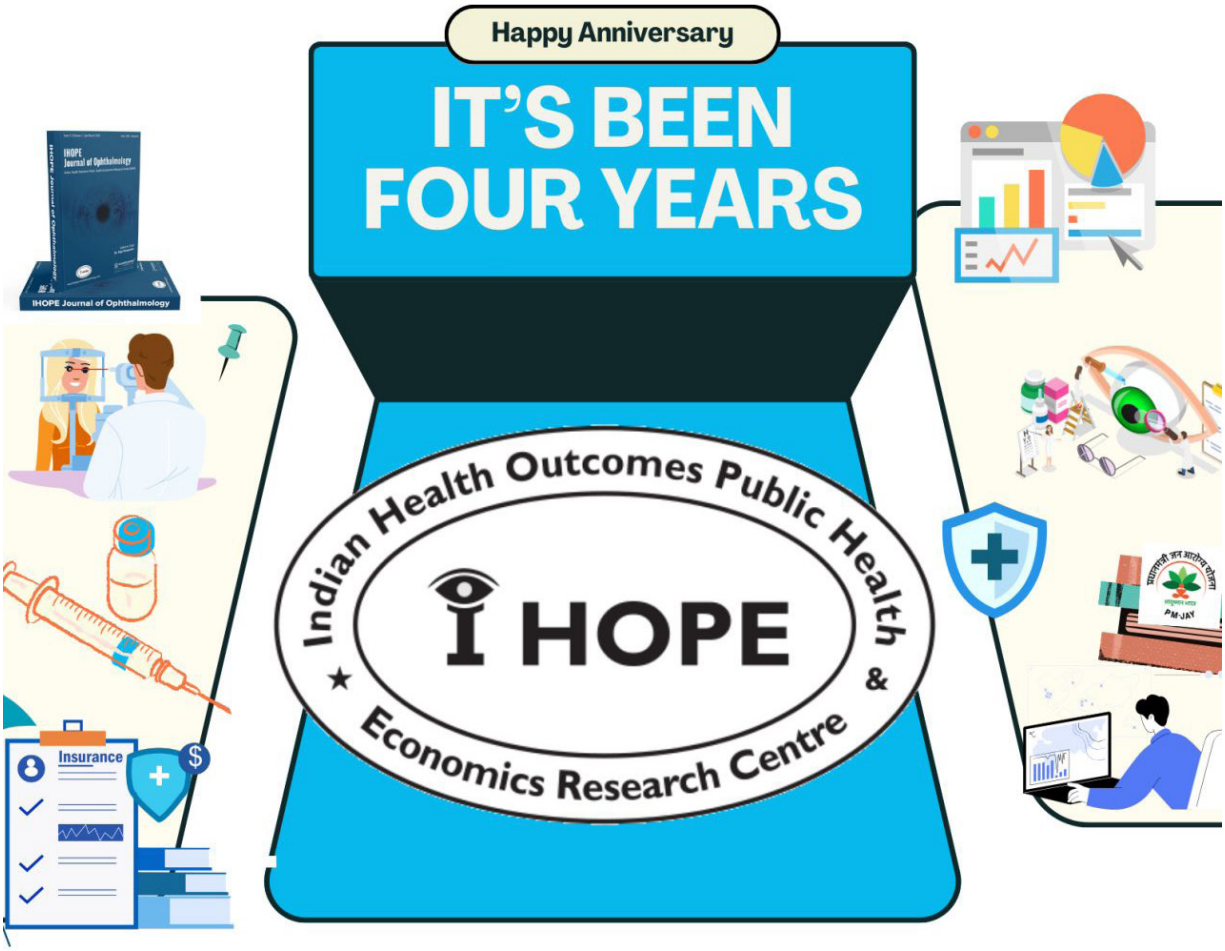
IHOPE

Newsletter

March 2024



Celebrating 4 years, I HOPE drives multi - institutional and multi-colloborative research. Through interdisciplinary studies, online courses, and monthly webinars, we empower healthcare professionals and policymakers, fostering collaboration and progress towards a healthier future.

Meet the newest addition to our team

Hemendra has completed his MS in Statistics from BHU, Varanasi. His experience includes linear non linear data modelling, time series and optimization.

ISCR Conference - Recap

Dr. Raja Addresses Discrepancies Between Clinical Trials and Real-World Evidence at ISCR Joint Workshop!

Dr. Raja, a distinguished expert in the field of clinical research, recently took the stage as a speaker at the USFDA and ISCR joint workshop on clinical trials. In his enlightening address, he shed light on the critical disparities that exist between the controlled environment of clinical trials and the dynamic landscape of real-world patient care.

Clinical trials serve as vital stepping stones in drug development, offering patients a "Red Carpet Treatment" experience with access to free check-ups and treatments utilizing innovative drugs or interventions. However, Dr. Raja emphasized the stark contrast faced by patients once they transition from the trial setting to the real world. Here, they encounter challenges such as difficulty in securing appointments, exorbitantly priced treatments, and the inability to adhere to frequent visit schedules.

One of the key points underscored by Dr. Raja was the paramount importance of meticulous evaluation of inclusion and exclusion criteria for trial enrollment by regulatory agencies. By ensuring alignment between trial populations and real-world patients, regulatory bodies can help mitigate the potential for significant discrepancies between clinical trial outcomes and real-world evidence.

Dr. Raja's call to action resonates deeply within the clinical research community, urging stakeholders to collaborate in bridging the gap between clinical trial settings and real-world healthcare delivery. By working collectively to address these challenges, we can strive towards a future where the benefits observed in clinical trials translate seamlessly into tangible improvements in patient care and outcomes.

Reflecting on the ISCR Conference : A Summary

Introduction

The Indian Society for Clinical Research (ISCR) conference 2024 involves participants with the theme of "Transformation in clinical research for better Patient Outcomes". As a delegates, we found ourselves immersed in a myriad of discussions, presentations, and networking opportunities. It also made the way to learn, understand and imbibe the transformation happening in the clinical research practices and about what the future holds. In this article, we explore our experiences and key takeaways into various aspects of clinical research and healthcare from the workshop and conference.

Pre – Conference Workshop

Among the different available sessions, we were interested on Clinical Data Management, Biostatistics, and Medical Writing the theme of this workshop is "From designing to Reporting: Collaboration as the key for Navigation through Protocol to study Reporting in Clinical Trials". This interactive session included a combination of presentations and worksheet exercises, providing practical perception into key areas of clinical research. We gained insights into the intricacies involved in the clinical trial process right from the protocol development to the preparation of final study reports for regulatory approvals. Additionally, we expanded our knowledge into how multidisciplinary teams collaboratively contribute to the successful execution of clinical trials within the pharmaceutical industry.

The aims of the workshop is on the practical session and hands –on approach in understanding the links and the collaboration of data managers, statisticians, and medical writers in clinical trials. The statistician session on the results interpretation was particularly insightful, offering oversight on how to interpret and analyse clinical trial data tables.

Each participant was grouped into different tables, each table comprising of medical writers, statisticians, and data managers, with connections and discussions. The webinar highlights, communication protocols, procedural steps, common challenges, and strategies for resolution. Engaging activities were conducted throughout the sessions, ensuring our active participation. Worksheet Analysis for drug trial endpoint was provided on each table during the workshop, to analyze the primary efficacy and endpoint of a drug trial & data management key elements like data management plan, case report form (CRF) design, edit checks, validation and result interpretation for a particular clinical trial. This hands-on exercise enabled participants to apply their knowledge and skills in data analysis, contributing to a deeper understanding of clinical trial methodologies. Initially, it was difficult to understand the overall process but the staffs at ISCR made their best efforts to understand the sheets.

Conference – Scientific Writing

The conference also featured informative sessions on Medical Writing, Pharmacovigilance (PV), Real World Evidence (RWE), and Health Economics and Outcomes Research (HEOR). These sessions covered various topics, including best practices in medical writing, pharmacovigilance strategies, providing real-world data for evidence generation, and economic considerations in healthcare decision-making.

Medical writing sessions were engaging and important though it is a complex part of clinical

research which includes the preparation of key aspects like research protocols which outline objectives, design, methodology, and statistical analysis plan of the study, and regulatory documents like clinical study reports (CSRs), approval of investigational new drug (IND) or medical device document, collaborating with researchers and clinicians to prepare manuscripts which adhere journal guidelines which further help to implicate in clinical practice, developing informed consent forms, study brochures which help the patient understand the purpose, benefits, and risk of participating in a clinical trial. Terms like adverse events (AE), serious adverse events (SAE), and clinical study report (CSR), etc. were introduced. Importance of using generative artificial intelligence (AI) in content creation.

Conference – Real World Evidence & Health Economics and Outcomes Research

I attended sessions in the "Real-world Evidence and Health Outcomes Research" track, which closely resonated with the research focus of the I HOPE Center. Distinguished national and international speakers elaborated on the significance of real-world evidence in health technology assessment (HTA) of various interventions. Furthermore, discussions centred on the functioning of the HTA hub in India and the pivotal role real-world evidence plays in facilitating evidence-based clinical practices for healthcare professionals.

Conference – Biostatistics & Statistical Programming

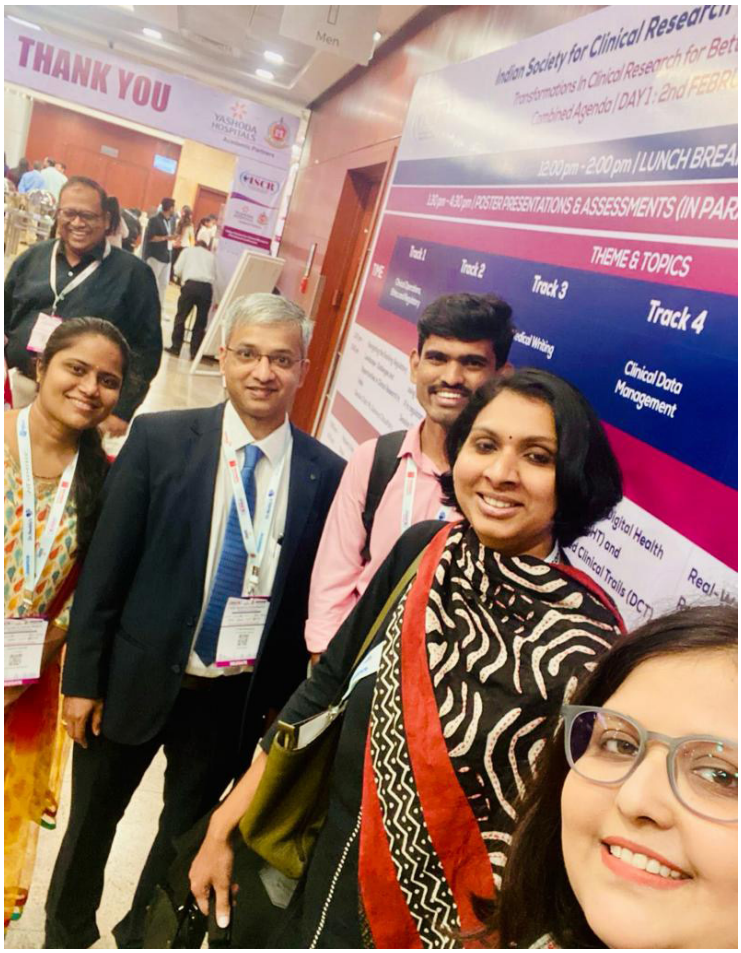
We began with an engaging session on statistics, where we explored various R packages commonly used in the pharmaceutical sector. We also learned how statistics are applied in real-world case studies and reports, providing valuable insights into their practical applications.

Additionally, a diverse array of topics illuminated the forefront of clinical research. Discussions on Bayesian logistic regression models for risk prediction in chronic diseases showcased advancements in predictive analytics. The panel explored into the relationship between new technologies such as artificial intelligence, machine learning and their impact on biostatisticians and statistical programmers, debating whether they pose threats or blessings. Moreover, the exploration of statistical approaches in clinical train design, highlighted the evolving methodologies aimed at enhancing trial validity and interpretation. These discussions underscored the dynamic nature of clinical research, emphasizing the imperative for continuous innovation and adaptation in the pursuit of improved patient outcomes.

Also, we had the opportunity to visit the exhibition stalls of national and multinational pharmaceutical companies involved in clinical trials. This provided valuable insights into the latest advancements, technologies, and services in the field of clinical research.

Overall, our experience at the ISCR 2024 Conference was enriching and informative. We gained valuable knowledge, practical skills, and networking opportunities that will contribute to my professional development in the field of clinical research.


Indian Society for Clinical Research
17th Annual Conference
1st - 3rd FEBRUARY, 2024
Novotel Hyderabad Convention Centre.
Gold Partners
at 17th Annual Conference of ISCR
#ISCR2024
NOVOTEL
HYDERABAD CONVENTION CENTRE
ISCR
1ST - 3RD FEBRUARY, 2024


THANK YOU
THEME & TOPICS
Track 3
Track 4
Clinical Data Management

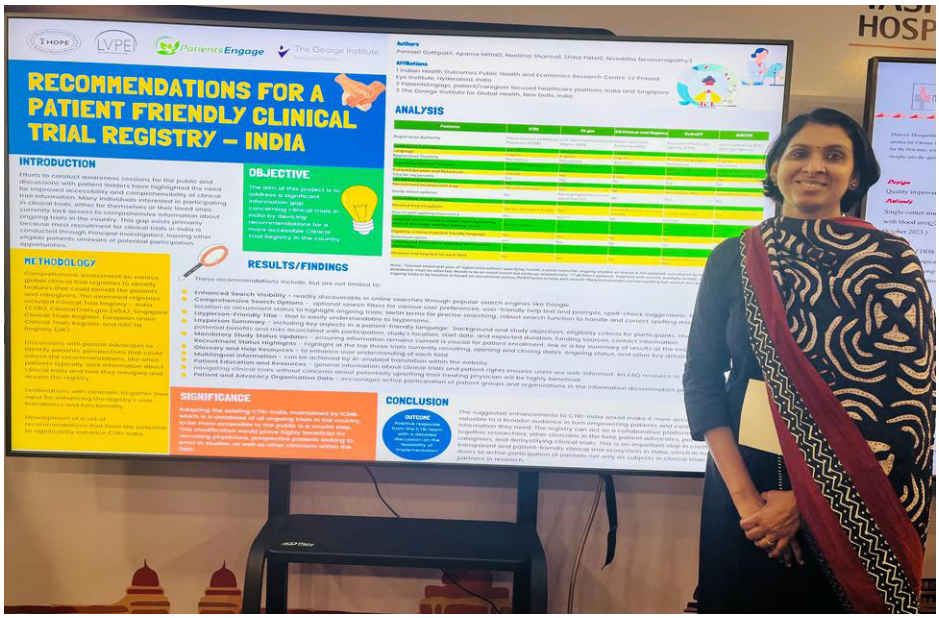

Indian Society for Clinical Research
17th Annual Conference
1st - 3rd FEBRUARY, 2024
Novotel Hyderabad Convention Centre.

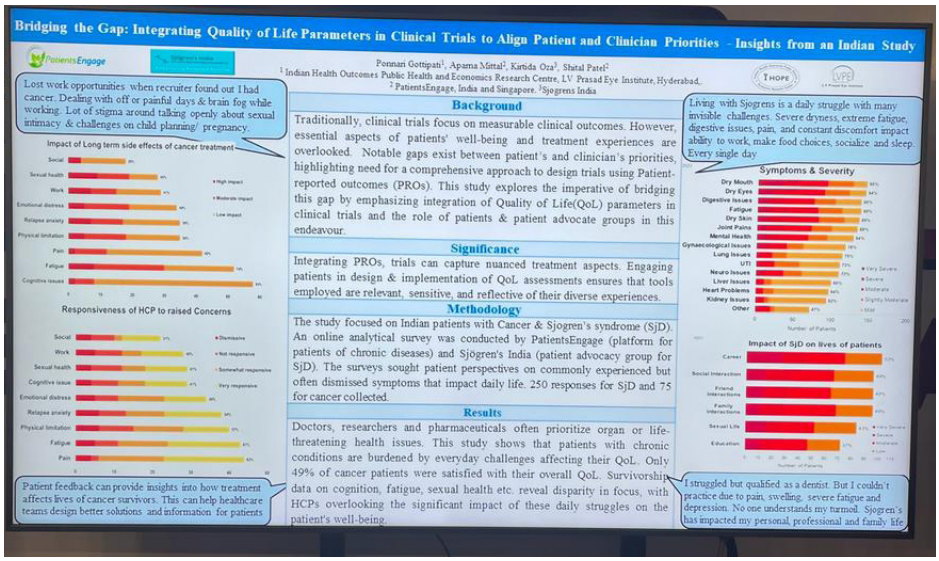
Highlighting Dr. Ponnari's Poster Presentations at ISCR Conference!

Dr. Ponnari,recently showcased two insightful poster presentations at the prestigious ISCR Conference. Her contributions shed light on crucial aspects of clinical trials, focusing on enhancing patient experiences and integrating quality of life parameters.

The first poster, titled "Recommendations for a Patient-Friendly Clinical Trial Registry - India," underscores Dr. Ponnari's dedication to improving accessibility and transparency in clinical trial information. By proposing patient-friendly features for clinical trial registries, Dr. Ponnari aims to empower individuals seeking clinical trial participation, ultimately fostering greater engagement and inclusivity in medical research.

In his second presentation, "Bridging the Gap: Integrating Quality of Life Parameters in Clinical Trials to Align Patient and Clinical Priorities - Insights from an Indian Study," Dr. Ponnari delves into the importance of incorporating quality of life metrics into clinical trial designs. By aligning patient-centric outcomes with clinical priorities, Dr. Ponnari's research aims to bridge existing gaps in healthcare research methodologies, ensuring that trials address the holistic needs of patients.





Funding triumph: IHOPE Team Clinches Grants for Health Care Projects

NIHR GRANT

We are thrilled to announce that Raghul Durairaj, hailing from India, has been awarded the prestigious NIHR Early Career Grant for his groundbreaking project titled “Development and Validation of Risk Score-Based Screening Tool for Diabetic Retinopathy Screening in India.”v

Raghul’s innovative research proposal aims to revolutionize diabetic retinopathy screening in India by developing a risk score-based screening tool. This tool promises to enhance early detection and intervention, potentially saving countless lives and preventing vision loss among diabetic individuals.

IRMI GRANT

We are thrilled to share the fantastic news that Neelima Sharma has been awarded the prestigious IRMI Grant by India Alliance/ Wellcome Trust, marking a significant milestone in her journey.

Please join us in congratulating Neelima Sharma on this well-deserved achievement! Let’s celebrate her dedication, passion, and commitment to pushing the boundaries of knowledge and making a meaningful impact on the world.

Webinars in the last quarter

The webinar hosted by IHOPE, featured esteemed speakers **Dr. Manisha Agarwal** and **Dr. Sanjay Agarwal**, with **Dr. Raja Narayanan** moderating the session. They illuminated the latest guidelines set forth by RSSDI (Research Society for the Study of Diabetes in India) and VRSI (Vitreoretinal Society of India) in collaboration with IHOPE.

The webinar took place on Friday, March 29, 2024, from 4:00 PM to 5:00 PM (IST). Diabetic Retinopathy, a common complication of diabetes that can lead to vision loss if not managed effectively, was the focal point. Understanding these guidelines was deemed crucial for healthcare professionals and caregivers involved in diabetic patient care.

During the webinar, participants gained insights into the latest recommendations for screening and managing Diabetic Retinopathy. They also delved into the advancements in treatment modalities and their implications. Moreover, attendees had the opportunity to engage directly with renowned experts in the field through a Q&A session, enriching their understanding of this critical aspect of diabetic care.

Access to guidelines:
https://guidelines.ebmportal.com/diabetic-retinopathy-screening-guidelines-physicians-india-position-statement-rssdi-research

Aparna Mittal from PatientsEngage delivered a compelling talk on the changing role of patient engagement in research during a webinar hosted by I HOPE and moderated by Ponnari Gottipati.

During the session, Mittal elaborated on the concept of patient engagement in research, emphasizing its significance in the early stages of research design. She provided insights into why involving patients from the outset is crucial. The talk also included illuminating case studies from various parts of the world, showcasing real-world examples of effective patient engagement in research initiatives.

Mittal reiterated several key points throughout her presentation. Firstly, she emphasized that patients are not merely a data source but active participants whose perspectives are invaluable to the research process. Secondly, she highlighted the misconception of information asymmetry, stressing that healthcare professionals and researchers do not inherently possess all necessary insights about patients' experiences and needs. Lastly, she underscored the principle of "nothing about us, without us," advocating for the inclusion of patients in decision-making processes that affect their healthcare journey.

Publications

Topic	Real-World Experience of Full-Thickness Traumatic Macular Hole among Young Patients
Authors	Ragukumar Venugopal, MPH , Anthony Vipin Das, FRCS, Brijesh Takkar, MS, Michael W. Stewart, MD, Raja Narayanan, MD
Abstract	To describe the demographics, clinical, and imaging characteristics, and visual outcomes in young patients with full-thickness traumatic macular hole (TMH).
Journals	International Journal of Retina & Vitreous. 2024 Feb 21; 10(1):20. doi: 10.1186/s40942-024-00539-3. PMID: 38383490; PMCID: PMC10882818.

Topic	Hemiretinal vein occlusion: Characterizing a rare retinal vasculopathy.
Authors	Yogita Kadam B.Optom, Pratima Thakur, Anthony Vipin Das FRCS, Raja Narayanan MD, Sirisha Senthil, Brijesh Takkar MS
Abstract	To characterize hemiretinal vein occlusion (HRVO) in patients presenting to a multi-tier ophthalmology hospital network.
Journals	Indian J Ophthalmol. 2024 Jan 8. doi: 10.4103/IJO.IJO_1712_23. Epub ahead of print. PMID: 38189486.

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