# Scientific Best Practices in Electronic Clinical Outcome Assessments: A Literature Review from Past to Present

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## Introduction

- Clinical Outcome Assessments (COAs) capture how patients feel and function, providing key insights into treatment impact on symptoms and quality of life. Electronic COA (eCOA) solutions offer operational advantages over paper-based methods, such as higher compliance[1], real-time data capture[2] and improved data integrity[3]
- Early eCOA development was grounded in behavioral science and usability testing[4,5], however, as adoption scaled, priorities shifted toward speed and cost. This commoditization led to a proliferation of platforms (e.g., Bring Your Own Device (BYOD), provisioned devices, web backups) but relatively few contemporary empirical studies showing how to implement eCOA to optimize patient experience and data quality
- This review quantifies the proportion of eCOA literature grounded in empirical research versus non-empirical sources, providing a clear snapshot of the scientific foundation supporting modern eCOA practices

## Methods

- An exploratory literature review was conducted from February to March 2025 using PubMed, Google Scholar, and libraries from pre-competitive consortia (C-Path eCOA/PRO Consortia; CDISC). Key search terms included eCOA/electronic Patient-Reported Outcome (ePRO), electronic diaries, patient engagement, compliance, site training, and data quality. Six reviewers screened abstracts and iteratively refined criteria; additional relevant articles were added based on expert knowledge
- Seventy-five publications (1998–2025) were reviewed and categorized into four types: empirical studies, best practices recommendations, consensus and theoretical / conceptual papers (see Table 1 for definitions)

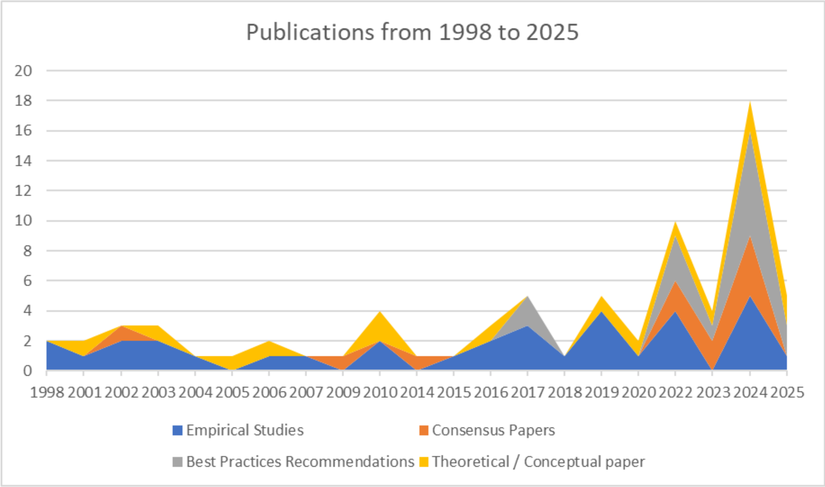
**Table 1. Definitions for Categories of publications**

| Definitions for categories | |
|---|---|
| **Empirical studies** | Papers presenting original research through hypothesis testing. |
| **Best Practices Recommendations** | Documents providing standardized guidance for implementation, migration and validation. |
| **Consensus Papers** | Formal recommendations from regulatory bodies or task forces (e.g., C-Path, CDISC). |
| **Theoretical /Conceptual papers** | Papers exploring frameworks, models or theoretical considerations. |

## Results

- Of the 75 publications reviewed, 34 were empirical and 41 non-empirical.
- The non-empirical group included 11 consensus papers (e.g., C-Path, CDISC), 15 theoretical / conceptual papers, and 15 best practice recommendations papers.
- Figure 1 depicts a temporal shift where empirical studies seem to have dominated early years, while theoretical /conceptual and best practice recommendations papers have grown in recent years.
- Between 2020 and 2025, non-empirical publications (28) far outnumbered empirical studies (11), reflecting a shift toward theoretical and best-practice papers, likely influenced by increased publication activity during the COVID-19 pandemic and rapid adoption of decentralized and BYOD approaches.
- Content-wise, design elements like alarm frequency and reminder windows, once empirically validated, are now largely absent from recent literature, while new features (e.g. reminder windows to improve completion rates) are introduced without comparable evidence, creating a gap in modern eCOA research.

**Figure 1 Temporal trends in the four categories of the identified publications identified (1998–2025).**




## Conclusions and limitations

- **This review highlights a notable shift in the eCOA research: While early empirical studies focused on foundational design, more recent work has shifted toward exploring stakeholder perspectives.**
- **Despite an overall increase in publication volume, hypothesis-driven empirical studies have not kept pace with the growth of non-empirical publications and retrospective evaluations. As a result, consensus, theoretical, and best-practice papers now outnumber empirical investigations.**
- **This imbalance raises concerns about the scientific basis and rigor of current eCOA implementation practices. To address this, forthcoming research by our team will examine the nature of empirical evidence emerging in recent years.**
- **Strengthening the empirical foundation of best practices will require a renewed focus on prioritizing hypothesis-driven research to support evidence-based implementation.**

### References

[1] Abrams, P., Paty, J., Martina, R., Newgreen, D. T., van Maanen, R., Paireddy, A., Kuipers-deGroot, T., & Ridder, A. (2016a). Electronic bladder diaries of differing duration versus a paper diary for data collection in overactive bladder. Neurourology and Urodynamics, 35(6), 743–749. https://doi.org/10.1002/nau.22800
[2] Quinn, P., Goka, J., & Richardson, H. (2003). Assessment of an electronic daily diary in patients with overactive bladder. BJU International, 91(7), 647–652. https://doi.org/10.1046/j.1464-410x.2003.04168.x
[3] Hufford, M. R., Stokes, T. E., & Paty, J. A. (2001a). Collecting Reliable and Valid Real-Time Patient Experience Data. Drug Information Journal : DIJ / Drug Information Association, 35(3), 755–765. https://doi.org/10.1177/009286150103500314
[4] Jamison, R. N., Raymond, S. A., Slawsby, E. A., McHugo, G. J., & Baird, J. C. (2006). Pain Assessment in Patients With Low Back Pain: Comparison of Weekly Recall and Momentary Electronic Data. The Journal of Pain, 7(3), 192–199. https://doi.org/10.1016/j.jpain.2005.10.006
[5] Stone, A. A., Shiffman, S., Schwartz, J. E., Broderick, J. E., & Hufford, M. R. (2002). Patient non-compliance with paper diaries. https://doi.org/10.1136/bmj.324.7347.1193

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