Maritza Garcia, MD
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Professional Summary

MD/Neurosurgeon; 18 years in Clinical Operations as CRA (Senior/Expert).
Extensive site selection, SIV/IMV/COV, training, and issue management across Phase II–III.
Strong focus on quality, compliance, and proactive risk escalation to CTL/LM.
Experienced in complex protocols across multiple therapeutic areas (listado breve).

Education / Qualifications		
1988	Hermanos Ameijeiras Hospital. Havana, Cuba	Neurosurgeon
1983	Higher Institute of Medical Science. Havana, Cuba	Medical Doctor

Core Competencies / Key Skills

- Site Selection/SIV/IMV/COV
- Site Training
- Vendor/IMP handling
- Issue escalation
- CAPA follow-up
- TMF/eTMF (si aplica)
- RBQM/RBQM mindset
- Protocol deviations
- Query management.

Employment History	
Medimar Solutions, LLC. Apr 2025 to present	CEO
Novartis Clinical Operations, Inc. Sep 2009 – Mar 2025	Senior Clinical Research Associate (2009-2023). Expert CRA (2023-2025)
Quintiles, Inc. Miami, FL Dec 2007 – Sep 2009	Sr. Clinical Research Associate (Apr 2009 – Sep 2009) Clinical Research Associate II (Dec 2007 – Apr 2009)
J. Tyson & Associates, Inc. September 2006 – Dec 2007	Clinical Research Associate.
University of Miami July 2002 – August 2006	Research Associate III (Neuroscience)
Pastor Oropeza Hospital Barquisimeto, Venezuela 1995 - 2001	Neurosurgeon

L. Alvarado University Barquisimeto, Venezuela 1995 - 2001	Professor of Morphological Science to medical students.
Juan M. Marquez Hospital Havana, Cuba1988 - 1995	Pediatric Neurosurgeon
Hermanos Ameijeiras Hospital Havana, Cuba1984 - 1988	Neurosurgery Residency
Rafaela Padilla Hospital Masaya, Nicaragua.1983 – 1984	General Practitioner

<table>
<tr><th colspan="3">Selected Trial Experience</th></tr>
<tr><th>Phase</th><th>Indication</th><th>Work description</th></tr>
<tr><td>II</td><td>Generalized Anxiety Disorder / Anxiolytic</td><td rowspan="14">Selection of sites.
Site Initiation visits and site staff training.
Provide monitoring visits and site management for a variety of protocols that are complex and/or require knowledge in advanced therapeutic areas.
Administer protocol and related study training to assigned sites and establish regular lines of communication with sites to manage ongoing project expectations and issues
Evaluate the quality and integrity of study site practices related to the proper conduct of the protocol and adherence to applicable regulations.
Escalate quality issues to Clinical Team Lead (CTL) and/or line manager
Manage the progress of assigned studies by tracking regulatory submissions and approvals, recruitment and enrollment, case report form (CRF) completion and submission, and data query generation and resolution.
Create and maintain appropriate documentation regarding site management, monitoring visit findings and action plans.
Act as a mentor for new clinical staff and may provide assistance to the CTL as designated.</td></tr>
<tr><td>II</td><td>Major Depression disease</td></tr>
<tr><td>II and III</td><td>Multiple Sclerosis (Several trials)</td></tr>
<tr><td>III</td><td>Influenza Vaccines</td></tr>
<tr><td>II and III</td><td>COPD</td></tr>
<tr><td>II</td><td>COVID</td></tr>
<tr><td>II</td><td>Alzheimer Disease</td></tr>
<tr><td>II and III</td><td>Cardiovascular Diseases</td></tr>
<tr><td>II</td><td>Liver Transplant</td></tr>
<tr><td>II and III</td><td>Immune Hepatitis.</td></tr>
<tr><td>III</td><td>Eczema</td></tr>
<tr><td>III</td><td>Hidradenitis</td></tr>
<tr><td>III</td><td>Tendonitis</td></tr>
<tr><td>II and III</td><td>Hypertension</td></tr>
<tr><th colspan="3">Device Projects Experience</th></tr>
<tr><td colspan="3">Multi-Center, prospective, randomized study comparing endovascular repair using the Stent system versus</td></tr>
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ultrasound surveillance for management of small abdominal aortic aneurysms.

- A dual arm factorial randomized trial in patients with St segment elevation AMI to compare the results of using either anticoagulation with unfractionated heparin plus routine GP llIb/IIIa inhibition with bivalirudin and bail-out GP (No Suggestions) inhibition, and primary angioplasty with stent implantation with either a slow rate-release paclitaxel-eluding stent or and otherwise identical uncoated bare metal stent.
- Carotid Angioplasty and Stenting versus Endarectomy in Asymptomatic Subjects with Significant Extracraneal Carotid Occlusive Disease.
    - Protected Carotid Artery Stenting in Subjects at High Risk for Carotid Endarectomy.

Professional Training

HIPAA Training Program: 20 Hours Complying with the Privacy Rule in Research by Medical Research Management, Inc

Clinical Research Associate Education and Training Program Conducted by Medical Research Management, Inc an accredited provider through ACPE.

"Fundamentals of Clinical Research" February, 2006

140 hours Training Program included the following topics*:*

- The drug research and development process, Identifying and reporting of non-serious and serious adverse events, principles of data management and query resolution, protocol development, case report form design, and informed consent writing.
- Good clinical practices 21 CFR 312 IND, 21 CFR 50 Protection of Human Subjects, 21 CFR 56 IRB, 45 CFR 46, 21 CFR 54 Financial Disclosure by Clinical Investigators. International Conference on Harmonization (E6) GCP Consolidated Guideline and (E2A) Clinical Safety Data Management.

- **Multiple Trainings in GCP, monitoring expertise, SOPs provided by sponsors.**

Systems Experience/IT Skills

eDC System extensive experience in Drug and Device trials.
PC Skills: Windows, Microsoft Office applications (Word, Excel, Access and Power Point, Teams), Internet, Networking, AI capabilities.

Other Relevant Details

Language: Bilingual English/Spanish.