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.

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Tomorrow, Today….

Systems Approaches to Enhance Pharmacovigilance and Risk Management

A Workshop in Systems Thinking

facilitated by

Greg Koski, PhD, MD

President and CEO

Alliance for Clinical Research Excellence and Safety (ACRES)

Systems Thinking--Introducing SSM

SSM is a methodology used to support and to structure thinking about, and intervention in, complex organisational problems.

*These materials have been adopted and modified for educational purposes from the Operational Research Society. For more details, please visit is website: https://www.theorsociety.com/

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What Is The Thinking Behind SSM?

- A process for managing: for undertaking the process of achieving organised action.
- Practitioners take managing to be the process of thinking-out and implementing organised action, and of reacting to changes in the world which might affect that action.
- Managing, in these terms, is an activity performed by all sorts of individuals, at all sorts of levels, in all sorts of formal and informal organisational groupings.

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What Is The Thinking Behind SSM?

- Assumes that each individual will see the world differently. Different world-views inevitably lead to varying understandings and evaluations of any situation, which lead in turn to different ideas for positive action.
- Developed out of systems thinking
  - traditional systems thought was found to be an inappropriate set of tools for dealing with problems in which there was no clearly defined and commonly agreed set of outcomes.
- Developed to enable rational action, taking such mismatches into account.

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What is Systems Engineering?

- Traditional systems engineering
  - First consider the purpose or objective,
  - Then working backwards to find ways of achieving that objective.
  - From sets of possible solutions, the most promising is selected on the grounds of fitness for purpose and economic viability.
- SSM developed as a result of the failure of this approach in some management situations.
  - Without a consensus on objectives, the results of traditional systems engineering will be confusion and, most likely, dissatisfaction on the part of those whose view of the objectives is not implemented.
- SSM is a methodology for understanding and dealing with this diversity of views and interests.

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Why are SSM Techniques Useful?

- The methodology was developed to help to make sense of the difficult problems which contained their own, internal contradictions.
- Many projects have failed as a direct result of their failing to take into account the various perspectives, motivations and vested interests which are at play within human organisations.
- SSM provides a structure which is engineered to deal with these difficulties.

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What is an SSM Intervention?:

- A structured organised intervention is used to deal with complexity of an organisational problem in a flexible and knowing way.
- An SSM intervention involves
  - finding out about the situation
  - thinking about systems which are, or might be, employed in the situation;
  - comparing the thinking to the systems which exist in the real world;
- Taking action according to what has been learned.
  - Not a simple matter of performing these four stages, after which a 'right' answer will be produced.
  - Rather, it is about taking these four as bases for action, each of which should be kept in mind.

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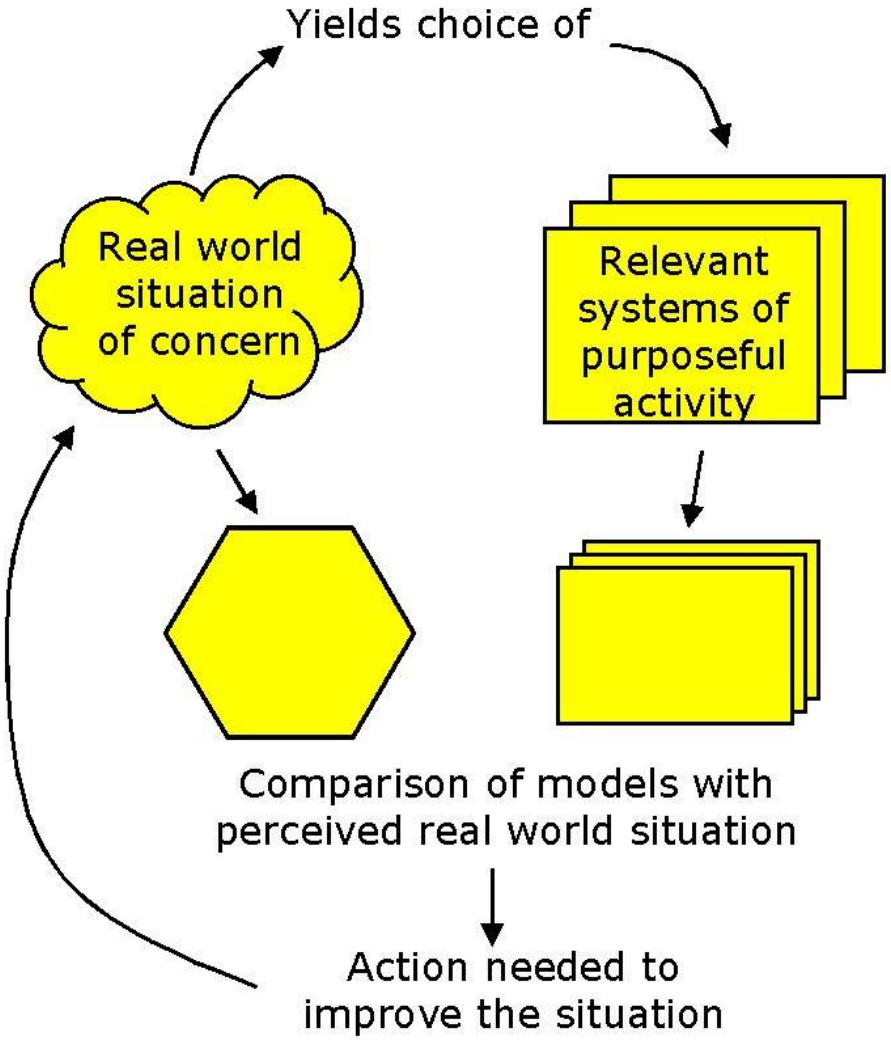
Applying Soft Systems Thinking



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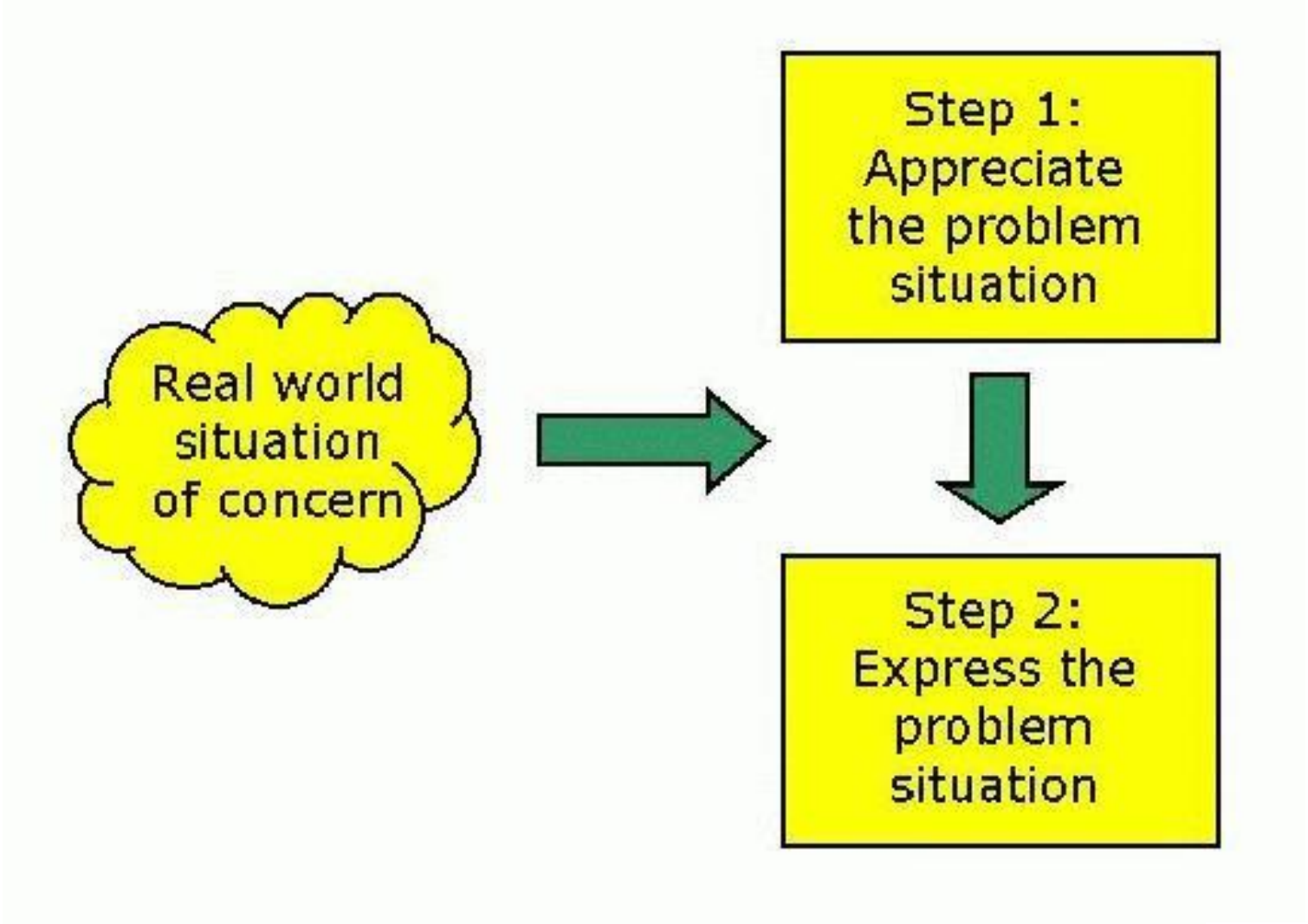
Applying Soft Systems Thinking



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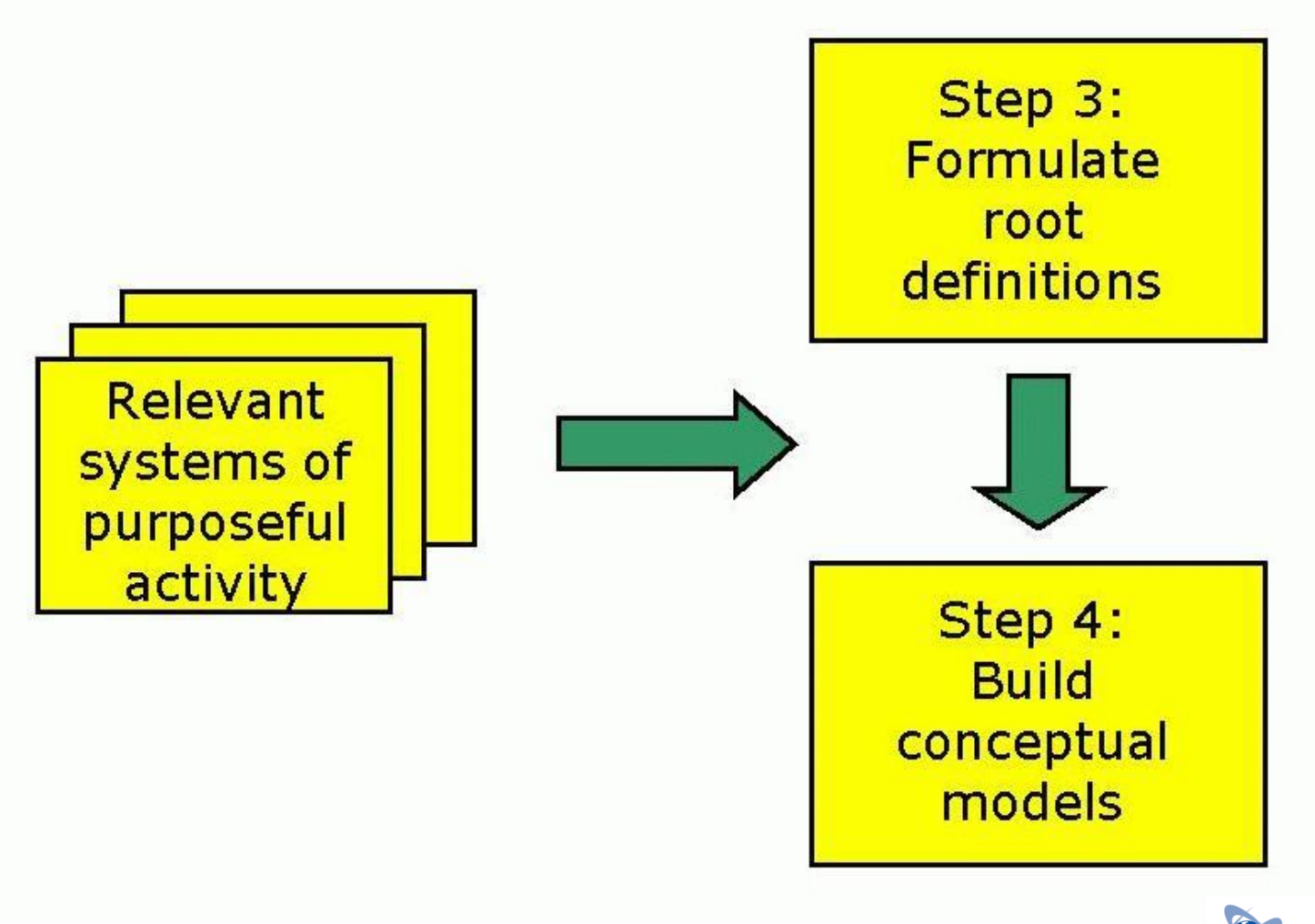
Applying Soft Systems Thinking



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SSM--CATWOE Analysis

- **C = Customers**
- Who is on the receiving end?
- What problem do they have now?
- How will they react to what you are proposing?
- Who are the winners and losers?

Adapted from Creating Minds. http://creatingminds.org/tools/catwoe.htm

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SSM--CATWOE Analysis

- **A = Actors**
- Who are the actors who will 'do the doing', carrying out your solution?
- What is the impact on them?
- How might they react?

Adapted from Creating Minds. http://creatingminds.org/tools/catwoe.htm

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SSM--CATWOE Analysis

- **T = Transformation process**
- What is the process for transforming inputs into outputs?
- What are the inputs? Where do they come from?
- What are the outputs? Where do they go to?
- What are all the steps in between?

Adapted from Creating Minds. http://creatingminds.org/tools/catwoe.htm

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SSM--CATWOE Analysis

- **W = World View**
- What is the bigger picture into which the situation fits?
- What is the real problem you are working on?
- What is the wider impact of any solution?

Adapted from Creating Minds. http://creatingminds.org/tools/catwoe.htm

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SSM--CATWOE Analysis

- **O = Owner**
- Who is the real owner or owners of the process or situation you are changing?
- Can they help you or stop you?
- What would cause them to get in your way?
- What would lead them to help you?

Adapted from Creating Minds. http://creatingminds.org/tools/catwoe.htm

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SSM--CATWOE Analysis

- **E = Environmental constraints**
- What are the broader constraints that act on the situation and your ideas?
- What are the ethical limits, the laws, financial constraints, limited resources? regulations, and so on?
- How might these constrain your solution? How can you get around them?

Adapted from Creating Minds. http://creatingminds.org/tools/catwoe.htm

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Let’s Go to Work…

- What is the ultimate goal of an ideal pharmacovigilance system?

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Let’s Go to Work…

- What is the ultimate goal of an ideal pharmacovigilance system?

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Let’s Go to Work…

- What “real-world” factors stand in the way?

Let’s Go to Work…

- What tools do we have to use today?

Let’s Go to Work…

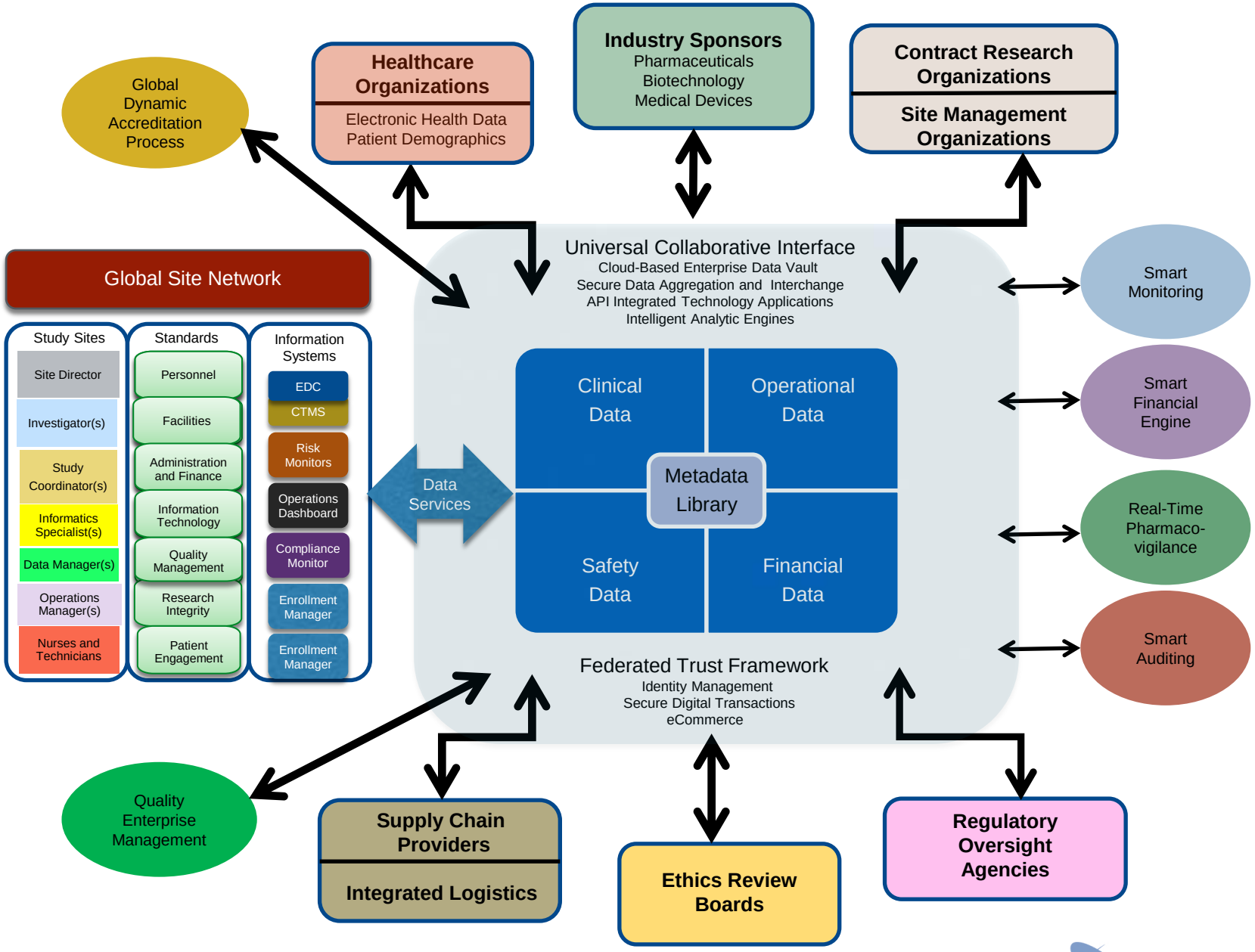
- What tools do we not have to use today but will need tomorrow?

Let’s Go to Work…

- How can we better assemble these tools to use them more effectively as part of the pharmacovigilance system of tomorrow?

Let’s Go to Work…

- What transformational steps must we take today to begin building a system for tomorrow?



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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/