

NECESSITY: the different stages of patient involvement in the project

The NECESSITY project is led by a Public-Private Consortium whose partners are Industries, Academics and a Patient Association.

The French Patient Association, AFGS, is the partner representing the patients and has been participating from the beginning of the project.

Before launching the project, a lot of work had to be performed. AFGS participated to preliminary meetings in Brussels, Basel and Paris. Important documents such as the Grant Agreement and the Consortium Agreement have been thoroughly reviewed by the patient representatives and great attention has been given that the patient expectations from the project be expressed in the documents.

There were several proposals before acceptance by the European Commission.

Then, there was the kickoff meeting in Paris, and the first activities of the patients officially started.

- Management of the budget allocated to AFGS for the travels and meetings of the patients all along the project.
- First test of the WebApp to assess dryness.
- Setting up of a Patient Advisory Group (PAG). Eight countries are participating in the project. The Patient Associations of these countries were contacted and asked to nominate a volunteer. The patients in the group were appointed in strict compliance with the GDPR. Unfortunately, not all countries have a Sjögren's patient Association, and it must be kept in mind that illness is a heavy burden when you want to work for a PAG. [Patient Advisory Group - NECESSITY](#)
- Review of the Protocol, of the Patient Information Sheet and Informed Consent, sometimes translation in the concerned country language. The PAG gave advice for some modifications of the protocol so that the clinical trial be smoother for the patients. The patient information documents were made as easy to understand as possible.
- Participation in the construction of the website (patient corner) and the lay brochures.
- Participation to the first proposition of the STAR (Sjögren Tool for Assessing Response).
- Organisation of a DELPHI survey for patients to give their best choice of STAR definition and confrontation to the researcher definition.
- Letter of support of NECESSITY and STAR written by the PAG and sent to the EMA (well received) and another to the FDA by the Sjögren's Foundation.
- Attendance to the Executive Project Management Team (EPMT) meetings and to the yearly General Assemblies
- Participation to the Workshops where patients are given a large say.
- Letter written by the PAG and discussed with the researchers to express the patient definition of flares.
- Same work as for STAR with the researchers to build up the STAF (Sjögren Tool for Assessing Flares).
- Survey about STAF sent to the Sjögren community.
- All along the project, communication about NECESSITY within the patient associations and during congresses and seminars.

Of course, the PAG cannot work on the part of the project concerning the biomarkers, the statistical methodology, the stratification but for the rest of the tasks, the patients are working from the beginning and will continue up to the end of the project.