Delivering electronic data capture for a clinical trial in breast cancer
“Having used MACRO for over a decade in combination with our robust data management procedures, we were confident that it would demonstrate sufficient rigor to manage a large-scale clinical trial taking place in multiple sites throughout different countries.”

Hannes Fohler
Managing Director of ABCSG

A history of clinical excellence:

The PALbociclib CoLlaborative Adjuvant Study (PALLAS) registration trial (NCT02513394) is one of the most recent high-profile clinical trials undertaken by the Austrian Breast & Colorectal Cancer Study Group (ABCWG), a non-profit academic research organisation world-renowned for its patient-centered approach in delivering clinical excellence.

PALLAS is conducted by ABCSG in collaboration with Alliance Foundation Trials, LLC (AFT) and with the support of Pfizer Inc. to evaluate whether the drug palbociclib decreases the chance of breast cancer recurring beyond endocrine therapy alone in people living with HR+/HER2-, stage II/III early invasive breast cancer. Breast cancer has a high incidence rate compared to other cancers and affects millions of people globally each year. In the United States, a majority of breast cancers fall into this category. Enrolling 5,600 participants, it is the largest global phase 3 trial of palbociclib for patients with hormone receptor positive early breast cancer. To ensure the PALLAS trial runs smoothly, ABCSG is using Elsevier’s MACRO electronic data-capture solution to coordinate all related trial’s activities, located in 242 centers across 20 countries worldwide.
Delivering a tailored EDC approach using MACRO:

As part of the trial conception, ABCSG worked with its pharmaceutical and academic partners to demonstrate that MACRO could match other large-scale clinical trial Electronic Data Capture systems, satisfying all parties that:

- The solution’s intuitive system would make it easy for ABCSG as well as contracted personnel to adapt to the technology, improving the speed and simplicity of inputting and monitoring patient data.
- MACRO’s data integrity, data management capabilities and compliance would strengthen the integrity of ABCSG’s research.
- MACRO has proven to be successful in multi-market clinical trials.
- MACRO is widely used and has passed inspections across many European regulatory agencies, bolstering ABCSG’s confidence that MACRO would be fit for purpose.
- MACRO is proven to meet all requirements of registering a clinical trial with the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA), a critical dimension of the solution’s success.

Coordination and operational preparation in terms of data collection and clinical data management systems used by the US (AFT) and Non-US (ABCSG) sponsors started in early 2014. ABCSG needed to configure MACRO to ensure that the solution considered the complexities of the PALLAS trial and was tailored to focus on compatibility with the system used by the US sponsor, the outcomes and the user-friendliness. Elsevier’s MACRO team worked closely with ABCSG to ensure that the unique configurations made to ABCSG’s tailored MACRO solution would operate seamlessly during the PALLAS trial.

With MACRO’s adaptability and flexible reporting, and some ingenious system integration work by ABCSG, they are able to pool the two data sets and collect the different eCRFs seamlessly. The highly-dedicated and expert staff, conduct training and validation services, and work on every update and change, ensuring that the system is constantly fit for purpose and all global trial sites are prepared for the trial.
“The expertise of the staff at ABCSG and clinical research organization sites globally relies on robust methodologies and an EDC capable of delivering consistent and high-quality data. MACRO has proven to be a reliable and user-friendly system to support this requirement.”

Karin Zehetner
ABCSG’s Head of CDM

The PALLAS trial is ongoing and estimated primary completion dates will be in September 2020, while long-term follow-up data will be collected if the trial meets its primary endpoint.

Elsevier’s MACRO provides high-profile clinical trials with a dynamic and intuitive system that has simplified the process of setting up studies and increased efficiency in conducting increasingly complex and global clinical trials. From artificial intelligence to clinical solutions, technology has greatly transformed the clinical research and drug discovery processes globally. As the pool of stratified data has increased exponentially in recent decades, health and healthcare have shifted from ‘one size fits all’ to a more tailored approach requiring highly detailed data capture and planning.

Elsevier’s MACRO is committed to supporting clinical trial designers, researchers, organisations and institutions, such as ABCSG, to conduct research and clinical trials that focus on compliance with all regulations, highly efficient data collection and complete integrity of the outcomes. MACRO is constantly evolving to meet the individual needs of each clinical trial and to advance clinical research.

About MACRO

Elsevier’s MACRO is committed to supporting clinical trial designers, researchers, organisations and institutions, such as ABCSG, to conduct research and clinical trials that focus on patients’ needs and outcomes. MACRO is constantly evolving not only to meet the individual needs of each clinical trial, but also to account for the different needs of different patient populations.