

Ethics Committee Online Meeting held on 16-AUG-2023 at 03:00 PM IST in the DIRECTOR ROOM of RIO, KOLKATA

Following members were present in the meeting;

1. **Dr. Santanu Sen**
2. **Dr. Purban Ganguly**
3. **Dr. Lakshmi Kanta Mondal**
4. **Dr. Manab Nandi**
5. **Mr. Rajesh Arora**
6. **Ms. Mandabi Bhattacharrya**
7. **Mr. Rakesh Arora**
8. **Ms. Suparna Ray**

Determination of quorum- Quorum was complete with the presence of seven members.

Disclosure of Conflict of Interest: Chairman called for disclosure of Conflict of Interest (COI) in the protocols scheduled for deliberation in the meeting.

Reading and Approval of the minutes of the last meeting: The Chairperson presided over the discussion of the minutes of the meeting held on **16th August, 2023**. All members of the IEC approved the minutes.

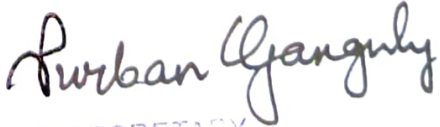
Sl No.	Agenda Item	Discussion	Action/Recommendation	Responsibility	Target Date	Remarks
1.	<p>Dr. Lakshmi Kanta Mondal Principal Investigator (RLS/OPT/2020/03) Professor Department of Ophthalmology Regional institute of Ophthalmology 88, College Street Kolkata- 700073 West Bengal, India</p> <p>Protocol Number.: RLS/OPT/2020/03; Version 2.0</p> <p>Protocol Title: A prospective, multi-center, single arm, open label, study to evaluate safety and efficacy of RanizuRel™ containing Ranibizumab for intra-vitreous injection manufactured by Reliance Life Sciences, Pvt. Ltd. India in patients with neovascular (wet)</p>	<p>Dr. Lakshmi Kanta Mondal presented this study in details in Power Point Slides before the members of Ethics Committee.</p>	<p>After detailed discussion, all the members present in the meeting unanimously APPROVED the study to perform in its presented form.</p>			APPROVED

	age-related macular degeneration.					
2.	<p>Dr. Lakshmi Kanta Mondal Principal Investigator (CUKG489C11N01) Professor Department of Ophthalmology Regional institute of Ophthalmology 88, College Street Kolkata- 700073 West Bengal, India</p> <p>Protocol Number: CUKG489C11N01; Version 1.0</p> <p>Protocol Title: A Non-randomized, Non-Interventional, Prospective, Multicenter, Post Marketing Surveillance Study to Assess the Antibacterial Effectiveness and Safety of 0.5% Moxifloxacin Hydrochloride Ophthalmic Solution in Perioperative (Preoperative and Postoperative) Sterilization in Patients Undergoing Ophthalmic Surgery.</p>	<p>Dr. Lakshmi Kanta Mondal presented this study in details in Power Point Slides before the members of Ethics Committee.</p>	<p>After detailed discussion, all the members present in the meeting unanimously APPROVED the study to perform in its presented form.</p>			<p>APPROVED</p>
3.	<p>Dr. Anindita Mandal Principal Investigator (ICR/21/021) Professor Department of Ophthalmology Regional institute of Ophthalmology 88, College Street Kolkata- 700073 West Bengal, India</p> <p>Protocol Number: ICR/21/021; Version 2.0</p> <p>Protocol Title: A Prospective, Multi-centre, Single-arm, Phase IV Study to Assess the Safety and Efficacy of</p>	<p>Dr. Anindita Mandal presented this study in details in Power Point</p>	<p>After detailed discussion, all the members present in the meeting unanimously APPROVED the study to perform in its presented form.</p>			<p>APPROVED</p>

	Cyclosporine 0.09% wv Ophthalmic Solution to Increase Tear Production in Patients with Keratoconjunctivitis Sicca (Dry Eye).	Slides before the members of Ethics Committee.				
4.	<p>Dr. Soumyadeep Majumdar Principal Investigator (0248-22) Assistant Professor Department of Ophthalmology Regional institute of Ophthalmology 88, College Street Kolkata- 700073 West Bengal, India</p> <p>Protocol Number: 0248-22; Version 1.0</p> <p>Protocol Title: A Prospective, Interventional, Single Arm, Multi-Centre, Phase 4 Study to Assess the Safety and Efficacy of Ranibizumab in Participants with Retinopathy of Prematurity.</p>	Dr. Soumyadeep Majumdar presented this study in details in Power Point Slides before the members of Ethics Committee.	After detailed discussion, all the members present in the meeting unanimously APPROVED the study to perform in its presented form.			APPROVED
5.	<p>Dr. Asim Kumar Ghosh Principal Investigator (ML43435) Director Department of Ophthalmology Regional institute of Ophthalmology 88, College Street Kolkata- 700073 West Bengal, India</p> <p>Protocol Number: ML43435; Version</p> <p>Protocol Title: A Phase IIIB, Multicenter, Open-Label, Single-Arm Study To Investigate Faricimab (Ro6867461) Treatment Response In Treatment-Naïve, Underrepresented Asian Indian Patients With Diabetic Macular</p>	Dr. Asim Kumar Ghosh presented this study in details in Power Point Slides before the members of Ethics Committee.	After detailed discussion, all the members present in the meeting unanimously APPROVED the study to perform in its presented form.			APPROVED

	Edema					
6.	<p>Dr. Ashis Majumdar Principal Investigator (BDOBDALK-01) Senior Resident Department of Ophthalmology Regional institute of Ophthalmology 88, College Street Kolkata- 700073 West Bengal, India</p> <p>Protocol Number: BDOBDALK-01</p> <p>Protocol Title: A Dual Perspective: Analyzing Big Bubble DALK and Diamond Burr Assisted Modified Manual DALK</p>	Not Presented	Need to be Present the Study in the Next EC Meeting.	PI should be present to place the study in the EC Meeting.	Next EC Meeting.	REJECTED due to unavailability of PI.
7.	<p>Dr. Ashis Majumdar Principal Investigator (DermoidALK-01) Senior Resident Department of Ophthalmology Regional institute of Ophthalmology 88, College Street Kolkata- 700073 West Bengal, India</p> <p>Protocol Number: DermoidALK-01</p> <p>Protocol Title: Enhancing Dermoid Excision with ALK: Diamond Burr Assisted Polishing and Donor Lenticule Implantation from Previous DSEK in Goldenhar Syndrome</p>	Not Presented	Need to be Present the Study in the Next EC Meeting.	PI should be present to place the study in the EC Meeting.	Next EC Meeting.	REJECTED due to unavailability of PI.

8.	<p>Dr. Ashis Majumdar Principal Investigator (KSHD-01) Senior Resident Department of Ophthalmology Regional institute of Ophthalmology 88, College Street Kolkata- 700073 West Bengal, India</p> <p>Protocol Number: KSHD-01</p> <p>Protocol Title: Hormonal Dysregulation and Its Impact on Keratoconus Severity: Unravelling the Complex Connection</p>	Not Presented	Need to be Present the Study in the Next EC Meeting.	PI should be present to place the study in the EC Meeting.	Next EC Meeting.	REJECTED due to unavailability of PI.
9.	<p>Dr. Ashis Majumdar Principal Investigator (PVDexEKC-01) Senior Resident Department of Ophthalmology Regional institute of Ophthalmology 88, College Street Kolkata- 700073</p> <p>Protocol Number: PVDexEKC-01</p> <p>Protocol Title: Comparative Analysis of Povidone Iodine (1.0%) with Dexamethasone (0.1%) versus Moxifloxacin (0.5%) with Dexamethasone (0.1%) for Treating Epidemic Keratoconjunctivitis</p>	Not Presented	Need to be Present the Study in the Next EC Meeting.	PI should be present to place the study in the EC Meeting.	Next EC Meeting.	REJECTED due to unavailability of PI.


 MEMBER SECRETARY
 ETHICS COMMITTEE
 R.I.O., KOLKATA-73