Development of Core Outcome Measures sets for paediatric and adult Severe Asthma (COMSA)


1Clinical and Experimental Sciences and Human Development and Health, Faculty of Medicine, University of Southampton, Southampton, UK. 2Institute for Lung Health, Leicester NIHR Biomedical Research Centre, University of Leicester, Leicester, UK. 3Centre for Paediatrics and Child Health and National Heart and Lung Institute, Imperial College, Royal Brompton Hospital, London, UK. 4Department of Respiratory Medicine and Allergy, Karolinska University Hospital and Department of Medicine, Karolinska Institutet, Stockholm, Sweden. 5PhyMedExp, University of Montpellier, Montpellier, France. 6National Heart and Lung Institute, Imperial College London, London, UK. 7Institute of Infection, Immunity and Inflammation, University of Glasgow, Glasgow, UK. 8Biomedical Sciences, Queen Mary University of London, London, UK. 9Centre for Paediatrics and Child Health and National Heart and Lung Institute, Hôpitaux Pédiatriques de Nice CHU-Lrnval, Nice, France. 10Centre for Genomics and Child Health, Blizard Institute, Queen Mary University of London, London, UK. 11Department of Respiratory Medicine, Ghent University Hospital, Ghent, Belgium. 12Faculty of Biology, Medicine and Health, School of Biological Sciences, Division of Infection, Immunity and Respiratory Medicine, University of Manchester, NIHR Manchester Biomedical Research Unit, Manchester University NHS Foundation Trust, Manchester, UK. 13Department of Paediatric Respiratory Medicine, King’s College Hospital, London, UK. 14Children’s Center Bethel, Department of Pediatrics, University Bielefeld, Bielefeld, Germany. 15Department of Pediatric Respiratory Medicine and Allergy, Emma Children’s Hospital, Amsterdam UMC location University of Amsterdam, Amsterdam, The Netherlands. 16Department of Respiratory Medicine, Amsterdam UMC, Amsterdam, The Netherlands. 17Department of Women's and Children's Health and Centre for Allergy Research, Karolinska Institutet, Stockholm, Sweden. 18University of Groningen, University Medical Center Groningen, Beatrix Children's Hospital, Department of Pediatric Pulmonology and Pediatric Allergology, Groningen, The Netherlands. 19University of Groningen, University Medical Center Groningen, Groningen Research Institute for Asthma and COPD (GRIAC), Groningen, The Netherlands. 20Department of Clinical Science and Education Södersjukhuset, Karolinska Institutet, Stockholm, Sweden. 21Department of Pulmonology, Cliniques Universitaires Saint-Luc and Pole of Pulmonology, ENT and Dermatology, Institute of Experimental and Clinical Research (IREC), UCLouvain, Brussels, Belgium. 22Department of Respiratory Medicine, Respiratory Research Unit, Bispebjerg Hospital, Copenhagen, Denmark. 23Department of Paediatric Respiratory Medicine, Bristol Royal Hospital for Children, Bristol, UK. 24Department of Mother and Child Health, Azienda USL Toscana Nord Ovest, Pisa, Italy. 25Division of Allergology, Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines, Langen, Germany. 26Department of Medicine, Pulmonary and Critical Care Medicine, Philips University of Marburg (UMR), Marburg, Germany. 273TR Respiratory Patient Working Group, Brussels, Belgium. 28University of Groningen, University Medical Center Groningen, Department of Pulmonary Diseases, Groningen, The Netherlands. 29Department of Children and Adolescent Medicine, Division of Pulmonology, Allergology, Cystic Fibrosis, University Hospital Frankfurt, Goethe-University, Frankfurt, Germany. 30Department of Respiratory Medicine, Ghent University Hospital, Ghent, Belgium. 31Translational Science and Experimental Medicine, Research and Early Development, Respiratory and Immunology, BioPharmaceuticals R&D, AstraZeneca, Gothenburg, Sweden. 32Global Medical Affairs Respiratory, Allergy and GI, Sanofi Genzyme, Cambridge, MA, USA. 33Royal Brompton Hospital, London, UK. 34Adept Biologica Consulting Limited, London, UK. 35University Children's Hospital Basel, University of Basel, Basel, Switzerland. 36Department of Respiratory Sciences, Leicester NIHR Biomedical Research Centre (Respiratory Theme), University of Leicester, Leicester, UK. 37Pediatric Pulmonology and Allergology Department, Hôpitaux Pédiatriques de Nice CHU-Lrnval, Nice, France. 38Université Côte d’Azur, Nice, France. 39Centre for Genomics and Child Health, Blizard Institute, Queen Mary University of London, London, UK. 40Wellcome-Wolfson Centre for Experimental Medicine School of Medicine, Dentistry and Biomedical Sciences, Queen’s University Belfast, Belfast, UK. 41Division of Pediatric Pulmonology, Marmara University Faculty of Medicine, Istanbul, Turkey.
A European multi-stakeholder working group has reached a consensus on Core Outcome Measures sets for paediatric and adult Severe Asthma (COMSA). These should inform future clinical trials and enhance comparability of findings. https://bit.ly/3yO2gB2


This single-page version can be shared freely online.

Effectiveness studies with biological therapies for asthma lack standardised outcome measures. The COMSA (Core Outcome Measures sets for paediatric and adult Severe Asthma) Working Group sought to develop Core Outcome Measures (COM) sets to facilitate better synthesis of data and appraisal of biologics in paediatric and adult asthma clinical studies.

COMSA utilised a multi-stakeholder consensus process among patients with severe asthma, adult and paediatric clinicians, pharmaceutical representatives, and health regulators from across Europe. Evidence included a systematic review of development, validity and reliability of selected outcome measures plus a narrative review and a pan-European survey to better understand patients’ and carers’ views about outcome measures. It was discussed using a modified GRADE (Grading of Recommendations Assessment, Development and Evaluation) Evidence to Decision framework. Anonymous voting was conducted using predefined consensus criteria.

Both adult and paediatric COM sets include forced expiratory volume in 1 s (FEV₁) as z-scores, annual frequency of severe exacerbations and maintenance oral corticosteroid use. Additionally, the paediatric COM set includes the Paediatric Asthma Quality of Life Questionnaire and Asthma Control Test or Childhood Asthma Control Test, while the adult COM set includes the Severe Asthma Questionnaire and Asthma Control Questionnaire-6 (symptoms and rescue medication use reported separately).

This patient-centred collaboration has produced two COM sets for paediatric and adult severe asthma. It is expected that they will inform the methodology of future clinical trials, enhance comparability of efficacy and effectiveness of biological therapies, and help assess their socioeconomic value. COMSA will inform definitions of non-response and response to biological therapy for severe asthma.