Personalized Healthcare in a Learning Healthcare System

Eleventh Population Health and Care Coordination Colloquium

Philadelphia, PA

March 15, 2011

Massachusetts Institute of Technology

Center for Biomedical Innovation

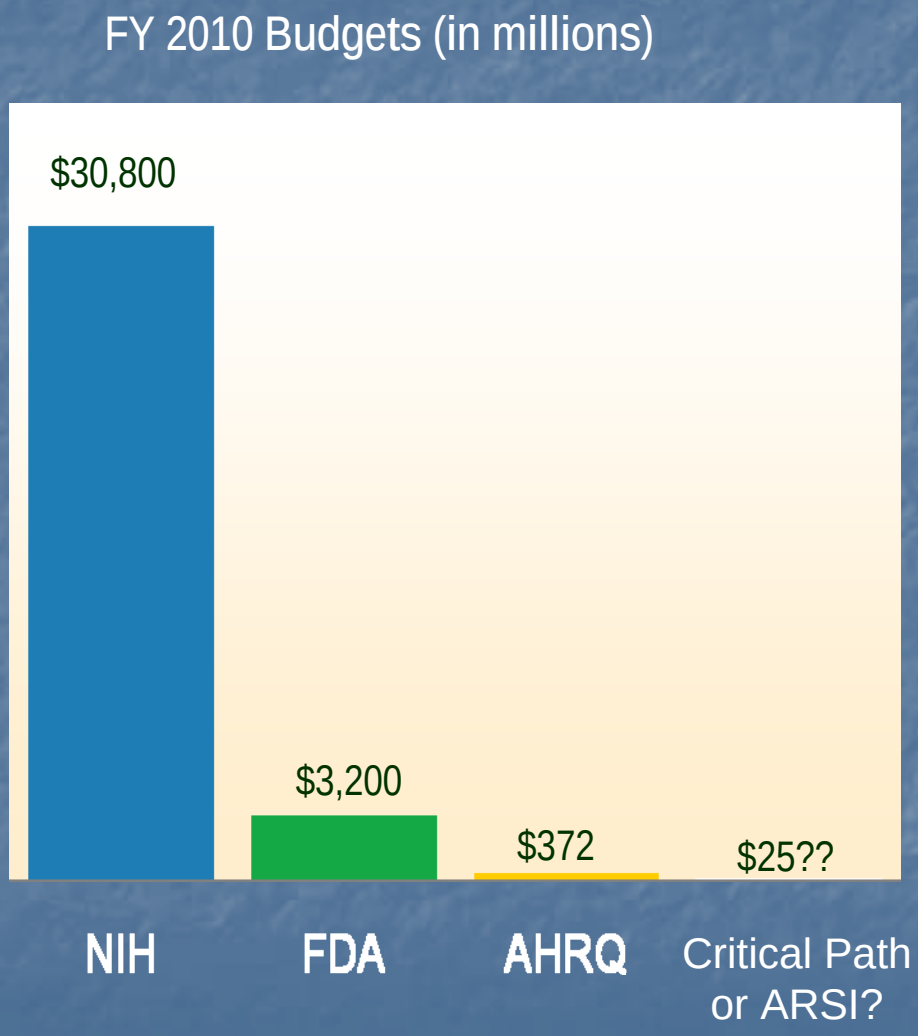
PMC Personalized Medicine Coalition

The Underlying Cause of Change

- Healthcare expense grow-in now pervasive
  - Affecting all stakeholders; patients, employers, private payers, states, and the federal government.
- The quality of care being delivered today is increasingly recognized as suboptimal
  - recommended care not implemented effectively and misaligned incentives not serving the patient.

The current situation is not sustainable, and no single part of healthcare, any single industry, any one company or agency can do it alone.

...and With Minimal Resources to Fund Change

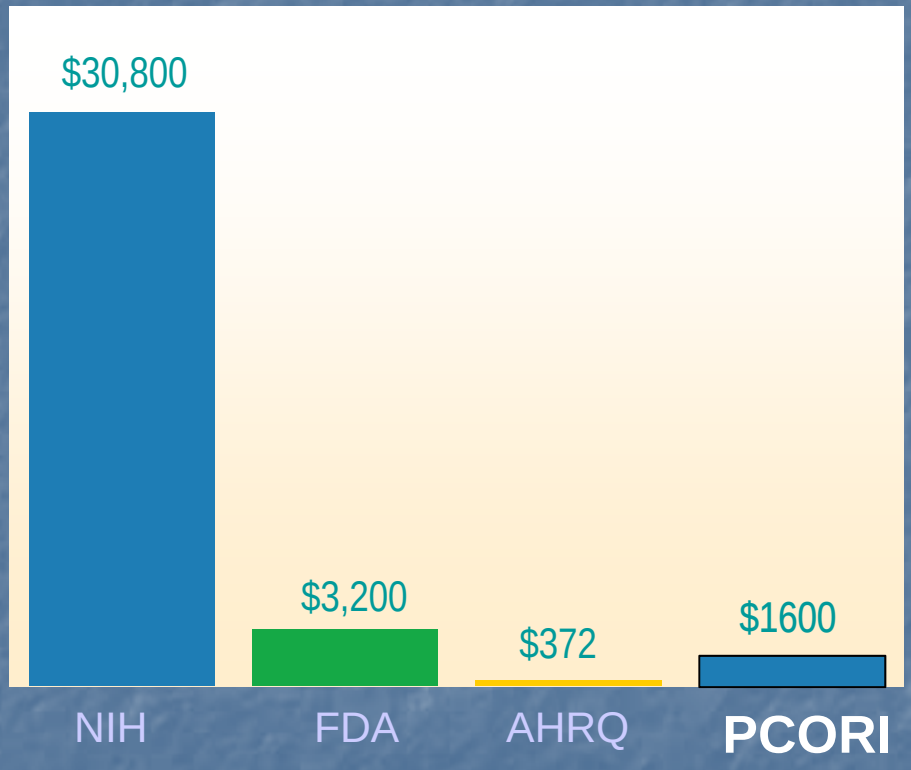


"Starkly put, for every dollar Congress allocates to develop breakthrough treatments, it allocates one penny to ensure that Americans actually receive them."

Dr. Steven Woolf, The Washington Post January 8, 2006

...and a New Kid on the Block

FY 2010 Budgets (in millions)



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Patient-centric Outcomes Research Institute

Elicits a re-evaluation of the basic value proposition...

Value in health care is often expressed as the increment in clinical benefit achieved (health and/or quality of life improvement), for those receiving a particular service or set of services, in conjunction with the investment required.

...and generates a new refrain in healthcare

Pay for What Works

Eliciting a new series of questions

What works?

...What works best?

...for whom?

...under what circumstances?

...in a cost effective way?

That can be interpreted as

- What works – efficacy and safety
- ...What works best – comparative clinical effectiveness
- ...for whom – personalized healthcare
- ...under what circumstances – real world effectiveness
- ...in a cost effective way – coverage and reimbursement

For Healthcare Sectors
e.g. Product Developers

- New thinking is required
  - The old hurdles...
    - Efficacy
    - Safety
    - Production assurance

  ...are no longer sufficient

For Healthcare Sectors
e.g. Product Developers

- New thinking is required
  - Three new hurdles must be cleared as well...
    - Effectiveness
    - Coverage
    - Reimbursement

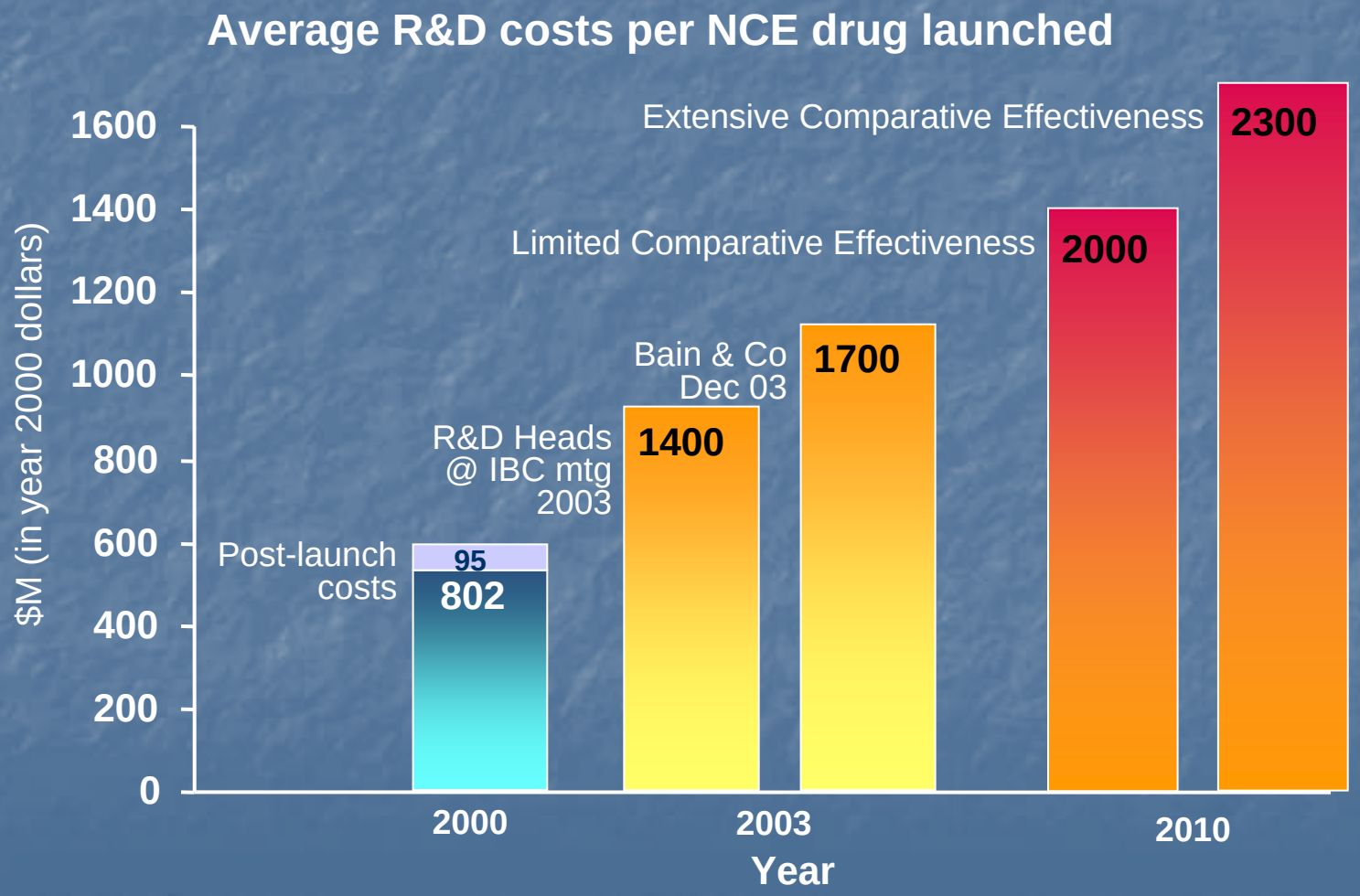
  ...looking beyond market approval toward greater embedment in clinical practice.

For Healthcare Sectors
e.g. Product Developers

- New thinking is required
  - Innovation itself is no longer sufficient, the value of innovation must be proven
    - In the clinic
    - With real patients
    - And real providers
    - In a cost effective way

The Problem

Unsustainable Cost of Innovation



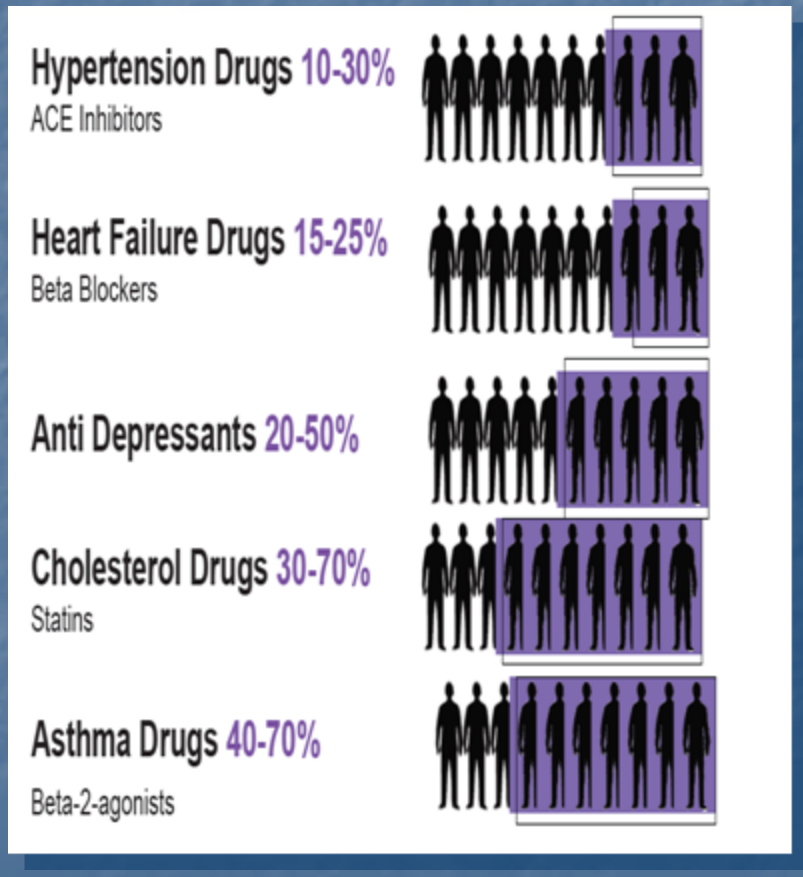
Historical data from DiMasi, Tufts Center for Drug Development

Plus:
Everybody responds to therapy differently

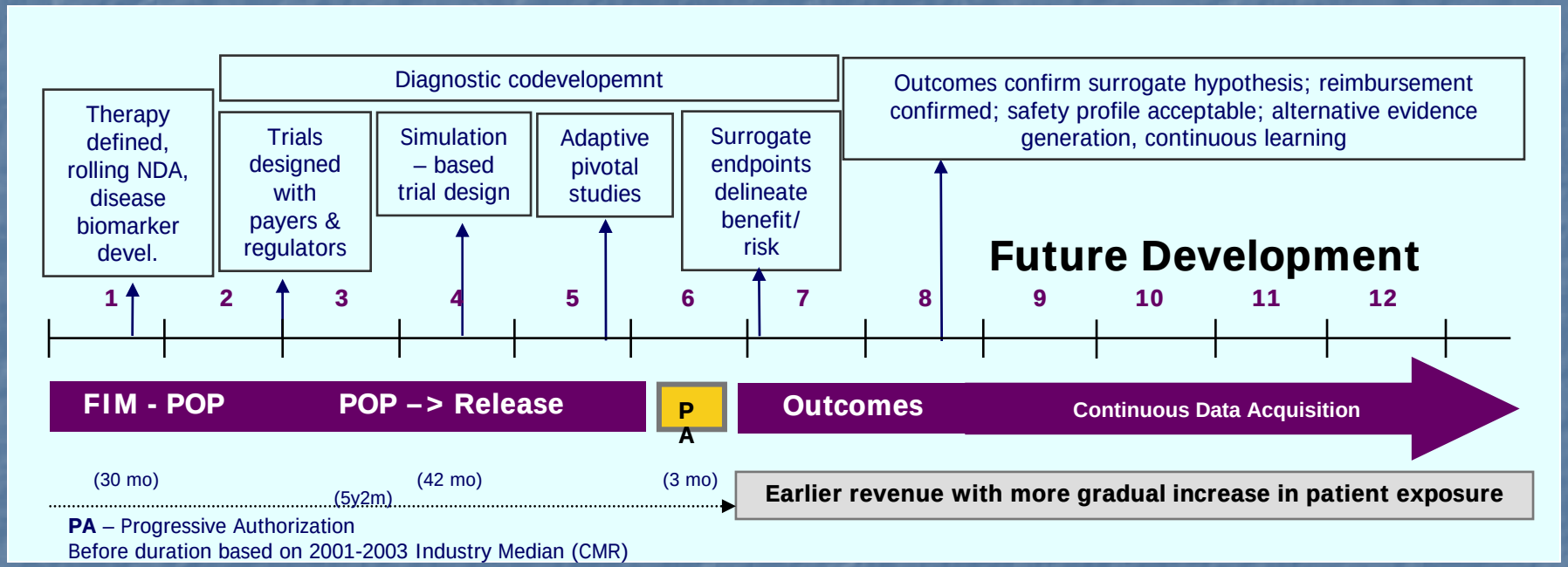
Who suffers when therapies don't work?

- Patients
- Physicians
- Payers

Percentage Non-responders



The Solution
New development paradigms



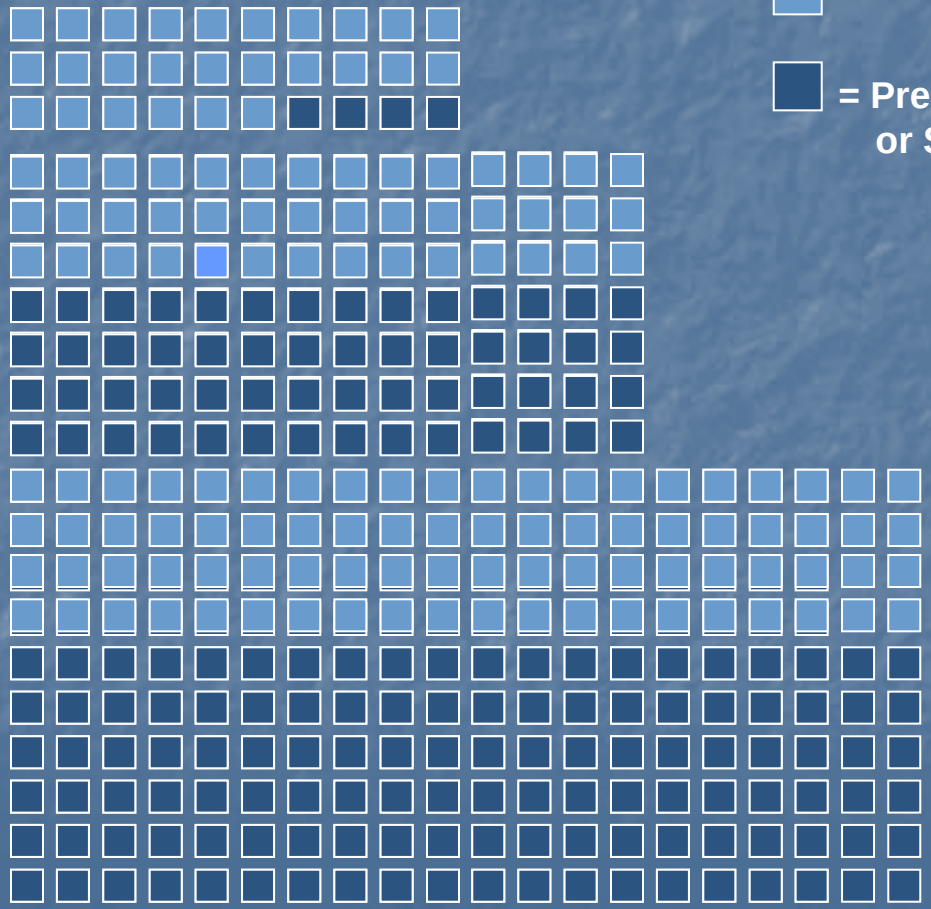
The Solution:
Access to the right therapy

Patient Population

Severe Symptoms

Moderate Symptoms

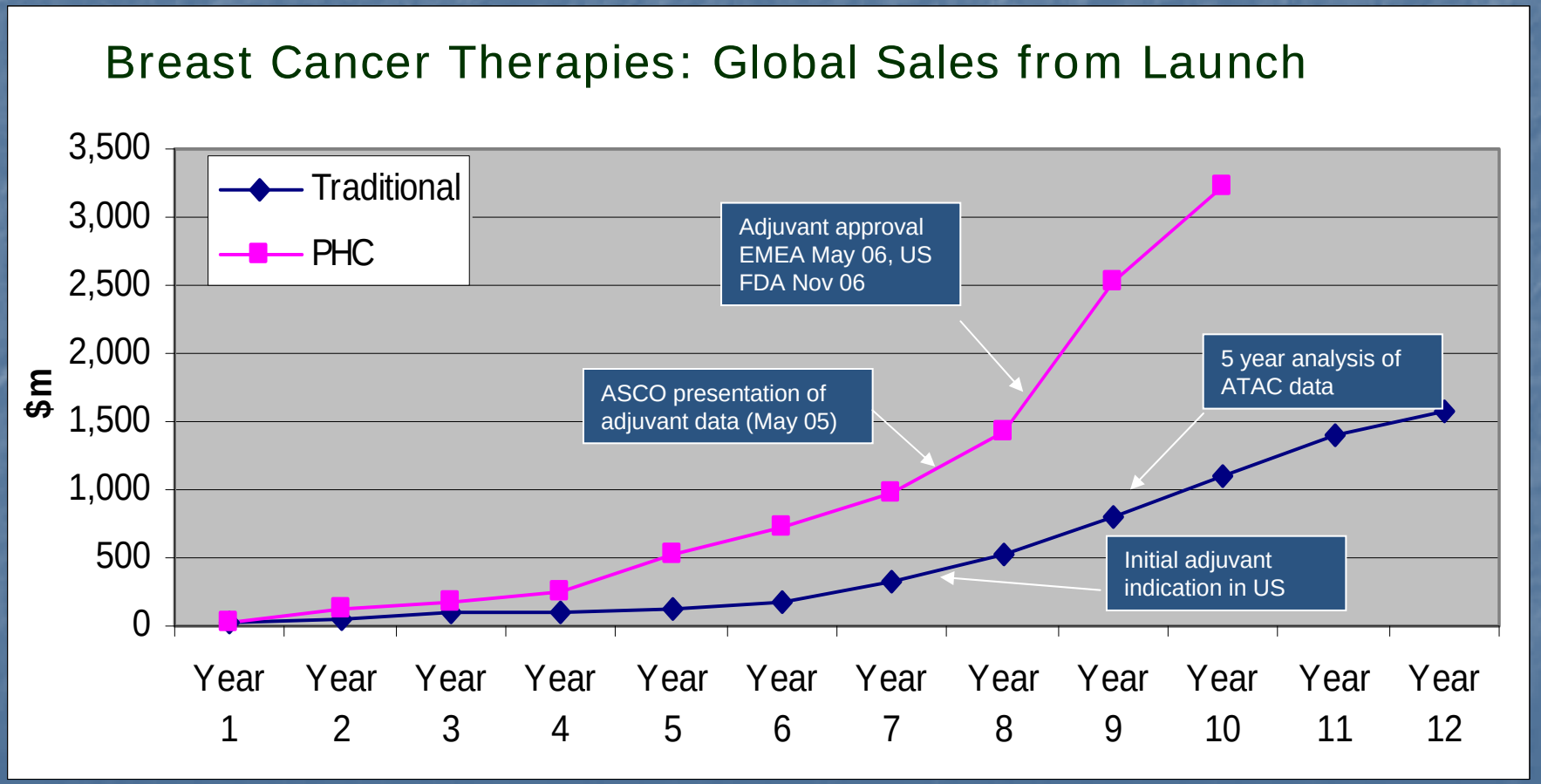
Mild Symptoms



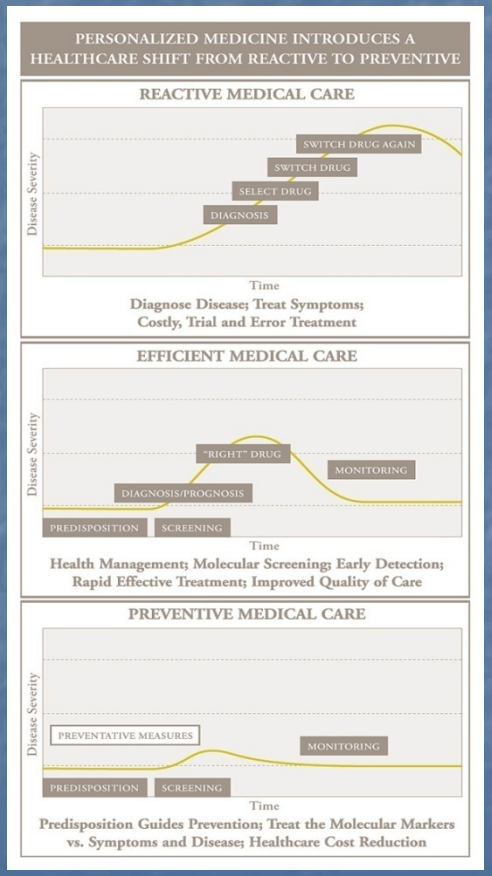
= Predicted Responders

= Predicted Low Efficacy or Side Effects

The Solution:
Quicker uptake of therapeutic value



The Solution:
Towards Preventive Medicine



- Avoiding futile medicine
- Predictable therapeutic response
- Earlier intervention
- Delay onset and minimize severity

Two needs for evidence...

- Confirming real-world **comparative clinical effectiveness** must constitute a core element of clinical development plans,
  - developed not only in consultation with the FDA,
  - but with other entities, i.e.,
    - Center for Medicare Services (CMS),
    - Agency for Healthcare Research in Quality (AHRQ),
    - Health Technology Assessment (HTA) at private payers,

...and...

    - NICE comes to America (PCORI)

…and…

- Generating meaningful segmentation of patient populations, by whatever technology is appropriate (genomic, imaging, informatic), in order to increase the benefit of therapy

…**Personalized Healthcare**

...evolving the “P” for the future

P...ersonalized Healthcare ➔

P...rescriptive

⬇

P...recision

⬇

P...reventive

⬇

P...articipatory

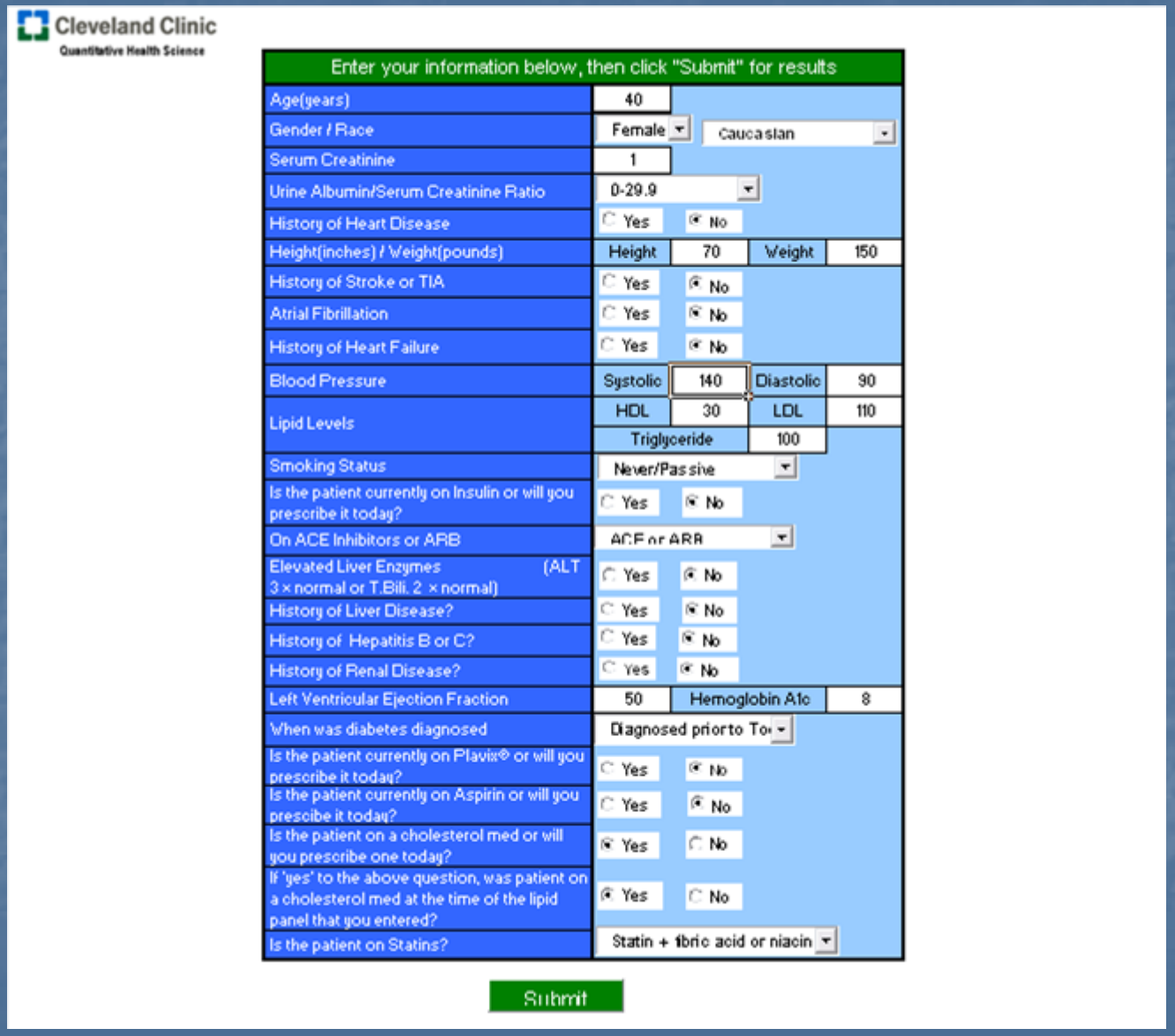
⬇

P...erformance??

Is PHC only about genomics?

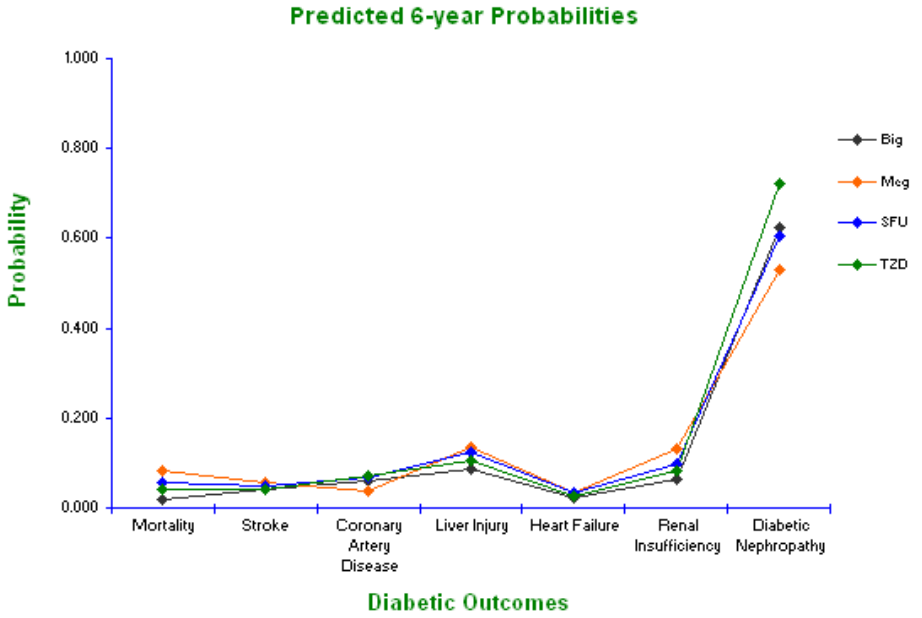
Case Study – Informatic PHC

Can a large and fully integrated Electronic Health Record System (EHR) be used to demonstrate the value of antidiabetic therapy, in terms of comparative benefit and risk, in an environment reflecting actual clinical use of the therapy?


Cleveland Clinic
Quantitative Health Science
Enter your information below, then click "Submit" for results
Age(years)
40
Gender / Race
Female
Caucasian
Serum Creatinine
1
Urine Albumin/Serum Creatinine Ratio
0-29.9
History of Heart Disease
Yes
No
Height(inches) / Weight(pounds)
Height
70
Weight
150
History of Stroke or TIA
Yes
No
Atrial Fibrillation
Yes
No
History of Heart Failure
Yes
No
Blood Pressure
Systolic
140
Diastolic
90
Lipid Levels
HDL
30
LDL
110
Triglyceride
100
Smoking Status
Never/Passive
Is the patient currently on Insulin or will you prescribe it today?
Yes
No
On ACE Inhibitors or ARB
ACE or ARB
Elevated Liver Enzymes (ALT 3 x normal or T.Bili. 2 x normal)
Yes
No
History of Liver Disease?
Yes
No
History of Hepatitis B or C?
Yes
No
History of Renal Disease?
Yes
No
Left Ventricular Ejection Fraction
50
Hemoglobin A1c
8
When was diabetes diagnosed
Diagnosed prior to To
Is the patient currently on Plavix® or will you prescribe it today?
Yes
No
Is the patient currently on Aspirin or will you prescibe it today?
Yes
No
Is the patient on a cholesterol med or will you prescribe one today?
Yes
No
If 'yes' to the above question, was patient on a cholesterol med at the time of the lipid panel that you entered?
Yes
No
Is the patient on Statins?
Statin + fibric acid or niacin
Submit

OUTCOMES (6 year probabilities)	DRUG CLASS			
	Big	Meg	SFU	TZD
Mortality	0.018	0.083	0.058	0.042
Stroke	0.042	0.055	0.048	0.043
Coronary Artery Disease	0.059	0.036	0.068	0.073
Liver Injury	0.086	0.135	0.124	0.106
Heart Failure	0.023	0.034	0.033	0.027
Renal Insufficiency	0.064	0.132	0.097	0.082
Diabetic Nephropathy	0.623	0.530	0.605	0.721
BMI	25.6	26.8	25.4	27.6
Hemoglobin A1c(%)	8.0	8.1	7.9	7.8
HDL(mg/dl)	43.7	41.8	42.3	42.5
LDL(mg/dl)	96.3	94.8	96.0	95.3
Triglyceride(mg/dl)	115.8	113.2	117.7	105.5

Rank



This is a prototype that has not been fully tested.

Do not distribute.

Not for clinical use.

Predictions do not necessarily assume that patients will remain on this drug class for 6-years.

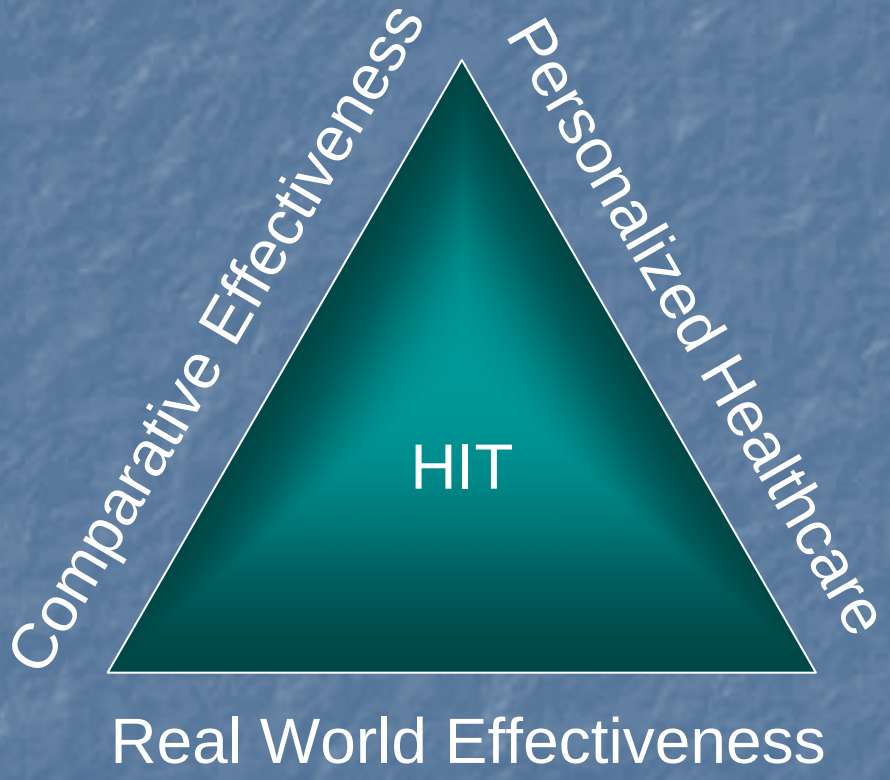
Big = Biguanides(e.g. metformin)

Meg = Meglitinide Analogue(e.g. nateglinide)

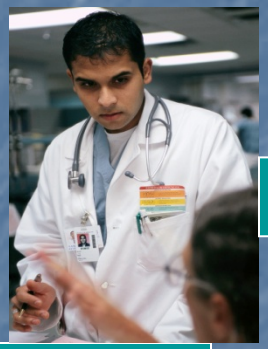
SFU = Sulfonylurea Derivatives(e.g. glyburide)

TZD = Thiazolidinediones(e.g. rosiglitazone), including SFU-TZD combination pill(e.g. Avandaryl®)

The new refrain in healthcare



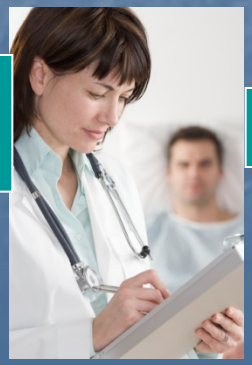
Creating a Learning Healthcare System



Patient Care Episode

Evidence-based Decision Support

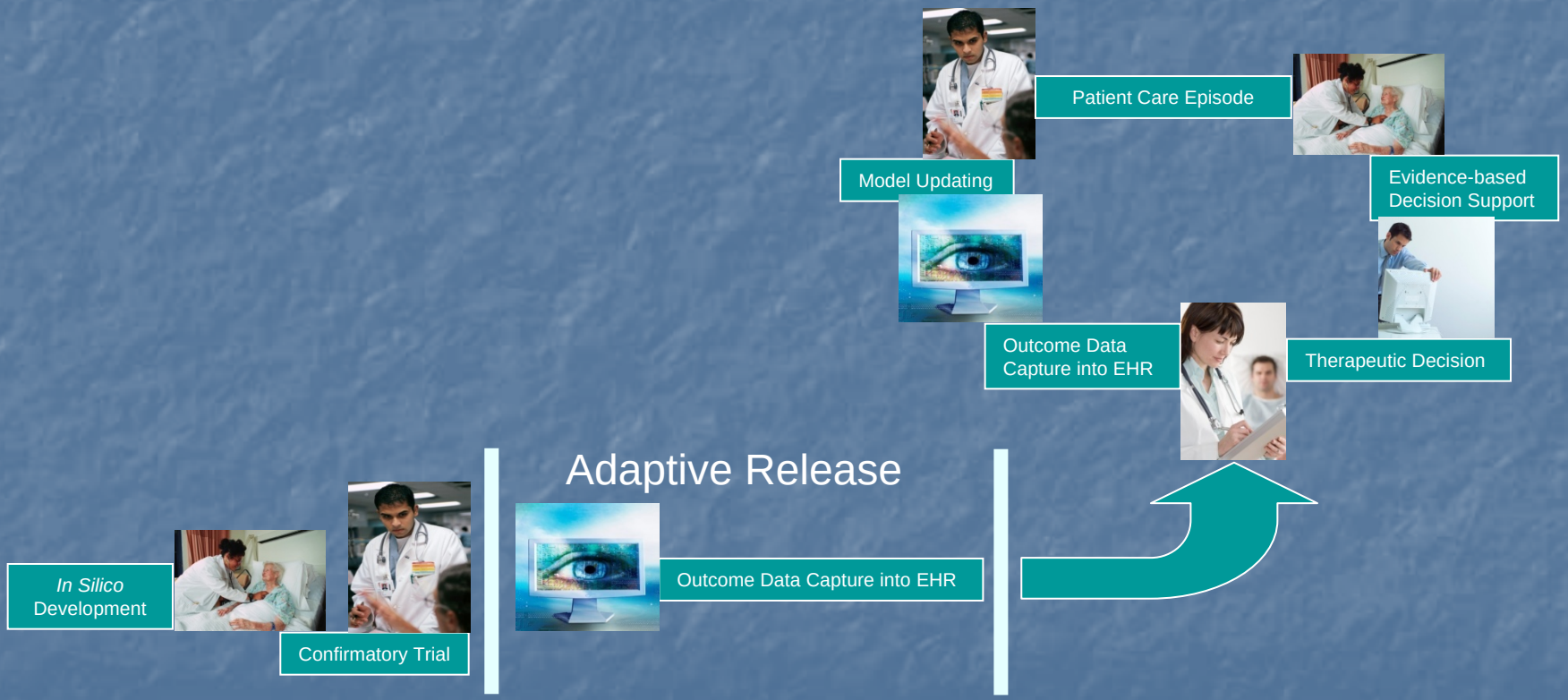
Therapeutic Decision



Outcome Data Capture into EHR

Model Updating

...and a Learning Development System



Requires a Brave New World of Future Partners

Pharma and Biotech

HUMANA. Guidance when you need it most

WELLPOINT

KAISER PERMANENTE

Payers

Patient

Diagnostic/Device

THE CLEVELAND CLINIC

Duke UNIVERSITY

MayoClinic.com Tools for healthier lives

Providers

Google

Technology Providers

CMS Centers for Medicare & Medicaid Services

AHRQ

NATIONAL INSTITUTES OF HEALTH

FDA Centennial 1906-2006

U.S. Food and Drug Administration

U.S. Department of Health and Human Services

Government Agencies

Thank-you

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