



★ TEAM-PRRC ★ ANNUAL SUMMIT FOURTH EDITION

PRRC'S MEETING ORGANIZED BY TEAM-PRRC:



Round Tables



Workshops



Presentations



Networking

OCTOBER 23 & 24 2025

HOTEL CARDO ROMA, AUTOGRAPH COLLECTION

Viale del Pattinaggio, 100
ROME / ITALY



PROGRAMM

1ST DAY: THURSDAY 23 OCTOBER

13.00 – 14.00

REGISTRATION - WELCOMING ALL ATTENDEES

14.00 – 14.15

TEAM-PRRC welcoming presentation by Elem AYNE and the whole Board

14.15 – 15.00

AUTHORITIES EXPECTATIONS FROM A PRRC

Presenter: Alessandra BASILISCO – Servizio Sanitario Nazionale, Ministry of Health

15.00 – 16.15

DISCUSSION WITH STAKEHOLDERS (MDCG, Authorities, NB, MedTech Europe ...)

State of Play EU MDR & EU IVDR

Overview about the potential future legislative changes and their potential impact on the role

Round Table moderated by Bassil AKRA

Guests :

- Orla DALY – Policy and Legal Officer, MDCG (tbc)
- Alessandra BASILISCO – Servizio Sanitario Nazionale, Ministry of Health
- Giulia MAGRI – Quality & Regulatory Affairs Director, Confindustria Dispositivi Medici
- Merlin RIETSCHER – Senior Manager, MedTech Europe
- BVMed (tbc)

16.15 – 16.20

PHOTO WITH ALL ATTENDEES

16.20 – 16.40

COFFEE BREAK / NETWORKING

16.40 – 17.15

EUDAMED: updates

Presenter: Richard HOULIHAN – Founder, EirMed

17.15 – 18.00

LIABILITY

An example of a concrete case

Presenters:

- Erik VOLLEBREGT - Partners, Axon Lawyers
- Alex DENOON - Partner, Bristows Law Firm

19.30 – 00.30

MEETING AT THE LOBBY TO GO TO DINNER ALL TOGETHER IN THE CENTER OF ROME
By BUS TRANSFER

RETURN TO THE HOTEL by VANS (by small group)



PROGRAMME

2ND DAY: FRIDAY 24 OCTOBER

9.30 – 10.30

ROUND TABLE WITH PRRCs

Feedback from daily activities, their feeling in the position

Round table moderated by Anne JURY

Guests:

- Silvia ZANCOLA, PRRC from a MF (Theras Lifetech)
- Lyudmila DASHDAMIROV, PRRC working within an AR (HOYA Surgical Optics GmbH)
- Adam RAE, Outsourced PRRC (Founder of The Other Consultants)

10.30 – 11.10

REGIONAL UPDATES

PRRC requirements in the various Member States

Presenters:

- Sandra FERRETTI - Lead Representative PRRC, TEAM-PRRC
- Piero COSTA - Representative for Italy, TEAM-PRRC

11.10 – 11.30

COFFEE BREAK / NETWORKING

11.30 – 12.00

IMPACT OF THE IMPLEMENTATION STUDY ON SHORT-TERM REGULATORY CHANGES

Changes foreseen within the regulations

Presenter: Françoise SCHLEMMER – Director, Team-NB

12.00 – 12.30

CLINICAL EVALUATION vs CLINICAL INVESTIGATION:

What is expected by the PRRC to fulfil the requirements?

Presenter:

- Amie SMIRTHWAITE – MedTech consultant, Clinical & Regulatory Strategy

12.30 – 13.30

LUNCH BREAK

13.30 – 14.15

PMS & VIGILANCE

Presenter: Bre...

14.15 – 15.00

A CASE STUDY

who used their...
on the Union...

Presenter:

- Alice RA...

15.00 – 15.20

COFFEE BREAK

15.20 – 16.45

Q&A and DISCUSSION

MDR & IVDR...
overview of the...

Round table n...

Guests:

- Madd...
- Danie...
- Carlo...
- Anoth...

16.45 – 17.00

CLOSING SESSION