

**GILAD S. GORDON, M.D., M.B.A.**

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EXPERIENCE:

**ORRA Group, Boulder, CO**

5/2004-present

*President*

Consultant to various healthcare organizations with responsibilities that include:

- CEO of 2 University of Colorado start-up companies focused on immuno-therapies and diagnostics
- Acting Chief Medical Officer for companies with Hepatitis C, oncology, and hematology products; wrote clinical development plans, submitted INDs, started multi-site Phase I trials; coordinated business development and licensing discussions which lead to partnerships with major pharmaceutical companies
- Acting Chief Medical Officer for company with oncology and inflammation products; developed oncology and inflammation clinical strategies; lead FDA interactions; submitted 6 INDs; monitored Phase I & II clinical trials
- Analyzed, developed plans for clinical opportunities in oncology, hematology, infectious disease, hepatitis, cardiology, inflammation and medical devices; recommendations lead to licensing and funding of over \$100M
- Acting Chief Safety Officer for company with oncology, dermatology, and ophthalmology products
- Member of Data Safety Monitoring Board for innovative Hepatitis C trial
- AP4 Facilitator - consortium between the U. of Colorado Cancer Center, NCI, and private industry
- Performed due diligence on potential health care investments for venture capital firms and hedge funds
- Lecturer on health economics, public policy, and health care pricing

**FeRx, Inc., Aurora, CO; San Diego, CA**

6/2002-5/2004

*Vice President of Medical Affairs*

Biotechnology company developing localized drug delivery systems for human oncology applications utilizing drugs that bind to iron particles in conjunction with magnetic targeting.

- Directed all medical aspects of the clinical trials for the treatment of hepatocellular carcinoma including pivotal multi-national Phase II/III and Phase I trials
- Coordinated interactions with the FDA and EMEA which led to approval of Phase II/III regulatory strategy
- Developed strategy and protocols for new indications for existing and new products
- Served as member of the three person “road-show” team that represented the company in fund raising and corporate alliances initiatives; obtained term sheet for a \$40M funding commitment from a leading U.S. venture capital firm
- Directed medical interactions during business development discussions; efforts led to three term sheets from potential partners in the United States, Europe, and Asia
- Served as Medical Safety Officer; responsible for monitoring and reporting on the safety of all of the products
- Developed reimbursement strategy

**Ribozyme Pharmaceuticals, Inc., Boulder, CO**

2000-2002

*Director, Clinical Research*

Biotechnology company developing ribozymes for human oncology and virology applications.

- Directed team that in five months developed the clinical strategy, directed the submission of the INDs, wrote the protocols, recruited the investigators and started five major Phase I and Phase II trials for three products (Heptazyme for Hepatitis C, and Angiozyme and Herzyme for oncology) in two countries
- Directed clinical development partnership with two multi-billion dollar partner companies; actions directly led to renewal of a partnership that generated significant revenues
- Recruited entire clinical research department, consisting of two MDs, seven CRAs, one safety specialist, and eight support staff
- Established safety department to monitor safety reporting across all clinical trials. Directed the development of a state-of-the-art serious adverse event tracking software

**Independent Consultant, Boulder, CO**

1998 – 2000

Assignments included serving as Acting Vice President and Chief Medical Officer for a publicly traded biotechnology company and medical advisor to venture capital firms and start-up companies.

- Led team that designed Phase III clinical trials and presented plans to FDA for a biotechnology company; client received FDA approval to conduct trials
- Led clinical strategy negotiations with major pharmaceutical firm that resulted in a long-term clinical development and marketing partnership agreement for the client
- Developed the oncology clinical trial strategy for product registration for a biotechnology company
- Performed due diligence on potential investments for venture capital firms; positive recommendations led to multi-million dollar investments in healthcare companies specializing in cardiology, diagnostics, and specialty healthcare
- Developed medical strategies and wrote the business plans for start-up web-based medical information company; efforts led to company receiving early-stage funding
- Served as member of health economics and outcomes research advisory committees

**Bolder Heuristics, Boulder, CO**

1996 – 1998

*Vice President, Health Care*

Software development company specializing in complex custom software products for medical and telecommunications applications.

- Managed healthcare software development division; grew segment to over \$4 million per year in 2 years
- Led team that implemented \$2 million telephone-based medical triage application for disease management company that resulted in increased sales, decreased operational costs, and additional outside funding for client
- Led team that designed, programmed, and installed a \$4 million medical management application for a leading HMO
- Developed strategic business and informatics plan for web-based home health care monitoring organization that resulted in client obtaining funding from leading venture capital firms
- Served as member of the team that negotiated merger of company

**MediQual Systems, Inc., Westborough, Massachusetts**

1994 - 1996

*Medical Director*

Leading clinical information system company with over 400 hospital clients and a 30 million patient database.

- Managed 40 person client support (clinical and IT) organization chartered with helping client organizations to interpret and utilize the database to improve clinical decision making and patient care and to decrease costs
- Started and developed pharmaceutical consulting division that generated in excess of \$1 million in first-year revenues
- Led pharmaceutical funded multi-organization study that analyzed clinical outcomes and validated guidelines for therapy of patients with pneumonia. Study was awarded “Best Research” prize by the American College of Chest Physicians
- Developed new marketing strategies utilizing claims databases that expanded the company’s portfolio of services and led to increased revenue
- Re-organized wholly owned subsidiary that provided clinical chart abstraction services for hospitals; this directly resulted in increased revenue and profitability
- Served as a member of company’s executive committee

**Synergen, Inc., Boulder, CO**

1991 - 1994

*Director, Clinical Research*

Biotechnology company whose primary product was targeted at sepsis, rheumatoid arthritis, and other inflammatory diseases.

- Directed cross-organizational team (Synergen, CRO, and outside consultants) that reviewed, compiled, and analyzed the Phase III clinical data; this permitted un-blinding of the clinical data four months ahead of schedule
- Led 200-person team that submitted PLA to European regulatory agencies three months ahead of schedule
- Managed the following departments: project management, health economics, medical safety, and medical writing (30 professionals)
- Directed health economics department that conducted collaborative, multi-national cost-effectiveness, quality of life, pharmaco-epidemiology, public policy, and pricing studies
- Conducted Phase I-III clinical trials on additional indications

## **Eli Lilly and Company**

*Clinical Research Physician*, Surrey, United Kingdom

1990 - 1991

*Associate Clinical Research Physician*, Indianapolis, Indiana

1988 - 1990

Major international pharmaceutical company.

- Led team that completed pediatric Phase III studies for a new antibiotic, submitted NDA to the FDA, and received FDA approval in record time
- Led team that completed European Phase III studies for a new antibiotic and submitted dossier to European regulatory agencies; drug received marketing approval in Europe
- Coordinated team that responded to accusations and demonstrated the safety of Prozac and Human Insulin. As a result, the FDA strongly supported Lilly and did not take regulatory action against the products.
- Developed new methodology for undertaking cost-effectiveness and quality of life research during Phase II-III clinical trials in both the United States and Europe

## **EDUCATION:**

### **Harvard University**

A.B., *Magna Cum Laude* in Biochemistry, 1979

John Harvard Scholar 1975 - 1979

### **Harvard University/Massachusetts Institute of Technology**

Division of Health Sciences and Technology

M.D., *Cum Laude*, 1983

### **University of Washington**

M.B.A., 1988

## **POSTGRADUATE TRAINING AND FELLOWSHIP APPOINTMENTS:**

**University of Washington**, July 1986 - June 1988

Senior Fellow - Robert Wood Johnson Clinical Scholars Program

**University of Colorado Health Sciences Center**, June 1983 - June 1986

Internship and Residency in Internal Medicine

## **FACULTY APPOINTMENTS:**

**Department of Medicine, University of Colorado Health Sciences Center**, 1992 - present

Clinical Assistant Professor of Medicine

**Department of Medicine, University of Indiana Medical School**, 1988 - 1992

Assistant Professor of Medicine

## **BOARD MEMBERSHIPS**

**Caring for Colorado Foundation** (Board appointed by Governor of Colorado)

2008 - present

**Colorado Foundation for Medical Care**

Board member – 1994-2000

**Indiana State Board of Health, Chronic Disease Advisory Committee**

Vice-Chairman- 1989-1991

**Industrial Labs, Inc.** (Drug and Nutraceutical testing company, \$3 million in annual sales)

Denver, Colorado – 1994-present

**Colorado Biogenix, Inc.** (Biotechnology company concentrating on periodontal disease)

Denver, Colorado - 1996 – present

## **ATTENDING PHYSICIAN**

**Denver Veteran's Administration Hospital** (1 month per year), 1992 - present:

**Indianapolis Veteran's Administration Hospital** (1 month per year), 1988 - 1991

**Regenstrief Institute of Wishard Hospital** (1/2 day per week), 1988 - 1991

## **SPECIAL CERTIFICATION:**

Diplomate, American Board of Internal Medicine, 1987

## **MEDICAL LICENSE:**

Colorado

## **PROFESSIONAL SOCIETIES:**

American College of Physicians

American Society of Clinical Oncology

American Federation of Clinical Research

Society for General Internal Medicine - Program Committee

International Society of Technology Assessment in Health Care

American Medical Informatics Association

## **PUBLICATIONS AND LECTURES**

61 abstracts and peer-reviewed articles

27 invited lectures