

Walter Sujansky, MD PhD

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Summary

- A seasoned professional with a medical degree, medical informatics graduate training, and over 30 years of industry experience designing, building, and operating clinical software applications.
- A successful track record of leading a data-engineering consulting firm providing services to large H.I.T. vendors, provider organizations, and government agencies.
- Capabilities and interests include electronic health records, clinical data analysis, health data standards and interoperability, and expert-witness services for IP and malpractice litigation.

Skills

- Clinical informatics, including the modeling and analysis of clinical data in EHRs, disease registries, data warehouses, and other information systems and knowledge-management tools, as well as the exchange and ingestion of health data using interoperability standards.
- Clinical data standards, including HL7 FHIR, HL7 v2 messaging, OMOP data model and analytical tools, bioinformatics knowledge bases (ClinVar, dbSNP, PharmGKB, etc.) and numerous standard clinical terminology systems (ICD-10, SNOMED-CT, LOINC, RxNorm, etc.).
- Machine learning, including linear/logistic regression, neural networks, and unsupervised learning techniques. Feature engineering for ML.
- Modern technical environments and tools, including database management systems (MySQL, MS SqlServer), programming languages (Java, R, SQL), IDEs (Eclipse, Git), and knowledge-engineering environments (Protégé).
- Broad-based knowledge of the healthcare and health I.T. industries, including landscape of provider organizations, payers, ancillary service providers, I.T. vendors, and trade associations.
- Extensive knowledge of government policies that impact healthcare and health I.T., including HIPAA, ASTP EHR Certification, CMS alternative payment models, electronic prescribing regulations, and CLIA laboratory requirements.
- Expert witness services, including general consultation, expert reports, deposition testimony and trial testimony for intellectual property and medical malpractice cases involving biomedical software.

Work History

President and Senior Consultant Sujansky & Associates, LLC San Carlos, CA 01/2003 – Present

- Leads a healthcare I.T. consulting practice that addresses data-engineering challenges in the development of novel clinical software applications and data warehouses. See www.sujansky.com for details. Engagements include 5-year position with eClinicalWorks EHR vendor.
- Has managed a team of up to 10 medical informatics consultants and support staff.
- Has served over 50 clients, some repeatedly, and achieved gross billings over \$15M. Clients have included EHR vendors (eClinicalWorks, McKesson), pharmaCos (Johnson and Johnson, Lilly), provider organizations (Kaiser Permanente, Amazon One Medical, Partners Healthcare), government agencies (Veteran Health Administration, ASTP/ONC, FDA), and non-profits (California HealthCare Foundation, Robert Wood Johnson Foundation).

Subject Matter Expert, Clinical Data Modeling FDA Silver Spring, MD **07/2022 – 07/2024**

- Provided clinical data-modeling expertise to the FDA Center for Devices and Radiologic Health in its initiative to improve the standardization, aggregation, and analysis of laboratory testing results. Authored the functional requirements document for the Lab Interoperability Data Repository (LIDR), an industry-wide resource to improve the safety and standardization of lab testing data.
- Developed novel methods for the representation of absent and negated observations in FHIR resources, which HL7 is considering as enhancements to the FHIR standard.
- Developed enhancements to the SNOMED-CT terminology model to address deficiencies in the model's handling of context modifiers for clinical observations, such as negation and timing. Published a detailed description of these enhancements and implemented a working prototype.

EHR Interoperability & Safety Lead eClinicalWorks Westborough, MA **08/2017 – 06/2022**

- Evaluated and ensured compliance with federal certification requirements for EHR interoperability functions, including FHIR APIs, CCDA Documents, and HL7 v2 messages. Developed rigorous QA methodologies to prevent regression errors in these features.
- Guided client in applying formal development and testing processes for “software as a medical device” (SaMD) to ensure product quality and safety, including IEC 62304, ISO 13485, and ISO 14971.
- Evaluated accuracy and robustness of clinical decision support features, including AI predictive algorithms.

Chief Technology Officer CA Joint Replacement Registry San Francisco, CA **02/2010 – 07/2016**

- Designed the functional specifications for the first regional level-3 joint replacement registry in the United States, including specifications for data engineering, data ingestion, and data analysis. Oversaw the technical implementation, data collection, and operations of this cloud-hosted statewide resource,
- Recruited, onboarded, and helped to support 30 academic medical centers and community hospitals using the registry for quality improvement and research, including Stanford University, Sutter Health, and Providence Health. Over 100,000 patient cases were collected and analyzed in the registry.
- In 2016, facilitated the successful exit of the CJRR when it merged with the National Joint Replacement Registry.

Adjunct Professor Stanford University Stanford, CA **03/2020 – Present**

- Adjunct Faculty Member, Center for Biomedical Informatics Research (part time).
- Taught over 250 graduate and undergraduate students taking courses offered by the BMIR, including BIOMEDIN 210: Modeling Biomedical Systems.
- Developed over 300 instructional slides for new lecture topics in EHRs, clinical data modeling, health data interoperability, probabilistic reasoning, and machine learning.

Additional Experience

Director, Product Development ePocrates, Inc. (mobile health) **San Carlos, CA**

Director, Commercial Products Apelon, Inc. (terminology middleware) **Alameda, CA**

Director, Clinical Data Engineering Oceania, Inc. (EHR) **Redwood City, CA**

Education

Stanford University, Stanford, CA

- Earned M.D. and Ph.D. in Medical Informatics. Doctoral work addressed the integration of heterogenous clinical databases and data sources.

Harvard College, Cambridge, MA

- Earned B.A. in Economics.

Continuing Education Certification

Supervised Machine Learning: Regression and Classification DeepLearning.AI

Advanced Learning Algorithms DeepLearning.AI

Unsupervised Learning, Recommenders, Reinforcement Learning DeepLearning.AI

Understanding and Applying Text Embeddings DeepLearning.AI

References available upon request.

Other Activities and Honors

- Adjunct Faculty Member, Biomedical Informatics Research Department, Stanford Medical School. January 2020 - Present.
- Co-chair, Special Interest Group on Interoperability and Health Information Exchange, American Medical Informatics Association, 2017 – present.
- Member of Scientific Committee, Frontier of AI-Assisted Care Scientific Symposium, Stanford Medical School. 2019.
- Invited expert at Workshop on Exploring Legal Challenges to Fulfilling the Potential of mHealth in a Safe and Responsible Environment. American Association for the Advancement of Science (AAAS). October 6-7, 2014.
- Member of Advisory Panel to HHS Health Information Technology Policy Committee on the topic of disease registries as data intermediaries for clinical quality measures. 2013 – 2014.
- Member of Expert Panel for Lab Data Integration for Diabetes Care Improvement. Brookings Institution, November 2009.
- Member of Technical Expert Panel for the development of “Privacy and Security Solutions for Interoperable Health Information Exchange -- Perspectives on Patient Matching.” 2009.
- Judge, Electronic Medical Record Product Awards. Towards Electronic Patient Records (TEPR) Conference. 2003-2005.

Notable Speaking Engagements

- *Guest Lecturer, Biomedical Informatics 210, Stanford University.* Prepared and presented five lectures for this graduate -level course on biomedical data modeling and decision support, covering the topics of probabilistic reasoning, clinical data modeling, and health information exchange. Annually, 2020 - 2024.
- *To Switch or Not to Switch: A Guide for Community Clinics Considering Changing EHRs.* Presentation at California Primary Care Association Annual Conference. October, 2019.

- *Open Issues in Measurement Frameworks for Interoperability Standards.* Presentation at the 2019 Office of the National Coordinator Interoperability Forum Standards Measurement Workshop. August, 2019.
- *The State of Interoperability and Health Information Exchange: Advancing Steadily or Treading Water?* Panel Presentation at the American Medical Informatics Association Annual Symposium. November, 2017.
- *Health Information Exchange: Challenges and Methods.* 3-hour education session, American Medical Informatics Association 2015 Annual Symposium. San Francisco, CA. November, 2015.
- *The Informatics of Health Information Exchange.* 3-hour education session, American Medical Informatics Association 2012 Annual Symposium. Washington, D.C. November 3, 2012.
- *Standards for Storing and Exchanging Clinical Data in Electronic Health Record Systems.* 3-hour education session, American Medical Informatics Association 2010 Annual Symposium. Washington, D.C. November 13, 2010. Also presented this tutorial at the 2007, 2008 and 2009 Annual Symposia.

Publications

W. Sujansky W, K. Campbell. A Formal Model for the Representation of Binary Temporal Relations in Healthcare Applications and an Efficient Algorithm for Logic-Based Temporal Subsumption Testing and Pattern Matching. *MedRxiv* 2023. <https://medrxiv.org/cgi/content/short/2023.11.17.23298715v1>.

W. Sujansky, K. Campbell. Modeling Limitations of the Argonaut HL7 FHIR Implementation Guide: Implications for Patient Safety. Submitted to the Proceedings of the American Medical Informatics Association Annual Symposium, March 2020.

W. Sujansky. To Switch or Not to Switch: A Guide for Community Clinics Considering Changing EHRs. *California Health Care Foundation*. May 2019. (<https://www.chcf.org/publication/switch-guide-community-clinics-changing-ehrs/> accessed April 2, 2020).

W. Sujansky. Promise and Pitfalls: A Look at California's Regional Health Information Organizations. *California Health Care Foundation*. January 2019. (<https://www.chcf.org/publication/promise-pitfalls-californias-regional-health-information-organizations/> accessed April 2, 2020).

W. Sujansky, T. Wilson. DIRECT Secure Messaging as a Common Transport Layer for Reporting Structured and Unstructured Lab Results to Outpatient Providers. *The Journal of Biomedical Informatics*. Volume 54, April 2015, Pages 191–201.

W. Sujansky, D. Kunz. A Standards-Based Model for the Sharing of Patient-Generated Health Information with Electronic Health Records. *Personal and Ubiquitous Computing*. Volume 19, Issue 1 (2015), Page 9-25.

W. Sujansky. Evaluation Results from the SoCalHIE Pilot: An Implementation of DIRECT Messaging and Provider Directory Services for Health Information Exchange in North San Diego County. *California Health Care Foundation*. March 2014. (<https://www.chcf.org/wp-content/uploads/2017/12/PDF-EvaluationTestingHIEDIRECTMessaging.pdf> accessed April 2, 2020).

W. Sujansky, S. Faus, et. al. A Method to Implement Fine-Grained Access Control for Personal Health Records using Standard Relational Database Queries. *The Journal of Biomedical Informatics*. 2010 Oct;43(5 Suppl): S46-50. Epub 2010 Aug 7.

W. Sujansky, M. Overhage, et. al. The Development of a Highly Constrained HL7 Implementation Guide to Facilitate Electronic Laboratory Reporting to Ambulatory EHRs. *The Journal of the American Medical Informatics Association*. 2009; 16: 285-290.

W. Sujansky, R. Sterling, R. Swafford. Practice Management Systems for Safety-Net Clinics and Small Group Practices: A Primer. *California Health Care Foundation*. February 2009.
(<https://www.chcf.org/publication/practice-management-systems-for-safety-net-clinics-and-small-group-offices-a-primer/> accessed April 2, 2020).

W. Sujansky & S. Chang. The California Clinical Data Project: A Case Study in the Adoption of Clinical Data Standards for Quality Improvement. *The Journal of Health Information Management*. 2006. Vol. 20, Num. 3.

W. Sujansky. Clinical Terminologies for Data Analysis and Structured Data Entry. Book chapter in J. Silva, Ed. *Cancer Informatics: Essential Technologies*. 2002. Springer-Verlag, New York.

W. Sujansky. Heterogeneous Database Integration in Biomedicine. *The Journal of Biomedical Informatics*. 2001 Aug; 34(4):285-98.

W. Sujansky. A Document-Centric Electronic Medical Record System with Database-Centric Reporting Capabilities. *Toward An Electronic Patient Record, Proceedings Manual*. San Antonio, TX. 1999.

W. Sujansky. The Benefits and Challenges of an Electronic Medical Record: Much More than a "Word-Processed" Patient Chart. *Western Journal of Medicine*, 169(3): 176-83, Sept. 1998.