Anonymised Data Ethics Protocols & Transparency Committee (ADEPT) Annual Report

1 January 2025 to 31 December 2025

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Glossary

ADEPT	Anonymisation Data Ethics Protocols & Transparency Committee
AUKCAR	Asthma UK Centre for Applied Research
COPD	Chronic obstructive pulmonary disease
EHR	Electronic health records
HES	Hospital episode statistics
HRU	Healthcare resource utilisation
IBD	Inflammatory bowel disease
iHARP	International helping asthma in real-life patients
ILD	Interstitial lung disease
ISAR	International Severe Asthma Registry
MREC	Medical Research Ethics Committee
NIHR	National Institute for Health Research
OPC	Optimum Patient Care Ltd
OPCRD	Optimum Patient Care Research Database
OPRI	Observational and Pragmatic Research International Ltd
PRO	Patient-reported outcomes
RCT	Randomised clinical trial
REG	Respiratory Effectiveness Group
SOP	Standard operating procedure
UK	United Kingdom

Foreword from the Chair of ADEPT Committee (to be revised)

Submissions to the ADEPT Committee have continued over the past year, demonstrating the ongoing commitment of researchers to real-life studies that support improved patient care.

We received thirteen applications during the year, and the time taken to complete the review process remained very acceptable and comparable to previous years (average review time in 2025 was a mean (median) of 1 (1) working day compared with 2 (2) working days in 2024). It is encouraging to see that real-life research remains a priority for investigators, and we remain grateful to the reviewers for their continued support and engagement in this important work.

The studies submitted continue to address relevant and timely topics, highlighting the value of real-world research in informing practice and contributing to guideline development. In 2025, most protocols approved by the ADEPT Committee were related to respiratory research (77%; n = 10), while the remaining approvals were distributed across cardio-renal-metabolic, digital/AI, and health services research (8% each; n = 1), which demonstrates the widening reach of real-life research and real-world evidence.

We hope you enjoy reading the ADEPT 2025 Annual Report and look forward to discussing new and innovative research projects with you in 2026.

Daryl Freeman, MBChB FRCGP
ADEPT Chair

1. Introduction

The Respiratory Effectiveness Group (REG) is an international research and advocacy group led by clinical academics with expertise in respiratory medicine and real-world research. REG initiatives target unmet needs in routine clinical care and the group provides leadership in real-world evidence generation through collaborative working, knowledge sharing and demonstration of quality research in practice.

The Anonymised Data Ethics and Transparency Committee (ADEPT) is an independent body commissioned by the REG to assess the feasibility and scientific merit of real-world research studies and to provide expert critique, as appropriate (see **Section 2**).

This ADEPT Annual Report outlines the Committee's role and operating procedures and summarises its activities over the period 1 January 2025 to 31 December 2025.

2. Governance and Review of Research Applications

2.1 Role of ADEPT

2.1.1 Database governance

ADEPT is an independent body of experts and regulators commissioned by the REG to quality appraise research protocols involving the use of electronic health records (EHRs) and clinical databases, such as:

- The Optimum Patient Care Research Database (OPCRD, https://opcrd.co.uk)
- The International Severe Asthma Registry (ISAR, http://isaregistries.org)
- The Implementing Helping Asthma in Real Patients Database (iHARP, https://opcrd.co.uk/international-helping-asthma-in-real-life-patients-iharp/)
- Hospital Episode Statistics (HES, https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/hospital-episode-statistics)

The ADEPT review process involves an evaluation of a proposed study's clinical relevance and quality of design, as well as an assessment of its practical feasibility using the intended database. The process does not constitute formal medical research ethics committee (MREC) approval. All ADEPT-approved protocols remain subject to local/institutional MREC approval requirements, as appropriate for the outlined research.

In addition to applications for formal protocol approval, ADEPT is also open to requests for expert guidance on the optimum design of studies intending to use EHRs and clinical databases. Requests for such expert input must be made prior to submission of related study protocols to relevant ethical bodies.

2.1.2 Terms of reference

ADEPT approval is contingent on the submitted protocol meeting (as a minimum) the following quality standards – the proposed research must:

- Ensure practice and patient confidentiality will be maintained throughout the study
- Address a well-defined research hypothesis or address a clear research question

- Propose the use of a data source (e.g. EHRs or a clinical database) adequate for the intended research
- Outline methods appropriate for the proposed research
- Demonstrate scientific rigor in the study design and approach
- Have previously secured (or will prior to commencement) all necessary ethical approvals
- Involve a team with experience in (or supported by experts) in real-life research

2.2 Membership

ADEPT is a committee made up of independent clinical experts and scientists with expertise in statistics, epidemiological experience and/or EHR-based research.

2.2.1 Member appointment

ADEPT membership is voluntary but limited to expert or lay collaborators of the REG. Self-appointment from a body of pre-identified experts in real-world research, such as REG, not only ensures the expertise of the Members, but also a broad range of specialisms within the Committee so that protocols can be aligned by topic to the most appropriate reviewer.

2.2.2 Membership over the reporting period

Throughout the 2025 calendar year covered by this report, there were 20 ADEPT members, including the Chair. The full list of is detailed in

Appendix 1. ADEPT Committee Members**.**

In January 2022, Dr Freeman, Associate Clinical Director Norfolk Community Health & Care, Clinical Respiratory Lead Norfolk & Waveney ICB, took up the position of Committee Chair again. The reviewers are Professor Jennifer Quint, Imperial College London, UK, Dr John Blakey, Sir Charles Gairdner Hospital Medical School, Curtin University, Perth, Australia and Dr Bernadino Alcazar Hospital Universitario Virgen de las Nieves, Granada, Spain.

2.3. Committee working

During the 2023 reporting period, all protocols submitted for ADEPT review were processed virtually. Committee members received no renumeration for their review of ADEPT applications; all applications were reviewed on an honorary basis.

Application processing and review was facilitated by the very efficient ADEPT Secretariat and conducted by the Committee in accordance with the new ADEPT SOP, as summarised in **Section 2.8 Review of research protocols** of this report.

2.4 ADEPT Secretariat

The ADEPT Secretariat is made up of REG employees who provide administrative support to the Committee.[1] The Secretariat forwards ADEPT applications for Chair and Committee

[1] Address: ADEPT Secretariat, ESpace North, 181 Wisbech Road, Littleport, ELY, Cambridgeshire, CB6 1RA

review, communicates Committee decisions to applicants and invoices and processes application submissions, as appropriate.

2.5 Application channels

Researchers applying for ADEPT review must submit their research protocols and supporting materials for the Chair and Committee's attention. Applications can be submitted to the Secretariat by email (to application@adeptcommittee.com) or via an web-based submission form on the REG website (https://www.regresearchnetwork.org/adept).

From 2019, the online application infrastructure was supported by Smartsheet content management software (Smartsheet Inc, https://www.smartsheet.com).

2.6 Application fees

The REG charges a processing fee for all ADEPT applications. The fee is intended to cover administrative cost of the ADEPT Secretariat and Committee.

The fee level is set by the nature of the research (e.g. commercial or academic) and profile of the applicant (e.g. academic, REG supporter or non-supporter), with discounts offered for applications submitted by REG supporters or pertaining to academic studies.

The ADEPT fee is waived for any research application responding to an REG-identified research priority. Invoices are issued following by the ADEPT Secretariat following their confirmation of a complete submission.

Table 1. ADEPT fees, 2025

Applicant type		**Fee**
Commercial	**Non REG supporter**	£2500
	REG supporter	£1250
Academic		£550

2.7 Application requirements

ADEPT applicants must complete and provide the following documents:

- Covering letter on headed paper
- ADEPT application form
- Research protocol
- Chief Investigator CV

The ADEPT Secretariat assesses each submission for completeness. Once it has been confirmed that all necessary documentation has been provided, the Secretariat confirms receipt by issuing a formal email to the corresponding applicant. The confirmation of receipt email includes the protocol's assigned "ADEPT number" and any relevant information relating to the dates of meeting(s) at which the protocol will be discussed.

The Secretariat then releases the application to the ADEPT Chair and reviewers for onward processing.

2.8 Review of research protocols

In 2022, the updated SOP which was approved by the ADEPT Committee came into force. The review procedure was updated as follows:

The ADEPT committee aim to provide timely, high-quality peer review of protocols; whilst recognising that the quality of the research ultimately remains the responsibility of the applicants. The committee have a period of up to 20 working days from receipt of a valid application to give their response to the applicant. The application is valid if the application form is complete, and all of the required supporting documentation is enclosed. The ADEPT secretariat will notify the applicant if the application is valid or not. The ADEPT secretariat can send a single request for further information to be supplied. At this point the clock on the 20-working daytime period is stopped until the supplementary information is supplied.

The application can be processed via two key streams either Chairman's or a panel approval which will usually be the chair plus 2 members of the Committee chosen as their areas of expertise align with the protocol content. If the application has already received an institutional ethics committee approval, the approval can be reviewed and approved/rejected by the chair. If the application has no institutional ethics committee approval, the application will be reviewed by the chair and 2 members of the committee.

2.9. Approval Opinion

Submissions can be reviewed and adjudicated by the Chairman, in isolate, under Chairman's actions, or circulated to Committee Members for wider review depending on whether an institutional ethics committee review has approved the application. In addition, the scope of the proposed study will inform the Chairman's decision to adjudicate on the proposal under Chairman's actions or to involve the Committee in its review.

2.9.1 Chairperson's actions

Submissions eligible for Chairman's actions (or "fast-track review") must meet the following scope criteria, they must be:

- Already have institutional ethics committee approval

2.9.2 Committee's actions

Submissions that meet any of the following scope criteria must be reviewed by at least TWO members of the ADEPT Committee in addition to the Chairman:

- No institutional ethics committee approval
- Forward-looking / prospective studies involving an a priori defined follow-up (within the historical dataset) after a defined index date
- Or other studies which the Chair feels would require evaluation by the Committee

2.9.3 Committee / Chairman's Decision

The ADEPT committee can provide differing opinions of the application including:

- Full Approval
- Conditional Approval

- Resubmission with Amendments
- Rejection

If the application is not given a favourable ethical opinion and it is felt that the reasons given for this by the committee can be addressed, the research proposal should be revised accordingly and resubmitted to the ADEPT committee.

Following approval, if substantial changes to the protocol or changes to the study procedures that may affect the conduct of the study are to be made the amended protocol, with changes highlighted should be sent to the ADEPT secretariat along with the original ADEPT protocol approval number for review. The changes will be reviewed by the Chair within 15 working days.

2.10. ADEPT contributions to research

2.10.1 Publications

ADEPT has supported the real-world research efforts of a wide range of expert researchers (clinical, commercial, academic, public health workers) from around the world. Research protocols reviewed by ADEPT have led to an extensive number of publications in MEDLINE®-listed, peer review journals, particular within the field of Respiratory Medicine.

ADEPT-approved studies have helped to address important questions relating to routine care management practises, real-world (comparative) effectiveness, real-world tolerability of interventions, natural history of disease, prognostic and predictive risk markers and opportunities for early intervention to reduce disease burden.

REG publications originating from ADEPT-approved protocols can be found on the REG website: https://www.regresearchnetwork.org/publications

2.10.2 Acknowledgement

All authors of publications resulting from ADEPT-approved protocols are requested to include a statement acknowledging *a priori* protocol approval by ADEPT (citing their ADEPT reference number) when publishing their work.

3. Activities and Outputs

During the 2025 reporting period, ADEPT reviewed 13 protocols, of which 13 were for new studies. The Committee approved all protocols submitted for review in 2025.

3.1 2025 ADEPT applications by research database

Protocols submitted in 2025 involved use of multiple research databases. The OPCRD and ISAR were each proposed in 46% of applications (n = 6 each), while one protocol (8%) proposed use of another data source (**Table 2**).

Table 2. ADEPT applications in 2025 by research database of interest

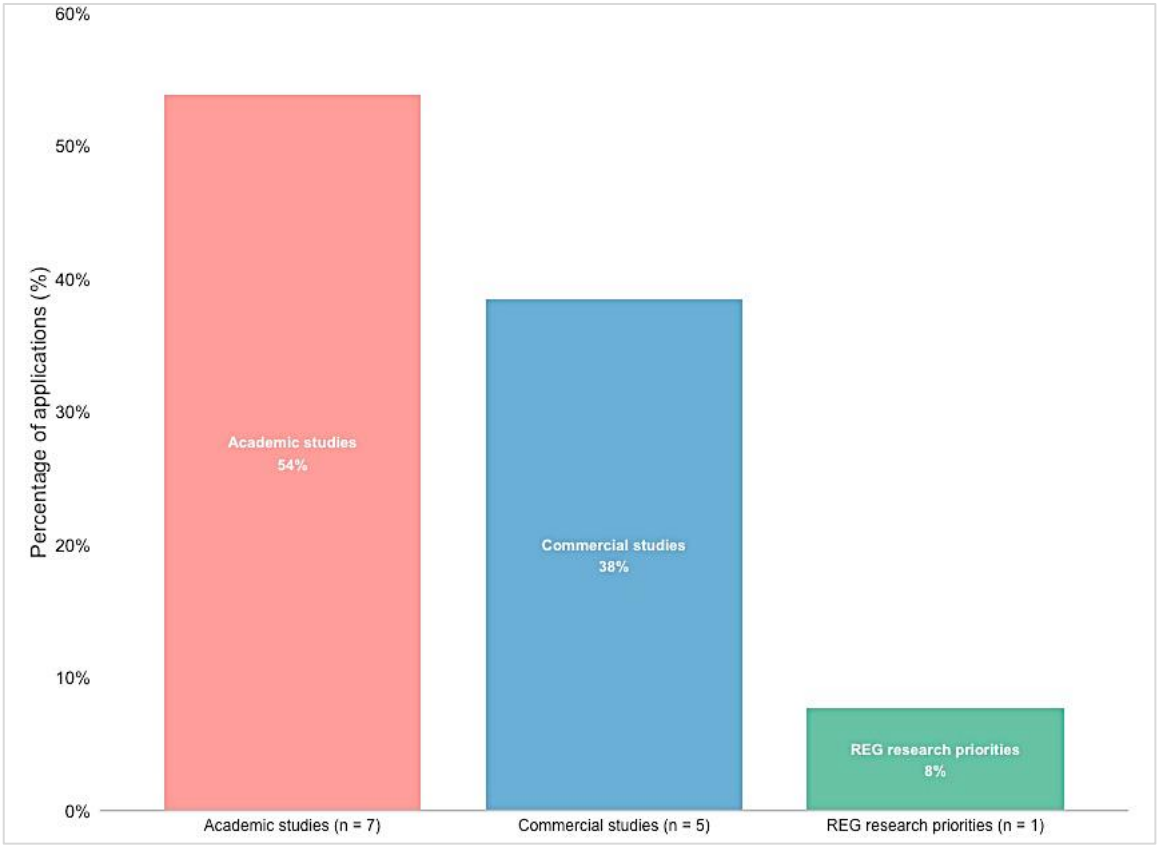
Database	Distribution of Applications, N (%)

	2025 (N = 13)	2024 (N = 20)
OPCRD	**6 (46%)**	**14 (70%)**
ISAR	**6 (46%)**	**3 (15)**
CPRD	**0 (0%)**	**1 (5)**
Others	**1 (8%)**	**2 (10)**

3.2 Research protocol funding

The commercial and academic distribution of research protocols submitted for ADEPT approval in 2025 is shown in Figure 1a, while Figure 1b compares the corresponding profiles for 2025 and 2024.

Figure 1a. Commercial / academic profile of ADEPT-approved protocols, 2025



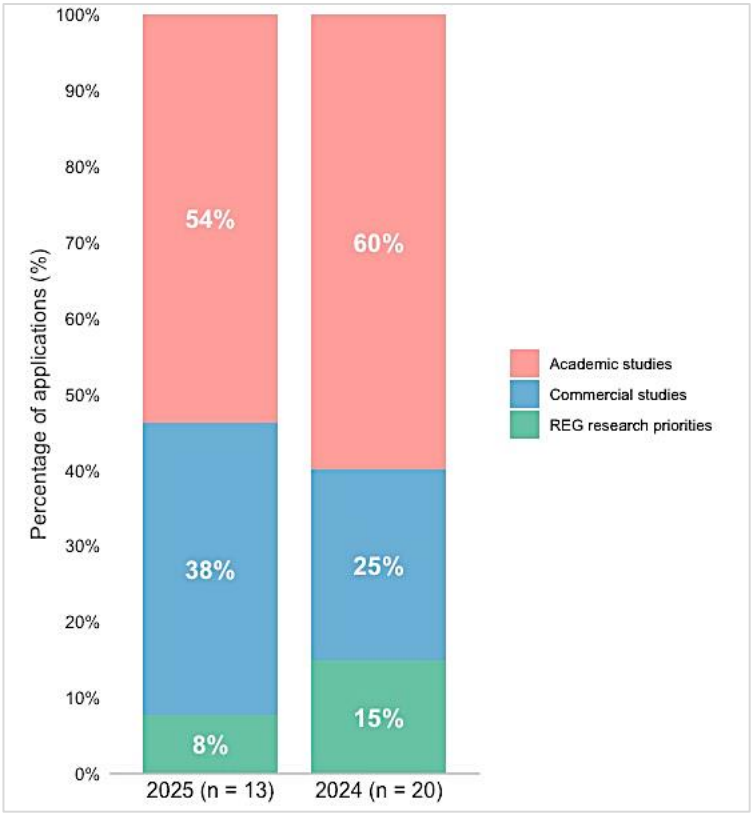
In 2025, one protocol (8%; n=1) focused on REG-identified research priorities, while most protocols approved by ADEPT (54%; n = 6) were academic studies.

Approved academic protocols were submitted by the National Institute for Health and Care Research (NIHR) Academy (n = 1), OPC (n = 4), Queen's University Belfast (n = 1), and the Saw Swee Hock School of Public Health, National University of Singapore (n = 1).

During the same period, ADEPT also approved five protocols (38%) for commercial research. These studies were funded by AstraZeneca (n = 2), Chiesi (n = 1), Srotas Health Limited (n = 1), and Lane Clark & Peacock (n = 1).

ADEPT approvals in 2025 showed an increase in commercial studies (38% *vs* 25%) and a reduction in REG-identified research priority protocols (8% *vs* 15%) compared with 2024, with little change in academic research (**Figure 1b**).

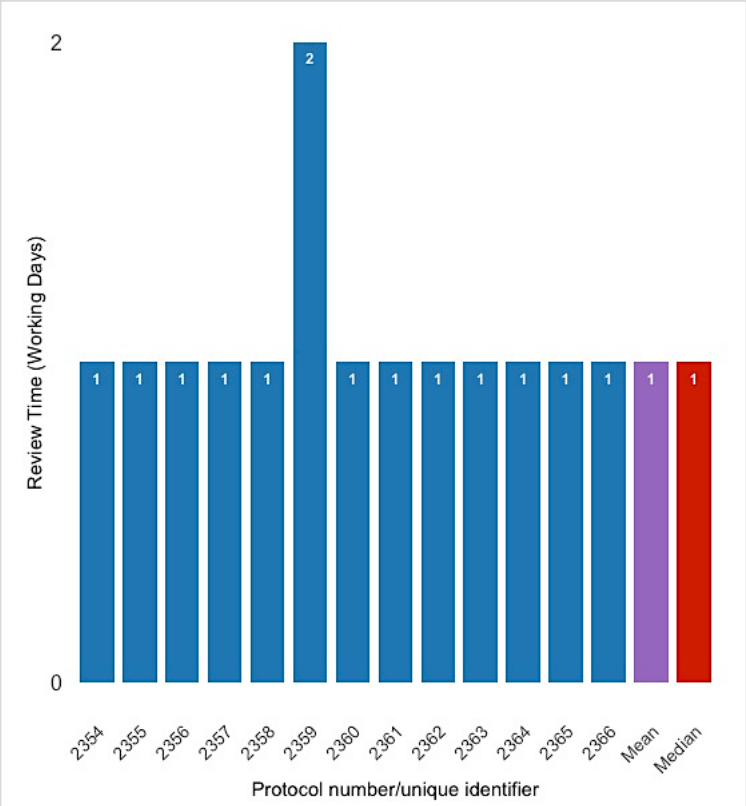
Figure 1b. ADEPT-approved protocols by commercial/academic profile, 2025 vs 2024



3.3 Protocol turnaround time: submission to approval

The average duration of ADEPT review in 2025 was well within the Committee's target of 20 working days, with a mean review time of 1 working day and a median (range) of 1 (1) working days (**Figure 2a**).

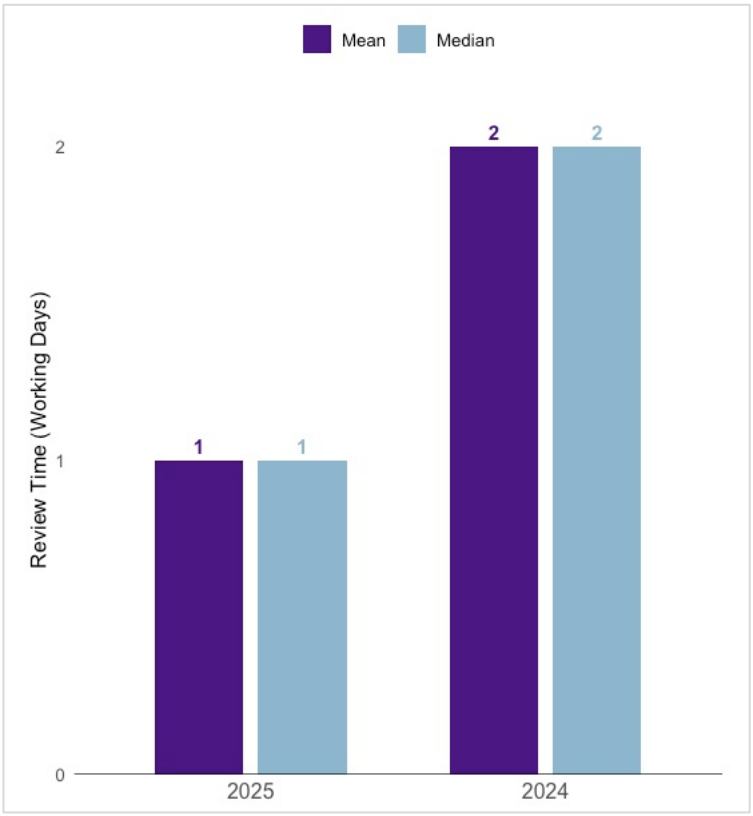
Figure 2a. ADEPT review times from protocol submission to approval in 2025



*Submitted for Protocol Amendment Review with Chair.

Overall, ADEPT review duration in 2025 was similar to 2024, with a mean (median) of 1 (1) working day compared with 2 (2) working days in 2024 (**Figure 2b**).

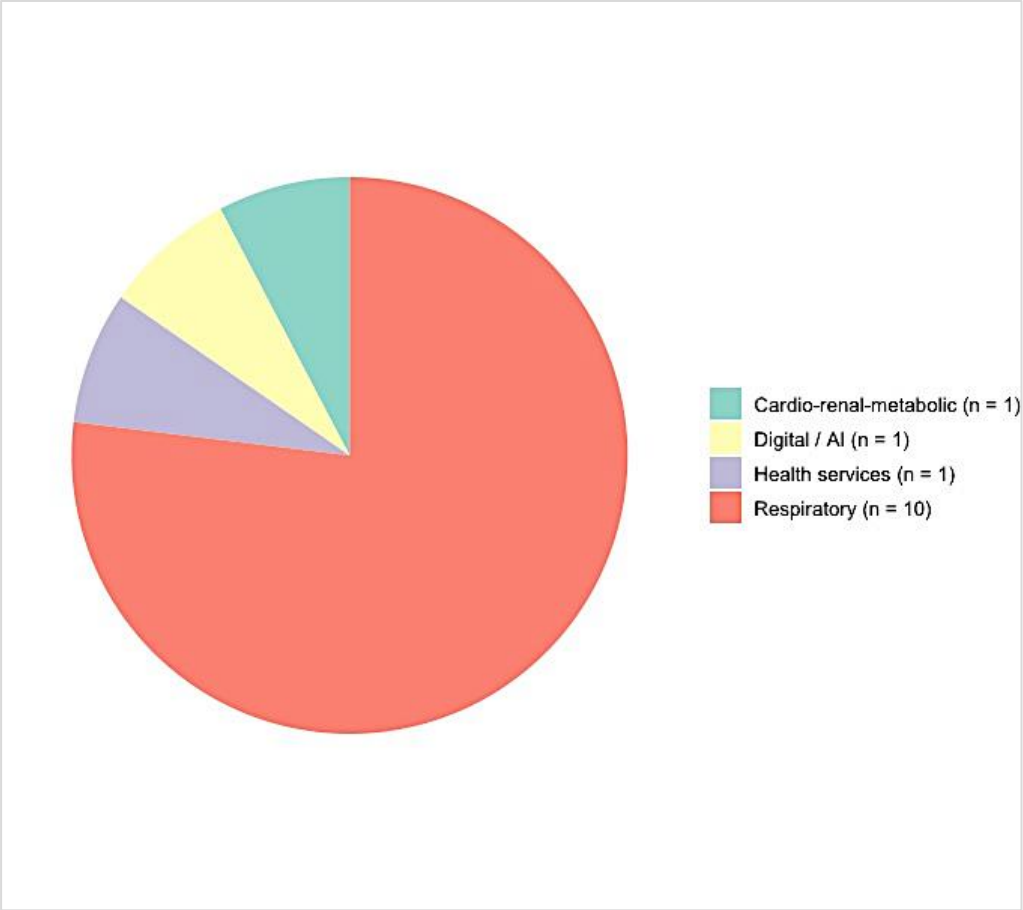
Figure 2b. Average review times for protocols approved by ADEPT in 2025 versus 2024



3.4 Areas of research interest

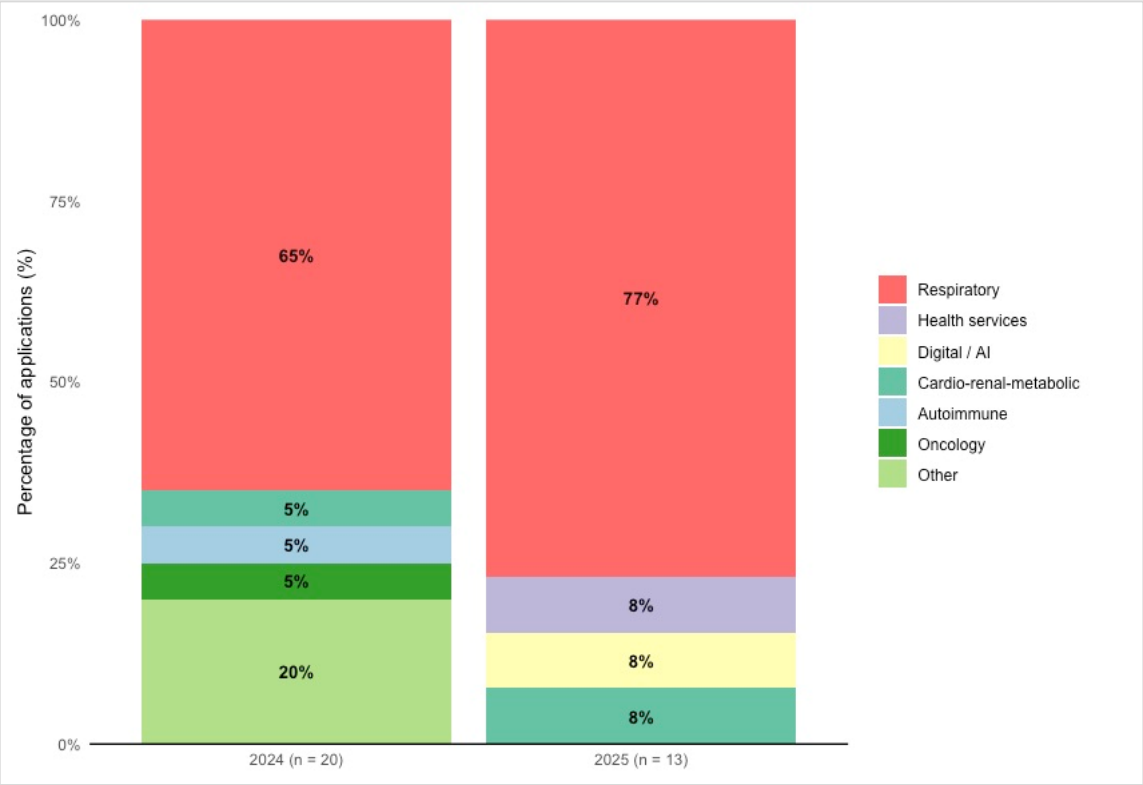
Most protocols approved by ADEPT in 2025 were related to respiratory research (77%; n = 10), while the remaining approvals were distributed across cardio-renal-metabolic, digital/AI, and health services research (8% each; n = 1) (**Figure 3a**).

Figure 3a. Protocols approved by ADEPT in 2025 by therapy area



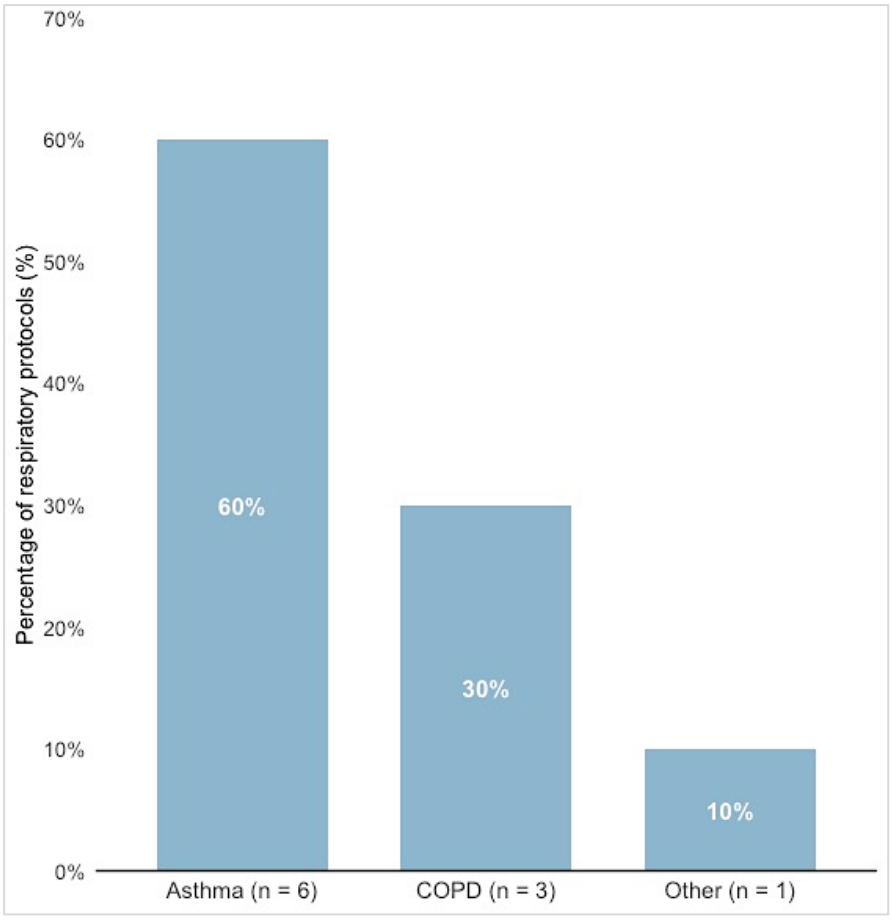
Respiratory research accounted for the majority of protocols submitted for ADEPT review in both 2024 and 2025, increasing from 65% in 2024 to 77% in 2025 (**Figure 3b**).

Figure 3b. Protocols approved by ADEPT in 2025 by therapy area, 2025 vs 2024



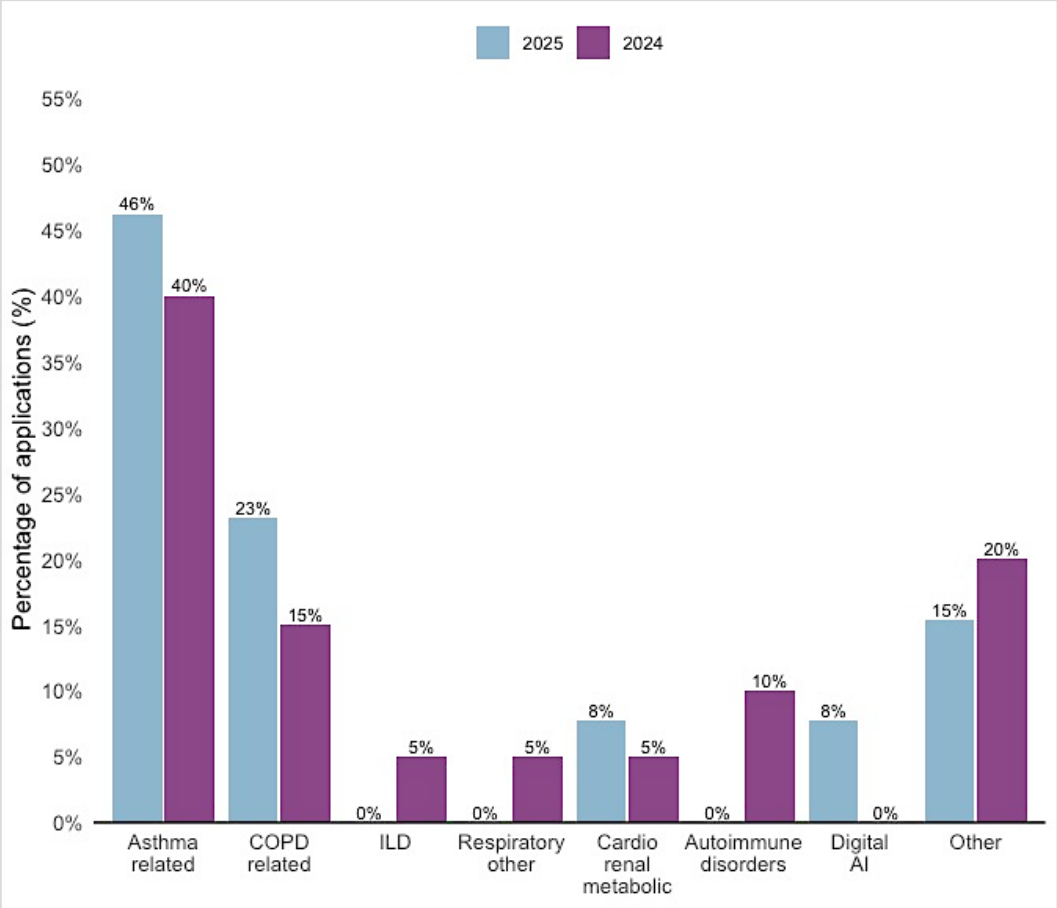
When considered at a disease-specific level, asthma was the most common disease focus (60%; n = 6), followed by Chronic Obstructive Pulmonary Disease (COPD, 30%; n = 3). Research involving other conditions accounted for another 10% of protocols (**Figures 3c**).

Figure 3c. ADEPT-approved protocols by disease, 2025



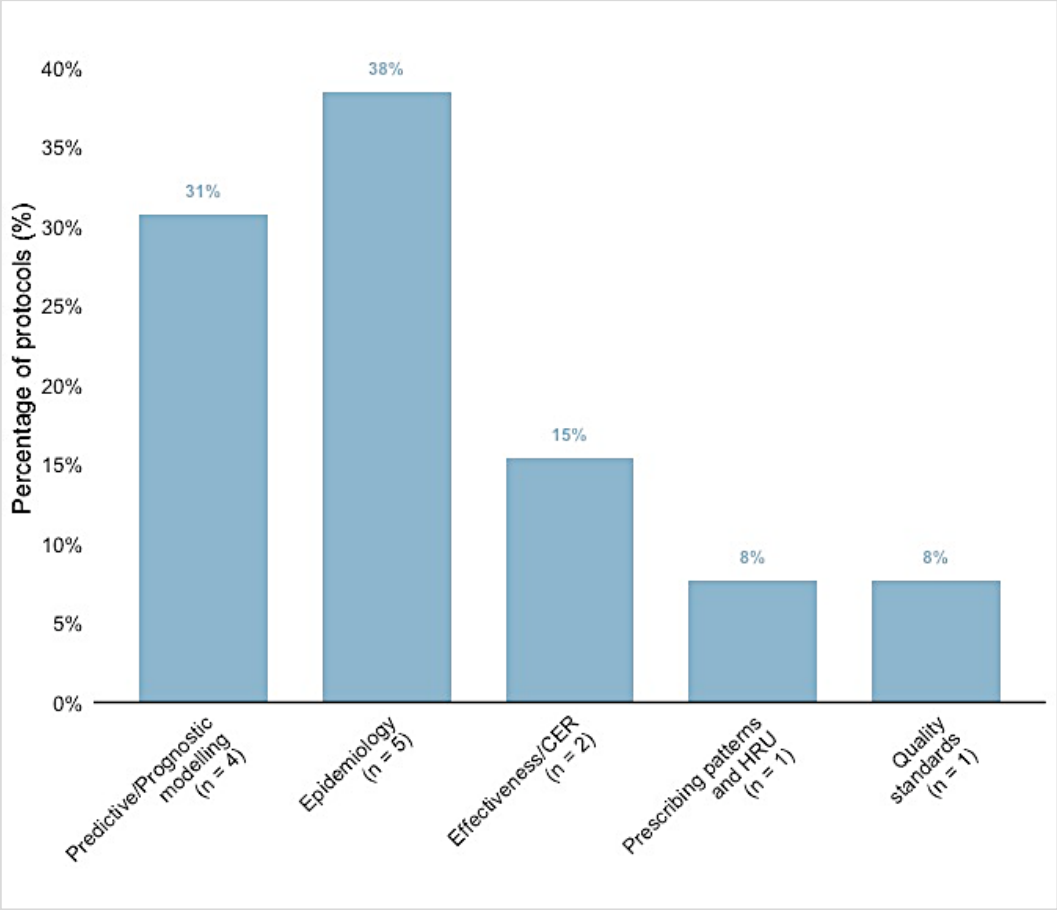
Between 2024 and 2025, there was modest variation in the distribution of ADEPT applications by disease area. Asthma- and COPD-related protocols increased in 2025, whereas applications relating to interstitial lung disease (ILD) and other respiratory conditions were not observed. Non-respiratory research areas accounted for a smaller proportion of applications in both years (**Figure 3d**).

Figure 3d. ADEPT-approved protocols by disease, 2025 vs 2024



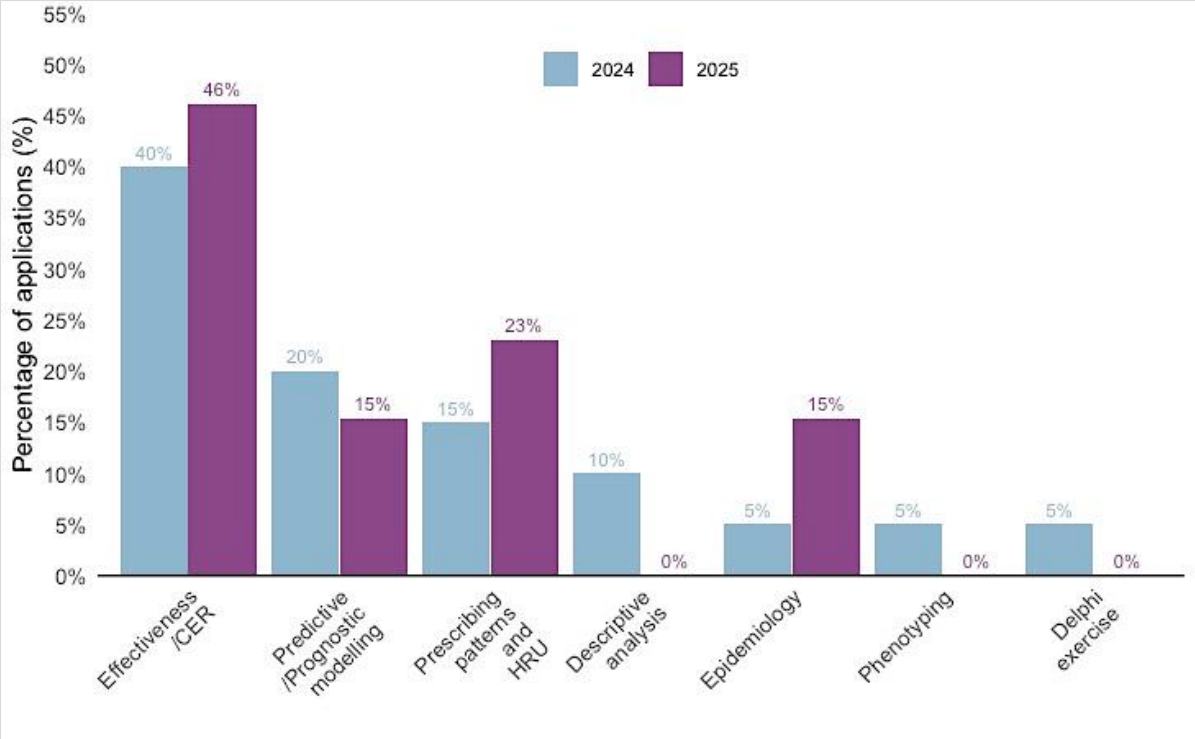
In 2025, ADEPT-approved protocols addressed a broad range of research topics, most commonly epidemiology and predictive or prognostic modelling, alongside comparative effectiveness research, prescribing patterns and healthcare resource use, and quality standards (**Figure 3e**).

Figure 3e. ADEPT-approved protocols by research topic, 2025



The nature of research topics addressed by ADEPT-approved protocols varied between 2024 and 2025. Increases were observed in effectiveness research, prescribing patterns and healthcare resource use, and epidemiology in 2025, whereas predictive or prognostic modelling declined and several study types observed in 2024 were not represented in 2025 (**Figure 3f**).

Figure 3f. ADEPT-approved protocols by research topic, 2025 vs 2024



3.5 Overview

This is the seventh annual report of the ADEPT Committee. It summarises the work of the Committee in 2025 and the scope of that work in comparison to activities in 2024.

During the 2025 reporting period, the Committee received and approved 13 research protocols, all of which were new submissions.

The mean (median) duration of protocol review in 2025 was 1 (1) working days, similar to the mean (median) times of 2 (2) working days for 20 protocols in 2024. The average review times in 2025 were similar than in 2024 and is within the Committee's 20-working-day target.

Academic studies accounted for the majority of protocols approved by ADEPT in 2025 (54%). Respiratory medicine was the therapy area of greatest research interest in both 2025 and 2024 (focus of 77% and 65% of approved protocols, respectively). Asthma was the most frequently studied condition in 2025 (46%) of applications, compared with 40% in 2024, alongside a smaller number of non-respiratory conditions.

Protocols submitted in 2025 covered a diverse range of research topics and study designs, as was the case in 2024. In both years, submissions included epidemiological studies, effectiveness or comparative effectiveness research, prescribing patterns and healthcare resource use, and predictive or prognostic modelling.

Appendix 1. ADEPT Committee Members, 2025

ADEPT Chair

Daryl Freeman, (MD) Associate Clinical Director Norfolk & Waveney UK

Dr Freeman is an Associate Clinical Director for Norfolk Community Health & Care, which involves a clinical role (working across community hospitals in Norfolk) and working with the Integrated Care System across Norfolk & Waveney to improve hospital care. She also serves as the Chair of the Norfolk & Waveney Right Care Respiratory Working Group which aims to standardise & prioritise respiratory care across all providers in Norfolk. She is current Chair of the Service Development Committee for the Primary Care Respiratory Society, and former Clinical Director for NHS England Respiratory Strategic Clinical Network.

Her non-respiratory interests include equestrian trauma – which combines her love of horses (she owns 3) with a desire to keep her acute medical skills up to date.

Dr Freeman has been a member of the REG since it was founded in 2013.

Todor (Ted) Popov, Professor at the University Hospital Sv. Ivan Rilski in Sofia, Bulgaria

ADEPT Reviewers

Bernardino Alcazar, Pneumologist at the Hospital de Alta Resolución de Loja, and Assistant Professor in the Department of Medicine at the University of Granada, Granada, Spain

John Blakey, Adjunct Associate Professor Curtin University and Senior Medical Practitioner in Respiratory Medicine, Sir Charles Gairdner Hospital, Perth, Australia

Jenni Quint, Reader in Respiratory Epidemiology in Respiratory Epidemiology, Occupational Medicine and Public Health at the National Heart and Lung Institute and Honorary Consultant Physician in Respiratory Medicine at Royal Brompton Hospital, London

Members

George Christoff, Professor, Faculty of Public Health, Department of Health Technology Assessment, Medical University, Sofia, Bulgaria

Alexandra Dima, Senior Research Fellow, Health Services and Performance Research (HESPER) Claude Bernard University Lyon 1, Lyon, France

Elizabeth Kern, Professor of Medicine, Division of Medical, Behavioral & Community Health National Jewish Health, Denver, CO, USA

Fabrizio Luppi, Associate Professor, Respiratory Disease Department, Universita degli Studi di Milano-Bicocca, Milan, Italy

Andrew McIvor, Professor, Division of Respirology, Department of Medicine, Firestone Institute of Respiratory Health, St. Joseph's Healthcare, MacMaster University, Hamilton, Ontario, Canada

Nicolas Roche, Professor of Respiratory Medicine, University Paris Descartes, Respiratory and Intensive Care Medicine department, Hôtel-Dieu Hospital, Paris, Franc

Miguel Roman-Rodríguez, Research Director, Instituto de Investigación de Palma de Mallorca, Mallorca, Spain

Richard Russell, (MD) Department of Respiratory Medicine, University of Oxford, Oxford, UK

Patrick Souverein, Assistant Professor of Pharmacoepidemiology, Division of Pharmacopathology and Pharmacotherapy, Utrecht University, Utrecht, The Netherlands

Jens Søndergaard, Head of Department, Research Unit for General Practice, University of Southern Denmark, Odense, Denmark

Mihaela Stefan, Associate Director of the Institute for Healthcare Delivery and Population Science and Associate Professor of Medicine at University of Massachusetts Medical School-Baystate, Baystate Medical Center, Springfield, MA, USA

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

Job van Boven, Assistant Professor, Universitair Medisch Centrum, Groningen, Groningen, The Netherland

Andrew Wilson, Clinical Professor, Norwich Medical School, University of East Anglia, Norfolk, England, UK