



Government of Pakistan  
Ministry of National Health Services, Regulations & Coordination  
**DRUG REGULATORY AUTHORITY OF PAKISTAN**  
TF Complex, Sector G-9/4, Islamabad  
\*\*\*\*\*

**“SAY NO TO CORRUPTION”**

Updated till: 09<sup>th</sup> April 2021.

**LIST OF APPROVED CLINICAL TRIALS / STUDIES,  
UNDER THE BIO-STUDY RULES 2017.**

S.No.	Registration No.	Clinical Studies	License Number	Clinical Trial Site	Status
01	CT-0001	Tranexamic Acid (TXA) For reducing postpartum bleeding in women with Anemia: An International, Randomized, Double Blind, Placebo Controlled Trial Women-II Trial	CTS-0001	Gynae Unit-I & II, Holy Family Hospital, Said Pur Road. Rawalpindi.	Approved. Dated 18 <sup>th</sup> July 2019.
			CTS-0005	Department of Gynae & Obstetrics, Benazir Bhutto Hospital, Rawalpindi.	
			CTS-0006	Gynae Section, Services Institute of Medical Sciences, Lahore.	
			CTS-0007	Department of Gynae & Obstetrics, Nishtar Medical University & Hospital, Multan.	
			CTS-0008	Department of Gynae & Obstetrics, Sir Ganga Ram Hospital, Fatima Jinnah Medical University, Lahore.	
			CTS-0009	Gynae Unit-II, Allama Iqbal Medical College, Jinnah Hospital, Lahore.	
			CTS-0010	Department of Gynae & Obstetrics, Pak-Emirates Military Hospital, Rawalpindi.	

			CTS-0011	Department of Gynae & Obs, Shaikh Zaid Women Hospital, Chandka Medical College, Shaheed Benazir Bhutto Medical University, Larkana.	
			CTS-0012	Department of Gynae & Obstetrics, Federal Govt Poly Clinic Hospital, Islamabad.	
			CTS-0013	Gynae Unit-I & II, Bahawal Victoria Hospital, Bahawalpur.	
			CTS-0014	MCH Unit-II, Pakistan Institute of Medical Sciences (PIMS), MCH Centre, Islamabad.	
			CTS-0015	Dow University of Health Sciences / Dr Ruth Km Pfau Civil Hospital, Karachi.	
			CTS-0016	Gynae Ward-09, Jinnah Postgraduate Medical Centre, Karachi.	
			CTS-0017	Gynae Unit-II, Aziz Bhatti Shaheed Teaching Hospital, Bhimbar Road Gujrat, Nawaz Sharif Medical College, University of Gujrat.	
			CTS-0023	Sandeman Provincial Hospital, Quetta.	
			CTS-0024	Department of Gynae & Obstetrics Bolan Medical Complex, Quetta.	
			CTS-0025	Department of Gynae & Obstetrics Ayub Medical Teaching Institution, Abbotabad.	
			CTS-0028	Gynae Section Koochi Goth Women Hospital, Karachi	
02	<b>CT-0002</b>	Lonafarnib / 100mg Ritonavir Bid With & Without 180mcg PEG IFN-Alfa-2a for 48 Weeks, Compared with PEG IFN-Alfa-2a Mono-therapy and Placebo Treatment in Patient Chronically Infected with Hepatitis Delta Virus Being Maintained on Anti-HBV Nucleos (T) Ide Therapy ( <b>D-LIVR</b> ).	CTS-0003	The Aga Khan University Hospital, Clinical Trial Unit (CTU) Karachi.	Approved. Dated 13 <sup>th</sup> November 2019.

03	<b>CT-0003</b>	An International, Multi-Centre Controlled Randomized Clinical Trial to Evaluate Rifampicin 1200 Mg and 1800 Mg Daily in the Reduction of Treatment Duration for Pulmonary Tuberculosis from 06 Months to 04 Months. <b>(Rifa-Shot)</b>	CTS-0003	The Aga Khan University Hospital, Clinical Trial Unit (CTU) Karachi.	Approved. Dated 12 <sup>th</sup> February 2020.
			CTS-0004	Shaukat Khanum Memorial Cancer Hospital, Lahore.	
04	<b>CT-0004</b>	Lactoferrin evaluation in anemia in pregnancy <b>(Leap-1)</b> – a multicounty randomized control clinical trial”,	CTS-0003	The Aga Khan University Hospital, Clinical Trial Unit (CTU) Karachi.	Approved. Dated 15 <sup>th</sup> April 2020.
05	<b>CT-0005</b>	<b>endTB</b> (Evaluating Newly Approved Drugs for Multidrug Resistant TB) Phase-III Clinical Trial, At the Indus Hospital Karachi,	CTS-0002	Ghauri Clinic of the Indus Hospital, Karachi.	Approved. Dated 10 <sup>th</sup> February 2020.
			CTS-0036	Institute of Chest Diseases Kotri, Jamshoro, Sindh, Pakistan. (CTS-0036), approval date 24th August 2020.	
06	<b>CT-0006</b>	<b>endTB-Q</b> Evaluating Newly Approved Drugs in Combination Regimens for Multi Drug- Resistant TB with Fluoroquinolone Resistance (Q) (EndTB-Q) Phase-III Clinical Trial, at the Indus Hospital Karachi.	CTS-0002	Ghauri Clinic of the Indus Hospital, Karachi.	Approved. Dated 10 <sup>th</sup> February 2020.
			CTS-0036	Institute of Chest Diseases Kotri, Jamshoro, Sindh, Pakistan. (CTS-0036), approval date 24th August 2020.	
07	<b>CT-0007</b>	Perioperative Ischemic Evaluation-3 (Poise-3)	CTS-0026	Shifa Clinical Research Center, Shifa International Hospital Ltd, Islamabad	Approved. Dated 12 <sup>th</sup> February 2020.
08	<b>CT-0008</b>	A Multi-Country, Multi-Center, Two Arm, Parallel, Double Blind, Placebo Controlled, Randomized Trial of Antenatal Corticosteroids (Dexamethasone) For Women at Risk of Imminent Birth in The	CTS-0030	Liaquat University Hospital, Jamshoro.	Approved. Dated 3 <sup>rd</sup> February 2020.
			CTS-0031	Sheikh Zaid Hospital, Raheem Yar Khan.	

		Early Pre-Term Period ( <b>Action – I Trial</b> ) And Late Pre-Term Period ( <b>Action – II Trial</b> ) In Health Facilities in Low-Resource Settings to Improve Newborn Outcomes			
09	<b>CT-0009</b>	Open-Label Study of Oral Ibrexafungerp (SCY-078) in Patients with Auris-SCY-078-Aga Khan Hospital-Phase-II CT	CTS-0003	The Aga Khan University Hospital, Clinical Trial Unit (CTU) Karachi.	Approved. Dated 27 <sup>th</sup> August 2020.
10	<b>CT-0010</b>	Observational Study Program Assessing Effectiveness and Tolerability of Gliclazide 60 mg Modified Release Tablet in patients with Type-II diabetes, fasting during Ramadan.	CTS-0018	Akram Medical Complex, Lahore.	Approved. Dated 12 <sup>th</sup> February 2020.
			CTS-0019	Diabetes Institute of Pakistan, Jail Road, Lahore.	
			CTS-0020	National Hospital and Medical Center, Lahore.	
			CTS-0021	Hayatabad Medical Complex (Medical Teaching Institute), Peshawar.	
			CTS-0027	Baqai Institute of Diabetes and Endocrinology, Karachi.	
11	<b>CT-0011</b>	Prevention of maternal and neonatal death/infections with a single oral dose of azithromycin in women in labor (in low & middle-income countries). A Randomized, Controlled Trial (A-PLUS)	CTS-0029	Gynae Department, Jinnah Postgraduate Medical Center (JPMC) Karachi.	Approved. Dated 12 <sup>th</sup> February 2020.
12	<b>CT-0012</b>	Heparin Anticoagulation to improve Outcomes in Septic Shock (HALO-Trial)	CTS-0032	The Indus Hospital, Karachi.	Approved. Dated 20 <sup>th</sup> February 2020.
			CTS-0033	Mayo Hospital, Lahore.	
			CTS-0034	Dow University of Health Sciences Karachi, (For two sub sites) i. Shaheed Mohtarma Benazir Bhutto Trauma Center, Karachi. ii. Medical Unit of Dr. Ruth K.M. Pfau, Civil Hospital, Karachi	
13	<b>CT-0013</b>	Colchicine for the Prevention of Perioperative Atrial Fibrillation in Patients Undergoing Thoracic Surgery" (COP-AF)	CTS-0026	Shifa Clinical Research Center, Shifa International Hospital Islamabad.	Approved. Dated 03 <sup>rd</sup> September 2020.

		Protocol No. 2017-001-COPAF.			
14	<b>CT-0014</b>	Open labelled randomized Phase-I / II Clinical Trial to assess the Safety & efficacy of Iodine Complex (Renessans)”	CTS-0037	M/s Lahore General Hospital, Post Graduate Medical Institute, Lahore	Approved. Dated 20 <sup>th</sup> October 2020.
15	<b>CT-0015</b>	APPLICATION FOR APPROVAL AND REGISTRATION OF CLINICAL TRIAL TITLED “PHASE-III, DOUBLE BLIND, PLACEBO-CONTROLLED, RANDOMIZED CLINICAL TRIAL OF RECOMBINENT NOVEL CORONA VIRUS VACCINE (ADENOVIRUS TYPE 5 VECTOR)” F.NO. 03-44/2020 DD (PS)	CTS-0003	Aga Khan University Hospital, Karachi.	Approved. Dated 24 <sup>th</sup> August 2020.
			CTS-0002	The Indus Hospital, Karachi.	
			CTS-0004	Shaukat Khanum Memorial Cancer & Research Hospital, Lahore.	
			CTS-0026	Shifa International Hospital, Islamabad.	
16	<b>CT-0016</b>	APPLICATION FOR APPROVAL OF CLINICAL TRIAL TITLED “RANDOMIZED, DOUBLE BLINDED, PARALLEL, PLACEBO CONTROLLED, PHASE-I CLINICAL TRIAL TO EVALUATE THE SAFETY & IMMUNOGENICITY OF INACTIVATED SARS-CoV-2 VACCINE IN HEALTHY POPULATION AGED 18 & ABOVE” F.No. 03-41/2020 DD (PS)	CTS-0002	The Indus Hospital, Karachi.	Approved. Dated 24 <sup>th</sup> August 2020.
17	<b>CT-0017</b>	Effect of Micronutrients and life Skills Education on the Health and Nutrition of Adolescent and young women in Pakistan.	CTS-0003	The Aga Khan University’s Matiari Research & Training Center, Matiari, Sindh,	Approved. Dated 24 <sup>th</sup> August 2020.
18	<b>CT-0018</b>	Capsule Endomicroscopy for visualization of the Small Intestine in EED (Environmental Enteric Dysfunction) population Pakistan.	CTS-0003	The Aga Khan University’s Matiari Research & Training Center, Matiari, Sindh,	Approved. Dated 28 <sup>th</sup> August 2020.
19	<b>CT-0019</b>	A Multicenter, Randomized, Double Blind, placebo Controlled, Phase-II Clinical Trial on The Effectiveness &	CTS-0002	The Indus Hospital, Karachi.	Approved. Dated 25 <sup>th</sup> August 2020.

		Safety of Jinhua Qinggan Granules (JHQQ) for the Treatment of COVID-19 patients			
20	<b>CT-0020</b>	Chloroquine/ Hydroxychloroquine Prevention of Coronavirus Disease (COVID-19) in the Healthcare Setting; a Randomized, Placebo controlled Prophylaxis Study (COPCOV)	CTS-0003	Aga Khan University Hospital, Karachi.	Approved. Dated 28 <sup>th</sup> August 2020.
21	<b>CT-0021</b>	Clinical evaluation of the Panbio™ COVID-19 Ag Antigen Test in Symptomatic Subjects (CATSS)	CTS-0003	Aga Khan University Hospital, Karachi.	Approved. Dated 27 <sup>th</sup> August 2020.
22	<b>CT-0022</b>	Immunoglobulin Therapy for Passive Immunization of Critically Ill Covid-19 Patients.	CTS-0040	M/s Dow University Hospital, Dow University of Health Sciences-Ojha Campus, Karachi	Approved. Dated 22 <sup>nd</sup> January 2021.
			CTS-0041	M/s Sindh Infectious Diseases Hospitat & Research center, Karachi	
23	<b>CT-0023</b>	A Phase III Randomized, Double Blind, Placebo Controlled Clinical Trial in 18 Years of Age and Above to Determine the Safety and Efficacy of ZF2001, A Recombinant Novel Corona Vaccine (CHO Cell) For Prevention of COVID-19.	CTS-0003	Aga Khan University Hospital, Karachi.	Approved. Dated 19 <sup>th</sup> March 2021.
			CTS-0002	The Indus Hospital, Karachi	
			CTS-0020	National Hospital & Medical Center, Lahore.	
			CTS-0004	Shaukat Khanum Memorial Cancer Hospital & Research Center, Lahore	

			CTS-0038	University of Health Sciences, Lahore.	
			CTS-0051	Chughtai Laboratory, Lahore.	
			CTS-0048	Abdul Waheed Trust, Avicenna Dental College, Lahore. AVECINNA	
			CTS-0049	Central Park Teaching Hospital, Lahore	
			CTS-0050	M/s Aziz Fatima Hospital, Faisalabad.	
			CTS-0044	M/s Al-Shifa Trust Research Center	
			CTS-0052	Clinical Assessment Unit, Examination Unit of M/s Shaheed Zulfiqar Ali Bhutto Medical University, Islamabad	
24	<b>CT-0024</b>	A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase-II Clinical Trial to Evaluate the Efficacy & Safety of CBP-307 in Subjects with Moderate to Severe Ulcerative Colitis (UC).	CTS-0003	Aga Khan University Hospital, Karachi.	Approved. Dated 17 <sup>th</sup> March 2021.
26	<b>CT-0026</b>	A Multicenter, Seamless, Blind clinical Trial to Evaluate the Safety	CTS-0003	Aga Khan University Hospital, Karachi.	Approved. Dated 31 <sup>st</sup> March

		& Efficacy of Meplazumab (Injection) In Addition to Standard Care for The Treatment of COVID-19 In Hospitalized Adults'			2021.
27	<b>CT-0027</b>	Open-Label Study to Evaluate the Efficacy and Safety of SCY-078 (Ibrexafungerp) in Patients with Fungal Diseases That Are Refractory to or Intolerant of Standard Antifungal Treatment (FURI).	CTS-0003	Aga Khan University Hospital, Karachi.	Approved. Dated 31 <sup>st</sup> March 2021.

\* errors and omissions excepted.



