

Marla Beth Sultan

235 East 42nd Street
New York, New York 10017

Professional Experience: *Executive Director, Global Clinical Lead/Manager–Rare Disease-*

Current Position

tafamidis/Vyndaqel, Vyndamax

Select Key Accomplishments:

- FDA approval: Vyndaqel and Vyndamax
- PMDA approval: Vyndaqel

Selected as *Industry Representative for the Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC)*, Center for Drug Evaluation and Research, United States Food and Drug Administration
Term: March 31, 2016 - October 31, 2019

July 2010 – April 2014

Senior Director, Global Clinical Lead/Manager – Ophthalmology

Macugen/Xalatan/Xalacom (July 2010 – April 2014)

Early Candidate Clinical Lead -Ophthalmology, Pfizer Inc.

- Led Multidisciplinary Team by convening and chairing meetings, documenting conclusions, and managing Team decisions
- Led design and management of all scientific aspects of clinical trials Phase I to III
- Chair- Therapeutic Area Standards Committee-Ophthalmology
 - Convened and chaired meetings in the establishment of standards for content of clinical reporting activities - case report form development, content data collection, data points
- Member – Ocular Safety Council, Retina Strategy Committee
 - Provided ophthalmologic expertise to support risk/benefit understanding/advice
- Support provided to external governmental regulatory agency needs within Pfizer to the Medical Development Group, Medical Pharmacovigilance, Safety Risk Management, Legal, and Commercial Groups including, but not limited to: retrieving and disseminating knowledge across Pfizer
 - Advised Teams – provided subject matter expertise -

Ophthalmology, defined ocular endpoints

- Provided general inline product support – including to the Periodic Safety Update Report, Product Benefit Risk Committee, Ophthalmology Publication Subcommittee, Medical Subcommittee for Xalatan and Macugen, Labeling Activities

Marla Beth Sultan

- Provided business development support for due diligence initiatives, including evaluation of potential in-licensing candidates

Select key accomplishments:

- EMA: Type II Macugen DME filing

235 East 42nd Street
New York, New York 10017

June 2008 – July 2010 **Director, Global Clinical Lead – Macugen- DME, Xalatan SR Clinical Affairs/Research & Development, Pfizer, Inc**

- Designed, conducted, analyzed, interpreted, and reported studies conducted internally for Clinical Affairs and other Pfizer groups
- Led and managed studies conducted by outside contractors
- Provided clinical support for investigational and marketed products including Xalatan, Xalacom, Xalatan SR and biologics (e.g., Macugen)
- Provided subject matter expertise: Ophthalmology
- Provided business development support for due diligence activities

Select key accomplishments (2008-2010)

- Successfully negotiated the terms for the design and execution of a Macugen Registration Program with the EMA, PMDA and TGA
- Collaborated with Clinical Triad to develop a novel analysis of relevant diabetic retinopathy pediatric information that led to the successful submission of the pediatric investigation plan (PIP) waiver for Macugen.

Aug 2007–June 2008 **Global Medical Director–Ophthalmology (Glaucoma/Xalabrand) World Wide Pharmaceutical Operations, Pfizer, Inc**

- Developed clinical protocols for Glaucoma
- Responsible for independent and sponsor studies from concept through execution and data analysis / reporting
- Provided scientific presentations on clinical data and selected scientific topics
- Prepared regulatory reports, answered worldwide regulatory reviewer questions including Europe, Japan and Canada
- Planned, organized and led team meetings, advisory panels and study sessions
- Interacted with KOLs to guide study evolution and data analysis, advisory boards, and other related activities

Jan 2005-Aug 2007 **Director, Regional Medical and Research Specialist – West US Medical – Pfizer Global Pharmaceuticals, Pfizer, Inc.**

Marla Beth Sultan

- Product Launch Responsibilities-
US Macugen launch–AMD January 2005
- Supported Post-Marketing Clinical Research
- Planned, organized and led team meetings, advisory panels and study sessions
- Interacted with KOLs to guide study evolution and data analysis, advisory boards, and other related activities
- Supported Pipeline and Business Development Opportunities

Jan 1999-Jan 2005 *Physician and Chief Executive Officer Sultan*

Eye MD, P.C.

Medical and Surgical Retina -Comprehensive Ophthalmology

- Responsible for patient care and office activities including hiring and supervision of office staff

Jan 2004-present

Associate Adjunct Surgeon, Department of Ophthalmology New York Eye & Ear Infirmary

- Responsibilities include patient care and teaching residents & medical students

Medical Training:

Retina Associates of Long Island, P.C.

Preceptorship – Medical and Surgical Retina and Vitreous

Armed Forces Institute of Pathology

Fellow Ophthalmic Pathology

State University of New York Health Science Center at Brooklyn

Chief Resident, Clinical Assistant Instructor

Residency - Department of Ophthalmology

Winthrop University Hospital - State University of NY at Stony Brook

Internship Department of Internal Medicine

Education:

M.B.A. New York University Stern School of Business Executive MBA
Program

New York, New York

M.D. University of Miami School of Medicine

Miami, Florida

B.S. University of Miami

Honors & Privileged Studies- Honors Program in

Medicine Coral Gables, Florida **Research, Publications, Courses:**

Maurer, M, Schwartz, J, Gundapaneni, Perry, E, Merlini, G, Cruz, M, Kristen, A, Grogan, M, Witteles, R, Damy, T, Drachman, B, Shah, S, Hanna, M, Judge, D, Barsdorf, A, Huber, P, Patterson, T, Riley, S, Schumacher, J, Stewart, M, Sultan, M, Rapezzi, C, Tafamidis Treatment for Patients with Transthyretin Amyloid Cardiomyopathy. N Engl J Med 2018; 379 1007-1016.

Sultan MB, Gundapaneni B, Schumacher J, Schwartz JH, Treatment with Tafamidis Slows Disease Progression in Early-Stage Transthyretin Cardiomyopathy. Clin Med Insights Cardiol. 2017, vol.11; 1-4.

Marla Beth Sultan

Maurer MS, Elliott P, Merlini G, Shah, S, Cruz, M, Flynn, A, Gundapaneni, B, Hahn, C, Riley, S, Schwartz, J, Sultan, M, Rapezzi, C, ATTR-ACT Investigators, Design and rationale of the phase 3 ATTR-ACT clinical trial (Tafamidis in Transthyretin Cardiomyopathy Clinical Trial). *Circ Heart Fail* 2017;10(6):e003815-e003815.

Huang K, Sultan MB, Zhou D, Tressler CS, Mo J. Ocular Safety of Intravitreal (IVT) Injection of Age-related Macular Degeneration Treatments in A Prospective Observational Cohort Study in Europe. *Journal of Clinical Research and Ophthalmology: Volume (2), Issue 3 (2015), page 1-5.*

Basile AS, Johnson TR, Klamerus KJ, Zhou D, Sultan, MB, Amantea M, Nickens DJ. Integrating disease progression models, non-clinical pharmacokinetic data and treatment response endpoints to optimize intravitreal dosing regimens. *International Journal of Clinical Pharmacology and Therapeutics* 2014, Vol. 52; 52 (7):574-586.

Huang K, Sultan M, Zhou D, Tressler C, Mo, J. Practice patterns of ophthalmologists administering intravitreal injections in Europe. *International Conference on Pharmacoepidemiology & Therapeutic Risk Management (ICPE)*, October 24-27, 2014, Taipei, Taiwan. Poster Presentation.

Tressler, CS, Sultan, MB, Mo, J, Zhou, D, Huang, KA. Effect of repeated intravitreal injections of anti-vascular endothelial growth factor agents on intraocular pressure in patients with age-related macular degeneration. *American Glaucoma Society Meeting 2014, Feb 27 – Mar 2, Poster presentation.*

Marla Beth Sultan

Xu, W, Huang, K, Sultan, M, Zhang, M. Long-term Safety of Latanoprost in Pediatric Populations: Design and Rationale of an Ongoing Cohort Study. Poster Presentation. 29th International Conference on Pharmacoepidemiology & Therapeutic Risk Management. August 25-28, 2013.

Huang K, Sultan MB, Zhou D, Tressler C, Mo J and the Macugen A5751019 Study Group, Ocular Safety of Intravitreal Injection of Macugen for Age-Related Macular Degeneration (AMD) Treatments in a Prospective Observational Study in Europe. Oral Presentation 13th Euretina Congress, 29 September 2013, Hamburg, Germany.

Dombi TM, Kwok, KK, Sultan, MB. A retrospective, pooled data analysis of the safety of pegaptanib sodium in the treatment of age-related macular degeneration in subjects with or without diabetes mellitus. *BMC Ophthalmology*. 2012, 12: 37.

Sultan, MB, Starita, C, Huang K. Epidemiology, risk factors and management of paediatric diabetic retinopathy. *British Journal of Ophthalmology*. Mar 2012, 96/3(312-7).

Sultan MB, Zhou D, Loftus J, Dombi T, Ice K for the Macugen 1013 Study Group. A Phase 2/3, Multicenter, Randomized, Double-Masked 2-Year Trial of Pegaptanib Sodium for the Treatment of Diabetic Macular Edema. *Ophthalmology* 2011;118(6):1107-1118.

Loftus, JV, Sultan, MB, Pleil AM for the Macugen 1013 Study Group. Changes in Vision- and Health-Related Quality of Life in Patients with Diabetic Macular Edema Treated with Pegaptanib Sodium or Sham. *IOVS* 2011: 52 (10) 74987505

Dombi TM, Kwok, KK, Wiseman, RL, Sultan, MB. Systemic safety of pegaptanib sodium in the treatment of age-related macular degeneration (AMD) in subjects with diabetes mellitus (DM): A pooled analysis. *ARVO* (May 1-5) Poster

Ice K, Sultan, MB, Zhou, D, Dombi, T, Loftus, J. A 2-year, randomized, double-masked, phase 2/3 trial of pegaptanib sodium in patients with diabetic macular edema. *Euretina* (May 26-29) Oral paper.

Dombi TM, Kwok, KK, Sultan, MB. A retrospective, pooled data analysis of the safety of pegaptanib sodium in the treatment of age-related macular degeneration in subjects with or without diabetes mellitus. *BMC Ophthalmology*. 2012, 12: 37.

Sultan, MB, Starita, C, Huang K. Epidemiology, risk factors and management of paediatric diabetic retinopathy. *British Journal of Ophthalmology*. Mar 2012, 96/3(312-7).

Sultan MB, Zhou D, Loftus J, Dombi T, Ice K for the Macugen 1013 Study Group. A Phase 2/3, Multicenter, Randomized, Double-Masked 2-Year Trial of Pegaptanib Sodium for the Treatment of Diabetic Macular Edema. *Ophthalmology* 2011;118(6):1107-1118.

Dombi TM, Kwok, KK, Wiseman, RL, Sultan, MB. Systemic safety of pegaptanib sodium in the treatment of age-related macular degeneration(AMD) in subjects with diabetes mellitus (DM): A pooled analysis. Poster Presentation. *ARVO* 2011.

Marla Beth Sultan

Ice K, Sultan, MB, Zhou, D, Dombi, T, Loftus, J. A 2-year, randomized, double-masked, phase 2/3 trial of pegaptanib sodium in patients with diabetic macular edema. Oral Presentation. Euretina 2011

Trocme, S, Huang, L-J, Bean, G, Sultan, MB. The role of benzalkonium chloride in the occurrence of punctate keratitis: a meta- analysis of randomized, controlled clinical trials. World Cornea Congress VI, poster #822, April 7- 9, 2010.

Sultan, M and Lee, P. (2010). IOP Fluctuation. In: Giaconi, J et al Pearls of Glaucoma Management. Berlin:Springer-Verling. p105-111.

Sultan MB, Mansberger SL, Lee PP. Understanding the Importance of IOP Variables in Glaucoma: A Systematic Review of the Literature. Surv of Ophth 2009 Nov; 54, 643-662.

Lee PP, Sultan MB, Grunden JW, Cioffi GA; for the IOP Consensus Panel. Assessing the Importance of IOP Variables in Glaucoma Using a Modified Delphi Process. J of Glaucoma 2010, Jun-Jul; 19(5):281-7.

Palmberg P, Sultan MB, Zhou D, Bean G, Hwang L-J, Kim E, Tressler C. Ocular adverse events (OAEs) and preservative concentration in latanoprost (LAT), travoprost (TRA), and bimatoprost (BIM). AAO (Presented at American Academy of Ophthalmology 2008 and SOE 2008 Annual Meeting). November 9, 2008; Abstract #PO077.

Varma R, Hwang L, Grunden J, Bean G, Sultan M. Assessing the Efficacy of Latanoprost vs Timolol Using an Alternate Efficacy Parameter: The Intervisit Intraocular Pressure Range. Amer Journal of Ophth. 2009 Aug; 148(2), 221-226.

Sultan MB, Grunden J, Cioffi GA, Lee PP. Understanding the value of IOP changes in glaucoma using a modified Delphi Process with glaucoma experts. Oral Presentation. World Ophthalmology Congress 2008. June 28, 2008; Abstract #6645.

Sultan MB, Hwang L-J, Zhou D, Kim E, Tressler C. Corneal safety of glaucoma medications: Results of a 5-year, multinational, randomized, post-marketing safety surveillance study. Poster. World Ophthalmology Congress 2008. June 28, 2008; Abstract #6642.

Tressler C, Kim E, Hwang J-J, Bean G, Zhou D, Sultan M. Impact of doubling the amount of benzalkonium chloride (BAK) in latanoprost-treated patients on the incidence of punctate epithelial erosions (PEE) in double-masked, prospective, controlled trials of latanoprost versus timolol. Poster. World Ophthalmology Congress 2008. June 28, 2008; Abstract #6659.

Kim E, Kwok K, Tressler CS, Sultan M, Grunden JW, Bean G. Incidence of ocular irritation in ocular hypertensive patients treated with latanoprost: Findings from a large internet registry. Poster. World Ophthalmology Congress 2008. June 28, 2008; Abstract #6709.

Goldberg I, Sultan MB, Zhou D, Hwang L-J, Kim E, Grunden JW, Tressler CS. Corneal safety of glaucoma medications in a human study. Poster. European Glaucoma Society Quadrennial Meeting. June 1, 2008; Abstract #P36.

Hwang L-J, Bean GW, Fain JM, Sultan M, Kim E, Grunden J, Tressler CS. Punctate epithelial erosions (PEE): Incidence in double-masked, prospective, controlled trials of latanoprost and timolol. Poster. European Glaucoma Society Quadrennial Meeting. June 1, 2008; Abstract #P37.

Marla Beth Sultan

Kim E, Kwok K, Tressler CS, Sultan MB, Grunden JW, Bean GW. Incidence of ocular irritation with a topical prostaglandin analogue from a registry study. Poster. European Glaucoma Society Quadrennial Meeting. June 1, 2008; Abstract #P40.

Hwang L-J, Bean G, Fain J, Sultan MB, Kim E, Grunden J, Tressler CS. The incidence of punctate epithelial erosions (PEE) in double-masked, prospective, controlled trials of latanoprost versus timolol. Poster, Association for Research in Vision and Ophthalmology, May 2009 Investigative Ophthalmology & Visual Science. 2008;49:E- Abstract 1218.

Goldberg I, Sultan M, Zhou D, Hwang L-J, Kim E, Grunden J, Tressler C. Corneal safety of glaucoma medications in a human study. Poster. American Glaucoma Society 2008 Annual Meeting. March 6, 2008; Abstract #35.

Sultan, MB, Fain, J, Lee, PP. A Practical Guide to Understanding Ophthalmic Literature Through Critical Evaluation and Assessment. Course, American Academy of Ophthalmology. November 2007.

Cioffi, GA, Lee, PP, Sultan, MB, Grunden, JW, IOP Consensus Panel. Assessing the Measurement and Value of IOP Changes in Glaucoma Using Modified Delphi Process With Glaucoma Experts. Poster Presentation, Association for Research in Vision and Ophthalmology, May 2007. Investigative Ophthalmology & Visual Science. 2007;48:E- Abstract 1267

Meehan, R.H., Castro, C., Sultan, M.B., Gopal, L., Safety Patterns of Work-Related Ophthalmic Injuries at an Urban Level-One Trauma Center. Poster, Association for Research in Vision and Ophthalmology, May 2001.

Sultan, M.B., Deegan, W., Hidayat, A.A., Choroidal Melanoma Treated with Transpupillary Thermotherapy. Presentation. AOA-Armed Forces Institute of Pathology 2001 meeting, April 2001.

Castro, C., Meehan, R.H., Sultan, M.B., Chu, T.T., A Retrospective Study of Open Globe Injuries Seen at a Level- One Trauma Center from 1992 to 1997. Paper Presentation, Association for Research in Vision and Ophthalmology, May 1998.

Sultan, M.B., Meehan, R.H., Castro, C., The Impact of Ocular Disease on the Instrumental Activities of Daily Living. Paper Presentation, Association for Research in Vision and Ophthalmology, May 1997.

Castro, C., Sultan, M.B., Meehan, R.H., Significant Epidemiological Data Concerning Ophthalmic Dog Bites. Poster Presentation, Association for Research in Vision and Ophthalmology, May 1997.

Sultan, M., Kelly, M.E., Hilliard, G., Horowitz, M.D., Complications of Plombage in a Cuban Exile. J. Florida M.A., 1994; 81: 815-817.

Affiliations:

Fellow - American Academy of Ophthalmology

Member - Association Research in Vision and Ophthalmology

Certifications:

Diplomate, American Board of Ophthalmology, 2000, re-certified: 2010

Diplomate, National Board of Medical Examiners, 1994

Physician Licensure State of New York, Florida, and California

235 East 42nd Street
New York, New York 10017

marla.b.sultan@pfizer.com

Marla Beth Sultan

Special Qualifications:

Basic and Medical Spanish

Some Medical Russian Basic

French