



CLINICAL RESEARCH WEEK

SUMMARY OF PANELS



SINDUSFARMA



Introduction

In recent decades thanks to the advances and discoveries coming from Clinical Research in Brazil and worldwide, new drugs, health products, advanced therapies, among other products, were developed improving people's quality of life. However, this would not be possible without the volunteer work of the research participants and the work of the various professionals involved in this chain of clinical development.

Without Clinical Research, with its well-defined stages and with the due scientific rigor, it would not be possible to prove the safety and efficacy of the new therapies under development, such as new vaccines and revolutionary treatments for chronic diseases, rare and ultra-rare diseases, as well as some types of cancers previously considered incurable.

In the "1st Week of Clinical Research", held by the Pharmaceutical Products Industry Union (Sindusfarma) and its supporters, from May 18 to 21, it was possible to hear the opinions of several interlocutors, such as research participants (patients), family members, doctors/researchers, pharmacists, nurses and other health professionals, sponsors, and representatives of ethical and regulatory bodies. The attendees discussed the importance and relevance of Clinical Research for the Brazilian population and the technical and scientific development of the country.



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SUMMARY OF PANELS

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Clinical Research Week – Panel I

The importance of Clinical Research in the patient's perspective

Panel I took place on May 18, 2020, with the participation of guests: Dr. Nelson Mussolini – Executive President of Sindusfarma, Rosana Mastellaro – Technical-Regulatory and Innovation Director of Sindusfarma, Dr. Fabio Franke – Oncologist and President of Aliança Pesquisa Clínica, Ita Monteiro, Luis Henrique Dario and Lourdes de Fátima Cavalheiro da Rosa – participants in clinical research and Vanice do Carmo Dario – Luis Henrique Dario's mother. The panel was moderated by Nilva Bortoleto, biochemical pharmacist and partner director of Inovatie Serviços em Saúde and lasted 1 hour and 9 minutes.

Nelson Mussolini was this panel's keynote speaker. In his speech, he said that it is from the pharmaceutical industry that the solution to the problem we face at the moment (COVID-19 pandemic) will come. He also noted that this solution goes through clinical research, conducting clinical studies ethically and transparently following international guidelines and those of the Ethics Committees in Brazil. Mussolini believes that Brazil can be a principal player in clinical research due to the excellent Research Centers and researchers in the country.

The discussion was initiated by Nilva Bortoleto, asking the patients if before participating they knew about clinical research. Ita Monteiro informed she and her relatives were not aware of this area. Then Luiz Henrique Dario said he had very little knowledge, only of cases that showed sporadically in the media.

Continuing with the panel, Nilva Bortoleto asked the patients how they had learned about the clinical research in which they participated. Luiz Henrique Dario explained that it was through his sister, who followed the Brazil Huntington Association (ABH) on social media, where she learned about the study



one year ago. Luiz Henrique volunteered to participate in this study and is still in treatment so far. Ita Monteiro informed that her father found out about the research carried out at Albert Einstein Hospital in 2001. She was diagnosed with Chronic Myeloid Leukemia and was in an accelerated phase when she learned about the study.

Nilva Bortoleto then asked the patients about the importance and benefits of having participated in clinical research. For Ita Monteiro, it was fundamental. As she had done several treatments that present no results, and the possibility of cure was minimal, her life trajectory changed when she entered the research.

In less than a year, she got better and improved her quality of life. She also said that she became a mother and today has an 11-year-old son, even after the doctors said she couldn't have children due to the number of treatments performed. At the moment, Ita Monteiro is attending her second university and thinks that participation in the research gifted her with a new life cycle.

Luiz Henrique Dario reported that it was a "knockdown" when he received the diagnosis of Huntington's disease two years ago. He had inner peace and dreams, which were broken by this diagnosis. His father died of the same illness, and Dario would not like to be in the same place. For Luiz Henrique Dario, one of the positive points of participating in clinical research is that he sees the love, affection, and concern of those who treat him. Dario had no life prospects, and today can play guitar, study, and work. It took Luiz Henrique Dario 6 months to accept the disease after he started his treatment one year ago. From the moment he faced it, he began to dedicate himself even more to the treatment, which made all the difference.

Nilva Bortoleto congratulated Luiz Henrique Dario and emphasized the importance of accepting the diagnosis and letting oneself be taken care of while making life easier for the caregivers when there is a health problem.

Nilva Bortoleto gave the word to Luiz Henrique Dario's mother, Vanice do Carmo Dario, asking about her perspective on what it was like to see her son participate in a clinical study. For Vanice do Carmo Dario, to see her son take part in it was something marvelous because there was no therapeutic possibility when her husband was ill. Today there is a real possibility of improvement due to the research in which her son is taking part. Great hope was born in the family following the study. Vanice do Carmo Dario always says that when a person gets sick, everyone in the family gets sick as well, and currently, the whole family is being "healed" alongside Luiz.

A recording of the patient Lourdes de Fátima Cavalheiro da Rosa was then broadcast. The patient was asked if she already knew the Clinical Research before being a participant. She answered that she did, but she thought it was impossible to take part and that it wasn't for everyone. However, today she is participating in a research and evaluates the experience as positive.

The patient Lourdes de Fátima Cavalheiro da Rosa was also questioned about the impacts on her treatment after she participated in a clinical study. She reported that after the treatment, she had her life back. Before that, there were no more options in Brazil, and that when she arrived in the United States, she was very ill. When she started the treatment with the new drug it already started to make a difference in her health. She also reported that she enjoyed participating in the research, that the medication is excellent, and that she had few adverse reactions.

When asked about this experience, the patient Lourdes de Fátima Cavalheiro da Rosa informed it had



been the best thing in the world. The patient encouraged anyone who has the opportunity to participate, to do so without fear because that was when she discovered the cure and had her life back. It was through the research, the effort of the medical team, the researchers, and everyone who worked with this study that she could have a second chance. She said she was born again and is extremely happy. Lourdes de Fátima Cavalheiro da Rosa finished the recording thanking the people who are part of the teams that work with the clinical research. She also wished that they have the strength to continue doing good for those in need because she believes that these researches are the patient's salvation.

Nilva Bortoleto gave the word to Dr. Fabio Franke, doctor of Lourdes de Fátima Cavalheiro da Rosa. He begins his report by informing that the main thing he heard from all the patients participating in this panel

was the word hope. He believes that Clinical Research brings such hope to patients, researchers, and those involved.

He reports that the patient Lourdes de Fátima Cavalheiro da Rosa has a fascinating story because it illustrates many similar cases happening in Brazil. She had advanced cervical cancer and had already undergone surgery, radiotherapy, and all the possible lines of chemotherapy, but unfortunately did not achieve satisfactory results. At the time, there was an international study about immunotherapy under ethical and regulatory analysis in the country, but because it was taking too long, she was unable to participate in this research in Brazil. Then came the possibility to participate in the same research, but in Miami, with all expenses reimbursed by the sponsor. Her treatment started at the end of 2019, and in May 2020 she returned to Brazil to continue the treatment since all ethical and regulatory approvals had been obtained. He reflects on how much clinical research has brought new life expectancy, the possibility of improving quality of life, how science evolved developing treatments with fewer side effects, and greater management ease. He believes that we must look firmly to the future to gain more access to clinical research for all types of diseases, not just the most serious and rare ones. He also believes that patients in Brazil should have more access to innovative therapies, seek alternatives to conventional treatments that do not present results. He says that it is possible to bring to patients everything that is under development since there are thousands of researches carried out annually. He reported that participating in a panel that involves patients gives meaning to everything, the same for being part of the clinical research, stating that he fights every day for better treatments for his patients, and clinical research is what brings this and will continue to do so.

Nilva Bortoleto asked the patients what the reaction of those close to them was when they heard about the participation of the patients in clinical research. To Ita Monteiro's family, it was great hope because she had been in hospitals from when she was 9 to 15 years old. Her family gave her a lot of support. They believed it was important because it could be her last chance. Some friends who were not that close to her didn't have the same opinion. In the case of Luis Henrique Dario, his family saw that there was a light at the end of the tunnel, and from the moment he started in the research, everyone saw that there was hope. Today he considers the patients who were cared for in the same clinic as his family too.

Nilva Bortoleto asked Dr. Fabio Franke if in Brazil there is still the concept that the patient is a kind of guinea pig. Dr. Fabio Franke believes that this concept only exists in those who are against clinical research because of some ideological reasons. He used the example of the 'gaucho' journalist, David Coimbra, who wrote a chronicle entitled 'Being a guinea pig is a blessing'. David has participated in two different clinical researches, one in Ijuí and another in Boston. Today he is doing very well after being in



treatment for seven years. In his chronicle, he writes that clinical research allows the patient to have access to the best there is, regardless of whether they live in a poor community in Brazil or if they are a successful Japanese entrepreneur.

Dr. Fabio Franke believes that the democratic access clinical research brings is the best thing we can have. Therefore, this image of “guinea pig” is becoming outdated and it is possible to demystify it in thematic panels and in situations where patients who have participated in research can be seen, and show how well they are doing, and how much they are contributing to the evolution of medicine. If patients do not volunteer for clinical research, it will obviously not be possible to evaluate new drugs. It takes courage to participate in a clinical research protocol.

Nilva Bortoleto asked Dr. Fabio Franke how it was for him to get involved in clinical research while in the city of Ijuí. He said that the hospital he works at is public, and it is a reference center for the whole region. When he returned from the American Congress of Oncology in 2005, there was no more drug stock in the oncology center. For several months, SUS (Brazilian public health system) had not transferred funds to the Institution, and there was no treatment available for the patients. He had attended the presentation of a Canadian doctor in the American Congress who said that the best way for patients to have access to innovative medicines would be through clinical research. Then, he started to look for alternatives because the research centers were limited to the Capital cities, and there was a preconception about opening a research center in the countryside. In 2013, there was a major crisis in clinical research in Brazil due to the delay in obtaining the ethical-regulatory approvals to conduct clinical trials. From this challenge, a patient's idea to create a bill presented to the senators arose, an idea that has been going through the Senate and is currently also in the National Congress (PL 7082), and aims to debureaucratize clinical research in Brazil. We need more studies with more agile approval time. Brazil loses many opportunities because of this. Dr. Fabio Franke believes that there must be a joining of forces for the patients who need it because any one of us can be a patient.

Dr. Fabio Franke replied to Nilva Bortoleto that he managed to save the lives of many patients, but he believes that it is possible to do much more, since poli-treated patients could have access to initial studies that, unfortunately, do not exist in Brazil yet.

Nilva Bortoleto asked Vanice do Carmo Dario, Luiz Henrique Dario's mother about the beginning of her son's treatment through a research protocol after the experience she had lived with her family. Vanice reported that this experience was a source of renewal for everyone because before, there was only palliative medication, and that was an extraordinary gift for her son and family. She also reported that her son met other people who are in a similar situation and that this strengthened a lot his faith and hope.

Nilva Bortoleto asked Ita Monteiro if she believes that having participated in clinical research has interfered with her personal and professional choices. Ita Monteiro confirmed it, but in a positive way, because she felt very welcome when she was participating in the research and, for this reason, chose to work in the nursing area, so she could also contribute.

Nilva Bortoleto informed there were questions from the spectators for Dr. Fabio Franke. The questions were about the number of studies he was conducting at his center in Ijuí, how many patients were being treated in those studies, and how many more patients he could treat if the regulatory deadlines were similar to those of Australia and the United States.

Dr. Fabio Franke said there are more than 100 research protocols in progress, and the center has already



participated in almost 200 protocols. On average, 200 patients benefited from these treatments. He feels there is the potential to offer much more and that we could have many more phases 1 and 2 studies.

To conclude, Nilva Bortoleto asked Luiz Henrique Dario what message he would like to leave the doctors, patients, and their caregivers. Luiz Henrique Dario said he feels a lot of gratitude for the doctors and other professionals of the clinic and that he wishes the patients hope because they must accept the diagnosis and never leave their dreams behind and that everything is possible with the new researches.

Ita Monteiro transmitted a message of gratitude to the doctors and asked them to continue to support the clinical research in Brazil as many patients need them. For the patients, Ita Monteiro said that they should believe and have trust, for technology is very advanced, and if they have the opportunity to participate, they should talk to their doctor to receive all the orientation. Luiz Henrique Dario's mother, Vanice do Carmo Dario, thanked the doctors for their affection and dedication. For the other mothers, Vanice advised them never to give up and lose faith. Their children and loved ones deserve every chance to be cared for to alleviate their suffering, whether physical, psychological or emotional.

In his final message, Dr. Fabio Franke told doctors not to give up on their patients and seek new alternatives which may be closer than they imagine. For the patients, he asked them to be inspired by the examples presented during the panel, which prove to be an alternative. Also, he stressed to patients the importance of not giving up on life, which is the most precious possession, and therefore they should seek other possibilities. Perhaps in the near future, the person who is the sufferer of today can be a beautiful example of success like those who now are models of the battle for our health and life.

Nilva Bortoleto left her final message to doctors who are not researchers. She asked them not to give up on their patients and to help in the search for studies that are in the recruitment phase. For the patients, she pointed out that information about clinical studies is not always available and that they should look for patient associations since, in general, there is where this information is. The patient must ask their doctor and the people around them as it is not all researches that are advertised.



Clinical Research Week – Panel II

What does society need to know about Clinical Research?

Panel II was held on May 19, 2020, with the participation of guests: Dr. Camille Rodrigues – Pulmonologist and Partner Director of Inovatie Health Services, Dr. Felipe Ades – Oncologist Responsible for the breast cancer and the melanoma units at Oswaldo Cruz Hospital, Dr. Joyce Macedo – Doctoral Student at UNICAMP and Clinical Researcher at CRO/ Azidus Brasil Research Center and Dr. Lenio Alvarenga – Access Director and doctorat Roche.

The panel was moderated by Clovis Nery, representative of the Clinical Research Working Group of Sindusfarma, and lasted 1 hour and 6 minutes.

Dr. Felipe began his presentation by answering question 1 (What is clinical research and what is its importance for society?): clinical research (CR) is an essential part of the development of society as a whole and in a broad way. The CR is a method, a way to analyze and come to the validation of hypotheses and, thus, society can reach new development levels in the several areas where the CR is employed. Clinical research is a way of asking and discovering the world and, consequently, a way of discovering the events that surround us. It is through clinical research that scientists develop new medications and exams, with which they increase the life expectancy of humanity.

Evolution of society: In less than 150 years, life expectancy has increased from 40 years on average to almost 80 years. For this, the CR was fundamental, because it is one of the tools available for the evolution of the human species, as when the expected result is obtained, it is shared among people. Clinical research has this beauty, being collaborative.

Dr. Lenio presented a practical example, as an ophthalmologist, on question 1: often, you have a patient without an effective treatment or one that is not fully effective or one that will bring several side effects. Thus, as long as this situation continues to exist, it will be necessary to use the method described by Dr. Felipe.



The importance of learning about the method is fundamental for us as a society because the more we conduct earnest and ethical clinical research with appropriate methodologies, the better it will be for patients, doctors, and for all who are involved, directly or indirectly. We will gain more experience with the method and, in return, we will have the possibility of developing an innovative treatment, which will be useful for all.

About question 1, Dr. Camille made a further comment: in these moments of the Coronavirus pandemic, where, in practice, there is still not enough scientific evidence for all the issues, with strong enough scientific evidence, especially because there has not yet been enough time for scientists, doctors, health professionals, in general, to obtain the necessary information in search of an effective treatment - clinical research adds value in the way we take care of patients and our health on a daily basis, without having the real awareness of how much it is part of our lives.

Dr. Joyce commented on question 2 (How are the regulatory entities such as ANVISA, CONEP, CTNBio, etc. and how do you see the importance and relevance of these agents/regulatory entities for the appropriate conduct of clinical research in Brazil?): Regarding the ethical and regulatory scenario, we currently have a more harmonious and complementary picture to the one we had a few years ago, when these regulatory entities had recently been created, and their regulations were still in the beginning or under elaboration. These regulations have undergone transformations and improvements over the years.

In the past, approximately 11 years ago, there was not the same opportunity, and access to these Regulatory Bodies, as well as the international harmonizations, were not so effective. Today we are growing in this direction. There is still room for improvement, but certainly, there has been positive growth over the years.

Dr. Camille added that ANVISA has been doing a very interesting job, in the same way, that CONEP has also been very active. "When we look back, no doubt, in these last 15 to 20 years, it is possible to notice that these Regulatory Entities have worked a lot in the professionalization of ethics committees. But it certainly has no use evolving without speeding up project approvals, especially those of the international CR", she explains.

"As participants in this system, there is a third need, that of replicating information to society about clinical research, in an understandable, objective, direct, dynamic, positive and informative way".

Rosana Mastellaro, Sindusfarma's Technical-Regulatory and Innovation Director, highlighted the work done in recent years and commented on the need to foster an open communication channel between the Regulatory Authority and the Regulated Sector. Open discussions on both sides enabled the advancement of clinical research in the country.

"We cannot confuse speed with a lack of quality or bypass processes. Clinical research is a process in which there must be ethical and regulatory analyses, but the deadline for such tasks must be fast because if they are not conducted in Brazil, they will certainly be conducted abroad".

About question 3 (How does research start?), Dr. Felipe commented about his experiences in Academic Research (Hospital/University) and about the question of the existence of a scientific hypothesis to be answered, from which a specific development protocol is created to compile the data and obtain a conclusion. He said that in general, this type of Academic Research uses funds from the hospital itself or from some promoting agency (FAPESP, foundation that supports research and innovation, or CNPq, National Council for Scientific and Technological Development).



Dr. Joyce added to the Research of Universities, Industry, and Representative Organizations of Clinical Research (ORPCs or, in English, CRO - Contract Research Organization).

Dr. Joyce explained the different phases of clinical research for the development of medicines: the pre-clinical phase (models of research in animals before use in humans) and the different phases of research in humans (phases 1, 2, 3, and 4). Phase 1 consists of the studies in healthy individuals for the dosage setting and safety analyses. Phase 2 examines the efficacy and safety issues in a small, controlled group of patients. Phase 3 performs the validation of treatment concepts and outcomes demonstrated in the other phases, to verify if the benefit obtained outweighs the risks of the new treatment. And, finally, Phase 4, which evaluates safety and efficacy aspects in the general population, when the drug is commercialized in the country, where, in general, there is already access by the population to be treated on a larger scale.

Dr. Lenio addressed the importance and relevance of the Pharmaceutical Industry to Clinical Research. For him, the social role of the Pharmaceutical Industry is very clear: “we, in this sector, have to ensure that the progress of science is somehow reverted into benefits for the health of patients because that is the fundamental point. Furthermore, it is interesting to think of clinical research as the maturity phase, in which, analogously, the pre-clinical phase is the childhood part, and clinical research is the phase where the potential for the development of the product/medication studied is,” he explains.

“The candidates (product/medicine to be studied/developed) are born from the meeting between the advances that allow scientists and researchers to understand the mechanisms of the disease functioning, with the progress made to understand the biological mechanisms and processes that must be intervened. And so, when there is a lot of knowledge on one side and new tools on the other, new drugs arise and are studied to fight existing diseases, especially those that do not yet have an effective or specific treatment. Therefore, the importance of investments in basic and applied research”.

Dr. Lenio shared two examples of experiments he is working on, talking about development tools/platforms: “if we take the antibody, that protein that looks like “Y”, in nature, the two “little legs” of that protein always bind to the same substance. However, today it is possible, thanks to the development of new substances, to have one of these “little legs” connecting to one thing and the other connecting to a totally different one. Thus, it is possible to develop new drugs through this new technology. For example, scientists can use the knowledge obtained from medication for the treatment of hemophilia to design a medicine to fight cancer”.

One of the webinar participants asked Dr. Joyce about what she had previously explained regarding the phases of research development: how long does each phase of CR development take on average? Dr. Joyce explained that it depends on the type of disease that will be studied, but on average, a Phase 1 study can take one year, while a Phase 2 study can last from one to two years, and a Phase 3 study can take several years. Thus, a Phase 3 study may require between 5 and 10 years of research and development until it is known how the new product/medicine studied will be suitable - or not - for the treatment of a particular disease. The CR deadlines are directly related to the systematic and standardized processes that are carried out throughout the research itself (recruitment and inclusion of participants, generation of reports, analysis of the statistical part, etc.).

Regarding question 4 (What is the role of the health professional in stimulating clinical research?) Dr. Camille highlighted that the health professional is the heart of the research, and usually, research centers are composed of multi-professional teams (doctors, nurses, pharmacists, among others).



She says she always “teases” the Monitors during the qualification visits, saying that they will be impressed with the “beauty of the place” (equipment, physical space, etc.), but that this is not the most important part.

For her, the most important is the people who are working at the Research Center, with their experiences, expertise, skills, and professional abilities, reflected in the results of the research coming from this center.

The quality of clinical research at any research center is directly related to the quality of the professionals involved in them.

On question 4, Dr. Lenio added the following comments: he highlighted the information aspect, in which the health/research professional needs to know how to adequately replicate the information and provide the necessary explanations in a didactic way to the potential participant of the research, bringing clearly and objectively what is relevant for them to know and that will help them in the decision to participate in CR, explaining all the peculiarities of the research.

“Brazil will become a better country if patients know about the existence of clinical research and how they can participate and contribute. Furthermore, the patient must have access to information about the possibilities of the research, having the guidance of a health professional who explains the procedures and the existing possibilities for the interested patient”.

Another fundamental point is the integrity of the data. In clinical research, everything is done and conducted thinking about society. In the research, the health professional needs to be careful in collecting and registering the data that will be used together with the international data of that same study. These data will be used in the countries where that drug/product is registered and commercialized, allowing access to the world population.

In short, the health professional who works in clinical research needs to be able to explain to the participant and know how to interact with him/her, showing the value of CR and pointing out the beauty existing in the potential perceived bureaucracy.

Regarding question 5 (What is the role and/or importance of the different professionals involved in clinical research?), Dr. Joyce commented that, in general, the clinical research team is led by a doctor, appointed as Principal Investigator, who has the ethical, technical and moral obligation of sharing knowledge with his team. It is very important to highlight that a doctor alone does not do research.

She also commented on the structure of a team in a clinical research center (nurses, pharmacists, doctors, technicians, biomedical, etc.) and the need for alignment among the people who work in this center so that the study is properly conducted, allowing the participating patients to benefit from the research.

Dr. Felipe echoed the words of the other debaters, highlighting the importance of clinical research and the different professionals involved, about the need to motivate the team to conduct it with the necessary relevance because there will be a future impact. The CR may or may not benefit the participant, therefore the importance of this altruistic role in favor of others, where the data generated in the clinical research will be critical for the patients of the future product/medicament to be registered in the countries.

Dr. Joyce further elaborated on the importance of the role of research centers in Brazil, which, in general, are very active in studies that are in Phase 3. She questioned how things are structured in the country,



since, many times, clinical research protocols are elaborated and brought from abroad, as well as emphasizing the issue of the lack of specific educational grids on research training in national colleges and universities.

On question 6 (What is the role of the media in the dissemination of clinical research in the country?), Dr. Lenio commented that a person can be biased, but the method or ethical evaluation is never.

He believes that the media has the role of passing on the correct information to the population, highlighting the importance of Clinical Research to society, and clarifying that the participation of people is always voluntary.

Dr. Lenio pointed out that the use of the term “guinea pig” is in the past and that the correct one is “research participant”. The role of research participants is protected by the existing Ethics Committees in the country and the world. They ensure that the rights and guarantees of participants are preserved in any clinical research conducted on human beings.

In Dr. Lenio’s opinion, the media should clarify that the participation of patients is voluntary and that there are ways for them to be informed about clinical research. The objective is that, in the future, other patients going through this same difficult journey in search of a cure or improvement for their disease can contribute to the learning and development expected by participating in clinical research.

Dr. Felipe stressed that it is important that the media work in favor of research, communicating the right terms and issues that are relevant to the population, bringing adequate information, and not misinformation.

Regarding question 7 (Who can participate in a clinical research?), Dr. Camille said that she would like to allow all individuals and potential participants, however, it is a fact that the patient needs to meet some pre-established criteria in the protocol (criteria of inclusion or exclusion) to be able to participate in a clinical research. She further emphasized that she believes it is critical to make it clear that before having a proposed clinical trial protocol with well-established criteria, it is necessary to ensure that the CR will not offer risk to the potential participant. Patients should seek treatment that potentially brings more benefits than risks.

Dr. Joyce added that a clinical research protocol should be designed to be performed under ideal conditions, seeking the best response for a product/medication/therapy, under adequate and rigorous control for the choice of people to be studied. In the future, when the drug is launched, it will be used in similar conditions, but not always as ideal as in clinical research. Hence the importance of continuous monitoring of existing drugs on the market, such as through new studies and Pharmacovigilance monitoring activities.

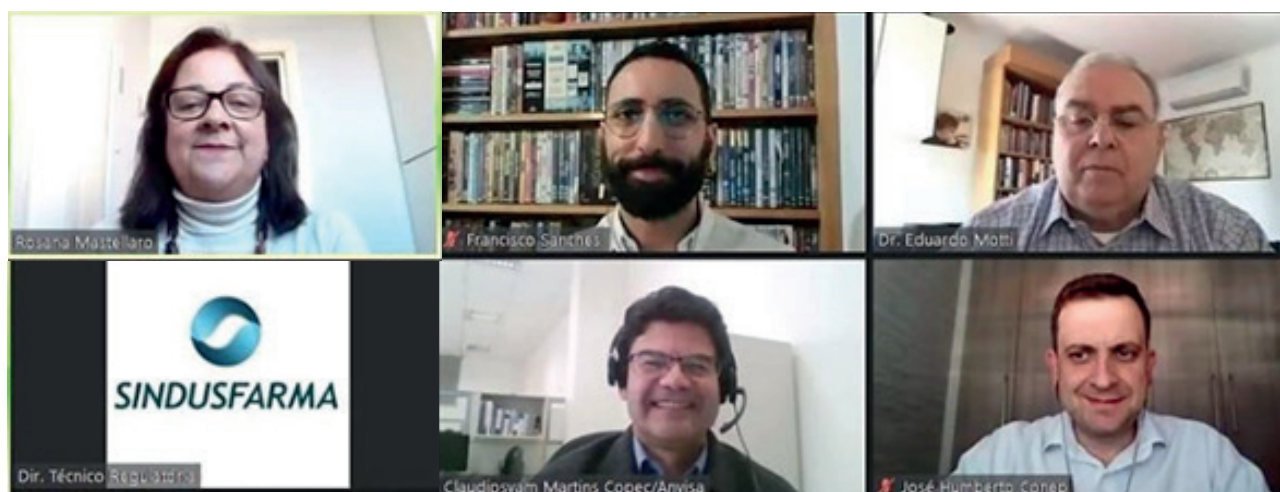
Dr. Lenio emphasized that all this is regulated by specific protection frameworks existing in the country. He also said that society needs to promote the meeting of clinical research with those patients who can participate in it. Dr. Lenio believes that digitalization in the health area will solve most of these problems, besides encouraging clinical research in the country, because there is already a lot of relevant information that can benefit future study participants.

Dr. Felipe corroborated with Dr. Lenio’s comments on the digitization of medical records in hospitals and research centers in the country, which will contribute to the automatized selection of participants for



clinical research. He also highlighted the contribution of clinical research to unburden and relieve the Unified Health System (SUS) since it favors the access of a portion of the population to state-of-the-art therapies, which are being studied and developed in the country and worldwide.

Rosana Mastellaro highlighted that a good part of the questions raised will be addressed in the other days of the Clinical Research Week and highlighted the existence of a free Electronic Training Platform available at Sindusfarma's website on the subject of clinical research.



Clinical Research Week – Panel III

How can we increase patient access to Research – Where are we and where do we want to go?

Panel 3 took place on May 20, 2020, with the participation of guests: Francisco Sanches, leader of the WG of clinical research of the All Together Against Cancer Movement and Director of Abracó; Dr. Claudiosvam Martins, coordinator of COPEC (Coordination of Clinical Research within ANVISA – National Health Surveillance Agency); Dr. José Humberto, Hospital A.C. Camargo and member of CONEP (National Commission on Ethics in Research); and Dr. Eduardo Motti, consultant, and doctor with over 30 years of experience in clinical research. The panel was moderated by Rosana Mastellaro, Technical-Regulatory and Innovation Director of Sindusfarma, and lasted 1 hour and 15 minutes.

The discussion was initiated by Francisco Sanches, who emphasized the importance of the topic of clinical research in the current days of the COVID-19 pandemic, both for science and society. There is a considerable popular pressure around clinical studies since all bets were placed in it when thinking of the return of the feeling of safety. Clinical research is the methodology that will bring more chances of finding a solution through safe and reliable information. Besides, the questioning about the quality of research was also raised: is there a perfectly designed research? Does the perfect treatment really exist? Is it possible to make some evaluation parameters more flexible?

About the increase in the volume of clinical research in Brazil, Francisco highlighted the importance of national research. He considers essential the local development of research, aiming at the prioritization of national interests, and for the development of Brazilian universities, which may include in their scope the researches encouraged by pharmaceutical industries and also those of academic level.

Francisco also highlighted the international research developed by multinational industries and questioned the interest of these industries in conducting studies in Brazil, as it is often considered easier to conduct such research in the United States and the European Union. He listed some points related to the use of international research that would benefit Brazil: the first point was the financial investment and the improvement of the economy when an international study is conducted in Brazil, which generates jobs and moves the economy. The second point was the scientific development



because the research brings information sharing, good clinical practices, and training of health professionals.

The third point is the expansion of participant's access to personalized and often higher quality treatment and care than the public health care system. The fourth point is the offer of new treatments for the Brazilian population, making the regulatory agency and the Brazilian doctors have contact with the molecule since the initial phase of development.

The fifth point raised was the development of better structures in the research centers due to the financial investment of the international pharmaceutical industries, which are also responsible for the treatment and follow-up of the study participants and, therefore, relieving the SUS (Unified Health System). Finally, the participation and reporting of patients in Panel I was mentioned, raising the importance of research in helping individual participants and their families, with research often being the factor that will, in fact, save the patient.

Continuing the discussion, the moderator Rosana Mastellaro questioned the participant, Dr. Eduardo Motti, about the challenges in conducting clinical research in Brazil. Dr. Eduardo grouped the challenges into two crucial points, the first being: how to bring more research to Brazilians? And the second: how to bring more Brazilians into the research? Two central aspects must be considered: education and publicity. He highlighted the importance of professionals in the area to disseminate clinical research with correct and elucidative information since it is still very little known by the population. Fortunately, the participating patients act as disseminators and educators of clinical research, sharing their own experiences, as was done on the first day's Panel, making them "advocates" of clinical research.

Clinical Research. Some months before the pandemic, there was a difficulty in bringing clinical research to the mainstream media. There was no interest from the press because they believed that the population would not understand a complex subject. However, with the outbreak of the pandemic, concepts previously classified as complexes are divulged at all times. Nonetheless, people indeed have no knowledge of these subjects. In this scenario, it is important to be aware of what will be transmitted to the media and how it will be done.

Moderator Rosana Mastellaro added, informing that we should take advantage of this moment to divulge correct information about the clinical research, considering that now it has aroused the interest of the population about the theme.

Later, Dr. Eduardo Motti mentioned the impedance: resistance to the flow of projects - first it is said "no" and after extensive arguments, there is the convincing. He believes that it is necessary to work on reducing impedance, both from the point of view of regulatory agencies and of ourselves.

Then, the following question was asked to Dr. Claudiosvam: How can we reduce these challenges?

Dr. Claudiosvam highlighted the complexity of the research and the steps that a drug must undergo until, finally, it is registered and benefits the population. He cited that the ethical and regulatory instances appear in several of these stages and, therefore, are often criticized. However, other steps are also complex, such as bringing international studies to Brazil (feasibility process, for example).

He also mentioned that currently, during the pandemic, ANVISA is being frequently questioned about study designs, academic research (which are not in the scope of ANVISA), and clinical research in general. The deadline was also raised - a determining point in the choice of the country in which to conduct the



research – and, for this reason, ANVISA has been working on the revision of the norm that regulates the research, aiming at improving these deadlines and taking into consideration what really needs to be evaluated during the approval of a clinical trial, optimizing and making it more flexible, always considering the safety of the participant. Also, it was mentioned by the moderator that clinical research did not stop during the pandemic and that the agency is working to keep the deadlines. Dr. Claudiosvam followed, mentioning as an example the cases of participants who were in research in other countries but who could not return because of the pandemic, leading to the discussion on how to treat these participants locally and the number of Brazilian patients participating in international research. Dr. José Humberto was asked about the achievements and improvements observed in Brazil concerning clinical research.

He mentioned the shortening of the project's analysis queue at CONEP after Dr. Jorge Venâncio joined the committee coordination. In addition, Dr. José cited the publication of the manual of pending issues often raised by CONEP. With the publication of this material, a decrease in the questionings was observed, allowing the approval of several studies without any pendency. It was also pointed out that CONEP never intended to hinder the conduct of clinical trials in Brazil, and its action was focused on ensuring the safety of research participants.

In this way, CONEP became more open to receiving sponsors to discuss the study designs in person. In short, the great achievements are the speed, standardization, and openness of CONEP.

The COVID pandemic brought improvements in CONEP's processes: first of all, the holding of virtual remote meetings, which allows them to be daily and no longer monthly, bringing speed in the evaluation of projects. A curious point, in this period, was observed the increase of interest of the academy in studies – until now CONEP had received more academic studies than the pharmaceutical industries, which, in fact, brings the relevance of the country when starting to produce its own research. This raised an important point related to the need for change in the writing of national protocols.

Dr. Humberto pointed out that the protocols received presented significant methodological flaws that could bring losses to participants. This led CONEP to publish a manual with minimum requirements expected for a safe clinical trial (such as rules for reporting adverse events, creation of a monitoring committee, etc.) and brought to discussion the need to develop this level of expertise in the country.

In conclusion, he pointed out that the CEP-CONEP system has developed at a speed never imagined before the pandemic and that he believes that this will not be lost, that the system will no longer be the same as before.

Dr. Eduardo complemented Dr. Humberto's statement by bringing a very important point for discussion: it is possible that not many international COVID studies have been submitted since Brazil has a history of uncompetitive deadlines, which is a determining and significant factor at a time of this pandemic, in which studies should begin as soon as possible. He believes that with the deadlines achieved for COVID studies, the country is showing decision-makers in whether or not to bring a study to Brazil that we are a competitive country both in terms of deadlines and the ability to evaluate well-designed studies that need methodological improvements.

Completing this line of reasoning, Dr. Claudiosvam believes that by joining efforts between CONEP and ANVISA, it is possible to take advantage of the experience of international industries to increase the development of research by the national industry and academia.

Francisco stressed that these improvements made by CONEP and ANVISA are celebrated and widely



disseminated to reduce the impedance in selecting or not Brazil to participate in clinical trials, concluding that we must work on the image of the country abroad in regard to deadlines.

Moderator Rosana introduced another question: How can we make Brazilian patients aware of the ongoing clinical studies in the country?

Dr. Eduardo said that this is one of the biggest obstacles we have. You can't just depend on luck to find the studies. The solutions that we have today, such as websites of associations and companies do not solve them. He believes that social networks, even with their flaws, can be the solution. He also mentioned an experience he had at Princess Margaret Hospital, in Canada, in which all patients who enter the hospital receive information that they can participate in a clinical trial being conducted there.

This results in approximately 25% of patients participating in a clinical trial at the hospital. He believes that this is an action that can be implemented in Brazilian hospitals, that can be effective, in addition to being cost-free. It is also effective for information to be disseminated within the clinical staff of hospitals. He also cited Google's search tool, which can generate an advertisement about clinical research directed to those who are researching the disease.

Dr. José Humberto added by talking about the dissemination through 'Plataforma Brasil', which he believes failed to be a search tool for the general population. He believes that the tool could have a mode of search open to the public that ended up not being achieved at the time it was developed. Another national dissemination site is the REBEC (Brazilian Registry of Clinical Trials), but he believes that it is not an easily accessible site and source of information for the lay public. In conclusion, he believes that the country lacks a platform that brings together all this information from clinical trials. We also lack a way to disseminate the studies, citing as an example the advertisements that are made in other countries safely and ethically for patients; would there be barriers for this to be done?

Another point is the virtuous circle of clinical research: the more efficient the studies are in the country (with a regulated environment), simpler, faster, and more integrated (perhaps integrating ethical and regulatory instances), the more studies will be conducted in Brazil and this way the research will be more known by all. Another point is to train and develop the technical capacity of Brazilian research teams and researchers to design and conduct research locally, making research stronger and better known in Brazil.

To Dr. Claudiosvam, another way to spread the research in the country is to make it less concentrated in states of the South and Southeast regions. By decentralizing the research, space would be given to other states to conduct it and, therefore, more patients could have access to them.

With this finding, the question arises: are there enough research centers in Brazil? Francisco answered yes, but there is a lack of experience and training for many of them. According to the registration made by ABRACRO (Brazilian Association of Representative Organizations of Clinical Research), there are 400 research centers registered and distributed throughout the country. According to a study prepared by Aliança Pesquisa Clínica Brasil, ABRACRO and Interfarma - "The importance of clinical research for Brazil" - Brazil has the ninth largest GDP in the world, the fifth largest country in the number of pharmaceutical industries installed, the seventh largest pharmaceutical market in the world; however, we occupy the twenty-seventh position of countries that conduct clinical research in the world, which leads us to believe that we could do much more. We are behind countries like Egypt, Iran, Russia; countries that do not have the same position as Brazil in the questions raised above. He also raised



the point of the quality of Brazilian research centers and researchers, which continues to ensure the election of Brazil as a participating country in clinical research.

Dr. Claudiosvam raised that ANVISA, in 2019, approved 221 clinical trials in all phases, most of them in Phase 3, in 420 research centers, approximately half of which are located in the Southeast.

Dr. Eduardo Motti further added that during a query with a courier responsible for collecting biological samples of clinical trials, they found that there were more than 2,000 research centers in his registry. That corroborated the idea that Brazil has enough centers, but they are poorly allocated. Besides, more than half of the inspections carried out by the FDA (Food and Drug Administration - regulatory agency in the United States) at Brazilian centers did not observe important findings and deviations during the conduct of clinical trials, and no negative impacts were identified in the data collected.

In conclusion, participants discussed what would be the ideal scenario for conducting clinical research in Brazil. For Dr. Eduardo Motti, the ideal setting is that Brazil participates in at least 10% of all clinical trials that are conducted in the world.

He believes that this is possible, and that Brazil has this capacity. Francisco stressed that it would be important to increase the amount of international clinical research and also to leverage national production and notes that we have achieved many advances in recent years, highlighting the virtual meetings held by agencies.

Dr. Claudiosvam highlighted the integration between the different actors of clinical research: ANVISA being more open and listening to all those involved so that the regulation is possibly closer to reality, decentralization of research in Brazil, improvement of regulatory deadlines, and increase of research in early stages, which is still little explored in the country. Dr. José Humberto mentioned an action for decentralization of clinical research, which is the accreditation of Ethics Committees and summarized in two topics what he believes to be the ideal scenario, the first topic being: simplified, integrated, and decentralized regulated environment and, the second related to the development of national research.

The conclusion of Panel III is to reinforce that clinical research needs, indeed, to be controlled and regulated to ensure the necessary safety for society and researchers, but there is room to eliminate unnecessary barriers and simplify processes.



Clinical Research Week – Panel IV

The New Normal – Impacts on Clinical Research

The IV panel took place on May 21, 2020, with the participation of guests: Dr. Fábio Franke, president of the Clinical Research Alliance; Dr. Claudiosvam Martins, coordinator of Clinical Research in Drugs and Biological Products (COPEC/ANVISA); and Dr. Luis Augusto Tavares Russo, director of the Brazil Institute of Clinical Research.

The panel was moderated by Francisco Sanchez, leader of the clinical research workgroup of the Todos Juntos Contra o Câncer (All Together Against Cancer) movement and director of Abracro, and lasted 59 minutes.

COPEC/ANVISA issued a Technical Note for conducting clinical research during the pandemic.

– Claudiosvam: ANVISA deals with a series of fronts linked to the context of the pandemic (import, registration, consent in research, laboratory tests, among others) and we are publicizing, almost daily, about conduct. Thus, right at the beginning of the pandemic, at the end of April, we published about the procedures and adaptations that could be made in terms of conducting clinical research for sponsors, researchcenters, and CROs, to enable and not stop clinical research.

This technical note (NT 14, of 04/22/2020) aims to provide answers and guidance for the difficulties that are arising, for example, the delivery of medication at the residence of research participants because of the contingency of mobility that has occurred in several states. However, we also identified difficulties in importing, in the participation of Brazilian patients in research outside the country, and about not being able to continue the studies or patients who came from other countries to participate in research and are not being able to return to their country of origin. A series of obstacles.

And, our concern is to ensure that these efforts have practical results in the pandemic context. Our very small team is directed to serve what is relevant in this complicated context that we are living in.

– Francisco: How has this pandemic affected your research center and your patients, Dr. Fabio?



- Fabio Franke: We have a diversity of situations throughout Brazil, with different scenarios, most centers interrupting recruitment, whether due to a sponsor's problem, a problem with the research center staff, or a supply problem. Here, in Rio Grande do Sul, we have made an early quarantine, and the situation is relatively calmer. We are working on-site and with all the necessary care. We have canceled on-site monitoring and are taking advantage of the wave of doing things remotely, so both monitoring and initiation visits are taking place remotely. The dispensing of oral medication is taking place directly at the patient's home, which decreases the need for displacement and face-to-face visits.

This is a readaptation of reality, without forgetting the main benefit of clinical research, which is the patient.

With the pandemic, we cannot forget that patients need treatment. There are concerns with COVID indeed, but also a concern that they continue to have access to their treatment. The challenge is to ensure that this can be safe and effective. Yes, it is necessary to be flexible, but without losing confidentiality and quality of data. That is the challenge. One concern is the uncertainty of information, today's reality may not be the reality of next week or next month, we do not know how the pandemic will evolve and we are putting together strategies to keep the center active, to be able to keep both patients in treatment and the inclusion of new patients in studies because the scenario varies. Some sponsors canceled new inclusions, some kept, and some analyze case by case; how much to keep the patients in treatment already active. These are new situations, for which we need to find quick solutions, not allowing the patient to have any kind of damage. And, for all of this, the exchange between the centers, and the exchange of experiences between all, are extremely important.

I see with good eyes the use of technology. We advanced in years what would take a long time for people to develop. We have gained a legacy in process agility, but these need to pass through the quality sieve and we must be sure that the data is not lost.

- Francisco: Interesting what Dr. Franke said about data safety and quality, as the EMA has published an extensive guide mentioning what has to be done to maintain the safety of research participants and the quality of the data and, if there is any doubt about the possibility of them occurring together, to prioritize the safety of participants.

- Fábio Franke: Of course. Always consider the inclusion of patients in the studies, if it is necessary at this time, always rethink and prioritize so that safety is not compromised.

- Francisco: I want to know about Dr. Russo, who is in Rio and has another reality in the face of the pandemic, how is it at your center?

- Russo: This is a disruptive moment caused by a virus of 15 genes, the human DNA/genome has 30 thousand genes. A millimetric virus has paralyzed the planet. This disruption also reached clinical research, where many things were already happening, but the pandemic accelerated the processes.

We were already using platforms, but everything came to accelerate the digital process, with monitoring and remote meetings, delivery of medicines in the participant's homes, electronic platforms, and telemedicine. Maintaining the integrity and safety of patients first. This way we will be able to conduct much more research in Brazil.

- Francisco: We managed to get a positive message, that despite everything, we are not locked down.

We are using the moment to accelerate processes. Actually, thinking about accelerating processes, I want



to check with Claudiosvam, because ANVISA created a committee to evaluate what is related to the pandemic. I wanted to know how this is working in practice.

- Claudiosvam: At the beginning of the pandemic it was necessary to create a group of specialists in various areas (registration, inputs, post-registration, biologicals, and research), with the participation of the second board, with Dr. Alessandra, intending to give speed to the demands of COVID.

Then the processes related to COVID give access to this committee via e-mail, initially, and, in parallel, do the legal/administrative procedural formalities requesting the documentation. Thus, upon possession of this document, it immediately begins the analysis of all the areas involved, already listing the doubts and the questions that are also forwarded by e-mail. With the inquiries, we asked to schedule a meeting for clarification. All in parallel to petitioning the documentation.

Thus, within 72 hours after the official petition, there is the possibility of publishing the approval or not of the process. This has been a lot of work, but we have been able to give this rapid response to society and I see this as an opportunity. I believe that we will win after having a new look and agility in processes and the use of available tools to help in the clinical research process.

As new information comes out, we will also update the Technical Note, as in the case of remote monitoring. There will be a lot of important learning and we will leave with a different perspective onto the regulatory processes.

- Francisco: We had a look to not waste time and continue the processes of clinical research. But what is the look to the future? Dr. Russo, what do we gain from all this?

- Russo: I think we will gain agility. Looking also to our end, we have to commit that after the approval of the research we start quickly to include the patients.

Currently, we have two ethical approvals (CEP and CONEP), in parallel to regulatory approval. After all is approved, we have imports of medication, selection of centers, initiation visit, scheduling of the initial visit of patients already with all kits, and medication at the center. This can all be accelerated and advanced with the digitalization of the processes. Doing our homework, which is not to take so long in the logistics of distribution of kits and medications, do things more efficiently and quickly. This will facilitate the arrival of the vaccine for COVID, which I believe we will have in record time.

Claudiosvam, I think your big challenge is to equalize the RDC 9/2015 analysis deadlines (biological, synthetic, immunological, vaccines). We need this.

CONEP also needs to take care of the CEPs with harmonization. Debureaucratize clinical research in Brazil.

- Francisco: Before giving the floor to Claudiosvam to answer us, I would like to hand it over to Dr. Franke, so that he can tell us if we can take good lessons from this moment and what clinical research in Brazil can gain from this scenario.

- Fábio Franke: The experience we have had with fast approvals in regulatory and ethical processes is positive. The challenge will be to maintain agile deadlines, because, as Claudiosvam shared with us, they are making a superhuman effort to maintain this speed.

We also have to think about how we, as a society, as researchers and associations, can help to leave this as an inheritance, so that Brazil can have faster approval deadlines.

Decentralize the actions of CONEP without doubt, delegating powers to local ethics committees. And



with all this, what has already caught my attention is that I have been called to fulfill the feasibility of phase 1 study, which has always been unfeasible precisely because of the approval deadlines we have.

What we want is to leave this as a legacy, so that Brazil has competitive deadlines, so that it is always seen as a potential country to receive protocols of relevance. There is a lot of innovation going on (biologicals, vaccines, advanced therapies) and we must be part of it, so we are fighting for a Bill to harmonize and establish deadlines. But what else can be done and what can we do as a society?

- Francisco: Claudiosvam, without wanting to increase the pressure anymore, I don't think anyone expects the protocols to arrive in Brazil and can be approved in 10 days, as you are doing now, in this effort. But, will it be possible to take advantage of this learning from now on to improve deadlines in the future? Are you already planning to change the regulations?

This moment has favored collaboration, so I also reinforce it: how can we help in this?

- Claudiosvam: Even before the pandemic, we already worked trying to identify what points in the process we could optimize. During the pandemic, we continued working on interactions to identify and improve these points. From this background, we have identified that we have devoted a great deal of time to the quality analysis of the experimental drug, we have found an opportunity to improve this process of DDCM quality analysis specifically, which is important and relevant and takes a reasonable amount of time.

With this, we published a service order (OS 69/2019) to establish flexible conditions, but we realized that this OS was still restrictive, not generating the expected positive result. Therefore, we are resuming this OS to try to improve and optimize the process, creating other conditions for recognition, for example, of experimental drugs that already have been recognized by some agency, we are studying which would be the appropriate agencies.

At this moment in the discussion, we have some proposals and we have held meetings with the sector (Sindusfarma, Interfarma, and sponsors).

Our focus, at this time, is to invest in improving and optimizing this part of the DDCM (quality) to make it more flexible, of course not to generate a free pass, but to make it more flexible for the analyses to be focused on the clinical protocol, on the safety of research participants and the quality of the research. Very soon we will have this OS reviewed, which will result in a significant reduction in time.

We actively participated in the discussions on Bill No. 7082. There were many interactions to reach the proposed deadlines. We believe that we can go a long way and improve the deadlines even more.

- Francisco: It makes sense, from the perspective of dedicating more time and energy to higher risk protocols, which have passed through a finer sieve, without prior analysis by other agencies. It's an excellent idea.

- Claudiosvam: Exactly. Previously, we talked about what could be done to increase the attractiveness of Brazil in clinical research and national development. I left with the impression that it is a consensus that national clinical developments are important and need to be encouraged and stimulated. National research still needs to mature, and we are willing to help and contribute to that. Today, these developments are included in the RDC with a longer period of analysis.

Dr. Franke mentioned greater feasibility in phase I studies; we have a very big effort to bring these initial studies to Brazil. Perhaps this search is a response to our investment with sponsors, giving alternatives



for these studies to actually start coming to Brazil. Currently, phase 3 studies correspond to almost 80% of the studies we have in the country, we want to keep them and increase the studies in early phases.

- Francisco: Perfect. It is very good to hear this information from the source responsible for making, thinking, and discussing. It gives us a lot of hope.

I want to ask, in the final round of each one, to say what we need to do to be prepared for this future?

- Fábio Franke: To train ourselves for this future that has already begun.

We need to be competent to send the documents correctly so that the processes can be more agile so that the analyses that we want to confer celerity can be done calmly. I have already participated in protocols that the study did not open. And this did not happen because of ANVISA, but because of the sponsors or the CROs, who got in the way when the documentation package was made.

I am happy and can say “yes” to Claudiosvam. I believe that the feasibility of phases is already the answer to these actions, and we have to surf this wave.

It will be a legacy of this technology to reduce distances and physical displacements. And from what I see through the Clinical Research Alliance, that we have a network of clinical research centers throughout Brazil to access patients with greater need.

Electronic processes to be agile (contracts, consent form, meetings, center activation, monitoring) and to direct energy to what is an essential evaluation of the research.

It's going to be a great learning experience, we now have tools. A short time ago, we would have barriers to training or remote monitoring. That's the future now, the new normal. And from that, we will establish new rules and processes. Without a doubt, this will modernize Brazil's access and make us get in touch with groups of researchers all over the world, with exchanges of experiences.

We have to remain focused to obtain the approval of Bill no. 7082 by Congress so that we have a regulatory framework in Brazil with very clear rules. At the same time, we need to work on improving our deadlines. Thus, we will be, soon, talking about many studies that will come to the country.

- Russo: Dr. Franke has approached this part of digital life very well.

I think it's important to talk a bit about numbers, 80% of the research in the world is conducted by developed countries (the USA and Europe). Brazil, unfortunately, has not participated since the beginning of the ICH and created CONEP. Therefore, Brazil conducts between 1 and 2% of the surveys. We need to get out of this situation. We have qualified professionals, with ethical/scientific behavior and trained in good practices throughout Brazil.

At this moment, we need better-trained ethics committees, a decentralization of the system that gives autonomy and stimulus for ethics committees to work independently, under less supervision by CONEP. At the time of the creation of CONEP in 1996, there were regional CEPs and everything went wrong, some approved the study and CONEP disapproved. Therefore, the creation of the regional CEPs is to go back to the past which did not work out. It has to decentralize the system; the CEP cannot be a “mere dispatcher”.

There are 2 key points:

First - the access to post-study drugs. It is not possible that every trial forces expanded access to drugs, this keeps the research away from Brazil. In other countries, this does not exist as an obligation.



Second - the use of a placebo. We know that the FDA requires the use of placebo in many studies and when the study arrives in Brazil, CONEP says it can not have a placebo in the study. This dichotomy of speaking a different language from the world is what puts Brazil in this situation (19th country in the rank of clinical research capacity, with Brazil being the 7th pharmaceutical market in the world).

- Francisco: Yesterday, in this Week of Clinical Research, we had the opportunity of an exchange with CONEP, in which Dr. José Henrique proactively mentioned a necessary integration with ANVISA, to improve the analysis of the processes. Let's root for that.

- Claudiosvam: What we need to do is to be together more and more and think together about these improvements.

It is no longer possible for regulators and ethical agencies to work in isolation.

ANVISA has given openness to discussions and I believe that this is the way for us to elaborate, with contributions, norms that communicate with reality. I believe that we have room for improvement. The question of decentralization of studies is also very important, we have centers and researchers trained throughout Brazil and, even today, we have between 70% and 80% of studies in the South-Southwest axis.

The regulatory issue is also not the only issue related to the lack of attractiveness of clinical trials in Brazil. Being competitive within the time frame is determinant, but it is necessary to list all the points raised in the feasibility, regulatory part, and deadlines.

- Rosana: I was thinking that this meeting is the last one of this Clinical Research Week and I don't have words to thank all this exchange and contributions. We will leave important and necessary lessons for the improvement of research in the country.



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