

Zaid Daniel Smith, PhD
+1 941 993 6099
1661 Ringling Blvd, Suite 2691, Sarasota FL 34230
z@zaidsmith.com

About me

I've been freelance writing since 1991. I write for medically-educated audiences, including physicians, managed-care medical directors, and FDA regulatory officers.

I have written extensively about medical devices and procedures, as well as about pharmaceuticals.

My depth of training and experience with regulators and opinion leaders lets me understand the contextual subtleties that surround every work—marketing, regulatory or scientific—ensuring that an accurate message is delivered to your particular audience.

Services

Regulatory writing

ICH eCTD submissions (IND, NDA)

Mod 2:

Nonclinical Overview

Clinical Overview

Clinical Summary

Mod 5:

Clinical Study Report (CSR),

Integrated Summary of Efficacy (ISE),

Integrated Summary of Safety (ISS)

Annual Reports (IND, NDA, IDE)

IND:

Investigator's Brochure (IB)

General Investigational Plan (GIP)

Orphan Drug Designation

AMCP Dossier

Journal Research Articles

Journal Reviews

Medical Education Reviews

Abstracts, Posters & Slides for Presentation

Editing for content, concepts, factuality

Zaid Daniel Smith, PhD

Topics

Diseases and Conditions

Acne
Actinic keratitis
Acute lymphoblastic leukemia
Acute myocardial infarction
Age-related macular degeneration, wet & dry
AIDS
Alcoholic liver disease
Alzheimer's disease
Angina pectoris
Asthma
Atrial fibrillation
B-cell lymphoma
Blepharitis
Bone fracture nonunion
Brachial plexitis
Breakthrough cancer pain
Breast cancer
Carpal tunnel syndrome
Cervical cancer
Cluster headaches
Contraception
COPD
Coronary artery disease
Cystic fibrosis
Diabetes, Types I and II
Diabetic macular edema
Dry eye
Emphysema
Endometriosis
Gastric, duodenal ulcers
Gastroesophageal reflux
Glaucoma
Head trauma
Hepatitis C
Herpetic keratitis
Hyperbilirubinemia
Hypertension
Inflammatory bowel disease
Influenza
Keratoconjunctivitis
Knee cartilage defects
Leiomyomatoma
Liver cancer
Lung cancer
Lupus
Mantle cell lymphoma
Medical abortion
Melanoma
Meniere's disease
Menorrhagia
Migraine headache
Multiple myeloma
Onychomycosis
Osteoarthritis
Osteoporosis
Pancreas cancer
Parkinson's disease
Pneumonia
Post-surgery ophthalmic inflammation
Prostate cancer
Respiratory failure
Seborrheic dermatitis
Spinal compression
Stroke
Ulcerative colitis
Uveitis
Varicose veins
Venous reflux

Zaid Daniel Smith, PhD

Treatments and Therapeutic Agents

ACE inhibitors
Adrenocorticoids
Alkylating agents
Amino-salicylate anti-inflammatories
Analgesics
Anticoagulants
Antifungals
Antivirals
Botulinum toxin
Cancer diagnostic antibodies
Cancer prognostic markers—e.g., Ki67, CD23
Chondrocyte transplantation
Coated stents
ECMO
Endoluminal gastroplication
Endolymphatic pressure pulsation
Endometrial cryoablation
Endoscopic surgery for GERD
Estrogens and analogs
External counterpulsation
Extracorporeal membrane oxygenation
Fallopian tube inserts
H2 blockers
High-dose chemotherapy and myeloablation
High-frequency chest compression
Human bone morphogenic protein (rhBMP-2)
Human growth hormone
Human osteogenic protein
Hyaluronic acid
Hyperbaric oxygen therapy
Immunomodulators for cancer
Insulin analogs
Interferon alpha 2
Interleukin 2
Intestinal transplanation
Intravenous immunoglobulins
Islet cell transplantation
Kidney transplantation
Kinase inhibitors
Liver transplantation
Lung transplantation
Lung volume reduction surgery
Macular surgery
Meniscal allograft transplantation
Microtubule stabilizers
mTOR inhibitors
Opioids
Pallidotomy

Pancreas transplantation
Percutaneous kyphoplasty
Phototherapy
Plasminogen activators
Platelet gels
Progestins and analogs
Prostate cryosurgery
Proteasome inhibitors
Proton-pump blockers
Psychosocial rehabilitation
Purine analogs
Right heart catheterization
Spinal fusion surgery
Stem cell transplantation, allogeneic and autologous
Synthetic bloods
Thalamic stimulation
Thermal endometrial ablation
Topical steroids (derm and ophtha)
Topoisomerase inhibitors
Uterine embolization
Vaccines
Venous ablation
Vertebroplasty
Vitreous surgery
anti-CD20 MAbs
anti-VEGF Mabs

Medical Specialties

Cardiology
Dermatology
Endocrinology
Genetic Medicine
Gastroenterology
Hematology
Immunology/Allergy
Infectious disease
Internal Medicine
Interventional Radiology
Neonatology Neurology
Obstetrics/Gynecology
Oncology
Ophthalmology
Orthopedic surgery
Pediatrics
Pulmonology
Thoracic Surgery
Urology
Vascular surgery

Zaid Daniel Smith, PhD

Employment and Experience

Freelance Medical Writer, 1991-present, Sarasota, FL
Insured sole proprietorship

Sirion Therapeutics (previously Rx Development Resources) Tampa, FL
Director, Technology Assessment/Business Development (Sirion)
Manager, Scientific and Regulatory Communications (Sirion, RxDR)

FMQAI (Florida Medicare QIO) Tampa, FL
Senior Medical Writer

ECRI Institute, Philadelphia
Senior Health Technology Analyst, and contract writer

DataTactics Inc, Philadelphia
Research Analyst, Pharma Marketing Research

Cheney University of Pennsylvania
Adjunct Assistant Professor

Biomedical Research

Howard Hughes Medical Institute, UT Southwestern Medical Center
Yale University Medical School, Department of Cell Biology

Education

PhD, Univ of Virginia, Neuroscience
MS, Univ Calif Irvine, Psychobiology
BA, Yale University, Psychology
Graduate-level course in statistical meta-analysis with Ralph Rosnow,
Temple University
Graduate-level course in medical cost-effectiveness analysis with David Nash,
Thomas Jefferson University

Environments and Software

Livelihood, Documentum eRoom, Acrobat, Word, Excel, PowerPoint, RefMan, ProCite, ISI Writer, Project,
Dreamweaver, InDesign, Photoshop, Fireworks

Organizations

AAAS, Sigma Xi, American Medical Writer's Association

Zaid Daniel Smith, PhD

Journal Publications

CAT-152 0102 Trabeculectomy Study Group, Khaw P, Grehn F, Holló G, Overton B, Wilson R, Vogel R, Smith Z. A phase III study of subconjunctival human anti-transforming growth factor beta(2) monoclonal antibody (CAT-152) to prevent scarring after first-time trabeculectomy. *Ophthalmology* 2007 Oct;114(10):1822-30.

CAT-152 Trabeculectomy Study Group, Grehn F, Holló G, Khaw P, Overton B, Wilson R, Vogel R, Smith Z. Factors affecting the outcome of trabeculectomy: an analysis based on combined data from two phase III studies of an antibody to transforming growth factor beta2, CAT-152. *Ophthalmology* 2007 Oct;114(10):1831-38.

Albakri E.F., Richards Ferdinand III, Hall M., Dion C, Miranda L.S., Turkel R., Sand C., Vasey P., McDonald P., Michelman M., Smith Z., Davison K., Pfannerstill L. Cooperative efforts improve compliance with acute stroke guidelines. *Southern Medical Journal* 2003 Jan; 96(1): 23-28

Buckles GR, Smith ZD, Katz FN. mip causes hyperinnervation of a retinotopic map in *Drosophila* by excessive recruitment of R7 photoreceptor cells. *Neuron* 1992 Jun;8(6):1015-29.

Smith ZD, Caplan MJ, Jamieson JD. Immunocytochemical localization of plasmalemmal proteins in semi-thin sections of epithelial monolayers. *Journal of Histochemistry and Cytochemistry* 1988 Mar;36(3):311-6.

Smith ZD, Caplan MJ, Forbush B 3rd, Jamieson JD. Monoclonal antibody localization of Na⁺-K⁺-ATPase in the exocrine pancreas and parotid of the dog. *American Journal of Physiology* 1987 Aug;253(2 Pt 1):G99-109.

Shrivastava R, Chorney MJ, Lawrence SK, Pan J, Smith Z, Smith CL, Weisman S. Structure, expression and molecular mapping of a divergent member of the Class I HLA gene family. *Proceedings of the National Academy of Science* 1987. 84:4224-4228

Smith ZD, D'Eugenio-Gumkowski F, Yanagisawa K, Jamieson JD. Endogenous and monoclonal antibodies to the rat pancreatic acinar cell Golgi complex. *Journal of Cell Biology* 1984 Jun;98(6):2035-46.

Smith ZD, Gray L, Rubel EW. Afferent influences on brainstem auditory nuclei of the chicken: n. laminaris dendritic length following monaural conductive hearing loss. *Journal of Comparative Neurology* 1983 Oct 20;220(2):199-205.

Muresan V, Iwanij V, Smith ZD, Jamieson JD. Purification and use of limulin: a sialic acid-specific lectin. *Journal of Histochemistry and Cytochemistry* 1982 Sep;30(9):938-46.

Gray L, Smith Z, Rubel EW. Developmental and experimental changes in dendritic symmetry in n. laminaris of the chick. *Brain Research* 1982 Jul 29;244(2):360-4.

Zaid Daniel Smith, PhD

Smith ZD Organization and development of brain stem auditory nuclei of the chicken: dendritic development in N. laminaris. Journal of Comparative Neurology 1981 Dec 10;203(3):309-33.

Rubel EW, Smith ZD, Steward O. Sprouting in the avian brainstem auditory pathway: dependence on dendritic integrity. Journal of Comparative Neurology 1981 Nov 1;202(3):397-414.

Smith DJ and Rubel EW. Organization and development of brain stem auditory nuclei of the chicken: Dendritic gradients in n. laminaris. Journal of Comparative Neurology 1979; 186:213-240

Rubel EW, Smith DJ, Miller LC. Organization and development of brain stem auditory nuclei of the chicken: Ontogeny of n. magnocellularis and n. laminaris. Journal of Comparative Neurology 1976; 166:469-489

In addition, there are numerous journal publications for which my authorship was not for attribution.

Other Publications

Thrombolysis (Activase) for acute myocardial infarction

Intravenous immunoglobulin therapies for autoimmune diseases

Recombinant human growth hormone (Serostim) for AIDS wasting

Oral transmucosal fentanyl citrate (Actiq) for breakthrough cancer pain

Hyaluronan based therapy (Synvisc, Hyalgan) for osteoarthritis of the knee

Intravenous immunoglobulin for systemic lupus erythematosus

Interleukin-2 (Proleukin) for HIV infection

Mifepristone (RU 486) for medical abortion

Botulinum Toxin (Botox) for the prevention of migraine headache

Extracorporeal membrane oxygenation (ECMO) for newborn respiratory failure

External counterpulsation for the treatment of stable angina

High frequency chest compression for cystic fibrosis

Endovenous radiofrequency obliteration (VNUS Closure System) for varicose veins

Endoluminal gastroplication (EndoCinch) for gastroesophageal reflux disease (GERD)

Stretta™ procedure for GERD

Interbody cage with bone morphogenetic protein (InFUSE/LT-CAGE) for spinal fusion

CA 15-3 monoclonal antibody diagnostic for breast cancer

High-dose chemotherapy with autologous bone marrow transplantation for breast cancer

High-dose chemotherapy and stem cell rescue for multiple myeloma

Cryosurgical ablation of the prostate (CSAP) for localized prostatic cancer

Nonmyeloablative conditioning and allogeneic stem cell transplantation for acute lymphoblastic leukemia

Oxygen therapy for cluster headaches

Percutaneous kyphoplasty for osteoporotic spinal compression fracture pain

Pallidotomy for the treatment of Parkinson's Disease

Thalamic stimulation for Parkinson's Disease

Neural surgery for carpal tunnel syndrome

Lung volume reduction surgery

Uterine embolization for the treatment of fibroids

Transurethral needle ablation (TUNA) of the prostate for benign prostate hyperplasia

Meniscal allograft transplantation for damaged or removed meniscus

Zaid Daniel Smith, PhD

Lung transplantation
Liver transplantation for alcoholic liver disease
Pediatric living-donor liver transplantation
Autologous chondrocyte transplantation for knee cartilage defects
Adult-to-adult living-donor liver transplantation
Living-donor pancreas transplantation
Islet cell transplantation for type 1 diabetes
Intestine and intestine/liver transplantation
The Clubhouse Model for psychosocial rehabilitation
High-dose chemotherapy and stem cell transplantation for systemic lupus erythematosus
Enteryx for GERD
Her Option™ uterine cryoblation therapy system for menorrhagia
Meniett device for Meniere's disease
NovaSure™ endometrial ablation for menorrhagia
Essure for permanent contraception
Insulin glargine (Lantus) for type 2 diabetes
Osteogenic protein-1 (Osigraft) for spinal fusion
Platelet gel for spinal fusion
Intranasal live-attenuated influenza vaccine (FluMist)
ABO-incompatible living donor kidney transplantation
Early treatment of pneumonia
Treatment of atrial fibrillation
Management of hyperbilirubinemia
Influenza vaccination
Emergency treatment of stroke
Right heart catheterization
Treatment of mantle cell lymphoma
High-dose chemotherapy with bone marrow transplant for metastatic breast cancer
Sexual transmission of hepatitis C
Treatment of nail fungus infections
Carpal tunnel syndrome from automobile accidents
Treatment options for atrial fibrillation
Prevention of Alzheimer's disease
Brachial plexitis
Therapies for seborrheic dermatitis
Vitreotomy surgery for macular holes