

Enhancing Development of Novel Medical Products and Clinical Applications

**Neal H. Cohen, MD, MPH, MS
Professor, Anesthesia and Medicine
Vice Dean, School of Medicine
Director, International Service
University of California, San Francisco**

Disclosure

- **No financial disclosures**
- **No conflicts of interest**



PATIENTS & CITIZENS
Individualized Care & Prevention Options

**UCSF PRECISION
MEDICINE PLATFORM**



BIOMEDICAL RESEARCH
New Correlations
New Hypotheses
New Transdisciplinary Teams



CLINICAL MEDICINE
New Diagnoses
New Therapy Implications
New Health Outcomes

Enhancing Product Development - Challenges and Opportunities

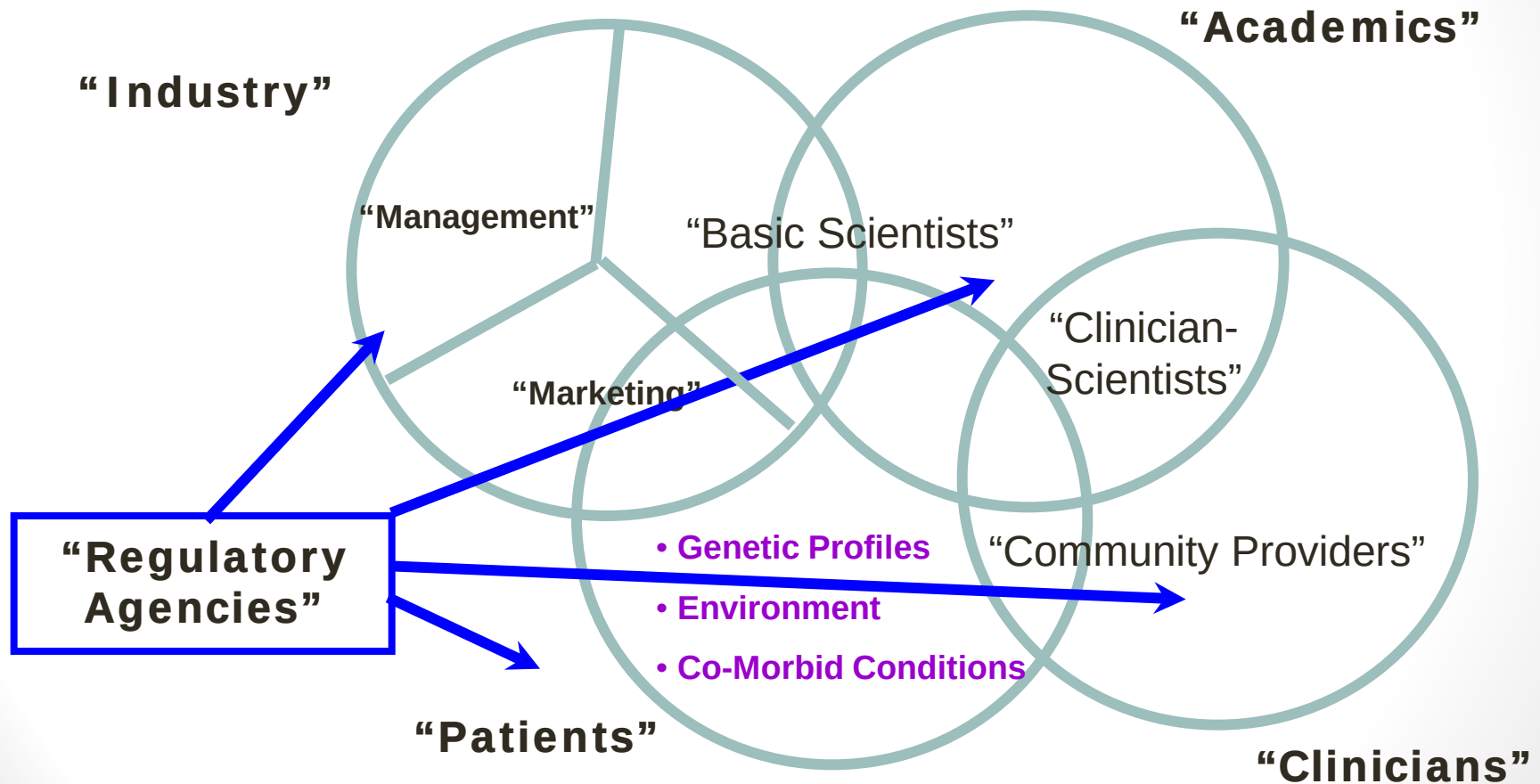
■ Challenges

- Competitive Environment
- Conflicts – both real and perceived
- Intellectual property
- “Academic” Freedom (Autonomy)

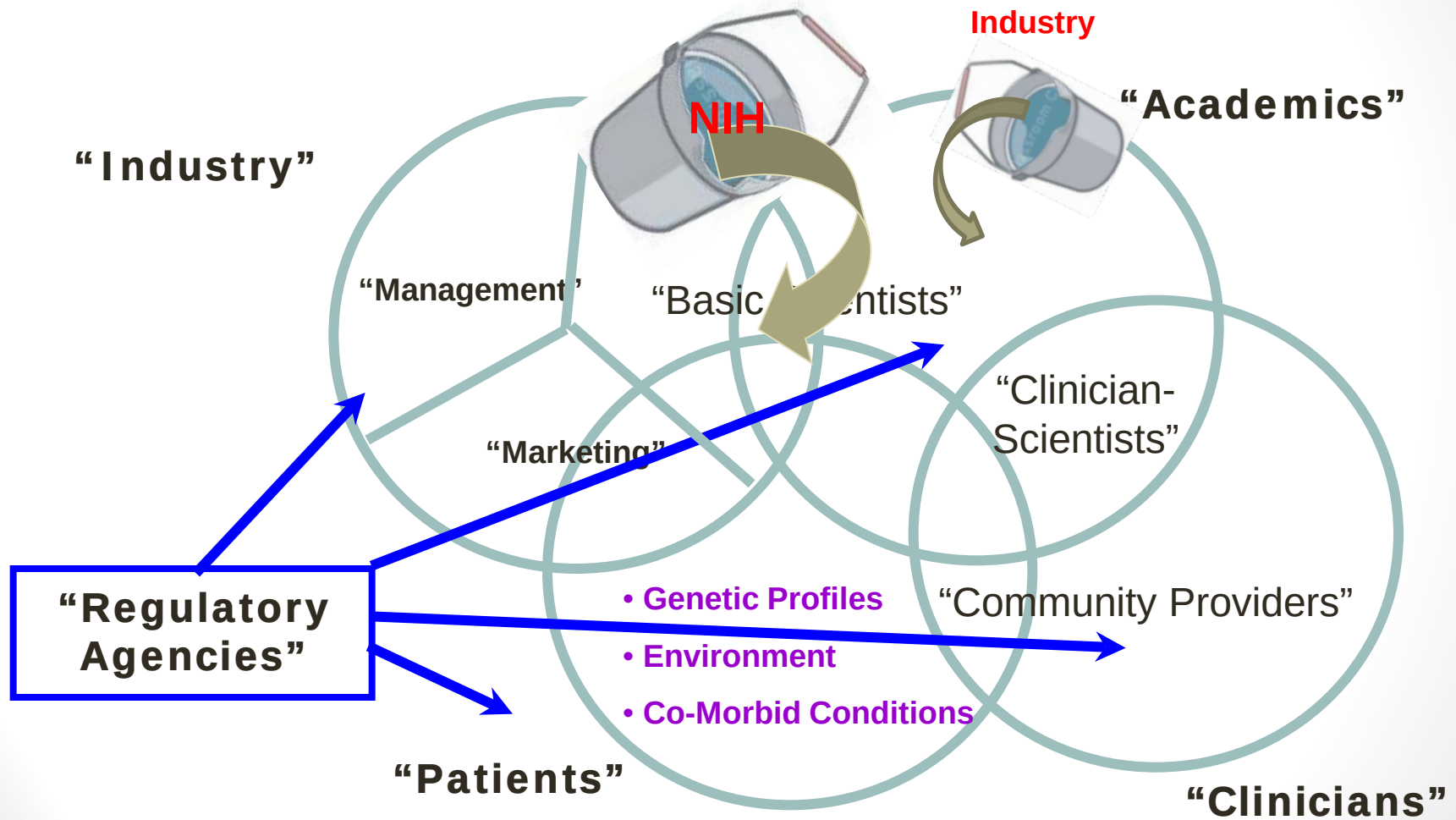
■ Opportunities

- Manage conflicts
- Create new models for academic industry relationships

Industry Academic Relationship



Industry Academic Relationship



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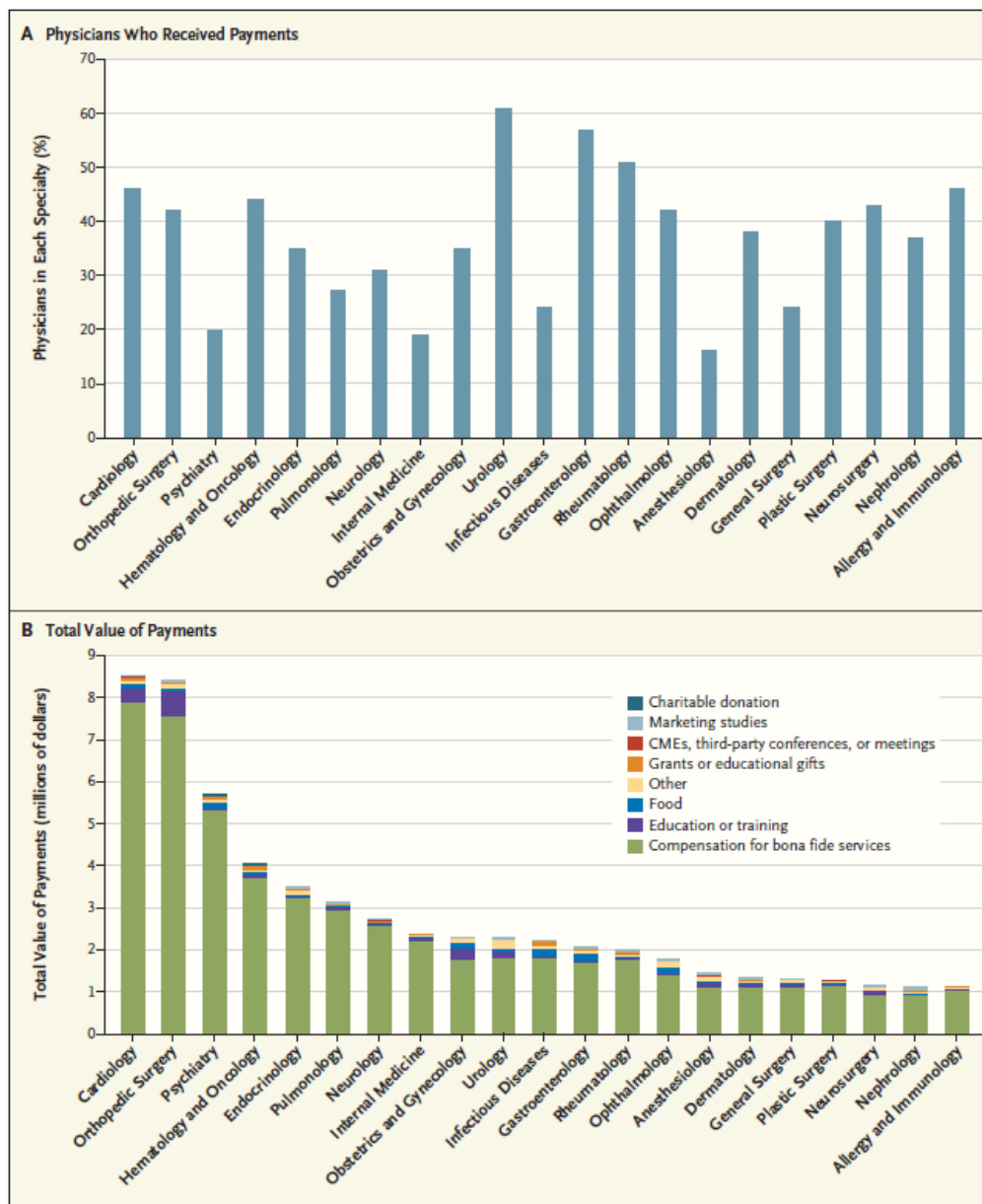
Faculty get mixed messages

- Create and disseminate new knowledge
- Secure extramural research support (with ICR)
- Commercialize advances
- Transfer knowledge, technology (IP, Licensing)
- Create New Businesses
- Utilize new technologies, drugs to benefit patients

Industry Academic Relationship

While at the same time...

- **Avoid conflicts of interest or commitment**
- **Protect intellectual property**
- **Ensure academic freedom**
- **Be transparent**
 - **Report on all activities for which there is a potential, real or perceived conflict**
 - **To whom?**
 - **At what cost?**



Percentages of All Licensed Massachusetts Physicians in Each Specialty Who Received Payments (Panel A) and Total Value of Payments Received by Such Physicians, According to Specialty (Panel B), 2009–2011.

Data include only those specialties registering total payments of more than \$1 million.

Kessleheim As, et al. NEJM 368;22, 2013

“Transparency”

Disclosure Requirements

- **Disclosure Requirements are challenging – and confusing – to some...**
- **Conflict of Interest Disclosures Differ**
 - **Administrative Roles**
 - **Research**
 - **Clinical Care**
- **Faculty Compensation Plans**
 - **Internal roles and responsibilities**
 - **External relationships**

Penny Pritzker

The \$80 Million “Clerical Error”

- **Pritzker underreported 2012 income**
- **Earnings related to Pritzker’s role managing family trust**
- **\$54 million in offshore fund based in the Bahamas**

Institutional Conflicts

- Conflicts of Mission
- Create *and disseminate* new knowledge
- Academic standing (NIH, US News)
- Intellectual Property
- Royalties
- Philanthropy (including naming opportunities)
- Outreach Efforts
 - Community Service
 - Board Participation



“Less scrutiny at institutional level”

Universities Struggle with Falling Royalties

Jens Krogstad; USA Today

November 25, 2012

- Universities profit from “breakthroughs”
- Income from royalties provide critical support for the academic missions
 - Northwestern University led the U.S. with **\$191 million** in licensing income in 2011
 - Of universities that earned more than \$2 million in royalties in 2009, the University of Minnesota saw the biggest drop in revenue

Industry Conflicts

- **Control over intellectual property**
- **High cost of product development**
- **Regulatory burdens**
- **Balance of “academic” freedom, scientific integrity with need to commercialize advances, acknowledged need for collaboration with university faculty, clinicians**

And Other Organizations are Not Immune...

- **Government Agencies**
 - Food and Drug Administration
 - National Institutes of Health
 - Department of Defense
 - Veterans Administration
 - Centers for Medicare and Medicaid Services (CMS)
- **Commercial Payors, Health Plans**

The Ongoing Debate...

“Patients will continue to be at risk for potential harm until physicians themselves stop participating in these relationships [with industry].”

**Robert Pearl
CEO, Kaiser Permanente
WSJ, 2013**

Getting the Relationship Right!

“We’re taught to distrust the physicians and university researchers who consult the most with industry, yet it’s often these experts who are the smartest scientists or the most experienced clinicians.”

“There is a way to cultivate, not demonize, collaboration between physicians and [industry]”

Shaywitz, D: The Atlantic; 2013

Where Can We Go From Here?

Enhancing Academic-Industry Interaction

- **How do we maximize benefits *and* minimize risks?**
- **What is the right balance in terms of collaboration and coordination of activities?**
- **How can we optimize the relationship while continuing to hold investigators, academic institutions, industry and government accountable?**

Creating the Right Balance

- **Address the conflicts**
- **Ensure transparency, responsibly**
- **Create new models that enhance research and clinical collaborations**

Addressing the Conflicts

- **Acknowledge them**
 - Define “conflict” – both real and perceived
 - “Manage” the conflicts
 - Human subjects protection paramount
- **Disclose relationships**
 - Transparency is essential
 - Economic relationship
 - *Critical value of collaboration*
 - Create a *single template using standard definitions*
 - “Informed” consent (where appropriate)

Physician Payments Sunshine Act

Reporting Requirements

- Designed to *help patients make informed decisions and discourage financial relationships that inflate health care costs*
- Mandates disclosure for all transfers of value to physicians and teaching hospitals
- Compliance cost ~ \$1billion over 5 years
- Public reporting under National Physician Payment Transparency Program (2014)

But Will Disclosure Work?

- **Public reporting of relationships between academics, industry and government is important – and may discourage some behaviors**
- **Impact of disclosure conflicting**
 - Both data and message implied by it are complicated
 - Limited data suggest that behaviors may not change
 - Patient decisionmaking impacted by other, more important issues
 - Implications on decisionmaking or quality of science unclear
- **Difficult to differentiate the desirable from undesirable implications**
 - Reporting misrepresents the nature and value of the relationship
 - Reporting must be put in context

Industry-Academic Collaborations

Creative Alternatives

- **Break down silos between industry and academics**
 - New models for precompetitive collaboration
 - Open innovation research networks (compound libraries, screening facilities, personnel sharing)
 - Incubators
 - Provide academic “credit” for industry relationships
- ***Manage the relationship***
 - Negotiate master agreements
 - Define oversight structure
 - Share “credit” for discovery
 - Share financial risks and benefits

Model for Industry-Academic Collaboration



Academic Industry Collaborations

- **Accelerated Drug Development**
 - Athena Project (Breast Cancer)
 - Lung Cancer (Small Cell)
- **Technologic Innovation**
 - Fetal Therapy
 - Magnetic Applications
 - Pectus excavatum
 - Bowel anastomoses

Faculty - Industry Research Consulting Program

- **Changes the nature of interaction between faculty and industry**
 - University becomes party to historically independent consulting relationships
 - Lowers barrier to partnership - single point of contact; matchmaking
 - Ensures compliance with regulatory and legal requirements, University policy; protects intellectual property
- **Upholds academic mission and highest ethical standards**
 - Protects faculty from creating unrecognized conflicts
 - Provides resources to expedite consulting process
 - Maximizes University's opportunities, particularly in clinical trials, product development

UCSF Center for *dHealth Innovation*

- Public private partnership
- Leverages UCSF strengths in clinical care, health sciences discovery, education, and innovation with industry expertise in development, manufacturing, and commercialization
- Focus on developing standards-based, open platforms for *data exchange* and *incubating dHealth start-ups to commercialization*
- Foster clinical and translational informatics to support Precision Medicine



The Health eHeart Study™

Using big data to reduce heart disease

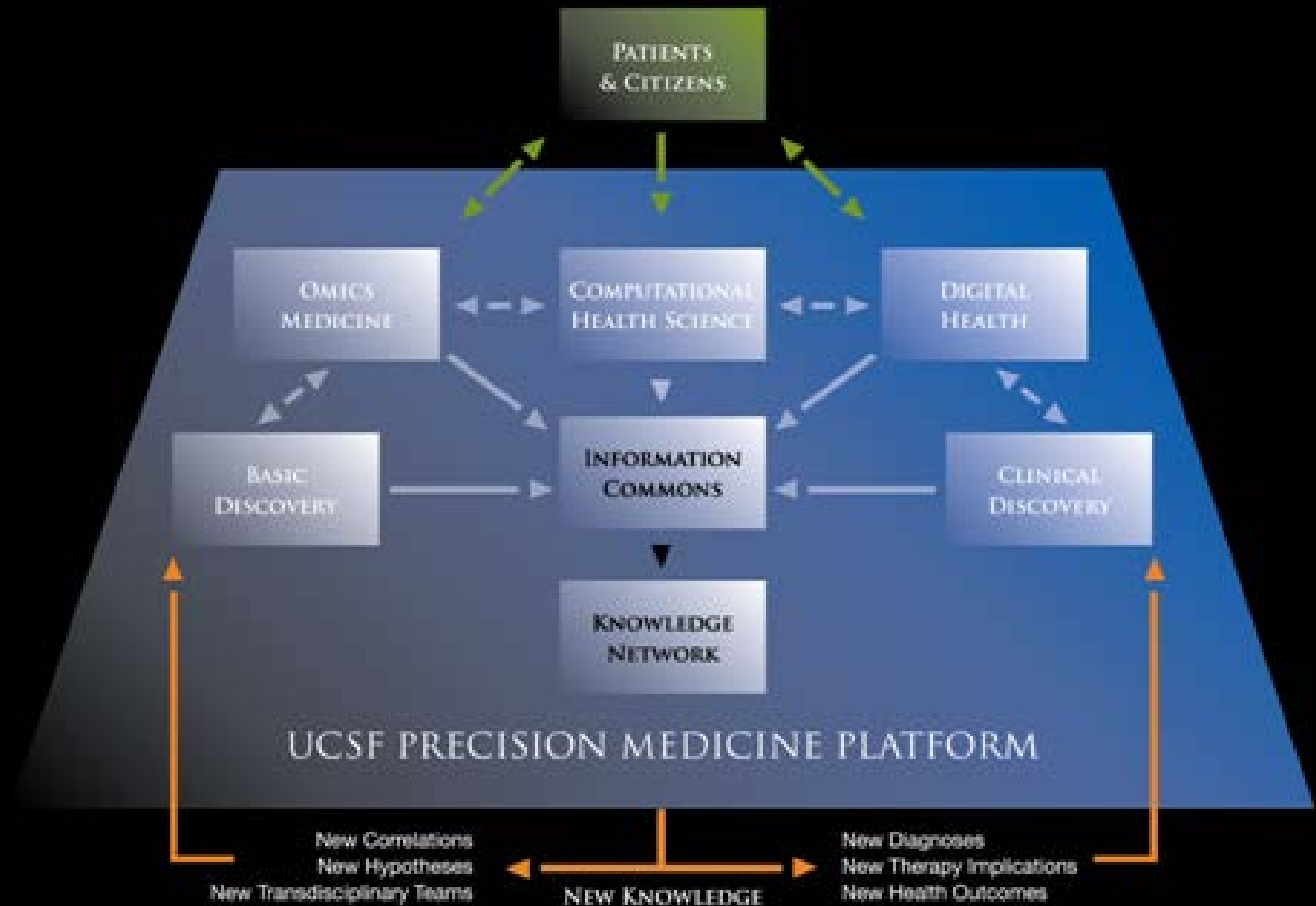
- **Social media-based clinical trials and therapeutic management platform**
- **Patient and device recorded data and surveys**
- **Genetic and blood analysis with specimen banking**
- **Device integration**
 - Heart rate and rhythm, heart rate variability, oxygen saturation, temperature, volume status, etc.
- **Geo-fencing to detect health care interactions**
- **Rapid creation of large (10^{4-5}) cohorts for registries, clinical trials**
- **Framingham trial at 100x the power and $1/10^{\text{th}}$ the time!**

Enhancing Product Development - *Next Steps*

- **Maintain commitment to core values**
- **Acknowledge value of academic-industry collaboration**
- **Identify and manage conflicts, both real and perceived**
- **Transparency and disclosure are important, but not sufficient**
- **New models for collaboration can be successful and not undermine integrity of science, trust, if done thoughtfully**

Enhancing Product Development - Challenges and Opportunities

Questions?





greendotdiabetes.org

- **Device-independent diabetes data platform**
 - Collects data from all BT enabled glucometers and insulin pumps
 - Consolidates silos of data onto a single platform
 - Provides dashboard for patients and providers
 - Mobile client, integrated communications
- **Integrates with EHRs**