

Patient Panel 2 project report

Executive Summary:

On March 11-13, 2016 LUPUS EUROPE organized a Patient panel, bringing together 9 Lupus affected persons from all over Europe to share their experience of living with lupus. This panel, coming after the Helsinki Convention kick off, Brussels Patient panel 1 on Treatment, and Vienna Convention delegates panel, aimed at further exploring the burden of living with lupus, and to dive into the burden of treatment day after day. Deliverables targeted were (i) “Verbatim” that frame Lupus patient’s experience (around treatment), leading to scientific level publication by Davide Mazzoni (LUPUS EUROPE Co-opt advisor in charge of research); (ii) Video recorded testimonies on living with lupus, building further on the Patient Panel 1 video series, and (iii) Ideas on how Clinical Trials and Treatment may be improved, a key area of concern in the development of new treatments.

The Panel was conducted through a series of interactive presentations, team discussions and working groups. Unfortunately, Davide Mazzoni, one of our planned facilitator had to cancel last minute due to disease activity. He was replaced last minute by Kirsi Myllys (Treasurer of LUPUS EUROPE)

BACKGROUND:

After its 2013 Convention in Paris, LUPUS EUROPE engaged on a project to conduct Patient panels, following an insight of Professor N. Costedoat that understanding of patients thoughts and feelings in the area of treatment was critical to help people with lupus improve their quality of life, and that such understanding would be best achieved if patients would talk among themselves, where different things are expressed than when talking to doctors.

During the 2014 Convention in Helsinki, delegates focused on a definition of treatment, which should be viewed very broadly, defining it as “ANY PRODUCT OR ACTIVITY THAT AIMS AT IMPROVING THE PERSON



WITH LUPUS’ QUALITY OF LIFE.” The participants further elaborated on a high level treatment map, identifying how various elements of this treatment could broadly differ, and would correspond also to different patterns in terms of Access and Adherence (see attachment 1). This map has been used as starting point for our next Panel events.

Following the Helsinki Convention, a First panel was conducted in Brussels at the end of Year 2014. This panel explored the difficulties in adhering to treatment. In September 2015, the Patient panel findings were shared with Doctors in the format of a poster during the International Congress on Lupus, and with patient

organizations in the form of a presentation in the patient parallel program of ICL. A workshop was also held as part of LUPUS EUROPE convention, sharing findings and looking at future questions to be addressed in Patient panel II.

BRUSSELS PANEL 2:

Participants:

As for the prior event, the patient panel was conducted by and for people living with lupus. The organization and the facilitating of the panel and its workshops/discussions was done by Bernadette Van Leeuw (with Lupus, Chair of lupus Belgium – FR), Kirsi Myllys (Finland, with lupus, LUPUS EUROPE trustee), and Alain Cornet (Belgium, Lupus Europe Secretariat).

The panelists were recruited through lupus Europe network, seeking to bring in “new people” in the discussion, as representative as possible of the Lupus European community. All agreed English would be used as the working language. Participants were:

Mandy (Netherlands, 27, Female); Katre (Estonia, 37, Female); Stefania (Italy, 42, Female); Susanna (Finland, 48, Female); Susana (Spain, 48, Female); Florence (France, 48, Female); Daiva (Lithuania, 41, Female); Anna (Greece, 35, Female); Annelies (Belgium, 24, Female). Participants did not know each other and had no contacts with each other prior to meeting in Brussels.

UCB staff (Kuyler Doyle and Sabine Bongardt), and Nick Hicks from Commutateur attended as Note takers and observers.



Prior to joining:

Ahead of joining the panel, participants were required to participate in a phone/skype interview with Davide Mazzoni, LUPUS EUROPE co opt Trustee in Charge of Research, and Researcher in psychology at the university of Bologna. These interviews, which lasted from 33 minutes to 1hr 15 gave an opportunity to patients to discuss their lupus history, encouraging the panelists to talk in a non directed way about the following questions used as discussion starting points: Could you describe how you received the diagnosis of Lupus? How did your life change after the diagnosis? Could you talk to me about your treatment and how it affects your day to day life? Are there other things that you do for your health? Are you satisfied with the therapy of your illness? What do you think could be done to reduce the burden of (treatment for people) living with lupus? Interviews have been recorded and transcribed, and are being analyzed by Davide Mazzoni. Their content will be the subject of a separate article with a view to publication.



FRIDAY MARCH 11 PM - INTRODUCTIONS:

The face-to-face panel started on Friday March 11 evening with an opening session around a drink where each participant introduced him/herself and his/her lupus story. Participants also had the opportunity to voice their hopes and/or fears ahead of this panel. Positive relations and trust were quickly established. The introduction session continued with an informal dinner in a nearby restaurant.

SATURDAY MARCH 12 AM – GATHERING VERBATIM:

On March 12, the day started with a presentation of LUPUS EUROPE and how this panel fits into LUPUS EUROPE's strategic objectives and reason for being, a discussion of the Panel's objectives, agenda and deliverables, and the review of the Helsinki definition of treatment. The introduction did not extensively discuss findings of the first patient panel, so as to leave all patients exempt from any prior interference. In Both sessions, full verbatim have been transcribed for use by Davide for his Research. Each group discussed its topic during 45 minutes. After the coffee break, the groups swapped subject, with facilitators changing table. As the objective was to collect unbiased verbatim, there has been no summing up / reporting of results, as such would have required gathering and organizing such conclusions by the groups during their discussion, which could have influenced the thoughts expressed.

Session #1 – Treatment and feeling better

In this workshop, where Bernadette replaced Davide as Moderator, half of the participants were asked to reflect on their experience based on the following questions: With regards to your treatment, which thoughts, behaviors and feelings made you feel better... or worse? The 3 areas were explored sequentially, again in a fairly non directive way, where the facilitator focused on seeking participants to clarify or expand on their experience. As this section will be extensively covered by Davide's research paper, we will not discuss its key outcomes in detail here, just pointing out few repeat thoughts: Most prefer not to think at lupus, that very thought making them feel less well. Reducing pain, fatigue or any other symptoms helps just "forgetting about lupus", while anything that reminds that you are sick is making you feel less well. Positive thinking helps! Staying active, keeping a professional life to the extent possible and/or having a hobby (painting, writing, ...) help feeling better, but when you can't deliver, you then feel very bad, particularly as so many people don't understand since Lupus is not visible.. Several view the mere fact of being reminded through taking medicine, ... as negative in itself. Finally, feeling loved and having a pet was quoted several times as being of great support.



Session #2 – Control or cooperation?

In Parallel with Workshop 1, the other half of the participants, under the non directive lead of Kirsi, discussed the question "With regards to your treatment, who is controlling? You, your doctor, both?". The key points coming out of the discussion can be summarized as follows:

Most participants highly trust their doctors, and do not debate or discuss the substance of the treatment prescribed, the reason for a given choice or the specific reason of each prescribed element. Rather, most questions of patients to their doctors will go about side effects, which is the key worry they have. They are often concerned about asking too many questions because "doctors are very busy and don't have much time".

Through the discussion, the huge level of trust placed in doctors, gradually left room for the recognition that patients make then their individual choice on some elements of the treatment. (Perceived or real) side effects is the key reason for deliberately deviating from the doctor's prescription, sometimes mentioning it then later to the doctor (mostly after the facts), sometimes not. Most participants mention the absence of warning about side effects as a key concern. Only one of the participant mentioned that when she does not want a specific prescribed medication, she tells her doctors and they discuss it together, reaching an agreement that increases her commitment.



Participants also mentioned that the absolute number of pills does not influence their willingness to take them, but that they will often actively seek to reduce total drug in-take particularly for painkillers, “symptom relief – non core disease” treatment. A “healthy life style”, with sports, good food, ... is considered important to minimize the medication need.

Panelists expressed that they view the need for collaboration of treatment to be even more needed between doctors themselves. In many cases, they are referred to several doctors, but feel like they act independently, each prescribing its own treatment, or defining unaligned

hospital visit agenda's. Even within the same hospital, the lack of coordination is a real issue, and while patients would appreciate coordinated visits (even dreaming of seeing both doctors together as one of them experienced when she was a child), none dared talking about that with their doctors. When several doctors are involved, it however appears that most often the rheumatologist or lupologist is making the final choice about what to keep and what to skip in the prescribed cumulative medication.

Finally, with regards to what participants would most like to change in their treatment, the one word that immediately comes up is “cortisone”... how to get rid of it...

Session #3 – quick numeric probe:

After both workshop concluded, a little “game” was organized, to collect quick approximate numerical feedback on matters directly related to Topic 2. The 2 facilitators with Lupus participated.

1. More or less “pills”: the objective was to assess which elements from a list formed part of each participant’s treatment, and if positive, whether they were taking such based on their doctor’s prescription or on their own choice. To collect the feedback, 3 big round dots where laid on the floor, showing respectively “NO”, “Yes, Doctor prescribed” and “Yes, Me”. Participants were asked to move to the dot that best expressed their answer to the question raised, and counted by the observers. Here are the results:

What	Doctor Prescribed	Self Medication	Not part of treatment
Vitamin D	4	6	1
Vitamin C	0	6	4
Other Vitamins complex	1	5	4
Mineral Complement	2	1	7
Calcium	6	1	3
Pain killers	5	1	5
Sleep aid	5	0	6
Homeopathy	2	0	9
Acupuncture	0	4	6
Physiotherapy	4	1	5
Exercise/Sport (1)	2	9	0
Exercise/Sport (2)	9	1	1
Massage	0	6	5
Meditation/Yoga	0	4	7

Note: On exercise/sport, the question was first raised asking if specific exercise/sport was or not prescribed by the doctor, leading to 2 positive answers. It was then raised asking to show as Doctor prescribed if the doctor was actually encouraging to exercise/practice sport without prescribing specific exercises. The score then moved to 9.

From 85 “treatment elements” that are being taken (the sum of the 2 first columns), 40 are doctors prescribed, while 45 are taken on patient’s initiative. While this result is influenced by the fact that we did not include “core medication”, it does show that when it goes about more peripheral parts of the treatment, patients do take some level of control. This is particularly true with regards to Exercise, use of vitamins, and Massage. Most doctors seem to encourage sport (in a non directive way), prescribe calcium, and about half prescribe pain killers, sleeping aids, physiotherapy and/or Vitamin D. Very few patients use Homeopathy, acupuncture or mineral complements, or experience meditation/Yoga as part of their treatment.

2. Sources of Information: In the second quick probe, the 3 dots were replaced, by other ones, showing respectively “YES”, “MAYBE” and “NO”, and we assessed the possible sources of information that patients would use when faced with a new medication. Specifically, we developed the following scenario: Your doctor just prescribed you a new medication. As you leave the doctor’s office, you mention this new pill to a friend, and your friend answers “are you really going to take that?” What will you do?

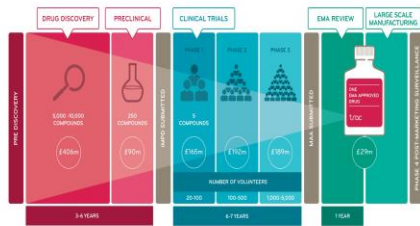
	Y	N	M
READ NOTICE	10	0	1
GOOGLE	10	1	0
WEBSITES	6	5	0
DISC FORUM	4	4	3
FACEBOOK PAGE	4	5	2
ASK NATIONAL GROUP	2	4	5
OTHER DOCTORS	5	4	2
"FRIENDS"	0	9	2
GUTS	5	3	3
BOOKS	3	5	3

Action	Yes	No	Maybe
Read the notice	10	0	1
Google it	10	1	0
Check on a Patient Website	4	2	5
Follow your guts	5	3	3
Check on the Pharma website	6	5	0
Check on a Medical website	5	4	2
Check with another doctor	5	4	2
Ask on a discussion forum	4	4	3
Ask on a moderate Facebook page	4	5	2
Ask your national group	2	4	5
Check in a printed book	3	5	3
Ask “friends”	0	9	2

To facilitate reading, answers have been ranked from the highest to the lowest positive scores (with “Maybe” counting as half). By far, the most likely source of extra information to take such decision/information is the notice, and Google. Checking on a specific website (whether patient, pharma or medical), or following your own guts come at about 60% of the “notice” score. Printed literature, national groups and friends are least likely!

SATURDAY MARCH 12 PM : Patients role in getting new treatments

After lunch, we transitioned to another aspect of cooperation with patients related to treatment. While we



trac

Drug Development Process

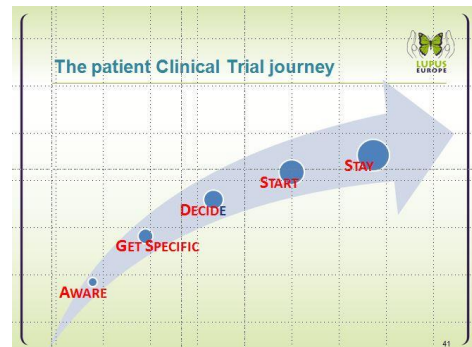
have seen that collaboration between patients and their doctors is critical for effective treatment, as it increases adherence, patients also have a role to play in the development of new treatment options. Whether through the development of new drugs, or the expansion of existing medication to new areas, collaboration between patients and the medical sector is necessary. For Lupus, the challenge is huge, because of the relative rarity of the disease, its complexity with many different forms, and the fact that clinical trials require an often very effective already base treatment for all, in such way that the new medication test leg does

not easily show statistically sufficient results, even if the medication is very effective in some forms of lupus.

Sabine starts the afternoon by providing all participants with a background on the new treatment development process, highlighting how thousands of possible components are narrowed down to very few, and how clinical trials then help validate their efficacy. Participants are stunned by the complexity of the task, the time it takes and the huge size of documentation required (often more than a million pages) before a treatment option can be offered.

Clinical trials is the place where there is most interaction between the medical community and patients in this process.

In parallel with the treatment development journey, each patient involved in clinical trial is also going through his/her own journey, where we identified 5 stages : general awareness, getting specific about a trial, deciding to join, starting, and staying till the end. The afternoon workshops explore each of these stages.



Session #4 – General awareness:

Overall, while most participants were aware that medical trials were going on somewhere, most thought this was “far from them”, some believing it was only in US. Only few had realized this was something that they maybe could have been involved with. Net, the awareness was very theoretical, disconnected from most people reality. Two participants had been involved in trials or “off label” medication, and had a clearer view of research as something taking place in many locations, including their own country or region. Most however were interested to know more about research option, and when the fact that patients were often needed for research, all felt like it was something they would consider.

None knew where to search for information on clinical trials for lupus. Sabine explained all trials were registered on www.clinicaltrials.gov and showed that the database listed 317 SLE studies, of which 65 were actively recruiting (Phase1/2/3).

Session#5 – Getting specific



From this base, we then considered the possible need for simple information posters that could let people with lupus know that a clinical trial or a research is planned or taking place and inviting them to join. As a key conclusion, if a poster is ever done to encourage people with lupus to participate to research, it should very prominently say “LUPUS”, and the text should use very simple words, of everyday’s language. Even the term “lupus flare”, often used in US and in congresses, is not part of average patients language, but is a rather specialized term to which maybe patient organizations and “expert patients” got used to, but which is not immediately connecting with the broader base of people living with lupus.



Session#6 – Deciding to join and staying through the program

After a coffee break, the groups resumed and Kuyler presented a 2015 research from UCB on Lupus clinical trials attendance.

After reviewing these results and discussing them as a group, we again split in 2 work teams, one only panelist



with no research experience (group A), the other with panelists with some level (even very reduced) of research experience, such as participation to CT, off label use, ... (group B). Each Group was asked to imagine that they have been offered to participate in a 1 year clinical trial, with monthly appointments at the hospital, and a need to strictly follow medical prescription day after day. They are also told that all participants will get a “normal treatment”, but some will get an extra substance believed to be active, and others a placebo. They are then asked to create a “word Cloud” similar to those regularly worked on web applications on the factors that would contribute to them joining (or not) the

study (group A) and Staying (or not) in the study till the end (group B). The green and red colors were used to highlight positive vs. negative factors respectively. The largest and most central elements reflect the most important ones.

With regards to deciding to join, key motivations included the fact of benefitting from better Lupus monitoring, the help of others, the efficacy of the treatment, the adventure offered by joining a trial, and the expectation to keep benefiting from a better medicine if it works. The key negatives were Risks, side effects, scheduling with work, and the fear of disappointment if it does not work. The opinion of “my doctor”, and the trust (including the availability of a help line), as well as logistics, would play a key role in positive or negative.

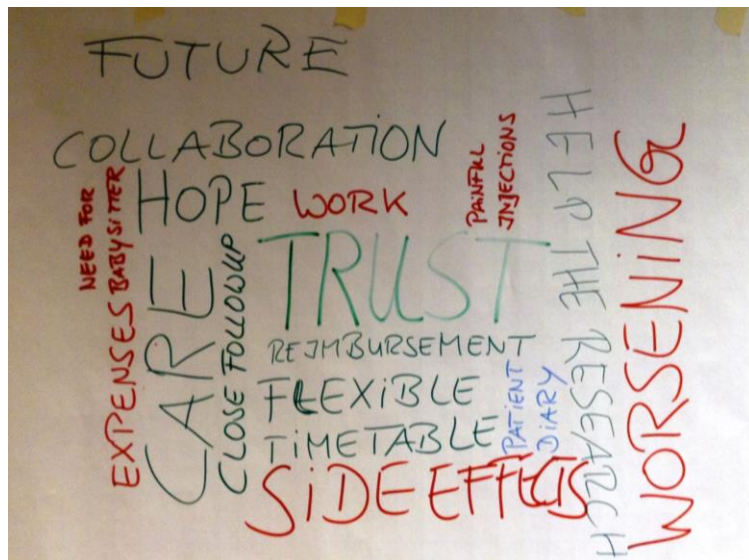
Once being in a Trial, the number one motivator to stay is Trust, but many others play a critical role, like reimbursement, flexibility of the timetable, close follow up, the Care demonstrated, the collaborative spirit, the hope and expectation of future treatment, and the feeling of helping the research. However, patients would probably leave the trial if their health is worsening, if they face side effects (or painful injections, ...),

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or if the participation results in expenses (like the need for babysitter, the scheduling with work, ...). The panelists were divided about the impact of that patient diary, which some viewed as motivating, but some perceived as a negative factor as it reminds them daily of the disease.

When talking of their world-clouds, both groups insisted on the trust as a core element of their decision, and embed that trust with their doctor. If my doctor asks me to join, it will be a strong positive. If he tells me not to, no way I will join!

The team then walked to the original “Chez Leon” restaurant, and after a pleasant dinner, came back with a detour by the “Grand Place” and the famous “Manneken Pis”



SUNDAY MARCH 13

Session # 7 – Meet with the Doctor:

After a team dinner and a good night rest, we had a great opportunity to meet at 08:50 with professor Bernard Lauwerijs, Professor at the UCL University and Lupus researcher who accepted to answer participants questions on Lupus and treatment.

The following areas were addressed during the session:

- Why Lupus: Why does lupus attack? Is there any new idea to catch source and deal with it?
- Core Treatment: What are the main treatments for lupus? Are some more effective than others? What about biological treatment? Any results? Are there really resistant lupus, that fail to respond to any treatment or only non adherent patients and/or Doctors lacking the full available expertise?
- Other elements of Treatment: Beside vitamin D, can other vitamins help us too? Must all people affected by Lupus protect themselves of sunshine?
- Lupus Consequences: In which circumstances can lupus generate physical disability? Neurologic / cognitive issues? Cardiac issues?

Session #8 – What should change?

Our panel discussions have brought to light many aspects of treatment, which have been mentioned in different contexts. The next workshop exercise attempted to list the key elements that we could take as inspiration as we look at the priorities in the need for change. To that end, participants were asked to stick on Flipcharts post it notes with their keyword thoughts on the following 3 key areas:

1. What should change about treatment? (small or big)
2. What can we concretely do about that?
3. What could be done to reduce the burden of living with lupus?

After all had completed the task, under the leadership of Kirs, the team gathered around each of the flipcharts successively to clarify what was meant by each post it, regroup duplicates or similar ideas, and then highlight the most important of the identified areas. In parallel with this work, panelists that had volunteered to be video interviewed left the room (one by one) to perform these.

What should change about treatment ultimately saw the emergence of 4 themes:



- HOLISTIC Approach was marked first when prioritizing. This included the need for a global approach to medication, but also lifestyle change, physical/outdoor activities as part of the treatment
- “LESS” : Less pills, less medication, Less side effects, ...and less cortisone
- “ACCESS”, regrouping request for easier access to people (rheumatologist emergency calls, easier referral to specialists, physiotherapists), technology (scans, ...) but also information. The need to reduce time between symptoms emergence and proper treatment was grouped by participants into that theme.
- “DELIVERY”, with a suggestion that “once a week treatment would possibly be better than daily pills, even if that once a week would need to be infusion) but also a separate suggestion that infusions at home rather than in the hospital should be available. (small or big)

When looking at what can concretely be done about that, two concepts emerged as ex-aequo in terms of priority.

- “Information”, with a repeated call for more information by doctors, in literature, and in reliable websites, information brochures at hospitals, sharing of knowledge, seminars on how to have a better life with lupus.
- Recovery plan: A suggestion to develop a “1 month lupus recovery plan” got significant traction. The concept is to offer a plan that links drugs, food, activity, ... seeking to engage in the holistic approach talked before and where patients engaged at the same time into medication and lifestyle adjustments, with a positive mind.
- Distant following concepts included doctors having more time, nurses at home, or a general increase in Lupus knowledge on social media.

Answers to “what could be done to reduce the burden of living with lupus” clearly were influenced by the discussions of Saturday morning on what makes us feel better.

- Numerous suggestions related to positive mindset (Be Zen, positive thinking, meaningful activity helping others, more love, art therapy, take things easy, do things you CAN do and make you happy) and life balance (make sports more accessible, sports & hobby, meditation and exercise, ...)
- Another string of post it relates to breaking the isolation: “not feeling alone”, but also more widely sensitize the world, trying to let more people know more about lupus (including the family), seeing positive examples of people living with lupus, meeting people with lupus (patient associations, at hospital, including meeting as a group with doctors, ...)
- Finally, a group of suggestions covered an improved access: common appointments with /better connections between different doctors, multi-disciplinary teams, psychologist cell at hospital, financial and material assistance, or a central email address where people can send their questions about lupus and get a quality answer.



Session #9 – Living with Lupus in 20 years

The Final session asked panelists to take pencils and draw their view on living with lupus in 2036. These can be essentially grouped as follows:

For many, the drawing represents the aspiration of living a normal life, “simply like any other person”. Lupus is not gone, but its effects are fully controlled by simple medication with no side effect. They can enjoy a normal life, being in the sun, enjoying, dancing and living with their family. In several of these drawings, colorful butterflies appear, symbolizing the lupus disease still being there, but under its most friendly face.



A few drawings are more radical, depicting a world where lupus is gone. Lupus clinics are in ruins, syringes are thrown in garbage bins because nobody needs them anymore.

On the other hand, two of the drawings are much darker, showing a tough life (one participant said “people in my family live old, so I will need to support lupus for many many years”), but the hope is then symbolized by a heart in the middle, or the sun shining. These drawings show that while a “normal” life where lupus is tamed or cured remains the basic aspiration of most, the credibility that this is possible is still to further built.

Participants agreed that copies of all drawings would be distributed to all.

The panel ended with the usual evaluations (both verbal and written). Overall program scored 10 in terms of being of interest, with duration considered somewhat too short (3.4 with 0 being much too short and 10 much too long), and logistics an average 9.1 on 10. Session’s average scores was 9.25, with the opening (individual presentations scoring highest at 10, and the drawings lowest at still a very good 8.4). Details by session are attached.



As we closed the panel after a final group picture, the panelists decided to create a facebook group amongst them, and exchanged email addresses. I still recently got testimonies that several are effectively in contact regularly.

Attached to this report is the summary received from Annelies, the 24 years old Belgian participant, which provides a participant's view of the event.

Alain H. Cornet

Annelies' report from the patient panel

When I saw the announcement on facebook that there was a patient panel having place in Brussels, I directly applied to be part of it. I was really happy when I got the positive answer few day later. Although, I was a bit nervous for the skype interview.

All panelists were present on Friday 11th at 5 PM in hotel St-Catherine in Brussels. I was a bit nervous but couldn't wait for the activities to begin. The first part was the hardest, in my opinion. We all sat together and presented ourselves and our lupus. Listening to all these stories, reminding me of what I personally had lived or what, maybe, could happen to me, was not that easy. Everyone listened to each other in a very respectful way; and I believe without any judgment.

Later we went eating in a typical Belgian restaurant which was very pleasant.

Next day was my favourite. We started the morning with a discussion activity during which two themes were discussed. We talked about our treatments, and the people in charge of decisions about it. Did we make our own decisions or did we fully trust our doctors ? Or something in between. It was really interesting to find out the different ways of coping with a treatment and with health issues. We also discussed about the things that made us feel better, or feel worse. It seemed that mindfulness and zen attitude is really important in our lives and I learned a lot. After a tasty meal together at the hotel we started an afternoon dedicated to pharmaceutical trials during which UCB presented and explained what is a trial. There after, we had an activity about the communication between pharmaceutical companies and the patients to which they aim their trials at; in this case lupus patients.

After a great evening at Chez Léon, and a good night sleep at the hotel, we started the third and last day. This was the most interesting day, in my opinion. A doctor, Pr. Lauwerijs came and answered to some previously asked questions of the panelists. We also had the opportunity to testimony on video record, which I think is very important to sensitize or help people. At the end of the day we drew our future 20 years from now and presented our drawings to the others. This activity was also really interesting. It made us think about what really matters.

We ended the panel with a kind of evaluation of it and everyone said something about his experience of the panel.

As a conclusion, I would say that it was a very rich opportunity for me. I made new friends, I felt understood and I had the feeling that the patient's opinion matters; which is very important for us, patients. I also learned some things I didn't know and was confronted to people experiencing the disease in a different way of mine, this making me think about my proper way to live with it.

If I had to do it again, I certainly would. Thank you for having given me the opportunity !

Annelies