

COVID-19 Global Rheumatology Alliance / EULAR COVID-19 Policy Document

Combined EULAR Registry-GLOBAL Registry Project Application Policy, V2

Current as of 11-July-2020

Purpose

EULAR and the C-19 GRA would like to facilitate the conduct of projects across both the EULAR and global Registries. These projects should not address overall risk factors for the prognosis/outcome of COVID-19 (e.g. hospitalisation, death, mechanical ventilation; this type of analyses will be primary covered by the GRA/EULAR steering committees). Combined analyses with other international initiatives (e.g. IBD/psoriasis registries) would also fall under the umbrella of the GRA/EULAR steering committees. The projects should address a specific disease, or a group of diseases (e.g. RA vs SLE), or a specific variable or groups of variables (e.g. lab results, certain comorbidities, certain countries or specific sub-populations). To ensure that there is appropriate representation from the contributing countries in the EULAR zone and the global zone this policy document supports the formation of these projects. This policy does not relate to analysis of individual country data where those data have been collected in an independent fashion to the GRA/EULAR database and then shared with the GRA/EULAR. Moreover, individual institutions/countries submitting their data via the GRA/EULAR database are also entitled to receive their data without the need to submit a project proposal.

Project Team Composition

At least one member of the project team should have contributed with more than 5 cases or to the regulatory approval or set-up of the EULAR (or EULAR National Society) or Global registry. If requesting access to the merged Global/EULAR dataset, the team should include three people from the EULAR region, three people from the US/Canada, and three global-non-US/Canada/Europe people (please contact EULAR/GRA in case you need support identifying potential collaborators). There is now, however, no specific limit on cumulative authorship. If requesting access to individual EULAR/Global datasets, the team should include people from at least three countries from the respective regions. If requesting access to data from specific countries at least two members from each country should be included. The gender ratio should not be less than 4:5 in favour of men or women. There should be a minimum of two trainees (fellows or registrars) on each project using the merged Global/EULAR dataset, and a minimum of one trainee (fellow or registrar) on each project using the individual EULAR/Global datasets.

Selection Process

Two to three rounds of applications are expected to occur per year. Applications will be reviewed and scored by a joint sub-committee of the global and EULAR registry steering

committees, who will make the final approval decisions. The Global SC will contribute four members (not including the EULAR designate (currently PMM)), and the EULAR committee will contribute four members. There will be co-chairs, one selected by each main SC. Decisions will be by consensus where at all possible. Voting should be avoided but may be required. Where there is deadlock, the committee may seek mediation through a separate process.

There will be no pre-specified requirements for the project team beyond participation in the project, gender, geographical representation and trainee representation. This will allow skills and knowledge to be integrated onto the project team as necessary.

If there are circumstances that require it, and there is $\frac{2}{3}$ agreement from the appointment committee, the gender, geographical representation and trainee representation minimums may be reduced or eliminated entirely. This should only be done in exceptional circumstances where the quality or viability of the project is threatened by these minimum requirements.

Restrictions on Multiple Project Participation

Any one individual cannot be on more than two active project teams or project submissions in each submission round.

Mentor

For each approved project, one mentor from the Global steering committee and one mentor from the EULAR steering committee will be nominated (if using data from both registries). Key roles of the mentor are to advise the project team in the context of other ongoing GRA/EULAR initiatives/analyses and to make sure that there is consistency with regards to what is being reported by the various project teams and the main analyses being undertaken by the steering committee.

Use of data

- The confidentiality of the patients and contributing hospitals must not be compromised by use of the data. The reputation of GRA/EULAR must not be compromised through unethical, premature or opportunistic data analysis.
- The data can only be used by the individuals named on the application form. Data must be used only in the manner stated and for the research purposes specified. GRA/EULAR data, in whole or in part, cannot be processed, disseminated or otherwise made available or used for any other purpose, and none of the data can be distributed to third parties.
- Analyses are allowed only accordingly to the protocol described in the application; major changes will require a new application. If in doubt, please discuss this with the relevant GRA/EULAR team.

- Data users should notify the GRA/EULAR study team of any errors or inconsistencies discovered in the data.
- Data users must provide their derived variables to enrich the GRA/EULAR databases.

Publications

EULAR/GRA require a copy of all works to be published prior to submission for publication or presentation for review by the EULAR/GRA Steering Committees. EULAR/GRA will also require the files with the statistical analyses scripts/syntaxes and outputs for review. The applicant must respond to any comments to the committee's satisfaction before submitting the work for publication. For abstracts for conference presentation, slides and posters the committee will give their initial response within 10 working days and for full papers 15 working days. The Committee's comments are limited to fact and interpretation and will be collated and fed back to the applicant for their response. The committee will not withhold consent unless it feels that the reputation of EULAR/GRA would be compromised through publication (e.g. because of insufficient quality of the work). The work will also be reviewed by EULAR/ACR steering groups who will also use quality criteria to decide regarding approval of the submission.

The scope of the project should be aimed at the publication of one or two scientific papers, posters, abstracts or presentations within one year from the date when the requested dataset is received by the data users. Users can subsequently submit new applications for data if they wish to do further analyses.

Acknowledgement of the use of EULAR/GRA data must be included in the methods section.

Please include the relevant following acknowledgement/disclosures on published papers:

- "The author(s) would like to thank the COVID-19 Global Rheumatology Alliance (GRA)/European League Against Rheumatism (EULAR) for use of this data."
- "The authors would like to thank all rheumatology providers who entered data into the registry. See also Appendix 1, Members of the COVID-19 Global Rheumatology Alliance." (*Appendix 1 to be included as online supplementary material*).
- "The views expressed here are those of the authors, and do not necessarily represent the views of the COVID-19 Global Rheumatology Alliance, American College of Rheumatology, the European League Against Rheumatism (EULAR), or any other organization."