ADVANCES IN... REAL-LIFE RESPIRATORY MEDICINE

The Respiratory Effectiveness Group Newsletter

2015 – A Very Good Year for REG

It's been an incredible year for REG, we've seen substantial growth in our Collaborator-base and kicked off some strong research projects. This is in part thanks to the collaborative meetings held at respiratory conferences throughout the world this year - we know how frantic those conferences are for everyone and really appreciate that you continue to give up your time to attend our meetings and contribute to the research projects.

As we move into 2016, it seems like the right time to reflect on our successes and look at how we can further improve in the coming year. To this end, we are organising an expansion of the REG Executive Committee in order to ensure we evolve from a short-term initiative to a longer-term organisation and are future proofed to continue to deliver valuable research. The changes will help us to remain responsive and agile in this developing field. You will find further details of the nomination and voting process below. We will inform you of the results in the New Year.

We will also be looking to see how we can use technology to our advantage to foster greater collaboration and reduce administraion and the workload. We've already made some great advances this year with online registration to events and the implementation of an online tool to collect responses for the REG/EAACI Asthma Comparative Effectiveness Literature Quality Standards Assessment (see pp7). The upcoming new REG website will include a platform for secure collaboration and document sharing, e-commerce facilities for event registration and donations, and more resources for Collaborators and Supporters alike.

A highlight of next year's plans is the upcoming REG 2016 Summit in Lyon, France on 15th and 16th April. We're delighted to be working with the team at ASTRO-LAB to ensure our events dovetail and provide opportunities for delegates to attend both events. We're lining up a range of informative talks, interactive sessions, demonstrations of technology as well as opportunities for networking and a chance to enjoy the sights of Lyon after the sessions. Find out more about our plans for the event on pp2-3 and register today to secure your place at the biggest REG event yet.

Finally, as the year draws to a close, Season's Greetings from the REG Operational Team - Alison, Setti, Thao and Zoe wish you a happy, healthy and peaceful new year.

Extending the REG Executive Committee

When they met at the time of the ERS in September, the REG Council recommended an expansion to REG's existing Executive Committee (currently David Price, Chairman and John Haughney, Governance Lead). The recommendation reflects the need to share the workload and decision making across a wider number of individuals as a result of our early successes and rapid growth.

From January 2016, the new Executive will include 5 voting members who will be jointly responsible for the financial and legal probity of the group and for signing off resource spend such that REG activities continue to reflect our principle goal of providing leadership and advocacy within real-life respiratory research. The aim in the long term will be to elect a new Chairman for REG.

The REG Operational Team will support the Executive to ensure their responsibilities are feasible and that REG continues to be a responsive and agile organisation.

Nominations closed on 11th December 2015. Voting will take place following the close of nominations and the new Executive Committee will be announced in the new year.

Contents

REG 2016 Summit

Join us at the Embarcadere in Lyon, France on 15th and 16th April for the REG 2016 Summit. We are planning a packed programme of presentations, interactive demonstrations, lively debates and panel discussions, working group meetings and numerous oral abstracts and posters showcasing the latest real-life research in the respiratory field.

Registration to the event is **free** for all REG Collaborators and you can sign up on our website today.

We also have a range of opportunities for our Supporters to get involved, including support of networking events, interactive conference tools that will facilitate voting and polling of delegates and the opportunity to showcase your work on a dedicated stand and book a private meeting room for detailed discussions. Contact Thao Le (thao@effectivenessevaluation.org) to find out more.

Scientific Committee
Bernardino Alcázar-Navarrete, Spain
Aji Barot, UK
George Christoff, Bulgaria
Nemr Eid, USA

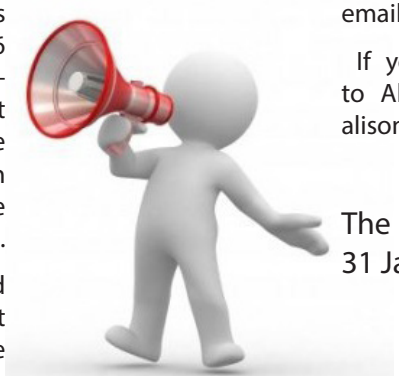
Call for Abstracts

You are invited to submit an abstract on your research for oral or poster presentation to be considered for the 2016 REG Summit. This is a great opportunity to showcase your work to some of the world's leading researchers and clinicians in the field of respiratory medicine in an open and collaborative environment. Please note that membership to REG is not a pre-requisite for submission.

We will be presenting both abstracts and posters in themed sessions throughout the REG 2016 Summit to address hot topics in the field of real-life respiratory research and will also support the overall theme of the event, examining the impact and influence of real-life research in terms of improvements to patient care and the development of new guidelines and best practices.

All the abstracts from the event will be collected and published following the event, in a format similar to the abstract books produced for the 2014 and 2015 Summits.

DEADLINE FOR ABSTRACT SUBMISSION: 31 JANUARY 2016.



A template for abstract submission is available from the event page of the REG website. Please note that you must follow this template or your abstract may not be accepted and will be returned to you for your revision and re-submission. You are permitted to include a maximum of 1 table and 1 figure in the abstract.

Please submit all abstracts via the web form http://bit.do/REG2016Abstract or you can send via email to enquiries@effectivenessevaluation.org

If you have any queries, please direct these to Alison Chisholm, Chief Scientific Officer at alison@effectivenessevaluation.org

The deadline for abstract submission is 31 January 2016.

REG 2016 Summit

Register today for the REG 2016 Summit.

Visit the website at www.effectivenessevaluation.org to find out more about the event, download a copy of the draft programme and register your interest.

Registration is free for all REG Collaborators.

Early Bird rates are available for all other delegates until 31st January 2016.

	Early Bird	Standard
Non-REG Delegate	£500.00	£650.00
Astro-Lab Special Rate	£400.00	£520.00
Delegate from developing country	£300.00	£300.00
Fellows & Students	£180.00	£230.00
REG Supporters - representatives from pharmaceutical & technology organisations.	£500.00	£650.00

ASTRO-LAB Final Symposium

The 2016 REG Annual Summit will take place on 15th – 16th April 2016 in Lyon, France to coincide with the Final Results Symposium of ASTRO-LAB (Assessment of the safety of Long-acting Beta Agonists in Asthma Routine Care by combining healthcare databases and direct patient follow up) on 14th April 2016.

REG has strong ties to the ASTRO-LAB team through Alex Dima and the REG Adherence Working Group Lead Eric van Ganse, who is the ASTRO-LAB Principal Investigator.

The partnership allows us to welcome ASTRO-LAB stakeholders (including EU funders, regulators, respiratory clinicians and allied health professionals) to take part in REG events and also opens up the opportunity for current REG collaborators and supporters to attend the ASTRO-LAB events free of charge and speak with ASTRO-LAB delegates.

Long-acting beta-agonists (LABAs) and inhaled corticosteroids (ICS) are currently the main preventer treatments for achieving and maintaining control over asthma. Despite their broad use, evidence is still limited on the benefit/risk ratios of using LABA in monotherapy or in combination with ICS, in single or separate inhalers. For the past 4 years, the ASTRO-LAB consortium has followed up a large cohort of adults and young people with asthma in France and in the UK, and collected data from multiple sources on their treatment and health status. These data offer us unique insights into how asthma is managed in primary care in these two countries. This symposium represents an unique opportunity to share these new insights and discuss common solutions for improving asthma care in Europe.

The symposium takes place on 14th April 2016 at L'Embarcadère in Lyon, France.

Find out more about the project online at: http://www.astrolab-project.eu/

Programme Overview

10h45 – 11h30 Welcome
11h30 – 12h45 ASTROLAB at a glance
12h45 – 13h45 BUFFET LUNCH: OPEN DISCUSSION AND POSTERS SESSION
13H45 – 15h00 How safe are LABAs in asthma management?
- Linking different data sources in the
15h00 – 15h30 COFFEE BREAK
15h30 – 17h Round table: Patients', caregivers' and health care professionals' roles in the asthma care process in the EU?

Register for the event via the REG 2016 Summit registration form or visit the ASTRO-LAB website to secure your place.

ASTROLAB

SEVENTH FRAMEWORK PROGRAMME

ASTRO-LAB Research Fellowship - Lyon Pharmacoepidemiology Unit, University Claude Bernard

ASTROLAB propose to welcome a researcher to work on ASTROLAB data from August 2016, after the official end date of the European Community (EC) funded Project (FP7). The theme is: Asthma, observational studies on large databases and the study will last for 6-12 months in Lyon, France. Candidates should possess the following:

- Education level: minimum of Masters degree in the Respiratory field
- Basic knowledge of SAS to perform data analysis and epidemiology
- Past experience and willingness to publish in peer- reviews.
- Fluent English
- Country of Origin: other than France

The deadline for applications to the ERS is 31st January 2016.

For more information, contact eric.van-ganse@univ-lyon1.fr or visit the website **http://www.astrolab-project.eu**

ERS Long Term Research Fellowships

The ASTRO-LAB Research Fellowship will be funded by the ERS. Long-Term Research Fellowships (LTRF) enable investigators and clinicians in the early stages of their career to carry out basic, translational or clinical research projects. Through this experience, young scientists learn and apply advanced research procedures and techniques not available at their home institute. Since 2015, ERS has increased the number of fellowships on offer by welcoming applicants from scientifically developing countries, and through partnerships with other organisations. Applicants are selected based on their scientific merit and the skills and experience they can bring to a new centre.

Visit the website www.ersnet.org

ERS International Congress 2015

The ERS Congress in Amsterdam proved to be one of the busiest conferences for REG to date. We held key meetings for the REG Council and Committees to determine the strategy for the organisation in 2016, a well attended AGM reviewing the successes from 2015 and debating future plans and members from each of the 12 Working Groups meeting to progress studies during the event. Slides for all the meetings in Amsterdam are available via Slideshare at www.slideshare.net/RespiratoryEffectivenessGroup

The AGM coincided with the publication of the *REG Review*, which recaps the history, development and acitivities of REG since it was initially founded in 2012. A copy of the *REG Review* is available from the REG website or you can request a copy by contacting our Communications Officer, Zoe Mitchell (zoe@effectivenessevaluation.org).

We also met with many valued, long-term REG Supporters in Amsterdam to discuss future research projects and connected with some new supporters looking to work with the organisation to promote international co-operation on a range of research projects.

As well as the many events taking place alongside the ERS Congress, the profile of REG within the respiratory community was raised by the inclusion of a number of oral abstracts and poster presentations from REG Working Groups and Collaborators on a range of topics.

Posters were presented on:

- Characterisation of Real-Life, Longitudinal ICS Adherence Patterns in the UK Asthma Population
- Predicting Asthma Exacerbations in Children - an Obersational Study in Real-Life
- Dose-Response Effect of Small Particle vs. Standard Partcle ICS on Severe Asthma Exacerbations by Sex

Oral abstracts were presented on Predictors of Frequent Severe Asthma Exacerbations and the doses and effect on asthma treatment outcomes of extrafine (ciclesonide) vs standard particle inhaled corticosteroids (ICS).

We would like to thank John Blakey, Alexandra Dima, Marjan Kerkhof, Dirkje Postma and Steve Turner for delivering the posters and oral abstracts.

WAO World Allergy Congress 2015

REG held a symposium at the World Allergy Organisation (WAO) World Allergy Congress (WAC) in Seoul in October on the subject of **Harnessing the Real World to Address Unmet Needs in Allergy Care**.

Chaired by REG Collaborator Pascal Demoly, the session included presentations and panel discussion on

- Identifying Obstructive Lung Disease Using Routine Clinical Data;
- Methods and Real-Life Research Opportunities;
- Guiding Guidelines Towards a More Patient-Centric Approach;

as well as a presentation from Prof. David Price on Building an "Optimum" Database and a lively question and answer session with the panel.

We would like to thank our presenters and chairs - Job van Boven, Walter Canonica and Pascal Demoly, Prof. David Price and Prof. Dong Ho Nahm - for contributing to such an informative session at the WAC 2015.

One of the priorities for REG in 2016 is to expand our activities in the APAC region and to launch some new and interesting studies with supporters and collaborators in 2016. The WAC 2015 was a great opportunity to engage with new Collaborators and Supporters from the region and discuss future regional and global projects to further the profile and impact of real-life research in the respiratory field.

We look forward to the expansion of the REG network in the APAC Region.

Watch this space for some interesting new studies, coming soon.

ISPOR 18th Annual European Congress

REG Collaborators presented a panel discussion at the ISPOR 18th Annual European Congress in Milan last month on the best available evidence for health technology assessment decision making: efficacy or effectiveness.

The panel considered the implications of using randomised controlled trial generated efficacy data versus real-world effectiveness data to inform health technology appraisals of respiratory interventions - reviewing what the panel referred to as evidence domains on an effectiveness-efficacy continuum.

Moderator Dr. McQueen introduced the presentations and debated with the panel - Dr. Dilokthornsakul, Dr. Campbell and Prof. Price - on the issues relating to this topic of growing importance in the respiratory field.

Real-life research has a significant role to play in this area in ensuring the value of the innovations in health monitoring technology to affect patient care. REG will be revising and expanding on the topic at our own summit next year and the first Cost Effectiveness Working Group meeting will be held at the event to lay out plans for REG in the cost-effectiveness/Health Economics space.

REG represented at recent EU Symposium: European Need for Precision Medicine in Allergy and Airways Disease

REG was represented at a recent EU Symposium held in October at the European Parliament in Brussels, Belgium alongside key figures from European Academy of Allergy and Clinical Immunology (EAACI) and the European Respiratory Society (ERS). Policy makers, patients, industry representatives and the scientific allergy and asthma community came together to discuss the need for Precision Medicine in airways disease. The discussions laid the foundation to define an action plan on how to deliver the cost-effective precision medicine to the allergic patient.

Precision Medicine (PM) is an emerging approach for disease treatment and prevention that takes into account individual characteristics of a patient in genes, environment and lifestyle. PM will change Europe's healthcare dramatically as disease management will shift from acute and reactive medicine to a more tailored approach that is predictive, preventive, personalized and participatory, with patients as partners in the development of treatment options. PM will allow more accurate prediction of which treatment and prevention strategies for a particular disease will work, when and in which groups of people. The benefit is improved patient-centred care, reduced costs of side-effects and better prevention, which increases public health.

The European Commissioner for Health and Food Safety Vytenis Andriukaitis and MEP Sirpa Pietikäinen highlighted the value of this meeting aiming to add to the previous initiatives of EAACI to tackle the allergy burden in Europe, where more than 150 million people are affected by an allergic disease. In parallel EAACI is developing in cooperation with the American Academy of Allergy, Asthma and Immunology (AAAAI) a consensus statement on PM in allergic diseases led by EAACI President Antonella Muraro that will be published at the beginning of 2016.

Respiratory Conferences in 2016

February		
Asthma, Allergy and COPD Forum	Dubai, UAE	6-10 Feb
NOVAIR 2016	Rome, Italy	14-16 Feb
March		
AAAAI Annual Meeting	Los Angeles, USA	4-7 Mar
ASTROLAB Final Symposium	Lyon, France	14 Apr
REG 2016 Summit	**Lyon, France**	**15-16 Apr**
May		
ATS International Conference	San Francisco, USA	13-18 May
ISPOR International Conference	Washington DC USA	21-25 May
IPCRG 8th World Congress	Amsterdam, The Netherlands	25-28 May
June		
EAACI Congress	Vienna, Austria	11-15 Jun
September		
ISPOR APAC Conference	Singapore	3-6 Sep
ERS International Congress	London, UK	3-7 Sep
November		
APSR Congress	Bangkok, Thailand	12-15 Nov

Recent REG Publications

Predicting frequent COPD exacerbations using primary care data
Kerkhof M, Freeman D, Jones R, Chisholm A, Price DB. International Journal of COPD 2015:10 (1)

Increased Dose of Inhaled Corticosteroid versus Add-On Long-acting ß-Agonist for Step-Up Therapy in Asthma
Israel, E Roche, N Martin, RJ Colice, G Dorinsky, PM Postma, DS Guilbert, TW van Aalderen, WMC Grigg, J Hillyer, EV Burden, A von Ziegenweidt, J Thomas, V and Price, DB. Annals ATS.201412-580OC

Predicting frequent asthma exacerbations using blood eosinophil count and other patient data routinely available in clinical practice
Price, D Wilson, A Chisholm, A Rigazio, A Burden, A Thomas, M King, C. Journal of Asthma and Allergy 2015

Our sincere thanks to all of REG's Supporters for their invaluable continued support in 2015

Working Group Updates

Idiopathic Pulmonary Fibrosis (IPF) / Interstitial Lung Disease (ILD) Working Group

The IPF/ILD working group only met for the first time at the ATS earlier this year, but under the Leadership of Luca Richeldi the group have already developed two important research proposals:

1. Characterisation of the path to IPF diagnosis within UK primary care
2. Global characterisation of diagnostic practice and multidisciplinary team (MDT) diagnostic agreement & accuracy.

In the era of new efficacious therapies that slow, but do not reverse, the course of IPF, the two studies will use real-world data to identify opportunities for earlier and more accurate diagnosis with a view to optimising timely access to therapy and treatment outcomes.

The first study is a retrospective cohort study looking at trends in healthcare resource utilisation in the years preceding IPF diagnosis (including potential mis-diagnoses and missed opportunities to diagnose IPF). The study repeats themes of a the previous REG Study *Opportunities to diagnose chronic obstructive pulmonary disease in routine care in the UK* (Jones et al. Lancet RM 2014; 2: 267–76), which found that opportunities to diagnose COPD at an earlier stage are being missed, and could be improved by case- finding in patients with lower respiratory tract symptoms and concordant long-term comorbidities.

The second study will be a global collaboration, bringing a global expert steering committee and aiming to characterise clinical practice in IPF (from a diagnostic standpoint) on a scale never before attempted in terms of the number of countries involved and the range of healthcare settings that will be included.

Both studies have received substantial interest from potential supporters who the REG team are now following up with to formalise offers of support and put in place the funding necessary to kick-start both projects.

Study 1 (Characterisation of the path to IPF diagnosis within UK primary care) is currently under funding consideration with Boehringer Ingelheim and we anticipate a response soon. As Study 2 (Global characterisation of diagnostic practice and multidisciplinary team (MDT) diagnostic agreement & accuracy) is on a much bigger scale and has important information for all working in IPF (clinically, R&D, market access), we are going for a cooperative funding approach. Nine companies have noted their interest in supporting (financially and or offers of tools / data in kind): Biogen, Veracyte, BI, Roche & Genentech, GSK, Gilead, PatientsLikeMe, and Proterris, Genetech—and we've been liaising with the Patient Centred Outcomes Research Institute in the US as to the potential suitability of the study for a PCORI grant (there definitely seems to be potential to explore).

To date, Biogen and Veracyte have formally confirmed their support (all others are still under discussion) and we would like to thank them for their commitment to this important study.

Thanks and welcome to our new supporters

Biogen

veracyte

Asthma-COPD Overlap Syndrome Working Group

There has been a review and reconsideration of the optimum approach for the proposed ACOS Proof of Concept Study—a study 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 some extensive discussions at the ERS. Working Group Lead, Jerry Krishnan (in discussion with David Price) developed a proposed action plan that revisits the original rationale, aims and objectives of the study and considers the trade-off associated with the different possible approaches.

Ultimately, there is no one perfect approach—each has strengths and weaknesses—but there is a need to start somewhere and develop a standardised platform for ACOS research that can be further refined and developed in future work. The lack of standard tools and definitions are a barrier to future ACOS research.

The plan was discussed at a recent working group call and the protocol is now being finalised so that funding can be formally secured with a view to hopefully starting the study (5 database-strong study) in Q1 2016. At this time we'd also like to thank Nicolas Roche for stepping forward as Co-Chair of the group. Under Nicolas' and Jerry's joint leadership, the study and future projects will be in very safe hands.

Adherence Working Group

There are currently two major Adherence Working Group projects underway:

1. Bi-directional adherence study
2. *JACI: In Practice* special issue on respiratory adherence.

The study—a two-part research project—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 of the study is now complete (evaluation of control patterns and patterns of different adherence measure rates over a continuous 3-year period) which will inform the correct inputs for the multi-level interaction analysis of adherence and control planned in phase two. We anticipate phase two commencing early in 2016. Our thanks to Alex Dima (University of Amsterdam), Patrick Souverein and Ellen Koster (University of Utrecht) for their work on phase one and we look forward to working with Marcia Vervloet and colleagues on the phase two analysis in the New Year.

The *JACI: In Practice* special issue is the output of the Adherence Expert Panel Meeting held in Barcelona in June 2015 just after the EAACI congress. We have had lengthy discussions with the journal editors who are very supportive of the publication (although all papers will of course be subject to peer review) and we have agreed an issue comprising an introductory editorial and 5 articles covering different aspects of respiratory adherence, e.g.

- The appropriate taxomony and measures of evaluation of respiratory adherence;
- The challenges of optimising adherence in different age groups; the role of the healthcare system, healthcare professionals and different modes of therapy delivery on adherence to therapy, as well as
- The ASTRO-LAB model of adherence that has been developed by Eric van Ganse, Alex Dima, Marijn de Bruin and colleagues as part of the ASTRO-LAB initiative.

All papers are to be submitted by 1 February and will be published online early as soon as they are accepted, but then collated in a special issue (with topical cover image and article titles features on the cover) with an allocated publication date of Sept. 2016.

Working Group Updates

Allergy Working Group

REG held a real-world themed session at the recent 2015 World Allergy Congress in Seoul, Korea (see p4), title: ***Harnessing the Real World to Address Unmet Needs in Allergy Care***.

In other "Allergy News", the proposition to collect data on nasal and bronchial hyper-responsiveness (put forward by Working Group Lead Peter Hellings at the inaugural working group meeting in Barcelona at the time of EAACI) in the pharmacy setting, primary and secondary care to underpin future Allergy research is being carried forward from a primary care perspective by Optimum Patient Care in the UK. With input from Peter and Thys van der Molen additional questions will be included in the OPC questionnaire on triggers, symptoms and control. To make way for these new questions some of the existing questions in the OPC questionnaire need to be removed. The OPC team are carrying out various analyses to establish which questions they should retain (i.e. which are most strongly associated with control, disease burden, etc.). The statistical work will conclude this month with a view to integrating the new questions as early as Q1 2016. We hope there may also be opportunity to capture similar data in the pharmacy setting (potentialy in collaboration with Sinthia Bosnic-Anticevich in Sydney and/or Aji Barot via PatientsConnect) and in secondary care through the Allergy Working Group members.

In conjunction with Wystke Fokkens, some preliminary work is also underway to develop algorithms to differentiate between chronic and acute rhinosinusitis using the OPC database with a view to quantifying the true burden of chronic disease.

Biomarkers Working Group

The Biomarkers group are currently working on an Editorial highlighting the differences (reasons for and implications of) the National Insitute for Health and Care Excellence's (NICE) and the Global Initiative for Asthma's (GINA) recommendations on the use of FeNO.

Kjell Alving, Zuzana Diamant and Leif Bjermer drafted a version for discussion at the group's meeting at the time of the ERS and the paper is now being revised to incorporate the feedback and pitched for submission to the Lancet Respiratory Medicine.

Another REG biomarkers paper is also under way from a study that predates the formal establishment of the working group, but includes a number of the group's members as part of the steering committee. The paper is explores the utility of blood eosinophils as a predictor of future risk in COPD and is, we believe, a very important publication.

Follow-on work is also to be discussed in December with members of the working group to conduct possible validation work to evaluate how responsive and stable blood eosinophils are and whether they can really be used as a reliable biomarker. Future studies called for by the group at the time of the ERS included a prospective evaluation of the value of FeNO to predict ICS responsiveness in COPD eosinophils; potential funding discussions have begun.

Child Health Working Group

The Group has numerous projects under way. The Paediatric Step-up Study has now been completed and one paper has already been published; a second has recently been submitted to *JACI: In Practice* and a third is in development.

In terms of active paediatric studies, there is one under way and another shortly to begin:

Underway: evaluation of treatment choice in pre-school asthma/wheeze with a view to establishing potential differential effect of extrafine inhaled corticosteroid (ICS) treatment. 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. We expect to have the results in early Q1 2016.

Planned: a protocol and steering committee confirmed (members from the Child Health Group and Asthma Risk Predictors Study co-authors) for a study being led by Nikos Papadopolous and Clare Murray to evaluate the comparative effectiveness of adding antibiotics to usual care (oral steroids) for the management of asthma exacerbations. The study will commence in the New Year.

Also under discussion by members of the group (proposition by Nikos Papadopolous) is the development of a study protocol to examine the association between bronchiolitis under 2 years and paediatric asthma and a protocol will be completed by the end of the year.

COPD Control Working Group

Under the leadership of working group lead Marc Miravitalles, 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 complete and a final report has now been circulated to the group for review / comment from which we hope to submit an abstract to an appropriate conference in 2016. In parallel, we have been confirming sites and securing the necessary ethics, patient questionnaire translations, and developing the electronic CRF for the (~2-year) prospective validation study that will include approximately 300 patients from Spain, the UK, Ireland, Singapore, possibly Canada and France and, we hope, Korea. We hope to commence trial recruitment in Q2 2016.

A protocol has also been developed for a real-life WISDOM study to explore the effect of ICS dose reduction and cessation in real-world COPD management. Funding for the study is not yet secured.

Databases & Coding Validation Working Group

The key priority of the Databases and Coding Working Group is to secure funding for the planned Checklist Delphi Project, seeking to develop a checklist for the "ideal" respiratory database and also what minimum criteria are required to build a database with research utility. Led by Job van Boven, a protocol has been put together for the work, which would be run in collaboration with the International Primary Care Respiratory Group's UNLOCK Group who have done considerable work in this area already. We have also been in touch with the PCORnet group in the USA who are currently building a common data model that will extract standardised data across linked healthcare systems and sites within the USA to accrue data on around 100 million patients when it goes live, hopefully some time in 2016. PCORnet are keen to invite input from subject experts to make sure the common data model includes meaningful data that will enable specialist research.

From a coding standardisation and harmonisation perspective, we hope to start sharing code lists via a secure page on the new REG website for REG collaborator use. The website is due to go live in January 2016.

Working Group Updates

Technologies Working Group

The inaugural Technologies working group meeting was held in Amsterdam in September at the time of the ERS.

It was amply apparent that it is a vast topic and there is real interest in this area. What the group need to establish is what REG's role is within the world of medical technologies—a "standards setter" for what data are meaningful (and ethical) to capture, and how to store and use that data? Even focussing on this remit was shown to be wider than initially thought when discussions in Amsterdam turned to identifying who the end user is for the intended App or technology-based solution. For any new technology to have utility and, as a result, uptake, it has to address a need. The nature of that need will depend on the intended end user.

A position paper is under discussion to capture some of the challenges, barriers and opportunities in this field, as is a protocol to develop a checklist of requirements to inform future technology developments through engagement of a wide range of different stakeholders (potential end users) in a Delphi.

These themes and REG's role in the Technologies sphere will be revisited at the 2016 REG Summit in Lyon in a session that will focus on the role of technologies in remote monitoring and evaluation in lung disease.

Small Airways Study Group

As mentioned in the Child Health Working Group update (p7) the on-going comparative effectiveness study of treatment options in pre-school asthma /wheeze is being run, jointly, by the Child Health and Small Airways Working Groups as the study was motivated by prior small airways studies that suggest potential benefit of using extrafine ICS to target therapy at the inflammation present in the small airways – particularly relevant in younger age groups. The baseline analysis is now complete and the unmatched and matched outcome evaluations are underway.

A second funder (now two of a necessary three) has been secured for the proposed systematic review of the EF ICS comparative effectiveness literature – a project motivated by a poster at the 2014 British Thoracic Society Conference that concluded (from a review of the efficacy RCT literature) that ICS particle size has no differential effect on treatment outcomes. This finding flies in the face of the REG Small Airways Study Group's research findings for the last 7-8 years.

The group have published 3 papers already this year and have another 5 underway, or due to commence shortly.

Call for Research – Deadline 31 Jan 2016

On **31 January 2016**, all ideas that are currently passing through the working groups will be collated and submitted to the Research Review Committee for prioritization. The process will generate a list of studies endorsed by the organization that can be targeted to (or by) external funders, but also provide us with a list of studies that REG can support through our core grant funding stream. Funding is currently being sought for the following proposed studies:

- (Extension Study): UK "State of the Union": – current asthma morbidity in the UK
- Evaluation of the association between duration of antibiotic courses (for respiratory infections) and issuance of repeat prescriptions
- Development, Validation and Evaluation of a Short form of EXACT (Exacerbations of Chronic Pulmonary Disease Tool) Questionnaire for Clinical Use and Self-(tele) Monitoring
- Validation of the COPD UK Risk Prediction Model and development of a claims-based algorithm
- Comparative effectiveness of triple (ICS/LABA/LAMA) vs dual therapy (ICS/LABA) in COPD
- Development of a Longitudinal Asthma Treatment Step Algorithm and Association with Asthma Outcomes
- Towards Optimum Reporting of Pulmonary Effectiveness Databases and Outcomes (TORPEDO) Checklist
- Systematic review & meta-analyses of the effect of ICS particle size on real-life asthma outcomes
- (Extension Study) Metabolic and long-term implications of ICS particle size in obstructive lung disease
- Asthma-COPD overlap syndrome: comparability of population definitions within and between global databases - developing tools for observational research
- Characterising the primary care pathway to idiopathic pulmonary fibrosis (IPF) diagnosis – a UK database study
- Implications of ICS dose reduction and withdrawal in real-world COPD management ("real-life WISDOM")
- Role of ICS particle size in the management of asthma and GERD
- Reaching consensus on end-user needs of respiratory technologies - a multi-stakeholder Delphi project.

Spontaneous research ideas are welcomed throughout the year. These should be submitted to Alison Chisholm (alison@effectivenessevaluation.org) who will direct the idea to a relevant working group to develop the concept further.

REG / EAACI Quality Standards Taskforce

Following successful beta-testing of the literature quality assessment tool that the taskforce has developed, more than 50 volunteers from across the REG network (and beyond) are currently using the assessment tool (now available as an online version) to screen comparative effectiveness studies in asthma published in the last 10 years in terms of their quality and eligibility to be considered by developers of future asthma guidelines.

Each paper is reviewed by two individuals taking part in the pilot study, and a third reviewer will be allocated in instances where there is disagreement. Reports on each paper are submitted online and aggregated by the assessment tool, providing the team with real-time results. Papers were circulated for review in early December with a view to completing the screening stage of the work by the end of 2015.

Thereafter, any papers graded by the tool as being of sufficient quality for future guideline consideration will be summarised in a standardised one-page format in terms of their potential utility. Following completion of these reports (in February 2016), the Taskforce aim to complete their final report by March/April 2016 and present the results at the upcoming REG 2016 Summit.

Advocacy meetings with relevant society, journal and regulatory representatives will also be organised for the event in order to develop an action plan based on the results of the report.