**Identify, Train and Inspire Emerging PIs – The New Zealand Breast Cancer Foundation**

**• Describe your solution.** The NZ Breast Cancer Foundation will identify, train and inspire emerging principal investigators for breast cancer clinical trials. The program will provide accreditation in line with the increasing trend for mandatory certification of Principal Investigators. Candidates may include registrars, newly-qualified specialists, younger practising specialists, clinicians returning from overseas.

**• How will you do it?**

**Identify future Principal Investigators:** New Zealand has fewer than 10 health boards that run clinical trials, so we anticipate this will not be hard. Candidates will be identified via conversations with existing PIs, trial nurses/coordinators, pharmaceutical companies, medical school deans, HR departments at District Health Boards, clinical leaders. Candidates will be personally invited to join the program.

**Train future Principal Investigators:** A training course specifically for investigators in the New Zealand regulatory and clinical environment will be developed in conjunction with local regulators, health boards, existing investigators and pharmaceutical companies. The course will be registered for CME.

Local training will be supplemented by the potential to visit trial sites overseas.

**Inspire future Principal Investigators:**

* Part of the program will be taught by an inspiring principal investigator from a top US institution
* Pharmaceutical companies will be asked to provide briefings (under NDA) of new opportunities
* Our organisation (The NZBCF) will guarantee a level of support for their first trial that will increase investigators’ chance of successful recruitment
* There will be an opportunity for participants to form a peer group for future networking & support

**• How does it work?**

Investigators who have completed the course will have training and certification that overcomes their lack of experience. We anticipate they will be younger, more enthusiastic, less caught up in “the system” than some of their more experienced peers, so will approach trials with a level of enthusiasm and flexibility that will enable more creative recruitment policies. Their first trial will receive a support package from the NZ Breast Cancer Foundation designed to maximize their success. As a result, more New Zealand women will have access to trials, and current geographic inequalities will be addressed. NZ’s international reputation as a trial center will be enhanced as a result of successful recruitment.

• What does it look like?

* One-day PI training seminar (CME accredited).
* Educational topics covered include: Conducting ethical research, Informed consent; Statement of investigator; Oversight of investigational agents (drugs); Reporting adverse events; Maintaining accurate records; Adhering to protocol**; Clinical Trial Budgets; Clinical Study Agreements; Monitoring Visits / Audits; Standard Operating Procedures for Research Site** (course content based on *Clinical Investigator Responsibilities*, Baer et al., *Journal of Oncology Practice* (2011) and Clinical Investigator GCP & Trials Management Program developed by Society of Clinical Research Associates (SOCRA)
* Inspirational topics covered will include: Teaching component by inspiring USA investigator; Importance and role of trials; Non-Disclosure Agreement-subject presentation of upcoming trials; possibly a patient story; Importance of national recruitment; Support provided by the NZBCF
* A follow-up support package to be supplied by our organisation (the NZBCF). This could include: the NZBCF to fund a Fellow to assist on their first trial; NZBCF to contribute a specific amount for travel costs for out-of-town participants plus cover additional coordinator costs associated with out-of-town participants; travel for the PI on an educational trip to the primary study site.

**• How will you implement it?**

The program will be taught face-to-face to a small group, to maximize networking and learning opportunities. The course could be easily be replicated in future, as more potential PIs emerge.

**• Where will you implement it?**

The course will be taught in a single location, with attendees travelling from their home location. New Zealand is a small country, so the maximum flight time for out-of-town delegates would be 1hr 30mins.

**• Who will be involved (stakeholders)?**

The NZ Breast Cancer Foundation (NZBCF) will lead the program, in consultation with stakeholders such as clinical leaders, existing investigators, regulators, patient advocacy groups, pharmaceutical companies, medical school deans, hospital HR departments. Candidates for the program may include registrars, newly-qualified specialists, younger practising specialists, clinicians returning from overseas.

**• How much will it cost to create the solution (an estimation)?**

PhD student to scope program in consultation with NZBCF / other stakeholders $15,000

Cost of designing and developing materials and undergoing CME certification: $1,000

**Total cost to create solution: NZ$16,000 (c.US$13,000)**

Cost of our NZBCF staff is covered by existing salaries. Other stakeholders (regulatory authorities, existing investigators, clinical leaders, pharmaceutical companies, etc.) would be expected to contribute their expertise to the planning and development of the course at no cost.

**• How much will it cost to implement the solution (an estimation)?**

Travel costs and honorarium for visiting USA guest speaker $12,000

Catering for training day $500

Travel and accommodation for out-of-town attendees $3,000

**Total implementation of PI Training Day NZ$15,500 (c.US12,000)**

 **Additional Costs** (to be funded from a number of sources), assuming that 5 attendees from the first course go on to act as Principal Investigator on a trial

Salary of a Fellow to assist on PI’s first trial (0.5 FTE) $40,000

Out-of-Town Patient Allowance (fixed sum for data coordinator costs and travel) $10,000

Education trip for the PI to lead study site $12,000

**Cost per trial: $62,000 (US$45,000)**

**Total additional cost for 5 trials NZ$310,000 / c.US$230,000**

**• How many people will be impacted?**

We estimate up to 10 new investigators will be trained, a huge benefit not only in breast cancer, as some of our oncologists work across multiple tumor streams. Last year, no New Zealand women were admitted to new drug trials for breast cancer, as far we know, and in 2013 fewer than 5 women were. If we can secure 5 new breast cancer trials over three years, each admitting 10 patients as a result of strong national recruitment, we will have achieved a quantum leap in breast cancer alone.

**• How long will it take to create the proposed solution?**

Two months to create the program while simultaneously identifying suitable candidates.

**• Why will it work? Why is it viable?**

It addresses a clear, existing gap in the training and inspiration of principal investigators. It provides professional development opportunities for young clinicians. The proposed support package from the NZBCF will be an incentive to put the training into action by acting as principal investigator and will help ensure successful recruitment to the investigator’s first trial.