

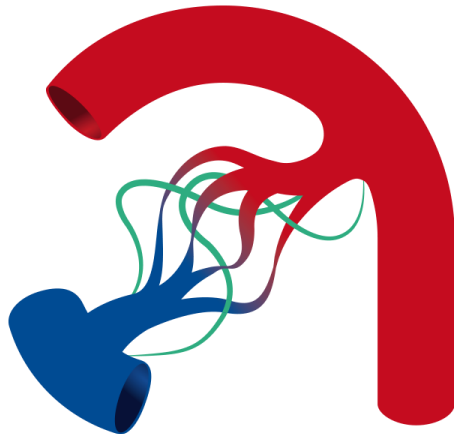


**European
Reference
Network**

for rare or low prevalence
complex diseases

 **Network**

Vascular Diseases
(VASCERN)



VASCERN DAYS 2019

ANNUAL BOARD MEETING

**Terms of Reference: update and
approval**



Terms of Reference: update and approval

- **New**
 - Authorship Guidelines
 - Event Endorsement Agreement
 - Rules for exclusion of a HCP team
- Following slides: ToR, not latest version on USB - will be put on our website after VASCERN Days
- Authorship guidelines: full version on USB

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*
- Oversee the development of the strategic action plan and annual activity report
- Integrate new HCP Members and Affiliated Partners (in line with official ERN processes)
- Monitoring, evaluation and feedback to the VASCERN Council

Patient engagement in decision-making

- **ePAG Chair and 5 ePAG co-chairs are Board Members**

Roles and responsibilities

- **Deciding body**
- Governing & Strategic Decision Making Body
- Impulse long-term vision & strategies
- Adopt the Terms of Reference, action plan, annual activity report, budget



Procedures

- 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 Chair is predominant

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

Procedures

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

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

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
- **Project-Team for Coordination and management: Project Manager, Project Officer, Project Assistant, IT heldepsk & End-User support specialist**
- **5 years Framework Partnership Agreement** signed with the European Commission + 1st year Specific Grant Agreement

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 meetings
- 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 , **answer new calls**

Terms of Reference Council



Composition

- Chairs of the WGs, 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 chair is predominant

Roles and responsibilities

- **Operational** Decision-Making Body
- 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 (1 per HCP, substitute when necessary)
- **The ePAG Patient Group Co-chair for the relevant diseases group**, responsible to coordinate views of patient group and to disseminate information
- Specific sub-projects can be allocated to a HCP representative working with other selected Members

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
- Report to the Council & the Board

Procedures

- The WG **meet 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 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

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 or Task Forces are established to work specifically on topics such as eHealth, Ethics, Patient Registry, and Training & Education, Communication
- Report to the Council & the Board

Procedures

- The WG meet 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 5 Co-chairs (1 per Rare Diseases Working Groups (RDWG), currently 5)
- All other patient representatives willing to be involved (at different levels) can participate according to their expertise and willingness to participate
- 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 5 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 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, organised in cooperation with EURORDIS
- 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 lead is predominant.

Levels of engagement

- ePAG Chair
- ePAG 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
- 5 years (like Coordinator - framework partnership agreement)
- 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
- **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. **Reference point for national network.**
- 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

Meetings (teleconf, F2F,...)

Chair(s)

- Meetings are coordinated by the Chair of the respective meeting:
 - 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

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 or 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

Role

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

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
- **Other ERNs ? European commission ? Eurordis ?**
 - **Feed back**

Terms of Reference Other ERNs Representatives



Composition

- Appointed representatives from relevant ERNs will participate to the VASCERN Activities
- VASCERN application:
 - VASCA-WG overlapping with ERN-Skin “Cutaneous Mosaic Disorders - Nevi & Nevoid Skin Disorders and vascular malformations”
 - **reciprocal representation in the two ERNs:** the Vascular Anomaly (VASCA) WG of the Rare Multisystemic Vascular Diseases ERN has Prof May El Hachem, from the ERN-SKIN as a Co-co-chair and vice-versa, the sub-group of the SKIN-ERN has Prof Schultze Kool from the VASCA-WG of the Rare Multisystemic Vascular diseases ERN as a Co-co-chair
 - recommendations will be drafted by the two WGs of both ERNs together; reciprocal web-site links will be created, and sub-thematic (Vascular Anomaly) meetings will be organized with all the members involved from the 2 ERNs
 - 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
- **ERN overlaps work in progress**

Terms of Reference HCPs Membership Affiliated Partners



- **“Center cooperating with a RDWG “ (not formal/ recognized ERN membership or affiliated status):**
 - During VASCERN transitory initial period
- **To become a VASCERN HCP full 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 partners”:**
 - 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 ERN**



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,...)



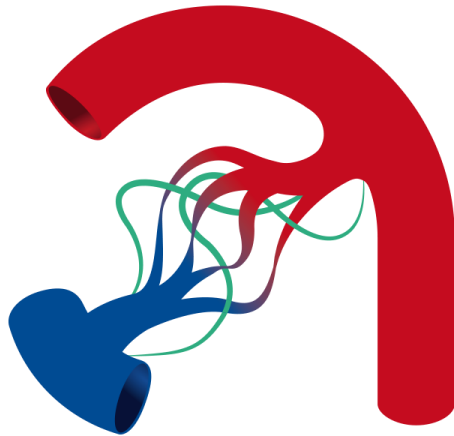
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VASCERN Rules for the exclusion of a HCP team



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:


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

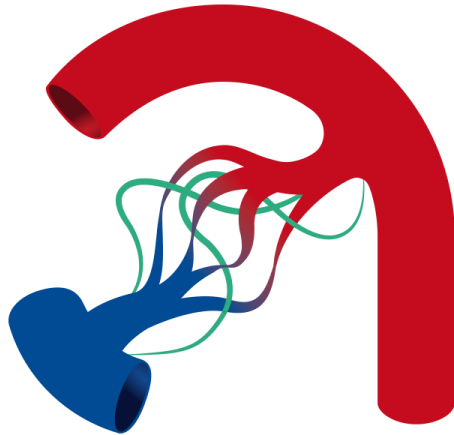
- The absence of the HCP (either the HCP expert Team Lead or by a recognized Healthcare Provider expert substitute representative providing expertise) to **4 monthly meeting in a row** leads to an alert/warning of the HCP Lead.
- After the absence to **12 monthly meetings** (= not participating during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



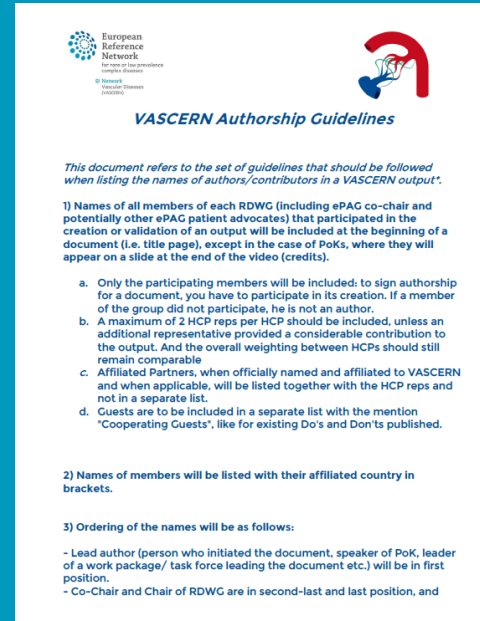
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VASCERN Authorship Guidelines



The thumbnail shows the cover of the 'VASCERN Authorship Guidelines' document. It features the European Reference Network logo on the top left and a stylized red and blue graphic on the top right. The title 'VASCERN Authorship Guidelines' is centered. Below the title, there is a paragraph stating: 'This document refers to the set of guidelines that should be followed when listing the names of authors/contributors in a VASCERN output'. This is followed by three numbered sections: 1) Names of all members of each RDWG (including ePAG co-chair and potentially other ePAG patient advocates) that participated in the creation or validation of an output will be included at the beginning of a document (i.e. title page), except in the case of PoKs, where they will appear on a slide at the end of the video (credits). 2) Names of members will be listed with their affiliated country in brackets. 3) Ordering of the names will be as follows: - Lead author (person who initiated the document, speaker of PoK, leader of a work package/ task force leading the document etc.) will be in first position. - Co-Chair and Chair of RDWG are in second-last and last position, and

VASCERN Authorship Guidelines




VASCERN Acknowledgement	Situation
<p><u>For all (even when you are the sole VASCERN author of publication): Add VASCERN to your author affiliations.</u></p> <p>Ex: Department of Clinical Genetics and Cardiology, Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands; VASCERN HTAD European Reference Centre</p>	<p>A general option that can be added to an author's affiliation in order to give attention to the ERN.</p> <p>Full HCP reps add: "VASCERN (RDWG) European Reference Centre"</p> <p>Affiliated partners add: "VASCERN (RDWG) Affiliated Partner Centre"</p>
<p>1. " <u>Two (or more) of the author(s) of this publication is/are (a) member(s) of the European Reference Network on Rare Multisystemic Vascular Diseases (VASCERN) - Project ID: 769036</u></p>	<p>A general option that members can use regardless of there being 2 or more HCPS involved. This gives attention to the existence of ERN without it acknowledging any direct input from it.</p>
<p>2. "This work is generated within the European Reference Network on Rare Multisystemic Vascular Diseases (VASCERN) - Project ID: 769036</p>	<p>An option that an HCP can choose to add if the work has come into being by the work carried out by at least 2 or more ERN members working within the structure of the network (WP/SNW)</p>
<p>3. "This study/project/publication/Guidelines/survey¹ has been supported by the European Reference Network on Rare Multisystemic Vascular Diseases (VASCERN) - Project ID: 769036, which is partly co-funded by the European Union within the framework of the Third Health Programme "ERN-2016 - Framework Partnership Agreement 2017-2021."</p> <p>¹please choose appropriate wording</p>	<p>If funding is allocated to a publication/project/etc.¹</p> <p>This can apply if the project was discussed during RDWG face-to-face meetings, which are funded by VASCERN, or if VASCERN provides funding for the article-processing charges.</p>

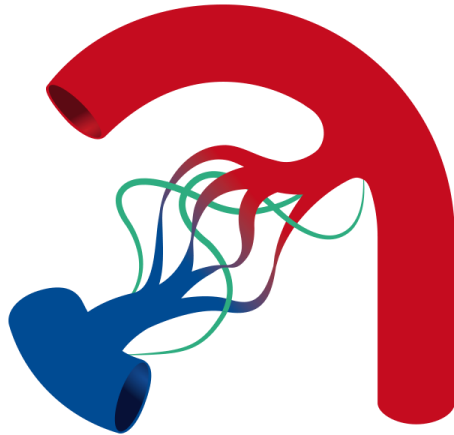
***Please note that centres external to VASCERN can participate in the scientific research projects of the RDWGs, following the rules of scientific journals for journal publications and for VASCERN outputs they will be listed in a separate author list under the heading « cooperating guests ».**



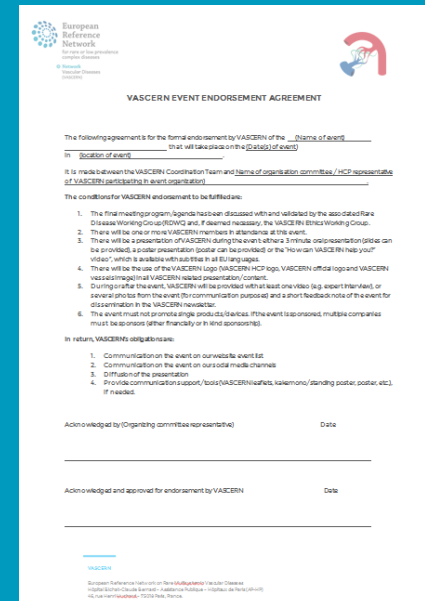
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VASCERN Event Endorsement



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 illustration 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 organizer')."
- 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 [this link](#) in all languages.
 - There will be the use of the VASCERN Logo, VASCERN HCP logo, VASCERN official logo and VASCERN video (available on VASCERN social 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 (or communication material) 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 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.