

GENERAL ASSEMBLY 2022/2023



TEAM-PRRC General Assembly

March 20th, 2024

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(no vote)
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GENERAL ASSEMBLY 2022/2023



**1 - Resolution #1 President's report
(no vote)**

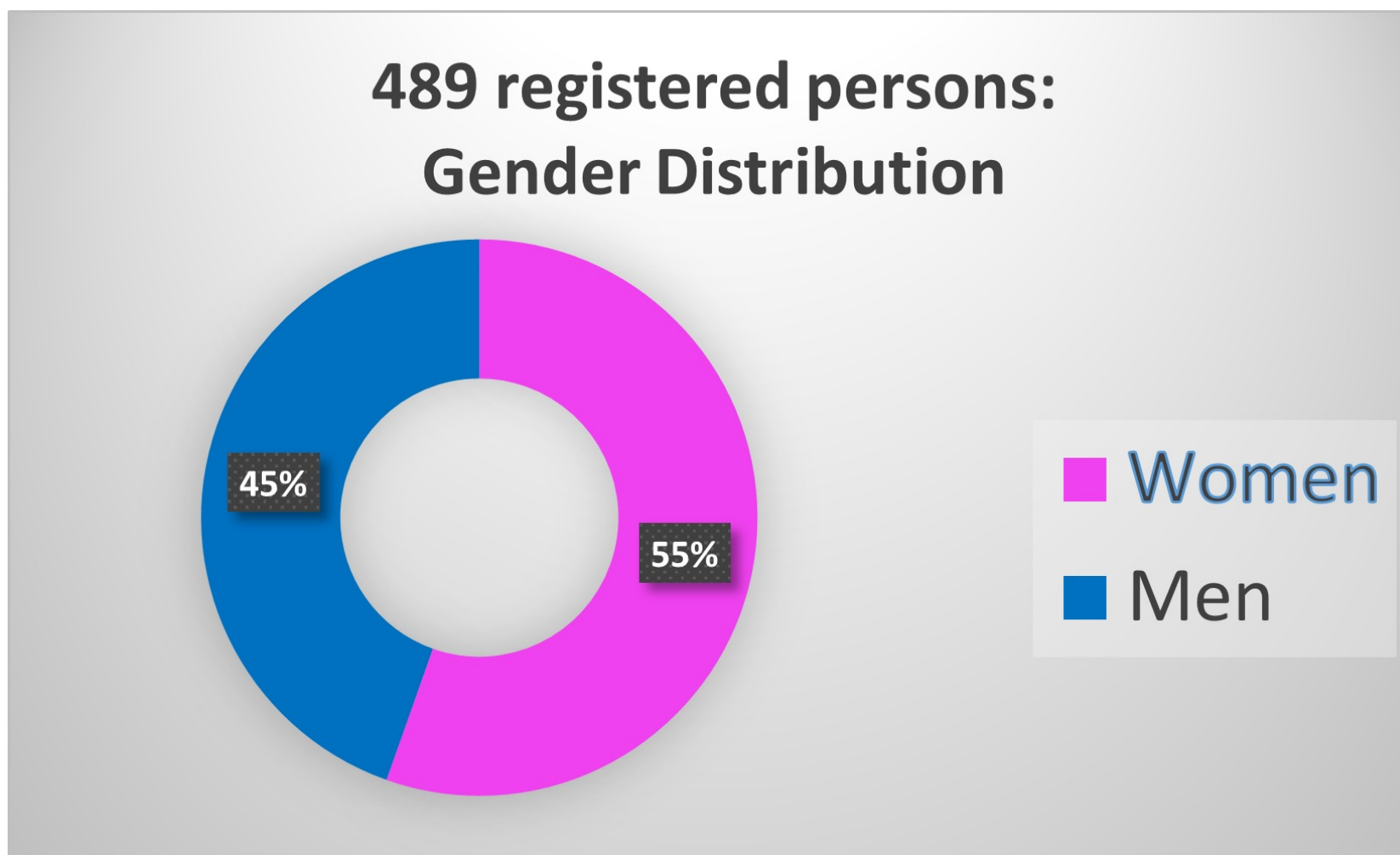
Resolution #1 Moral report

❖ Purpose

1. Bringing together persons responsible for regulatory compliance (PRRC) of medical devices as defined by European regulations.
2. Discuss the issues faced by PRRC in their daily activities, propose and exchange solutions.
3. Establish, maintain and develop a high level of professionalism of PRRC.
4. Exchange information with the health authorities in charge of national, European and international regulations.
5. Act at the request of a PRRC as mediator in the challenges encountered in its activity.
6. Working for the enhancement of Public Health.
7. Pursue mutual assistance among the members of the association.

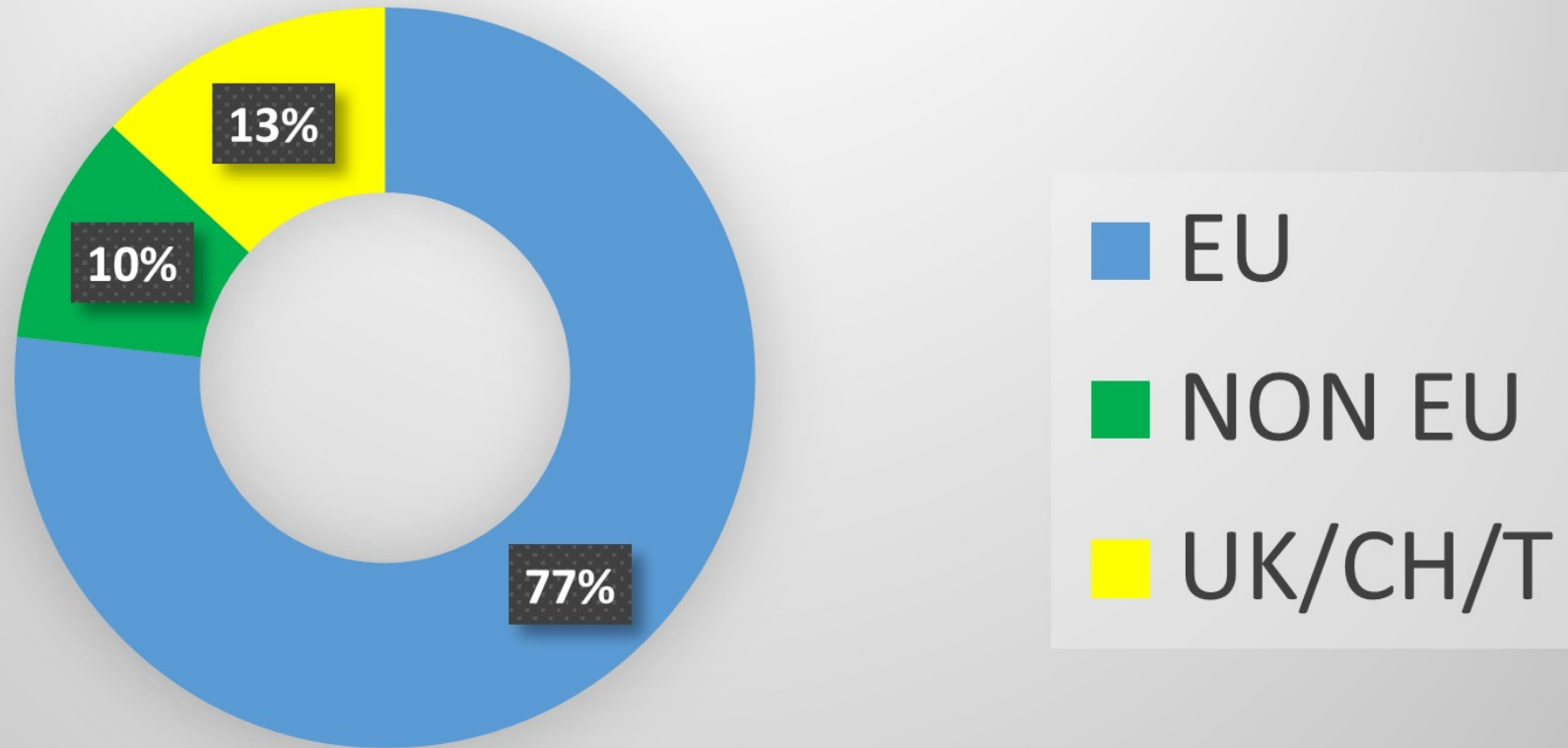
Resolution #1 Moral report: Statistics

With 489 registered members on March, 1st 2024



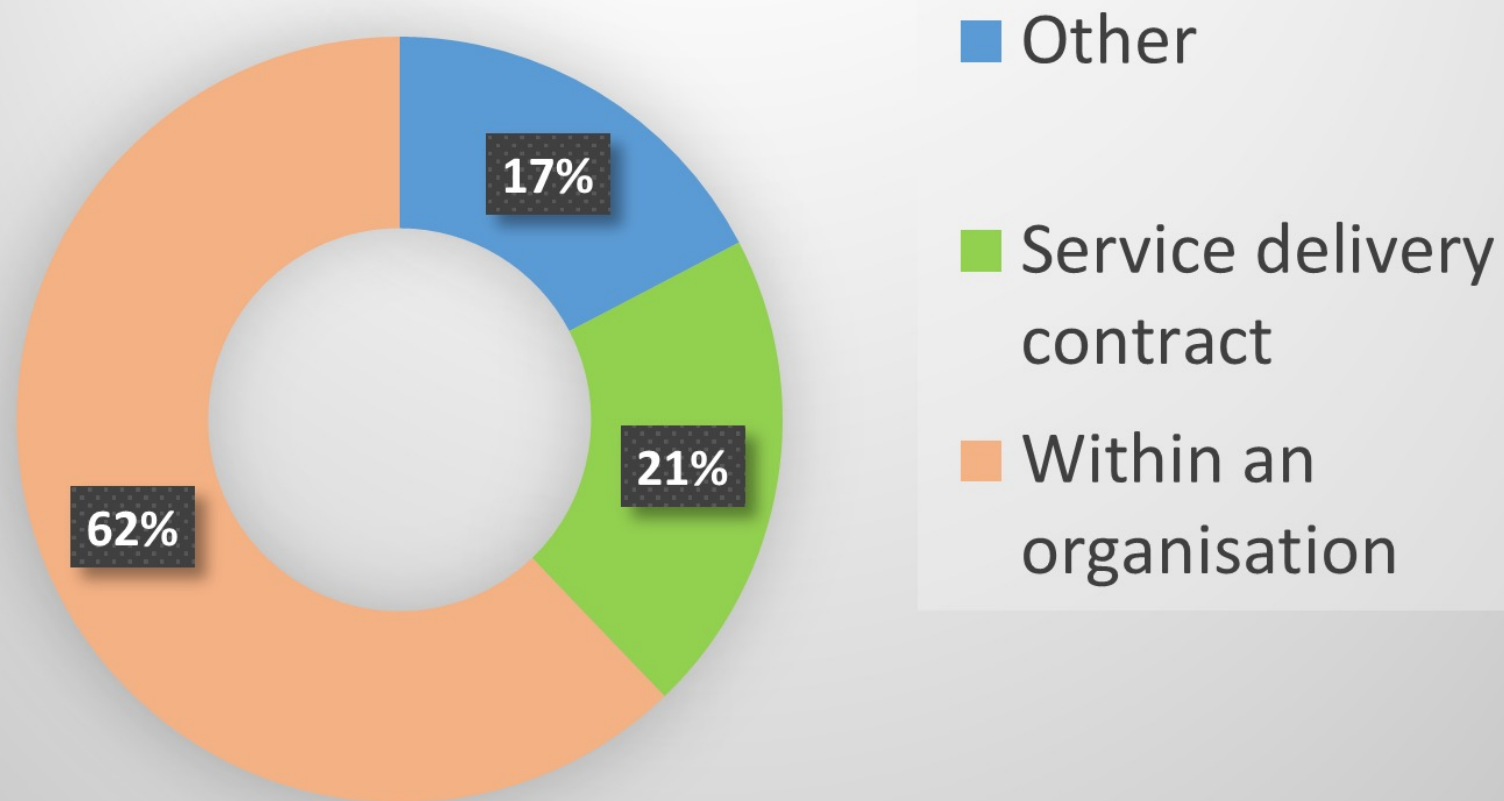
Resolution #1 Moral report: Statistics

489 registered persons: GEOGRAPHIC Distribution



Resolution #1 Moral report: Statistics

Position of members (444 answers)



Resolution #1 Moral report

❖ Communication

- By participating in trade fairs and interviews:
 - *“La Rentrée du DM” in Besançon (France) on October 3rd & 4th, 2022*
 - *MEDICA (Dusseldorf, Germany) on November 14-17, 2022.*
 - *RMD 2023 7th EAAR annual conference (Brussels February 02nd & 03rd 2023)*
 - *IMDRF 2023 International Medical Device Regulators Forum (Brussels March 27th & 28th 2023)*
 - *IMDRF 2023 International Medical Device Regulators Forum (Berlin September 25th & 26th 2023)*
 - *MEDICA (Dusseldorf, Germany) on November 14th – 15th, 2023*
 - *Articles written for DeviceMed magazine in 2022 and 2023*
 - *1 article for TOPRA is planned for 2024*

Resolution #1 Moral report

❖ Communication

- By organizing webinars and Round table: 2022
 - 1) Virtual Discussion table presented - 11/01/22
 - 2) Webinar about our 2 position papers - 8/02/2022
 - 3) Cybersecurity and the role of the PRRC - 12/01/22 (In French)
 - 4) Cybersecurity and the role of the PRRC - 16/02/22
 - 5) Webinar about Clinical Investigation - 22/03/2022
 - 6) Webinar about VIGILANCE - 29/03/2022
 - 7) Webinar about MDCG 2022-4 - 8/04/2022
 - 8) Webinar about sanctions - 12/04/2022
 - 9) Webinar about how a PRRC should communicate with authorities - 28/04/2022
 - 10) TEAM-PRRC Round Table : feedback from your daily activities as a PRRC for the past 1 year - 13/06/22
 - 11) The role and responsibilities of the PRRC under the IVDR - 22/09/22
 - 12) TEAM-PRRC Webinar : How US manufacturers live the MDR ? - 25/10/22
 - 13) TEAM-PRRC Webinar : Post-Market Surveillance (PMS) by Anna AMICH - 24/11/22
 - 14) TEAM-PRRC Webinar about the summary of Brussels Event + RAPS intervention - 28/11/22
 - 15) TEAM-PRRC Webinar : Position paper 3 and 4 about responsibilities of a PRRC within a Manufacturer and an Authorised Representative - 06/12/22

Resolution #1 Moral report

❖ Communication

- By organizing webinars and Round table: 2023-2024
 - 1) TEAM-PRRC Webinar about artificial intelligence 27/02/23
 - 2) TEAM-PRRC Webinaire sur la stérilisation et la surveillance par la PCVRR 30/03/23
 - 3) TEAM-PRRC Webinar : the role of the PRRC within an IVD Device 04/04/23
 - 4) TEAM-PRRC Webinar on Sterilization and Surveillance by PRRC 06/04/23
 - 5) TEAM-PRRC Round Table about the MDR/IVDR transitional provisions 26/04/23
 - 6) TEAM-PRRC Webinar : MHRA last news 12/06/23
 - 7) TEAM-PRRC Webinar : vigilance and MDCG 2023-3 guidance on Q&A on vigilance terms 29/06/23
 - 8) TEAM-PRRC Webinar : LAST UPDATES ABOUT EUDAMED 11/10/23
 - 9) Summary of Strasbourg Event with our Representatives 05/12/23
 - 10) Webinar about MDCG 2019-07 guidance updated 07/02/24
 - 11) RAPS Workshop about the role of the PRRC 29/02/24 & 01/03/24
 - 12) Webinar about Artificial Intelligence and the PRRC in French 19/03/24
 - 13) Webinar about Artificial Intelligence and the PRRC in English 26/03/24

Resolution #1 Moral report

❖ Communication

- By organizing webinars and Round table: To come in 2024
 - **YOU SAID eQMS !?**
 - Integrated eQMS presented by Matrix Requirements
 - eQMS in SaMD & SiMD presented by Trace-X
 - eQMS dedicated to UDI & DHR presented by Ackomas
 - Webinar about Clinical Evaluation (May 7th)
 - Webinar : Update on EUDAMED (date tbc)

Resolution #1 Moral report

❖ Communication

- By organizing TEAM-PRRC Annual Events:

➤ TEAM-PRRC INAUGURAL EVENT:

November 3rd & 4th 2022

BRUSSELS ; 78 attendees



➤ TEAM-PRRC SECOND ANNUAL SUMMIT:

November 16th & 17th 2023

STRASBOURG ; 99 attendees



Resolution #1 Moral report

❖ Position Papers and other templates finalized

- Position Paper N°1 : Qualifications of the PRRC
- Position paper N°2 : Contracts and location
- Position paper N°3 : The Responsibilities of the PRRC within a Manufacturer
- Position paper N°4 : The Responsibilities of the PRRC within an Authorised Representative
- Job description template
- Position Paper N°5 : The sanctions of the PRRC
- PRRC letter of appointment
- Agreement for external contract services of PRRC
- Job description template

❖ Position Papers and other templates in process

- Other templates (e.g. procedure to replace the PRRC)

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2 – Resolution #2 Financial report by the Treasurer (vote 1)

Resolution #2 General financial report

❖ Treasurer position :

- We had a treasurer (Kawtar IDIHYA) but she has to leave due to personal and professional choices
- Jean-Louis is covering that role since she leaves.
- TEAM-PRRC is covering its costs.
- The association is stable and is not in minus.
- Costs of the association are :
 - SOFRADOM
 - Website platform Springly
 - Insurance, and bank account
 - Emails and ZOOM licence
 - Expenses of the Board in case of travel for the event and benefit of TEAM-PRRC
 - Exceptional financial compensation for the hard work done in certain cases

Resolution #2 General financial report

❖ Financial compensation revised:

- 1) Revision of all statutory documents including code of ethics, policy, internal regulation and Statutes: 300 €
- 2) Management of the TEAM-PRRC ANNUAL SUMMIT event for the year : 1000 €
- 3) Managing the administration and treasuring part for the year : 1000 €
- 4) Writing a template or a position paper : 300 €
- 5) Reimbursement of the room and travel expenses where the Board can be invited
- 6) In exceptional cases, where a preparation or any research is needed to organize a webinar or a round table : 200 €

Resolution #2 – vote 1 :
Do you agree with the financial compensation amount ?

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3 – Resolution #3 Internal Regulations (vote 2)

Resolution #3 vote on the Internal Regulations changes

The Internal Regulation describes in detail some articles of the Statutes. The main changes are:

❖ *To avoid having many people uninterested in becoming members in our database:*

1.2. Membership process

The membership will be 250 € for the year for a period of January 1st to December 31. The renewal fee will be the same.

❖ *Digital membership card*

A digital membership card will be sent to members who paid the annual fee.

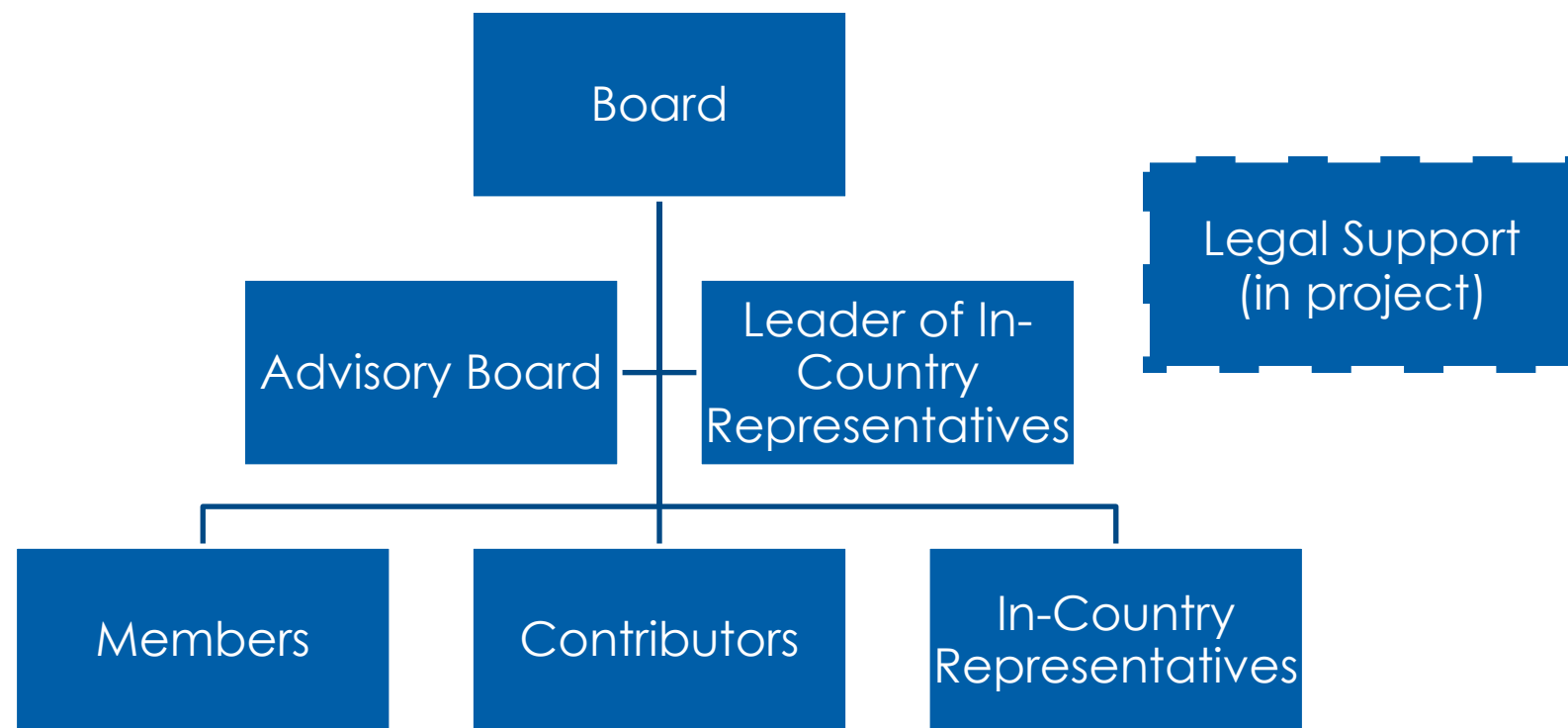
❖ *Sponsorship*

From now, TEAM-PRRC will not propose anymore the sponsorship for organizations. However, a discount can be proposed to organizations with many PRRCs according to the quantity of PRRC.

Resolution #3 - vote 2: Do you agree with the Internal Regulations changes ? (YES/NO)

Resolution #3 vote on the Internal Regulations changes

❖ *Structure of the association:*



Resolution #3 - vote 3: Do you agree with the structure changes ? (YES/NO)

Resolution #4 vote for the Board

Update of the Board structure :

It is proposed to confirm existing members :

- Elem AYNE
 - Jean-Louis DIVOUX
 - Bassil AKRA
 - Anne JURY
-
- Ronald BOUMANS : is no longer a member of the Board

Resolution #4 - vote 4: Do you agree with the update and proposed members of the Board ? (YES/NO)

Resolution #5 vote for the responsibilities within the Board

We propose to give the following responsibilities within the Board:

- President: Elem AYNE
- Secretary & Treasurer : Jean-Louis DIVOUX
- Vice-President: Anne JURY
- Vice-President: Bassil AKRA

We propose to give the following responsibility for the In-Country-Representative:

- Leader of In-Country Representatives : Sandra FERRETTI

Resolution #5 – vote 5: Do you agree with the proposed functions into the Board ? (YES/NO)

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DIALOGUE WITH MEMBERS

Dialogue with members

1

**Resolution #6 Call for contributors
(no vote)**

2

**Resolution #7 Questions and
suggestions from members (no
vote)**

Resolution #6 Call for contributors (without vote) – starting in September 2022

#	Topics	Contributors (members)
1	Representative on Member States (legal issues, insurance, translating)	Duties of an In-Country-representative
2	Legal Support	Lawyers
3	Project to create a PRRC service	A leader is needed
4	Creation of Working Groups on some topics that will be submitted by TEAM-PRRC	Some leaders will be needed, with some members
5	Interviews with members - Newsletter	members
6	Look for our Treasurer and assistant and digital marketing people	

Resolution #6 without vote

Resolution #8 Questions and suggestions from members (without vote)



- Exchange experience
- Exchange ideas
- Exchange recommendations

What are your expectations from TEAM-PRRC?

Resolution #8 without vote

GENERAL ASSEMBLY 2022/2023



THE END



Questions ?

Please inform your colleagues about TEAM-PRRC. The more members we have the greater our voice!

**THANK YOU FOR
LISTENING**

For more information about TEAM-PRRC go to:
www.team-prrc.eu or send us an email to : inform@team-prrc.eu