KERALA MEDICAL TECHNOLOGY CONSORTIUM (KMTC)

IN ASSOCIATION WITH

KERALA UNIVERSITY OF HEALTH SCIENCES(KUHS)

6TH

STAKEHOLDERS CONNECT MEET (SCM)

MAY 2023

SENATE HALL, KUHS, THRISSUR, KERALA

30TH MAY 2023

POST-MEET REPORT

12TH JUNE 2023

REPORT CONTENTS

1. INVITE, PROGRAM AGENDA & NOTE ON THEME

The 6th KMTC Stakeholders Connect Meet (SCM) was organized in close association with Kerala University of Health Sciences (KUHS) at their campus in Thrissur, Kerala on 30th May 2023. The theme of the SCM was selected as "NAVIGATING CLINICAL TRIALS FOR SUCCESSFUL DEVELOPMENT OF MEDICAL DEVICES / MEDICAL TECHNOLOGY".

The following Invite was sent out to the Kerala MedTech Ecosystem – across stakeholder groups like Research Institutions, Hospitals, Industry, Startups, Universities.

KERALA MEDICAL TECHNOLOGY CONSORTIUM (KMTC)

INVITATION TO THE

6TH KMTC STAKEHOLDER CONNECT MEET

ON TUESDAY, 30TH MAY 2023

AT KERALA UNIVERSITY OF HEALTH SCIENCES, THRISSUR

KMTC is excited to invite you to the 6th KMTC Stakeholder Connect Meet (SCM), which is being organized in association with Kerala University of Health Sciences (KUHS), at their campus in Thrissur on Tuesday, 30th May 2023, between 9:00 AM and 4:30 PM. The theme for the event has been chosen to be "**NAVIGATING CLINICAL TRIALS FOR SUCCESSFUL DEVELOPMENT OF MEDICAL DEVICES / MEDICAL TECHNOLOGY"**, because of the information asymmetry around it in Kerala's current context.

DATE	30TH MAY 2023 | 9:00 AM – 4:30 PM*
VENUE	SENATE HALL KERALA UNIVERSITY OF HEALTH SCIENCES, THRISSUR, KERALA [ON GOOGLE MAPS]
THEME	**NAVIGATING CLINICAL TRIALS FOR SUCCESSFUL DEVELOPMENT OF MEDICAL DEVICES / MEDICAL TECHNOLOGY**

*PLEASE NOTE THAT REGISTRATION WILL START AT 8:15 AM AT THE VENUE

Clinical Trials are an essential component of the Medical Technology (MedTech) or Medical Devices product development cycle, and they play a crucial role in ensuring that Medical Devices and Technologies are safe, effective, and meet regulatory requirements. However, navigating the clinical research process can be complex and challenging, particularly for entrepreneurs or small and mid-sized MedTech companies.

The Stakeholder Connect Meet aims to bring together stakeholders in the MedTech ecosystem in Kerala to discuss the latest trends, challenges, and opportunities in clinical research trials. Participants will have the

opportunity to hear from industry experts, share their experiences, and learn best practices for navigating the clinical research process. Some of the topics that will be covered include regulatory considerations, trial design, patient recruitment, data management, and ethical considerations.

Whether you are a startup, an established company, a researcher, or a regulator, this event will provide valuable insights and networking opportunities to help you successfully navigate the clinical research trials in the MedTech product development cycle. Don't miss this opportunity to connect with fellow stakeholders and learn from the best in the field!

For further information on the program, please refer to the attached Program Agenda

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The Government of Kerala is committed to transitioning the state's economy into a high value, knowledge-based economy. This is in alignment with Kerala's inherent advantages over other parts of the country, taking into consideration the rich natural resources, skilled talent, and some ground-breaking research institutions. The Govt recognizes the immense potential that has in an industry like Medical Devices, Medical Technology, which is an R&D intensive domain requiring specialized expertise and knowledge and has designated it a priority sunrise sector.

Kerala Medical Technology Consortium (KMTC) is a flagship endeavor of the Govt of Kerala, initiated in June 2022, to establish Kerala as the Top Medical Devices / Medical Technology Hub of India in the next decade. One of the key strategies identified early on to achieve this ambitious goal, is to bring together the existing ecosystem of industry, researchers, academia, startups, hospitals, regulators, policymakers, suppliers, distributors and Govt agencies, to meaningfully interact and exchange ideas and information, and to catalyze close clusters of partnerships & collaborations.

The Stakeholder Connect Meet (SCM) is a monthly ecosystem-building platform that is designed to bring all stakeholders in the Kerala MedTech Ecosystem together and is especially focused on connecting academia and research with industry. The KMTC SCM is a great opportunity for stakeholders to keep themselves updated on the latest developments in the ecosystem, find strategic partners and explore growth opportunities.

With close consultation with subject matter experts and partners in the Kerala MedTech Ecosystem, the following Program Agenda was finalised for the event and circulated.

KERALA MEDICAL TECHNOLOGY CONSORTIUM (KMTC)

6TH KMTC STAKEHOLDERS CONNECT MEET – MAY 2023

A unique interactive event that brings together all the stakeholders in the Medical Technology / Medical Devices space, including the industry; Research Institutions and Organizations; Healthcare Professionals, Healthcare Providers and Institutions; Entrepreneurs and Start-ups; Incubation & Acceleration Agencies; Universities & Colleges and the Government to promote collaboration, research, development and innovation in Medical Devices and Technology.

PROGRAM AGENDA

DATE	TUESDAY | 30TH MAY 2023 | 9:00 AM – 4:30 PM
VENUE	Senate Hall, KERALA UNIVERSITY OF HEALTH SCIENCES, THRISSUR, KERALA

THEME	**NAVIGATING CLINICAL TRIALS FOR SUCCESSFUL DEVELOPMENT OF MEDICAL DEVICES / MEDICAL TECHNOLOGY**

AGENDA		
TIME		PROGRAM / ACTIVITY
1.	8:30 – 9:00 AM	ARRIVAL OF PARTICIPANTS & **REGISTRATION**
2.	9:00 – 10:00 AM [60 Mins]	**INAUGURAL CEREMONY** ● KUHS Anthem ● Welcome Address – **Dr VIJAYAN C P**, PRO VICE CHANCELLOR, KERALA UNIVERSITY OF HEALTH SCIENCES (KUHS) ● Opening Address – Mr C PADMAKUMAR, SPECIAL OFFICER, KERALA MEDICAL TECHNOLOGY CONSORTIUM (KMTC) ● Presidential Address – **Prof. (Dr) MOHANAN KUNNUMMAL**, VICE CHANCELLOR, KERALA UNIVERSITY OF HEALTH SCIENCES (KUHS) ● Inaugural Address – **Dr RATHAN U KELKAR IAS**, SECRETARY (IT & HEALTH – MEDICAL EDUCATION), GOVT OF KERALA ● Felicitation – **Dr SHAJI K S,** DEAN (RESEARCH) & CONVENOR, INNOVATION CELL, KERALA UNIVERSITY OF HEALTH SCIENCES
3.	10:00 – 10:20 AM [20 Mins]	KERALA MEDTECH ECOSYSTEM – OBJECTIVES, ACTIVITIES AND UPDATES SESSION BY TEAM KMTC
4.	10:20-10:35 AM [15 mins]	TEA & REFRESHMENTS BREAK
5.	10:35 – 10:55 AM [20 Mins]	**INTRODUCTION TO CLINICAL TRIALS AND GUIDELINES – A CRO PERSPECTIVE** SESSION BY **ROSHAN STANLY**, MANAGER (CLINICAL DATA ANALYTICS), GENPRO RESEARCH
6.	10:55 – 11:15 AM [20 Mins]	**CLINICAL TRIALS & MEDICAL DEVICES DEVELOPMENT** SESSION BY **DR ANJU GOPAN,** MEDICAL DIRECTOR (ONCOLOGY)**,** IQVIA
7.	11:15 – 11:25 AM [10 Mins]	**REGIONAL CANCER CENTRE & CLINICAL RESEARCH** SESSION BY **Dr LAKSHMI S**, ADDITIONAL PROFESSOR, CANCER RESEARCH, REGIONAL CANCER CENTRE (RCC), THIRUVANANTHAPURAM

AGENDA		
TIME		PROGRAM / ACTIVITY
8.	11:25 AM – 12 NOON [35 Mins]	**ASK THE EXPERTS: CLINICAL TRIALS** INTERACTIVE QUERY HANDLING SESSION BY EXPERTS FROM REGULATORY, INDUSTRY, HEALTHCARE **Moderator: C PADMAKUMAR** ● **DR ANJU GOPAN,** MEDICAL DIRECTOR (ONCOLOGY)**,** IQVIA ● **PROF. (DR) RAJMOHAN V**, PROFESSOR, SCHOOL FOR PUBLIC HEALTH STUDIES, KERALA UNIVERSITY OF HEALTH SCIENCES (KUHS) ● **MR ANOOP S NAIR,** AUDITOR & ASSESSOR (MEDICAL & REGALATORY AFFAIRS)**,** DET NORDK VRTITSD (DNV) [QUERIES / QUESTIONS WILL BE COLLECTED BEFOREHAND FROM PARTICIPANTS, AND WILL TAKEN UP BY THE EXPERTS TO HELP]
9.	12 NOON – 1:10 PM [70 Mins]	**PRESENTATIONS ON RESEARCH ACTIVITIES AND CLINICAL TRIALS PARTNERSHIPS** ● AMALA INSTITUTE OF MEDICAL SCIENCES, THRISSUR ● INSTITUTE FOR COMMUNICATIVE & COGNITIVE NEUROSCIENCES (ICCONS), PALAKKAD ● INSTITUTE OF MENTAL HEALTH AND NEURO SCIENCES (IMHANS), KOZHIKODE ● MALABAR CANCER CENTRE, THALASSERY ● MALANKARA ORTHODOX SYRIAN CHURCH (MOSC) MEDICAL COLLEGE & HOSPITAL, KOLANCHERRY ● SCHOOL FOR FUNDAMENTAL RESEARCH IN AYURVEDA, KUHS ● SCHOOL FOR PUBLIC HEALTH STUDIES, KUHS ● SCHOOL FOR FAMILY HEALTH STUDIES, KUHS
10.	1:10 – 2 PM [50 Mins]	NETWORKING LUNCH BREAK
11.	2 – 2:40 PM [40 Mins]	**PRESENTATIONS ON RESEARCH ACTIVITIES RELATED TO HEALTHCARE / MEDTECH** ● SCHOOL OF NANOSCIENCES & MOLECULAR MEDICINE, AMRITA VISHWA VIDYAPEETHAM, KOCHI ● CENTER FOR MATERIALS FOR ELECTRONICS TECHNOLOGY (C-MET), THRISSUR ● NATIONAL INSTITUTE TECHNOLOGY (NIT) CALICUT, KOZHIKODE ● COCHIN UNIVERSITY OF SCIENCES & TECHNOLOGY (CUSAT), KOCHI ● CENTRE FOR DEVELOPMENT OF ADVANCED COMPUTING (CDAC), TRIVANDRUM
12.	2:40 – 3:30 PM [50 Mins]	**PANEL DISCUSSION WITH EXPERTS** **"PRACTICAL CHALLENGES IN CONDUCTING CLINICAL TRIALS"** MODERATED BY Dr **SATHEESAN B**, DIRECTOR, MALABAR CANCER CENTRE ● **Dr ABI SANTHOSH APRAM**, ASSOCIATE VICE PRESIDENT (R&D), HLL LIFECARE LIMITED ● **Dr ANJU GOPAN**, MEDICAL DIRECTOR (ONCOLOGY), IQVIA ● **Dr SUMA T K,** DIRECTOR, FILARIASIS RESEARCH UNIT, WHO CC FOR LYMPHATIC FILARIASIS MORBIDITY MANAGEMENT & DISABILITY PREVENTION (LF MMDP), KUHS / EX-PRINCIPAL, TD MEDICAL COLLEGE, ALAPPUZHA
13.	3:30 – 3:40 PM [10 Mins]	PARTICIPANTS FEEDBACK COLLECTION – THROUGH ONLINE FORM

AGENDA		
TIME		PROGRAM / ACTIVITY
14.	3:40 – 4:00 PM [20 Mins]	WRAPPING UP ● KEY TAKE-AWAYS OF THE DAY – **Mr C PADMAKUMAR**, SPECIAL OFFICER, KERALA MEDICAL TECHNOLOGY CONSORTIUM (KMTC) ● NATIONAL ANTHEM
15.	4:00 – 4:30 PM [30 Mins]	NETWORKING TEA & REFRESHMENTS

As basic, preliminary reading for the participants of the Meet, the following Note on the theme was included in the Program Agenda as well.

CLINICAL TRIALS FOR MEDICAL DEVICES IN INDIA

INTRODUCTION

Clinical Trials are an essential component of the MedTech product development cycle, and they play a crucial role in ensuring that Medical Devices and Technologies are safe, effective, and meet regulatory requirements. However, navigating the clinical trials process can be complex and challenging, particularly for researchers, innovators, entrepreneurs, and small and mid-sized MedTech companies. In this note, we will briefly look at what regulations say regarding Clinical Trials for Medical Devices / Medical Technology in India. We will also discuss some of the challenges and best practices for navigating clinical research trials in the MedTech product development cycle.

CLINICAL TRIALS ARE FOR CERTAIN MEDICAL DEVICES

Not all medical devices require clinical trials for sale in India. The Drugs Controller General of India (DCGI) has a list of medical devices that are exempt from clinical trials. These devices are considered to be low-risk and have a long history of safe use.

Here are some of the medical devices that require clinical trials in India:

- Implantable medical devices
- Devices that are used to diagnose or treat serious diseases
- Devices that are used to treat children
- Devices that are used to treat pregnant women
- Devices that are used to treat people with weakened immune systems

Clinical trials for medical devices in India are regulated by the Central Drugs Standard Control Organisation (CDSCO)under Directorate General of Health Services,Ministry of Health & Family Welfare,Government of India, which is the National Regulatory Authority (NRA) of India. The CDSCO has published a set of guidelines for conducting clinical trials of medical devices in India, which can be found on their website.

The following are some of the key requirements for conducting clinical trials of medical devices in India:

- The medical device must be approved by the CDSCO before it can be used in a clinical trial.
- The clinical trial must be conducted in accordance with the Good Clinical Practice (GCP) guidelines.
- The clinical trial must be registered with the CDSCO.
- The clinical trial must be conducted by a qualified investigator.

- The clinical trial must be approved by an ethics committee.

There are four phases of clinical trials for medical devices in India:

1. Phase 0 trials are early-phase trials that are conducted to assess the safety of a new medical device in a small group of healthy volunteers.
2. Phase 1 trials are conducted to assess the safety and pharmacokinetics of a new medical device in a small group of patients with the condition that the device is intended to treat.
3. Phase 2 trials are conducted to assess the efficacy and safety of a new medical device in a larger group of patients with the condition that the device is intended to treat.
4. Phase 3 trials are conducted to compare the efficacy and safety of a new medical device to the standard of care in a large group of patients with the condition that the device is intended to treat.

After a medical device has successfully completed clinical trials, it can be submitted to the CDSCO for regulatory approval. If the device is approved, it can be marketed and sold in India.

There are some of the key differences between clinical trials for medical devices and clinical trials for drugs:

- Clinical trials for medical devices are typically shorter than clinical trials for drugs.
- Clinical trials for medical devices typically involve fewer patients than clinical trials for drugs.
- Clinical trials for medical devices are typically less expensive than clinical trials for drugs.

CHALLENGES IN CONDUCTING CLINICAL TRIAL

1. One of the biggest challenges in conducting clinical trials is patient recruitment. It can be difficult to find enough eligible patients who are willing to participate in a clinical trial. In addition, patient recruitment can be time-consuming and costly, particularly for rare diseases or conditions.

2. Another challenge is trial design. Developing an appropriate trial design is critical to the success of a clinical trial. The trial design should be based on scientific and clinical principles, as well as regulatory requirements. The trial should also be designed to minimize the risk of bias and ensure that the results are reliable and valid.

3. Data management is another challenge in clinical trials. The data collected during a clinical trial must be accurate, complete, and secure. Data management systems should be designed to ensure that data is captured in a standardized manner, and that the data is accessible and understandable by all members of the research team.

4. Finally, ethical considerations are a significant challenge in clinical trials. Clinical trials must be conducted in an ethical manner, with respect for the dignity, rights, safety, and well-being of trial participants. This includes obtaining informed consent, ensuring confidentiality, and minimizing risks and harms.

BEST PRACTICES FOR CONDUCTING CLINICAL TRIALS

1. Patient recruitment: To address the challenge of patient recruitment, MedTech companies can collaborate with patient advocacy groups, healthcare providers, and social media to increase awareness about clinical trials. Companies can also use digital tools such as patient recruitment websites, mobile apps, and social media campaigns to reach potential participants.

2. Trial design: To ensure an appropriate trial design, companies can consult with experts in the field, including regulatory agencies, academic institutions, and Clinical Research Organizations (CROs). Companies can also conduct pilot studies to test the feasibility of the trial design and identify any potential problems.
3. Data management: To ensure accurate and secure data management, companies can use electronic data capture systems, which can reduce errors and increase efficiency. Companies can also ensure that data is stored securely and that access is limited to authorized personnel.
4. Ethical considerations: To address ethical considerations, companies should ensure that clinical trials are conducted in accordance with ethical principles, including the principles of autonomy, beneficence,

non-maleficence, and justice. Companies can also establish ethical review boards to ensure that the trial design and conduct is ethical.

2. ATTENDANCE & PARTICIPATION

A total of 100+ representatives participated in the SCM, with representation from all stakeholder groups. The Meet was successful in getting participants to interact with each other and discuss critical issues on the theme / topic.

Speakers & Resource Persons:

#	NAME	DESIGNATION & INSTITUITION
1	Mr Roshan Stanly	Manager (Clinical Data Analytics), GENPRO RESEARCH
2	Dr Anju Gopan	Medical Director (Oncology), IQVIA
3	Dr Lakshmi S	Additional Professor, Cancer Research, Regional Cancer Centre (RCC), Thiruvananthapuram
4	Dr Deepak Roshan V G	Assistant Professor Division of Genetics and Cytogenetics, MCC
5	Dr Anitha Ayyappan Pillai	Associate Professor, Dept. of Neurogenetics, ICCONS, Shornur
6	Ms Anusree A Kumar	Research Associate, Centre for Interdisciplinary Brain Sciences, IMHANS
7	Dr Sunu Lazar Cyriac	Associate Professor of Medical Oncology, Amala Institute of Medical Sciences
8	Dr Serah Johny	Assoc. Prof, Dept. of Pharmacology, Malankara Orthodox Syrian Church (MOSC) Medical College & Hospital, Kolencherry
9	Dr Sudhikumar K B	Professor, School for Fundamental Research in Ayurveda, KUHS
10	Dr Rajmohan V	Professor, School for Public Health Studies, KUHS
11	Dr Geetha Govindaraj	Professor, School for Family Health Studies, KUHS
12	Dr Raghu N	Director, Center for Materials for Electronics Technology(C-MET), Thrissur
13	Prof. (Dr) Manitha Nair	Senior Scientist, Amrita School of Nanosciences and Molecular Medicine, Amrita Vishwa Vidyapeetham, Kochi
14	Prof. (Dr) Deepthy Menon	Senior Scientist, Amrita School of Nanosciences and Molecular Medicine, Amrita Vishwa Vidyapeetham, Kochi
15	Dr Jayaraj P B	Asst. Professor, NIT, Kozhikode
16	Dr Sajeevan T P	Professor, Dept. of Marine Biology, CUSAT
17	Byju N B	Scientist E, CDAC, Thiruvananthapuram
18	Dr Satheesan B	Director, Malabar Cancer Centre, Thalassery
19	Dr Abi Santhosh Apram	Associate Vice President (R&D), HLL Lifecare Limited
20	Dr Suma T K	Director, Filariasis Research Unit, WHO Centre for Lymphatic Filariasis Morbidity Management & Disability Prevention

Other Participants

#	NAME	INSTITUTION
1	ADITHI VISWANATH	JDT Islam College of Pharmacy, Kozhikode
2	DR AISWARYA G	JDT ISLAM COLLEGE OF PHARMACY
3	AJMAL RAHMAN K K	Santhi College of Nursing, Omassery
4	DR. AMMU K SASI	Ahalia Ayurveda Medical College, Palakkad
5	DR ANOOP KUMAR N	School of Family Health Studies, Kerala University of Health Sciences
6	ANU MATHEW	Believers College of Nursing
7	ARCHANA K	Kerala University of Health Sciences
8	ASWATHY RAJA DS	Ruckmoni College of Nursing
9	BINCY K CHACKO	Pushpagiri College of Pharmacy

#	NAME	INSTITUTION
10	DR BINDU. B.R	Shree Viddhadhiraja Homoeopathic medical college
11	DR BINDU MOHANDAS	KMCT Medical College
12	CHRISTY ANTONY	St James College of nursing chalakudy
13	DEEPA GEORGE	Carmel College of Nursing Aluva
14	DR DEEPU GEORGE MATHEW	Annoor Dental College and Hospital
15	DIVYA. K	JDT ISLAM COLLEGE OF NURSING
16	DR. E.TAMIL JOTHI	Devaki Amma memorial college of pharmacy
17	DR FAIZAL CP	Kannur Dental College
18	FIAZ SHEMSHUDEE	Indira Gandhi Institute of Dental Sciences
19	GEETHU BABY	Malankara Orthodox Syrian Church College of Nursing, Kolenchery, Ernakulam
20	ISHA.S	MIMS College of Nursing, Malappuram
21	JAYAN JAMES	Holy Family College of Nursing, Thodupuzha
22	JESLIN MARY SH (SR)	Thiruhrudaya College of Nursing, Kottayam
23	DR JIKKU JOSE	Scire Science
24	JOSE THOMAS	Future3D
25	JOSEPH JOHNY	Sree Anjaneya Institute of Dental Sciences
26	DR JYOTHI P K	School of Fundamental Research in Ayurveda
27	PROF KISHORE P	Amala Institute of Medical Sciences
28	DR. LAKSHMI. S	HLL Lifecare Ltd
29	LEENA. L	Ruckmoni College of nursing, Vellarada
30	MADHUMITA RAJENDRAPRASAD	National Institute of Physical Medicine and Rehabilitation
31	DR MERCY PJ	Kerala University of Health sciences
32	DR.NILA MARY VARGHESE	ELIMS College of Pharmacy
33	P K RADHAKRISHNAN	SFO Technologies
34	DR.P.V.NANDINI	Vaidyaratnam Ayurveda College
35	PAMITHA ELIZABATH BABY	Si-met College of Nursing, Malampuzha
36	DR PRADEEP SAMUEL	Educare institute of dental sciences
37	PRESTHIENA LOFI EL	Kerala University of Health Sciences
38	R REJEESHKUMAR	BCF COLLEGE OF PHYSIOTHERAPY
39	RAVI SV	KMCT dental college
40	RIJU MATHEW	Believers Church Medical College Hospital, Thiruvalla
41	RINU DAVID	Amala college of nursing Thrissur
42	SAJITH KUMAR R	Govt Med College Kottayam
43	SANCY MARY SAM	Al azhar Medical College
44	DR SANDHYA K N	KUHS
45	DR SUMI PAUL	Jubilee Mission College of Nursing
46	SHABEESH BALAN	Institute of Mental Health and Neurosciences (IMHANS)
47	DR ANNE VARGHESE	MOSC Medical College, Kolenchery
48	SHEENA P	Seventh Day Adventist College of Nursing, Ottapalam
49	DR.SIMI MOHAN.J.S	Institute of Nursing Sciences and Research, Malabar Cancer Centre, Thalassery
50	SKARIAH KOSHY	MGM Muthoot college of Nursing, Kozhencherry
51	DR.SOJA S.L.	Govt.College of Nursing Kottayam
52	DR.SREEKANTH.K.S	Sree Gokulam Medical College and Research Foundation
53	DR.SREERAJ.S.K	School of Fundamental Research in Ayurveda-KUHS

#	NAME	INSTITUTION
54	SRUTHY K B	Kerala University of Health Sciences
55	DR. SUBASH CHANDRAN M P	Sree Krishna College of Pharmacy and Research Centre
56	SUBASH INDRA KUMAR C L	N.S Memorial College of Nursing (N113), Kollam
57	DR. SUPRIYA K	Govt. College of Nursing, Thrissur
58	DR T SENGOTTUVEL	Prime College of Pharmacy Palakkad
59	U.SOUNDARAPANDIAN	Santhigiri Siddha Medical College
60	USHAS JOSE	Nehru College of Nursing,Ottapalam
61	JINESH. P	SFO Technologies, Cochin
62	DR. ANJANA.R	Karkinos Healthcare
63	DR.MEERA KRISHNA	Terumo Penol Pvt. Ltd
64	ADDL.PROF. HARIHARAN S.	RCC Trivandrum
65	DR.SUDHIR PRAYAGA	Prayaga Scientific Laboratories
66	DR.SUBHADRA KT	KUHS
67	DEEPAK.R.U.	CDAC
68	AMARNATH.H	NAWE Robotics
69	DR. P. KRISHNAKUMAR	IMHANS
70	DR. BINULAL	AIMS
71	DHANYA P JACOB	CUSAT
72	MEENU MS	CUSAT
73	CHARLES ABRAHAM	GenPro
74	DR. K.S. RISHAD	Zygene Biotechnologies
75	S ANOOP	DNV
76	DR. DEEPU KRISHNAN	KSUM
77	DR.SN.POTTY	C-MET, Thrissur
78	DR.SAILAJA GS	CUSAT
79	DR. NV.JUDY	CUSAT
80	JEETHU JOSEPH	CUSAT

3. BRIEF SUMMARY OF THE MEET

INAUGURAL SESSION

The meet commenced at 9 AM with the Inaugural Ceremony, with the Inaugural Address delivered by Dr. Rathan U Kelkar, Secretary (IT and Medical Education), Govt of Kerala who appreciated the efforts being taken by KMTC and KUHS, and urged stakeholders to come together and share capabilities and partner for greater innovations in the MedTech sector in the state. The Welcome Address was given by Dr. Vijayan C P, Pro Vice Chancellor, KUHS, who welcomed dignitaries, speakers and participants for this first-ever Meet in KUHS on the intersection of Medical Technology and Clinical Trials. He went on to mention the University Innovation Cell initiative, which are also working in synergy to promote innovation in the Health space.

The Opening Address was delivered by Mr C Padmakumar, Special Officer, KMTC and pointed to the vibrant and existing Kerala MedTech ecosystem and the importance of improving communications and interactions between stakeholders. His address set the context for the one-day Meet and encouraged speakers and participants to explore opportunities for partnering and collaboration. The Inaugural Ceremony was presided over by Prof. (Dr) Mohanan Kunnummal, Vice Chancellor, KUHS and his address emphasized the importance of connecting all stakeholders and seizing the opportunity of the “unmet need” that India is, not just the growing market, highlighting the alarming number of deaths caused by the lack of high quality, affordable Medical Devices. He pointed out the need for Indian devices to meet international standards and gain the trust of our own healthcare professionals. While he recognized the journey of KUHS so far as a disseminator of knowledge, he underlined the commencement of the next phase of creation of knowledge. He referred to and lauded the effort to eliminate filariasis as a shining example of success and went on to emphasize the need for Assistive Technology in an ageing society that was Kerala’s context and would soon be a global need. Dr Kunnummal expressed confidence in the high skill level of the Indian workforce and referenced the significant cost difference in AIDS medication manufactured by Cipla for the world. Overall, the speech highlighted the need for improved healthcare products, knowledge creation, and addressing the challenges faced in the Indian healthcare industry.

The session ended with a Felicitation Address by Dr. Shaji K S, Dean (Research) and Convenor, Innovation Cell, KUHS who highlighted the efforts being taken by KUHS to inculcate and promote a culture of applied research among the students, researchers and faculty and welcoming more such collaborations with agencies like KMTC.

KMTC SESSION

The team of KMTC led the first session of the program outlining the goals and objectives of KMTC’s efforts, mapping out the Kerala MedTech ecosystem, along with updates on activities. Details on previous events and the feedback and suggestions received to improve the program were also shared.

SESSIONS ON CLINICAL TRIALS

1. Genpro’s Roshan Stanly, highlighted the key stages involved in Clinical Trials for the drug development and approval process, comparing and contrasting the same with Medical Devices development. The flow chart outlines the sequence of steps, starting from Discovery, followed by Development, FDA Review, and eventually Patient Access.
    - The Development stage is divided into Preclinical and Clinical phases. The Preclinical phase involves laboratory testing and animal studies to evaluate the safety and efficacy of the drug candidate before human trials.
    - Clinical Trials consists of four main phases:

- Phase 1 focuses primarily on assessing the safety of the drug in a small group of 15-30 participants.
- Phase 2 expands the study to a larger group of 100-300 individuals and evaluates both safety and efficacy.
- Phase 3 is a crucial stage that involves testing the drug on a larger scale, typically involving thousands of participants, to further assess its efficacy, safety, and potential side effects.
- Phase 4, known as Post-Marketing Surveillance (PMS), occurs after the drug has been approved and made available to the general public. This phase involves monitoring the drug's safety and effectiveness in a real-world setting, gathering additional data and addressing any emerging issues.

In summary, the session provides an overview of the drug development process, emphasizing the importance of various phases such as safety assessment (Phase 1), efficacy evaluation (Phase 2), large-scale testing (Phase 3), and post-approval monitoring (Phase 4).

2. Dr Anju Gopan's (Medical Director (Oncology, Haematology, Medical and Science Strategy – Asia at IQVIA) session titled "Clinical Trials and medical Devices Development" provided a solid foundation for all participants, with some insightful take-aways.
   - The session covered various aspects of the clinical trial process and related considerations.
     - Clinical Trials can be categorized as interventional, technology-enabled, or involving in vitro diagnostics (IVD). These trials often require an additional risk mitigation plan to ensure participant safety and trial integrity.
   - Pilot studies serve as exploratory or feasibility assessments before proceeding to pivotal trials. Pivotal trials focus on evaluating both safety and efficacy and typically involve a larger group of 100-300 participants.
   - Post-Marketing Surveillance (PMS) is an essential phase that follows the approval of a medical product. It involves monitoring the product's safety and effectiveness in real-world settings.
   - The reporting of Serious Adverse Events (SAEs) is mandatory in clinical trials, even if they are unrelated to the intervention being studied. In the European Union (EU), inspections can occur unannounced, unlike in the United States.
   - Taiwan and China are recognized as clinical trial hubs, along with Australia, which specifically excels in Phase 1 trials. Software as Medical Device (SaMD) is a growing area in the field of Medical Technology.
   - The reliance on imports accounts for approximately 70% of medical devices used in clinical trials. The development process for complex medical devices can be time-consuming due to regulatory requirements and other challenges.

   In summary, the session touched upon the categorization of clinical trials, risk mitigation, pilot and pivotal studies, post-marketing surveillance, reporting of SAEs, regional differences in inspections, clinical trial hubs, SaMD, import reliance, and the complexities involved in medical device development.

ASK THE EXPERTS PANEL

It was discussed by the experts how DSIR Certification individual institutions for funding; clinical trials IEC registration with DHR; clinical trials through CRO registered with CDSCO

The session was moderated by Mr C Padmakumar, Special Officer, KMTC and the experts on the panel were Dr Anju Gopan (IQVIA), Prof Rajmohan V (KUHS) and Mr Anoop S Nair (DNV).

A total of 57 queries were received from the registered delegates ahead of the event. These were screened by KMTC and a few questions were selected broadly covering the following points:

1. Regarding approvals related to clinical trials
2. Clarifications related to single, double- and triple-blind studies
3. Legal and ethical issues around clinical trials
4. Funding related to clinical trials

In addition, there were questions from the audience during the session. which were answered by the experts.

PRESENTATIONS BY HOSPITALS, HEALTHCARE RESEARCH INSTITUTIONS

Various hospitals (Amala, IMHANS, ICCONS, MOSC) presented information on their relevant departments and associated research being conducted in various departments and faculties. Some also presented their ongoing clinical trials. The thrust areas of research included oncology, cognitive and neurosciences, public and family health. The presenters were able to provide an overview of the teams and facilities at their institutions and conveyed their openness to partner and collaborate with other stakeholders for the benefit of the research projects.

#	NAME OF PRESENTER / SPEAKER	DESIGNATION OF PRESENTER / SPEAKER	INSTITUTION / ORGANIZATION
1.	Dr Lakshmi S	Additional Professor, Cancer Research	Regional Cancer Centre (RCC), Thiruvananthapuram
2.	Dr Deepak Roshan V G	Assistant Professor, Division of Genetics and Cytogenetics	Malabar Cancer Centre (MCC), Thalassery
3.	Dr Anitha Ayyappan Pillai	Associate Professor, Dept. of Neurogenetics	Institute for Communicative and Cognitive Neuro Sciences (ICCONS), Shornur
4.	Anusree A Kumar	Research Associate, Centre for Interdisciplinary Brain Sciences	Institute of Mental Health and Neuro Sciences (IMHANS), Kozhikode
5.	Dr Sunu Lazar Cyriac	Associate Professor of Medical Oncology	Amala Institute of Medical Sciences
6.	Dr Serah Johny	Associate Professor, Dept of Pharmacology	Malankara Orthodox Syrian Church (MOSC) Medical College & Hospital, Kolancherry
7.	Dr Sudhikumar K B	Professor, School for Fundamental Research in Ayurveda	Kerala University of Health Sciences (KUHS)
8.	Dr Rajmohan V	Professor, School for Public Health Studies	Kerala University of Health Sciences (KUHS)
9.	Dr Geetha Govindaraj	Professor, School for Family Health Studies	Kerala University of Health Sciences (KUHS)

PRESENTATIONS BY ENGINEERING, TECHNOLOGY RESEARCH AND APPLIED RESEARCH INSTITUTIONS

Multiple institutions presented the ongoing projects related to biomaterials, biomedical devices, diagnostics and other solutions in various health areas like oncology, neurology, cognitive sciences, nano sciences, health technology etc.

#	NAME OF PRESENTER / SPEAKER	DESIGNATION OF PRESENTER / SPEAKER	INSTITUTION / ORGANIZATION
1.	Prof. Deepthy Menon	Senior Scientist	Amrita School of Nanosciences and Molecular Medicine, Amrita Vishwa Vidyapeetham, Kochi
2.	Dr Raghu N	Director	Centre for Materials for Electronics Technology (C-MET), Athani
3.	Dr Jayaraj P B	Asst Professor	National Institute of Technology Calicut (NIT-C), Kozhikode
4.	Dr Sajeevan T P	Professor, Dept of Marine Biology	Cochin University of Science & Technology (CUSAT)
5.	Byju N B	Scientist E	Centre for Development of Advanced Computing (CDAC), Thiruvananthapuram

[MORE INFORMATION AVAILABLE ON REQUEST. PLEASE GET IN TOUCH WITH KMTC (Binchu Samuel at binchusamuel.kmtc@gmail.com or Rojini A R at rojini.kmtc@gmail.com) IF YOU ARE INTERESTED IN MORE DETAILS ON ANY PRESENTATION OR WANT TO GET IN TOUCH WITH THE INSTITUTION.]

PANEL DISCUSSION

The panel discussion was moderated by Dr Satheesan B, Director, Malabar Cancer Centre, Thalassery on the topic of "Practical Challenges in Conducting Clinical Trials" with panellists Dr Abi Santhosh Apram, Associate Vice President (R&D), HLL Lifecare Limited, Dr Anju Gopan, Medical Director (Oncology), IQVIA and Dr Suma T K, Filariasis Research Unit, WHO CC for Lymphatic Filariasis Morbidity Management & Disability Prevention (LFMMDP), KUHS. All the panellists provided their perspectives on issues as well as best practices.

The key take aways from the panel discussion were as follows:

- CULTURE OF RESEARCH: There is serious lack of a culture of research in most public and private healthcare institutions where it is seen as a time and cost intensive exercise. It was also pointed out that there are no incentives, financial or qualitative, for taking up such Clinical Trials and Research.

- ADEQUATE TIME & RESOURCES: Clinicians do not have adequate time or resources for research – between Academic responsibilities, Patient Care, Administrative responsibilities and then Research – clinicians find it hard to prioritise Research especially in the absence of support system and requisite infrastructure. A suggestion was made to dedicate / budget time for research for the clinicians who are interested.

- LACK OF A TRAINED SUPPORT SYSTEM: A clinical trial involves a lot of activities outside the general day-to-day functioning of most clinicians. Therefore, a sophisticated support system consisting of

trained manpower specifically in the areas of Scientific Writing, Biostatistics and Data Management. Clinicians are not trained in these areas either, where some learning can be drawn from CMC Vellore and Tata Memorial Hospital, Bombay where such training is imparted to all clinicians.

- RELUCTANCE OF DOCTORS: Doctors are reluctant to undertake clinical trials due to various reasons – the lack of continuity caused by frequent transfers (projects get stalled mid-way, or become non-starters), perception of having to work with "unethical, Big Bad Pharma". This reluctance to get into research can also be attributed to their lack of holistic understanding of how to do clinical trials, the requirement of extensive facilities and teams, as well as time required, knowledge of regulations and to rightly choose the trials.

- NEGATIVE PUBLIC PERCEPTIONS: Public perception is a major concern as the negative perception stems from ill-informed perspectives about the safety, risks and benefits of Clinical Trials. The sensationalist Media adds to the distortion / exaggeration of mishaps, without getting to the factual root cause of incidents.

- REGULATPORY COMPLEXITIES AND TIMELINE: The process for regulatory and institutional approvals for proposing and conducting Clinical Trials is another hurdle, and thus time periods are also unpredictable.

- PATIENT DATA PROTECTION & MANAGEMENT: there lies enormous amounts of data in healthcare institutions and there they have no clear policy for utilizing this for the benefit of patients in a secure and privacy-preserving way. In Clinical Trials, Data Protection & Management is quite critical, as the panel pointed out, and the ownership of this data and prevention of abuse of this data are some things each institution must take steps to resolve.

- EDUCATING CLINICIANS: It was discussed how the culture and mindset of clinicians could be influenced to help ensure that more research happens within healthcare institutions and they are open to conducting and taking up more Clinical Trials – young medicos and nursing students are the best candidates to be trained on specific topics related to research and clinical trials.

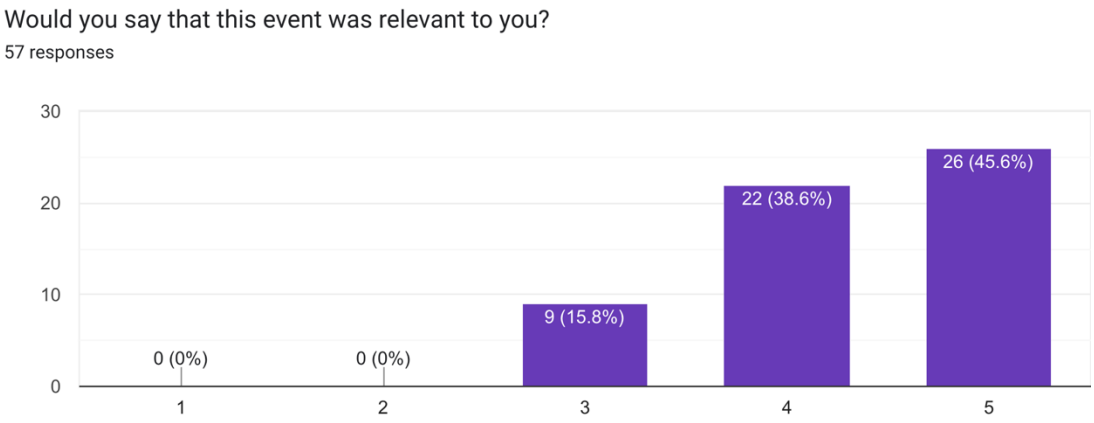
4. MEET FEEDBACK FROM DELEGATES

Feedback was collected from participants via an online form, towards the end of the Meet with a few questions for quantitative measure of the relevance, quality and the overall event and some for qualitative feedback and suggestions.

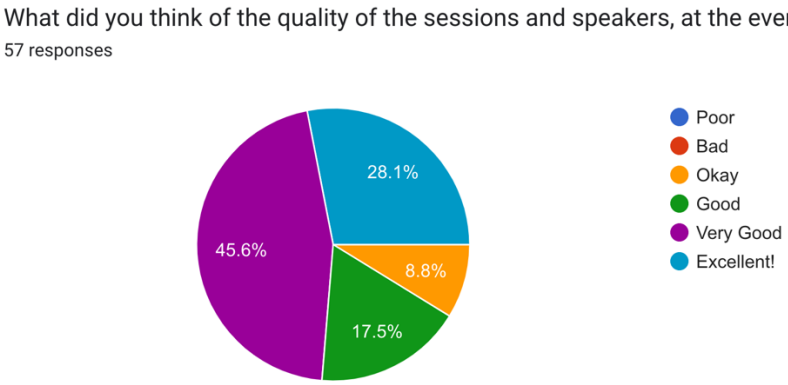
OBJECTIVE FEEDBACK

Here are the graph visualizations for the quantitative feedback collected from participants. A total of 57 participants responded to the feedback survey.

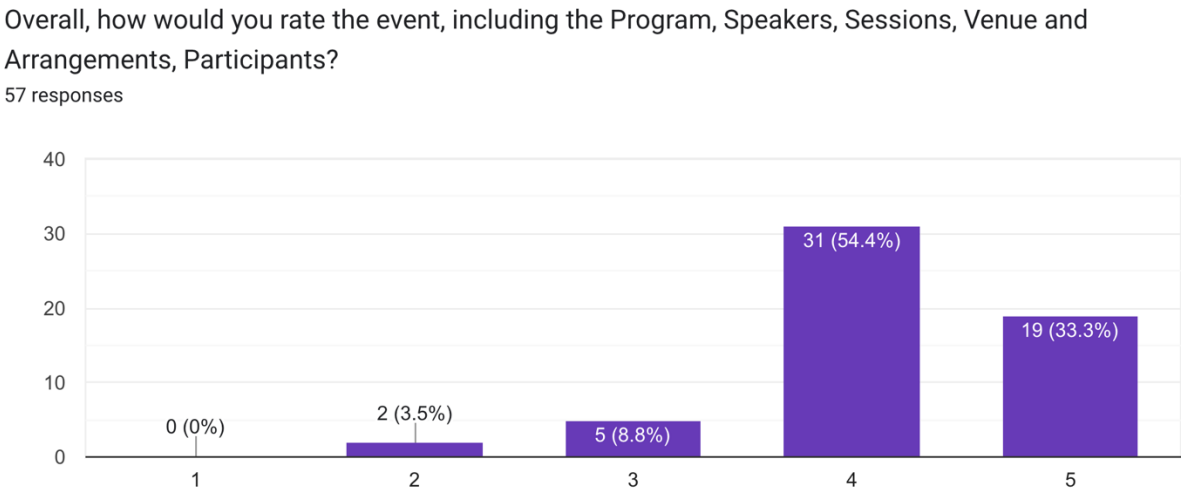
1. The Relevance of the Meet for the Participant



2. The Quality of Speakers and Peers, and Theme / Content in the Meet



3. Overall Rating for the Meet by the Participant



SUBJECTIVE FEEDBACK

After analysing the qualitative feedback from the participants, the major areas and sentiments expressed can be summarized as follows, prioritizing the most repeated ones:

1. Request for Improvement in Program Structure:
   - Participants suggested reducing the number of presentations to allow more time for each session and interactive discussions.
   - Desire for small group discussions and allocating more time for addressing stakeholders' questions and clarifications.

2. Inclusion and Representation:
   - Participants expressed the need for representation from device developers and manufacturers in future programs.
   - Request to include faculties from all modalities interested in research, including nursing discipline.
   - Focus on non-clinical trials and expanding interactions with other disciplines.

3. Safety, Regulatory Compliance, and Collaboration:
   - Participants recommended arranging a day seminar with safety and regulatory bodies like TUV, UL, CDSCO, ICMR, etc.
   - Desire to create a specialist group working with agencies like CDSCO and evolving protocols for clinical trials.
   - Suggestions to involve government and facilitate clinical trials in collaboration with institutions like Sree Chitra and medical colleges.
   - Emphasis on safety and regulatory compliance and the need for protocols, procedures, and insurance coverage for stakeholders.

4. Documentation and Contact Details:
    - Participants suggested compiling and distributing collated ideas, presentations, and papers to participants for future reference.
    - Request to compile contact details of presenters and other involved individuals for potential follow-up projects and collaborations.

5. Research and Curriculum:
    - Proposal to make research work and publishing papers mandatory in the curriculum, including UG students' involvement in research.
    - Recommendation to identify research subjects with faculty support and approval by an expert committee.
    - Suggestion to award the best research paper each year.

6. Overall Positive Feedback and Suggestions:
    - Participants expressed satisfaction with the meeting and found it informative, enriching, and useful.
    - Appreciation for the effort of organizers and KMTC members in creating a consortium for developing MedTech devices.
    - Desire for more similar meetings in the future and periodic conduct of informative sessions.
    - Requests for focused meetings on specific areas and more time dedicated to practical problems and solutions.
    - Recommendation to allot adequate time for presenters based on the relevance and significance of the topic.
    - Suggestions to enhance capacity building training programs in the clinical research area.

7. Technical and Logistics Issues:
    - Participants mentioned technical errors, glitches in AC, and audio-visual equipment, suggesting thorough vetting of the venue in the future.

In summary, the participants expressed the need for improvements in session structure, inclusion of device developers and manufacturers, collaboration with safety and regulatory bodies, documentation and contact details compilation, and emphasis on research and curriculum. The overall feedback was positive, highlighting the usefulness and informative nature of the meeting, with some suggestions for future enhancements.