



# *Nicaraguan Institute for Biomedical Research (INVBIOM), period 2023 to 2033*

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## **ABSTRACT**

To publicize the potential for organizational and institutional innovation of FCC Médicas UNAN-Managua, this article is presented. This potential is aimed at the modernization of biomedical research processes and graduate education, both in medical specialties and in the public health sector of Nicaragua. The following relevant findings stand out: 1) The INVBIOM, based on the R+D+i Model evolved to the year 2022, assumes the logic of the research process, with a holistic, systemic, and anthropocentric vision, to generate new knowledge and technologies, applied to the different medical specialties. 2) The INVBIOM is proposed as an innovative institute of scientific research and postgraduate studies, aimed at strengthening the Research, Development, and Innovation competencies of the basic doctors of the MINSA hospitals and clinical-surgical teachers of the FCCMédicas. 3) The INVBIOM will contribute to improving the scientific training of Resident Physicians of Medical Specialties, through three MOOC courses: (a) Scientific Research Methodology, (b) Biostatistics, and (c) Scientific Writing. 4) INVBIOM will be organized into six Academic Programs, four specialized structures, a Scientific Research Center, and 14 Research Units at the hospital level. For the development of INVBIOM, it is proposed to create Biomedical Research Committees in the hospital environment, to contribute to improving the quality, relevance, and impact of the results of Biomedical Research, which will increase the scientific productivity of the public health sector at the national level.

## 1. INTRODUCTION

The Nicaraguan Institute of Biomedical Research (INVBIOM) of the Faculty of Medical Sciences of the UNAN-Managua, is a proposal for the creation of an innovative institute of scientific research and postgraduate studies, aimed at strengthening the competencies of Research, Development, and Innovation, (R+D+i Model), of the basic doctors of the MINSA hospitals and clinical-surgical teachers of UNAN-Managua, who attend the Medical Specialties of the Faculty of Medical Sciences of the UNAN-Managua, in the hospitals of the MINSA and Non-MINSA, aimed at strengthening the health sector as an engine of sustainable human development of the Nicaraguan family.

The INVBIOM will facilitate the development of new competencies, capacities, skills, and professional skills necessary to design research by observational (analytical) or experimental (clinical trials) methods, to achieve levels of knowledge both descriptive, correlational, causal analytical, and even predictive/prognostic, to plan, apply bio-ethical standards and Carry out the corresponding field phase, applying advanced bio-statistical data analysis and interpretation. Likewise, INVBIOM will facilitate compliance with the fundamental standards of Lines of Research and Technical Scientific Writing, to increase and qualitatively improve the scientific productivity of the Nicaraguan health sector.

These new professional competencies are aimed at ensuring the timely graduation of new medical professionals, through theses in their medical specialty, master's or doctorate, essays, and scientific articles, with better quality and relevance. In this way, increase the scientific productivity of both the FCCMédicas of UNAN-Managua and the Nicaraguan health sector.

The Nicaraguan Institute for Biomedical Research (INVBIOM) is aimed at strengthening the capacities of Research, Development, and Innovation (R+D+i Model), expressed in the continuous improvement of the competencies of teachers and researchers, in three major scenarios:

- a) at UNAN-Managua level, facilitating the development of a new culture of scientific research;
- b) at the level of the public health sector, strengthening their competencies in the fields of Science, Technology and Innovation, Entrepreneurship, and Society, in the different institutions of the country, located in the health sector (SILAIS, MINSA Teaching Hospitals, Non-MINSA Teaching Hospitals ).
- c) at the level of different Higher Education Institutions of Nicaragua (HEIs) in the field of public health, increasing and improving the quantity and quality of graduates at the graduate level.

The current context is increasingly demanding, typical of the knowledge society, which has shaped a very complex, changing, dynamic, and heterogeneous society. An important part of the complexity of the 21st century involves considering the emerging paradigms of the change of era that we are experiencing, to improve the quality of education and research, which according to De Sousa (1999) are the following: Institutional Changes, Organizational Changes and Paradigm Shifts.

At UNAN-Managua, very positive institutional changes have been developed as part of a process of modernization for the future of Nicaragua, demonstrating that it is capable of reinventing itself, transforming itself, to contribute to the social and technological transformation of Nicaraguan society. In this sense, the concept of competence, adopted by UNAN Managua (2021, p. 40), stands out: Competencies are "the ability to put into practice in an integrated and dynamic way knowledge, skills, attitudes and values to face the solution of life's problems, whether these are of a personal, professional or social nature".

It is precisely in this context that this article is developed, with the general objective of publicizing the potential of organizational and institutional innovation of the FCC Médicas UNAN-Managua, through the proposal of creation of an innovative institute of scientific research and postgraduate studies, aimed at strengthening the competencies of Research, Development and Innovation. (R+D+i Model), which is aimed at the modernization of biomedical research processes, both in medical specialties and in the public health sector of Nicaragua.

## **2. DEVELOPMENT**

### **2.1. Background of the Nicaraguan Institute for Biomedical Research (INVBIOM)**

In the period 2011-2016, from DIRINVES, a broad and deep process of Institutional and Organizational Innovation of Research was developed at UNAN-Managua (Pedroza 2018a), which led, among other relevant actions, to the following:

1) With the support of Dr. Freddy Meynard, Dean of the Faculty of Medical Sciences of UNAN-Managua, from 2010 to 2016, the creation and promotion of free Postgraduate Courses in "Biomedical Research" was promoted, aimed at R3 resident doctors of the different medical specialties. From these postgraduate courses, an average of 20 doctors graduated per year, completing a total of 140 resident doctors who graduated in various postgraduate courses carried out at the FCCM, plus 60 teaching doctors from the FCCMedic who graduated with two Research Diplomas, plus 15 general practitioners who graduated individually.

In the same period 2010-2016, a total of 165 theses were attended, of which 87.27% (144) were at the Graduate level; 10.90% (18) were at the Undergraduate level and 1.81% (3) were at the Doctoral level. Undoubtedly, this is an example of the growing scientific productivity

that UNAN-Managua achieved, through the free advice of Undergraduate and Graduate Theses of UNAN-Managua.

2) Creation and development of the Master's Program in "Scientific Research Methods (MEDINV)" at FAREM Carazo, UNAN-Managua. This program was promoted by DIRINVES and approved by the University Council of UNAN-Managua on December 6, 2013, starting on March 8, 2014. This program has completed three cohorts to date, starting its Third Cohort on February 5, 2018, at the Faculty of Sciences and Engineering UNAN-Managua (Pedroza 2013).

3) Creation and development of the Doctoral Program "Management and Quality of Scientific Research (DOGCINV)" FAREM Estelí, UNAN-Managua, First Cohort 2016-2019. This program was promoted by DIRINVES and approved by the University Council of UNAN-Managua, on January 19, 2016, it was inaugurated on July 7, 2016, graduating the first twelve PhDs, on December 18, 2019 (Pedroza 2016, Pedroza 2017, Pedroza 2019 a and Pedroza 2019 b).

4) From DIRINVES and with the support of Dr. Freddy Meynard, Dean of the Faculty of Medical Sciences of UNAN-Managua, Dr. Pedroza promoted in 2013, the creation of the "Doctoral Program in Biomedical Research" PRODIB of the Faculty of Medical Sciences of UNAN-Managua, which was approved by the University Council of UNAN-Managua. on December 19, 2015. PRODIB was inaugurated on October 5, 2017, and coordinated by Dr. Marlene Muñoz and Dr. Marianela Corriols (Corriols, 2017).

5) From the FCCMédicas, the Master's and Diploma Program in "Biomedical Research" (PROMIB) of the Faculty of Medical Sciences of UNAN-Managua was promoted. The first cohort was inaugurated on October 12, 2017, graduating 47 basic physicians 32 of them graduates, who are teaching physicians in MINSA and non-MINSA hospitals ( Pedroza, 2019 c and Pedroza, 2020). PROMIB is currently operating successfully with a second cohort that began on September 23, 2021, with 89 basic physicians in MINSA and non-MINSA hospitals.

The first proposal of the Master's Program in Biomedical Research (PROMIB) was presented by Dr. Manuel Enrique Pedroza to Dr. Freddy Meynard, Dean of the Faculty of Medical Sciences, on November 21, 2016, which was presented as part of a new Model of Management of Scientific Research in the area of medical sciences. an integrated model of Research, Development, and Innovation processes, typical of the R+D+i Model. Finally, PROMIB was approved by the University Council of UNAN-Managua on June 19, 2020.

Currently, the transversal axis of scientific research at the postgraduate level in Postgraduate Courses, Diplomas, Master's, and Doctorate in "Biomedical Research", has

worked correctly in the Faculty of Medical Sciences of UNAN-Managua. The experience of the FCCMédicas of the UNAN-Managua is highlighted, developing the Master's Degree in Sexual and Reproductive Health, as well as the Diploma in Diabetology and Toxicology, organized between 2000 and 2016. These programs have been developed in compliance with the criteria of the Regulations of the System of Graduate Studies and Continuing Education, SEPEC-UNAN-Managua (UNAN-Managua, 2011 a).

## **2.2. INVBIOM's Organizational Innovation**

The INVBIOM of the Faculty of Medical Sciences of the UNAN-Managua is a true organizational innovation of research and postgraduate studies for seven main reasons:

1) integrate in six different graduate programs (three master's and three doctorate), the talents in scientific research that UNAN-Managua currently has with experts from the different clinical and surgical areas of the health sector, as well as international experts of recognized prestige;

2) implement a multidimensional vision of scientific research, promoting organizational and institutional innovation in the health sector (Pedroza, 2018a);

3) advise the Scientific Research Committees of the health sector (CTIES\_Salud);

4) advise the Bioethics Committees of the health sector;

5) advise on the updating of the Lines of Research in the Health Sector (Pedroza 2013 y Pedroza, 2023);

6) advise the Nicaraguan System of Research, Development, and Innovation of the health sector (CTIES\_Salud) (Pedroza, 2010);

7) develop the virtual education of the Research axis with a Mixed Approach at the postgraduate level, (Dicovski and Pedroza 2019), etc.

At INVBIOM, two main lines of work stand out:

a) Biomedical research as a fundamental basis for the development of new competencies, to improve the quality and relevance of postgraduate education in 28 medical specialties of UNAN-Managua, and this in turn is the indispensable means to contribute to the human development of Nicaraguans.

b) Scientific research that contributes to solving problems and making visible the impact of the public health sector, to improve the country's scientific productivity and contribute to the human development of the Nicaraguan family.

The INVBIOM promotes a "Holistic, Systemic, and Anthropocentric Vision of Scientific Research Methods", which integrates as a whole the application of quantitative and qualitative methods in Biomedical Research and Scientific Research in the public health sector, in the search for solutions to relevant problems that affect Nicaraguan society (R+D+i Model, Pedroza 2015).

The INVBIOM will be guided by a professional vision focused on:

(a) Identity and commitment to the homeland, loyalty and institutional commitment to UNAN-Managua University and MINSA.

(b) Development of Biomedical Research through clinical observation up to ECAC Clinical Trials and Multicenter Trials, as well as Experimental and Non-Experimental Research in the public health sector, to contribute from scientific research to the sustainable human development of the Nicaraguan family.

(c) The application of the R+D+i Model underpins the application of the Holistic, Systemic, and Anthropocentric Approaches to Scientific Research and involves the integration of Quantitative and Qualitative methods for the development of Scientific Research.

The INVBIOM will promote scientific research and postgraduate studies based on the R+D+i Model, therefore, it will promote an institutional strategy of modernization and integration of the actors and processes of research-innovation-entrepreneurship, extension, and society (CTI\_ES), which is aimed at investigating problems in the health sector, in the search for possible solutions, with validity and reliability, evidenced by scientific research.

To facilitate this strategy of modernization and integration, INVBIOM will facilitate the development of the Research Lines of each unit of the Public Health Sector (SILAIS and MINBSA Teaching Hospitals), which will allow the construction of the Minimum Prioritized Agenda for Scientific Research in the Nicaraguan Health Sector. This agenda constitutes the fundamental starting point to make it possible to improve research processes in different sectors and levels, from each SILAS to each MINSA teaching hospital.

The INVBIOM will promote collaborative relations and institutional synergy with the different institutional actors of research and postgraduate studies of the UNAN Managua, the Universities of the CNU, the MINSA, the MEDE, THE INTA, THE INATEC, THE MEFCCA, THE IPSA, THE MARENA, and the MAG, developing joint actions through the management of processes and inter-institutional knowledge management.

### **2.3. Philosophical Foundations of INVBIOM**

The philosophy of the INVBIOM of the Faculty of Medical Sciences of UNAN-Managua is based on: (1) the Mission and Vision of UNAN-Managua, (2) the Principles and



Values of UNAN-Managua, expressed in its Strategic Plan 2015-2019, (3) the Research and Postgraduate Policies of UNAN-Managua, and (4) the commitment to contribute to the fulfillment of the Strategic Programs of the National Plan to Fight Poverty, 2022-2026 (PNDH, 2021).

In the Institutional Strategic Plan, 2015-2019, UNAN-Managua states in the Modernization Axis that: "Because it is a human and professional education, university management includes values, beliefs, interests, principles, hypotheses, premises, theories, aspirations, commitments, contradictions and therefore complexity and diversity are inherent to science and technology institutions. UNAN-Managua, at all levels of training, must contribute to sustainable development by training professionals and technicians who have an entrepreneurial, ethical and critical attitude, both in their professional, personal and social work" (UNAN-Managua, 2011 c).

The University faces the challenge of promoting, building, and developing through research, new internal and external competencies, strengthening the strategic alliance with the health sector, and discovering new knowledge and technologies, which promote the creation of new possibilities of transformation that facilitate scientific-technological development in the public health sector. The excellent human capital of FCCMédicas UNAN-Managua constitutes a great academic potential that must innovate, explore, and propose initiatives of national interest to strengthen the University and Nicaraguan society as a whole.

The UNAN-Managua Educational Model highlights the sociological foundation that: "Nicaragua is a multicultural country rich in natural resources. In spite of these factors, it faces a situation of impoverishment and backwardness in the development of science and technology. This lack of conditions to be able to promote innovations and creations limits the economic growth of the country and the human development of Nicaraguans" (UNAN-Managua, 2011 b).

Based on the R+D+i Model (Pedroza, 2015), INVBIOM promotes the "Anthropocentric Approach", which leads to strengthening the "Identity and Social and Institutional Commitment" of the entire university community as a whole. The "Anthropocentric Approach" proposes, among other things, to prioritize attention to Nicaraguan society, to better serve the people and to strengthen the: (a) spirit of collaboration among all and each member of the university community; implement (b) effective communication among all; (c) develop a more horizontal and therefore less bureaucratic institutional management; (d) and to apply a spirit of unwavering service on a day-to-day basis.

The INVBIOM, based on the R+D+i Model (Pedroza 2015), assumes the logic of the research process, with a holistic, systemic, and anthropocentric vision, to generate new knowledge and technologies. These are concretized through a creative invention or innovation,

which will be applied in a specific production or service system, in this case, the different medical specialties in the public health sector of Nicaragua (figure 1), a model evolved to the year 2022 (Pedroza 2022).

Therefore, INVBIOM takes on new challenges and challenges to contribute to closing the gaps in information, knowledge, and technologies, through the creation, adoption, and dissemination of new knowledge, applying new paradigms, approaches, methods, and research techniques, in the training of new medical specialists, which will contribute in general to improving the quality of new professionals in the country. with a multidimensional vision of scientific research (Pedroza, 2022). On the other hand, innovation includes mechanisms for the adoption, absorption, and adaptation of knowledge, transforming it into prototypes and functional models of technologies, until the implementation of entrepreneurship, which are the goods and services useful to Nicaraguan society (Pedroza, 2015).

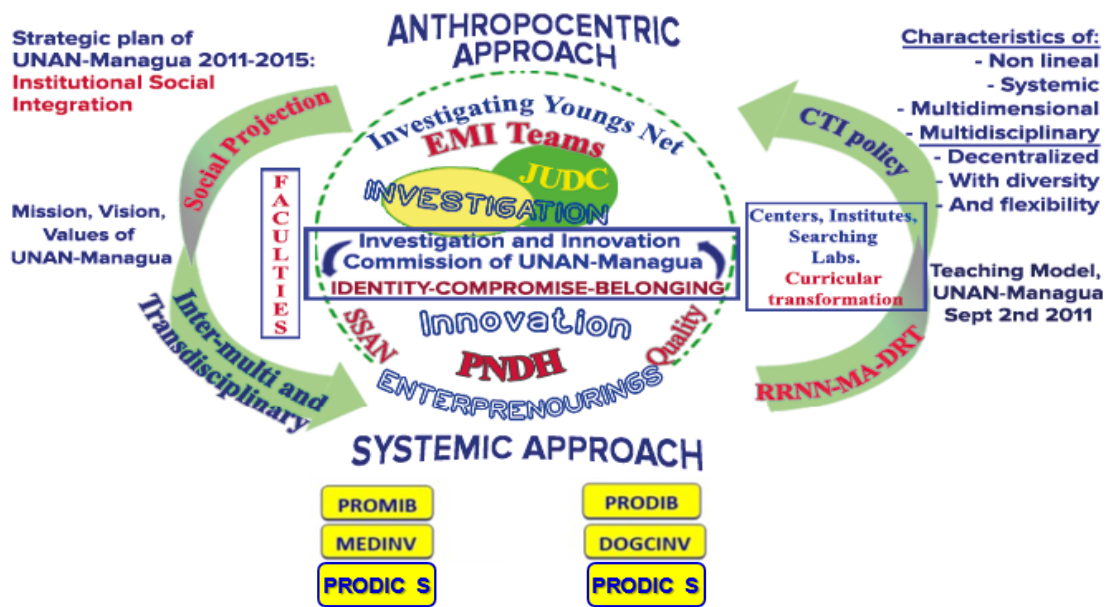


Figure 1. Research, Development, Innovation Model (R+D+i), up-to-date as an image Objective of the INVBIOM, evolved to the year 2022 (Pedroza, 2022).

INVBIOM promotes an institutional strategy of modernization and integration, research-innovation-entrepreneurship, extension, and society (CTI\_ES), promotes institutional and organizational innovation of scientific research in the Nicaraguan Public Health sector, which will contribute to the necessary paradigm shift of traditional research in Nicaragua. This paradigmatic shift goes from research to innovation, entrepreneurship, extension, and society, contributing from the R+D+i Model, to be part of the Public Health sector, a sector capable of transforming itself and contributing to the transformation of Nicaraguan society, developing other ways of doing science to create new knowledge and technologies.



To achieve this strategy, INVBIOM bases its present and predictable future development on five major philosophical principles, which were the success factors of the DOGCINV Doctoral Program first cohort, cited in Pedroza (2019 b), such as:

### ***2.3.1. The Epochal Change, given by the Paradigm Shift, Technological Change, Organizational Change and Institutional Change***

To turn the Nicaraguan university into a transformative university, capable of transforming itself and the society in which we live, through the route called research-innovation-entrepreneurship and society (CTI\_ES), which is based on the Context-Centered Mode for the generation of new knowledge, aimed at solving the problems of the complex, changing and dynamic world in which we live (De Souza, 1999).

#### ***2.3.2. Some Strategic Elements for a New CTI\_ES Policy***

- a) Knowledge Management, Process Management, Quality Management, and Time Management
- b) Learning by Doing Methodology in each of the stages of the research process,
- c) A New Teaching Pedagogy in scientific research, based on competencies and oriented to CTIE\_S.

#### ***2.3.3. The DOGCINV Monitoring and Evaluation Process***

Aimed at improving the institutional culture of monitoring and evaluation, which allows continuous improvement and improved management, this process is done to improve the quality of research work. Therefore, you must be open-minded to change, and.... it must be changed because we can be better, to improve the work of STI.

#### ***2.3.4. The DOGCINV Self-Assessment and Continuous Improvement Process***

It can be improved through the continuous measurement of processes to identify strengths and weaknesses and from this, an Institutional Improvement Plan is based, which facilitates the empowerment of the actors and allows improvements to be made based on quality. With the DOGCINV, a paradigm shift was promoted based on the R+D+i Model of the UNAN-Managua, which assumes the commitment of the socio-critical paradigm, which is the foundation of the mixed research approach, which leads to a holistic, systemic, and anthropocentric vision of the research processes, all this implies the integral application of qualitative-quantitative methods and techniques.

#### ***2.3.5. Knowledge Management***

Closing knowledge gaps, creating added value from existing information and technologies in all areas of knowledge. These gaps can be closed by promoting a continuous process of feedback

and self-evaluation at all levels. In this way, Knowledge Management is based on three basic principles that define it:

a) The Social Construction of Knowledge. Knowledge is in itself an indivisible social construct and not a commodity.

b) Sharing Human Knowledge. It is necessary to share knowledge, learn to listen, consult, and inter-consult from an interdisciplinary perspective to enrich human knowledge. This depends on the attitudes of each person, for this reason, the educator must be a facilitator of sustainable human development, through Knowledge Sharing.

c) Dissemination of Knowledge. Highlight the empowerment of virtual societies, making the correct use of social networks, ICTs, digital platforms, and virtual education, and making the most of the scientific bibliographies systems available in all CNU universities.

#### **2.4. Justification**

The modern world is living in an era of changes, which in the community of UNAN-Managua, is expressed in deepening its Humanist character and Social Change, because that is the perennial action and vocation consistent with the mission and vision of the institution and because it is the sign of the times, a time of continuous and sustained transformations in a context of search for full social equity. (UNAN-Managua, 2013).

Strengthening the quality of graduate education and research is imperative in Nicaragua. This leads the university to implement a serious commitment to strengthen and improve the quality of university teaching, innovating in Education, strengthening online courses, and implementing the tools offered by the virtual work environment of Moodle, Class Room, Gotomeeting, Meet, Zoom, Teen Platforms, etc. Likewise, innovating in Research is strengthened by the Mixed, Holistic, Systemic, and Anthropocentric Approaches to Research Methods, the processes of innovation, entrepreneurship, and university extension.

INVBIOM responds to the needs of sustainable human development of Nicaraguans, as an Institute that trains human talents at the highest level of scientific research, for the national Public Health sector, as one of the engines and facilitators of preventive human health, promoter of the Health, Family and Community Model (MOSAFC). as a driving force for the modernization of undergraduate and graduate education in medical sciences. INVBIOM responds to the growing demand for skills training at the postgraduate level, both from UNAN-Managua and from the Public Health sector in the field of Science, Technology, Innovation, and Society in the country.

At INVBIOM, the integration of research, innovation, and entrepreneurship is highlighted as an added value of the postgraduate teaching-learning process, which makes the impact of

scientific research visible, improving productivity in the health sector, increasing scientific publications (essays and articles)), sensitizing new professionals to academic excellence and walking the path of continuous improvement, to achieve a greater social projection from the university to Nicaraguan society (spillover effect), thus contributing to the solution of problems in reality and serving as support for the sustainable human development of the Nicaraguan family.

## **2.5. General Objective of INVBIOM**

In its general objective, INVBIOM proposes: To contribute to strengthening the competencies in the field of Research, Development, and Innovation, (R+D+i Model), of the clinical-surgical professors of the Faculty of Medical Sciences of the UNAN-Managua and of the basic doctors of the hospitals of MINSA and Non-MINSA, who attend to Medical Specialties, They are the driving forces and facilitators of the sustainable human development of the Nicaraguan family in the health sector.

## **2.6. The INVBIOM Professional Profile**

1. It trains human talents at the highest level of scientific research, Master's and Doctorate levels, for the national Public Health sector, as a driving force and facilitator of the sustainable human development of the Nicaraguan family.

2. It plans the biomedical research and public health processes of its Master's and Doctoral Programs, guaranteeing their methodological coherence, quality, and relevance.

3. It evaluates the biomedical research processes of its Master's and Doctoral Programs, guaranteeing their quality and relevance.

4. He advises methodologically, scientifically-technically and professionally, the biomedical research, typical of its Master's and Doctoral Programs.

5. She manages parametric and non-parametric biostatistical analysis and interpretation strategies, for the correct analysis and interpretation of data from biomedical research, typical of her Master's and Doctoral Programs.

6. It increases the scientific productivity of the FCCM of UNAN-Managua and the national public health sector, increasing the number of scientific publications.

7. It promotes Research, Development, and Innovation Networks (R+D+i Model), through Multi, Inter and Transdisciplinary Research Teams, contributing to the improvement of the quality of scientific education and research processes, at the highest level of Master's and Doctorate degrees. Likewise, it expresses respect for Ethics and Bioethics, to strengthen research processes in life sciences.

## 2.7. The INVBIOM Organization

The INVBIOM will be organized into six Academic Programs (three master's and three doctorate), four specialized scientific research structures, plus a Scientific Research Center at the Master's and Doctoral levels and 14 Research Units at the hospital level, which will be able to carry out the Scientific Research Programs at the undergraduate level. They will be oriented to the field of Biomedical Research of the FCCMédicas and the national public health sector.

The INVBIOM is an integral and organic part of the Faculty of Medical Sciences, to strengthen the Research and Postgraduate Sub-System of UNAN-Managua, in coherence with the Research and Postgraduate Policies of UNAN-Managua (UNAN-Managua, 2016). The basic structure of INVBIOM is as follows:

Six Postgraduate, three Master's and three Doctoral Programs:

1. Master's and Doctorate Program in "Biomedical Research" (PROMIB / PRODIB).
2. Master's and PhD Program in "Scientific Research with a major in Health Sciences" (PRODIC\_S).
3. Master's and Doctorate Program in "Medical Biotechnology" (PRODBIOM).

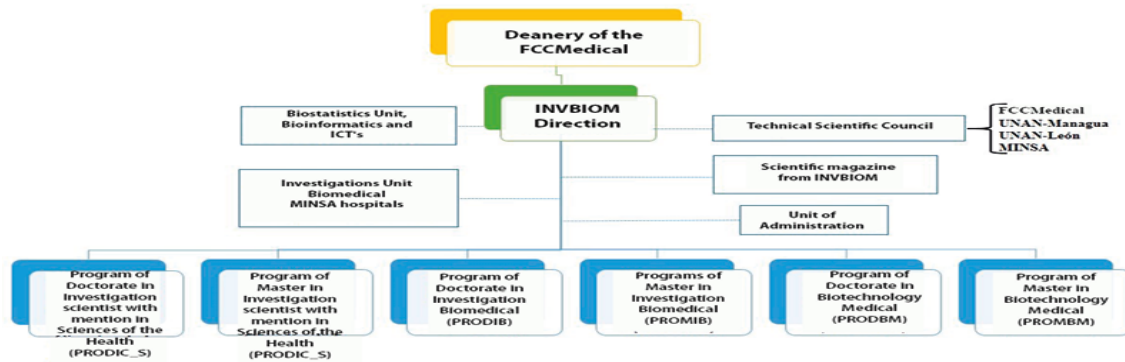
Four specialized structures:

1. Biomedical Research Unit of MINSA Hospitals
2. the Biostatistics, Bioinformatics, and ICT Unit,
3. the Scientific Publications Unit, INVBIOM Scientific Journal, and
4. the Financial Administrative Unit.

A Center for Scientific Research at the Master's and Doctoral level

- a) The Center for Research in Medical Biotechnology.

Below is the General Organizational Chart of the INVBIOM of the FCCMédicas UNAN-Managua.



## 2.8. The Biomedical Research Committees in the MINSA-Faculty of Medical Sciences Strategic Alliance of UNAN-Managua

As a concrete expression of CONIS, defined in Ministerial Agreement No. 491-2020 (MINSA 2020 a), the creation and development of Biomedical Research Committees is proposed, in a strategic alliance MINSA-Faculty of Medical Sciences-UNAN-Managua, these are an expression of the Local Scientific Ethics Committee of CONIS, according to the CONIS Regulations. These Committees will contribute to the hospital environment to improve the quality, relevance, and impact of the results of Biomedical Research of the Resident Physicians, who will be graduates in the 28 Medical Specialties of the FCCMédicas, UNAN-Managua.

### 2.8.1. Institutional Context of Biomedical Research Committees

In the current global, regional, and national context, a set of processes of educational, technological, socio-economic transformation, etc., are taking place, which are typical of the change of epoch that humanity is experiencing, as described by De Souza (1999): "we are living in an era of changes that is changing the era in which we live.... Epochal change, institutional change, paradigm shift... Humanity is witnessing the dawn of a new epoch." This context has been aggravated by the COVID-19 pandemic since January 2020.

In today's world, we are experiencing continuous and accelerated changes typical of the "Society of Knowledge, Computerization and Learning", focused on seven megatrends: Biotechnology, Biomedicine, Biostatistics, Bioinformatics, Biorobotics and GIS, Climate Change and Paradigm Shift, which define a new institutional context of paradigm breaking, new skills, and dynamic learning at a global level. regional, national, and local (Pedroza, 2015).



In the national context, new challenges arise aimed at the continuous improvement of the quality of university education and research in Nicaragua and thus improve the level and quality of life of the Nicaraguan family. Since November 2011, the new transformations in the field of scientific research that are being experienced in our "alma mater" UNAN-Managua were based on the R+D+i Model of UNAN-Managua. Given this new conceptual model, the different research processes are integrated into a single system, as a set of research, innovation, entrepreneurship, extension, and society processes, aimed at contributing to the sustainable human development of Nicaraguan society (Pedroza, 2015).

In this new strengthened institutional context of UNAN-Managua, the "Diploma, Master's (PROMIB) and Doctorate (PRODIB) Programs in Biomedical Research" of the Faculty of Medical Sciences (FCCM) of UNAN-Managua, First Cohort, 2017-2020 (Pedroza 2020) were initiated. These programs originated in 2013, with the strategy implemented by the Research Directorate of UNAN-Managua, to strengthen the research processes of the FCCM Médicas UNAN-Managua.

In the health sector, at the national level, there have been significant qualitative leaps that strengthen research processes in medical specialties, such as:

- a) Ministerial Agreement No. 491-2020 MINSAs, which approves the document "Regulations of the National Committee for Health Research" CONIS (MINSAs 2020 a).
- b) The Local Scientific Ethics Committees, by the CONIS Regulations (MINSAs 2020 b).
- c) MINSAs Standard 166, "Standard for the Regulation of Clinical Trials of Medicines in Human Beings" (MINSAs 2020 c).

### **2.8.2. The problem to be solved**

According to the Medical Residency Regulations,

Chapter X: Criteria for Promotion and Completion of Studies

Art. 95. To be promoted to the next higher year, the student must have passed all the theoretical modules, practical rotations, and the final exam of the academic year independently.

Art. 96. Comply with the tuition requirement for the academic year.

Art. 97. To be promoted to the next higher academic year, students must pass, within the established academic calendar, the stages (protocol or progress) of their research work (thesis) that correspond. The student who is No At the end of the academic year loses the right to continue your studies in the specialty.

In a strategic alliance with UNAN-Managua-MINSA and to facilitate the fulfillment of "Promotion and Completion of the Studies of Resident Physicians", from 2018 to 2023 inclusive, the Faculty of Medical Sciences began a process of strengthening at the postgraduate level in Biomedical Research, aimed at resident doctors of medical specialties. Through this process, they have been taught three Online Graduate Certificate courses each year, such as:

- 1) Scientific Research Methodology, aimed at Resident Physicians R1.
- 2) Biostatistics, aimed at R2 Resident Physicians.
- 3) Technical Scientific Writing, aimed at R3, R4, and R5 Resident Physicians.

The problem to be solved

- a) Research protocols are not delivered on time, to promote the first year of residency.
- b) Resident theses are not submitted on time, to have a timely graduation.
- c) There is no Monitoring and Evaluation System to accompany Resident Physicians.

### **2.8.3. Proposed Solution to the Problem**

Given the problems described above very complex institutional situations arise. To overcome the problems mentioned above and to strengthen the transversal axis of Biomedical Research in Medical Specialties, it is proposed to create the Biomedical Research Committees in Strategic Alliance MINSA-Faculty of Medical Sciences of UNAN-Managua and continue with the Online Postgraduate Certificate courses for Resident Physicians.

### **2.8.4. Rationale and Objectives of the Biomedical Research Committees in the MINSA-Faculty of Medical Sciences Strategic Alliance of UNAN-Managua**

The strengthening of the Competencies in Biomedical Research of medical specialties is undoubtedly an institutional responsibility of great importance, which implies great challenges and entails great teamwork between professors of the Faculty of Medical Sciences of UNAN-Managua and specialist doctors of MINSA and not MINSA. To successfully fulfill this institutional responsibility, it is necessary to further strengthen the MINSA-UNAN Managua strategic alliance, through the institutional improvement of Research Management and Quality.

Among these new challenges is the process of continuous improvement of postgraduate teaching-learning, of Biomedical Research in the hospitals of MINSA and non-MINSA, to meet the objective of improving the quality and relevance of postgraduate courses in Biomedical Research of the 28 medical specialties of the FCCMédicas UNAN-Managua.

With the strategic objective of strengthening the MINSA-UNAN Managua strategic alliance, it is proposed the creation of the Biomedical Research Committees in strategic alliance with the MINSA.

To accomplish this objective, MINSA must appoint a basic physician to be the Coordinator of this unit for each national reference hospital, plus two basic physicians, who will be members of this Committee and must meet the requirement of being graduates of PROMIB I or II Cohort.

#### **2.8.5. Functions of Biomedical Research Committees**

The Biomedical Research Committees MINSA-FCCMédicas UNAN-Managua proposed they will fulfill the following institutional functions.

1) Contribute to improving the scientific training of resident physicians of the 28 medical specialties of the Faculty of Medical Sciences of UNAN-Managua, through the Coordination, Supervision, Evaluation, and Quality Control of the Online Postgraduate Courses (POSGIB), taught by the Faculty of Medical Sciences of UNAN-Managua.

2) Contribute to strengthening the capacities of the public health sector for scientific biomedical research as a facilitator of sustainable human development (DHS) for the Nicaraguan family.

3) Facilitate the development of the Scientific Research Committees of the Health Sector (CTIES\_Salud).

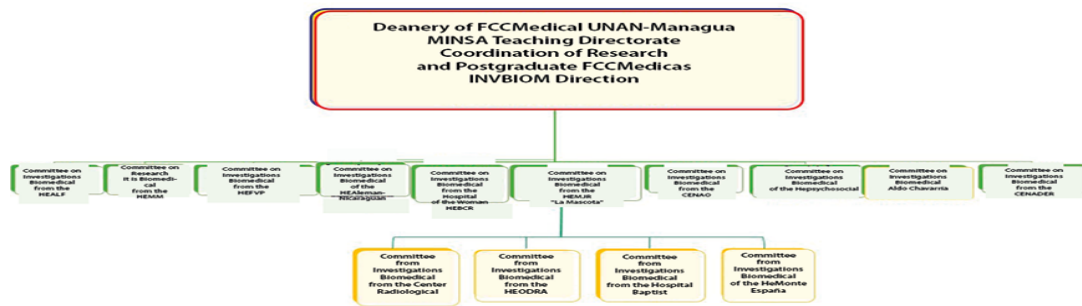
4) Facilitate the development of Bioethics Committees in the Health Sector.

5) Contribute to the updating and implementation of the Lines of Research in the Health Sector.

6) Facilitate the development of the Nicaraguan Biomedical Research Network.

7) Contribute to increasing the scientific productivity of the Faculty of Medical Sciences of UNAN-Managua, increasing and improving the quality of scientific publications, through support for medical specialties in MINSA hospitals.

The following is a proposal for the organization of the Biomedical Research Committees.



### 3. CONCLUSIONS

The INVBIOM, based on the R+D+i Model evolved to the year 2022, assumes the logic of the research process, with a holistic, systemic, and anthropocentric vision, to generate new knowledge and technologies, which will be applied in a specific productive or service system, in this case, the different medical specialties and the public health sector of Nicaragua. Based on this philosophical foundation, the following conclusions are presented.

1. The INVBIOM is a proposal for the creation of an innovative institute of scientific research and postgraduate studies, aimed at strengthening the competencies of Research, Development, and Innovation, (R+D+i Model), of the basic doctors of the MINSA hospitals and clinical-surgical teachers of the FCCMedicas UNAN-Managua, through 1) the Master's and Doctoral Program in Biomedical Research of the FCCM (PROMIB and PRODIB); 2) The Master's and Doctorate Program in Scientific Research with a major in Health Sciences PRODIC\_S; 3) The Masters and Doctorate Program in Medical Biotechnology.

2. It is expected that INVBIOM will contribute to improving the scientific training of the Resident Doctors of the Medical Specialties of the FCCM, UNAN-Managua, in strategic alliance with the MINSA, through three MOOC (Massive Online Open Course) courses in Biomedical Research (POSGIB): ( 1) Scientific Research Methodology, 2) Biostatistics, 3) Scientific Writing.

3. The INVBIOM will be organized into six Academic Programs (three master's and three doctorate), four specialized scientific research structures, plus a Center for Scientific Research at the Master's and Doctorate levels, which will be oriented to the field of Biomedical Research of the FCCMédicas of UNAN-Managua and the national public health sector.

4. For the development of the INVBIOM, it is proposed to create the Biomedical Research Committees, in a strategic alliance MINSA-Faculty of Medical Sciences-UNAN-

Managua, to contribute to the hospital environment to improve the quality, relevance, and impact of the results of Biomedical Research of the Resident Doctors, of the different Medical Specialties of the FCCM, UNAN-Managua.

5. The INVBIOM will facilitate increasing the scientific productivity of the national public health sector, increasing and improving the quality of scientific publications.

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