



**ACRES**

Alliance for Clinical Research Excellence and Safety



*Enhancing Safety, Quality and Efficiency in Medicines Development  
and Health Research through Systems Solutions*

# Translating Principles to Performance— Creating a Global System to Promote Responsible Conduct of Human Research by Physicians

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President and Chief Executive Officer, Co-Founder

# Medicines Development: A Complex Enterprise under Intense Environmental Pressures

## The Big Picture...



In a rapidly  
changing  
environment, the  
ability to survive  
is determined by  
the ability to  
adapt!

## Current Situation in a Nutshell

- Medicines development has been almost entirely proprietary and conducted largely in corporate silos, an approach fraught with inefficiency
- Clinical trials are not “global”—they are international
- “Harmonization” is simply a nice way to say “failure to standardize”
- Public respect for the endeavor has plummeted and participation is low
- One cannot keep doing things the same way and expect different results

# Principles for Physicians Engaged in Clinical Research

- Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications.
- Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

*Declaration of: Helsinki, 2013*

But, in reality....

- There are minimal formal professional training requirements for physician investigators.
- Most “physician investigators” do only one clinical trial during their career.
- Ethical lapses and scandals have tarnished respect for and confidence in the research enterprise at all levels.
- The stage is set and the time is right for fundamental systemic change!



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## Sites Matter!

“For too long, the industry has failed to recognize the importance and value of well-established, sustainable, high-performing research sites. They are a resource that we have undervalued. Now is the time for us to take a more systemic approach that promotes site productivity and sustainability...”

*--Briggs Morrison, MD*

*Vice-President for Global Medicines Development*

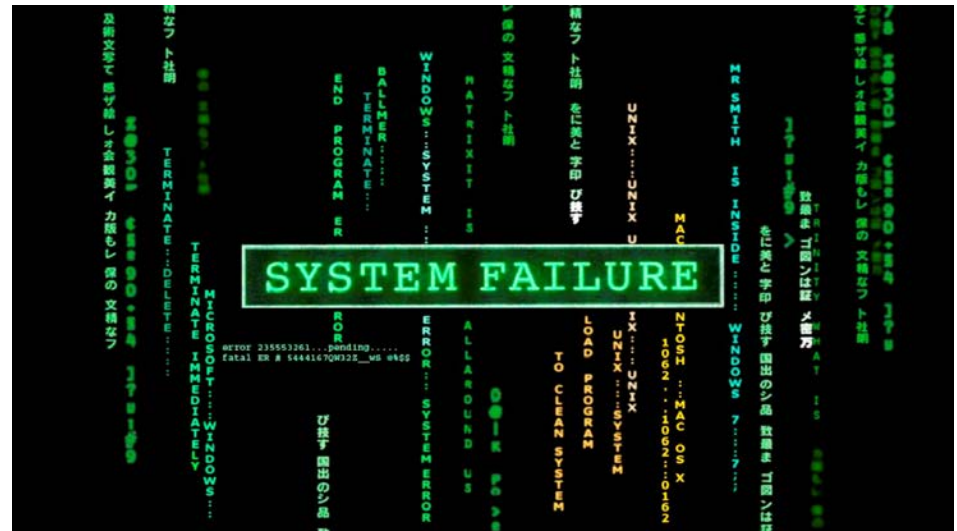
*and Chief Medical Officer, AstraZeneca*

*Member of the ACRES Board of Directors*

# It takes a crisis!

“The current approach to drug development is inefficient, ineffective and unsustainable.”

*Consensus DIA Europe, 2010*





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# What is ACRES?

A multi-sector alliance of like-minded  
organizations working collaboratively  
to build a shared  
Global System for Clinical Research



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# An 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, where all the individuals are motivated by what they are endeavoring to create.

# What is ACRES?

## **A neutral, not-for-profit organization operating in the public interest**

- a “home” for collaboration among Stakeholder Alliances
- an “incubator” for innovation
- an “adapter” of successful models and practices from other highly-regulated and complex research-focused industries
- a “coordinator” for multi-stakeholder activities
- an “integrator” for complex cross-cutting initiatives

# A Transformative Multi-Sector Alliance

ACRES—through and with its allies—is working to build an 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



## What are ACRES goals?

- The Alliance for Clinical Research Excellence & Safety is working to:
  - positively align ethics, scientific integrity and good business practices
  - provide appropriate opportunities and incentives to further the mission of medicines and device development globally
  - to ensure that clinical trials are conducted in a safer, scientifically sound, socially responsible and ethical manner that rewards all participants and stakeholders, including patients, everywhere

# ACRES Foundation Initiatives

Initial projects are underway in each of four operational domains where critical processes for research sites, sponsors, CROs, regulatory authorities, ethics committees, and research subjects intersect to achieve "clean data" with greater efficiency, safety and interoperability -- at the points where change is most needed.





# Ongoing Global Initiatives

- Promoting professionalism, performance and sustainability through competency-based education, training, and accreditation.
- Driving creation and adoption of standards and metrics through effective implementation of a shared technology infrastructure and informatics
- Fostering more effective and efficient ethical and regulatory oversight through standardization, innovation, collaboration, and stakeholder engagement
- Building an enterprise-wide culture that embraces safety as its highest priority and most valued asset



## ACRES Alliance Approach to Initiatives

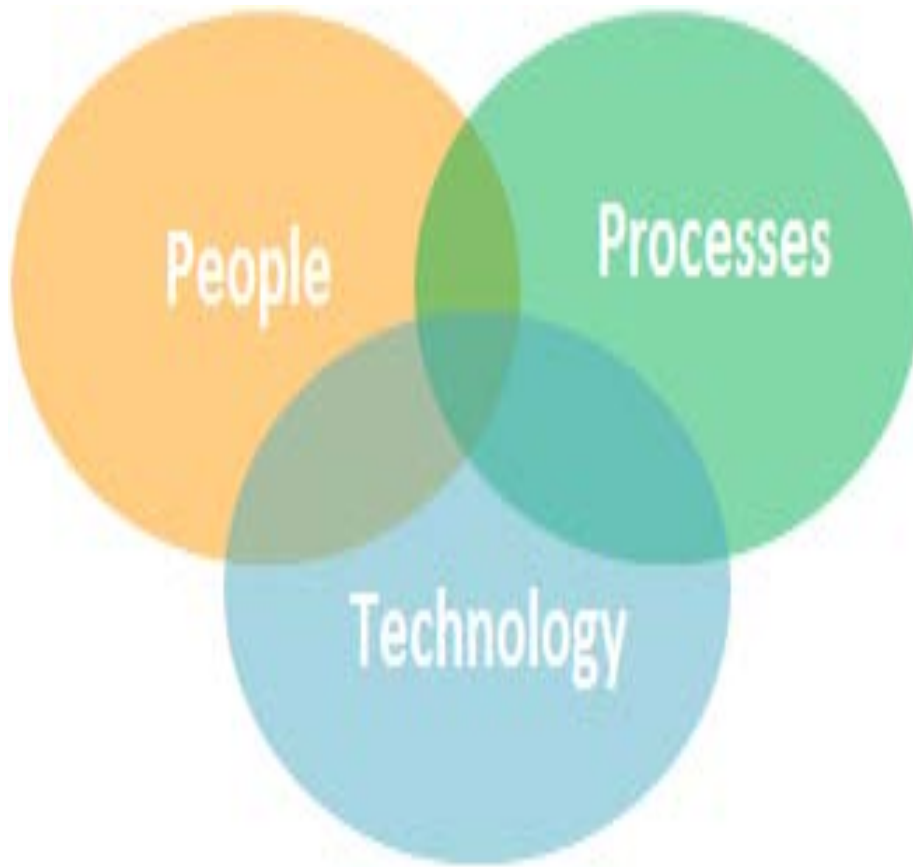
Each ACRES initiative is intended to leverage investments for the mutual benefits of all stakeholders – like-minded organizations and individuals driven by principles of inclusivity, integration, integrity and innovation to achieve effective implementation with close attention to eliminating waste, mitigating risk and learning from variation, while enhancing responsible ethical conduct of research and professionalism.

# Opportunities for Collaboration

- The WMA and ACRES share common beliefs that clinical research is highly-valuable and that it must be done in a responsible manner by well-trained, qualified investigators and research teams within an ethical framework and with effective oversight:
  - ◆ Competency-based guidelines for education and training for physician investigators during graduate and post-graduate medical education.
  - ◆ Pathways to professionalism for clinical investigators through professional certification as part of a program for global accreditation to recognize and reward excellence in clinical research.



# Fundamental Elements of an Enterprise System

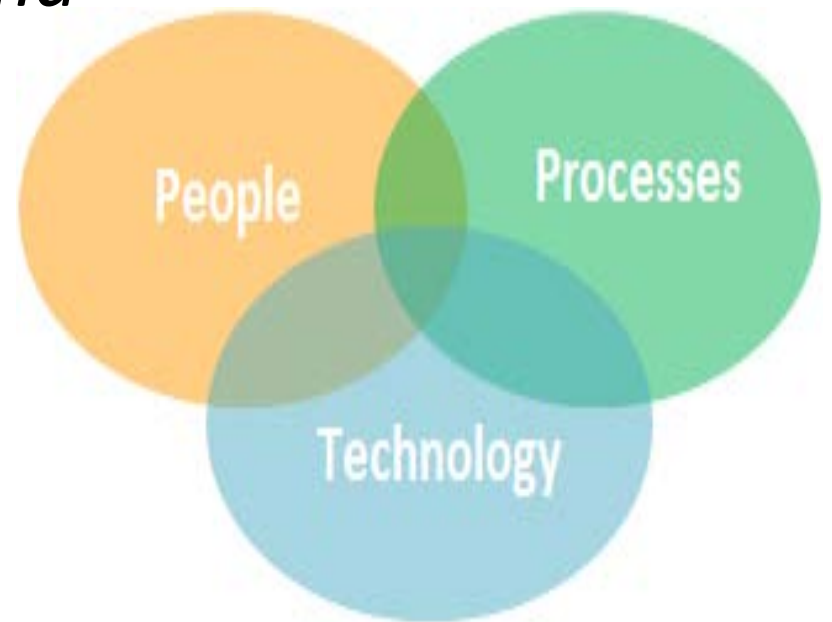


*“A system is an entity that maintains its existence through the mutual interaction of its parts to achieve a specific goal or goals.”*

**Richard Wright**

# Systems Thinking!

*Drug development is far behind other industries in the application of a system approach to standardize and integrate mission critical processes.*





# Current Drug Development Process from a Systems Perspective



In it's time, it  
performed  
adequately...

The times and  
the environment  
have changed !

# Successful Systems Models Do Exist

Other industries can help us envision a better future for Drug Development:

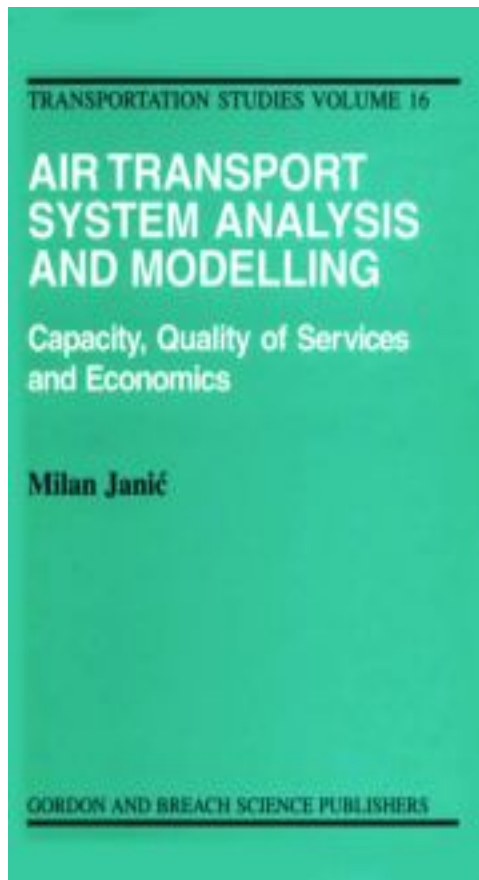
- Information Technology
- Transportation
- Communications
- Shipping

# The Systems-Focused Intelligent Organization



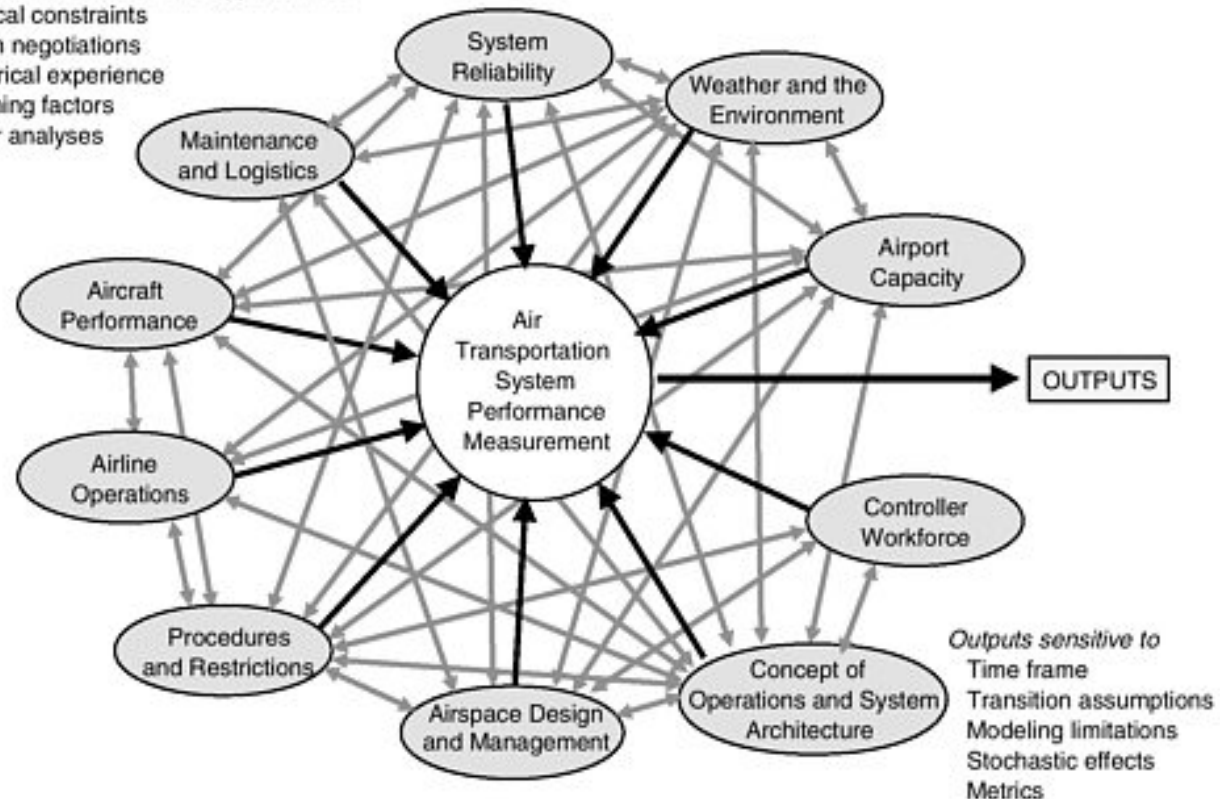


# Systems Thinking: The Global Air Transport System



*Inputs derived from*

Budget size and allocation  
 Technical limitations and opportunities  
 Political constraints  
 Union negotiations  
 Historical experience  
 Planning factors  
 Other analyses



# Current Drug Development Process from a Systems Perspective

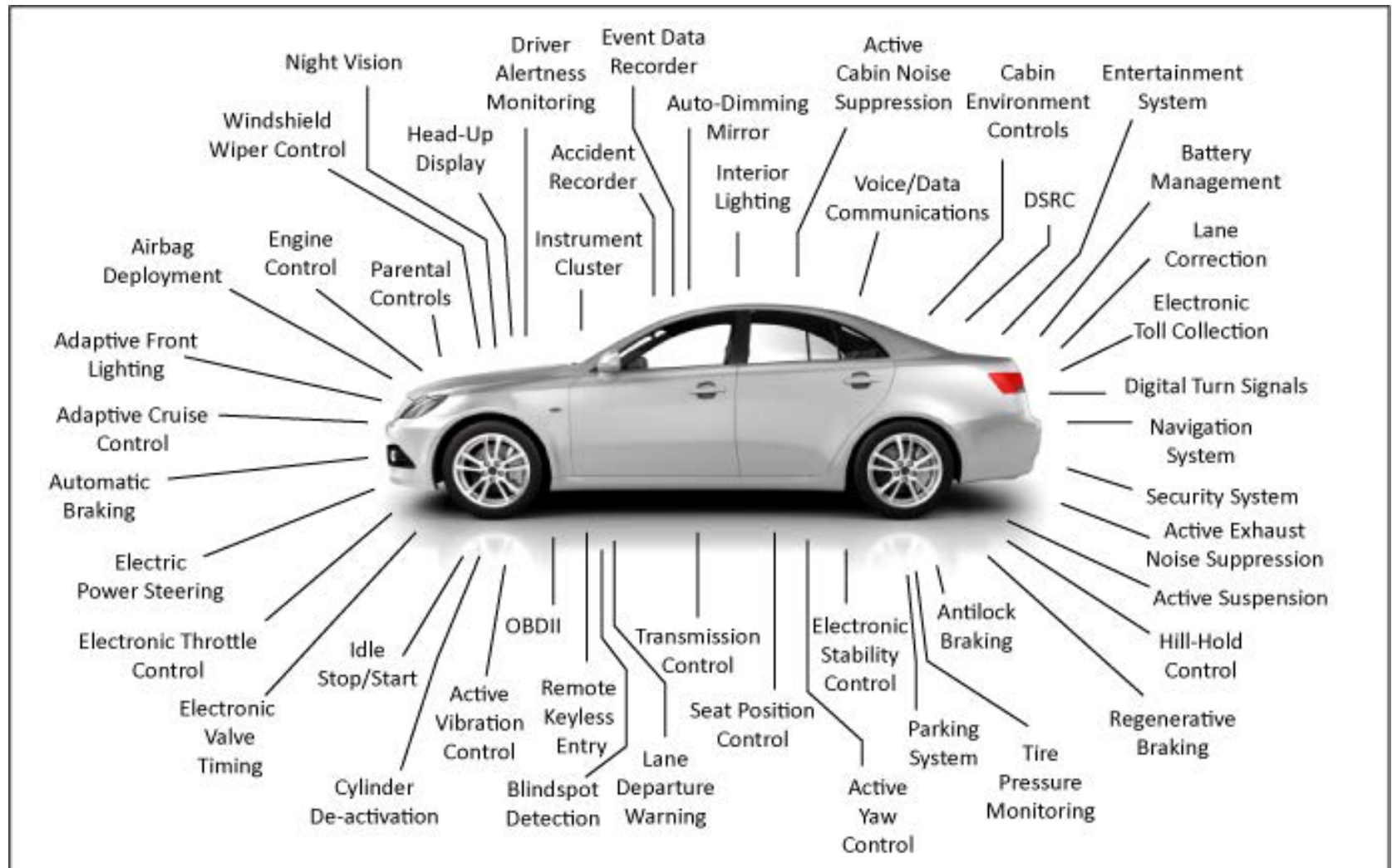


No matter how much we tinker with the parts, what we are left with has limited ability to perform adequately in today's demanding environment!

***Systemic*** change is necessary....

# How do we get there...?

## Systems Thinking!





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We cannot achieve effective solutions using the same tools, processes and thinking that created the current ineffective approach...



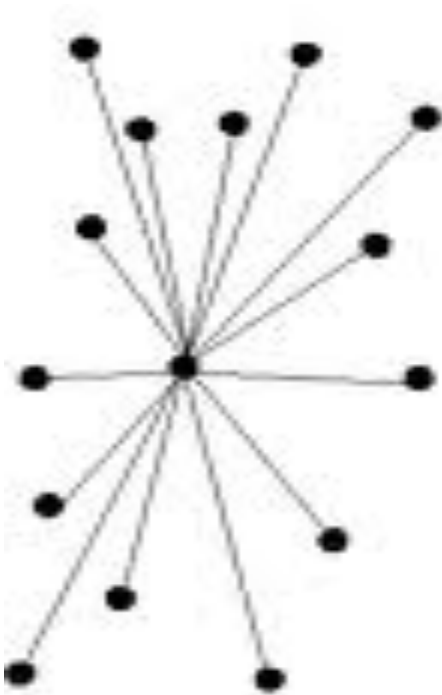
# Benefits of a Systems Approach

- Drive and reward standardization
- Drive regulatory simplification and compliance
- Promote and value professionalism
- Enhances performance
  - Increase efficiency
  - Reduce redundancy
- Promote and enhance safety
- Reduce costs and time-to-approval
- Promote investment in sustainable clinical research capacity in emerging nations and markets
- Align ethics and good business practices
- Increase transparency and improve public trust

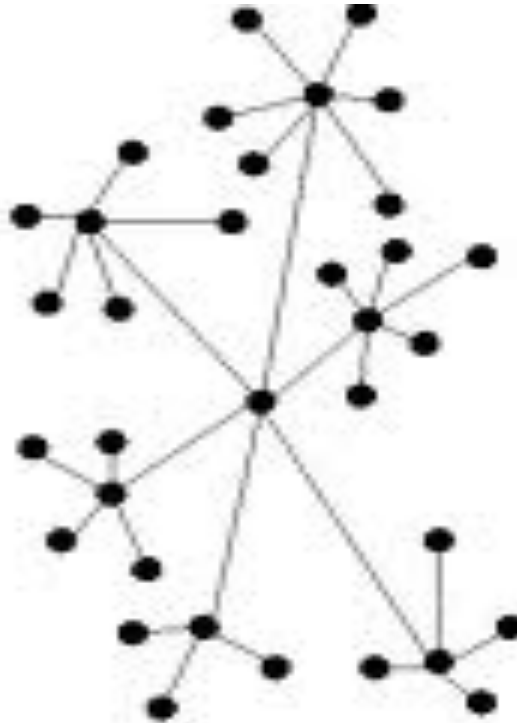
All stakeholders across all sectors of the enterprise must embrace systems thinking and collaborate for their mutual benefit...



# Network Systems Architectures



(a)



(b)



(c)



# ACRES Collaborative Information Technology Infrastructure

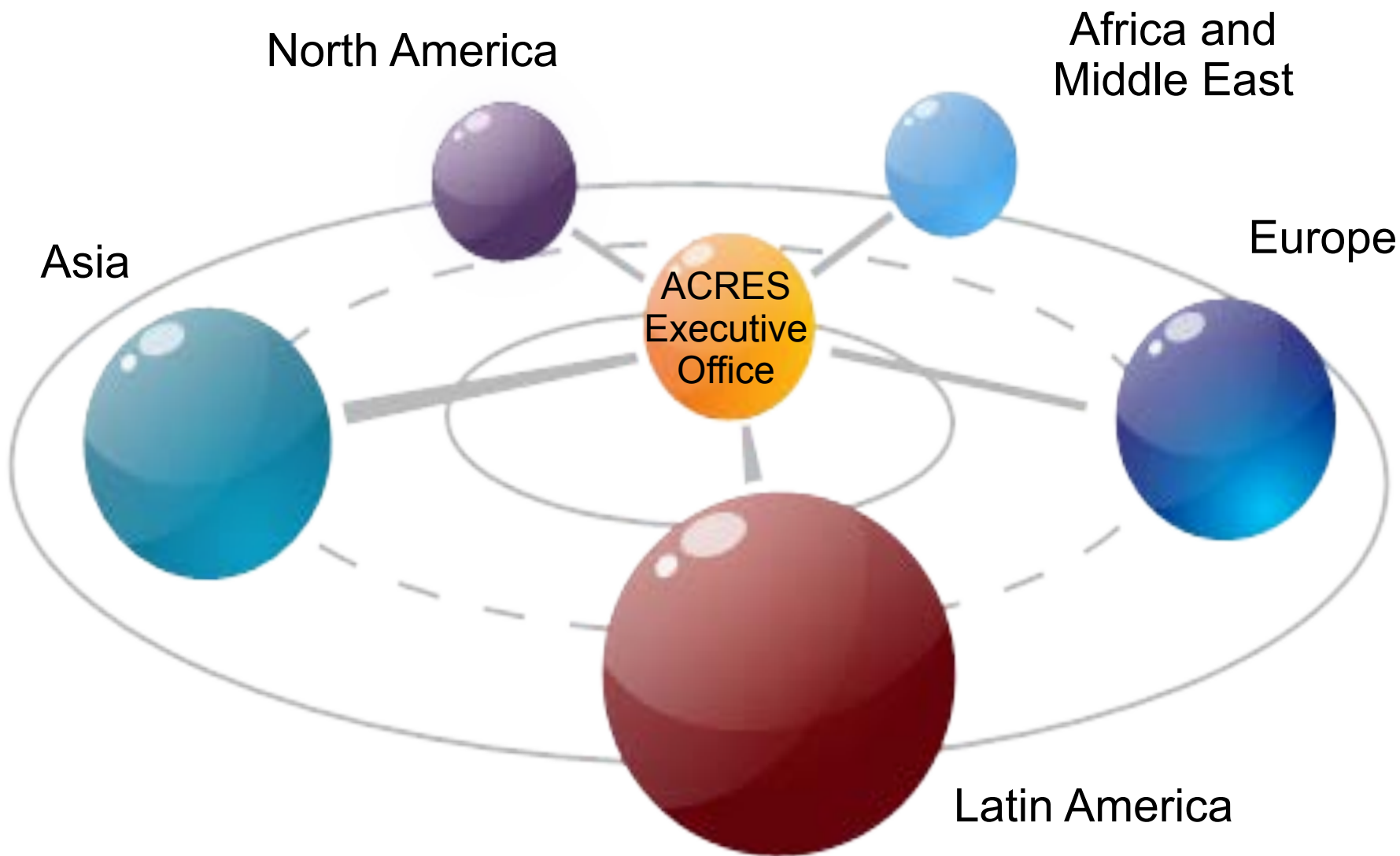
- Web-enabled, “cloud-based” integrated information system with a shared virtual data warehouse and knowledge engines
- System support/facilitation of all operations
  - Point-of-entry EDC and CTMS, including AE reporting and performance dashboard/metrics
  - SOP driven continuous compliance/quality control
  - Shared data-base for trial initiation and support
  - Remote risk-based quality management, safety and performance monitoring— “site optics”



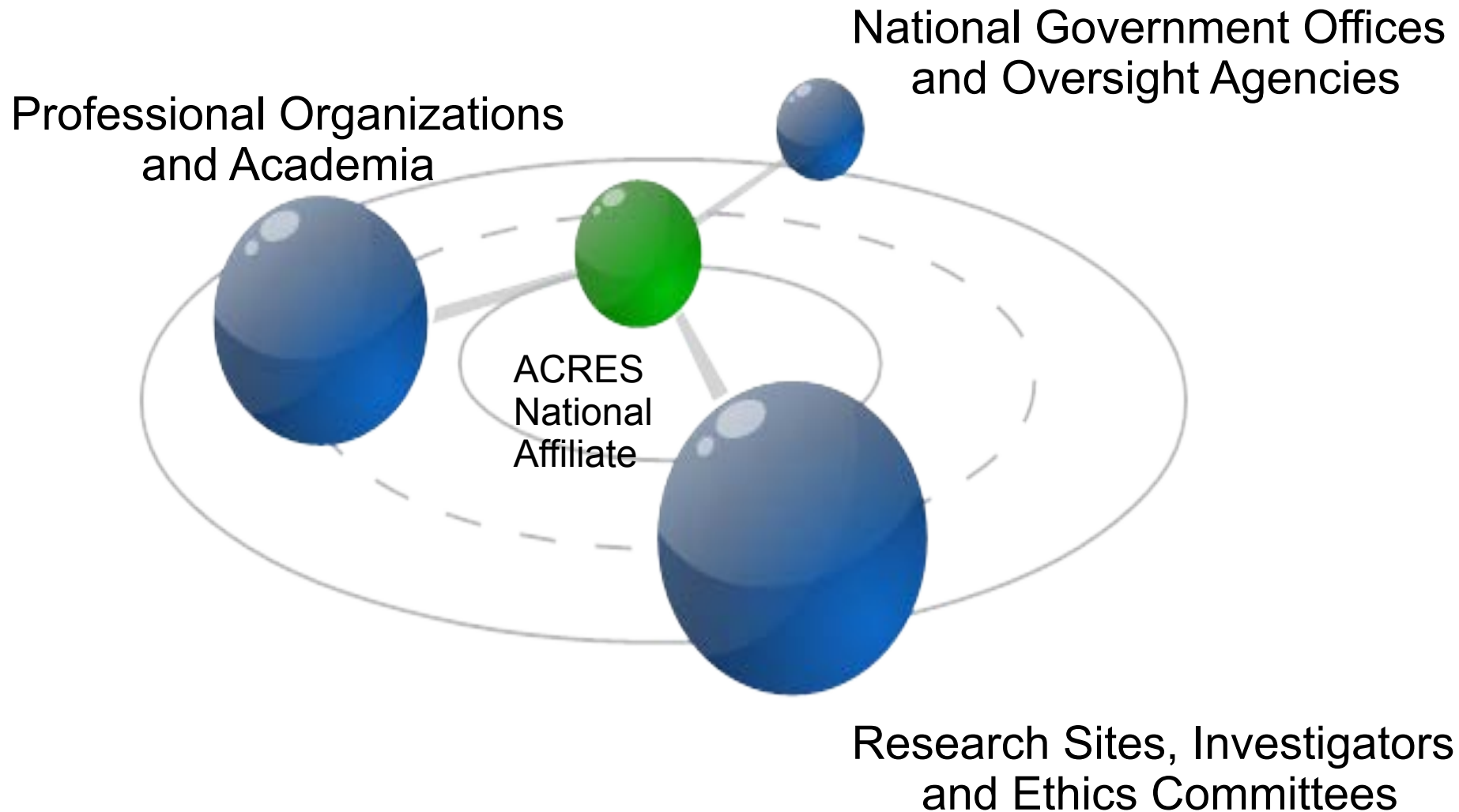
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## ACRES Global Headquarters and Regional Coordinating Centers



# ACRES National Co-Development Affiliates

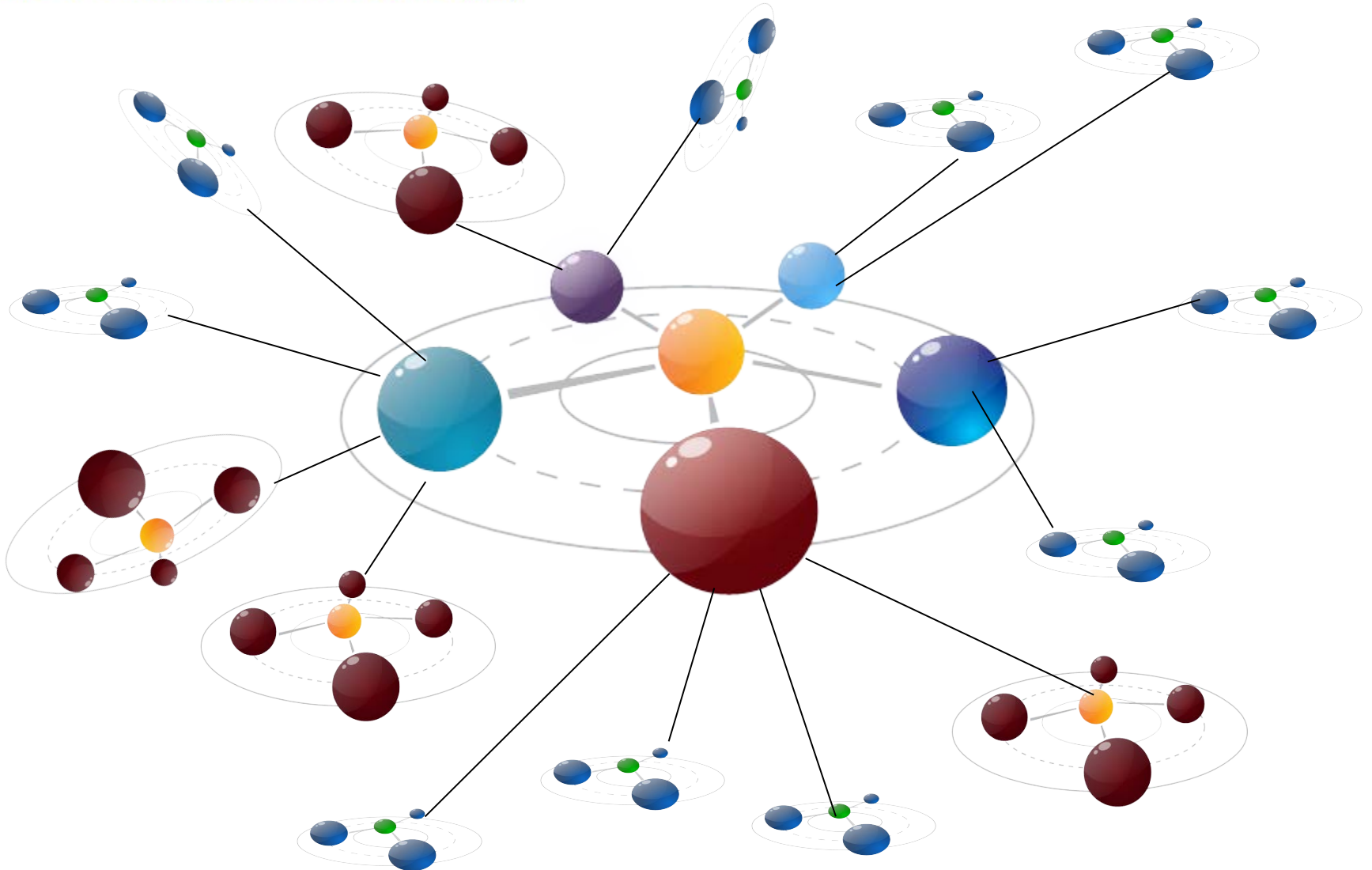




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## An Integrated Global Network



# ACRES Value Proposition

## Urgent Challenges

- Education and training
- Trial complexity
- Site selection
- Performance
- Monitoring
- Data management
- Pharmacovigilance
- Regulatory compliance
- Delays and redundancy
- Time to market
- Ethical review
- Misconduct
- Public confidence
- Economic pressures
- Global disparities

*More effective application (redirection) of existing resources to build a sustainable, shared “system infrastructure” will provide a handsome return on investment, economically and socially.*

**Current estimates of waste due to inefficiency and redundancy in the clinical trials process is approximately 30%**

**An effective system could realize *annual* savings in excess of 10 Billion Euro**

# Why ACRES?

- “Constructive transformation”
- Unique global integrated systems approach
  - Comprehensive
  - Inclusive
- Solution oriented--implementation focused
  - Established plan
  - Coherent strategy
- Multi-sector expertise, credibility and collaboration
  - Experience
  - Capability
  - Leadership



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*--building a global collaborative ecosystem for  
clinical research, together!*

<http://www.acresglobal.net>