Lessons Learned in the Early Phase of the MI-HEART Clinical Trial
Yves A. Lussier§, M.D., Rita Kukafka§, Dr.PH., Tamiru L. Mammo, M.P.H., Allison Linfante B.PH, Vimla L. Patel, Ph.D., James J. Cimino, M.D.
Department of Medical Informatics, Columbia University, New York, New York, USA

Objective. To provide guidelines for enhancing the patient accrual process in clinical trials using community-based Web-based Information Technology (WebIT).

Background and Significance. Previous IT-administered education studies have been conducted in controlled environments: the computers are usually 1) supplied to the patients1, 2) in an setting where a research facilitator can assist patients using the IT-based education2,3,4,5 or 3) are supplied by the pa[...]

Content Covered. 1) The presentation will first address the barriers to recruitment and the observed patient accrual rates resulting from several patient enrollment strategies covering a period of eight months will be presented. 2) The lessons learned from interesting and unexpected preliminary demographics, process variables and findings will also be presented to foster enhanced recruitment strategies for clinical studies involving WebIT.

Enrollment Strategies.
1) Direct patients solicitation
2) Repetitive brochure distribution in clinics
3) Patients Educational Events
4) Public Announcements
5) National and International Recruitment
   a) Internet Interest Group
   b) Electronic Medical Record –Based Qualification
   c) Personal Contact with Peers

Some Lessons Learned. (1/2)
1) Self-enrollment of patients that are required to use WebIT may favor a subset of wealthy, knowledgeable and self-efficacious individuals with a low belief in treatment efficacy. This group may only portray a subset of the assortment of health education needs of a non-biased patient population. (figure 1, table 1).

§ These authors have contributed equally to the work

Some Lessons Learned. (2/2)
2) Supervised or assisted kiosk-based education may provide an opportunity to reach the non-users or novice users of WebIT.

Acknowledgements. This work has been supported by the NLM (Contract NO1-LM-3534, training grant LM07079) and training grants from the Medical Research Council of Canada.

References