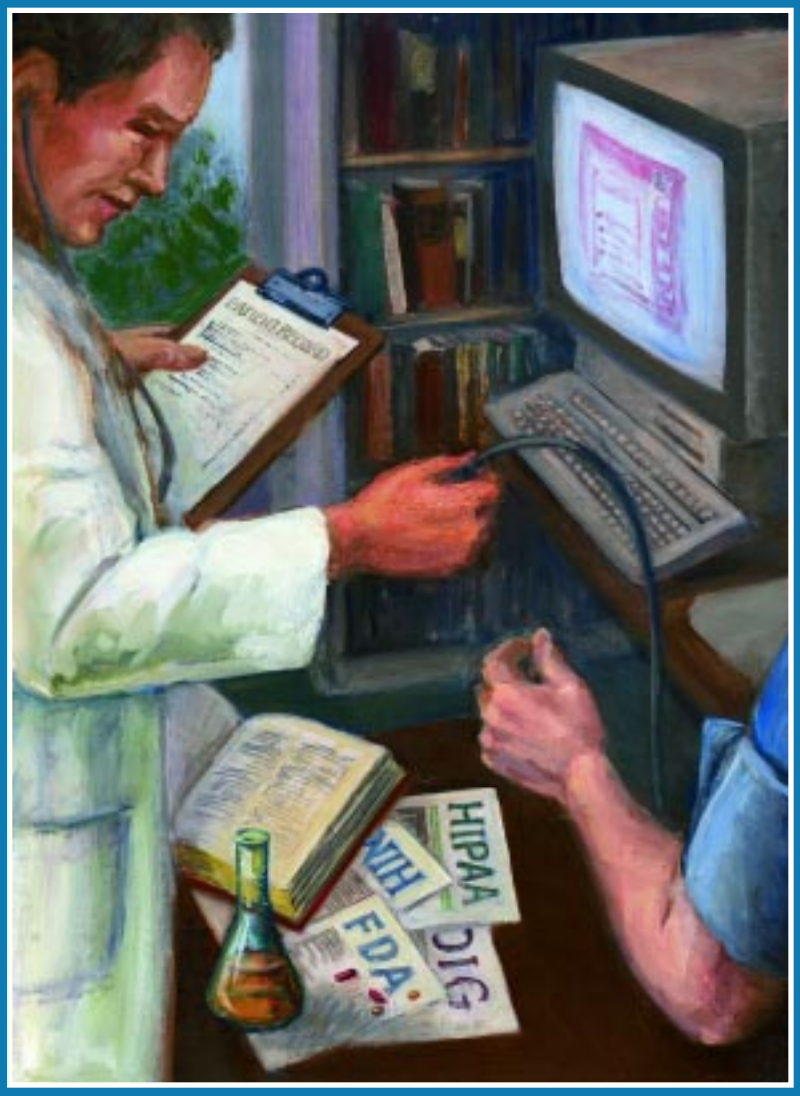
THE SECOND ANNUAL

Medical Research Summit

The Leading Forum on the Law, Regulation and Ethics of Medical Research in the United States



March 24-26, 2002

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William R. Braithwaite, MD, PhD, Director, PricewaterhouseCoopers and former Senior Advisor on Health Information Policy, DHHS

Michael Carome, MD, Director, Compliance Oversight, Office for Human Research Protections, DHHS

Jeffrey M. Cohen, Ph.D., Associate Director of Education, Office for Human Research Protections, DHHS

Alan E. Guttmacher, MD, Senior Clinical Advisor, National Human Genome Research Institute, NIH

David Hoffman, Esq., Assistant U.S. Attorney, Civil Division, Eastern District of Pennsylvania

John Iglehart, Founding Editor, Health Affairs and National Correspondent, New England Journal of Medicine

Julie A. Kaneshiro, Office of Science Policy and Planning, NIH

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Richard Kusserow, President, Strategic Management Systems and former Inspector General, DHHS

Joanne R. Less, Ph.D., Director, IDE/HDE Programs, Center for Devices and Radiological Health, FDA

Mary Faith Marshall, Ph.D., Chairperson, National Human Research Protections Advisory Committee

John H. Mather, MD, Chief Officer, Office of Research Compliance and Assurance, Department of Veterans Affairs

Thomas Puglisi, Ph.D., Clinical Research Consulting Team, PricewaterhouseCoopers and Former Director, Human Subject Protections Office for Human Subjects Research Protections, DHHS

Michele Russell-Einhorn, Esq., Director, Clinical Research Consulting Team, PricewaterhouseCoopers and Former Director of Regulatory Affairs Office for Human Research Protection

Sandra M. Sanford, RN, MSN, CCRC, CIP, Director of Human Research Protection Accreditation, NCQA

Karen Santoro, Esq., Deputy Ethics Counselor, National Institute for Allergies and Infectious Diseases, NIH

Dixie R. Snider, Jr., MD, Associate Director of Science, CDC

Marjorie A. Speers, Ph.D., Executive Director, Association for Accreditation of Human Research Protection Programs

Stan W. Woollen, Deputy Director, Division of Scientific Investigations, FDA

Mark Yessian, Esq., Regional Inspector General for Evaluations and Inspections, Office of Inspector General, DHHS

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Goals & Objectives:

- To provide an overview of medical research initiatives in the United States
- To establish the legal and regulatory context for medical research
- To analyze the ethical implications of medical research and the appropriate institutional approaches to addressing these ethical issues
- To investigate through case studies strategies to comply with legal, regulatory and ethical constraints on medical research initiatives

Prerequisites: There are no prerequisites for this educational activity.

Who Should Attend:

- Chief Executive Officers
- Chief Operating Officers
- Chief Technology Officers
- Chief Financial Officers
- Compliance Officers
- Health Law Attorneys
- Medical Directors
- Physicians
- Managed Care Professionals
- Medical Group Managers
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Agenda

Sunday, March 24, 2002

1:00 p.m. to 5: 00 p.m.

PRECONFERENCE SYMPOSIA
(concurrent sessions; chose one session only)

Preconference I: The Basics of Medical Research Law, Regulation, Ethics and Compliance
Michele Russell-Einhorn, Esq., *Director, Clinical Research Consulting Team, PricewaterhouseCoopers LLP, and Former Director of Regulatory Affairs Office for Human Research Protection, Department of Health Human Services, Bethesda, MD*

Preconference II: Privacy and Security in Medical Research
Sponsored by International Association of Privacy Officers

Faculty to be listed at www.ResearchSummit.com.

Monday, March 25, 2002

8:00 a.m. **Welcome and Introduction**

Robert M. "Skip" Nelson, M.D., Ph.D., *Associate Professor of Anesthesia and Pediatrics, Chair, Committee for the Protection of Human Subjects, The Children's Hospital of Philadelphia, Philadelphia, PA*

Michele Russell-Einhorn, Esq., *Director, Clinical Research Consulting Team, PricewaterhouseCoopers LLP, and Former Director of Regulatory Affairs Office for Human Research Protection, Department of Health Human Services, Bethesda, MD*

(Conference Co-chairs)

8:05 a.m. **Human Subject Protections: Food and Drug Administration Policies**

Stan W. Woollen, *Deputy Director, Division of Scientific Investigations, Food and Drug Administration, Rockville, MD*

8:30 a.m. **Office for Human Research Protections Initiatives**

Greg Koski, MD, *Director, Office for Human Research Protections, Department of Health and Human Services, Rockville, MD*

9:00 a.m. **Health Care Fraud Investigations Update**

Richard Kusserow, *President, Strategic Management Systems, and former Inspector General, DHHS, Alexandria, VA*

9:30 a.m. **Health Care Enforcement Update**

David Hoffman, Esq., *Assistant U.S. Attorney, Civil Division, Eastern District of Pennsylvania, Philadelphia, PA*

10:00 a.m. **Healthcare Privacy, Data Security and HIPAA Compliance in the Medical Research Context**

William R. Braithwaite, MD, PhD, *Director, PricewaterhouseCoopers LLP, and former Senior Advisor on Health Information Policy, Department of Health and Human Services, Washington, DC*

10:30 a.m. **BREAK**

11:00 a.m. **CONCURRENT SESSIONS I**

1.01 A Primer on the Regulation of Human Subject Research
Michele Russell-Einhorn, Esq., *Director, Clinical Research Consulting Team, PricewaterhouseCoopers LLP, and Former Director of Regulatory Affairs Office for Human Research Protection, Department of Health Human Services, Bethesda, MD*

1.02 Advanced Compliance Strategies for Academic Medical Centers
Dr. Kenneth L. Dretchen, *Director, Office of Regulatory Affairs, Professor and Chairman, Department of Pharmacology, Georgetown University Medical Center, Washington, DC*

Sheila Cohen Zimmet, *Director, Research Assurance and Compliance, Georgetown University Medical Center, Washington, DC*

1.03 Responding to Medical Research Misconduct
Kendra Dimond, Esq., *Partner, Arent Fox, and Former Investigative Counsel, Senate Special Committee on Aging, Washington, DC*

1.04 The Effect of HIPAA on Human Subjects Research
Mark Barnes, Esq., *Partner, Ropes & Gray, and Member, National Human Research Protections Advisory Committee, New York, NY*

1.05 IRBs in the Community Hospital Setting
Cynthia G. Kenny, *CMSC, CP, CIM, President and Chief Executive Officer, IRB Specialists, Inc., Battle Ground, WA*

Harry Shulman, Esq., *Partner, Davis Wright Tremaine LLP, San Francisco, CA*

Noon **Luncheon and Presentations**

John Iglehart, *Founding Editor,* Health Affairs, *and National Correspondent,* New England Journal of Medicine, *Washington, DC (Conference Co-chair)*

12:30 p.m. **Medical Research and the Human Genome Project**

Alan E. Guttmacher, MD, *Senior Clinical Advisor, National Human Genome Research Institute, National Institutes of Health, Bethesda, MD*

1:15 p.m. **Medical Research Accreditation Roundtable**

Jeffrey M. Cohen, Ph.D., *Associate Director of Education, Office for Human Research Protection, Department of Health and Human Services, Rockville, MD*

John H. Mather, MD, *Chief Officer, Office of Research Compliance and Assurance, Department of Veterans Affairs, Washington, DC*

Sandra M. Sanford, RN, MSN, CCRC, CIP, *Director of Human Research Protection Accreditation Program, National Committee on Quality Assurance, Washington, DC*

Paul M. Schyve, MD, *Senior Vice President, Joint Commission on Accreditation of Healthcare Organizations, Oakbrook Terrace, IL*

Marjorie A. Speers, Ph.D., *Executive Director, Association for Accreditation of Human Research Protection Programs, Washington, DC*

2:15 p.m. **TRANSITION BREAK**

2:30 p.m. **CONCURRENT SESSIONS II**

2.01 Coverage and Billing Issues for Clinical Research
John E. Steiner, Jr., Esq., *Chief Compliance Officer, Cleveland Clinic Health System, Cleveland, OH*

2.02 Issues in Human Subject Research Compliance
James A. Moran, Esq., CPA, *Executive Director, Compliance, School of Medicine, University of Pennsylvania, Philadelphia, PA*

2.03 Financial Conflicts of Interest in Medical Research
Karen Santoro, Esq., *Deputy Ethics Counselor, National Institute for Allergies and Infectious Diseases, Bethesda, MD*

2.04 HIPAA's Implications for Medical Research
Julie A. Kaneshiro, *Office of Science Policy and Planning, National Institutes of Health, Bethesda, MD*

2.05 Approaches to Human Research Protection Program Accreditation: A Comparison of the NCQA and AHHRPP Standards
Carole Klove, Esq., *Partner, Deloitte & Touche LLP, Los Angeles, CA*

Diane Lee, Esq., *Partner, Davis Wright Tremaine LLP, San Francisco, CA*

3:30 p.m. **TRANSITION BREAK**

3:45 p.m. **CONCURRENT SESSIONS III**

3.01 The Context of Clinical Research: Challenges and Opportunities
Eric G. Campbell, Ph.D., *Instructor in Health Policy, Harvard Medical School, Cambridge, MA*

Leslie A. Platt, JD, *Principal and Leader, Health Sciences Research Compliance Group, Ernst & Young LLP, McLean, VA*

3.02 Making Your IRBs and Clinical Investigators HIPAA-Ready
Thomas E. Jeffry, Esq., *Partner, Davis Wright Tremaine LLP, Los Angeles, CA*

John E. Steiner, Jr., Esq., *Chief Compliance Officer, Cleveland Clinic Health System, Cleveland, OH*

3.03 Conducting a Clinical Compliance Risk Assessment in the Pharmaceutical Industry
John Bentivoglio, Esq., *Partner, Arnold and Porter, and former Special Counsel for Healthcare Fraud, and Chief Privacy Officer, United States Department of Justice, Washington, DC*

Brenton Saunders, JD, MBA, *Partner, PricewaterhouseCoopers LLP, Past President, Health Care Compliance Association, and Founder, International Association of Privacy Officers, Washington, DC*

3.04 Clinical Research Integrity – A Practical Approach to Investigating and Acting upon Alleged Improprieties
Dr. Gary T. Chiodo, DMD, *Associate Director, Center for Ethics in Health Care, Corporate Compliance Officer, Oregon Health & Science University, Portland, OR*

Carol Pratt, JD, PhD, *Davis Wright Tremaine, Portland, OR*

3.05 Update on OIG Investigations Regarding Clinical Research
Mark Yessian, Esq., *Regional Inspector General for Evaluations and Inspections, Office of Inspector General, Department of Health and Human Services, Boston, MA*

4:45 p.m. **TRANSITION BREAK**

5:00 p.m. **The New National Human Research Protections Advisory Committee's Role in Protecting Human Subjects**

Mary Faith Marshall, Ph.D., *Chairperson, National Human Research Protections Advisory Committee, and Professor of Medicine and Bioethics, Kansas University Medical Center, Kansas City, KS*

6:00 p.m. **Adjournment and Networking Reception**

7:30 p.m. **Performance by the Capitol Steps**

Tuesday, March 26, 2002

8:00 a.m. **Welcome and Introduction to Day Two**

8:15 a.m. **An Update - When Things Go Wrong in the Conduct of Clinical Research: Lessons Learned**

Stephen F. Hanlon, Esq., *Member, Holland & Knight, Tallahassee, FL*

Alan C. Milstein, Esq., *Partner, Sherman, Silverstein, Kohl, Rose & Podolsky, Pennsauken, NJ*

9:15 a.m. **The Future of Pharmaceutical Research and Development**

J.D. Kleinke, *President, Health Strategies Network and Author,* Bleeding Edge: The Business of Health Care in the New Century *and* Oxymorons: The Myth of a U. S. Health Care System, *Denver, CO*

10:15 a.m. **Responding to the Threat of Bioterrorism: A Status Report on Vaccine Research in the United States**

Dixie E. Snider, Jr., M.D., *Associate Director of Science, Center for Disease Control and Prevention, Atlanta, GA*

11:15 a.m. TRANSITION BREAK

11:30 a.m. CONCURRENT SESSIONS IV

4.01 Academic Medical Centers and Pharmaceutical Companies: Improving Relationships in the Medical Research Context
Steven Peckman, *Associate Director-Human Subjects Research, Office for Protection of Research Subjects, University of California, Los Angeles, Los Angeles, CA*

4.02 Billing and Research: A Practical Approach Towards Compliance
Kim St. Amant, CPA, *Senior Manager, National Clinical Research Consulting Team, Deloitte & Touche LLP, Boston, MA*

Sandy Peirsol, *Senior Manager, National Clinical Research Consulting Team, Deloitte & Touche LLP, Philadelphia, PA*

4.03 Epidemiological Studies: to Research or not to Research, That is the Question?
Thomas Puglisi, Ph.D., *Clinical Research Consulting Team, PricewaterhouseCoopers LLP, and Former Director, Human Subject Protections, Office for Human Subjects Research Protections, Department of Health and Human Services, Bethesda, MD*

4.04 Negotiating Clinical Trials Agreements
William A. Knowlton, Esq., *Partner, Ropes & Gray, Boston, MA*

4.05 Overview of Financial and Administrative Commitments of Clinical Research
Timothy J. Fournier, *Higher Education and Health Care Consulting, Arthur Andersen LLP, Chicago, IL*

12:30 p.m. Luncheon and Presentations

1:00 p.m. Adverse Event Reporting: Trials and Tribulations

Michael Carome, MD, *Director, Compliance Oversight, Office for Human Research Protections, Department of Health and Human Services, Rockville, MD*

Joanne R. Less, Ph.D., *Director, IDE/HDE Programs, Center for Devices and Radiological Health, Food and Drug Administration, Rockville, MD*

Steven Peckman, *Associate Director-Human Subjects Research, Office for Protection of Research Subjects, University of California, Los Angeles, Los Angeles, CA*

2:00 p.m. Annual Roundtable on Medical Research Compliance, Legal Counsel, Ethics and Privacy

John Bentivoglio, Esq., *Partner, Arnold and Porter, and former Special Counsel for Healthcare Fraud, and Chief Privacy Officer, United States Department of Justice, Washington, DC*

Thomas E. Merchant, Esq., *Vice President, R & D Legal Operations U.S., GlaxoSmithKline, King of Prussia, PA*

John H. Mather, MD , *Chief Officer, Office of Research Compliance and Assurance, Department of Veterans Affairs, Washington, DC*

Steven Peckman, *Associate Director-Human Subjects Research, Office for Protection of Research Subjects, University of California, Los Angeles, Los Angeles, CA*

John E. Steiner, Jr., Esq., *Chief Compliance Officer, Cleveland Clinic Health System, Cleveland, OH*

Jay H. Tureen, MD, *Director, Research Education and Compliance Program, Clinical Professor of Pediatrics, University of California at San Francisco, San Francisco, CA*

Paul E. Kalb, JD, MD, *Partner, Sidley Austin Brown & Wood, Washington, DC, (Moderator)*

3:15 p.m. TRANSITION BREAK

3:30 p.m. CONCURRENT SESSIONS V

5.01 Developing and Managing a Clinical Research Department in Your Hospital
Diane Lee, Esq., *Partner, Davis Wright Tremaine LLP, San Francisco, CA*

5.02 Advanced Issues In Research Compliance
Edward B. Goldman, Esq., *Health System Attorney, Office of General Counsel, University of Michigan Health System, Ann Arbor, MI*

5.03 Managing Institution-Investigator Relationships
Sandra A. Davis, *Director, Risk and Compliance Services, Huntington Memorial Hospital, Pasadena, CA*

5.04 Benchmarking Clinical Research Compliance Efforts: Identifying and Avoiding Key Areas of Risk
Guy Collier, Esq, *Partner, Shaw Pittman LLP, Washington, DC*

4:30 p.m. Adjournment

Continuing Education Credits: Maximum credit hours include 2 hours for Preconference.

AAPC - This program is pending prior approval from the American Academy of Professional Coders (AAPC) for 20.25 CE credits.

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of Medical Education Collaborative and Healthcare Conference Administrators, LLC. Medical Education Collaborative (MEC), a nonprofit education organization, is accredited by the ACCME to provide continuing medical education for physicians.

Medical Education Collaborative designates this educational activity for a maximum of 20.25 hours in category 1 credit towards the AMA Physician's Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

ACHE - Medical Education Collaborative is authorized to award 20.25 hours of pre-approved Category II (non-ACHE) continuing education credit for this program toward advancement or re-certification in the American College of Healthcare Executives. Participants in this program wishing to have the continuing education hours applied toward Category II credit should list their attendance when applying for advancement or re-certification in ACHE.

ACMPE – This program may qualify for continuing education credit in the American College of Medical Practice Executives (ACMPE). To apply for ACMPE credit, submit a generic credit hour form with a copy of the brochure. Forms will be available on-site.

Medical Education Collaborative, Inc. is approved by the American Council on Pharmaceutical Education as a provider of continuing pharmaceutical education. Medical Education Collaborative, Inc. has assigned 20.25 contact hours/2.02 CEUs of continuing pharmaceutical education credit. ACPE universal program number: 815-999-02-098-L04.

Participants will be required to complete an evaluation form for credit. Registration fee includes statement of credit, which will be mailed within six weeks after the meeting.

AHIMA – This program is pending approval for 20 CE credits for use in fulfilling the continuing education requirements of the American Health Information Management Association (AHIMA).

ANCC (Nursing Credit) – Approved for 23.4 contact hours of continuing education for RNs, LPNs, LVNs, and NPs. This program is cosponsored with Medical Education Collaborative, Inc. (MCE). MEC is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. Provider approved by the California BRN provider number: CEP-12990 for 23.4 contact hours.

HCCB - This program is pending approval for HCCB continuing education credits for compliance certification for 20 CE credits.

NAMSS - This program is pending approval by the National Association of Medical Staff Services for 20.25 CE credits.

MCLE – Required sponsor documentation has been forwarded to and credit requested from most MCLE states with general requirements for all lawyers. We have requested a total of 20.25 CLE hours from most MCLE states. Lawyers seeking credit in Pennsylvania must pay fees of $1.50 per credit hour directly to the PA CLE Board. Medical Education Collaborative pays applicable fees in other states where the sponsor is required to do so, and in states where a late fee may become applicable. Please be aware that each state has its own rules and regulations, including its definition of CLE; therefore, certain programs may not receive credit in some states. For information on approved credit hours for your state, please contact Medical Education Collaborative at (303) 420-3252 ext 24 starting two to three weeks prior to the program date.

NASBA – Registered with the National Association of State Boards of Accountancy (NASBA) as a sponsor of continuing professional education on the National registry of CPE Sponsors. State boards of accountancy have final authority on the acceptance of individual courses for CPE credit. Complaints regarding registered sponsors may be addressed to the National Registry of CPE Sponsors, 150 Fourth Avenue North, Nashville, TN 37219-2417. Telephone: 615-880-4200.

A maximum of 24 credits based on a 50-minute hour will be granted. Recommended experience level for this course is intermediate to advanced.

P.A.C.E.® - Medical Education Collaborative has applied for approval as a provider of continuing education programs in the clinical laboratory sciences by the ASCLS P.A.C.E.® program for 20.25 CE credits.

PAHCOM - This program is pending approval by the Professional Association of Health Care Office Management for 20.25 CE credits.

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Mon. 11:00 – 12:00
❑ 101 ❑ 102 ❑ 103 ❑ 104 ❑ 105

2:30 – 3:30
❑ 201 ❑ 202 ❑ 203 ❑ 204 ❑ 205

3:45 – 4:45
❑ 301 ❑ 302 ❑ 303 ❑ 304 ❑ 305

Tues. 11:30 – 12:30
❑ 401 ❑ 402 ❑ 403 ❑ 404 ❑ 405

3:30 - 4:30
❑ 501 ❑ 502 ❑ 503 ❑ 504

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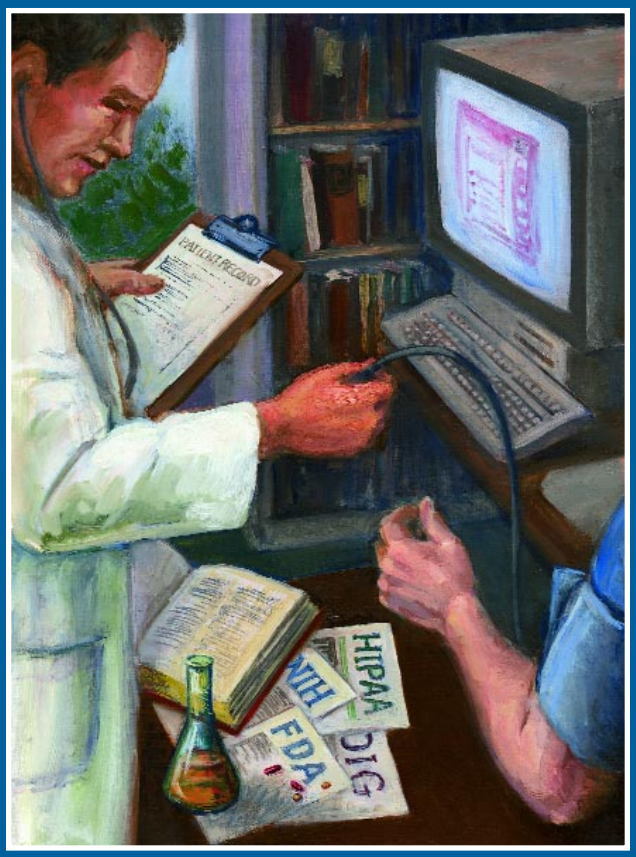

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