

## Online supplementary text

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### Procedure of patient involvement in the elaboration and validation of the PsAID

Making the involvement of patients with PsA an integral part of the development and validation of the PsAID has been essential for the project. To incorporate the patient perspective people with PsA have been involved in different roles, different phases and in different numbers. They carried out the following tasks:

- Collaborating as Patient Research Partner (n=12; during the entire project)
- Acting as member of the Steering Group (n=2; during the entire project)
- Prioritizing important domains (n=139; step 1)
- Pre-testing of translated items through cognitive debriefing (n=65, 5 per country; step 2)
- Filling in questionnaires (n=499; step 3)

The 12 patient research partners were actively involved in many phases of the study. Here we will describe their role as well as that of the members of the Steering Group.

#### Patient Research Partners

##### *Recruitment and selection*

Proportional representation of patients as equal collaborators in the project was sought during the first as well as the second meeting of the entire research team. This means that there was an almost equal number of patient research partners (n=12) compared to the number of national principal investigators (n=13). The patients came from 12 different European countries and the recruitment was carried out through the clinics of the participating investigators. They were able to make an adequate assessment of whether a patient was competent to contribute to this research project and whether a patient fulfilled the inclusion criteria as recommended by EULAR<sup>1</sup> among which personal experience with the disease under research and being fluent in English.

##### *Identifying domains*

During the breakout session on the morning of the first research team meeting (January 2011) the patient research partners met as a subgroup and identified important domains that reflected the impact of the disease on their health. They came up with a total number of 16 domains. In the afternoon a plenary session with the investigators took place discussing the 16 domains and trying to formulate brief descriptions of the domains.

##### *Translation process*

Some research partners were involved in the process of translating the English version of the PsAID to their national language, as part of a multi-disciplinary team.

##### *Decision making process*

Along the way the research partners were involved in many decisions that were taken. Sometimes this process was carried out through emails or telecalls. Some decisions were taken during short meetings at existing annual conferences of the

American College of Rheumatology (ACR) and the European League Against Rheumatology (EULAR). These meetings were attended by some of the national principal investigators that were attending the conference and only a few research partners. The most important decisions were taken during the two research team meetings. The research partners had full voting rights and received in advance of the meetings all documents written and explained in lay language (see below among 'support').

#### *Co-authorship*

Research partners who contributed during different phases of the study and who reviewed and commented on the draft article were offered co-authorship of the manuscript.

### **Members of the Steering Group**

The Steering Group consisted of five investigators and two expert patients with extensive experience in international collaboration with researchers. They followed the EULAR recommendations for the inclusion of patient representatives in scientific projects.<sup>1</sup> The inclusion of the patient perspective was felt a shared responsibility. Here we describe the role of the Steering Group in supporting the patient research partners and the additional task of the patient representative.

#### *Supporting the patient research partners*

Enabling patient research partners to contribute to the research process requires additional support by the researchers before, during and after meetings. The Steering Group undertook the following actions to make sure that the patient research partners were prepared for their role and were well informed about the research process:

- A personalized invitation letter and background information, including a lay version of the protocol.
- Patient sessions before the start of the first and the second research team meetings (90 min.); participation by national investigators was optional.
- Meeting reports, newsletters and regular project updates in lay language
- Pre-meeting patient guide before the second meeting
- Additional individual support was provided by the participating national investigators.

#### *Moderation of sessions*

An important challenge for the Steering Group was to preserve the characteristics of a genuine dialogue between research partners and physicians in which arguments were shared in an open and safe atmosphere and where all participants felt equally facilitated to contribute to the discussions without limitations caused by traditional doctor-patient hierarchy. Especially for the first breakout session during the first research team meeting it was thought essential that the patients would not feel restricted to speak up due to the presence of their treating physician. Therefore it was decided to organize two homogeneous subgroups led by different moderators. One patient member of the Steering Group with professional moderation skills, together with an experienced nurse researcher, facilitated the discussion in the patient group to identify the domains of interest for patients. Two

investigators of the Steering Group facilitated the discussion in the physician group to discuss the instruments to measure the potential domains.

Two weeks in advance of the second research team meeting (November 2012) patient research partners received a 12 page introduction package explaining the previous steps of the project, the validation process of the PsAID, the objectives of the second meeting and a glossary of often used terms and abbreviations. During the second meeting the facilitators were keen to make sure that all participants could follow the discussions and felt confident to contribute to the discussions at all stages. At the end of the day the meeting was evaluated and the patient research partners confirmed that they believed that they had contributed something that the physicians could not provide. They felt well supported in the process and satisfied about their role.

### **Added value of involving patient research partners**

The input of patient research partners during the first meeting of the research team resulted in a concrete list of 16 relevant domains from the patient perspective. Thereafter the research partners were involved in lively discussions with the researchers on the formulation of the 16 domains (wording, phrasing). Similarities, overlap or differences between different terms used in the questions were explained. This discussion included also the length of the recall period (1 week or 1 month) and the choice of the instrument: NRS or other tools.

There was a long debate during the first meeting regarding the domain 'coping'. The physicians argued that "coping" does not represent the impact of the disease and should be seen as another dimension. The patients experienced the extent to which one is able to cope with the disease as a clear outcome of the treatment and therefore also as an appropriate symptom or feature of the impact of the disease. Because the patients felt strongly about this domain the research team decided to keep 'coping' in the list of relevant domains.

During the second research team meeting the input of the research partners was less tangible because of the nature of the meeting: presenting the final data and statistical analyses from the validation process. However, patients were involved in several discussions on outstanding issues that needed to be decided on. These discussions included the decision about the number of items (9 or 12). The result was a compromise that achieved a high level of agreement, suggesting 9 items as the recommended version for clinical trials and the 12 items as the recommended version for clinical practice. Patients wanted to keep the three domains 'embarrassment and shame', 'social participation' and 'depression' because there was a strong believe these domains are important for people with PsA although patients often don't want to admit or acknowledge that their disease contribute to the experience of feeling down, depressed, socially isolated or not valued as a person. The assumption was that there exists a hidden impact of PsA that it often not recognized by patients as well as physicians. And because the PsAID will hopefully also be used in clinical practice, keeping these 3 items in, would facilitate treating physicians to focus on separate items of the composite score, including the 3 items that are not contributing to the pooled result. Most of the physician present at the meeting acknowledged the opinions of patients and accepted the view of the patients as being decisive for developing a patient derived PRO. For this reason they voted in favor of the 12-item version for clinical practice. Patient representatives did acknowledge the arguments of the physicians that for

clinical trials short questionnaires are needed. Because the data showed no significant difference in performance of the 9 and 12 item versions, the research partners accepted the 9 item version as recommended for clinical trials. The research partners also agreed with the decision for different weighting systems for the 9 and 12 item versions.

1. de Wit MPT, Berlo SE, Aanerud GJ, Aletaha D, Bijlsma JW, Croucher L, et al. European League Against Rheumatism recommendations for the inclusion of patient representatives in scientific projects. *Annals of the Rheumatic Diseases* 2011;70(5):722-6.

**Online supplementary table S1. The final PsAID questionnaires in English.  
Separate document**

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