Clinical Trials of the Future: A Systems Approach

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Disruption
Transformation
Where are we today?

• The clinical trial is the essential pathway through which a new agent can become a new medicine
• The process takes about 13-15 years and costs about $2.6 billion dollars for a single agent
• The endeavor is fraught with inefficiencies, despite innovative enabling technologies
• Major transformational change is needed
What lies ahead?

• Re-integration of healthcare and health research—realization of precision medicine
What lies ahead?

• Re-integration of healthcare and health research

• Continuing innovation and adoption of enabling technologies
Neural Networks

- It is self-learning
- It assumes
- It adapts
- It predicts
- It finds typical and untypical patterns
- It analyses and suggests the most valuable decisions for the user
What lies ahead?

• Re-integration of healthcare and health research
• Continuing innovation and adoption of enabling technologies
• Emergence of a new patient-centered approach to care and clinical research
What lies ahead?

- Re-integration of healthcare and health research—realization of precision medicine
- Continuing innovation and adoption of enabling technologies
- Emergence of a new patient-centered approach to care and clinical research
- Transformational change in the pharmaceutical industry and healthcare
The Problem

“The drug development model has not fundamentally changed in more than 50 years, when the Kefauver-Harris Amendments of 1962 established the current standard for the clinical testing of investigational drugs”

--Kenneth I. Kaitin, PhD
Tufts CSDD Director

- It currently takes $2.6 B and 12-15 years to get a single new drug to market
- The current fragmented process wastes in excess of $20 B annually
- Despite a 25-fold real increase in R&D expenditures, the number of new compounds approved each year is essentially unchanged, and prices have soared
We cannot achieve effective solutions using the same tools, processes and thinking that created the current ineffective approach...

The capability of a system is made possible only by the connectivity and inter-operability of its components—working together they achieve a synergy not otherwise possible.

The future of clinical research depends upon networks, and networks of networks—operating as neural nets.

Rob Califf,
FDA Commissioner
March 7, 2016
Systems: What do we mean?

• “A system is an organized totality, made of inter-dependent items that can be defined only by considering ones to the others and according to their place in this totality.”
  -- Ferdinand de Saussure

• “A system is an entity that maintains its existence through the mutual interaction of its parts to achieve a specific goal or goals.”
  -- Richard Wright
An Integrative System

• Integrative System
  – Examples of an integrative system are charitable organizations or business endeavors where individuals band together to accomplish some common desired objective or goal.
  – "Where you and I do something together because of what we both want to accomplish."
  – The greatest leverage is found in integrative systems when all the individual stakeholders are motivated by what they are endeavoring to create.

So what is a “smart system”?

- **Smart systems** incorporate functions of *sensing*, *actuation* and *control*.
- They are capable of *describing* and *analyzing* a situation, and making *decisions* based on the available data in a *predictive* or *adaptive* manner.
- In most cases the “smartness” of the system can be attributed to autonomous operation based on closed loop control, energy efficiency and networking capabilities.
Smart Systems

Input → Process → Output

Smart Sensors
Smart Systems
Smart Systems are everywhere—except in clinical research!
Data Silos in Healthcare and Health Research Impair Development of New Therapeutic Regimens and Safety

Healthcare
- Clinical Care PHI
- Clinical Research

Industry
- Pre-Clinical Data
- Clinical Trials & Safety Data

Regulatory
- Efficacy Data
- Safety Data
Realizing the Power and Opportunity of Big Data Requires Bridging these Silos through Technology and Collaboration

Integration
Aggregation
Analytics
Healthcare
Industry
Regulatory
Innovations in data and technology offer the promise to speed research advances and improve care delivery. But the science, data, and research results are trapped in silos, preventing faster progress and greater reach to patients. It’s not just about developing game-changing treatments — it’s about delivering them to those who need them.”

-- Joe Biden, VP
“Several cutting-edge areas of research and care — including cancer immunotherapy, genomics, and combination therapies — could be revolutionary. Innovations in data and technology offer the promise to speed research advances and improve care delivery. But the science, data, and research results are trapped in silos, preventing faster progress and greater reach to patients.”
Integrated Safety & Efficacy Data Vault

Clinical Trials Data
Genomic Data
Adverse Event Data
Personal Health Info
Prescription Data

“Mega Data”

Identity Management and Security

Analytics
- Retrospective
- Real-Time
- Predictive

Master Patient Index & Unique Patient Identifier

Health Care Providers
Clinical Investigators

Who got it?
Did it work?
Was it safe?
What side effects?
What interactions?
What toxicities?
Systems Development and Application

Accreditation

Study Site(s)
- Site Director
- Study Coordinator(s)
- Operations Manager(s)
- Data Manager(s)
- Investigator(s)
- Administrative Support Specialist(s)

Personnel

Facilities

Administration

Information Technology

Quality Management

Integrity

Recruitment and Enrollment

Performance & Clinical Data

Monitoring & Oversight

Analytics

Quality Management

Site-Based Information Management Systems
ACRES System Overview and the Apollo Collaboration Platform
ACRES—through and with its allies—is building a shared global system that

- *Leverages* stakeholder collaboration, innovation and investment to implement change
- *Promotes* and *improves* the use of existing tools, policies and processes rather than re-inventing
- *Facilitates* and *streamlines* clinical research while improving safety and quality
- *Reduces* waste, redundancy and inefficiency in the clinical trials process
- *Responds* fairly to the world's health needs

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**What is ACRES doing?**

2014 – Focused on developing a global collaborative network of stakeholders who understand that collaboration is the way to accelerate medicines development by enhancing performance and professionalism.

2015 – Focused on development and implementation initiatives using technologies and standards as a catalyst.

2016 – Focusing on implementation of deliverables for all stakeholders.

2017 – Focus on implementation and demonstrating ROI from deliverables.
“In times of change, ones ability to survive is determined by ones ability to adapt.” — Dr. Samuel Thier

This is just the beginning!