ERS EUROPEAN RESPIRATORY SOCIETY every breath counts

COMMUNICATION

SHARP Severe Heterogenous Asthma Research collaboration Patient-centered

Progress on SHARP Federated Analysis Platform (FAP), Projects ongoing in Programmes 2 and 3, and on COVID-19 Research response.

Dear SHARP colleagues,

Thank you very much for your continued and enthusiastic participation in the SHARP (Severe Heterogenous Asthma Research collaboration, Patient-centred) Clinical Research Collaboration (CRC)!

To begin, SHARP just published a New Article in ERJ Open Research!

The SHARP second article describe the Federated Analysis Platform (FAP) and how SHARP have been set out to facilitate the generation of more real-world data and evidence on severe asthma by bringing together existing asthma registries across Europe and facilitating the development of new asthma registries in countries that lacked such a registry.

Article: **SHARP: enabling generation of real-world evidence on a pan-European scale to improve the lives of individuals with severe asthma.** Eur Respir. J. Open Research Apr 19;7(2):00064-2021. doi: 10.1183/23120541.00064-2021.

Link: https://openres.ersjournals.com/content/7/2/00064-2021

SAVE THE DATE: Our next SHARP Stakeholder Board meeting!

The Stakeholder Board meeting will be held on **Thursday 27th of May** at 4:00 to 7:00pm (CET) and **Friday 28th of May** at 4:00 to 7:00pm (CET).

The agenda and details of the meeting will be circulated soon to all members.

General SHARP Progresses

Our CRC has made lot of progresses over the past months despite the COVID-19 pandemic and its impact on communications, timelines and availability of the SHARP Stakeholders. We are, therefore, very pleased to circulate this fifth issue of the SHARP Newsletter so as to share our achievements and to remind ourselves of the plans for 2021. Here is a summary of our current projects:

SHARP Federated Analysis Platform (FAP)

The main objective of the FAP project is to enable analysis of data from individual registries to be conducted using a distributed model where all individual data remain in the host institution while summary aggregate statistics (also conducted in individual registries) are shared between participating sites to produce powerful and meaningful results.

Current status: We have now signed Collaboration Agreements with a large number of countries. This includes the 11 countries hosting their patient data within the SHARP Central Registry (Croatia, Estonia, Hungary, Latvia, Lithuania, Netherland, Poland, Romania, Serbia, Slovenia and Sweden) and the following countries that already had their own National Registries: Belgium, Czech Republic, Denmark, France, Germany, Greece, Italy, Portugal, Spain, Switzerland, Turkey and UK.

4 registries (13 countries) are now fully connected to the FAP, and more countries will follow.

Plan: Our IT team (ITTM) is now working hard on the harmonization of the registries to the SHARP Common Data Model and to technically connect them to the FAP.

The most **B**othersome aspects **I**n patients with severe **A**sthma and availability in the severe asthma **R**egistries: the BIPAR Study

The main objective of the project is to identify discrepancies between patients and physicians regarding the patient's most bothersome symptoms or problems and to assess whether they are well reflected in the registries. **Current status:** All 7 participating countries have started the study. 2 countries (Slovenia and Czech Republic) have already completed the recruitment of 20 patients. The 5 other countries are actively recruiting patients to complete the survey.

Plan: Closure of survey planed by middle of May. A Quality Analysist has been recruited and already started cleaning the data and organise the analysis. A set of preliminary data is currently under analysis for a first check.

The Use of Biologics in Europe

The main objective of the project is to compare the current availability and the rules and criteria of prescription of biologics in European countries.

Current status: Collection of answers form the survey completed by the 28 National Leads in SHARP and from the online survey circulate among asthma experts.

Plan: When all the answers collected, then the analysis will be performed and finalised. A meeting will be organised at the end of analysis to discuss the results with Physicians and Patients

The Health Economics of Severe Asthma

The main objective of this project is to adapt the Italian Budget Impact model for OCS analysis (already published) to the wider European context.

Current status: The Steering Committee approved the project proposal and budget. The contract with SAVE (Studi Analisi Valutazioni Economiche) has been signed and kick off meeting with SAVE and Barbara Mascialino (GSK) who will manage the project was held middle of April.

The proposed countries for the study are Italy, Belgium, Spain, Slovenia, Sweden, Poland

Plan: Start the feasibility and data collection phase. The final model with results is expected for July.

UNISA: Use of Nucala In Severe Asthma

The main objective of this project is to understand the use of mepolizumab in usual clinical practice (as opposed to clinical trials) and assess the benefits within the mepolizumab-using patient population. This will provide information about the actual use of these agents across Europe and improve the understanding of how and when patients initiate and/or change therapy. The results will, in turn, help to determine which patients would most benefit (or those who may not) from mepolizumab to control their disease.

Current status: 14 countries will participate to the study, and all of them attributed national coordinators. The protocol is finalised. The data Analysis Plan (DAP) has been finalized and the first scripts test has been launched.

Plan: Analysis scripts need to be run and tested in all the registries to be refined and finalized. Summary data collection with first results are expected in July.

Severe Asthma Questionnaire (SAQ): Burden of Asthma

The main objective of this project is to investigate the real-life impact on the quality of life of living with severe asthma across 11 European countries. The study will collect longitudinal data to assess changes in HRQoL via the PatientCoach app or online questionnaires over a 12-month period and compare with other outcome measures such as asthma control and exacerbations in the SHARP registry data.

Current status: 5 countries have their Data Sharing Agreement signed and are ready to start the study. 6 countries are still waiting for their approval. The PatientCoach app is under final setting and refinement.

Plan: The launch of the project is expected in July 2021.

COVID-19 research response

The main objective of the project is to increase the understanding of the impact of COVID-19 on people with severe asthma so as to provide clear, informed guidance to patients, physicians, national societies, and healthcare systems to be prepared for possible future waves of COVID-19.

Current status: 16 participating countries are finalizing the patients and physician's recruitment to complete the surveys. So Far 1021 patient's surveys have been completed and 263 physician's surveys.

The study team is getting organised to start the analysis and the preparation of the manuscript.

Plan: The manuscript submission is expected for end of July.

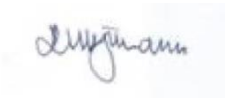
COVID-19 research extension: Vaccination study

The main objective of the project is to evaluate patient's perception of COVID-19 vaccination and reveal patient's vaccination status, hesitancy, and impact on asthma.

Current status: The protocol, the survey (online and paper version) and legal documents have been finalized. 13 countries will participate, and 8 countries do not need additional EC approval and will be able to start without delay.

Plan: The survey is now open. The data collection will hold for 5 weeks. Start of analysis expected in end of

We very much look forward to an exciting and successful year working with you all.



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