

# Accelerating Clinical Research with the Adoption of PHRs

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# Some vocabulary...

- What is Research?

“a systematic investigation...designed to develop or contribute to generalizable knowledge.” 45 CFR 46.102

# Types of Clinical Research

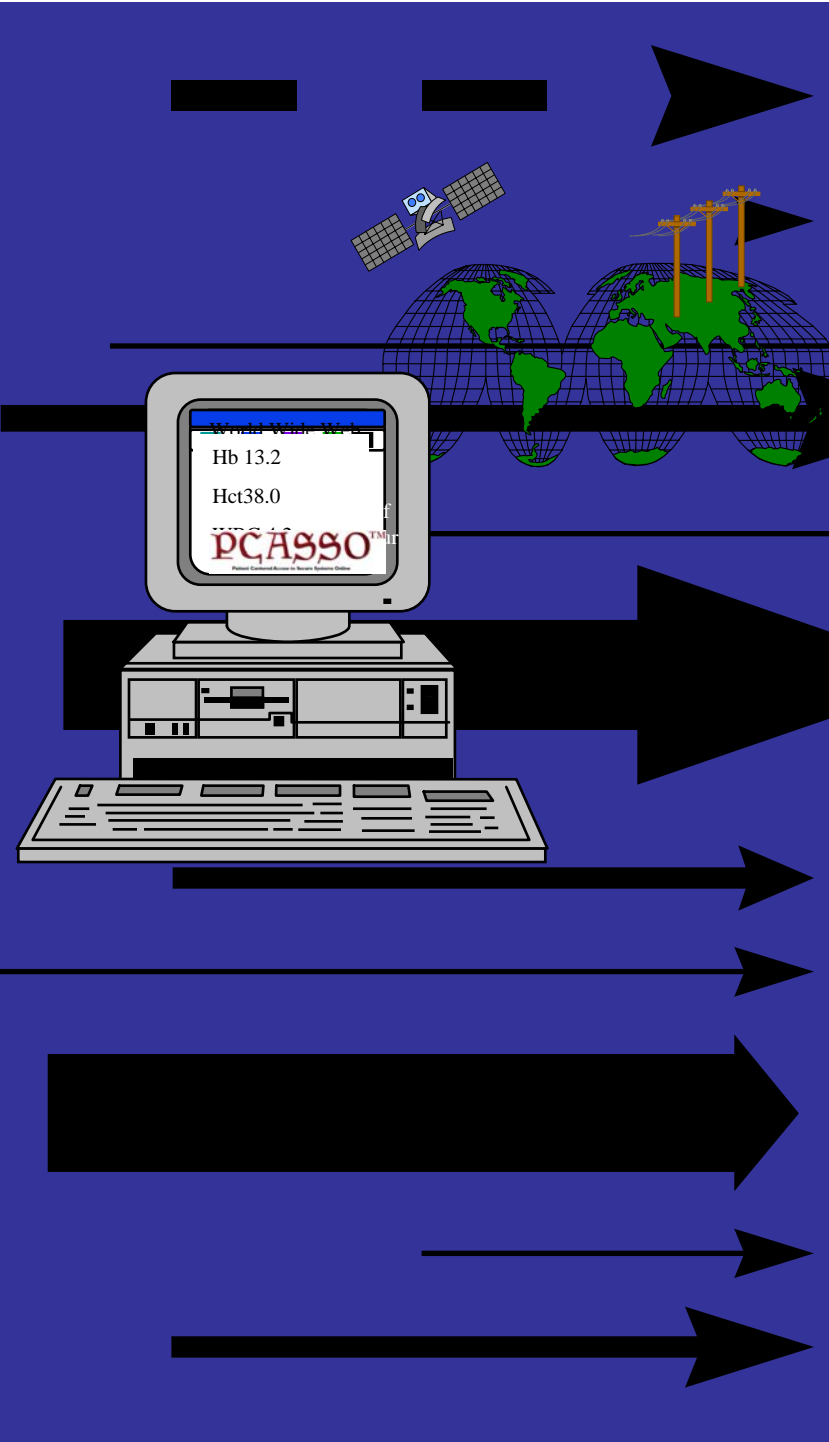
- Observational studies
  - “Watch and measure without making changes”
- Interventional studies
  - To understand disease and approaches to preventing, diagnosing and treating it (“NIH model”)
  - To prove safety and efficacy of new drugs and devices (“FDA model” – premarketing approval)
- Health Services Research studies
  - Effectiveness and cost effectiveness in organizational and community settings (“AHRQ model”)
- Population Health studies

# Interventional Clinical Trials

- Phase I – toxicity testing
- Phase II – efficacy testing
- Phase III – compare to current best available
- Phase IV – post-marketing surveillance

# PHRs and Clinical Research

- PHRs – born with NLM support into a research setting
  - 1996 Telemedicine program creates the first patient portals: Columbia PATCIS and UCSD PCASSO
  - Emphasis: safety and efficacy of the technology itself



# **Patient-Centered Access to Secure Systems Online**

A National Library of Medicine  
Telemedicine Research Contract

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**PCASSO Client**

Context Audit Provider Logout Help

**PCASSO Login**

Using the PCASSO Graphic Keyboard, click the mouse on the characters to enter your PCASSO Id, Password, and Key Password. Press the Enter button on the Graphic Keyboard when finished entering each field. Then, click the mouse on the Login button.

PCASSO User Id:

PCASSO Password:

Key Password:

**Additional Authentication**

None

PCASSO Card

SecureID

**Login**

Java Applet Window





Context



Logout



Feedback



Help



Audit Log



Providers

Patient: PATIENT, SAMPLE MR# 55555 Role: PATIENT

Demographics

Lab

Reports/Notes

Select the type of medical report to display

RADIOLOGY

Level	Date	Report Date	Status	Description
	06/22/98	06/30/98	Final	RADIOLOGY
	06/22/98	07/03/98	Final	RADIOLOGY

Previous Reports

Next Reports

## REFERENCE FILMS:

06/21/98 at 0600

## FINDINGS/IMPRESSION:

1. There has been slight increase in the bilateral diffuse air space opacification. This is more pronounced on the left side than on the right side. Query asymmetric edema versus aspiration versus infection.
2. The right chest tube has been removed. A tracheostomy tube and nasogastric tube are in place and unchanged from the reference examination.

Change Level

Reply received from PCASSO Server



Signed by Science Applications International Corporation



Logout

Data Entry

Data Review

Advice

Education

Help

Comments

## Welcome to PatCIS

### The Patient's Clinical Information System

The intent of PatCIS is to:

- help you understand health issues
- help you understand your own health status
- provide recommendations about your health
- improve communication with your health care provider

If you need instructions on how to use PatCIS, click the "Help" button.

If you have questions or suggestions for the system developers, click the "Comments" button

We would appreciate it if you would read the disclaimer carefully: [Disclaimer](#)





### Data Entry

Vital Signs

Blood Sugars

Logout

If the information you are entering was measured earlier, please change the DATE and TIME.

Month  Date  Year  Time

Data Entry

Data Review

Advice

Education

Help

Comments

Morning (Fasting).  Before Lunch.  After Lunch.  Before Dinner.  After Dinner.  Bedtime.  
 Overnight.

Insulin Dose (U)	NPH	<input type="text"/>
	Regular	<input type="text"/>
	Long Acting	<input type="text"/>
	Mix(70/30)	<input type="text"/>
	Mix(50/50)	<input type="text"/>

• Glucose Meter check is:  mg/dl



# My Health at Vanderbilt



[Help: Using MyHealth](#)

Home Page For: **MASYS, DANIEL**

## All Health Topics

- [View all Health Topics](#)

## Be Healthy, Stay Healthy

- [Blood Pressure Screening](#)
  - [Cholesterol Screening](#)
  - [Colorectal Cancer Screening](#)
- [more stories]

## Health News You Can Use

- [Vanderbilt-Ingram Cancer Center Opens New Chemotherapy Clinic](#)
  - [Vanderbilt University Licenses Cancer Cell Identifying Technology to DiaTech Oncologyder](#)
  - [Two Vanderbilt Epilepsy Efforts to Offer Answers about Complex Condition](#)
- [more stories]

**70,000 users**

## Account Access

- [View others who have access to MASYS, DANIEL](#)

## Messaging

- [Message Your Doctor's Office](#)

## Clinical Record

- [View Your Clinical Record](#)

## Appointments

Request an appointment with

- [Your Doctor](#)
- [New Doctor](#)
- [View Existing Appointments](#)

## Billing

- [Ask a question about your bill](#)
- [View Account Summary](#)
- [View Insurance Information](#)

## Account Maintenance

- [Update Secret Questions](#)
- [Change Email](#)
- [Change Password](#)
- [Personal Information](#)

## Health Screenings

- [Peripheral Artery Disease! Are you at risk?](#)

## Research Opportunities

- [Sign up to be contacted for research opportunities](#)
- [Search currently enrolling clinical studies](#)

## Patient Resources

- [Information about a Doctor](#)
- [Healthcare Breakthroughs](#)
- [Quality of Care](#)
- [Maps & Directions](#)
- [Key Telephone Numbers](#)
- [Subscriber Agreement](#)



# Synergies between PHRs and clinical research: theory

- Automated Eligibility for studies modulated by patient preferences regarding research
- Study recruitment
- Direct participant data entry during observational and interventional studies
- Re-use of patient entered observations for phase 4 drug studies (Medwatch for patients)
- Population health studies

# Synergies between PHRs and clinical research: practice

- Ken Mandl: PING/Indivo and the Informed Cohort
- Jonathan Wald: Practice-Linked Online Personal Health Records for Type 2 Diabetes
- Greg Downing: DHHS Personalized Healthcare Initiatives