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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) during 2020!

To begin, please accept our very best wishes for 2021!

Our CRC has made much progress over the past year 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 fourth 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.

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

The most Bothersome aspects In patients with severe Asthma and availability in the severe asthma Registries: 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 the study documents have been finalized and sent to the participating countries. Among the 7 countries taking part in the study, 4 have already received their Ethics approval and have started to recruit patients to complete the survey.

Plan: we hope to have Ethics approval for the 3 remaining countries soon so that all the countries are in the active phase.

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: A survey of 11 questions has been completed by the 28 National Leads in SHARP and is now under analysis. A shorter version of the survey on the effectiveness criteria of biologics as well as the way to assess the toxicity of OCS is currently circulating among the asthma experts of the 28 SHARP countries.

Plan: Collect the answers from the survey and perform analysis.

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: A proposal to adapt the SANI study from S.A.V.E. (Studi Analisi Valutazioni Economiche) has been reviewed and accepted by the study team. The team is now refining the project protocol regarding: how it will be delivered; the number of participating countries and which one; what should be done by individual registries.

Plan: Finalise and submit to the steering committee a full proposal.

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: The protocol and the legal documents for the ethics commission have been sent to the participating countries and are now under review.

Plan: The launch of the project is expected in March 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: The protocol, surveys (online and paper version) and legal documents have been finalized. IRB packages have been sent to all participating countries (18). 10 countries have received IRB approval and have already started the surveys. 8 countries are in the process to obtain IRB approval.

Plan: The analysis phase is expected to start in the middle of March/beginning of April 2021.

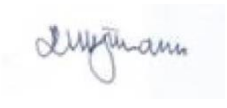
NEW PROJECT: SHARP-GSK Study on use of Mepolizumab

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: The protocol is finalised. The core group of the study has been agreed and timelines have been established.

Plan: Determine and finalise the list of participating countries; determine a national study coordinator for each country; agree on authorship; build up the script to be run in the FAP to answer the study questions.

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



Ratko Djukanovic
Co-Chair

Elisabeth Bel
Co-Chair

Dominique Hamerlijnck
Patient, Co-Chair