



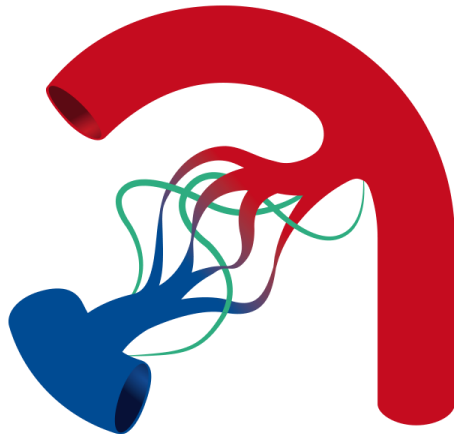
European Reference Network

for rare or low prevalence
complex diseases



Network

Vascular Diseases
(VASCERN)



9.35-9.45

**Inter-ERN Working Group on Legal & Ethical
Issues and Relations with Stakeholders:
cooperation with the industry (Romain
Alderweireldt)**

<https://vascern.eu/expertise/transversal-wgs/ethics-wg/>

 **#VASCERNdays2020**



Introduction

Plan

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



1. VASCERN (1/2)

Requests (2019/2020)

1. **CPMS videos - asking for consent for the names of non VASCERN doctors appearing on videos**
 - Suggestion to add a link to the privacy policy
 - Reminder of the evidence to be provided
 - Who has given consent?
 - first and last name of the individual/doctor (e.g. user ID and browser ID);
 - When consent was collected?
 - e.g. via online records that include timestamps, retention of an email, etc. ;
 - What (the information)?
 - a copy of the consent statement in use at the time;
 - How consent was collected?
 - e.g. via the version of the consent management interface, email, etc. ;
 - If individuals have withdrawn their consent, this information should also be retained (without retaining it unjustifiably; except where there is a legal obligation to do so).
 - Reminders at appropriate intervals
 - Reminder that they can withdraw their consent at any time (via a simple method)



1. VASCERN (2/2)

Requests (2019/2020)

2. Review of a force majeure clause in relation to deposits in the context of COVID19

- *Le réseau européen qui loue la salle regroupe à ce jour des participants provenant de 17 pays différents membres de l'UE. De ce fait, dans le cadre de la présente convention, sont par exemple considérés comme cas de force majeure permettant le report à J+1 an: (1) l'interdiction par le gouvernement français des rassemblements à Paris aux dates du séminaire ; (2) les interdictions par les gouvernements étrangers faites à leurs citoyens de se rendre à Paris aux dates du séminaire ; (3) l'imposition par les gouvernements français et/ou étrangers de mesures de quarantaine dont le respect rendrait déraisonnable la participation au séminaire, etc. Cette énumération d'exemples est non exhaustive et on retiendra que la survenance de tout évènement qui empêcherait (ou rendrait exagérément difficile) au minimum à 15 personnes de participer au séminaire permettrait d'activer la clause de report à J+1 an*

3. Question regarding the articulation of VASCERN's work with industry

- Need for a specific GDPR global assistance

- That leads to the interERN Level





1bis. VASCERN ePAG

Request @DLA: Kaat Scheerlinck and Heidi Waem

- Questions regarding ownership of data and use of Google surveys for patient journeys:
 1. What it entails for the patient organisations to be the owner of the raw data?
 2. If the patient associations have the ownership of the data then do they also own the end results (i.e. the patient journeys they have developed in collaboration with their wider patient community)? In other words, who will be the "author" of these patient journeys?
 3. When a 2FA security (2 way authentication security process) is applied in a survey, is it OK to use Google Forms to gather the data? (does it comply with the GDPR rules?)
- Pro Bono work, could be solicited for other contributions



2. LES

Reminder | First period (1/3)

- **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.



2. LES

Reminder | Second period (2/3)

- 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;



2. LES

Reminder | Third period (3/3)


- 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
 - Goal: finalize the following documents:
 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)
 - Two pilot projects (on clinical trials and registries) are discussed
 - Next virtual meeting: **28 October 2020**



2. LES



Third period | Support (1/2)

Coline Van Hecke – Travel and Event Manager at Tipik



Message More...

Coline Van Hecke · 3rd
Travel and Event Manager at Tipik
Brussels Area, Belgium · 339 connections · [Contact info](#)

 Tipik
 ISIT - Institut Supérieur d'Interprétariat et de...

Anna Mirandola – Legal Officer at European Commission




Message More...

Anna Mirandola · 1st
Legal Officer at European Commission
Brussels, Brussels Capital Region, Belgium · 121 connections · [Contact info](#)

 European Commission
 Vrije Universiteit Amsterdam

Everybody's got a story,
we know how to tell yours.




Tipik
Public Relations & Communications · Brussels · 4,530 followers

Everybody's got a story, we know how to tell yours.

+ Follow Visit website

1 person from your school was hired here
[See all 97 employees on LinkedIn](#)



we are talking about
ICT / Health / Environment / Fundamental science / Space / Energy / ...

Open to work
Legal Officer, Legal Counsel, Data Protection Consultant, Intellectual Property Consultant and Policy Officer roles
[See all details](#)



2. LES

Third period | Achievements (2/2)

- Two documents finalized (and a well advanced third)
 - ✓ 1. A policy document on "Managing Conflicts of Interests"
 - ✓ 2. A disclosure form on "How to disclose Conflicts of Interests"
 - + 3. An addendum to the BoM statement (Not communicable)
 - ✗ 4. A Code Of conDuct (COD)



2. LES

Managing Conflicts of Interest | Definition, crucial, suppletive, wide goals (1/6)

1. A 17 pages long document, that contains the following definition of conflict of interest:
“A conflict of interest is a set of circumstances that creates a risk that professional judgement or actions regarding a primary interest of the science or the patient will be unduly influenced by a secondary interest. Conflict of interest may distort the interpretation of results and evidence, the analysis of data, and the development of research methods.”
2. Recognition that “Engagement of the ERNs with industry is crucial” (p. 4)
3. Recognition of the suppletive nature of this document because:
“ERNs members, as healthcare providers (HCPs) following national legislations and regulations, **must already respect and sign the existing national requirements and documents**. The present policy document is not meant to replace such national framework, but to **complement it with a framework common to all ERNs**” (p. 4)
4. Ambitious policy with wide variety of goals:
Some are clear: “Ensure that no influence is applied from industry” (p. 7)
Some less obvious: “Respect the national laws and guidelines of the country where the funded activity is considered to take place” (p.7) *Who? How? When?*



2. LES

Managing Conflicts of Interest | ERNs Individuals (2/6)

5. Target groups/ ERNs Individuals (p. 2, 8, 9 and 11):

- 1) **Members of the ERNs Boards, committees or any other governing body in the ERNs,**
- 2) **Professionals employed by the HCPs that are individual members of an ERN and are engaged with the activities of that ERN.**
- 3) **All patient representatives who are active in the governance structure and activities of the ERNs.**
- 4) **ERNs coordination officers (project management and ERNs support staff, such as IT staff to be hired for CPMS activities).**
- 5) **In certain cases, such as in the CPMS, individual external experts invited to contribute in panels members can be included within this definition.**
- 6) **Affiliated Partners: Associated National Centres, National Coordination Hubs and Collaborative National Centres chosen by Member States with no member of a given Network, particularly if the objectives of the Network are among those listed under Article 12(2)(f) and (h) of Directive 2011/24/EU.**

3), 4), 5) and “Professional judgement”?



2. LES

Managing Conflicts of Interest | Target activities (3/6)

6. Target activities (pp. 10-11):

- 1) ERNs meeting
- 2) Patient care (CPMS)
- 3) Patient pathways
- 4) Clinical guidelines and general clinical recommendations
- 5) ERNs specific indicators
- 6) ERNs specific training materials or educational course
- 7) Data management and Registries
- 8) Other activities or results as defined by ERN

Three different procedures to disclose conflict of interest:

- One for activity 1) (p. 10);
- Another for activity 2) (p. 11);
- Third one for activities 3) to 8) (p. 11)



2. LES

Managing Conflicts of Interest | Identification of COI *prime responsibility* (4/6)

7. Identification of a Conflict of Interest

Three level of COI (p.12):

- 1) **Actual:** *“it currently exists”,*
- 2) **Potential:** *“it may arise, given specific circumstances”,*
- 3) **Perceived:** *“members of the public could reasonably form the view that a conflict exists (or could arise) that may improperly influence the individuals’ performance of his or her duty to the ERNs”.*

The identification of a conflict of interest is ***“the prime responsibility of the ERN individual”*** (p.12)

“A COI needs to be reported as soon as the ERN individual is aware of the fact that any of his or her personal interests is (possibly, actually or perceived to be) in conflict with the interest of the ERNs and if this conflict has not been reported already” (p. 13)



2. LES

Managing Conflicts of Interest | Ex-post + ex-ante (5/6)

8. Reporting personal interest

In addition to the procedures for the disclosure of conflicts of interest (ex-post), the text cumulatively requires that all ERNs individuals (p.9) must disclose their interests by filling in yearly a declaration of interest form (ex-ante)

“as soon and as long as they are engaged in an ERN activity that requires the disclosure of their personal interests” (p. 11) ?

In the absence of an ex-ante declaration of interest, the procedure ex-post applies:

“In case a not-previously-declared COI occurs, the general procedure described in Section 4 for reporting a COI should be followed” (p.12)?

SEE HEREAFTER ERN DISCLOSURE FORM



2. LES

Managing Conflicts of Interest | Procedure (6/6)

9. Procedure of evaluation of COI

- 1) As soon as the ERN individual is aware of the COI, *“he/she must abstain from any decision or act that may be related to the COI”*
- 2) Reported as soon as reasonably possible to the Board of the Network via the ERN Coordinator
- 3) Reported through the disclosure form of interest + suggestions for mitigating or neutralizing the COI
- 4) Depending on the circumstances, decisions are taken by:
 - 1) Discussions between ERNs individuals and ERNs coordinators or
 - 2) an *ad hoc* body (within ERN ?)
 - 3) The ERN board,
 - 4) The ERNs Coordinators’ Group
 - 5) The ERN Board of Member States
 - 6) DG SANTE

**Note in case of COI by ERNs
Coordinators decision belongs to 4), 5)
or 6)**



2. LES

Personal interest | ERN disclosure form: definition and introduction (1/8)

1. Definition: *“Immediate family member – Refers to a person’s parents, or spouse of a person’s parent if that parent has remarried, and siblings, as well as his own family. Immediate family also refers to a person’s spouse and children. Immediate family can include individuals not related by blood, such as stepchildren or adopted children. Further, a person’s immediate family for legal purposes also includes the spouse of his child, brother, or sister, as well as the father, mother, brother, and sister of his spouse”* (pp.2-3)

2. ERN board: Indicate to your ERN Board *“any financial or other[= non-financial] interest in companies, institutions and groups”* that could make them able “to apply the procedures concerning conflicts of interest” (p. 3)

3. Code of Conduct: *“The assessment of any potential conflict of interest is done in accordance with the ERNs Code of Conduct (under development within the ERNs LES WG) and ERNs policy on conflict of interest (version x, date x)”* (p. 3) **As long as this Code of Conduct is not available it will be difficult to implement the policy**



2. LES

Personal interest | 1. Financial interests | a. Personal financial gain (2/8)

A financial COI arises when an ERN individuals receive income or monetary support that could affect its ERN activity “*this includes both personal financial interests and the interests of the individual’s immediate family members (defined as per above)*”.

Did you or an immediate family member receive remuneration over the reported period from a commercial third party in the biomedical arena?

If yes, is this personal gain in conflict (actual, possible or perceived) with the interest of the ERN activities and results you are engaged with?

Name of commercial third party	Description	Period	Relates to whom?	Monetary value (appr)	COI? (none / actual / perceived)



2. LES

Personal interest | 1. Financial interests | b. Research (3/8)

Within the past 3 years, have you or has your research unit received support from a commercial third party in the biomedical arena for research, (financial or non-financial, such as donations of drugs, equipment, laboratory space, etc.)? Include all research that you have performed during the past 3 years and include an expected end date if the research is still ongoing.

If yes, is this support for research in conflict (actual, possible or perceived) with the interest of the ERN activities and results you are engaged with?

Name of commercial third party	Type ⁶	Research topic ⁷	Period	Monetary value (appr) (please specify if money or other costs)	COI? (none / actual / possible / perceived)



2. LES

Personal interest | 1. Financial interests | c. Investment interests (4/8)

2.c. Investment interests

Do you or an immediate family member have current investments in a commercial third party in the biomedical arena? These include stocks, bonds, stock options, or commercial business interests (e.g. proprietorship, partnerships, joint ventures, board memberships, controlling interest in a company)?

If yes, is this investment in conflict (actual, possible or perceived) with the interest of the ERN activities and results you are engaged with?

Name of commercial third party	Type of interest	Belongs to you or a family member?	Monetary value (appr)	COI? (none / actual / perceived)



2. LES

Personal interest | 2. Other relations with commercial third parties (5/8)

3. Other relations with commercial third parties, including indirect funding

Do you or an immediate family member have relations with commercial third parties that are not yet mentioned that might be relevant for the ERN activities and results?

If yes, is this relation in conflict (actual, possible or perceived) with the interest of the ERN activities and results you are engaged with?

Name of commercial third party	Type of interest	Belongs to you or a family member?	Monetary value (appr)	COI? (none / actual / perceived)



2. LES

Personal interest | 3. Intellectual Property Rights - Patents & Copyrights (6/8)

4. Intellectual Property Rights - Patents & Copyrights

Do you have any Intellectual Property Rights, whether planned, pending or issued, broadly relevant to the work?

If yes, are these Intellectual Property Rights in conflict (actual, possible or perceived) with the interest of the ERN activities and results you are engaged with?

Intellectual Property Rights	Type	Licensee	Stage ⁸	Royalties	Comments	COI? (none / actual / perceived)



2. LES

Personal interest | 4. Non-financial personal interests (7/8)

Non-financial: *“Examples include a desire for professional advancement or prestige or a drive to publish, to obtain research funding, or to improve one’s personal standing in the scientific community. One type of non-financial interest is referred to as an “intellectual conflict of interest”, defined as “academic activities that create the potential for an attachment to a specific point of view that could unduly affect an individual’s judgment about a specific recommendation” (p. 3)*

Do you have a non-financial personal interest that relates to the ERNs activities that might result in a COI?

If yes, is this non-financial personal interest in conflict (actual, possible or perceived) with the interest of the ERNs activities and results you are engaged with?

Type of non-financial conflict	Belongs to you or a family member?	Monetary value (appr)	COI? (none / actual / perceived)



2. LES

Personal interest | 5. Interests not covered above (8/8)

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, your contribution to the ERNs activities or results?

Type of interests not covered above	Belongs to you or a family member?	Monetary value (appr)	COI? (none / actual / perceived)



3. Observations (1/2)

A slow process & questions still need to be resolved

1. Who collects and stores COI disclosure forms? **Each ERN coordinator**
2. Who checks their conformity? **Ex-ante: Nobody. Ex-Post: It depends (real weakness)**
3. What is the consequence in case of non-compliance? **Application of Ex-post**
4. How and when are the declarations updated? **Yearly via a web-interface (TO DO)**
5. How is the storage of these declarations (which contain personal information) conducted in order to ensure compliance with the GDPR? **No answer yet**
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? **Subsidiarity affirmed but how to deal with it?**
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?** **Is the collection of personal data of patient advocates (see family wide definition) proportionate with their involvement? Is it GDPR compliant?**



3. Observations (2/2)

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** joining 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.