

Norman M. Goldfarb

Career

First Clinical Research LLC Managing Director (2005-Present)

First Clinical Research provides clinical research best practices information, consulting and training services, and publishes the Journal of Clinical Research Best Practices.

First Clinical Research, Inc. CEO and Founder (2002-2005)

First Clinical Research conducted clinical research across a broad range of medical specialties in the San Francisco Bay Area. It was the only investigative site that offered sponsors a satisfaction guarantee.

D2K, Inc. President and CEO (2001)

D2K developed the first distributed business process management and integration software for the EAI and B2Bi markets.

PointSpeed, Inc. CEO and Founder (1998-2001)

PointSpeed was the leading online Purchasing Services Provider for companies that serve the small business market. Operated online purchasing centers for industry leaders such as AT&T, Wells Fargo Bank and Paychex.

Plenary Software, Inc. CEO and Cofounder (1997-98)

Plenary Software developed and marketed the first knowledge management solution for software teams.

WhiteLight Systems, Inc. CEO and Cofounder (1992-1997)

WhiteLight Systems developed and marketed the first enterprise OLAP (On-Line Analytical Processing) software capable of integrated decision processing.

StereoCAD, Inc. CEO and Cofounder (1990-92)

StereoCAD developed and marketed the industry-leading low-cost virtual reality software for architects and mechanical engineers.

Pillar Corporation CEO and Organizer (1988-89)

Pillar successfully pioneered software for enterprise financial budgeting and forecasting. Pillar, now a business unit of Hyperion Solutions, still leads the industry, with annual sales in excess of \$100 million.

Expressway, Inc. CEO and Organizer (1986-87)

Expressway developed and marketed the leading suite of CASE tools for Tandem Computers. It reached a revenue run-rate of \$8M/year.

Calgene, Inc. CEO and Founder (1980-85)

Calgene was the leading plant genetic engineering company in the 1980s. It went public in 1985 and was acquired by Monsanto in 1987.

Education	<p>Stanford University, M.B.A., 1976</p> <p>Yale University, B.A. in Economics, <i>cum laude</i>, 1974</p>
Other	<p>Founder and Chairman of MAGI (2003-). Co-founder and Board Member of the Joint Task Force on Clinical Trial Competency (2013-), Founder and Chairman of the Clinical Research Relief Organization (2005-2008). Member, National Cancer Institute CRIX Steering Committee (2005-2007). Member, CIRCARE Board of Directors (2007-2011). Member, ACRP Site Managers Forum Steering Committee (2004-2009). Founded and led the California Industrial Biotechnology Association (1984-85); the Encina Foundation, a non-profit organization that established a program of international teacher exchanges (1986-); and Stepwise, possibly the first community-based, advertiser-supported website (1994-96). Clinical Research Contract Professional (CRCP) certification, 2004. Member, Association of Clinical Research Professionals, Drug Information Association, and PRIM&R. In 2016, PharmaVoice Magazine honored him as one of the 100 most inspiring people in the pharmaceutical industry. In 2017, ACRP honored him with its award for innovation.</p>
Publications & Presentations	<p>Over 1,000 talks, articles, book reviews, and columns, and one book, including:</p> <p>"Investigative Sites Speak Out About Remote Monitoring," Journal of Clinical Research Best Practices, May 2017</p> <p>"Patient Engagement in Clinical Studies," Journal of Clinical Research Best Practices, March 2017</p> <p>"An Organizing Principle for Innovation in Clinical Research", Journal of Clinical Research Best Practices, December 2016</p> <p>"The Cost to Sites of Remote Monitoring", Journal of Clinical Research Best Practices, September 2016</p> <p>"How to Negotiate Study Budgets", Journal of Clinical Research Best Practices, August 2016</p> <p>"FMV and the Market Failure in Clinical Research", Journal of Clinical Research Best Practices, July 2016</p> <p>"Informed Consent for New Investigators", Journal of Clinical Research Best Practices, June, 2016</p> <p>"What Is Patient-Centricity?", Journal of Clinical Research Best Practices, April 2016</p> <p>"Using Sunshine Act Data for Competitive Analysis and Other Purposes", Journal of Clinical Research Best Practices, November 2015</p> <p>"A Code of Ethics for Institutional Review Boards", Journal of Clinical Research Best Practices, October 2015</p> <p>"Lessons from the Markingson Controversy", Journal of Clinical Research Best Practices, August 2015</p> <p>"Wasteful Clinical Research Processes", Journal of Clinical Research Best Practices, August 2015</p> <p>"Clinical Research: A Time to Change", Journal of Clinical Research Best Practices, June 2015</p> <p>"Clinical Research Information Technology: The Future is Here ", Journal of Clinical Research Best Practices, April 2015</p>

"Payments to Study Participants", Journal of Clinical Research Best Practices, October 2014

"Clinical Research as a Learning Industry", Journal of Clinical Research Best Practices, March 2014

"The Golden Age of Clinical Research Innovation", Journal of Clinical Research Best Practices, May 2014

"Coercion and Undue Influence: The Worst Consent Ever?", Journal of Clinical Research Best Practices, April 2013

"Do the Best Hospitals Do the Most Clinical Research?", Journal of Clinical Research Best Practices, March 2013

"Moral Licensing", Journal of Clinical Research Best Practices, January 2013

"Adverse Event Terminology", Journal of Clinical Research Best Practices, July 2012

"Sponsor Report Cards", Journal of Clinical Research Best Practices, April 2012

"Is This Study Exploitative?", Journal of Clinical Research Best Practices, April 2011

"A National Registry for Healthy Volunteers in Phase 1 Clinical Trials", David B. Resnik, Norman M. Goldfarb, and Greg Koski, Journal of the American Medical Association, March 23/30, 2011

"Driving the Performance of a Clinical Research Site with Metrics", Journal of Clinical Research Best Practices, February 2011

"Reporting Unanticipated Problems to IRBs", Journal of Clinical Research Best Practices, June 2010

"Which Rules Apply? FDA vs. OHRP vs. ICH", Quincy J. Byrdsong and Norman M. Goldfarb, Journal of Clinical Research Best Practices, November 2009

"Solving the Revenue Collection Problem for Clinical Research Sites", Journal of Clinical Research Best Practices, September 2009

"Subject Recruiting: How Sites, Sponsors – and Subjects – Can Work Together", Association of Clinical Research Professionals Annual Meeting, April 28, 2009

"Investigator Disclosures of Financial Conflicts", Journal of Clinical Research Best Practices, October 2008

"Much Ado about Subject Compensation", Journal of Clinical Research Best Practices, September 2008

"The Personal Side of Subject Recruitment", Journal of Clinical Research Best Practices, August 2008

"Individual vs. Community: Balancing Rights, Benefits & Risks", Norman M. Goldfarb & Adil Shamoo, Association of Clinical Research Professionals Annual Meeting, April 27, 2008

"Confucius on Clinical Research", Journal of Clinical Research Best Practices, March 2008", Journal of Clinical Research Best Practices, March 2008

"The Tranquil World of IND Safety Reports", Journal of Clinical Research Best Practices, February 2008

"Should You Be a Clinical Research Principal Investigator?", Journal of Clinical Research Best Practices, January 2008

"Therapeutic Misconception, or Not?", Journal of Clinical Research Best Practices, October 2007

"How to Manage Any Organization", Journal of Clinical Research Best Practices,

August 2007

"We Can Get a Lot Smarter about Site Monitoring and Data Analysis", Drug Information Association Annual Meeting, June 21, 2007

"Ethical Pitfalls for Sponsors in Developing Countries", Journal of Clinical Research Best Practices, April 2007

"Adaptive Site Performance Management", Journal of Clinical Research Best Practices, April 2007

"Systematic Customer Service for Clinical Research Sites", Journal of Clinical Research Best Practices, April 2007

"The Site Monitor Reborn as Consultant, Trainer and Manager", Michael Rosenberg and Norman M. Goldfarb, Journal of Clinical Research Best Practices, March 2007

"How to Solve the Quality Problem in Clinical Research", Journal of Clinical Research Best Practices, February 2007

"Subject Recruitment: The Missing Links", Fox Chase Cancer Center, November 10, 2006

"Are Site Monitoring and Data Cleaning a Waste of Time?", Journal of Clinical Research Best Practices, November 2006

"Accelerating the Process of Negotiating Clinical Trial Agreements", Journal of Clinical Research Best Practices, October 2006

"The Case of the Faulty Facility: Investigative Reporting on SFBC", Journal of Clinical Research Best Practices, October 2006

"The Road to Informed Consent: Can We Get There from Here?", Society of Clinical Research Associates Annual Conference, September 23, 2006

"Faster, Better, Cheaper: Working Together to Save the Clinical Research Industry", Drug Information Association Annual Meeting, June 20, 2006

"Hiring, Training, Managing and Retaining Study Coordinators", Journal of Clinical Research Best Practices, June 2006

"Informed Consent Form Makeover", Norman M. Goldfarb and William DuBay, Journal of Clinical Research Best Practices, May 2006

"Informed Consent in the TeGenero TGN1412 Trial", Journal of Clinical Research Best Practices, May 2006

"Breaking the Bottleneck in Clinical Trial Agreements", Association of Clinical Research Professionals annual meeting, April 28, 2006

"Now Is the Time to Decide the Future of Clinical Research in India", Journal of Clinical Research Best Practices, April 2006

"Clinical Research Terminology Codes: What We Do and How Much It Costs", Journal of Clinical Research Best Practices, March 2006

"The Seven Hats of an IRB (and which Members Wear Them)", Journal of Clinical Research Best Practices, December 2005

"Bringing Method to the Madness: Protocol Deviation & Violation Codes", Journal of Clinical Research Best Practices, November 2005

"eSource: The Future is Here", Journal of Clinical Research Best Practices, November 2005

"Subject Recruiting: The Missing Links", Journal of Clinical Research Best Practices, October 2005

"Readable Informed Consent Forms Are Not Optional", Journal of Clinical Research

Best Practices, September 2005

"What is Killing Off the Investigators? A Clinical Research Mystery", Journal of Clinical Research Best Practices, July 2005

"The Triumph of Hope Over Experience: Why Johnny Can't Forecast Subject Enrollment", Journal of Clinical Research Best Practices, July 2005

"Obtaining Informed Consent in Extremis", Good Clinical Practices Journal, June 2005

"Becoming a Successful Clinical Research Investigator", David Ginsburg, Norman Goldfarb, Barry Miskin, Ann Neuer and Karen Woodin, CenterWatch, 2005

"Caught in the Middle: How Sponsors, Sites and CROs Can Work Together Effectively", Journal of Clinical Research Best Practices, May 2005

"How Industry Collaborations Will Save the Clinical Research Industry", Society of Research Administrators International Western Section annual meeting, May 2, 2005

"The Worst Informed Consent Ever: How a Physician Can Coerce and Unduly Influence a Patient", PharmaVoice, April 2005

"Something for Everyone: Standard Operating Procedure Products for the Investigative Site", Journal of Clinical Research Best Practices, April 2005

"A Win-Win Solution to the Study Budget Problem", The Monitor, December, 2004