



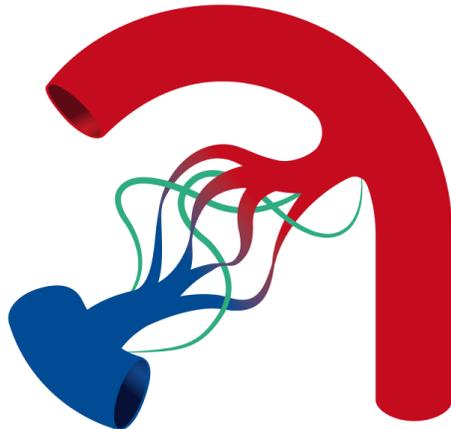
**European
Reference
Network**

for rare or low prevalence
complex diseases



Network

Vascular Diseases
(VASCERN)



Ethical and Legal issues

Romain Alderweireldt



Introduction

Plan

1. **VASCERN**
2. **LES = ERN WG on Legal & Ethical Issues
and relations with Stakeholders**
3. **Proposal**



VASCERN (1/2)

Requests (2018/2019)

1. **Potential limitation of the reimbursement of Naveus flammeus and hemangioma treatments**
 - Possible misunderstanding regarding the planned modification
2. **Liability regarding content of PPT/ video POK**
 - What is the content in question? Why could this content be liable? What is the liability of my own advice?
3. **Conditions to use patients' photos for communication and social networks**
 - Replication of Eurordis' solution
4. **GDPR and (i) the use of CPMS, (ii) the use of “Survey monkey”, (iii) the need of a Private Policy for the VASCERN website**
 - Need for a specific GDPR global assistance



VASCERN (2/2)

Requests (2018/2019)

5. **Should patient advocates comply with a system of declaration of interest?**
 - Only if they are effectively involved in the governance structure of the ERN and the development of care guidelines

6. **Can patient advocates respond positively to compensated solicitations from consulting firms that need their experience in ERN?**
 - Answer from the Commission: it is a personal issue, person who received this offer should decide based on its own ethics and situation.
 - Commission notes, however, that: it is compulsory for its staff to refuse this kind of solicitation

7. **The procedure being lengthy at the interERN level, could ePag group elaborates its own Conflict Of Interest (COI) document?**

➤ **That leads to the interERN Level**





LES (1/4)

First period

- **First period (2017-2018) : LES chaired by Nicoline Hoogerbrugge**
 - Adopts a light and manageable approach: **Declaration Of Interest (DOI)** procedure coupled with a precise **Code Of conDuct (COD)**;
 - **Expects supports** from DG SANTE's lawyers (that never happened);
 - Relies on **Board Of Member States (BoM)** validation (that generates back and forth exchanges between groups);
 - Produces several drafts with many iterations from BoM;
 - Nicoline Hoogerbrugge had to resign for personal reason;
 - The process gets stuck.



LES (2/4)

Second period

- Second period (2018-2019) : LES chaired by Maurizio Scarpa
 - To increase efficiency (and avoid back and forth between groups) **BoM representatives are integrated into the LES group;**
 - **A staff member of the Commission joins the group and organizes its works;**
 - To contextualize the process and **understand the real needs** before drafting a COD, a reflection is carried out on **how ERNs could interact with stakeholders** (and in particular with industry (i.e. pharmaceutical companies));
 - After a **meeting** organized at the Commission it emerges that **setting up a pilot project** could help to understand how and at what level collaborations could exist;
 - Maurizio Scarpa had to resign for personal reason;



LES (3/4)

Third period

- **Third period (2019-now) : LES chaired by Nico Wulffraat**
 - The ERN Board of Member States adopts on the 25th June 2019 a statement on ERNs and industry
https://ec.europa.eu/health/sites/health/files/ern/docs/statement_industry_conflict_of_interest_en.pdf
 - Two pilot projects (on **clinical trials** and **registries**) are discussed;
 - Following documents are still under development:
 1. An **addendum** to the BoM statement
 2. A policy document on "**Managing Conflicts of Interests**"
 3. A disclosure form on "**How to disclose Conflicts of Interests**"
 4. A **Code Of conDuct (COD)**
 - Next virtual meeting: **8 November 2019**



LES (4/4)

A slow process & several questions still need to be resolved

1. Who collects and stores COI disclosure forms?
2. Who checks their conformity?
3. What is the **consequence** in case of non-compliance?
4. How and when are the declarations **updated**?
5. How is the storage of these declarations (which contain personal information) conducted in order to **ensure compliance with the GDPR**?
6. If similar COI declarations are already collected at the national level would it not be redundant to collect them a **second time** at ERN level? If there are no such declarations at national level, why should there be any at the ERN level?
7. Why should patient advocates sign a COI declaration when the **justification for their presence is precisely to defend the interest of their patient associations**?



PROPOSAL

Creation of a real ERN lawyers group

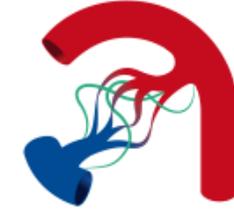
- Lawyers have perhaps been **forgotten** in the construction of ERNs.
- To be sustainable, ERNs must have **lawyers** (just as they need translators, IT specialists, etc).
- A real transversal lawyers group could answer both intra- and inter-ERN legal issues.
- This group could include **four categories** of lawyers:
 1. Lawyers from **the Commission**;
 2. Lawyers from **ERNs hospitals**;
 3. Lawyers from **ERNs patient associations**;
 4. **Independent** lawyers selected by tender.
- This group should combine **various expertise** (e.g. health regulatory, intellectual property, GDPR, social law, ethics, competition law, etc.).
- A basic system of **fix uniform hourly rate** should be defined to compensate for the work provided and paid at the hospitals, patient associations or firm of the lawyer.



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 consists of 31 highly specialised multidisciplinary Healthcare Providers (HCPs) from 11 EU Member States and of various European Patient Organisations and is coordinated in Paris, France.

Through our 5 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://vascern.eu>

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