



**SHIFA CLINICAL
RESEARCH CENTRE
ANNUAL REPORT
2022**

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

ANNUAL REPORT



2022



Where to find us?

Shifa Clinical Research Centre-Ao, Shifa International Hospital

DIRECTOR'S MESSAGE

DR. MUHAMMAD AYAZ MIR

Shifa Clinical Research Center is an affiliate of Shifa International, with a 500 bed JCI accredited Hospital, e-Shifa, Shifa Tameer-e-Millat University, Shifa College of Medicine and Shifa Schools for Nursing & Pharmacology.

SCRC ensures the 4 pillars of any Clinical Trials Unit:

- **ROBUST TEAM** of Principal and Co-investigators, Clinical Research Associates (CRAs), Physicians, Biostatisticians, Data Managers and Coordinators.
- **TRACK RECORD** of enrolling thousands of patients in numerous multi-center clinical trials across the globe.
- **QUALITY ASSURANCE** guided by Joint Commission, Good Clinical Practice principles to ensure ethical, transparent and seamless execution of benchmarks.
- **VIABILITY** of clinical research as a defining facet of who we are as an organization with leadership committed to advancement of healthcare.

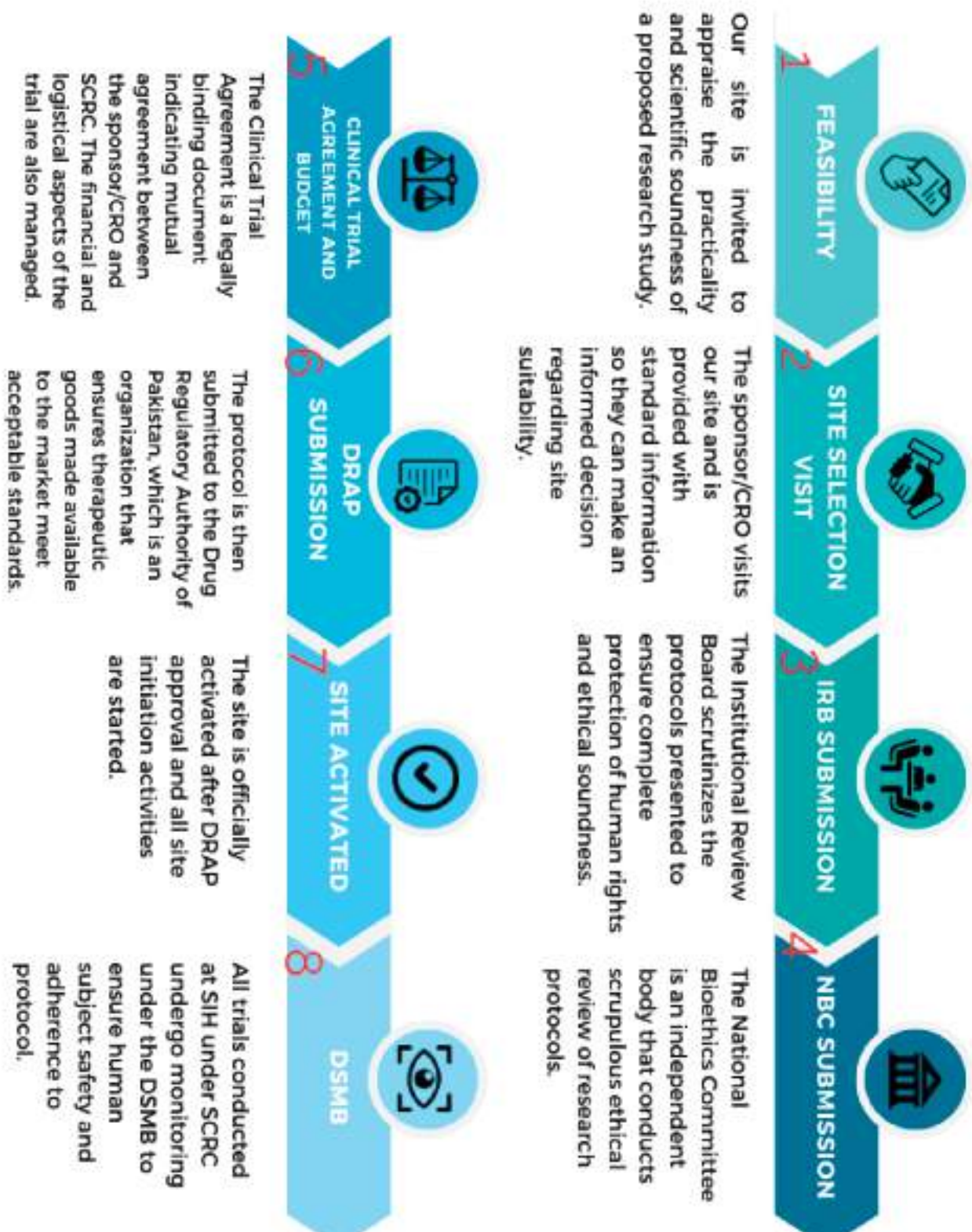


Collaboration is the name of the game in clinical research, and we offer a unique platform in this region unrivalled in bringing the pieces together for meaningful research that changes clinical practice and opens undiscovered avenues.

SCRC is a one-stop-shop from study feasibility, identifying PI, forming a team, IRB presentation, Clinical Trial negotiation and agreement, enrollment, follow-up and sorting out AEs until trial is completed.

OUR PROCESS

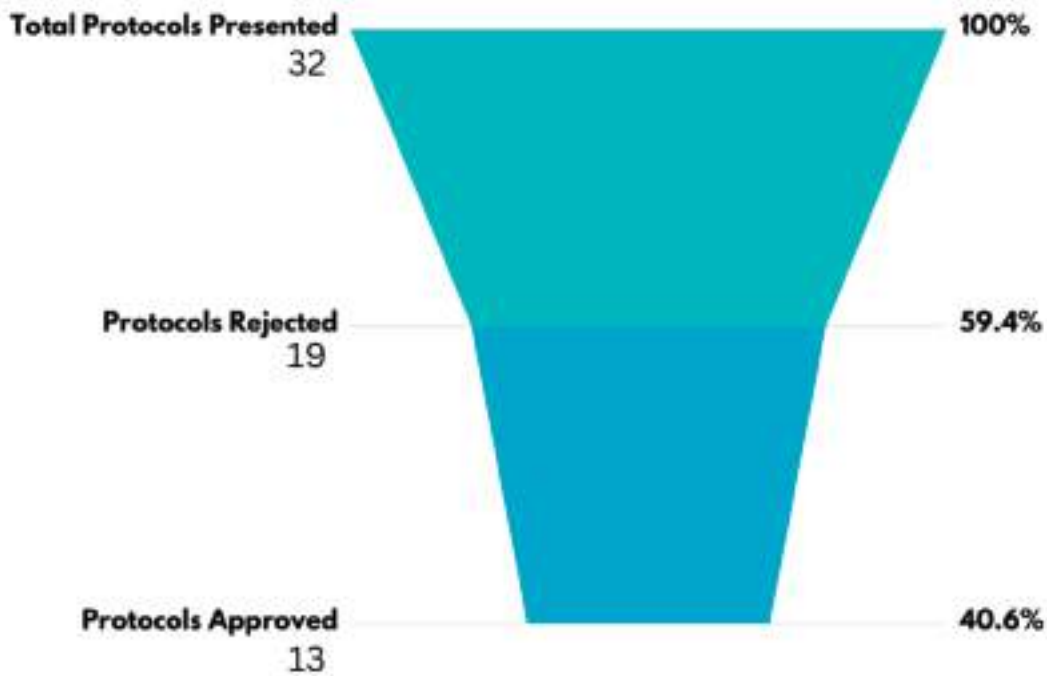
The Clinical Trial approval process / Work flow



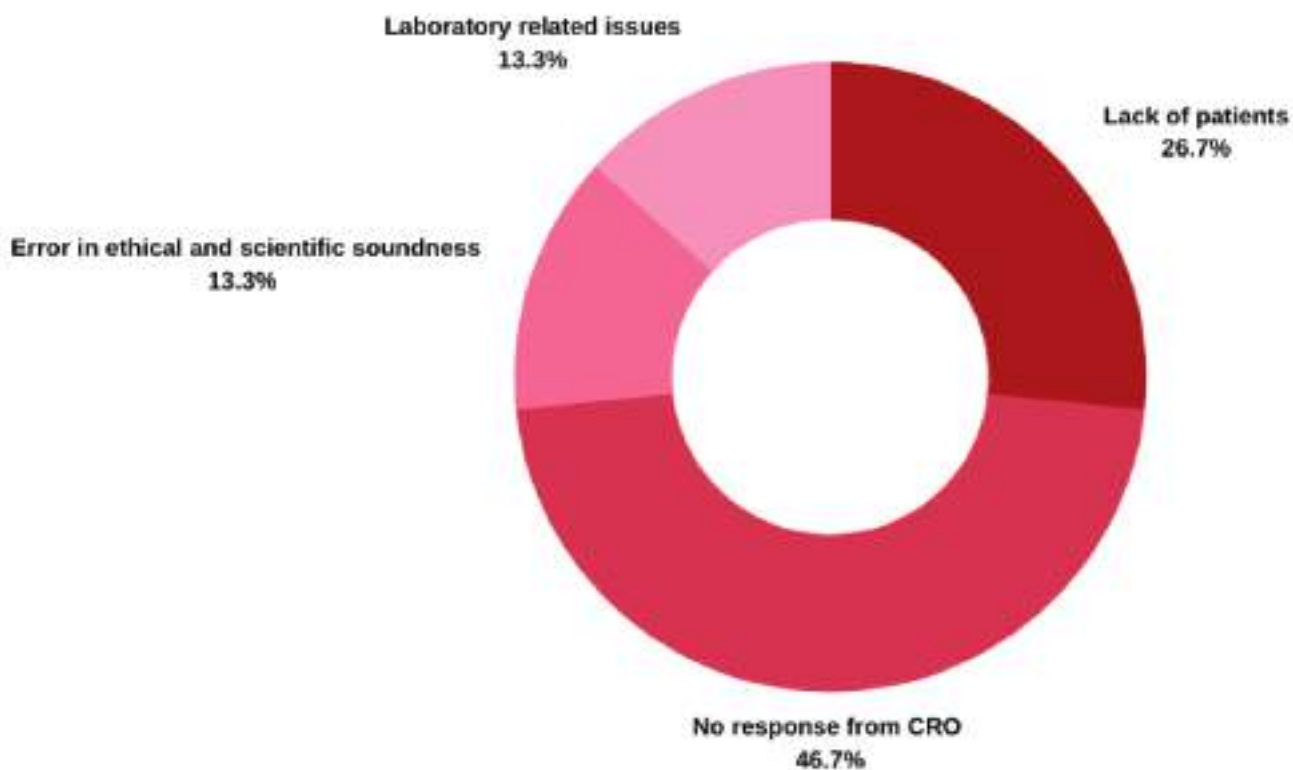
TRIAL BREAKDOWN

FEASIBILITY

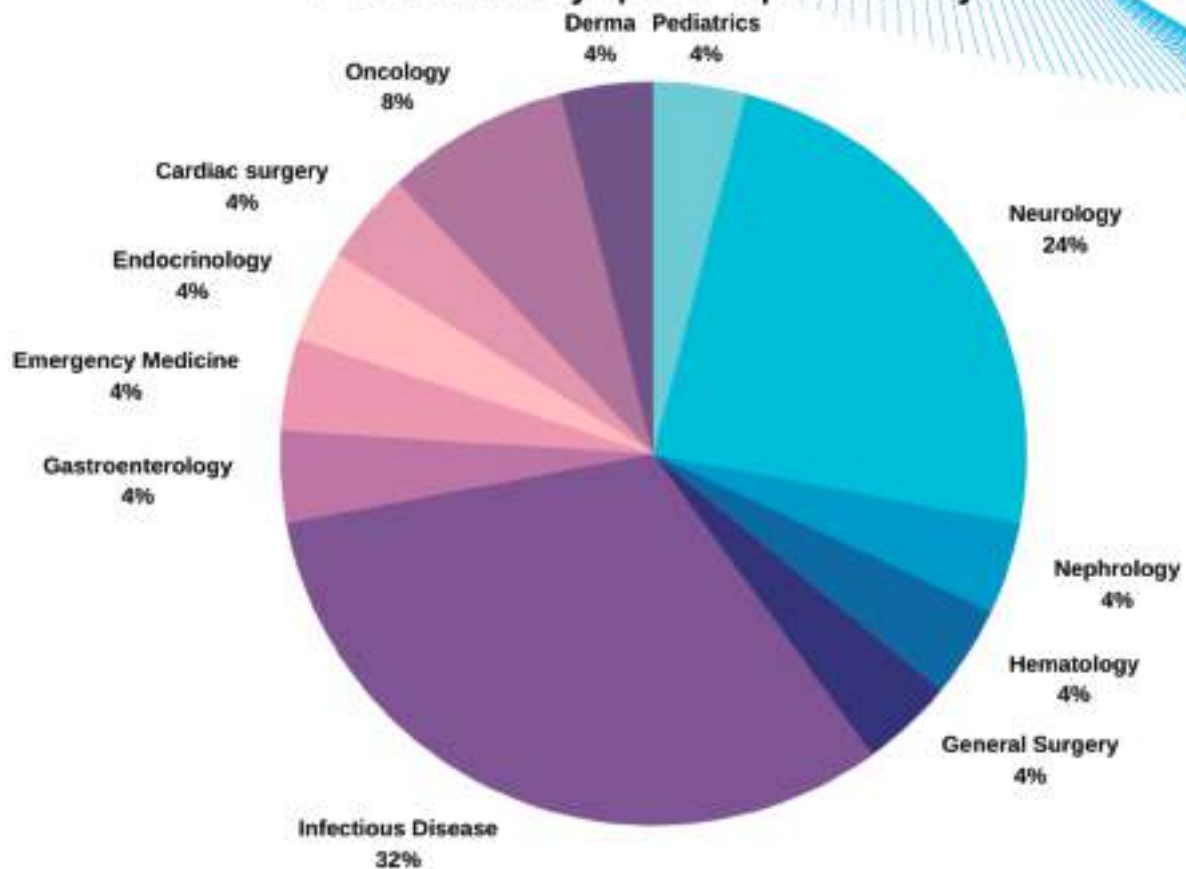
Protocols presented



Protocol rejection rationale



Feasibility per specialty



UPDATED SCRC POLICIES FOR 2022

Policy for MoU

Policy for Third party vendors

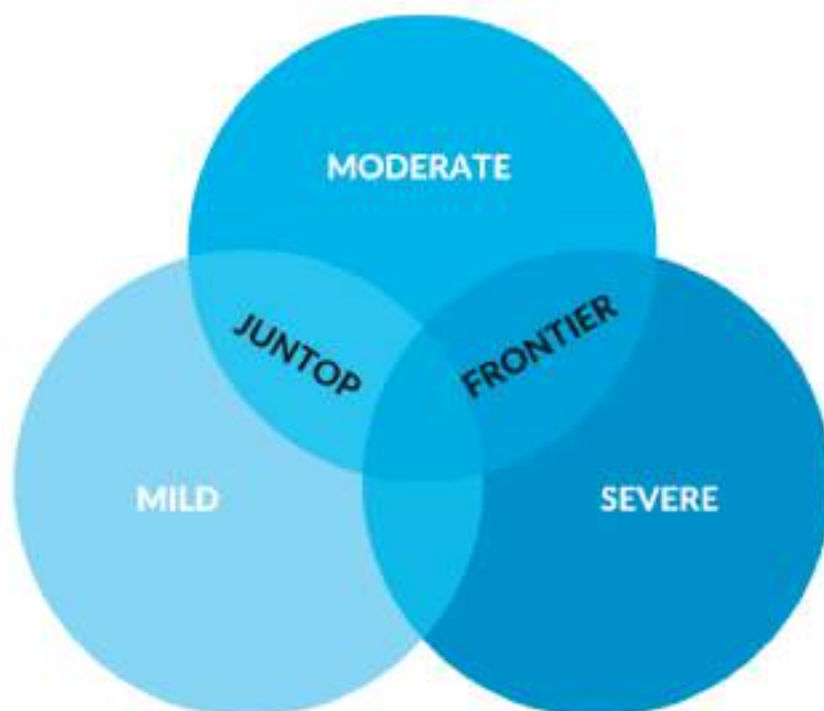
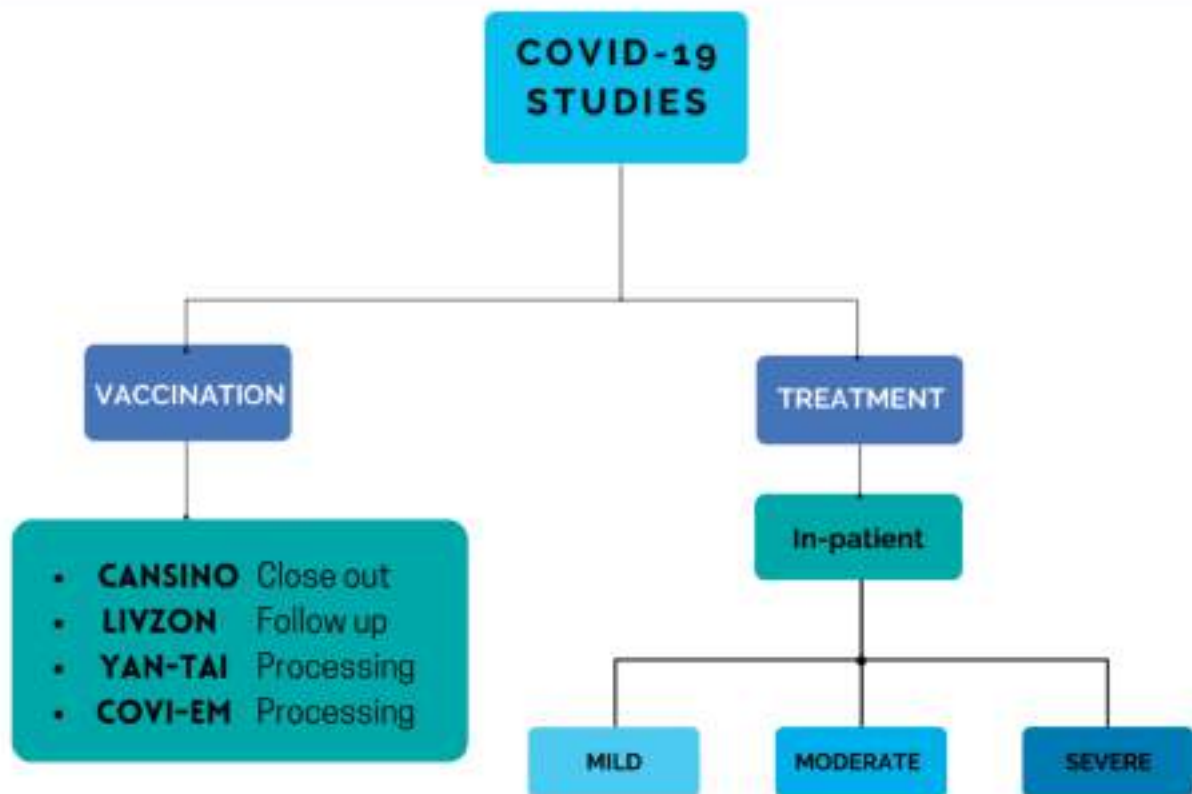
Policy for Co-PI

Policy for feasibility studies

Policy for SCRC staff involvement as contributors

TRIAL BREAKDOWN

COVID-19



SCRC CLINICAL TRIAL DASHBOARD

CLOSEOUT PHASE						
Trial Name	Trial Intervention	Outcomes	Sponsor	Principal Investigator	Current Status	Total Recruitment
Cansino	Adenovirus COVID-19 vaccine in healthy volunteers	Adverse events COVID-19 illness	Cansino Biologics, China	Dr. Ejaz Khan	CLOSED OUT (Sep 2020-Nov 2022)	5485
POISE-3	IV Transamine during general surgery	Peroperative myocardial ischemia Cardiovascular outcomes	Population Health Research Institute, Canada	Dr. M. Amir	CLOSED OUT (Feb 2019-Jul 2022)	92
FOLLOWUP PHASE						
Trial Name	Trial Intervention	Outcomes	Sponsor	Principal Investigator	Current Status	Total Recruitment
LIVZON	Fusion protein COVID-19 vaccine for healthy volunteers	COVID-19 illness	Livzon Mabpham, China	Dr. Anjad Sohal	End of study phase	2003
ACTIVE 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	Actively recruiting since November 2022	44
COP-AF	Colchicine to thoracic surgery patients	Atrial Fibrillation	Population Health Research Institute, Canada	Dr. M. Amir	Actively recruiting since April 2021	18

CONTINUED

TRIALS IN PIPELINE							
Trial Name	Trial Intervention	Outcomes	Sponsor	Principal Investigator	Current Status	Pending issues	
Melanoma	Pembrolizumab bio similar for unresectable metastatic melanoma	Overall response rate	BIOCAD, Russia	Dr. Saad Ghazi		Submitted to DRAP on 23-DEC-2022	
Gates MRI-301	Probiotic nutritional supplement formula (Bi-26) for underweight infants	Change in weight	Bill and Melinda Gates Research Institute, USA	Dr. Munir Malik			
JUNTOP	Oral COVID-19 (remdesivir analog) treatment for stable outpatients	COVID-19 illness	Junshi Medical, China	Dr. Naveed Rashid		To be submitted to DRAP by CRO	
SCORPIO	Oral COVID-19 treatment for stable outpatients	COVID-19 illness	NIH, USA	Dr. Ejaz Khan		To be submitted to DRAP by CRO	
ALVOEYE	Aflibercept (Eyvea) bio similar intravitreal injection for wet AMD	Change in Visual Acuity	Alvotect, Germany	Dr. Amer Awan		Recruitment to begin soon	
DEPOSITION	IV vs Intra-pericardial Transamine during cardiac surgery	Post operative ischemia and seizures	Population Health Research Institute, Canada	Dr. Asghar Nawar		Submitted to DRAP on: 15/NOV/2022	
ASPIRE-AF	Eivaroxaban and Apixaban to prevent atrial fibrillation after general surgery	Atrial fibrillation and Stroke	Population Health Research Institute, Canada	Dr. Saeedullah Shah		Issue regarding pharmaceutical documents (resolving)	
HIP-ATTACK2	Accelerated orthopaedic surgery vs standard of care in hip fracture patients with myocardial injury	Post operative ischemia	Population Health Research Institute, Canada	Dr. Amer Nabi Nur		DRAP submission later this week	

CLINICAL TRIAL APPRAISAL COMMITTEE AND DATA SAFETY MONITORING BOARD

2022


CTAC:

A committee consisting of administrative heads who vet the logistical, administrative and financial viability of clinical trials.

DSMB:

An independent data monitoring committee that oversees all human subject research especially adherence to protocol and subject safety.



 CTAC meeting

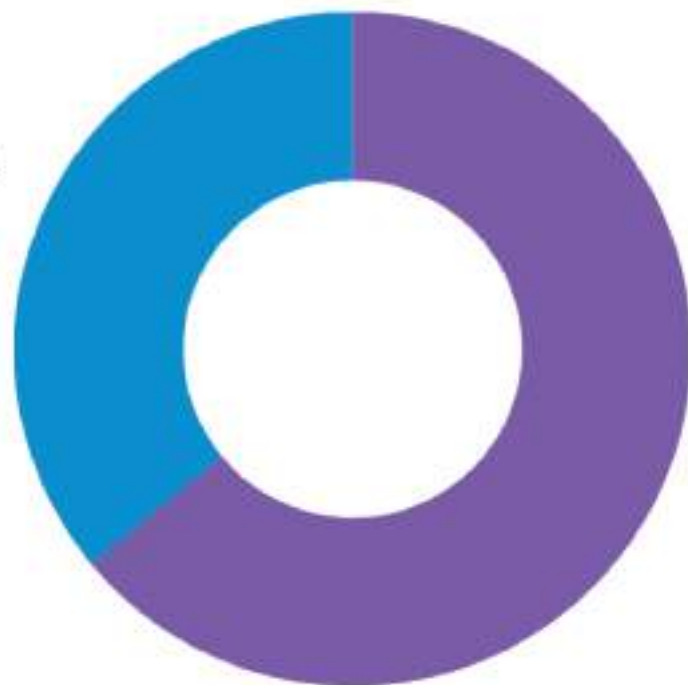
 DSMB meeting

RESEARCH TRAVEL GRANTS EVALUATED BY SCRC

Research Travel
Grants presented
to SCRC in 2022
Total Travel
grants= 25

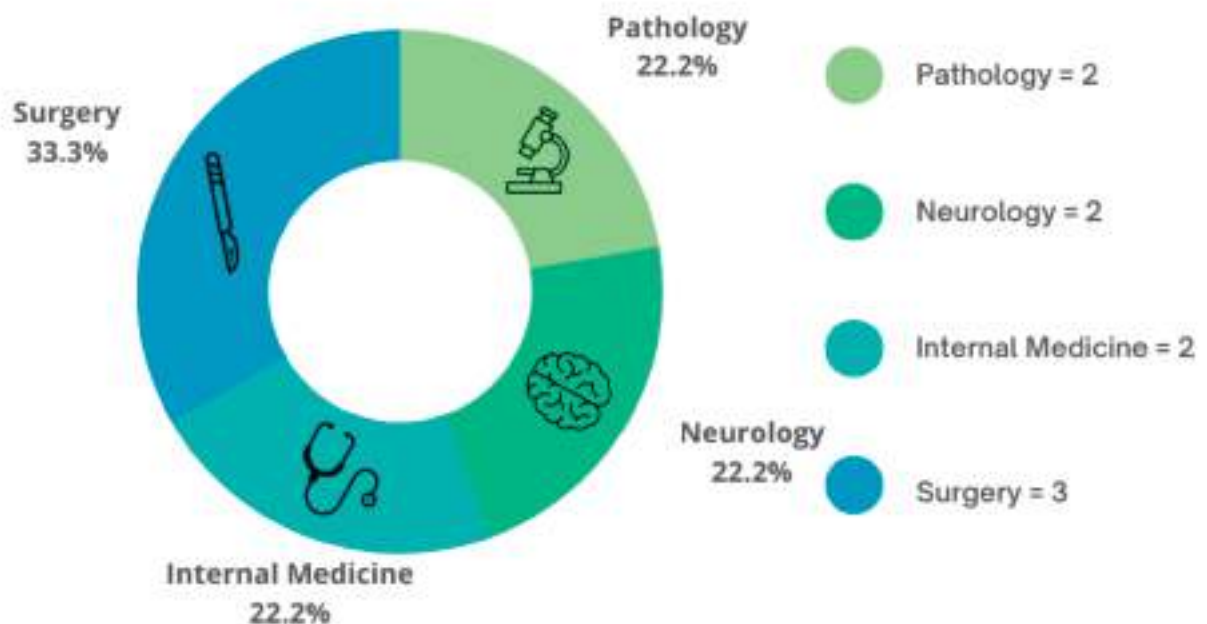


Rejected
36%



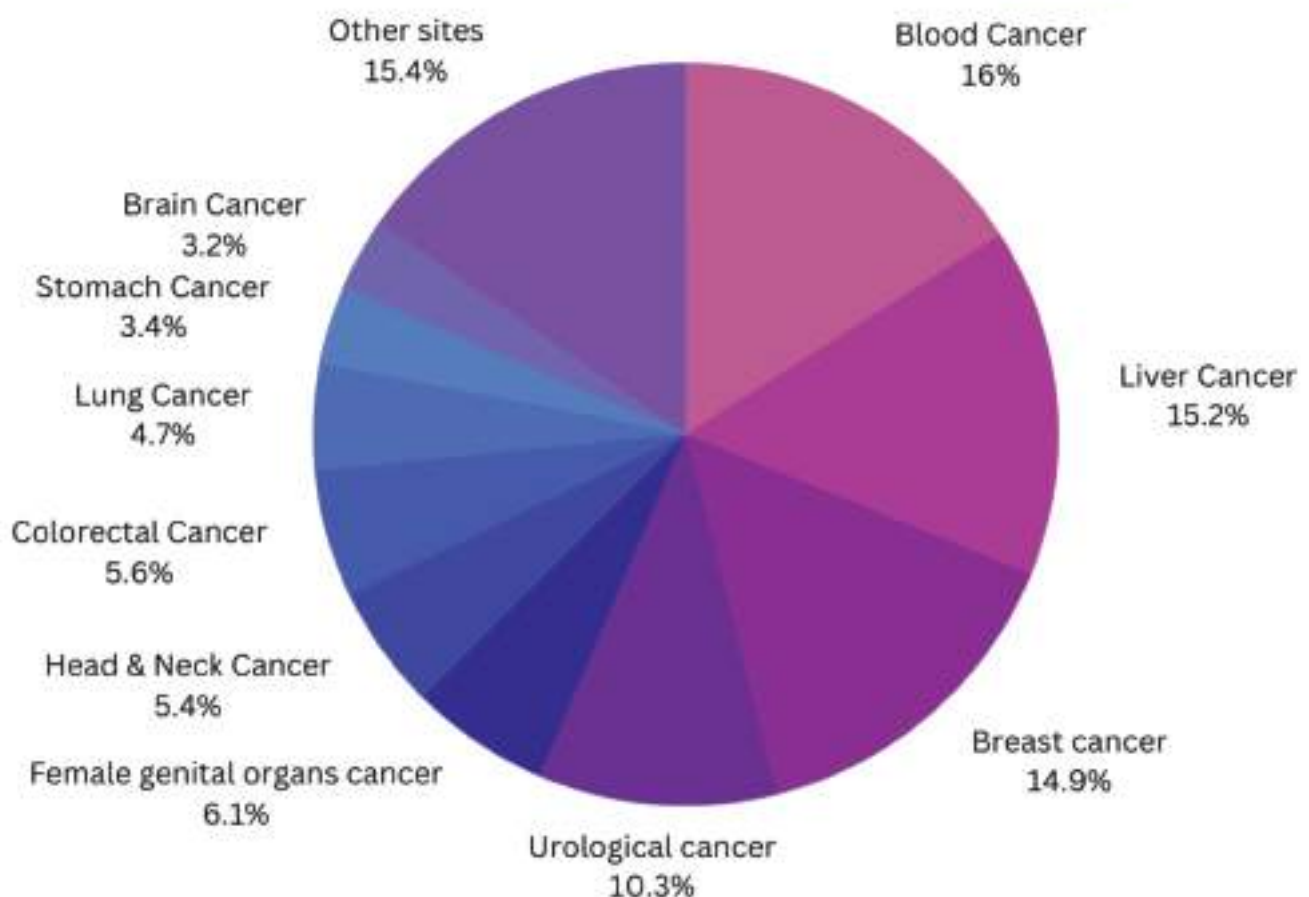
Approved
64%

Grant approval by Department



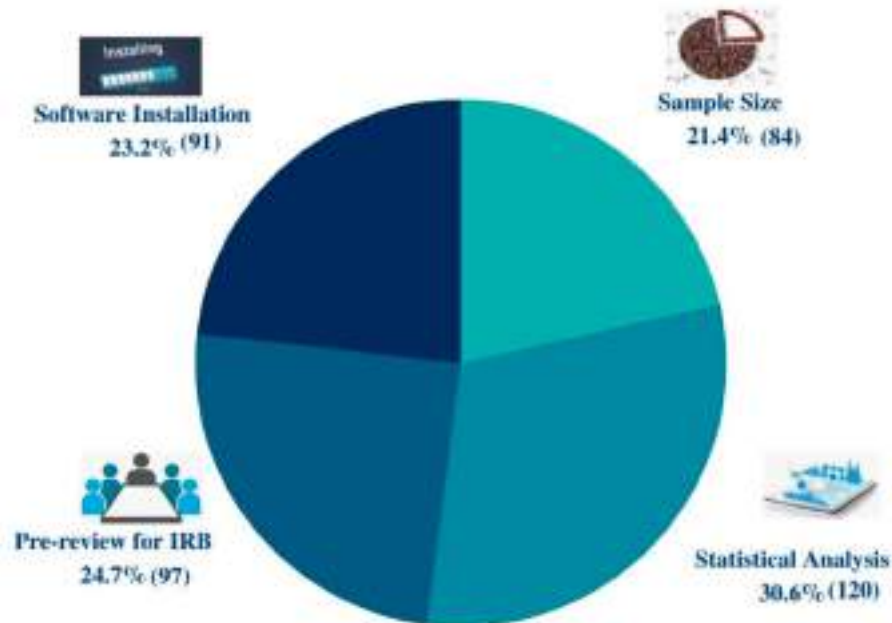
SHIFA INTERNATIONAL HOSPITAL CANCER REGISTRY

Shifa Clinical Research Center launched their first cancer registry report comprised of 3 years of cancer data (n = 8988) from 2018 to 2020, which includes basic demographics, TNM stage, grade, cancer family history, and treatment.



SCRC BIOSTATISTICS

Facilitations



SCRC PUBLICATIONS

UPDATE

Tranexamic acid for acute gastrointestinal bleeding (the HALT-IT trial): statistical analysis plan for an international, randomised, double-blind, placebo-controlled trial

Anthony Brenner^{1*}, Adefemi Afolabi², Syed Masroor Ahmad³, Monica Kuzick⁴, Ian Gilmore⁵, Christopher Hawkey⁶, Vipul Jha⁷, Muhammad Arif Hadeem¹², Haleema Shakur¹³, and HALT-IT Trial Collaborators

ORIGINAL RESEARCH | VOLUME 394, P237-246, SEPTEMBER 01, 2017

Safety and tolerability of subcutaneous trastuzumab treatment of human epidermal growth factor receptor 2-positive breast cancer: SafeHer phase III study's primary analysis

Beyhan Ataseven¹, Mark Verrill², Xinyi Pi³, and Xinyi Pi on behalf of the SafeHer Investigators

ESMO

EUROPEAN SOCIETY FOR
MEDICAL ONCOLOGY

ORIGINAL ARTICLE

Final results from the PERUSE study of first-line pertuzumab plus trastuzumab plus a taxane for HER2-positive locally recurrent or metastatic breast cancer, with a multivariable prognostic approach

D. Miles^{1,2}, E. Ciruelos^{1,3}, A. Schneeweiss⁴, F. Puglisi^{5,6}, T. Peretz-Yabfonski⁷, H. Erilhami⁸, S. Paluch-Shimon^{9,10}, A. Wardley^{11,12,13}, J.-L. Merot¹⁴, P. Trask¹⁵, D. Klingbiel¹⁶ & T. Bachelot¹⁷, on behalf of the PERUSE investigators

THE LANCET

ARTICLES | VOLUME 395, ISSUE 10225, P698-708, FEBRUARY 25, 2020

Accelerated surgery versus standard care in hip fracture (HIP ATTACK): an international, randomised, controlled trial

the HIP ATTACK Investigators¹ • Show all authors

THE LANCET

ARTICLES | VOLUME 394, ISSUE 10216, P1713-1723, NOVEMBER 04, 2019

Effects of tranexamic acid on death, disability, vascular morbidity and blood transfusion in patients with acute traumatic intracranial haemorrhage: a randomised, placebo-controlled trial

JOURNAL ARTICLE

Adjuvant Subcutaneous Trastuzumab in HER2-Positive Early Breast Cancer: Subgroup Analysis of Safety and Active Medical Conditions and Weight in the SafeHer Phase III Study

Kyung Hae Jung¹, Beyhan Ataseven², Mark Verrill³, Xinyi Pi⁴, Nedal Al-Sakaff⁵, Sabine Lauer⁶, Mona Shing⁷, Joseph Glendon⁸, and SafeHer Investigators

The Oncologist, Volume 23, Issue 10, October 2018, P1000-1007

ONCOLOGY

THE LANCET

ARTICLES | VOLUME 395, ISSUE 10221, P1073-1081, JANUARY 11, 2020

Final efficacy analysis, interim safety analysis, and dose of recombinant novel coronavirus vaccine in adults 18 years and older: an international, multicentre, randomised, placebo-controlled phase 3 trial

Prof Guillermo M Ruiz-Palacios^{1,2}, Prof Guillermo M Ruiz-Palacios, MD • et al. Show all authors

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

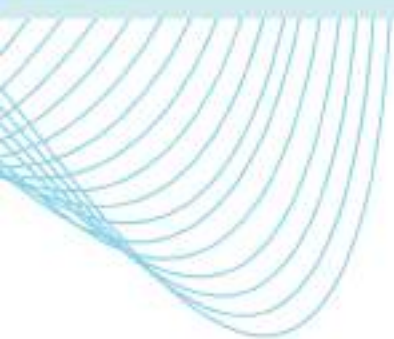
Maura Marcucci^{1,2,3*}, Thomas W. Painter^{4,5}, David Conen^{2,3}, Kate Leslie^{6,7}, Vladimir V. Lomivorotov^{8,9}, and POISE-3 Investigators



SCRC TEAM



Right to left: Maltha Aziz (Biostatistician), Sumaira Gulzar (Data Abstractor, Cancer Registry), Dr Sundus Dadan (Clinical Research Associate), Daniyal Sajid Khan (Research Coordinator), Muhammad Irfan (Office Assistant), Zafar Iqbal Armani (Tumor Registrar, Cancer Registry), Dr Muhammad Ayaz Mir (Director SCRC), Raja Waseem Akram (Research Pharmacist), Mehwish Rafique (Senior Biostatistician), Dr Tehreem Zahid (Clinical Research Associate) and Dr Palwasha Alavi (Clinical Research Associate).





Shifa
International
Hospitals Ltd.

