JIMENA GONZÁLEZ HUERTA

Clinical Researcher | Clinical Validation | Regulatory Affairs (EU MDR, GDPR) | ICH-GCP

Madrid, Spain · +34 648 24 13 80 · jimenaglezhuerta@icloud.com · linkedin.com/in/jimena-gonzalez-a34a9b30b · bioninsight.netlify.app

PROFESSIONAL SUMMARY

Clinical researcher and regulatory affairs professional working at the intersection of clinical validation and healthcare innovation. Path from bench to bedside to boardroom: laboratory research at CSIC (tumor microenvironment), a hospital interventional cardiology internship in Germany, and clinical trial monitoring at CERC, coordinating 35+ hospitals across Spain, the Czech Republic, Malaysia, the UAE and the UK under GCP/ICH. Now at Mential (digital health, AI): clinical validation strategy, EU MDR and GDPR compliance, and European funding and consortia. First author of an oral presentation at GICS 2026 and e-Poster at EuroPCR 2026. Founder of BioInsight and NewroPlay.

PROFESSIONAL EXPERIENCE

Clinical Research & Regulatory Affairs

Mential (digital health, AI) · Alcobendas, Madrid · Jul 2026 - present

- Mential's AI engine turns text, voice and questionnaire data into FHIR-coded longitudinal clinical markers.
- Clinical validation: authored SOP-EST-01, the marker stability protocol (determinism, domain and temporal stability, acceptance thresholds, re-validation triggers), and ran the analyses behind it. Defined engagement and usability markers for the fertility vertical.
- Regulatory: EU MDR intended purpose, use-case and classification documentation; GDPR consent, clinic contract clauses and DPIA scoping.
- European funding and consortia: built the funding intelligence base (funder, deadline, TRL, consortium type, role) and opened consortium and pilot conversations with hospitals, universities, research centres, CROs and industry across Spain, Europe and LATAM, including proposals with Dutch, Greek and Flemish partners via the Enterprise Europe Network.
- Scientific positioning: co-authored the Scientific & Rationale Dossier extending the behavioural data layer beyond mental health (fertility and pharma appendices); launched the Research-as-a-Service line.

Clinical Research Associate (CRA)

Cardiovascular European Research Center (CERC, academic CRO) · Paris, France · Sep 2025 - Apr 2026

- Monitored and coordinated international multicentric trials across 35+ hospitals in Spain, the Czech Republic, Malaysia, the UAE and the UK.
- Site Initiation Visits, on-site, remote and e-visit monitoring; Source Data Verification against EDC; query resolution, database log review and data cleaning to keep timelines and data integrity.
- Maintained CTMS and eTMF; reviewed site regulatory documents (ISF) and supported Ethics Committee submissions across multiple regulatory frameworks.
- Project lead in new research initiatives: funding applications, international consortia, NDAs, sponsor communication and stakeholder alignment.
- Compliance with study protocols, SOPs, ICH-GCP E6(R3) and EU Regulation 536/2014.

Clinical Internship in Interventional Cardiology

Klinik Vincentinum · Augsburg, Germany · Jun 2025 - Aug 2025

- Supported patient care and procedures: coronary angiography, angioplasty, transoesophageal echocardiography (TEE) and ECG; interpreted clinical results and recorded clinical data.

Research Intern - Bachelor's Thesis

CSIC · Madrid, Spain · Feb 2025 - Jun 2025

- In vitro model of fibroblast - endothelial cell crosstalk in the tumor microenvironment under ionizing radiation and PDGF: fibroblast and endothelial cultures, proliferation and tubulogenesis (angiogenesis) assays, image analysis with ImageJ.

Dining Room Supervisor / Host

La Lonja del Mar (La Lonja del Palacio del Siglo XXI SL) · Madrid · Jun 2021 - Sep 2022

- Promoted to supervise shifts of up to 15 people; reservations, events and service coordination.

EDUCATION

- **MSc in Clinical Trials Monitoring and Management** · CESIF · 2024-2025 · 1,500 h · 60 ECTS · GPA 3.6
- **BSc in Biomedicine** · Universidad Alfonso X el Sabio (UAX), Madrid · 2021-2025
- **Higher Technical Degree in Dietetics and Nutrition** · Campus Training · 2025-2027 (in progress)
- **Stem Cell Medicine: From Scientific Research to Patient Care** · Harvard University · Feb 2026

PUBLICATIONS AND CONGRESS COMMUNICATIONS

- Gonzalez Huerta J, Rechner M, Schon B, Lengler S, Jockel J, Pyxaras S, Behnes M, Christiansen EH, Mashayekhi K, Gutierrez-Chico JL. Massive positive remodelling after PCI of CTO, resulting in gross late-acquired undersizing. Oral presentation, GICS 2026 (first author).

- Cost-effectiveness of percutaneous revascularisation of coronary chronic total occlusions in Ukraine. e-Poster, EuroPCR 2026, Paris.
- Attendee, XI and XII Biomedical Research Congresses, Universitat de Valencia (2023, 2024).

INDEPENDENT PROJECTS

- **BioInsight** - founder and editor of a bilingual (ES/EN) biomedical science communication platform; daily evidence-based articles with cited sources.
- **NewroPlay** - founder of a healthtech project for neuromotor and neurocognitive rehabilitation. Selected for Santander X Explorer 2025.

SKILLS, LANGUAGES AND TRAINING

- **Regulatory and clinical:** clinical validation protocols and SOPs · EU MDR (intended purpose, classification) · GDPR, DPIA · ICH-GCP E6(R3) · EU Reg. 536/2014 · CTMS · eTMF · EDC · SDV.
- **Data and digital:** R · SQL · ImageJ · Kanban/Miro · prompt engineering · Claude AI · Obsidian.
- **Languages:** Spanish (native) · English (native/bilingual; Oxford Test of English Advanced C1, 142/170) · Italian, French, German (elementary).
- **Certifications:** SQL for data science with R · Lean Kanban workflows in Miro · Introduction to ImageJ · Prompt engineering for ChatGPT · Oxford Test of English Advanced (C1).