

Phase III germline BRCA mutated (gBRCAm) metastatic pancreatic cancer



Oncology



12 countries



77 sites

Innovative Trials' Clinical Enrolment Managers enabled sites to significantly increase enrolment in a complex pancreatic cancer study.

Background

Innovative Trials were approached by the study sponsor to boost enrolment for a phase 3 study in pancreatic cancer.

The study required patients with gBRCAm metastatic pancreatic cancer whose disease had not progressed on first line platinum based chemotherapy.

Challenges

At the time of the study the majority of patients with pancreatic cancer were unaware of their BRCA status and needed to undergo testing to confirm. Understandably, many people were reluctant to delay their treatment whilst waiting for the BRCA test result. Furthermore, for those that did enrol in the study the screen failure rate was exceptionally high as patients were not meeting the gBRCAm requirements.

Solution

Innovative Trials' Clinical Enrolment Managers (CEMs) were deployed in 12 countries to develop site specific recruitment plans and assist sites with recruitment. Patient pathways were reviewed to ensure that the sites were identifying all potential candidates.

Phase 3
study in
pancreatic
cancer

CEMs were
deployed in
12 countries

Discussions were held around the site's existing referral networks and strategies were proposed as to how sites could extend their reach to other physicians. Hospital pharmacies were requested to run a list of potential patients based on prescribed medications.

Links with the sites' genetic counselling team were strengthened to gain referrals and information on patients with the germline BRCA mutation.

Sites were supported with hosting lunch and learn sessions.

Sites were supported with effectively targeting their Electronic Medical Record searches.

Outcome

Sites receiving CEM support were more likely to enrol overall and enrolled more patients compared to sites that did not receive CEM support.

Recruitment activities at sites increased significantly following CEM activities.



The number of sites actively enrolling was higher for those receiving CEM support compared to those that opted out of CEM activities

92% vs **70%**
of CEM supported sites screened one or more patients
of the non supported sites



Enrollment at sites participating in CEM activities was also higher.

CEM supported sites enrolled

16% ↑
more patients compared to the unsupported sites