Alliance for Clinical Research Excellence and Safety

About OMICS Group

OMICS Group is an amalgamation of Open Access Publications and worldwide international science conferences and events. Established in the year 2007 with the sole aim of making the information on Sciences and technology 'Open Access', OMICS Group publishes 500 online open access scholarly journals in all aspects of Science, Engineering, Management and Technology journals. OMICS Group has been instrumental in taking the knowledge on Science & technology to the doorsteps of ordinary men and women. Research Scholars, Students, Libraries, Educational Institutions, Research centers and the industry are main stakeholders that benefitted greatly from this knowledge dissemination. OMICS Group also organizes 500 International conferences annually across the globe, where knowledge transfer takes place through debates, round table discussions, poster presentations, workshops, symposia and exhibitions.

OMICS International Conferences

OMICS International is a pioneer and leading science event organizer, which publishes around 500 open access journals and conducts over 500 Medical, Clinical, Engineering, Life Sciences, Pharma scientific conferences all over the globe annually with the support of more than 1000 scientific associations and 30,000 editorial board members and 3.5 million followers to its credit.

OMICS Group has organized 500 conferences, workshops and national symposiums across the major cities including San Francisco, Las Vegas, San Antonio, Omaha, Orlando, Raleigh, Santa Clara, Chicago, Philadelphia, Baltimore, United Kingdom, Valencia, Dubai, Beijing, Hyderabad, Bengaluru and Mumbai.

Application of Systems Thinking and Systems Engineering Principles to Enhance Safety and Pharmacovigilance through Real-Time Informatics

Greg Koski, PhD, MD
President and CEO
Alliance for Clinical Research Excellence and Safety

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Drug Development Today—A Complex Ecosystem under Intense Environmental Pressure

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

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Tufts Center for the Study of Drug Development

"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

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Change Management—
It takes a crisis!

> "The current approach to drug development is inefficient, ineffective and unsustainable."
>
> *DIA Europe, 2010*

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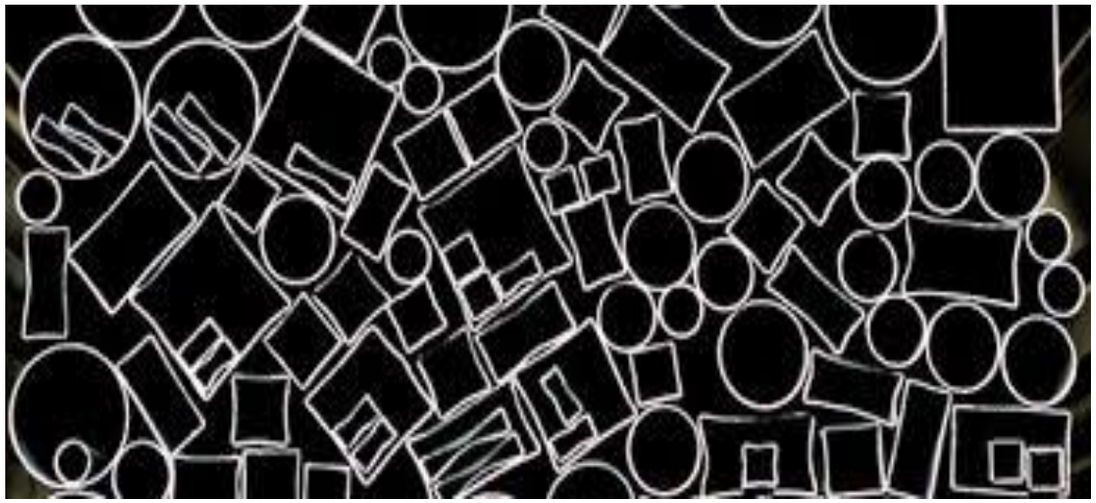
From Silos to Network Systems



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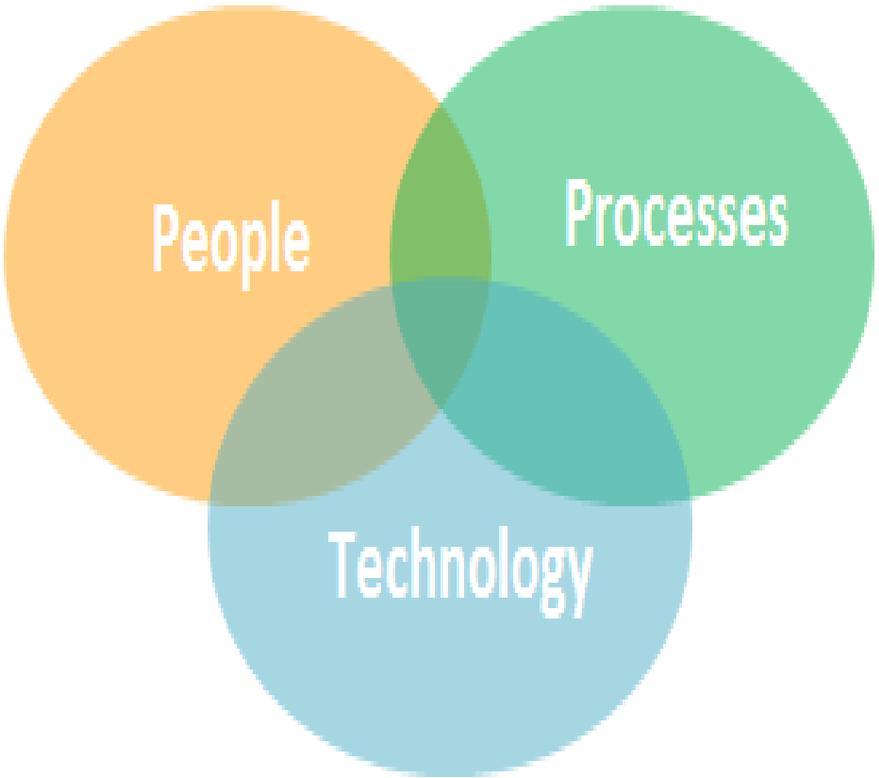
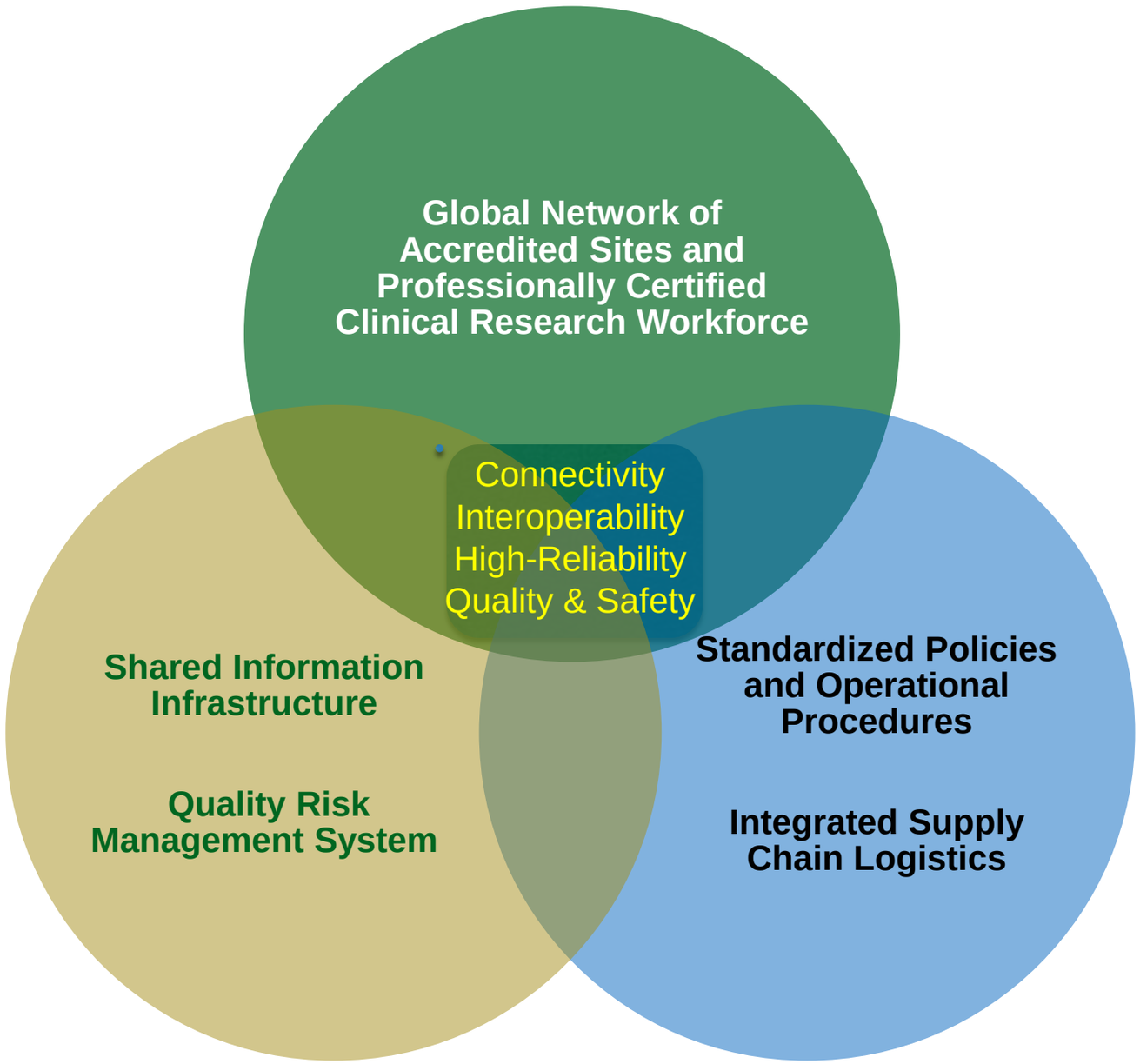
Fundamental Elements of an Enterprise System for Clinical Research





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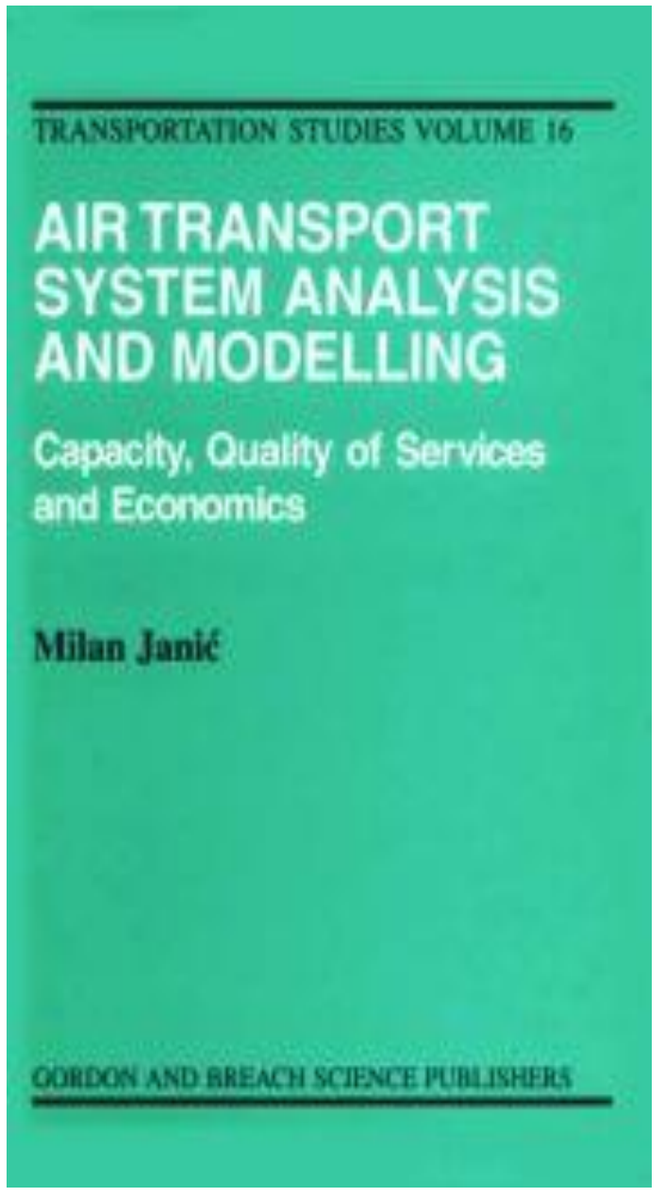
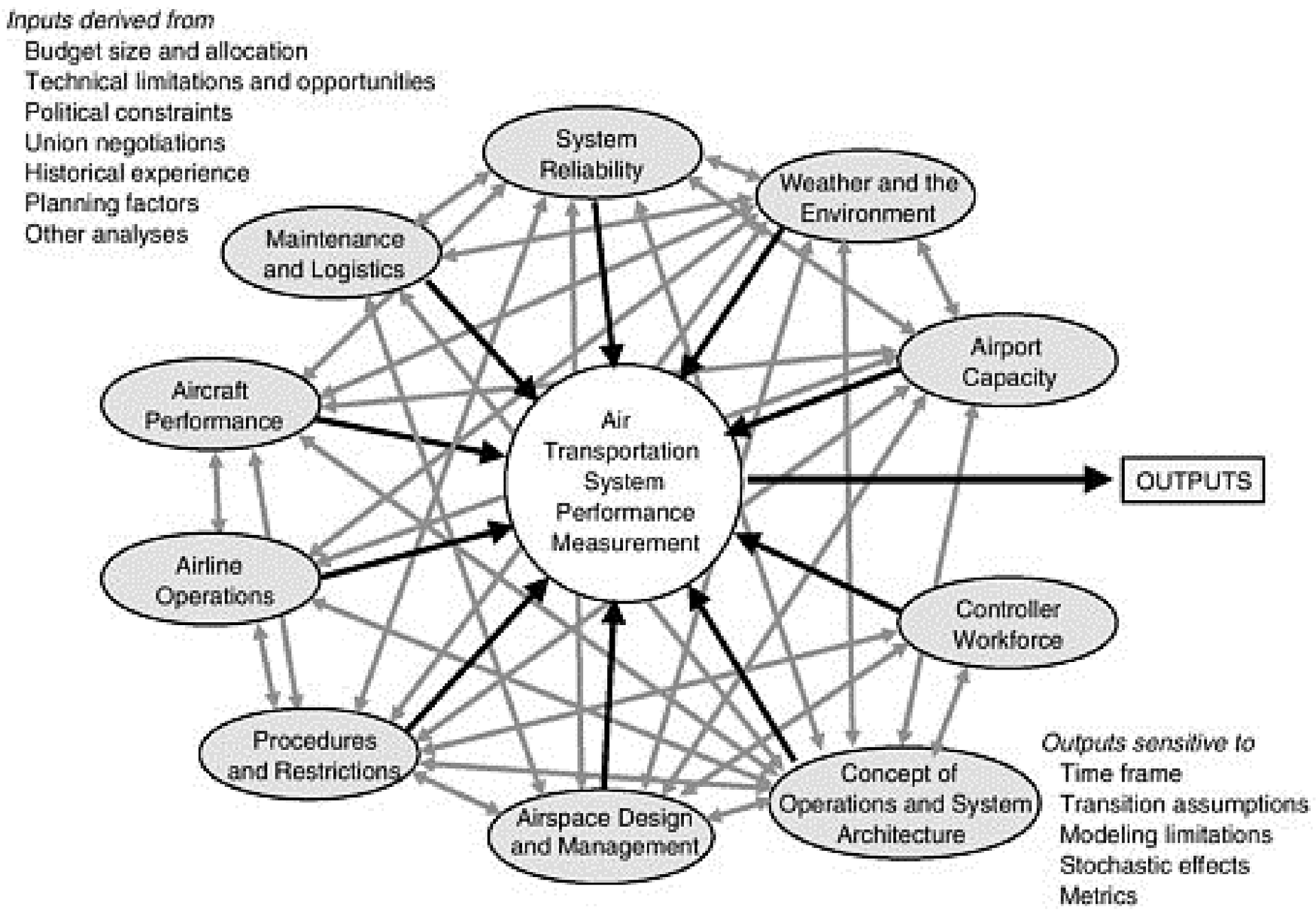
Systems Thinking:
The Global Air Transport System



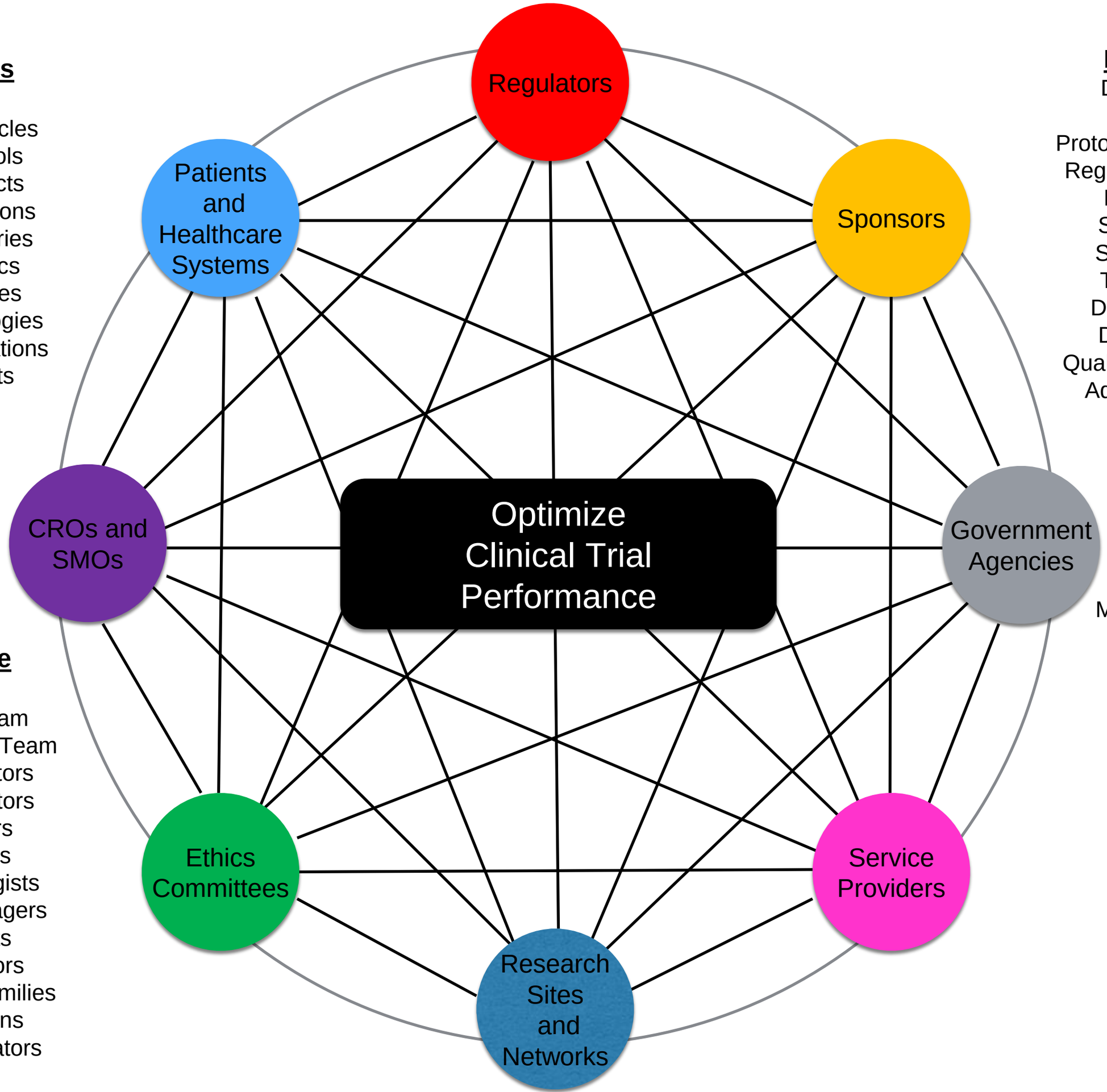


Inputs

Test Articles
Protocols
Contracts
Regulations
Boundaries
Logistics
Finances
Technologies
Collaborations
Patents

People

R&D Team
Operations Team
Investigators
Coordinators
Monitors
Auditors
Technologists
Data Managers
Ethicists
Regulators
Patients/Families
Physicians
Administrators



Processes

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Protocol Development
Regulatory Approval
EC Approval
Site Selection
Study Start-up
Trial Conduct
Data Collection
Data Analysis
Quality Management
Adverse Events
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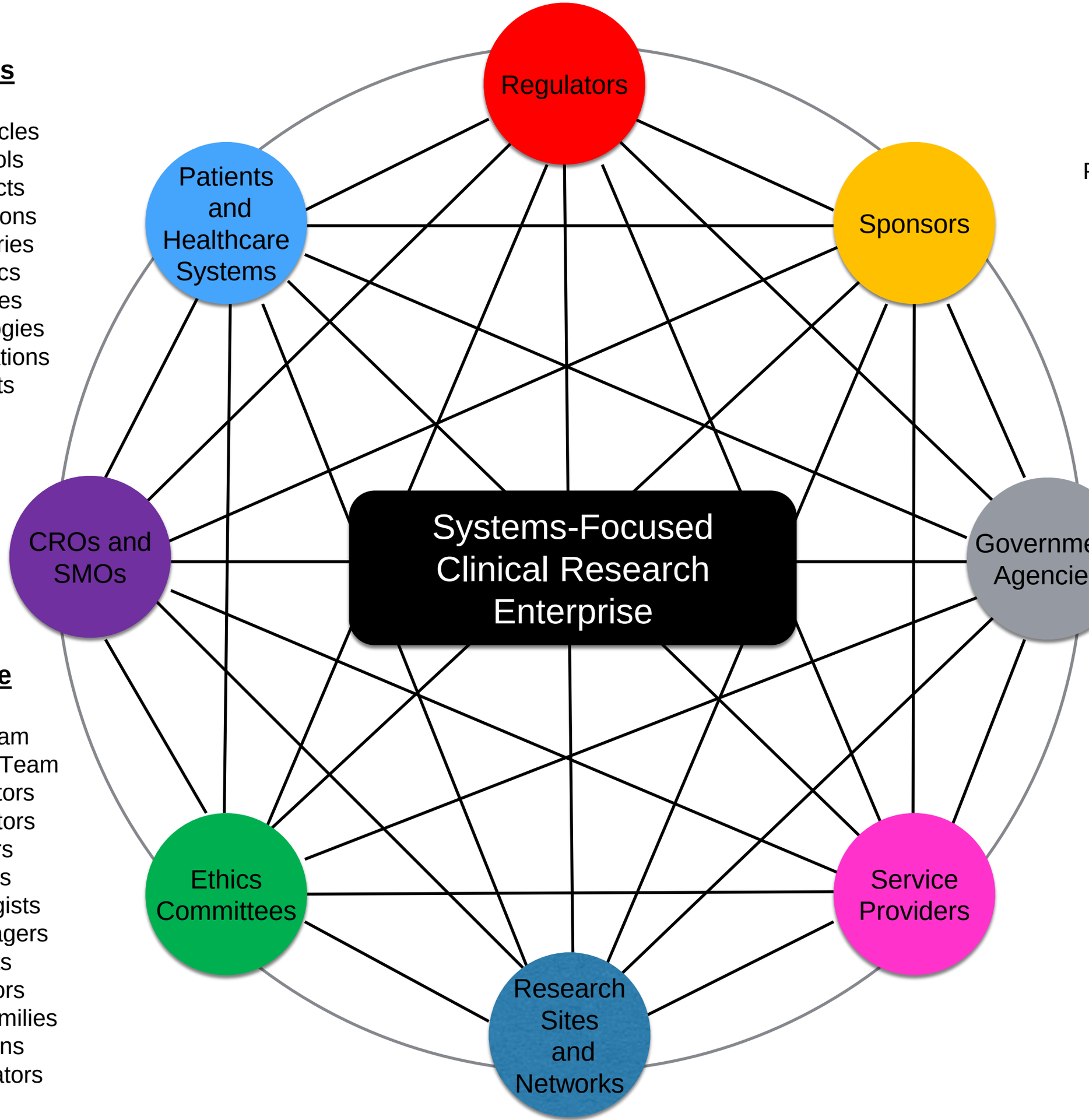

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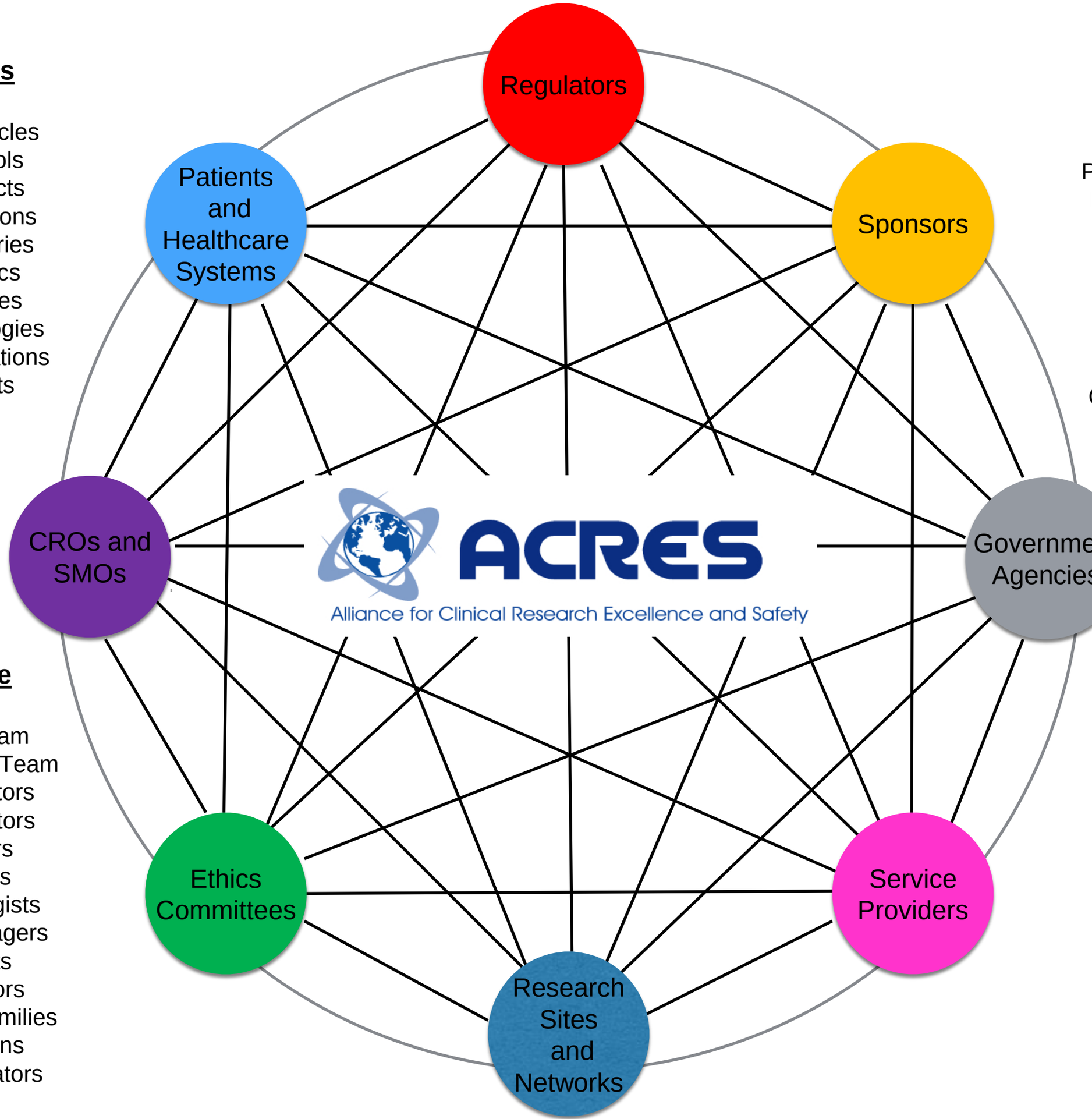

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ACRES
Alliance for Clinical Research Excellence and Safety

What is ACRES?

A non-profit multi-sector alliance of like-minded people and organizations working collaboratively in the public interest to build a shared global system for clinical research excellence—

To promote Accountable Research™ by aligning ethical principles and profesionalism with good business, scientific, medical and regulatory practices, within an enterprise safety culture.

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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.

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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

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The Harsh Reality of Clinical Research Sites Today

- 70% of clinical research sites never do more than one clinical trial in the business lifetime
- Fewer than half of sites meet enrollment goals and 10% never enroll a single subject
- Few sites have professionally trained and certified research personnel
- Many sites are still using paper records without EDC/CTMS
- Monitoring accounts for nearly one-third on clinical trial budgets
- Redundancy, delays, non-compliance, and poor quality are the norm rather than the exception

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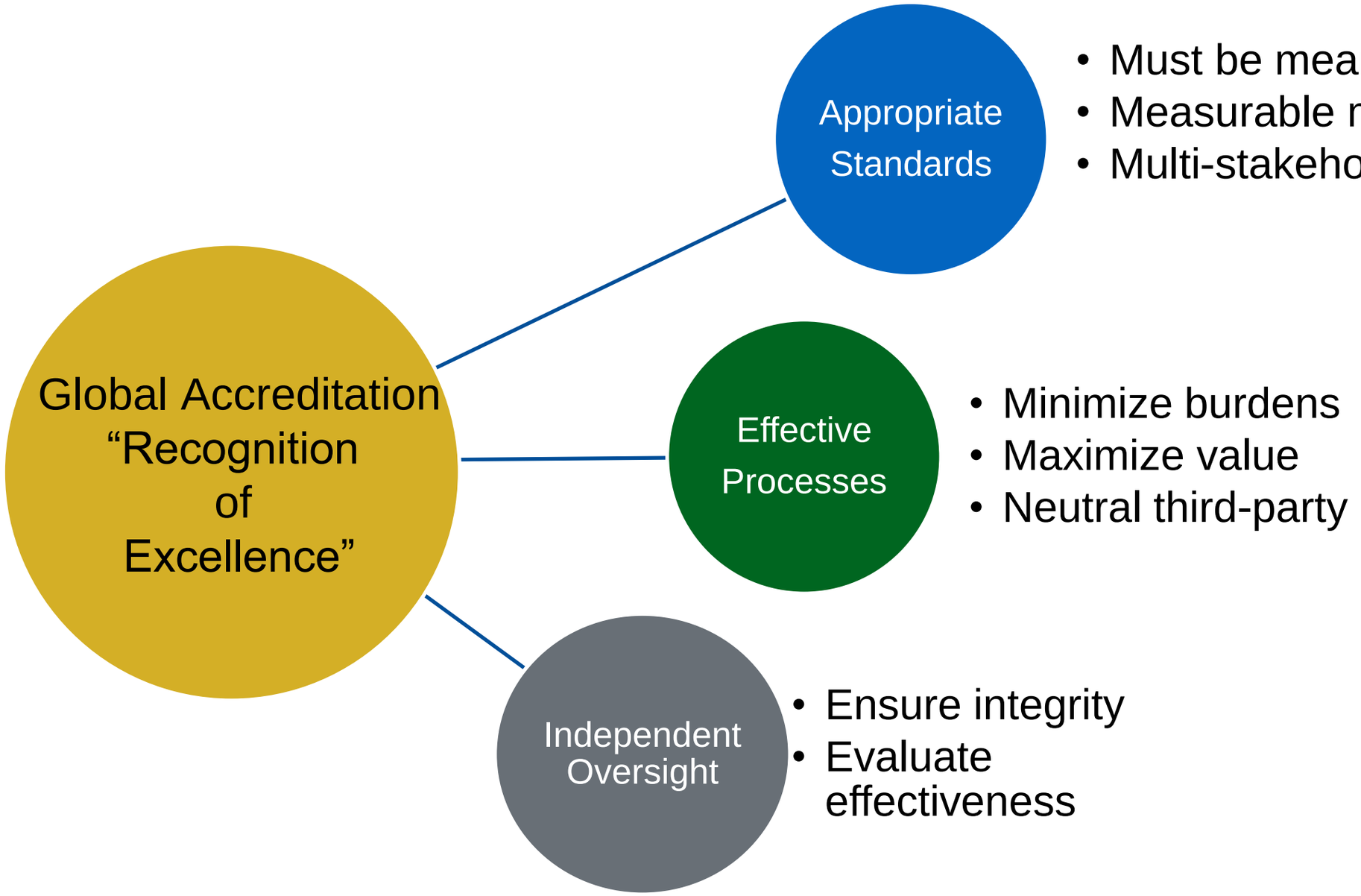
Elements of Effective Accreditation



- Must be meaningful
- Measurable metrics
- Multi-stakeholder

- Minimize burdens
- Maximize value
- Neutral third-party

- Ensure integrity
- Evaluate effectiveness

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Site Accreditation Standards Initiative

2013

Establish an efficient, effective and representative Project Steering Committee

Engage critical stakeholders to champion efforts for site accreditation and workforce certification

2014

Convene broad-based Collaboration Summit (s) to refine Scope, Strategy and Structure

Empower a Global Working Group for Standards and Process Development

2015

Develop and Implement necessary standards and agreements

Pilot Test and feedback from stakeholders

2016

Refine standards and implementation through regional networks

Evolving needs of Society and Stakeholders

- **Public Trust**
- **Professionalism**
- **Quality Assurance**
- **Site Performance**
- **Risk Management**
- **Information Technology**

Sustainable system infrastructure to drive clinical research quality, safety and efficiency

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ACRES Value Proposition

More effective application of existing resources to build a sustainable, shared "system infrastructure" will provide a handsome return on investment-- economically, scientifically and socially.

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

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 $20 Billion

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Implementation Strategy and Timeline

Maturation and Consolidation

New Standards and Metrics; New strategic alliances; Performance Excellence; Self-sustaining organization

Establishment and Growth of the Network

Site identification; education and training ; regional expansion; products and services delivery; ”modular growth” opportunities by adding existing networks

Engaging Alliance Partners and Stakeholders

Standards, Metrics, Processes; Guidelines; IT Integration; Education, Certification and Accreditation Criteria; Quality Assurance

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Safety and Pharmacovigilance— Why are we flying blind?

Personal Health and Biological Information (including Genomics)

Clinical Trials and Trial-Generated Adverse Reaction Data

Monitoring and Oversight Data

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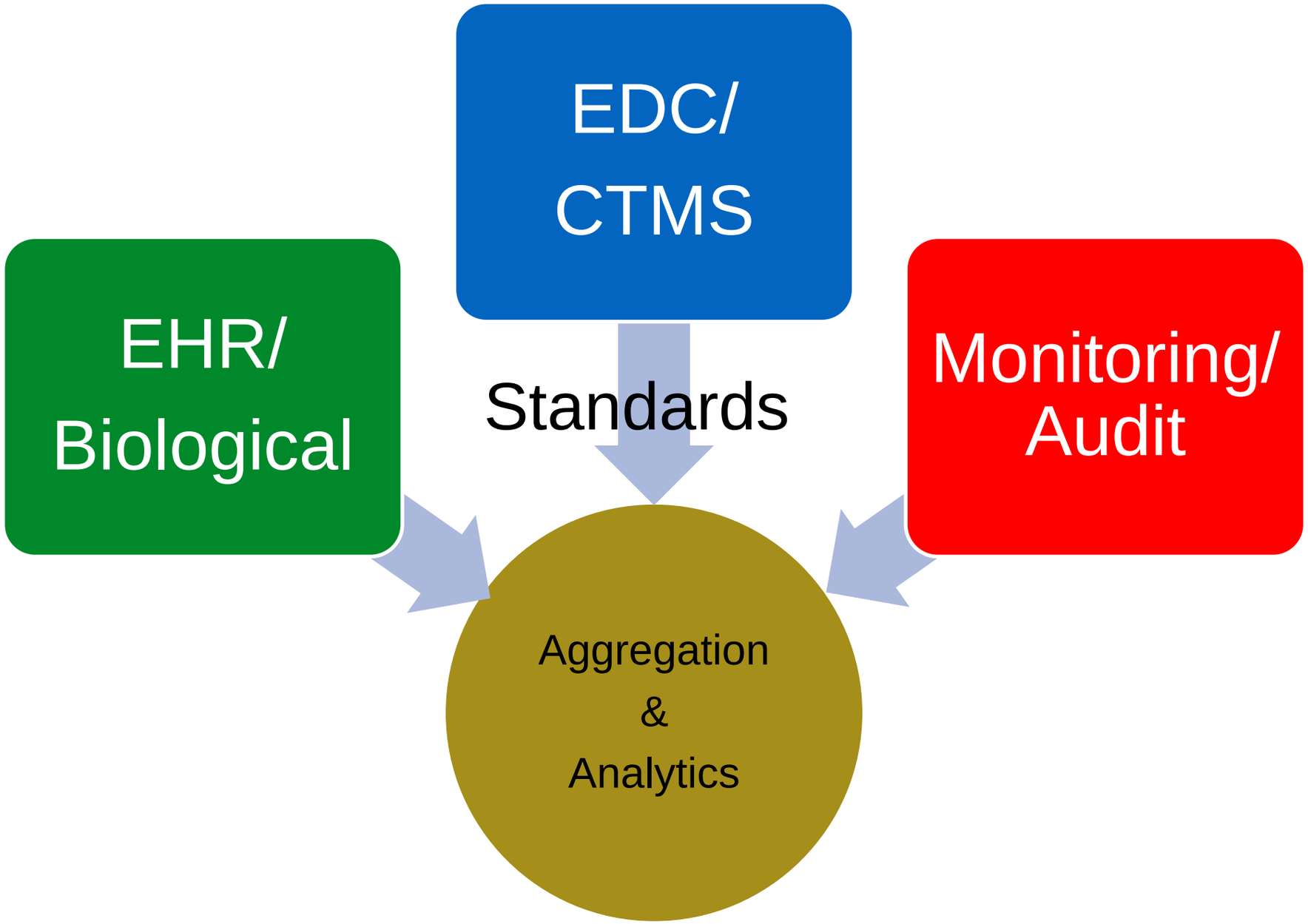
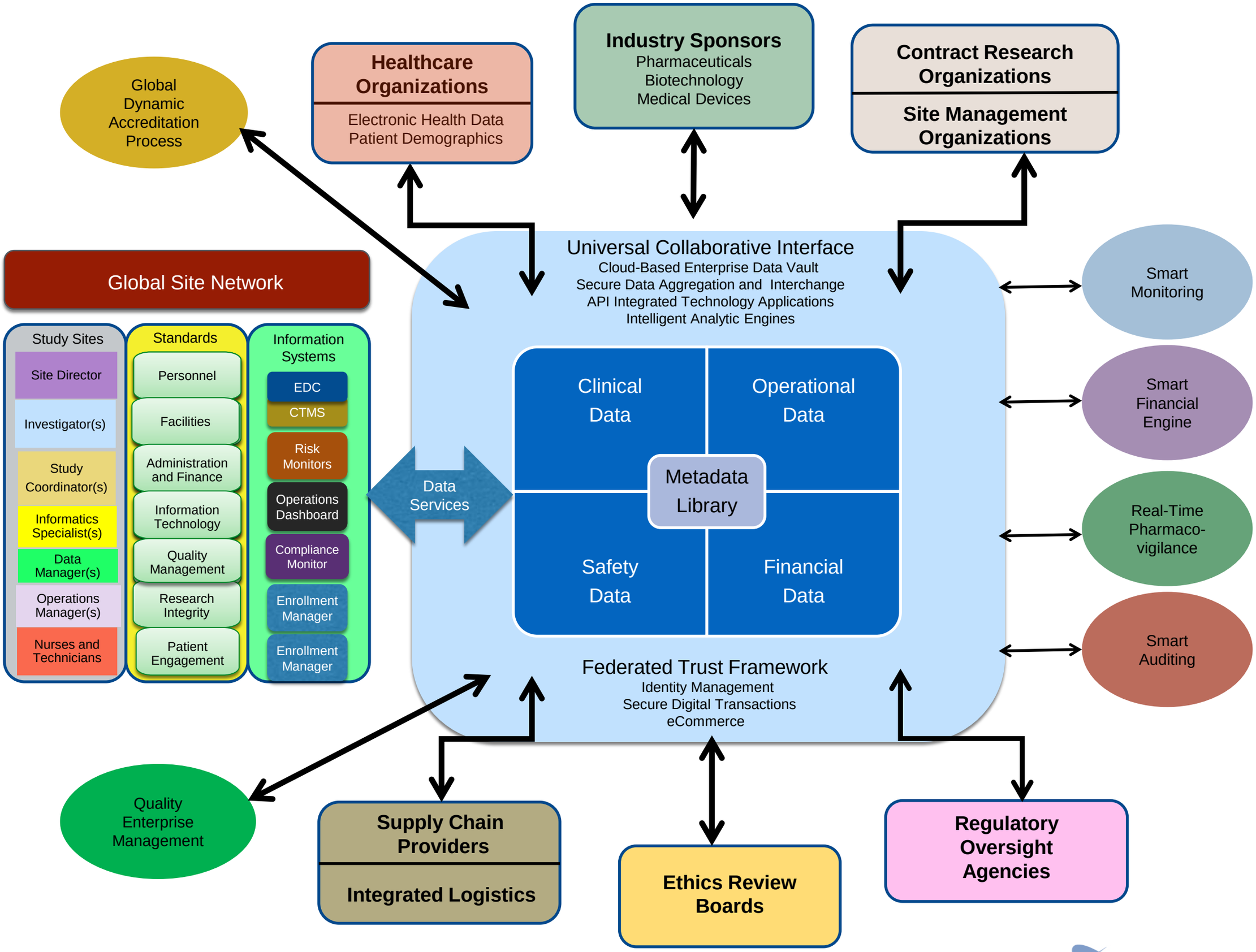
The Power of Data Standards, Sharing and Aggregation





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Committed to Systems Solutions for Accountable Research™

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Let us meet again..

We welcome you all to our future conferences of OMICS International

5th International Conference & Exhibition on Pharmacovigilance & Clinical Trials

On

September 19 - 21, 2016 at Vienna, **Austria**
http://pharmacovigilance.pharmaceuticalconferences.com/