






Progress on SHARP Projects ongoing in Programmes 2 and 3, on COVID-19 Research response and Announcement of Future Projects – Newsletter 6.

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Dear SHARP colleagues,

Thank you very much for your continued and enthusiastic participation in SHARP. We are delighted to share our achievements and to remind ourselves of the plans for 2021 and 2022.


To begin, several SHARP projects are at the manuscript writing stage and will soon be published!

This issue also includes an interview of 4 engaged leaders from the different stakeholder groups in SHARP!

 **Interview of 4 engaged leaders from the different Stakeholder groups**

Name & Stakeholder group	Questions	Answers
<p>Hans Kroes, Rising Star</p> 	<p>Why did you get involved in SHARP?</p>	<p><i>My involvement within SHARP started with the UNISA study. Before joining the UNISA study, I was closely involved in the Dutch RAPSODI registry as part of my PhD projects. My projects within the RAPSODI registry are supervised by Anneke ten Brinke and through her I was introduced to SHARP. I have learned a lot during my involvement in SHARP and it is an absolute pleasure to work with clinicians and patients across Europe.</i></p>
	<p>What does the SHARP vision mean to you?</p>	<p><i>The current era of technology provides great opportunities to combine our knowledge. Instead of every research group for themselves, SHARP enables us to work together, combining our resources. This leads to larger and more studies, ultimately helping clinicians to optimize treatment. For me, the ultimate execution of the SHARP vision is a world in which we can prevent the use of oral corticosteroids, treat severe asthma patients as good as possible and reduce the disease burden, leading to a better quality of life for the patients.</i></p>
		<p><i>Honestly, the wide variety of the different SHARP studies is what excites me the most. It is very exciting to be a part of a workgroup which involves</i></p>

	Which SHARP project excites you the most and why?	<i>the greatest minds in severe asthma. If I had to pick the most exciting project, I would pick the UNISA study. This study is the first study proving the applicability of the Federated Analysis Platform and paves the way for future studies involving thousands of patients across Europe. Does it get any more exciting?</i>
	Why is patient centrality of SHARP important?	<i>The ultimate goal of medical scientific research, ranging from the smallest single centre studies to large global initiatives like SHARP, is always (and should always be) optimizing treatment for the patient. Without the patients, these studies are futile. Patient involvement, as accomplished in SHARP, is therefore paramount. The patients' input is of great value to us researchers, since they know best what concerns them. The value of scientific research is greatly enhanced by patient centrality.</i>
<p>Betty Frankemölle, Patient</p> 	Why did you get involved in SHARP?	<i>I was, and still am, involved in EPAP PAG and the members were asked who was interested being involved in SHARP which was about to be established. I was interested so I got involved. A PAG started and we are allowed to think and talk about research questions and other topics with another stakeholders. The patients' perspective is very important.</i>
	What does the SHARP vision mean to you?	<i>To tackle severe asthma together with doctors, researchers and patients means a lot to me. Only in collaboration we will get results We put all our views together. Patients know how it feels having severe asthma and doctors/researchers know how it works. Bringing these together will get more and better results about care, daily life, medical treatment, etc.</i>
	Which SHARP project excites you the most and why?	<i>COVID-19 Project excites me most because it is very actual, and at the start a rather unknown disease. The combination with severe asthma is very interesting but that worries me. It is a new disease, and I am involved from the start with some other patient representatives. Our voices are heard and very useful. I am a full-fledged member of the working group. All the participants are nice and respectful to each other.</i>
	Why is patient centrality of SHARP important?	<i>Because patients are experienced having severe asthma. Sometimes patients' needs differ from what doctors/researchers think. For example: fatigue has a higher place on the agenda. Bringing the knowledge of science and the knowledge and experience of the patients together is very valuable and important. These yield interesting and sometimes surprising points of view.</i>
<p>Alessandro Marcon, Epidemiologist</p> 	Why did you get involved in SHARP?	<i>As an academic researcher, I am constantly looking for stimulating collaborations in international settings. Since I was involved in SHARP, the openness and inclusiveness of the team in welcoming new members, ideas and proposals impressed me.</i>
	What does the SHARP vision mean to you?	<i>SHARP is a lively network of researchers, clinicians, patients, and other stakeholders, who collaborate together striving for excellence. I am honoured to take part in such an inspiring partnership that can make the difference for patients with asthma.</i>
	Which SHARP project excites you the most and why?	<i>What I like most is the possibility to develop new research projects where researchers can get access both to available data in the registries throughout Europe and to the knowledge and experiences of clinicians and patients connected in the network through ad hoc surveys.</i>
	Why is patient centrality of SHARP important?	<i>After presenting my research proposal during a recent meeting, a patient representative candidly – and provocatively – asked: “Why would your research be relevant to patients?”. This kind of questions is exactly what researchers need, to prevent them from treating patients like numbers, and diseases like statistics. Patients' perspectives are key to make the right questions and help getting useful answers from data.</i>

<p>Thomas Paulsson, Pharma Partner</p> 	<p>Why did you get involved in SHARP?</p>	<p><i>I am passionate about utilising data from the clinical practice setting to inform decision making, regardless of if this is for policy or day-to-day clinical patient management. SHARP offers that opportunity in a potentially very impactful way. Additionally, I found that the vision and objectives of SHARP was something a wide variety of stakeholders could agree and align on. So, in the end, how could I not?</i></p>
	<p>What does the SHARP vision mean to you?</p>	<p><i>For me it is about delivering for patients with a debilitating disease, a disease that can be managed more effectively and with less impact on the individual. Seeing patients, academia, registry holders and industry working jointly towards that very same vision is a powerful thing.</i></p>
	<p>Which SHARP project excites you the most and why?</p>	<p><i>The SHARP project itself is what excites me the most. The common data model will play a key part for delivering on the SHARP vision and its specific objectives. Seeing registry holders come together to build a joint model and effectively a pan-European registry is fantastic. This will definitely amplify the impact of the data and will enable the overall SHARP vision.</i></p>
	<p>Why is patient centrality of SHARP important?</p>	<p><i>Independent of your affiliation, we all ultimately aim to improve patient care and outcomes. As such it is central to understand the patient perspective, their burden of disease and what matters most for them. Putting the patient at centre in the SHARP collaboration gives the project an extra edge and value compared to many other European collaborative projects.</i></p>

General SHARP Progresses

Our CRC has made a lot of progress over the past months despite the COVID-19 pandemic and its impact on communications, timelines and availability of the SHARP Stakeholders. Here is a summary of our current projects:

The most Bothersome aspects In patients with severe Asthma and availability in the severe asthma Registries: the BIPAR Study

The main objective: 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 completed the study. 134 completed surveys have been collected and the analysis is ongoing.

Plan: Finalise the analysis and start writing the manuscript.

The Use of Biologics in Europe

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

Current status: The first draft of the manuscript with detailed results has been circulated.

Plan: A meeting will be held (end of October) to discuss the results and the manuscript with Physicians and Patients. Submission expected in November:

The Health Economics of Severe Asthma

The main objective: to adapt the Italian Budget Impact model for OCS analysis (already published) for use in the wider European context.

Current status: Data collection in the literature is ongoing for the fifth initial countries (Belgium, Spain, Slovenia, Sweden and Poland) and Spanish and Swedish models are under validation. There are some gaps regarding the costs of comorbidities.

Plan: Fill the gaps with the help of National Leads and move to the 2nd wave with 5th additional countries.

UNISA: Use of Nucala In Severe Asthma

The main objective: to understand the use of mepolizumab in usual clinical practice (as opposed to clinical trials) and assess the benefits for the mepolizumab-using patient population. The results will help to determine which patients starting treatment would most benefit from mepolizumab to control their disease.

Current status: 14 countries participating. Data collection underway via the Federated Analysis Platform (FAP).

Plan: Summary data collection with first results are expected in December.

Severe Asthma Questionnaire (SAQ): Burden of Asthma

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

Current status: 6 countries have signed Data Sharing Agreements and are ready to start and 5 are awaiting approval. The PatientCoach app is under final setting and refinement.

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

COVID-19 research response

The main objective: to understand 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 any future waves of COVID-19.

Current status: The analysis phase is completed and the manuscript is under preparation.

Plan: Manuscript submission is expected for end of October/beginning of November.

COVID-19 research extension: Vaccination study

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

Current status: The analysis is ongoing.

Plan: The first draft of the manuscript is expected in November.



New SHARP projects:

- **The Case Series of Rare Asthma** is a programme which aims to provide better understanding of different disease mechanisms of asthma and bring awareness of specific asthma phenotypes by focusing both on very rare asthma cases as well as series of lookalike cases with similar phenotypic features. The project will start in Autumn 2021.
- **The Investigator-led Initiative in FAP and SHARP central** programme aims is discussing how to gather and prioritise ideas from different investigators to use the FAP and SHARP Central. The following projects are under construction or already ongoing:
 - **Real-Life characteristics of Biologicals-treated severe asthma patients across SHARP Central** _ lead Stefania Principe, Netherland
 - **Use of LAMAs in severe asthma: a real-life assessment through the SHARP network** _ lead Alessandro Marcon & Marco Caminati, Italy
 - **Investigation of the effect of treatment with biologics on clinical asthma outcomes in patients eligible for 'explanatory' RCT vs ineligible** _ lead Jacob Sont & Anneke ten Brinke, Netherland
- **Bringing awareness value outside of SHARP** is a programme that aims to provide a communication plan that effective delivery of information to appropriate stakeholders. The plan is to identify the messages we need to promote, who we are targeting with those messages and through which channel(s).

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

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