PEC PHARMA EDUCATION CENTER
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EUROPEAN PHARMACOVIGILANCE CONGRESS 2023

Global Conference

27 - 28 November | Virtual
1 December | Milan

The European Pharmacovigilance Congress is recognized as one of the most important and appreciated global conference on Pharmacovigilance.

Last year, delegates from more than 50 countries worldwide have joined the **two days of virtual event** followed by **the day in presence in Milan.**

The European Pharmacovigilance Congress gathers professionals at all career levels, including **key decision makers** (e.g. Directors, VPs and Executives) interested in the always evolving pharmacovigilance world and its new trends, and willing to implement more efficient and effective strategies and tools for their departments.

To further improve the value of the congress, the Scientific Board has been widened with the addition of new prestigious, renowned **international PV key opinion leaders**. Their deep knowledge and experience, as well as the involvement of excellent speakers on each topic, will ensure the highest scientific level of the program.

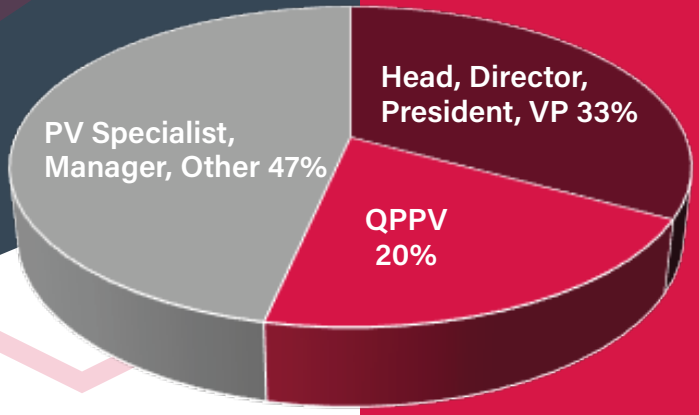
The conference will cover topics of global relevance offering in each session dedicated time for discussion with the involvement of delegates.

PARALLEL SESSIONS
More practical aspects of specific topics will be addressed during the parallel sessions with the involvement of delegates.

New!

The European Pharmacovigilance Congress 2023, in collaboration with the Media Partner SAGE, Therapeutic Advances in Drug Safety (Impact Factor: 3,842), an international peer-reviewed Open Access journal, will select the 2 best scientific articles published by the journal in 2022.
The authors will present their work in the event agenda.

Audience composition



FEATURED TOPICS

- EVOLVING PHARMACOVIGILANCE STRATEGIES
- PHARMACOVIGILANCE IN DRUG DEVELOPMENT
- PHARMACOVIGILANCE IN ATMP
- REGULATIONS IMPACTING ON THE GLOBAL PV SYSTEM
- EXTRA-EU PHARMACOVIGILANCE REGULATORY REQUIREMENTS
- SIGNAL DETECTION & RISK MINIMIZATION
- REAL WORLD EVIDENCE IN PHARMACOVIGILANCE
- RISK COMMUNICATION
- APPLYING ARTIFICIAL INTELLIGENCE TO PHARMACOVIGILANCE
- EUDRAVIGILANCE & CTIS UPDATES
- PHARMACOVIGILANCE QUALITY SYSTEM - INSPECTIONS & AUDITS
- PHARMACOEPIDEMIOLOGY

Delegates' feedbacks

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"Excellent congress!"

"It was well done with high level presentation"

"Excellent event, high quality content, very well organized, clear communication! I plan to attend every year. Thank you!!"

"Really interesting topics! Thank you!"

SCIENTIFIC BOARD

Glyn Belcher
CEO of PV Consultancy Ltd

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Head of Drug Safety and Italy and UK LPPV | Orchard Therapeutics

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SPEAKERS

Fazil Afzal
Medical Assessor at Medicines and Healthcare products Regulatory Agency

Ayman Ayoub
Vice President, Business Unit Area Head, Safety Surveillance and Risk Management | Pfizer

Amalia Alexe
Policy and Liaison Lead, QPPV PRRC Office | Novartis

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Head of Global Pharmacovigilance, EU&UK, QP for Pharmacovigilance

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Azira Čajić
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Thomas Debray
Founder, Smart Data Analysis and Statistics B.V.

Marcela Fialova
Chief Operating Officer | iVigee

Alberto Gramaccioli
Director, Quality Management and Inspections, World Wide Safety | Pfizer inc.

Ilaria Grisoni
Exec. Dir., Head of EU/International PV & Office of QPPV, EEA QPPV | Jazz Pharmaceuticals

Sarah Hall
Managing Director | Mipsol Limited

Thierry Hamard
Director, Safety Observer

Kendal Harrison
Head of Vigilance Development at Medicines and Healthcare products Regulatory Agency (MHRA)

Paola Kruger
Expert Patient | EUPATI (European Patient's Academy for Therapeutic Innovation)

Vojtech Kvita
CVO | NextPV Services s.r.o.

Hervé Le Louët
Head of PV policy intelligence strategy| Takeda, President of CIOMS, Past CEO of the UMC, Past President of ISOP

Maddalena Lino
Neurologist, Safety Risk Lead Director | Pfizer

Calin A. Lungu
DDCS S.A., CEO

Arduino Mangoni
Strategic Professor in Clinical Pharmacology | Flinders University, Senior Consultant in Clinical Pharmacology and General Medicine

Zeljana Margan Koletic
Croatian PRAC Alternate Member, Head of Department for Pharmacovigilance and Rational Pharmacotherapy | HALMED

Niteeka Maroo
Head Pharmacovigilance |Piramal Group-India

Larissa Mege
Global Safety Officer, Sanofi Rare Diseases, Specialty Care Business Unit

Nicholas Moore
Emeritus Professor, specialist in Cardiology and Pharmacology | University of Bordeaux

Charalampos Nakos
EU-QPPV | Drug Safety Solutions

Helen Byomire Ndagije
Product Safety Director | the National Drug Authority in Uganda, President of the ISoP Africa chapter

Eriko Ogura
Global Head of Drug Safety | Shionogi & Co.,Ltd.

Nuccia Oneto
Patient Oriented Programs Governance Lead/Novartis Farma S.p.A.

Maria Beatrice Panico
Principal Consultant | Scendea

Susana Perez-Gutthann
VP, Global Head Epidemiology| RTI Health Solutions

Elena Prokofyeva
Head of the Drug Safety Team, R&D Department, DG PRE | FAMHP

Lembit Rago
Secretary-General | Council for International Organizations of Medical Sciences (CIOMS)

Hadir Rostom
Lecturer | MSA university & President of ISoP Egypt Chapter

Annette Rudolph
Pharmacovigilance scientist | Uppsala Monitoring Centre

Jennifer Stevenson
Consultant Pharmacist for Older People, Guy's and St Thomas' NHS Foundation Trust

Monica Da Luz Carvalho Soares
Health Regulatory Expert, Pharmacovigilance Adviser|Brazilian Health Surveillance Agency (Anvisa)

Sofia Trantza
MSc, MSc PV, Senior pharmacovigilance expert

Michael Von Forstner
Global Head of Clinical Safety and Pharmacovigilance | Biogen

Anna Van Troostenburg De Bruyn
EU QPPV and VP Pharmacovigilance & Epidemiology at Gilead Sciences

Qun-Ying Yue
Associate Professor Senior Pharmacovigilance Expert | Uppsala Monitoring Centre

Gloria Bustos
Senior Director, Head of Pharmacovigilance EMEA and APAC | Baxter

Dominique Hamerlijnck
EUPATI fellow, Patient Expert

Romina Fernanda Heredia
PV Intelligence Coordinator, Head of Project Managers and Business Development | PhV Latam

Gianluca Trifirò
Full Professor of Pharmacology – Department of diagnostics and public health | University of Verona

Lucia Biagiotti,
EU & UK QPPV | Quality Assurance | Pharmacovigilance system assessment | Pharma D&S

Andrea Pieri
Business Development Director | Pharma D&S

Sara Lazzarin
Global Head of Pharmacovigilance Unit | OPIS s.r.l.

Ivona Bahnik Bisevac
Director Benefit-Risk Management | PrimeVigilance

AGENDA 27 NOVEMBER

all times are UTC +1 **Virtual**

09.00 **Welcome by the Chairperson of the congress**
Marco Sardella, Chief Pharmacovigilance Officer & EU QPPV | ADIENNE Pharma & Biotech

09.10 **A word from the Editor-in-Chief of Therapeutic Advances in Drug Safety - Eu PV Congress Media Partner**
Arduino Mangoni, Strategic Professor in Clinical Pharmacology | Flinders University, Senior Consultant in Clinical Pharmacology and General Medicine, Adelaide, Australia

SESSION 1. MAIN GLOBAL PV UPDATES

09.15 **Introduction by the Chairperson of the Session**
Gian Nicola Castiglione, Director Global Pharmacovigilance, EU QPPV | Chiesi

09.20 **New regulations and guidelines in PV**
Thierry Hamard, Pharmacovigilance & Regulatory Intelligence | Safety Observer

09.40 **How to keep oversight over the pharmacovigilance regulatory intelligence landscape globally**
Marcela Fialova, COO and Co-founder | iVigee

10.00 **Global PV regulatory requirements – current challenges in handling Local PV requirements in a global setting**
Ilaria Grisoni, Exec. Dir., Head of EU/International PV & Office of QPPV, EEA QPPV | Jazz Pharmaceuticals

10.20 **Round Table & Q&A Time**
Moderator: GN. Castiglione
Panelists: M. Fialova
I. Grisoni
S. Hall | Mipsol Limited
T. Hamard

10.50 **Coffee Break & Networking**

SESSION 2. SIGNAL DETECTION & RISK MINIMIZATION

11.10 **Introduction by the Chairperson of the Session**
Arduino Mangoni, Strategic Professor in Clinical Pharmacology |Flinders University, Senior Consultant in Clinical Pharmacology and General Medicine, Adelaide, Australia

11.15 **Risk minimization measures types and tools**
Klaudija Marijanovic Barac, Sr. Director, EU&UK QPPV deputy, Head Periodic Reports and Risk Management Unit | TEVA

11.35 **Detection of high impact signals**
Qun-Ying Yue, Associate Professor, Senior Pharmacovigilance Expert | Uppsala Monitoring Centre

11.55 **Effectiveness of risk minimisation measures**
Zeljana Margan Koletic, Croatian PRAC Alternate Member, Head of Department for Pharmacovigilance and Rational Pharmacotherapy | HALMED

12.15 **Global safety monitoring of COVID-19 vaccines: how pharmacovigilance rose to the challenge**
Annette Rudolph, Pharmacovigilance scientist | Uppsala Monitoring Centre

12.35 **Round Table & Q&A Time**
Moderator: **A. Mangoni**
Panelists: **K. M. Barac,**
F. De Gregorio | Shionogi Europe,
Z.M. Koletic
A. Rudolph,
M. Von Forstner |
Biogen International
Q.Y. Yue

1.05 **Lunch & Networking**

SESSION 3. REAL WORLD EVIDENCE IN PHARMA-COVIGILANCE

2.00 p.m. **Introduction by the Chairperson of the Session**
Michael Von Forstner, Global Head, Patient Safety and Pharmacovigilance Biosimilars | Biogen International

2.05 **The European Health Data & Evidence Network (EHDEN) in pharmacovigilance**
Thomas Debray, Founder, Smart Data Analysis and Statistics B.V.

2.25 **The role of real-world data and methods in evaluating the safety of medical interventions**
Susana Perez-Gutthann, Vice President, Global Head Epidemiology | RTI International

2.45 **Interplay of spontaneous reporting system and longitudinal healthcare databases for signal management**
Gianluca Trifirò, Full Professor of Pharmacology – Department of diagnostics and public health | University of Verona

3.05 **Round Table & Q&A Time**
Moderator: **M. Von Forstner**
Panelists: **T. Debray**
S. Perez-Gutthannn
G. Trifirò

3.30 **Coffee Break & Networking**

SESSION 4. APPLYING ARTIFICIAL INTELLIGENCE TO PV

3.50 **Introduction by the Chairperson of the Session**
Jan Petracek, CEO | iVigee, Director of Institute of Pharmacovigilance, ISoP Advisory Board

3.55 **AI models in use/development at the MHRA**
Kendal Harrison, Head of Vigilance Development | MHRA

4.15 **AI tools in pharmacovigilance**
Maria Beatrice Panico, Principal consultant | Scendea

4.35 **Tbd | Slot reserved for the sponsor**

4.55 **Round Table & Q&A Time**
Moderator: **J. Petracek**
Panelists: **M.B. Panico**
K. Harrison

5.20 **Closing Remarks by the Chairperson of the congress and introduction of Lectio Magistralis**
Marco Sardella, Chief Pharmacovigilance Officer & EU QPPV /ADIENNE Pharma & Biotech

SESSION 5. SIGNAL DETECTION & CAUSALITY ASSESSMENT (parallel session)

3.50 **Introduction by the Chairperson of the Session**
Giovanni Furlan, Worldwide Safety Site Lead - Thessaloniki (Greece), Safety Risk Lead, Director | Pfizer S.r.l.

3.55 **Signal detection in clinical trial settings – challenges in global environment**
Ivona Bahnik Bisevac, Director Benefit-Risk Management | PrimeVigilance

4.20 **Causality assessment**
Maddalena Lino, Safety risk Lead Director | Pfizer

4.50 **Q&A Time with Experts:**
I.B. Bisevac, G. Furlan, M. Lino

5.15 **Closure of parallel session**

SESSION 6. LECTIO MAGISTRALIS

5.20 **Pharmacopidemiology is an important pharmacovigilance tool, but pay attention to biases and confounding factors**
Nicholas Moore, Emeritus professor of clinical pharmacology | University of Bordeaaux

6.15 **Q&A Time**

6.30 **Closure of day 1**

AGENDA 28 NOVEMBER

all times are UTC +1 **Virtual**

09.00 **Welcome by the Chairperson of the congress**
Marco Sardella, Chief Pharmacovigilance Officer & EU QPPV | ADIENNE Pharma & Biotech

09.10 **A word from the Editor-in-Chief of Therapeutic Advances in Drug Safety - Eu PV Congress Media Partner**
Arduino Mangoni, Strategic Professor in Clinical Pharmacology|Flinders University, Senior Consultant in Clinical Pharmacology and General Medicine, Adelaide, Australia

SESSION 7. EXTRA-EU PHARMACOVIGILANCE REGULATORY REQUIREMENTS (UK-Japan-India)

09.15 **Introduction by the Chairperson of the Session**
Margherita D'Antuono, EU-UK QPPV | Piramal Critical Care

09.20 **UK Pharmacovigilance Requirements - A Regulator's Perspective**
Fazil Afzal, Senior Medical Assessor | Medicines and Healthcare products Regulatory Agency (MHRA)

09.40 **A new emergency approval system and post-marketing PV activities in Japan**
Eriko Ogura, Global Head of Drug Safety | Shionogi & Co.,Ltd

10.00 **Global Pharmacovigilance regulations**
Niteeka Maroo, Head Pharmacovigilance | Piramal Group-India

10.20 **Round Table & Q&A Time**
Moderator: **M. D'Antuono**
Panelists: **F. Afzal**
S. Hall | MIPSOL Limited
N. Maroo
E. Ogura

10.50 **Coffee Break & Networking**

SESSION 8. RISK COMMUNICATION

11.10 **Introduction by the Chairperson of the Session**
Hervé Le Louët, Head of PV policy intelligence strategy |Takeda, CIOMS President

11.15 **Evidence-based benefit-risk communication - what is next in the field of pharma?**
Frederic Bouder, Professor in Risk Management |University of Stavanger, Norway

11.35 **Safety Information in the product and patient information**
Anita Blackburn, Global Labeling Lead | Labcorp

11.55 **Pharmacogenomic information in the label**
Giovanni Furlan, Worldwide Safety Site Lead - Thessaloniki (Greece), Safety Risk Lead, Director | Pfizer S.r.l.

12.15 **Patients support programs: examples to communicate with patients, improve adherence and lower risks.**
Nuccia Oneto, Patient Oriented Programmes Governance Lead | Novartis Italy

12.35 **Round Table & Q&A Time**
Moderator: **H. Le Louët**
Panelists: **A. Blackburn**
F. Bouder
G. Furlan
P. Kruger | EUPATI

1.05 **Lunch & Networking**

SESSION 9. EUDRAVIGILANCE: UPDATES (parallel session)

12.05 **Introduction by the Chairperson of the Session**
Chairperson PEC

12.10 **Eudravigilance updates**
Calin Lungu, CEO | DDCS S.A.

12.45 **Q&A Time**

01.00 **Closure of Parallel session**

01.05 **Lunch & Networking**

SESSION 10. PV IN ATMP

02.00 **Introduction by the Chairperson of the Session**
Mattia Calissano, Head of Drug Safety and Italy and UK LPPV | Orchard Therapeutics

02.05 **The risk management of ATMP 's: practice and regulation**
Jan Petracek, CEO | iVigee

02.25 **Safety aspects of Adeno-Associated Virus (AAV)-mediated Gene Therapy (GT)**
Larissa Mege, Global Safety Officer, Sanofi Rare Diseases, Specialty Care Business Unit

02.45 **Application of Immunogenicity and Tolerance Principles to Immunogenicity Risk Assessment Advanced Therapy Medicinal Products (ATMPs)**
Anne De Groot, CEO/CSO and Director | EpiVax

3.05 **Round Table & Q&A Time**
Moderator: **M. Calissano**
Panelists: **D. Chonzi** | Instil Bio
A. De Groot
L. Mege
J Petracek

SESSION 11. CTIS: UPDATES (parallel session)

3.30 **Introduction by the Chairperson of the Session**
Mircea Ciuca, Global Therapeutic Area Head in Global Clinical Safety and Pharmacovigilance

3.35 **Pharmacovigilance in Clinical Trial: highlights from the inside**
Sara Lazzarin, Global Head of Pharmacovigilance Unit | OPIS s.r.l.

3.55 **CTIS updates**
Vojtech Kvita, CVO, Co-Founder | NextPV Services

4.15 **Q&A Time**

4.40 **Closure of Parallel session**

SESSION 12. PV IN SPECIAL POPULATIONS

3.30 **Introduction by the Chairperson of the Session**
Glyn Belcher, CEO | PV Consultancy Ltd

3.35 **Optimising data collection & risk management in pregnant and breastfeeding women**
Amalia Alexe, Policy & Liaison Lead, QPPV PRRC Office | Novartis

3.55 **Drug safety in older adults**
Jennifer Stevenson, Consultant Pharmacist for Older People, Guy's and St Thomas' NHS Foundation Trust

4.15 **Round Table & Q&A Time**
Moderator: **G. Belcher**
Panelists: **A. Alexe**
D. Hamerlijnck | EUPATI
J. Stevenson
Q.Y. Yue | UMC

SESSION 13. EXTRA-EU-PHARMACOVIGILANCE REGULATORY REQUIREMENTS (MENA-LATAM- CHINA)

4.40 **Introduction by the Chairperson of the Session**
Valentina Mancini, Senior Director Pharmacovigilance QPPV | Shionogi Europe

4.45 **LATAM PV Regulatory requirements**
Romina Fernanda Heredia, PV Intelligence Coordinator, Head of Project Managers and Business Development | PhV Latam

5.05 **Middle East PV Regulatory requirements**
Lana Arafat, Associate Director, Pharmacovigilance | Hikma Pharmaceuticals

5.25 **PV regulatory requirements in China**
Gloria Bustos, Senior Director, Head of Pharmacovigilance EMEA and APAC | Baxter

5.45 **Round Table & Q&A Time**
Moderator: **V. Mancini**
Panelists: **L. Arafat**
G. Bustos
R. Heredia
H.B. Ndagije | National Drug Authority in Uganda
Hadir Rostom | ISoP Egypt Chapter

6.10 **Closing Remarks by the Chairperson of the congress**
Marco Sardella, Chief Pharmacovigilance Officer & EU QPPV / ADIENNE Pharma & Biotech

AGENDA 1 DECEMBER

all times are UTC +1 **Milan**

08.45 **Registration of attendees**

09.20 **Welcome by the Chairperson of the congress**
Marco Sardella, Chief Pharmacovigilance Officer & EU QPPV | ADIENNE Pharma & Biotech

09.30 **A word from the Editor-in-Chief of Therapeutic Advances in Drug Safety - Eu PV Congress Media Partner**
Arduino Mangoni, Strategic Professor in Clinical Pharmacology|Flinders University, Senior Consultant in Clinical Pharmacology and General Medicine, Adelaide, Australia

SESSION 14. EVOLVING PHARMACOVIGILANCE STRATEGIES

09.35 **Introduction of the Round Table**
Lembit Rago, Secretary-General |Council for International Organizations of Medical Sciences (CIOMS)

09.50 **Presentation & Panel Discussion**
Eriko Ogura, Global Head of Drug Safety- Shionogy
Ayman Ayoub, VP Business Unit Area Head Safety Surveillance & Risk Management | Pfizer
Andrew Bate, VP Safety Innovation & Analytics| GSK
Sophia Trantza, Senior pharmacovigilance expert
Anna Ruth van Troostenburg De Bruyn, Senior VP Pharmacovigilance & Epidemiology | Gilead Sciences

10.50 **Coffee Break & Networking**

SESSION 15. PHARMACOVIGILANCE IN DRUG DEVELOPMENT

11.20 **Introduction by the Chairperson of the Session**
Mircea Ciuca, Global Therapeutic Area Head in Global Clinical Safety and Pharmacovigilance

11.25 **Aggregate data in clinical trials: a fresh perspective**
Maria Beatrice Panico, Principal consultant | Scendea

11.45 **TBD**
Anne Ruth van Troostenburg De Bruyn, EU QPPV and VP Pharmacovigilance & Epidemiology | Gilead Sciences

12.05 **Pharmacovilgilance in clinical trials under CTR: an update, bridgring from safety in clinical trials to postmarketing.**
Elena Prokofyeva, Head of the Drug Safety Team, R&D Department| DG PRE, FAMHP

12.35 **Round Table & Q&A Time**
Moderator: **M. Ciuca**
Panelists: **M.B. Panico**
E. Prokofyeva
A.R. Van Troostenburg De Bruyn

1.00 **Lunch & Networking**

SESSION 16. PV QUALITY SYSTEM - INSPECTION & AUDIT

01.50 **Introduction by the Chairperson of the Session**
Calin Lungu, DDCS S.A., CEO

01.55 **Inspection trends**
AIFA representative (invited)

02.15 **Pharmacovigilance Inspections in Brazil**
Monica Da Luz Carvalho Soares, Health Regulatory Expert, Pharmacovigilance Adviser | Brazilian Health Surveillance Agency (Anvisa)

02.35 **TBD**
PV inspector | FAGG -AFMPS (tbc)

02.55 **TBD**
Tea Babić, Director, Head of global PV audits and inspections | Teva Pharmaceuticals

3.15 **Round Table & Q&A Time**
Moderator: **C. Lungu**
5 *Panelists*: **T. Babic,**
Raj Bhogal, Jazz Pharmaceuticals
M. Da Luz Carvalho Soares
A. Gramaccioli | Pfizer
C. Nakos | Drug Safety Solutions

3.45 **Coffee Break & Networking**

SESSION 17. IMPLEMENTING EFFICIENCY IN PHARMACOVIGILANCE OPERATIONS

4.15 **Introduction by the Chairperson of the Session**
Hrvoje Maček, VP Medical & Scientific Affairs, EUQPPV | PrimeVigilance

4.20 **PV system efficiency, from theory to practice**
Laura Boga, Head of Global Pharmacovigilance, EU&UK, QP for Pharmacovigilance | Dompé farmaceutici S.p.A.

4.35 **Opportunities coming from the partnership with PV providers**
Lucia Biagiotti, EU & UK QPPV | Quality Assurance | Pharmacovigilance system assessment| Pharma D&S
Andrea Pieri, Business Development Director | Pharma D&S

5.00 **Round Table & Q&A Time**
Moderator: **H. Macek**
Panelists: **L. Boga**
A. Pieri

5.30 **Chairperson Congress Closing Remarks and end of congress**
Marco Sardella, Chief Pharmacovigilance Officer & EU QPPV / ADIENNE Pharma & Biotech

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Med COMMUNICATIONS

VENUE December 1

Hilton Garden Inn Milan North

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	Face to Face December 1	Virtual November 27 - 28	Virtual + Face to Face November 27 - 28 December 1	
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VAT not included

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Discounts are not cumulative

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