

Transparency, Reproducibility, and Accessibility of Clinical and Experimental Studies in Allergy (TRACES): Study design and protocol



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Background: The sphere of academia is currently confronting a “reproducibility crisis” in the fields of science and medicine, which could undermine the quality and validity of evidence used in decision-making processes. Various studies have been launched to scrutinize research transparency, reproducibility, and accessibility across multiple medical disciplines. However, these factors remain largely unexplored within the field of allergy research.

Objective: This report aims to elucidate the design and protocol of the Transparency, Reproducibility, and Accessibility of Clinical and Experimental Studies in Allergy (TRACES) study.

Methods: The TRACES study is a longitudinal, systematic, meta-research study conceived to measure the evolution of research transparency, reproducibility, and accessibility, as well as their associated influences.

Results: All research articles published in allergy journals indexed in MEDLINE will be identified, and a random sample of 500 articles (100 from each of 5 different time points) will be retrieved and scrutinized. Various indicators of transparency, reproducibility, and accessibility will be extracted from these articles, including the following: presence of conflict of interest and funding statements; availability statements for protocols, data, materials and analysis scripts; preregistration statements; and open access status. These will be compared across the various time points sampled. The study will also delve into any characteristics that may predict improved research transparency, reproducibility, and accessibility.

Conclusion: The TRACES study aims to provide valuable benchmarking data that will aid various stakeholders in the international allergy research community in enhancing research practices within the specialty. (J Allergy Clin Immunol Global 2025;4:100447.)

Key words: Transparency, reproducibility, accessibility, openness, research practices, allergy, protocol, study design

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Abbreviations used

ISSN: International Standard Serial Number
TRACES: Transparency, Reproducibility, and Accessibility of Clinical and Experimental Studies in Allergy

INTRODUCTION

Allergy medicine is a rapidly evolving field. In recent decades, there has been a significant increase in the prevalence of allergic diseases such as asthma, allergic rhinitis, drug and/or food allergy, and anaphylaxis.¹⁻⁵ This increase has been accompanied by a surge in interest, awareness, and scientific research related to these conditions.⁶⁻⁹ However, although the volume of publications has escalated, the quality of these studies can vary. In recent years, there has been a shift toward prioritizing best research practices, with transparency, reproducibility, and accessibility considered essential elements.^{10,11} Reproducibility, as defined by the US National Science Foundation Subcommittee on Replicability in Science, refers to “the ability of a researcher to duplicate the results of a prior study using the same materials as were used by the original investigator.”¹² Fundamentally, this is related to, or even determined by, the transparency in reporting and accessibility to primary reports (open access availability), study methods (eg, protocols, materials, analytical code) and participant-level data.^{11,13} Reproducibility is particularly pertinent in allergy research, in which basic and translational studies often require extreme precision and detailed methodology for successful replication. Despite journal articles being required to provide an outline of their methodology, it is not uncommon for the provided information to be insufficient for third-party reproduction of the study’s results, thus contributing to a “reproducibility crisis” in medicine.¹⁴ In response to this, researchers across various specialties, such as anesthesiology, cardiology, and nephrology among others, have published reports investigating research transparency, reproducibility, and accessibility within their fields.¹⁵⁻¹⁹

Alarming, such critical assessment remains absent in the field of allergy. Therefore, the Transparency, Reproducibility, and Accessibility of Clinical and Experimental Studies in Allergy (TRACES) study has been designed to address this evidence gap. With TRACES, we aim to investigate the trends of research transparency, reproducibility, and accessibility in allergy, as well as to identify any predictors of better research practices.

RESULTS AND DISCUSSION

This article outlines the study protocol for TRACES, which is a longitudinal, systematic, meta-research study registered with the Open Science Framework. The study is anticipated to be conducted from September to December 2024. The protocol report aligns with the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) protocol guidelines where applicable.²⁰

The design of the TRACES study, illustrated in Fig 1, involves review and analysis of 500 randomly selected records (100 samples from each of the 5 study time points [2003, 2008, 2013, 2018, and 2023]) from all articles published in allergy journals, which are classified as those listed under the category allergy in the Journal Citation Reports 2023 (Clarivate, London, United Kingdom). These time points were selected because 2023 was the latest elapsed year when the protocol was prepared and could therefore best reflect the recent situation. The inclusion criteria will encompass only English journals indexed in MEDLINE, with no restrictions placed on study design, article type, or geographic limitations or on specific criteria for population, intervention, comparator, or outcome.

A search of the MEDLINE database will be conducted via PubMed (US National Library of Medicine, Bethesda, Md) using the query string = “(electronic International Standard Serial Number [ISSN] of the first eligible journal)[Journal] OR (electronic ISSN of the second eligible journal)[Journal] OR ... (electronic ISSN of the last eligible journal)[Journal].” A total of search attempts will be made for the years 2023, 2018, 2013, 2008, and 2003. For each year sampled, a data set will be exported as a Microsoft Excel spreadsheet. Within each data set, duplicates, if any, will be removed, and each record will be assigned a unique identifier for subsequent sampling. Using the *sample* function from the R Base package in R version 4.3.1 (R Foundation, Vienna, Austria), 100 unique random numbers will be generated for each data set and the corresponding records will be retrieved. The full texts of these 500 publications will be stored in a password-protected cloud drive accessible only to the investigators. A round of screening will subsequently be conducted by at least 2 reviewers, who will designate the publications as either empirical or nonempirical studies. In this study, we define empirical studies as those containing original data and/or analysis. Hence, systematic review with or without meta-analysis, as a form of knowledge synthesis, will be considered empirical studies. Discrepancies will be settled by reconciliation between the reviewers, and if necessary, adjudication by additional reviewers will be sought.

Adapting the methods by Okonya et al¹⁵ and Hardwicke et al,²¹ the full text of the 500 sampled articles will be reviewed by at least 2 independent reviewers, who will record the information of interest on a standardized data extraction form. To maintain interrater reliability, compulsory training will be offered to all investigators before commencement of the review process. A calibration exercise will also be conducted with the first 10 articles sampled in 2023 and the last 10 articles sampled in 2003 to pilot test the data extraction form and ensure intercoder concordance. After data extraction, a consensus meeting will be held to unify the separately collected data. In the event of unresolved disagreements, another independent reviewer will be responsible for further review and verdict if needed.

As shown in Fig 1, the proposed data items to be extracted include the articles' metadata, including title, authors, country of origin (as defined by the affiliated country of the corresponding author), journal and year of publication, and article type, accessibility (open access vs subscription-based), the conflict of interest statement, and the funding statement. We will also verify the articles' open access status by using the Open Access Button platform (<https://openaccessbutton.org/> [OA.Works, London, United Kingdom]). In addition, for empirical studies, we will retrieve their statements regarding protocol, data, materials, and analysis script availability (depending on their study design), as well as preregistration statements. In addition, we will screen their citations on the Web of Science (Clarivate) to identify evidence synthesis (ie, systematic review and/or meta-analysis and replication studies [the study replicating or being replicated by the report of interest]) related to them. For all identified allergy journals, we will extract their electronic ISSN (or linking ISSN if not available), countries of origin, publishers, and most recent impact factors from the Journal Citation Reports 2023 (Clarivate).

The primary study outcome is the trend of transparency, reproducibility, and accessibility in allergy research from 2003 to 2023. The secondary outcome is the presence of study characteristics that may predict transparent and reproducible research practices and open access availability, if any. Our primary hypothesis is that research practice in allergy is becoming increasingly transparent, reproducible, and accessible over time, similar to the situations demonstrated in other neighboring biomedical fields.²²⁻²⁴ We also hypothesize that because of their editorial policy, particular publishers or journals might be factors associated with transparent and reproducible study practices.²⁴

Statistical analysis will be conducted using IBM SPSS Statistics, version 28.0 (IBM, Armonk, NY). We will first present a descriptive summary for the records reviewed. We will describe and examine the trends in transparency, reproducibility, and accessibility over the years, with comparison of categorical and continuous variables, as determined by the chi-square test and the Mann-Whitney *U* test, or their equivalents, respectively. To identify predictors of transparent and reproducible research practices or open science, a bivariate association analysis (between study characteristics and indicators of transparency, reproducibility, and accessibility) will be performed, preceding a multivariate logistic regression that incorporates variables whose bivariate *P* value is less than .10. Unless otherwise specified, categorical and continuous variables will be expressed respectively as number (percentage) and median (lower quartile–upper quartile). All 2-sided *P* values less than .05 will be considered statistically significant.

On completion, the study's results will be published in peer-reviewed journals and may also be shared at local and international conferences. The final reporting of this study will adhere to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses protocol when appropriate. In addition to this protocol, all data, materials, and analysis scripts necessary for study replication will be made available in the Open Science Framework (or other public repositories). This study does not require ethical approval, as it will review only publicly accessible scholarly records and will not involve human or animal subjects.

To our knowledge, the TRACES study will be the first in the field of allergy focusing on research transparency, reproducibility,

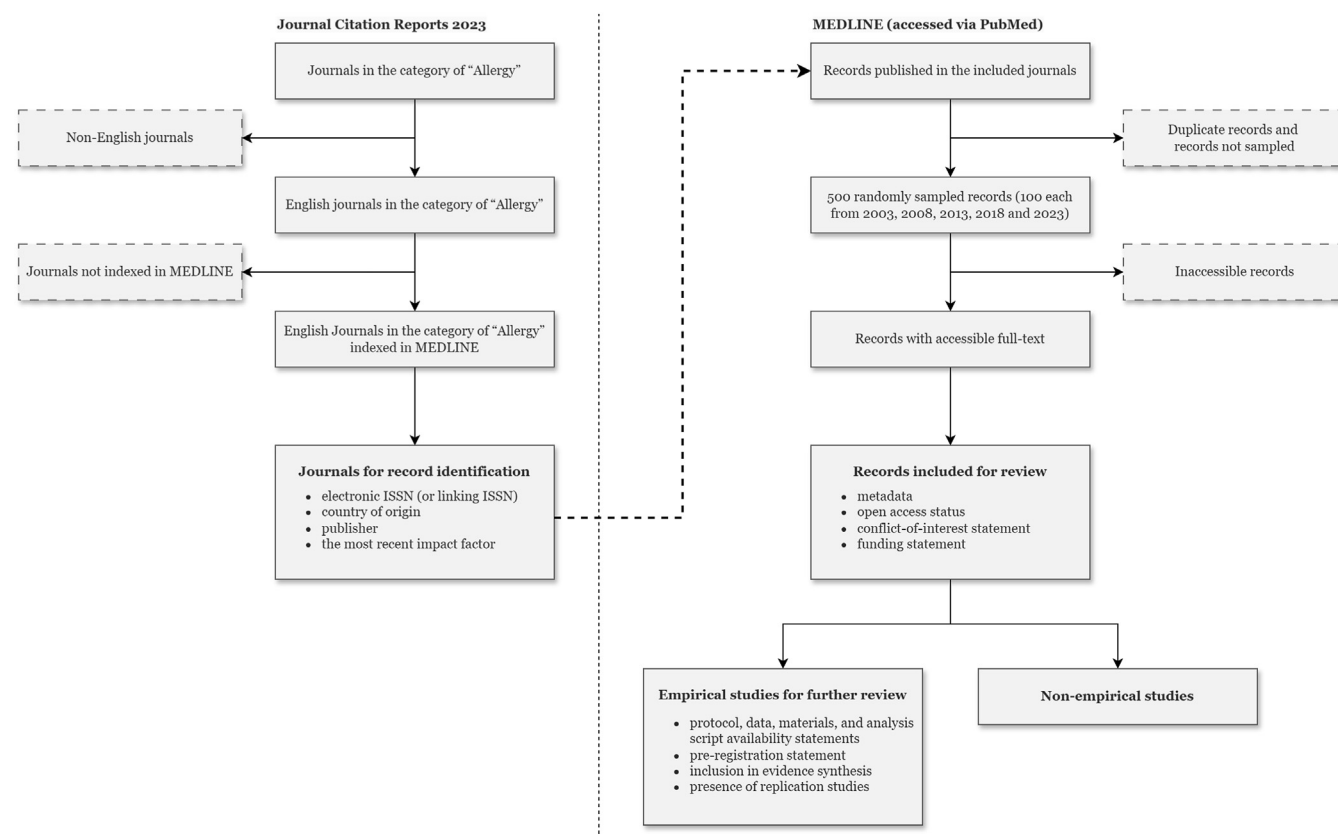


FIG 1. Study design and outcomes of the TRACES study.

and accessibility. It will also be the first longitudinal meta-research study seeking to identify predictors of open science as well as transparent and reproducible research practices. The results of this study will hold significant value and relevance for the entire allergy community and beyond, encompassing clinicians, researchers, institutions, journals, funding agencies, government bodies, patients, and the general public. We hope that our findings will prompt the allergy community to investigate and address this issue in our field. Ultimately, specific guidelines or position statements, which require efforts from multiple stakeholders across institutions and localities, might be formulated to promote best research practices. In summary, the TRACES project is a pioneering, systematic meta-research study that is poised to provide invaluable insights for potential strategies that advance transparency, reproducibility, and accessibility in allergy science.

DISCLOSURE STATEMENT

Disclosure of potential conflict of interest: The authors declare that they have no relevant conflicts of interest.

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