



Industry Report:

2023 Clinical Research in Argentina



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1. Introduction.

The purpose of this report is to inform about the growth and development of clinical research in Argentina in recent years.

Clinical research is defined as the activity conducted by pharmaceutical companies, through clinical trials, to develop products for human health. It involves the systematic collection or analysis of data with the intention of generating new generalizable knowledge for application in medicine, life sciences and related technologies. This implies that the efficacy and safety of new treatments, drugs or vaccines, is verified from clinical trials. (Goldstein 2021). Therefore, the growth of clinical research in Argentina means that the country participates to a greater extent in the testing process of new technologies that will be used by the health sector around the world.

This process is carried out by means of a clinical trial, an investigation in which the investigator selects individuals with inclusion and exclusion criteria, actively intervenes on the independent or predictor variable, and observes and analyzes the changes that occur in the dependent or outcome variable as a result of the intervention. When two interventions are compared, the research hypothesis is evaluated against a null hypothesis. Interventions on health can be: synthetic drugs, biological or biotechnological products, vaccines, medical devices, surgical techniques, etc. (CAOIC 2023).

In Argentina, companies involved in clinical research are grouped into two major chambers: CAOIC (Argentine Chamber of Clinical Research Organizations) and CAEME (Argentine Chamber of Medicinal Specialties). CAOIC is a non-profit organization that brings together and represents Clinical Research Organizations (CROs) in Argentina. CAOIC's objective is to contribute to the development of Clinical Research in Argentina in all its aspects, both from the regulatory framework and professional training, trying to generate a space for collaboration with all the actors of the sector (CAOIC 2023).

2. Impact of the clinical research industry on the population.

2. 1. Direct impact on health and society.

For decades, the pharmaceutical industry has been witnessing an increasing development of new synthetic and biotechnological molecules based on research conducted by companies dedicated to clinical research and development (Murray, 2021).

Among the main tangible benefits it produces, clinical research applied to human health provides new diagnostic and therapeutic procedures, new production techniques and new drugs for complex pathologies. To this end, it draws on advances in basic research in the life sciences and exact sciences, and contributes to decisive progress in the comprehensive understanding of diseases and the functioning of the human body (Murray, 2023b).

In response to the news published by the specialized media in the field, among the most innovative technologies applied to human health, the most noteworthy are recombinant DNA/RNA (genomics, DNA sequencing, genetic engineering), proteins and macromolecules (hormones, growth factors), cell and tissue cultures (vaccines, cell cultures), process

biotechnology (fermentation, bioreactors), DNA drugs (gene therapy, viral vectors), stem cells and bioinformatics (Murray 2023a; Murray, 2023b).

Undoubtedly, in the last century, health improvements driven by pharmaceutical innovations such as vaccines and antibiotics, along with investments in sanitation and nutrition, saved millions of millions of lives and boosted economic growth by expanding the labor force and boosting productivity, with the consequent social benefits that this brings (McKinsey 2020).

Consequently, life expectancy has increased in all countries of the world, reaching values equal to or above 60 years depending on the country. The world is experiencing an increase in both the number and proportion of older people in the population. By 2030, one in six people in the world will be 60 years of age or older. At that time, the population group aged 60 and over will have risen from 1 billion in 2020 to 1.4 billion. By 2050, the world's population of people aged 60 and over will have doubled (2.1 billion). The number of people aged 80 and over is expected to triple between 2020 and 2050, to 426 million (WHO, 2022).

In addition to the increase in life expectancy, it is also worth noting the improvement in the quality of life in serious pathologies (Alzheimer's disease, rheumatoid arthritis, etc.), the conversion into chronic diseases that used to cause very high acute mortality, such as AIDS, the gain in life expectancy for cancer patients in the last 30 years, estimated at 83% attributable to the new technologies, or the cure for Hepatitis C, as some of the examples in the path of technological innovation applied to medical treatments (Murray 2023b).

2.2. Impact of the clinical research industry on economic activity.

In economic terms, clinical research is an activity with a growing impact. If we take into account what is happening in the rest of the world, the industry has grown in recent years (Murray 2023a; Murray 2023b). While this growth is largely in response to the COVID19 pandemic, the momentum of clinical research predates and has been consolidated post-pandemic. In this regard, clinical trials globally increased by 25%, between 2017 and 2021, from 4296 to 5387, excluding COVID19-linked research from the numbers (Murray 2023b).

According to a report by EvaluatePharma (2020) on the global pharmaceutical sector, R&D (research and development) investment has steadily increased from USD 136 billion in 2012 to USD 186 billion in 2019. In turn, projections indicate that total global R&D investment in the sector could reach USD 233 billion by 2026 (Goldstein 2021). The star therapeutic area in this world is oncology: this segment occupied the largest share of the global market in 2020, with a 23.4% share, and its share is expected to continue to increase. The healthcare industry currently spends more than USD 38 billion on clinical and preclinical trials for the development of cancer therapeutics (Goldstein 2021).

Focusing on Argentina, it can be noted that the positive trend observed worldwide is becoming more acute. This is reflected in different data that show the period of great growth that the industry is going through in Argentina. Regarding the volume of activity, between 2017 and 2021, the number of clinical trials increased by 79%, from 124 to 222 (ESID 2022). On the other hand, in terms of investment in clinical R&D, it increased by 130% in that period, well above any other sector. While investment in the clinical research sector grew, in the rest of the sectors private investment decreased, so that investment in clinical R&D largely explains the growth in

private R&D investment between 2017 and 2021. In this context, in 2022, private investment in clinical research reached almost half of private business investment in R&D (42.5%). Moreover, 92.1% of the investment in clinical R&D comes from the external sector, from foreign parent companies (the vast majority 91.8%) and other foreign private sources, so it is foreign direct investment, which implies a direct foreign exchange income for the country (ESID 2022).

3. The clinical research industry in Argentina: CAOIC and CAEME.

Thanks to the boost given to the activity in Argentina in the last 10 years, the business organizations of this sector have also grown. In this sense, CAOIC is in permanent evolution, promoting the adhesion of new members. Currently, it is made up of 18 member companies (CAOIC 2023).

In September 2023, CAOIC celebrated its 17th anniversary. Between all its members, it has more than 3,500 employees according to its own records at the end of 2022. In 2022, investment in clinical research and development by CAOIC members amounted to \$40 billion. Delving deeper into the impact this organization has on Argentine society, 95% of COVID vaccine studies were conducted by CAOIC member companies (CAOIC 2023).

Regarding the people working within this ever-growing industry, CAOIC and CAEME gather 74% of the HR exclusively dedicated to clinical studies in Argentina (ESID 2022). If we look at their training, they are highly qualified personnel: physicians, biochemists, pharmacists, biologists, professional nurses, nutritionists, among other professions.

According to ESID 2021, a survey conducted by the Ministry of Science and Technology among companies to evaluate their performance in research and development, CAOIC members are the main employers of HR for clinical research, with more than 2,600 employees directly dedicated to clinical trials, representing 54% of the total (ESID 2022). Subsequently, in ESID 2022, we can observe that the personnel employed for clinical R&D amounted to 21.1% of the total personnel dedicated to R&D in the business sector (ESID 2023).

In line with global trends driving the reduction of gender inequality, more than 72% of HR dedicated to clinical research are women, well above the corporate average of 35% (ESID 2022).

In response to the training needs in the industry, CAOIC works intensively in the training of HR dedicated to clinical research, conducting courses and webinars in collaboration with other organizations such as FEFyM, FADEPOF and IPEGSA. In addition to this, CAOIC belongs to the group of Training Entities within the regime of Employment Promotion through Training Practices established by Law No. 6393 of the Government of the City of Buenos Aires. Through the talent program, CAOIC provides an HR database for its associates and the rest of the industry (CAOIC 2023).

On the other hand, CAOIC and CAEME seek to constantly increase the level of federalization of the activity, through different initiatives, reaching different corners of Argentina, so that the benefits it generates have an impact on the entire population of the country. To achieve this goal, CAOIC and CAEME have collaborated in the drafting of the Clinical Research Law of the Province of Buenos Aires; in CABA and PBA, they are working to add public hospitals as research sites; and in Cordoba and Mendoza, they are seeking to expand the number of clinical trials conducted there (CAOIC 2023). Currently, investment in R&D for contracting health institutions

reaches 20 jurisdictions in Argentina: CABA, Buenos Aires, Córdoba, Santa Fe, Tucumán, Mendoza, San Juan, Rio Negro, La Rioja, Corrientes, Salta, Neuquén, Jujuy, Santiago del Estero, La Pampa, Entre Rios, Formosa, San Luís and Misiones (ESID 2023).

The therapeutic areas in which clinical studies are conducted in Argentina have diversified enormously: oncology, immunology, infectious diseases, respiratory system, central nervous system, cardiovascular system, ophthalmology, digestive system, genitourinary system, metabolism, dermatology, rare diseases, among others (ESID 2022).

Finally, the modernization work carried out since 2017 in the regulatory agency of the national government, ANMAT, stands out within the panorama of the clinical research industry in Argentina. As a result of changes in ANMAT regulations, protocol approval times have been significantly reduced, from 137 in 2017 to 65 days in 2022 (Goldstein 2021). At the height of the pandemic, CAOIC and ANMAT worked together, achieving a radical reduction in the evaluation time of clinical studies related to the COVID issue, reaching 36 days (CAOIC 2023).

4. Conclusions

Specifically, in 2022, companies engaged in clinical research invested \$75,904 million current pesos in R&D activities, and the country currently ranks 22nd in the world by number of trials, representing about 1.55% of the total number of trials registered globally (Goldstein 2021).

However, there are indications that Latin America has begun to host new trials as a result of the global redistribution process of clinical trials. In this context, Argentina has all the necessary elements to take advantage of this opportunity and concentrate most of these offshored clinical trials.

Of the total private investment in R&D in the country, clinical research ranks first as a sector, with a share of almost half of the business investment in research and development, 42.5%, according to ESID 2022 (ESID 2023).

Our country has ideal conditions for conducting clinical research:

- Available and rapidly recruiting population.
- Infrastructure of health centers with highly experienced researchers in clinical research.
- Highly trained personnel (teams from research sites and company clinical operations)
- Adequate costs
- Quality, monitoring of good clinical practices with a focus on excellence
- A regulatory agency with international prestige and agile and digitized processes (reduction of ANMAT approval times since 2017)

Anyway, to continue with this upward path of investment in R&D of products for human health, there are a series of requirements that we should observe:

- Strengthen the human capital of regulatory agencies in order to accelerate protocol approvals (quantity and training).
- Define interjurisdictional governance (to avoid overlapping) and encourage national-provincial coordination.

- Include a greater number of public research sites.
- Reduce bureaucracy in administrative processes in research sites.
- Increase infrastructure, especially in public centers.
- Take advantage of the potential of the resources present in the interior of the country (federalize).
- Promote coordination among research ethics committees (CEI) to improve competencies and promote training in specific topics.

The potential for future innovations that will have a significant impact in the coming years will be much more mediated by digitalization and artificial intelligence, which will require continued investment in research by both industry and academia, requiring a commitment from both the private and public sectors to deepen R&D investment.

The main innovations today come from the private sector: more than half of the 300,000 million dollars in R&D in the health sector (globally). Therefore, the margin for growth in Argentina by attracting investment is very large. We are facing a great opportunity for growth that will require coordinated efforts by all stakeholders to promote transformations in healthcare systems that will lead to achieving the goal of better health and a consequent economic and social improvement.

In the history of medicine, the contributions of clinical research have transformed the lives of millions of people around the world, as was evident during the last pandemic. The development of new drugs, new vaccines and better diagnostic methods and techniques have helped to prevent, alleviate and cure diseases, improving the health of the population and giving hope to thousands of patients.

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