
BIOGRAPHICAL SKETCH

NAME SAIDON PATRICIA CLAUDIA patricia.saidon@gmail.com	POSITION TITLE MD		
EDUCATION/TRAINING			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
School of Medicine, University of Buenos Aires, Argentina	MD	1981	MEDICINE
College of Neurology, Argentina	Neurologist	1984	Neurology

NOTE: The Biographical Sketch may not exceed four pages. Follow the formats and instructions below.

1. Personal Statement

My main area of work is clinical pharmacology and regulatory affairs and quality assurance in clinical trials. From 1994 until now I develop activities at the Center of Epilepsy in the Ramos Mejia Hospital, Buenos Aires, Argentina. I work in pharmacology area in this team. From 1993 to 2004, I developed activities as head of Good Clinical Practices in the National Administration of Food, Drug and Medical Devices (ANMAT). I was from 1999 until 2004, the coordinator of the Good Clinical Practice Working Group (GCP WG) of the Pan American Network for Drug Regulatory Harmonization which is coordinating by the Pan American Health Organization (PAHO) and I coordinated the document on GCP "Document of the Americas" that drew up the working group. I was a member of the working group convened by the World Health Organization (WHO) to draft the "Handbook for good clinical research practice Guidance for implementation", World health Organization, Geneva, 2005. I was member of the working group convened by the International Organizations of Medical Sciences (CIOMS) for writing the book: CIOMS VI "Management of Safety form clinical trials", CIOMS Geneva, 2005. Since 2004 until now, I work in regulatory affairs and quality assurance in academic studies for academic coordinating centers, cooperative groups, and governmental organizations, I had previous experience in different sectors of the clinical research: regulatory agency, ethics committee and as an investigator, allowing me to analyze situations from different perspectives. My previous experience in regulatory affairs and quality assurance was at the following studies: "Candid I vaccine against argentine hemorrhagic fever produced in Argentina. Immunogenicity and safety" for the National Ministry of Health ; "Randomized, multicenter, placebo-controlled, on the effectiveness of omega 3 fatty acids in the maintenance sinus rhythm in patients with previous atrial fibrillation (FORWARD) conducted by Gesica Foundation, and "The ω -3 fatty acids for Prevention of Post-Operative Atrial Fibrillation trial. OPERA" conducted by Harvard School of Medicine (Boston, USA), Mario Negri Institute (Santa Maria Imbaro, Italy) and Gesica Foundation (Buenos Aires, Argentina)

B. Positions and Honors

- 1995 - 2004: head of Good Clinical Practices Department at National Administration of Food, Drug and Medical Devices (ANMAT)
- 2000 - 2004: Coordinator of the Good Clinical Practices working group (GCP WG). Pan American Network for Drug Regulatory Harmonization. Pan American Health Organization
- 2001-2005 Member of the working group for drafting of the "Handbook of Good Clinical Research Practice" World Health Organization (WHO)
- 2001-2005 Member of working group CIOMS VI for drafting "Management of Safety form clinical trials", CIOMS Geneva, 2005
- 2006-2007: Member of the Ethics Committee of the Ramos Mejia Hospital of the City of Buenos Aires
- 2007-2008: Member of the Central Committee of Bioethics of the Ministry of Health of the City of Buenos Aires
- 2008-present: Advisory Committee on Ethics in Clinical Trials of the National Institute of Health in Peru

- 2009-present: Member of the National Commission of cell therapies under the Ministry of Science and Technology of the Nation
- 2009 to present Member of the Advisory Committee on Cellular Therapies and Regenerative Medicine. Ministry of Sciences and Technology
- 2001-present: Director of the on GCP training course at the IBYME, National Council of Research (CONICET).
- 2002: Coordinator Pan American Network for Harmonization training course on GCP Peru and Guatemala
- 2006: Speaker in the Course "Inspections of Clinical Investigators" for staff of the Brazilian Agency of Medicines (ANVISA)
- 2008: Coordinator of the Course: "Introduction to GCP" for staff-ANMAT.
- 2008: Coordinator Workshop "Standard operating procedures for clinical investigators inspections" for staff ANMAT
- 2011: Speaker training course "Good Clinical Practice" National Institute of Health in Peru
- 2011: Co-director of the course: "Research ethics, education and training procedures, monitoring and auditing for ethics committees" Ministry of Health Buenos Aires City.
- Member of the Neurological Society Argentina.
- Member of the League against Epilepsy Argentina
- Reviewer Journal: "REVISTA ARGENTINA DE SALUD PÚBLICA" Ministry of Health ISSN 1852 - 8724 | ISSN 1853-810X

Awards:

- Neurological Society of Argentina for "Pharmacoeconomic assessment of AEDs in Argentina" Saidón P., Bolanos R
- Young Investigator Bursary Award, 25th International Epilepsy Congress. "Ictal manifestations in refractory temporal lobe epilepsy patients". 25th International Epilepsy Congress, Lisbon, 2003.

C. Selected Peer-reviewed Publications (from 46 indexed publications)

1. Risk factors associated with dress syndrome produced by aromatic and non-aromatic antiepileptic drugs. Nahuel Pereira de Silva, Paulo Piquioni, Silvia Kochen y Patricia Saidon. *European J. Of Pharmacovigilance* 2011 Feb 26.
2. Periventricular nodular and subcortical neuronal heterotopia in adult epileptic patients. *Medicina (B Aires)*. 2006; 66(2):101-7. Consalvo D, Kochen S, Alurralkde A, Centurión E, Salgado P, Saidon P, Sica REP
3. Visual defects associated with vigabatrin: a study of epileptic argentine patients. Moreno MC, Giagante B, Saidon P, Kochen S, Benozzi J, Rosenstein RE. *Can J Neurol Sci* 2005 Nov; 32(4):459-64
5. Mechanism of Action of Antiepileptic drugs. Saidón P. *Vertex* 2003 Mar-May; 14(51):53-8
6. Expanding Virchow Robin spaces in the midbrain causing hydrocephalus. Papayanis C., Saidon P, Rugilo C., Hess D., Rodríguez G, Sica RE, Rey RC; *AJNR Am J Neuroradiol*. 2003 Aug; 24(7):1399-403
7. Mesial Temporal lobe epilepsy and hippocampal sclerosis: cognitive function assessment in Hispanic patients. Oddo S, Solis P, Consalvo D, Giagante B, Silva W, D'Alessio L, Centurion E, Saidon P, Kochen S. *Epilepsy and Behavior*, 4(2003) 717-722
8. Clinical-EEG patterns at seizure onset in patients with hippocampal sclerosis. Giagante B, Oddo S, Silva W, Consalvo D, Centurion E, D'Alessio L, Solis P, Salgado P, Seoane E, Saidon P, Kochen S. *Clinical Neurophysiology* 2003; Vol 114/12: 2286-2293.
9. Declaration of Helsinki: its vicissitudes during the last five years. Klimovsky E, Saidón P, Nudelman L, Bignone I. *Medicina*. 2002; 62(4):365-70
10. Pharmacokinetic variability of Oxcarbacepine in epileptic patients. Viola MS, Bercellini A, Saidon P, Rubio MC. *Medicina* 2000; 60(6): 914-8
12. Mesial temporal sclerosis syndrome in adults patients. Consalvo D, Giobellina R, Silva W, Rugilo C, Saidon P, Schuster G, Kochen S, Sica R. *Medicina* 2000; 60(2): 165-169
13. Clinical Features and Prognosis of Nonepileptic Seizures in a Developing Country W. Silva, B. Giagante, R. Saizar, S. Oddo, D. Consalvo, P. Saidón, S. Kochen. *Epilepsia*, vol. 42, no. 3, pp. 398-401, 2002
14. Magnetic resonance findings in epileptic patients. D. Consalvo, W. Silva, C. Rugilo, P. Salgado, E. Centurión, P. Saidón, M. Albarenque, R. Giobellina, G. Schuster, S. Kochen. *Journal of The Neurological Sciences - J NEUROL SCI*, vol. 150, pp. S235-S236, 1997

Books

1. Chapter "Antiepileptic drugs" in "Pharmacology" Rotlhin, Tessler y Zieher. Editorial Coopgrafica. Bs As, 1993
2. Chapter "Epilepsy" in "Clinical neurology". Sica-Muchnick. Editorial López. First edition 2003 pages 103-133
3. Chapter "Epileptic seizures management" in *Advances in Medicine*. Argentina Society of Medicine. First Edition 1996
4. Chapter: "Migraine and epilepsy" in "Migraines" Saravia-Zavala y Sica. Editorial El Ateneo, 1999
5. Chairman of "Documento de las Americas". Pan American network on drug regulatory harmonization" Pan American Health Organization, 2004
6. Member of Drafting Committee in "Management of Safety Information from Clinical Trials: Report of CIOMS Working Group VI" Edits: CIOMS 2005

7. Member of Drafting Committee in “Handbook of Good Clinical Research Practices- Guide for Implementation”
World Health Organization 2005

D. Research Support

1. 2009 at present : Principal Investigator in the project “The impact on morbidity and mortality of a system of good pharmacovigilance practices in public hospitals of the city of Buenos Aires ”
2. 2008: Coordinator collaborative study: “Standard Operating Procedures for ethics committees in Argentina”
3. 2001: Coordinator collaborative study: “The role of community member in the ethics committees”