

#### **Personal Information**

Last Name	Saud Martinez	
Full first name(s)	Andrea	
Primary Function	Chief Director, Clinical Research – LATAM	
Title(s)	M. Sc. Pharm. D.	
Country and city of residence	Brazil, São Paulo	
Nationality	Spanish, Brazilian	
Language skills		
Fluent verbally in	<ul><li>Portuguese – fluent (native language)</li><li>English – fluent (native language)</li><li>Spanish – fluent (native language)</li></ul>	
Fluent in writing in	<ul> <li>- Portuguese – fluent (native language)</li> <li>- English – fluent (native language)</li> <li>- Spanish – fluent (native language)</li> </ul>	
Computer skills		
Regular business software	Very good	
Specific software knowledge	VMS-VAX – Oracle, SAS, Access, InForm, EDC RAVE/Medidata, ADEPT, CTMS (IMPACT), IRT (SUVODA), eTMF, Veeva Sites, Clinical, Vault, eSOCDAT, IMPACT, SPARK, DrugDev, RedCap, LifeSphere, SUVODA, ClinTrak among others.	

#### **Formal Education & Qualifications**

Timeframe	Education/Qualification	Place & Institute
Nov 2017	Registered Quality Assurance Professional – GCP Lead Auditor	US Society of Quality Assurance (SQA)
1994-1999	Doctorate Degree - "Urinary Glucoproteins and Biochemical Markers of Bone Metabolism"	Paulista University - São Paulo, Brazil (in partnership to London University, UK)
1996 - 1998	Master Degree Sensu Strictu - "Exportation of Medicines and perishable products to the European Community"	Paulista University - São Paulo, Brazil

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Timeframe	Education/Qualification	Place & Institute
1987 - 1992	Bachelor in Pharmacy and	Paulista University - São Paulo,
	Biochemistry	Brazil

#### **Employment History**

Timeframe	Position	Employer
Jan 2010 - ongoing	Chief Director, Clinical Research Latin America	AVANTI Pesquisa Clínica, Ltd.
Jan 2009 - ongoing	Lead Auditor, GCP	Quality Plus Auditoria e Educação Farmacêutica, Ltd
Nov 2007 – Nov 2009	Vice President, Clinical Operations, South America	AAIPHARMA Brazil Ltd (Formerly IPCSP)
May 2007 – Nov 2007	General Manager, South America	AAIPHARMA Brazil Ltd (Formerly IPCSP)
Feb 2000 – May 2007	Founder/President / CEO	Instituto de Pesquisa Clínica de São Paulo Ltd. (IPCSP)
Aug 1999 – Feb 2000	Associate Director, Clinical Research	ARONEX Europe, Ltd.
Nov 1998 – Jul 1999	Manager, Clinical Research	ARONEX Europe, Ltd.
Jan 1996 – Feb 1999	Consulting in Clinical Research and Regulatory Affairs in Latin America	COVANCE Central Laboratory, Inc
Nov 1997 - Oct 1998	Senior Project Manager	PPD PHARMACO
Jul 1997 - Oct 1997	Senior Clinical Research Associate	PPD PHARMACO
Jan 1997 - Jun 1997	Senior Clinical Research Associate	PFIZER Inc.
Sept 1996 - Dec 1996	Product Manager – Job rotation	MERCK Research Laboratories (MRL Division)

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Timeframe	Position	Employer
Apr 1995 – Aug 1996	Clinical Data Management	MERCK Research Laboratories (MRL Division)
Apr 1994 – Mar 1995	Quality Assurance Auditor	MERCK Research Laboratories (MRL Division)
Jun 1992 – Mar 1994	Clinical Research Associate	MERCK Research Laboratories (MRL Division)
Mar 1991 – Jun 1992	Clinical Study Coordinator	MERCK Research Laboratories (MRL Division)

#### **Clinical Project Experience**

Timeframe	Clinical project	Therapeutic area	Position
Apr 2022 – Ongoing	Phase II International Trial (iDentical)	Dentistry - Dental Implant	Country Project Leader
Mar 2022 – Ongoing	Phase IV International Trial (ATTACC-CAP)	Infectious diseases - CAP	Country Project Leader
May 2021 –	Phase III International Trial (ARCHER)	Cardiology – Acute	Country Project
Ongoing		Myocarditis	Leader
May 2021 – Ongoing	IIS National Trial (CANABIC)	Cardiology – Heart Failure	Country Oversight Leader
Mar 2021 –	Phase IV International Trial (COVID-RASi) Brazil and Mexico	Infectious diseases -	Country Project
Ongoing		COVID-19	Leader
Feb 2021 –	Phase IV International Trial (ACTIV4A) Mexico	Infectious diseases -	Country Project
Ongoing		COVID-19	Leader
Feb 2021 –	Phase IV International Trial (FREEDOM)	Infectious diseases -	Country Project
Ongoing		COVID-19	Leader
Nov 2020 –	Phase II International Trial (AÇAÍ COVID)	Infectious diseases -	Country Project
Ongoing		COVID-19	Leader
Nov 2020 –	Phase II International Trial (ASPEN)	Infectious diseases -	Country Project
Ongoing		COVID-19	Leader

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Timeframe	Clinical project	Therapeutic area	Position
Oct 2020- Ongoing	Phase IV International Trial (DD-OV-01) Chile	Dental Implant	Project Leader
Aug 2020 –	Phase IV National Trial (HEPMAB)	Infectious diseases -	Country Project
Ongoing		COVID-19	Leader
Jun 2020 –	Phase II International Trial (REPAVID)	Infectious diseases -	Country Project
Ongoing		COVID-19	Leader
Jun 2020 – Ongoing	Phase IV National Trial (KIOS)	Gastroenterology – acute gastritis	Country Project Leader
Jun 2020 –	Phase III International Trial (ATTAC)	Infectious diseases -	Country Project
Ongoing		COVID-19	Leader
Dec 2018 -	Phase III Interventional Trial (ON-04-30)	Oncology -	Country Project
Ongoing		Myelodisplasic Syndrome	Leader
Sep 2018 - Ongoing	Phase I Interventional Trial	Endocrinology – DM Type	Country Project Leader
Mar 2018 -	Phase III Interventional Trial	Circulation/Vascular –	Country Project
Ongoing		Varico Veins	Leader
Oct 2017 -	Phase III Interventional Trial	Cardiology – Acute Heart	Country Project
Ongoing		Failure	Leader
Jul 2017 - Ongoing	Non – interventional international trial	Oncology - NSCLC	Country Project Leader
Oct 2016 – Ongoing	Phase II international trial	Dentistry - Horizontal Ridge Augmentation	Country Project eader
Jun 2015 –	Phase II B international trial	Oncology - Head and	Country Project
Ongoing		Neck Cancer	Leader
Sep 2014 –	Phase III international trial	Cardiology/	Local Lead
Jun 2017		Hypercholesterolemia	CRA
Jan 2014 –	Phase III international trial	Gynecology -	Country Project
Aug 2014		Fibromyalgia	Leader
Sep 2013 –	Phase IV international trial	Dentistry - Horizontal	Country Project
Aug 2014		Ridge Augmentation	Leader

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Timeframe	Clinical project	Therapeutic area	Position
Jan 2013 – Aug 2014	Phase III international trial	Ophthalmology - DMRI	Country Project Leader
Jan 2013 – Aug 2014	Phase III international trial	Oncology - Breast Cancer	Country Project Leader
Jan 2013 - Aug 2014	Phase III international trial	Oncology - NSCLC	Country Project Leader
Oct 2012 – Aug 2014	Phase III international trial	Oncology - Non-Hodgkin lymphoma	Country Project Leader
Oct 2012 – Aug 2014	Phase III international trial	Rheumatology - Rheumatoid Arthritis	Country Project Leader
Jan 2011 – Jan 2012	Phase III international trial	DM - Human Nutrition	Country Project Leader
Nov 2009 – Jun 2014	Phase III international trial	Cardiology - Heart Failure	Country Project Leader
Sep 2009 - Jun 2014	Phase III international trial	Cardiology - Acute Coronary Syndrome	Country Project Leader
Jan 2009 – Feb 2014	Phase III international trial	Oncology - Melanoma	Country Project Leader
Jan 2009 – Dec 2009	Phase III international trial	Cardiology - Acute Coronary Syndrome	Country Project Leader
Jan 2009 – Dec 2009	Phase III international trial	Cardiology - Chronic Coronary Syndrome	Country Project Leader
May 2007 – Dec 2009	Phase III international trial	Cardiology - Acute Coronary Syndrome	Country Project Leader
May 2007 – Dec 2009	Phase III international trial	Cardiology - Chronic Coronary Syndrome	Country Project Leader

#### **Trainings**

Training Date	Training Description	Place & Institute
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Training Date	Training Description	Place & Institute
Sep-2023	GCP Re-Training – NIDA Clinical Coordinating Center	Remote training
May-2023	Cybersecurity Training SEC-107: Demonstrate your mastery – SkyViewTek HIPAA Certificate	Remote training
Jul-2023	HIPAA Certificate Education Program	Remote training
Nov-2022	Professional Corporate Training – Mutual respect CSL Behring	Remote training
Apr-2021	Brazilian General Personal Data Protection Law (GDPR)	Atlantis Clinical, Online training
Feb-2021	GCP Test-Out Challenge: Demonstrate Your Mastery of GCP	ACRP, Online
Nov-2020	GCP Re-Training – NIDA Clinical Coordinating Center	Remote training
Oct-2020	CSL312_COVID-19 Investigators Meeting	Remote training
Jul-2019	RAVE - EDC	Web training – MEDIDATA Academy
Jul-2019	eTMF Training	Web conference training – 04-30 Bionical
Jun-2019	Site Monitoring, eTMF Management, Monitoring and Data Management	Web conference training – 04-30
Aug-2018	A Refresher Course GCP & ICH E6, Rev 2 - Atlantis Clinical	São Paulo, Brazil
Mar-2018	GCP - NIDA Clinical Coordinating Center	Web Training
Feb-2018	GCP-ICH E6 R2 Training session	Remote training - webminar
Jan-2018	Society of Quality Assurance – webinar "How to survive a regulatory mock inspection: a case study in what not to do"	Remote training - webminar
Dec-2017	ICH GCP Refresher, NIDA Platform for RISE study	Remote training - webminar
Sep-2017	The 3rd International Congress on Clinical Trials for Medical Devices	Budapest, Hungary

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Training Date	Training Description	Place & Institute
Mar-2017	The International Congress on Clinical Trials in Oncology & Hemato-Oncology	London, UK
Sep-2016	The 2nd International Congress on Clinical Trials for Medical Devices	Berlin, Germany
May-2016	The International Congress on Market Access & Regulatory Affairs in Medical Devices	Dusseldorf, Germany
Feb-2016	39th SIMASP Conference – Clinical Research Seminars	São Paulo, Brazil
Nov-2015	Workshop Clinical Research RDC 09/2015 & RDC 10/2015 ANVISA	Brasilia, Brazil
Oct-2015	The International Congress on Clinical Trials for Medical Devices	Vienna, Austria
Aug-2015	Indústria Farmacêutica Brasileira, Uma Agenda para Inovação	Brasilia, Brazil
Mar-2015	38th SIMASP Conference – Clinical Research Seminars	São Paulo, Brazil
Sep-2014	Biosimilars: A Global Perspective of a New Market – Opportunities, Threats and Critical Strategies	Webminar / Thompson Reuters
Aug-2012	II Forum Latin American of Biosimilars	São Paulo, Brazil
Apr-2012	Regulations and Development ANVISA & Carta Capital	São Paulo, Brazil
Apr-2012	Good Clinical Practices and ANVISA IN#4, Brazilian Society of Clinical Research Professionals	São Paulo, Brazil
Jan-2011	Recycling Clinical Research Program Federal Pharmacy Council	São Paulo, Brazil
Sep-2010	Improving Trial Outcomes: How organizations can leverage the integration of safety & clinical for reducing costs and gaining efficiencies Webminar / Aris Global, INC.	São Paulo, Brazil
Oct-2005	How to prepare from FDA Clinical Research Audit Webtraining / Perkins & Perkins	São Paulo, Brazil
Oct-2005	Conference on Clinical Research – Audits in Research Centers/ Hospital Israelita Albert Einstein	São Paulo, Brazil

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Training Date	Training Description	Place & Institute
Jun-2005	Methodology & Clinical Research/ Hospital Sírio Libanês	São Paulo, Brazil
Apr 2005	Genaco, INC Molecular Differential Diagnosis: Infectious Diseases Surveillance in Hospitals	São Paulo, Brazil
Sep 2004	Osvaldo Cruz Foundation Clinical Research Management	São Paulo, Brazil
Aug 2004	Viral Hepatitis Workshop Foccus Medicina Diagnóstica	São Paulo, Brazil
Jun 1999	DIA - Clinical Forum on Pediatrics	London, UK

#### **Participation in Study Meetings**

Participated in more than 50 Investigator's Meetings, Congresses and Conferences globally

Meeting Date	Meeting Description	Place & Institute
Aug-2023	ARCHER Investigators Meeting	São Paulo, Brazil
Aug 2022	AEGIS II Investigators Meeting	São Paulo, Brazil
Jul 2022	AEGIS II Investigators Meeting	Buenos Aires, Argentina
Jun 2022	AEGIS II Investigators Meeting	Mexico City, Mexico
Jan 2020	AEGIS II Investigators Meeting	Cuzco, Peru
Aug 2019	AEGIS II Investigators Meeting	Rio de Janeiro, Brazil
Jun 2019	ONCONOVA 0430 - Investigator's Meeting	São Paulo, Brazil
May 2019	The 4rd International Congress on Clinical Trials for Medical Devices	Wien, Austria
May 2019	GCP according to ISO 14155:2011 – Prof. Dr. Gudrun Denke	São Paulo, Brazil

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Meeting Date	Meeting Description	Place & Institute
Mar 2019	AEGIS II Investigators Meeting LATAM	Cartagena, Colombia
May 2018	GCP-ICH Rev 2 Training session	Web Training
May 2018	AEGIS II Investigators Meeting	Miami, FL
Feb 2018	GCP-ICH E6 R2 Training session Sponsored by Quintiles	Web Training
Apr 2017	INSPIRE - Investigator's Meeting	San Diego, USA
Apr 2017	INSPIRE - Investigator's Meeting	Washington, USA
Nov 2016	NIRVANA - Investigator's Meeting	São Paulo, Brazil
May 2016	INSPIRE - Investigator's Meeting	São Paulo, Brazil
Apr 2016	SPIRE - Investigator's Meeting	Lima, Peru
Oct 2015	SPIRE - Investigator's Meeting and Steering Committee Meeting	São Paulo, Brazil

I agree that this CV may be filed with clinical project documents for the statutory time limit (minimum 15 years).

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