Armonización de Competencias en Investigación Clínica

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ICH - GCP

Principios:

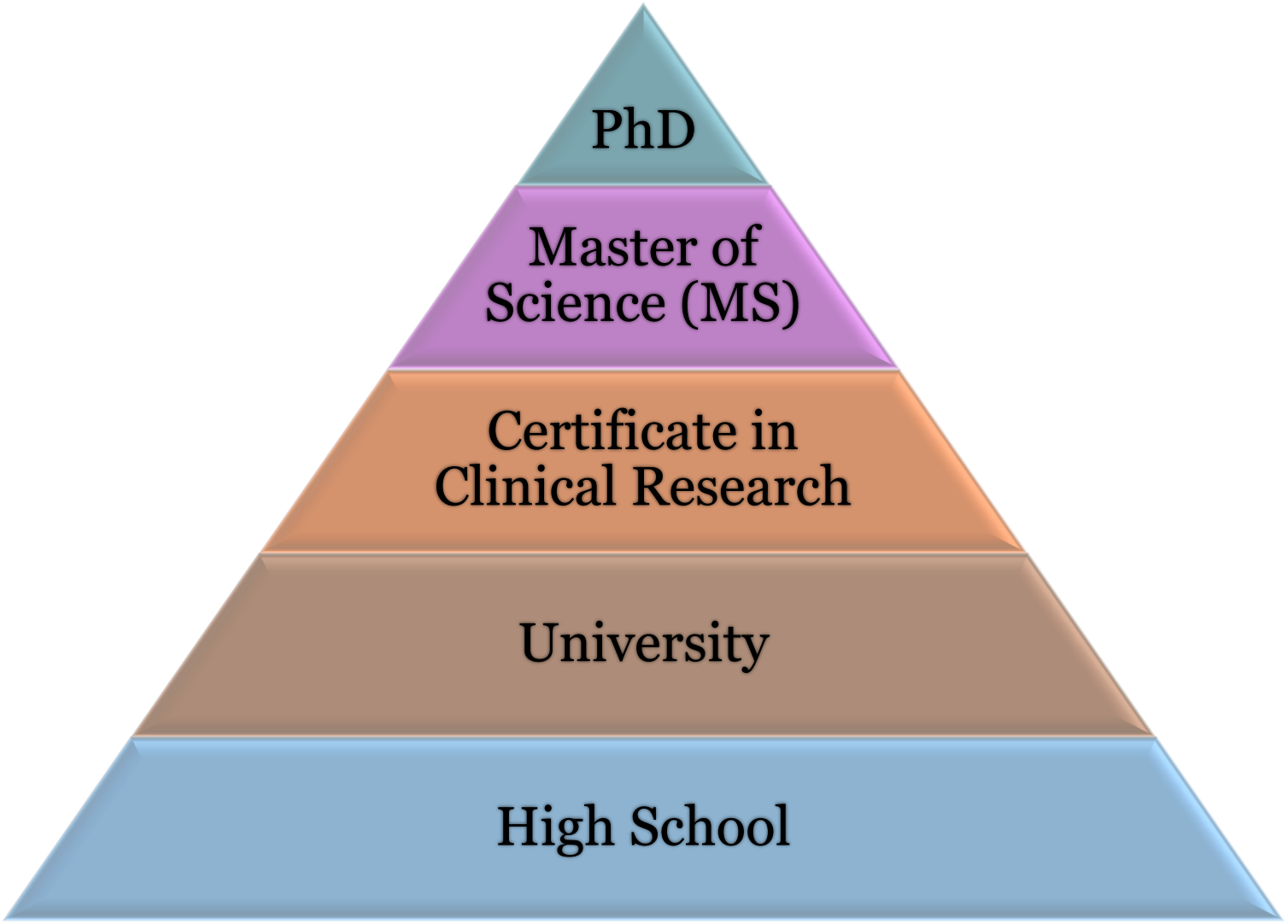
2.8. Cada individuo implicado en la realización de un ensayo deberá estar cualificado por su educación, entrenamiento y experiencia, para realizar sus tareas respectivas.

VALOR DE LA PROFESIONALIZACIÓN

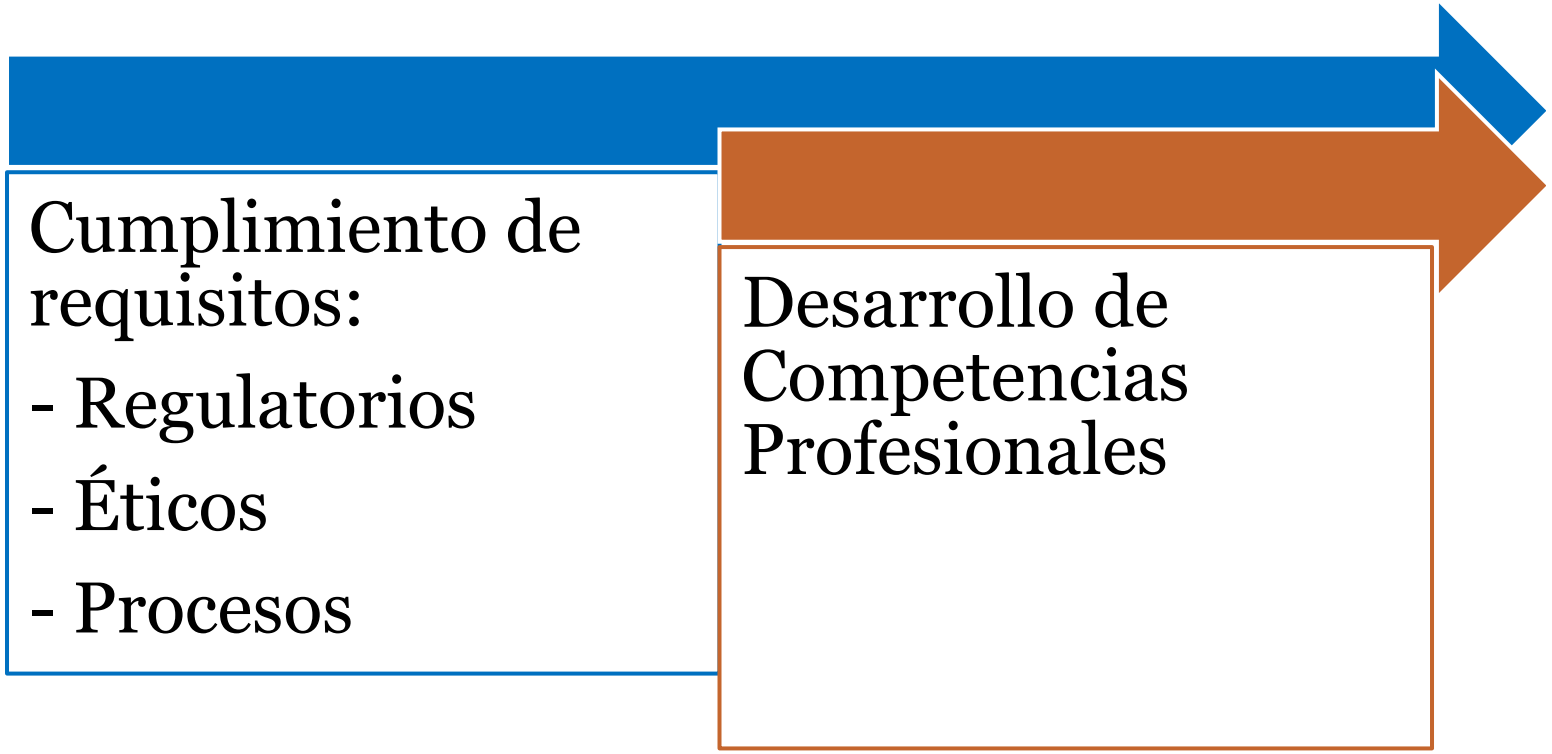
- Dominio profundo de conocimientos teóricos que sustentan la profesión
- Relación dialéctica entre el pensar y el hacer regida por valores humanos
- Independencia cognoscitiva sólida

Pérez, A., (2001). Propuesta de estrategia metodológica para la profesionalización del maestro de Literatura y Español. Tesis en opción al Master en Educación de Avanzada. ISPEJV. C de La Habana.

MODELO DE ESCUELA



“EDUCACIÓN Y ENTRENAMIENTO BASADO EN COMPETENCIAS”



Armonización de roles e indicadores de desempeño

Joint Task Force for Clinical Trial Competency Contributors and Collaborators

Academy of Physicians in Clinical Research
Association of Clinical Research Professionals
Amgen
Alliance for Clinical Research Excellence and Safety
Clinical & Translational Science Awards
Clinical Trials Transformation Initiative
Collaborative Institutional Training Initiative
Consortium of Academic Programs in Clinical Research
Deloitte
Drug Information Association
Global Health Network
Inter-American Foundation for Clinical Research
International Academy of Clinical Research
International Federation of Associations of Pharmaceutical Physicians
Korea National Enterprise for Clinical Trials
MAGI
Multi-Regional Clinical Trial Center
Pfizer
PharmaTrain
TransCelerate Biopharma, Inc.
UK Clinical Research Collaboration

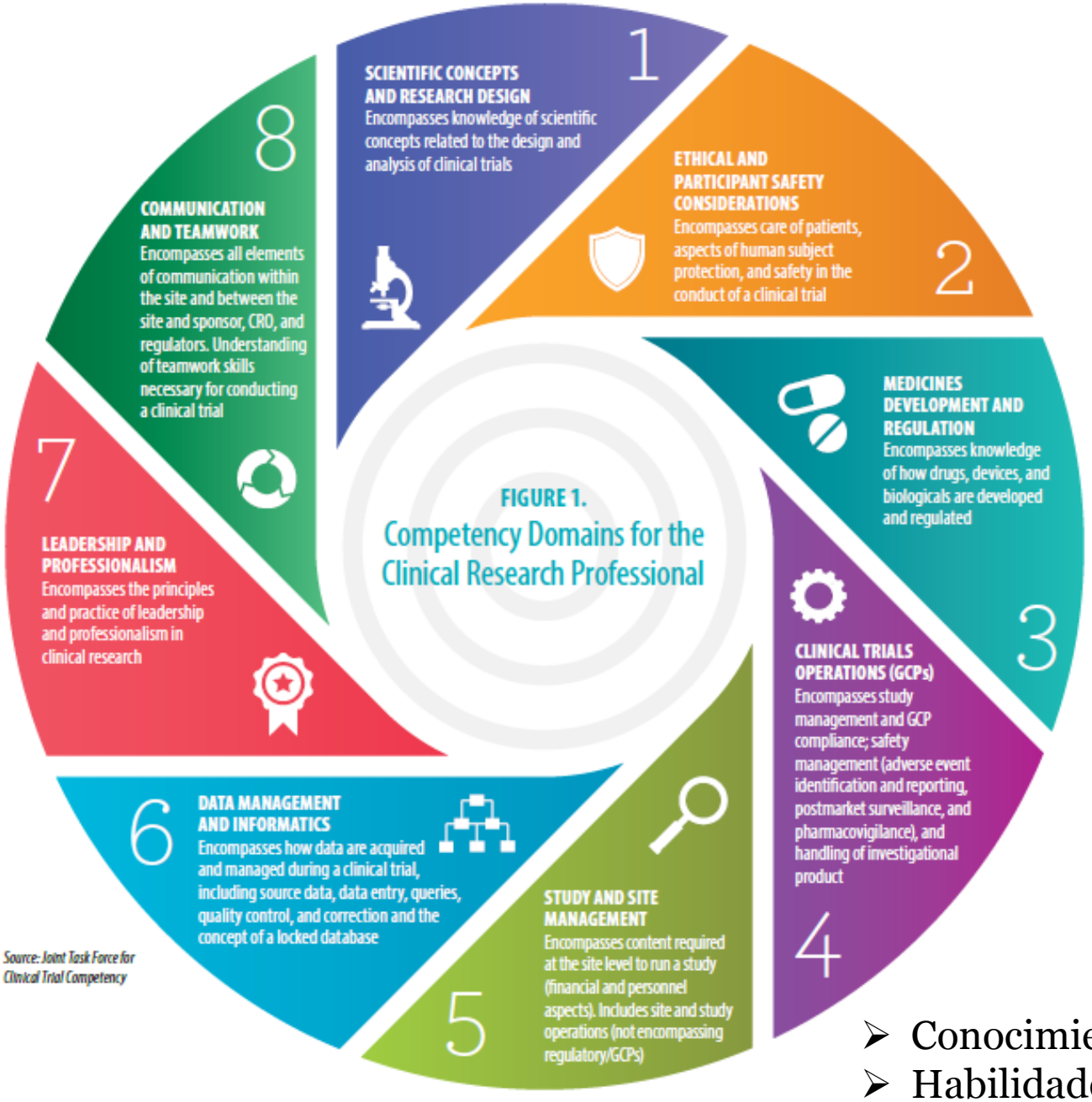


FIGURE 1.
Competency Domains for the Clinical Research Professional

Source: Joint Task Force for Clinical Trial Competency

- Conocimientos
- Habilidades
- Actitudes

TABLE 2. Competencies and Study Methods

DOMAIN	STUDY METHOD	
Scientific and Research Design	**Observational**	**Interventional**
Demonstrate knowledge of pathophysiology, pharmacology, and toxicology as they relate to medicines discovery and development	Optional	Required
Identify clinically important questions that are potentially testable clinical research hypotheses, through review of the professional literature	Required	Optional
Explain the elements (statistical, epidemiological, and operational) of clinical and translational study design	Required	Required
Design a clinical trial	Required	Optional
Critically analyze study results with an understanding of therapeutic and comparative effectiveness	Optional	Optional
Study and Site Management		
Describe the methods used to determine whether or not to sponsor, supervise, or participate in a clinical trial	Required	Required
Develop and manage the financial, timeline, and cross-disciplinary personnel resources necessary to conduct a clinical or translational research study	Required	Required
Describe the reporting requirements of global regulatory bodies relating to clinical trial conduct		
Apply management concepts and effective training methods to manage risk and improve quality in the conduct of a clinical research study	Required	Required
Use elements of project management related to organization of the study site to manage patient recruitment, complete procedures, and track progress	Required	Required
Identify the legal responsibilities, issues, liabilities, and accountability that are involved in the conduct of a clinical trial	Required	Required
Identify and explain the specific procedural, documentation, and oversight requirements of PIs, sponsors, CROs, and regulatory authorities that relate to the conduct of a clinical trial	Optional	Required

TABLE 3. Competencies by PI, CRC, and CRA Roles

DOMAIN	PI Role	CRC Role	CRA Role
Clinical Trial Operations			
Evaluate the conduct and management of clinical trials within the context of a Clinical Development Plan	Required	Optional	Optional
Describe the roles and responsibilities of the clinical investigation team as defined by GCP guidelines	Required	Required	Required
Evaluate the design conduct and documentation of clinical trials as required for compliance with GCP guidelines	Required	Optional	Required
Compare and contrast the regulations and guidelines of global regulatory bodies relating to the conduct of clinical trials	Required	Optional	Required
Describe appropriate control, storage, and dispensing of investigational products	Required	Required	Required
Differentiate the types of AEs that occur during clinical trials, understand the identification process for AEs, and describe the reporting requirements to IRBs/IECs, sponsors, and regulatory authorities	Required	Required	Required
Describe how global regulations and guidelines assure human subject protection and privacy during the conduct of clinical trials	Required	Optional	Optional
Describe the reporting requirements of global regulatory bodies relating to clinical trial conduct	Required	Optional	Optional
Describe the reporting requirements of global regulatory bodies relating to clinical trial conduct	Required	Optional	Optional
Describe the role and process for monitoring of the study	Required	Optional	Required
Describe the roles and purpose of clinical trial audits	Required	Optional	Required
Describe the safety reporting requirements of regulatory agencies both pre- and post-approval	Required	Required	Required
Describe the various methods by which safety issues are identified and managed during the development and post-marketing phases of clinical research	Optional	Optional	Optional
Study and Site Management			
Describe the methods used to determine whether or not to sponsor, supervise, or participate in a clinical trial	Required	Optional	Optional
Develop and manage the financial, timeline, and cross-disciplinary personnel resources necessary to conduct a clinical or translational	Required	Optional	Optional

EVALUACIÓN DE NECESIDADES DE EDUCACIÓN

Education and Training Needs Among Clinical Investigators and Medicines Development Professionals from Two Latin American Countries

PEER REVIEWED | Honorio Silva, MD | Gustavo F. Kesselring, MD | Juan Luis Yrivarren, MD | João Massud Filho, MD | Thomas M. Thomson, PhD | Alejandro Silva, MS | Stephen Sonstein, PhD | Marcelo V. de Lima, MD | Pablo A. Pulido, MD, DMSc

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CONOCIMIENTOS BÁSICOS

TABLE 3. Percentage of Respondents Rating Basic Knowledge Area as "Important" or "Very important" for Daily Clinical Research Practice

BASIC KNOWLEDGE AREA	PERU (n = 220)	BRAZIL (n = 490)
Drug Discovery Process	86.3	74.7 *
Clinical Pharmacology Basics	77.9	59.5 *
Understanding Regulations	95.1	92.4
The Clinical Trials Process: Why? What? How?	96.1	83.3 *
GCP and Clinical Trial Operations	98.0	92.2 **
Ethical and Legal Aspects	97.1	95.4
Ethics Committees and Informed Consent	95.1	86.1 *
Norms for Clinical Trials and Standard Operating Procedures	95.1	89.3
Project Management and Project Management Tools	85.8	85.2
Quality Assurance and Audits	91.7	85.7 **
Contracts and Legal Matters	82.4	74.7 *
Site Selection and Monitoring	89.2	80.7 *
Drug Safety and Pharmacovigilance	93.1	68.2 *
Basic Biostatistics	78.9	55.0 *
Data Management and Statistical Analysis Plan	77.0	55.9 *
Basic Epidemiology and	84.3	61.3*

TABLE 4. Percentage of Respondents Who Thought Additional Training was Needed in a Basic Knowledge Area

KNOWLEDGE AREA	PERU	BRAZIL
Clinical Pharmacology Basics	76.3	53.9 *
Understanding Regulations	76.8	60.9 *
The Clinical Trials Process: Why? What? How?	81.3	58.5 *
GCP and Clinical Trial Operations	82.8	87.4
Ethical and Legal Aspects	81.8	83.4
Ethics Committees and Informed Consent	85.4	89.3
Norms for Clinical Trials and Standard Operating Procedures	82.8	76.5
Project Management and Project Management Tools	84.3	79.8
Quality Assurance and Audits	79.3	80.7
Contracts and Legal Matters	86.9	83.5
Site Selection and Monitoring	81.8	73.2 *
Drug Safety and Pharmacovigilance	76.8	73.6
Basic Biostatistics	83.8	59.4 *
Data Management and Statistical Analysis Plan	76.3	49.5 *
Basic Epidemiology and Clinical Trial Design	74.2	54.8 *
Trends in Clinical Research	77.3	55.3 **
Information Technology	79.8	72.1 *
Healthcare Economics	75.8	52.8 *

HABILIDADES

TABLE 5. Comparison of Percentage of Respondents Who Rated Interpersonal and Business Management Skills as Highly Relevant for their Daily Work

SKILL	PERU	BRAZIL
Communication and Presentation Skills	96.5	97.3
Leadership	96.5	94.3
Teamwork	98.5	97.5
Tutoring and Mentoring Others	96.0	94.3
Negotiation	90.4	89.1
Medical Writing	84.3	64.0 *
Network Development	89.4	90.1
Conflict Management and Resolution	94.4	94.0
Media Skills	84.3	53.4*
Communication with Study Participants	90.4	71.1 *
Interpersonal Communication with the Team	94.9	93.3
Decision Making	98.0	96.8
Project Planning	96.4	91.0 *
Crisis Management	91.3	90.0
Human Resources Management	91.3	84.0 **
Financial Management	90.8	71.9 *
Time and Stress Management	93.4	91.7

*$p < 0.001$. **$p < 0.05 > 0.001$.

TABLE 6. Percentage of Respondents Who Needed Additional Training in Interpersonal and Business Management Skills

SKILL	PERU	BRAZIL
Communication and Presentation Skills	86.3	87.8
Leadership	84.8	87.8
Teamwork	85.3	87.5
Tutoring and Mentoring Others	83.8	83.8
Negotiation	82.2	87.2
Medical Writing	80.7	62.1 *
Network Development	80.2	77.9
Conflict Management and Resolution	88.3	90.3
Media Skills	77.2	56.3 *
Communication with Study Participants	77.2	71.5
Interpersonal Communication with the Team	88.8	85.9
Decision Making	86.7	90.0
Project Planning	87.8	88.9
Crisis Management	84.2	88.5
Human Resources Management	85.2	86.5
Financial Management	88.3	77.5 **
Time and Stress Management	87.8	88.7

*$p < 0.001$. **$p < 0.002$.

VALOR DE LA ACREDITACIÓN/CERTIFICACIÓN

TABLE 7. Perception of Value (Agreement/High Agreement) of Accreditation and Certification Initiatives to Leverage Clinical Research Quality (as percentage of total)

INITIATIVE	PERU	BRAZIL
Certification of Principal Investigators	60.1	66.6
Certification of Research Staff	79.0	84.2
Investigational Site Accreditation	76.9	84.8
Accreditation/Certification by National Regulatory Agency	60.3	79.5
Accreditation/Certification by International Nonprofit Organization	73.0	80.7
Accreditation/Certification by International For-Profit Organization	27.0	58.8

TABLE 8. Comparative Perception of Value (High/Very High) of CPD Activities (as percentage of total)

CPD ACTIVITY	PERU	BRAZIL
Conferences, Courses	85.1	66.5*
Interactive Workshops	87.0	66.8*
e-Learning Programs	72.1	38.7*
Teaching, Training, Tutoring	77.9	66.2**
Team Learning	85.6	69.8*

*$p < 0.001$. **$p = 0.02$.

EVALUACIÓN BASADA EN COMPETENCIAS DE LAS NECESIDADES EN EDUCACIÓN Y ENTRENAMIENTO EN INVESTIGACIÓN CLINICA

Relevancia por Perfiles y Portafolios de Competencias

Una Iniciativa Internacional

FEPAFEM PAFAMS

IAFCR

ASOCIACIÓN PERUANA PARA PROMOVER LA INVESTIGACIÓN CLÍNICA

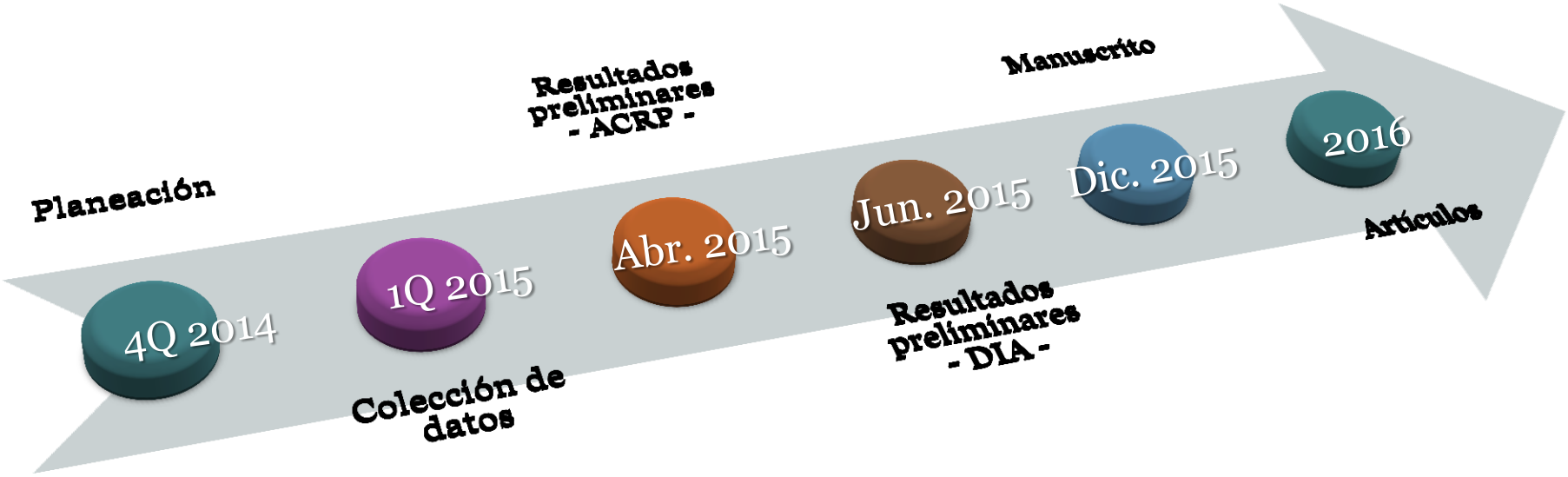
IFAPP Pharmaceutical Medicine

AVANZAR

ACRES Alliance for Clinical Research Excellence and Safety

SBMF Associação Brasileira de Medicina Farmacêutica

CRONOGRAMA


Planeación
4Q 2014
1Q 2015
Colección de datos
Resultados preliminares - ACRP -
Abr. 2015
Jun. 2015
Resultados preliminares - DIA -
Manuscrito
Dic. 2015
2016
Artículos









COLOMBIA