

**CURRICULUM VITAE**  
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## EDUCATION

1979-1983 **DOCTOR OF PHILOSOPHY**  
Major: Biochemistry  
Minor: Immunology  
Department of Biochemistry  
University of Sussex, England, United Kingdom

1973-1977 **BACHELOR OF SCIENCE**  
Major: Biology  
Department of Biological Sciences  
Faculty of Science, University of Tabriz, Iran

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## EXPERIENCE

**NovoMed Consulting** 2007 - Present  
**Silver Spring, MD, US**

**Senior Biomedical Scientist (Drug Development and Regulatory Sciences)**

Recent Activities:

- Reviewed datasets and literature related to pharmaceutical and recombinant products with relevancies to neurodegenerative disorders, such as multiple sclerosis and cerebral stroke.
- Appraised risk-benefit profiles of investigational and marketed drug products, including clinical and preclinical aspects: focusing on the use of steroids in connection with cerebral atrophy, optic nerve inflammation and neurodegeneration, mechanisms of pathophysiology in humans and disease models, from translational sciences perspectives.
- Performed metadata computations and detailed assessments of outcome measures, treatment configurations, quality of experimental and investigational designs, with relevancies to drug safety and effectiveness.
- Collaborated on research and development of diagnostic antibody-screening test kits and vaccines for prevention of brain cysts in toxoplasma infections.

- Reviewed articles on heparins and their therapeutic use as anticoagulants, and reported scientific assessment of their potential risks on cancer stem cells.
- Served as external consultant for the US-FDA, Division of Biology, Office of Science and Engineering Laboratories (OSEL), Center for Device Evaluations and Research (CDRH): provided expertise in identifying, addressing and coordinating a biodefense research initiatives, including model biological agents (H1N1 influenza virus, staphylococcus aureus, coli phage) and chemicals—identified scientific data gaps, raised questions/comments, wrote statements-of-work (SOW), evaluated progress reports, provided responses, communicated project goals, offered advice for methods/process validations, standards development for viral decontaminations and countermeasures, and participated in site-visits.
- Reviewed WHO 2010 Immunotoxicity Risk Assessment guidance document; participated in internal discussions, such as emerging medical device related neurotoxicity issues—wrote a research proposal on drug-eluting stents coated with porous microparticles encapsulating model drugs and synthetic peptides for safety and efficacy evaluations.
- Reviewed and analyzed data related to formulation ingredients and in-situ-forming microparticles and liposomes, and wrote research plans on controlled-release drug delivery systems related to small molecule drugs.
- Reviewed articles on surfactants and their therapeutic utilities for lung injuries and prepared the briefing documents for business development.
- Communicated with companies for outsourcing R&D, formed alliances with contractors that provide preclinical (Pharm/Tox) and regulatory submissions (eCTD).

**NovoMed Pharmaceuticals, Inc.**  
**Germantown, MD, US**

2000-2007

**Co-founder, Director of R&D**

- Prepared orphan drug regulatory submissions for the following drugs: i) a (Gimatecan, ST1481) for treatment of gliomas (in development), ii) Cysteamine for ocular cystinosis (developed), iii) 9-Nitrocamptothecin for pediatric AIDS (not developed).
- Assembled Pre-IND documents for a live vaccine, based on recombinant adenoviruses (Ad5, Ad35) for prevention of tuberculosis —Reviewed/revised CMC and clinical development sections, co-designed pharm-tox testing plans, and provided input to questions to US-FDA.
- Evaluated technology and clinical outcome measures for a generic cyclosporine, including formulations, excipients, manufacturing, bioequivalence, and bioavailability.
- Reviewed and investigated preclinical data toward developing recombinant vaccines for toxoplasma and leishmania.
- Researched a business case for cephalosporin antibiotics; and potential use of anticancer drugs such as 9-nitrocamptothecin for AIDS therapy.

**Institute of Medical Technologies  
Finnish Immunotechnologies, Ltd.  
Tampere, Finland**

1999-2000

**Research Associate Professor (sabbatical)  
Director of Vaccines and Regulatory Affairs**

- Researched molecular construction and applications of a papilloma-virus based replicating DNA vaccine for prevention of HIV infection; Put together the DMF and IND documents.

**Georgetown University Medical Center  
Washington DC, US**

1997-1999

**Visiting Associate Professor**

- Researched antiviral drugs, HIV/AIDS; Collaborated on cloning, elucidation and evaluation of transforming genes of herpes viruses (HHV-6 and KSHV).

**Food and Drug Administration/CBER  
Rockville, MD, US**

1993-1997

**Section Chief, Laboratory of Molecular Immunology**

- Directed research in HIV therapeutics, diagnostics and recombinant single-chain antibodies.
- Supervised two postdoctoral fellows, one premed student, and one research assistant.
- Reviewed safety, efficacy, and manufacturing data of biologics license applications (BLA, 510K, Pre-IND, IND) for diagnostic test kits and devices for human retroviruses (HIV, HTLV-1), participated in industry meetings, wrote response letters.
- Obtained certificates of training in: i) US-Federal Drug Law; ii) IND Applications; iii) Inspections; iv) Blood and Blood Components; v) Attended courses in Clinical Trials Design and Analysis; Studying a Study and Testing a Test.

**National Cancer Institute, NIH  
Bethesda, MD, US**

1985-1993

**Senior Staff /Fellow**

- Researched human retroviruses (HIV, HTLV) in Laboratory of Tumor Cell Biology, focusing on molecular basis of HIV-1 pathogenesis and structure-function analyses of the viral regulatory genes; Obtained Fellowship from Fogarty International; trained two post-doctoral fellows, one research associate, three students.

**Post-Doctoral Fellow**

- Obtained Fellowship from Leukemia-Society-of-America; Researched cloning, biochemical and immunochemical characterizations of the proliferating cell nuclear antigen (PCNA) associated with certain human autoimmune disease; trained one premed-student in laboratory of protein synthesis.

**SELECTED EARLY CAREER RESEARCH ACCOMPLISHMENTS AT US-NIH AND FDA:**

- First to identify functional domains of HIV-1 Tat protein, using site directed mutagenesis methods
- First to report that HIV-1 Tat and Rev proteins are synthesized from separate mRNAs
- First to report that stripping HIV-1 gp120 envelope protein renders the virus noninfectious and retains the viral particulate structure
- Co-inventor of the therapeutic targets of HIV-1 Tat protein – US Patent: 6686333, 2004
- Developed a sensitive diagnostic test/validation assay: a quantitative RNA polymerase chain reaction (qRT-PCR) capable of detecting latent/cell-associated HIV-1 in blood

**EDITORIAL BOARD:**

Journal of Experimental and Clinical Neurosciences (JECNS) Jul 2013-present  
<http://jecns.com/JECNS>, Swedish Science Pioneers

Journal of Medical Research and Science (JMRS) Jan 2012-present  
AcademyPublish.org, USA

Iranian Biomedical Journal (IBJ) Jun 1996-2006  
Pasteur Institute of Iran

**REGULATORY/SCIENTIFIC MEETINGS ATTENDED:**

- CDRH staff college course: Application of Tools for Risk Assessment and Risk Management, June 2010
- CDRH staff college courses (Missing Data and Propensity Score Analysis; Bayesian Clinical Trials: Planning for Non-inferiority or Superiority; Total Product Life Cycle, April 2010)
- Workshop on Computer Methods for Cardiovascular Devices, Rockville, Maryland, June 1-2, 2009
- FDA Advisory Meeting of Peripheral and CNS Drugs, NDA discussion on Vigabatrin (Sabril) indicated for refractory complex partial seizures in adults, Rockville, Maryland, January 7-8, 2009
- Successful Clinical Trial Management: Challenges and Solutions, Workshop organized by Covance, Bethesda Hyatt Regency, MD, October 18, 2007
- Oncologic Drugs Advisory Committee, CDER, FDA, Rockville, MD, July 24, 2007
- FDA/SBA Small Pharmaceutical Business Workshop, College Park, MD, April 12, 2007
- Third International Nanomedicine and Drug Delivery Symposium, University of Maryland, Baltimore, Maryland, September 26-27, 2005
- Continuing Series of Biotech Seminars: Patton Boggs, Attorneys at Law, Rockville, MD, May 15, June 12, 2002
- NIH AIDS Vaccine Research Committee Workshop: New Concepts in HIV Vaccine Development, Bethesda, MD, May 3-5, 1999
- Prenatal Gene Transfer: Scientific, Medical, and Ethical Issues, Bethesda, MD January 7-8, 1999
- Lentiviral-based Vectors for Gene Therapy, NIH, Bethesda, MD, March 9, 1998
- FDA/NIH Conference on Gene Therapy, Bethesda, MD, July 15-18, 1997

- New Opportunities for HIV Therapy- from Discovery to Clinical Proof-of-Concept, Vienna, VA, June 22-26, 1997
- Blood Safety and Screening, McLean, VA, April 14-16, 1997
- Intl. Conference on the Virological Safety of Plasma, Bethesda, MD, November 1996
- Society of Exp. Biol. Med Symposium, Bethesda, MD, March 1996
- Creutzfeldt - Jakob disease Workshop, Bethesda, MD, February 1996
- Gene Therapy IND Issues, Gaithersburg, MD, September 1995
- Infectious Disease Testing for Blood Transfusions, Bethesda, MD, January 1995
- Gene Therapy for HIV/AIDS, Washington, DC, May 1994
- Viral Safety of Pharmaceutical Products, Bethesda, MD, June 1994
- Workshop on Human Tissue Intended for Transplantation, Washington, DC, June 1994

#### **PRESENTATIONS AT INTERNATIONAL MEETINGS/WORSHOPS:**

- The 7<sup>th</sup> Congress of Biochemistry, University of Medical Sciences, Ahwaz, Iran, January 26-29, 2004
- 3<sup>rd</sup> EU Biotechnology Meeting on Vaccinology, Biarritz, France, October 14-16, 1999
- The IV European Conference on Experimental AIDS Research, Tampere, Finland, June 18-21, 1999
- Retrovirology/AIDS Meeting, LTCB/National Cancer Institute, Bethesda, MD, August 1994
- 1<sup>st</sup> Latino-American Congress on Retroviruses and AIDS, Buenos Aires, Argentina, March 18-23, 1993
- Retrovirology/AIDS Conference, LTCB/National Cancer Institute, Bethesda, MD, August 1992
- Annual Meeting of LTCB, National Cancer Institute, Bethesda, MD, August 1990 and 1991
- 7<sup>th</sup> International Congress of Immunology, Berlin, Germany, August, 1990
- 5<sup>th</sup> International Conference on AIDS, Montreal, Canada, June 4-9, 1989
- 4<sup>th</sup> International Conference on AIDS, Stockholm, Sweden, June 12-16, 1988
- Annual Meeting of LTCB/National Cancer Institute, Bethesda, MD, September 1989
- 3<sup>rd</sup> International Conference on AIDS, Washington DC, June 1-5, 1987
- Modern Approaches to New Vaccines Including prevention of AIDS, Cold Spring Harbor Laboratory, New York, September 14-18, 1988
- Modern Approaches to New Vaccines Including prevention of AIDS, Cold Spring Harbor Laboratory, New York, September 9-13, 1987
- RNA Tumor Viruses, Cold Spring Harbor Laboratory, New York-USA, May 20-25, 1986
- International Symposium on Prevention and Detection of Cancer, Vienna, Austria, November 6-29, 1984
- 4<sup>th</sup> FEBS meeting, Biochemical Society, Edinburgh-Scotland, March 29-April 3, 1981

**MEETING ABSTRACTS:** Approximately forty-five (not listed).

#### **PUBLICATIONS:**

1. **Sadaie MR:** Isolation and identification of a novel species of Nocardia. B.Sc. Honor Thesis, University of Tabriz, Iran, 1977
2. **Sadaie MR:** Studies on RNA-containing autoantigens of human rheumatic diseases. PhD Thesis. University of Sussex, Brighton, England, UK, 1983
3. MacGillivray AJ, Carroll AR, Dahi S, Naxakis G, **Sadaie MR**, Wallis CM, Jing T: The composition of the nuclear antigens Sm and RNP of human rheumatic and connective tissue diseases and the relevance of their autoantibodies as probes for RNA processing mechanisms. FEBS Lett. 141:139-147, 1982

4. **Sadaie MR**, Jing T, MacGillivray AJ: Studies on the SnRNP particles, which act as autoantigens in rheumatic disease. Biochem. Soc. Trans. 10:453-454, 1982
5. **Sadaie MR**, Mathews MB: Immunochemical and biochemical analysis of the proliferating cell nuclear antigen (PCNA) in HeLa cells. Exp Cell Res. 163:423-433, 1986
6. Heisig V, Benter T, Josephs SF, **Sadaie MR**, Okamoto T, Gallo RC, Wong-Staal F: Interaction of viral and cellular factors with the HTLV-III LTR target sequences in vitro. Haematol Blood Transfus 31:423-429, 1987
7. **Sadaie MR**, Benter T, Wong-Staal F: Site-directed mutagenesis of two trans-regulatory genes (tat-III, trs) of HIV-1. Science 239:910-913, 1988
8. **Sadaie MR**, Benter T, Josephs SF, Rappaport J, Willis R, Gallo RC, Wong-Staal F: Functional analysis of the *tat* and *trs* genes of human immunodeficiency virus by site-directed mutagenesis. In Chanock R, Brown F, Lerner A, and Ginsberg H (Eds.): Vaccines, New York, Cold Spring Harbor Press, pp. 303-310, 1988
9. Wong-Staal F, **Sadaie MR**: Role of the two essential regulatory genes of HIV in virus replication. In Franza R, Cullen B, and Wong-Staal F (Eds.): The Control of Human Retrovirus Gene Expression, New York, Cold Spring Harbor Press, pp. 1-10, 1988
10. **Sadaie MR**, Rappaport J, Benter T, Josephs SF, Willis R, Wong-Staal F: Missense mutations in an infectious human immunodeficiency viral genome: functional mapping of tat and identification of the rev splice acceptor. Proc Natl Acad Sci ,USA, 85:9224-9228, 1988
11. **Sadaie MR**, Benaissa ZN, Cullen BR, Wong-Staal F: HIV-1 *rev* protein displays a *trans*-repressor role that inhibits virus replication - implications for virus latency. In Chanock, R., Ginsberg, H., Lerner, A., and Brown, F. (Eds.): Vaccines, Cold Spring Harbor Press, New York, pp. 47-55, 1989
12. **Sadaie MR**, Benaissa ZN, Cullen BR, Wong-Staal F: Human immunodeficiency virus types 1 rev protein as a negative trans-regulator. DNA 8:669-674, 1989
13. **Sadaie MR**, Tschachler E, Valerie K, Rosenberg M, Felber BK, Pavlakis GN, Klotman ME, Wong-Staal F: Activation of tat-defective human immunodeficiency virus by ultraviolet light. New Biol. 2:479-486, 1990
14. Okamoto T, Benter T, Josephs SF, **Sadaie MR**, Wong-Staal F: Transcriptional activation from the long-terminal repeat of human immunodeficiency virus in vitro. Virology 177:606-614, 1990.
15. **Sadaie MR**, Mukhopadhyaya R, Benaissa ZN, Pavlakis GN, Wong-Staal F: Conservative mutations in the putative metal-binding region of human immunodeficiency virus tat disrupt virus replication. AIDS Res Hum Retroviruses 6:1257-1263, 1990
16. **Sadaie MR**, Kalyanaraman VS, Mukopadhyaya R, Tschachler E, Gallo RC, Wong-Staal F: Biological characterization of noninfectious HIV-1 particles lacking the envelope protein. Virology 187:604-611, 1992
17. Mukhopadhyaya R, **Sadaie MR**: Nucleotide sequence analysis of HTLV-I isolated from cerebrospinal fluid of a patient with TSP/HAM: comparison to other HTLV-I isolates. AIDS Res Hum Retroviruses 9:109-114, 1993

18. Arya SK, **Sadaie MR**: Fusogenicity of mutant and chimeric proviruses derived from molecular clones of cytopathic and noncytopathic human immunodeficiency virus type 2. J Acquir Immune Defic Syndr. 6:1205-1211, 1993
19. Krohn KJE, Hakharainen K, Aavik E, Dewhurst S, **Sadaie R**, Mullins JJ: Transcomplementation of SIV Rev with HTLV-I Rex. J. Virol. 67:5681-5684, 1993
20. Kashanchi F, Thompson J, **Sadaie MR**, Doniger J, Duvall J, Brady JN, Rosenthal LJ: Transcriptional activation of minimal HIV-1 promoter by ORF-1 protein expressed from the Sall-L fragment of human herpesvirus 6. Virology 201:95-106, 1994
21. **Sadaie MR**, Hager GL: Induction of developmentally programmed cell death and activation of HIV by sodium butyrate. Virology 202:513-518, 1994
22. Kashanchi F, Khleif SN, Duvall JF, **Sadaie MR**, Radonovich MF, Cho M, Martin MA, Chen SY, Weinmann R, Brady JN: Interaction of human immunodeficiency virus type 1 Tat with a unique site of TFIID inhibits negative cofactor Dr1 and stabilizes the TFIID-TFIIA complex. J Virol. 70:5503-5510, 1996
23. Kashanchi F, **Sadaie MR**, Brady JN: Inhibition of HIV-1 transcription and virus replication using soluble Tat peptide analogs. Virology 227:431-438, 1997
24. Kashanchi F, **Sadaie MR**: Molecular biology of human immunodeficiency viruses: HIV-1 and HIV-2. Medical J. Iran 10:321-336, 1997
25. Araujo JC, Doniger J, Stoppler H, **Sadaie MR**, Rosenthal LJ: Cell lines containing and expressing the human herpesvirus 6A ts gene are protected from both H-ras and BPV-1 transformation. Oncogene 14:937-943, 1997
26. Kashanchi F, Melpolder JC, Epstein JS, **Sadaie MR**: Rapid and sensitive detection of cell-associated HIV-1 in latently infected cell lines and in patient cells using sodium-n-butyrate induction and RT-PCR. J Med Virol. 52:179-189, 1997
27. Moulton S, Pantazis P, Epstein JS, **Sadaie MR**: 9-Nitrocamptothecin inhibits tumor necrosis factor-mediated activation of human immunodeficiency virus type 1 and enhances apoptosis in a latently infected T cell clone. AIDS Res Hum Retroviruses 14:39-49, 1998
28. **Sadaie MR**, Zamani M, Whang S, Sistrun N, Arya SK: Towards developing HIV-2 lentivirus-based retroviral vectors for gene therapy: dual gene expression in the context of HIV-2 LTR and Tat. J Med Virol. 54:118-28, 1998
29. **Sadaie MR**, Arya SK: HIV-derived lentiviral vectors: current progress toward gene therapy and DNA vaccination. Iranian Biomedical J. 2:95-103, 1998
30. Muralidhar S, Pumfery AM, Hassani M, **Sadaie MR**, Kishishita M, Brady JN, Doniger J, Medveczky P, Rosenthal LJ: Identification of kaposin (open reading frame K12) as a human herpesvirus 8 (Kaposi's sarcoma-associated herpesvirus) transforming gene. J Virol. 72:4980-4988, 1998

31. **Sadaie MR**, Doniger J, Hung CL, Pantazis P: 9-nitrocamptothecin selectively inhibits human immunodeficiency virus type 1 replication in freshly infected parental but not 9-nitrocamptothecin resistant U937 monocytoid cells. AIDS Res Hum Retroviruses 15:239-245, 1999
32. Razavi-Deligani MR, **Sadaie MR**, Richinski V, Noori-Dalooi MR, Aziz M, Amanzadeh A, Assmar M: Cloning and expression of leishmanolysin gene from leishmania major in primate cell lines. J. Sci. I. R. Iran 12:117-125, 2001
33. Hung CL, Doniger J, Palini A, Snyder SW, Radonovich MF, Brady JN, Pantazis P, **Sadaie MR**: 9-Nitrocamptothecin inhibits HIV-1 replication in human peripheral blood lymphocytes: a potential alternative for HIV-infection/AIDS therapy. J Med Virol. 64:238-244, 2001
34. **Sadaie MR**, Mayner R, Doniger J: A novel approach for the treatment of HIV infection and AIDS: adapting non-nucleoside anticancer chemotherapeutics. Antiviral Research 61:1-18, 2004
35. Kashanchi F, **Sadaie MR**, Brady JN: Inhibition of HIV replication using soluble Tat peptide analogs; US-Patent, 6686333, 2004
36. Golkar M, Shokrgozar MA, Rafati S, **Sadaie MR**, Assmar M: Construction, expression and preliminary immunological evaluation of a DNA plasmid encoding the GRA2 protein of *Toxoplasma gondii*. Iranian Biomedical J. 9:1-8, 2005
37. Golkar M, Shokrgozar MA, Rafati S, Musset K, Assmar M, **Sadaie R**, Cesbron-Delauw MF, Mercier C: Evaluation of protective effect of recombinant dense granule antigens GRA2 and GRA6 formulated in monophosphoryl lipid A (MPL) adjuvant against *Toxoplasma* chronic infection in mice. Vaccine 25:4301-4311, 2007
38. Malykh AG, **Sadaie MR**: Piracetam and piracetam-like drugs: from basic science to novel clinical applications to CNS disorders. Drugs 70: 287-312, 2010
39. **Sadaie MR**: Can heparins stimulate bone cancer stem cells and interfere with tumorigenesis? Therapeutic Advances in Drug Safety 2:271-282, 2011
40. Samiy N, Thomas GA, Rosenbaum RE, **Sadaie MR**: Glucocorticosteroids: risk-benefit appraisals in multiple sclerosis and MS-associated optic neuritis. Journal of Experimental and Clinical Neurosciences 1:3-12, 2014
41. **Sadaie MR**, Samiy N, Rosenbaum RE, Thomas GA: Steroids impact on myelin repair, neurogenesis and visual pathway in multiple sclerosis: preclinical perspectives. Journal of Experimental and Clinical Neurosciences 1:13-20, 2014
42. Babaie J, **Sadaie MR**, Golkar M: Immunization of C57BL/6 mice with GRA2 combined with MPL conferred short-term, but not long-term, immune protection against *toxoplasma gondii*, Diagnostic Microbiology and Infectious Disease (submitted)
43. **Sadaie MR**, et al: What does the research say about androgenic steroids use, and cerebrovascular events? (In preparation)