CASE STUDY

Moving beyond paper: eCOA successfully delivered across three Phase I oncology studies

Improved data quality and participant compliance across three early-phase trials

The challenge

Regulators are emphasizing patient-reported outcomes (PROs) use in early-phase oncology studies. Maintaining participant motivation and compliance in the presence of symptoms presents a significant hurdle.

Consistent and accurate remote participant reporting can be hindered by:

- Traditional paper diaries, which are prone to loss and recall issues
- Poorly designed digital solutions that lack engagement features, leading to poor data quality
- Burdening participants with overly frequent assessments

These challenges can threaten data integrity and participant retention in Phase I trials. They can also hinder effective Phase II and III dose selection and ability to differentiate.

Sponsors should implement user-friendly, engaging digital solutions. These can provide insights into adverse events and participant experiences and help optimize dosing strategies.

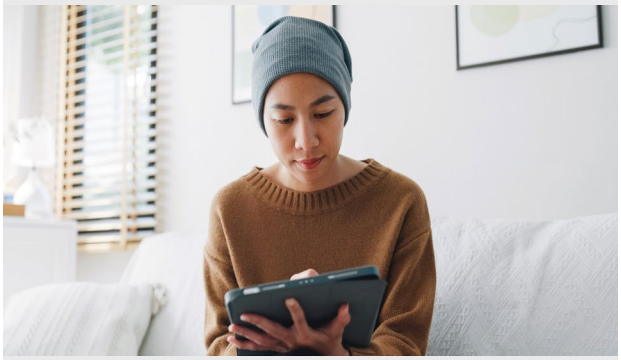
Situation

An APAC sponsor selected Clario for three Phase I eCOA oncology trials across the U.S., Europe and APAC with over 300 participants.

The project involved transitioning from the traditionally paper-based approach to at-home eCOA to capture symptomatic adverse event data.

Summary

- Three Phase I eCOA oncology studies for APAC sponsor
- Remote eCOA data collection performed by Clario
- Digital data collection combined with Clario's consultative, science-led solutions key to success



Success factors

✓ **Digital data collection and engagement features**
- Drove participant engagement and compliant reporting and reduced site burden

✓ **Consultative science-led solution**
- Provided expert advice to minimize participant burden

✓ **Real-time compliance reporting**
- Enabled the sponsor to take fast, corrective action when needed

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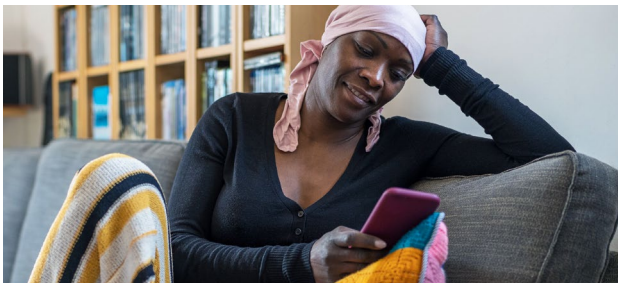
Clario solution

Clario's consultative, science-led solution included:

- At-home eCOA with intuitive eDiaries for remote assessments
- Engagement features, reminders and notifications to complete assessments in a timely manner
- Site training and 24/7 multilingual support
- Trial oversight for sponsors and sites including near real-time operational and clinical data reporting



Impact

Regulatory-compliant, accurate data

- High-quality data ensured by Clario's scientific expertise and eDiary with alerts and engagement tools

Participant and site burden minimized

- At-home solution preferred by participants[1] and reduced site workload

Early insights guided by effective Phase II and III strategies

- Valuable insights into the participant experience provided by eCOA, helping optimize dosing strategy in later phases and enabling differentiation from the competition

Clario's success factors

Clario's expert-led approach involved:

Digital data collection

- User-friendly, intuitive app with built-in engagement features to drive high compliance
- At-home solution that was preferred by participants[1] while reducing site workload
- Assurance of timely, consistent entries and avoidance of missing and illegible data

Expert support from eCOA Science

- Specialist guidance on assessment timing and frequency and diary design to minimize participant burden and drive compliance
- Support throughout the trial, with regular touchpoints and oversight

Near real-time compliance reporting

- Participant compliance reports available to the site and sponsor
- Site notification of participant non-compliance for fast corrective action

Notifications, reminders and alarms

- Automated engagement alerts to prompt participants to complete assessments on time and accurately

1. 88% preferred at-home reporting, ISPOR Latin America 2019 Yamamoto & Dallabrida

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