The Leela Bhartiya City

Jul 11, 2025 8:00 AM - Jul 12, 2025 5:30 PM

6/2, Thanisandra Main Rd,, Devin Paradise Enclave, Kannuru, Thirumenahalli, Bengaluru 560064, KA, India

DIA Medical Writing Conference - 2025

Transforming Medical Writing through Collaboration, Innovation and Technology.

Print Agenda

Day 1 Jul 11, 2025

8:00 AM — 8:45 AM

Registration And Welcome Coffee

8:45 AM — 9:00 AM

Welcome Remarks from DIA & Meeting Opening Remarks by Program Chair

Welcome the audience, house rules & introduce Program Chair

Meeting Opening Remarks by Program Chair

Session Chair(s)

Dr. Ashok Kumar Swain

General Manager, India
DIA, India

9:00 AM — 11:00 AM

Opening Plenary: AI, Ethics, and the Future File: Reimagining Regulatory Writing in the Digital Era

As regulatory writing enters a new era shaped by artificial intelligence, evolving global requirements, and heightened ethical expectations, this session brings together thought leaders to explore how technology is transforming submission strategies, content integrity, and the writer's role. This plenary session offers key insights into how regulators perceive the evolving landscape of medical documentation, and what it means for driving innovation, ensuring compliance, and upholding ethical accountability.

Session Chair(s)

Dr. Pooja Phogat, PhD

Founder and Co-CEO
Krystelis Ltd., India

Pooja Phogat holds a PhD in Microbiology and has over 20 years of pharmaceutical industry experience. For the past 18 years, she has specialized in medical writing, clinical trial disclosure, and data transparency, including Board-level leadership and regulatory consulting. As Co-Founder and Co-CEO of Krystelis, she leads global medical writing, communications, and trial transparency services. A recognized thought leader, she chairs the DIA India Medical Writing Community and co-chairs multiple DIA and EMWA working groups. She is also a member of ISMPP and ISCR and has presented at global conferences, authoring peer-reviewed publications and earning national awards.

Speaker(s)

Evolving Regulatory Submissions: A Regulator's Perspective on the Future of Medical Writing

Bikash Roy

ADC, CDSCO Bengaluru Zone
CDSCO , India

Exploring AI in Medical Writing and Beyond

Mohit Gupta

Vice President Products and Solutions
Freyer Solutions , India

Mohit Gupta is an accomplished professional with over 28 years of experience in IT development and implementations. He studied Engineering in Computer Science and Technology, and has led major projects across the industry. Currently, Mohit manages the products and solutions area at Freyr Solutions, driving innovation and excellence in technology delivery.

Intellectual Property and Ethical Integrity in the Digital Age

Tarun Khurana

Founding Partner and Patent Attorney
IIPRD and Khurana & Khurana Advocates and IP Attorneys, India

Tarun, Co-Founding Partner of Khurana & Khurana and IIPRD, has 22+ years of experience in IP and Commercial Law. His firms, with 10 offices in India and global presence across the US, UAE, SEA, and South Asia, serve clients from startups to Fortune 5 companies. Ranked by IAM 1000 and IAM 300, he specializes in IP litigation, arbitration, and patent strategy, representing clients at the Supreme Court, High Courts, and global tribunals. With core focus on tech sectors, he also leads patent support services. Tarun holds degrees in Engineering, Law, MBA (IIM Lucknow), and is pursuing a PhD, with certifications from IIT, WIPO, and more. He's a frequent speaker at global IP forums.

With Additional Presence Of:

Amit Dang, MD

Founder and CEO
MarksMan Healthcare Communications , India

Dr. Amit Dang is a physician-entrepreneur, thought leader, and the Founder & CEO of MarksMan Healthcare Communications - a global healthcare consulting firm specializing in HEOR, RWE, market access, and medical affairs. With over 15 years of experience, he has led strategic engagements across pharma, biotech, and life sciences, helping shape evidence-driven decisions and access strategies. He is also the host of "Pharma Insights Unplugged", a podcast featuring leaders from the pharmaceutical industry. Dr. Dang is passionate about transforming healthcare communication through scientific integrity, innovation, and cross-functional collaboration and has over 100 publications to his credit.

11:00 AM — 11:30 AM

Tea/Coffee & Networking Break

11:30 AM — 1:00 PM

T1S1: Publication Planning: From Design to Dissemination

The role of the medical writer is no longer confined to execution. This session explores how medical writers can expand their impact by being valued strategic partners in publication planning. It discusses their role in shaping publication plans through strategic thinking, navigating ethical and regulatory requirements, and their understanding of critical success factors to assess the impact of publications. We close with a panel discussion tackling the timely issue of recognition of the contribution by medical writers to journal publications — addressing current challenges and envisioning reforms for the future. Attendees will gain practical insights to elevate their roles from writers to strategic partners within publication teams.

Session Chair(s)

Dr. Natasha Das, MBBS

Independent Medical Communications Consultant
India

Dr. Natasha Das brings over 28 years of experience as a healthcare communicator, medical writer, reviewer, editor, and mentor. A leading visionary in the field, she has presented at conferences and published research papers, reviews, textbook chapters, books, and blogs on various aspects of medical communications. As a peer reviewer for several MEDLINE- and SCOPUS-indexed journals and an editor of the Indian Journal of Medical Sciences, Dr. Das contributes to maintain the integrity & rigor of published research. She has trained and mentored medical writers, students and faculty of medical, pharma and other institutes, pharmaceutical & research professionals, and ethics committee members, ensuring they excel in medical communications.

Speaker(s)

From Executor to Strategist: The Medical Writer’s Role in Publication Planning

Shalini Nair

Publication and Medical Education Excellence Lead, Global Medical Affairs
Novartis, India

Shalini Nair received her PhD in Biochemistry from Mumbai University and completed post-doctoral research in Molecular Biology at the National Institute for Research in Reproductive Health (NIRRH), Mumbai, and Hackensack University, USA. She has been recognized with several academic awards and scholarships and also holds a Diploma in Health Economics, Health Care Financing, and Policy. With over 16 years of experience in scientific communications, Shalini has led the development and execution of publication and medical education strategies for global brands across a broad range of therapeutic areas.

Navigating the Ethical and Regulatory Landscape in Publication Planning

Shirin Ghodke

Publications Capability Lead
Eli Lilly Services India Pvt. Ltd., India

Dr. Shirin Ghodke has 12 years of experience in publication writing and medical communications. In her current role as a publication capability lead at Eli Lilly, she focuses on developing the capability, publication strategy, enhancing publication document quality and compliance, learning and development, and innovation. Prior to this, she was a publication lead, where she led the publication plans of several molecules across the therapeutic areas. She holds a PhD in Nanosciences from Aarhus University, Denmark, and has post-doctoral experience from Johannes Gutenberg University, Mainz, Germany. She is a member of ISMPP and ISCR and has presented at global conferences and authored peer-reviewed publications.

Metrics and Critical Success Factors (CSF): Measuring the Impact of Publications

Kirandeep Kaur

ISMPP representative ,Professor at Dayanand MCH, Ludhiana , India

Dr. Kirandeep Kaur is a Professor of Pharmacology at Dayanand Medical College and Hospital. She has extensive experience in writing manuscripts, trial protocols, conducting meta-analyses, and reviewing for numerous high-impact-factor journals. Her work focuses mainly on inflammatory bowel diseases.

With the Additional Presence Of:

Hetal Shah

Founder - Director
MeWriT Healthcare Consulting, India

Dr. Hetal Shah, a PhD Pharmacologist and SME-Medical Writing with 20+ years of experience, is Founder at MeWriT® Healthcare Consulting. A gold medalist with 70+ publications, recipient of the ‘Woman Entrepreneur in Pharma & Healthcare’ Award (2019) by AIC-LMCP, ISCR’s Hall of Fame Awards (2021-2023), and certified for ‘Do your Venture: Entrepreneurship for Everyone’ by IIMB's NSRCEL Women Startup Program. She is ISCR life member, Medical Writing Council co-chair (2024-25), and Section Editor for Perspectives In Clinical Research. As a current active member of DIA-India, she serves as an SME and Speaker at various forums. A sought-after trainer & speaker, she has trained 2,500+ professionals since 2008.

With the Additional Presence Of:

Dr. Anant Patil

Professor, Dept of Pharmacology
Dr. DY Patil Medical College, India

Dr. Anant Patil, with over 20 years of post-PG experience, is an Editorial Board Member of six journals and Associate Editor of five books. He has received multiple awards, including the "Best Teacher Award" (2022), "Sherlock Holmes Award" (2023), "National Research Scholar Award" (2023), and "MPS Promising Senior MD Pharmacologist Award" (2024). Dr. Patil has conducted medical writing and statistics workshops across India, Bangladesh, and Sri Lanka, served as resource faculty for conferences, and worked in various pharmaceutical domains. He has authored 145+ articles, with 1,700+ citations, an H-index of 20, and an i10-index of 38.

11:30 AM — 1:00 PM

T2S1: Role of Medical Writers in Amplifying Patient Voice

Patient perspectives are becoming increasingly essential in regulatory decision-making, and medical writers play a pivotal role in facilitating patient-centric communication in clinical trials. This session will provide an in-depth discussion on the role of medical writers in creating patient-centered clinical trial documents, in simplifying and effectively communicating critical information to patients through clinical study protocols and informed consent forms, Additionally, the session will explore the role of technology in enhancing patient engagement and collaboration. Attendees will gain valuable insights into fostering patient engagement, incorporating patient perspectives and on effectively communicating with patients in clinical trials.

Session Chair(s)

Annie Jose

Associate Director, Medical Writing
GSK, Bengaluru, India

Annie is a seasoned medical writer and passionate people leader with over 17 years of experience in global organizations. She has a proven track record in managing teams, driving submissions, and delivering diverse medical writing projects. In her current role as Associate Director at GSK, Annie leads a team of experienced medical writers, overseeing the development of complex regulatory documents, including submission documents. She is a recognized subject matter expert in clinical study reports and is highly regarded for her strong leadership, coaching, and mentorship skills in medical writing. Annie holds a Master's degree in Biotechnology and a Diploma in Clinical Research from the University of Pune.

Speaker(s)

Protocol Design with Purpose: Embedding Patient Voice in Clinical Studies

Binutha Pereira

Principal Medical Writer
Eli Lilly, India

Binutha is a medical writer with more than a decade of experience in the field. Before her tenure at Eli Lilly, she worked with GlaxoSmithKline (GSK) Pharmaceuticals Limited.Her writing portfolio includes study protocols, informed consent forms, clinical study reports, investigator brochures, and clinical summaries.She has contributed to a range of therapeutic areas, including immunology, diabetes, respiratory conditions, oncology and infectious diseases.Binutha holds a postgraduate degree in Microbiology from St. Joseph's College in Bangalore.

From Concept to Practice: Embedding Patient Centricity in ICFs

Vilok Purohit

Principal Medical Writer,
Thermo Fisher, India

Vilok has >12 years of experience in the clinical research and pharmaceutical industry. He has experience in authoring and reviewing ICFs, protocols, CSR, narratives, IB, submission modules, and clinical trial disclosure. He holds a Master's Degree in Pharmacy Practice from NIPER, Mohali, India.

Beyond the Words: Amplifying Patient Voices in Plain Language Summaries through Innovation and Inclusion

Vidhi Vashisht, MS

Vice President, Head of Plain Language Services
Krystelis Ltd, India

Vidhi believes that success and wisdom doesn't always come with age and experience, but with an open mind and willingness to take action. While working as a medical writer, she developed passion for understanding and applying the timeless principles of success and saw the positive impact of these principles in her career and personal life. She now wants to share her learning with others so that more and more people a life of success and fulfillment.

With the Additional Presence of:

Akshata Rao

Director- Global Medical Writing, India
Merck Group, India

Dr. Akshata holds a BDS, PG Diploma in Clinical Research, and MBA in Pharmaceutical Management. With over 18 years of experience in clinical research, she has spent 14+ years leading operations across Medical Writing, Pharmacovigilance, Medical Data Review, Data Transparency, and Quality processes. She has managed global teams, driven transformation initiatives, and led continuous improvement programs. As a service delivery lead for 7 years, she has hands-on experience in planning, contract negotiations, financial management, and business expansion.

1:00 PM — 2:00 PM

Lunch Break

2:00 PM — 3:30 PM

T1S2: Science of Artificial Intelligence and Art of Scientific Communication

This session explores the transformative impact of Artificial Intelligence (AI) on scientific communications. It highlights how AI-driven tools are enhancing research dissemination, improving knowledge sharing, and accelerating scientific progress. Expert speakers will examine current trends, applications, and future directions in AI-powered scientific communications. The discussion will also address how AI supports more effective sharing of scientific findings, fosters collaboration, and drives innovation in the field.

Session Chair(s)

Rajesh Pandey, MD

Head, Medical Writing & Medical Affairs
Tata Consultancy Services, India

Dr. Rajesh is a Physician (MD) by qualification with MBA in Healthcare & has around 25 years of industry experience in Medical Writing & Medical Affairs. He brings rich medical writing experience throughout product life cycle spanning across Regulatory Writing, Clinical Trial Disclosures, Safety writing, Scientific Communications and digital content writing. He has expertise in building strategic Medical writing partnerships for various global pharma's, and contribute to development of innovative technology solutions for Medical writing domain. He is currently working as Head of Medical Writing and Medical Affairs at Tata consultancy Services and is based out of Mumbai. He is happily married and blessed with two lovely daughters.

Speaker(s)

Reimagining Scientific Communications - AI as a Collaborative Partner in Medical Writing

Nishchay Shah

Chief Technology Officer
Cactus Communications, India

Nishchay is the Group CTO and EVP, Products and AI at Cactus Communications. Nishchay heads the AI powered products business at Cactus consisting of products like Paperpal, Preflight, R Discovery and Mind The Graph and oversees technology and innovation across all products and brands at CACTUS.

The Double-Edged Sword: AI's Promise and Perils in Scientific Communications

Raghuraj Puthige

Function Head
Enago Life Sciences, India

Dr. Raghuraj Puthige, Ph.D., eMDP, is the Function Head of Medical Communications at Enago Lifesciences with 17+ years of leadership in pharma and life sciences. He has driven revenue growth, expanded global client bases, and led large teams at Novartis and Accenture, where he delivered major operational efficiencies. Holding a Ph.D. from Bangalore University and executive training from XLRI, he is recognized by MAPS and ISMPP as a thought leader in medical communications. His expertise spans scientific writing, strategic leadership, and global project delivery. Passionate about patient-centric solutions, he continues to mentor professionals and lead innovations across the US, EU, and Asia-Pacific.

With the Additional Presence of:

Seema Gurbani

Vice President
Freyr Solutions, India

Dr Seema is a Physician and a Post-Graduate in Hospital and Healthcare Management with over 25 years of Clinical Development and Clinical Research experience from diverse set-ups such as Third Party Administrators (TPA), Contract Research Organization (CRO), Pharmaceutical Industry and the Sourcing Industry (BPS).In her current role as the Head- Clinical Service at Freyr Solutions, India, she is leading the Clinical Medical Writing team providing End to End Medical Writing services to support Global regulatory submissions. She is responsible for overall operations ensuring compliance with regulatory requirements and achieving delivery excellence.

2:00 PM — 3:30 PM

T2S2: Evolving Strategies for Accelerating Regulatory Submission

In today's rapidly changing regulatory environment, medical writers are expected to move beyond traditional authoring to act as strategic partners in regulatory strategy and compliance. This session explores the evolving role of medical writers in the preparation of Clinical Study Reports, Clinical Summaries, and Clinical Overviews. Attendees will gain insights into how medical writers contribute to ensuring data transparency, compliance with evolving global standards, and the facilitation of accelerated submission timelines. The session will discuss new expectations, challenges, and best practices for aligning clinical documents with regulatory expectations, emphasizing the importance of clear, concise, and consistent key messages that effectively communicate study findings to regulatory authorities.

Session Chair(s)

Sherin Babykutty

Senior Manager - Regulatory Writing
Eli Lilly Services India Private Ltd, India

Sherin has over 11 years of experience in medical writing, including regulatory writing and medical communications. She holds a Master of Pharmacy degree in Pharmacology from Manipal University. In her current role as a Senior Manager at Lilly, she leads a team of regulatory writers, manages few assets, and actively coaches writers to develop their submission expertise. Sherin is skilled in the development and management of regulatory documents for global submissions. She specializes in crafting content strategies for submissions. Additionally, she is a certified structured authoring trainer and has served as a panelist and speaker at multiple ISCR conferences and workshops.

Speaker(s)

CSRs to Clinical Summaries: The Backbone of Evidence to Unlock Regulatory Approvals

Shruthi Reddy K

Group Head, Regulatory Writing & Submissions
Novartis Healthcare Pvt. Ltd, India

Shruthi has an M. Pharm in Pharmaceutics, with 12+ yrs of Medical Writing experience. In her career, she authored/reviewed/lead authored complex CSRs, DSURs, RMPs, BBs, SCEs, SCSs, COs, ACOs and special reports. She coaches less experienced writers and manages a group of MWs, QCers and Transparency managers.

Clinical Overviews: Building A Strategic Narrative

Naved Shaikh

Senior Scientific Writer II (Senior Manager)
Bristol Myers Squibb, India

Dr Naved Shaikh is a Dental Surgeon with 15 years of experience in regulatory medical writing. He has worked with leading global pharmaceutical companies, authoring a wide range of high-quality clinical and safety documents that have supported regulatory submissions to major health authorities worldwide.

With the Additional Presence Of:

Mohammed Salman

Associate Director II
Astra Zeneca, India

Dr. Mohammed Salman has 16+ years of experience in the pharmaceutical industry, with an M.Pharm in Pharmacology and a Ph.D. in Clinical Research. He has contributed across the various domains of drug development—including pre-clinical studies, clinical pharmacology, and both early and late-phase clinical development—as well as regulatory writing. Currently, Salman serves as Associate Director of Clinical Regulatory Writing at AstraZeneca in Bangalore,

after previous roles at Novartis, Advinus Therapeutics, and ClinSync Clinical Research. He has played pivotal roles as both regulatory writer and submission lead on numerous NDA/BLA submissions in various therapeutic areas.

With the Additional Presence Of:

Karuna Mandar Zambare

Team Lead – Medical Regulatory Writing
Sanofi, India

With M. Pharm (Pharmacology) and Ph.D in Clinical Research, Karuna comes with a total 15+ years of experience in core Pharma Industry in Regulatory Medical Writing and Project Management. She has supported to various Health Authorities submissions of New chemical entity molecules, biologic drugs and established products in various therapy areas. She has worked on various regulatory documents like study outline, protocols, Clinical study reports, ICDs, IBs, PIPs, PSP, CTD modules (2 and 5), Clinical bridging reports, IMPDs and Real World Evidence (RWE) writing documents, across all phases of clinical trials.

3:30 PM — 4:00 PM

Tea/Coffee & Networking Break

4:00 PM — 5:30 PM

T1S3: Omnichannel Excellence: Redefining Interaction Paradigms

Omnichannel strategies are revolutionizing pharmaceutical customer engagement through consistent, personalized interactions across all platforms. This session explores how these approaches drive deeper engagement while providing valuable insights. Key topics include the latest trends, strategic implementation frameworks, emerging technologies, ethical considerations, industry-specific challenges, and maximizing omnichannel effectiveness to create seamless, impactful customer experiences.

Session Chair(s)

Ubhayabharathi Gurunath

Ad-interim Group Lead - Scientific Writing
Sanofi, India

Ubhaya has 18 years of experience in medical communications. Prior to joining Sanofi, she has worked on publications, medical communications projects, and regulatory documents at Biocon,

Novartis, Siro ClinPharm Pvt Ltd, and GSK, across therapeutic areas. She is an ISMPP Certified Medical Publication Professional (CMPP™) and excels in strategic leadership, publication strategy, operational efficiency, developing high-performing teams, and transversal collaboration. She is a part of the ISCR Medical Writing Council (2024, 2025).

Speaker(s)

Understanding Omnichannel Imperative in Pharma

Sandeep Gantotti

Associate Vice President, Enterprise Medical Solutions
Indegene Pvt Ltd, India

Sandeep Gantotti is a clinical pharmacist by background and Associate VP, Enterprise Medical at Indegene, Pvt Ltd, a leading multinational healthcare solutions provider. He has held positions of increasing responsibility in medical information, medical communications, and medical affairs at Zeneca Pharma, GSK, and Amgen. Sandeep has participated in several DIA local champion events and industry forums such as PhactMI and MAPS to contribute to a performance-driven culture within medical affairs. He is focused today on pioneering the use of modern technologies to solving today's challenges in content development, multichannel engagement, and demonstrating organizational value of medical affairs .

Strategic Implementation and Navigating Industry Specifics

Pooja Srivastava Banerjee, MPharm

Senior Director
Krystelis Ltd, India

With 18+ years of experience, Pooja holds a Master's degree in pharmaceutical chemistry and a postgraduate diploma in health communications. She currently leads Medical Communications at Krystelis, managing publications, medico-marketing, and medical education. Pooja specializes in strategic communication for pharma and biotechnology, having worked on public health campaigns, advisory boards, RWEs, and developing consensus statements and clinical guidelines. She has worked with top pharma clients, and other healthcare stakeholders. Pooja is also a published author, having received the PRS Global Open "Best International Collaboration-Gold Award" in 2020. Actively involved as a faculty member in workshops and conferences.

Optimizing Impact, Ethical Considerations And Future Horizon

Seema Kashyap

Director- GOSO- Dynamic Targeting & Omnichannel Capability
Eli Lilly, India

Seema Kashyap is a seasoned leader with over two decades of experience at the intersection of advanced analytics, martech, and strategic consulting. As the Director – Omnichannel Capability at Lilly Capability Centre India (LCCI), she leads the global Omnichannel and Dynamic Targeting practice for Eli Lilly, helping shape how the organization

delivers personalized, data-driven engagement across both commercial and medical domains. Seema is known to building resilient, high-performing teams and enabling future-ready capabilities. Her work focuses on designing product-like-service models, AI accelerators, and reusable assets that support both personal and non-personal omnichannel activation.

4:00 PM — 5:30 PM

T2S3: Regulatory Submission and Documentation Strategies for Pediatric Drug Development

Pediatric Drug Development has made exceptional strides in the last decade and continues to evolve further. This presentation will cover regulatory (US FDA & EMA) considerations as well as documentation strategies for pediatric drug development leading to successful approval of pediatric indications and labels.

Session Chair(s)

Shivanand Jigajinni

Director- Head of India MW Operations. Global Medical Writing - DSSM
IQVIA, India

Dr. Shivanand is Director and Head of India Medical Writing operations at IQVIA. He joined legacy Quintiles in January 2015, bringing over 19 years of medical writing experience, supported by medical and pharmacy qualifications and a clinical research diploma. His prior experience spans inVentiv Health, Cognizant, and Accenture, where he authored key clinical regulatory documents and led medical writing teams. A dynamic leader, he excels in team building, strategic planning, and project management. His passion for innovation and technology has driven impactful automation initiatives enhancing efficiency and fostering a culture of collaboration and excellence.

Speaker(s)

Paediatric Drug Development - FDA Perspective

Shakti Ranjan Rath

Senior Manager, Regulatory Writing,
Bristol Myers Squibb, India

Shakti is a result driven, hands-on professional, with a successful record of accomplishments in the field of regulatory and safety medical writing for more than 15 Years. He has a rich experience in writing and reviewing a broad range of regulatory as well as safety deliverables including Module 2 summaries, Briefing Books, and HAQ response documents. He is currently employed with Bristol Myers Squibb (BMS) as a Senior Scientific Writer, primarily responsible for leading document strategy and authoring of regulatory documents in support of submissions and approvals in key markets.

Paediatric Drug Development - EMA Perspective

Richa Jackeray

Lead Medical Writer
Novo Nordisk, India

Dr. Richa Jackeray is a Lead Medical Writer at Novo Nordisk. She did PhD from IIT Delhi in 2010 and has 15 years of industry experience. Dr. Richa specializes in pediatric writing and has successfully led submissions to key health authorities.

Day 2 Jul 12, 2025

9:15 AM — 9:30 AM

Welcome Remarks From DIA

9:30 AM — 11:00 AM

Plenary Session: Beyond the Manuscript: Expanding Impact Through Cross-Sector Collaboration, Engagement, and Identity

This plenary explores the evolving role of medical writers beyond traditional deliverables, highlighting their impact across real-world evidence generation, public health communication, and academic-industry collaboration. It also delves into personal career growth, offering perspectives on building a distinctive professional identity in a dynamic landscape.

Session Chair(s)

Dr. Natasha Das, MBBS

Independent Medical Communications Consultant
India

Dr. Natasha Das brings over 28 years of experience as a healthcare communicator, medical writer, reviewer, editor, and mentor. A leading visionary in the field, she has presented at conferences and published research papers, reviews, textbook chapters, books, and blogs on various aspects of medical communications. As a peer reviewer for several MEDLINE- and SCOPUS-indexed journals and an editor of the Indian Journal of Medical Sciences, Dr. Das contributes to maintain the integrity & rigor of published research. She has

trained and mentored medical writers, students and faculty of medical, pharma and other institutes, pharmaceutical & research professionals, and ethics committee members, ensuring they excel in medical communications.

Speaker(s)

Collaboration Across Medical Writing Disciplines: A Novel Training Concept

Roopa Basrur

Vice President, Global Safety Medical Writing Services
Parexel International, India

Over 22 years of experience at pharma and service provider organisations, in medical writing (safety, clinical, regulatory, medcom), document quality, data management, technology, and medical services.She has also held site and country head positions. She Leads the Safety Medical Writing team within Parexel's Global Safety Services, which includes aggregate, signal evaluation and risk management reports. Expertise in growing large teams of medical writers and bridging teams across regions. She is Physician with Post-graduate diploma in medical law and ethics and EMWA certificate in medical writing

Medical Writing Across Academia, Public Health, and Industry: Shaping Science Beyond Drug Development

Ananya Chakraborty

HOD-Pharmacology
Vydehi Institute of Medical Sciences and Research Centre, India

Dr. Ananya, Professor & Head of Pharmacology at Vydehi Institute, has 20 years' post-MD experience. She leads initiatives like PHARMAQUEST and edits VyVidhya. An active researcher, she has published widely and authored book chapters. A dedicated teacher, she mentors MD/PhD students, serves on academic boards, and her students received ICMR and RGUHS grants. She contributes to medication safety at Vydehi Hospital and chairs ADR and materiovigilance units. She chairs ethics at Manipal Hospital, serves on ethics boards at Narayana Hridayalaya & Vydehi Dental, and is an ISCR EC member. She also leads PROYASH. A recipient of Vydehi Best Teacher and ISCR Hall of Fame awards, she holds a health management certification from IIM Kozhikode.

With the Additional Presence of

Hetal Shah

Founder - Director
MeWriT Healthcare Consulting, India

Dr. Hetal Shah, a PhD Pharmacologist and SME-Medical Writing with 20+ years of experience, is Founder at MeWriT® Healthcare Consulting. A gold medalist with 70+ publications, recipient of the 'Woman Entrepreneur in Pharma & Healthcare' Award (2019) by AIC-LMCP, ISCR's Hall of Fame Awards (2021-2023), and certified for 'Do your Venture: Entrepreneurship for Everyone' by IIMB's NSRCEL Women Startup Program. She is ISCR life member, Medical Writing Council co-chair (2024-25), and Section Editor for Perspectives In Clinical Research. As a current active member of

DIA-India, she serves as an SME and Speaker at various forums. A sought-after trainer & speaker, she has trained 2,500+ professionals since 2008.

With the Additional Presence of

Rajesh Pandey, MD

Head, Medical Writing & Medical Affairs
Tata Consultancy Services, India

Dr. Rajesh is a Physician (MD) by qualification with MBA in Healthcare & has around 25 years of industry experience in Medical Writing & Medical Affairs. He brings rich medical writing experience throughout product life cycle spanning across Regulatory Writing, Clinical Trial Disclosures, Safety writing, Scientific Communications and digital content writing. He has expertise in building strategic Medical writing partnerships for various global pharma's, and contribute to development of innovative technology solutions for Medical writing domain. He is currently working as Head of Medical Writing and Medical Affairs at Tata consultancy Services and is based out of Mumbai. He is happily married and blessed with two lovely daughters.

With the Additional Presence of

Nomita S Saxena

Independent Regulatory Writing Consultant, India

Dr Nomita Saxena is a physician by qualification and global medical writing leader with 20+ years in pharma. At AstraZeneca, she built and scaled a 30+ member regulatory writing team, led successful IND/NDA submissions, and drove strategic document planning across programs. She spearheaded AI-powered automation for CSR quality control, reducing review time by 95% and transforming expert review logic into scalable solutions. A recognized thought leader and speaker, Nomita is passionate about merging technology with regulatory excellence to drive efficiency, quality, and innovation.

With the Additional Presence of

Annie Jose

Associate Director, Medical Writing
GSK, Bengaluru, India

Annie is a seasoned medical writer and passionate people leader with over 17 years of experience in global organizations. She has a proven track record in managing teams, driving submissions, and delivering diverse medical writing projects. In her current role as Associate Director at GSK, Annie leads a team of experienced medical writers, overseeing the development of complex regulatory documents, including submission documents. She is a recognized subject matter expert in clinical study reports and is highly regarded for her strong leadership, coaching, and mentorship skills in medical writing. Annie holds a Master's degree in Biotechnology and a Diploma in Clinical Research from the University of Pune.

11:00 AM — 11:30 AM

Tea/Coffee & Networking Break

11:30 AM — 1:00 PM

T1S4: Patient-Centric Communication: Bridging Science and Support

As healthcare continues to evolve toward greater transparency and inclusivity, patient-centric communication is more important than ever. This session explores how scientific information can be transformed into accessible, meaningful content for patients. Through three focused presentations, we will delve into the development of plain language summaries of publications and the creation of effective patient educational materials. Join us to discover strategies, best practices, and real-world examples that bridge the gap between complex scientific data and patient understanding, ultimately supporting informed decision-making and better health outcomes.

Session Chair(s)

Dr. Pooja Phogat, PhD

Founder and Co-CEO
Krystelis Ltd., India

Pooja Phogat holds a PhD in Microbiology and has over 20 years of pharmaceutical industry experience. For the past 18 years, she has specialized in medical writing, clinical trial disclosure, and data transparency, including Board-level leadership and regulatory consulting. As Co-Founder and Co-CEO of Krystelis, she leads global medical writing, communications, and trial transparency services. A recognized thought leader, she chairs the DIA India Medical Writing Community and co-chairs multiple DIA and EMWA working groups. She is also a member of ISMPP and ISCR and has presented at global conferences, authoring peer-reviewed publications and earning national awards.

Speaker(s)

Empowering Patient Understanding: Plain Language Summaries and Engaging Educational Tools

Vatsal Vithlani

Group Lead – Scientific Writing
Sanofi, India

Mr. Vatsal Vithlani is a seasoned Medical Affairs expert with 15+ years in scientific writing and clinical research. Holding a Master's in Pharmaceutical Chemistry, he excels in publications, medical education, and patient-centric communications, contributing to advancing evidence-based healthcare communication.

Balancing Accuracy and Empathy: The Medical Writers' Role in Clear Communication

Dr. Natasha Das, MBBS

Independent Medical Communications Consultant
India

Dr. Natasha Das brings over 28 years of experience as a healthcare communicator, medical writer, reviewer, editor, and mentor. A leading visionary in the field, she has presented at conferences and published research papers, reviews, textbook chapters, books, and blogs on various aspects of medical communications. As a peer reviewer for several MEDLINE- and SCOPUS-indexed journals and an editor of the Indian Journal of Medical Sciences, Dr. Das contributes to maintain the integrity & rigor of published research. She has trained and mentored medical writers, students and faculty of medical, pharma and other institutes, pharmaceutical & research professionals, and ethics committee members, ensuring they excel in medical communications.

With the additional presence of

Sonica Batra, MD

Associate Vice President Enterprise Medical;Global Head- Regulatory Affairs
Indegene Ltd., India

I am an MD physician by training, with 20 years of experience in drug development and medical and scientific affairs. I am presently AVP and Global Head for Medical Affairs and Regulatory at a global technology enabled healthcare solutions provider. I have led many successful global Regulatory Authority engagements across the globe, for developed as well as the Rest of the World- emerging/ developing countries, enabling clinical development plans, strategies, marketing authorisations and post approval compliances for various products including biosimilars. I have a keen interest and experience in enhancing medical value add and scientific information dissemination for medicinal products, in the peri approval and post approval space.

11:30 AM — 1:00 PM

T2S4: AI-Driven Regulatory Writing: Balancing Innovation with Compliance

AI is transforming regulatory writing by enhancing speed, accuracy, and consistency. Yet, its adoption raises concerns around compliance, data integrity, and regulatory acceptance. This session will explore practical applications of AI in regulatory writing, share industry experiences, and discuss strategies to balance innovation with compliance. Attendees will gain key insights to navigate this evolving space responsibly and effectively.

Session Chair(s)

Nomita S Saxena

Independent Regulatory Writing Consultant, India

Dr Nomita Saxena is a physician by qualification and global medical writing leader with 20+ years in pharma. At AstraZeneca, she built and scaled a 30+ member regulatory writing team, led successful IND/NDA submissions, and drove strategic document planning across programs. She spearheaded AI-powered automation for CSR quality control, reducing review time by 95% and transforming expert review logic into scalable solutions. A recognized thought leader and speaker, Nomita is passionate about merging technology with regulatory excellence to drive efficiency, quality, and innovation.

Speaker(s)

Streamlining GenAI-Augmented Structured Content Authoring of Regulatory Documents

Shruti Diggavi, MSc

Document Quality Reviewer, Medical Writing Services
Parexel International, India, India

Shruti Diggavi has 18 years of team leadership experience in clinical quality assurance, auditing, medical data review in centralized/risk-based monitoring (Quintiles-Amgen FSP), and medical writing. She has expertise in quality, project management, operational efficiency, data visualization, and regulatory compliance. At Parexel Medical Writing Services, she specializes in the quality review of regulatory and safety documents. Shruti is a subject matter expert in structured content authoring and generative AI, with a focus on enhancing medical writing efficiency and quality through innovation. She is a published author in EMWA, a member of ISCR, and holds a M.Sc. in Biomedical Technology and B.Sc. in Biochemistry.

AI-Assisted Medical Writing: Tools for Efficiency and the Need for Oversight

Lalit Doshi

Medical Writing Specialist
Novo Nordisk, India

Lalit Doshi is a Medical Writing Specialist at Novo Nordisk India. He has 19 years of experience, including 14 years in Regulatory medical writing. Current role is of Clinical Submission Lead (4.5 years) of global MW teams delivering high-quality submissions. Also, an Automation and AI enthusiast.

AI Driven Structured Content Authoring: Navigating Compliance, Risk, Ethical Standards And Upskilling For The Future

Tapasya Bhardwaj, DDS, MHA

Director Innovation & Technology
Syneos, India

Dr. Tapasya Bhardwaj is the Associate Director of Regulatory Operations at Syneos Health, with a 12-year track record in healthcare management and innovation. Armed with a master's in health and Hospital Management, she applies her expertise in AI, NLP, and analytics to advance clinical research and technology. She is adept at steering product development from conception to practical applications. Presently, Dr Bhardwaj is dedicated to enhancing digital processes, refining submission strategies, and bolstering operational effectiveness in healthcare.

With the Additional Presence of

Dev Bhaskar Baruah

Associate Director, Clinical Regulatory Writing
AstraZeneca, India

Dev is an accomplished pharmaceutical professional with over 18 years of experience, including 16 years in regulatory medical writing. Currently Associate Director II, Clinical Regulatory Writing at AstraZeneca, Dev holds a master's degree in pharmacy and has held key roles at Biocon Biologics, Parexel, Novartis, Dr. Reddy's Labs, and Sanofi. Dev has extensive expertise in authoring complex and high-level clinical regulatory documents for major health authorities. For the past 2 years, Dev has also been involved in automation initiatives for CSRs and other regulatory documents at AZ, leveraging structured content authoring, rule-based automation, and AI.

1:00 PM — 2:00 PM

Lunch Break

2:00 PM — 3:30 PM

T1S5: Strategic Role of RWE in Evidence Planning

As the demand for robust, patient-centered data grows, RWE is becoming a critical component in shaping regulatory, market access, and clinical decisions. The sessions will cover best practices, evolving methodologies, and the future landscape of RWE in driving more informed and impactful evidence strategies.

Session Chair(s)

Shruti MP, MSc

Director-Real World Data Solutions
Parexel International, India

Overall, Shruti has 16 years of clinical research experience in real world data (RWD) solutioning, medical writing, product strategy and medical communications, at Parexel and at GSK. Extensive experience in the development of RWD strategies across different therapeutical areas (e.g., oncology, respiratory, cardiovascular, metabolic, and rare diseases). ?Expertise in regulatory writing, authoring protocols, study reports and consent forms. As a Lead Publications Manager, building communication plans and overseeing publication development for three vaccine portfolios. Thought leadership engagements include presenting at Clinical Trials Europe, EMWA, DIA India and ISCR. She holds a MSc in Biochemistry from Bangalore University.

Speaker(s)

Role of RWE In Evidence-Based Medicine

Amrita Ostawal

Managing Director
Arete Access, India

Amrita Ostawal is the Founder and Managing Director of Arete Access. With nearly 15 years of leadership experience in medical affairs and health economics and outcomes research (HEOR), she has driven evidence-based healthcare decisions across global pharmaceutical and medical device markets. Her expertise spans health technology assessments, payer value communications, and medical writing, developed through senior roles at leading healthcare innovators and consulting companies in India and Europe. Amrita is passionate about leveraging data science to bridge medical affairs and market access, helping organizations demonstrate value through evidence-based insights.

Integrated Evidence Generation Plans- Bridging Clinical Trials, RWE and Market Access

Sriram Govindan

Associate Director-Publications, Global Scientific Communications
Eli Lilly Services India Private Limited, India

Sriram Govindan has 14 years of experience in the pharma industry, including 11 years in medical writing. In his current role at Eli Lilly, he manages a team of managers, publication leads, writers, and PMs responsible for global, Japan, and China publications, with a focus on HEOR and RWE publications.

With the Additional Presence of

Ambika Subramanian

Head Medical Writing, Life Sciences Consulting
NTT Data, India

A medical writing expert with 18 years of experience across regulatory, medical communications, and RWE. A strong track record of building teams, driving process automation, supporting business development, managing client relationships, and delivering high-quality reports across Pharma and CROs.

With the Additional Presence of

Alben Sigamani

Director & Founding Professor
Carmel Research Consultancy Pvt. Ltd., India

Dr. Alben Sigamani is a physician-researcher and clinical trials expert with 20+ years of experience. He bridges science and communication, advancing medical writing, translation research, and real-world evidence to improve patient-centered outcomes. A passionate mentor, he actively trains young writers and researchers in clinical communication and evidence synthesis.

2:00 PM — 3:30 PM

T2S5: Trust Through Transparency: The Future of Clinical Trial Communication

As the global clinical research landscape evolves, transparency has emerged not just as a regulatory mandate but as a cornerstone of public trust. This session will explore how modern transparency practices are transforming clinical trial communication, offering insights into how transparency is being redefined to serve regulators, researchers, and most importantly, patients. We will delve into the impact of the EU Clinical Trials Regulation (EU-CTR) in elevating disclosure standards and reshaping sponsor responsibilities. The session will also highlight the growing importance of plain language summaries, both for protocols and results, as a means to foster meaningful engagement with patients and the public. Additionally, we will examine anonymization methods and their pivotal role in ensuring data privacy while preserving the utility of clinical data. Throughout the session, we will emphasize the evolving and strategic role of the medical writer in driving these initiatives — shaping content, ensuring compliance, and acting as a bridge between regulatory expectations and patient needs.

Session Chair(s)

Sonica Batra, MD

Associate Vice President Enterprise Medical;Global Head- Regulatory Affairs
Indegene Ltd., India

I am an MD physician by training, with 20 years of experience in drug development and medical and scientific affairs. I am presently AVP and Global Head for Medical Affairs and Regulatory at a global technology enabled healthcare solutions provider. I have led many successful global Regulatory Authority engagements across the globe, for developed as well as the Rest of the World- emerging/ developing countries, enabling clinical development plans, strategies, marketing authorisations and post approval compliances for various products including biosimilars. I have a keen interest and experience in enhancing medical value add and scientific information dissemination for medicinal products, in the peri approval and post approval space.

Speaker(s)

Evolving Role of Medical Writers Towards Ensuring Clinical Trial Transparency

Priyanka Kumari, DMD

Director, Regulatory Affairs & Labeling
Indegene, India

Dr. Priyanka, a dental surgeon with a postgrad diploma in clinical research, has 20+ years' experience in clinical and pharmaceutical sectors. After 7 years in clinical practice, she transitioned into clinical research and gained 13+ years of diverse experience. Currently Director – Regulatory Affairs at Indegene Ltd, she leads Regulatory Operations. Her expertise includes regulatory medical writing, labeling, strategic consulting, and clinical trial transparency across geographies. She is skilled in managing large teams and addressing queries from global regulatory bodies.

Regulatory Document Submissions, Anonymization Techniques And EU CTR

Sandeep Undavalli, MS

Clinical Transparency Specialist
Novo Nordisk Service Centre India Private Ltd, India

Sandeep works for Novo Nordisk as a Senior Disclosure Medical Writer. He has an overall experience of 8 years in clinical trials disclosure and transparency. His expertise includes registration and results submissions on ClinicalTrials.gov and EudraCT, clinical document redaction/anonymization for public disclosure to support European Medicines Agency Policy 0070, Health Canada Public Release of Clinical Information, and other global disclosure regulations.

With the Additional Presence of

Dr. Pooja Phogat, PhD

Founder and Co-CEO
Krystelis Ltd., India

Pooja Phogat holds a PhD in Microbiology and has over 20 years of pharmaceutical industry experience. For the past 18 years, she has specialized in medical writing, clinical trial disclosure, and data transparency, including Board-level leadership and regulatory consulting. As Co-Founder and Co-CEO of Krystelis, she leads global medical writing, communications, and trial transparency services. A recognized thought leader, she chairs the DIA India Medical Writing Community and co-chairs multiple DIA and EMWA working groups. She is also a member of ISMPP and ISCR and has presented at global conferences, authoring peer-reviewed publications and earning national awards.

3:30 PM — 4:00 PM

Tea/Coffee & Networking Break

4:00 PM — 5:30 PM

T1S6: Demystifying HEOR, GVD, and AMCP: Essential Insights for the Evolving Medical Writer

This session will introduce medical writers to the fundamentals of HEOR, Global Value Dossiers (GVD), and AMCP (Academy of Managed Care Pharmacy) dossier submissions, highlighting their role in shaping access and reimbursement narratives. Attendees will gain practical insights into structure, content expectations, and collaboration with cross-functional teams, equipping them to contribute effectively to value communication and market access strategies.

Session Chair(s)

Amit Dang, MD

Founder and CEO
MarksMan Healthcare Communications , India

Dr. Amit Dang is a physician-entrepreneur, thought leader, and the Founder & CEO of MarksMan Healthcare Communications - a global healthcare consulting firm specializing in HEOR, RWE, market access, and medical affairs. With over 15 years of experience, he has led strategic engagements across pharma, biotech, and life sciences, helping shape evidence-driven decisions and access strategies. He is also the host of “Pharma Insights Unplugged”, a podcast featuring leaders from the pharmaceutical industry. Dr. Dang is passionate about transforming healthcare communication through scientific integrity, innovation, and cross-functional collaboration and has over 100 publications to his credit.

Speaker(s)

With The Additional Presence Of:

Praveen Raj

Medical Affairs Leader & Health Economics Expert
Biocon, India

Dr. Praveen R has over 15 years of experience in medical affairs, specializing in diabetes, immunology, and oncology. Currently, he serves as the General Manager and Head of Global Medical Affairs at Biocon Biologics Ltd, where he develops and implements medical strategies and engages with thought leaders. He leads the medical plan focusing on insight generation, medical education, real-world evidence, and publications. He has held significant positions at Biocon Biologics Ltd, Abbott Healthcare, and GVK Bioscience, contributing to clinical development, strategic planning, and compliance with regulatory standards.

With The Additional Presence Of:

Amit Kandhare

Principal Scientific Writer– Health Economics and Value Assessment
Sanofi, India

Dr. Amit D. Kandhare is Principal Scientific Writer-HEVA/HEOR at Sanofi and managing various HEVA/HEOR-related value communication deliverables. He has completed his Ph. D. in Pharmaceutical Sciences and has over 14 years of experience in Pharma and Neutra industries.

With The Additional Presence Of:

Bharath H.S

Trials, Publications and ME Lead
AstraZeneca, India

With The Additional Presence Of:

Shiva Kumar V

Team Lead
Eli Lilly and Company, India

Shiva Kumar is a Manager (Team Lead) at Eli Lilly, leading evidence generation strategies for Immunology and Oncology. His 12+ years of HEOR expertise span across systematic literature reviews, burden modules, payer dossiers, real-world evidence, and health technology assessment for novel therapies.

4:00 PM — 5:30 PM

T2S6: Strategic Product Labelling: Ensuring Accuracy and Compliance Across the Product Lifecycle

Product labelling is a critical interface between healthcare products and their users, requiring precision, consistency, and regulatory compliance across global markets. This session will delve into current challenges and best practices in labelling and compliance management, including evolving regulatory expectations, digital solutions, and lifecycle oversight. Experts will share insights to help stakeholders ensure label accuracy, reduce risk, and maintain alignment with global compliance requirements.

Session Chair(s)

Sameera Kashyap

Regulatory Affairs Director and Global Regulatory Lead, Oncology,
AstraZeneca, India

Speaker(s)

Strategic Product Labelling

Rajesh Ameti

Head TA Labelling -Established Brands
Merk Group, India

Rajesh Ameti is a seasoned regulatory affairs professional with over 16 years of experience in global labeling, having worked with Merck, GSK, Novartis, and global service providers. He has held roles ranging from Global Labeling Manager to SME and leadership positions, supporting end-to-end labeling across the product lifecycle. Currently Head of Therapeutic Area Labeling – Established Products at Merck, Rajesh leads a team of experts providing strategic labeling direction across diverse therapeutic areas. His leadership enables effective regulatory submissions, global label negotiations, and post-marketing activities. He is passionate about strategic labeling that ensures compliance, enhances patient safety, and drives product value.

Navigating Compliance In Global Product Labelling: Integrating Internal Governance with Evolving Regulatory Expectations

Nagaraj Bannur

Director of Regulatory Affairs
AbbVie, India

With the Additional Presence of

Ramya YS

Senior Medical Director
Eli Lilly Services India Private Limited, India

With the Additional Presence of

Dr. Anant Patil

Professor, Dept of Pharmacology
Dr. DY Patil Medical College, India

Dr. Anant Patil, with over 20 years of post-PG experience, is an Editorial Board Member of six journals and Associate Editor of five books. He has received multiple awards, including the "Best Teacher Award" (2022), "Sherlock Holmes Award" (2023), "National Research Scholar Award" (2023), and "MPS Promising Senior MD Pharmacologist Award" (2024). Dr. Patil has conducted medical writing and statistics workshops across India, Bangladesh, and Sri Lanka, served as resource faculty for conferences, and worked in various pharmaceutical domains. He has authored 145+ articles, with 1,700+ citations, an H-index of 20, and an i10-index of 38.

5:15 PM — 5:30 PM

Closing Remarks & Vote Of Thanks