

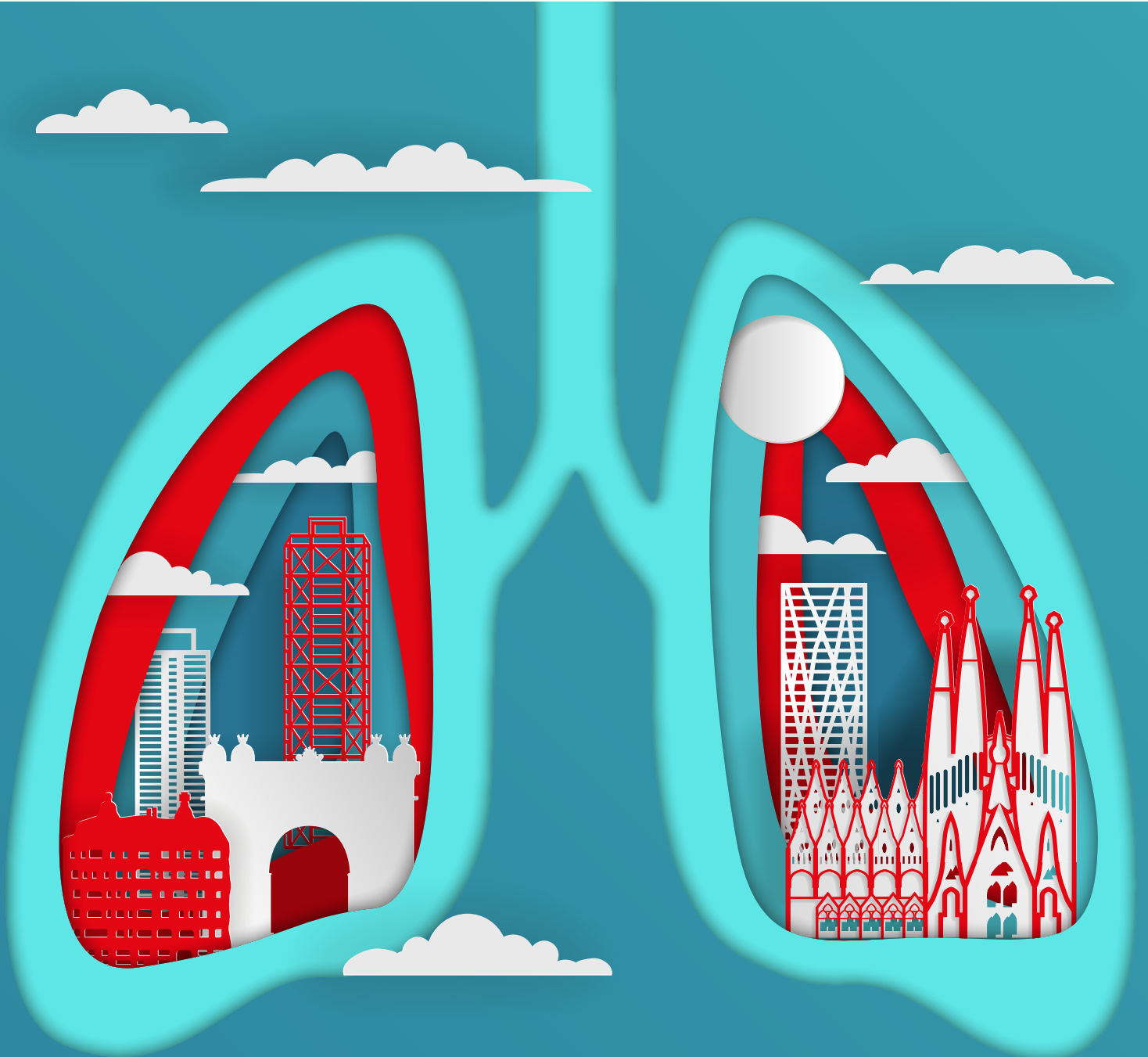


Respiratory
Effectiveness
Group

ADVANCES

in Real-life Respiratory Research

The Respiratory Effectiveness Group Newsletter
ISSUE February 2022



www.regresearchnetwork.org

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THE RESPIRATORY EFFECTIVENESS GROUP NEWSLETTER ISSUE FEBRUARY 2022

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 enquiries@regresearchnetwork.org

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EDITORIAL

Sinthia Bosnic-Anticevich REG President

DEAR COLLEAGUES,

I find myself writing to you for the last time as President of REG and it is with mixed emotions that I reflect on the last 2 years.

Undeniably, it has been a privilege to work with the REG Board (Antonio Anzueto (USA), Walter G Canonica (Italy), Alan Kaplan (Canada), Marc Miravittles (Spain), Nikos Papadopoulos (Greece), Nicolas Roche (France), Dermot Ryan (UK), Joan Soriano (Spain), Omar Usmani (UK)) and Oversight Committee (Keith Allan, Nick May, Trevor Lambert); an amazing group of individuals, who are passionate about real life research and the critical role it plays in informing meaningful practice guidelines, management, drug licensing and prescribing decisions. They have made my time as President not only fruitful but a lot of fun. I thank them for everything they do for the organisation and for people with respiratory conditions.

However, it is reasonable to say, that the last 2 years have also been filled with challenges. Being President of an organisation, which is founded on networking, yet being in Australia and unable to leave the country is most certainly less than ideal. In addition to late night virtual meetings, the last 2 years have

meant that as an organisation, we have needed to focus on continuing to achieve the goals of REG, with a reliance on established networks, rather than the creation of new ones. We have most certainly missed this and look forward to moving forward in leaps and bounds post COVID.

Despite this, over the last 2 years the organisation has continued to thrive, a big part of which can be attributed to the outstanding day-to-day leadership of Michael Walker (REG CEO) and his team of REG researchers, Dr Sarah Lucas and Dr Graham Lough. Michael continues to bring energy, understanding and a pragmatic approach to the work of the REG. His breadth of experience and skills never ceases to amaze me, and it has been such a great pleasure working with Michael to achieve the goals of REG! I am pleased to say that over the last two years, we have seen the completion and publication of several global projects including the COPD Control study, Phase 1 of the PeARL & TORPEDO projects and the Real-Life WISDOM database project. We have secured funding for several global projects, continue to publish position papers/expert commentaries and generate new knowledge through real-world research. The future is most certainly bright and with the re-commencement of face-to-face meetings, I know that the REG, its collaborators and global network will thrive. In fact, I look forward to witnessing the continued leadership of the REG collaborators in advocating for real-world research in our ever-changing world. Please make sure you engage with our working groups to be included in our leadership projects.

So in closing, I would like to thank you for your contributions, for your resilience and commitment to REG and I look forward to seeing you at the REG Summit in Barcelona.

Signing off one last time, with best wishes

Sinthia Bosnic-Anticevich

Professor

Woolcock Institute of Medical Research
University of Sydney, Sydney, Australia

REG TEAM UPDATE



Michael Walker
REG CEO

The REG Team has seen some changes. I am very pleased to welcome Valeria Perugini to the REG team as a scientific researcher. Valeria joins us from the University of Brighton, England, where she has been conducting several research projects focussed on regenerative medicine. Valeria joins the team to replace Sarah Lucas, who left REG at the end of 2021. On behalf of all the REG

collaborators and supporters, I would like to warmly thank Sarah for all her hard work, professionalism and team support at REG and wish her all the best in the continuation of her career.

Overall, 2021 was a busy year for many of the working groups with 5 new publications and another 4 manuscripts in preparation. New projects are in development, due to start later this year, and will be discussed during the face-to-face working group meetings at the REG Summit on Thursday 17th March.

The last few months have been focused on the preparation of the REG Summit 2022, which will be held in Barcelona from 17th - 19th March. The programme and speakers have now all been

finalised and the schedule for the working group meetings has been prepared. We hope that many of you will be participating in the Summit and Working Group meetings, which are open to all collaborators and sponsors.

I would like to acknowledge the support from a number of long-term Sponsors. Without their ongoing support, much of the work of REG would not be possible. I hope others are encouraged and inspired by the activities of REG and the Summit in March and will collaborate with us later this year or plan to in the future.

I look forward to meeting our many collaborators and supporters at the REG Summit 2022 in Barcelona.



REG 2021 PUBLICATIONS



A real-life comparative effectiveness study into the addition of antibiotics to the management of asthma exacerbations in primary care

2021

Clare S. Murray, Sarah J. Lucas, John Blakey, Alan Kaplan, Alberto Papi, James Paton, Wanda Phipatanakul, David Price, Oon Hoe Teoh, Mike Thomas, Steve Turner, Nikolaos G. Papadopoulos

European Respiratory Journal 2021; in press

ONLINE LINK

<https://erj.ersjournals.com/content/early/2020/12/10/13993003.03599-2020>



Childhood asthma outcomes during the COVID-19 pandemic: Findings from the PeARL multi-national cohort

2021

Nikolaos G Papadopoulos, Alexander G Mathioudakis, Adnan Custovic, Antoine Deschildre, Wanda Phipatanakul, Gary Wong, Paraskevi Xepapadaki, Rola Abou-Taam, Ioana Agache, Jose A Castro-Rodriguez, Zhimin Chen, Pierrick Cros, Jean-Christophe Dubus, Zeinab Awad El-Sayed, Rasha El-Owaidy, Wojciech Feleszko, Vincenzo Fierro, Alessandro Fiocchi, Luis Garcia-Marcos, Anne Goh, Elham M Hossny, Yunuen R Huerta Villalobos, Tuomas Jartti, Pascal Le Roux, Julia Levina, Aida Inés López García, Ángel Mazón Ramos, Mário Morais-Almeida, Clare Murray, Karthik Nagaraju, Major K Nagaraju, Elsy Maureen Navarrete Rodriguez, Leyla Namazova-Baranova, Antonio Nieto Garcia, Cesar Fireth Pozo Beltrán, Thanaporn Ratchataswan, Daniela Rivero Yeverino, Eréndira Rodríguez Zagal, Cyril E Schweitzer, Marleena Tulkki, Katarzyna Wasilczuk, Dan Xu, PeARL collaborators.

PeARL Think Tank Allergy 2021 Feb 20.

ONLINE LINK:

<https://onlinelibrary.wiley.com/doi/10.1111/all.14787>

Withdrawal of inhaled corticosteroids versus continuation of triple therapy in patients with COPD in real life: observational comparative effectiveness study

2021

Magnussen, H., Lucas, S., Lapperre, T. Quint J.K., Dandurand R.J., Roche N., Papi A., Price D., Miravittles M. on behalf of the Respiratory Effectiveness Group.

Respir Res 22, 25 (2021).

ONLINE LINK

<https://doi.org/10.1186/s12931-021-01615-0>

ONLINE
ARTICLE



REG 2021 PUBLICATIONS



Management of asthma in childhood: study protocol of a systematic evidence update by the Paediatric Asthma in Real Life (PeARL) Think Tank

Alexander G Mathioudakis, Michael Miligkos, Cristina Boccabella, Gioulinta S Alimani, Adnan Custovic, A Deschildre, Francine Monique Ducharme, Omer Kalayci, Clare Murray, Antonio Nieto Garcia, Wanda Phipatanakul, David Price, Aziz Sheikh, Ioana Octavia Agache, Leonard Bacharier, Apostolos Beloukas, Andrew Bentley, Matteo Bonini, Jose A Castro-Rodriguez, Giuseppe De Carlo, Timothy Craig, Zuzana Diamant, Wojciech Feleszko, Tim Felton, James E Gern, Jonathan Grigg, Gunilla Hedlin, Elham M Hossny, Despo Ierodiakonou, Tuomas Jartti, Alan Kaplan, Robert F Lemanske, Peter N Le Souëf, Mika J Mäkelä, Georgios A Mathioudakis, Paolo Matricardi, Marina Mitrogiorgou, Mario Morais-Almeida, Karthik Nagaraju, Effie Papageorgiou, Helena Pité, Paulo M C Pitrez, Petr Pohunek, Graham Roberts, Ioanna Tsiligianni, Stephen Turner, Susanne Vijverberg, Tonya A Winders, Gary WK Wong, Paraskevi Xepapadaki, Heather J Zar, Nikolaos G Papadopoulos.

2021

BMJ Open, Volume 11, Issue 7.

ONLINE LINK: <https://bmjopen.bmj.com/content/11/7/e048338>

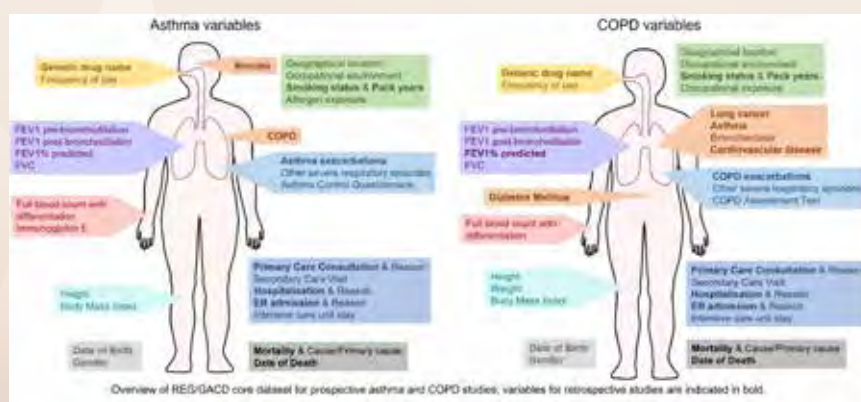
Towards Optimum Reporting of Pulmonary Effectiveness Databases and Outcomes (TORPEDO): identifying a core dataset for asthma and COPD studies

FM van Boven, Sarah J Lucas, Gary Parker, Alan Kaplan, Antígona Trofor, Billie Bonevski, Bruce J Kirenga, Dermot Ryan, Emilio Pizzichini, Eric van Ganse, Erick Wan-Chun Huang, Evelyn Brakema, Gillian Gould, Janwillem Kocks, Jennifer Alison, Jennifer K Quint, Joan B Soriano, John Hurst, Kamran Siddiqi, Katherine Boydell, Marc Miravittles, Mario Alberto Flores-Valdez, Marise Kasteleyn, Mark FitzGerald, Melanie Boeckmann, Michael Chaiton, Miguel Roman Rodriguez, Muralidhar Kulkarni, Nicolas Roche, Niels Chavannes, Nikolaos G Papadopoulos, Panagiotis Behrakis, Sarah Dennis, Shalini Bassi, Siân Williams, Toby M Maher, Trishul Siddharthan, Veena Kamath, Katia MC Verhamme.

2021

medrxiv.org October 22, 2021.

ONLINE LINK: <https://www.medrxiv.org/lookup/doi/10.1101/2021.10.14.21264843>





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DATE



THE RESPIRATORY
EFFECTIVENESS GROUP

REG

www.regsummit2022.org

SUMMIT 2022

17-19 March

REG SUMMIT 2022 LIVE

LIVE, 17 – 19 March 2022

REG looks forward to the return of the REG Summit as a face-to-face live meeting. The meeting will be held in Barcelona and will bring together real-life research experts from around the world to discuss the latest findings and new areas for collaboration in their respective fields of real-life respiratory research.

The REG Summit is a well-known meeting of global respiratory key opinion leaders who actively conduct real-life research using and creating Real World Evidence. REG collaborators (researchers, clinicians, general practitioners and allied health professionals) have conducted numerous database projects as well as prospective pragmatic trials and continue to seek answers to the many complex issues faced by respiratory patients.

The REG Summit starts on Thursday 17th March with the REG Working Groups meeting to review progress on projects as well as developing new ideas and areas for further investigation. The scientific programme follows all day on Friday 18th and concludes at 13:00 on Saturday 19th March.

The scientific programme will include robust and informative discussions and debate on the latest thinking on treatment strategies and what are the needs to move the field forward to have a better understanding of how to improve patient outcomes. Participants will debate the hottest topics in the field, in a variety of interactive and informative sessions.

The scientific programme will welcome an impressive list of experts who will speak about new perspectives and challenges in the management of COPD, severe asthma, IPF, asthma in children as well as debating different treatment alternatives and strategies.

The meeting also provides an excellent opportunity for networking in person with some of the world's leading experts in the respiratory field and to re-connect after such a long period of only online meetings.

The REG Summit 2022 will be the year's most important meeting in the field of respiratory real-life research, and everyone is encouraged to participate and get involved with the REG and its projects.

We look forward to seeing you safely in Barcelona!

REG SUMMIT 2022

PRELIMINARY SCIENTIFIC PROGRAMME

17-19 March 2022

THURSDAY 17 TH MARCH	CET/Time		
	12:00-18:30	REG Working Group Meetings	
		ROOM 1	ROOM 2
	12:00-13:00	NETWORKING / LUNCH	NETWORKING / LUNCH
	13:00-14:00	ILD/IPF	Adherence
	14:00-15:00	Allergy	Database & Coding
	15:00-16:00	Environment, Epidemiology and Airways	COPD
	16:00-16:30	COFFEE BREAK	
	16:30-17:30	Cost Effectiveness	Biomarkers & Severe asthma
17:30-18:30	Technologies	Child Health	

FRIDAY 18 TH MARCH	CET/Time	
	08:50-09:00	Welcome Prof. Sinthia Bosnic-Anticevich (Australia)
	09:00-09:45	COVID-19 INFECTION Chair: TBA Targeting the end of the COVID-19 pandemic, Joan Soriano
	09:45-10:40	REG-APAACI JOINT SYMPOSIUM - RHINITIS AND ASTHMA Chair: Ruby Pawankar and Iñigo Ojanguren - COVID-19 Allergies and Asthma: Asia Pacific Perspectives, Ruby Pawankar - Asthma and Chronic rhinosinusitis with nasal polyposis, G. Walter Canonica - Real world data for rhinitis and asthma, Jean Bousquet
	10:40-11:00	COFFEE BREAK
	11:00-12:00	ASTHMA IN CHILDREN - DIAGNOSIS, MONITORING, TREATMENT Chair: Clare Murray & James Paton - The new ERS pediatric asthma diagnosis recommendation, Alexander Moeller - The new PeARL asthma monitoring recommendations, Nikos Papadopoulos - The new GINA treatment suggestions for children, Paulo Pitrez
	12:00-12:30	Poster Viewing
	12:30-13:30	LUNCH BREAK
	13:30-15:00	COPD SESSION Chair: Nicolas Roche and Janwillem Kocks 13:30 – 13:50: Antibiotics for prevention of chronic lung disease exacerbations, Therese Lapierre 13:50 – 14:40: Roundtable: Pharmacotherapy in COPD and mortality, Speaker: David Halpin Panel: Mona Bafadhel, Antonio Anzueto, Marc Miravittles 14:40 – 15:00: COPD control, does this work in practice?, Marc Miravittles
	15:00-15:30	COFFEE BREAK

REG SUMMIT 2022

PRELIMINARY SCIENTIFIC PROGRAMME

17-19 March 2022

FRIDAY 18 TH MARCH		CET/Time
CROSSROADS IN RESPIRATORY CARE Chair: Dermot Ryan and Omar Usmani		
15:30-16:15	Pro/Con A. GINA 2021 – A two track approach to asthma management Pro: TBA Con: Désirée Larenas Linnemann	
Chair: Andrew Menzies-Gow and Celeste Porsbjerg		
16:15-17:00	Pro/Con B. Do we need a sixth asthma biologic? Pro: Kostas Kostikas Con: Christian Virchow	
Chair: Omar Usmani and Dermot Ryan		
16:15-17:00	Pro/Con C. Triple Therapy in asthma? Pro: Alberto Papi Con: Renaud Louis	

SATURDAY 18 TH MARCH		CET/Time
09:00-09:30	ILD SESSION Chair: Maria Molina-Molina and Pilar Ortega Post-COVID fibrosis and other ILDs – new perspectives	
09:30-11:00	THE INTERNATIONAL SEVERE ASTHMA REGISTRY (ISAR): KEY UPDATES AND RESEARCH FINDINGS Chair: Prof. Andrew Menzies-Gow - ISAR through time: Achievements and vision for the future, Prof. David Price - Prevalence of comorbidities and their impact on clinical outcomes in severe asthma patients (PRISM project), Dr. Celeste Porsbjerg - Characterisation of patients with non-Type 2 asthma and assessment of biologic effectiveness in patients with different Type 2 biomarkers (EMBER and IGNITE projects), Prof. George Christoff - Defining and characterising biologic treatment responders in severe asthma patients (BEAM project), Dr. Luis Perez-de-Llano - Impact of biologic initiation on clinical outcomes in severe asthma patients with high exposure to oral corticosteroids (GLITTER project), Dr. Mohsen Sadatsafavi - Comparing the effectiveness of Anti-IL5 versus Anti-IgE biologic therapies in severe asthma patients eligible for both (FIRE project), Prof. David Price	
11:00-11:30	COFFEE BREAK	
11:30-12:15	TECHNOLOGIES SESSION Chair: Ron Dandurand and Esther Metting Digital technology advances in respiratory medicine the potential to improve patient outcomes, TBA	
12:15-13:00	THE FUTURE OF REAL-LIFE RESEARCH Chair: Sinthia Bosnic-Anticevich and G. Walter Canonica - Patient perspective, Samantha Walker - HCP Perspective, David Price	
13:00	Meeting Close G. Walter Canonica	

ENDING THE COVID-19 PANDEMIC: LA COMMEDIA È FINITA?



Joan B Soriano, M.D.
Respiratory Effectiveness Group

Not only respiratory patients, but the entire respiratory community of doctors, nurses and allied healthcare professionals in primary and hospital care have immensely suffered the pain of COVID-19. We all want to end it. In the immortal opera *Pagliacci* ("clowns"), with music and libretto by Ruggero Leoncavallo, published in 1892, Canio stabs Nedda, and then kills Silvio as well. The horrified audience then hears the celebrated final line: "*La commedia è finita!*" that is "-The comedy is finished!".

All human pandemics have come to an end. And, without a doubt, the ongoing COVID-19 pandemic will end, somehow, sometime. But perhaps the key issue is not when, but if we can set up the conditions to control COVID-19 the sooner the better and with the minimum toll possible. SARS-CoV-2 is a new, potentially lethal, bad virus, still full of surprises. On the one hand, as of January 2022 there have been over 300 million confirmed cases of COVID-19, including 5.5 million deaths reported to WHO. On the other hand, it is a bad virus, that replicates poorly and continuously produces new variants that escape natural immunity and existing vaccines.

Reputed voices such as Dr Tedros Adhanom Ghebreyesus, WHO Director-General, and Bill Gates have recently stated that "-2022 must be the year we end the pandemic". This is not only wishful thinking. To establish a roadmap and calendar aiming for the end of the COVID-19 pandemic is an attainable achievement. However, it will require incremental efforts and investment from multiple stakeholders, and at the global level. Not doing so, will produce a much greater burden in terms of lost lives and economic costs. Regrettably, the level of disinformation and un-coordination has been unprecedented at all levels of COVID-19 since the alert on December 31, 2019 in Wuhan, Hubei Province, China due to a cluster of 27 hospitalized patients with pneumonia of unknown aetiology. History repeated itself again with shows of panic, hopelessness, despair, denialists, conspiratory theories, fake news, irrationality, pandemic tiredness, ... After more than 215,000 peer-reviewed publications on all sorts of COVID-19 related topics, many questions remain unanswered.



Therefore, revisiting how previous pandemics were ended/controlled, and further implementing/reinforcing individual and community strategies of proven efficacy, we can envisage the end of the COVID-19 pandemic, sooner rather than later. We can start by implementing individual, community and global health governance interventions. A key, new scientific landmark is still pending for the progressive elimination of SARS-CoV-2 across the globe. On the horizon are new, more effective vaccines, and potentially antivirals, that interrupt virus transmission, and produce neutralising antibodies to provide sterilising immunity against re-infection. All of the above should be accompanied by significantly more financial support to national and international Public Health agencies, that should work independent of any political drivers. Without health, there is no economy.



The final answer to COVID-19 will not only be medical, but research-based and focused on solid science and implementation research. The remit of REG, as a think tank, is well positioned to capitalise the knowhow and help delivering the key findings and solutions to the respiratory community, and beyond. All with a truly global, planetary perspective. It is now time to sit down, prioritize, administer and implement in practice such roadmap. Then, we will sing along with full lungs and even hitting a high C: "La commedia de COVID-19 è finita!!" (Figure).



Figure. Hopefully soon: "La commedia de COVID-19 è finita!!"...

WHAT REG MEANS TO ME

We are all familiar with the concept of efficacy of a treatment or an intervention, but not many people are aware of the differences between efficacy and effectiveness. The efficacy demonstrated in rigorously designed and conducted clinical trials may be significantly modified in real life and result in different outcomes, this is the concept of effectiveness.

Traditionally, effectiveness studies (or the so-called real-life studies) have been considered of an inferior category compared with efficacy trials and more subjected to biases; however, they are of great value because they reflect what clinicians can expect in their daily practice. The Respiratory Effectiveness Group (REG) had one of its main objectives to increase the standards of effectiveness trials to better inform the clinical practice in respiratory diseases. During the years of activities of REG, its different working groups have covered several areas of respiratory diseases, from chronic airways diseases to interstitial lung disease and respiratory infections. I have been involved in the chronic obstructive pulmonary disease (COPD) working group, which includes specialists from countries in Europe, Asia, America and Australia and have been active in the development of both, retrospective database analyses and observational prospective studies. The retrospective database studies have improved our knowledge about the characteristic and evolution

of the asthma-COPD overlap (ACO), the practices of diagnosis and treatment of alpha-1 antitrypsin in the United Kingdom and the results of the discontinuation of inhaled corticosteroids in patients with COPD in Primary Care, just to mention a few.

In the field of prospective studies, the international group of investigators of the COPD working group has conducted a study to validate the concept of control of COPD, that identifies patients that require an intensification in treatment in order to avoid future adverse outcomes such as exacerbations, hospitalisations or death. This control tool is being implemented in guidelines to help physicians, particularly in Primary Care, to better manage their patients with COPD.

The REG has given me the opportunity to work with an enthusiastic international group of colleagues with the same interest in translating clinical research into the best clinical practice for our respiratory patients.

MARC MIRAVITLES

Chair of the COPD Working Group of REG
Pneumology Department, Hospital University
Vall d'Hebron
Vall d'Hebron Barcelona Hospital
Campus, Barcelona, Spain



REG is a fantastic initiative, not only to improve the lives of people with respiratory disease across the globe, but an opportunity to network and collaborate and build on experiences. The inclusivity and diversity of the working groups has led to long term collaborations and its enjoyable to work with likeminded colleagues. It's been rewarding over the years to see projects all the way through from conception to outputs and the drive for change in clinical practice.



JENNIFER QUINT

Faculty of Medicine,
National Heart & Lung Institute
Professor of Respiratory Epidemiology
London, UK



AstraZeneca Respiratory and Immunology is on a medical mission to work in partnership with healthcare systems around the world to reduce the burden of respiratory long term conditions. In order to deliver that ambition it is vital that we are able to engage with like-minded clinicians and scientists around the world to help develop, implement and measure the interventions that can bring about the improvements in respiratory care that our patients deserve. The Respiratory Effectiveness Group (REG), focussing as it does on changing the clinical management of patients with respiratory diseases, provides a perfect vehicle to do just this. The REG structure, consisting of working groups, scientific meetings, and governance/advisory bodies fosters a strong collaborative spirit across academic institutions, professional societies and industry. If the current COVID pandemic has taught us nothing else, then it has demonstrated that when Academics, Clinicians and Industry combine their efforts for the common good then significant progress in disease management can be made.

From a medical evidence perspective, research networks such as REG are essential to deliver the impactful evidence we need and ensure its

implementation in professional guidance documents and routine care. REG has always taken an enlightened view to working with industry, encouraging early involvement and participation. The ability to partake in the sharing and disseminating of findings from a broad range of real world practice changing, pharmacoepidemiology and outcomes research studies has been extremely beneficial. We have a significant opportunity as a respiratory community post-COVID to raise the profile of respiratory disease in a wider medical and general public. By partnering together across the respiratory community, I believe the Respiratory Effectiveness Group can be an important player in that process, providing high quality evidence to drive awareness and change outcomes for respiratory patients. Both AstraZeneca and I look forward to being part of that journey.

HANA MÜLLEROVÁ, PHARMD PHD

Medical Evidence Strategy Lead
Head NOVELTY study
AstraZeneca, UK



Looking back over the years I realize that a decade has elapsed since the inauguration of the Respiratory Effectiveness Group (REG) in 2012. The idea to take an alternative path to randomized controlled trials by collecting real life data as evidence to substantiate the progress in respiratory medicine was very lucrative, but sounded somewhat like wishful thinking. In the course of the next years, though, I witnessed how the appropriate selection of highest level of experts in different fields of scientific research made the initial nucleus of crystallization expand and acquire a complex structure necessary to carry out ground-breaking research.

Being an outgoing Chair of the Anonymized Data Ethics and Protocol Transparency (ADEPT) Committee, I had the opportunity to look at the ever-growing number of proposed research projects encompassing a diversity of topics, some of which way beyond the domain of respiratory medicine. Actually diversity is a key word when talking about REG. The specific experience of people from all over the globe is the mix which makes the brain-storming discussions during the online and face-to-face meetings so prolific. A perfect example is the International Severe Asthma Registry: a database of thousands of patients reflecting the specific ethnic, healthcare and socio-economic features of their respective countries.

A history of 10 years may not seem such a long period, but the deliverables of REG follow a remarkable progression. The scientific publications are now eyed with due respect by the research community as judged by the growing numbers of citations. I am optimistic that in the near future the initial expectation that real-life research will be the counter balance and corrective of the inferences from randomized controlled trials will come true. Incorporating results from real life research into clinical practice guidelines will have a positive impact on national and international health strategies and possibly on drug licensing.

In a nutshell: I feel utmost satisfaction of being part of REG.

TODOR (TED) A. POPOV, MD, PHD

Professor at the University Hospital "Sv. Ivan Rilski"
Sofia, Bulgaria





JANUARY 2022

WORKING GROUP UPDATE





ALLERGY WORKING GROUP

The group is developing new project ideas in the areas of rhinitis and AIT that will be explored at the REG Summit in March.



TECHNOLOGY WORKING GROUP

A study which aims to identify the acceptability and usability of a package containing a triple formulation digital inhaler, sensor, and app in patients with poorly controlled asthma is under review by funders and a research protocol has been approved. Other potential areas of research will be explored in the next working group meeting at REG Summit.



COUGH WORKING GROUP

The group is discussing the next phase of the 'burden of chronic cough on adults in primary care in the UK' project.



ENVIRONMENT, EPIDEMIOLOGY & AIRWAYS WORKING GROUP

Phase 1 of the collaboratively funded (AstraZeneca, Boehringer Ingelheim, Chiesi and Kindeva) inhaler choice & environment (ICE) project, which assesses the impact of inhaler choice on patient care and the environment, has been completed. Two questionnaires were rolled out internationally to measure asthma/COPD patient and HCP perspectives and experience. Analysis is underway and the group is preparing phase 2 of the project: an exciting modified Delphi and priority setting task. Visit the study site for more details: <https://www.regresearchnetwork.org/research-2/inhaler-choice-the-environment/>.



ILD WORKING GROUP

The new project characterising ILD diagnosis through distanced electronic multidisciplinary team meetings (eMDTs) in the post-COVID era has been submitted for funding. This project is a follow up to the working group's previous paper 'The characterisation of interstitial lung disease multidisciplinary team meetings: a global study'. The project aims to identify characteristics of fibrotic interstitial lung disease (ILD) diagnostic practice and the features, strengths and limitations of distanced electronic multi-disciplinary team (eMDT) meetings, and open discussion on the prevalence of post-COVID fibrosis. The proposal is under review by potential funders.



COST EFFECTIVENESS WORKING GROUP

The group has developed a research proposal for a project which aims to identify COPD specialist opinion on priorities in the development and practical implementation of clinical COPD guidelines, focussing on potential gaps in the guidelines where cost of treatment is (not) considered. This project is currently seeking funding.



ADHERENCE WORKING GROUP

The scoping review project is ongoing, which aims to assess how the monitoring and management of adherence can be addressed with personalised medicine, including strategies that have been adopted to encourage adherence. The articles for inclusion are being finalised and are under secondary review. To date, over 644 papers have been identified and classified for the further stages of this analysis. Discussion in the Working Group meeting in September included another potential research project to assess adherence within the current guidelines.



CHILD HEALTH WORKING GROUP

The Paediatric Asthma in Real Life (PeARL) project aims to produce evidence-based recommendations regarding controversial aspects of paediatric asthma is progressing. Following the publication of the results of a survey on research priorities in paediatric asthma in JACI In Practice, the group is now working on three systematic reviews. One review on stable asthma management is currently in the writing phase and research is ongoing on the second, which aims to investigate treatment for acute asthma exacerbations. A survey has been sent to healthcare professionals and other stakeholders to gather information on how paediatric asthma is currently monitored worldwide.

A proposal has been developed for a project to determine the prevalence of severe asthma in children in UK primary care. This study also aims to determine which patients with potentially severe asthma are being referred for specialist assessment and which are being missed, remaining treated solely in primary care. The project is currently seeking funding.



COPD WORKING GROUP

A prospective, observational multicentre study is underway to assess the prevalence of suboptimal peak inspiratory flow in patients with COPD and to assess the predictive value of peak inspiratory flow for COPD exacerbations and symptom burden. The study aims to recruit 400 patients. COVID-19 has unfortunately caused delays at many centres, however patient recruitment has now begun at 15 centres, and, to date, 284 patients have been recruited.

The Working Group are currently developing a project for a risk prediction model that could be used at the time of COPD diagnosis to predict the 5-year risk of a severe exacerbation episode, in order to allow earlier, more intensive interventions to be given to patients at greatest risk. There have also been discussions around a future study to investigate macrolide use in those with COPD.



SEVERE ASTHMA AND BIOMARKERS WORKING GROUP

The Working Group are currently developing ideas around a potential project to investigate the predictive value of biomarkers in determining the response to biologics along with associated comorbidities. There are also plans for a project to map the patient journey to biologic treatment.



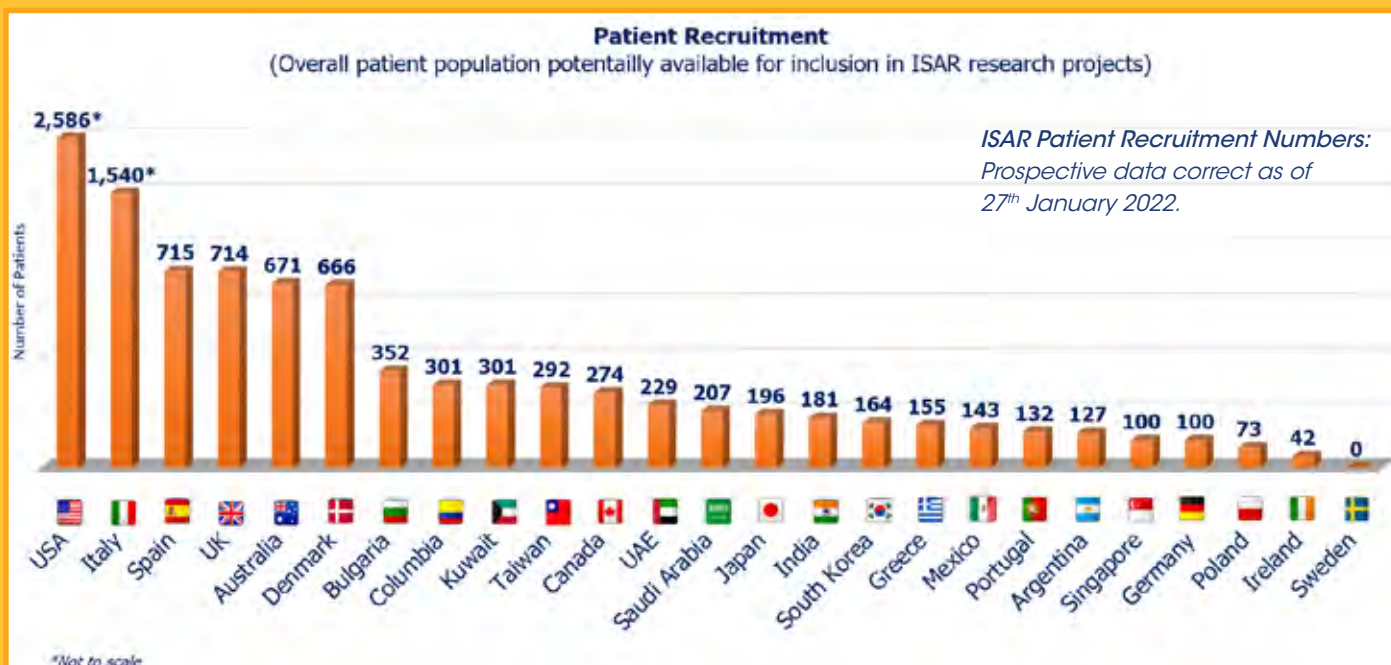
DATABASES AND CODING WORKING GROUP

The new Working Group Chair is Jenni Quint. The results of the TORPEDO study have now been published and are available online - Towards Optimum Reporting of Pulmonary Effectiveness Databases and Outcomes: identifying a core dataset for asthma and COPD studies, and on developing future project ideas. During the Working Group meeting in September, the group agreed to develop the TORPEDO Phase II project, which aims to identify databases suitable for respiratory (pharmaco-) epidemiology and to identify whether they contain the minimum criteria/variables identified in phase I of TORPEDO.

INTERNATIONAL SEVERE ISAR ASTHMA REGISTRY

◆ ISAR Country Updates

The International Severe Asthma Registry (ISAR) has ended its 4th year with data from 12,860 severe asthma patients (including 10,161 patients with prospective data) from our 24 collaborating countries. ISAR is delighted to welcome Poland as our newest collaborator to the registry. Moving into 2022 and our 5th year, our plan is to continue global collaborations with a focus on the sustainability of ISAR, and to seek to welcome additional countries such as Brazil, Finland, France, and Iceland. It is ISAR's goal to have prospective data from 15,000 patients.



◆ ISAR Publications and Abstracts in 2021/2022

We are pleased to share 3 additional ISAR studies were accepted and published in 2021, with 10 more submissions planned for 2022. Furthermore, 3 abstracts presented as e-posters at the ERS International Congress 2021 have been published in the European Respiratory Journal. ISAR continues to contribute to the development of high-quality academic research that will enhance our understanding of severe asthma management and care.

Menzies-Gow A, et al. **"Real-world Biologic Use and Switch Patterns in Severe Asthma: Data from the International Severe Asthma Registry and the US CHRONICLE Study"**
J Asthma Allergy, 2022

Aim: To describe real-life global patterns of biologic use (continuation, switches, and discontinuations) for severe asthma, elucidate the reasons underlying these patterns, and examine associated patient-level factors.

Conclusions: 79% of patients with severe asthma continue treatment with their initial biologic; of the 10.8% of patients who switched, the most common first switch was from omalizumab to an anti-IL5/5R therapy.
Click [here](#) to read the full article.

◆ ISAR Publications and Abstracts in 2021 /2022

Porsbjerg C, et al.

"Global Variability in Administrative Approval Prescription Criteria for Biologic Therapy in Severe Asthma"
J Allergy Clin Immunol Pract, in press

Aim: To compare global differences in ease-of-access to biologics.

Conclusions: The Biologic ACcessibility Score (BACS) was developed based on biologic prescription criteria; it highlighted substantial variations in ease-of-access to biologics globally.

Click [here](#) to read the full article.

Busby J, et al.

"Impact of Socioeconomic Status on Adult Patients With Asthma: A Population-based Cohort Study from UK Primary Care" *J Asthma Allergy, 2021*

Aim: To investigate the effect of socioeconomic status (SES) on clinical outcomes in a UK primary care asthma cohort

Conclusions: Patients from the most deprived SES quintile had poorer asthma control and greater exacerbation rates than those from the least deprived quintile, but rates of respiratory referrals were comparable.

Click [here](#) to read the full article, and [here](#) for the slide deck.

➤ More information on ISAR publications is available on the ISAR website [here](#) and on slide share [here](#).

A summary of the e-Poster live discussion at the session '**Severe asthma: evaluation using patient reported outcome measures (PROMs) and biomarkers, comorbidities and treatments**' on 5th September 2021 (13:15-14:15 CEST) can be found [here](#). The three abstracts were published in a supplement of the **European Respiratory Journal**.

Baseline characteristics of severe asthma patients initiating biologic treatment worldwide (BEAM)

Perez de Llano L, et al.

Aim: To describe the characteristics of biologic users at initiation

Conclusions: At biologic initiation, patients receiving anti-IL5/5R seemed to have more severe asthma characteristics, such as poorer lung function and greater use of long-term oral corticosteroids, than patients receiving anti-IgE.

Click [here](#) to read the full abstract.

Comparative Effectiveness of Anti IL5/5R Versus Anti IgE in Patients Eligible for Both (FIRE)

Nasloon A, et al.

Aim: To assess clinical responses of initiating anti-IL5/5R versus anti-IgE among patients eligible for both.

Conclusions: Both biologics reduced exacerbations among severe asthma patients, though matched patients receiving anti-IL5/5R were less likely to report exacerbations than those receiving anti-IgE.

Click [here](#) to read the full abstract.

Characterisation of severe, steroid dependent asthma patients who initiate biologics versus those who do not (GLITTER)

Chen W, et al.

Aim: To characterize severe asthma patients with high exposure to oral corticosteroids (HOCS) who initiated biologics versus those who did not.

Conclusions: About 71% of ISAR patients with HOCS initiated biologics; biologic initiators were more likely to be eosinophilic, atopic and have uncontrolled asthma than those who did not initiate biologics.

Click [here](#) to read the full abstract.

➤ For more information on our Abstracts, Posters and Oral presentations, please visit the [ISAR Website](#). ISAR's research and quality improvement initiatives are summarized in the ISAR Research Summary slide deck ([Link](#)). If you wish to submit a research question utilising ISAR data, you may do so [here](#). To register interest in joining the registry as a collaborating country, please contact us [here](#).

ISAR Featured in the Spectator Briefings (Podcast)

Improving the status quo: can severe asthma be better treated?

Professor David Price (founder of the Observational and Pragmatic Research Institute) takes us through the adverse effects of steroid overuse, the cost of prescribing steroids for the UK's National Health Service (NHS), and the role of ISAR in understanding severe asthma. Gabby Perry (student with severe asthma) talks about the dual edged swords that are steroids, and Syed Ali (medical affairs manager at AstraZeneca) discusses alternative treatments such as biologics.

Click [here](#) to listen to the full podcast.

ISAR Steering Committee (ISC) and Research Meetings 2022

ISAR Open Research Meeting 1 (for Asia-Pacific remote attendees)

17th March 2022, 8-11am CE

ISAR Closed Steering Committee Meeting

17th March 2022, 12-1.30pm CET

ISAR Open Research Meeting 2 (for EU and US remote attendees)

17th March 2022, 2-5pm CET

Agenda: ISAR research updates, network proposal ideas and sustainability objectives

ISAR Session at REG Summit 2022

ISAR Session Title: **The International Severe Asthma Registry (ISAR): Key updates and research findings**

Date & Time: **Saturday 19th March 2022, 9.30-11am CET ([Link](#))**

1. ISAR through time: Achievements and vision for the future.
2. Prevalence of comorbidities and their impact on clinical outcomes in severe asthma patients (PRISM project).
3. Characterization of patients with non-Type 2 asthma and assessment of biologic effectiveness in patients with different Type 2 biomarkers (EMBER and IGNITE projects).
4. Defining and characterising biologic treatment responders in severe asthma patients (BEAM project).
5. Impact of biologic initiation on clinical outcomes in severe asthma patients with high exposure to oral corticosteroids (GLITTER project).
6. Comparing the effectiveness of Anti-IL5 versus Anti-IgE biologic therapies in severe asthma patients eligible for both (FIRE project).

If you wish to submit a research question utilising ISAR data, you may do so via the **["submit a proposal or research request"](#)** tab on ISAR website.



ISAR website

The ISAR website has had a facelift. It now contains a new "Dissemination" tab for the latest news on ISAR abstracts and publications, and a "FAQ" tab which provides answers to frequently asked questions about ISAR.

www.isaregistries.org

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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We would also acknowledge the support of the following companies:



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