THE IMPORTANCE OF SITE MANAGEMENT IN OBSERVATIONAL STUDIES

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BACKGROUND

- Site management is crucial for data integrity and scientific quality in observational studies.
- Observational research differs from interventional trials:
  - ✓ No alteration of patients' therapeutic pathways
  - ✓ Less intensive oversight.
- We aim to demonstrate how adaptive site management strategies enhance investigator engagement and effectively address challenges in patient enrollment and data collection (Figure 1).

METHODS

- Operational challenges and site strategies to ensure high-quality data collection have been examined.
- IQVIA's recent observational study of 936 epileptic patients across 50 Italian sites provided insights into key performance factors, including:
  - ✓ Ethics and regulatory processes
  - ✓ Resource allocation
  - ✓ Data collection workflows (with a focus on the availability of electronic health records)
  - ✓ Sites activation and enrollment rates (Figure 2), data entry timelines, consistency and completeness of collected information.

RESULTS

- Our experience highlights the need for an adaptive, context-driven approach to site management, tailored to real-world clinical settings (Figure 3).
- Key challenges reported by sites include limited personnel and technological resources and restricted time for investigators to dedicate to patient recruitment and data collection, activities often deprioritized in favor of routine clinical care.
- Effective site management in observational research depends on active collaboration among Principal Investigators, Study Coordinators and Site Staff.
- To enhance investigator engagement, the CRO implemented a proactive strategy, providing dedicated support from the initial patient identification phase. A thorough clinical record review aligned with study eligibility criteria has been pivotal in improving patient recruitment.
- Close collaboration between the CRO and sites has provided deeper insights into local organizational dynamics and operational workflows. Early identification of enrollment and data collection challenges has enabled timely resolution through targeted interventions, including onboarding additional investigators and specialized training on study protocols and data collection.
- The integration of electronic informed consent (eConsent) and electronic Patient-Reported Outcomes (ePROs) systems plays a key role in improving data accuracy and completeness.

CONCLUSIONS

- **Effective site management is crucial for the success of observational clinical research. Key drivers for streamlining processes, mitigating risks and promoting a culture of continuous improvement are:**
  - ✓ **Targeted budget allocation**
  - ✓ **Investigator engagement**
  - ✓ **Staff training and recognition of team members' strategic role**
  - ✓ **Clear and structured communication among sponsors, investigators and patients**
  - ✓ **Adoption of technologies: eConsent, ePROs, EDC (Electronic Data Capture) Platforms (Figure 4)**
  - ✓ **Early patient involvement in the study design phase.**

Figure 1: Site Management vision

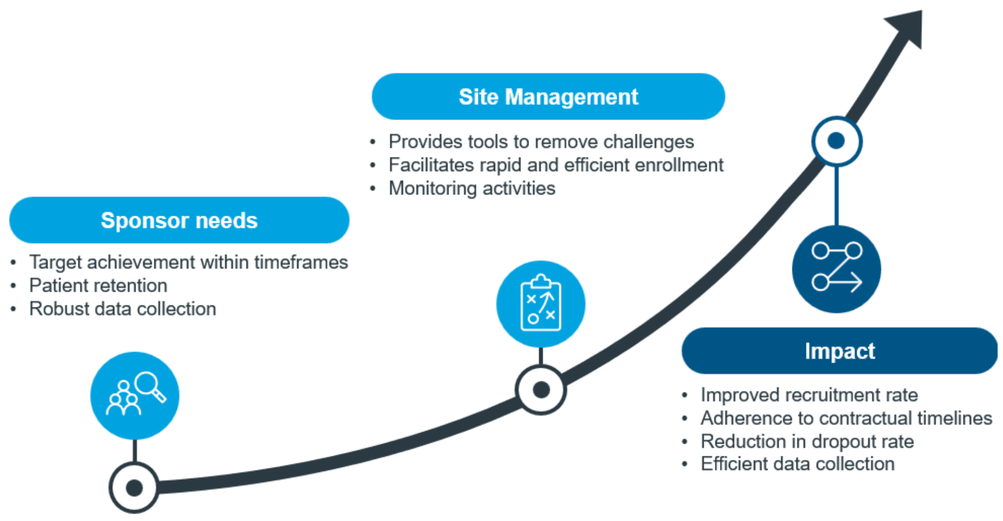


Figure 2: Sites activation and enrolment trends - IQVIA study

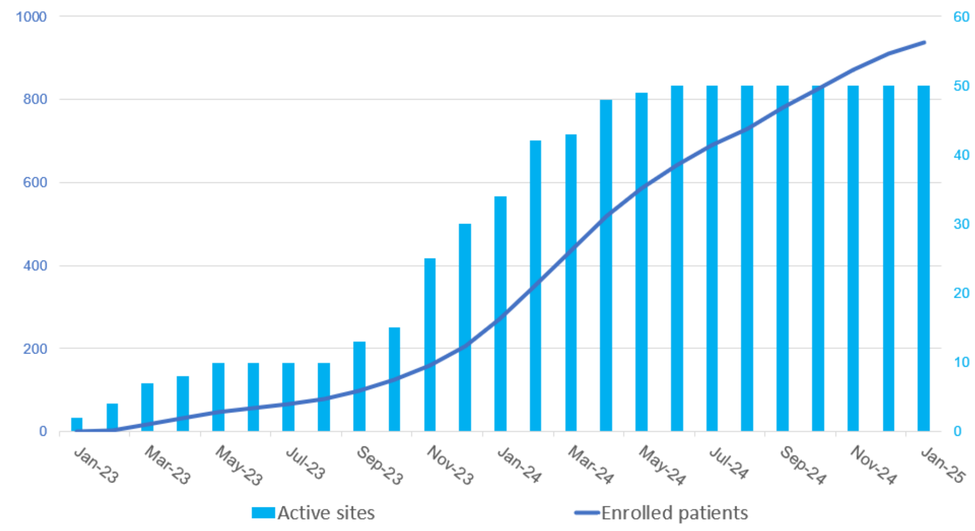


Figure 3: Adaptive Site Management approach

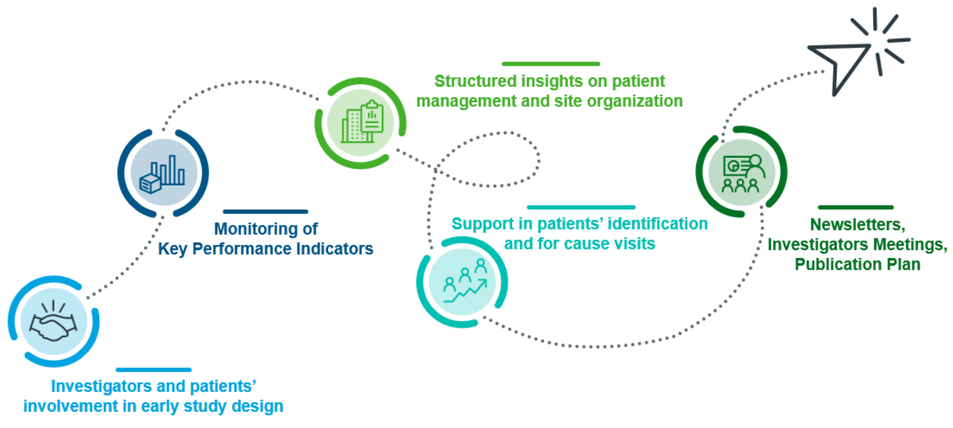
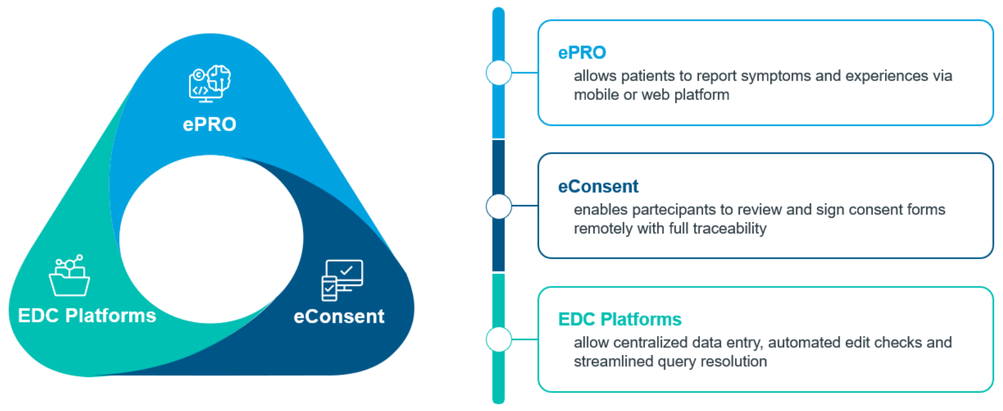


Figure 4: Digital Innovation in Observational Studies



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1. Alward V, Haque Z. Data management considerations in observational studies. Quintiles; 2015
2. Lamberti MJ, Dirks A, Kikuchi N, Patel Cervantes N, Getz K. Benchmarking site activation and patient enrollment. Ther Innov Regul Sci. 2024;58(4):696–703
3. Miller J. A roadmap for real-world and late phase research site selection and engagement: developing a strategy to drive positive outcomes. Durham, NC: Quintiles; 2016

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