Interview with Oriana Zerbini, Managing Director, CROM

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Tags: CROM

You are specialised in Cardiology at Padua University, in Tropical Medicine and Hygiene at London University and in Pharmacology at Modena University, in Communication at Bocconi University in Milan, and also have 12 years of experience in all aspects of drug development in a major international pharmaceutical company. What aspect of such a rich and diverse experience did you successfully apply to start up the operations of CROM?

Following long studies before starting my career has given me a strong scientific methodology, working in a multinational company has provided me with an interesting background- and the combination of both these assets led me to start up CROM in 1997.The key to success is consistency. One has to strongly believe in its final goals, and focus its efforts on concrete daily activities avoiding to waste time and energy. Indeed, after several years of activities, CROM adopted an internal motto inspired by a saying from Eistein: “Genius is 1% inspiration and 99% perspiration”.

Looking at how you applied this motto day by day, could you give us an overview of what have been the main milestones and achievements since you started this entrepreneurial experience?

CROM was established in 1997 on the legacy of an existing biostatistics company, CROS.At the time, the Italian legislation did not really enable to conduct research in Italy, and for this reason CROM started developing its activities abroad -mainly in eastern Europe-coordinating everything from the Italian legal headquarters. Indeed, Italian players could not provide regulatory data, and this is why CROM developed in other countries, also offering good recruitment opportunities – such

as Poland, Ukraine, Bulgaria, Russia and the Czech Republic.CROM always strongly believed in these markets, but ten years ago such a strategic choice was not easy to defend in front of customers who were still a bit reluctant to establish strong business relationships with Eastern Europe. However, this strategy proved to be really successful, and enabled to sustain the company's growth so far.

How did the 1998 Ministerial Decrees, which drastically changed the regulatory environment for clinical trials in Italy, impact the first steps of CROM in the Italian perspective?

Surely, 1998 has been a main milestone in terms of clinical research regulations. However, overall, even after such a significant change in the legal framework, Italy remained one step behind in the European scene, in terms of regulatory delays and recruitment processes. Indeed, Italian clinical research has been – and is still to a certain extent- hardly reaching targets on time. This is a main obstacle when it comes to be involved in international trials. Thus, in order to remain competitive and deliver results at the same pace than other European participants involved in these kind of trials, organizations like CROM need to involve other countries with a high recruitment potential.

Indeed, for these reasons, Italy is not seen as the most strategic place to conduct clinical research, despite the size of the market. What do you think could be done to further enhance innovation in the country, especially in the field of clinical trials?

Since 2006, CROM has been participating actively in AIFA's technical committees, promoting the industry's interests, underlining the key issues, and suggesting potential solutions.On the regulatory side per se, the situation is now satisfying. However, a lot of work is currently dedicated to promote and facilitate start-up processes, especially from a financial perspective (i.e. contracts with hospitals or Universities).More challenging is to increase the motivation level of Italian investigational sites- and Western ones in general.Looking at the recruitment aspect, two main issues have to be solved. Firstly, the necessary timeframe to get the first patient involved should be reduced; and in addition, the rate of tested patients per month should increase and stick to the previsions of the feasibility analysis.In order to adapt to this framework and overcome its challenges, CROM's efforts are considerably orientated towards the feasibility phase. The main objective of this process is to go beyond the first- level sites proposed by customers (mainly the more important and recognized Universities), and assess the potential of second- level sites, with less ongoing trials but with a higher number of potential patients. Surely, such sites are less experienced, but CROM can work with them to provide training to the teams. Overall, such strategy enables to increase the company's effectiveness in conducting clinical trials, by saving a precious amount of time as well as financial resources.

Looking at how CROM’s strategy has been converted into numbers, how do you assess 2008 performance in terms of growth and revenues?

2008 turnover overpasses 2007 performance by 30%. In terms of the numbers of sites and projects, there has been a 15% growth within the same timeframe.Last but not least, the feasibility ratio has increased by 25%.

Throughout the years, CROM has been consolidating and widening its services portfolio, as to offer a full service structure. In which steps of clinical development can CROM bring more added value to customers in Italy?

In the next three to five years, CROM will increasingly focus in bringing more “quality by design” to its customers.Indeed, since clinical research is produced by human beings, it is crucial to effectively prevent potential mistakes, and standardize all the processes and activities. CROM has been conscious of the importance of quality since its earliest stages of development, and has been the first Contract Research Organization (CRO) to be certified ISO 2001 in Italy- back in the times when no one was really aware of the value of such guidelines and certifications in the country.Having in mind this ambition of building up a sound organization that could rely on specific operational and managerial procedures at all levels, the company implemented a quality team, now involving six collaborators. Project Managers work hand in hand with quality leaders, as quality is a concept that has to be applied from the very beginning of project design- even back in the feasibility studies- in order to prevent errors instead of having to solve them at a later stage.

Obviously there is a need for multinationals and local players to require CROM services, yet these large companies are also the ones with the capacity to perform these tasks internally. Why should they outsource part of their clinical research to you?

Among CROM’s key assets is its capacity to attract both multinationals and medium-sized clients, thanks to a great level of competence and flexibility.Whereas multinationals are often more interested in specific competences, and looking for expert “fingers” to deliver them; medium-sized players need CROs that are able to involve all their capabilities in order to approach problems in an integrative way, and to concretely solve them. CROM surely has this kind of approach, and can really offer a 360° vision and a full service structure. The teams are highly competent in providing methodologies and a quality approach, much beyond the organization core services. In a few words, they are used to work with both their heads and their fingers.Of course, not all the players are willing to consider these “additional services”; indeed, most multinationals do not need such external competences and have their own internal dedicated procedures. CROM can still offer these

competences to SMEs, who really appreciate the fact that they can have a single interlocutor able to provide full competences.However, CROM remains a middle-size structure itself, which is a main competitive advantage towards bigger multinational CROs. Indeed, not only do we offer a much more adaptable structure, but we also enable customers to establish direct contacts with the whole team, including managers who can be reached very directly.

Both CROM’s reliability and solidity enabled a successful international expansion, through the establishment of structures in Russia, Ukraine, Poland, Czech Republic, Spain, Bulgaria, and Hungary amongst others. What will be the future guidelines of your international strategy?

CROM is willing to consolidate its international presence without losing its identity by becoming a real multinational. Close links with customers have to be maintained, as well as the company’s “problem- solving” approach.Hence, future direct expansion will be mainly focused on European countries. After the opening of offices in UK, happened in 2008, our German and France offices will soon be operative and able to respond to the high demands of this very sophisticated market.Some clients do ask for an even wider international network, and this is why CROM also has projects in the USA. In particular, overall, while in this Country we are thinking to open our offices, in emerging markets such as South Africa, Brazil and India- the strategy will be to develop partnerships with other strong and well-identified CROs, in order to provide globally competitive products.

Further expansion also means expanding human capital- in the context when CROs have to outperform laboratories themselves. How does CROM attract and retain the best talents?

The human being is considered by CROM as one of the five main keys to success; together with training, standardization, flexibility and innovation.All the collaborators are extremely enthusiastic, and because they are passionate about their daily work, they are also able to involve the clients in each step of their work and make them feel part of the team.Attracting and retaining the best talents does not require any particular strategy other than taking care of the employees and understand their skills. For instance, if an individual does not have the personal characteristics to become Project Manager, it is all about trying to understand in which task he/she would be more at ease and likely to develop his/her abilities.Training is also part of CROM’s daily life. Weekly seminars are organized to discuss simple issues and brainstorm together about possible ways to solve them. In addition, specific training courses have been implemented. Overall, all these initiatives are aiming at keeping the people focused on their work and building their professionalism.

As the company is building its development on strong and intangible values, what are your personal ambitions for CROM in the next 3 years?

Three year plans first include the consolidation of the European operations.Then, the increased penetration in specialized networks comes as a second objective. Of course, as a CRO, CROM’s mission is to work in all therapeutic areas; but since the company is especially strong in the oncology, respiratory, cardiovascular, HIV, CNS and vaccines fields, it needs to consolidate its network of investigational sites.In terms of client portfolio, the target is to reach more medium-sized biotech companies, who really need 100% of CROM’s potentialities.Finally, looking at the evolution of the company’s competences, an internal technology is currently being developed to digitalize archived data and to offer IVRS and pharmacovigilance services to our clients in the coming 24 months.

On a personal note, what would you say are the main challenges and opportunities of being a woman in the industry?

From my personal experience, it has not been that easy to lead a career as a woman.Holder of a Medical degree since 1978, I started my professional career as a GP in the North part of the Garda Lake- a region where no one had ever been examined by a woman doctor before, which was surely a challenge to cope with.Then, when I joined a multinational company, there were only two women among the 72 directors; which shows how difficult it is still for Italian men to recognize that women are able to reach equal performances .On the contrary, precisely because being a woman in the industry is not easy, we are able to carry on several tasks at the same time, without looking for personal success- and the results often speak for themselves.

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