



Respiratory
Effectiveness
Group

Respiratory Group Annual Report 2023

Pioneers in real-life respiratory
data and research

regresearchnetwork.org



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The Respiratory Effectiveness Group looks to a future with Real World Evidence

A global not-for profit collaboration of clinicians, scientists and epidemiologists, working together to identify and fulfil the real-life research needs in respiratory medicine, advocating for change to drive improved patient management.

Our Vision

To transform respiratory patient care by maximising/exploiting/utilising real-life research & evidence.

Our Mission

To integrate real-life evidence into clinical practice guidelines, policy, and budgetary decision-making for the benefit of all stakeholders in respiratory medicine.

REG Strategy

REG will achieve its goal by:

- Nurturing an international network of primary and secondary care respiratory experts with an interest and expertise in real-life research.
- Establishing alliances with partner organisations (e.g. APSR, ATS, EACCI, ENCePP, ERS, ESPACOMP, IPCRG, IPSE, ISPOR, patient organisations).
- Using RWE to address current key questions in respiratory medicine and impact on relevant international guidelines and health policies.
- Acting as a think-tank to meet challenges in respiratory medicine in a pragmatic way.
- Implementing a multi-faceted programme of activities aimed at improving the understanding of respiratory medicine with REG collaborators, partners and supporters.

REG Direction and Philosophy

- REG leads the development and promotion of high-quality real-life collaborative research in respiratory medicine.
- Setting quality standards:
 - Real-life research studies, especially database studies, comparative effectiveness research and pragmatic clinical studies.
 - Databases to be used in real-life observational research.
 - Use of real-life research by developers of guidelines and decision-makers.
 - Publication of real-life research protocols and results.
 - Assessment of real-life research protocols and results.
- Academic partner to the International Severe Asthma Registry (ISAR).
- Development and assessment of methods used in real-life research, e.g. bias reduction, patient selection, outcome measures.
- Provision of advice and methodological help to researchers developing real-life research projects.

Operational Objectives

RESEARCH:

- To identify and prioritise the real-life research needs in respiratory medicine.
- To stimulate, drive and/or facilitate the development of collaborative real-life research projects to address the identified needs.

- To change the perception of real-life research.

COLLABORATION:

- Grow an international collaboration of clinical and scientific expertise in real-life research, meeting and working together either wholly as REG or within designated Working Groups.
- Facilitate the development of networks of partners and supporters involved in real-life observational research, including academic researchers, industry, service providers, guideline developers, decision makers, regulatory agencies, journal editors, funding agencies, scientific societies, institutional bodies, and patients' organisations, to improve levels of expertise and support research needs.
- Advocate for change in the way journals, guideline committees, and regulatory authorities appraise evidence to better integrate high-quality real-world data into recommendations, clinical decisions and policies.

QUALITY METHODOLOGY:

- Define and set quality standards for real-life research in respiratory medicine, through per protocol historic cohort analyses (database studies) and pragmatic clinical studies.
- Develop, assess and standardise coding and methodology used in real-life research.
- Develop rational prescribing pathways, and clinical management, & decision support tools.
- Drive the publication and appreciation of real-life research validity through:
 - Quality publications in high-impact journals.
 - Incorporation of real-life research into guideline development and health care resource utilisation decision-making.
- Be the "Go to" organisation for advice, assistance, and training on real-world research methodology.

REG's Structure

REG Board

BOARD COMPOSITION 2022 - 2024

President – Walter Canonica, *Professor Respiratory Medicine, Humanitas University Head Personalised Medicine Asthma & Allergy Clinic-Humanitas Research Hospital, Italy.*

Past President – Sinthia Bosnic-Anticevich, *Woolcock Institute of Medical Research, University of Sydney, Australia.*

REG Company Directors (Board members)

Nikos Papadopoulos, *Professor of Allergy and Paediatric Allergy, National and Kapodistrian University of Athens, Athens, Greece.*

Nicolas Roche, *Pneumologie et Soins Intensifs Respiratoires, Groupe Hospitalier Cochin, Assistance Publique-Hôpitaux de Paris, and Université Paris Descartes, France.*

Antonio Anzueto, *Pulmonary/Critical Care, University of Texas Health Science Center at San Antonio, USA.*

Dermot Ryan, *Strategic Clinical Director. Optimum Patient Care.*

Alan Kaplan, *Department of Family and Community Medicine, University of Toronto, Toronto, Ontario, Canada.*

Board members

Omar Usmani, *Reader in Respiratory Medicine and Consultant Physician at the National Heart and Lung Institute (NHLI), Imperial College London & Royal Brompton Hospital (RBH).*

Marc Miravittles - *Investigador Senior / Senior Researcher, Pneumologia, Hospital Universitari Vall d'Hebron (HUVH), Vall d'Hebron Institut de Recerca (VHIR), Barcelona, Spain.*

Joan B Soriano - *Associate Professor of Medicine, Hospital Universitario de la Princesa, Universidad Autónoma de Madrid, Diego de León 62, Madrid, Spain.*

Oversight Committee members - Nick May, Trevor Lambert, Keith Allan.

The Board members have representation across the following geographic and care-domain areas, reflecting the high calibre of our collaborators:

- Asia-Pacific, Europe & North America
- Asthma, Allergy, COPD
- Primary, secondary & pharmacy care
- Adult and paediatric specialisms

Working Group Chairs

Adherence – Sinthia Bosnic-Anticevich, Australia

Allergy Working Group – Désirée Larenas-Linnemann, Mexico

Biomarkers and Severe Asthma – Leif Bjermer, Sweden

Child Health Working Group – Clare Murray, UK

COPD Working Group - Marc Miravittles, Spain

Cost Effectiveness Working Group – Brett McQueen, USA

Database and Coding Working Group – Jennifer Quint, UK

ILD/IPF – Pilar Rivera-Ortega, UK

Environment, Epidemiology and Airways Working Group – Omar Usmani, UK

Technologies Working Group – Ron Dandurand, Canada

The year in review

Staff

We are very appreciative and acknowledge all the great work that Dr Graham Lough and Dr Valeria Perugini have done in 2023. There have been a number of challenges through the year, but good progress has been made, and they have been instrumental in supporting REG and the working groups to keep the momentum in the delivery of our projects. A big thank you and congratulations to them both for their hard work over this past year.

Governance

Our REG Board has met regularly online and in person during 2023 to address the organisational needs and are aware of the need to grow collaborations and supporters. The REG Board has continued to carry out its duties and support the goals of the organisation.

Scientific Outputs

Scientific Outputs are primarily achieved through the REG Working Groups. The Working Groups continue to develop and execute projects in their respective scopes of operation. Many Working Groups held meetings during the REG Summit and online. For more detailed information on the Working Groups and their projects, please refer to the Working Groups

reports (Page 5). During this past year, 3 pieces of original research were published, and a further 2 manuscripts were submitted for review. At year end, there are four active studies and six projects in development.

Finance

In 2023, corporate support was renewed, and new project funding secured. Careful planning and use of resources have enabled REG to deliver projects within budget and yielded a small operating gain (see Balance Sheet at the end of the report). We continue to closely monitor our spending with the goal to be as economical as possible. The valuable work of REG, both in terms of its research networks and its political influence, depends on the continued collaboration with our valued supporters, and we thank them for their on-going financial and expert contributions.

Meetings

The annual REG Summit returned as a successful live in-person event from 16 – 18 March 2023 in Lisbon. The REG Summit remains a key vehicle to showcase the many achievements of the organisation and our valued Collaborators, together with providing an interactive programme of presentations and debates covering the hot topics in respiratory medicine. The live meeting was warmly received by all participants. The next Summit is planned to take place from 14-16 March 2024 in Vienna. A report on the Summit appears later in this report, as well as our other congress activities in 2023.

Communications

The REG Newsletter provides REG collaborators and supporters with comprehensive updates of the work of REG and is published twice a year. Regular updates are sent out by email and posted on the REG website www.regresearchnetwork.org

International Conference & Congress Activities

REG Summit 2023, 16 – 18 March, Lisbon

The REG Summit 2023 was held as a live face-to-face event.

The REG Summit 2023, titled “Capitalizing on real-life research for best clinical guidance” lived up to expectations. As a live meeting, participants warmly welcomed the return to the face-to-face format and the opportunity to reconnect with colleagues. Participants from 25 countries, and brought together researchers, students and industry collaborators who are working together and looking for opportunities to establish new collaborations. Noted international speakers created nine plenaries and three pro-con debates.

We held meetings of 10 Working Groups, which were well attended with reviews of current outputs and wonderful ideas for new initiatives. Additionally, we had eight abstracts submitted/presented during our poster sessions.

A full report of the REG Summit 2023 and the abstracts can be found in the September 2023 REG Newsletter

https://www.regresearchnetwork.org/wp-content/uploads/NEWSLETTER-SEP-2023_final.pdf

ERS Congress, Milan, 9 - 13 September 2023

A joint ERS/REG session took place on Tuesday, 12th September, from 15:30 - 17:00 during the ERS congress in Milan. The Mini Symposium was entitled 'Next Generation Evidence-Based Decision-Making In Respiratory Medicine'. The programme included 'Real-world" evidence vs randomized controlled trials: friends or foes?" presented by G. Walter Canonica, Italy, "The future of evidence generation using mHealth tools" presented by H. Pinnock, UK, and "Building registries to inform decision-making: potential and challenges" presented by D. Price, Singapore. In addition, Dr Graham Lough, REG Researcher, presented a poster on the REG project "Role of virtual multidisciplinary team meetings in the post-COVID era: a global survey to evaluate the ILD diagnostic pathway."

Working Group update

Adherence Working Group

The year 2023 has been characterised by steadfast commitment, collaborative efforts, and a relentless pursuit of excellence within the scoping project. This substantial undertaking entails the ongoing development of two manuscripts, currently in the works and anticipated for submission in the upcoming months. Phase I focuses on identifying key elements of effective adherence in managing chronic respiratory diseases through innovative technologies. Meanwhile, Phase II will assess existing methods for monitoring adherence and address common barriers in respiratory disease management, examining how guidelines tackle these challenges.

Allergy Working Group

The group met at REG Summit in March 2023 and EAACI Congress in June 2023 and discussed a prospective study on secondary prevention in moderate allergic asthma with AIT. The study aims to identify and standardise priority clinical outcomes within the first year of AIT in allergic asthma patients and assess the real-world effectiveness of AIT in different regions. A research proposal was developed and refined and sent to AIT companies for potential funding. New projects will be discussed at REG Summit in March 2024.

Child Health Working Group

The group spearheaded significant research initiatives, showcasing their dedication and proactive engagement in advancing respiratory research activities in 2023. A prominent endeavour was the ongoing Paediatric Asthma in Real Life (PeARL) project aiming to identify and prioritise research questions in paediatric asthma. Through the meticulous application of the Delphi methodology, systematic reviews, meta-analyses, and Delphi exercises, the group diligently evaluated available evidence to reach consensus on critical inquiries. Their commendable efforts yielded results published across scientific journals with notable impact factors.

Simultaneously, the group diligently worked on a retrospective epidemiological database study focused on unravelling the annual incidence of severe asthma in UK primary care settings and exploring the prevalence of asthmatic children referred to specialists or deemed eligible for biological treatments. Leveraging diverse criteria to define severe asthma in paediatric patients, the group received a dataset from OPCR, marking the start of data analysis and highlighting their unwavering commitment to advancing respiratory paediatric research in asthma. The analysis will be complete in Q3 2024.

Cost effectiveness Working Group

A research proposal has been developed to model and estimate the cost-effectiveness of time to initiation of biologic treatment in severe asthma patients. This project aims to evaluate

global and national-level cost-effectiveness of biologics and quantify national disease burden. The feasibility of the study was assessed and approved by ISAR and the proposal will be sent to potential funding companies.

COPD Working Group

Throughout 2023, the COPD WG embarked on ground-breaking research, demonstrating unparalleled dedication and tireless efforts. Their primary focus centred on understanding Peak Inspiratory Flow (PIF) in COPD patients. In September 2023, a significant milestone was reached in the PIF project, with complete patient information collected from follow-up visits across 17 international centres. The data was subsequently locked, paving the way for a meticulous analysis aimed at determining the prevalence of suboptimal PIF in COPD patients and exploring its predictive value for exacerbations and symptom burden, expected to be completed in the coming months alongside the study.

Simultaneously, patient information from baseline visits was analysed, culminating in the recent submission of a manuscript titled "Assessment of Peak Inspiratory Flow in Patients with Chronic Obstructive Pulmonary Disease: A Multicentre, Observational, Prospective, Real-life Study" to the Pulmonary Pharmacology & Therapeutics journal.

In 2023, the group's diligent efforts led to the successful securing of funding for a new COPD project focused on developing a risk prediction model for the first severe exacerbation in COPD patients as part of the PRECISE-X study. Since then, they have been working towards accessing the CPRD database, which has recently been granted. This milestone facilitates the initiation of the critical analysis process, planned for completion in Q3 2024. In parallel, the group developed a proposal and budget for the Triple Therapy project, which seeks to investigate the effects of triple therapy on post-discharge outcomes in COPD patients, leveraging data from hospital databases across 12 international study centres. The study proposal is currently under review by supporters with the aim of securing funding within 2024.

Database and Coding Working Group

Throughout 2023, the WG worked diligently to promote the STANDOUT project and garner support for standardising respiratory definitions and outcomes using real-world data. The WG embarked on a series of initiatives aimed at highlighting the project's strengths and fostering deeper engagement within the broader real-world community. Leveraging targeted communication strategies and proactive outreach efforts, they raised awareness about the significance of their work while also seeking to secure funding to further develop the project this year.

Environment, Epidemiology and Airways Working Group (formerly Small Airways Working Group)

The manuscript 'Inhaler Choice: A Global Survey to Identify Patient & Healthcare Professionals' was completed and, after further refinement, is now currently under review at CHEST journal. An REG opinion piece has also been written and once approved by the REG board, will be submitted for publication.

ILD/IPF Working Group

Following the closure of surveys for the research study aimed at characterizing ILD diagnosis in the post-COVID era, a final report was submitted to funders. Simultaneously, a manuscript was produced 'The Interstitial Lung Disease patient diagnostic pathway: from referral to treatment,' which is currently under review at Annals of ATS. Additionally, an abstract 'Role of virtual multidisciplinary team meetings in the post-COVID era: a global survey to evaluate the ILD diagnostic pathway' was accepted and presented as a poster at ERS Congress 2023.

The group developed a proposal for a project focusing on developing a risk assessment tool using diagnostic tests for the development of pulmonary hypertension in ILD patients. This proposal has been submitted to potential funders and is under review.

A proposal is currently being developed for a project aimed at identifying missed diagnostic opportunities among respiratory patients who met guidelines criteria for ILD referral but were not referred. Additionally, the project aims to retrospectively analyse patient data to delineate specific criteria associated with different subtypes of ILD diagnoses.

Severe Asthma and Biomarkers Working Group

At the last WG meeting, the group explored alternative possibilities for their future projects. They meticulously considered various options and innovative ideas, aiming to discover new approaches for their upcoming research activities. The next step for the group will be to develop the most effective strategies to advance their work, showing their expertise and dedication in advancing respiratory real-life research.

Technology Working Group

At REG Summit 2023, new technologies were discussed but new project ideas could not be established. Potential new project ideas will be discussed at the working group meeting at the upcoming REG Summit.

Vaccines Working Group

During ERS 2023, collaborators expressed keen interest in delving into vaccine coverage and adherence within respiratory care. Subsequently, a new research proposal has been crafted, focusing on examining vaccine uptake among COPD patients and evaluating the clinical and economic implications of vaccination. This proposal has been submitted to potential funders and is currently undergoing review.

Active and planned projects

Project name	Description	Current phase
COPD		
Assessing the utility of Peak Inspiratory Flow as a predictor for COPD exacerbations (PIF in COPD)	A prospective trial to assess the role of PIF in predicting COPD exacerbations	Follow-up visits completed and data set received for final data analysis. Manuscript on the baseline characteristics submitted to a peer-reviewed journal.
PREdiCTing the risk for first COPD Severe EXacerbation (PRECISE- X)	Development of a risk prediction model for first severe COPD exacerbation	Study protocol approved from CPRD. Awaiting dataset for data analysis
Child Health		



PeARL: Paediatric Asthma in Real Life	A standard setting exercise in paediatric asthma based on systematic review, expert consensus and ontological analysis of the unanswered questions in paediatric asthma	Manuscripts submitted
Determining the prevalence of severe asthma in children in UK primary care	Retrospective database study to assess the prevalence of severe asthma in children (5-16 Y) in UK primary care and the proportion of asthmatic children referred to a specialist and/or eligible for biologic treatments	Data set received from OPCR. Data analysis ongoing.
Environment, Epidemiology & Airways		
Expert opinion on the impact of inhaler choice on climate change and patient outcomes	Survey and position statement on choice of inhaler delivery method (DPI, pMDI & SMI) and the impact of on climate change and patient outcomes	Manuscript under review at peer-reviewed journal. Position statement to be reviewed by REG board.
Adherence		
Adherence monitoring and management	Literature reviews to assess how adherence is currently incorporated within guidelines and to determine how adherence can be monitored and managed with personalised medicine.	Manuscripts finalised and now under revision.
COPD		
Effects of triple pharmacological therapy on post-discharge outcomes in patients with COPD	A prospective study to investigate the frequency and risk factors for readmission and early exacerbations in patients discharged after an exacerbation of COPD and the impact of triple therapy in prolonging the time to the next admission	Proposal+budget developed, and now seeking funding.
Database and Coding		



Standardisation of respiratory definitions and outcomes using real world data	The project will establish definitions and standards for use of European RWD sources while monitoring and improving their mapping to common data models	Seeking to secure funding.
Towards Optimum Reporting of Pulmonary Effectiveness Databases and Outcomes (TORPEDO)- PHASE 2	Survey to determine a list of current databases and which of the minimum variables from Phase 1 they contain, and a tool for the website to add selection of variables for prospective studies	Proposal drafted.
ILD		
Global Evaluation of the Interstitial Lung Disease (ILD) Diagnostic Pathway in the Post-COVID Era	Survey to identify the current structure of vMDTs / standardized diagnostic approach in the post-COVID era and challenges in post-COVID fibrosis and COVID-associated complications	Manuscript submitted and under review at peer reviewed journal.
Pulmonary hypertension in ILD patients: Development of a risk assessment tool using diagnostic tests	Using retrospective and registries to develop a risk assessment tool using diagnostic test data for the development of pulmonary hypertension in ILD patients	Research proposal has been submitted to funders and under review.
Uncovering Missed Opportunities in ILD Diagnosis	Retrospective database study to identify missed diagnostic opportunities among respiratory patients who met criteria for ILD referral but were not referred.	Proposal in development.
Severe Asthma & Biomarkers		
Biomarkers to predict the outcome of biological treatment	Using data from various registries to look at blood eos, FeNO, and IgE changes in response to treatment with biologics and investigate the interactions between different biomarkers and comorbidities to predict the use of biologics.	Discussed at WG meeting during the REG Summit 2023.
Allergy		
Secondary Prevention in Moderate Allergic Asthma with AIT	Prospective observational study to	Research proposal has been submitted to



	demonstrate in patients with allergic asthma of moderate severity AIT can improve disease control and reduce the frequency of severe exacerbations.	funders and under review.
Cost Effectiveness		
A global evaluation of the economic impact of time to initiation of biologic treatment of severe asthma patients	Economic model to estimate the cost-effectiveness of early vs late biologics in severe asthma patients.	Research proposal has been developed and will be sent to funders.
Vaccines		
Vaccine Uptake and Exacerbations in COPD Patients	Database study to vaccine coverage and uptake trends in COPD patients and evaluate the clinical and economic impact of vaccination.	Research proposal has been developed and will be sent to funders.

Publications in 2023

In 2023, REG achieved 3 publications of its research and activities. A further 2 manuscripts are in preparation. A full list of REG research publications is available on the REG website: <http://regresearchnetwork.org/reg-research-publications/>

Role of virtual multidisciplinary team meetings in the post-COVID era: a global survey to evaluate the ILD diagnostic pathway

Graham Lough, Rayid Abdulqawi, Gina Amanda, Katerina Antoniou, Arata Azuma, Ahmed Bayoumy, Milind Baldi, Jürgen Behr, Elisabeth Bendstrup, Demosthenes Bouros, Kevin Brown, Nazia Chaudhuri, Tamera J Corte, Vincent Cottin, Bruno Crestani, Kevin Flaherty, Ian Glaspole, Leticia Kawano-Dourado, Michael Keane, Martin Kolb, Fernando J Martinez, Maria Molina-Molina, Ferran Morell, Iñigo Ojanguren, Laurence Pearmain, Ganesh Raghu, Paola Rottoli, Stefan Cristian Stanel, Gabriela Tabaj, Carlo Vancheri, Brenda Varela, Bonnie Wang, Athol Wells, Pilar Rivera-Ortega *European Respiratory Journal* 2023 62: PA3921. doi: 10.1183/13993003.congress-2023.PA3921.

https://erj.ersjournals.com/content/62/suppl_67/PA3921

Next generation health guidelines: The role of real-life data in evidence-based medicine

G. Walter Canonica, Ioana Agache, Holger J. Schünemann, Nicolas Roche, David Price, Stefano del Giacco *Allergy* 2023; 79(1):12-14. doi: 10.1111/all.15887.

<https://onlinelibrary.wiley.com/doi/epdf/10.1111/all.15887>

Current and optimal practices in childhood asthma monitoring among multiple international stakeholders

Nikolaos G. Papadopoulos, Alexander G. Mathioudakis, Adnan Custovic, Antoine Deschildre, Wanda Phipatanakul, Gary Wong, Paraskevi Xepapadaki, for the PeARL Think Tank *JAMA Network Open* 2023;6(5):e2313120. doi:10.1001/jamanetworkopen.2023.13120.

<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2804856>

Financial summary

Profit and Loss

Respiratory Effectiveness Limited Trading as REG (Respiratory Effectiveness Group)

For the year ended 31 December 2023

	2023	2022
Turnover		
Restricted Income	341,484.83	195,880.42
Unrestricted Income	58,586.05	124,995.50
Total Turnover	400,070.88	320,875.92
Cost of Sales		
Research Costs	227,435.01	116,790.14
Summit Costs	2,016.76	25,914.73
Total Cost of Sales	229,451.77	142,704.87
Gross Profit	172,635.87	204,085.78
Administrative Costs		
Administrative Costs	167,339.74	139,553.07
Total Administrative Costs	167,339.74	139,553.07
Total Costs	396,791.51	282,257.94
Net Profit/(Loss)	3,279.37	38,617.98



Balance Sheet

Respiratory Effectiveness Limited Trading as REG (Respiratory Effectiveness Group)

As at 31 December 2023

	31 DEC 2023	31 DEC 2022
Assets		
Bank		
BARC EUR	121,634.59	162,855.21
BARC GBP	270,245.44	395,350.66
BARC USD	28,633.88	30,208.73
Total Bank	420,513.91	588,414.60
Current Assets		
Accounts Receivable	10,132.70	11,912.03
Total Current Assets	10,132.70	11,912.03
Total Assets	430,646.61	600,326.63
Fixed Assets		
Tangible Assets		
Office Equipment - accumulated depreciation	(585.33)	(585.33)
Office Equipment - at cost	586.33	586.33
Total Tangible Assets	1.00	1.00
Total Fixed Assets	1.00	1.00
Total Assets	430,647.61	600,327.63
Liabilities		
Creditors Liabilities		
Accounts Payable	524.16	7,913.96
Deferred Revenue	284,939.80	442,633.20
PAYE & NIC Control	344.08	-
Pension Fund	328.53	328.53
VAT Control	(413.19)	(269.29)
REG Barclaycard	346.86	138.25
Total Creditors Liabilities	286,070.24	450,744.65
Total Liabilities	286,070.24	450,744.65
Total Liabilities	286,070.24	450,744.65
Net Assets	144,577.37	149,582.98
Equity		
Accumulated Surplus	141,298.00	110,965.00
Current Year Earnings	3,279.37	38,617.98
Total Equity	144,577.37	149,582.98