# Paving the Way for Personalized Medicine

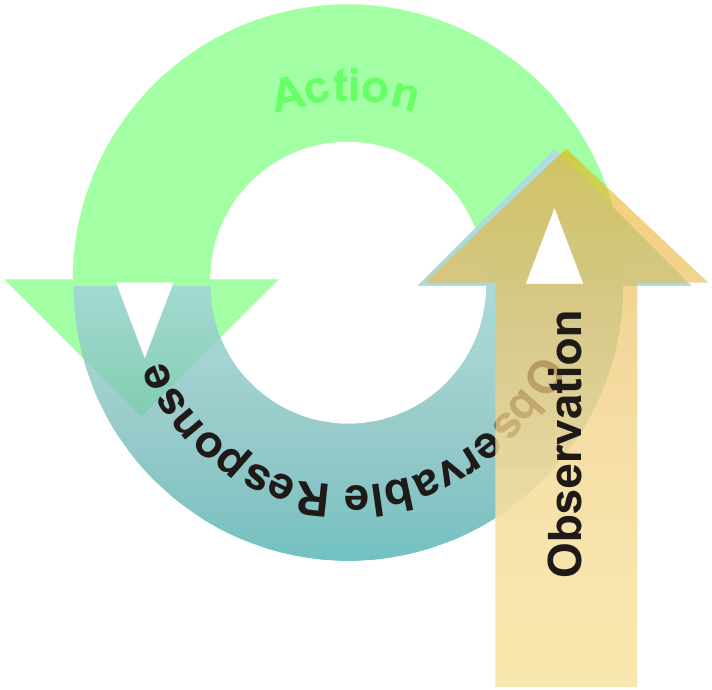
## SFEE's Role in the New Era of Medical Product Development

# Personalized Medicine

"If it were not for the great variability among individuals, medicine might as well be a science and not an art"

**Sir William Osler, 1892**

# Old Paradigm: Trial and Error Medicine

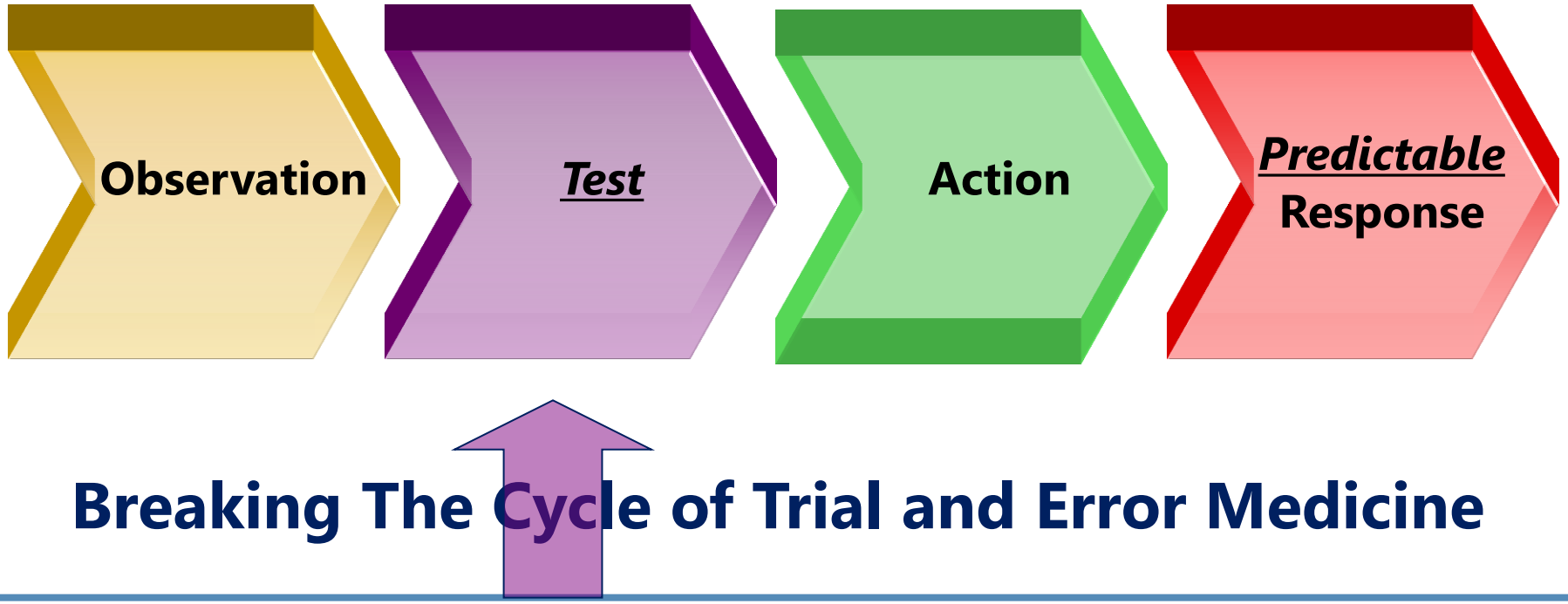



Successful When it Leads to Innovation and Improves Standard of Care.

Fails When We Settle for "Trial and Error" Medicine *AS* the Standard of Care.

# New Paradigm: Personalized Medicine

## *Linking Tests to Action and Therapy*



# Personalized medicine takes into account individual genetic differences

- Traditionally, doctors used:
  - Family history
  - Socioeconomic circumstances
  - Environmental factors

- Now:
  - genomic/genetic testing
  - proteomic profiling
  - metabolomic analysis (study metabolites at microcellular level)

# Pharmacogenetics

- Study of genetic variation that gives rise to different responses to drugs
- It is estimated that genetics can account for 20 to 95 percent of variability in drug disposition and effects.
- Nongenetic factors include: age, organ function, concomitant therapy, drug interactions, and the nature of the disease

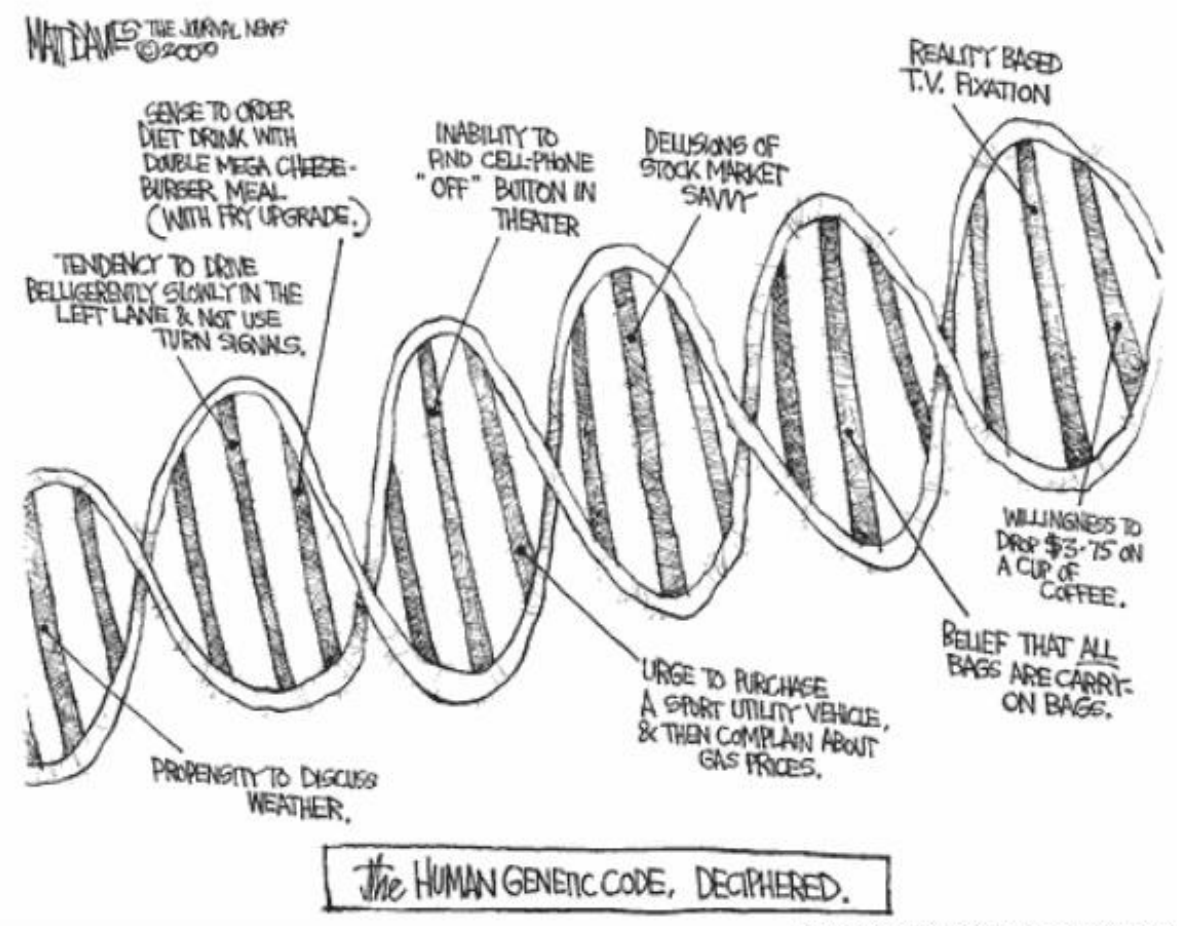
# Personalized medicine ~~today~~ yesterday

- Cytochrome P450 genotyping test
  - Enzyme group 'cytochrome P450' (CYP450
  - Many types of medications(including antidepressents, anticoagulants, proton pump inhibitors, etc)
  - Determine dosing and effects of these drugs.
- Thiopurine methyltransferase test
  - Thiopurine
  - Thiopurine methyltransferase (TPMT)
- UGT1A1 TA repeat genotype test
  - Irinotecan (Camptosar)
  - UGT1A1 enzyme
- Dihydropyrimidine dehydrogenase test
  - 5-flourouracil (5-FU)
  - Dihydropyrimidine dehydrogenase enzyme
  - Responsible for breaking down 5-FU

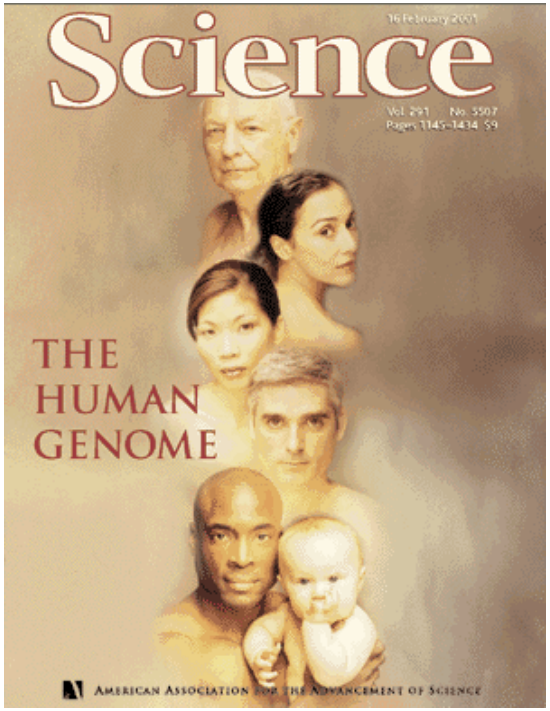
# Human Variation

- In human beings, 99.9 percent bases are same.
- Remaining 0.1 percent (~3M bases) makes a person unique.
  - Different attributes / characteristics / traits
    - how a person looks,
    - diseases he or she develops.

- These variations can be:
  - Harmless (change in phenotype)
  - Harmful (diabetes, cancer, heart disease, Huntington's disease, and hemophilia )
  - Latent (variations found in coding and regulatory regions, are not harmful on their own, and the change in each gene only becomes apparent under certain conditions e.g. susceptibility to lung cancer)


MATT DAVIES THE JOURNAL NEWS ©2000
SENSE TO ORDER DIET DRINK WITH DOUBLE MEGA CHEESE-BURGER MEAL (WITH FRY UPGRADE.)
INABILITY TO FIND CELL-PHONE "OFF" BUTTON IN THEATER
DELUSIONS OF STOCK MARKET SAVVY
REALITY BASED T.V. FIXATION
TENDENCY TO DRIVE BELLIGERENTLY SLOWLY IN THE LEFT LANE & NOT USE TURN SIGNALS.
WILLINGNESS TO DROP $3.75 ON A CUP OF COFFEE.
BELIEF THAT ALL BAGS ARE CARRY-ON BAGS.
URGE TO PURCHASE A SPORT UTILITY VEHICLE, & THEN COMPLAIN ABOUT GAS PRICES.
PROPENSITY TO DISCUSS WEATHER.
The HUMAN GENETIC CODE, DECIPHERED.

# Why Now?
## *The Human Genome Project*


# Why Now?
## *Explosion of the "Omics"*

- Proteomics
- Allergenomics
- Bibliomics
- Biomics
- Cardiogenomics
- Cellomics
- Chemogenomics
- Chemoproteomics
- Chromatinomics
- Chromonomics
- Chromosomics
- Combinatorial Peptidomics
- Computational RNomics
- Cryobionomics
- Crystallomics
- Cytochromics
- Cytomics
- Degradomics
- Ecotoxicogenomics
- Eicosanomics
- Embryogenomics
- Enviromics
- Epigenomics
- Epitomics
- Expressomics
- Fluxomics
- Fragmentomics
- Fragonomics
- Etc…

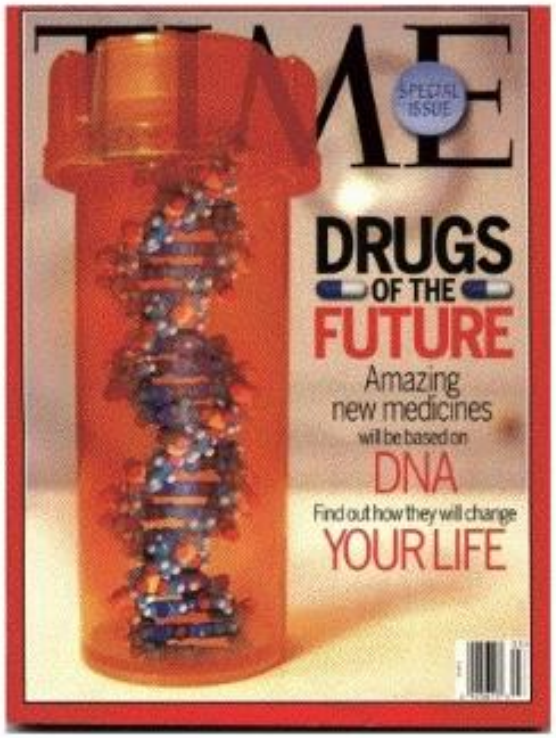
*http://www.genomicglossaries.com*

# Personalized Medicine
## *Why is it Important?*

***Diagnosis Save Lives***

***Diagnosis Save Money***

# Personalized Medicine




The ability to offer

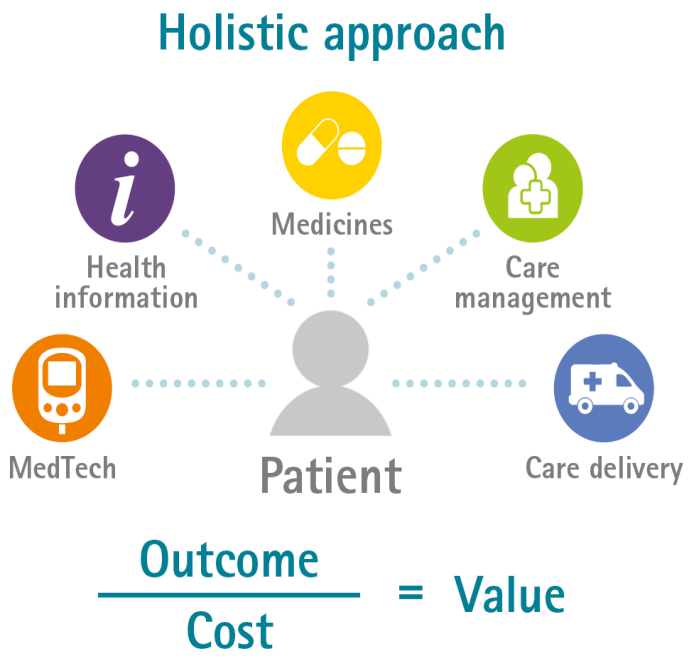
- **The Right Drug**
- **To The Right Patient**
- **For The Right Disease**
- **At The Right Time**
- **With The Right Dosage**

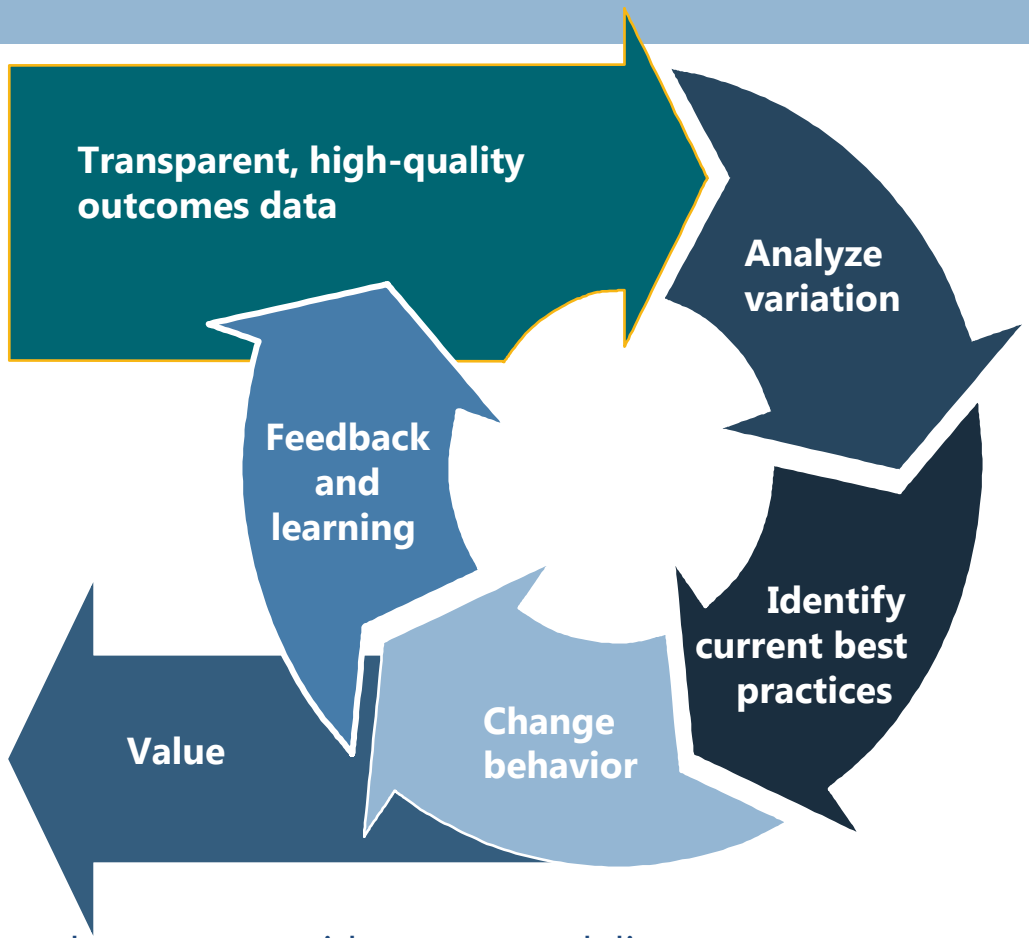
Genetic and metabolic data will allow drugs to be tailored to patient subgroups

# Benefits of Personalized Medicine

- Better **matching** patients to drugs instead of "trial and error"
- Customized pharmaceuticals may **eliminate** life-threatening reactions
- **Reduce costs** of clinical trials by:
  - Quickly identifying total failures
  - Favorable responses for particular backgrounds
- **Improved efficacy** of drugs

# The way to personalized medicine requires a holistic patient centric approach




Industry is keen to engage in the debate and to partner with payers to deliver outcomes driven **sustainable healthcare systems**

EFPIA

# SfEE's unique role & responsibility in personalized medicine

SFEE's mission is to protect and promote the health of all Greeks through:

- **Assuring that the right prevention and treatment is provided for the right patient at the right time**, whilst the pharmaceutical industry is under increasing pressure (ageing population, reduced investment , cuts in healthcare spending, increased participation of patients)

- **Driving a new and integrated approach**, with engagement and coordinated co-operation between all key stakeholders in the delivery of healthcare today

- **Focusing on research and innovation via defining the research priorities adopting innovative clinical trial design and establishing Greece as a leader in medicines development.** These are after all the key elements that support the aim of the European Health 2020: "to improve the health and well-being of populations, reduce health inequalities, and ensure sustainable people-centered health systems"

# From discovery to delivery

Four major areas have been identified where an integrated approach will have significant impact on increasing the probability of success and reducing the overall cost of new medicines:

**1. Target identification and biomarker research** *(efficacy and safety)*

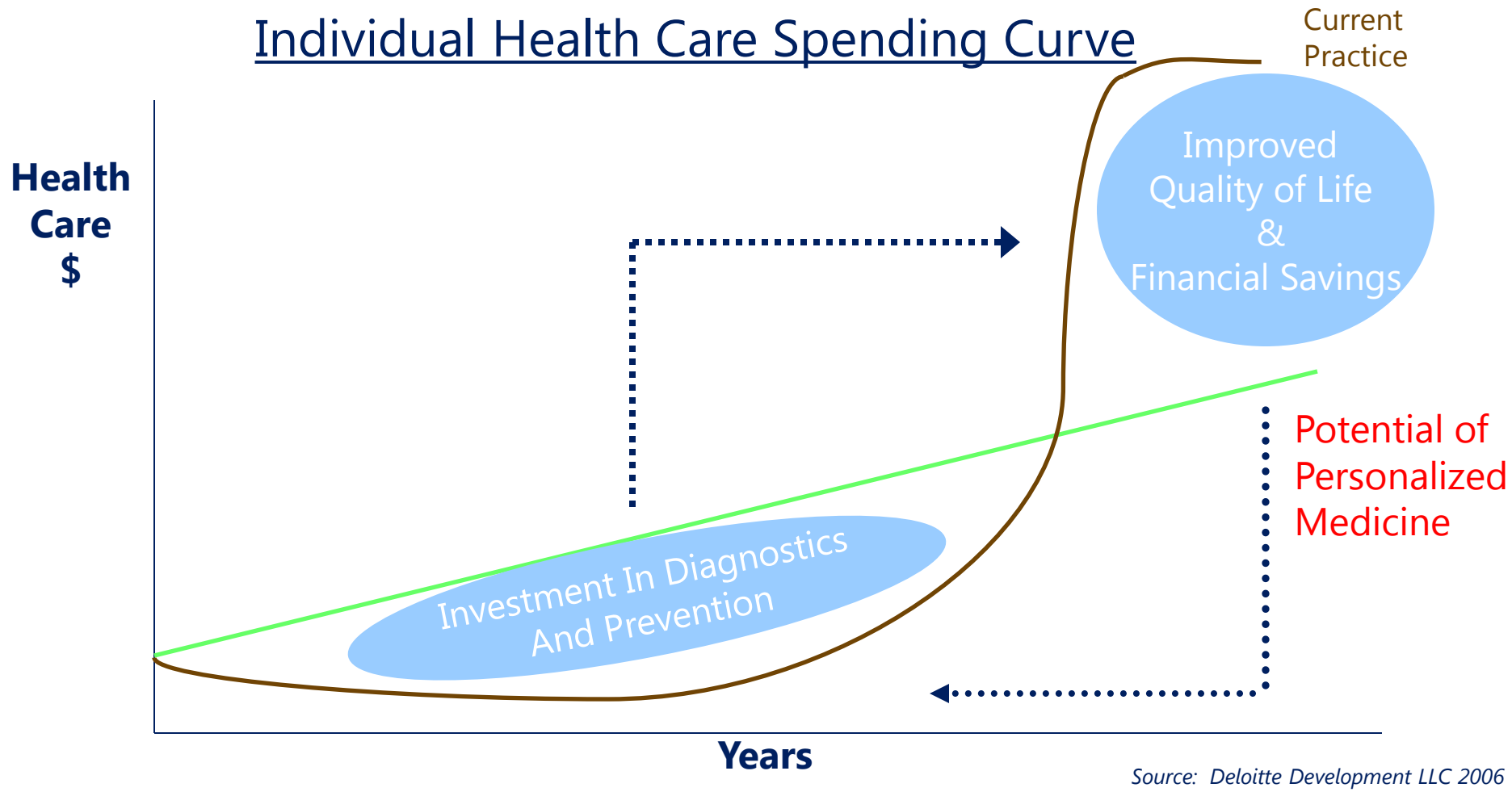
**2. Driving the adoption of innovative clinical trial design**, *development of new patient focused clinical outcome measures; new clinical trial paradigms to support the evaluation of benefit/risk in small numbers of stratified patient populations; and the development of infrastructures for the collection and sharing of trial data*

**3. Emphasis on Innovative Medicines**

- *Preventive medicine*
- *Medicines for areas of high public health concern*
- *Patient tailored adherence programs*
- *Focus on vaccines*
- *Enabling Technologies*

**4. Successful implementation**, *through operational excellence in all phases of the value chain, from early research up to the regulatory process and the market*

# Future Health Care Spending




*Source: Deloitte Development LLC 2006*

# To conclude with…

*… It's far more important to know what person the disease has than what disease the person has*

*– Hippocrates*