

LUPUS EUROPE

CONVENTION 2022

report

#LupusConvention: access



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During the Convention, there were two waves of Open Space sessions followed by sessions dedicated on reporting from Open Space.

In this Convention Report the summaries from the Open Space sessions have been presented in a mixed way.

Introduction

Since 2019, our hope was to hold the LUPUS EUROPE Convention in Bratislava, with the support of our Slovak member group, Klub Motylik. This plan was defeated in 2020 and 2021 due to Covid, and in 2022 the Ukrainian war forced us to move the Convention to a safer place, back to Leuven, where the Board of directors has its usual face to face meetings.

39 delegates from **16 countries** and **6 industry partners** joined in person, and 22 additional delegates from 14 countries joined a significant part of the event online.

Please note that the summary below is based on notes taken by the secretariat and reviewed by some Board members. It should not be taken as a complete and literal abstract of the presenters' work and might contain simplifications or unintended omissions. Slides used by the presenters are available for members in the restricted section of our website.

Opening session

Welcome

Jeanette Andersen (Chair - Lupus Europe) welcomed all participants, as well as the industry guests that joined us for the first day of the Convention. For our Patient Advisory Network (PAN), this was already the 2nd day of meeting as they met on the Friday for a full day, both to benefit from training on “Patients involvement in clinical trials”, to share their progress in the many projects they are involved in, and to discuss issues of common interest.

After sharing the full agenda of the Convention, where individual involvement and “open space” sessions were core components, Jeanette introduced the current year Convention theme: “Access”. The “Living with lupus in 2020” survey has highlighted the importance of this theme for the lupus community. Across Europe, while 83% feel they have appropriate access to prescribed medication, less than 7 out of 10 patients consider they have access to an experienced lupus doctor or to affordable medication, and less than half to multidisciplinary teams, a nurse that knows lupus, physiotherapy, social support or professional psychologic support. The need for change is clear.

Another key element that drove our choice of “Access” as Convention theme is that, after years of struggling with research and clinical trials, we are seeing more positive results. New products like Anifrolumab, Voclosporin, or several others in the pipeline will hopefully offer better treatment options for all. But to gain real access to these new treatment options fast, patients have a role to play, showing the big unmet need to national HTA bodies, in such a way that timely decisions are made about pricing and reimbursement ...

Current State of play for Lupus Europe

Jeanette then introduced the review of Lupus Europe's current progress towards its strategic goals 2018-2023. With some time yet to go, we want to make sure that we deliver the missing elements, and at the same time that we build a solid 2023-2028 plan to drive our actions yet to another level.

With regards to our first strategy – **People with lupus participate in, and benefit from, Lupus Research**. All objectives are well on track. The patient Advisory Network is now 27 members strong, and many members have progressed to high levels of expertise. Jeanette introduced the four levels of the PAN program: Trainee, Ambassador, Expert and Fellow. To each level corresponds a recognition of both the build-up of skills through training, and the experience gathered through participation in different projects. The levels provide not only a recognition, but also a path for growth, with suggested training, mentoring programs, etc... that help each PAN member pursue objectives for their benefits and the benefit of the community at its own rhythm. Jeanette awarded Ambassador, Expert and Fellow level recognition certificates to each PAN member that has achieved the appropriate requirements.

To fully deliver our 2023 objectives on the Research strategy, we now need to ensure that we keep the momentum and convene a patient panel on “aging with lupus”, already delayed twice due to covid.

Annemarie Sluijmers (Secretary – Lupus Europe) then shared the progress on our second strategic objective: **Member organisations are enthusiastic and empowered**. The Convention and the growth of our network are the most visible part of this objective, but several other projects are equally important, including the Kick Lupus contest, the Members capacity building program, or the organisation of webinars. The one project where we are struggling is the build-up of a collaboration platform for our members. We will try with the Basecamp tool, but demand appears lower than expected. In 2022/23 we will focus on energising the Youth group, launching the lupus care pathways project, and ensuring more of our messages are effectively made available to patients through our members.

Elfriede Wijsma (Treasurer - Lupus Europe), then led us through strategy 3 – **Lupus Europe is heard and acting**. We are progressing in all three target audiences: broad dissemination, people living with lupus, and highly specialised experts. For the broadest dissemination, stepwise we have changed our web presence, with our Facebook page reach crossing the 100,000 people mark (+40.8% vs. last year), active presence on Twitter and Instagram and a YouTube channel that now totals more than 25,000 views. For people living with lupus, we are progressing with the creation of lupus100.info, a website that will answer in many languages the top 100 questions people living with lupus have on the disease, and for the most specialised experts, we have doubled our presence in ERN ReCONNET, the European reference network that groups the leading lupus doctors and hospitals. In the coming 12 months, a special effort will be made at formalising our key messages for various audiences, so that our full network can amplify those messages by speaking with a more common voice.

Aldevina Sturiene (Board member), then reviewed the 4th strategy, on **sustainability**. The move to Brussels is now fully complete, and our organisation structure is well established. Having now achieved the appropriate level of financial resources, our current challenge is to grow our human resources support without losing Lupus Europe's personality, which is truly unique. Our goal is to grow the secretariat from two to four part time contractors all having a close connection to lupus, so that we can deliver more projects and better support our volunteers and members. All other goals have been achieved in the sustainability area, so we are well on track.

Jeanette closed the session reminding all participants that our Strategic plan is up for renewal next year. As the Board starts the thinking on the 2023-2028 strategic plan, Jeanette highlights three big questions that we have on our mind: (i) **HTA** (with more new products succeeding in clinical trials, how do we step change the support downstream piecemeal, versus our current support more at clinical trials level), (ii) **Data** (the topics is everywhere, but what role should we play? Where can we/should we make a significant difference? What strategies do we want to put in place: lead the effort, work via partners? ...), and (iii) **Volunteering**: with a growing network of volunteers, and the need to grow it further, how do we best grow our operating systems to attract, retain, motivate, and delight our volunteers). These three topics will be a key element to discuss during this Convention...

PAN meeting

On Friday June 17th, our Patient Advisory Network (PAN) members had a Pre-Convention Day training session and a General PAN meeting.

Léa Proulx, Patient Voice Partner from Roche and member of the EUPATI Editorial Board, delivered this very interesting training on “Contributing to the Design of Patient-Centric Clinical Trials”. A General PAN meeting followed; this was a very well attended meeting that provided a wonderful opportunity for our PAN to reconnect in person, to learn more about ongoing and new projects we are involved in and find out about new and exciting training opportunities!

Both the meetings were hybrid, so PAN members who were unable to join us in person could take part.

Opening Speech on Access

by Yann LeCam

Our Opening Speaker on Saturday June 18th was Yann Le Cam, **Chief Executive Officer of EURORDIS – Rare Diseases Europe.**

Yann was one of the original cofounders of EURORDIS and he has been the organisation's CEO for 22 years. Yann joined EURORDIS originally as a volunteer, as the parent of a child with a rare condition. Before he joined EURORDIS he worked extensively in health and medical research for non-governmental organisations.

As an opening session for the Convention's theme of access, Yann designed the talk to give delegates a lot of information they could reflect on this general theme. Although lupus is not a rare disease everywhere in the world, it is registered in Orphanet as a rare disease; lupus has many issues in common with other rare diseases because of its heterogeneity and complexity.

The vision of EURORDIS is a world where all persons living with a rare disease can live longer and better lives, reaching full potential and well-being, included in a society that leaves no one behind. To reach one's full potential and well-being they must be recognised as equal citizens and have their rights fully respected, they must be diagnosed with accuracy and in a timely fashion, they must be supported with state-of-the-art medical and social care, and they must be included in society in all aspects of life and live independently.

EURORDIS brings all rare diseases together at the European level. As patient organisations working together at the National level and at the European level means that we have more influence on European policy, on research and on engaging with industry. EURORDIS does this across borders and across all rare diseases. In this way, when there is a common issue and common solutions it is now possible to work together across organisations, across diseases and across Europe.

For Yann, when it comes to access and to developing a strategy on access it is important to have a clear mindset of what are the philosophical, policy concepts supporting the access, such as social justice and equity.

To try to have a perspective of where the science is taking things in rare diseases, towards 2030-2040, EURORDIS launched a pan-European foresight study; Rare 2030. This was a 2-year project that ended in a presentation to the EU Parliament with policy recommendations for the most critical areas of rare diseases. Rare 2030 has been useful in identifying trends and in helping us – the rare disease community – to prepare and design the future as we want it to be. The Rare 2030 Foresight Study concluded with eight different recommendations for a generation of new rare disease policies that will lead to a better future for people with rare

diseases - see [here](#). All eight recommendations are very important for all rare diseases, including lupus. A policy recommendation for earlier, faster and more accurate diagnosis of rare diseases which, according to Yann, carries with it the ambitious goal of bringing down diagnosis time for rare diseases to a maximum of six months from symptom onset, might be of particular relevance to lupus patients. Another policy recommendation that seems key for lupus is that of available, accessible and affordable treatments that aims to establish streamlined regulatory, pricing and reimbursement policies for rare disease treatments across Europe.

Yann also told us that the Health Technology Assessment (HTA) system will be centralised and pan-European from 2025 for all rare cancers and advanced therapies and from 2028 onwards for all rare diseases (including lupus). This will hopefully streamline the way new medicines are approved across different European countries, making the current system a lot more affordable, a lot more predictable for industry and providing access to new drugs in different countries quickly for patients.

From the Rare 2030 Foresight Study, EURORDIS has made a European Action Plan for Rare Diseases. People living with a rare disease have a high level of unmet needs; EURORDIS are introducing tangible goals for the next 10 years (such as decreasing the diagnosis time for rare diseases to a maximum of six months). Rare diseases do not work in silos; a European plan ensures that Europe continues to enable the rare disease community to create the critical mass of patients, experts, knowledge, guidelines, and resources needed by coordinating and adding value to national efforts.

Yann went on to discuss the difference between equality and equity (insert picture on equity from presentation here) Equality is when governments, or we as individuals, provide the same type of efforts or allocation of resources for everyone. But that kind of approach doesn't help people with different needs.

What equity does is to provide a support that is proportionate and adequate to your needs.

Universal Health Coverage is a commitment that all European countries have made at the level of the United Nations (UN); it is a major new strategy of the international community in the area of health. Yann explained to us that there are three dimensions of universal health coverage:

- 1 Population, which means that more people would have access to health care (including people with rare diseases). It must be said that rare diseases are explicitly mentioned in this political declaration of the UN on universal health coverage.
- 2 Services, which mean that progressively more services should be covered in each member state (and services can include diagnostic tests, social support, therapies et cetera).

- 3 Direct cost, which means that the strategies should reduce the out-of-pocket expenses for people.

Universal Health Coverage requires measures that strengthen healthcare systems in a way that contributes to ensuring health equity, reducing inequalities, and facilitating equal opportunities to attain the greatest level of health and well-being for all persons, including the most vulnerable populations such as people living with a rare disease.

Yann then went on to talk about Cross Border Healthcare in Europe. For Yann the goal when it comes to cross border healthcare for rare diseases, is for people to be able to access centres of care for their condition across Europe. For that goal to be reached, there needs to be information on standards of treatment and care, information on reimbursement rules and on the best legal pathway to use. Each country has a National Contact Point that can provide information on all the above. In practice progress on Cross Border Healthcare has been slow and there are a lot of difficulties with the system, with parts of it not working well or at all.

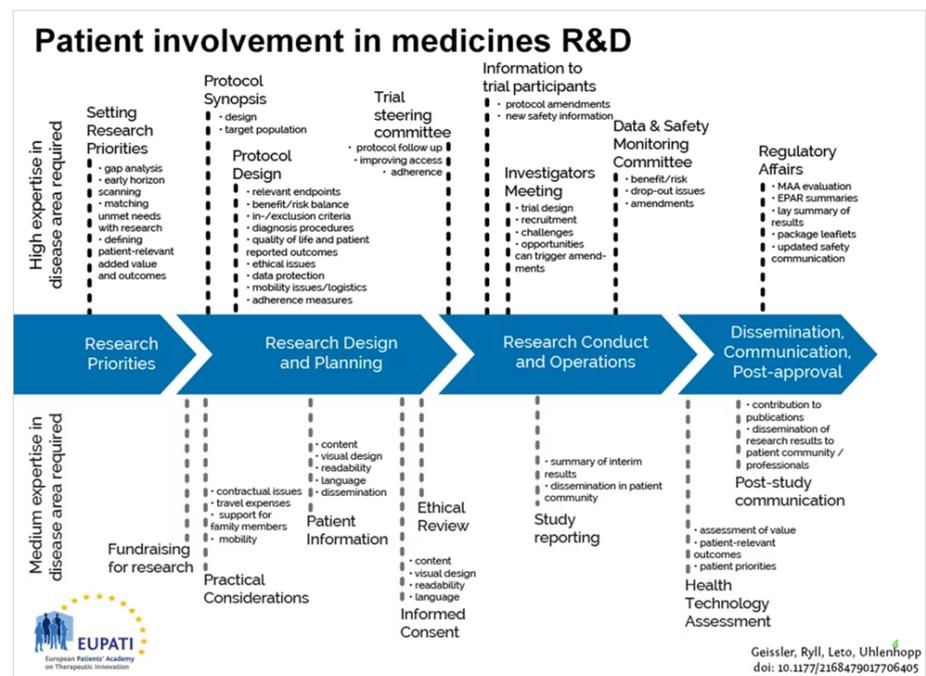
Yann mentioned that EURORDIS used a survey to ask people living with rare diseases in the EU whether they would be willing to travel to another country to receive medical treatment; a resounding 86% of respondents indicated they would. Of those surveyed who would be willing to travel to another EU country for medical treatment, 84% would do this to access treatments that are not available in their country, 59% would do this to access better quality treatment and 45% would do it to access treatment from a renowned specialist. Few citizens are using cross-border planned care. There are still many barriers to accessing cross-border planned care in Europe, especially when it comes to rare disease patients. EURORDIS is trying to change this.

A very interesting and interactive Q&A session followed this talk; delegates had many questions for Yann to further understand these important issues.



Dominique Hamerlijnk, who is a EUPATI trained patient ambassador and advocate from the Dutch Lung Foundation gave us a presentation on **what HTA is and how we as patients and patient organisations can be involved in HTA assessments.**

The goal is to have patients involved in ALL stages of clinical development. Ideally patients should be involved from the beginning of the process. But this does not happen that often, though it is changing.

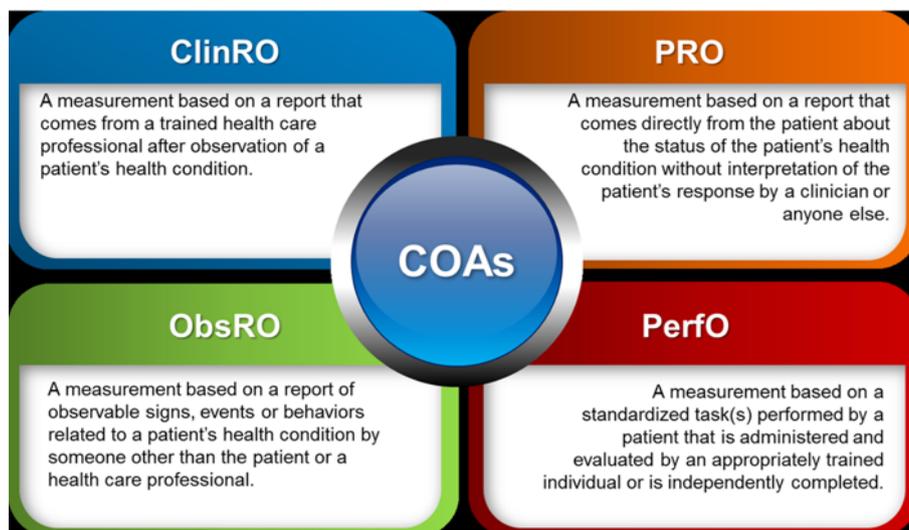


This is just an indication of what patients bring to the table in the different steps of medicine R&D. But it shows how you can prepare.

One of the problems we face in HTA at the moment is that because patients haven't been involved in the earlier stages of the clinical trial, they need to go back and look at the outcomes of the trial (which are often not PROIs). This is what we can bring to the table – our own lived experiences and unmet needs. A new development we are beginning to see is that more and more patient groups are looking at what is important for them as primary outcome in research. What has the biggest impact on their lives. This is often different from the standard traditional clinical trial outcome measure. It is important to think about what would be important in your disease area. With new diagnostics and differentiation in diseases sometimes different outcome measures are needed. The Dutch Lung Foundation has recently developed a quality-of-life questionnaire for severe asthma, as the traditional one did not capture the quality of life well enough.

The primary outcome measure is important because that is the one on which the amount of people needed in the study is calculated to be able to make statistically relevant statements about what the treatment does.

When discussing the assessment with researchers, a trial organisation or among patients themselves it is good to keep in mind what is relevant for the patients with the disease. And if the assessment was developed with or without patients.



Most of the “traditional’ outcome measurements were developed by clinicians, often as a way of diagnosing the disease and getting an idea of what was happening with the patient. But as mentioned before the traditional outcome assessments are not always the most relevant ones from a patient perspective. It does not make them irrelevant, but you need to consider what is important and find a balance. Dominique often encounters the idea that patient relevant outcomes are always patient reported outcomes and most of the times measured with questionnaires. Many of the clinicians and researchers Dominique talks to see that as qualitative and less relevant information, not as scientifically sound. However, the FDA (the US food and drug administration) has created guidelines to develop patient relevant outcome measures to be used in clinical trials and regulatory decision making. They can be developed using sound scientific processes and be validated both for clinical trials and clinical practice. It might not be the standard in the EU yet, but it is becoming a more and more accepted practice. As patients we can promote this development.

- **Definition of HTA:** “HTA is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system” from www.inahta.org
- **Health technology assessment body:** “A public organisation that provides recommendations on the medicines and other healthcare interventions that can be paid for

or reimbursed. These organisations look at the relative effectiveness and cost effectiveness of medicines that have been authorised.” from www.ema.europa.eu

HTA is a formal, systematic, and transparent process, and uses state-of-the-art methods to consider the best available evidence. The dimensions of value for a health technology may be assessed by examining the intended and unintended consequences of using a health technology compared to existing alternatives. These dimensions often include clinical effectiveness¹, safety, costs and economic implications, ethical, social, cultural, and legal issues, organisational and environmental aspects, as well as wider implications for the patient, relatives, caregivers, and the population. The overall value may vary depending on the perspective taken, the stakeholders involved, and the decision context.

And: HTA can be applied at different points in the lifecycle of a health technology, i.e., pre-market, during market approval, post-market, through to the disinvestment² of a health technology.

EMA, national and regional or local authorities can be a health technology assessment body. You need to find out how it works in your country, who decides and how you can become involved in the assessment.

- In the future, European cooperation between medicine regulators and HTA bodies will be governed by the [Regulation on Health Technology Assessment \(EU\) 2021/228](#) when it takes effect in January 2025.
- EMA is working closely with the [European Network for Health Technology Assessment \(EUnetHTA\) 21 consortium](#) to prepare for the entry into application of the Regulation.
- The European Commission has contracted EUnetHTA21 to continue HTA cooperation in Europe, building on the foundations laid down by the former [European Network for Health Technology Assessment \(EUnetHTA\) network](#) since 2010.

The new HTA regulation in Europe should have a positive impact on the patient engagement and patient relevant outcomes in the HTA process. We are just at the beginning of this process.

In the current system, if a drug goes through EMA for the scientific evaluation, we know that patients are involved in all evaluations in the PRAC (the pharmacovigilance risk assessment committee).

Each country has its own practice of involving patients in HTA. You need to find out what the practice in your own country is.

¹ The benefit of using a technology, programme, or intervention to address a specific problem under general or routine conditions, rather than under controlled conditions, for example, by a physician in a hospital or by a patient at home.

² The deliberate and systematic reduction of funding for a health technology of questionable or comparatively low value.

- Between 2021 and 2023, EMA and EUnetHTA 21 are focusing on the following jointly agreed priority areas:
 - Joint scientific consultation for robust evidence generation
 - Exchange of information on assessments of medicines
 - Generation of patient-relevant data and information to support decision-making
 - Methodologies to engage patients and healthcare professionals
 - Horizon scanning and preparedness of HTA and regulatory systems
 - Optimisation of regulatory outputs as reference for down-stream decision-making
 - Study methods and guidelines³ of real-world evidence
 - Tools to support assessment in smaller populations
 - Assessment work related to companion diagnostics

In the new regulation patients/patient organisations not only get to be involved in the individual HTA processes, but they also get a role in the steering committee. This process builds on the EUnetHTA process but takes it further. As it is still being developed, Dominique is not sure how you can get involved at what level. It might be good to work together with other patient organisations on an EU and a country level to get involved in this development.

The new EU HTA regulation combined with the EU clinical trial and EU medical devices regulations with the obligation to register all trials in the EU CTIS (the clinical trial information system) and the requirement of adding the data results of all trials, even if they failed, will give us more access to information. This combined with the requirement of publishing a lay language summary as well, means that information will become even more accessible. It will still require work and effort to understand what is happening in our own disease area, and it will be a while before the first trials are added in the system and the first lay language summary of the results will be published.

There is even an IMI⁴ project that is looking at if we can make a system that will make it possible for patients to see what trials are coming and get access to information if the trial might be fit for them all (matching the right patient with the right trial) over the world. It is still too early to be sure it will happen, but many companies and organisations are thinking along these lines. CTIS will also have a system of finding if there are trials coming, but it is unclear how easy it will be to use.

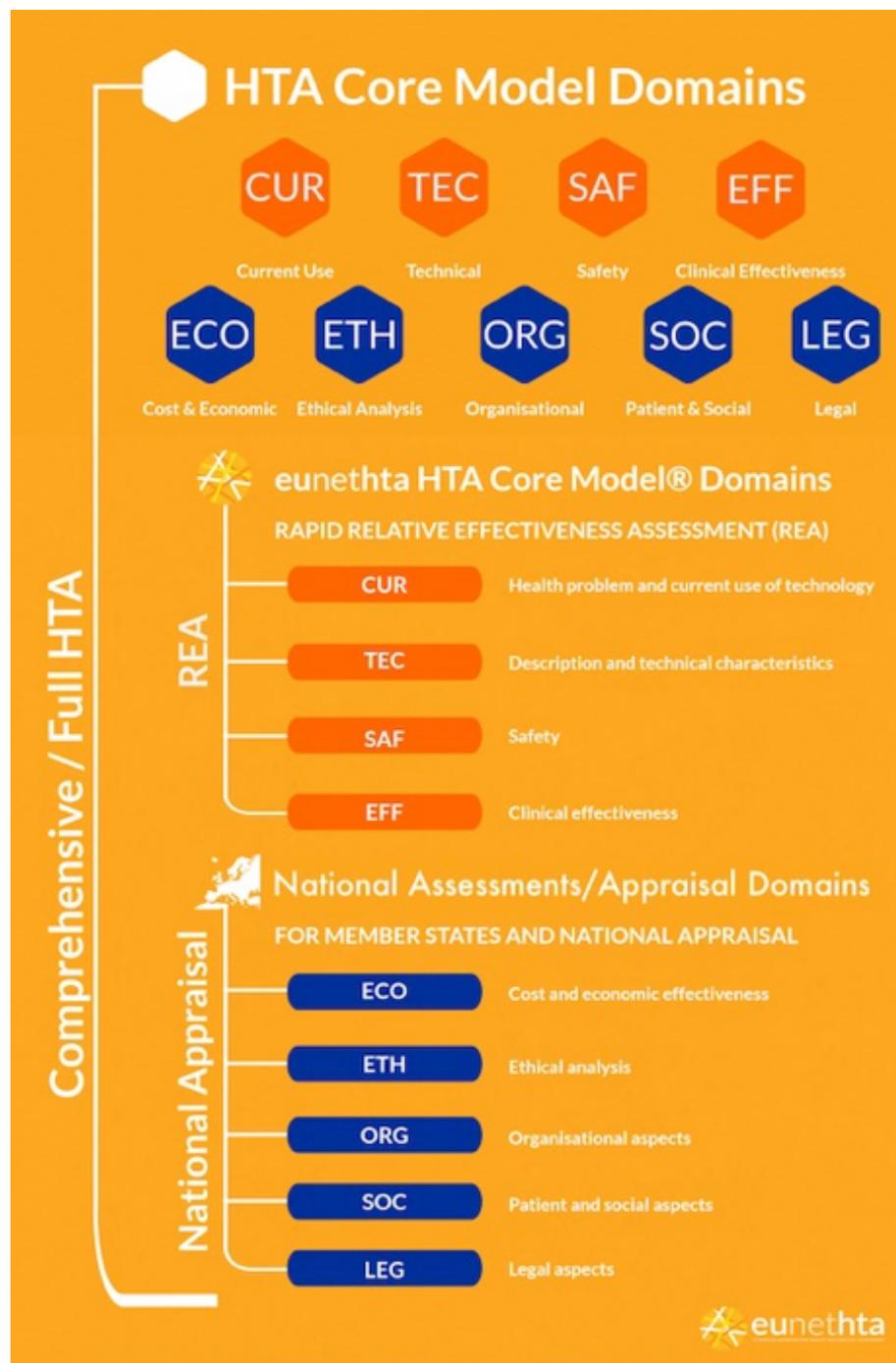
The whole new HTA-process in Europe will be based on what has been developed in the EUnetHTA project which started in 2013. EUnetHTA has been working with the national authorities and the EU to achieve more cooperation in Europe in the HTA process. Instead of every country doing their own full HTA for drugs that have not passed through EMA, they suggest a joint section, the REA (Rapid Relative Effectiveness). This is a method all national authorities have agreed upon so that they can work together and share HTA information. It

³ **Guidelines** | A document providing guidance on the scientific or regulatory aspects of the development of medicines and applications for marketing authorisation. Although guidelines are not legally binding, applicants need to provide justification for any deviations.

⁴ **IMI** | Innovative Medicines Initiative

contains the basic steps to come involved in and generic, of value in all countries, questions that should be considered in HTA. Two definitions are important in REA:

Relative efficacy can be defined as the extent to which an intervention does more good than harm, under ideal circumstances, compared with one or more alternative interventions.

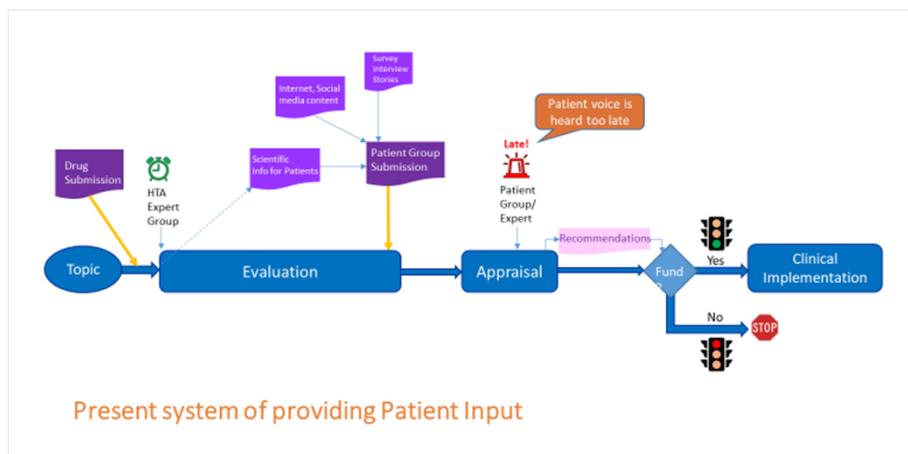


Relative effectiveness can be defined as the extent to which an intervention does more good than harm compared with one or more alternative interventions for achieving the desired results when provided under the usual circumstances of health-care practice.

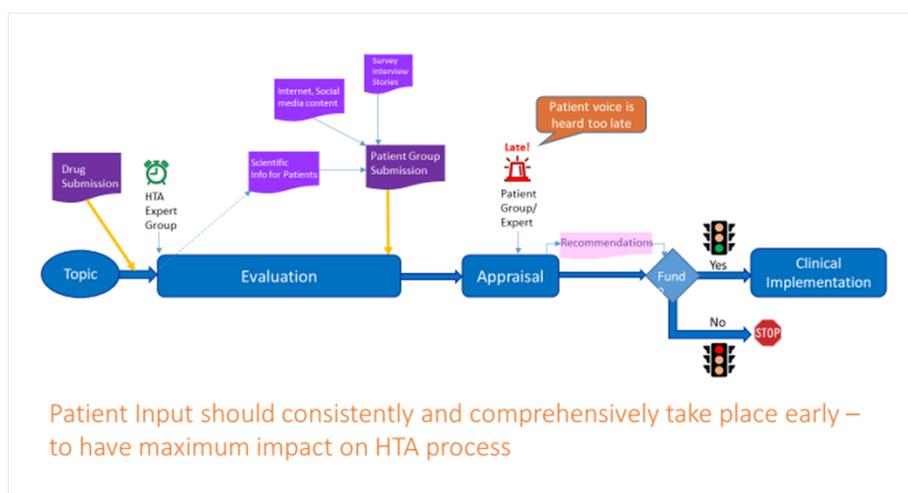
REA looks at the general health problems and current use of treatment, description and characteristics, safety and clinical effectiveness.

The second part is held in the individual countries and looks at country specific information. It looks at the cost and economic evaluation, which is dependent on the country's own rules and what they are willing to pay. Ethical analysis looks at what is happening for that patient group in that country etc. Organisational aspects like how care is organised, is the care system equipped to deal with the new drug etc. Patients and social aspects, and legal aspects.

With the new EU HTA regulation, the intention is that all drugs get a joint REA and then in each country the national appraisal is done. So far EUnetHTA has involved patients in the evaluation in some of their REA's. We can advocate that disease specific patients are involved in all REA's.



This is a general overview of how the HTA process is organised in many countries. Sharing the assessment reports is key to facilitate effective patient involvement. Patients/patient organisations don't get to see the assessment report in all countries. They ask patient organisations to input data into the process without informing them on what came out of the clinical trials and what the assessments of these results were. According to Dominique this is sending you in blind. You are giving input into a scientific meeting without knowing what the shared information is. This is one of the reasons that the scientific committee often judges the input from patients as less relevant. Because patients are not at the table you cannot explain the relevance of the information you are sharing.



This is where we want to move to. Patients get the same assessment report as the rest of the committee. This is already the practice at EMA. Only then can you disseminate the information and prepare for the meeting on a similar footing as the rest of the committee. It would also be helpful if the patients invited to sit at the table are supported by the patient community and the HTA organisation in preparing for their role in the best way possible. As this is the gateway to getting a drug accepted in each country, reimbursed and available for the patients, it is an important step for patients.

It is encouraged to report the side-effects you experience when taking a medication – you can find your National Contact Point through the European EudraVigilance website [here](#) or you can report it directly to the manufacturer of the medicines using the instructions in the patient leaflet. Be aware that when you report a side-effect the pharmaceutical company is obliged to investigate it, so only report the more “severe” ones, that really makes a difference in your life and that doesn’t disappear.

Preparing for the HTA Meeting

1 Impact/burden of the disease	2 Current Treatments	3 New Treatment Expectations	4 Patient Perspective
<ul style="list-style-type: none"> • challenges • limitations • impact on work, family, carers • differences in disease 	<ul style="list-style-type: none"> • what is available • effect on patients • benefits of current treatment • burden of current treatment • what do the treatments do not solve 	<ul style="list-style-type: none"> • benefits compared to current • control of important signs and symptoms • limitations • side effects • burden 	<ul style="list-style-type: none"> • importance of the outcomes • minimal level of improvement • why would it not be used • advantages and disadvantages • impact

When engaging in a Health Technology Assessment these are the four main subjects you need to look at and prepare information on.

You don’t need to know everything, but it’s good to think about what information you already have and which unanswered questions you still have. This is where it’s good to be a part of a pan European patient group where we can work together to figure out the answers to the questions. Some might require new questionnaires and others might require us to ask doctors or nurses or other specialists and together we are able to do that.

We have two major sources of information available: Living with SLE in 2020 patient survey [here](#) and the EMA assessment report from 2021 on Saphnelo [here](#) & the CHMP⁵ summary of opinion [here](#).

Be aware that just because there is a new drug – that doesn’t necessarily mean that it has value for you as a patient! The treatment should bring benefits and if it doesn’t – there’s no need to invest in it.

⁵ CHMP | Committee for Medicinal Products for Human Use

All in all, this session was a great preparation for all the work that needs to be done by lupus patients around Europe in the next years, where we will hopefully see a lot of new treatments coming out and needing to be evaluated for reimbursement or not through an HTA process.



Talk to the Doctor

with Prof. Matthias Schneider

Prof. Matthias Schneider from Düsseldorf gave us a **presentation** on the **treatment of SLE now and in the future, treatment strategies** and **his retirement project called CHRONIN**.

He begins with describing the basic treatment of lupus, which ALL lupus patients should receive. Unfortunately, that is not always the case (in Germany e.g., around 70% receive it).

- Vitamin D (20.000 IU/W)
- Hydroxychloroquine (200 mg/d)
- Sun protection, SPF50
- Vaccinations: basics + influenza, pneumococci (non-live)
- Arteriosclerosis⁶: Risk factor control

The aim of any lupus treatment is remission. According to the DORIS⁷ you are in remission when you don't have any clinical manifestations of SLE and you are allowed to take up to 5 mg. of corticosteroids (e.g. Prednisolone), antimalarials (e.g. hydroxychloroquine) and immunosuppressants (including biologics) and it's still called remission. Prof. Schneider estimates that within the next five years it will no-longer be allowed to take any corticosteroids when in remission. According to new findings up to 70% of lupus patients can withdraw completely from taking steroids and have no flares afterwards. They are needed in an acute situation, but you do not need to take them forever.

Long term studies of Belimumab (Benlysta) show that the drug reduces damage in the long run and is very safe to use (has very few side-effects). It is not a powerful drug, but is recommended if you have consistent disease activity, where you would normally take steroids. With Belimumab you can reduce the dosage of steroids needed. It also works for lupus nephritis without a significant increased risk of infections.

75% of lupus patients have a high amount of the cytokine called interferon alpha, which increases the risk of disease flares and organ manifestations. At the same time, it reduces the respond to/effect of steroids.

Many have tried to create therapies that block interferon alfa, but it does not have the desired effect. The cytokines interact with a receptor on the cells and others have tried to develop a therapy that blocks the receptor instead and that seems to work better. Anifrolumab (Saphnelo) is using that exact method (antibody against interferon type 1 receptor). It is

⁶ **Arteriosclerosis** is the thickening, hardening, and loss of elasticity of the walls of arteries.

⁷ **DORIS** | Definition Of Remission In SLE

especially effective for skin manifestations. The one notable safety issue is that you have a significantly higher risk of developing herpes zoster, and it is recommended to be vaccinated against this when you receive the treatment.

Another therapy coming out soon is called Voclosporin and it's for lupus nephritis. It was approved by the U.S. Food and Drug Administration (FDA) for the treatment of lupus nephritis (LN) in January 2021. It's sold under the brand name Lupkynis, is a calcineurin inhibitor used as an immunosuppressant medication.

If you ask a lupologists which product they have the most hope for, it's Obinutuzumab. It's a third line Rituximab (attacking CD20 – a signal on B-cells) and is intended for use in lupus nephritis. It is a product developed for lymphoma and is not yet approved for lupus but is in phase 3 at the moment.

A new and more experimental therapy is called CARR-T⁸ Cell treatment. It's a therapy developed for lymphoma⁹ and malignancies. T-cells are taken out of your body and transfected (modified) with a receptor (signal CD19), which attacks B-cells (CD-20) and infused back into the patient. It's a very expensive method and has only been tried on five lupus patients in Erlangen (Germany) as a last resort. The first two (a 20-year-old woman and a 22-year-old man) no longer have any antibodies or symptoms of lupus (the disease has disappeared), but we don't know what will happen in the long run. It's a sort of resetting of the immune system, but not as risky as e.g., bone marrow transplantation, where you have a high risk of infection. You only have to do the procedure once, but it causes your immune memory cells to lose the information they have, and we don't know the consequences of that yet. It could potentially be a new hope for lupus treatment, but we need much more data and to learn how to choose which patients to administer it to.

A completely different aspect is based on the idea from oncology (cancer) that you support your own system to fight for you against your immune system (interlucine-2), stimulating T-reg-cells (regulatory T-cells).

Deucravacitinib, AN TYK2 INHIBITOR is a JAK¹⁰ (Janus Kinase) inhibitor addressing interferon-1 (like Anifrolumab), IL-12 and IL-23. It has showed efficacy on especially skin and joints in phase two.

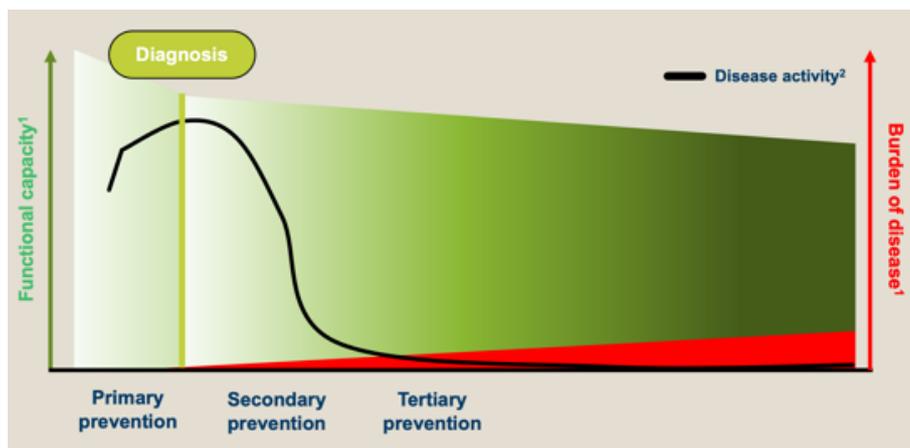
SUSTAINABLE LUPUS TREATMENT

20% of all lupus patients only have one flare and then never again. It does not make sense to start treating those with corticosteroids.

⁸ T-lymphocytes

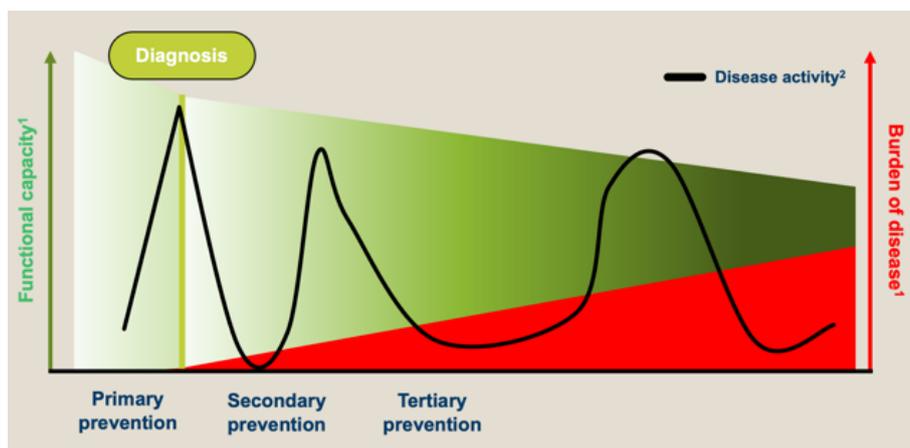
⁹ Lymphoma is a cancer that starts in cells that are part of the body's immune system

¹⁰ Baricitinib (which failed phase 3) was also a JAK inhibitor



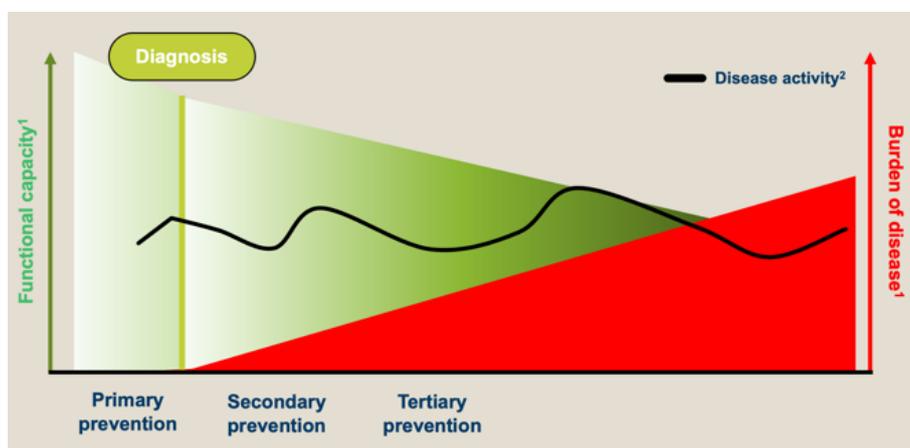
This means that their long-term burden of the disease is low and that they keep almost all of their functional capacity. It would not make sense to keep these patients on cortico-steroids.

60% of patients have several flares but remission in between flares.



This means that their long-term burden of the disease is not that high and that they keep some of their functional capacity for a longer time.

20% of patients never really go into remission but have flares going up and down all the time.



This means that their long-term burden of the disease is high and that they lose most of their functional capacity early on.

It makes a difference what you aim for. In lupus we should aim for remission. It has nothing to do with lab parameters/serological activity¹¹. In remission you are allowed to take antimalarials and immunosuppressants (incl. biologics), there should be no disease activity (cSLEDAI¹² = 0) your PGA¹³ score should be no more than 0,5 (on a scale from 0-3) and your glucocorticoid dose shouldn't exceed 5 mg. pr. day. In the German cohort in Düsseldorf, they reach remission in 39% of patients. A physician would say that only 30% are in remission (PGA) but at the same time they say that for 92,1% of those patients not in remission they would not increase therapy. According to Prof. Schneider this is a mistake - if you are aiming for remission. There are many benefits from being in remission (HRQoL¹⁴ is improved, damage accrual is reduced, pain and depression is reduced) and equally there are disadvantages from NOT being in remission (the survival rate is halved).

According to the new sustainable lupus strategy you start the treatment and set a goal for where you want the patient to be after 24 weeks and if you haven't achieved it at week 24 you increase/modify the treatment and make a new 24-week assessment. This way you identify the drug/therapy that works best for the individual patient, not after years but after a short time. Prof. Schneider is starting a clinical trial in Germany that measures standard of care against treat to target (with the target being remission). Trials today show that when you are in remission you have a better outcome, Prof. Schneider is making a trial to show that when you bring someone from active disease into remission it creates a better outcome. The trial lasts for 120 weeks and includes all five German centres with lupus patients (300 patients). The primary outcome is reduction of damage, and the secondary outcome is improved quality of life. It will be interesting to see how physicians will behave when they are forced to bring patients into remission. A training for the patients on shared decision making is included in the trial. Type two patients (the ones with fatigue, widespread or diffuse pain, anxiety, depression and brain fog not related to the condition and that do not respond to standard immunosuppressants) are not going to have their treatment adjusted in the trial. It would be interesting to have a look at what helps those patients, though...

For Prof. Schneider what we need in sustainable lupus treatment is shared decision making on a primary target point, hit it hard at the beginning and optimised monitoring.

There was a question from a participant about prof. Schneider's recommendations regarding hydroxychloroquine (HcQ). You should not take more than 5 mg. pr. kg. actual bodyweight pr. day. Unless there are any contraindications you can safely take the drug for five years without

¹¹ **Serological activity** in SLE generally refers to the presence of anti-DNA antibodies and/or hypocomplementemia

¹² **cSLEDAI** | clinical SLE Disease Activity Index

¹³ **PGA** | Physician Global Assessment

¹⁴ **HRQoL** | Health Related Quality of Life

needing an eye examination (you should always have an initial baseline eye examination by an ophthalmologist) and after the first five years you should have a yearly examination. As long as you tolerate it you should keep taking it because of all the positive benefits.

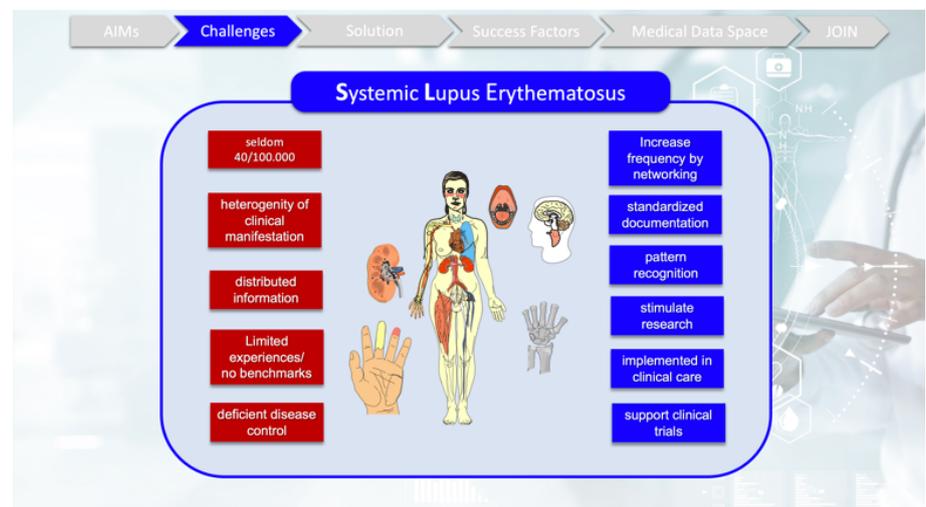
Extensive research shows, that half of the patients don't adhere to their HcQ treatment. That's why some physicians prefer to give 400 mg. pr. day to 200 mg. (when it's a borderline case) and then have the non-adherent patients taking 400 mg. once in a while rather than 200 mg. once in a while.



CHRONIN is a cloud-based network where operators can access all data and samples to:

- optimise all patients' daily care, (monitoring, clustering, prevention & prediction)
- stimulate collaborative research (international clinical research, basic science & global studies) and
- create precise interventions (new trial designs, precise medicine & specific targets).

And it starts with lupus!



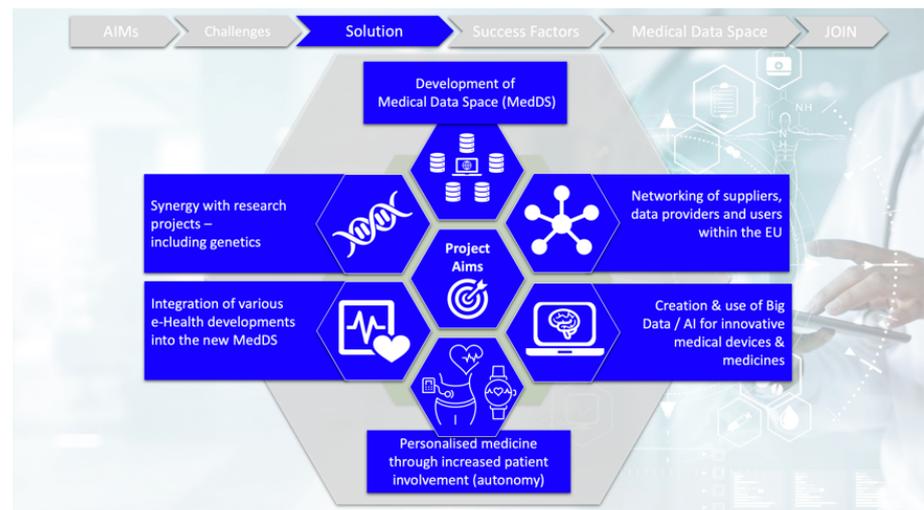
The problem/challenge with lupus is that it's rare¹⁵/uncommon, the heterogeneity of clinical manifestations, distributed information (it sometimes takes a week to get all the information

¹⁵ Prevalence of 40/100.000

you need from a patient), the physicians have limited experiences/no benchmarks and there is still deficient disease control.

What they want to reach with CHRONIN is:

- to increase the frequency by networking,
- a standardized documentation (working on a core data set for lupus for EULAR¹⁶, so all physicians know what the basis for documentation is for lupus)
- a pattern recognition (disease subgroups)
- to stimulate research
- to implement it directly in clinical care and
- to support clinical trials



The project aims to develop a Medical Data Space (MedDS) (a database of ALL lupus patients in Europe). That means that they need a network of all people who see lupus patients (Networking of suppliers, data providers and users within the EU). They need to use new technology to support them in the care (by creating & using Big Data/AI for innovative medical devices & medicines). Personalised medicine through increased patient involvement (autonomy) means that the patient owns their own data and decides what it is being used for. They want to take all data from the health care system and integrate them into this data space (integration of various e-Health developments into the new MedDS). The goal is to offer researchers that they can conduct their research on the background of the data in the database and supporting them in that (synergy with research projects – including genetics). They want to integrate all the registries that already exist. It should make it possible for a doctor with a complicated patient to access the database and search for similar issues and possible solutions. The data from all the lupus patients will be combined into a biobank. They also want to use the data for phase four trials (real world evidence) investigating long-term safety. Having a database with information on all patients provides the opportunity to identify which patients fit into which trials and to contact them directly. The system can support clinical trials in phase

¹⁶ EULAR | European Alliance of Associations for Rheumatology

2 & 3 (both academic and those from pharma companies), create new designs, patient-identification, -information and -consent.

The EU has created rules for developing a medical data space that they need to follow and that means that they (mostly) only have to take care of the technical parts. There are a lot of legal regulations, ethics and anonymisation that must be followed, and the cloud technique is also very challenging, so it's a huge project.

The starting point is ERN¹⁷. They already have two universities, and a company responsible for data protection involved, but they are looking for more partners and they would very much like Lupus Europe to become such a partner. By the end of 2022 they will have the first prototype that can be evaluated. Prof. Schneider's ambition is to be done with the project in five years.

Patients and Patient Organisations can help the project by showing their support and spreading the word about it. There is a website, where you can learn more: www.chronin.eu.



¹⁷ ERN | European Reference Network

Soft Skill Training

How to Tell your Story

by Cyril Rachetta

Cyril Rachetta, public speaker, and expert in strategic communication, ran a highly interactive hybrid workshop on “How to Tell Your Story”.

The workshop’s goal was to equip our delegates with tools and techniques to craft a story that they could then tailor to the specific needs of different audiences.

Being able to communicate effectively with different audiences is a key skill for patient advocates and our Convention participants who come from National lupus groups across Europe.

Our Living with lupus research [here](#) has also shown the big gaps that remain in terms of access to multifunctional teams, to physiotherapy, specialised lupus nurses and professional psychologic support. We all have a role to play to change this and improve access to treatments and therapies for people with lupus around Europe and telling our story can be a big help to achieve this.

Further novel treatments like Anifrolumab and Voclosporin have successfully gone through regulatory approvals. But any treatment can only be of value if patients around Europe are able to access it. In many countries, as patient groups, we have a role to play, together with rheumatologists, to build the case for reimbursement, explain what living with lupus entails and what the unmet needs are and, in this way, concretely help people living with lupus to access novel treatments.

Cyril began with a series of interactive exercises. The delegates reflected on past presentations they had been given and discussed what made a presentation good and what made it bad. Cyril explained to us that the power of stories is that they are memorable, portable, repeatable, and universal. He then went through the structure of stories; stories have a beginning, a middle and an end and talked about key elements of stories such as a plot, characters and a moral. All stories serve a purpose.

We then went through the audience triangle, a very good tool that emphasises the audience is at the centre of communication. We first need to know who we’re talking to to understand their level of knowledge and what it is our audience may want to hear from us and to therefore now what content we should share and how best to communicate it. Our content and its delivery would change depending on whether we were talking to academics, industry, other lupus patients or the general public.

Then it was time for an interactive exercise; “Audience Analysis”. We thought of the next time we would need to tell our stories and analysed who our audience would be. In doing the audience analysis, participants had to think of what the audience would expect from us, what they would want from us, what they would need from us and what would be in it for them (i.e., what is the reason they care about our stories).

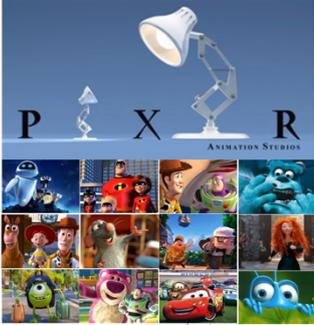
This was followed by another exercise: “Your Purpose”. We took the same situation we had thought of for the “audience analysis” and we consciously considered what the objective of sharing our story would be in that scenario, what we needed to achieve by sharing our story. When the audience and the purpose of sharing the story had been identified, Cyril gave delegates tips on how to create their story’s timeline, how to compare their individual story with the data from the Living with Lupus survey and how to create visual supports to enhance the story’s impact. We all learned the magic rule of three and that, when telling our stories, we should stick to three things if possible, such as why the story we are sharing is important, what living with lupus has taught us and a conclusion that includes a clear and assertive call to action!

Based on the audience analysis and the identified purpose from previous exercises, delegates then had a chance to craft their own stories during the workshop using the Pixar framework as a structure guide. Some participants chose to share the stories they crafted with us in the session.

THE PIXAR FRAMEWORK

- Once upon a time, there was _____
- Every day, _____
- Then one day, _____
- Because of that, _____
- Because of that, _____
- (because of that, ...)
- Until finally, _____







2022LUPUS EUROPE CONVENTION 202229

Delivery of a story is part of effective communication as well. Logistics such as considering the venue and any relevant technical details and thinking about how we’re feeling beforehand are important. If the delivery is virtual and not in person, then we need to consider technical aspects including lighting, the optics of the background and good sound quality.

Rehearsing the story with someone else is key as is using a timer during rehearsal and adapting the story’s content if, during rehearsal, it becomes obvious that the story goes over the allotted time. Dressing the part on the day is important as well: Cyril stated that people remember the way others look and that it is therefore a good idea to wear something that helps us stand out.

Delegates were able to ask Cyril questions throughout the workshop. For Cyril, the three takeaways from his workshop were to always start crafting a story with the audience in mind, to be clear on the purpose of the story and include a call to action and to rehearse!

Watch this session [here](#)



Poster Session

The poster session was a wonderful option for our delegates to share something they have done in the past year in their National Groups with us all.

Lupus UK shared a great poster on their "Support Network for Parents/Carers of Children with Lupus" with a wealth of information on what the network offers!



Support network for Parents/Carers of children with lupus

LUPUS UK

Launched in spring 2021

- Five hour-long virtual meet-ups
- 8-15 parents attending each meet-up
- Guest speakers from Great Ormond Street, Alder Hey and Evalina Children's Hospitals
- Discussions about treatments, COVID-19, support for mental & emotional wellbeing & research.
- Accompanying Facebook group.

"Since the recent diagnosis of daughter I've been looking for resources and support on my own. It was good to see and hear from other parents going through similar experiences and from those more experienced for practical advice. Thank you for organising."



Lupus Suisse shared a very interesting poster on their “Newsletter” and the establishment on direct and fast communication to all their members in three languages (German, French, Italian)!





NEWSLETTER

ESTABLISHMENT OF A DIRECT AND FAST
COMMUNICATION
TO OUR LUPUS SUISSE MEMBERS IN 3
LANGUAGES (GERMAN, FRENCH, ITALIAN)

Since November 2021, we have sent:

- 4 newsletters and
- 1 Lupus Europe survey

The emails are sent to almost 400 members out of the 500 with an average opening rate of +60%.

We include an introduction and 3 topics with one of them always being on Research advancement. We also include upcoming events. We use mailjet.com tool.

lupus  suisse



From Cassandra Alexis (**Lupus Europe Youth Group**) came a fascinating poster on “Therapeutic Patient Education” and information on how teenagers and young lupus patients can access this type of education in France!

**WHAT IS
THERAPEUTIC
PATIENT
EDUCATION ?**

IT AIMS TO HELP
PATIENTS DEVELOP
OR MAINTAIN THE
SKILLS THEY NEED
TO BEST
MANAGE
THEIR LIVES
WITH
CHRONIC
DISEASE



ETP

EDUCATION THERAPEUTIQUE
DU PATIENT


TPE


workshops
and a
website
especially
for lupus
teenagers
in France



Le savais-tu ?

JE PRÉPARE UN VOYAGE
Je prépare un voyage

J'ai un
Lupus

Tout savoir sur la maladie

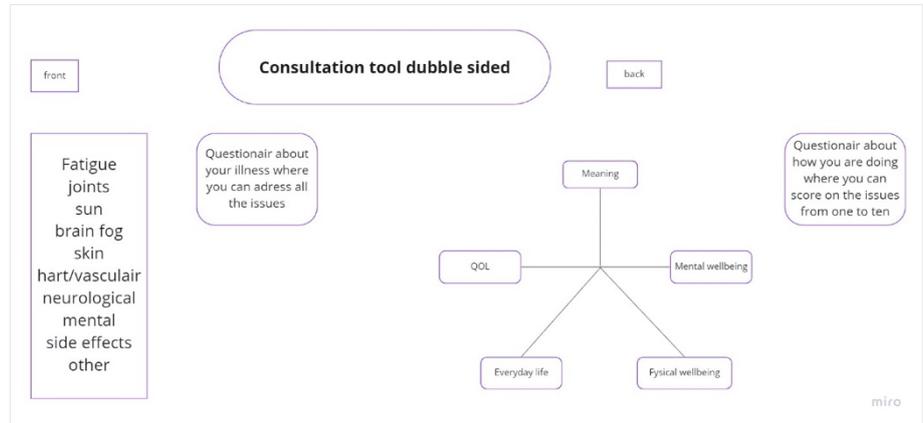
The french national reference lupus center at the Pitié-Salpêtrière Hospital in association with the National reference centre for rare pediatric rheumatologic and systemic autoimmune diseases (RAISE) have created a new TPE program in connection with the transition of adolescents and young adults from the pediatric service to the adult service.

Workshops with themes such as :

- Living with lupus in adolescence
- Going out with friends when you have lupus
- Knowing how to explain your disease and plan for the future
- Pregnancy, Sexuality and Contraception

There are also several topics, questions and answers, testimonies and videos on the website : www.adolupus.fr

NVLE made a great poster and mind map about how lupus patients in the Netherlands were engaged in the development of a Consultation tool!



NVLE Nationale vereniging voor mensen met lupus, APS, sclerodermie en MCTD

neurologische klachten
1 2 3 4 5 6 7 8 9 10

hersenmist
1 2 3 4 5 6 7 8 9 10

psychische klachten
1 2 3 4 5 6 7 8 9 10

droge mond / ogen
1 2 3 4 5 6 7 8 9 10

hart en vaat problemen
1 2 3 4 5 6 7 8 9 10

huidklachten
1 2 3 4 5 6 7 8 9 10

gewrichten
1 2 3 4 5 6 7 8 9 10

pijn
1 2 3 4 5 6 7 8 9 10

vermoeidheid
1 2 3 4 5 6 7 8 9 10

bijwerkingen medicatie
1 2 3 4 5 6 7 8 9 10

last van de zon
1 2 3 4 5 6 7 8 9 10

overige klachten
1 2 3 4 5 6 7 8 9 10

Geef op een schaal van 1 tot 10 aan wat de ernst van de klachten zijn.
Hierbij is 1 geen klachten en 10 ernstige klachten.

www.nvle.org



Gruppo LES Italiano shared with us a very interesting poster on some of the work their group has been doing in the past year in a number of different areas to provide support and up-to-date information for lupus patients in Italy!



LUPUS EUROPE CONVENTION

Leuven 2022

Our Mission

We continue working hard to provide Lupus sufferers with support, assistance, up-to-date information about Lupus and new therapies, and to increase patients' awareness of their rights.

Live broadcasts

Since the beginning of the pandemic we were closely connected with our Lupus patients and tried to help them. We were able to disseminate the best and correct information possible through our social media and networking, the only means we had to communicate.

In April 2020 we started our live broadcast service

- broadcasting every two weeks
- hosting specialists who talked about topics related to the current situation
- helping patients and trying to clear up their doubts
- answering to all patients' questions

Institutional web conference

In June we had a Roundtable (web meeting) attended by patients jointly with clinicians and institutional decision makers on:

- correct diagnosis
- access to care equity
- new perspectives for patients and doctors: therapeutic and doctor-patient relationship continuity
- empowerment in the management of the disease
- patients associations participating in health assessment processes



Annual Convention and Council

Finally we were able to host the much-awaited annual Convention in Bari on April 9th.

It was the first face-to-face event after two years. A number of participants were directed to the Gruppo LES Facebook page to follow the sessions as they livestreamed.

The theme for the convention was "Comparison of the various experiences"



WORLD LUPUS DAY - May 10th

"My Lupus Story" - Italian Contest in collaboration with GSK
"Be yourself the key figure, write your story. . . !!!"

All stories were reported in our live broadcasts. The best ones were used to make two videos; artists played patients' role and narrated their experiences.

A special webinar was held on May 10th: interesting patients-doctors dialogue, the specialists listened to their life experiences and answered to all their questions.

After a two-year stop we're finally starting again the distribution of Saintpaulia violets, with stalls in some Italian cities, to raise funds and public awareness about Lupus.



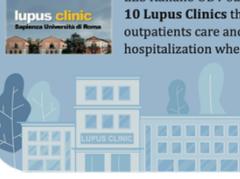

FINANCIAL SUPPORT

Initiatives aimed at improving patients' conditions (Lupus Clinics)

LES Italiano ODV sustains and financially supports **10 Lupus Clinics** throughout Italy capable of providing outpatients care and day treatment up to full hospitalization when needed.

Scientific Research projects on SLE

We have awarded a research project for € 30,000 on the topic "Impact of the SARS-CoV-2 pandemic on patients with lupus: acute and long-term".



Participation in two congresses organized by the Italian Scientific Societies

CREI (Italian Rheumatology College) 

SIR (Italian Society of Rheumatology) 



The Lupus Group of the Cyprus League of People with Rheumatism (CYPLER) made a wonderful poster on “Access” about all the different services lupus patients in Cyprus are able to access!



Kick Lupus

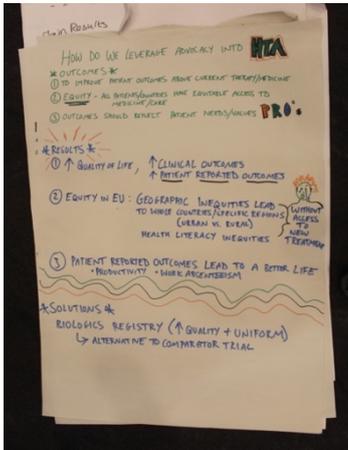
Competition 2022

This year's Kick Lupus Competition happened during the Convention! We asked delegates, PAN members and industry partners "what is the one change you would like to see in terms of access?" and video recorded their responses! On Sunday, June 20th, all Convention participants voted for the winning video!

Paul Howard's video was selected as the winning video! Paul identified that lack of information appears to be a barrier to access and the practical step to overcome that barrier might be to spread information on the different ways people can get access - whether that access refers to psychological support, social support, physiotherapy et cetera.

To watch Paul's video, click [here](#)

Open Spaces Feedback



Feedback from Open Space session

on HTA¹⁸/access (online) led by Jeanette Andersen

There was a consensus on the importance of involving patients in HTA assessments. There is an added value in understanding the disease through the voices of patients. What we need to do (as patients) in these discussions is to identify the gaps (unmet needs) and the obstacles in our everyday lives and how to fill that gap. What is the disadvantage of living with lupus when you compare with “normal” healthy people, and can this be solved/helped with the product being assessed? They already have the clinical data on the burden but are missing the patient reported views. It’s important to have both the physician and the patient voice in the assessments as there’s a gap between what physicians think is important and what patients think is important.

It was news to many participants that you can report side-effects of a treatment as a patient. We agreed that this is good, but that it’s all in vain, if you do not analyse the data that comes out of these reports.

We (in the patient organisations) have so much information about what is important for lupus patients and gives them a good quality of life. It is our job to bring that forward and remember, that we are representing a lot of patients and can back up our statements. The job for Lupus Europe is to keep explaining about HTA and doing educational webinars etc. (we need to hear it more than once). Patients need to convince the assessors that the more expensive treatment might be “cheaper” in the end when you look at the overall cost for society (the heightened quality of life, the ability to work more or even work at all, reduced need for other medications etc.). It may require many discussions to identify what you need to tell and build trust and relations between the parties.

Analysing the cost of living with lupus is a key issue! It needs to be patient organisations, who calculate these costs. It gives value that it comes from patients instead of pharma. Patients have a better idea of ALL the costs that living with the condition entails. Lupus Europe has a role to play to give credibility behind the data. We should not generate new data just for the sake of data. Only if required by the HTA-bodies. There is already so much data available. It is better to focus on “dressing” the patient to tell their story and backing it up with data that is already available. Lupus Europe and other PAs¹⁹ are essential in building the competencies of the patient community to become part of those HTA discussions.

¹⁸ HTA | Health Technology Assessment

¹⁹ PA | Patient Associations

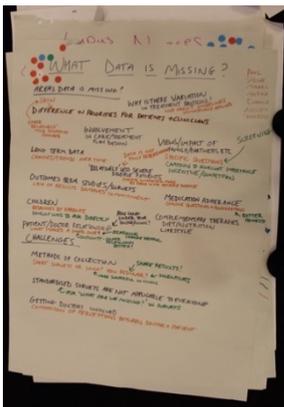
Feedback from Open Space session
on HTA (in person) by Paul Howard

The problem is that we cannot have comparator (existing treatment compared to the new one) studies all the time. How can we get past that so new treatments can be approved? The outcome goal is to improve treatment options for people with lupus and ultimately their long-term outcomes and to improve equity in access to new treatments in all countries. The outcomes should reflect the needs for people living with lupus (PROs²⁰).

The results:

Ultimately, we are looking for a better quality of life, a better clinical outcome and better PROs. There are issues around geographic equity in the EU both between countries but also within countries (between regions and/or between rural/non-rural areas). Health literacy can also be an issue. People who are not as engaged in their healthcare may not know about other treatment options, thus not getting the best available care.

One solution could be to have a biologics registry with high quality and uniformed data across the continent. This would hopefully enable us to compare real world treatment with the clinical trial data, so you don't have to run a comparator study each time, but could compare the trial data with the results of real world use of other/older treatments/standard therapies. There are examples of this already; like the British Isles lupus assessment group biologics register (BILAG) in the UK and there are plans of doing one for the rest of Europe in prof. Matthias Schneider's (CHRONIN) project as well.



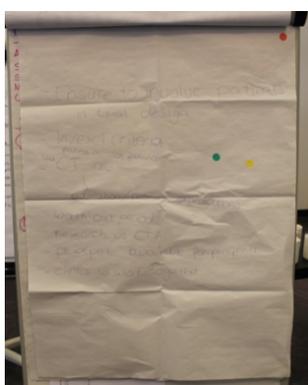
Feedback from Open Space session
on What data is missing led by Paul Howard

It is important that we have comprehensive and fully representative data that catches the true experience of people living with lupus. The group came up with lots of ideas for which data is missing (potential future projects for Lupus Europe):

- The difference in priorities for clinicians and patients; what are the differences and why?
- Why is there a variation in treatment protocols? Why aren't the guidelines being universally followed?
- How involved are people in their care and treatment plans and in designing those plans?
- What are the views of family and carers to people living with lupus? They represent a big pool of people who are affected by lupus but not often heard. Also, important when you look at the cost of the disease.

²⁰ PRO | Patient Reported Outcomes

- Are those with relatively less severe disease actively engaged with the organisations (in surveys etc.)? Skewing the data in a more “severe” direction?
- Do we have long term data about how trends change over time? We know that diagnostic delays aren’t improving but are there other things that are? These answers might help us investigate the impact of PAs and research on the lives of people living with lupus over a longer term.
- Medication adherence?
- The impact of complementary therapies, like nutrition and lifestyle?
- What makes a good patient/doctor relationship? Could give advice to clinicians on how to give “good” quality treatments.
- The next challenge is how we collect these data. Through surveys? If yes, how should they be? How do we get doctors involved as well?



Feedback from Open Space session

on **How do we continue to recruit and reach participants for clinical trials**

by Wendy Zacouris-Verweij

How do we reach the doctors and the right patients? Maybe the solution to this question will be solved by Matthias Schneider’s CHRONIN project in a few years? But for now, we need to get patients involved in clinical trial design as a first step. This way we can help make sure that the trials are designed in a way that attracts patients and retains them (inclusion/exclusion criteria, good conditions etc.). We need to change the perception of clinical trials. Patients think it means they will become Guinea pigs and that keeps them from wanting to join. Maybe we should change the term clinical trial into research or something similar without bad connotations? There must be a wash out period (where all participants are aligned with the optimised standard of care) before the trial begins to avoid a bias (false positive placebo-effect). A patient expert should be available for all trial participants to answer all the questions they might have. Clinics need to work together because one clinic alone will most likely not have enough patients.

Feedback from Open Space session

on **DATA (online)** led by Dalila Tremarias

What could Lupus Europe do in the next five years?

- 1 Patients are willing to help, but they are afraid and worried about sharing their data (even if it’s anonymised), so transparency and trust in the organisation you are sharing your data with is fundamental. Things like online medical files, wearables and artificial intelligence are a reality now and very important for our future, but patients don’t understand or know how their data is managed. So, Lupus Europe could play an important role here by:
 - a Providing education and training on GDPR, data and data sharing in clinical trials and hospitals to patients through webinars, leaflets, workshops etc. What happens to healthcare data once you have shared it?

- b Developing public information website that helps lupus patients to understand the process in an easy way, so they feel more willing to collaborate, if they know what red flags to look for. E.g., don't share your data, if you see this...
- 2 Provide training to Lupus Europe's volunteers and staff so they can understand and spread how Lupus Europe collects and manages data they got through surveys and other activities.
- 3 Lupus Europe could partner with other big organisations, that are more experienced in managing data and learn from them. Together they could create policies on managing big data on lupus.
- 4 Lupus Europe could manage a lupus database that fills in the knowledge gaps in the health service and research. The data should be available to other big organisations that are working with lupus.
- 5 Data is creating the future treatments for lupus patients. We are getting new information on new treatments and new combinations of treatments etc., so more people are exposed to more different treatments, and it would be good to decide what to do with all this new information and the role that the organisation can have here. Gathering missing information and helping researchers manage all this information – being the bridge between patients and the new data and researchers and clinical trials.

Feedback from Open Space session

on **Volunteers** by Sabine Schanze and Zoe Karakikla-Mitsakou (online)

We held an Open Space session for in-person delegates and an online workshop for online participants; both sessions were on the topic of 'Volunteers'! The sessions were energised, with a lot of participants bringing in a wealth of ideas and raising important issues!

Sabine Schanze reported on the Open Space session and Zoe reported on the online workshop.

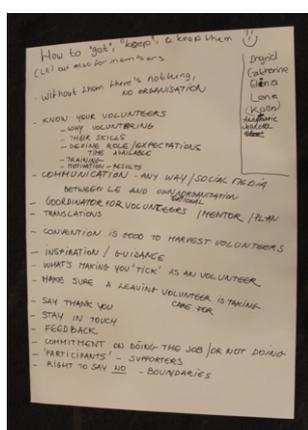
From both sessions came the following findings:

Most Lupus Europe national member organisations are patient-led and volunteer-based; volunteers are the life force of our organisations. As organisations we are always stronger together; we need a strong and unified voice on this topic of volunteers.

Being a volunteer can be difficult. It is easy for people to drop out, if they don't have the right support, especially when they first start volunteering for an organisation. Long term engagement from people can be tricky. We should introduce short term projects for volunteers, making the tasks they have small and let them find their place in the organisations.

There are multiple barriers too. Barriers can range from socio-economic barriers, health literacy, across Europe the issue of languages, different cultures, stigma, digital exclusion, age, differences in opportunities (i.e., some people may not hear about existing opportunities from their doctors, nurses, or local charities).

We can work together, creatively to find many solutions to tackle these challenges. To tackle digital exclusion we can offer education, training and we can also use older technology (i.e., letters or the telephone) to reach people. To tackle socio-economic issues, we might try setting really clear expectations, breaking down the tasks as much as possible, being a lot more flexible and meeting people in the middle and giving a variety of opportunities to get more people involved.



Feedback from Open Space session on **Volunteering** by Annemarie Sluijmers

Annemarie Sluijmers reported on the Open Space session Volunteering for Lupus Europe. This was a great reporting session about a very interesting topic: volunteering and volunteering for Lupus Europe.

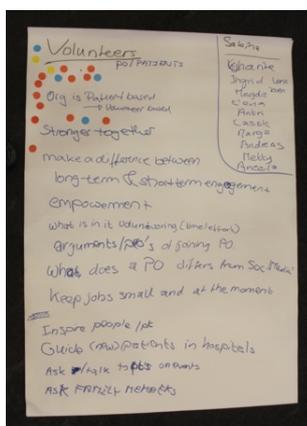
Without volunteers we have no organisations. As an organisation we have to do a number of things to find volunteers and to keep them happy. We have to know our volunteers, why they want to volunteer, what their skills are, we have to work together to define their role, set clear expectations and figure out what time they have available to volunteer. We have to arrange training, motivate our volunteers, and keep them motivated and we have to always keep the lines of communication open with volunteers; always reporting back to them and giving them feedback on what they do.

We also have to use the right communication tools: for example, younger people are typically more active on social media than older volunteers. We need to communicate with our member organisations about volunteers. We need a coordinator to keep an eye on volunteers, communicate with them, try to find the right things for them to do, get them to not do too much. We always need volunteers for translations, there's a lot of information that needs translating to reach the maximum number of people.

What gives volunteers their positive energy? How do we keep our volunteers positive and energised? Never forget we can inspire volunteers like they inspire us.

Say thank you to volunteers, give feedback even if a project is dormant or ongoing, find the right way to keep the volunteers committed to the project they are engaged with. Let volunteers know that if they're working on a project and it's not a good fit, they can always let us know! Do make sure that when volunteers are leaving the organisation they're taken care of.

The job of Lupus Europe now is to create a workgroup for volunteers where we create a detailed plan for the needs, the times, and the functions we have!



Feedback from Open Space session (2nd Wave)

on **Volunteers** by Sabine Schanze

Sabine Schanze reported on the second wave of the Open Space session on volunteers.

This Open Space session focused on the general problem common to so many volunteer-led groups, recruiting and volunteers and as a result it came up with two messages, we should tell our members when looking for volunteers:

“We need help, and you can do it!”

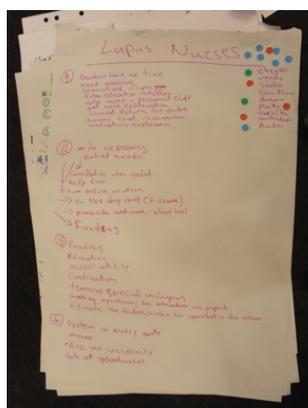
Participants of the Open Space realised some of our members may not be able to have regular 9-5 jobs, but they still have talents and things to offer, and they can be volunteers if they want to! They differentiated between regular volunteering and one-time projects and discussed what volunteering actually means, what to expect, what the experience will be for volunteers and what we as an organisation can offer as training. We need to have clear expectations for both sides; we need clear job descriptions! The group talked about new ways to recruit; social media was at the top of the pyramid but talking to family and friends was also discussed as they may have things to offer too, medical students and all students should also be in the pool of possible volunteers as they may be able to help with projects!

The creation of a volunteer handbook was identified as a possible aim, to have a clear message for people and clear expectations. This can be uploaded onto a website or sent electronically, it doesn't need to be in print. Short testimonial videos could also be used. It's important to have a clear training schedule, to identify what onboarding looks like, how volunteers should be trained and a schedule of 1:2:1 meetings with volunteers. A possible goal might be to increase volunteers to reach double digits in the next three years.

There are a number of challenges, including how to get volunteers, how to keep volunteers, how to keep them interested and motivated in helping. Having small, specialised tasks that are personalised to volunteers and suited to their skills and getting to know the volunteers well were potential ways to deal with some of those challenges. Focusing on diversity is also key, so we can reach the maximum number of people and ensure we are representing the entire lupus community.

The group came up with ambitious goals; the most important one was to establish a working group within Lupus Europe to have a regular exchange on how volunteers and the retention of volunteers works for different organisations and to talk about positive aspects, discuss what

works and what doesn't work and to help each other figure out ways to gain and retain volunteers.



Feedback from Open Space session on **Lupus Nurses** led by Chryso Yiasoumi

The lupus nurse theme was selected as one of the three winning Open Space topics, which were discussed a 2nd time on Monday. This summary presents the combined findings of both sessions.

We need lupus nurses because sometimes doctors do not have time to answer all our questions. Nurses specialised in lupus, with extra education and on-going training on what's new in lupus would help to have more time, but also to talk about more personal things that we don't always dare or have time to ask the doctor. They would also clarify more what the doctor told us or explain more about medication. This should first be face to face as the human contact is important, but after a few meetings, having a help line with a nurse would also help. There is also an opportunity to use lupus nurses to free up time for the doctors, if they could prescribe medicine, or discuss some topics before the visit, and clarify questions after...

To progress on this requires a willingness from clinics to have such nurses and give them time to engage. It also requires that such nurses are properly trained.

Looking at what this would take on a high-level basis to reach success on such a plan, the group identified the following key elements:

We should clarify what a lupus nurse actually is, which tasks they perform, what responsibilities they have, requirements to be able to perform, and benefits provided across the whole system.

This should be based on data collection from countries with experience in this topic (incl. UK and US...). But funding will also be critical for education of both nurses and doctors. It is critical to raise awareness in the overall system that lupus nurses are needed, and because each country has its own system, this is pretty much needed everywhere.

As other possible elements, the group mentioned the opportunity to invite lupus nurses to the Lupus Europe Convention or send persons living with lupus in nurse auditoriums to raise awareness.

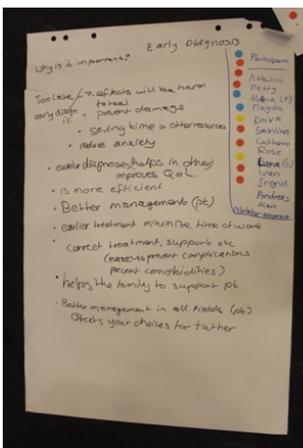
Universities/nurses' schools would be key partners to help building the training program that is needed and ensure the additional training is certified and recognised. EULAR/SLEuro²¹ would be critical to generate support to the cause.

²¹ SLEuro | The European Lupus Society

As first next step, the plan is to group all arguments and gather data that shows the benefits. Lupus UK offered to contribute evidence, as they fund some lupus nurse positions. Part of the program is to report back on what the lupus nurse is doing, the impact, the goals achieved, how much clinic time is saved for consultants, ... that information could be analysed to build the argument.

On the basis of that information, we can start an awareness raising program, first with our members, explaining what lupus nurses do to help build support. The following step would be to broaden the awareness campaign so that it becomes obvious to decision makers that a trained lupus nurse should be included in the lupus multidisciplinary teams.

Challenges remain significant: how to make it attractive, how to reach the right people, who will make the course (also including the language barrier), how to free up nurses' time to train... and obviously the usual question around funding...



Feedback from Open Space session on Early Diagnosis led by Susan Frankel, then Annemarie Sluijmers

Early diagnosis was the 2nd topic voted for extra discussion. Both sessions are covered in this summary.

Early diagnosis is key because any delay in treatment increases damage, excess medication with its side-effects, on-going time and resources, as well as social costs of more severe diseases (comorbidities, time off work, impact on family, hospital visits). Early diagnosis reduces anxiety and improves quality of life, and leads to better management for the patient, including making choices for the future by knowing what you are dealing with.

The key need to achieve this is more training and education for GP²²'s particularly, but also rheumatologists and other HCPs²³ to better spot early symptoms from the start. Cooperation between primary and secondary health care system could be significantly better and waiting times should be reduced. Next to education and awareness, there is likely a big place for IT systems to help GPs identify the possible diagnosis of lupus when they are confronted with symptoms that they don't understand.

Some ideas were proposed on how to indeed raise awareness and education level amongst doctors and HCPs. One of the participants has a doctor, who regularly has trainees attending his consultations. He asks some patients to come 30 minutes early and use this time to talk about their lupus experience with the trainees. This maximises the knowledge of lupus amongst

²² GP | General Practitioner

²³ HCP | Health Care Professionals

new doctors. Another initiative for RA, used in several countries is the talk by people living with the disease in HCP auditoriums (PPP²⁴). EULAR is designing materials for this type of activity (but not lupus specific, so we should add lupus to the list). What role do we need to play, should we have a list of good ideas?

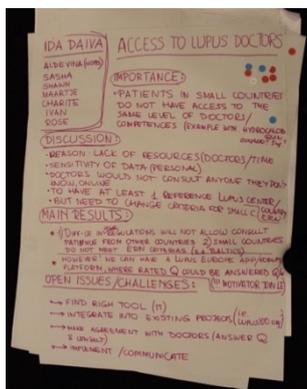
Lupus Europe is also part of Lupus Academy, where CME²⁵ credit programs are designed for doctors. We will raise the topics with that group and see what could be achieved.

The discussion moved on to the on-going challenge of too short doctor visits. This is because of lack of resources, not lack of willingness of the doctors. How realistic is it that doctors will have time for education, realising the current challenges they face just to find time for the patients.

Having the time that is needed rather than time constrained visits is particularly critical when diagnosis is initially made, as you can't digest the impacts in a normal appointment length, but also later as your disease evolves.

A possible way to help is to better prepare for doctor visits. For this, we have two initiatives under way: (a) As part of the lupus in 100 questions, we have prepared a pre-visit checklist and suggestions. They will be online after summer; (b) NVLE (our Dutch member) did cards focused on "how you feel from a body and mind point of view", a sort of 'self-consultation' before going to the doctor. This could be expanded in more languages for lupus, and in more ERN ReCONNET disease areas. This saves time for the doctor as you are ready with key points and ensures that the key issues identified by the patient are all raised.

The communication gap between patients and doctors also remains a significant issue. Even if there is enough time, you often have the impression that the consultants do not listen or take into account what you are saying. Training in listening skills would be great as well!



Feedback from Open Space session on Access to Lupus doctors led by Daiva Povilaite

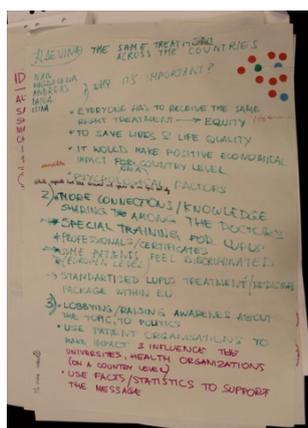
The topic is very important for small countries which often lack real experts. As a result, new standards of care are not applied, or information is not sufficiently available. Doctors in small countries can often not focus on lupus as they do not have enough consultations (and hence time) assigned to this disease and not enough patients to specialise in it. Online consultations could be a solution, but confidentiality of data and the fact that not enough doctors are willing to do online consultation are highlighted as obstacles. There should be at least one reference centre for lupus in each country, but most small countries cannot meet the criteria to qualify.

²⁴ PPP | Patient Partner Program

²⁵ CME | Continuing Medical Education

Cross border health care is still far from being a reality, so consulting in another country does not work.

Short term, one of the remedies to minimize the impact of lack of available lupus doctors is to have a web-based platform where patients can get reliable answers to some questions (not online consultations, but general questions that could be prioritised and answered for example every month). The team suggests to integrate this within Lupus Europe's planned lupus100.info website.



Feedback from Open Space session on Same Treatment Across Countries led by Aldevina Sturiene

Again, an issue due to lack of information and doctors' availability in smaller countries, but also lack of financial priorities in bigger ones. No one should be discriminated against for their quality of care. Applying best care everywhere would improve patients' quality of life and reduce impact on work. Doctors often have only few patients with lupus, so do not want to dedicate time to lupus particularly. Some patients feel discriminated due to lack of trained doctors.

ERNs were supposed to bring a solution to this, but there is still a lot of work to do, particularly as the countries/hospitals that have the biggest needs do not meet ERN access criterions. Should we raise this issue to the European Parliament? Lobbying, raising awareness should help raise the topic, particularly with politicians, health organisations and universities. Facts and statistics could support the message.

General Meeting

On Sunday morning, Lupus Europe held its general meeting, with attendance of 15 full voting members and one associate member. The annual activity report and the financials (reviewed by W. Zacouris) were approved at unanimity. Lupus Europe continues to be on track to achieve all its 2023 objectives, and financials are healthy thanks to the increased number of sponsoring partners. To note, from 2021 onwards, Lupus Europe is including in its financial report the in-kind value of volunteering hours performed. Under this methodology, volunteers are contributing more than any single external partner we have. The budget for 2022, in equilibrium, was also approved by the members.

Hrönn Stefánsdóttir, Chair of Lupus Iceland, then presented their association, applying for full membership. All voted in favour.

With regards to the Board, Anne Charlet, Elfriede Wijsma and Marisa Costa's mandates expired this year. The Assembly elected Dalila Tremarias and re-elected Elfriede Wijsma and decided to keep the vacant seat till 2023 elections, where only one mandate is expiring. The assembly particularly thanked Anne Charlet for 11 years of service on the Board, including six years as Vice-Chair.

Finally, the assembly discussed the modalities of next general meeting organisation. With the need to hold such a meeting within six months of closing the account, it would either require to consistently hold our Convention in the first half of the year, or to uncouple the general meeting from then Convention. The emerging direction is to advance Convention and maintain both events connected. As a result, our next Convention will be held in April-June 2023.



from left to right the NEW BOARD

Aldevina Sturiene | Board Member

Elfriede Wijsma | Vice-Chair & Treasurer

Amy Somers | Board Member

Annemarie Sluijmers | Vice-Chair & Secretary

Jeanette Andersen | Chair

Dalila Tremarias | Board Member (online)

Closing

At the closing of the 2022 Annual Lupus Europe Convention the Chair, Jeanette Andersen, expressed her joy over finally being able to meet face-to-face again after two years of Covid-19 restrictions. She drew forward a few outcomes from this year's Convention:

The Board of Lupus Europe received a lot of valuable input on their next 5-year strategic plan (2023-2028) which they were very grateful for.

Yann Le Cam from EURORDIS told the participants about the many things they do for people with rare diseases (including lupus patients) in Europe. What the national Lupus Europe groups can do to support their work is to disseminate surveys and information from them to their members and to collaborate with ERN ReCONNET (through surveys and projects).

Patients with lupus play an important role in national HTA²⁶ assessments of new lupus treatments. We can use the Living with lupus survey results (find them [here](#)) and our own personal lupus story to help in the HTA assessment talks.

According to Prof. Matthias Schneider from Germany not all lupus patients need to take steroids! Prof. Schneider is retiring – but he has a plan! He told the participants about his big new project of building a European data space for autoimmune diseases called CHRONIN.

From Cyril Racchetta's presentation on How to tell your story the participants learned that all they need to think about when they tell their individual lupus stories is Pixar's Finding Nemo.

Some of the input the Lupus Europe Board of Directors received from participants were:

- There are so many ways we can use data as an advantage in lupus research. Lupus Europe needs to have a position on data and to include it in their next strategic plan.
- Volunteers are a very important part of Lupus Europe, and it is necessary to form a working group focusing on the area and have a policy and a detailed plan. This is yet another area that needs to be a priority in the next strategic plan. National member organisations would like Lupus Europe to have regular updates from all organisations on their plan for volunteers.
- All lupus patients have a role to play in HTA and Lupus Europe needs to educate lupus patients on the area and help them prepare for the important talks on HTA.

²⁶ HTA | Health Technology Assessment

- Lupus nurses are important and can potentially play a much bigger role in the future. Lupus Europe needs to create a paper on the role of a lupus nurse and disseminate it to all organisations, doctors etc.
- Lupus Europe needs to have a focus on earlier diagnosis. This can be done by educating doctors, patients etc. on lupus, data-collaboration between all stakeholders and awareness: from GPs, in hospitals etc. Here patients play an important role.

The next steps for the Lupus Europe Board will be to create a working group on volunteers, to incorporate the collected input into the strategic plan for 2023-2028, to create online meetings for participants in the Telling your story session and finally, to work with ERN on supporting the CHRONIN.eu project.

Unfortunately, the destination for the Convention 2023 wasn't confirmed yet at the end of the closing session. No matter where it will be – the Lupus Europe Board is looking forward to welcoming all the delegates again!



the traditional group photo 2022