
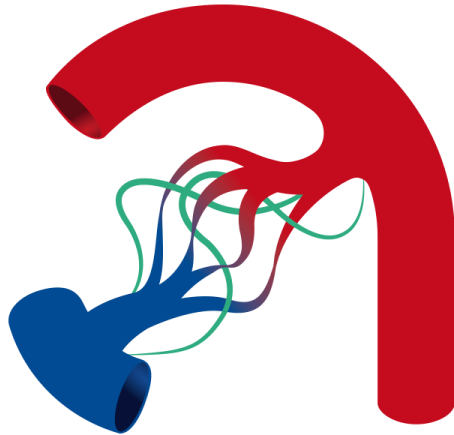




European Reference Network

for rare or low prevalence complex diseases

 **Network**
Vascular Diseases
(VASCERN)



VASCERN

Terms of Reference

October 2024 version



More information available at: <https://vascern.eu>



Co-funded by
the Health Programme
of the European Union

Terms of Reference Board *(requested by the EU)* Chaired by the Coordinator



Composition

- 1 designated representative for each **Healthcare Providers (HCPs) Member of the Network, the HCP Representative** (appointed to represent the HCP multidisciplinary team)
- HCP Members have also appointed a **substitute representative**, who will attend as substitute, when necessary
- Total number of HCPs per RDWG per country is maximum 1/20M inhabitants. Each represented country has 1 representing HCP in each RDWG. Additional HCPs are called “non representing HCP”. Non representing HCPs give procuration to the representing HCP in the Board.
- Oversee the development of the strategic action plan and annual activity report
- Integrate new HCP Members, Affiliated Partners (in line with official ERN processes) and other partners,
- Monitoring, evaluation and feedback to the VASCERN Council

Patient engagement in decision-making

- ePAG Chair and 6 ePAG co-chairs are Board Members

Roles and responsibilities

- Final Decision Making Body : adopt the Terms of Reference, action plan, annual activity report, budget
- Meet face-to-face once a year
- Each decision is taken by consensus, but vote is possible if necessary
- In case of equality, the voice of the coordinator is predominant



Procedures

Terms of Reference

Assembly



Composition

- HCP members, including extended teams and more patient representatives from the Patient Group (ePAG representatives)
- Affiliated Partners
- with a limited number of participants in function of the budget

Roles and responsibilities

- Enable broader HCP & Patient Organisation participation and discussion in the framework of Board meetings
- Ensures a better representation and consultation, as well as larger networking

Procedures

- Once a year in the framework of the Board annual meeting

Terms of Reference

Coordinator & Coordination Project-Team



HCP Coordinating Member & Coordination & Project-team:

- **Assistance Publique-Hôpitaux de Paris (AP-HP), Hôpital Bichat-Claude Bernard**, Centre of Reference (CRMR) for Marfan Syndrome and related Disorders, Paris, France
- Coordinator: **Prof. Guillaume Jondeau**, Cardiologist, Coordinator of the CRMR for Marfan Syndrome and related Disorders
- The coordinator coordinates the network with the help of the coordination team, which he or she hires.
- A call for application and election is to be made at the end of each project duration throughout the network to choose the new coordinator.

Roles and responsibilities

- Impulse strategies with the Board & Council
- Organise and Chair the Board & the Council (Governance bodies) meetings
- Facilitate coordination & monitoring of all ERN activities
- Administrative, Human Resources & financial project management
- Monitor the implementation of the Action Plan & Report to the European Commission
- Organise, monitor & follow up of Working Groups (online and onsite)
- Implement Communication Strategy (internal and external) and ensure good circulation of information
- Develop, promote, and expand the Network (new HCPs, affiliated, partnerships, etc.) in cooperation with all
- VASCERN Contact point & Represent VASCERN within ERN Coordinators Group (ECG) and other ERN related Conferences and events
- Production & dissemination of Annual VASCERN Activity & Evaluation Report
- Coordinate transversal ERN projects in relation with Chairs
- Management of subcontracting and partnerships
- Develop new EU projects for VASCERN

Terms of Reference Council



Composition

- Chairs of the RDWGs, Technical Transversal WGs, ePAG Chair, the Coordinator and Project Manager
- Chaired by Coordinator and Project Manager
- *Co-chairs can attend when necessary, as substitutes*

Procedure

- Meet (*virtual*) at least **every 4 months or more**, depending on needs
- Decisions are taken by consensus, but vote is possible if necessary. In case of equality, the voice of the coordinator is predominant

Roles and responsibilities

- **Operational Decision-Making Body**
 - Decisions have to be validated by the board.
- Monitoring and implementation of the action plan
- Feedback to Working Groups
- Report and ask feedback to Board

Terms of Reference

Rare Diseases Working Groups



Composition

- **A Chair and a Co-chair** are responsible for the implementation of VASCERN action plan by the WG
- **HCPs representatives** taking care of the pathologies defined (maximum 2 per HCP, substitute when necessary)
 - A third representative can participate if <45 years, and willing to take over in the future.
- **The ePAG Patient Group Co-chair for the relevant diseases group and Deputy Co-Chair**, responsible to coordinate views of patient group and to disseminate information
- Task forces can be constituted for specific subjects . They are chaired by an HCP representative working with other selected Members,
 - They can include non members for research task forces.

Roles and responsibilities

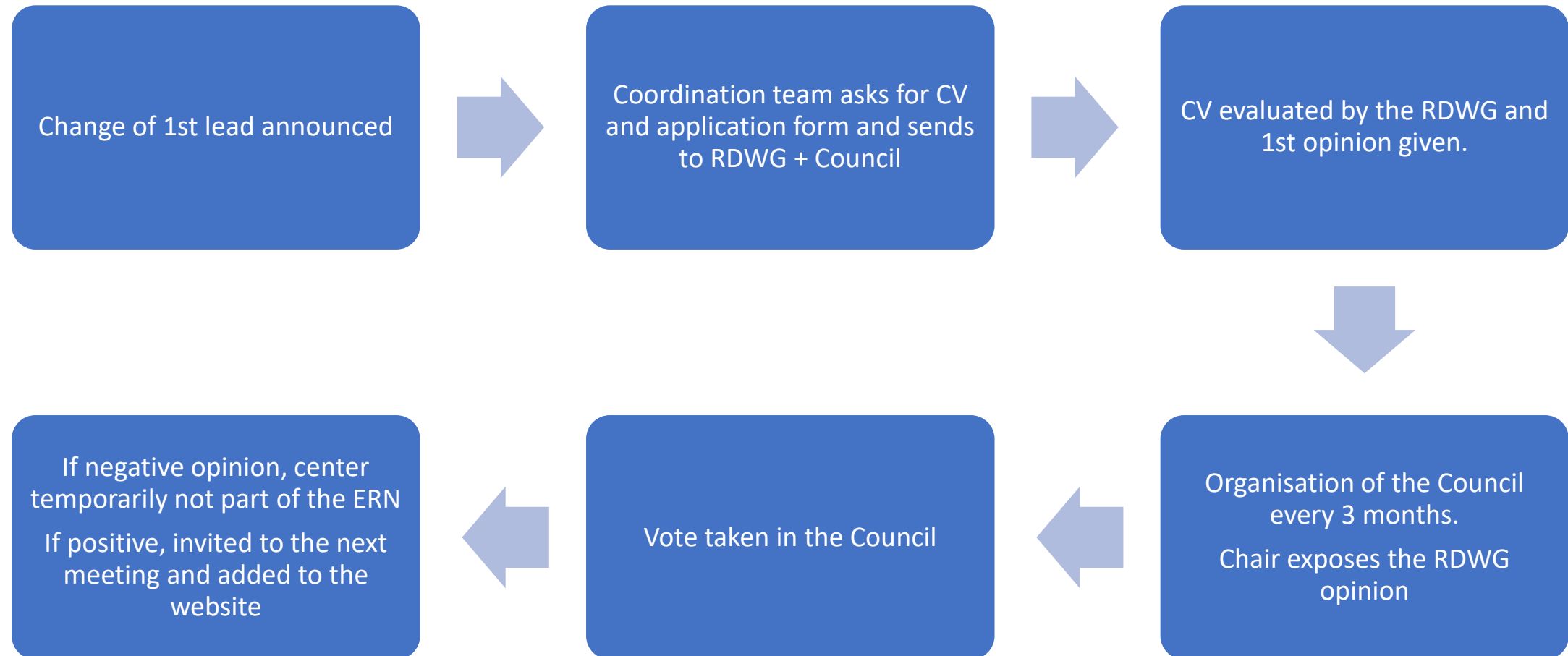
- RDWGs are responsible for organizing patient care in the EU, defining best practice, writing recommendations, implementing registries, among others.
- Use the ERN Clinical Patient Management System provided by the EU
- The Chair reports to the Council & the Board

Procedures

- The WG meets virtually **once a month** by videoconference call
- 1 hour meeting, at least the last 15mn are for Clinicians discussion on complex cases (using the CPMS)
- Chairs and Co-Chairs are elected among the WG members for a duration of 3 years, with no limit of mandate
- Each decision is taken by consensus, but vote is possible if necessary. In case of equality, the voice of the Chair is predominant
- In case of HCP first lead change, see the procedure in the following slide.



Change of HCP first lead process



Terms of Reference

Transversal Working Groups



Composition

- A **Chair** and a Co-chair are responsible for the implementation of VASCERN action plan by the WG
- HCPs representatives or team members if necessary (expertise) (1/HCP) and patient representatives willing to participate actively

Task forces

- Specific Task Forces will be created if necessary

Roles and responsibilities

- Transversal Working Groups are established to work specifically on topics such as eHealth, Ethics, Patient Registry, and Training & Education, Communication, Pregnancy or Psychology
- Report to the Council & the Board

Procedures

- The WG meets virtually **once a month** by videoconference call (or less, depending on needs)
- Chairs are elected among the WG members
- Each decision is taken by consensus, but vote is possible if necessary
- In case of equality, the voice of the Chair is predominant



Terms of Reference Patient Group (ePAG)

- In Annex: VASCERN ePAG specific ToR

Composition

- The VASCERN Patient Group has a Chair and 6 Co-chairs and 6 Deputy Co-Chairs (1 per Rare Diseases Working Groups (RDWG))
- All other patient representatives willing to be involved (at different levels) can participate according to their expertise and willingness to participate to either RDWG or transversal WG projects. They can attend RDWG monthly meetings in listening mode
- The VASCERN Patient Group is continuously open to new affiliations, and has continuous link with the broader patient communities through national, European and international networks

Role and responsibilities

- The Patient Group has important roles and missions, such as in governance, ethical issues, care, research, evaluation, and as expert patients in information sharing to the wider community
- VASCERN Patient group has 1 ePAG Chair and 6 ePAG Co-chairs (one per RDWG) who are members of the relevant RDWG and have the important role to disseminate information to other patient committee members and wider community
- The ePAG Chair and Co-chairs are also Board members

- The VASCERN ePAG Chair is participating to the Council, Co-chairs as substitutes as necessary
- A detailed annex on the levels of involvement for ePAG representatives and ePAG member organisations is available

Procedure

- Monthly videoconference call meetings
- Chair is elected among the Co-Chairs and Co-Chairs are elected among the RDWG ePAG members
- Each decision is taken by consensus, but vote is possible if necessary.
- In case of equality, the voice of the Co-Chair is predominant.

Levels of engagement

- ePAG Chair
- ePAG Co-chairs
- ePAG Deputy Co-Chairs
- ePAG Advocates
- ePAG Members (Epag Community)

Terms of Reference Chairs & Co-chairs Roles



- Coordinate and organize, in cooperation and with the help of the Co-chair, the work of the WG
- Chairing the WG meetings
- Proposing new projects
- Implementation of the VASCERN action plan by the WG
- Diffusion of information to WG Members & ask feedback from them
- Ensure the reporting / ask feedback to the **Council** to which they have to attend every 4 months or more depending on needs, and to the Board, on behalf of the WG
- 3 years mandates. Voters are the HCP member representatives of the relevant WG. Candidates are the representatives of the HCP of the WG
- Chairs Reporting to
 - **the Coordination team**
 - **the Council**
 - **the Board**

Terms of Reference

HCP Member Representative's Role & Responsibilities



- Sit in the VASCERN Board once a year, capacity to decide and act on behalf of the HCP (represent the HCP multidisciplinary team)
- Participate in the decision-making process, monitoring, feedback on VASCERN activities
- Ask his substitute representative or another team member to attend in case of absence
- Offer the better care for the patients affected by the rare diseases of the WG. This will be evaluated regularly by outcome measures that are defined by the WG and validated by the Council and the Board, and by feedback from the patient group
- Use of the ERN Clinical Patient Management System to discuss patient cases
- Include patients in clinical trials and registries
- Participate actively in the RDWG monthly virtual meetings & activities, or at least ask a substitute representative to participate
- Propose new projects
- Participate to monitoring, evaluation, audits, as requested and provide the relevant data and information to support monitoring and evaluation
- Implement registries, guidelines, participate in clinical trials, research, opportunities and functional projects offered by VASCERN
- Propose new HCP Members to the ERN, when excellence is guaranteed
- Travel to meetings when require
- Give feedback and evaluation



Terms of Reference

Possibility of an HCP young representative

- Purpose: Would enable their continuous training + continuous expertise within the center
- Each HCP has the possibility to involve a 3rd representative under certain criteria:
 - Less than 45 years old, anticipated permanent position, and wants to pursue career in the named Rare Disease(s)
 - Training completed, clinical expertise as suggested by CV
 - Publications on the disease(s) if 40-45 yo
 - Commitment to attend 70% of meetings. First 2 leads should also attend
 - Self-funding for F2F meetings if first 2 attend (max 2 funded per center)
 - Discussed by the members of the RDWG without the members of the HCP proposing
- F2F presence limited by funding (invited when possible)
 - They can pay themselves if the room capacity allows it



Terms of Reference

Meetings

Chair(s)

- Meetings are coordinated by
 - Network Coordinator for the Assembly, Board and Council meetings
 - WG Chairs, assisted by Co-chairs for all Working Groups

Agenda

- Meetings will be planned ahead enough
- Draft agenda will be submitted to the participants as ahead as possible of the meeting together with the invitation for the meeting. This enables brainstorming and more efficiency during meetings
- Documents may be provided for discussion
- The Agenda shall be in accordance with the Network's objectives, priorities and initiatives in order to implement the Action Plan
- The Agenda is adopted at the start of the meeting

List of attendees

- A list of attendees and excused participants is elaborated for each meeting and written in the Minutes

Minutes of Meeting (MoM)

- Minutes of Meeting discussion on each point of the agenda will be sent to participants as shortly as possible after each meeting
- The participants shall send any comments they may have on the MoM in writing

Length

- Regular Council meetings last for 1,5 hour.
- Working Group Meetings usual length is one hour. Usually virtual and sometimes face-to-face meetings.
- Assembly and Board meetings will take place during a 1 to 2 days seminar.

Role

- Meetings are a very important part of VASCERN activities, as it will enable the implementation of the action plan.

Terms of Reference

Advisory Board: to be developed

Who?



Composition

- Representatives from public authorities, scientific societies, other relevant experts, for instance from the industry, foundations, international medical groups

Procedure

- The Advisory Board is going to be consulted by the Council, and can also contact the Council at every moment to suggest proposals, actions, and partnerships on specific projects for instance

Role

- Consultative, external body
- Suggest proposals, actions and partnership
- consulted by the VASCERN Council, whenever needed

Terms of Reference Other ERNs Representatives



Composition

- Appointed representatives from relevant ERNs will participate to the VASCERN Activities
- VASCERN application:
 - In case of overlapping with ERNs **reciprocal representation in the two ERNs should be looked for.**
 - Similar Collaborations to establish within specific RDWGs with other ERNs.

Role

- Appointed representatives from relevant ERNs and sub-thematic area of expertise will have the role and responsibility to ensure an effective cross-ERNs cooperation and discussion among the Diseases Working Group, when relevant.
- They will also be consulted at any time, and be invited to participate to Assembly meetings

Procedure

- The representatives are appointed by the relevant ERNs and sub-thematic area of expertise / diseases groupings

Terms of Reference

HCPs Membership

Affiliated Partners

Developing Partners



- **To become a VASCERN HCP Member:** There will be new specific **EU Call for HCP Membership** to ERN from the European Commission. The process will be the same as in 2016 (1st call) for HCPs:
 - recognition by the national government (letter of endorsement)
 - application to the EU Commission Call for proposals
 - technical assessment by Independent Assessment Body
 - maybe on-site audit
 - Criteria for HCP Membership to ERN and criteria set up by the network specific RDWG should be fulfilled.
- **To become an “Affiliated / Associated / Collaborative Member”:**
 - It depends upon **Member States choice** to nominate such Affiliated Members for ERNs
 - In any case, as of today, these members should be from countries with no already existing members in the ER
- **To become a « Developing partner »:**
 - Center that does not conform to VASCERN expert criteria
 - Center willing to become an expert and apply to the next call for application launched by the European Commission

The graph on the next slide details the different kinds of stakeholders

VASCERN

EU-recognised

Non EU-recognised

Full members

Affiliated partners

Developing Partners

Supporting Partners

Center/team fulfilling VASCERN criteria,
part of a EU recognized HCP
Went through EU process
1/20M inhabitants

Center chosen by their governments,
possible when no center of the
respective country is a full member
across the whole ERN

Not recognised by EU but
recognized as partner by VASCERN.
Individuals, not teams/centers

Representing center is chosen
among and by all full members
from that country. Elections every 3 years

Developing Partner
(acquiring expertise):
1/RDWG/country

Supporting partner
(according to projects)

Representing member (1
per country)

Non-representing
members

- ✓ Voting rights in the Board (as country representative)
- ✓ Participate in GA
- ✓ Actively participate in monthly meeting
- ✓ Participate in Taskforces
- ✓ Participate in CPMS

- ✓ Voting rights in the Board (procuration given to representing)
- ✓ Remotely participate in GA
- ✓ Listens in monthly meeting
- ✓ Actively participate in Taskforces
- ✓ Actively participate in CPMS

- ≠ Voting rights in the Board
- ✓ Participate in GA
- ✓ Participate in monthly meeting
- ✓ Participate in Taskforces
- ✓ Participate in CPMS

- ≠ Voting rights in the Board
- ≠ Participate in GA
- ✓ Participate in monthly meeting
- ✓ Participate in Taskforces
- ✓ Participate in CPMS

- ≠ Voting rights in the Board
- ≠ Participate in GA
- ± Depending on the projects:
± Participate in monthly meeting
- ± Participate in Taskforces
- ± Participate in CPMS

Obligation to participate to EC evaluation every 5 years and yearly monitoring

Can apply in EU call to become full member

Can apply in EU call to become full member if their country is EU member

Title

Criteria

Representativity

Participation

EC procedures in the future

Terms of Reference Information & Transparency



- Website: www.vascern.eu
- Info on Members, structure, governance, WGs, activities, area of expertise, scope, contact
- Dissemination of guidelines, Pills of Knowledge, Publications, etc.
- To be updated, improved and new sections added!
- Communications tools (Newsletters, social media networks, collaborative platform,...)



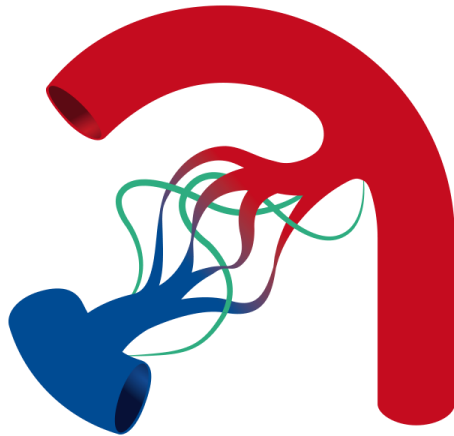
**European
Reference
Network**

for rare or low prevalence
complex diseases



Network

Vascular Diseases
(VASCERN)



VASCERN Rules for the exclusion of a HCP team



As per VASCERN Terms of Reference, a HCP team Member of VASCERN has to participate actively to the RDWG activities, provide its expertise, participate to monthly meetings, travel to meetings when required (reminder of the rules approved in October 2017 in the next slide).


VASCERN's Council has established the following rules for exclusion of a HCP team on February, 20th, 2019:

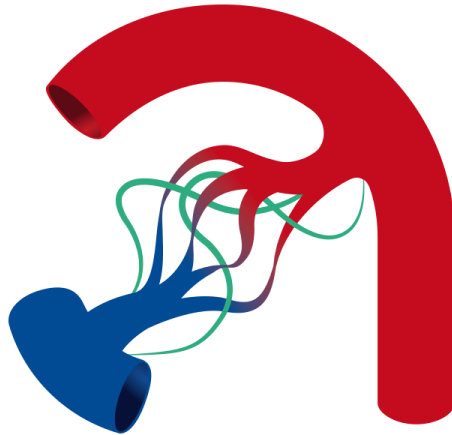
- The absence of the HCP (either the HCP expert Team Lead or by a recognized Healthcare Provider expert substitute representative providing expertise) to 4 monthly meeting in a row leads to an alert/warning of the HCP Lead.
- After the absence to 12 monthly meetings (= not participating during 1 year), the HCP team is excluded from VASCERN.



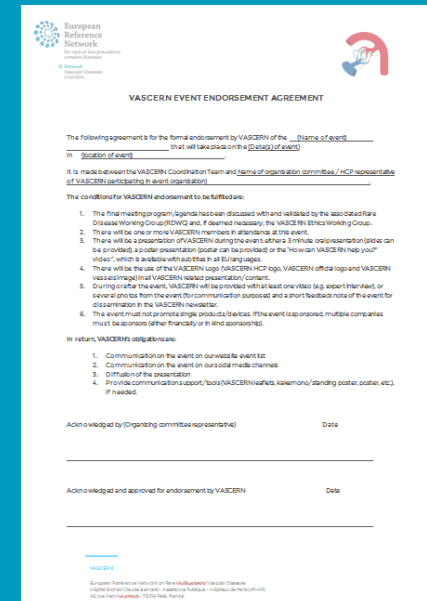
European Reference Network

for rare or low prevalence complex diseases

 **Network**
Vascular Diseases
(VASCERN)



VASCERN Event Endorsement



The image shows a thumbnail of the VASCERN Event Endorsement Agreement form. The form is titled "VASCERN EVENT ENDORSEMENT AGREEMENT" and includes the following sections:

- Header:** European Reference Network logo and a small icon of a hand holding a heart.
- Introduction:** "The following agreement is for the formal endorsement by VASCERN of the ... (Name of event) ... that will take place on the (Date of event) in (Location of event) ..."
- Parties:** "It is made between the VASCERN Coordination Team and (Name of organization committee / HCP representative) of VASCERN (hereinafter the event organization) ..."
- Conditions:** "The conditions for VASCERN endorsement to be fulfilled are:
 - The final meeting program/agenda has been discussed with and validated by the associated Rare Disease Working Group (RDWG) and, if deemed necessary, the VASCERN Ethics Working Group.
 - There will be one or more VASCERN members in attendance at the event.
 - There will be a presentation of VASCERN during the event, either a 3-minute (co)presentation (slides can be provided, a poster presentation (poster can be provided) or the "How can VASCERN help you?" video, which is available via youtube in all EU languages.
 - There will be the use of the VASCERN Logo / VASCERN HCP logo, VASCERN official logo and VASCERN logo on signage at VASCERN related presentation content.
 - During or after the event, VASCERN will be provided with at least one video (e.g. expert interview), or a presentation from the event (for communication purposes) and a short feedback note of the event for dissemination in the VASCERN newsletter.
 - The event must not promote single products/brands. If the event is sponsored, multiple companies must be sponsored either financially or in kind (sponsored).
- Obligations:** "In return, VASCERN'S obligations are:
 - Communication on the event on our website event list.
 - Communication on the event on our social media channels.
 - Confirmation of the presentation.
 - Provide communication support / tools (VASCERN's website, telegram/standing poster, etc.), if needed.
- Signatures:** Two lines for signatures and dates, labeled "Acknowledged by (Organizing committee representative)" and "Acknowledged and approved for endorsement by VASCERN".
- Footer:** "VASCERN" logo and "European Reference Network on Rare and Orphan Diseases" text.

VASCERN Event Endorsement



The conditions for VASCERN endorsement to be fulfilled are:

- The final meeting program/agenda has been discussed (and modified if necessary) with and validated by the associated Rare Disease Working Group (RDWG) and, if deemed necessary, the VASCERN Ethics Working Group.
- There will be one or more VASCERN members in attendance at this event.
- There will be a presentation of VASCERN during the event: either a 3 minute oral presentation (slides can be provided), a poster presentation (poster can be provided) or the “How can VASCERN help you?” video”, which is available with subtitles in all EU languages.
- There will be the use of the VASCERN Logo (VASCERN HCP logo, VASCERN official logo and VASCERN vessels image) in all VASCERN related presentation/content.
- During or after the event, VASCERN will be provided with at least one video (e.g. expert interview), or several photos from the event (for communication purposes) and a short feedback note of the event for dissemination in the VASCERN newsletter.
- The event must not promote single products/devices. If the event is sponsored, multiple companies must be sponsors (either financially or in kind sponsorship).

In return, VASCERN's obligations are:

- Communication on the event on our website event list
- Communication on the event on our social media channels
- Diffusion of the presentation
- Provide communication support/tools (VASCERN leaflets, kakemono/standing poster, poster, etc.), if needed.

Both parties must sign a **VASCERN endorsement agreement, agreeing to the above terms.**



European
Reference
Network

VASCERN

Gathering the best expertise in Europe
to provide accessible cross-border healthcare
to patients with rare vascular diseases



VASCERN, the European Reference Network on Rare Multisystemic Vascular Diseases, is dedicated to gathering the best expertise in Europe in order to provide accessible cross-border healthcare to patients with rare vascular diseases (an estimated 1.3 million concerned). These include arterial disease (affecting aorta to small arteries), arterio-venous anomalies, venous malformations, and lymphatic diseases.

VASCERN currently gathers 48 expert teams from 39 highly specialized multidisciplinary HCPs, plus 6 additional Affiliated Partner centers, coming from 19 EU Member States, as well as various European Patient Organisations, and is coordinated in Paris, France.

Through our 6 Rare Disease Working Groups (RDWGs) as well as several thematic WGs and the ePAG (European Patient Advocacy Group), we aim to improve care, promote best practices and guidelines, reinforce research, empower patients, provide training for healthcare professionals and realise the full potential of European cooperation for specialised healthcare by exploiting the latest innovations in medical science and health technologies.

More information available at: <https://www.vascern.eu>

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