

Patient Recruitment, Retention and Follow-up

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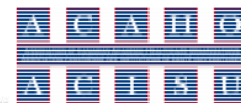


Canadian Clinical Trial Summit
September 15, 2011

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Is Recruitment a problem?

Number of subjects recruited in Clinical Studies						Source: Rx&D 2011
Year	CAN	Global	Relative position CAN/Global	Decline CAN	Decline Global	
2008	7845	227389	3.5%			
2010	4485	168876	2.7%	-43%	-26%	

- Canada represents 0.5% of the global population
(Source:Wikipedia 2011)
- The ugly truth: Canada is considered one of the least cost-effective countries to conduct research

Possible reasons to poor recruitment- macro level

- Access
- Universal health coverage and perception of good care
- Lack of trust and knowledge
- Inefficient infrastructure
- Focus on operational improvements

Possible reasons – patients perspective

A pilot study by CanMed in Vancouver Island (Trytten, Pommerville, Waldner, de Boer, 2011)



Top reasons for declining

- 65% : Health benefit not guaranteed
- 55%: Placebo
- 48%: Inconvenient
- 42%: "Guinea Pig"/danger
- 26% : GPs did not support
- 26% : Families did not support

Possible reasons- patients perspective

Top reasons for consenting

- 97/96% Liked/trusted Study Coordinator and PI
- 85% Safety risks were acceptable
- 83% Benefit to society
- 77% Access to health care services
- 75% Improved health outcomes anticipated
- 48% Free medication

Possible solutions

- « You're either part of the solution or part of the problem » - Eldridge Cleaver
- What if patients were both?
 - Difficult to identify and recruit and yet the best positioned to tell us how what they need to join our research efforts?
- Let's look at some patient-centered solutions

Possible Solutions

Recruitment, Retention/Follow-up

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Pre- Educating Study Volunteers

Print and video educational materials

- Sites that pre-educated study volunteers:
 - Had fewer and more effective screenings
 - Had patient randomization rates four times faster than sites that did not
 - Randomized the majority (68%) of the patients for the study)

Source: Tufts Center for the Study of Drug Development

Public Service Campaign 'Medical Heroes'

Volunteers in clinical research are the heroes in the discovery of new medical treatments

Campaign developed with input from patient advocacy groups, FDA, NIH, PhRMA, NHC, academic institutions, pharmaceutical companies, CROs, investigative sites, patient recruitment service companies and IRBs

Print, Radio and TV ads

PSA series with people of different ages, races, genders, occupations

Eli Lilly & Co. Pilot Test involved two pain studies; 30 sites across 18 markets

	Recruitment Ad Only	Med Hero + Recruitment Ad	Improvement
WAVE 1	2.9 Patients/Month	4.0 Patients/Month	38%
WAVE 2	4.0 Patients/Month	9.6 Patients/Month	140%

AWAREforAll

Clinical Research Education Days

Impact measures to date from grassroots outreach:

- Community Outreach: 429,000 households
- Community Partners: 867
- Attendees: 4,657 (approximately 40% minorities)
- Webcast Sites: 115 (most in the US; Australia, Canada, Europe)
- Honorary Committee members: 438
- Educational Workshops: 138
- Physicians/Speakers: 322

Public Survey: After the AWARE program, how likely are you to participate in a clinical research study? **75% of respondents: "More Likely"**

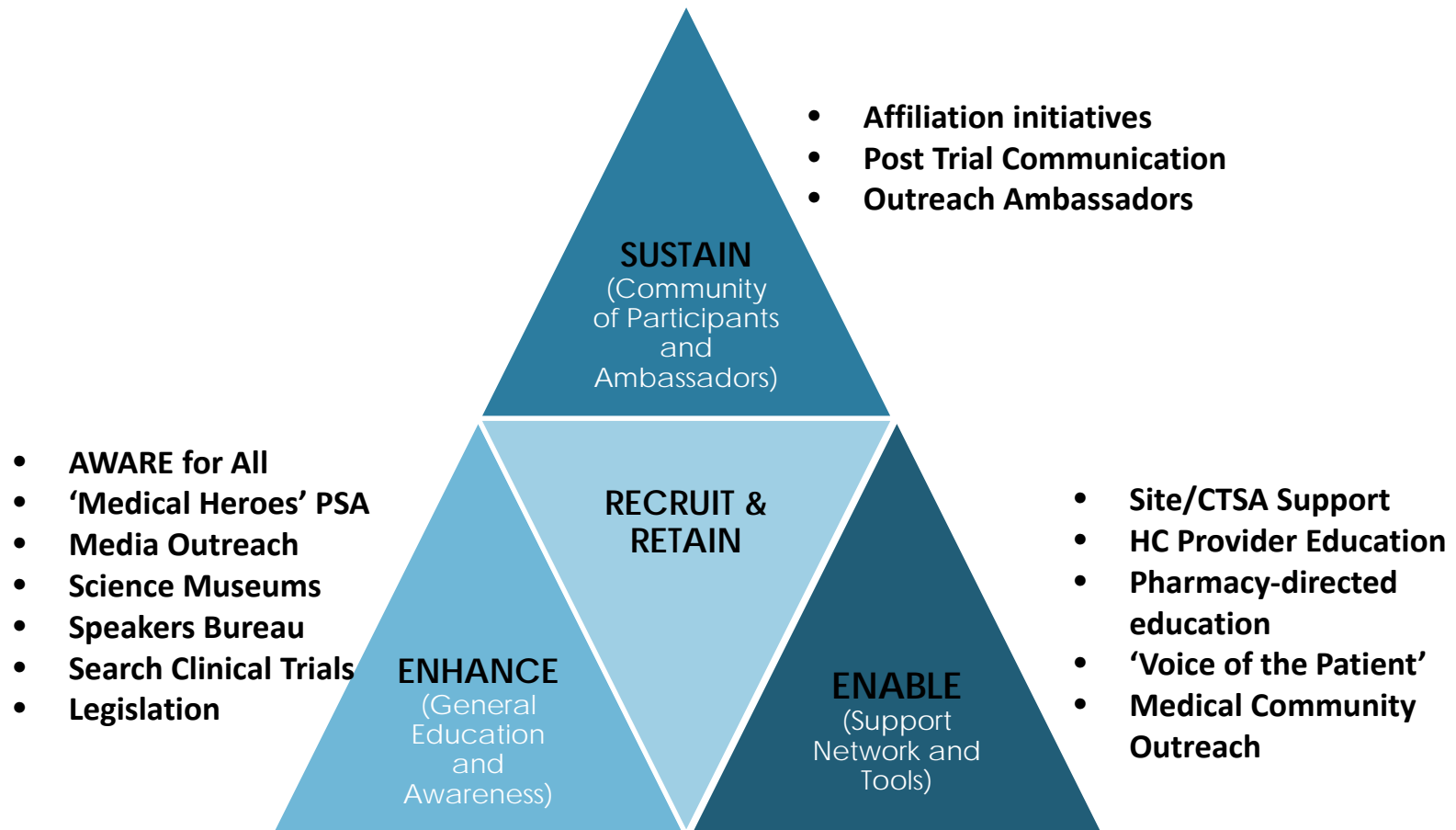
Post-Trial Communication

- **NO FOLLOW-UP:** 79% of study volunteers report that they never hear from the research center once their participation has ended
- **SKEPTICAL THAT SPONSORS WILL SHARE ALL INFORMATION:** Only 14% of study volunteers believe that drug companies will eventually disseminate all information -- positive or negative -- about an investigational treatment

Communicating Trial Results Pilot program:

- Sponsored by Pfizer
- Multiple formats (print, webpage, hotline)
- Study staff integral to entire process
- Extremely positive reception from volunteers and sites
- Planning national roll-out with several sponsors

Support for Long Term Success



The solution(s) require a multi-stakeholder collaborative effort

Have a productive workshop!