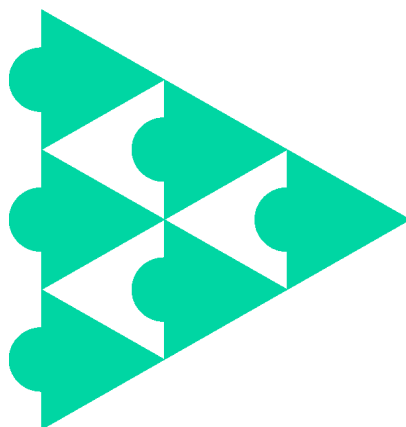


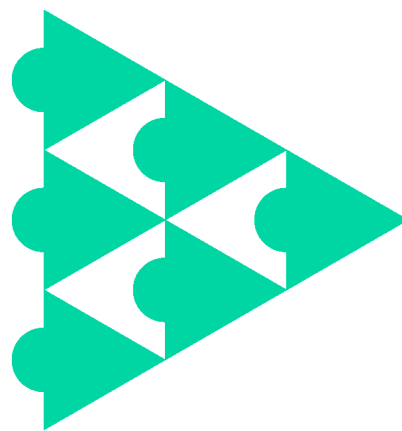
MINISTRY OF HEALTH OF BRAZIL

ACTION PLAN FOR  
**CLINICAL  
RESEARCH**  
IN BRAZIL



MINISTRY OF HEALTH OF BRAZIL  
Secretariat of Science, Technology, Innovation and Health Strategic Inputs  
Department of Science and Technology

ACTION PLAN FOR  
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2020 Ministry of Health of Brazil.



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# LIST OF ABBREVIATIONS AND ACRONYMS

- Abrasco** – Brazilian Association of Collective Health
- Anvisa** – Brazilian National Agency of Sanitary Surveillance
- APPMS** – Agenda of Research Priorities of the Ministry of Health of Brazil
- BNDES** – Brazilian Development Bank
- GCP** – Good Clinical Practice
- CAT** – Technical Council for Advanced Therapies
- CEP** – Research Ethics Committee
- CIS** – Health Industry Complex
- CNS** – Brazilian National Health Council
- Conep** – National Research Ethics Commission
- CNCD** – Chronic Non-Communicable Diseases
- CRO** – Contract Research Organization
- DDCM** – Drug Clinical Development Dossier
- Decit** – Department of Science and Technology
- DICD** – Medical Device Clinical Investigation Dossier
- DL** – Distance Learning
- Fiocruz** – Oswaldo Cruz Foundation
- Gfarm** – Pharmacovigilance Management
- HCor** –Heart Hospital
- ICF** – Informed Consent Form
- ICH** – International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
- ICT** –Institute of Science and Technology
- Inca** – Brazilian National Cancer Institute
- MoH** – Ministry of Health of Brazil
- PIDM** – Program for International Drug Monitoring
- Proadi-SUS** – Institutional Development Support Program of the Unified Health System
- RDC** – Board Resolution
- RD&I** – Research, Development and Innovation
- Rebec** – Brazilian Clinical Trials Registry
- RNPC** – Brazilian National Clinical Research Network
- SCTIE** – Secretariat of Science, Technology, Innovation and Health Strategic Inputs
- SIM** – Information System on Mortality
- SUS** – Unified Health System
- UMC** – Uppsala Monitoring Center

# TABLE OF CONTENTS

- PRESENTATION.....6**
- INTRODUCTION.....9**
  - The Clinical Research Scenario in Brazil.....9
- THE CONSTRUCTION OF THE ACTION PLAN FOR CLINICAL RESEARCH IN BRAZIL.....17**
  - Situational Diagnosis.....17
  - The Process of Building Actions.....24
- THE ACTION PLAN.....26**
  - General Purpose.....26
  - Specific Purposes.....26
  - Axes.....26
  - Action Axis 1 – Ethics Regulation.....27
  - Action Axis 2 – Sanitary Regulation.....28
  - Action Axis 3 – Scientific and Technological Development.....29
  - Action Axis 4 – Qualification in Clinical Research.....30
  - Action Axis 5 – Brazilian National Clinical Research Network – RNPC.....31
  - Action Axis 6 – Knowledge Management.....32
- REFERENCES.....33**
- ANNEX – GM/MOH ORDINANCE NO. 559, DATED MARCH 9, 2018.....38**

# PRESENTATION

As a part of its mission to coordinate health science and technology actions to subsidize public policies; promote technologies that improve the health of the Brazilian population; and articulate the roles of players in the Health Science, Technology, Innovation System aiming at the development of researches that fulfill the principles and guidelines stipulated by the Unified Health System (SUS), the Science and Technology Department (Decit) of the Secretariat of Science, Technology, Innovation and Health Strategic Inputs (SCTIE) of the Ministry of Health of Brazil (MoH) elaborated this Action Plan for Clinical Research in Brazil, created through GM/MoH Ordinance no. 559, dated March 9, 2018 (BRASIL, 2018a).



THE PURPOSE OF THIS PLAN IS TO INCREASE BRAZIL'S ABILITY OF DEVELOPING AND ATTRACTING CLINICAL RESEARCHES THROUGH ACTIONS AIMED TO:

- 1 Improve the system of ethical analysis in researches involving humans (CEP/Conep).
- 2 Support the Brazilian National Agency of Sanitary Surveillance (Anvisa) in the improvement of the sanitary regulatory system for clinical research.
- 3 Promote the scientific installed capacity in the area.
- 4 Promote the continued education of human resources.
- 5 Improve the governance in the Brazilian National Clinical Research Network (RNPC).
- 6 Support the transference of knowledge to managers, research participants and to the population in general.

IN THE PROCESS OF STRUCTURING THE ACTION PLAN, DECIT LISTENED TO SEVERAL STRATEGIC PLAYERS, OBTAINING A DIAGNOSIS OF THE SITUATION BY IDENTIFYING THE GAPS THAT HINDER THE CLINICAL RESEARCH DEVELOPMENT IN BRAZIL, FURTHER RECEIVING CONTRIBUTIONS FROM POSSIBLE ACTIONS CAPABLE OF CHANGING THIS SCENARIO. THE RESULT OF THESE DISCUSSIONS WAS USED AS THE BASIS FOR THE PRODUCTION OF THE PRESENT DOCUMENT, WHICH ADDRESSES THE CLINICAL RESEARCH SCENARIO IN BRAZIL, FOR THE PROCESS OF ELABORATING THIS PLAN, AND FOR THE EXPOSURE OF PURPOSES, STRATEGIC ACTIONS AND ACTIVITIES RELATED TO SIX AXES:

**1**  
**ETHICS  
REGULATION**

**2**  
**SANITARY  
REGULATION**

**4**  
**QUALIFICATION  
IN CLINICAL  
RESEARCH**

**5**  
**BRAZILIAN  
NATIONAL  
CLINICAL  
RESEARCH  
NETWORK  
(RNPC)**

**3**  
**SCIENTIFIC AND  
TECHNOLOGICAL  
DEVELOPMENT**

**6**  
**KNOWLEDGE  
MANAGEMENT**





# ACTION

The activities were planned for short, medium and long-term development, being focused on the Decit responsibilities. However, it should be stressed that this document is a flexible, dynamic instrument, whose actions may be adapted according to the particulars and needs of the Brazilian clinical research sector, as well as that, for attaining its purposes, the involvement and active participation of all strategic players are crucial.

In addition to being a historical record of the clinical research overview in Brazil, of the challenges faced in the area for its full development and of the governmental strategies to face these issues, the present document also seeks to honor the achievements made, keeping the commitment to the transparency of our actions and making this Action Plan a state response.

DEPARTMENT OF SCIENCE  
AND TECHNOLOGY



# INTRODUCTION

## THE CLINICAL RESEARCH SCENARIO IN BRAZIL

Clinical research is that conducted in humans with direct or indirect researcher-patient interaction, which includes the management of their data and/or biological material. Clinical research types encompass studies on the development of diseases (etiopathogenesis); translational researches; studies on the clinical knowledge, detection, diagnosis, prognosis, and natural history of diseases; epidemiological studies; therapeutic interventions, including clinical trials of drugs, biological products, devices, and instruments; (primary and secondary) prevention and health promotion studies; and behavioral researches and researches for the assessment of health services, including cost effectiveness studies (UNITED STATES OF AMERICA, 2019a; PAULA *et al.*, 2012).

All of these researches are crucial to respond to issues related to the health promotion, cause, prevention, diagnosis, treatment and impact of diseases on health services and on society. The set of these researches contributes even more to the economy of the country and to the sustainability of SUS, making it ready to respond to future challenges related to the health of the population. In this perspective, clinical research has been understood as a strategic vector for the health sector development (DAINESI; GOLDBAUM, 2012) through a joint accountability by the government, education and research institutions, and the productive sector for the development of new technologies aiming to improve the quality of life of the population.

ACCORDING TO ZAGO (2004), CLINICAL RESEARCH HAS A STRONG POTENTIAL TO CONTRIBUTE TO AND INFLUENCE THE ELABORATION OF PUBLIC POLICIES AND THE SOLUTION OF CONJUNCTURE PROBLEMS IN BRAZIL. SIXTEEN YEARS AFTER THE PUBLICATION OF THE ABOVEMENTIONED ARTICLE, THE PROBLEMS MENTIONED BY THE AUTHOR REMAIN CURRENT, AMONG WHICH:



1

The increasing demand for new health products and services, arising from the population aging and from the quick technological innovation in the areas of diagnosis, treatment and rehabilitation of patients with chronic diseases.

2

The persistence of social inequalities, which are reflected in the quality of life and health, contributing to the prevalence of infectious diseases and poverty-related issues, such as the lack of sanitation.

3

The need for streamlining the use of financial resources available to the health sector.

4

The increasing importance of the aggravations arising from or associated with urbanization and industrialization, such as violence, accidents, and alcohol and drug abuse.

5

The need for improvement of the Health Industry Complex (CIS), with technological independence and participation in efforts related to export and economic strengthening of Brazil.

Among all topics mentioned above, the last one should be highlighted as a fundamental pillar for SUS to be understood as an inducer and sponsor of economic development and social wellbeing, with capacity to respond to its own demands. Therefore, it is important to stimulate and support the CIS development for the consolidation of a health innovation system and the constitution of a competitive industry at international level, considering the demographic and epidemiological profile of the Brazilian population.

The demographic, nutritional and epidemiological transitions in Brazil have resulted in an increase of Chronic Non-Communicable Diseases (CNCD), though Brazil presents a triple burden of diseases represented by the coexistence of the CNCD, infectious and parasitic pathologies, and aggravations caused by external and preventable causes (MENDES, 2010). As a worsening factor, disease burden studies have been pointing out that the increase in the life expectancy is not being followed by a proportional increase in the healthy life expectancy, resulting in years lived with disabilities and chronic diseases (JAMES *et al.*, 2018; MARINHO; PASSOS; FRANÇA, 2016; LEITE *et al.*, 2015; SALOMON *et al.*, 2012; SCHRAMM *et al.*, 2004).

The fragility of health promotion, prevention, and clinical control strategies in relation to these diseases favors the yearly occurrence of more than one million hospitalizations processed by SUS, which demand resources estimated in R\$ 1.8 billion (BRASIL, 2011b). This situation gives rise to the need for promoting a reorganization in assistance of SUS, significantly affecting expenses incurred with health (MENDES, 2010). This scenario presents some factors responsible for the worsening in the health system crisis, which can be overcome by increasing the attraction of investments in clinical researches.

The study that investigated the research involving humans in Brazil between 2007 and 2012 (SILVA *et al.*, 2015) identified that most clinical studies approved in this period were related to the main causes of death registered in the Information System on Mortality (SIM), CNCD like diabetes, cancer, cardiovascular diseases and respiratory diseases. In general, researches on the treatment of chronic diseases involve high-cost drugs and are mainly financed by pharmaceutical industries. On the other hand, neglected diseases and infectious and parasitic diseases were the less studied ones, being primarily financed by the government. The lack of research on poverty-related diseases generates a small number of therapeutic innovations in this area. A similar result was found by Santana and Leite (2016) between 2012 and 2015, regarding the management

report of the Clinical Research Coordination of Anvisa (AGÊNCIA..., 2018a) for 2017. According to this document, the main diseases investigated by the studies approved by the Agency are related to comorbidities of global importance, mostly tumors (40%).

Researches of national scope (SANTANA; LEITE, 2016; SILVA *et al.*, 2015) found a trend of increase in the participation and conduction of multicenter clinical trials of international cooperation under the surveillance of international institutions. However, this increase was lower when compared to that of other countries with a similar economic development level, like South Africa, India, Russia, and China. Nonetheless, Brazil has consolidated itself as the main clinical research reference in Latin America (GOMES *et al.*, 2012).

The internationalization of clinical research to other emerging countries gave rise to the possibility of Brazil becoming a part of the drug development chains, however in stages of lower density and technological risk (GOMES *et al.*, 2012). Reproducing clinical protocols elaborated in international research centers is a characteristic of emerging countries, and its consequence is a preponderant development of phase-III studies (AGÊNCIA..., 2018a; VIEIRA *et al.*, 2017; SANTANA; LEITE, 2016; SILVA *et al.*, 2015). As a result, Brazil has a low capacity of producing innovation and responding to its own demands.

Initial stage researches, especially those of phase I, involve a higher knowledge and technological infrastructure, being focused in countries where the headquarters of large-sized pharmaceutical companies are located (AGÊNCIA..., 2018a). The elaboration of clinical protocols for phase-I studies is complex due to the difficulty of determining the causality of adverse effects (GOMES *et al.*, 2012). A report published by the Brazilian Development Bank (BNDES) on clinical trials in Brazil highlights that this stage involves a higher technological challenge due to requiring specific training by the researcher to identify and manage adverse events, in addition to an exclusive infrastructure, since the examinations necessary for the monitoring of the volunteers differ from those available in the assistance network (GOMES *et al.*, 2012).

The description of the clinical research scenario in Brazil can be supplemented through data provided in the report of activities of Anvisa (AGÊNCIA..., 2018a), according to which, in 2017, 71 Drug Clinical Development Dossiers (DDCM) were authorized. Out of these, 65% were related to biological drugs, 49% were already registered with a regulatory agency (Anvisa or other international authority), and 16.9% included pediatric formulations in their development.

The development of these studies occurs in an uneven way in Brazil, being predominantly concentrated in the Southeast and in the South (AGÊNCIA..., 2018a; SANTANA; LEITE, 2016; SILVA *et al.*, 2015; ZUCCHETTI; MORRONE, 2012; ZAGO, 2004), which demonstrates the inequality of infrastructure and reveals the need for reducing such geographic unbalance to stimulate the development of this sector in the country (ZAGO, 2004). To illustrate this unequal concentration of the installed capacity in clinical research, in a survey carried out in 2013 by a multinational company responsible for supporting the planning of clinical trials, the city of São Paulo appeared in the 9th place among the cities with the larger number of clinical

trial poles in the world. However, in relation to the number of studies developed, the capital of the state of São Paulo is placed 57<sup>th</sup> (SAÚDE BUSINESS, 2013).

According to BNDES (GOMES *et al.*, 2012), the choice of a country to participate in a clinical trial and, thus, its competitiveness in relation to other countries, is based on criteria like the quickness in the recruiting of patients, costs, infrastructure, personnel qualification, product commercial potential, and ethical-regulatory environment. This last aspect was pointed out by BNDES as one of the most fragile ones, concluding that the average of approval terms is still higher than those identified in other countries, though the regulation for clinical research in Brazil adheres to the international legislation both from the ethical and sanitary perspectives, especially due to the acceptance of Anvisa as a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (GENEVA, 2016; AGÊNCIA..., 2016). The ethical and regulatory environment and the incipient infrastructure for phase-I and phase-II tests are challenges to the strengthening of this sector in Brazil.

Other publications highlighted the following aspects affecting the clinical research development: insufficient qualification of health professionals in clinical research, specially from the medical field; distant relationship between universities and the pharmaceutical industry (ZAGO, 2004); need for qualifying researchers on the conception and design of clinical trials (GOMES *et al.*, 2012); and lack of harmonization in the ethics assessment process by CEPs, whose members lack in updates on Bioethics, Biostatistics, Biobanks, Biorepositories, and Clinical Research topics.

Other aspects mentioned are the current fragile legal standardization for Clinical Research in Brazil, exclusively formed by non-statutory norms (BARBOSA; FRANCISCO; MARTINEZ, 2018); redundancy in the assessment of studies classified as special thematic areas, i.e., double analysis of these protocols by the CEPs and by the National Research Ethics Commission (Conep) (GOMES *et al.*, 2012); the bureaucracy in the regulatory authorities (RIZZO; CAMARGO, 2013); and lack of a legislation establishing a legal security for the conduction of clinical researches in the country.

In Brazil, the norms for the analysis of ethics are non-statutory, within the scope of the Brazilian National Health Council (CNS). According to the players involved in clinical research, this scenario undermines

the sponsor of the study, the researchers and the research participants, because of the lack of a legally binding rule to regulate all processes and ethical requirements for clinical research. Since 2015, this discussion has been resumed through the proposal of a Bill, currently pending as Bill no. 7082/2017, which provides for the regulation of clinical research in humans and creates the Brazilian National System of Ethics for Clinical Research in Humans.

Despite the undermining points mentioned above, developments by the regulatory authorities through ongoing efforts to improve and streamline the process of clinical research approval in Brazil should be acknowledged. Regarding the ethics regulation, according to data from management reports by Conep and their administrative bulletins (CONSELHO NACIONAL DE SAÚDE, 2018), there is no waiting list for ethics analysis anymore, i.e., all research protocols referred monthly for deliberation by the Commission have their rulings issued within 25 days, in average.

REGARDING THE SANITARY REGULATION, THE ADHESION OF ANVISA AS A MEMBER OF ICH, IN 2016 (AGÊNCIA..., 2016), DEMONSTRATES THE COMMITMENT OF THE AUTHORITY IN ALIGNING THE BRAZILIAN LEGISLATION WITH THE BEST INTERNATIONAL PRACTICES. THE PUBLICATION OF THE FOLLOWING RESOLUTIONS BY THE BOARD RESOLUTION (RDC) CAN BE FURTHER MENTIONED:

14

**RDC no. 9, dated February 20, 2015 (BRASIL; AGÊNCIA..., 2015a):**

Provides for the regulation for the conduction of clinical trials involving drugs in Brazil. It harmonized the Brazilian legislation with the international guidelines for clinical research involving drugs and defined fixed terms for Anvisa to assess the DDCMs, promoting higher agility in the analyses made by the Agency.

**RDC no. 10, dated February 20, 2015 (BRASIL; AGÊNCIA..., 2015b):**

Provides for the regulation for the conduction of clinical trials involving medical devices in Brazil. It harmonized the Brazilian legislation with the international guidelines for clinical research involving medical devices and defined fixed terms for Anvisa to assess the Medical Device Clinical Investigation Dossier (DICD), promoting higher agility in the analyses made by the Agency.

2015

**RDC no. 172, September 8, 2017 (BRASIL; AGÊNCIA..., 2017a):**

Provides for the procedures required for the import and export of goods and products destined to scientific or technological research and to research involving humans, among other provisions. In this case, article 25 should be highlighted, according to which “imports destined to expanded access programs, compassionate use, and drug supply after study and clinical trials and whose purpose is to register or change the register of the product in Brazil should be analyzed within five days of the protocol and fulfillment of the legal requirements”. Therefore, a definition and reduction in the time used in import procedures are reached.

**RDC no. 204, dated December 27, 2017 (BRASIL; AGÊNCIA..., 2017b):**

Provides for the classification of applications for registration, post-registration and prior consent in clinical research involving drugs in the priority category. This signaling of priority category started being performed alongside the entry of applications in the electronic system of Anvisa, which eliminated stages in this process. It further stipulated an order of priority and importance for the evaluation of the applications, promoting higher agility in the procedure.

**RDC no. 205, dated December 28, 2017 (BRASIL; AGÊNCIA..., 2017c):**

Establishes a special procedure for consent in clinical trials, good manufacturing practice certification and registration of new drugs for treatment, diagnosis, or prevention of rare diseases. Besides, it exempted the presentation of the CEP opinion to Anvisa for obtaining consent for clinical protocols and subsequent amendments.

**RDC no. 208, dated January 5, 2018 (BRASIL; AGÊNCIA..., 2018a):**

Provides for the simplification of procedures for the import of goods and products subject to the Sanitary Surveillance. Extinguished the requirement of documents that companies could only obtain after the arrival of the related cargo in Brazil, which used to generate storage costs and increased the final price of the products.

**RDC no. 214, dated February 7, 2018 (BRASIL; AGÊNCIA..., 2018b):**

Provides for the Good Practice for Human Cell Therapy and clinical research. This Resolution established rules for technical and quality standards for the processes of obtaining, processing and supplying human cells for use in clinical research and therapies, filling a gap in the Brazilian regulation, which did not provide for specific norms encompassing procedures required for research and development of advanced cellular therapies. Therefore, a regulatory environment favorable for this type of research was created, harmonized with the international standard.

**RDC no. 260, dated December 21, 2018 (BRASIL; AGÊNCIA..., 2018c):**

Provides for the rules for the conduction of clinical trials using advanced therapy investigational products in Brazil. Supplemented RDC no. 214/2018, stimulating the development of this type of research in Brazil to enable its future registration by the Agency.





At the same time, it should be highlighted that Brazil has a potential to attract clinical researches due to its broad and diversified population; to the existence of a public health system, which facilitates the recruiting of patients and their monitoring; to the high incidence of diseases that are more prevalent in developed countries; to the existence of ethical research norms that are compatible with the ones of other countries, of qualified personnel and of a good infrastructure of hospitals and reference centers for clinical trials of phase III. These centers can present smaller costs than those of traditional institutions abroad (GOMES *et al.*, 2012; ZUCCHETTI; MORRONE, 2012).

Considering all strengths and weaknesses, opportunities and threats to the full development of clinical research in Brazil, the countless direct and indirect benefits that this sector brings to Brazil, currently and in the future, are undisputed. In addition to the innovation in health, the investment in clinical research stimulates the generation of jobs, the qualification of human resources, the access by patients to innovative treatments, and the support to decision makers aiming at the incorporation of technologies that have the best cost effectiveness. Therefore, clinical research is an area of interest for patients, the government, the public and private manufacturing sectors, and for the whole society.



# THE CONSTRUCTION OF THE ACTION PLAN FOR CLINICAL RESEARCH IN BRAZIL

Since the event *Fórum Pesquisa Clínica no Brasil: competitividade internacional e desafios* (Forum Clinical Research in Brazil: international competitiveness and challenges), considered the starting point of discussions, held on October 25, 2016, until the meeting to validate the planned actions together with the players involved in the area, Decit arranged ten meetings in nine months. This participative character acquires even greater proportions when considering all events in which the Department took part to disclose and present the Plan. These moments were crucial not only to disseminate the work developed, but to rethink strategies, redirect efforts and, mainly, prospect partnerships. The Department works from the perspective that the change to the current clinical research scenario and the overcoming of faced challenges will only be possible through joint efforts to be made by the concerned sectors.

## SITUATIONAL DIAGNOSIS

When organizing the Forum, the MoH sought to start the work in situational diagnosis by listening to the different sectors involved in clinical research: researchers, clinical research centers, representatives of the pharmaceutical industry and representatives of the organized civil society. This survey was continued at other meetings separately held with the participation of each of these players, in addition to the regulatory authorities for research and development agencies, aiming at reaching a consensus.

CAREFULLY LISTENING TO DIFFERENT VIEWS ON THE ISSUE, REFERRING TO THE LITERATURE AVAILABLE AND TO THE ETHICAL AND REGULATORY NORMS AND LEGISLATIONS IN FORCE MADE POSSIBLE FOR DECIT/SCTIE/MOH TO LIST THE FOLLOWING TOPICS THAT ARE CRITICAL FOR THE FULL DEVELOPMENT OF CLINICAL RESEARCH IN BRAZIL:

1. Slowness in the ethics analysis by the CEP/Conep System.
2. Lack of harmonization in the analysis of research protocols by the CEPs.
3. *Plataforma Brasil* (Brazil Platform) has a deficient operational interface, not allowing the interoperability between databases, a difficult updating of normative rules in force, and few functionalities that meet all of its users' needs.
4. Administrative processes at Anvisa are marked by multiple overlapping stages, from the submission for consent in clinical research protocols to the product registration.
5. Slowness in the processes of import of investigational products for clinical research.
6. Lack of harmonization between the ethics and sanitary guidelines and normative rules.
7. Public funding of clinical research with exclusively academic purposes and with a low potential for generating innovative health products, processes, or services.
8. Deficient interaction between the government, Science and Technology Institutes (ICTs), and the productive sector for the conduction of clinical trials.
9. Low productive and innovative capacity in the area of drugs in the country.
10. Existence of few clinical research centers with proper infrastructure.
11. Lack of proper qualification of human resources at Clinical Research Centers and universities on ethics and sanitary regulation, quality management, data and sample management, Good Clinical Practices (GCP) and on the coordination of clinical trials.
12. RNPC management undermined the attainment of its full potential.
13. Lack of actions directed to the Knowledge Translation that allow that evidences generated in Clinical Research be effectively disseminated to the public and implemented by the health managers.

The topics related to the ethics regulation in Brazil were pointed out as the most concerning ones by all consulted players, especially due to the slowness in the ethics analysis of research protocols by the CEP/Conep System. This issue is related to the existence of a double analysis of protocols classified as of special thematic areas (GOMES *et al.*, 2012), by the CEPs and by Conep and to the high asymmetry in the infrastructure, capacity and quality of analysis of the more than 800 CEPs operating throughout Brazil.

According to a Conep bulleting (CONSELHO NACIONAL DE SAÚDE, 2018), the average time required for the analysis of protocols by the Commission is 25 days, which demonstrates that the System's bottleneck is the analysis performed by the CEPs. On the other hand, there is an expectation that the double analysis be extinguished when Resolution no. 506, dated February 3, 2016 (CONSELHO NACIONAL DE SAÚDE, 2016), related to the process of CEP accreditation, starts being applied to promote the strengthening of the System's decentralization. However, it is understood that the accreditation will not be sufficient to promote the System agility without there being a higher harmonization of the ethics analysis by the CEPs.

The higher agility in the processing of research protocols by the CEP/Conep System may further be achieved through the improvement of the operating efficiency of Plataforma Brasil. It is undeniable that the creation of this platform was an important step in the obtainment of transparency and agility in the ethics assessment process; however, it is also important to recognize that there are challenges to be overcome in relation to its operation and interface (MATOS, 2012).

According to Loretto (2012), the current Platform should have been built with an intelligent data basis, capable of supplying real-time information on the reality of research in Brazil, with functionalities meeting the needs of all of its users and in compliance with the related normative rules. Pointed out since the construction of the current version of Plataforma Brasil, these issues were not controversial among the players consulted in the process of building the Plan.

In relation to the sanitary regulation, the aspects surveyed in the situational diagnosis regarding the issue are regulated by acts, decrees and resolutions (BRASIL, 1999). Therefore, on what concerns the operation of the MoH in relation to these obstacles, though it plays an important role as articulator, its potential of operation is very limited. Nevertheless, Decit has been seeking to open dialogue channels with Anvisa.



Regarding the slowness of the importing process of products for research, although the cause is not multifactorial and the legislation of the Agency is not one of its factors, the developments obtained in the area with the publication of RDC no. 172/2017 (BRASIL; AGÊNCIA..., 2017a) and RDC no. 208/2018 (BRASIL; AGÊNCIA..., 2018b) should be highlighted. On April 20, 2018, the Agency published a note (AGÊNCIA..., 2018b) informing that the electronic form of request of imported goods in the Siscomex System was changed, allowing the selection of a field called *Condições Especiais* (Special Conditions). There is a list of the criteria used to prioritize the analysis of imported products therein, among which there is a specific item for the import of products for clinical research, compassionate use and expanded access considering an estimate of up to five days as per Art. 25 of RDC no. 172/2017 (BRASIL; AGÊNCIA..., 2017a). Therefore, more objective rules were defined to reduce the time required for import procedures.

In addition to the RDCs related to the import process, the Agency rendered other Resolutions that aimed at promoting higher agility in the analyses of the requests for consent in clinical protocols: RDCs no. 9/2015 (BRASIL; AGÊNCIA..., 2015a) and no. 10/2015 (BRASIL; AGÊNCIA..., 2015b), which defined fixed terms for Anvisa to assess the DDCM and DICD; RDC no. 204/2017 (BRASIL; AGÊNCIA..., 2017b), which established an order of priority and importance for the assessment of requests; and RDC no. 205/2017 (BRASIL; AGÊNCIA..., 2017c), which established a special procedure for the consent in clinical trials involving rare diseases, among other provisions.

The regulation of advanced therapy products (which encompasses the cellular therapy products, tissue engineering products, the gene therapy products), with the promulgation of RDC no. 214/2018, may be further listed as an important development by Anvisa, that established the technical and sanitary requirements for the cycle of production of cells and advanced therapy products for clinical research and therapeutic use. In December of the same year, RDC no. 260/2018 (BRASIL; AGÊNCIA..., 2018c) was published, defining the procedures and regulatory requirements for the conduction of clinical trials involving advanced therapy investigational products in Brazil, whether for registration or scientific research only.

Regarding the management of processes by Anvisa, since the Agency adhered to ICH, some procedures will be harmonized with the international guidelines. Further on this subject, the adoption of Vigimed in December 2018 may be mentioned. It is a new system for the registry management, processing and sharing of adverse events related to drugs and vaccines resulting from a partnership between the Pharmacovigilance Management (Gfarm) of Anvisa and the Uppsala Monitoring Centre (UMC). This Center is responsible for the operationalization of the Program for International Drug Monitoring (PIMM) of the World Health Organization (WHO) since 1978, supporting the development of pharmacovigilance systems in several countries that adhered to the program, including Brazil. The notifications provided by Brazil will contribute to the monitoring of the safety of drugs at global level, alongside the adverse events informed by more than 120 countries.

Considering all initiatives previously mentioned and led by Anvisa, the effort made by the Agency to improve the legal framework to make the regulatory environment more attractive and

competitive for the conduction of clinical trials should be highlighted. It is also important to stress that these measures are recent – some of them are still in the stage of implementation and lack the required time for their effects to be noticed by the regulated sector.

Though the aspects related to the ethics and sanitary regulation in Brazil are the ones that affect the most the stimulation to innovation and to the attraction of investments for clinical research in the country, there are other contributing factors, such as: (a) the small number of researchers with expertise to design and conduct clinical researches; (b) the lack of the proper infrastructure for the promotion of the research translation from basic research into clinical stages; and (c) the regional differences in the existing scientific capacity in Brazil. Concerning this last topic, the South and Southeast concentrate the most specialized intellectual capital in the area, the financial resources, the infrastructure, and the graduate and professional qualification programs in clinical research. Thus, the standards of knowledge offering essentially organize the Brazilian science and technology system (GUIMARÃES, 2013).

Regarding the qualification of human resources and researchers in clinical research, it should be stressed that, numerically and qualitatively, it is still critical (ZAGO, 2004). Consequently, most researches carried out in Brazil, excepting those financed by industries, are strictly academic, are not aligned with the legislations for consent in clinical trials and product registration, have a low potential for generating products, and promote an insufficient interaction between the productive sector and the academy. According to Zago (2004), only 10% to 20% of the circa 9,500 physicians yearly graduated in Brazil are in contact with the medical research system. To stimulate the qualification of professionals in the area, is crucial not only to qualify future researchers, but to promote the training of health professionals for the understanding and application of research results. Players consulted by the Department identified the need for promoting training programs in: quality management, project management, data management, ethics and sanitary systems, new clinical study designs, statistical methodology applied to clinical trials, development of drugs with a focus on non-clinical studies.

Health professionals often are the link between the research participants and the research team in an institution. The dissemination of knowledge to this group can enhance the qualification of professionals in the area of clinical research and promote knowledge on the benefits of the technology being tested before its incorporation into the services. Therefore, the probability of the research results being applied to the population, with a stimulus to the use of evidence in the decision making, is increased. The latter is also applicable to the managers, who should be able to recognize the importance of research for society in general.

The need for promoting knowledge translation in clinical research for managers, health professionals and for the general population was unanimously pointed out by all consulted players as a priority among the gaps to be mitigated. They highlighted the importance of researches having patients better informed on their role, in addition to having a clear Informed Consent Form (ICF). Disseminating clinical research knowledge to the general society can, moreover, facilitate the recruiting of patients.

While thinking about the obstacles to the development of clinical research in Brazil, one should keep in mind that the phase-III clinical trial is the most common type of research submitted for Anvisa's consent (AGÊNCIA..., 2018a), involving the most qualified Brazilian researchers.

Though it is an important stage for the promotion of the training of professionals and for the development of research in the country, it involves a lower applied knowledge. Most phase-III trials and experienced researchers in this stage are closely related to the installed infrastructure capacity for clinical research in Brazil.

According to a report published by BNDES (GOMES *et al.*, 2012), the country has a good infrastructure of hospitals and reference centers for phase-III clinical trials. On the other hand, when it comes to phases I and II, it was identified that they correspond to less than 30% (UNITED STATES OF AMERICA, 2019b) of the clinical trials carried out in Brazil, as per the records of the platform ClinicalTrials.gov. This situation can be explained by the small number of professionals highly qualified to design, plan and conduct clinical research protocols following the ethics and sanitary regulatory process and to the small number of institutions having proper infrastructure to conduct this type of study (GOMES *et al.*, 2012).

The infrastructure deficiency for phase-I and phase-II studies was also reported by the key players consulted, who further mentioned the need for promoting improvements in the entire Research, Development, and Innovation (RD&I) chain. Therefore, other issues identified as critical in this process include the deficiency of structures for the production of pilot batches for research and the fact that some clinical research centers depend on public funds to operate. It should be stressed that the most developed countries in RD&I are those who have stimulated the interaction between the government, ICTs and the productive sector. This is one of the major challenges in Brazil.

Studies have been indicating that this interaction is growing, however more strongly in situations in which medium and low-complexity technologies are involved (PINHO, 2011). The new legal Science, Technology and Innovation framework, Act no. 13.243/2016 (BRASIL, 2016), regulated by Decree no. 9.283/2018 (BRASIL, 2018b), seeks, as a priority, to promote the creation of innovating environments in the country through instruments that stimulate the interaction between ICTs and the productive sector. However, due to the recent promulgation of the Act and its regulation, it is not possible yet to measure if the actions for the stimulation of innovation provided for therein are efficient to leverage the Brazilian development.

The last public call in infrastructure made by Decit/SCTIE/MoH took place in 2005 and was directed for structuring Clinical Research Centers. Nineteen institutions were covered, which, together, gave rise to the first RNPC configuration (BRASIL, 2010). The goal was to create an infrastructure of Clinical Research Centers in the country with capacity to improve the scientific and technological production throughout the Brazilian territory and to join efforts to respond to the main issues that the Brazilian population faces, in addition to promoting the integration of these research centers and a greater exchange among researchers. In 2009, the Network was extended, being composed of 32 centers (BRASIL, 2011a).

Meetings with coordinators of the largest research centers of RNPC enabled understanding their activities in the RD&I scenario, mainly carrying out researches together with pharmaceutical industries and cooperating with other centers, which, from their perspective, characterizes a networking operation. Some key players diverge from this perspective, affirming that the RNPC does not operate as a research network. An in-depth critical analysis allowed concluding that the issue is not only focused on the heterogeneity of the centers composing the RNPC in regard to their capacity to perform and coordinate studies, but also on the Decit/SCTIE/MoH distancing in relation to the monitoring of the activities performed by the members of such Network. The Department found out that a self-assessment was needed in order to be closer to the RNPC management.

It should be stressed that the RNPC centers experience different realities, and many of them did not have their sustainability projects put into practice. Besides, it was found that five institutions of the Network do not perform clinical research nor have the minimum infrastructure required to operate as a Clinical Research Center. This information was part of the results of the project *Mapeamento e Avaliação da Capacidade Brasileira para a Realização de Ensaio Clínicos* (in free translation, Mapping and Assessment of the Brazilian Capacity to Perform Clinical Trials), requested in 2013 by Decit to the Brazilian Association of Collective Health (Abrasco) in a partnership with the Oswaldo Cruz Foundation (Fiocruz) and the Heart Hospital (HCor), through the Institutional Development Support Program of the Unified Health System (Proadi-SUS).

Its main purpose was to characterize the clinical research centers in Brazil regarding their infrastructure, manpower and experience to subsidize the decision making and strengthen the national capacity for performing clinical trials. All 32 centers that compose the RNPC were part of the study sample. Considering the reality showed by the mapping project, Decit observed that the management model adopted for the Network impaired its potential.





# THE PROCESS OF BUILDING ACTIONS

After the situational diagnosis of clinical research in Brazil, it was noticed that the identified critical points were related to six major topics, which gave rise to the six strategic axes of the Plan: (1) Ethics Regulation; (2) Sanitary Regulation; (3) Scientific and Technological Development; (4) Qualification in Clinical Research; (5) Brazilian National Clinical Research Network (RNPC); and (6) Knowledge Management. The correlation between the diagnosis reached and the action axes are presented below:

## 1 ETHICS REGULATION

- Slowness in the ethics analysis by the CEP/Conep System.
- Lack of harmonization in the analysis of the research protocols by the CEPs.
- Plataforma Brasil has a deficient operational interface, without interoperability between databases, with difficult updating according to the normative rules in force, and with few functionalities meeting all of its users' needs.

## 2 SANITARY REGULATION

- Administrative processes before Anvisa are marked by multiple overlapping stages, from the submission for consent in clinical research protocols to the product registration.
- Slowness in the processes of import of investigational products for clinical research.
- Lack of harmonization between the ethics and sanitary guidelines and normative rules.

## 3 SCIENTIFIC AND TECHNOLOGICAL DEVELOPMENT

- Public funding of clinical research with exclusively academic purposes and with low potential for generating innovative health products, processes or services.
- Deficient interaction between the government, ICTs and the productive sector for the conduction of clinical trials.
- Low productive and innovative capacity in the area of drugs in the country.
- Existence of few Clinical Research Centers with proper infrastructure.

## 4 QUALIFICATION IN CLINICAL RESEARCH

- Lack of proper qualification of the human resources at the Clinical Research Centers and universities on ethics and sanitary regulation, quality management, data and sample management, GCP and on the coordination of clinical trials.

## BRAZILIAN NATIONAL CLINICAL RESEARCH NETWORK (RNPC)

- RNPC management undermined the attainment of its full potential.

## 6 KNOWLEDGE MANAGEMENT

- Lack of actions targeted at the knowledge translation encompassing the disclosure and dissemination of scientific evidences in clinical research to the different sectors of society and the implementation of the scientific evidences by the health managers.

The situational diagnosis and the definition of the action axes guided the organization of a first version of this strategic planning, presented at a meeting held on February 3, 2017, approximately three months after Fórum Pesquisa Clínica was held in Brazil. Representatives of the pharmaceutical industry and of its associations, of the Contract Research Organizations (CRO), of the organized civil society and of the official public laboratories were present. As a result of discussions held at such meeting, the participants submitted contributions on the presented planning. In general, the suggestions received were related to a further detailing of activities and ratified the position of Decit.

Between March and April, 2017, other seven meetings were held and attended by large clinical research centers in the country, federal government players, and research and development not-for-profit organizations aiming at improving the planning to present a version consolidating the contributions received during the process and including partners in its development on June 13, 2017. The positive reception of the document presented resulted in the publication of GM/MoH Ordinance no. 559, dated March 9, 2018 (BRASIL, 2018a) (Annex). This was a landmark for the Action Plan for Clinical Research for demonstrating the commitment by the MoH to the planned activities and to the players involved in the area for the effort made to result in a governmental strategy.



# THE ACTION PLAN

## GENERAL PURPOSE

To increase the ability of Brazil to develop and attract clinical researches aiming at strengthening SUS.



## SPECIFIC PURPOSES

1. To improve the system of ethical analysis in researches involving humans.
2. To support Anvisa in the improvement of the clinical research regulatory system.
3. To improve the installed scientific capacity for clinical research.
4. To promote the continued education of human resources in clinical research.
5. To improve the governance of RNPC (Brazilian National Clinical Research Network).
6. To support the translation and dissemination of knowledge in clinical research.

## AXES

1. Ethics Regulation.
2. Sanitary Regulation.
3. Scientific and Technological Development.
4. Qualification in Clinical Research.
5. Brazilian National Clinical Research Network (RNPC).
6. Knowledge Management.

# ETHICS REGULATION

**SPECIFIC PURPOSE: TO IMPROVE THE ETHICAL ANALYSIS IN RESEARCHES INVOLVING HUMANS<sup>1</sup>**

<p><b>STRATEGIC ACTION 1.1</b></p> <p>Modernization of Plataforma Brasil – development of a new system.</p>	<p><b>ACTIVITIES</b></p> <p><b>1.1.1.</b> Perform of public inquiry on the functionality and improvement of Plataforma Brasil and assessment of the contributions received.</p> <p><b>1.1.2.</b> Development of a new system with operational efficiency, adapted to the current norms, and flexible to changes.</p> <p><b>1.1.3.</b> Conduction of a pilot test with the main users of the system.</p> <p><b>1.1.4.</b> Monitoring of the performance of the new system and assessment of the new functionalities.</p>
<p><b>STRATEGIC ACTION 1.2</b></p> <p>Qualification of the Research Ethics Committees that compose the CEP/Conep System with focus on the harmonization of the ethical analysis process.</p>	<p><b>ACTIVITIES</b></p> <p><b>1.2.1.</b> Promotion of remote and in-person education and recognition actions for the CEP/Conep System.</p> <p><b>1.2.2.</b> Creation and monitoring of the Distance Learning (DL) course to be offered to all users of the CEP/Conep System.</p> <p><b>1.2.3.</b> Creation of ongoing improvement plans to enhance the ethical analysis process in relation to CEP members.</p>
<p><b>STRATEGIC ACTION 1.3</b></p> <p>Development of the process of accreditation of CEPs.</p>	<p><b>ACTIVITIES</b></p> <p><b>1.3.1.</b> Promotion of discussions on the risk classification criteria.</p> <p><b>1.3.2.</b> Conduction of a Public Inquiry on the risk classification criteria.</p> <p><b>1.3.3.</b> Public Call for the pilot Accreditation project, as per Resolution no. 506, of February 3, 2016.</p> <p><b>1.3.4.</b> Monitoring of the CEP selection and accreditation process.</p>

<sup>1</sup> The activities of this action axis shall be performed in a partnership with Conep.

**ACTION AXIS 2**

**SANITARY REGULATION**

**SPECIFIC PURPOSE:** TO ENHANCE ANVISA IN THE IMPROVEMENT OF THE CLINICAL RESEARCH REGULATORY SYSTEM

**STRATEGIC ACTION 2.1**

Promotion of discussions on the regulatory processes with Anvisa.

**ACTIVITIES**

- 2.1.1.** Promotion of an interaction between the regulated and the regulatory sectors.
- 2.1.2.** Monitoring of actions that have been implemented by Anvisa to simplify and streamline the administrative procedures for sanitary control in the customs clearance of inputs, equipment, and biological material for research.
- 2.1.3.** Promotion of discussions regarding the strategies to improve the administrative processes for submitting the DDCM and applying for the product registration.
- 2.1.4.** Promotion of discussions between Anvisa and Conep to promote the harmonization of guidelines and ethics and sanitary normative rules.
- 2.1.5.** Participation in the construction of regulatory procedures and requirements for the performance of clinical trials involving Advanced Therapy Investigational Products subject to registration with Anvisa, through the participation in the Technical Council for Advanced Therapies (CAT).

# SCIENTIFIC AND TECHNOLOGICAL DEVELOPMENT

**SPECIFIC PURPOSE:** TO IMPROVE THE SCIENTIFIC INSTALLED CAPACITY FOR CLINICAL RESEARCH

<p><b>STRATEGIC ACTION 3.1</b></p> <p>Promotion of pre-clinical and clinical trials targeted at the development of strategic technologies for SUS.</p>	<p><b>ACTIVITIES</b></p> <p><b>3.1.1.</b> Launching of Prospective Public Call for pre-clinical and clinical trials with potential for generating strategic technologies for SUS, for establishing partnerships and possible financing.</p> <p><b>3.1.2.</b> Public Call targeted at supporting pre-clinical and clinical trials.</p> <p><b>3.1.3.</b> Direct contraction of clinical trials that are strategic for SUS.</p>
<p><b>STRATEGIC ACTION 3.2</b></p> <p>Improvement of the Decit work process for the development of clinical researches that are strategic for SUS.</p>	<p><b>ACTIVITIES</b></p> <p><b>3.2.1.</b> Identification of clinical research subjects that are strategic for SUS in the Agenda of Research Priorities of the Ministry of Health of Brazil (APPMS).</p> <p><b>3.2.2.</b> Improvement of the selection process in clinical researches.</p> <p><b>3.2.3.</b> Improvement of the monitoring process in clinical researches.</p> <p><b>3.2.4.</b> Establishment of procedures to stimulate private-public partnerships for the conduction of clinical researches.</p>
<p><b>STRATEGIC ACTION 3.3</b></p> <p>Adjustment of the infrastructure of clinical research centers in ICT.</p>	<p><b>ACTIVITIES</b></p> <p><b>3.3.1.</b> Incentive for the structuring and modernization of clinical research centers.</p> <p><b>3.3.2.</b> Monitoring of the implementation of the infrastructure of the selected proposals.</p>

**ACTION AXIS 4**

# QUALIFICATION IN CLINICAL RESEARCH

**SPECIFIC PURPOSE:** TO PROMOTE THE CONTINUED EDUCATION OF HUMAN RESOURCES IN CLINICAL RESEARCH

**STRATEGIC ACTION 4.1**

Supporting short courses and specialization and graduate programs in clinical research.

**ACTIVITIES**

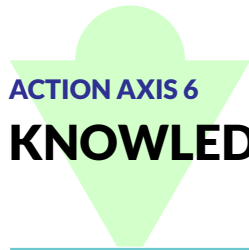
- 4.1.1.** Mapping of short courses and specialization and graduate programs in clinical research.
- 4.1.3.** Planning, support, evaluation, and monitoring of new educational proposals.
- 4.1.4.** Identification of public and private international institutions of excellence in clinical research aiming at promoting scientific and/or professional exchange in clinical research.

# BRAZILIAN NATIONAL CLINICAL RESEARCH NETWORK – RNPC

**SPECIFIC PURPOSE:** TO IMPROVE THE GOVERNANCE IN THE BRAZILIAN NATIONAL CLINICAL RESEARCH NETWORK (RNPC)

<b>STRATEGIC ACTION 5.1</b> Restructuring of the Brazilian National Clinical Research Network management model.	<b>ACTIVITIES</b> <b>5.1.1.</b> Definition of the organizational structure, operation and requirements for adherence of research centers to RNPC. <b>5.1.2.</b> Formalization and dissemination of this new model. <b>5.1.3.</b> RNPC promotion and monitoring.
<b>STRATEGIC ACTION 5.2</b> Collaborative work strengthening in the network.	<b>ACTIVITIES</b> <b>5.2.1.</b> Development of a virtual environment for disseminating the competences of the RNPC members. <b>5.2.2.</b> Incentive to the conduction of multicenter clinical trials in Network centers, including possible partnerships with the private sector.





**ACTION AXIS 6**

**KNOWLEDGE MANAGEMENT**

**SPECIFIC PURPOSE:** TO SUPPORT THE KNOWLEDGE TRANSLATION IN CLINICAL RESEARCH

**STRATEGIC ACTION 6.1**

Establishment of strategies of Knowledge Translation in Clinical Research.

**ACTIVITIES**

- 6.1.1.** Dissemination and ongoing improvement of the progression of actions within the scope of the Action Plan for Clinical Research in Brazil.
- 6.1.2.** Development of tools and products for the disclosure and dissemination of knowledge in clinical research in the proper language and format to different sectors – patients, managers, health professionals, and clinical research centers.
- 6.1.3.** Development of communication channels on the actions implemented by the Decit and by other players involved in the area of Clinical Research.
- 6.1.4.** Supporting the platform of the Brazilian Clinical Trials Registry (Rebec).

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GM/MOH ORDINANCE NO. 559, DATED MARCH 9, 2018

## MINISTRY OF HEALTH OF BRAZIL

Office of the Minister

ORDINANCE NO. 559, DATED MARCH 9, 2018

***Amends the Consolidation Ordinance no. 5/GM/MoH, dated September 28, 2017,  
to create the Action Plan for Clinical Research in Brazil.***

The BRAZILIAN MINISTER OF HEALTH, in charge of his attributions conferred by items I and II of the sole paragraph of Art. 87 of the Brazilian Constitution and

Considering art. 6, item X, of Act no. 8.080, dated September 19, 1990, which provides for the purposes and attributions of the Unified Health System – SUS in order to improve the scientific and technological development in compliance with the provisions of Art. 200, item V, of the Brazilian Federal Constitution;

Considering Act no. 13.243, dated January 11, 2016, which provides for stimulations to the scientific development, research, scientific and technological qualification, and innovation, under the Constitutional Amendment no. 85, dated February 26, 2015;

Considering the Brazilian National Policy on Health Science, Technology, and Innovation – PNCTIS, passed at the 2ª Conferência Nacional de Ciência, Tecnologia e Inovação em Saúde (2nd National Conference of Health Science, Technology, and Innovation), held in 2004, which is aimed at contributing for the Brazilian development to take place in a sustainable manner and with support for the production of technical and scientific knowledge adjusted to the economic, social, cultural and political needs of the country;

Considering Annex VII to the GM/MoH Consolidation Ordinance no. 3, dated September 28, 2017, which created the Brazilian National Clinical Research Network – RNPC;

Considering Anvisa's Board Resolutions – RDC no. 9 and 10, dated February 20, 2015, which provide for the regulation to conduct clinical trials involving drugs and medical devices in Brazil, respectively;

Considering Resolution no. 466, dated December 12, 2012, issued by the Brazilian National Health Council – CNS, which approves the guidelines and rules that regulate researches involving humans and provides for the attributions of the National Research Ethics Commission – Conep and of the Research Ethics Committee – CEP;



Considering the CNS Operational Norm no. 001/2013, which provides for the organization and operation of the CEP/Conep System and establishes that the Secretariat of Science, Technology, Innovation and Health Strategic Inputs under the Ministry of Health of Brazil – SCTIE/MoH exercises the function of Executive Office of Conep/CNS; and

Considering Art. 34 of Decree no. 8.901, dated November 10, 2016, which provides for the attributions and competences of the Science and Technology Department – Decit of SCTIE/MoH, resolves that:

Art. 1. The GM/MoH Consolidation Ordinance no. 5, dated September 28, 2017, shall enter into force with the following amendments:

“Section IX

The Action Plan for Clinical Research in Brazil

Art. 837-A. The Action Plan for Clinical Research in Brazil is hereby created with the purpose of increasing Brazil's capacity for developing and attracting clinical trials.

Sole paragraph. The Plan shall be made available at the website <http://portalms.saude.gov.br/ciencia-e-tecnologia-e-complexo-industrial>.” (NR)

“Art. 837-B. The purposes of the Action Plan for Clinical Research in Brazil are as follows:

I – To improve the ethical analysis in researches involving humans;

II – To support the Brazilian National Agency of Sanitary Surveillance – Anvisa in the improvement of the clinical research regulatory system;

III – To improve the scientific installed capacity for clinical research;

IV – To promote the continued qualification of human resources in clinical research;

V – To improve the governance in the Brazilian National Clinical Research Network – RNPC;

VI – To support the translation and dissemination of knowledge in clinical research.” (NR)

“Art. 837-C. The Action Plan for Clinical Research in Brazil is structured in six strategic axes:

I – ethics regulation;

II – sanitary regulation;

III – scientific and technological development;

IV – qualification in clinical research;

V – Brazilian National Clinical Research Network – RNPC; and

VI – knowledge management.” (NR)

“Art. 837-D. The Science and Technology Department of the Secretariat of Science, Technology, Innovation and Health Strategic Inputs under the Ministry of Health of Brazil – Decit/SCTIE/MoH shall be responsible for coordinating, implementing, monitoring and evaluating the actions that compose the Action Plan for Clinical Research in Brazil.

§ 1. The Decit/SCTIE/MoH shall be responsible for the articulation with the other Offices under the Ministry of Health of Brazil, Anvisa, the National Research Ethics Commission under the National Health Council – Conep/CNS, the Ministry of Science, Technology, Innovations and Communications,



the Ministry of Education, the Ministry of Industry, Foreign Trade and Services, and other direct and indirect bodies and entities of the public administration and of the organized civil society that engage in the field of science, technology and innovation, for them to take part in the activities of the Plan whenever pertinent according to their field of operation.

§ 2. To achieve the purposes of the Plan, Decit/SCTIE/MoH may further:

I – coordinate an improved integration between the regulated sector and the direct and indirect public administration bodies and entities; and

II – create working groups to fulfill specific purposes related to the Plan and invite representatives of other direct and indirect bodies and entities of the public administration, of the organized civil society, and of the regulated sector to take part in it.” (NR)

Art. 2. This Ordinance enters into force on the date of its publication.

RICARDO BARROS



Virtual Health Library of the Ministry of Health of Brazil  
<http://bvsms.saude.gov.br>



MINISTRY OF  
HEALTH OF BRAZIL



PÁTRIA AMADA  
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