

Kaiser Permanente Research



Kaiser Permanente Southern California

Center for
Vaccine Safety and
Effectiveness Research

About the Center for Vaccine Safety and Effectiveness Research

The Kaiser Permanente Southern California Center for Vaccine Safety and Effectiveness Research engages in innovative research with real-world implications.

Investigators leverage the rich resources of Kaiser Permanente's integrated health system to conduct a wide range of studies, from the incidence and outcomes of vaccine-preventable disease to the safety and effectiveness of widely used vaccines.

Through partnerships with clinicians, academics, federal funders, and industry sponsors, researchers ask and answer health questions that benefit the organization's members and the public at large.

Advancing Science, Enhancing Lives

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The Kaiser Permanente Southern California Difference

The Center for Vaccine Safety and Effectiveness Research efficiently conducts high-quality research involving large, diverse populations, providing timely evidence to decision-makers and the public.



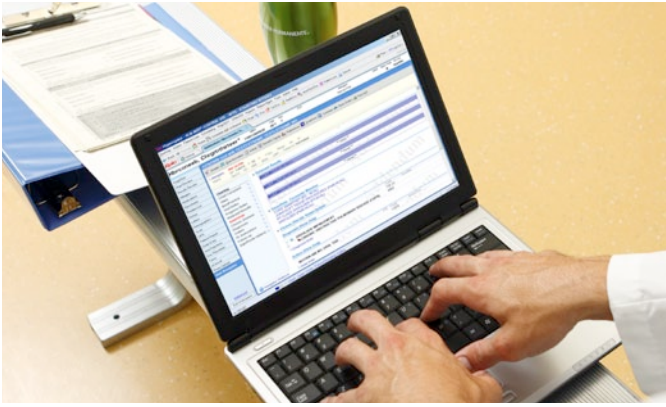
Large, diverse, and stable population

Kaiser Permanente is one of the nation's largest not-for-profit health plans. Southern California is the organization's largest region, with 3.6 million members who broadly represent the diversity of age, sex, and race/ethnicity in the California population. This population is highly stable, facilitating longitudinal research. The large, diverse, and stable population permits the rapid accrual of a representative sample size and offers the ability to evaluate long-term implications of immunization.

Integrated care delivery

Kaiser Permanente's unique integrated care delivery system is a model for the future. The delivery system connects care and health services across a variety of settings, spanning outpatient and inpatient care, and includes ancillary services such as pharmacies and laboratories. This model offers the ability to completely capture the total health care information about each member, unlike fee-for-service models.





Electronic health record

Kaiser Permanente HealthConnect® is the largest and most advanced civilian electronic health record system available in the United States. This electronic health record system has earned “Meaningful Use” certification. In addition to supporting patient care, this robust system facilitates research, providing access to electronic medical records for the Center for Vaccine Safety and Effectiveness Research team. Details of care are available at the fingertips of researchers in real-time.



Scientific expertise

The Center for Vaccine Safety and Effectiveness Research team includes investigators with expertise in vaccine safety and effectiveness, epidemiology, pharmacoepidemiology, biostatistics, infectious diseases, and clinical care. Combining this diverse scientific expertise with a resource-rich environment creates an unparalleled opportunity to advance knowledge about widely used vaccines.



Focus on prevention

Immunizations are an important part of Kaiser Permanente’s overall focus on preventive care. The organization is one of the top rated health maintenance organizations for meeting national standards of care, which include measures of childhood and adult immunization. Kaiser Permanente Southern California thus provides an excellent real-world setting to understand the safety and effectiveness of vaccines.



Regional Overview

As an integrated health care system, Kaiser Permanente Southern California provides an ideal environment for population-based epidemiologic, clinical, and health services research. The health plan's population includes more than 3.6 million Southern California residents who represent 200 different ethnicities and speak more than 120 different languages. Facilities include hospitals and medical offices, all linked by an information infrastructure that supports both clinical practice and business needs. Health information from this infrastructure can be leveraged for research purposes.

More than 90 percent of members remain in the health plan after one year; more than three-quarters remain after three years. As compared with the 2010 California census, membership was strikingly similar in terms of age, sex, and race.

Kaiser Permanente Southern California at a Glance

Medical Centers (Hospitals)	14
Medical Offices	209
Physicians	6,000
Nurses	20,000
Total Staff	61,000
Births per year	35,000

Map of Kaiser Permanente Southern California region with hospitals (diamonds), medical office buildings (circles) and other facilities (triangles).



Demographic characteristics of the Kaiser Permanente Southern California membership on January 1, 2014, compared with the California census population.

	Membership Number	Membership %	2010 CA Census %
Total population	3,633,210	100.0	100.0
Sex:			
Male	1,758,014	48.4	50.1
Female	1,875,196	51.6	49.9
Age:			
Under 5 years	198,338	5.5	7.4
5 to 9 years	226,419	6.2	6.7
10 to 14 years	247,228	6.8	7.0
15 to 19 years	274,356	7.6	7.3
20 to 24 years	272,669	7.5	7.2
25 to 34 years	462,737	12.7	14.5
35 to 44 years	474,588	13.1	14.1
45 to 54 years	509,980	14.0	14.1
55 to 59 years	250,822	6.9	5.7
60 to 64 years	212,868	5.9	4.7
65 to 74 years	310,010	8.5	5.9
75 to 84 years	144,678	4.0	3.7
85 years and over	48,517	1.3	1.6
Race:			
One race	3,562,161	98.0	96.2
White	2,159,528	59.4	62.7
Black or African American	398,859	11.0	6.1
American Indian & Alaska Native	24,258	0.7	0.8
Asian/Pacific Islander	471,941	13.0	12.9
Other race	507,574	14.0	13.8
Two or more races	71,049	2.0	3.8
Hispanic or Latino (of any race)	1,497,079	41.2	37.0

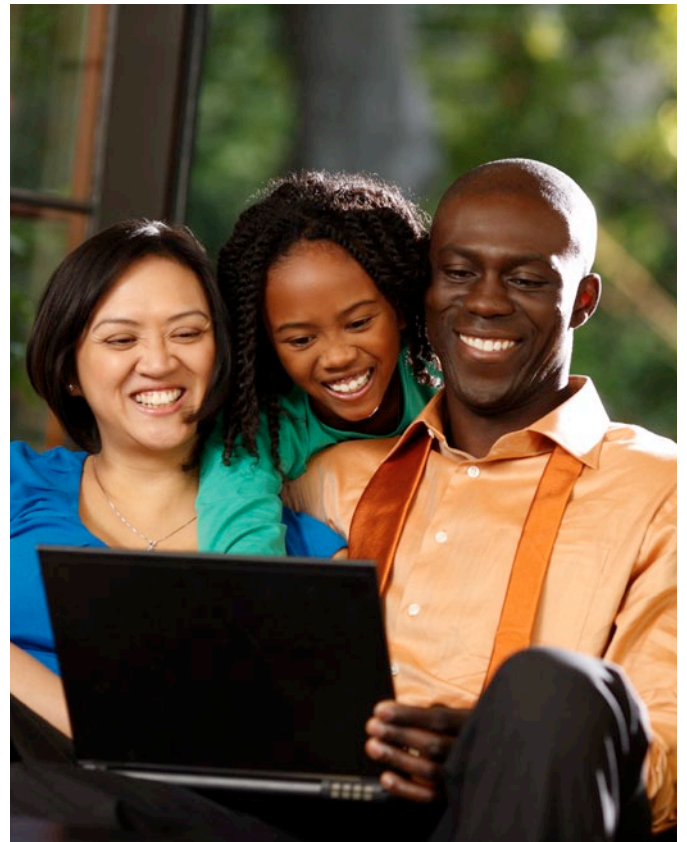
Research in Kaiser Permanente Southern California

The Center for Vaccine Safety and Effectiveness Research is part of the Department of Research & Evaluation, based in Pasadena, California. The department leads and collaborates on research projects with clinicians and with partners from government, academia, and industry.

The Department of Research & Evaluation employs more than 260 people, including research scientists, biostatisticians, programmers, research support staff, research finance staff, information technology specialists, and administrative support staff. The computing infrastructure consists of a local area network and a high-performance computing environment.

Research files

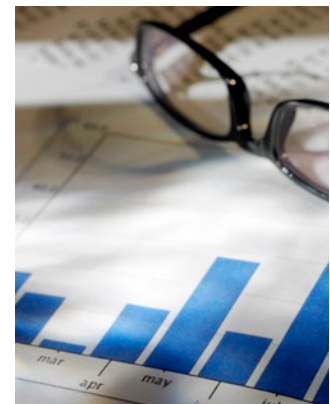
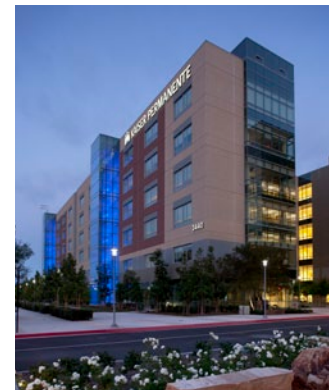
The medical record number serves as a unique identifier linking all medical encounters for each member. Care received in the outpatient, inpatient, and emergency settings is documented in the electronic medical record and captured in research databases. Care received outside the Kaiser Permanente Southern California system is captured through claims. The files are updated near real-time.





The following are examples of files that can be used for research:

- **Membership:** Includes demographic information such as name, sex, date of birth, race/ethnicity, address, and phone number.
- **Diagnosis:** Includes International Classification of Diseases, 9th revision (ICD-9) codes.
- **Procedure:** Includes ICD-9, Current Procedural Terminology (CPT), and Systematized Nomenclature of Medicine (SNOMED) codes.
- **Immunization:** Includes vaccine name, date of vaccination, route of administration, facility where vaccine was administered, dose, manufacturer, and lot number.
- **Laboratory:** Includes laboratory orders and results.
- **Pharmacy:** Includes National Drug Codes (NDC) and Generic Product Identifier (GPI) codes. More than 95 percent of members have a drug benefit with minimal copayments.
- **Mortality:** Includes deaths from hospital and membership databases, as well as from state and national death files. Also includes cause of death.
- **Birth:** Includes pregnancy related information such as gestational age, birth weight, and Apgar scores.
- **Registries:** Includes cancer and HIV registries containing information such as patient demographics, utilization, disease history, and risk factors.



Vaccine Research Capacity

The research team has expertise and experience in performing a vast array of vaccine research studies, ranging from epidemiologic studies of vaccine preventable diseases to Phase IV post-licensure studies.

The organization's unique infrastructure allows the team to

- Identify subjects with particular exposures or diagnoses through electronic medical records.
- Ascertain outcomes through health care utilization files.
- Validate diagnoses through medical record review.
- Estimate incidence rates based on identification of persons with new disease onset and the person-time denominator from the membership files.
- Evaluate the natural history and clinical course of disease through passive follow-up of cohorts that are assembled retrospectively or prospectively based on disease incidence or exposure.
- Minimize recall bias by utilizing information captured in the medical records prior to disease onset rather than relying on patient recall.
- Follow cohorts actively with a prospective assessment of outcomes (e.g., patient-reported outcomes, satisfaction, quality of life, etc.) by taking advantage of current patient contact information.
- Identify and screen potential subjects according to pre-specified eligibility criteria, minimizing effort in the field.
- Evaluate participation bias using background information for persons agreeing to participate in a study as well as those who do not.



The Center's capabilities span the entire process, from the inception of a project through dissemination of findings. Capabilities include

- Determining the appropriate study design and analytic approach to answer the research question of interest.
- Developing study protocols independently or collaboratively.
- Expediting Institutional Review Board (IRB) and Health Insurance Portability and Accountability Act (HIPAA) processes while ensuring human subjects protection.
- Developing standard documents to ensure quality and consistency.
 - Project Management Plan.
 - Vaccine Management Plan.
 - Risk Management Plan.
 - Data Management Plan.
 - Case Identification Algorithms.
 - Case review/Adjudication Standard Operating Procedure.
 - Statistical/Data Analysis Plan.
 - Scientific Review Committee Standard Operating Procedure.
- Assembling large cohorts of subjects rapidly.
- Studying special populations such as people who are immunocompromised or women who are pregnant.
- Distributing and tracking vaccines (including non-formulary vaccines) provided as part of post-licensure studies.
- Developing case identification algorithms using diagnosis codes, laboratory tests, and medications to identify outcomes of interest (e.g., autoimmune, rheumatologic, endocrine, neurologic, etc.).
- Conducting medical record review using the electronic health record system, Kaiser Permanente HealthConnect.
- Managing case review and adjudication processes, including assembling committees of physician specialists.
- Employing secure electronic data collection methods.
- Collecting patient-reported information through mailed questionnaires, phone surveys, and in-person interviews.
- Collecting clinical specimens for research.
- Performing analyses involving pre-specified outcomes of interest or general safety analyses.
- Coordinating an independent Scientific Review Committee.
- Preparing interim and final reports for regulatory agencies.
- Presenting results at scientific meetings and to national advisory groups.
- Publishing results in peer-reviewed journals.
- Coordinating kick-off meetings, site visits, and monitoring visits.
- Coordinating regular conference calls, including scheduling meetings, and preparing agendas and minutes summarizing discussion, decisions, and action items.
- Working with international collaborators.
- Providing strong project management support, including managing resources, communicating proactively, reporting on progress, and tracking timelines.
- Ensuring all deliverables are high quality and completed according to the scope of work, within budget, and on time.

Research Topics

The research team partners with clinicians, public health officials, universities, and vaccine manufacturers to conduct important research on the following topics:

- Safety of newly licensed vaccines or new recommendations for existing vaccines.
- Effectiveness of vaccines in a real-world setting.
- Vaccines in special populations such as pregnant women, the immunocompromised, and the elderly.
- Epidemiology of vaccine-preventable diseases.
- Vaccine coverage, uptake, and compliance with recommendations.
- Methodologies for assessing vaccine safety and effectiveness.



Selected Research Projects by Sponsor Type

Centers for Disease Control and Prevention (CDC)

- Vaccine Safety Datalink (VSD) Project.
 - Survey to determine the accuracy of Kaiser Permanente Southern California administrative data on influenza immunization.
 - Evaluation of the safety of Zostavax in the Vaccine Safety Datalink.
 - Rapid cycle analysis of PCV13 vaccine safety.
 - Tdap safety in off-label users age 65 years and older.
 - Safety of varicella and zoster vaccinations in patients on immunosuppressant drugs.
 - Secular trends in diagnostic code density in the Vaccine Safety Datalink.
 - Vaccine-associated febrile convulsions.
- Measuring effectiveness of two doses of varicella vaccine in Los Angeles County.
- Herpes zoster vaccine effectiveness for preventing postherpetic neuralgia in adults 60 years and older in a health maintenance organization.
- California Influenza Surveillance Program.
- Evaluation of the effectiveness of Tdap vaccination strategies at preventing infant pertussis.
- Long-term herpes zoster vaccine effectiveness in a health maintenance organization.

National Institute of Allergy and Infectious Diseases (NIAID)

- Zoster vaccine and risk factors of zoster and post-herpetic neuralgia.

Food and Drug Administration (FDA)

- Genetic risk factors for idiopathic thrombocytopenic purpura following MMR vaccination in children.

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- Agreement between medical record and parent report for evaluation of childhood febrile seizures.
- Impact of MMRV combination vaccine on childhood vaccination compliance.
- Factors associated with uptake of MMRV versus MMR+V.
- Occurrence of varicella breakthrough and herpes zoster after receiving one dose of varicella vaccination: A retrospective cohort study.
- Occurrence of herpes zoster among elderly population 60 or more years of age: A comparison between vaccinated and unvaccinated population.
- Trends in two-dose varicella vaccination coverage rate and correlates for uptake of two-dose vaccination in children in a large medical care organization.
- Uptake and correlates for initiation and completion of HPV4 vaccine among males.

Industry

- Large-scale observational post-licensure study of the short-term safety of ProQuad.
- A post-licensure surveillance program for the safety of Gardasil in a managed care organization setting.
- Uptake of Gardasil.
- A Phase IV study to assess the safety of Menveo vaccine being used by HMO subjects aged 11-21 years of age.
- Post-licensure observational safety surveillance study of quadrivalent meningococcal ACWY conjugate vaccine (Menveo) in children 2-10 years of age.
- An intervention study of reminder letter for Gardasil regimen completion.
- An in-depth interview study of immunization providers in a large managed care organization to understand practice patterns, barriers and facilitators for administering the 3-dose HPV vaccine series.
- Impact of Tier 6 in Medicare Part D on zoster vaccination uptake.

Research Team

Senior Investigators



Steven Jacobsen, MD, PhD

Dr. Jacobsen is the senior director of research for Kaiser Permanente's Department of Research & Evaluation. He has been the Kaiser Permanente Southern California site principal investigator for the Vaccine Safety Datalink since 2007. He led two major post-licensure safety studies of measles, mumps, rubella, and varicella (MMRV) and human papillomavirus (HPV) vaccines. He has served on the editorial board of the *American Journal of Epidemiology* since 1997, and *Vaccine* since 2011. Dr. Jacobsen received his medical degree from the Medical College of Wisconsin and his doctorate in epidemiology from the University of Illinois at Chicago.



Hung Fu Tseng, PhD

Dr. Tseng is a senior research scientist at Kaiser Permanente Southern California. He is the principal investigator of the Phase IV post-licensure safety study of meningococcal vaccine. He led three Vaccine Safety Datalink studies: safety of the herpes zoster vaccine, safety of the pneumococcal conjugate vaccine (PCV13) for children, and safety of the tetanus-diphtheria-pertussis (Tdap) vaccine in the elderly. He leads several other studies, including one NIH-funded R01 study and several CDC-funded studies. He has presented his findings to national advisory panels, and is a Fellow of the American College of Epidemiology and an Adjunct Research Professor at University of Southern California. Dr. Tseng received his doctorate in epidemiology from the University of California, Los Angeles.



Craig Cheetham, PharmD, MS

Dr. Cheetham practiced hospital-based clinical pharmacy for nearly 20 years before becoming a researcher at Kaiser Permanente Southern California. Dr. Cheetham has expertise in algorithms to identify pregnant women, and has been an investigator on FDA- and industry-funded studies of the safety of drugs and vaccines in pregnant women. He led a Vaccine Safety Datalink study on the safety of varicella-containing vaccines among immunosuppressant users. Dr. Cheetham received his doctorate in pharmacology and a master's degree in pharmaceutical economics from the University of Southern California.



Chun Chao, PhD

Dr. Chao is a cancer epidemiologist at Kaiser Permanente Southern California. She has led studies examining the trend and pattern of HPV vaccine uptake, as well as correlates for HPV vaccine initiation and series completion. She was the lead author for the publication of the autoimmune safety surveillance of HPV vaccine. Dr. Chao is currently evaluating multilevel factors within HPV vaccine and cervical cancer research including patient-level factors (e.g., adherence to the recommended HPV vaccine series and screening), provider-level factors (e.g., in-depth interviews of immunization providers), and system-level factors (e.g., patient reminder interventions). Dr. Chao received her doctorate in epidemiology from the University of California, Los Angeles.



Stephan Michael Marcy, MD

Dr. Marcy is an adjunct researcher at Kaiser Permanente Southern California and a Clinical Professor of Pediatrics at the University of Southern California and University of California at Los Angeles School of Medicine. He has served on numerous local, national, and international committees, including the American Academy of Pediatrics Committee on Infectious Diseases (Red Book Committee), the CDC Advisory Committee on Immunization Practice (ACIP), and the Brighton Collaboration, defining adverse events associated with immunization. He has been named to the list of Best Doctors and Best Pediatricians in America for many years. Dr. Marcy received his medical degree from the University of Pennsylvania.



Bradley Ackerson, MD

Dr. Ackerson is an infectious disease pediatrician at Kaiser Permanente Southern California. He has helped develop and conduct vaccine safety studies including a Phase III trial of the PCV13 vaccine and three large post-licensure safety studies. As an Assistant Clinical Professor of Pediatrics and Pediatric Infectious Diseases at Harbor-UCLA Medical Center, he teaches medical students, residents, and pediatric infectious disease fellows. Dr. Ackerson received his medical degree from the University of California, San Diego.



Bruno Lewin, MD

Dr. Lewin is a family medicine physician, director of the Travel Advisory Service at Kaiser Permanente Los Angeles, and the chairman of the Regional Immunization Practice Committee for Kaiser Permanente Southern California. As chairman, he coordinates appropriate use of vaccination and implementation of new immunization recommendations within Kaiser Permanente Southern California. Dr. Lewin received his medical degree from the University of California, Los Angeles.

Junior Investigators



Rulin Hechter, MD, PhD

Dr. Hechter is an infectious disease epidemiologist. She is the Principal Investigator of a CDC- funded study to examine syphilis treatment response among patients co-infected with HIV. She serves as a co-investigator at the Kaiser Permanente Southern California site of the Vaccine Safety Datalink (VSD). She led a VSD data quality study on secular trends in diagnosis density. She has led studies examining uptake and correlates for initiation and completion of HPV4 vaccine among males, coverage of zoster vaccine in the elderly, and hepatitis B screening and vaccination among high-risk populations. She has published a number of papers on vaccine uptake and effectiveness in peer-reviewed journals. She is experienced with multicenter studies, and has expertise in analytic methods for traditional cohort studies as well as implementation studies. Dr. Hechter received her medical degree from Suzhou Medical College in China and her doctorate in epidemiology from the University of California, Los Angeles.



Sara Tartof, PhD

Dr. Tartof is a molecular and infectious disease epidemiologist, with particular expertise and experience in vaccine-preventable diseases including pertussis, meningitis, and herpes zoster. She has extensive knowledge of principles of design and execution of epidemiologic studies. She has conducted and led outbreak and other field investigations domestically and internationally, and has analyzed data derived from surveillance systems and immunization registries. Additional areas of expertise include hospital infections, antibiotic stewardship, and hepatitis C. Dr. Tartof received her doctorate in epidemiology from the University of California, Berkeley.

Support Staff

The Department of Research & Evaluation has a pool of more than 60 programmers and biostatisticians and more than 60 project managers and research associates. This work unit model facilitates the ability to obtain well-qualified and trained study staff in a timely manner.

Biostatistics and Programming Support

Programmers extract and manage data, provide quality control, and generate reports. They have extensive experience extracting data from clinical care systems for research.

Biostatisticians consult on study design, calculate sample size, determine appropriate analytic methods, conduct analyses, and interpret results. The department's doctoral and master's level biostatisticians have expertise in traditional epidemiologic study designs such as cohort and case-control studies, as well as designs often used for vaccine safety research including self-controlled case series (SCCS), case-centered approach, and rapid cycle analysis (RCA).

Research Support

Project managers provide overall study coordination support, make sure studies comply with IRB and HIPAA requirements, manage resources and budgets, and ensure timely completion of deliverables. Our master's-level project managers have extensive experience managing large vaccine post-licensure studies.

Research associates perform medical record abstraction and validation, and collect patient data through mailed questionnaires, phone surveys, and in-person interviews. Our research associates have performed thousands of medical record abstractions and patient interviews to collect information on vaccine exposures and outcomes of interest.

Publications*

Findings from the Center's studies guide national immunization policy decisions and provide the public with the best available information regarding the risks and benefits of immunization.

For example, the team's finding of a two-fold increased risk of febrile seizure following the administration of the MMRV vaccine compared with the separate administration of MMR and varicella vaccines contributed to a new recommendation by the Advisory Committee on Immunization Practices to administer the vaccines separately rather than in combination for the first dose.



*Authors from Kaiser Permanente Southern California are in boldface.

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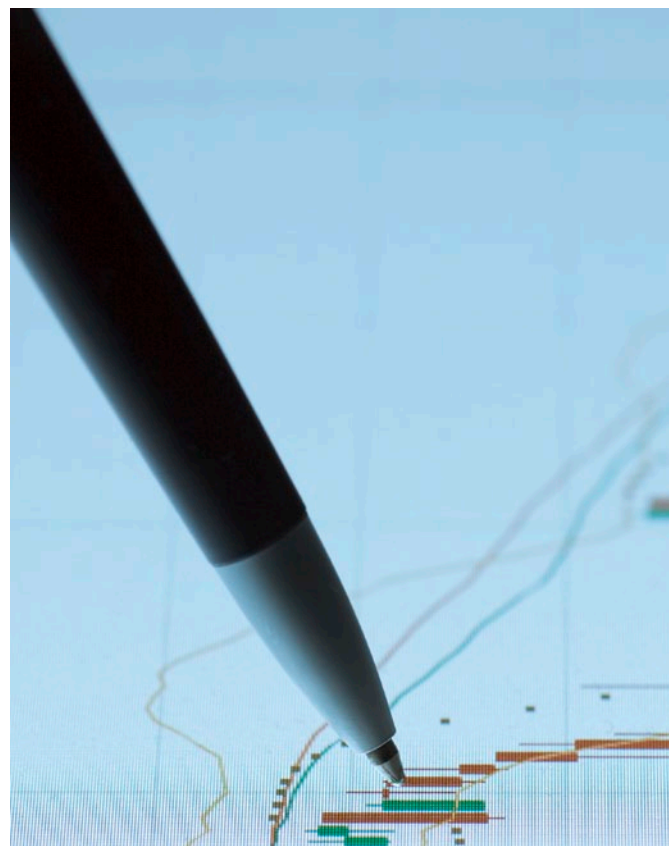
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