# **CASE STUDY**

# **Tracking participant preferences to deliver study updates**

The Gibbs Lab at the Walter and Eliza Hall Institute (WEHI) worked with the VCCC Alliance and the Beyond the Form team to develop a sub-study of an existing clinical trial: FORECAST-II. FORECAST-II is a diagnostic, single arm study for participants with unresectable or metastatic colorectal cancer.

The aim of the sub-study is to implement and, importantly, to evaluate some of the recommendations of the Beyond the Form project. Investigators chose to focus on the impact of providing a study update in a variety of formats (print, email, video, phone call and in-person conversation), and inviting participants to nominate if they would like a support person to receive the communications. The investigators formed a consumer consultation group, who discussed possibilities and wording for both the study updates and for the surveys that will be used to measure the impact of providing general study updates in accordance with participant preferences. The study updates will focus on:

* Study progress (number of active sites; number of participants enrolled)
* Information about the science of the study
* Information about study staff

Updates will be issued, via the participant’s chosen format, to participants or relevant support people every 6 or 12 months (in accordance with their preferences)

To evaluate the benefits and costs of delivering these updates to participants, the research team has included evaluation measures for participants, site staff, and WEHI staff in the study design. Participants and site staff will be given a survey after the first study updates have been delivered evaluating the clinical utility of the study updates. The participant survey asks about the participants’ experience of receiving and interacting with the study updates (did they receive them as expected? was the content useful and easy to understand?). Site staff will be asked to track the time required to deliver the study updates and will also be asked about how useful they thought the study updates were for participants. WEHI staff will record the time taken to track participant preferences and produce study updates.

**Seeking ethics review**

In an effort to reduce the administrative burden of conducting an ethics review of each six-monthly general study update in its multiple formats (in-person, telephone call, video, newsletter), for the Beyond the Form Pilot Project comprehensive templates for these communications have been developed. These templates, containing standardised wording and formatting, highlight the information that will be covered in general study updates, with indications of which pieces of information will change between updates highlighted (for example, the number of participants recruited to the FORECAST-II study). These templates have been submitted for ethics review, with the intention that obtaining approval for these templates will allow the study team to send general study updates using these templates without requiring additional ethics review for each update. It is foreseen that any substantial changes to the material or format of the general study update will require additional ethics review.