



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) during 2020!

Despite the COVID-19 pandemic and its impact on communications, timelines and availability of the SHARP Stakeholders (especially the clinicians) to work on SHARP projects, we managed to overcome the crisis and keep the SHARP projects moving.

We are pleased to welcome the Rising Stars, our young and promising investigators who have already engaged so well in SHARP projects.

Our CRC has made much progress over the past year so we are very pleased to circulate this third issue of the SHARP Newsletter to share our achievements and remind ourselves of the plans for the rest of this year and 2021.

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 and, applying meta-analysis, result in powerful and meaningful results. This project automates and streamlines existing processes, like running identical analyses workflows, on all involved registries without any risk to patient data.

Current status: All the components of the FAP have been developed. A pilot study federating a small set of clinical variables has been done using data from the Dutch (RAPSODI) and the Italian (SANI) registries, demonstrating that federation of summary data is possible. It is now also known that we can also undertake correlation (regression) analysis on such data.

We are now in the phase of contracting with each National Registry. The countries engaged with SHARP Central (Austria, Croatia, Estonia, Hungary, Latvia, Lithuania, Netherland, Poland, Romania, Serbia, and Sweden) as well as Belgium, Italy, Portugal, Switzerland, and Turkey, have already signed the Collaboration agreement.

Plan: We are expecting the 12 remaining countries involved in SHARP also to sign soon!

The most bothersome aspects in patients with severe asthma and availability in the severe asthma registries: 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 describe if they are well reflected in the registries.

Current status: The project details have been agreed 1) Identify the important symptoms/problems as seen by patients and physicians, 2) find differences in perspectives between patients and physicians, and 3) describe any discordance between registry variables and patients' and physicians' perspectives. This will help increase awareness amongst physicians regarding patients' perspectives on the burden of severe asthma and will provide evidence for any need to develop a new patient-reported outcome measure.

Plan: The protocol of the study is now finalised and under review by the SHARP Steering committee. The launch of the study is expected this October.

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 among European countries.

Current status: In a pilot study, a survey of 18 questions had been completed in 5 European countries (Belgium, Estonia, Romania, Sweden, UK) about the availability and rules for prescribing biologics for severe asthma. The survey shows 1) a good availability for omalizumab in all five countries, 2) that Romania is still lacking anti-IL-5 and anti-IL-5 receptor, 3) that Dupilumab is only available in Sweden, 4) disparities between reimbursement criteria, 5) a disparities between the duration of authorisation and the time at which response assessment is performed; 5) and that there are no clear criteria to assess the response to treatment.

Plan: The questionnaire is undergoing refinement in order to roll out the second wave survey to the rest of Europe by middle of September.

The Health Economics of Severe Asthma

The main objectives of this project are to 1) describe and characterize the burden and (health care) cost of disease for patients with severe asthma and 2) compare the burden of disease, clinical unmet needs and cost of severe asthmatics not treated with biologics.

Current status: The cost of data and analysis is prohibitive for appropriate delivery of the research questions and extend timelines. The project team and the SHARP co-chairs recently agreed on a path forward, whereby the project group will investigate opportunities for external funding. As the Health Economic impact of oral corticosteroids was identified as a prioritized research topic for SHARP, the project group will, in the meantime, seek to adapt an economic model to estimate the OCS burden and cost across SHARP registries and countries, which will support any future application for funding.

Plan: A full proposal is under development.

Severe Asthma Questionnaire (SAQ): Burden of Asthma

The main objective of this project is to investigate the real-life impact on quality of life of living with severe asthma across 11 European countries. The SAQ was developed with patients in the UK in response to the need for a specific severe asthma specific HRQoL scale. The study will collect longitudinal data to assess change 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 and SHARP registry data.

Current status: The project is now in a phase of refinement of the protocol to answer all the potential question and request for the ethic approval. The preparation of the legal document for the ethic commission as well as the Patient coach App development are under progression.

Plan: The launch of the project is expected for January 2021.

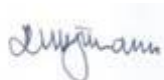
COVID-19 research response

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

Current status: The study is well advanced and organized in 3 different phases: 1) short patient and physician survey; 2) collect data of patients who had COVID-19 from patient dossiers; 3) perform blood withdrawal for serology/other measurements, combined with variables from registries and a comprehensive patient survey. The project team is in finalizing the protocol, including the patient's and physician's questionnaire.

Plan: The project is expected to start in autumn 2020.

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



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