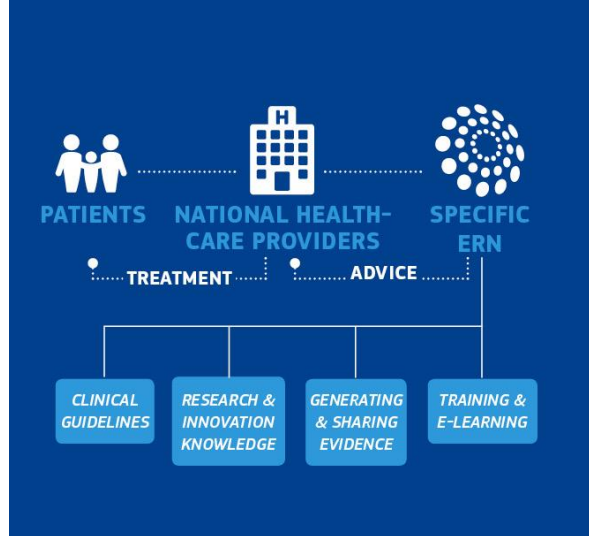




European Reference Network

for rare or low prevalence complex diseases

Network
Vascular Diseases (VASCERN)



EUROPEAN REFERENCE NETWORKS
FOR RARE, LOW-PREVALENCE AND COMPLEX DISEASES

Share. Care. Cure.



EUROPEAN COOPERATION

VASCERN

The European Reference Network **ERN**
on rare multisystemic **vascular** diseases

Board session Terms of Reference

www.VASCERN.eu



Supported by the



VASCERN 1st Annual Seminar, 13-14 October, 2017



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

- 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



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Terms of Reference Assembly

Composition

- HCP members, including extended teams and more patient representatives from the Patient Group (ePAG representatives)
- 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



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Terms of Reference

Coordinator & Coordination team

HCP Coordinating Member & Coordination 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
- **Coordination team**
- **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



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Terms of Reference Council

Composition

- **Chairs of the WGs and the Coordinator**, who chairs the Council
- *Co-chairs can attend when necessary, as substitutes*

Roles and responsibilities

- **Operational Decision-Making Body**
- Monitoring and implementation of the action plan
- Feedback to Working Groups
- Report and ask feedback to Board

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





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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



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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: 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
- 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)

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
- 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

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

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 Representatives
- ePAG Members



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Chairs & Co-chairs Roles

- Coordinate and organize, in cooperation and with the help of the Co-chair, the work of the WG depending on needs, and to the Board, on behalf 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
 - 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



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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
- 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

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.



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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



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



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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
 - Validate some of them
 - Very limited number (no more)
- **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 ERN**



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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 networks, collaborative platform,...)