



★ TEAM-PRRC ★ ANNUAL SUMMIT

FOURTH EDITION

PRRCs' 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



★ PROGRAMME ★

1ST DAY: THURSDAY 23 OCTOBER, 2025

13.00 – 14.00

REGISTRATION - WELCOMING ALL ATTENDEES

14.00 – 14.15

TEAM-PRRC welcoming presentation by Elem AYNE with the Board

14.15 – 15.00

AUTHORITIES EXPECTATIONS FROM A PRRC

Alessandra BASILISCO – Servizio Sanitario Nazionale, Ministry of Health

15.00 – 16.15

ROUND TABLE moderated by Bassil AKRA: STATE OF PLAY OF MDR & IVDR WITH STAKEHOLDERS

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

- *Alessandra BASILISCO – Servizio Sanitario Nazionale, Ministry of Health*
- *Giulia MAGRI – Quality & Regulatory Affairs Director, Confindustria Dispositivi Medici*
- *Merlin RIETSCHER – Senior Manager, MedTech Europe*
- *Christina ZIEGENBERG – Deputy Managing Director, BVMed*

16.15 – 16.20

PHOTO WITH ALL ATTENDEES

16.20 – 16.40

COFFEE BREAK / NETWORKING

16.40 – 17.15

EUDAMED: updates

- *Richard HOULIHAN – Founder, EirMed*

17.15 – 18.00

LIABILITY

An example of a concrete case

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

19.30 – 01.30 am

MEETING AT THE LOBBY TO GO TO THE GALA DINNER ALL TOGETHER BY BUS
RIPA GRANDE SALOTTO – Lungotevere Ripa 3, 00153 Roma RM



★ PROGRAMME ★

2ND DAY: FRIDAY 24 OCTOBER, 2025

9.30 – 10.30

ROUND TABLE WITH PRRCs moderated by Anne JURY

Feedback from daily activities, their feeling in the position

- 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

- 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

- Françoise SCHLEMMER - Director, Team-NB

12.00 – 12.30

CLINICAL EVALUATION & CLINICAL INVESTIGATION:

What is expected by the PRRC to fulfil the requirements?

- Amie SMIRTHWAITE – Clinical & Regulatory Strategy consultant, BTInternet

12.30 – 13.30

LUNCH BREAK

13.30 – 14.15

PMS & VIGILANCE: How the PRRC can ensure the compliance?

- Breda KEARNEY - Clinical Regulatory Lead, BSI Ireland

14.15 – 15.00

A CASE STUDY presenting real examples from a SaMD manufacturer who used their role to support the continuous safety of the devices on the Union market

- Alice RAVIZZA - Founder, InsideAI

15.00 – 15.20

COFFEE BREAK / NETWORKING

15.20 – 16.45

ROUND TABLE WITH NOTIFIED BODIES moderated by Bassil AKRA

MDR & IVDR Certification experiences, Transitional provisions, overview of the future legislations and impact on the MDR & IVDR

- Maddalena PINSI - Head of MD, BSI Italy
- Daniele BOLLATTI - Technical Manager, IMQ
- Carlo GHERARDI - Lead Auditor, TÜV SÜD
- Alessia FRABETTI - Head of MD, KIWA CERMET Italy
- Selene MALVICINO - MD Manager, BUREAU VERITAS Italy

16.45 – 17.00

CLOSING SESSION WITH THE BOARD OF TEAM-PRRC

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their generous support of the TEAM-PRRC Annual Summit"

