

# ***HarmonicSS virtual training course***

- Final report -

January 2021



This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No. 731944 and from the Swiss State Secretariat for Education, Research and Innovation SERI under Grant Agreement 16.0210.

## **1. Introduction**

The HarmonicSS project (*HARMONIZATION and integrative analysis of regional, national and international cohorts on primary Sjögren's Syndrome (pSS) towards improved stratification, treatment and health policy-making*) is a pilot for EULAR/PARE partnership in EU-funded research consortia aiming to provide the patient perspective to international, scientific projects on rheumatic and musculoskeletal diseases.

As an important dissemination activity of the project, EULAR PARE organized the *HarmonicSS virtual training course* focused on training patient representatives on collaborative research, the findings of the HarmonicSS project and future directions and opportunities for research on pSS. Originally planned as a face-to-face meeting in Amsterdam in March 2020, the course was postponed due to the COVID-19 pandemic and finally transformed into a virtual series of events. This lasted for 6 weeks, with each event taking place every Monday from 26 October to 30 November 2020 between 17:00-18:00 (Central European Time).

Twenty-one patient representatives from 14 European countries joined the course which included pre-meeting reading materials, video and live presentations by different speakers, including HarmonicSS scientific partners, as well as live discussions and group exercises. The live sessions were organized as meetings in MS Teams, while a shared folder in OneDrive was used to share the course materials and live session recordings with the participants. Before the start of the course an expectations survey was shared with participants, while a final course evaluation survey was shared at the end to collect their feedback.

## **2. Course Objectives**

- Informing patient representatives about the results of the HarmonicSS project: learning about registries, cohorts, stratification, biomarkers & biobanks in Sjögren's Syndrome.
- Empower representatives from pSS patient organisations to be able to disseminate the results of HarmonicSS products.
- Prepare patient representatives to participate in future Sjögren's Syndrome related research.

### 3. Course Agenda

DATE/TIME	SUBJECT	SPEAKERS
Monday, 26 <sup>th</sup> October, 17:00-18:00 CET	Introduction to and challenges of collaborative research	Maarten de Wit and Elsa Mateus (EULAR PARE)
Monday, 2 <sup>nd</sup> November, 17:00-18:00 CET	PROs (patient reported outcomes) and core outcome set development	Maarten de Wit (EULAR PARE)
Monday, 9 <sup>th</sup> November, 17:00-18:00 CET	Aims and results of HarmonicSS <i>Focusing on registries, cohorts, stratification, biomarkers &amp; biobanks</i>	Prof. Athanasios Tzioufas and Andreas Goules (project coordination team)
Monday, 16 <sup>th</sup> November, 17:00-18:00 CET	Involvement of patients in Sjögren's research  Involvement of patients in ERN ReCONNECT: A successful initiative raising patients' leadership at European level  The essential role of patient partners from the early stages of a clinical study? The example of NeceSSity	Ana Vieira (patient representative)  Coralie Bouillot (patient representative)
Monday, 23 <sup>rd</sup> November, 17:00-18:00 CET	Geographic variation in primary Sjögren's syndrome care and research in Europe	Prof. Chiara Seghieri and Enrico Lupi (project partners)
Monday, 30 <sup>th</sup> November, 17:00-18:00 CET	Final discussions and training wrap-up	Maarten de Wit and Elsa Mateus (EULAR PARE)

## 4. Course Programme

### 4.1 Session 1 - Introduction to and challenges of collaborative research

**Date:** Monday, 26 October 2020, 17:00-18:00 CET

#### **Additional materials:**

- Pre-recorded video presentation (26 minutes) and related slides by Maarten de Wit on “Introduction to collaborative research”;
- Scientific paper [European League Against Rheumatism recommendations for the inclusion of patient representatives in scientific projects.](#)

The video presentation focused on establishing the objectives and programme of the course as well as giving an introduction to the topic of collaborative research (e.g. motives for patient involvement in research, evidence based knowledge vs experience based knowledge, approaches to capture the patients’ perspective, types of patient roles in research, EULAR Study Group for Collaborative Research, EULAR recommendations for the inclusion of patient representatives in scientific projects, EULAR brochure on patient involvement in research, EULAR network of Patient Research Partners (PRPs), benefits of HarmonicSS for EULAR PARE, professionalisation of PRPs through the PRP online training courses of the EULAR School). Several questions for self-reflection were also provided during the presentation for later discussion during the live session. A week prior to the live session the additional materials were sent to participants for self-preparation.

#### **Agenda:**

1. Welcome and agenda
2. Introductions
3. Review objectives of the training course
4. Q&A and discussion regarding the pre-recorded introduction video
5. Optional: Scientific research and the pyramid of evidence
6. Confidentiality

#### **Summary:**

During the first live session of the course facilitated by Maarten de Wit and Elsa Mateus, the objectives and programme of the course were presented to the participants. All participants were asked to present themselves to the group, including sharing their motivation to become active in Sjögren’s research. After a quick recap of the pre-recorded video, participants were invited to share their questions and comments regarding the topic of collaborative research. The participants’ presentations and the video Q&A took most of the session’s time, therefore the optional section of the agenda was skipped so that the group could still discuss the principle of confidentiality in research projects.

## 4.2 Session 2 - PROs (patient reported outcomes) and core outcome set development

**Date:** Monday, 2 November 2020, 17:00-18:00 CET

### Additional materials:

- Pre-recorded video presentation (22 minutes) and related slides by Maarten de Wit on “Introduction to PROs and outcome research”;
- Scientific paper [\*Patient participation as an integral part of patient-reported outcomes development ensures the representation of the patient voice: a case study from the field of rheumatology.\*](#)

The video presentation focused on explaining the importance of the concept “outcome” (patient reported outcome, clinician report outcome, objective outcome) and “PROs” in clinical research, why outcome measures have to be validated, and why patients should be involved in the development, validation and selection of outcomes in clinical research. Several questions for self-reflection were also provided during the presentation for later discussion during the live session. A week prior to the live session the additional materials were sent to participants for self-preparation.

### Agenda:

1. Welcome and agenda
2. Objectives of session 2
3. PROs in primary Sjögren’s Syndrome
4. Breakout group discussions (20 min)
5. Breakout groups report back
6. Patient involvement in PRO development

### Summary:

In the beginning of the live session facilitated by Maarten de Wit and Elsa Mateus, the agenda and objectives of the session were presented to the participants. After a quick recap of the pre-recorded video, the EULAR Outcome Measures Library as well as the context of use of outcomes were presented. Four different outcomes for Sjögren’s, identified through the EULAR Outcome Measures Library, were explained: the Sjögren’s Syndrome Damage Index, the EULAR Sjögren’s Syndrome Patient Reported Index (ESSPRI), the EULAR Sjögren’s Syndrome Disease Activity Index (ESSDAI), and the clinical EULAR Sjögren’s Syndrome Disease Activity Index (ESSDAI) (clinESSDAI). Participants were then divided into 3 breakout groups (each with a different meeting room and a facilitator from EULAR PARE) to discuss more in-depth the Sjögren’s outcomes and a number of provided questions (with the goal to discuss more broadly which instrument measures best the quality of life of people with pSS). After 20 minutes, the participants returned from the breakout rooms and each facilitator shared with the larger group their respective discussions and conclusions. A question for self-reflection was given to the participants as homework: are the currently used outcomes in Sjögren’s disease developed with input from patients?

### **4.3 Session 3 - Aims and results of the HarmonicSS project (focusing on registries, cohorts, stratification, biomarkers & biobanks)**

**Date:** Monday, 9 November 2020, 17:00-18:00 CET

#### **Additional materials:**

- Two pre-recorded video presentations and related slides by Prof. Athanasios Tzioufas and Andreas Goules from the HarmonicSS project coordination team (Department of Pathophysiology, School of Medicine, National University of Greece) on:
  - “HarmonicSS project and progress” (26 minutes);
  - “Sjögren's Syndrome clinical phenotypes and novel biomarkers” (17 minutes).

The first presentation focused on explaining the goals and structure of the HarmonicSS consortium and its work packages (WPs), the functioning of the HarmonicSS platform, the first results of the data harmonization, the progress on the tasks and deliverables of WP6 on the clinical unmet needs of Sjögren's Syndrome, and the project's progress plan and schedule until the end of the year. The second presentation focused on giving an introduction to the clinical manifestations of Sjögren's Syndrome, and explaining the influence of the clinical phenotypes by demographic characteristics as well as novel biomarkers for lymphoma prediction discovered by the project. A week prior to the live session the additional materials were sent to participants for self-preparation.

#### **Agenda:**

1. Welcome and agenda
2. Objectives of session 3
3. Q&A and discussion regarding the two pre-recorded videos
4. Further topics for discussion regarding HarmonicSS

#### **Summary:**

In the beginning of the live session facilitated by Ana Vieira from the HarmonicSS Patients Advisory Group, the agenda and objectives of the session were presented to the participants. The objectives of the session were to inform about the results of the HarmonicSS project and to empower representatives from pSS patient organisations to be able to disseminate the results of HarmonicSS. Participants were invited to share their questions and comments regarding the two pre-recorded videos on “HarmonicSS project and progress” and “Sjögren's Syndrome clinical phenotypes and novel biomarkers”. Andreas Goules from the HarmonicSS project coordination team was present during the live session to answer any questions regarding the topics of the videos, as well as any other questions regarding the HarmonicSS project.

#### **4.4 Session 4 - Involvement of patients in Sjögren's research**

**Date:** Monday, 16 November 2020, 17:00-18:00 CET

**Additional materials:** None

##### **Agenda:**

1. Welcome and agenda
2. Objectives of session 4
3. Involvement of patients in ERN ReCONNET: A successful initiative raising patients' leadership at European level
4. Q&A
5. The essential role of patient partners from the early stages of a clinical study? The example of NeceSSity
6. Q&A

##### **Summary:**

In the beginning of the live session facilitated by Elsa Mateus, the agenda and objectives of the session were presented to the participants. Two live presentations (15-20 minutes) were made by patient representatives on the involvement of patients in other scientific projects on Sjögren's Syndrome. Ana Vieira (Portugal) explained the involvement of patients in the ERN ReCONNET project, a successful initiative raising patients' leadership at European level, while Coralie Bouillot (France) explained the essential role of patient partners from the early stages of a clinical study, the example of the NeceSSity project. Participants were then invited to share their questions and comments regarding the topics of the two live presentations.

## **4.5 Session 5 - Geographic variation in primary Sjögren's syndrome care and research in Europe**

**Date:** Monday, 23 November 2020, 17:00-18:00 CET

**Additional materials:** None

### **Agenda:**

1. Welcome and agenda
2. Objectives of session 5
3. Geographic variation in primary Sjögren's syndrome care and research in Europe
4. Q&A

### **Summary:**

In the beginning of the live session facilitated by Elsa Mateus, the agenda and objectives of the session were presented to the participants. A live presentation on “Geographic variation in primary Sjögren's syndrome care and research in Europe” was made by Prof. Chiara Seghieri and Enrico Lupi (MeS Lab, Scuola Superiore Sant'Anna Pisa), the project partners responsible for WP8 on health recommendations and health policy definition. The presentation focused on explaining the challenges that health systems still face today, the shift to personalized and population medicine, what are variations and value in health care, how can measurement improve value and evidence of this from the HarmonicSS project. Geographical variations were reported in the diagnosis and management of pSS patients along the different care settings – primary and specialist care – in Europe using population and reported data, which will guide the identification of policy recommendations to be tested in the primary care settings of Spain and Netherlands. Participants were then invited to share their questions and comments regarding the topics of the live presentation.

## 4.6 Session 6 - Final discussions and training wrap-up

**Date:** Monday, 30 November 2020, 17:00-18:00 CET

### **Additional materials:**

A week prior to the last live session of the course, participants were asked to reflect on the following questions and prepare their answers for a group discussion:

1. What do you see as an important outcome/benefit of the HarmonicSS project for people with Sjögren's Syndrome?
2. What have you learned yourself from the project or this training as a person living with Sjögren's Syndrome?
3. What could be the next step/action for you as a patient research partner in Sjögren's research or for your organization representing people with Sjögren's?

Participants were also asked to reflect on any aspects of the course content or the HarmonicSS project that needed further clarification and discussion during the last live session.

### **Agenda:**

1. Welcome and agenda
2. Objectives of session 6
3. Training recap
4. Breakout group discussions (20 min)
5. Breakout groups report back
6. Training wrap-up

### **Summary:**

In the beginning of the live session facilitated by Elsa Mateus and Maarten de Wit, the agenda and objectives of the session were presented to the participants. A recap of the training was given, focusing especially on the clinical findings and non-clinical outcomes of the project until now, as well as on future opportunities for patient involvement in Sjögren's research. Participants were then divided into 3 breakout groups (in different meeting rooms with facilitators from EULAR PARE), with each group being asked to discuss more in-depth one of the questions provided for reflection in advance of the live session. After 20 minutes, the participants returned from the breakout rooms and one participant from each group shared with the larger group their respective discussions and conclusions. The training was wrapped-up with the participants being provided with information on how to access the HarmonicSS project's scientific articles and newsletters, articles on the e-Breakthrough newsletter, and presentations by project partners for dissemination to the patient representatives' networks. Finally, participants were asked to fill out an evaluation survey of the training course and a group photo was taken.

## 5. Course Participants

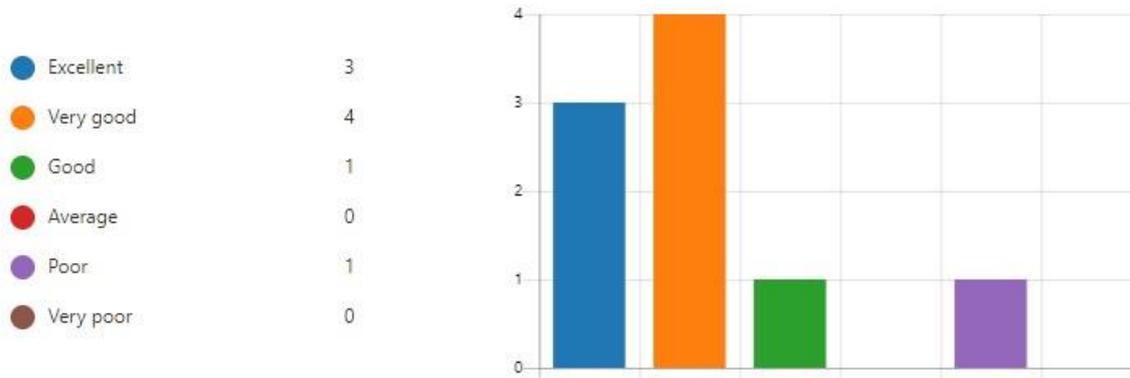
Twenty-one patient representatives from 16 different patient organizations based in 14 European countries joined the course, with the average number of attendees of the live sessions being 16. More information about the participants is detailed below.

Name	Country	Organisation
Ana Vieira	Portugal	Liga Portuguesa contra as Doenças Reumáticas
Coralie Bouillot	France	Association Française du Gougerot Sjögren et des Syndromes Secs
Mascha Oosterbaan	Netherlands	Onderzoek Nationale Vereniging Sjögrenpatiënten
Linda Stone	UK	British Sjögren's Syndrome Association
Joyce Koelewijn	Netherlands	Onderzoek Nationale Vereniging Sjögrenpatiënten
Ingebjørg Nordby	Norway	
Polina Pchelnikova	Russia	Russian Rheumatism Association
Yulia Zaytseva	Russia	Russian Society on Sjögren's Syndrome
Jenny Inga	Spain	Asociación Nacional Española del Síndrome de Sjögren
Ana Brenlla Iglesias	Spain	Asociación Nacional Española del Síndrome de Sjögren
Leena Ahtila	Finland	
Aouatif Cherkaoui	Poland	Association of People with Rheumatism & their Friends
Rozalina Lapadatu	Romania	Asociația Pacienților cu Afecțiuni Autoimune
Gabriela Serbanescu	Romania	Asociația Pacienților cu Afecțiuni Autoimune
Mary Vella	Malta	Arthritis & Rheumatism Association Malta
Alice Grosjean	-	Sjögren Europe
Eszter Rozan	Hungary	Magyar Reumabetegek Egyesülete
Antonella Spada	Switzerland	Association Romande du Syndrome de Sjögren
Josien Smit	Netherlands	Nationale Vereniging ReumaZorg Nederland
Coca Ancuta	Romania	Sindrom Sjögren România
Caoimhe O'Neill	Ireland	Irish Children's Arthritis Network
<b>21 participants</b>	<b>14 countries</b>	<b>16 organisations</b>

## 6. Results of Course Evaluation Survey

Nine participants from 21 answered the final evaluation survey of the training course. Their feedback is compiled below.

a. How would you rate the HarmonicSS virtual training course?



b. What did you like most about the course?

ID ↑	Name	Responses
1	anonymous	The contact with persons
2	anonymous	What i liked the most was the interaction between us and that my questions were answered to.
3	anonymous	The presentations and the Q&A sections.
4	anonymous	Being made aware of this project even though it did not include a UK site and did not appear to have any plans to do so.
5	anonymous	It's always so good to notice how many people are interested, scientifically based, in our Sjögren. Different views and the same target to patients' best. To realize once again how similar problems our pSS patients share, all over in different countries.
6	anonymous	To learn more about the disease and from others, to engage with other patients and the chances to discuss pertinent topics.
7	anonymous	Information about current research
8	anonymous	Interesting with partispsnts from mant countries.
9	anonymous	having an oppportunity to discuss current status of the pSS with the PRPs from different countries

c. What did you like the least about the course?

ID ↑	Name	Responses
1	anonymous	.
2	anonymous	There were too few courses.
3	anonymous	I did not find things which I did not like.
4	anonymous	Lack of clarification about the project aims and outcomes and the aims and objectives of the training - It would have been helpful to have these clearly set out before the sessions began. Lack of meaningful interaction with other participants. Taking 20-25 minutes of the 1st hour long session for participants to introduce themselves (when we could not see each other properly), and then spending some time presenting an article that we had all been sent to read in advance of the meeting was extremely frustrating.
5	anonymous	To be online, I would prefer personal contact when ever, if ever, it will be possible. I feel I'm in a remote corner of Europe and IT connections were a few time difficult.
6	anonymous	That patients didn't interact more leading to more fruitful discussions some times. But I fully understand this was quite a novelty for most of them, so they were possibly more willing to absorb info then to question it.
7	anonymous	All meetings were very usefull, thank you very much
8	anonymous	The number of people made it difficult to get to know each other.
9	anonymous	the discussions which require some preliminary work (look through the uploaded materials) sometimes probably don't work that well

d. Were your initial expectations met by this course?

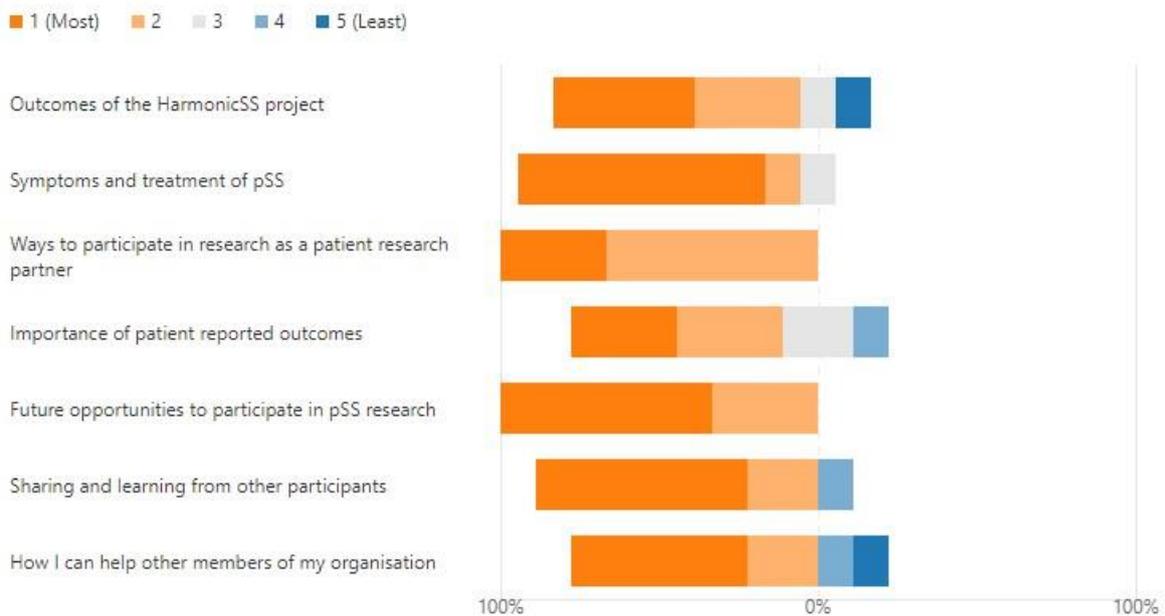
● Yes	7
● No	0
● Not sure	2



e. If not, can you please comment on what expectations were not met.

ID ↑	Name	Responses
1	anonymous	.
2	anonymous	-
3	anonymous	For the reasons set out in my answer to Qu3, I do not think that the opportunity to learn something new was maximised. Other than by disseminating information (to whom? and in what form?) it was unclear how the participants could apply this research.

f. What type of course content did you appreciate learning the most?



g. Will you use what you learned during the course in your future work at the national level?

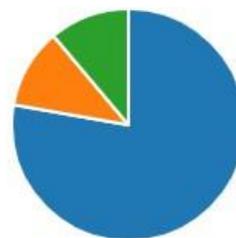


h. If yes, how will you use what you learned in your future work at the national level? If not, can you please explain why.

ID ↑	Name	Responses
1	anonymous	.
2	anonymous	I will try my best to pass on the information given to me at the course.
3	anonymous	I will disseminate what I learned in my organisation.
4	anonymous	I will endeavour to share the information as appropriate. A clear, unambiguous lay summary would be more easily shared.
5	anonymous	EULA and Harmonics are not well known in our group. First to introduce the organizations and shortly the outcome in our net and magazine. The story goes on with short presentations.
6	anonymous	Sharing the contents with our national patient group coordinator and together explore the different possibilities to make it available to patients.
7	anonymous	I will try to start the same projects in Russia, your information will help me use the right way
8	anonymous	I will communicate what I have learned to my organisations members.
9	anonymous	Disseminate lay summary of the results of the project

i. Would you recommend this course to others?

● Yes	7
● No	1
● Maybe	1



j. Any final comments?

ID ↑	Name	Responses
1	anonymous	I would love there to be more courses where i could bring the questions and problems of romanian patients
2	anonymous	Thank you for this course, it was useful.
3	anonymous	It was very frustrating to not be able to even see other participants, let alone have any meaningful discussion with them. It is unfortunate that this course had to be held in this way as opposed to the planned face to face meeting. It was difficult to gauge the level of understanding and engagement of participants. However, I do think that there is a lot to learn from this group of sessions which will inform future education and training. I have tried to criticise constructively as I do consider that organising this was a formidable task.
4	anonymous	Thank you for organizing this!
5	anonymous	It's a pity we didn't have access to all final results from the project, but it was clear this was not EULAR's responsibility. I think you've done a wonderful job with what was available.
6	anonymous	I really appreciate your work. Thank you and I hope we will meet next year. Happy New Year
7	anonymous	Thank you !

## 7. Lessons Learned

### What worked well:

- **MS Teams** worked well as the chosen digital tool for hosting online meetings: participants largely did not have issues joining the live sessions
- **OneDrive** worked well as the chosen digital tool for creating a shared folder with documents/files that participants could access
- Scheduling of **course programme throughout 6 weeks** worked well: large majority of participants attended all the live sessions
- **Frequent communication** with participants by email worked well: quick replies to requests, especially in the case of issues accessing live sessions or course materials
- **Pre-recorded videos** made available to participants in advance for self-preparation worked well in saving time for group discussions during live sessions
- Preparing **questions/challenges** in advance for individual self-reflection or group discussions worked well
- Division of participants into **breakout groups** worked well in allowing for more in-depth discussions and better engagement with shy participants
- **Division of roles among course organizers** worked well for smooth management of the work: admin support person (checking for questions/requests on the email address, liaising with speakers, moving slides for speakers, solving technical issues), session facilitator(s) (engaging with participants and speakers during live sessions, checking for raised hands and questions on the chat) and session speaker(s) (preparing and giving presentations, answering questions)
- Important to have prepared the participants' **expectations survey and the final evaluation survey** of the course, even if not all participants responded to these

### What could be improved:

- **Duration of live sessions** was sometimes short (1h): 1h15 or 1h30 would work better to allow for more in depth group discussions
- **Presentation of participants** during the first live session was necessary but took too much time: dedicated time should be saved for this in future events or, alternatively, short bios of the participants could be distributed prior to the start of the course
- Some participants received the MS Teams calendar invites on their spam folder: **meeting links** should be sent by email in addition to the calendar invites
- Participants lacked **information on the speakers** given in advance: short bios of speakers should be sent to participants in advance of live sessions
- Some **presentations did not follow the guidelines** (e.g. maximum time allowed, use of lay language, focus on patients as the audience): course organizers need to receive presentations with sufficient time in advance to check if appropriate and ask for changes if needed
- Sometimes **participants did not watch the videos/read the materials** in advance and therefore did not prepare questions for speakers: even if pre-recorded videos are available, speakers should give a 5-10 min recap of the videos during the live sessions
- Some **participants aimed mostly at receiving information about the disease** and therefore were not able to fully contribute to the discussions: basic and advanced knowledge levels of participants should be considered in the future

- Participants lacked **information in lay language** on the project's results: project coordinators need to prepare lay summaries or other materials in lay language for participants, either to be shared in advance or to distribute during the event