

Profile: Contract Research Organization

ethica Clinical Research Montreal, Quebec, Canada;
ethicamatrix Hyderabad, India

An interview with **Murray Jensen, director of clinical and scientific affairs;**
Martin Letendre, director of ethics and legal affairs; **Ramesh Chouhan,**
president (technical), Matrix Group

How and why was ethica founded?

MJ: The president of ethica, Dr. Janice Parente, founded the company in 2002. For 10 years prior to that, she was the president and co-owner of another CRO. She wanted to take that company in a different direction, so she sold her interest in it and started up ethica. Within one year, sales of ethica exceeded that of her old company. We've been growing ever since. It's a full-service CRO with everything from regulatory affairs, legal affairs through all aspects of clinical study management to data management and biostatistics. One of the main focuses that Janice had for the company was to ensure the highest ethical standards.

What distinguishes ethica?

MJ: The consulting that we can do is quite rare in the industry. For example, my background includes working 10 years at a pharmaceutical company and five years at a biotech. I've been involved in medical marketing, business development, pharmaceutical patents, GMP manufacturing, basically the whole gamut. So when we consult with a potential client or with a current client, we can provide great depth, whereas a typical CRO of our size would basically be a monitoring house—they would be implementers. ethica is more of an innovator. While our company can certainly implement a standard phase I to IV study, many times a client will ask us to run with just a concept that we'll develop into a full-blown clinical trial, watch it and run it through all the logistics and

pull up the data. Importantly, we can provide all necessary logistics in-house, such as the purchase of medication, GMP storage of medication, GMP manufacturing of patient kits according to randomization code. We are also typically mandated to manage all regulatory activities and act as a regulatory agent. Because we also have our own in-house legal team, we can also manage drafting and negotiating of clinical trial agreements with sites on behalf of the client, allowing for quicker site initiation.

Another differentiator is our IRB based in Toronto. This is a non-profit division of our company.

ML: The IRB comprises a group of consultants based in Toronto who review studies that are managed by our clinical team, other CROs or companies as well as studies for sites that are not affiliated with institutions in North America such as investigators at private clinics and private research centers. The IRB was established in 1996 and founded by Janice Parente because she was not satisfied with the ethical scrutiny and the rigor of private research ethics boards in Canada. She knew that it could be done better. She consulted a prominent ethicist from the University of Toronto who had *carte blanche* to set up the best board in terms of expertise and knowledge. This board has been the same in terms of membership since 1996. ethica's IRB is the only Canadian IRB and ethica is the only CRO in the world to be fully accredited by the Association for the Accreditation of Human Research Protection

Year founded: 2002
Year ethicamatrix founded: 2007
Employees: 30
Active trials: 40
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Programs [AAHRPP]. We put our entire organization through the AAHRPP accreditation process, so all of our SOPs [standard operating procedures], everything that we do as far as trial conduct, has been fully accredited by AAHRPP.

What is the relationship between review board and CRO?

ML: The IRB is a nonprofit division of ethica. Its management and finances are completely separate from the CRO activity. The surpluses generated from the IRB services are re-invested into subject protection initiatives.

MJ: ethica facilitates all the communications, documentation and administrative work to streamline the efficiencies of the IRB, but the board itself functions completely independently without any influence from the company. What we offer is basically a liaison between the researchers and the IRB and administrative support so that communications can be transmitted efficiently to researchers.

What challenges do you face?

ML: Forum shopping. In Canada, there's some complacency with respect to ethical guidelines and standards. In the U.S., for example, there are federal reg-

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ulations governing research in humans, but Canada doesn't have them. So there are a lot of inconsistencies in ethical review in this country. For an IRB like ours that is working to achieve the highest ethical standards, it can be challenging because there are a lot of things going on in Canada with respect to ethics review that we find problematic. Forum shopping to get a favorable ethics approval is a big problem here. Being a leader in research participant protection in your country within that normative context is a challenge.

MJ: Two of our biggest challenges are costs and access to a suitable patient population. One of the things that we decided to do was to create a new company with The Matrix Group, called ethicamatrix, in India, to address these challenges.

Tell me about The Matrix Group and your joint venture to create ethicamatrix.

RC: The Matrix Group is a Hyderabad, India-based complete healthcare company—soil health, plant health, animal health and now human health too. We are close to 1,100 employees. The best way to get into human health is not just producing a few molecules and putting them out on the market but to be involved in the selection and the appropriate delivery. That's how we decided to start the CRO with ethica. I've spent a lot of time in medical research. I have seen in the last couple of years a tremendous proliferation of CROs in India. Often these CROs are 10-by-10 rooms with people who have hardly been trained in any aspect of clinical research. Most of them are run by non-clinicians. I decided that I should look for somebody with real proper clinical trial [experience.]

MJ: It will be a joint venture between ethica and Matrix. We will be providing complete sets of SOPs, training, ICH-GCP training within the company itself, QA auditing, and also site training courses for investigators, coordinators with a very practical focus as opposed to theoretical. We want to build upon the medical expertise of the investigators and coordinators and give them hands-on practical training in how to conduct clinical research. That's our primary focus. We're really in a fortunate position where we just get to create another ethica. As ethicamatrix grows, and it's going to grow quickly, there are going to be projects that come through where maybe 75% of that project is within the current capabilities of ethicamatrix and for the other 25% ethica just steps in and carries that load. ethicamatrix will become a full-service CRO rapidly because it's going to have ethica's support.

ML: We want to establish a true partnership with Indian researchers, coordinators, research centers and participants. In India, because of the paucity of healthcare resources, the population often sees participation in clinical trials as the only way to obtain treatment and is therefore ripe for exploitation. We want to train and educate researchers and research personnel to be sensitized to the potential vulnerability of the population and lead by example in order to avoid such exploitation. We also want to promote our capabilities and help India-based companies to develop their products according to standards that meet the requirements of regulatory agencies in Europe and North America. If the clinical research conducted by these companies is not on par with the quality of research done in the West, or if it is plagued with substandard

ethical review and oversight, the full value of the product will not be realized when they seek out-licensing or partnership opportunities.

How much potential does the Indian pharmaceutical market hold?

MJ: We assume that we're going to have half of our projects coming from Indian pharma and half from North America and Europe. The Matrix Group has an incredible reach of contacts within India through the biotech and pharmaceutical industry and through research centers and teaching hospitals. We're well-positioned to capture some of this innovative business in India. We are already responding to inquiries from several potential clients. We expect more than enough business to meet our plans for growth.

What are your further plans for growth?

MJ: We're currently in the hiring phases for some key employees at ethicamatrix and we should be fully operational within the next few months. In terms of geography, there's always the thought of Eastern Europe, South Africa. Our concentration right now is to make sure that we get ethicamatrix to the proper size and with viable revenue as soon as possible. After that, we'll consider where we jump next.

RC: Matrix already has a connection to China. So once ethicamatrix, in terms of capabilities, becomes equal to that of ethica in Montreal it's very easy for us to get into China. We are already receiving inquiries. ethicamatrix will definitely be expanding to different parts of the world.



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