

Mirnaya Mujica-Alabaci

BA, CCRC | Curriculum Vitae

Business Development Specialist

Integrated Health Research LLC

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Clinical research professional with experience in business development, clinical trial budgets and contracts, regulatory operations, quality assurance, site management and study coordination. Fluent in English and Spanish.

PROFESSIONAL EXPERIENCE

Business Development / Regulatory Specialist

Genomics Medical Research, LLC | Cutler Bay, FL | 2022 - Present

- Manage site selection, trial preparation, clinical operations and assigned staff in accordance with protocols, GCP, ICH guidelines and federal requirements.
- Liaise with investigators, administrative staff, primary care providers, IRBs and sponsors; screen, enroll and follow participants, ensuring protocol compliance and staff oversight.

Contract / Budget Specialist

Genomics Medical Research, LLC | Cutler Bay, FL | 2022 - Present

- Review clinical trial protocols, develop investigator per-patient costs and budgets, and negotiate contracts.

Business Development / Contract / Budget Specialist

Ohana Medical Research, Inc. | Homestead, FL | 2022 - 2023

- Review protocols, develop investigator per-patient costs and budgets, and negotiate contracts.

Contract / Budget Specialist

Homestead Associates in Research, Inc. | Homestead, FL | 2018 - 2023

- Review protocols, develop investigator per-patient costs and budgets, and negotiate contracts.

Independent Clinical Research Consultant

MM Consulting Research Group Services | Miami, FL | 2018 - Present

- Coordinate training, planning, execution and interpretation of Phase II-IV studies across clinical research sites, following assigned protocols and FDA, GCP and ICH requirements.

PROFESSIONAL EXPERIENCE CONTINUED

Regulatory and QA Specialist / Lead Research Coordinator

Suncoast Research Group, LLC | Miami, FL | 2018 - 2023

- Manage site selection, trial preparation, operations and staff under protocol, GCP, ICH and federal requirements. Liaise with investigators, administrative teams, providers, IRBs and sponsors; oversee screening, enrollment and follow-up.
- Develop protocol-specific quality assurance plans, review documents, and train and supervise coordinators and support staff. Oversee source records, adverse event reporting and regulatory files.

Site Director / Regulatory and QA Specialist / Lead Clinical Research Coordinator

JM Clinical Research, LLC (formerly South Florida Clinical Research, LLC) | Miami, FL | 2015 - 2018

- Develop protocol-specific quality assurance plans, review documents before and during studies, and train and supervise coordinators and support staff. Manage site selection, preparation, trial conduct and staff under protocol, GCP, ICH and federal requirements.
- Liaise with investigators, administrative teams, providers, IRBs and sponsors; oversee screening, enrollment, follow-up, data and source documentation, adverse event reporting and regulatory files.

Site Manager / Regulatory and QA Specialist

Amun Medical Research | Miami, FL | 2013 - 2015

- Develop protocol-specific quality assurance plans; review documents and train and supervise staff. Manage site selection, preparation and trial conduct under protocol, GCP, ICH and federal requirements.
- Liaise with investigators, administrative teams, providers, IRBs and sponsors. Oversee screening, enrollment, participant follow-up, staff performance, source documentation, adverse event reporting and regulatory files.

Regulatory Administrator

Miami Research Associates | Miami, FL | 2012 - 2013

- Establish files for prospective and current studies and manage regulatory submissions to sponsors, CROs and IRBs.
- Maintain institution, investigator, sub-investigator and staff CVs; prepare and maintain regulatory and financial packages, study materials and site advertisements.

Senior Clinical Research Coordinator

Miami Research Associates | Miami, FL | 2002 - 2012

- Manage clinical trial operations and staff under protocol, GCP, ICH and federal requirements; liaise with investigators, administrative staff, providers, IRBs and sponsors.
- Screen, enroll and follow participants; supervise source documentation, adverse event reporting and regulatory file maintenance.

Clinical Research Coordinator

Miami Research Associates | Miami, FL | 1997 - 2002

- Obtain consent and medical histories; maintain source records and CRFs; recruit and schedule patients; perform phlebotomy, laboratory procedures and EKGs; maintain drug accountability and adverse event follow-up; coordinate with IRBs and sponsors; educate patients and train staff.

EDUCATION AND PROFESSIONAL DEVELOPMENT

EDUCATION AND LANGUAGES

Bachelor in Business Administration / Marketing | Tampa, FL | 1982-1986

CRCC Certification | Miami, FL | 1998

Languages | Fluent English and Spanish

LICENSES AND CERTIFICATIONS

NIH Certified | 2007 - Present

CITI Human Subjects course | 13 Sep 2022; expired 12 Sep 2025

IATA Certified | 2003 - Present

ACRP Certified Clinical Research Coordinator | 2001 - Present

CPR Certified | 1999 - Present

PROFESSIONAL MEMBERSHIPS

ACRP, Association of Clinical Research Professionals | 1998 - Present

SFACRP, South Florida ACRP Chapter | 1998 - Present

American Translators Association | 2005 - Present

SPECIALIZED COURSES AND TRAINING

- CITI Course in the Protection of Human Research Subjects | 2012
- NIH Human Participants Protection Education for Research Teams Certificate | 2007
- CITI Course in the Protection of Human Research Subjects | 2006
- Skills Enhancement for the Clinical Trials Research Professional | 2004
- Nursing Unlimited Phlebotomy Certificate | 2003
- TAP - Ensuring High Quality Clinical Research | 2003
- Pharmacia Investigator Support Initiative Training Course | 2001
- Eli Lilly Fibromyalgia Tender Point Assessment Training | 2001
- Association of Clinical Research Professionals (ACRP)
- Certified Clinical Research Coordinator since 2001
- Clinical Research: Tools for Success | 1999
- Fundación C.E.R.E.L.
- Latin-American Reality Study Center, Latin-American Markets Seminar | 1989
- United States Information Center, International Information Seminar | 1989

Credentials and memberships follow the source CV; CITI dates reflect the supplied certificate.

CLINICAL RESEARCH EXPERIENCE

Individual experience across prior research sites. Historical phases and enrollment figures below refer to the studies listed in Mirnaya's source CV. IHR's institutional scope is Phase II-IV.

- 001 **Glaxo Wellcome** | GERD meal study | 90 patients enrolled | 1997
- 002 **Glaxo Wellcome** | GERD meal study | 256 patients enrolled | 1997
- 003 **Merck** | Osteoarthritis | 41 patients enrolled | 1997
- 004 **Pfizer** | H. pylori | 32 patients enrolled | 1997
- 005 **Astra-Merck** | Duodenal ulcer / H. pylori | 19 patients enrolled | 1998
- 006 **TAP Pharmaceuticals** | GERD | 15 patients enrolled | 1998
- 007 **Wyeth-Ayerst** | Duodenal ulcer / H. pylori | 15 patients enrolled | 1998
- 008 **TAP Holdings** | Provocative meal study | 280 patients enrolled | 1998
- 009 **TAP Holdings** | Dyspepsia | 10 patients enrolled | 1998
- 010 **TAP Holdings** | Crohn's disease | 5 patients enrolled | 1998
- 011 **Wyeth-Ayerst** | Duodenal/gastric ulcer / H. pylori | 11 patients enrolled | 1999
- 012 **Wyeth-Ayerst** | Erosive esophagitis | 32 patients enrolled | 1999
- 013 **Wyeth-Ayerst** | GERD | 24 patients enrolled | 1999
- 014 **Wyeth-Ayerst** | Osteoarthritis of the knee | 27 patients enrolled | 1999/2000
- 015 **Roche** | Rheumatoid arthritis | 13 patients enrolled | 1999/2000
- 016 **Roche** | Osteoarthritis | 7 patients enrolled | 1999/2000
- 017 **Searle** | General osteoarthritis | 1999
- 018 **Knoll** | Back pain | 4 patients enrolled | 2000
- 019 **Parke-Davis/Pfizer** | Fibromyalgia | 14 patients enrolled | 2000
- 020 **Roberts Laboratories** | Osteoarthritis | 4 patients enrolled | 2000
- 021 **Searle** | Osteoarthritis / hypertension | 2000
- 022 **Sepracor** | Insomnia | 2001
- 023 **Takeda** | Insomnia | 2001/2002
- 024 **Neurocrine Biosciences** | Insomnia | 2002
- 025 **Amgen** | Rheumatoid arthritis | 2001/2002
- 026 **lomed** | Epicondylitis | 2000/2001
- 027 **Novartis** | Rheumatoid arthritis | 2001

CLINICAL RESEARCH EXPERIENCE CONTINUED

Individual study history and protocol references

- 028 **Merck** | Osteoarthritis | 34 patients enrolled | 2001/2002
- 029 **Forest** | Osteoarthritis of hip/knee | 12 patients enrolled | 2001/2002
- 030 **Pharmacia** | Osteoarthritis of the knee | 8 patients enrolled | 2001/2002
- 031 **Pfizer** | Osteoarthritis | 16 patients enrolled | 2002
- 032 **Immunex** | Rheumatoid arthritis | 13 patients enrolled | 2002
- 033 **Merck** | Osteoarthritis | 30 patients enrolled | 2002/2003
- 034 **Eli Lilly** | Fibromyalgia | 36 patients enrolled | 2003
- 035 **NEXT Pharmaceuticals** | Osteoarthritis | 30 patients enrolled | 2003/2004
- 036 **Pfizer** | Fibromyalgia | 21 patients enrolled | 2004
- 037 **Sanofi** | Fibromyalgia | 12 patients enrolled | 2004/2005
- 038 **Pfizer** | Fibromyalgia | 11 patients enrolled | 2004/2005
- 039 **Orphan Pharmaceutical** | Fibromyalgia | 4 patients enrolled | 2004/2005
- 040 **Pfizer** | Fibromyalgia | 13 patients enrolled | 2005/2006
- 041 **Cipher** | Osteoarthritis | 11 patients enrolled | 2005/2006
- 042 **NicOx Pharmaceuticals** | Osteoarthritis | 6 patients enrolled | 2005/2006
- 043 **Eli Lilly** | Fibromyalgia | 20 subjects enrolled | 2006
- 044 **Sanofi-Aventis** | Insomnia | 7 subjects enrolled | 2005/2007
- 045 **NicOx Pharmaceuticals (Extension)** | Osteoarthritis | 2005/2007
- 046 **Novartis** | Heartburn | 2006/2007
- 047 **Pozen** | Ulcer/NSAID | 30 subjects | 2006/2007
- 048 **Wyeth Research** | Phase I, osteoarthritis prevention | 22 subjects enrolled | 2007
- 049 **Acambis** | Phase I, influenza vaccine | 32 subjects enrolled | 2007/2008
- 050 **Novartis** | Influenza vaccine | 386 subjects enrolled | 2007/2008
- 051 **Solvay** | Phase I, influenza vaccine | 60 subjects enrolled | 2007/2008
- 052 **GlaxoSmithKline** | Avian influenza vaccine | 65 subjects enrolled | 2007
- 053 **Centocor** | Autoinjector | 30 subjects enrolled | 2008
- 054 **Neurogen** | Phase I, Parkinson's disease | 8 subjects enrolled
- 055 **Sanofi-Pasteur** | Phase I, avian influenza vaccine | 75 subjects enrolled | 2008

CLINICAL RESEARCH EXPERIENCE CONTINUED

Individual study history and protocol references

- 056 **Map Pharmaceuticals** | Phase III, migraine | 2008 (listed as ongoing in source CV)
- 057 **Emergent** | Phase II, typhoid vaccine | 67 subjects enrolled | 2008
- 058 **IDEA** | Phase III, osteoarthritis | 2008
- 059 **GSK** | Phase I/III, influenza vaccine | 129 subjects enrolled | 2008
- 060 **Dynport/Baxter** | Phase III, influenza vaccine | 379 subjects enrolled | 2008/2009
- 061 **MedImmune** | Phase II/III, influenza vaccine | 100 subjects enrolled | 2009
- 062 **Sanofi-Pasteur** | Phase II, A/H1N1 pandemic vaccine | 79 subjects enrolled | 2008
- 063 **Novartis** | Phase I, A/H1N1 pandemic vaccine | 230 subjects enrolled | 2009
- 064 **Baxter** | Phase I, West Nile virus vaccine | 56 subjects enrolled | 2009
- 065 **Pfizer** | Phase I, osteoarthritis | 20 subjects enrolled | 2009
- 066 **Novartis** | Phase I, muscle restoration | 24 subjects enrolled | 2010/2013
- 067 **BioCryst** | Phase II, gout | 6 subjects enrolled | 2011/2012
- 068 **Dynavax** | Phase I, lupus | 2011/2013
- 069 **Merck** | Phase I, herpes zoster vaccine | 99 subjects enrolled | 2011/2012
- 070 **Novartis** | Phase I, sarcopenia | 4 subjects enrolled | 2011/2013
- 071 **Pfizer** | Phase I, Staphylococcus aureus vaccine | 32 subjects enrolled | 2012
- 072 **Purdue Pharma** | Phase III, opioid-induced constipation | 2013/2014
- 073 **Sanofi MSC12665** | Phase III, rheumatoid arthritis | 2014/2015
- 074 **Sanofi EFC14092** | Phase III, rheumatoid arthritis | 2014/2015
- 075 **Vertex VX14** | Phase III, influenza treatment | 2014/2015
- 076 **SKK6603/1131** | Phase III, lumbar disc herniation | 2014/2017
- 077 **Eli Lilly** | Phase III, lupus | 2013/2015
- 078 **GW Pharmaceutical** | Cancer chronic pain | 2013/2015
- 079 **Jazz Pharmaceutical** | PRIALT observational | 2013/2015
- 080 **Boston Scientific** | Neurostimulation therapy | 2013/2015
- 081 **Myoscience** | Knee osteoarthritis | 2015/2016
- 082 **SKK6603/1132** | Open-label, lumbar disc herniation | 2015/2017
- 083 **OPC2065-5** | Double-blind, opioid analgesic therapy for chronic pain | 2016/2018

CLINICAL RESEARCH EXPERIENCE CONTINUED

Individual study history and protocol references

- 084 **Novartis CLCZ696B2320** | Double-blind, cognitive function in heart failure patients | 2016/2018
- 085 **Novartis CCNP520A2202J** | Double-blind, Alzheimer's disease | 2017/2023
- 086 **Novartis COMB157G2301** | Double-blind, multiple sclerosis | 2017/2023
- 087 **Novartis COMB157G2399** | Open-label, multiple sclerosis | 2017/2023
- 088 **Bayer 16244/17530** | Double-blind, diabetic kidney disease | 2016/2018
- 089 **Gan & Lee GL-GLAT1-3001** | Double-blind, diabetes I | 2017/2019
- 090 **Gan & Lee GL-GLAT2-3002** | Double-blind, diabetes II | 2017/2019
- 091 **Janssen FLZ3002** | Double-blind, influenza treatment | 2018/2019
- 092 **Amgen** | 20150230
- 093 **Astellia APGD** | 2693-CL-0302
- 094 **Boston** | BOS-589-201
- 095 **Bayer** | 15790
- 096 **Credo 3** | CL04041025
- 097 **Credo 2** | CL04041023
- 098 **Credo 4** | CL04041024
- 099 **Eli Lilly** | I1F-MC-RHCR
- 100 **Eli Lilly** | H9X-MC-GBGL
- 101 **Eli Lilly** | I8F-MC-GPGM
- 102 **Eli Lilly** | I8H-MC-BDCT
- 103 **Eli Lilly** | H0P-MC-CPMP
- 104 **Eli Lilly** | I4V-MC-JAJA
- 105 **Eli Lilly** | I8F-MC-GPHK
- 106 **Eli Lilly** | I8H-MC-BDCL
- 107 **Exact Sciences** | 2019-01
- 108 **Exact Sciences** | 2019-01B
- 109 **Genentech** | GB43311
- 110 **Gilead** | GS-US-417-0304
- 111 **Gilead** | GS-US-433-5305

CLINICAL RESEARCH EXPERIENCE CONTINUED

Individual study history and protocol references

- 112 **Gilead** | GS-US-433-5307
- 113 **GlaxoSmithKline** | 212390
- 114 **GlaxoSmithKline** | 217670 - Zoster - 091
- 115 **GlaxoSmithKline** | 217741
- 116 **Janssen** | VAC 31518 COV3001
- 117 **Janssen** | VAC 31518 COV3009
- 118 **Jazz** | JZP110-405
- 119 **Ironwood** | GERD C3718-302
- 120 **Mineralys** | MLS-101-201
- 121 **Molecular Partners / Novartis** | MP0420-CP320
- 122 **Moderna** | mRNA-1273-P301 - COVID-19 vaccine
- 123 **Novavax** | SARS-COV-2 2019nCOV-301
- 124 **Pfizer** | C4671002
- 125 **Pfizer** | C4671005
- 126 **Pfizer** | C4671006
- 127 **Radius** | BA058-05-021
- 128 **Sanofi** | VAT00002
- 129 **Sanofi** | VAW00001
- 130 **Theravance Biopharma** | 0164
- 131 **Theravance Biopharma** | 0173
- 132 **TILD** | 19-07 MZA5617
- 133 **Valneva** | VLA1553-301
- 134 **ZONA** | 001
- 135 **ZYDUS** | NASH Saro-20.002

Signature

Date