REG

Respiratory Effectiveness Group

ADVANCES

in Real-life Respiratory Research

The Respiratory Effectiveness Group Newsletter
ISSUE OCTOBER 2024

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THE RESPIRATORY EFFECTIVENESS GROUP NEWSLETTER
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EDITORIAL

Joan B. Soriano
REG President

A NEW CHAPTER IN THE RESPIRATORY EFFECTIVENESS GROUP

It is with great honour and a sense of responsibility that I step into the role of President of the Respiratory Effectiveness Group (REG), an investigator-led, global not-for-profit respiratory medicine research initiative. I would like to begin by acknowledging the remarkable leadership of my immediate predecessors, Dr. Miravitlles and Professor Walter Canonica. Under their guidance, REG has solidified its reputation as a leader in real-life respiratory research, driving advancements that have tangibly improved patient outcomes. Their dedication and vision, as well as that from previous Presidents, have set a high standard, and I am committed to building upon the strong foundation they have laid, with continuity and passion. No doubt the savoir faire and dedication of Michael Walker, our star CEO, will maintain the momentum and help to navigate any hurdles.

During the last decade, REG has established itself as a powerful, influential think-tank, driving the respiratory research agenda, sometimes ahead of more established, bigger organizations. Its reduced size and flexible structure helped to generate internal discussions, brainstorming, and solidifying initiatives. REG has changed the respiratory landscape for good, recently with documents and position statements on inhaler choices, COVID-19 protection with face masks, asthma monitoring in children, evaluation of ILD diagnostic pathways, on the carbon footprint of inhalers, and else.

As we embark on this new REG chapter, it is essential to reflect on the importance of real-life research in respiratory medicine. Unlike traditional clinical trials, which often take place in controlled environments, real-life research captures the complexities and variances of everyday clinical practice. This approach is critical for understanding how treatments perform in diverse, real-world populations—patients of all ages from all socioeconomic and educational ranges, who may have multiple comorbidities, varying degrees of disease severity, combinations of risk and protective factors, multimedicated, and different levels of adherence to therapy, among other.

In an era where personalized medicine is increasingly the goal, real-life evidence provides the nuanced insights needed to tailor treatments more effectively. It allows us to bridge the gap between clinical efficacy and real-world effectiveness, with a balanced cost-benefit, ensuring that our interventions truly help those who need them most. As the new President, I aim to fostering initiatives that continue to prioritize real-life research, ensuring that our work remains relevant, impactful, and aligned with the needs of both patients and their carers.

This is particularly important now, as new therapies in respiratory medicine are being developed, in particular the biologic drugs for asthma and COPD, new antifibrotics for interstitial lung disease, and vaccines, among others. Real-life experience with these new treatments and their devices is required both for registration, but also to change practice guidelines, to conduct a true implementation research.

I take this opportunity to invite you to attend our next REG Summit in London on March 20 to 22, 2025 where these topics, together with other very relevant aspects of respiratory medicine, will be addressed by our REG Board members plus a selected group of internationally recognised speakers. More importantly, I remind you the importance of participating in the different Working Groups which are the bases of our research activities.

Fine line managers of mine say that, leading is serving. Humbly, I look forward to working with all of you to further our mission and advance the field of respiratory medicine through innovative, patient-centered research.

Thank you

Joan B. Soriano
President of REG
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REG TEAM UPDATE

Michael Walker
REG CEO

The very successful REG Summit was held in Vienna from 14th to 16th March. The stimulating scientific programme provided participants with valuable opportunities for in-depth discussions on the many issues and controversies that challenge everyday care of patients. More details about the meeting can be found in this issue.

The Summit celebrated 10 years of Respiratory Effectiveness Group (REG). On the day prior to the Summit scientific programme, REG Working Groups gathered for a unique research brainstorming session to map out new areas of focus for our real-life research. These ideas will be further explored and developed into new research proposals by the Working Groups. Our Working Groups continue to provide an important opportunity for our collaborators and supporters to connect, continue our active projects, or discuss new projects in development.

The last few months have also been focused on the various REG research projects that are in development with an update available in this edition. Here are two examples of our current projects in progress:

- Severe Asthma in Children: To determine the annual incidence and prevalence of severe asthma in children in the UK community using primary care data and applying different criteria for defining severe asthma.
- Predicting the Risk for First COPD Severe Exacerbation (PRECISE-X): To develop a risk model using common respiratory variables as indicators to help clinicians assess an individual's risk of a severe exacerbation at the time of diagnosis.

A more detailed update of these activities can be found later in this issue. If you would like to know more about these or any of our other projects, please contact REG at enquiries@regresearchnetwork.org .

In this issue, you will find more insights into what REG means to our collaborators and supporters, as well as an update on the tremendous work of the International Severe Asthma Registry (ISAR).

An important Save The Date Announcement: the next REG Summit will be held in London, UK, from 20th to 22nd March 2025, at the prestigious Royal College of Physicians in Central London. We hope everyone can join us for what promises to be a very exciting and special programme.

Lastly, I would like to acknowledge the support from our long-term supporters. Without their ongoing collaboration, much of the work of REG would not be possible. I hope others are encouraged by the activities of REG and the REG Working Group meetings and will consider collaborating with us later this year or planning to do so in 2025. We will continue to support and reach out to our partners as we work together in real-life research.

REG SUMMIT 2024

The REG Summit 2024 was a tremendous success and attracted a wide audience from around the world.

The event took place as a live in-person event from 14th to 16th March. Close to 100 participants from 20 countries travelled to Vienna for the meeting. The Summit included a Working Group Research Ideas brainstorming session, 10 exciting sessions on a wide and diverse range of key issues and topics in respiratory health, featuring talks and debates from esteemed speakers and guests. The Summit was accredited by the European Accreditation Council for Continuing Medical Education (EACCME®) with 9.5 European CME credits (ECMEC®s) and received accreditation by European Board of Accreditation in Pulmonology (EBAP) for 14.5 CME credits covering the whole programme.

The Scientific Programme included sessions on:

- Vaccination in Respiratory Diseases
- ILD/IPF – Update on emerging drugs
- Asthma management – mild asthma and anti-inflammatory reliever and When to institute triple therapy
- COPD – New definitions of exacerbation and What's next after triple therapy?
- Rhinitis: New therapies, Rhinitis and asthma, AIT & Biologics –a new opportunity for combination treatment?
- PRO/CONs discussing "Remission in severe asthma is attainable in most patients" and "DPIs are the device of choice in COPD and asthma"
- Chronic cough
- Mild- Moderate disease management
- ISAR Registry - improving the patient journey in severe asthma - lessons learnt future research
- Keynote: What registries have taught us in the last decade

All sessions are available to watch on demand. For more information, go to www.regsummit2024.org

Thanks to all the speakers, session chairs and meeting participants for making it such a great meeting.

Thank you also for the support from our sponsors: Platinum: Chiesi and Sanofi-Regeneron, Gold: Menarini, Silver: Roche and Contributor: OPC

The REG Summit will be return next year in London, UK from 20 – 22 March 2025.

We look forward to seeing you there!

REG SUMMIT 2024 ABSTRACTS

The meeting attracted abstract submissions which were presented as posters with authors from Greece, Canada, Mexico and Austria

PP01

NON-ALLERGIST PHYSICIAN ALGORITHM FOR PRESCRIBING ALLERGEN IMMUNOTHERAPY

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Background: Allergic rhinitis (AR) affects the health and well-being of 20-25% of Canadians, with detrimental effects on sleep quality, cognition, mood, mental health, and learning. However, with approximately 1 allergist per 133,000 people, some treatments are inaccessible to allergic Canadians. Current management approaches include avoidance and pharmacotherapy including nasal corticosteroids and nasal or oral antihistamines, while allergen immunotherapy (AIT) offers an effective long-term solution. Sublingual (SLIT) immunotherapy can significantly improve AR and asthma symptoms, reduce allergen sensitivity, modify long-term tolerance, and potentially prevent the development of other allergic diseases. Despite clinical efficacy, safety, and cost-effectiveness, SLIT is underutilized, partly related to the limited number of allergists in Canada. Given the home administration and safety of SLIT, non-allergists can play a vital role in the delivery of SLIT to the allergic population.

Methods: AK conceptualized and developed the initial draft of a treatment algorithm for non-allergists. This algorithm and treatment set was reviewed at an in-person meeting of an expert panel of four family physicians with a special interest in allergic disease and seven allergists. Consensus agreement resolved discrepancies.

Results: A focused algorithm with treatment recommendations was developed for non-allergists to diagnose and implement SLIT in the allergic population. This protocol requires accurate diagnosis based on the history of the timing of clinical symptoms, and selected and focused investigations, including skin testing and serum-specific IgE. Patient selection was prioritized with relevant cautions highlighted. With an allergic history and investigations consistent with allergy to dust mites, trees, grass, or ragweed pollen, the initiation of SLIT by non-allergists was encouraged/recommended. An annual review of clinical effectiveness was highlighted; complicated patients or non-responders should be referred for allergist assessment. Future validation and implementation are pending.

Conclusion: Safe and effective SLIT treatment for AR can be implemented by non-allergists with a focused algorithm.

REG SUMMIT 2024 ABSTRACTS

PP02 SEMAGLUTIDE, A TREATMENT FOR ASTHMA?

Alan Kaplan
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Obese patients with Asthma are well known to have poorer control, more frequent exacerbations, and resistance to inhaled corticosteroids. Obesity can be multifactorial, with a quick division being those with T2 elevated asthma who are not controlled, do not exercise, and secondarily gain weight, or those who have obesity as a primary problem and can then present with either T2 elevated or T2 low disease. The common phenotype for the latter is a younger female with obesity and an older onset of asthma. Due to the ICS resistance, therapeutic options are somewhat limited, but evidence clearly has shown that weight loss from behavioral interventions or bariatric surgery can improve asthma outcomes. Diabetes is in itself a proinflammatory condition that increases risk of lung complications as well. As such, treatment with Semaglutide can lead to weight loss and has been shown in diabetic patients to reduce exacerbations better than other diabetic medications (1). Weight loss can mechanistically improve asthma outcomes due to mechanical factors or changing inflammation levels (2). The hypothesis, as shown in previous case series (3) for these cases is that Semaglutide can lead to weight loss, and potentially change the inflammatory milieu with different inflammatory mediators in obesity such as IL6, TNF alpha, adipokine leptin, adiponectin and improve asthma outcomes. I describe five patients, in four of whom the addition of Semaglutide for weight loss also significantly improved asthma control and allowed titration down of asthma medications as well as proton pump inhibitors. Unfortunately, in the fifth case, in a patient with concomitant binge eating disorder, there was no weight loss and the benefits were not seen. Semaglutide improves weight loss, and in obese asthmatic patients may control Asthma through a number of mechanisms and should be considered as a therapeutic asthma treatment.

Patient no.	Age	Stepped up therapy	FEV1 pre	Weight loss	Fev1 post	Asthma drug stepped down to	PPI	Patient satisfaction	T2?
1	54 F	High dose triple	60%	75 lb	90%	Low dose ICS/ LABA	Discontinued Symptoms free	High	BEC 300, FENO 13 Allergy to dog
2	29 F	High dose triple	100%	50 lb	120%	Medium dose ICS/LABA	Decreased to prn	High	BEC 400 IgE 174 FENO 42
3	32F	High dose triple	65%	15 lb	80%	Medium dose ICS/LABA	continued	Moderate	BEC 100
4	40F	High dose triple	55%	65 lb	100%	Low dose ICS	Decreased from BID to OD	High	FENO 11
5	39	High dose triple	75%	0	72%	High dose ICS/LABA. Application for biologic pending	BID	Low	FENO 50 BEC 400

REG SUMMIT 2024 ABSTRACTS

PP03

CURRENT AND OPTIMAL PRACTICES IN CHILDHOOD ASTHMA MONITORING: THE PERSPECTIVE OF CAREGIVERS

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Introduction: Childhood asthma control largely depends on rigorous and regular monitoring. A recent international multistakeholder survey study showed that in most cases evidence-based standards are followed across the globe, however, it also unveiled differences between actual and optimal monitoring practices. Therefore, the objective of this study was to assess current and optimal monitoring practices according to caregivers of children with asthma.

Methods: We surveyed parents or guardians of children with asthma between May and August 2021, regarding actual and optimal monitoring practices concerning various aspects of asthma management during and between office visits. The survey was disseminated globally through the European Federation of Allergy and Airways Diseases Patients' Associations (EFA), the Global Allergy and Airways Patient Platform (GAAPP), and Pediatric Asthma in Real Life (PeARL) members.

Results: Forty-nine participants, from across Europe, North America, Asia, and Africa, provided complete responses. More than 80% of the respondents had direct experience with children with mild/moderate asthma. Two-thirds of the participants reported regular monitoring visits at 2-6 months with an approximate duration of 10-30 minutes. Symptoms control, overall health, and lung function assessment were deemed as high or very high priority during office visits by more than 80% of the respondents, whereas medication adherence was additionally considered for self-monitoring. Different patterns emerged when assessing differences between actual and perceived optimal use of monitoring tools. Of note, the actual frequency of comorbidities assessment, various lifestyle parameters evaluation, and lung function measurements fell short of the perceived optimal ones. Less than 25% of the respondents were recommended any self-monitoring tool, the majority of whom found them useful.

Conclusion: The current survey suggests that patients' needs and expectations are only partly served by the existing monitoring practices. The advent and wide implementation of new digital technologies may assist in the optimization of the monitoring process, hopefully resulting in improved asthma-related outcomes.

REG SUMMIT 2024 ABSTRACTS

PP04

CLINICAL PROFILE OF 457 LATIN-AMERICAN SEVERE ASTHMA PATIENTS IN MEXICO: DIFFERENCES BETWEEN THOSE WHO ARE AND THOSE WHO ARE NOT ON BIOLOGICS (OMA, DUPI, ANTI-IL5).

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Background: Mexico has participated in the International Severe Asthma (SA) Registry (ISAR), a global registry of SA patients. We search to describe the baseline clinical profile of the Mexican SA patients in the ISAR database: those on omalizumab (OMA), dupilumab (DUPI), and anti-interleukin 5 agents (antiIL5) and those not on any biologic (NoBx).

Method: clinical data from SA patients 4-85 years old were uploaded into the ISAR online platform in 13 establishments throughout the country, including social security and private clinics. After data curation patients were divided into four groups according to their actual therapy: NoBx OMA, DUPI and antiIL5.

Results: 458 patients total. 174 (38%) OMA: of those 140 were already on the Bx before study-start, 32 started OMA during the study, 2 stopped. 54 (12%) on DUPI: 38 started the Bx before study-start, 14 were switched from OMA, 1 from antiIL5 and one was on DUPI+OMA. 111 (24%) antiIL5; of those 77 started the Bx before study-start, 9 with study-start, 22 were switched from OMA and 3 were on antiIL5+OMA. 58/111 were on mepolizumab, 45/111 on benralizumab. There were 119 noBx. In all 4 groups 20-35% was male and over 94% of Latin-American ethnicity. Median age 47-53y at study-entry was similar, except for DUPI, where more children were recruited (21y). Median age-of-asthma-onset was 28-32y (DUPI 9y), with most having a lapse between asthma and Bx start of 15-20 years. Median height 1.56-162cm, and BMI 23.6-29.1, which trended to be higher in No-Bx: 29.1 (Q1-Q3: 25.15-34.3kg/m2). As for asthma severity the anti-IL5 group tended to be slightly more severe with mean/median asthma control test 13.5/13 (others 14-15), more exacerbations needing systemic CS (2.8/3 per yr), emergency room visits (2.33/2 per yr) and hospitalizations (0.67/0 per yr), see table. Meanwhile, DUPI patients used more systemic CS, but less emergency department treatment. In each group, there were 1-2 patients with a history of bronchial thermoplasty. At baseline long-term CS were documented in 46% of no-Bx, 9.8% of OMA, 7.8 of antiIL4 and 18% of antiIL5 patients.

Conclusion: We only observed some differences between yes-NoBx groups. The high % of LT-CS in no-Bx is striking. The height of our ISAR patients is 2cm lower than the general Mexican population. Median BMI of NoBx is close to obesity (>30). Among the Bx the anti-IL5 group trended to be more severe.

REG SUMMIT 2024 ABSTRACTS

	N	Mean	SD	Min	Max	Median	Q1	Q3
Exacerbations needing systemic CS								
No Bx	113	1.59	1.14	0	5	2	1	2
OMA	162	1.81	1.68	0	7	1	0	3
antiIL4	45	3.02	2.08	1	12	3	2	3
antiIL5	98	2.79	1.32	1	6	3	2	3
Emergency room								
No Bx	109	1.19	0.833	0	4	1	1	2
OMA	113	1.88	2.741	0	10	0	0	3
antiIL4	46	0.57	1.48	0	7	0	0	2
antiIL5	99	2.33	1.97	0	12	2	0.5	3
Hospital								
No Bx	86	0.53	0.52	0	2	0	0	1
OMA	93	0.49	0.98	0	4	0	0	1
antiIL4	41	0.29	0.60	0	2	0	0	0
antiIL5	81	0.67	1.18	0	5	0	0	1

REG SUMMIT 2024 ABSTRACTS

PP05

COMORBIDITIES AND T2 INFLAMMATORY PROFILE OF 457 LATIN-AMERICAN SEVERE ASTHMA PATIENTS IN MEXICO: DIFFERENCES BETWEEN THOSE WHO DID AND DID NOT START BIOLOGICS (OMA, DUPI, ANTI-IL5).

Désirée Larenas-Linnemann[1], Saraid Cerda Reyes[2], Nidia Karen Castillón Benavides[2], Angélica Contreras-Contreras[3], Ulises García Ramírez[4], Lilia Barboa[5], Nadia Aguilar Hinojosa[6], Karen Rivera Alvarado[7], Itzel Ochoa García[8], María dela Luz García-Cruz[9], Ricardo Campos-Cerda[10], Yair González Tuyub[11], Victor González[12], Hugo Alberto Azuara[13], Elsy Navarrete[12], Laura Dafne Mendoza Reyna[14]

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Background: Mexico has participated in the International Severe Asthma (SA) Registry (ISAR), a global registry of SA patients. We search to describe the T2 biomarker profile of the Mexican SA patients in the ISAR database: those on omalizumab (OMA), dupilumab (DUPI) and anti-interleukin 5 agents (including mepolizumab and benralizumab, antiIL5), as well as those who are not on any biological treatment (NoBx), to compare between groups and later be able to compare them also to the global ISAR patients.

Method: T2 biomarker data from SA patients 4-85yo were uploaded into the ISAR online platform in 13 establishments throughout the country, both from social security and private clinics. T2 biomarkers included blood eosinophil count (BEC), fractional exhaled nitric oxide (FeNO), and total serum immunoglobulin E (IgE). Apart from the normal data cleaning, data curation included eliminating all post-Bx values. All patients were divided into four groups according to their actual therapy: NoBx OMA, DUPI, and antiIL5.

Results: There was a total of 458 patients. Of those, there were 119 noBx, 174 (38%) were on OMA, 54 (12%) on DUPI and 111 (24%) on an antiIL5 (58/111 on mepolizumab, 45/111 on benralizumab). Table 1 shows the frequency of comorbidities in the four different groups. Table 2 the pre-Bx biomarkers. As we only included biomarker values pre-any-biologic starting date, values in Table 2 are lower than the included patient numbers, as not all patients in the registry had pre-Bx biomarker values. Mean and median BEC values were higher in DUPI and anti-IL5 patients (median 500-540 versus 385-390, $p<0.01$), mean and median FeNO higher in the DUPI group, while mean and median total serum IgE was higher in OMA and DUPI patients ($p<0.05$).

Conclusion: In this large registry-based Latin-American SA patient group, anxiety, depression, and sleep apnea were more frequent in the no-Bx group. Nasal polyps were much more frequent in the antiIL5 group, partly due to limited access to antiIL4. We also observe several differences in the frequency of biomarkers pre-biologic initiation, related to what the biologic therapy best seems to tackle (e.g. higher pre-Bx IgE in anti-IgE and higher BEC in anti-IL5).

REG SUMMIT 2024 ABSTRACTS

Table 1. COMORBIDITIES (current and past)

Allergic*	Allergic rhinitis		Chronic rhinosinusitis		Atopic dermatitis		Nasal polyps	
	% Yes (current/past)	n/N	% Yes (current/past)	n/N	% Yes (current/past)	n/N	% Yes (current/past)	
No Bx	90%	91/101	60%	71/119	42%	50/119	10%	23/119
OMA	86%	111/128	39%	67/170	6%	10/171	19%	31/170
antiIL4	55%	23/42	19%	10/54	32%	17/54	13%	7/54
antiIL5	78%	69/88	80%	88/111	8%	8/111	55%	8/111
Non-allergic**	**Anxiety**		**Depression**		**Sleep apnea**		**GERD**	
	% Yes (current/past)	n/N	% Yes (current/past)	n/N	% Yes (current/past)	n/N	% Yes (current/past)	
No Bx	22%	26/119	13%	16/119	25%	25/102	4%	4/102
OMA	4%	7/127	2%	4/170	2%	3/129	4%	5/129
antiIL4	0	0/54	2%	1/54	0	0	5%	2/41
antiIL5	11%	12/111	7%	1/89	1%	1/89	18%	16/89

*Atopy in 58% of the no-Bx, 93% of the patients on OMA, 76% of those on DUPI and 94% of the anti-IL5 patients.
** There were a total of 10 EGPA or HES patients (4 in the no-Bx, 0 in the OMA, 1 in the antiIL4 and 5 in the anti-IL5 groups)

Table 2. BIOMARKERS (pre-biologic initiation)

	N	Mean	SD	Min	Max	Median	Q1	Q3
Blood eosinophil count (BEC)								
No Bx	108	486	472.6	40	3720	385	260.525	580
OMA	89	461	367.3	0	2160	390	230	610
antiIL4	37	559	537.6	1	2660	540	200	650
antiIL5	85	673	651.3	0	4833	500	300	830
FeNO								
No Bx	29	52	35.8	0	137	43	30	64
OMA	85	38	31.2	0	159	29	16	55
antiIL4	36	71	46.0	1	177	73.5	21.75	105.25
antiIL5	60	54	50.5	6	258	38	22.75	67
Total serum immunoglobulin E (IU/mL)								
No Bx	98	421	474.7	0	2520*	247.5	109.75	559.75
OMA	110	772	1625.3	8.5	13200	360	165.5	670
antiIL4	38	619	804.7	9	4134	384.5	115	713
antiIL5	87	363	622.4	7.2	3958.9	152	50.575	472

* Not taking into account a non-certified value of 6900 IU/mL

Transforming Respiratory Care

Our ambition is to transform Respiratory and Immunology care for patients, moving beyond symptom control to disease modification, remission and, one day, cure.

AstraZeneca

CLINICAL MANAGEMENT PERSPECTIVE

UNCONTROLLED COPD: DIFFERENTIATING DIFFICULT-TO-TREAT FROM SEVERE COPD

The Global Initiative for COPD (GOLD) defines COPD severity based on airflow limitation (GOLD I-IV), symptoms and exacerbations (GOLD A, B, E), irrespective of level of treatment. It further emphasizes that treatment goals are to reduce risk factors and control symptoms and exacerbations using (non-)pharmacological interventions. However, a significant proportion of patients experience persistent symptoms and/or exacerbations despite maximal level of (inhaled) therapy and may be referred to as uncontrolled COPD. Indeed, uncontrolled COPD has been shown to predict subsequent exacerbation risk in the next 6 months.[1]

Currently, GOLD does not include level of treatment intervention in the severity grading of COPD, and furthermore it does not differentiate uncontrolled patients into difficult-to-treat versus severe COPD. In contrast, severe asthma has been defined and differentiated from difficult-to-treat asthma by the Global initiative for asthma (GINA), with specific management recommendations for each subgroup. Where in many cases, the disease is difficult-to-control due to modifiable factors such as incorrect inhaler technique, poor adherence, smoking or comorbidities, or because the diagnosis is incorrect. In severe cases however, the disease is uncontrolled despite optimal management of these modifiable factors. It is recommended that severe asthma patients are treated by specialists, in multidisciplinary severe asthma clinics if available, with expertise to further phenotype patients and manage accordingly (often with biologicals).

Moving into a new era of biological treatments for COPD, we should therefore review the current COPD severity grading and consider differentiation between patients with difficult-to-treat COPD and those having severe COPD (Fig. 1). Such approach requires a multidimensional systematic assessment of behavioral, pulmonary and extrapulmonary treatable traits enabling optimization of care of difficult-to-treat COPD patients. Multidisciplinary consultation of remaining severe COPD patients allows phenotyping for further specialist care, such as lung volume reduction interventions, biological treatment, home non-invasive ventilation, and lung transplantation. Development of real world registries are required that will generate data that will complement clinical trials and inform clinical and policy decisions on managing patients with severe COPD.

Difficult uncontrolled COPD
(ICS/LABA/LAMA or LABA/LAMA during >12 months)

Systematic assessment*

Difficult-to-treat COPD	Severe COPD
Poor control related to:	**Poor control despite:**
• Poor adeherence	• Good adherence
• Suboptimal inhalation technique	• Optimal inhalation technique
• Exposure to cigarette smoke/irritants	• Management of exposures
• Unvaccinated	• Vaccinated
• Co-morbidities	• Management of co-morbidities
• Physical inactivity	• Pulmonary rehabilitation
• Poor self-management	• Self-management skills

*Including a minimum of 6 months of specialist management

Modified from Porsbjerg et al.; Eur Clin resp J. 2018

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References

Archivos de Bronconeumología, Volume 57, Issue 2, February 2021, Pages 122-129

WORKING GROUP UPDATE

ADHERENCE WORKING GROUP

The scoping project is progressing and includes two manuscripts currently under revision. The first manuscript explores existing knowledge and identifies areas for further research. The second manuscript will evaluate strategies for following respiratory guidelines and provide recommendations for improvements.

ALLERGY WORKING GROUP

The group are currently developing new project ideas in allergic asthma, rhinitis, and allergen immunotherapy.

CHILD HEALTH WORKING GROUP

The group has recently published a paper in Pediatric Allergy and Immunology - 2024 Apr;35(4): e14129 - titled "Recommendations for Asthma Monitoring in Children: A PeARL Document Endorsed by APAPARI, EAACI, INTERASMA, REG, and WAO." This paper is part of the PEARL project, which aims to identify and address critical clinical questions and policy needs in pediatric asthma, leading to evidence-based recommendations. Currently, the group is gathering new data on biomarkers and treatments, with plans to publish the reviews in the coming months.

The WG is also actively engaged in a retrospective database study and is currently analysing data obtained from the OPCRD to assess the prevalence of severe asthma in children within UK primary care, using seven different definitions. The results will be used to create a comprehensive report and a manuscript, both of which are expected to be submitted shortly.

COPD WORKING GROUP

The final results from the prospective observational study, which aimed to determine the prevalence of suboptimal PIF in COPD patients and investigate its predictive value for exacerbations and symptom burden, have been analysed. A report has been prepared and is currently under revision by the PIs. Additionally, a manuscript based on the patient data collected during the baseline visits have been submitted and is now under peer review.

The WG is also working on the PRECISE X project, which focuses on developing a risk prediction model for initial severe exacerbations in COPD patients. The analysis of data obtained from CPRD is currently underway, and the findings are expected to be reported and published in the coming months.

A significant achievement for the group is the study on the effects of triple pharmacological therapy on post-discharge outcomes in COPD patients, which has garnered interest from companies and recently secured funding. The study protocol has been prepared and is currently under revision, with plans to finalise the contractual arrangements and start the study by the end of the year.

COST EFFECTIVENESS WORKING GROUP

A research proposal for "A Global Evaluation of the Economic Impact of Time to Initiation of Biologic Treatment of Severe Asthma Patients" has been developed. This project seeks to assess the national-level cost-effectiveness of biologic treatment, examining and comparing the economic impact and lifelong disease burden associated with early versus delayed treatment between countries. The project is currently under discussion with potential funders.

DATABASES AND CODING WORKING GROUP

Several members of the WG have shown interest in exploring the onset and progression of COPD in people with Type II diabetes. The concept is still being finalised, and once complete, a proposal will be prepared to seek support for the project.

Also, the Standout study, which focuses on standardising respiratory definitions and outcomes using real-world data, has attracted interest from a few companies, but the project is still seeking to secure funding.

ENVIRONMENT, EPIDEMIOLOGY AND AIRWAYS WORKING GROUP

The manuscript "Inhaler Choice: A Global Survey to Identify Patient & Healthcare Professional Priorities" has recently been published in Chest (https://doi.org/10.1016/j.chest.2024.06.3774). The project used surveys to identify the priorities of HCPs and asthma/COPD patients in inhaler device choice and planetary health. The REG opinion piece on the subject has been submitted to the European Respiratory Journal and is under review.

A new research proposal has been developed on inhaler switching in asthma and COPD patients. Using retrospective UK primary care data, the project aims to investigate patterns of inhaler switching among asthma and COPD patients in primary care settings, assess the association between inhaler switching and exacerbation rates and healthcare resource utilisation, and identify factors influencing patient outcomes. Additionally, the project will examine the economic implications of inhaler switching. The proposal is currently under discussion with potential funders.

ILD WORKING GROUP

The ILD Working Group has had a busy time, with five projects in development:

- **Project 1**: "Mapping ILD Diagnosis: Risk, Referrals, and Missed Cases in Primary/Secondary Care". This project aims to analyse referral patterns to ILD specialist centres from primary/secondary care using UK primary/secondary care datasets. The research hopes to create a comprehensive map of referral pathways in the UK and identify potentially missed and undiagnosed ILD patients within the healthcare system via a risk prediction model.
- **Project 2**: "Development of a Global Composite Staging System for IPF/PPF Disease Progression". This project aims to determine the relevant diagnostic and clinical indicators associated with disease progression in IPF and PPF. The goal is to create and validate a global comprehensive staging system for IPF and PPF, utilising worldwide retrospective data from ILD centres and registry data.
- **Project 3**: "Towards Standardisation in IPF Registry Data: A Global Study of Key Outcomes and Data Elements for Disease Management". This project aims to determine essential data elements for standardisation across clinical registries to ensure consistency and comparability of data collection practices. It will also evaluate the ability of registries to assess multiple key outcomes, such as disease progression, treatment response, and healthcare utilisation.

Proposals are under review by the scientific steering committees.

Two research proposals have been developed, focusing on pulmonary hypertension in ILD patients (PH-ILD):

- **Project 4**: "Genetic Determinants of Pulmonary Hypertension in Interstitial Lung Disease: Uncovering Pathways for Early Detection". This project investigates the overlap and distinction of genes associated with Group 3 PH in ILD patients to highlight unique genetic markers for targeted screening and therapeutic interventions.
- **Project 5**: "Predicting Pulmonary Hypertension Risk in ILD Patients Using Real-World Data". This project aims to develop and validate a global risk prediction model to identify the most relevant diagnostic indicators associated with the risk of Group 3 PH development in ILD patients using ILD and PF registries. The project hopes to analyse geographical and demographic variations in the prevalence and risk factors of PH in ILD patients across different countries and regions, and identify potential gaps for linkage between ILD and PF registries.

Proposals are currently under discussion with potential funders.

Additionally, the manuscript "The Interstitial Lung Disease Patient Pathway: From Referral To Diagnosis" has been accepted by ERJ Open Research and will soon be published. The project aimed to characterise ILD diagnosis across 64 countries, identifying similarities and differences in the patient diagnostic pathway between ILD specialist centres, non-ILD-specialist centres, and different regions.

The group looks forward to holding a working group meeting at the 22nd International Colloquium on Lung and Airway Fibrosis (ICLAF) in Athens this October.

SEVERE ASTHMA AND BIOMARKERS WORKING GROUP

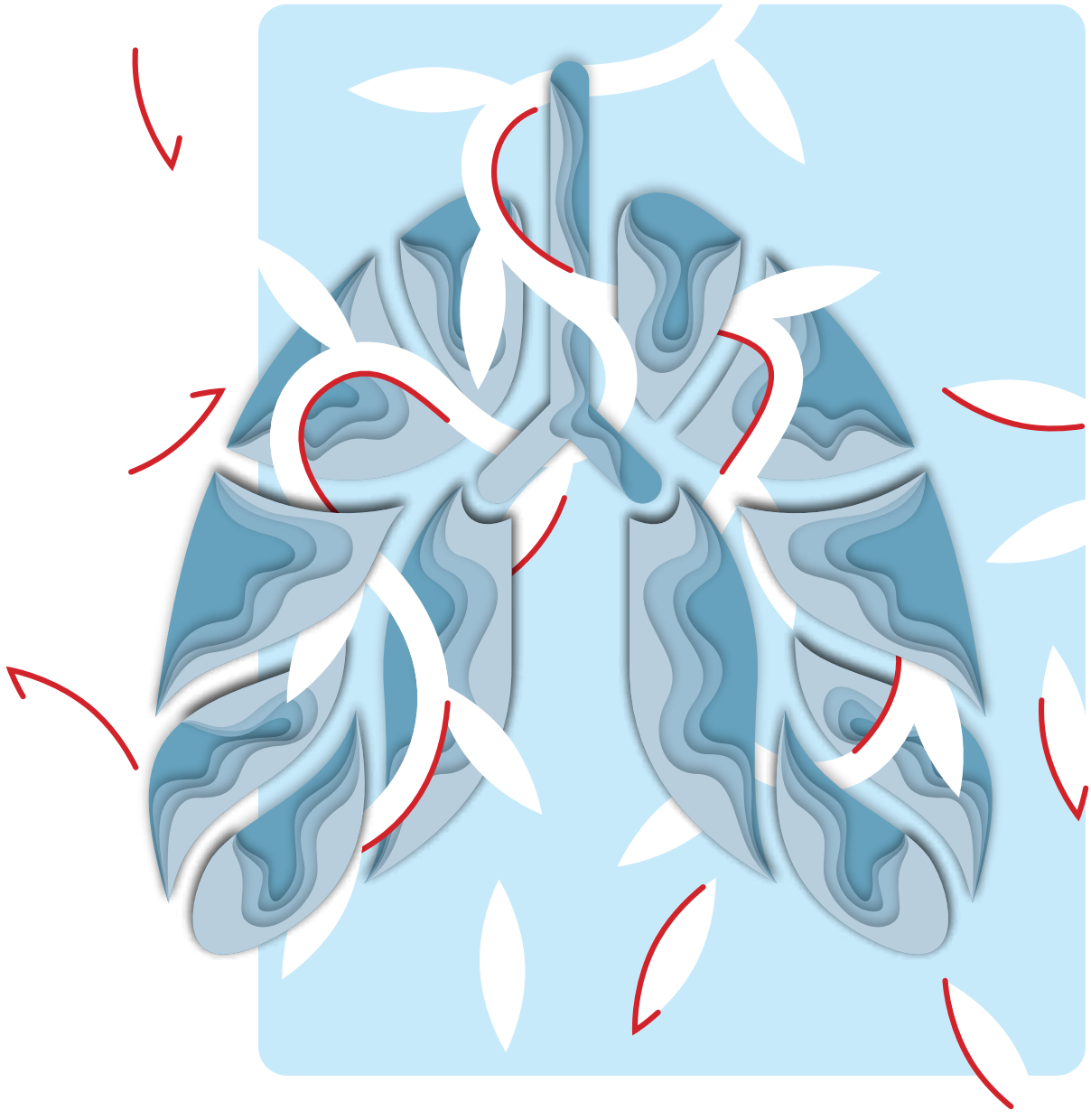
Project opportunities and new ideas are still under discussion.

TECHNOLOGY WORKING GROUP

Potential exciting new project ideas in artificial intelligence, remote consultation and digital health technologies are being discussed.

VACCINES WORKING GROUP

A number of collaborators have expressed interest in investigating the uptake and adherence of vaccine use recommendations in respiratory care. To this end, a proposal for the "Vaccine Uptake and Exacerbations in COPD Patients: A Retrospective Study" has been developed. The project aims to examine vaccine coverage and uptake trends in COPD patients, as well identify the clinical and economic impacts of vaccination. Support is being evaluated.



WHAT REG MEANS TO ME

I came to know about REG from one of my friends years ago, and since then I found that this self-selected, highly motivated group of professionals are one of my favourite places to engage, exchange ideas, clinical observations, and research in the field.

Members of REG have a common objective as to improve current healthcare practices and advance science to achieve this goal! Even though we meet most of our colleagues at regular annual meetings, but I discovered that REG meetings are unique!

REG meetings differ from other "bigger meetings" as it focusses on a group of passionate experts in the field of respiratory medicine and serves as a source of a great informal inspiration for research ideas with peers across different continents. These meetings crosses all geographical borders and provides a platform for sharing experiences and strategies from different countries and healthcare systems, enriching the global knowledge pool, something that might not be achieved else where! Working directly with Prof. Walter Canonica was a delight because of his unwavering dedication for using highly impactful clinical research to enhance patient outcomes and healthcare practices!

Yes, I have been pleasantly surprised by the diversity of experts I have met from all around the world! One of the main advantages of working at REG is the opportunity to collaborate with world-class professionals on a global scale.

Additionally, the high output of articles that have been published has established the benchmarks for assertions about respiratory health that REG has acknowledged as having a significant impact on the field!

With the REG family expanding rapidly, we must never lose sight of our core responsibility to our patients—better clinical outcomes and better management, which are in line with REG's aims and objectives!

MONA AL-AHMAD MD FRCPC

Professor of Internal Medicine, Allergy and Clinical Immunology
College of Medicine, Kuwait University
Chairman of Allergy Department, Al-Rashed Allergy center
Ministry of Health, Kuwait
President of Kuwait Society of Allergy and Clinical Immunology
Faculty Chair of Allergy and Clinical Immunology Fellowship program, Kuwait

To me, REG represents a hub for meeting people with the same interests but different ideas and expertise, united by the goal of improving the wellbeing of patients with respiratory diseases. From this perspective, REG is the ideal place for developing collaborative research based on the real needs reported by patients. It is the ideal spot for exploring, in daily practice, research hypotheses that are supported by scientific evidence and, conversely, for verifying to what extent the efficacy data of medical interventions are effective in real life. REG is a fantastic conceptual place for bringing research closer to practice by supplementing policy documents with scientifically incontrovertible data derived from real-life.

It makes me wonder what I can contribute to this amazing working group. As I reflect, I see 30 years as a respiratory specialist, in daily contact with patients with lung diseases. I see how our approach to diagnosis and therapy has changed over time and how this has been guided by the evidence brought by EBM research. I also see, unfortunately, that the gap between research findings and real-life results has remained very wide, indicating that something needs to change. I have always felt that research on patient-reported outcomes (PROs), to which I have devoted many years, conducted in real life with rigorous scientific methodology, is a game changer. I hope that the experience I have gained in the development, validation, and use of tools for the evaluation of PROs can contribute to the integration of evidence from real-life observations into clinical guidelines, one of the many goals of the REG.

FULVIO BRAIDO, MD

Professor of Respiratory Medicine - University of Genova (Italy)
Head of Respiratory Diseases and Allergy Department
Research Institute and Teaching Hospital San Martino - Genoa
President of Interasma - Global Asthma Association (GAA)
Editor in Chief of Journal of Asthma

WHAT REG MEANS TO ME

My name is Gina Amanda, a pulmonologist from Indonesia, with a special interest in interstitial lung diseases (ILD). I have been involved in the REG since 2022 in Idiopathic Pulmonary Fibrosis (IPF) /ILD working group. It was a great opportunity for me to collaborate with ILD experts around the globe, particularly for research in ILD field. In this field, many aspects require further investigation, including determining criteria and tools that can be used for diagnosing of disease, assessing disease progression, selecting the appropriate treatment, and predicting patient outcomes.

As I am based in a developing country in the Southeast Asia region, I noticed that several aspects are unequal compared with developed countries. In developed countries, ILD patients have access to a wide range of diagnostic procedures necessary for determining the appropriate diagnosis and treatment for their conditions. Additionally, both physicians and patients there can participate in many studies. Conversely, the diagnosis and treatment of ILD patients are very challenging and often precluding ideal management in developing countries. Moreover, many of us were not involved in the studies.

In REG, I found the approach was distinct. The IPF/ILD working group conducts studies that gather real-world data, reflecting the actual experiences of ILD patients and the physicians treating them across various regions. Such collaboration is crucial as it aims to ensure equitable access for ILD patients globally. It is also imperative to understand patient management strategies that consider race, genetic variants, beliefs, and geographic distribution.

Ultimately, I am honored to be part of this group and I strongly encourage my colleagues, mainly those in the Southeast Asia region, to also join REG. I am optimistic that our collective efforts will lead to significant advancements in patient health management.

GINA AMANDA
Pulmonologist, Jakarta Islamic Hospital Cempaka Putih, Indonesia

The Respiratory Effectiveness Group (REG) is a pivotal platform for collaborative innovation and critical analysis in the realm of chronic respiratory diseases. It unites key figures—from clinical specialists to industry affiliates—around a common goal: to explore a spectrum of issues, from cutting-edge technological advancements to biomarkers, pragmatic real-world evidence (RWE) studies, and the practical application of guidelines.

What sets REG apart is its hands-on approach, which zeroes in on addressing the actual data voids encountered in everyday clinical scenarios. The value of REG's open discourse and collective intelligence cannot be overstated; it plays a crucial role in shaping clinical practice guidelines, pharmaceutical development, and vigilant post-marketing oversight.

REG's commitment to the progression of respiratory medicine is truly commendable. Its activities range from scrutinizing extensive datasets to fostering global expert collaborations and disseminating pivotal findings. In essence, REG's efforts serve as a conduit between theoretical research and clinical application, ensuring that empirical evidence is effectively converted into tangible enhancements in patient care.

In recognition of REG's contributions: Thank you for being a lighthouse of evidence-based medicine, advocating for research that prioritizes patients, and effectuating a significant impact on countless lives.

GABRIELA ISPAS
Head of GMA Pipeline, AIR Chiesi Farmaceutici

INTERNATIONAL SEVERE ISAR ASTHMA REGISTRY

ISAR Country Updates

The **International Severe Asthma Registry (ISAR)**, marches through its 7th year, with data from **19,757 severe asthma patients** from **28 collaborating countrie**s. We look forward to implementing quality improvement initiatives with our collaborating countries during the 3-year ISAR extension (2024 – 2026).

ISAR in 2024: Publications

ISAR is delighted to have published six articles in the first half of 2024. Our FULL BEAM II study on "Exploring definitions and predictors of severe asthma clinical remission post-biologic in adults" was **published** in the esteemed Blue Journal; it is highlighted by Prof Ian Pavord to be "the largest prospective analysis and the most useful information we have on remission and its determinants in severe asthma" in his **editorial** published in the Blue Journal. To view ISAR's publications, please visit the **ISAR website.**

Wechsler M.E., et al.
"Association between T2-related co-morbidities and effectiveness of biologics in severe asthma"
Am J Respir Crit Care Med, 2024

Full Article | Press Release | Slide Deck

Conclusions: These findings highlight the importance of systematic comorbidity evaluation. The presence of chronic rhinosinusitis +/- nasal polyps or nasal polyps may be considered a predictor of biologic effectiveness in patients with severe asthma.

Lee T.Y., et al.
"International variation in severe exacerbation rates in patients with severe asthma"
CHEST, 2024

Full Article | Press Release | Slide Deck

Conclusions: Individuals with similar patient characteristics but coming from different jurisdictions have varied severe exacerbation risks, even after controlling for patient and disease characteristics. Disease management guidelines should recognize such between-country variability. Risk prediction models that are calibrated for each jurisdiction will be needed to optimize treatment strategies.

Porsbjerg C.M., et al.
"Association between pre-biologic T2-biomarker combinations and response to biologics in patients with severe asthma"
Front Immunol, 2024

Full Article | Press Release | Slide Deck

Conclusions: The ability of higher baseline BEC, FeNO and their combination to predict biologic-associated lung function improvement may encourage earlier intervention in patients with impaired lung function or at risk of accelerated lung function decline.

Perez-de-Llano L, et al
"Exploring definitions and predictors of severe asthma clinical remission post-biologic in adults"
Am J Respir Crit Care Med, 2024

Full Article | Editorial | Press Release | Slide Deck

Conclusions: One in 5 patients achieved 4-domain remission within 1-year of biologic-initiation. Patients with less severe impairment and shorter asthma duration at initiation had a greater chance of achieving remission post-biologic, indicating that biologic treatment should not be delayed if remission is the goal.

Scelo G, et al.
"Exploring definitions and predictors of response to biologics for severe asthma"
J Allergy Clin Immunol Pract, 2024

Full Article | Press Release | Slide Deck

Conclusions: Our findings underscore the multi-modal nature of 'response', showing that many responders experience residual symptoms post-biologic-initiation, and that predictors of response vary according to outcome assessed.

Denton E., et al.
"Real-world biologics response and super-response in the International Severe Asthma Registry cohort"
Allergy, 2024

Full Article | Press Release | Slide Deck

Conclusions: Most patients with severe asthma are ineligible for RCTs of biologic therapies. Biologics are initiated in patients who have worse baseline impairments than non-initiators despite similar biomarker levels. Although biologic initiators exhibited clinical responses and super-responses in all outcome domains, 40–50% did not meet the response criteria.

ISAR in 2024: Abstracts

ISAR presented posters and an oral presentation at ATS 2024 and EAACI 2024. We look forward to presenting three posters at the upcoming ERS 2024 congress. To view ISAR's abstracts, please visit the **ISAR website**.

Chen W., et al.
"Development and validation of an individualised risk prediction model for exacerbations in patients with severe asthma in real-world settings"
Am J Respir Crit Care Med, ATS 2024

Abstract

Conclusions: The most important predictor was exacerbation history in preceding 12 months. Risk prediction models with routinely collected clinic registry data can yield good discrimination on severe asthma patients, especially in predicting multiple (≥2) exacerbations in the next 12 months. This model can target high-risk patients for prevention, guide treatment escalation, and improve the efficiency of clinical trials.

Yadav C.P., et al.
"Unveiling the real-world causal interaction of essential risk factors in severe asthma exacerbation: a Bayesian network analysis"
Am J Respir Crit Care Med, ATS 2024

Abstract

Conclusions: Direct influencers of future asthma exacerbations included BEC, past 12-month exacerbation history, emergency room visits, invasive ventilation, and macrolide use. This study revealed the causal connections between essential prognostic factors of severe asthma exacerbations, which enhances knowledge translation and enables counterfactual prediction for clinical practice. The influence diagram further supports the design of patient-level simulation model for cost-effectiveness analysis of new asthma therapies.

Perez-de-Llano L., et al.
"Clinical Characteristics of Patients with Severe Asthma by Different Elevated Biomarkers Classifications: Patients from Spain in the ISAR Registry"
EAACI 2024

Abstract

Conclusions: Severe uncontrolled asthma patients with positive biomarkers experienced high disease burden. These patients reported elevated exacerbation rate and long-term OCS use, and reduced rate of well-controlled symptoms.

Perez-de-Llano L., et al.
"Baseline disease burden in severe asthma patients treated with biologics, and eligible but not treated: Spanish patients in the ISAR Registry"
EAACI 2024

Abstract

Conclusions: Similar to patients treated with biologics, severe uncontrolled asthma patients eligible but not treated with biologics experienced high disease burden and should be considered for biologics therapy.

Chan J.S.K., et al..
"Phenotype and biomarkers in patients who initiated biologic therapy stratified by oral corticosteroid use in the International Severe Asthma Registry"
Eur Respir J, ERS 2024 (in press)

Conclusions: LTOCS users had the worst lung function, with distinct biomarker patterns. Reasons for poor asthma control in OCS users and OCS' confounding effects on biomarkers need exploration.

Chan J.S.K., et al.
"Characteristics of long-term oral corticosteroid users stratified by blood eosinophil count in the International Severe Asthma Registry"
Eur Respir J, ERS 2024 (in press)

Conclusions: Patients with severe asthma and LTOCS use had a high steroid burden, among whom, those with high BEC had worse asthma control and lung function. Better access to steroid-sparing therapies is needed regardless of BEC.

Chan J.S.K., et al.
"Impact of biologic initiation on oral corticosteroids in the International Severe Asthma Registry and the Optimum Patient Care Research Database: a pooled analysis"
Eur Respir J, ERS 2024 (in press)

Conclusions: Compared to non-initiators, biologic initiators had greater reduction in LTOCS daily dose in both 1st (mg/day, -3.2 vs -2.0) and 2nd (-4.2 vs -3.5) year ($p<.001$). Biologic initiation results in reduced OCS burden in patients with severe asthma over two years versus usual care.

ISAR in 2024: Events

Respiratory Effectiveness Group (REG) Summit
Vienna, Austria
14-16 March 2024

Highlights:

QISAR and Quality Improvement (QI) goal 2024:

- The new ISAR QI tool, QISAR, was demonstrated 'live' to ISAR collaborators. The QI goal 2024 voted by the ISAR steering committee (ISC) is to standardize data collection during clinical consultations.

GLEAM and SOLAR working group meetings:

- The new ISC-prioritized research project GLEAM and active project SOLAR were discussed.

ISAR Session at REG:

- Prof Celeste Porsbjerg, Prof Chin Kook Rhee, Prof Celine Bergeron and Prof Matthew Peters delivered presentations on ISAR's achievements, practice change goals, QI and future research needs.

Severe Asthma Summit
Copenhagen, Denmark
11-12 April 2024

Highlights:

- Dr Pujan Patel and Dr Ghislaine Scelo presented "Remission in Severe Asthma - ISAR's research achievements in 2023 and 2024".
- The ISAR FULL BEAM poster was awarded the 2nd prize at the Severe Asthma Summit.

ATS 2024

American Thoracic Society (ATS) Conference
San Diego, California
17-22 May 2024

Highlights:

ISAR research updates and opportunities:

- New data was presented on the impact of biologics on OCS use and OCS related comorbidities.
- The opportunity to drive research focused on the use of Tezepelumab in severe and high-risk asthma was highlighted, with over 800 Tezepelumab patients expected in ISAR by the end of 2024.

Early biology driven care working group:

- Early recognition of patients who require targeted care, and the seamless incorporation of this to primary care in a way that allows the integration of clinical trials, was discussed.

ISAR Events 2024

ERS

European Respiratory Society (ERS) Congress
Vienna, Austria
7-11 September 2024

- **Three posters (including two from the STAR study) will be showcased.**
- **QI working group and a clinical trials working group are planned.**
- **A dinner for the ISC is planned to be held on 7 September 2024.**

Join ISAR today!

To register interest as a collaborating country, or to submit a research request or proposal, please contact us **here**.

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ACKNOWLEDGEMENTS

The work of REG would not be possible without the contributions from our invaluable supporters to fund innovative research projects developed by our expert Collaborators.

REG is looking to launch a number of ambitious research initiatives which offer the opportunity to impact clinical management guidelines and patient care.

We welcome any suggestions from Supporters and would be happy to discuss your ideas in more detail.

You can always get in contact with the REG team by email at
enquiries@regresearchnetwork.org,

or write to Michael Walker, REG CEO at
michael@regresearchnetwork.org

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