Academic Medical Centers as “Lead Users”

(1) they are at the leading edge of an important marketplace trend(s), and so are currently experiencing needs that will later be experienced by many users in that marketplace;

(2) they anticipate relatively high benefits from obtaining a solution to their needs, and so may innovate

Functional Hierarchy

Surgery

- Prior to 1846, surgery was done without anesthesia
- Surgical skill was defined by the speediness of the surgeon
  - "Strong arm and a deaf ear"

First public demonstration of the use of ether

“This is no humbug”

First limb reimplantation 1962

- Chief Resident led team
- No prior research

- The world's first successful limb reattachment was performed on Everett "Red" Knowles, whose arm was reattached in 1962 by an MGH surgical team led by Ronald Malt, MD.

Coronary Artery Angioplasty

Andreas Gruentzig, MD

"Gruentzig worked evenings in his kitchen with his assistant, Maria Schlumpf, her husband, Walter, and Michaela, Andreas' wife, and during those sessions, many versions of the balloon catheter were designed and built with tiny bits of rubber, thread, and epoxy glue."
(*Circulation.* 1996;93:1621-1629.)

ACC/AHA Guidelines for Percutaneous Coronary Intervention

"At this time, the Committee, therefore, continues to support the recommendation that elective PCI should not be performed in facilities without on-site cardiac surgery. As with many dynamic areas in interventional cardiology, these recommendations may be subject to revision as clinical data and experience increase."

Donna MacDonald had an emergency angioplasty at South Shore Hospital in 2003, but when another blockage was found last year, she had to be transferred to Boston for the procedure. (Globe Staff Photo / Jonathan Wiggs)

Small hospitals battle for right to do angioplasties

By Liz Kowalczyk, Globe Staff | February 13, 2005

Yuk!

- “If there’s anything in this world I hate it is leeches. Filthy little devils”
  - Humphrey Bogart, African Queen
- Microsurgery produced an unmet need (venous congestion)
  - Leeches provide painless low cost method of reducing venous congestion
  - Lepirudin-purified protein derived from leech spit!

Iressa (gefitinib)

- Drug works in a small minority of lung cancer patients
  - Women, Japanese ancestry, non-smoker, adenocarcinoma of lung

- When it does work, it is impressive
- Why does the drug work so well in some patients and not in others?
  - Mutation in EGFR gene predicts response

Hypertrophic Obstructive Cardiomyopathy

- Genetic Disorder
- Manifests early or late in life
  - Fatigue
  - Syncope
  - Arrhythmias
- Traditional treatment is surgical

Interventional Cardiology Approach

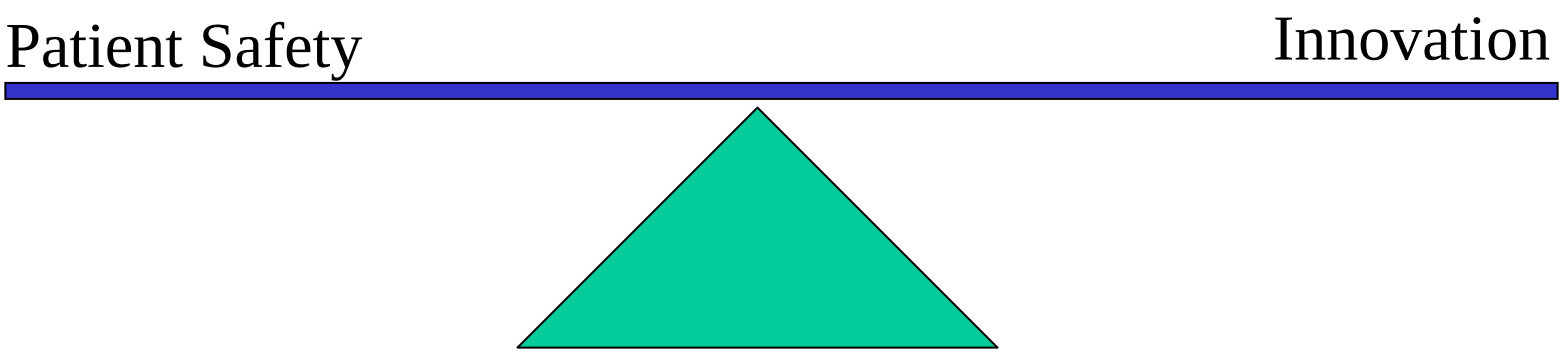
- Alcohol Septal Ablation
- Produces Septal Heart attack
  - Thins septal wall
- Provides human model for examining heart attack from onset
  - Proteomics research

Characteristics of Academic Clinician

- Practices in multiple dimensions
  - Patient care
  - Research
  - Education
- Free Revealing
  - Publication of results
- Functionally independent

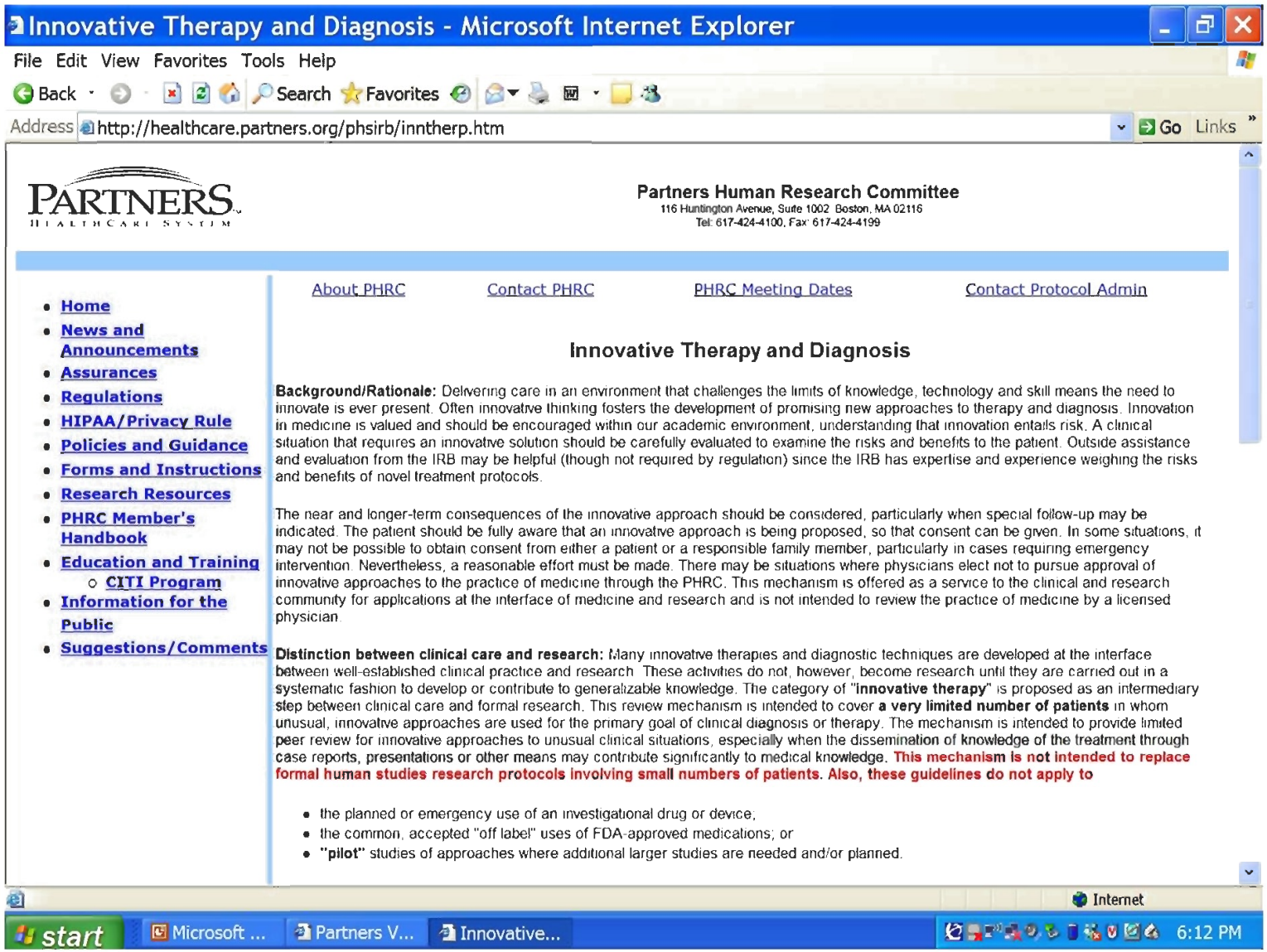
Lead Users as Cowboys

- Not all lead user ideas are necessarily good
- Bad idea can cause patient harm



Organizational Approach

- **Institutional Review Board**
  - Oversees Human Research
  - Subject protection
- **Council for Technology Adoption and Innovative Process Promotion**
  - Tasked with dual responsibility of promoting clinical innovation and “right sizing” technology adoption


Innovative Therapy and Diagnosis - Microsoft Internet Explorer
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Innovative Therapy and Diagnosis
Background/Rationale: Delivering care in an environment that challenges the limits of knowledge, technology and skill means the need to innovate is ever present. Often innovative thinking fosters the development of promising new approaches to therapy and diagnosis. Innovation in medicine is valued and should be encouraged within our academic environment, understanding that innovation entails risk. A clinical situation that requires an innovative solution should be carefully evaluated to examine the risks and benefits to the patient. Outside assistance and evaluation from the IRB may be helpful (though not required by regulation) since the IRB has expertise and experience weighing the risks and benefits of novel treatment protocols.
The near and longer-term consequences of the innovative approach should be considered, particularly when special follow-up may be indicated. The patient should be fully aware that an innovative approach is being proposed, so that consent can be given. In some situations, it may not be possible to obtain consent from either a patient or a responsible family member, particularly in cases requiring emergency intervention. Nevertheless, a reasonable effort must be made. There may be situations where physicians elect not to pursue approval of innovative approaches to the practice of medicine through the PHRC. This mechanism is offered as a service to the clinical and research community for applications at the interface of medicine and research and is not intended to review the practice of medicine by a licensed physician.
Distinction between clinical care and research: Many innovative therapies and diagnostic techniques are developed at the interface between well-established clinical practice and research. These activities do not, however, become research until they are carried out in a systematic fashion to develop or contribute to generalizable knowledge. The category of "innovative therapy" is proposed as an intermediary step between clinical care and formal research. This review mechanism is intended to cover a very limited number of patients in whom unusual, innovative approaches are used for the primary goal of clinical diagnosis or therapy. The mechanism is intended to provide limited peer review for innovative approaches to unusual clinical situations, especially when the dissemination of knowledge of the treatment through case reports, presentations or other means may contribute significantly to medical knowledge. This mechanism is not intended to replace formal human studies research protocols involving small numbers of patients. Also, these guidelines do not apply to
the planned or emergency use of an investigational drug or device;
the common, accepted "off label" uses of FDA-approved medications; or
"pilot" studies of approaches where additional larger studies are needed and/or planned.
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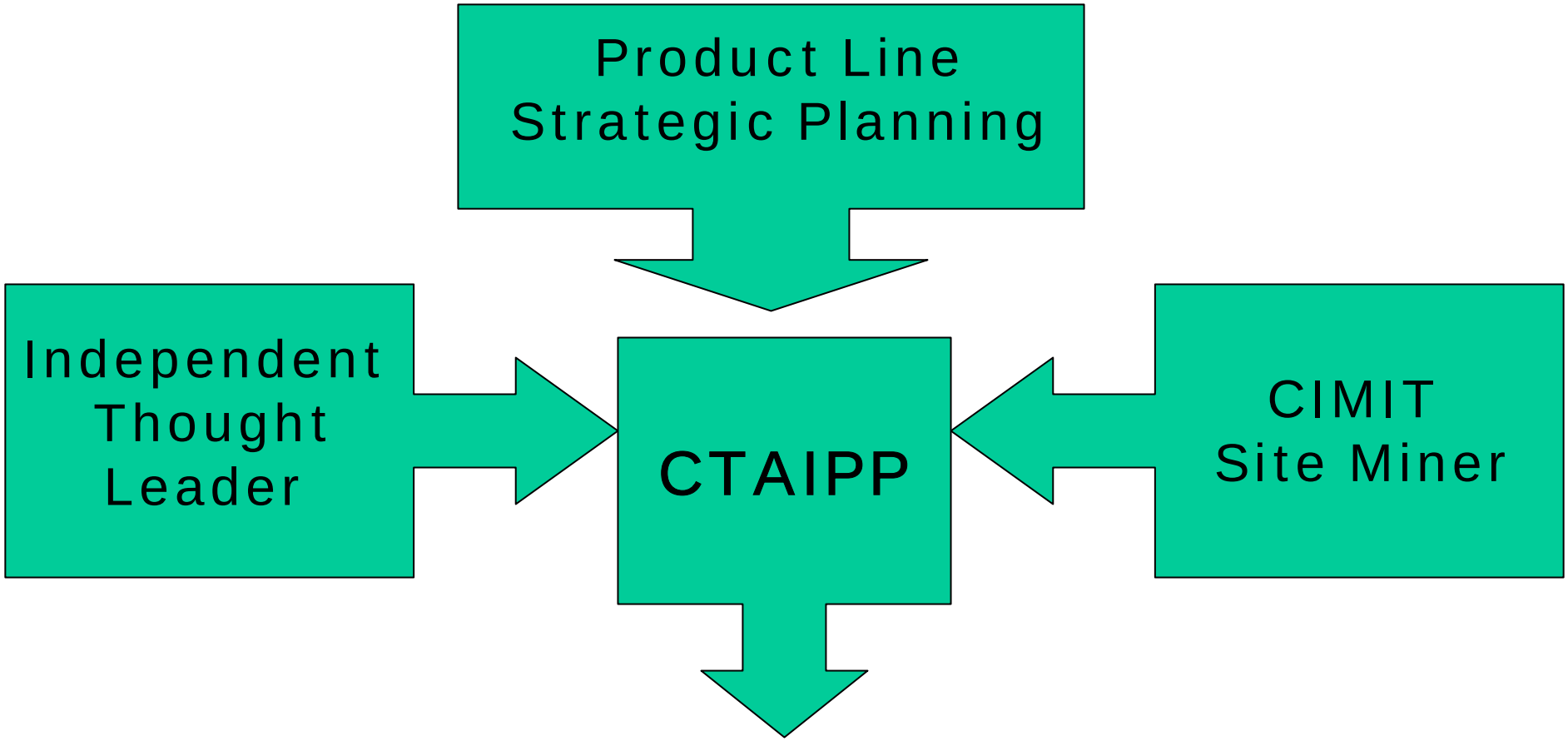
Paths to Innovation



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