WHY? SUMMITS

23 - 24 September
2025

Mumbai
India

2nd Global Drug Safety & PV Outsourcing Summit 2025

Updated: 3 April, 2025
for the latest programe update, please download agenda on conference website

Gold Sponsors

PRIMEVIGILANCE
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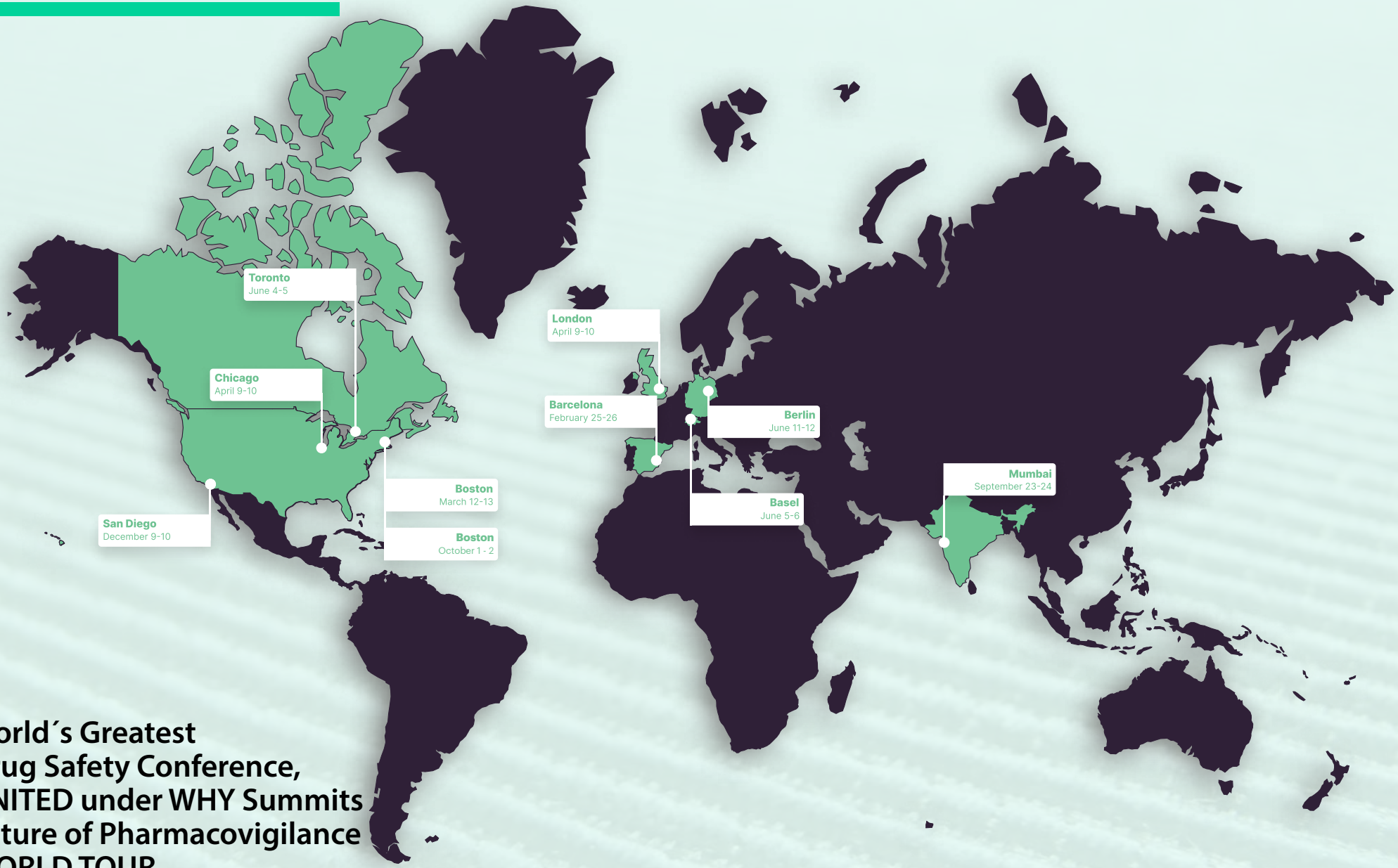
2025 Pharmacovigilance Summits Worldwide



World´s Greatest Drug Safety Conference, UNITED under WHY Summits Future of Pharmacovigilance WORLD TOUR

Future of Pharmacovigilance

Our prestigious Drug Safety Summit, a cornerstone of our Pharmacovigilance World Tour.

- **Meet** top Drug Safety professionals from our 2025 World Tour
- **Learn** about the most important issues that need to be addressed
- **Discuss** the vision for 2025 and lessons of 2024
- **Listen** to the most crucial current topics selected & presented by industry leaders
- **Enjoy** education & networking focused event in a non-vendor-driven environment
- **Create** lasting work groups and friendships with the possibility of meeting regularly on the next stops of our world tour

You will spend your time with

- **Drug safety & Pharmacovigilance executives**
- **Heads of global safety programs**
- **Benefit-Risk assessment management**
- **Medical affairs management**
- **Patient safety management**
- **Compliance specialists**
- **Post-market researchers**
- **PV auditors**
- **Regulatory affairs directors**
- **Compliance specialists**
- **Pharma IT management**
- **Safety consultants**

Always ask WHY?

Creating contrast to loud, expo- style meetings with limited focus and personal touch, WHY SUMMITS World tour of Pharmacovigilance conferences brings another kind of experience. Our Mumbai concentrated knowledge-focused meeting, is assembled in 8 blocks focusing on:

- **Strategic Overview: 2025 Outlook, Trends And Upcoming Challenges**
- **Expanding Pipeline & Increased Demand For PV Outsourcing**
- **Centralized PV Systems To Ensure Inspection-readiness**
- **Leveraging AI & LLM Technology To Meet Evolving PV Demands**
- **Aligning Outsourcing Strategy With The Overall Safety Function Strategy**
- **Advancements In Benefit-risk Assessment And Armms**
- **Optimizing PV Outsourcing For Post-market Safety Data**
- **Vendor Selection And Approaches To Effective Management**
- **Inspection Readiness Through Effective Third Party Management & Oversight**
- **Patient-centric Approaches In Signal Detection**
- **Key Considerations For Aligning External PV Services With Internal Workflows**

Industry Pioneers Attending From

WHY? SUMMITS

GSK Pfizer Lilly MERCK Roche sanofi AstraZeneca

Bristol Myers Squibb NOVARTIS abbvie Boehringer Ingelheim Johnson&Johnson

AMGEN VERTEX Genmab GILEAD Takeda novo nordisk

BAYER teva Biogen Daiichi-Sankyo CSL Otsuka Adaptimmune

Mylan astellas VIATRIS SANDOZ BIONTECH moderna

Testimonials

Sunil Thakur
Sr. Manager - Medical Affairs and QPPV
Exeltis India
★★★★★

"I had the privilege of attending the Global Drug Safety and PV Outsourcing Summit on 22 - 23 October 2024 in Mumbai. It was an incredibly insightful event, packed with valuable discussions and forward-thinking ideas. While many topics were discussed, I found the following particularly important: Cost Center vs. Cost-Effective, Patient-Centric PV, Biosimilars and PV, Leveraging AI and LLM"

Dr.Santosh Hulawale
Senior Manager- SERM & PvOI (India)
Glenmark Pharmaceuticals
★★★★★

"I had the privilege of sharing the stage with industry experts at the recent Global Drug Safety & PV Outsourcing Summit, organized by Why Summits on the topic of 'Challenges in Signal and Risk Management'.

The event featured in-depth discussions on a range of topics, including end-to-end pharmacovigilance activities, advances in signal detection, affiliate management, evolving regulations, and more, all offering valuable insights."

Ismail Ahmed
Deputy Manager
Viatris
★★★★★

"Just wrapped up an incredible experience at the Global Drug safety & PV Outsourcing Summit and AI tools (22 to 23 - Oct-2024 in Mumbai). A huge thank you to the organizers #whysummit for their exceptional hospitality and for creating such a welcoming and engaging atmosphere. The insights shared and the connections made were invaluable. From innovative solutions to thought-provoking discussions on the future of outsourcing, this event truly exceeded my expectations."

Dinesh Wagh
Manager, Safety Submissions (Clinical Trials)
Precision For Medicine
★★★★★

"Last week, Attended "Global Drug Safety and PV Outsourcing Summit 2024, Mumbai" as a Speaker and addressed on topic "Advances in Signal Detection & Risk Management". It was a mesmerizing experience ! Thank you Why Summits and Lubos Kusy for inviting !"

Dr. Shubhadeep D Sinha
Senior Vice President CD&MA
★★★★★

"Enjoyed it lot. Thanks Why Summits"

Dr. Deepak S, MD
Director, Pharmacovigilance- Medical Scientific Unit
Teva Pharmaceuticals
★★★★★

"I am truly honored to have had the opportunity to moderate such an engaging and thought-provoking panel discussion on "addressing challenges in signal detection and risk management" and "addressing inconsistencies in data reporting and leveraging technology solutions, how technology can help ? at WHY SUMMITS, GLOBAL DRUG SAFETY SUMMIT, MUMBAI."

Meet the first onboarded speakers to 2025 edition:

Dr Vaibhav Salvi
Director and Head – Clinical Study Unit, India and South East Asia R&D – Clinical Sciences and Operation
Sanofi

Geeta N. Shanbhag
Vice President – Pharmacovigilance & Medico -Regulatory Affairs
Ipca Laboratories Ltd

Dr. Anuja Jawale
Associate Director – R&D Procurement and Supplier Management
Organon

Kishore Darisi
SERM Associate Scientific Director
GSK

Dr Devang Patel
Head of Global Pharmacovigilance
Zydus

Rajendra Kumar Kasi
Vice President & Global Head – Pharmacovigilance
Glenmark Pharmaceuticals Limited

Sanket Mahajan
Safety Scientist, Pharmacovigilance
Shionogi Europe

Sakshi Shrivastava Desai
Director, LMS regional Lead APAC
Johnson & Johnson

Dr. Rahul S Kamble
Head Quality and Patient Safety
White Lotus International Hospital and Research Center

Mukesh Gori
Director Patient Safety & Pharmacovigilance ESP Engagement
Novartis

Dr. Shubhadeep Sinha
Senior Vice-President & Medical Director
Hetero

Vivek Gupta
Associate Director - Strategic Engagements & Vendor Management - Clinical & Medical Affairs
Organon

Deepak Shankarappa
Director, Pharmacovigilance-Medical Scientific Unit
Teva

Dinesh Wagh
Manager, Safety Submissions (Clinical Trials)
Precision For Medicine

Conference Agenda

DAY 1

DAY 0 – EVENING BEFORE SUMMIT

19:30 MEET & GREET

Informal meeting in the Lobby of the hotel for all attendees coming to the conference the night before. A unique chance to network in tighter, relaxed circles and to register and receive your batch in advance.

8:30 Morning Registration and early birds networking coffee

SUMMIT OPENING: PHARMACOVIGILANCE LANDSCAPE – 2025 TRENDS & CHALLENGES

9:00

OFFICIAL START OF 2ND GLOBAL DRUG SAFETY & PV OUTSOURCING SUMMIT WITH OPENING REMARKS OF THE CHAIRPERSON

9:10

KEYNOTE: STRATEGIC OVERVIEW: WHERE WE ARE AND WHERE DO WE GO FROM HERE?

- Reflections from 2024 to prepare us for 2025
- What's the top-priority for 2025?
- Key focus areas

9:30

OPENING TOWNHALL DISCUSSION: NAVIGATING THE FUTURE OF PHARMACOVIGILANCE: KEY TRENDS, INNOVATIONS, AND CHALLENGES AHEAD

- Emerging technologies to keep an eye on
- Growing importance of real-world data, patient-reported outcomes, and social media monitoring
- Addressing challenges of data privacy concerns, cross-border collaboration, and implementation of agile frameworks

10:00

RESERVED PRESENTATION: THE PHARMACEUTICAL INDUSTRY'S EXPANDING PIPELINE & INCREASED DEMAND FOR PHARMACOVIGILANCE SERVICES: VENDORS PERSPECTIVE

- The need for more comprehensive pharmacovigilance services to handle the growing number of drug approvals in biologics and gene therapies

10:30 MORNING BREAK: COFFEE, CAKE & NETWORKING

ADAPTING TO THE EVOLVING LEGAL AND REGULATORY FRAMEWORK

11:00

KEYNOTE: EVOLVING REGULATIONS & REQUIRED STRATEGIES TO ADAPT

- Updates to the Clinical Trials Regulation and safety reporting requirements
- Adaptation Strategies for Compliance
- Future-Proofing PV Operations

11:30

RESERVED CASE STUDY: INTEGRATING NEW COMPLIANCE REQUIREMENTS INTO EXISTING SYSTEMS

- Addressing the complexities of aligning new regulatory requirements with legacy systems
- Discover the solutions to leverage machine learning
- Cross-Functional collaboration

12:00 LUNCH BREAK

13:00

PANEL DISCUSSION: HOW TO FACILITATE REAL-TIME DATA SHARING AND REPORTING ACROSS IN-HOUSE AND OUTSOURCED TEAMS

- Innovative therapeutics legislation updates
- Which additional risk minimization measures should be added for post-marketing studies?

Conference Agenda

DAY 1

13:30

RESERVED KEYNOTE: GLOBAL HARMONIZATION CHALLENGES FOR LOCAL PHARMA STAKEHOLDER: A REGULATORY COMPLIANCE JOURNEY

- Streamline submission processes, accelerate approval times, and efficiently handle regulatory changes and updates
- Agile regulatory and reporting

14:00

PANEL DISCUSSION: LEVERAGING TECHNOLOGY TO MEET EVOLVING REGULATORY DEMANDS

- How will digital technologies help to meet new regulatory compliance demands while creating business value?

14:30 Coffee & Cake Break

ORGANIZATIONAL STRUCTURES FOR QUALITY ASSURANCE AND RISK MANAGEMENT

15:00

KEYNOTE: 2025 ORGANIZATIONAL STRUCTURES & PROCESSES FOR QUALITY MANAGEMENT SYSTEMS

- Best practices for creating robust organizational structures that support quality management
- Fostering a culture of continuous improvement, including ongoing training and development programs

15:30

CASE STUDY: WHAT TO CONSIDER FOR IN-HOUSE VS OUTSOURCING

- Strategic decision-making framework
- Cost-effectiveness, scalability, and alignment with long-term business goals

16:00

ROUNDTABLE DISCUSSION: OPERATIONAL EFFECTIVENESS WITHIN END-TO-END PV SERVICES

- Dealing with the complexities of aggregate reporting

17:00 END OF DAY 1 AND CLOSING REMARKS

(SPONSORSHIP OPPORTUNTIY AVAILABLE)

Conference Agenda

DAY 2

DIGITALIZATION, INNOVATION AND DATA MANAGEMENT

9:00

KEYNOTE: DATA OVERLOAD: NOW WHAT?

- The volume of PV data is immense and will continue growing faster than expected by 2027
- Case-study on how we used Big-Data to assist us
- Database networks for Post-Marketing surveillance

9:30

RESERVED KEYNOTE: AI-DRIVEN DATA FOR THE CATEGORIZATION AND PRIORITIZATION OF ADRs

- Enhancing data classification
- Assisting in the identification and prioritization of targets
- Achieving faster and more accurate identification of safety signals

10:00

PANEL DISCUSSION: QPPV KEY FOCUS AREAS TO CONSIDER – EXPERT OPINION

- How do you see QPPV changing and what should we prepare for?
- People, Process, Product – which to focus on in 2025?

10:30 NETWORKING BREAK

11:00

CASE STUDY: KEY CONSIDERATIONS FOR ALIGNING EXTERNAL PV SERVICES WITH INTERNAL WORKFLOWS

- Best practices for maintaining quality, accountability, and regulatory adherence

11:30

PANEL DISCUSSION: CLINICAL DATA PROJECTS ON THE HORIZON FOR 2025

12:00 LUNCH BREAK

ENHANCING SAFETY AND MITIGATION STRATEGIES

13:00

KEYNOTE: ADDRESSING CHALLENGES IN SIGNAL DETECTION AND RISK MANAGEMENT

- How RWE can improve risk assessment by providing a broader perspective
- Highlight strategies for using RWE

13:30

CASE STUDY: OPTIMIZING PV OUTSOURCING FOR POST-MARKET SAFETY DATA ON RISK MANAGEMENT STRATEGIES

- Techniques for integrating outsourced PV data with in-house systems to ensure seamless data flow
- Ensuring compliance with global regulatory requirements while outsourcing PV functions

14:00

PANEL DISCUSSION: AUTOMATION FOR HEIGHTENED EFFICIENCY, PRECISION, AND COMPLIANCE IN RISK MANAGEMENT

- Detecting subtle safety signals and ensuring accurate classification of adverse events
- Automatically updating procedures and documentation to reflect new requirements

14:30 Networking coffee break

INNOVATIVE SIGNAL DETECTION METHODS AND THEIR IMPACT

15:00

KEYNOTE: LEVERAGING OUTSOURCED EXPERTISE FOR ADVANCED SIGNAL DETECTION METHODS

- Generate a more holistic view of the safety data & broader data management solutions
- Centralising updated preclinical and clinical data for early-stage detection

Conference Agenda

DAY 2

15:30

TOWNHALL DISCUSSION: SIGNAL DETECTION CHALLENGES OF INTEGRATION

- Challenges in managing and integrating diverse data sources

1600

CLOSING REMARKS: REFLECTIONS AND NEXT STEPS: SHAPING THE FUTURE OF PHARMACOVIGILANCE IN INDIA

- Wrap-up

An open plenary discussion, with chairperson introducing the most interesting & unanswered questions raised via Sli.do during the 2-day event. The conference will end as a free interactive networking and discussion setting goals for 2025.

2025 Pharmacovigilance Summits Worldwide

1. 25 - 26 February, BARCELONA
   European Drug Safety & PV Outsourcing Summit
2. 12 - 13 March, BOSTON
   American Drug Safety Summit 2025 - East coast
3. 9 - 10 April, LONDON
   10th Global Pharmacovigilance & RWE FORUM
4. 9 - 10 April, CHICAGO
   2nd Annual American MedTech Summit
5. 4 - 5 June, TORONTO
   Canadian Pharmacovigilance Management & Compliance Conference
6. 5 - 6 June, Basel
   2nd Annual World Drug Safety Summit
7. 11 - 12 June, BERLIN
   2nd Annual European MedTech Summit
8. 23 - 24 September, MUMBAI
   2nd Annual Global Drug Safety & PV Outsourcing Summit
9. 1 - 2 October, Boston
   2nd American Drug Safety Summit 2025 - East Coast
10. 9 - 10 December, SAN DIEGO
    American Drug Safety Summit 2025 - Westcoast

Our Valued Partners, Past And Present

WHY? SUMMITS

Sponsorship

Additional sponsorship opportunities are available for those who wish to further customize their involvement.

Exhibiting

With a large and senior audience and decision makers, thoroughly selected, exhibiting at any Summit at 2025 FoP SUMMIT WORLD is a popular sponsorship option with great value for solution providers.

Sponsorship includes

- Selected Summit Three Access Passes
- Exhibition space
- Helping to prearrange face to face meetings with selected participants

Dinner Sponsorship

2025 FoP SUMMIT WORLD TOUR will host a series of dinners These dinners bring together thoughtfully selected groups of 15-20 peers from established pharma, biotech, healthcare, and medtech companies. The dines start with a 30-minute networking reception followed by a 60-minute seated dinner, with the option for participants to remain afterward to continue networking.

- Selected Summit Three Access Passes
- 30-minute reception, and 60 minute seated dinner

Speaking

Limited speaking opportunities are available for our sponsoring partners to demonstrate the expertise of their organization. Be sure to ask about these early so we can ensure your presentation flows seamlessly with the overall content. Speaking sponsorships has several options – keynote presentations, case study presentations, expert presentations, panel discussions, workshops, or roundtable leadership. Speaking opportunities are available for experts in the field of Drug safety specialists, QPPVs, Safety Heads, C-level pharmaceutical and biotech executives, hospital management, clinicians, epidemiologists, pharmacologists, Project and Portfolio Management, Contract Management, Consultancy, CROs, Data Management, Artificial Intelligence, Robotics and Digital Innovation experts

Contact us

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for the latest programe update, please
download agenda on conference website

Speaking:

Jan Cizek
jan.cizek@whysummits.com

Sponsoring:

Lubos Kusy
lubos@whysummits.com

Sponsoring:

Rakesh Multani
rakesh@whysummits.com

Disclamer:
Please note - all of the information in this document is subject to change at any time. Whilst every effort has been made to ensure the accuracy of the information, statements and decisions recorded in them, their status will remain that of a draft until such time as they are confirmed as a final version prior the subsequent meeting, Additionally, the user information is only valid at a certain moment in time and is subject to change due to movement and changes in bit rate requirements.

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