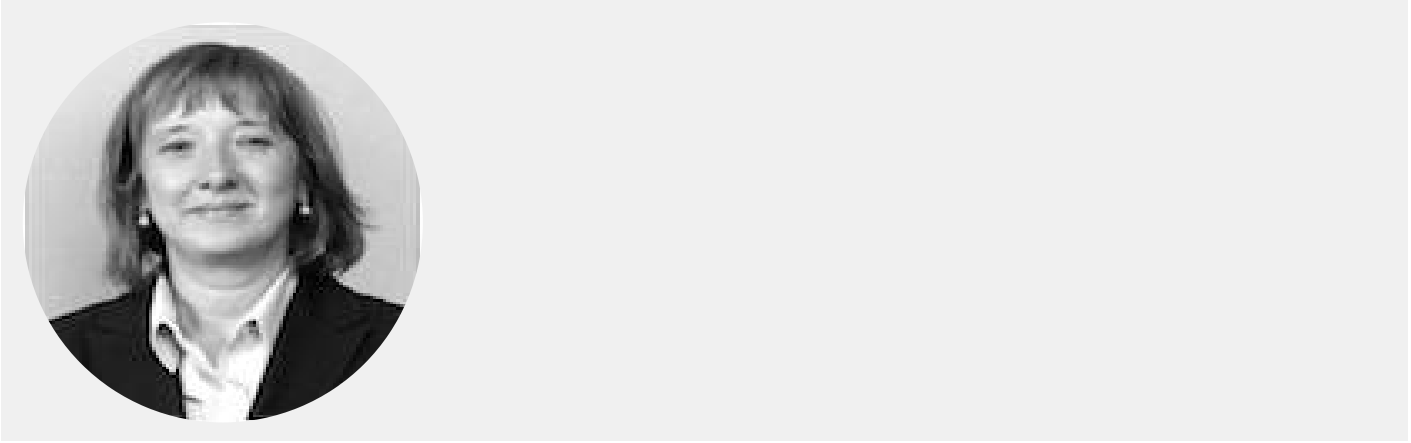
Wanda Dobrzanski – President, CAOIC & VP Latin America and General Manager, Vaccines and Infectious Diseases for inVentiv Health Clinical – Argentina



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Dr. Wanda Dobrzanski discusses Argentina's potential and attractiveness as a clinical research environment and the biggest challenges facing local and global CROs in Argentina.

How has political and popular opposition to clinical trials in Argentina changed over the last five years?

Five years ago, the perception of clinical trials was definitely negative, and in the last two or three years attitudes have changed significantly. Argentina has been a pioneer in the region in the field of clinical research, with ANMAT pushing the industry forward as it has evolved into a fully-fledged, well respected, and effective administration. As ANMAT's position was solidified, Dr. Chiale gained political credibility and was able to influence the attitudes of officials in the ministry of health and the government in general. The administration has also conducted some educational initiatives, eliminating much of the disinformation that was fueling human rights concerns. Much of this can be attributed to the profusion of experienced and talented technical employees and advisors in the ministry of health and ANMAT, who are able to provide support to many programs in the health sector, including the clinical research industry.

However, there is also a much simpler aspect as well—time has passed. Five years ago there were a few regrettable incidents and studies that were misrepresented in the media, including a GSK clinical trial that was falsely alleged to have killed 14 infants (they had actually all been given placebos). This had turned public opinion against clinical trials at the time, but by now the average citizen has largely forgotten about these events. ANMAT also responded by proposing updated legislation, which was passed, and by temporarily focusing on simpler, less risky clinical trials while the negative attention abated.

What advantages does Argentina have as a clinical research environment when compared to competitors in the region?

Speaking as a medical doctor, I can tell you that the factor with the most influence over a patient's decision to enroll in a clinical trial is the quality of the relationship with and the trust they have for their physicians. Thus, it is the excellent medical training system and the quality of Argentinian doctors that is the biggest asset the country has as a clinical research center. The public system, which makes patients across the large population base in and around Buenos Aires available, is also an important factor. Finally, the strength and professionalism of the regulatory institutions, meaning ANMAT and the associated ethical committees, is extremely important as companies can rely on them to operate predictably and with integrity.

Argentina is attractive for some other reasons as well; inVentiv's Latin American headquarters are here largely due to the low USD cost, as even taking inflation and the undervalued exchange rate into account, the overhead costs of maintaining an office and the cost of living for our employees are quite low. Argentina's talent pool is also of very high caliber, and teams here have the capacity to deal with any sort of project that we might be working on at the global level. Finally, the local industry's strong track record in terms of FDA and EMEA audits is also an asset, as it reduces the perceived risk of conducting a trial here compared to Brazil or Mexico.

Currently, there are no issues with the approval process here in terms of ethics or inadequate pre-clinical requirements. The timeline compared to other markets is slower and less predictable than in some other markets, and we haven't seen any improvements recently. This is preventing us from competing effectively with other countries in the region.

Has the growth and consolidation of the multinational CROs eradicated the market for smaller, niche CROs in Argentina?

No, there is still plenty of work for everyone. The local organizations are much cheaper so the value of the local CRO's service is much better for some customers and projects. For others, our more

comprehensive services that include data management, medical writing, clinical and medical monitoring, and project management are worth the added cost.

At what stages of clinical research is Argentina competitive?

For Phase I, we are only sporadically involved for proof of concept or if the trial must target a specific patient population. We usually become involved when Phase II starts, and Argentina and the rest of Latin America are definitely involved if a product makes it to Phase III. This is where the approval timeline becomes critical however, as the patient population required for Phase III are large enough that Argentina's size and public healthcare coverage allow us to recruit the required numbers relatively quickly, but we lose this advantage if the approval process delays the start of the trial enough for the same population to be recruited in smaller countries.

As the president of CAOIC, what are your highest priorities at the moment?

Improving approval timelines for clinical trials is by far my highest priority. Many of the different stakeholders, including the ministry of health, the pharmaceutical industry, ethical committees, and of course ANMAT have inefficient processes, and CAOIC is working closely with everyone involved to harmonize these processes and improve efficiency. Our goal is to achieve a high quality, streamlined system that meets all of the ICH and ECP guidelines, fully complies with relevant international and national regulations, and that is significantly shorter from start to finish than the current process.

Our second priority is to reduce the impact of, and hopefully to motivate the removal of, the many import and export restrictions that Argentinian companies complicated, and can restrict the approval process in some cases and make it more difficult to accurately forecast the timeline. This is obviously an economic issue on which we oppose the government along with many other Argentinians, however it is important to remember that political opinions aside, the current government has made amazing advancements in the public health system. Argentina is one of the few countries in the world with such a comprehensive public vaccination program, or that fully funds treatments for diseases such as HIV, and these benefits may be well worth the costs of the economic problems.

Have you seen an increase or change in the type of clients contracting inVentiv due to the economic crisis?

To an extent, yes. As a CRO we are a full service provider and differ from the pure third-party outsourcing resources. In general, pharmaceutical companies contract out clinical research

completely or manage it themselves using some outsourcing, so only some of the crisis-induced cost-cutting measures have translated into business for us. It really depends on what type and how many layoffs they have to make; some choose to let go of all the research staff and contract out completely, others hold onto a core research team that outsources specific tasks to a third party.

What makes inVentiv Health the partner of choice for the pharmaceutical industry in Argentina?

In Argentina, our teams are stronger than those of our competitors due to our lower turnover, which has been below four percent for the last three years, and has been as low as one percent in some years. They work together for years at a time and are able to build long lasting relationships with our clients, and these relationships ensure a lot of repeat business. Many of our competitors have higher employee turnover, so the team you work with now might be gone by the time your ready to contract out your next project. Every client is unique and has specific requirements and needs, and the long-term relationships we build with our clients allow us to deliver a more customized service.

InVentiv specializes in cardiovascular, infectious diseases, vaccines and oncology; what are the most important areas for the business in Argentina?

Oncology is certainly very active. CNS was also very active, but this is one of the areas that Dr. Chiale partially restricted a few years ago following ethical concerns related to involving Schizophrenia and Alzheimer’s patients in clinical trials.

How important is inVentiv Argentina to the global organization?

Argentina is the largest business for inVentiv in the Latin America region, and is the head office for the region. Since the Latin American market is one of the biggest sources of growth for the company, inVentiv Argentina is critical to the global organizations global strategy.

As the global head of the vaccines and infectious diseases for inVentiv, who is simultaneously the regional manager for Latin America, what are your biggest personal challenges?

The biggest challenge in the vaccine markets is getting business; the major players such as Sanofi Pasteur and GSK only outsource simple products like a flu vaccine, and tend to handle the development and research for most of their other products internally. The main products in the pipeline are for hepatitis C, which involves infectious diseases and vaccines, as well as new antibiotics. Over the last ten years, the infectious disease pipeline has shrunk relative to other

areas such as pain or oncology.

Having been with the company for 15 years, what are the biggest changes you have seen as the company has been acquired and rebranded multiple times?

When I started we were a much smaller group called i3 Research, and we acquired Latin Trials in 2006. The next year United Health sold us to inVentiv Health, and I am proud to say that we were able to hold onto almost all of our talent; our average employee has been with us for eight years, and we have a very low turnover. Aside from seeing this as evidence that our employees are happy, I accredit this to the fact that as a mid-sized firm we are able to build strong relationships with our employees and keep their strengths and personal goals in mind when assigning projects. Later when we acquired PharmaNet, the transition went equally smoothly and the new employees integrated themselves into our company culture very naturally.

What would you like to see achieved in the next five years, for both CAOIC and inVentiv?

CAOIC is quite young, and in the last two years we have accomplished a lot, including becoming a part of CAEMe. This has opened a lot of doors, as they are a much older and stronger organization. Over the next few years I would like to see our membership expand to include other CROs, and of course I hope we make some progress on streamlining the clinical trial approval process. More broadly, I hope we are able to attract some further political support to help bolster the clinical trial sector, as the country can benefit from the USD that the industry can bring into the country, last year CROs exported USD 4 billion in services, and of course patients can benefit from the access to new medications.

As for inVentiv, we are the fifth largest CRO globally, and our position here is about the same. Quintiles is definitely the largest here and worldwide, followed by PPD and Parexel, all three are significantly larger in terms of employees, and after them inVentiv, Icon, and INC are the next largest and have similar market shares. If we can maintain our low turnover and strong company culture, continue to bring service of the highest quality to our clients, and continue to work at the leading edge of the pharmaceutical industry, I will be very satisfied.

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