

Ethica held to a higher standard

EARNs INTERNATIONAL ACCREDITATION

Clinical research firm calls it a milestone that provides protection for participants

ROBERT GIBBENS
THE GAZETTE

Dorval's **ethica Clinical Research Inc.**, a contract drug organization, or CRO, said yesterday a key international accreditation it has just won should spur higher standards for clinical

trials in Canada and better protection of participants' rights and safety.

President Janice Parente said full recognition from the Washington-based Association for the Accreditation of Human Research Programs is an industry milestone and others in the con-

tract research industry should follow suit.

CROs research new treatments developed by drug, biotech and natural health product firms, partly to hasten their way to the marketplace. Ethica has its own non-profit research ethics board, staffed with lay people and professionals, vetting outside clinical trial proposals.

"It wasn't the money but the huge investment in time needed to meet all the Association's standards," said Parente, a PhD in medical science.

"This worldwide non-profit or-

ganization is working hard to raise the level of protection for all research participants, who often don't know the risks they may face."

She said Canada has a patchwork of regulations covering the CRO sector, but they are insufficient and few companies have ethics research boards. "Recent events have shown we need a fully transparent system of oversight ... it's the conduct of the actual clinical trials that's so critical."

Some have urged that Canada should have its own equivalent of the Washington-based Associ-

ation, she said. "But that would take 10 years to set up and would be a huge waste of resources."

Through the 18-month accreditation process, ethica, a private company with 30 employees, met all 77 Association criteria, demonstrating it had extensive safeguards built into every level of research, from protocol development to data management.

"It was a Herculean group effort and now we're publicly accountable for all our services and all our actions."

rgibbens@
thegazette.canwest.com

fasttrack

Haemacure tabs chairman as CEO

Haemacure Corp. said yesterday it expects to name chairman Joseph Galli as its new chief executive officer effective Feb. 1. Galli will remain chairman of the Haemacure board and Marc Paquin will continue as president and a director. The Montreal-based company also said it has closed a private placement raising gross proceeds of \$9.5 million to finance development of its fibrin sealant Hemaseel, currently in Phase 3 trials, and the hemostatic agent Hemaseel Thrombin. Haemacure specializes in the development of innovative biological adhesives, bio-