

## 4.4 ERN-EUROBLOODNET REPORT ON THE AVAILABILITY OF HIGHLY SPECIALIZED PROCEDURES FOR RARE HEMATOLOGICAL DISEASES

### ERN-EuroBloodNet European Reference Network on Rare Hematological Diseases

EUROPEAN REFERENCE NETWORKS  
FOR RARE, LOW PREVALENCE AND COMPLEX DISEASES

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## DOCUMENT INFORMATION

### 4.4 ERN-EUROBLOODNET REPORT ON THE AVAILABILITY OF HIGHLY SPECIALIZED PROCEDURES FOR RARE HEMATOLOGICAL DISEASES

Report document

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#### Short Description

Report on results from the different surveys conducted to assess the availability of specific procedures for diagnosis and/or treatment of rare hematological diseases considered as highly specialized procedures and expected to be involved in cross border health.

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## 1. INTRODUCTION

### CROSS-BORDER HEALTH ON RARE DISEASES

Although the vast majority of health care is obtained from providers within the patient's country, this situation may change when highly specialized procedures (HSP) are required. Given the scarcity and heterogeneous distribution of expertise on certain pathologies and of the allocation of specialized services, it is relatively common for patients suffering from complex disorders that the most appropriate care is offered in another Member State (MS). This situation is commonly faced for the management of Rare Diseases (RDs), defined as those affecting less than 1 person in 2000.

The EU Council Recommendation on an action in the field of rare RDs already outlined these disorders in 2009 out as a unique domain of very high added value of action at Community level due to the limited number of patients and scarcity of relevant knowledge and expertise. This added value can be achieved by gathering national expertise on RDs, which is scattered throughout the MS and organising collaboration between centres of expertise, healthcare providers, laboratories, patients and individual experts within and between MS to offer optimal cross-border services to all EU citizens.

In this context, Directive 2011/24/EU of the European Parliament and of the Council on the application of patient rights in cross-border healthcare provides rules regarding access and reimbursement for healthcare received in another EU country in order to encourage cooperation between EU Member States in the field of health.

### HIGHLY SPECIALIZED PROCEDURES IN THE CONTEXT OF RARE HEMATOLOGICAL DISEASES

As the basis for a cross-border health action, highly specialized procedures (HSP) are defined in the context of the network as those procedures that for a number of reasons i.e. economical, lack of expertise or awareness, are not available in all EU-MS, thus preventing the delivery of the best care for EU citizens suffering from a rare haematological disease (RHD) independently of their country of origin.

These HSP are classified as "under the scope" of the Directive 2011/24/EU if they are defined as standards of Care and/or included in the national basket of health services for patients or "out of the scope" in the cases that they are still performed on academic or experimental environment. In these cases, the European cooperation can be produced on the research field.

HSP involve both interventions for diagnosis and for treatment, and their complexity can rely on technological advances or expertise of multidisciplinary team, or both.

During the first and second year of ERN-EuroBloodNet implementation two surveys were conducted among ERN-EuroBloodNet members and non-members addressed to identify the European state of the art of Next generation sequencing (NGS) and Bone marrow transplantation (BMT) on non-oncological disorders as highly specialized procedures key for the diagnosis or treatment of many non-oncological RHD and presenting high inequalities for its access among MS. The two questionnaires were conducted among ERN-EuroBloodNet members with the gathering of 50 and 39 and responses received respectively. Answers allowed the identification of important gaps among the need and availability of a) NGS for rare anaemia disorders and b) BMT for Sickle cell disease (**Deliverable 3.2 State of the art of Bone marrow transplantation and Next generation sequencing for non-oncological rare haematological diseases in the context of ERN-EuroBloodNet, SGA2017, January 2019**).

This successful approach has now been expanded to highly specialized procedures for diagnosis of Primary vitreo-retinal lymphomas, which mapping has been identified of high added value for the achievement of the evidence needed to facilitate the shaping of policies or even the establishment of cross-border pathways as well as setting the basis for the establishment of European guidelines for their diagnosis.

### PRIMARY VITREO-RETINAL LYMPHOMAS CHALLENGES

Intraocular lymphomas (IOL) include different types of lymphomas that could involve many parts of the eye (vitreous, retina, choroid, ciliary bodies...). These IOLs could correspond to primary or secondary disease and are characterized by different histological subtypes or overall prognosis.

This mapping only concerns primary vitreo-retinal lymphoma (PVRL) and VRL occurring in a context of primary central nervous system lymphoma (PCNSL). PVRLs are rare high-grade extranodal non-Hodgkin lymphomas affecting the vitreous, the retina or exceptionally the optic nerve. The vast majority of PVRLs are high-grade diffuse large B-cell lymphomas.

The World Health Organization classification considers PVRL as a subtype of PCNSL, as both are closely linked together. Indeed, 65 to 90% of PVRL patients ultimately develop central nervous system dissemination within 30 months, while 15 to 25% of PCNSL patients will present intraocular involvement. As CNS involvement is responsible of the ultimate death of the patient, PVRL prognosis is still poor, estimated to 60 months in published series.

PVRL is a complex disease. The first ocular symptoms and the clinical signs of PVRL could be easily confounded with chronic uveitis, leading to a delay of diagnosis of 1 year on average. The common ophthalmologic examination (slit lamp and fundus examination)

but also more specific tests (fluorescein angiography, optical coherence tomography (OCT) of the retina...) could provide a high clinical suspicion of PVRL, which however need a cytologic evaluation of tumoral B-cells on ocular samples to confirm the diagnosis of PVRL. Ocular samples, mainly from vitreous, are provided by vitrectomy performed by ophthalmologist and give the opportunity to perform many more tests, as flow cytometry, immunohistochemistry, cytokine dosages (also on aqueous from anterior chamber tap) or molecular biology. However, all of these tests are not available in all care centers and the choice of ones from others depends on the practice of hematologist, neurologist and ophthalmologist.

The main goals of the treatment of PVRL are the management of the intraocular disease but also to prevent, if possible, the apparition of CNS involvement which is responsible of the bad prognosis of the pathology. However, precise guidelines are still lacking, and daily practice differs from team to team. While some teams prefer local treatment only (intraocular injection of methotrexate or, less frequently, rituximab), others teams use systemic treatment (high dose methotrexate ...) and use intravitreal treatments only in case of specific situations. Well-design prospective studies are not yet available in the literature to determine which alternative for first-line treatment or for relapse management would be the best choice. Even the definition of clinical response to treatment or relapse differs between specialists (hematologists, neurologists, ophthalmologists) and between teams.

All in all, the creation of a European task force bringing together different specialists hematologists, neurologists and ophthalmologists could be could be the optimum approach to face this challenges.

## 2. OBJECTIVES

As starting point, ERN-EuroBloodNet has conducted in collaboration with the multidisciplinary team of Institut Curie dealing with PVRL patients, a European mapping exercise to identify the state of the art of the management of PVRL across Europe and specifically to:

- Identify how these lymphomas are diagnosed, treated and monitored in “real life”
- Assess the necessity of the establishment of a European task force for epidemiological surveillance and the establishment of European guidelines

### 3. TASKS

## TASK 1. ERN-EUROBLOODNET EUROPEAN MAPPING OF HIGHLY SPECIALIZED PROCEDURES FOR PRIMARY VITREO-RETINAL LYMPHOMAS

For the conduction of the mapping exercise an online survey was designed in collaboration with the multidisciplinary team dealing with PVRL patients from Institut Curie, including:

- Denis Malaise, MD, Ophthalmologist
- Alexandre Matet, MD, PhD, Ophthalmologist
- Nathalie Cassoux, MD, PhD, Ophthalmologist
- Carole Soussain, MD, PhD, Hematologist

Survey is focused on addressing key parameters on the diagnostic procedures and clinical practice of the management of PVRL and ocular involvement of PCNSL for the identification of disparities between European countries on the physicians implicated in the management of these pathologies.

The first part of the survey concerns global information about the physician, as the type of hospital (public, private, referential center...) where PVRL are managed. Information that lead to the identification of the responder, including name and surname, mail and institution, was included in the exercise optionally in order to ensure the confidentiality of the answers in case responders were willing to provide answers in an anonymous basis.

Following block of questions are dedicated to the diagnosis of PVRL, with a different approach depending on the specialists (hematologist/neurologist versus ophthalmologist). Precise questions are asked on the type of ophthalmologic examinations requested in case of suspicion of PVRL (from basic examination to surgical biopsies and the type of analysis performed on ocular samples) and which systemic work-out is performed to exclude concomitant CNS involvement.

A specific question focusses on cytokine dosage on vitreous or aqueous sample, as it is a really interesting and low invasive (if aqueous) way to validate a high clinical suspicion of VRL.

The next section aim to determine which first-line treatment is mainly used (local treatment, systemic treatment or both) and how follow-up is performed by ophthalmologists, hematologists and neurologists. Also on the treatment used in case of intraocular involvement and which screening is performed to exclude secondary ocular involvement in case of pure PCNSL at diagnosis.

Final section is related to gather participants' expectations from a future European taskforce on intraocular lymphoma.

Survey was implemented in Google drive and tested among the Institut Curie team. Final version of the questionnaire was released based on feedback from real testing by experts. Full questionnaire in **Annex I. ERN-EuroBloodNet European mapping of highly specialized procedures for primary vitreo-retinal lymphoma**

## TASK 2. CONDUCTION OF THE EXERCISE

The mapping exercise was launched 22nd July 2020 with an introductory letter of the exercise explaining the main objectives and including the link to the survey to the following contacts:

- EuroBloodNet directory of experts, including
  - EuroBloodNet members (representatives, substitutes and experts from their multidisciplinary teams)
  - EuroBloodNet affiliated partners and
  - EuroBloodNet new members under current assessment for full membership
  - Other supporting stakeholders (contacts from meetings, workshops...)
- Scientific societies:
  - Hematology
    - List of National and International societies of hematologists collaborating with ERN-EuroBloodNet
    - International Extranodal Lymphoma Study Group (IELSG)
  - Neurology
    - European Association of neuro-oncology
  - Ophthalmology
    - Ophthalmic Oncology Group (OOG) of the European Organization for the Research and Treatment of Cancer
    - European Society of Retina Specialists (Euretina)

- International Ocular Inflammation Society (IOIS)
- Society for Ophthalmology-Immunoinfectiology in Europe (SOIE)
- ERNs coordination teams of ERN-RITA and ERN-EYE

The exercise was opened in a first stage until 31st July. An expansion of the deadline until 15th October was agreed with the objective to achieve further responses after summer period. New waves of dissemination were launched accordingly, including the diffusion through [dedicated pieces of news](#) for ERN-EuroBloodNet website and distributed through [ERN-EuroBloodNet monthly and dedicated Newsletter](#) and communication channels (Twitter, LinkedIn).

The image shows two screenshots related to the ERN-EuroBloodNet European Mapping exercise. The top screenshot is from the EuroBloodNet website, featuring a blue banner with the text: "Contribute to the ERN-EuroBloodNet European Mapping of Diagnostic Procedures: Primary Central Nervous System Lymphomas! Deadline extended until 15th October!!". Below the banner, there is a map of Europe with various icons representing different countries and a text box explaining the exercise. The bottom screenshot is a Twitter post from @ERNEuroBloodNet, dated Sep 15, which asks health professionals dealing with Primary Vitreoretinal Lymphomas (PVRL) to participate in a European mapping exercise to better understand the prevalence and management of these conditions. The tweet includes the hashtag #EuroBloodNet and a deadline of October 15th.



## 4. RESULTS

### PRELIMINARY RESULTS

A total of 25 responses have been gathered from 15 countries so far, including the participation of 13 Hematologists, 11 Ophthalmologists and 1 Neurologist (Fig 1).

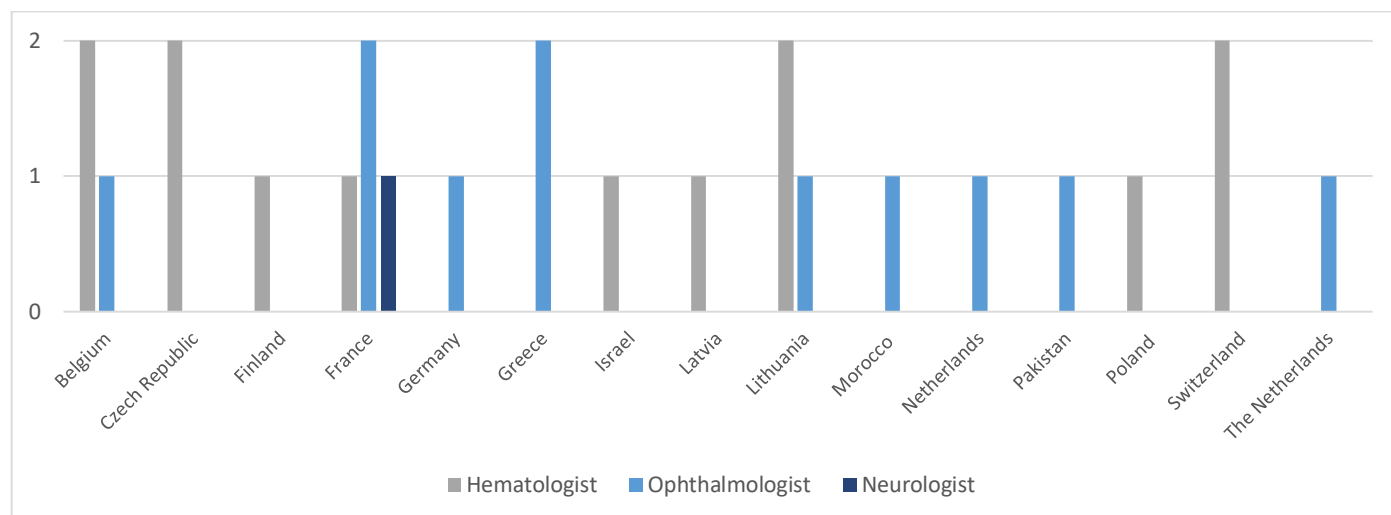


Fig 1. Number of participants per specialty and country

Regarding the type of institutions participating in the mapping, 44% of the participants belonged to a tertiary referential center, while 32% of them belong to a Public hospital, followed by Private clinic (12%) and University hospital (8%) (Fig. 2).

Attending to their involvement in ERNs, the majority of the participants belong to a center not linked to any ERN (72%), while a total of 5 of the participants belong to ERN-EuroBloodNet, and one belongs to ERN-Euracan (Fig. 3)

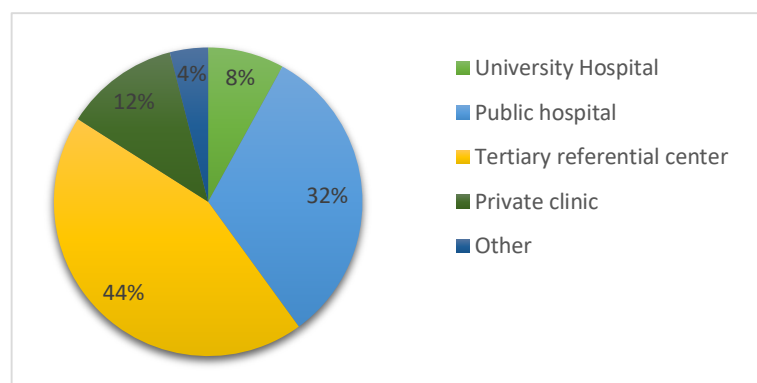


Fig 2. Participants' institution

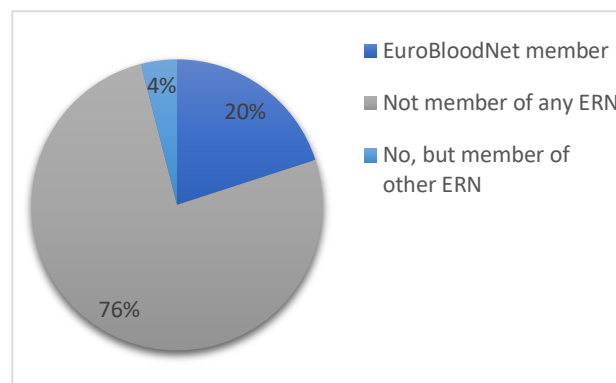


Fig 3. Participants' involvement to ERNs

64% of the ophthalmologists participating stated to have diagnosed or treated a primary intraocular lymphoma, while this number increased up to 79% of the hematologists and neurologists participating. From these first results, some interesting answers were provided:

A participant explained that pathologist for cytology (and others) is not available in the center where the sample is obtained, which represents a real problem for the quality of the sample. Another participant explained that different physicians (e.g. hematologist

and ophthalmologist) do not work in the same hospital, which complicates communication. These two points emphasize the need of improving communication by ie. creation of a dedicated protocol for communication among multidisciplinary teams.

Another interesting difference concerns "5.2 What are the modalities and duration of the intraocular monitoring after the end of the treatment for the PCNSL ». Some participants recommend systematic follow-up (timing depends) but others perform fundus examination only if complains. These comments are an interesting difference that could be discussed in a subsequent task force.

An additional key outcome are some disparities between countries on methods for diagnosis or assessment of the efficacy of the treatment (or follow up, systemic work-out...). Possible reasons that could be underlying this challenge include: a) problem of access to some techniques, b) lack of knowledge of a precise technique, c) "personal feeling" of some physicians on the interest/reliability of a technique. Further analyses are required to understand the basis for these disparities.

The need to work together between multidisciplinary teams is also highlighted, where synergies among the expertise from each team is highly required for the correct management of the patients, as for coping with technical difficulties, expertise on a concrete technique, or interpretation of results.

Moreover, comments from the responders are really enthusiastic on the initiative including the creation of the task force for this disease that "represents diagnostic and therapeutic issues".

Complete analysis on the different specific diagnostic procedures is ongoing in order to gather higher number of answers to achieve sufficient evidence to reach solid conclusions.

## EXPECTATIONS FROM A EUROPEAN NETWORK FOR PRIMARY INTRAOCULAR LYMPHOMAS

Attending to the expectations of the health professionals from the creation of a European network for primary intraocular lymphoma, the highest need identified for both groups of health professionals is the creation of Guidelines and discussions about work out, treatment and follow up, being especially high for Hematologists and neurologists (Fig. 4). This expectation is closed to the medical information about these disorders for both groups of professionals.

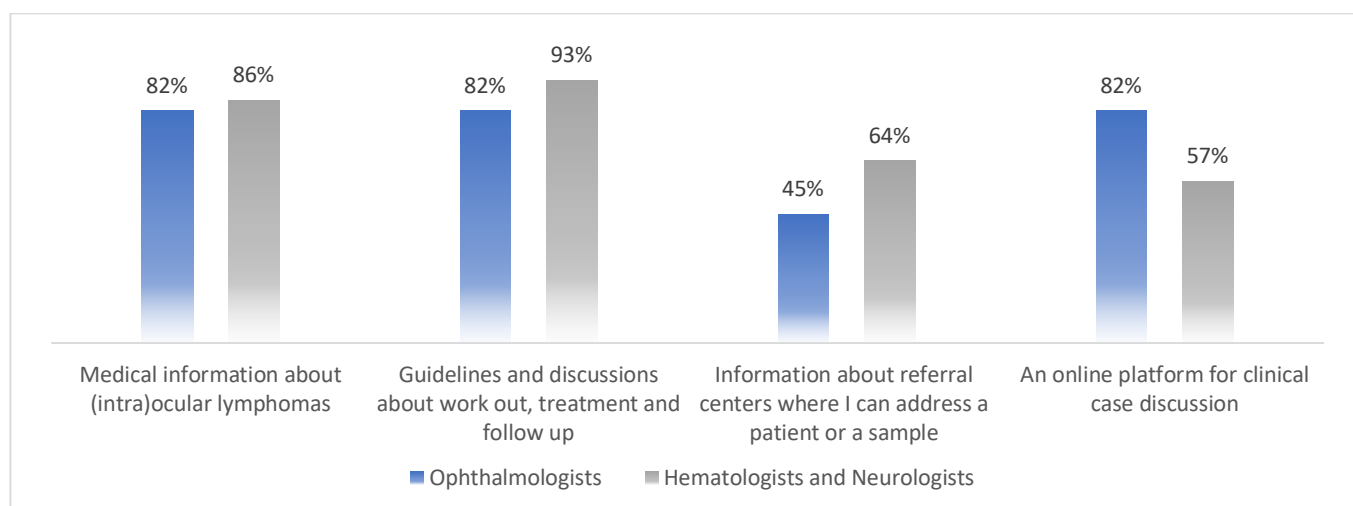


Fig 4. Expectations from the creation of a European Network for primary intraocular lymphomas

Taking into consideration the existing [Clinical Patient Management System \(CPMS\)](#), as the online platform for sharing rare complex cases among health professionals members and non-members of ERNs, the creation of a group for specifically discussing these disorders within the platform is one of the potential outcomes from this network. Interestingly, this expectation is higher for ophthalmologists (82%), than for hematologists and neurologists (57%). On the contrary, ophthalmologists do not find so important to have the information about referral centers to address patients or samples (45%). This reflects a much higher interest to share cases online by the ophthalmologist community than in cross border referral of patients and samples. Reasons of the discrepancy in expectation between specialties would need further analyses.

## 5. CONCLUSIONS AND NEXT STEPS

Diagnosis and management of PVRL is still a challenge, and the assessment of a European mapping on clinical experience about this pathology is an interesting opportunity to better determine what are the clinical practice of different European teams, which diagnostic techniques are used and why others are not, how they used to treat and follow patients, what are the main difficulties in the global management of PVRL and how a European taskforce could try to provide answers. Beside this major part of the mapping concerning PVRL, we would also determine how patients affected by PCNSL are screened for ocular involvement, as it could be an early sign of lymphoma relapse.

Moreover, communication between specialists (hematologists, neurologists and ophthalmologists) is not a clear evidence, and this mapping is a first step to create a taskforce bringing together all implicated physicians in the management of this rare and complex disease.

The launch of the European mapping exercise has allowed the gathering of 25 answers from 15 countries so far, allowing the identification of some key points shedding light on the current situation of PVRL diagnostic panorama on Europe. While the number of answers still are very preliminary to perform a deep analysis and interpretations of the situation in Europe, some important results are shown in the present report supporting the need for creating a European task force on the area and the expectations from its creation.

The mapping exercise will continue open until October 2020, when final analysis will be performed and the creation of the network will be assessed based on the results and needs identified.

# ANNEX I

## ERN-EUROBLOODNET EUROPEAN MAPPING OF HIGHLY SPECIALIZED PROCEDURES FOR PRIMARY VITREO-RETINAL LYMPHOMA



**European  
Reference  
Network**

for rare or low prevalence  
complex diseases



**Network**

Hematological  
Diseases (ERN EuroBloodNet)

Dear Colleagues,

Primary vitreo-retinal lymphomas (PVRL) is a rare subgroup of primary central nervous system lymphomas (PCNSL). The intraocular compartment of the eye can also be affected either at diagnosis or during the course of the PCNSL. The diagnosis, treatment and monitoring of intraocular lymphoma can be very challenging.

We aim to conduct a European mapping exercise to better know the prevalence of PVRL and intraocular involvement of PCNSL, and how these lymphomas are diagnosed, treated and monitored in “real life”. These data will allow to assess, within the European Reference Network on Rare Hematological Diseases (ERN-EuroBloodNet), the necessity of the establishment of a European task force for epidemiological surveillance and the establishment of European guidelines, bringing together different specialists: hematologists, neurologists and ophthalmologists.

As starting point, we have prepared a European mapping exercise to identify the state of the art of the management of these disorders across Europe.

If you are willing to be updated on the results of the analysis and on other related activities on the field, please provide your contact details, alternatively you can answer anonymously.

We would really appreciate that you collaborate to this European mapping and forward it to your colleagues implicated in the management of intraocular lymphomas, within or outside your center, it only will take you few minutes!

Thank you for your precious collaboration.

Sincerely yours,

Denis MALAISE, MD, Ophthalmologist  
Alexandre MATET, MD, PhD, Ophthalmologist  
Nathalie CASSOUX, MD, PhD, Ophthalmologist  
Carole SOUSSAIN, MD, PhD, Hematologist

Institut Curie, Paris, France

\*Required

1. Name and surname of responder (optional)

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2. Mail address (optional)

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3. Are you ERN-EuroBloodNet member? \*

*Tick all that apply.*

Yes

No, but member of other ERN

Not member of any ERN

Other:  \_\_\_\_\_

4. If you are member of other ERN/s, which one/s?

---

5. Country of work \*

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6. Region of work

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7. Name of your institution (optional)

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8. In which type of institution do you work? \*

*Mark only one oval.*

- Private clinic
- Private hospital
- Public hospital
- Tertiary referential center
- Other: \_\_\_\_\_

9. Health professional role of the responder \*

*Mark only one oval.*

- Hematologist     *Skip to question 16*
- Neurologist     *Skip to question 16*
- Ophthalmologist



### Ophthalmologists

10. 1. Have you ever diagnosed or treated a primary intraocular lymphoma (PIOL)? \*

*Mark only one oval.*

- Yes     *Skip to question 11*
- No     *Skip to question 39*

2. What work out could be performed in your care center in case of a suspicion of PIOL and which one do you recommend, if necessary?

11. 2.1 Intraocular work-out \*

*Tick all that apply.*

- i. Slit lamp + fundus examination
- ii. Angiography
- iii. Optical Coherence Tomography (OCT) of the retinal lesion
- iv. Anterior chamber tap for cytokine dosage
- v. Vitrectomy
- vi. Retinal biopsy

Other:  \_\_\_\_\_

12. If selected v. Vitrectomy, please specify

*Tick all that apply.*

- Cytology
- Immunohistochemistry
- Cytokine dosage
- Molecular biology

13. Comments on the 2.1 Intraocular work-out?

\_\_\_\_\_

14. 2.2 Systemic work-out \*

*Tick all that apply.*

- vii. CSF examination
- viii. Body CT scan or body TEP-scan
- ix. Cerebral MRI
- x. Not performed by the ophthalmologist

Other:  \_\_\_\_\_



15. Comments on the 2.2 Systemic work-out?

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*Skip to question 22*

**Hematologist and Neurologists**

16. 1. Have you ever diagnosed or treated a primary intraocular lymphoma (PIOL)? \*

*Mark only one oval.*

Yes     *Skip to question 17*

No     *Skip to question 37*

2. What work out could be performed in your care center in case of a suspicion of PIOL and which one do you recommend, if necessary?

17. 2.1 Systemic work-out \*

*Tick all that apply.*

i. CSF examination

ii. Body CT scan or body TEP-scan

iii. Cerebral MRI

Other:  \_\_\_\_\_

18. Comments on 2.1 Systemic work-out?

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19. 2.2 Intraocular work-out \*

*Tick all that apply.*

- iv. Slit lamp + fundus examination
- v. Angiography
- vi. Optical Coherence Tomography (OCT) of the retinal lesion
- vii. Anterior chamber tap for cytokine dosage
- viii. Vitrectomy (if selected, sub-questions)
- ix. Retinal biopsy
- x. Other/Comments (empty box for comments)

Other:  \_\_\_\_\_

20. If selected viii. Vitrectomy, please specify

*Tick all that apply.*

- Cytology
- Immunohistochemistry
- Cytokine dosage
- Molecular biology

21. Comments on 2.2 Intraocular work-out?

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*Skip to question 22*

22. 3. Can you perform a cytokine dosage in the anterior chamber or the vitreous as a routine procedure? \*

*Mark only one oval.*

- Yes
- No

23. Any comment?

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4. For a patient with a primary vitreo-retinal lymphoma:

24. 4.1 What is your first treatment option (why and which treatment)? \*

*Mark only one oval.*

- Local treatment
- Systemic treatment
- Both

25. Please specify

---

26. 4.2 Is the case discussed in a multidisciplinary staff meeting? \*

*Mark only one oval.*

- No
- Yes

27. If yes, which specialists are in this group?

---

28. 4.3 What is your routine work out for the follow-up? \*

*Tick all that apply.*

Funduscopy with slit lamp examination every 3/6 months

Cytokine dosage in the anterior chamber of the eye

Angiography

OCT

Other:  \_\_\_\_\_

29. Any comment?

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30. 4.4 What is the duration of the follow up?

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31. 4.5 Is a systemic evaluation for secondary brain involvement performed during the follow up? \*

*Mark only one oval.*

No

Yes

32. If yes, how and when?

---

**5. For a patient with a primary central nervous system lymphomas (PCNSL) WITH intraocular involvement:**

33. 5.1 Do you recommend a local treatment in addition to the systemic treatment?  
\*

*Mark only one oval.*

No

Yes

34. If yes, which one?

\_\_\_\_\_

35. 5.2 What are the modalities and duration of the intraocular monitoring after the end of the treatment for the PCNSL? \*

*Tick all that apply.*

Funduscopy with slit lamp examination every 3/6 months

Cytokine dosage in the anterior chamber of the eye

Angiography

OCT

Other:  \_\_\_\_\_

36. Duration of the monitoring? any comment?

\_\_\_\_\_

**6. For a patient with a primary central nervous system lymphomas (PCNSL) WITHOUT intraocular involvement:**

37. Do you recommend an ocular examination during the follow up? \*

*Mark only one oval.*

No

Yes

38. If yes, which one and when?

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39. 7. What would you expect from a European network for primary intraocular lymphomas? \*

*Tick all that apply.*

- Medical information about (intra)ocular lymphomas
- Guidelines and discussions about work out, treatment and follow up
- Information about referral centers where I can address a patient or a sample (aqueous humor, vitreous, retina, ...)
- An online platform for clinical case discussion
- Other (empty box for answer)

Other:  \_\_\_\_\_

40. Would you like to make any comment?

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