

Call on sex- and gender-related research projects in RMDs

Introduction

Many Rheumatic Musculoskeletal Diseases (RMDs) show gender differences with respect to their prevalence, clinical manifestation and disease course. Furthermore, sex hormones and other sex-dependent mediators are known to differentially affect the cells of the immune system as well as the musculoskeletal system, thereby affecting the pathogenesis of RMDs. In addition, sex- and or gender-related issues may affect treatment decisions and the general management of RMDs. To date, little is known about the mechanisms of how sex and gender influence RMDs.

FOREUM Foundation for Research in Rheumatology therefore considers studies on sex- and gender-related issues of key importance as they may help to better understand the pathogenesis of RMDs as well as to better interpret patients' clinical presentation and disease course. FOREUM aims to instigate research, which improves our knowledge on the influence of gender on pathogenesis, clinical presentation and disease course of RMDs. Overall this call aims to allow a better understanding of the role of sex and gender in patients with RMDs, which may be important for a more closely tackling the pathophysiological mechanisms of RMDs, for developing better and more individualized treatment and management strategies and overcoming potential gender-based limitations in the diagnosis and treatment of RMDs.

Scope

FOREUM seeks to support projects in the following areas:

- Influence of sex/gender on processes that influence the pathogenesis of RMDs
- Sex-/gender-related factors that impact on the disease course, prognosis and outcomes of RMDs
- The role of gender in optimizing the treatment of RMDs
- Sex/gender-related differences and disparities in the management of RMDs

Eligibility

FOREUM primarily encourages collaboration across Europe and therefore requires multi-center project applications involving partners from at least three different countries. Any given institution shall be allowed to lead on only one application. However, that institution, or its staff may participate in other projects as collaborators.

The call shall be open to participants from the global scientific community; however, we stipulate that the Principal Investigator should come from a **EULAR membership country**. Similarly, whereas participating centers may be from outside Europe to provide necessary expertise, the majority of contribution should be from EULAR member countries. Members of the FOREUM committees and EULAR Executive Committee are not allowed to submit or to participate in applications.

Budget

The call on sex- and gender-related research projects in RMDs is designed to fund a range of research projects. An individual proposal may be funded with up to a maximal amount of **600'000 Euro for a 3-year funding period**, provided the expenditure is appropriately justified. Collaborating partners should each have a substantial part of the budget to appropriately conduct research. Projects will be subjected to an interim evaluation of progress and will have to offer a written final report. Submitted publications can be used as part of the report.

How to apply

Applications should be made electronically (email to info@foreum.org). Necessary application forms can be downloaded at www.foreum.org.

Letter of intent

All applicants considering submission of a proposal are invited to send a short 'scientific letter of intent' by 10 September 2019 to FOREUM (email to info@foreum.org) accompanied by a 'lay summary letter of intent', for review by patients. For applying, please use the templates that are available at www.foreum.org. Letters of intent should not only include information on the study question and its novelty, but also the agreement of the participating centers to collaborate in data analyses or to provide aggregated or raw data in line with national regulations and their governing boards. Letters of Intent will be assessed by members of the FOREUM Scientific Committee. Applications deemed meritorious of full application will be selected on a competitive basis. Please note that the lay summary is a critical part of our evaluation as the views of people with RMDs are central in our decision making process. The Secretariat will respond by 10 October 2019 as to whether the proposal meets the scope, priority and requirements of the call such that a full application will be invited.

Full project proposal

Selected applicants will be invited to submit a full proposal; they will be sent the full project proposal template. To facilitate review by patients, additionally a lay summary proposal must also be completed at this stage. Both forms will be provided to applicants invited to submit a full proposal. Full research proposals must be submitted electronically by 30 November 2019 to the FOREUM Secretariat.

Participation of patient research partners

Participation of patient research partners is strongly recommended for clinical research projects and should be considered for all other research projects to provide experiential knowledge, with the aim of improving the relevance, quality and validity of the research process. Participation of patient research partners would be a strength in developing the proposal to underline the importance of patients providing experiential knowledge in the research process. For more information, please read the material on http://www.eular.org/pare_patient_research_partners.cfm.

Evaluation and decision

The proposals will then be externally, independently peer-reviewed to evaluate their feasibility, novelty, design, relevance and potential impact relative to the subject matter of the call. Based on this peer review, the FOREUM Scientific Committee will make a funding recommendation to the FOREUM Executive Committee, which will make funding decisions in January 2020. Final decisions will be communicated by the FOREUM Secretariat by February 2020.

Ethical aspects

FOREUM expects a high standard in the conduct of research it funds. For researchers this includes scientific integrity and adherence to the principles of good research practice. Patients subjected to investigation shall be included with due adherence to the declaration of Helsinki. Declaration of Interest forms will be completed by all successful applicants.

Management of the call

The FOREUM call and approval process will be administered by the FOREUM Secretariat, together with the FOREUM Scientific Committee. The call schedule will be as follows:

Call issued:	10 July 2019
Closing date for Letter of intent:	10 September 2019
Decisions on LoI announced:	10 October 2019
Closing date for full proposals:	30 November 2019
Decisions on full proposals announced:	1 February 2020

Inquiries

For general inquiries please contact the FOREUM Secretariat at info@foreum.org.