

## Michael H Silverman, MD, FACP

**Summary.** Clinical Research and Development Expert with more than 2 decades of international industry clinical research experience, including Phases 1-3 and the supporting Regulatory activities, encompassing Pharmaceutical, Biotechnology, Medical Device, and Diagnostics Industries. Areas of experience and expertise include:

- Clinical program strategic planning
- Protocol concept, design, implementation
- CRO selection and oversight
- Regulatory Strategy and interactions
- IND and NDA Filing
- International trials programs
- Early stage to POC development
- Virtual teams

### **Professional Experience**

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BioStrategics Consulting Ptd  
Founder, President: 1999-present

KPMG Healthcare Consulting  
Manager: 1997-1999

Biopure  
Vice-President, Clinical Research: 1995-1997

Telor Ophthalmic Pharmaceuticals, Inc  
Executive Director, Clinical Research: 1993-95

Sandoz Research Institute  
Director, Clinical Research: 1989-1993

Sterling-Winthrop Research Institute  
Clinical Project Director: 1986-1989

### **Education/Certification**

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**1969; BS**, University of Illinois, Urbana

**1973; MD**, University of Chicago Pritzker School of Medicine

**1976; Internal Medicine**, University of Iowa (Board Certified)

**1978; Rheumatology**, University of Colorado (Board Certified)

### **Drug Development Experience**

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- Managed Clinical Research programs in US, Western and Eastern Europe
- Extensive experience working with FDA and other authorities, including INDs, NDAs, PMAs
- IND planning, protocol development, first-in-man through POC trials in all therapeutic areas
- Small molecule, biologics, immunotherapeutics, medical devices, diagnostic agents
- Large and small company management, start-ups, virtual companies, global teams
- Technical assessments and due diligence activities

## **Selected Publications**

- Cook, J.A., Silverman, M.H., Schelling, D.J., Nix, D.E., Schentag, J.J., Brown, R.R. and Stroshane, R.M. Multiple dose pharmacokinetics and safety of oral amifloxacin in healthy volunteers. *Antimicrob Agents Chemother.* 1990;34:974-979.
- Boyko, E.J., Irvani, A., Silverman, M.H., Schelling, D.J. A randomized controlled trial of a 10 day course of amifloxacin versus trimethoprim-sulfamethoxazole in the treatment of acute, uncomplicated urinary tract infection. *Antimicrob Agents Chemother.* 1990;34:665-667.
- Solch, S., Nadler, P.I. and Silverman, M.H. Safety and tolerability of 2% cyclosporine ophthalmic ointment (Sandimmune®) in normal volunteers. *J Ocular Pharmacol.* 1991;7:301-312.
- Laibovitz, R., Solch, S., Andriano, K., O'Connell, M. and Silverman, M.H. Pilot trial of cyclosporine 1% ophthalmic ointment in keratoconjunctivitis sicca. *Cornea* 1993;12:315-323.
- Silverman MH, Hedley ML, Petry KU, and Weber JS. Clinical trials in cervical intraepithelial neoplasia: Balancing the need for efficacy data with patient safety. *J Lower Genit Tract Dis* 2002;6:206-211.
- Ujhelyi M, Hoyt RH, Burns K, Fishman RF, Musley S, and Silverman MH. Nitrous oxide sedation reduces discomfort caused by atrial defibrillation shocks. *Pacing Clin Electrophysiol* 2004;27:485-491.
- Garcia F, Petry KU, Mudersapch L, Gold MA, Braly P, Crum CP, Magill M, Silverman M, Urban RG, Hedley ML, and Beach KJ. ZYC101a for treatment of high-grade cervical intraepithelial neoplasia: a randomized controlled trial. *Obstet Gynecol* 2004;103:317-326.
- Van Troostenburg AR, Lee D, Jones TR, Dyck-Jones JA, Silverman MH, Lam GN, Warrington SJ. Safety, tolerability, and pharmacokinetics of subcutaneous Å6, an 8-amino acid peptide with anti-angiogenic properties, in healthy men. *Int J Clin Pharmacol Ther* 2004;42:253-259.
- Van Troostenburg A-R, Clark EV, Carey WDH, Warrington SJ, Kerns WD, Cohn I, Silverman MH, Bar-Yehuda S, Fong K-LL, Fishman P. Tolerability, pharmacokinetics, and concentration-dependent hemodynamic effects of oral CF101, an A<sub>3</sub> adenosine receptor agonist, in healthy young men. *Int J Clin Pharmacol Ther* 2004; 42:534-542.
- Berkenblit A, Matulonis UA, Kroener JF, Dezube BJ, Lam GN, Cuasay LC, Brünner N, Jones TR, Silverman MH, Gold MA. Å6, a urokinase plasminogen activator (uPA)-derived peptide in patients with advanced gynecologic cancer: A phase I trial. *Gynecol Oncol* 2005;99:50-57.
- SCT Working Group on Data Monitoring: Dixon DO, Freedman RS, Herson J, Hughes M, Kim KM, Silverman MH, Tangen CM. Guidelines for data and safety monitoring for clinical trials not requiring traditional data monitoring committees. *Clin Trials* 2006;3:314-319.
- Bar-Yehuda S, Silverman MH, Kerns WD, Ochaion A, Cohen S, Fishman P. The anti-inflammatory effect of A<sub>3</sub> adenosine receptor agonists: a novel targeted therapy for rheumatoid arthritis. *Expert Opin Investig Drugs* 2007;16:1-13.
- Silverman MH, Strand V, Markovits D, Nahir M, Reitblat T, Molad Y, et al. Clinical evidence for utilization of the A<sub>3</sub> adenosine receptor as a target to treat rheumatoid arthritis: data from a Phase II clinical trial. *J Rheumatol* 2008;35:41-48.
- Ghamande SA, Silverman MH. Huh W, Behbakht K, Ball G, Cuasay L, Würtz SO, Brunner M, and Gold MA. A Phase 2, randomized, double-blind, placebo-controlled trial of clinical activity and safety of subcutaneous Å6 in women with asymptomatic CA125 progression after first-line chemotherapy of epithelial ovarian cancer. *Gynecol Oncol* 2008;111:89-94.
- Avni I, Garzozzi HJ, Barequet IS, Segev F, Varssano D, Sartani G, Chetrit N, Bakshi E, Zadok E, Tomkins O, Litvin G, Jacobson KA, Fishman S, Harpaz Z, Farbstein M, Bar Yehuda S, Silverman MH, Kerns WD, Bristol DR, Cohn I, Fishman P. Treatment of dry eye syndrome with orally administered CF101: Data from a Phase 2 clinical trial. *Ophthalmology* 2010;117:1287-1293.

## **Professional Activities**

- Fellow, American College of Physicians
- Member, Advisory Boards and Data Safety Monitoring Committees
- Alumni Council, University of Chicago Medical & Biological Sciences Division Alumni Association
- Visiting Committee, University of Chicago Biological Sciences Division and Pritzker School of Medicine
- Invited lecturer on clinical trial topics (academic and industry groups)