

# ADVANCES IN... REAL-LIFE RESPIRATORY MEDICINE

## The Respiratory Effectiveness Group Newsletter

The first half the year has been exceptionally busy, with a number of exciting new projects launching across a range of Working Groups. A highlight so far has definitely been the REG 2016 Summit, which was the largest REG event to date. You can read more in this edition about the Summit, including details of prize winning abstracts and an upcoming Special Issue of the *Journal of Thoracic Disease* guest-edited by Prof. David Price.

The new REG Executive Committee met face-to-face for the first time at the event and discussed how to take REG to the next stage of its development and transform into a scientific research organisation which facilitates the very best in high-quality comparative effectiveness respiratory research. The Executive Committee are currently examining how to best develop the goals and ambitions of the organisation in order to ensure that we continue to support quality research which has a positive impact on regulatory guidelines and clinical care.

The REG Working Groups have taken on an ambitious number of projects both in scope and range which will contribute to the realisation of REG's extended aims and objectives. You can read more about the plans of each Working Group in this edition of the newsletter including a number of

projects which promise to have a significant impact in the field.

REG continues to maintain a presence at a number of key respiratory conferences across the globe. This edition of the newsletter includes details of planned meetings and events, including further details of the events to be held at the upcoming ERS 2016 Congress in London.

As highlighted in the Spring newsletter, the new REG website has now been launched; the new site now includes exclusive file sharing functionality for all REG Collaborators. The service is provided via a secure shared platform which will facilitate increased collaboration across REG by providing a convenient online resource to support numerous projects currently in the REG stable.

We would like to thank all of REG's Collaborators and Supporters for such an impressive start to the year - our continued success is based on the outstanding work and generous provision of time, expertise and resources across our network which allow us as an organisation to go from strength to strength.

### Welcome New Director Dermot Ryan

REG is currently undergoing structural changes in order to ensure that we continue to deliver real-life research projects in respiratory medicine which have a positive impact on the regulatory environment and clinical care.

David and Alison were the directors when REG was founded in January 2013 as a short-term initiative, but that now REG has become more established and is intended as a long-term research and advocacy group we are reviewing the organisational structure. The first step was the extension of the Executive Board/ Committee who are now reviewing the optimum structure to future proof the group, but a necessary initial step was for an immediate change in ownership. Both David and Alison have relinquished ownership and Dr Dermot Ryan is joining the Board as a voluntary Director of REG.

Recently retired from clinical practice, Dermot was a GP with a long-standing interest in respiratory disease and allergy

as encountered in primary care. Dermot is honorary clinical research fellow at the University of Edinburgh and chairman of the Primary Care Interest Group of the European Academy of Allergy and Clinical Immunology. He has been chairman of the Primary Care Respiratory Society and established the chair of Primary Care Respiratory medicine at the University of Aberdeen. He was instrumental in setting up Primary Care Respiratory Medicine, and was one of the clinical leads for respiratory disease for the East Midland Strategic Health Authority. He has undertaken research in ehealth, asthma and rhinitis and participates in a number of



REG Working Groups. We are confident that Dermot's increased involvement will have a positive impact on REG and we are delighted to welcome him to the team.

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# REG 2016 Summit

The event was the most successful for REG to date, with 102 delegates joining us from 15 countries. As well as the numerous productive sessions at the event, REG was delighted to welcome academic exhibitors to the event to share their work and consider opportunities for future collaboration.

The theme was the *Impact and Influence of Real-World Respiratory Evidence* and combined plenary talks with interactive panel sessions, pro-con debates and abstract sessions. 32 abstracts were presented at the event either as an oral presentation or as part of the varied poster presentation

which took place in the exhibition area. The REG 2016 Summit Scientific Committee was impressed to have received so many high-quality abstracts for inclusion in the event and worked closely with CSO Alison Chisholm to group them thematically across seven oral and poster sessions held over the two days. The abstracts will be published in an upcoming issue of the *Journal of Thoracic Disease* covering the theme of real-life research and will also carry an editorial from Prof. David Price and a summit report.

The summit was scheduled to dovetail with the final symposium for the EU Funded ASTRO-LAB Study (<http://www.astrolab-project.eu>; Seventh Framework Program under Grant Agreement n° 282



593). The ASTRO-LAB symposium was the culmination of a 4-year Assessment of the LABAs benefit/risk ratio in asthma in routine care by combining healthcare databases and direct patient follow-up. The coincident timing reflected the close working relationships of ASTRO-LAB investigators and REG collaborators and their shared ethos – that there is a need to look beyond the classical registration randomised controlled trial (RCT) evidence and to consider also long-term studies in broader patient populations conducted in routine care settings to understand the true effectiveness and safety profiles of routinely used respiratory medications.

The opening plenary session considered the application of Precision Medicine (PM) in respiratory conditions and set the tone of the event, which had the patient at the heart of future improvements in care and outcomes. The model proposes tailoring treatment to the individual patient and therefore there is significant potential for RWE to inform clinical management decisions and help to realise PM in chronic respiratory diseases. The presenters of the session, Prof. David Price and Dr Alan Kaplan, considered

PM in the context of asthma and COPD and agreed that personalised care is vital to the successful execution of precision medicine and that data gathered from such an approach can have a significant impact on patient outcomes.

The increasing importance of patient voice was also considered with respect to the value it has in ensuring that therapies have positive impact on patients' health-related quality of life. Plenary speaker Prof. Thys van der Molen highlighted how objective trial endpoints in respiratory medicine miss the impact of most importance to patients – dyspnoea – and fail to

capture many of the realities of living with chronic respiratory disease. Regulatory bodies are increasingly interested in patient voice and it is clear that patient perceptions of disease and desired treatment outcomes cannot be overlooked when appraising the risk-benefit of a potential intervention.

The discussion tied neatly into a presentation considering application of technology for remote assessment and the need for standards which ensure future developments deliver real benefits to patients. Technology can present both opportunities and risks and it is only when putting the patient at the heart of the discussion can any such advances help to alleviate pressure on the healthcare system and deliver real benefits. Technology is currently being driven by market forces, but a more patient-centric approach could be the key to both improved outcomes but also the collection of data with clinical value which will further the insights provided by real life research.

A presentation on the role of RWE in informing relevant and meaningful cost effectiveness evaluations also showed that the patient was at the heart of improvements to care.



REG 2016 SUMMIT GOLD SPONSOR



# REG 2016 Summit



Listening to patients and then aggregating and analysing the data provided in real life research can highlight opportunities to save costs. Cost effectiveness has, in recent years, been an additional regulatory hurdle for pharmaceutical innovations with both healthcare costs and treatment alternatives on the rise. A panel discussion at the summit included market access experts from the academic and commercial sectors, and addressed a number of areas from the question of affordability versus cost-effectiveness to consideration of indirect costs and pinpointing where within the healthcare system the cost is borne. A look at future research needs in the field of cost effectiveness showed that there is much work to be done, but a significant opportunity to place the patient at the heart of the process in

evaluation to be taken when developing guidelines. There is no doubt that real-world evidence can play a valuable role in establishing guidelines for care, but it is vital that this area of research has quality standards in place which proves this value. Leading the project, Professors Nicolas Roche and Jon Campbell reviewed the traditional GRADE approach to evidence evaluation. This approach is used by over 70 guideline developers and although GRADE considers observational studies low quality evidence, the taskforce did not seek to challenge this approach, but rather to examine the ways in which research can be considered low quality and how researchers can seek to mitigate these circumstances in the design and publication of real-life research. The project also led to the creation

a way that both reduces costs and increases benefits.

The summit also hosted an initial presentation of the results of the REG / EAACI Quality Standards Taskforce, formed in response to calls for an integrated approach to evidence

of a database of high quality real life respiratory research which could prove valuable in the development and implementation of guidelines.

This project highlighted the value of real life research in guideline development and reinforced the need for quality standards to ensure that observational studies are taken into account and therefore put the patient at the heart of the process when developing guidelines.

The output from the REG 2016 Summit made it clear that the patient should be at the heart of developments in care and that observational research has a valuable role to play in making that patient voice heard. The REG Working Groups will continue to address evidence gaps and provide high quality research which raises the profile and utility of observational research in clinical practice.



## REG 2017 Summit

We're still working on the details, but we can confirm that next year's REG Summit will be taking place in London, UK some time in Spring 2017.

More information to follow soon!

## Prize-Winning Abstracts

BEST POSTER:  
REG024a/b

Comparative effectiveness of prescribing similar versus dissimilar inhalers for COPD therapy / Comparative effectiveness of prescribing additional similar or dissimilar device inhaled COPD therapy.

Bosnic-Anticevich, S et al.  
(Presenting author: Simon Wan Yau Ming)



BEST METHODOLOGY: REG010  
Validation of real-world, non-research thoracic CT scans for quantitative analysis of COPD. Dandurand, R et al.

BEST CLINICAL MANAGEMENT: REG003  
Effect of beta-blockers on the risk of COPD exacerbations. Lahousse, L et al

BEST ASSESSMENT AND/OR DIAGNOSIS: REG011  
Validity of the five-level new version of the EQ-5D in asthma patients. Hernandez, G et al.

*All abstracts from the event are available in an issue of the Journal of Thoracic Disease due to be published at the end of July 2017. The abstracts are featured within this issue and include 30 examples of how real-world study methodologies can and are being used to: Quantify real-world and characterize respiratory conditions; Characterize real-world diagnostic and Management practices; Validate objective and patient-reported clinical and research tools. They also illustrate how RWE can be used to: explore and characterize adherence behaviours and inhaler device technique challenges and to evaluate: risk and its management; differential clinical outcomes associated with real-world management approaches and cost implications associated with specific conditions, treatment approaches, socioeconomic factors and comorbidities.*

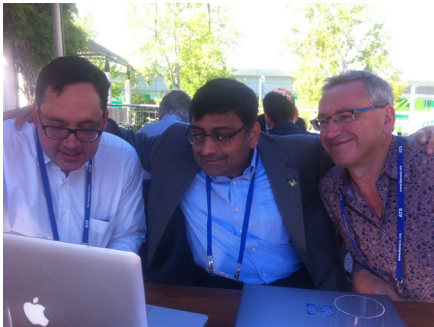


Journal of Thoracic Disease

# Working Group Updates

## ACOS Working Group

The aim of the ACOS Proof of Concept Study was to acknowledge and ameliorate the current situation, whereby a lack of standard tools and definitions pose a barrier to future ACOS research. A review of the optimum approach to the study ensured that it was designed to evaluate the respective prevalence and level of agreement between different definitions of ACOS (within and between a range of international databases) to develop future research tools for real-world ACOS research. Following discussions at the ATS between co-chairs of the group Jerry Krishnan and Nicolas Roche to finalise the protocol, the Group are now seeking funding in order to start the study across five databases.



ACOS Working Group in San Francisco during ATS 2016

The Group are currently working on a paper to report the initial outcome of the study and highlight the need for future work in this area, due to be submitted later in the summer.

## Adherence Working Group

Phase I of the Bi-Directional Adherence study has been completed and submitted for publication. The study is a two-part research project which aims to explore the relationship between asthma control status and asthma outcomes: whether good control results in poor adherence and/or whether high adherence results in controlled disease. The first phase - evaluation of control patterns and patterns of different adherence measure rates over a continuous 3-year

period - will inform the correct inputs for the multilevel interaction analysis of adherence and control planned in Phase II, which has just commenced.

Proofs are being finalised for the **JACI: In Practice Special Issue** covering the output of the Adherence Expert Panel Meeting held in Barcelona in June 2015, just after last year's EAACI congress. All peer-reviewed articles from the issue will be available online, with an allocated print publication date of September 2016.

## Allergy Working Group

The Chronic Rhinosinitis study led by Wytke Fokkens is currently in manuscript development; the aim was to develop algorithms to differentiate between chronic and acute rhinosinitis using the Optimum Patient Care (OPC) database with a view to quantifying the true burden of this chronic disease. Descriptive analysis is being finalised, including more drug breakdowns.

**The Allergy Working Group took place in Vienna during the EAACI 2016 Conference.**

## Biomarkers Working Group

The Biomarkers Group continue to work on an Editorial highlighting the differences (reasons for and implications of) the National Institute for Health and Care Excellence's (NICE) and the Global Initiative for Asthma's (GINA) recommendations on the use of FeNO. The paper is being drafted by Kjell Alving, Zuzana Diamant and Leif Bjerner. The outline has been completed for another Biomarkers paper which explores the utility of blood eosinophils as a predictor of future risk in COPD.

The Group are currently investigating funding options for a new study on the prospective evaluation of the value of FeNO to predict ICS responsiveness in COPD eosinophils.

**The next official meeting will take place during the ERS 2016 Conference in London. (pp.7)**

## Small Airways Study Group

The Group met at the REG 2016 Summit

in Lyon; the meeting marked the first time that new Working Group lead Omar Usmani chaired the meeting. The Group extended their thanks to former lead Richard Martin for all his outstanding work with the Group and discussed current projects and future plans. The Group have had three papers accepted for publication since last meeting and a further papers on the Ciclesonide Study under review.

The pre-school asthma / wheeze project is progressing – a baseline descriptive analysis was shared at the 2015 ERS 2015 and in Lyon, the Group discussed the preliminary matched analysis of extrafine ICE vs non-extrafine ICS. The original matching criteria led to a clear mis-match in terms of the extrafine vs non-extrafine patients in terms of their baseline exacerbations and the group agreed to revisit the matching criteria to progress the study.

The Group also discussed the REG / EAACI Taskforce systematic review and considered how the work can not only provide a synthesis of the real-world evidence, but also provide suggestions / rationale for where there may be differences in outcomes between RCTs and real-life studies, where found (e.g. different populations, different outcomes).

## COPD Working Group

Under the leadership of Working Group Lead Marc Miravittales, the group is conducting a number of studies to evaluate the clinical validity and utility of the concept of "control" in the real-world management of COPD (Soler-Cataluña JJ et al. Int J COPD 2014;9:1397-1405). The pilot database work is now at the manuscript stage.

Recruitment is now underway for the prospective validation study that will include approximately 300 patients in Spain, the UK, Ireland, Singapore, Poland, possibly Canada, France and Korea.

## NEW WORKING GROUP: OBSTRUCTIVE SLEEP APNOEA (OSA)

During a meeting at the recent ATS 2016 Conference, REG Collaborator Dr Mihaela Stefan proposed the creation of a new REG Working Group focussed on Obstructive Sleep Apnoea (OSA). The aim of the group would be to explore the implications on disease control and severity of having comorbid sleep apnoea in patients with other respiratory conditions (i.e. asthma, COPD). Real-world studies are required to target these patients as they are routinely

excluded from trials.

The first study for consideration by the group would explore whether positive airway pressure (PAP) reduces the utilization of medical services in patients with obstructive lung disease (OLD), the hypothesis being that use of PAP will be associated with an improvement in outcomes in patients with OLD and coexistent OSA.

Discussions on the plans for initial studies will be ongoing throughout the summer,

prior to the inaugural meeting of the REG OSA Working Group, which will be held in London during the ERS 2016 Conference in September.

**If you are interested in helping to form the REG OSA Working Group as a Collaborator or a Supporter and wish to be kept informed about the details of the forthcoming OSA Working Group Meeting, please contact [zoe@effectivenessevaluation.org](mailto:zoe@effectivenessevaluation.org).**

# Working Group Updates

## Cost Effectiveness Working Group

The Group met at the recent REG 2016 Summit in Lyon to confirm their scope and objectives, including plans to collaborate with other Working Groups within the REG network. This was followed up at the ATS in May with discussions focussing on how to maintain the sustainability of the Group and consider avenues of funding. The agreed aim is to evaluate respiratory interventions in terms of economic, clinical, and patient-centered outcomes. The focus will be chronic respiratory conditions, specifically, but not limited to obstructive lung diseases (e.g., asthma, COPD, and smaller populations such as cystic fibrosis). The primary objectives of the Group are as follows:

- Understand global health technology assessment (HTA) climate and data requirements for HTA decision-making
- Identify current evidence gaps in respiratory HTA/cost-effectiveness research
- Propose study designs and acquire funding for modelling exercises for HTA respiratory decision making requirements/cost-effectiveness research questions
- Lead on targeted cost-effectiveness

methodology and applications in respiratory research and disseminate the information to end users (clinicians, patients, and public and private payers)

- Support other REG working groups (and other collaborative partners) in addressing specific cost-effectiveness-related research questions.

The Cost-Effectiveness Working Group are currently agreeing priorities from a list of proposed research questions, which include a study into oral steroid sparing – examining the indirect cost of maintenance oral steroids. The biologics for severe asthma are having to meet increasingly high barriers to gain market access (e.g.  $\geq 4$  courses of oral steroids required before patients become eligible for mepo) and therefore the cost of steroid comorbidities is a significant area. A recent Thorax paper from Sweeney et al. (*Comorbidity in severe asthma requiring systemic corticosteroid therapy: cross-sectional data from the Optimum Patient Care Research Database and the British Thoracic Difficult Asthma Registry* Sweeney J, Patterson CC, Menzies-Gow A, et al. *Thorax* doi:10.1136/thoraxjnl-2015-207630) quantifies steroid

comorbidities but as yet there hasn't been any work considering the costs. It is a natural first step for the Cost Effectiveness Working Group to model the cost implications and REG is currently seeking funding to support this work.

Future plans for the Cost Effectiveness Group include a consideration of Interstitial Lung Diseases (ILD), in particular Idiopathic Pulmonary Fibrosis, (IPF). The challenge with IPF studies is that they require secondary care prescribing data but the Group are considering databases that may make this possible and will be working with the ILD Working Group to develop the project.

All the project ideas under discussion in Lyon and San Francisco are currently being clarified and will be put forward for consideration in the next REG Research Review, which is due to take place over the summer.

The team are also currently considering opportunities to develop a review article which will act as a position piece introducing the opportunities in the area of cost effectiveness and outlining research needs in this increasingly vital area.

## IPF / ILD Working Group

The Group met in San Francisco during the ATS 2016 to clarify the next steps for the project *Global Evaluation of Multi-Disciplinary Team (MDT) Diagnosis in the Real World*. The Group's overall aim is to identify features of ILD MDTs associated with more accurate diagnosis of IPF to improve diagnostic accuracy and patient stratification and optimise treatment outcomes worldwide.

Phase I aims to characterise diagnostic practice in different geographical areas (in terms of composition, functionality, etc.). The outputs from Phase I will be:

- Characterisation of the ILD diagnostic process globally
- Valuable insight as to current diagnostic practices to inform the robust design of Phase II
- Characterised global network of ILD centres for phase II diagnostic agreement / accuracy study and future ILD and IPF research (RCT and real-life studies).

Phase II aims to design a diagnostic agreement and accuracy study involving centres that reflect real-world practice.

The study will include both dedicated and non-

dedicated ILD centres and countries within both mature and expanding economies covering all continents. Of particular interest will be features of practice in BRIC countries, owing to their limited representation in previous studies and large population size. Lead collaborators will provide local expertise on geographical distribution and weighting of diagnostic case load across centres.

The Group are employing the Qualtrics platform to gather information via an online questionnaire designed to optimise data capture and completion by what is expected to be a diverse group of participating sites. The group have identified national / regional leads for the project to serve as dissemination nodes; they discussed any necessary local adaptations of the survey, such as translations, relevance checks and whether the online format would be practicable for all target sites. The final edits of the survey are currently taking place and it is expected to launch in the next month, with Phase I of the study completed by the end of the year.

**The next meeting of the iILD Working Group will take place at the ERS venue, ExCel London on Sunday 4th September.**

## SEVERE ASTHMA WORKING GROUP

A new working group has been proposed to examine the increasingly vital issue of Severe Asthma.

The proposed initial project of the group, which will be working closely with colleagues in the REG Biomarkers Working Group, will be to compile a Global Severe Asthma Registry. A protocol is currently being developed by REG Executive Committee members Walter Canonica and Nikos Papadopoulos.

Chaired by Rohit Katial (National Jewish Health, Denver, CO. USA), the inaugural meeting of the group will take place on Saturday 3rd September as part of the REG meetings and events taking place during the ERS from 09:00-10.30 at the Royal College of General Physicians (RCGP). All are welcome to attend. If you are interested in learning more about the Group or wish to join as a Collaborator or Supporter, email [enquiries@effectivenessevaluation.org](mailto:enquiries@effectivenessevaluation.org) for further details.

# Working Group Updates

## REG / EAACI Quality Standards Taskforce

The REG / EAACI Taskforce was put together to conduct a systematic critical review of the real-life asthma literature. Together, the Taskforce built a quality assessment tool to synthesise, discuss and conclude on quality, and potential influence of current comparative effectiveness literature on future guideline and/or need for additional studies. The initial results of the study were presented at the recent REG 2016 Summit in Lyon, France showing the performance of papers across a range of fields. The practical applications of the results were discussed - for guideline groups they may support the revision of guidelines and the appraisal of evidence; the tool may be used by journal editors to assess the quality of the submission and to train new researchers on best practice. The tool may also be used in advocacy to highlight limitations in the evidence and clear areas for improvement in the reporting of, if not the design of observational studies in the future.

## Child Health Working Group

A study which evaluates treatment choice in pre-school asthma/wheeze with a view to establishing potential differential effect of extrafine inhaled corticosteroid (ICS) treatment is in progress. The study is being led by Jonathan Grigg and conducted in

collaboration with the Child Health and Small Airways Working Groups. The baseline analysis has been completed and matching (relative to EF ICS) is now underway in parallel with the unmatched outcome analysis.

A project led by Nikos Papadopoulos and Clare Murray is also underway to evaluate the comparative effectiveness of adding antibiotics to usual care (oral steroids) for the management of asthma exacerbations.

## Technologies Working Group

A key priority for the Technologies Working Group is the development of a review article which acts as a position paper indicating the scope of the working group and seeking further engagement from the clinical respiratory community. The paper will build on the recent session held at the REG 2016 Summit – *Setting the Standards for Remote Assessment and Monitoring in Respiratory Medicine*. As such, it will consider both the opportunities and challenges that technology presents, including the potential to alleviate the pressure on healthcare systems through technology-supported patient self-management and the challenges to deliver technology solutions which offer a holistic solution which does not leave patients with chronic conditions such as asthma with a plethora of apps and

technologies which lead to more confusion. The Group considered their plans in light of the WHO Mhealth recommendations published in the BMJ and recognised the need for greater clinical guidance for app developers to ensure utility and also for greater involvement of regulatory bodies to ensure the effectiveness of new technologies to support patients in self-management. These areas will be covered as recommendations in the planned paper - a first draft has been drawn up and the Group hope to submit the paper later in the summer. The Technologies Working Group are also consulting on the upcoming Mundipharma app launched at the REG 2016 Summit; a demo version is currently being developed and the Group will provide input on specific aspects of the design, content and functionality of the solution. A beta version of the Online Asthma Risk Calculator is now live. This initial release covers the functionality of the tool. The Technologies Group are currently working on User Acceptance Testing of the application to ensure that it functions as expected and completes the calculations correctly.

The beta version of the site, a link is available on the Resources section of the REG website [www.effectivenessevaluation.org/ARC](http://www.effectivenessevaluation.org/ARC)

## Databases & Coding Validation Working Group

The Databases and Coding Validation Working Group met at the recent REG 2016 Summit and at the ATS in May; the discussion centred on opportunities to examine the scope of the "ideal" respiratory database to be used for observational respiratory research and to develop an inventory of existing databases.

The group explored what they could do to share and support common standards for minimum/maximum data collection and support improvements in database coding.

The Group are currently working on the development of a Delphi Study to support standardisation of data collection fields so that databases can be compared and partnered for consortia studies and grant applications more easily identified. The Towards Optimum Reporting of Pulmonary Effectiveness Databases and Outcomes (TORPEDO)-project will involve a carefully selected and well-balanced international expert panel (+/-30 members) with expertise in one or more specific respiratory fields (asthma, allergy, COPD, IPF/ILD, primary care, health economics and/or databases). The Delphi procedure will also involve a wide range of stakeholders – researchers, journal editors, society members, guideline writers etc. – to generate a complete list, akin to the method used by ISPOR to develop the CHEERS checklist

for health economic models.<sup>1</sup>

The International Primary Care Respiratory Group (IPCRG's) UNLOCK Group have already done some work on standardising data collection fields to facilitate international studies using multiple databases and the Group are currently looking at opportunities to collaborate with UNLOCK on the study.

Through the Delphi process, also identifying the minimum criteria that databases need to have to be used for respiratory research. This would potentially act as a quality assessment guide for researchers and as a development guide for those developing new databases.

Questions and fields for the Delphi study are currently being finalised and Phase I of the study will be distributed shortly.

Phase I of the study focusses on capturing the full scope of variables for an ideal database. Subsequent phases (Phase II and Phase III of the Delphi Study) will focus on reducing the list to the variables minimally required. Phase II will allow for voting / endorsing the variables and Phase III will be an exercise in prioritising those agreed. These subsequent phases will also look to target both the respondents and analysis by considering priorities in different disease areas – for example, asthma, COPD, IPF – and also by study type – for example comparative effectiveness, cost effectiveness

of epidemiological studies.

The Database Characterisation project will make use of the newly created TORPEDO checklist to ease comparison and stimulate data merging, as well as providing a valuable resource to support the design of new databases. The Group will be making use of the new REG website file-sharing functionality [www.effectivenessevaluation.org/files](http://www.effectivenessevaluation.org/files) to share and discuss different databases and the optimum fields required. All of the databases considered by the Group to offer sufficient information for quality research will be listed under Resources on the REG website as well as on the Databases and Coding Working Group page. This will include characterisation of the databases that are available to different group members and that have been used by group members (e.g. for past REG Summit abstracts). This work will supplement existing work from Bridge to Data and ENCePP by having a particular respiratory focus. It will fit well alongside the on-going ERS initiative to develop a repository of respiratory data sources at a European level. The ERS work will include registries, clinical networks, tissue banks as well as databases to support and plan projects at a European level and to support EU-funding bids.

1. <http://www.equator-network.org/wp-content/uploads/2013/04/Revised-CHEERS-Checklist-Oct13.pdf>.

# Event Calendar



## Respiratory Conferences in 2016

### September

ISPOR APAC Conference	Singapore	3-6 September
ERS International Congress	London, UK	3-7 September
REG Meetings and Events	London, UK	3-6 September

### October

37 <sup>th</sup> Brazilian Thoracic Congress	Rio de Janeiro, Brazil	11-15 October
Impact of age and gender on therapeutic response to asthma		12 October (11.30 - 12.00)
PRO/CON debate: Management of asthma in clinical practice: randomized controlled trials versus real-life studies		13 October, (09.40-10.30)

### November

APSR Congress	Bangkok, Thailand	12-15 November
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## ERS 2016

The Respiratory Effectiveness Group team will be attending the ERS 2016 Congress in London, UK and we are organising a number of meetings during the event.

The majority of the REG meetings will take place on Saturday 3rd September.

All the meetings will take place at the Royal College of General Practitioners (RCGP), 30 Euston Square, London NW1 2FB. [www.rcgp.org.uk](http://www.rcgp.org.uk)

REG Collaborators are also presenting in a poster session at the Congress.

### Sunday 4<sup>th</sup> September

**12.50-14:40:** Validation of the COPD control concept: a UK pilot Thematic Poster Presentation; Location T26

## REG Events at ERS 2016 Congress

Meeting Room G.4.5.RCGP, 30 Euston Square, London, NW1 2FB



Due to the time and resource available, we aren't able to hold a full meeting for each Working Group. If you would like to request a meeting in reference to specific project or Working Group that is not listed in this provisional timetable, or wish to organise a more informal meeting with any member of the team, contact [enquiries@effectivenessevaluation.org](mailto:enquiries@effectivenessevaluation.org) to schedule an appointment.

### Saturday 3<sup>rd</sup> September

- 09:00-09:30:** Future Risk (invitation only)
- 09:30-10:30:** Databases Working Group
- 10:30-11:45:** Asthma-COPD Overlap Working Group Meeting
- 11:45-12:15:** REG-EAACI Taskforce
- 12:15-13:45:** Executive Committee Meeting (invitation only)
- 13:45-15:00:** Severe Asthma & Biomarkers Working Group
- 15:00-16:00:** COPD Working Group
- 16:00-17:00:** Small Airways & Child Health Working Groups
- 17:00-18:15:** Obstructive Sleep Apnoea Working Group

### Tuesday 6<sup>th</sup> September

- 10:00 - 11:30:** ILD Working Group (ExCel London)
- 19:00 - 22:00:** App Development Committee (Chandos House, W1)  
*(In conjunction with Optimum Patient Care and Mundipharma)*

**A full schedule of events is available on the REG website**



**ERS INTERNATIONAL CONGRESS 2016**  
LONDON united kingdom, 3-7 september

## New Papers

### Pulmonary Therapy

Roche R, Colice G, Israel E, Martin RJ, Dorinsky PM, Postma DS, Guilbert TW, Grigg J, van Aalderen WMC, Barion F, Hillyer EV, Thomas V, Burden A, McQueen RB, Price D  
Cost-Effectiveness of Asthma Step-Up Therapy as an Increased Dose of Extrafine-Particle Inhaled Corticosteroid or Add-On Long-Acting Beta2-Agonist  
Pulm Ther. 2016;2(Online First): In Press  
<http://link.springer.com/article/10.1007%2F141030-016-0014-2>

### ERJ Open Research

Price D, Colice G, Israel E, Roche N, Postma DS, Guilbert TW, van Aalderen WMC, Grigg J, Hillyer EV, Thomas V, Martin RJ  
ICS or add-on long-acting  $\beta$ -agonist in combination or separate inhaler as step-up therapy for patients with uncontrolled asthma receiving ICS  
ERJ Open Research May 2016, 2 (2)

### BMC Pulmonary Medicine

van der Molen T, Postma DS, Martin RJ, Herings RMC, Overbeek JA, Thomas V, Miglio C, Dekhuijzen R, Roche N, Guilbert TW, Israel E, van Aalderen W, Hillyer EV, van Rysewyk S, Price D  
Effectiveness of initiating extrafine versus fine-particle inhaled corticosteroids as asthma therapy in the Netherlands  
BMC Pulmonary Medicine 2016 16:80

### JACI: In Practice

Steve Turner, Kathryn Richardson, Clare Murray, Mike Thomas, Elizabeth V. Hillyer, Anne Burden and David B. Price; on behalf of the Respiratory Effectiveness Group  
Long-Acting  $\beta$ -Agonist in Combination or Separate Inhaler as Step-Up Therapy for Children with Uncontrolled Asthma Receiving Inhaled Corticosteroids  
JACI: In Practice 2016 (In Press) a & Immunology  
<http://dx.doi.org/10.1016/j.jaip.2016.06.009>

# File sharing via REG website

The new REG website launched in May; as well as providing a fresh new design to present the broad range of REG projects and support easier navigation, the site now offers secure file sharing for all REG Collaborators.

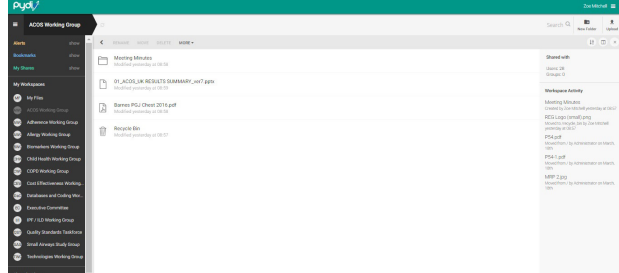
You should have received a log in for the REG file sharing service which will allow you to view all available documents for any Working Groups in which you participate.

The idea for file sharing originally began as a request from the Databases and Coding Validation Working Group, who were looking for a secure online space in which to share coding lists with the rest of the group.

If you have any suggestions for

future developments of the REG website, or if there are any additional solutions, such as file sharing or the recently adopted Qualtrics platform, which has been adopted by both the IPF/ILD and the Databases Working Groups, do let us know and we can consider available options and resources.

If you have not received your log in details for the file sharing site, or if you do not have access to all the relevant workspaces, please contact REG's Communications Officer Zoe Mitchell [zoe@effectivenessevaluation.org](mailto:zoe@effectivenessevaluation.org)



# Research Review

The 2015/2016 Research Review is underway; the aim of the review is to identify the projects which best reflect the key current real-world research needs in respiratory medicine and the interests of our Collaborators and Supporters. Currently, the number of ideas presented exceeds REG's ability to resource delivery of them all and therefore we have developed a transparent mechanism to review all the ideas put forward. The purpose of the review is to:

- Validate the ideas independently to confirm they are genuine research needs;
- Validate activities for REG resource.

The proposed projects have been collated and will be reviewed by the dedicated REG Research Review Committee. This committee acts similarly to an editorial board within the journal peer review process and their role is to confirm and quantify the clinical value of each idea and its strategic alignment with REG's core principles. Projects will be scored using an online tool which considers key aspects of the project – alignment with REG ethos, clear objective

and output / impact, strategic value, ease of delivery and estimated resource impact – which will deliver an overall priority score. Once this has been completed, all proposed projects will be presented to the Executive Committee Research Leads – Sinthia Bosnic-Anticevich and Nicolas Roche - with their priority scores for consideration and discussion within the Executive Committee, who will make the final decision on resource allocation.

All REG-identified research needs will also benefit from free review by the Anonymised Data Ethics and Transparency (ADEPT) Committee which convenes under REG but works independently to review applications to use the Optimum Patient Care (OPC) database for specified research purposes.

The review will take place over the summer and newly-approved and funded projects will be announced following meetings held at the ERS 2016 Congress in September.

## Real-Life Research Articles of Interest

### POINT: Do Randomized Controlled Trials Ignore Needed Patient Populations? Yes

*Katherine Courtright* *Chest* 2016;149(5):1128-1130.

### Biomarkers in asthmatic patients: Has their time come to direct treatment?

*Alalia Berry, MD, and William W. Busse, MD* *Madison, Wis J Allergy Clin Immunol*

### Assessing the Gold Standard — Lessons from the History of RCTs

*Laura E. Bothwell, Ph.D., Jeremy A. Greene, M.D., Ph.D., Scott H. Podolsky, M.D., and David S. Jones, M.D., Ph.D.* *N Engl J Med* 2016;374:2175-2181 June 2, 2016

### Integrating Randomized Comparative Effectiveness Research with Patient Care

*Louis D. Fiore, M.D., M.P.H., and Philip W. Lavori, Ph.D.* *N Engl J Med* 2016;374:2152-8

# Thanks to our Supporters

The work of REG would not be possible without our invaluable supporter base to fund the innovative and valuable research projects developed by our expert Collaborators.

REG is currently looking to launch a number of ambitious research projects which offer the opportunity to impact regulatory guidelines and clinical care. We welcome any suggestions from Supporters and would be keen to arrange meetings - either at the upcoming ERS 2016 Congress in London or via telephone conference if this is more convenient - to discuss how REG's supporters can work with us to ensure that we deliver high quality real life respiratory research.

If you would like to discuss opportunities for supporters or to book in a consultation to consider future research projects, contact: [thaole@effectivenessevaluation.org](mailto:thaole@effectivenessevaluation.org).

