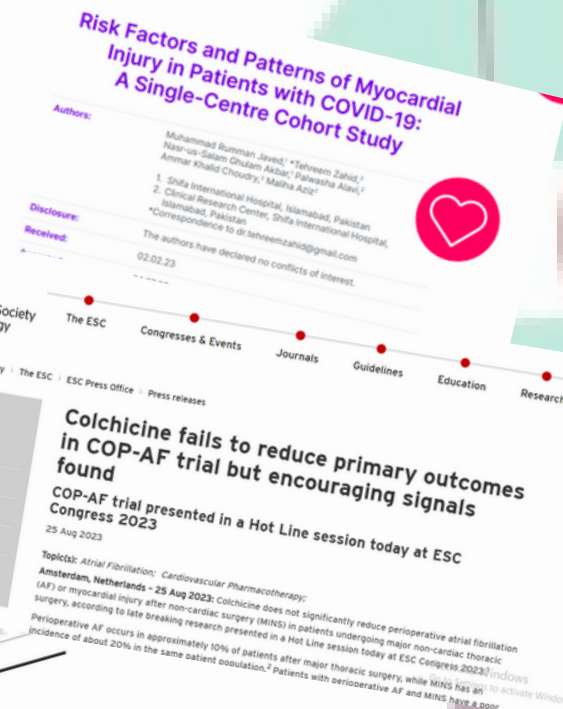
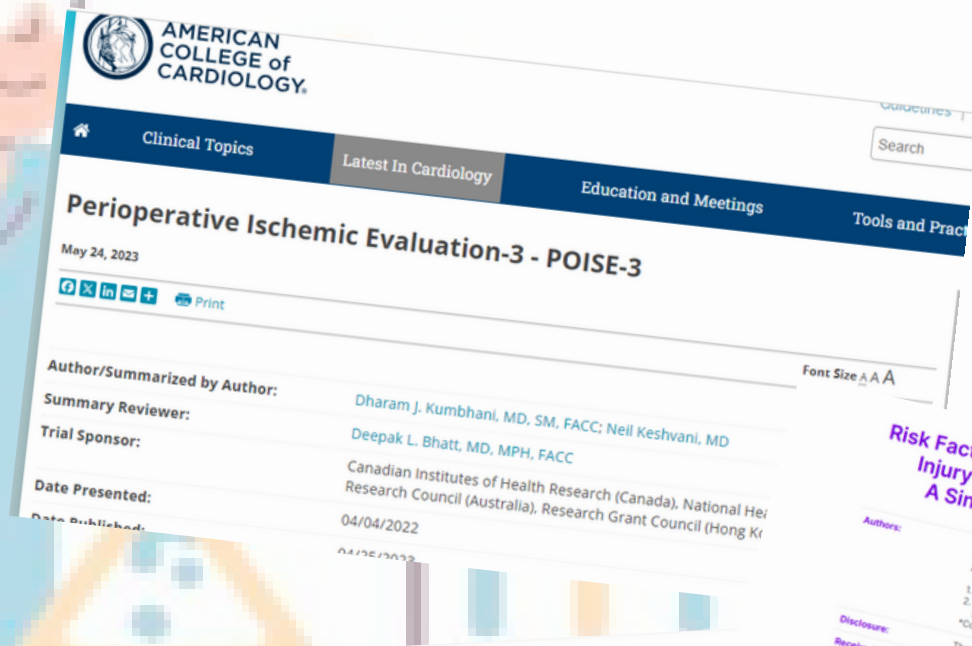
CONCLUDED TRIALS (2022)						
Trial Name	Trial Intervention	Outcomes	Sponsor	Principal Investigator	Current Status	Total Recruitment
Cansino	Adenovirus COVID-19 vaccine in healthy volunteers	Adverse events	Cansino Biologics, China	Dr. Ejaz Khan	CLOSED OUT (Sep 2020-Nov 2022)	5485
		COVID-19 illness				
POISE-3	IV Transamine during general surgery	Perioperative myocardial ischemia	Population Health Research Institute, Canada	Dr. M. Amir	CLOSED OUT (Feb 2019-Jul 2022)	92
		Cardiovascular outcomes				
Livzon	Fusion protein COVID-19 vaccine for healthy volunteers	COVID-19 illness	Livzon Mabpharm, China	Dr. Amjad Sohail	CLOSED OUT (November 2021- June 2023)	2003
COP-AF	Colchicine to thoracic surgery patients	Atrial Fibrillation	Population Health Research Institute, Canada	Dr. M. Amir	CLOSED OUT (April 2021- June 2023)	25
Melanoma/BCD-201	Pembrolizumab biosimilar for unresectable metastatic melanoma	Overall response rate	BIOCAD, Russia	Dr. Saud Ghazi	CLOSED OUT (May 2023-Oct 2023)	0

TRIALS IN PIPELINE						
Trial Name	Trial Intervention	Outcomes	Sponsor	Principal Investigator	Current Status	Pending issues
DEPOSITION	IV vs Intra-pericardial Transamine during cardiac surgery	Post operative ischemia and seizures	Population Health Research Institute, Canada	Dr. Asghar Nawaz	<div> <div>SCRC</div> <div>CTAC</div> </div> <div> <div>IRB</div> <div>NBC</div> </div> <div> <div>DRAP</div> </div>	Queries from DRAP responded, approval awaited.
IM WOMAN	IM/IV Tranexamic acid for postpartum hemorrhage	Postpartum hemorrhage	London School of Tropical Hygiene	Dr Shehnaz Nawaz	<div> <div>SCRC</div> <div>CTAC</div> </div> <div> <div>IRB</div> <div>NBC</div> </div> <div> <div>DRAP</div> </div>	DRAP & STMU
THE SHIPPS STUDY	Stress Hydrocortisone in Pediatric Septic Shock	Proportion of subjects with a poor outcome,	Canadian Institute of Health Research (CIHR)	Dr AttaUllah Khan	<div> <div>SCRC</div> <div>CTAC</div> </div> <div> <div>IRB</div> <div>NBC</div> </div> <div> <div>DRAP</div> </div>	Budget,DRAP,NBC
Chronic myeloid leukemia (CML)	PF-114 vs Imatinib in CML patients	Safety, Efficacy and MMR	JSC PHARMASYNTEZ NORD, RUSSIA	Dr. Ayaz Mir	<div> <div>SCRC</div> <div>CTAC</div> </div> <div> <div>IRB</div> <div>NBC</div> </div> <div> <div>DRAP</div> </div>	DRAP
LIMIT	Low INR to Minimize bleeding with machanical valves	Thrombosis/Thromb oembolism and major bleeding	Population Health Research Institute, Canada	Dr. Asghar Nawaz	<div> <div>SCRC</div> <div>CTAC</div> </div> <div> <div>IRB</div> <div>NBC</div> </div> <div> <div>DRAP</div> </div>	IRB
ERTUNASH	Ertugliflozin In (T2DM)	Change in radiologic liver parameters	GETZ	Dr Umar Yousaf Raja	<div> <div>SCRC</div> <div>CTAC</div> </div> <div> <div>IRB</div> <div>NBC</div> </div> <div> <div>DRAP</div> </div>	

ACTIVE PHASE						
Trial Name	Trial Intervention	Outcomes	Sponsor	Principal Investigator	Current Status	Total Recruitment
ALVOEYE	Aflibercept (Anti -VEGF) biosimilar intravitreal injection for wet ARMD	Change in Visual Acuity	Alvotech, Germany	Dr. Amer Awan	Screening officially ended (8th Sept 2023)	1
HIP-ATTACK2	Accelerated orthopaedic surgery vs standard of care in hip fracture patients with myocardial injury	90 day mortality	Population Health Research Institute, Canada	Dr. Amer Nabi Nur	Actively Recruiting	3
CONSTELLATION	Probiotic nutritional supplement formula (Bi-26) for underweight infants	Change in weight	Bill and Melinda Gates Research Institute, USA	Dr. Munir Malik	Screening in process	3
Perjeta /BCD-178	BCD-178 (Biosimilar of pertuzumab) for Breast CA	Overall response rate	BIOCAD, Russia	Dr. Azhar Shafi	Actively Recruiting	0
ACTIV 2D	Oral COVID-19 treatment(Protease Inhibitor) for stable outpatients	COVID-19 illnesss	NIH, USA	Dr. Ejaz Khan	Actively Recruiting	4
ASPIRE-AF	Rivaroxaban and Apixaban to prevent atrial fibrillation after general surgery	Atrial fibrillation and Stroke	Population Health Research Institute, Canada	Dr. Saeedullah Shah	Actively Recruiting	0

FOLLOW-UP PHASE						
Trial Name	Trial Intervention	Outcomes	Sponsor	Principal Investigator	Current Status	Total Recruitment
SEQIRUS	Influenza vaccine to paediatric population	Influenza-like illness	Novartis, United Kingdom	Dr. Ejaz Khan	Recruitment ended, Follow up until October 2023,CLOSING OUT	60
CONVERGE	Diabetes Management	Prescription patterns	NovoNordisk	Dr. Umar Yusuf	Recruitment ended	135

2023 PUBLICATIONS



THE LANCET



Trial Designs

Rationale and design of the colchicine for the prevention of perioperative atrial fibrillation in patients undergoing major noncardiac thoracic surgery (COP-AF) trial

David Conen MD MPH,^{1,2,3} Matthew T.V. Chan MBBS MMed PhD,⁶ Ekaterine Popova MD,^{4,5} Michael Ke Wang MD,^{1,2,3} Sadeesh K. Srinathan MD MSc,¹⁰ Giovanni Landoni MD,^{7,8} Cara Reimer MD MSc,⁹ Juan Carlos Trujillo Reyes MD PhD,¹⁴ Sean R. McLean MD,^{12,13} Ascensión Martín Grande MD,¹⁵

2023 PUBLICATIONS

Clinical Trial > Emerg Microbes Infect. 2022 Dec;11(1):1910-1919.
doi: 10.1080/22221751.2022.2088406.

Efficacy of heterologous boosting against SARS-CoV-2 using a recombinant interferon-armed fusion protein vaccine (V-01): a randomized, double-blind and placebo-controlled phase III trial

Xuan-Yi Wang^{1,2,3}, Syed Faisal Mahmood⁴, Fang Jin^{5,6}, Wee Kooi Cheah⁷, Muhammad Ahmad⁸, Mian Amjad Sohail⁹, Waheed Ahmad¹⁰, Vijaya K Suppan¹¹, Muneeba Ahsan Sayeed¹², Shobha Luxmi¹³, Aik-Howe Teo¹⁴, Li Yuan Lee¹⁵, Yang-Yang Qi^{1,2}, Rong-Juan Pei¹⁶, Wei Deng⁶, Zhong-Hui Xu¹⁷, Jia-Ming Yang¹⁷, Yan Zhang¹⁷, Wu-Xiang Guan¹⁶, Xiong Yu¹⁸

Affiliations + expand

PMID: 35686572 PMCID: PMC9347473 DOI: 10.1080/22221751.2022.2088406

THE LANCET

This journal Journals Publish Clinical Global health Multimedia Events About

ARTICLES | VOLUME 402, ISSUE 10413, P1627-1635, NOVEMBER 04, 2023

Effect of colchicine on perioperative atrial fibrillation and myocardial injury after non-cardiac surgery in patients undergoing major thoracic surgery (COP-AF): an international randomised trial

David Conen, MD, Michael Ke Wang, MD, Ekaterine Popova, MD, Prof Matthew T V Chan, PhD, Prof Giovanni Landoni, MD, Juan P Cata, MD, et al. Show all authors • Show footnotes

Published: August 25, 2023 • DOI: [https://doi.org/10.1016/S0140-6736\(23\)01689-6](https://doi.org/10.1016/S0140-6736(23)01689-6) • Check for updates

Rationale and design of the PeriOperative ISchemic Evaluation-3 (POISE-3): a randomized controlled trial evaluating tranexamic acid and a strategy to minimize hypotension in noncardiac surgery

Maura Marcucci^{1,2,3}, Thomas W Painter^{4,5}, David Conen^{6,7}, Kate Leslie^{8,9}, Vladimir V Lomivorotov^{10,11}, Daniel Sessler¹², Matthew T V Chan¹³, Flavia K Borges^{14,6,7}, Maria J Martinez Zapata¹⁵, C Y Wang¹⁶, Denis Xavier¹⁷, Sandra N Ofori^{14,7}, Giovanni Landoni^{18,19}, Sergey Efremov²⁰, Ydo V Kleinlugtenbelt²¹, Wojciech Szczeklik²², Denis Schmartz²³, Amit X Garg²⁴, Timothy G Short^{25,26}, Maria Wittmann²⁷, Christian S Meyhoff²⁸, Mohammed Amir²⁹, David Torres^{30,31}, Ameen Patel⁶, Emmanuelle Dupeppe^{7,32}, Kurtz Ruetzler³³, Joel L Parlow³³, Vikas Tandon⁶, Michael K Wang^{34,6,7}, Edith Fleischmann³⁴, Carisi A Polanczyk^{35,36}, Raja Jayaram³⁷, Sergey V Astrakov^{38,39}, Mangala Rao¹⁷, Tomas VanHelder⁴⁰, William K K Wu¹³, Chao Chia Cheong¹⁶, Sabry Ayad⁴¹, Marat Abubakirov⁴², Mikhail Kirov⁴³, Keyur Bhatt⁴⁴, Miriam de Nadal⁴⁵, Valery Likhvantsev^{46,47}, Pilar Paniagua Iglesias⁴⁸, Hector J Aguado⁴⁹, Michael McGillion^{7,50}, Andre Lamy^{7,51}, Richard P Whitlock^{7,51}, Pavel Roshanov⁵², David Stillo⁷, Ingrid Copland⁷, Jessica Vincent⁷, Kumar Balasubramanian⁷, Shikant I Bangdiwala^{14,7}, Bruce Biccadd⁵³, Andrea Kurz^{12,54}, Sadeesh Srinathan⁵⁵, Shirley Petit⁷, John Eikelboom^{6,7}, Toby Richards⁵⁶, Peter L Gross⁶, Pascal Alfonsi⁵⁷, Gordon Guyatt^{14,6}, Emily Belley-Cote^{6,7}, Jessica Spence^{14,7,40}, William McIntyre^{6,7}, Salim Yusuf^{6,7} • [https://doi.org/10.1016/S0140-6736\(23\)01689-6](https://doi.org/10.1016/S0140-6736(23)01689-6)

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Q

THE NEW ENGLAND JOURNAL OF MEDICINE

ORIGINAL ARTICLE
Transcatheter Aortic-Valve Replacement in Low-Risk Patients at Five Years



NEJM GROUP PODCASTS
DISCOVER NOW

IMAGE CHALLENGE
What is the diagnosis?



EDITORIAL
Liver Transplantation for Malvash Disease, an Inborn Error of Metabolism



ORIGINAL ARTICLE
Erdafitinib or Chemotherapy in Advanced or Metastatic Urothelial Carcinoma

Tranexamic Acid in Patients Undergoing Noncardiac Surgery

P.J. Devereaux, M.D., Ph.D., Maura Marcucci, M.D., Thomas W. Painter, M.B., Ch.B., David Conen, M.D., M.P.H., Vladimir Lomivorotov, M.D., Daniel I. Sessler, M.D., Matthew T.V. Chan, M.B., B.S., Ph.D., Flavia K. Borges, M.D., Ph.D., Maria J. Martinez-Zapata, M.D., Ph.D., Chew Yin Yan, M.B., Ch.B., Denis Xavier, M.D., Sandra N. Ofori, F.W.A.C.P., et al., for the POISE-3 Investigators*

Received: 18 May 2023

Revised: 8 September 2023

Accepted: 15 September 2023

DOI: 10.1111/sdi.13182

ORIGINAL ARTICLE

Seminars in Dialysis WILEY

Pantoea agglomerans: A rare infectious outbreak affecting maintenance hemodialysis patients in a tertiary care hospital

Danyal Hassan¹ | Nida Saleem^{1,2,3,4} | Muhammad Haneef¹ | Merina Khan¹ | Maliha Aziz⁵ | Muhammad Usman⁶

To evaluate the utility of Oxford classification in predicting renal outcome in IgA nephropathy patients

Nida Saleem^{1,6,7} • Humaira Nasir² • Fatima Anwar² • Maliha Aziz³ • Kiran Khurshid⁴ • Saima Bashir⁴ • Asrar Khan^{5,6}

MEDICAL STUDENT STUDIES

Investigating Outpatient High Dose Cytarabine for Acute Myeloid Leukemia in Pakistan: A Safety and Feasibility Study

Dr Daniyal Ghani, Zeeshan Khattak, Dr Sundus Dadan, Miss Mehwish, Asfand Bangash- MS5

1

Early Discharge and Outpatient Therapy for Acute Promyelocytic Leukemia

Arham Yahya Rizwan- MS5

2

Trends and Outcomes of Adult ITP in Pakistani population - a Tertiary Centre Experience

Abdul Wasaay Khurram, Ayesha- MS5

3

Allogenic Stem cell Transplant infective complications

Muhammad Ahmad Nadeem-MS5

4

Diffuse large B cell lymphoma outcomes in Pakistan

Haysum Khan-MS5

5

Innovative approach on AML with focus on BCL2

Mohammad Rehan Javed- MS5

6

Autologous Stem Cell Transplants for Myeloma in Pakistan - A Single-Center Experience

Hamna Ahmad-MS5

7

Low dose POMP maintenance for ALL in Pakistani Population

Rumun Gul- MS5

8

FLAG vs V3; A salvage bridge to allogenic transplant of acute leukemia

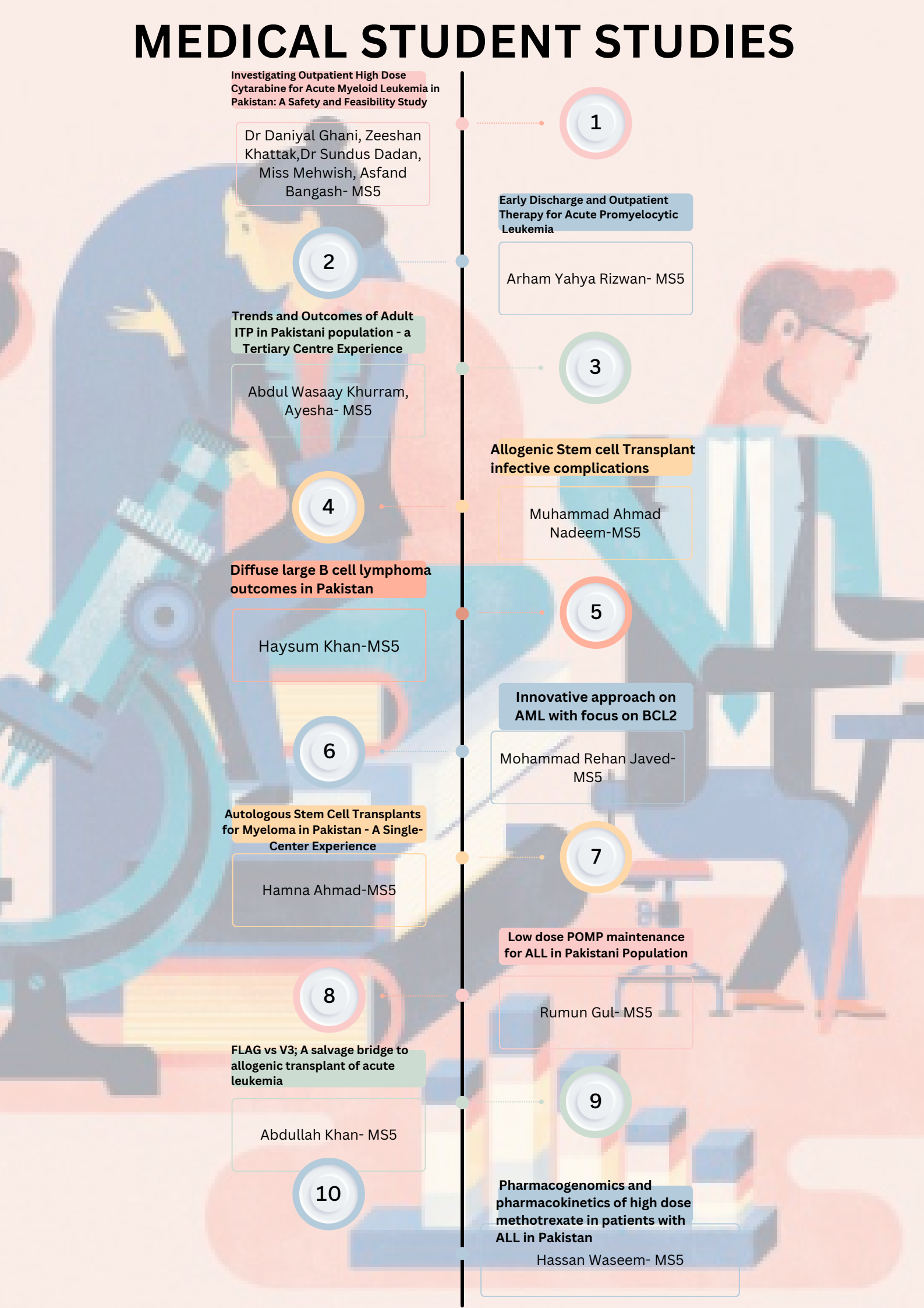
Abdullah Khan- MS5

9

Pharmacogenomics and pharmacokinetics of high dose methotrexate in patients with ALL in Pakistan

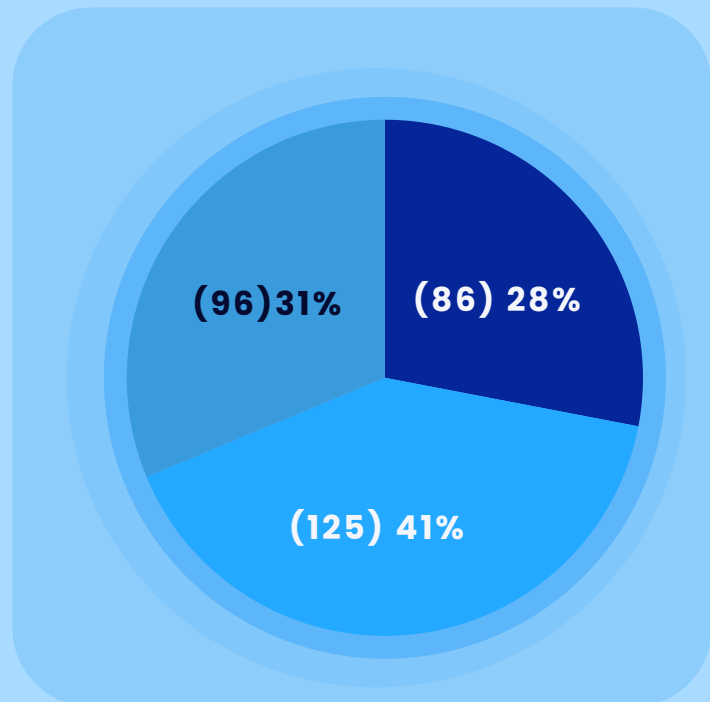
Hassan Waseem- MS5

10



BIOSTATISTICS FACILITATIONS

- Sample Size
- IRB Opinion
- Statistical Analysis



CAPACITY BUILDING



Premiers of Biostatistics

6 Months Course for Healthcare Providers Using SPSS Software



PGME Sessions

Monthly Core Competency Sessions

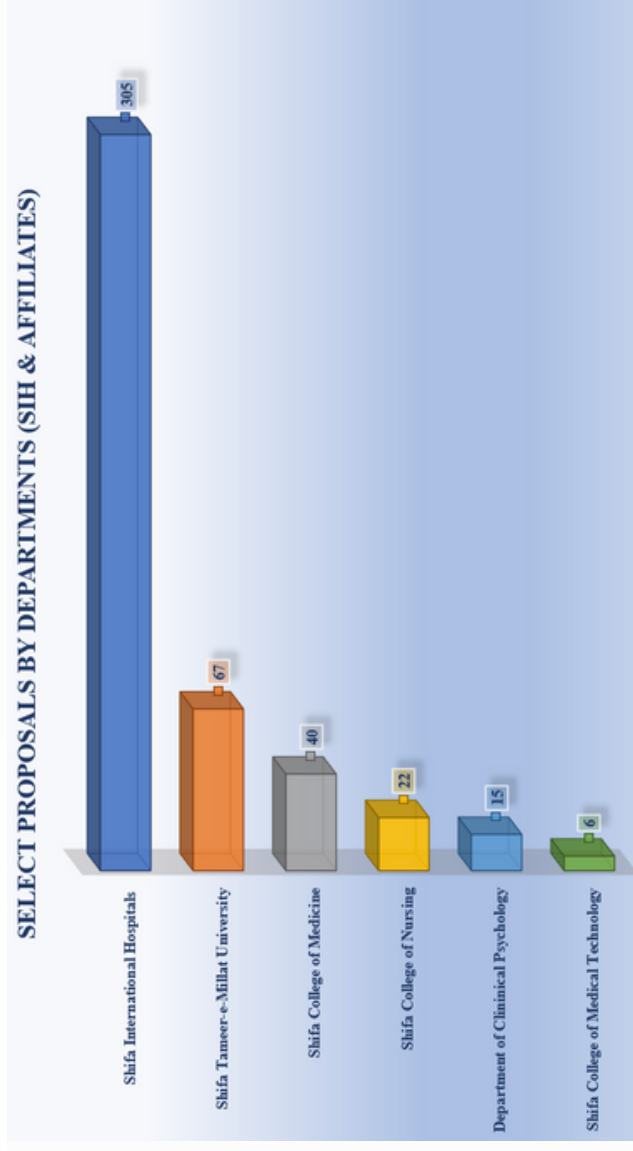
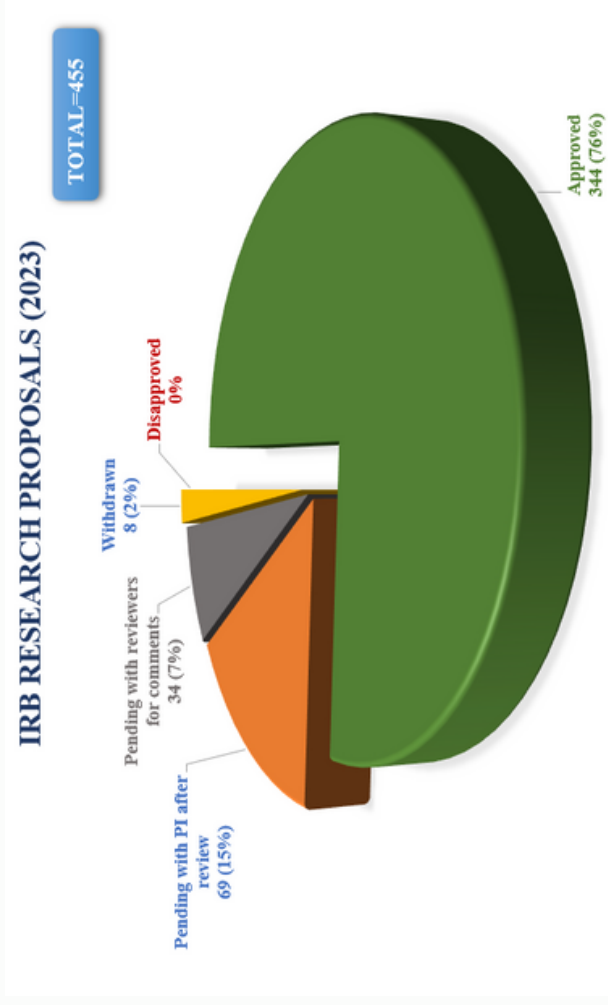


ASMT

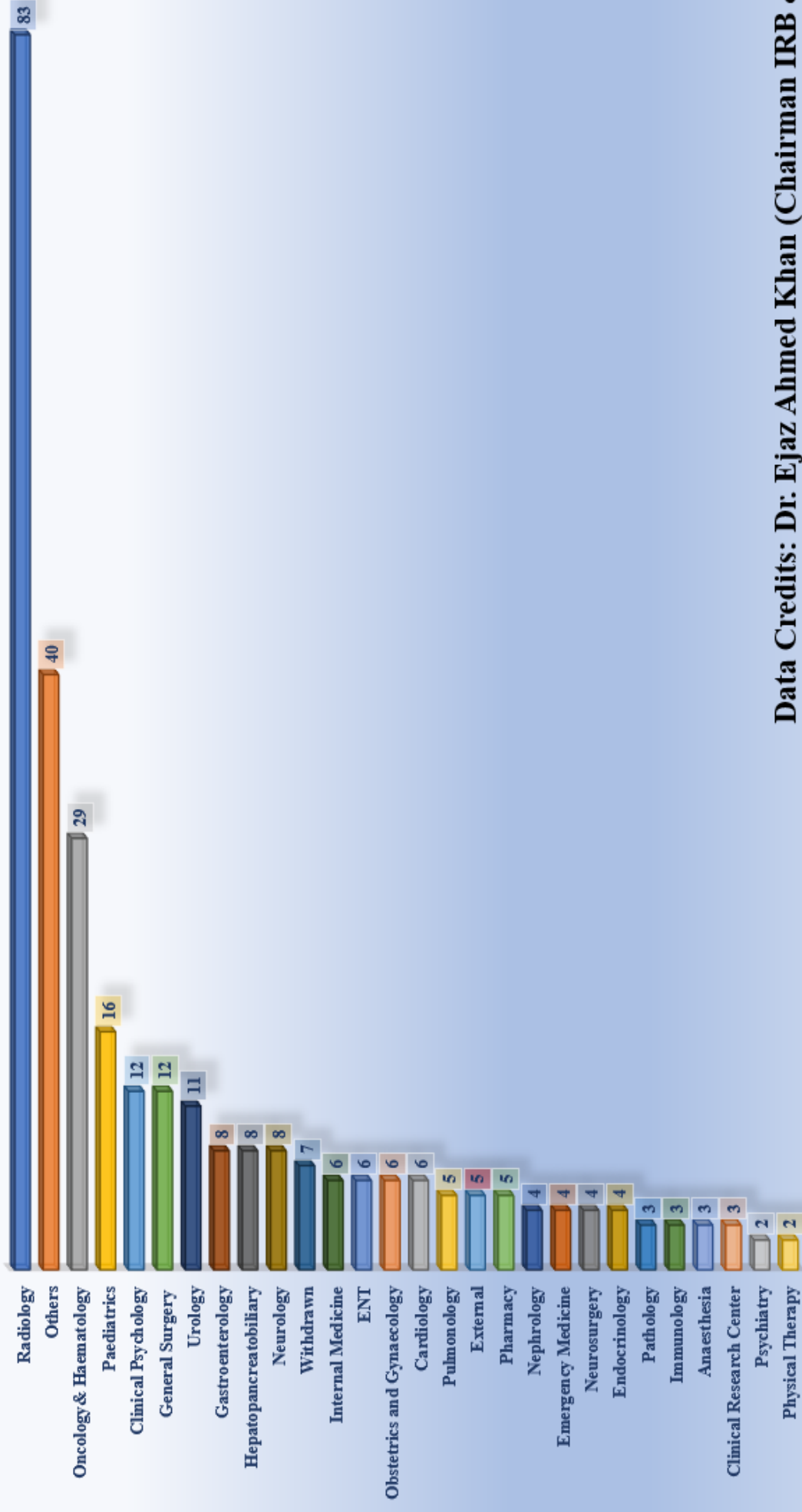
Associate of Science in Medical Technology Lectures



INVESTIGATOR INITIATED PROTOCOLS AT SIH (2023)



SELECT PROPOSALS BY DEPARTMENTS (SIH)



Data Credits: Dr. Ejaz Ahmed Khan (Chairman IRB & EC)



SHIFA CANCER REGISTRY



The SIH cancer registry has been growing consistently for the past six years between 2018 and 2023.

Manuals

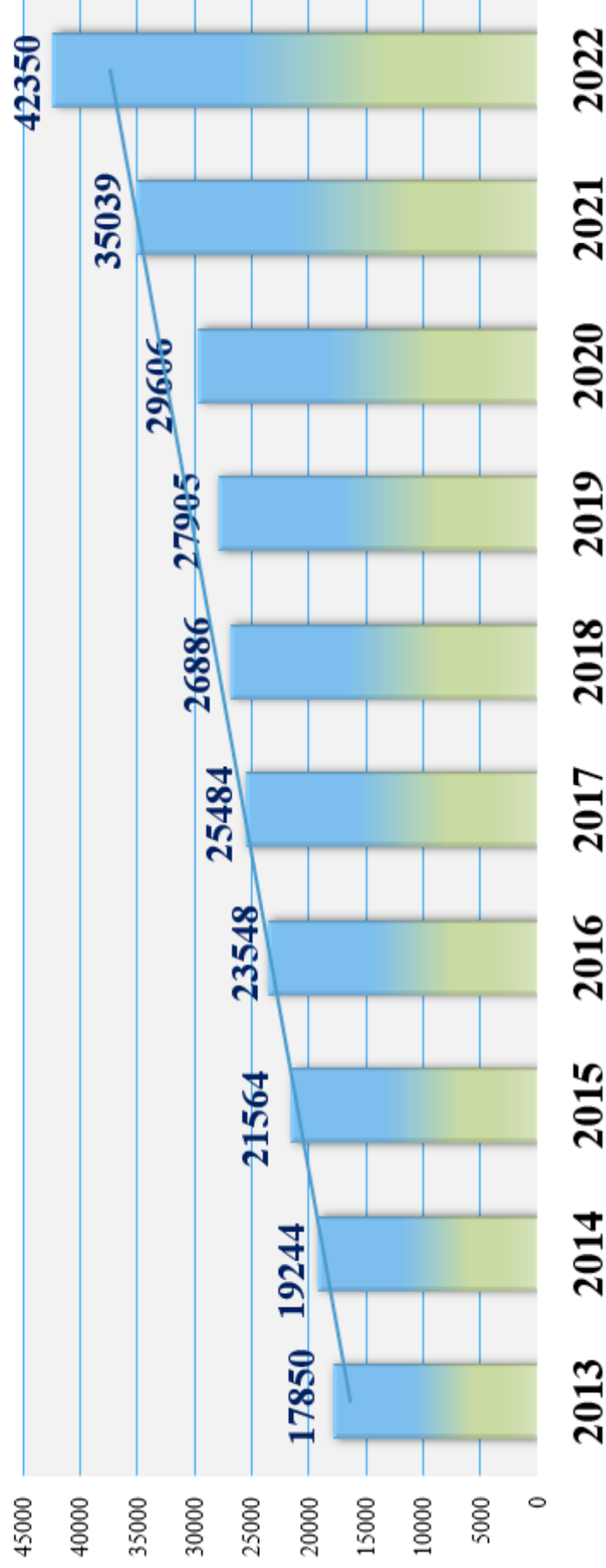


ICD-O3.2

AJCC staging system
8th edition

SEER stage 2000

Shifa Oncology Center 10 year total patients visit 2013-2022



Now incorporating the Genetic and Molecular Data in Cancer Registry

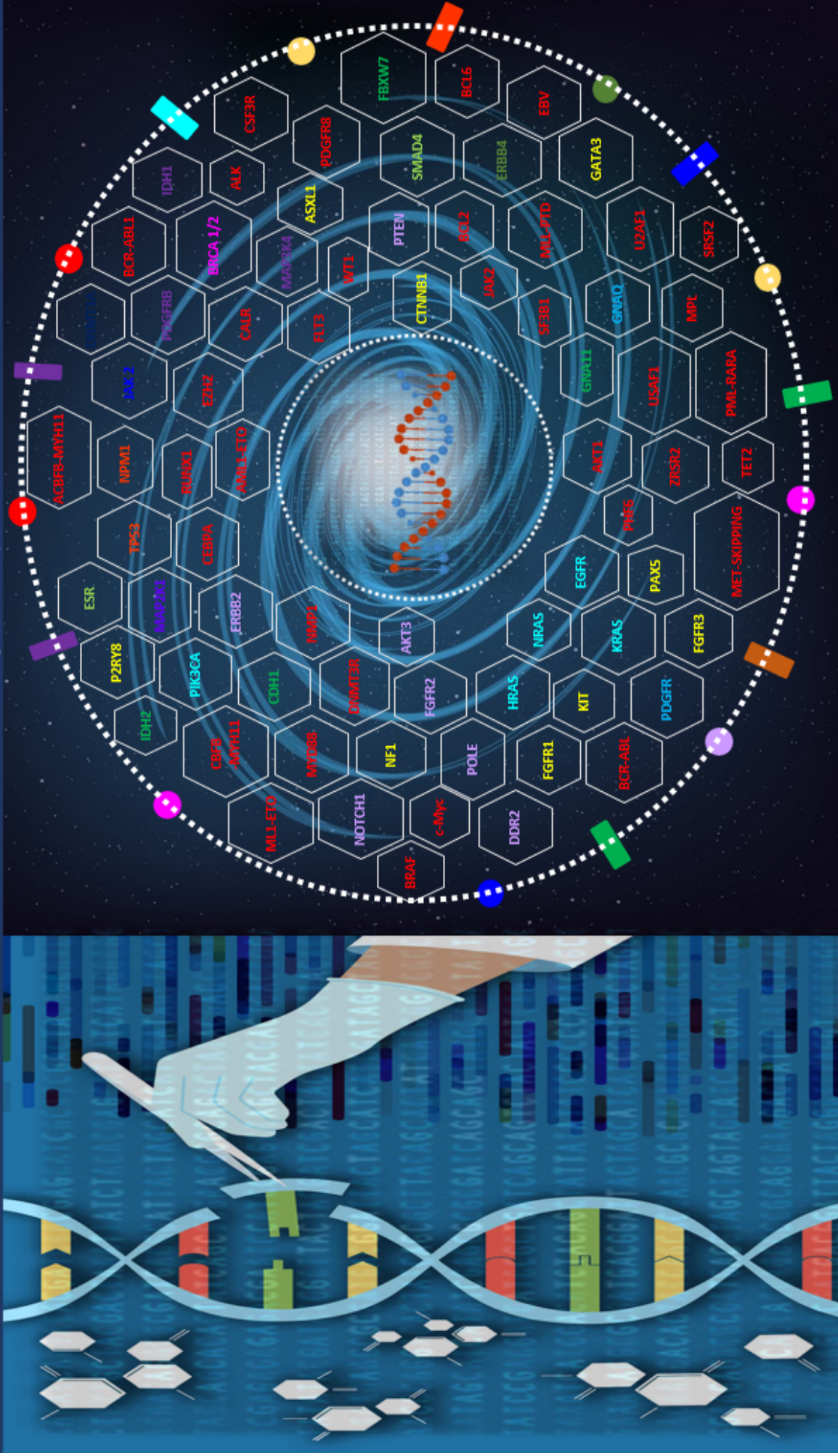


Photo Gallery



Ahmad Sabry and Catherine De Martel from World Health Organization(WHO) Confer with SCRC. Together, we embark on a groundbreaking journey to build a Hepatitis Database. Collecting longitudinal data for Hep B, Hep C, and HCC patients - a monumental leap towards comprehensive healthcare and global hepatitis elimination. Thrilled to shape the future of medical insights.

A team from Dow University of Health Sciences (DUHS) recently visited the Shifa Clinical Research Centre (SCRC) for potential collaboration. Both Dow and SCRC representatives engaged in productive talks, signaling a significant step towards efficient and sustainable clinical research trial practices.

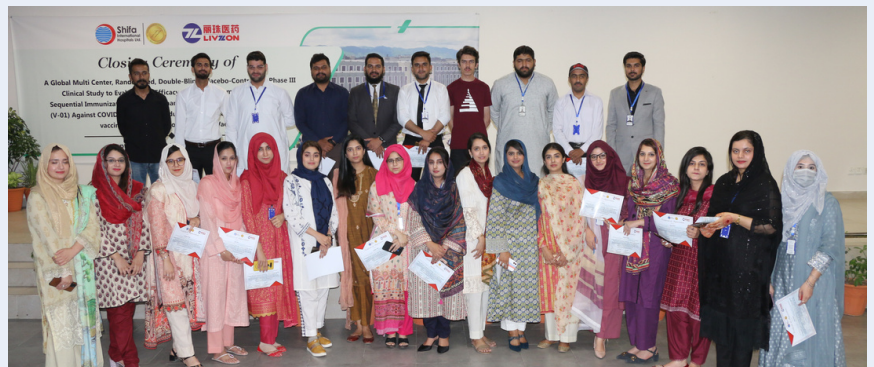


Mr. Ben Laverty (Head of R&DS Operations for Southeast Asia, Australia, and New Zealand - IQVIA) visited us on 25 May 2023 and met with top consultants with expertise in relevant disciplines to explore potential collaborations.



**Drug Regulatory Authority of Pakistan
Grants 2023
Re-Approval for Phase 3 and Phase 4
Trials at Our Clinical Trial Unit.**

**In a historic stride towards
overcoming the global pandemic,
LIVZON has achieved a remarkable
feat in Pakistan, enrolling over
1000 participants in one of the
nation's largest COVID-19 vaccine
trials.**



**The Premiers of Biostatistics for
Healthcare Providers Using SPSS a
six-month course was successfully
organized by the Shifa Clinical
Research Center.**

THE ROAD AHEAD..

- Infrastructure development
- Capacity building
- Financial safeguards
- Policymaking and implementation
- Partnerships and collaboration

- Integration of Clinical Research with Artificial Intelligence
- Initiate Phase I, bio-equivalence and medical device clinical trials
- Focus on investigator-initiated and undergraduate research

2022

2023

2024

2025

2026

- Core team expansion
- Building of state-of-the-art Research Clinic and Clinical Trial Repository
- Clinical Trial Portfolio diversification
- Digitalization of Cancer Registry



Contact Us:

AO-Shifa Clinical Research Center
scrc@shifa.com.pk

<https://www.shifa.com.pk/scrc-4/>