CASE STUDY

Clario delivers study setup in 10 weeks for a global chronic weight management study

Pharmaceutical company benefits from Clario's rapid setup in a Phase III trial

The challenge

Fast set-up times ensure sponsors can more easily meet IRB submission and first patient in (FPI) dates.

However, a number of factors can put pressure on timelines, such as:

- Complicated study documentation requiring detailed review and sign-off.
- Delayed involvement of study team members post kick-off rather than early during the proposal stage.
- Bespoke builds of assessments.
- Questionnaire licensing and device provisioning on a global scale.

Partnering with the right eCOA provider who has the tools, technology and expertise to get trials up and running quickly is key.

Situation

A pharmaceutical sponsor conducted a global Phase III chronic weight management study.

This study took place at more than 100 sites and at participants' homes in North America, Europe and APAC.

The sponsor required accelerated setup to meet study timelines as well as an eDiary to record blood glucose levels and ePRO responses.

Summary

- The sponsor required accelerated setup in a global Phase III study.
- Clario's rapid approach delivered study setup in 10 weeks from kick-off.
- Timelines were hit, sites were ready quicker and enrollment was accelerated.

Clario's rapid setup

✓ **Simplified eCOA Charter**

- Clario has a new simplified 25-page Customer Charter.

✓ **Early involvement of study team**

- Clario Solution Design and Programming teams were involved upfront.

✓ **Standardized assessments**

- Pre-built, pre-validated assessments from Clario's library were used.

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Clario solution

Clario was engaged to provide remote and at-site eCOA data collection for the study.

The solution involved:

- Provisioned at-site tablets with quality of life and suicide ideation and behavior (C-SSRS) assessments.
- Provisioned at-home handhelds with daily dosing diaries.
- U.S. English versions of assessments for translation.
- Assessment licensing and device provisioning for each country by Clario's global in-house logistics team.

Clario leveraged prior experience with working with the sponsor. This included re-using and re-engineering documentation and a library of sponsor-specific assessments, as well as integrating previous software builds and reporting.

Impact

Timelines hit

- Clario's accelerated approach ensured the sponsor's 10-week setup timeline was met.

Accelerated enrollment

- Clario's solution expedited the arrival of devices on site, which meant sites could get ready quicker.
- As a result, participant enrollment could start earlier.

Clario's success factors

Clario completed the study setup in 10 weeks from kick-off.

Our approach involved:

Simplified eCOA Charter

- Simplified and shorter documentation with accessible and easy-to-understand language.
- Reduction in specification document from 125 pages to 25 pages.

Early involvement of study team

- Pre-assigned involvement of operational resources during the proposal review stage including Clario Solution Design and Programming teams.
- Quick and early build-out of the study documentation ensured.

Standardized assessments

- Pre-built and pre-validated assessments from Clario's standardized library (representing half of those used).
- Minimal modifications to assessments prior to release, accelerating setup.

Our team of experts is ready for your questions about Clario's accelerated eCOA study setup. To contact us, go to clario.com/solutions/ecoa or email info@clario.com.

Clario generates the richest clinical evidence. Fusing our deep scientific expertise and global scale into the broadest endpoint technology platform, we empower our partners to transform lives.