PCR150

Looking Back to Go Forward: Reintegrating Scientific Considerations into eCOA Design and Implementation

Lindsay Hughes[1], Erieta Bountouva[2],Matthew Reaney[3]
[1]IQVIA New York, US; [2] QVIA Madrid, Spain; [3]IQVIA, Reading, UK

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[6].
- This review examines whether current eCOA systems remain scientifically informed, engage patients meaningfully, and ensure data completeness.

Methods

- An exploratory literature review was conducted from February to March 2025 using PubMed, Google Scholar, and libraries from pre-competitive consortia (Critical Path institute, eCOA/Patient Reported Outcomes [PRO] Consortia; Clinical Data Interchange Standards Consortium). Key search terms included eCOA/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-four English-language publications (1998–2025) were reviewed to address three core questions (Figure 1).
- Publications were categorized as "empirical" and "non-empirical".
  - Empirical publications were defined as “research investigations that collect and analyze data to generate evidence-based findings”6 and were further categorized by research design and analytic approach.
  - Non-empirical publications were defined as “theoretical papers not involving data collection or statistical analysis”.

Figure 1: The three core questions addressed in this reviews

Results

Of 74 publications reviewed, 33 were empirical and 41 non-empirical. Empirical studies included 16 using mixed methods, of which 12 involved focus groups, interviews, or surveys with patients, site staff, or clinical stakeholders. Non-empirical studies were theoretical (n=15), best practice (n=15), or consensus papers (n=11).

Question 1: Is “modern” eCOA being systematically informed by solid scientific research to ensure reliability and validity of eCOA?

- Only 17 empirical studies tested eCOA interventions using hypothesis testing, and just 3 of those were published in the last 5 years (Figure 2 and 3).
- While modern technologies (e.g., BYOD, digital interfaces) offer expanded capabilities, empirical evidence of their reliability and validity is lacking. Among the empirical studies, 1 evaluated BYOD, 12 evaluated digital interfaces but only 4 evaluated reliability and validity of them[5,8,9,10].

Question 2: Are current eCOA designs optimized to enhance patient engagement and reduce site burden?

- Modern eCOA can theoretically improve engagement and reduce site burden through automation, remote monitoring, and gamification, yet standardized frameworks remain limited. Early studies measured engagement directly[5], while recent research captures perceptions of burden without quantifying impact: Only 3 studies suggest reward-based gamification can encourage consistent data entry and ease burden.
- Current eCOA designs must balance trial needs with patient and site feasibility, yet guidance on tailoring device type, location, and frequency is limited to non-empirical commentaries, with no data-driven best practices available.

Question 3: What strategies are in place to monitor and ensure data completeness in modern eCOA systems?

- Traditional eCOA enabled real-time tracking and site intervention, while modern systems simplify interfaces and data transfer but add complexity, especially in trials without sites or with variable tracking.
- Most literature identifies proactive flagging and continuous monitoring as critical but provides no empirical evidence of their implementation.

Figure 2: Flow of empirical studies (1998–2019) by subsequent research design and analytic approach

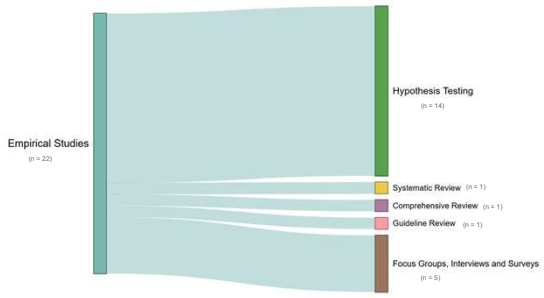
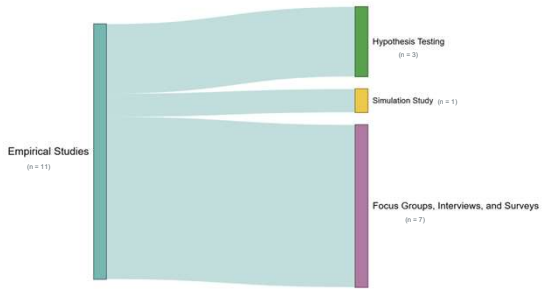


Figure 3: Flow of empirical studies (2020-2025) by subsequent research design and analytic approach



Conclusions

- **Early studies emphasized foundational design, while recent work highlights site and clinician perspectives. These qualitative insights are valuable but raise concerns about the scientific rigor of current eCOA design, usability, and operations.**
- **Future research must re-anchor eCOA best practices in empirical evidence that informs to boost patient engagement and reduce site burden.**
- **By looking back at foundational principles, we can move forward with more robust, patient-centered, and scientifically grounded eCOA implementations**

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