Globalization of Clinical Research: Enhancing Excellence and Safety

Greg Koski, M.D., Ph.D.
Director of Clinical Research, Division of Cardiovascular Anesthesia, Department of Anesthesia, Critical Care and Pain Medicine, Massachusetts General Hospital
Senior Scientist, James Mongan Institute for Health Policy, Massachusetts General Hospital and Partners Healthcare System
President and Co-founder, Alliance for Clinical Research Excellence and Safety (ACRES)

The world of clinical research is changing....

- The current approach to clinical trials is inefficient, ineffective and unsustainable
- The current approach to ethical review is increasingly characterized in the same way
- The traditional centers of activity are moving
- The need for global integration has never been greater
- Principles must be harmonized; policies and practices must be standardized

In the harsh light of reality...

- The failing silo business model must be reconsidered in light of dwindling pipelines, spiraling costs, growing regulatory burdens and declining productivity.
- The erosion of public trust in the pharmaceutical industry must be addressed and the practices that have taken us down the current path must be changed.
- Ethical review must contribute value if it is to be respected and supported
Scientifically sound research is sound wherever it is done.

Ethical human research is ethical wherever it is done.

A world of clinical research?

- Drug development has been almost entirely proprietary and conducted largely in silos.
- Clinical trials are not “global”—they are international.
- Harmonization is a euphemism for failure to standardize!
- One cannot keep doing things the same way and expect different results.

It is time for a different approach...

A systems approach—

A global approach!

“A goal without a plan is just a wish.”

Antoine de Saint-Exupery
French writer (1900–1944)
A Systems Approach?

- Systems share common characteristics, including:
  - structure, defined by components/elements and their composition;
  - behavior, which involves inputs, processing and outputs of material, energy, information, or data;
  - interconnectivity: the various parts of a system have functional as well as structural relationships to each other.

Adapted from Wikipedia

The Global Air Transportation System

The current approach to clinical trials is not a system!

- An effective system requires integration
  - An organized, purposeful structure regarded as a whole and consisting of interrelated and interdependent elements.
  - These elements continually influence one another (directly or indirectly) to maintain their activity and the existence of the system, in order to achieve the goal of the system.

http://www.businessdictionary.com/definition/system.html
A system for clinical research

- To deliver safe, effective and accessible drugs and devices to the people of the world in a timely manner to improve health, productivity and quality of life for all.
- Characteristics:
  - Safety
  - Effectiveness
  - Efficiency
  - Quality
  - Standardization
  - Connectivity
  - Interoperability

A Global Clinical Research System

- Global Network of Accredited Research Sites and Research Ethics Committees
- Shared Information Infrastructure and Pharmacovigilance System
- Standardized Policies and Operational Procedures

Site Development & Operations Support
Safety & Pharmacovigilance
Quality Management & Systems Improvement
Information Systems Management
A global system for drug development...

- Supported by a robust information technology platform to:
  - Ensure safety
  - Continually monitor and improve performance
- Provide a shared infrastructure for clinical research that:
  - Aligns good business practices with ethical principles to enhance safety and efficiency
  - While reducing the cost and time required to bring new medical products to market.
- Provide a framework for quality assurance and regulatory reform that would benefit the entire industry and the public

Benefits of a Systems Approach

- Drives and rewards standardization
- Drives regulatory simplification and compliance
- Enhances performance
  - Increases efficiency
  - Reduces redundancy
- Promotes and enhances safety
- Reduces costs
- Increases transparency and improves public trust
- Promotes investment in sustainable, self-supporting professional clinical research capacity in emerging nations and markets
Thank you!