## **CASE STUDY**

## **International drug trial for a chronic disease**

This multinational trial was sponsored by a major European pharmaceutical company. The FDA mandated a high participant retention requirement, which incentivised the sponsor to put a lot of effort into strategies to retain participants at all sites, including the establishment of a Retention Manager role for each country.

Approximately 330 participants were recruited at 12 sites in Australia, each being involved in the trial for 3-4 years. Following an extensive array of retention activities, 100% of Australian participants were retained.

**Study coordinator activities**

Study coordinators were identified from the outset as a crucial resource for participant retention and received regular site newsletters which included both international and Australian updates. Experienced study coordinators mentored less experienced coordinators, including on-the-job training. Annual in-person meetings and monthly teleconferences allowed coordinators to share challenges and discuss best practice.

**Participant activities**

Participants received regular newsletters with updates about the study's status at the national and global levels and health literacy information.

The sponsor funded sites to send out greeting cards and small gifts to encourage a healthy lifestyle. These were timed and themed to coincide with periodic in-person site events (e.g., a talk by a chef on how to cook nutritionally sound meals was linked to a gift of measuring spoons and cups). Participants were also given a subscription to a magazine relevant to their health condition. At clinic visits, study coordinators were encouraged to talk about any advice in this magazine that was relevant to the participants' situation, for example how to manage their condition while on holiday.

An end of year event where the site PI gave an update on the study to participants provided an opportunity for the participants to interact with the PI and ask questions directly. These events were very popular.

**Evaluation**

When the trial staff debriefed at the end of the trial, they considered the use of the magazine as a discussion tool as the most useful retention activity. The ongoing training of the study coordinators at different points of the trial was also beneficial, for example focusing more on retention activities as the trial progressed.

While this case study involves many activities that may be outside the possible budget of many projects, the actions of fostering learnings across sites and using existing health literacy materials as conversation aids were impactful and could be well within study budgets.