

## **Frugal innovation in bringing new drugs to market**

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**Ecron Acunova a/s**

Hon First Secretary Indian Embassy in Denmark, Dr. Ingelise Saunders Chairperson, Ecron Acunova a/s, representatives of Danish Government, distinguished invitees, colleagues and friends

It is a privilege to be invited to speak on the occasion of merger of aCROnordic a leading CRO from Denmark with Ecron Acunova, opening new possibilities in accelerating 'speed to market' of new drugs.

I was challenged to find new ways to reach diagnostic technology to doctors in India by GE. An Indian patient can pay only a fraction of the fees a patient in Europe or US pays for a ultrasound scan. Unless a scanner can be made available at a fraction of the cost of a Philips or GE scanner, it is not economically viable for the Indian clinic to own it. We looked at the most common need for a scan in India and the most essential features required. A GE scanner built in Japan with minimum features would still be unviable in Indian clinic. Studying the Indian clinic, increasing productivity of the doctor, decreasing maintenance cost, decreasing film cost, innovative financing and making this scanner in India brought the cost of scan in Indian clinic to one tenth of the cost in a US clinic!

Innovation in usage, redesign, new supply chain of parts, a new process of building a robust simple scanner and a new business model resulted in taking the benefit of new medical technology to a large number of Indian patients. It also opened up for GE new markets for this solution. This disruptive innovation was used to make CT, MRI, PET scans affordable. GE relocated corporate R&D to Bangalore. Siemens, Philips followed. Today there is a multibillion dollar global medical technology ecosystem there!

Another innovation in clinical service I was associated was setting up a remote radiology service between Boston and Bangalore using robust information technology. Images scanned at MGH- a Harvard Medical School Hospital during the day were interpreted at night in Bangalore and made diagnosis faster in Boston. This innovative service delivery created huge anxiety amongst American radiologists. Barriers setup in US did not

allow this innovation to grow. However National Health System in UK embraced it to bring down waiting times for diagnosis!

Can this be applied to drug development? Two decades back, US Pharma companies could not believe that API's (active pharmaceutical ingredient used in drug making) can be produced by Indian drug factories at an attractive price. Short cuts in manufacturing were suspected and USFDA started inspecting plants. Today India has largest number of 'GMP' drug factories certified by USFDA! It was process innovation and a global supply chain and not short cut. To serve the Indian and global patient, the API producers had to conduct clinical studies and analyze human testing samples in very sophisticated instruments. GCP and GLP compliance has been achieved by Indian CRO's innovatively. Today these generic companies have filed largest number of ANDA's and largest number of 'first to file' marketing authorization.

These examples of innovation have inspired Ecron Acunova to apply similar principles to accelerate speed to market in clinical research. Main difference in clinical research is it is multi-country, several disciplines and several years of experience brought together. A basic factor in speed to market is fast enrolment of patients in a clinical trial. We started in India, expanded to East Europe and South East Asia. We can make an intelligent combination of countries to speed recruitment at a modest cost.

Understanding regulatory guidelines for marketing authorization is key to study planning. Foreign patient inclusion criteria, guidelines for vaccine or a Biosimilar or a generic trial with clinical end points, all these factors influence study plan. We have USFDA expertise in Washington and EMEA expertise in Copenhagen.

Knowledge of disease and drug pharmacology is essential. We have centers of expertise in Oncology at Berlin, HIV in Bangkok, Cardio-vascular in Bangalore, Diabetes at Copenhagen. We have PK/PD units in India with experience of conducting 300 studies to provide insight.

Secondary end points in efficacy through imaging and biomarkers become important to know early the result. We have molecular diagnostic

capabilities in our central lab at Bangalore. We have deep expertise in use of imaging in trials at Frankfurt.

Biostatistics decides the valid sample size and progressive conclusion can optimize trial size using adaptive clinical trial design. We have highly experienced biostatisticians in Frankfurt and Washington.

Once a trial is completed to interpret data and write a clinical study report requires data management, medical writing and clinical safety experience. We have data management teams at Frankfurt and Bangalore. This report is attended to by regulator faster if it is in CDISC format. This expertise is at Copenhagen

A clinical development plan needs to look at data from animal studies and other data like from first in man studies. With all the above expertise available has to device a sound patient study. And interpret safety and efficacy from the study and defend it with regulator. Such expertise in specific therapy area is available in Copenhagen.

We have 380 professionals with 90 MD's and Ph D's who are our greatest asset. Re thinking the clinical development process, putting together the optimal combination, global service delivery in a new business model is the new recipe! That is Ecron Acunova for you.

Thank you for your patient hearing.