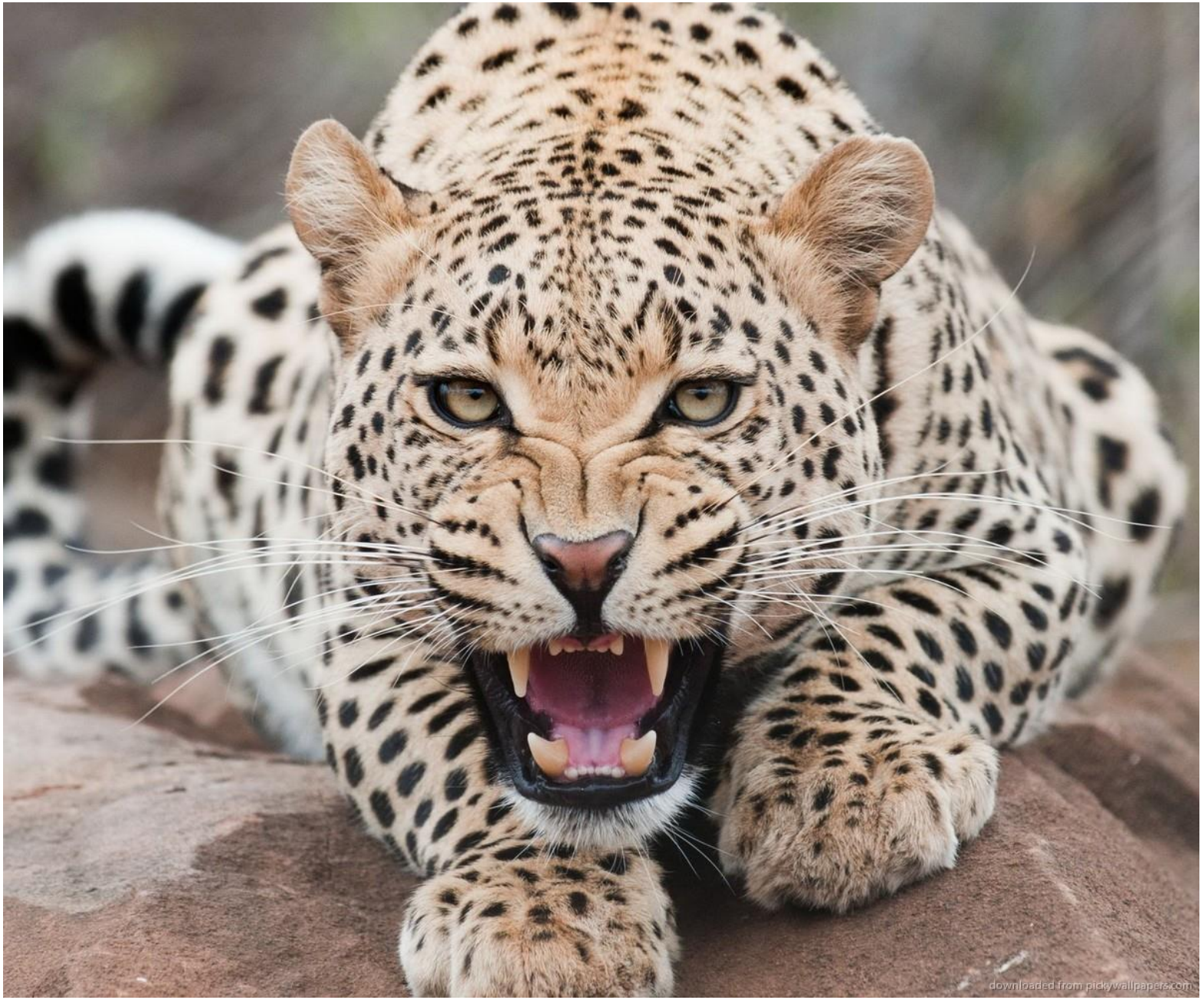
About OMICS Group

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.


downloaded from pickywallpapers.com

Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

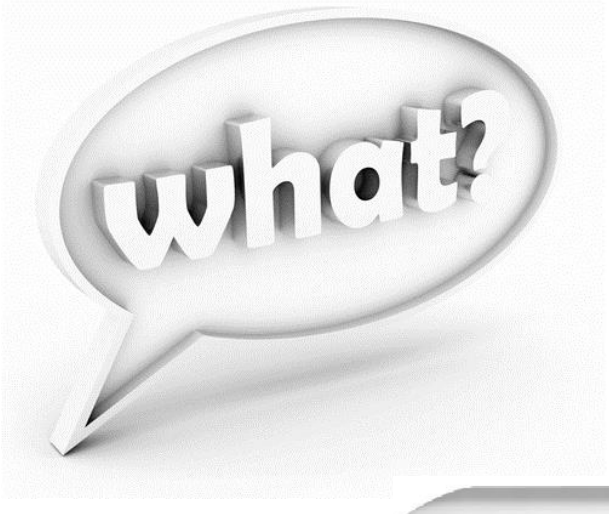
Lean, six sigma and ISO and their applications in clinical trials/research

4th International Conference and Exhibition on Pharmacovigilance and Clinical Trials

Pramod Wable, Manager QA GCP_GLP, Daiichi Sankyo Development, UK
11 August 2015

Lean Six Sigma and Its Applications in Clinical Research

Objective



Feel confident about using Lean Six Sigma

Let's discuss today!

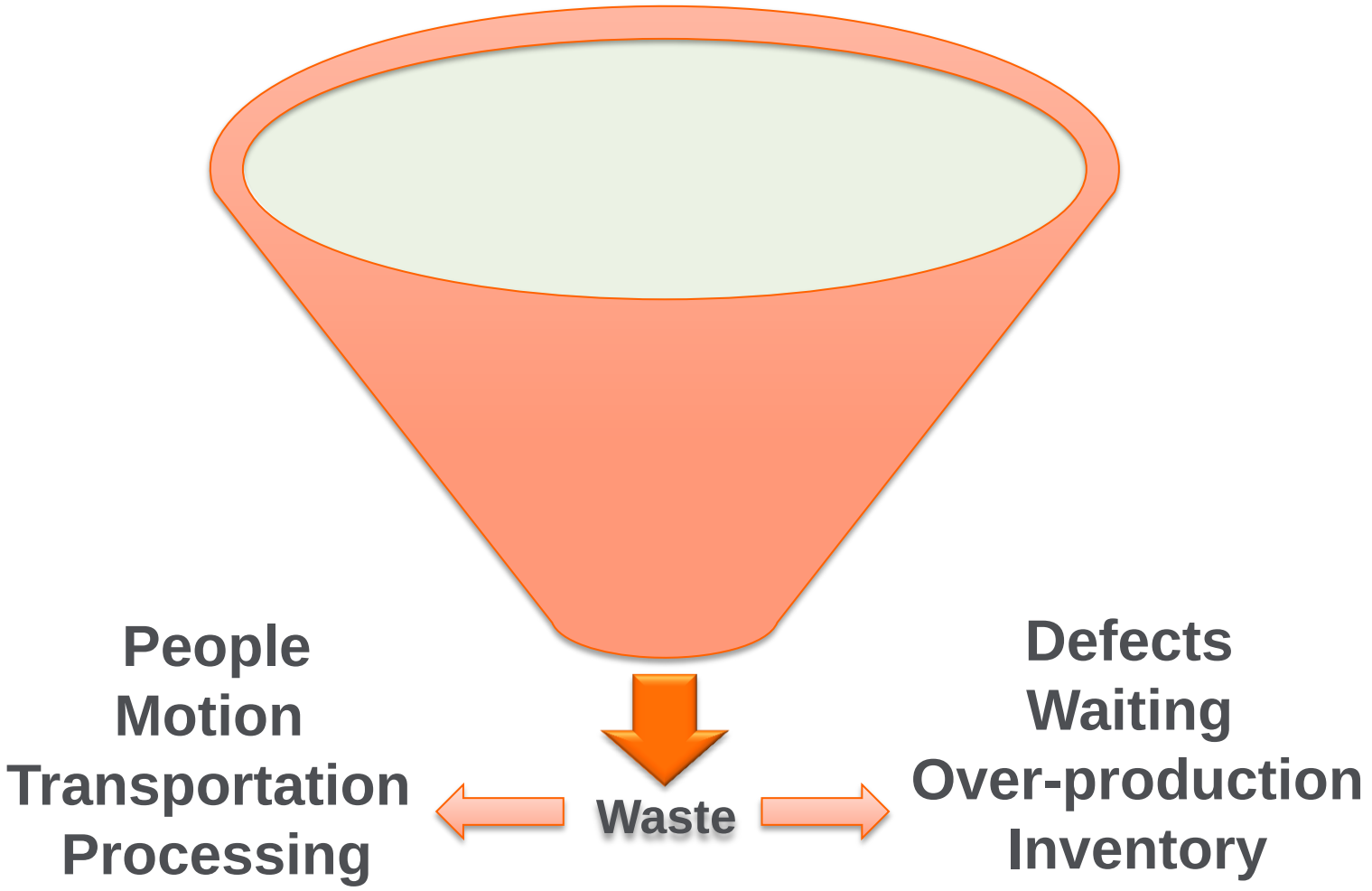
Daiichi-Sankyo

LEAN SIX SIGMA

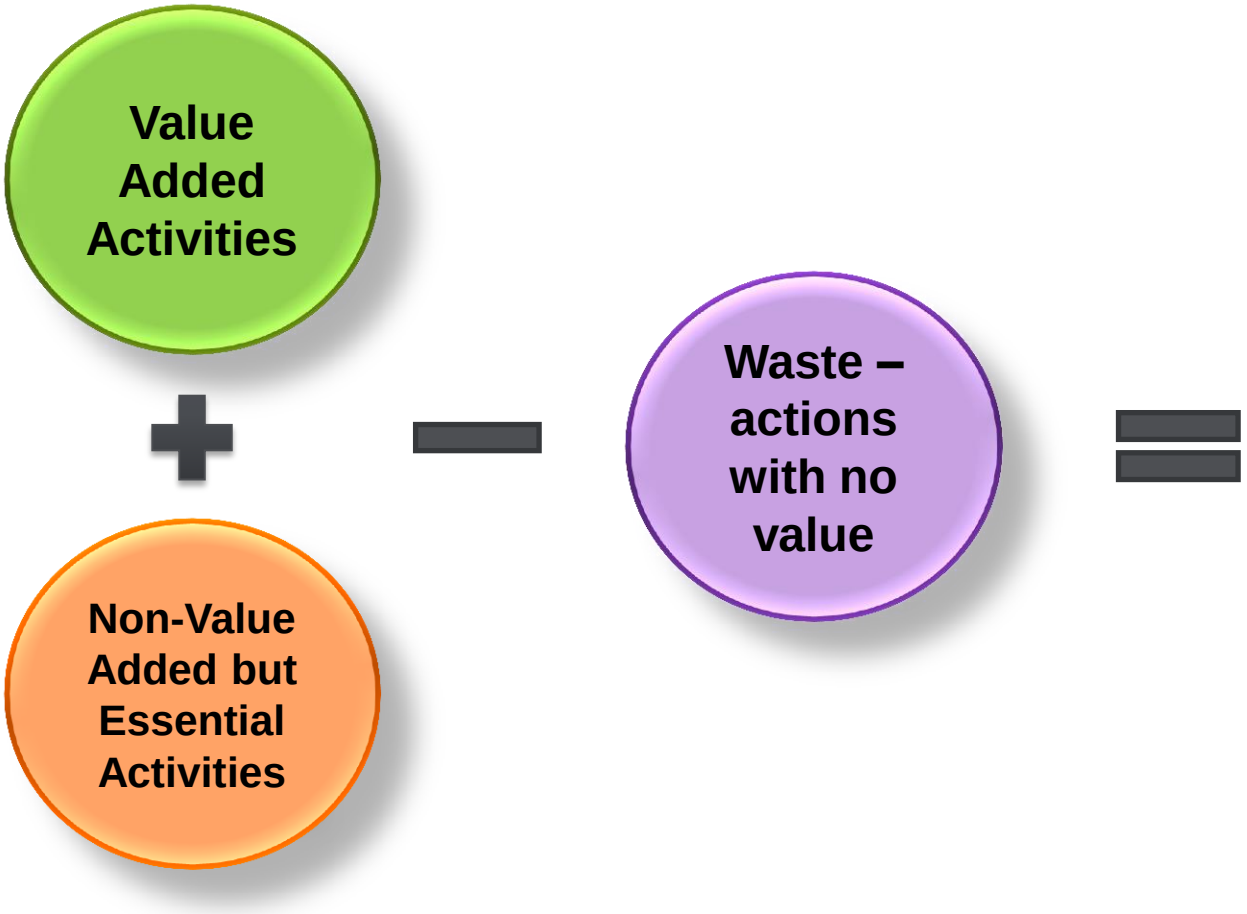
What is Lean?

"**Continuous removal** of the waste from process, product and service"

Five Principles of Lean



Lean Methodology - How



Six Sigma - 6σ

“Simply it is a set of techniques and tools for process improvement”

99.9997%

3.4 defective parts/million

Design For Six Sigma

DMAIC

Problem and objectives

Process and define factors of improvement

Maintain the improvements

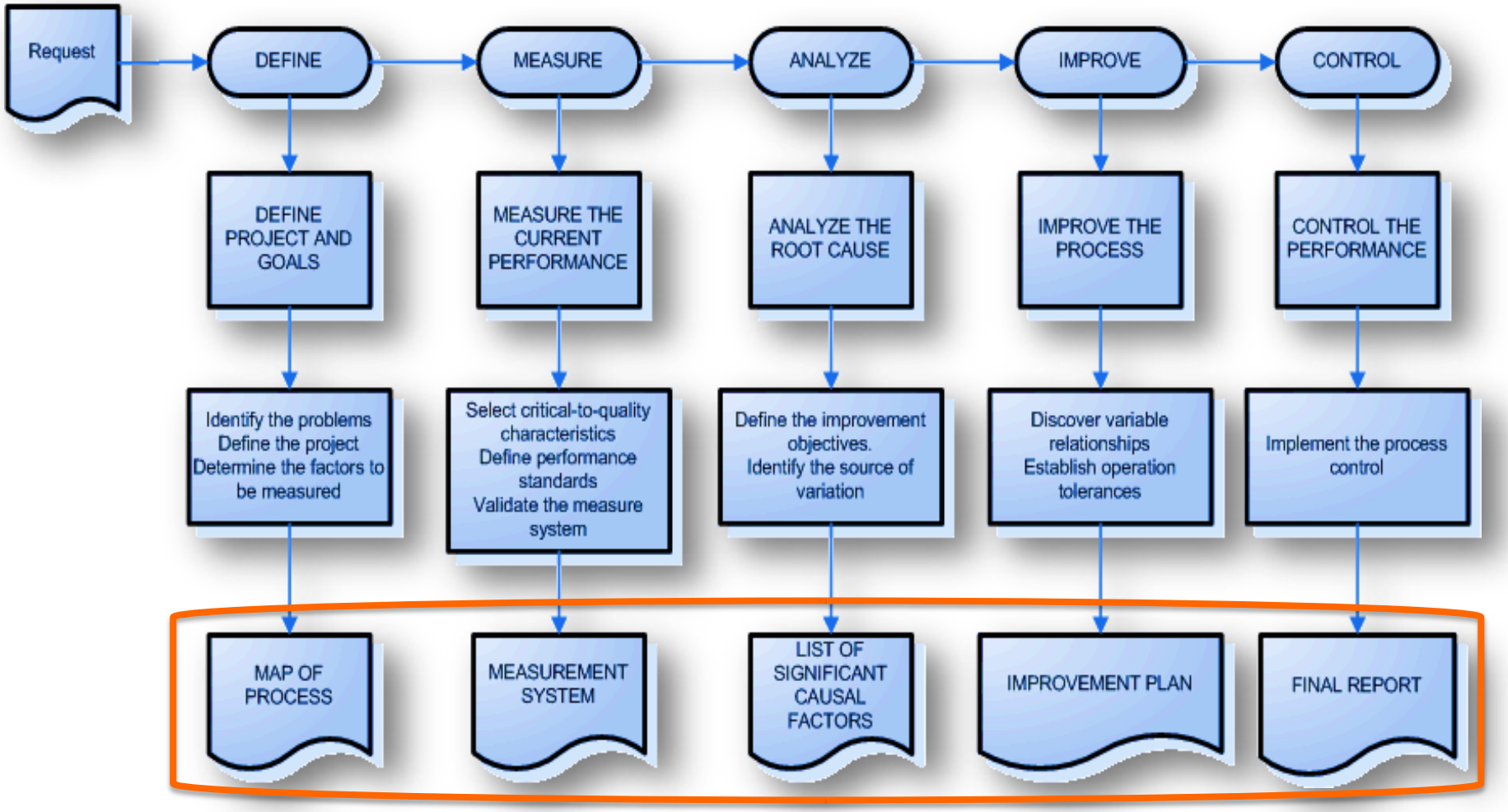
DEFINE → MEASURE → ANALYSE → IMPROVE → CONTROL

Problem – what do to improve?

Implement

Improved Process

Six Sigma Methodology



Lean Six Sigma

What is it?

Benefits

Cost Reduction

Employee, Customer and Stakeholder Satisfaction

Time Management

Enhanced Organizational Capability

Cycle Time Reduction

Accelerated Problem Solving

Improved Performance

Strategic Planning

Applications

“Industry Independent”

Manufacturing Industry

Service Industry

Process Driven Industry

In Clinical Research

Daiichi-Sankyo

Who is Lean Six Sigma Candidate in Clinical Research?

High performing companies

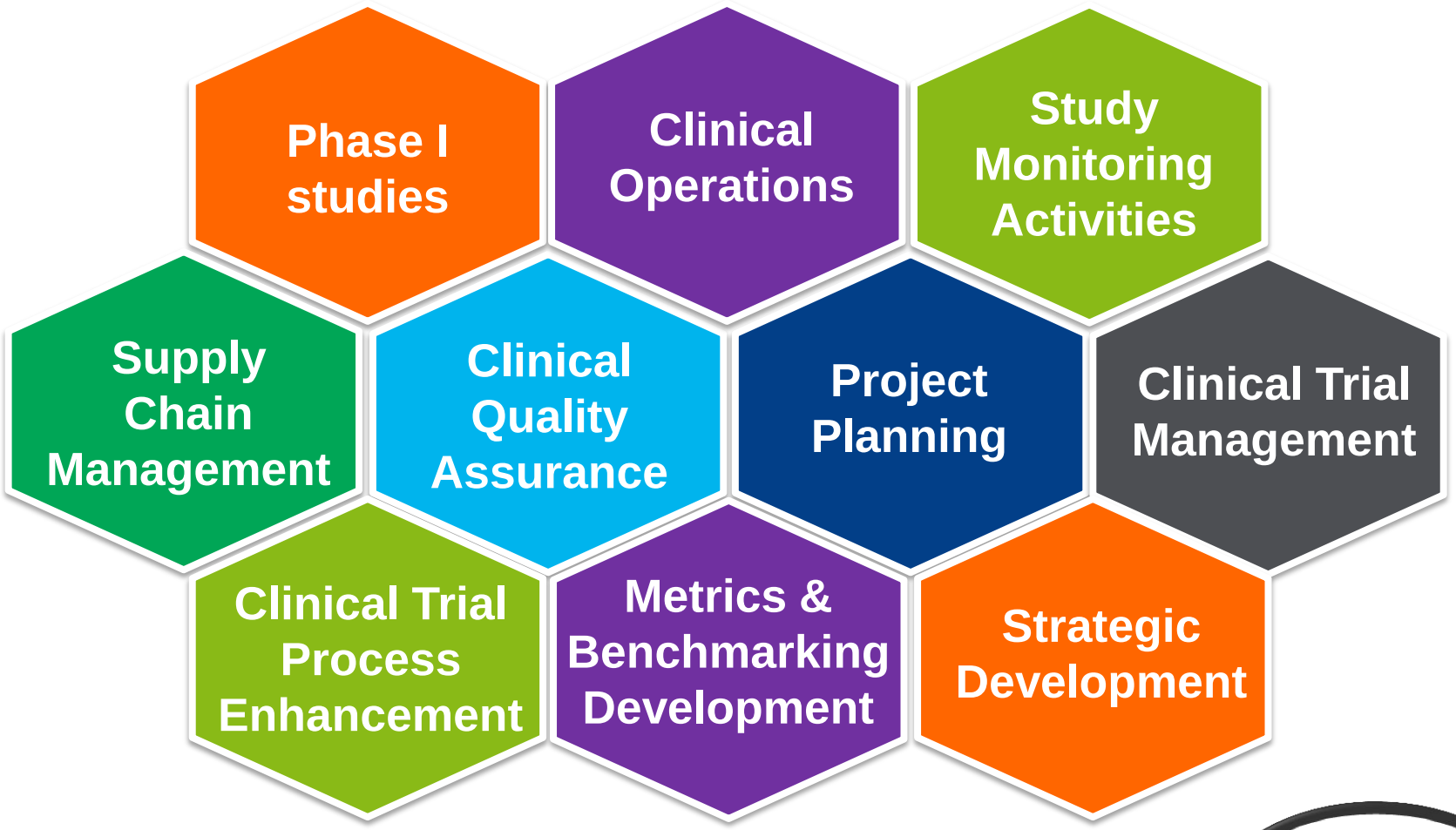
- Benchmark others
- Empower employees
- Continuously improve

Ultimate Aim = Customer Satisfaction

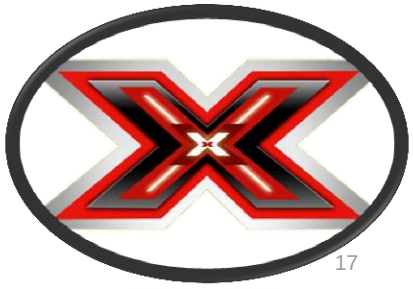
Who is Customer in Clinical Research?

- Patients
- Doctors
- For clinical operations
  - Biostatistics, Quality Assurance etc. (internal customer)
  - Regulatory Agencies such as FDA, MHRA, EMA (customer by proxy)
  - Insurance companies (intermediate)

Applications



Key – "Focusing on Output Measures" (The 'X' factor)



Key Potential Difficulties in Application

- Poor understanding
- Improper application of statistics/methodology
- “Going through the motions”
- Lack of time and clarity about project
- Resistance to change
- Negative perceptions
- Lack of effective system of communication

Case Study - Shopping…!

Case Study

"Highly Regulated and Expensive Industry"

Research and Development

14

Approx. Years

	Basic research	Discovery	Pre clinical development	Clinical development			FDA filing/approval and launch preparation
				Phase 1	Phase 2	Phase 3	
Milestone		Disc Target overy	Lead Candidate	IND filed		NDA filed	NDA approval
Duration (years)	2.5	3	1	1.5	2	2.5	1.5
% Years by phase	18	21	7	11	14	18	11
% Years by function	Research: 46%			Development: 43%			Other: 11%
% Cost by phase	4	15	10	15	22	31	3
% Cost by function	Research: 29%			Development:68%			Other:3%

Source of Table/Information: DOI: 10.1016/j.jala.2005.10.003

Ultimate Challenge = ↑Quality with ↓Cost

Case Study

Elliott Liu - Clinical Research during 2006

- **Objectivity** - reduction of a cycle time and improvement in the process
- **Process tested** – Paper Case Report Form (CRF)
- **Sample** – 32 patients and 21 CRF pages for each patient
- **Method –** Two methods of CRFs data entry were compared
    A. In-house/organization's current method of CRFs data entry
    B. Improved/enhanced CRF data entry process developed by using Lean Six Sigma
- **Measures** –
    - First data entry step
    - Second data entry step
    - Isolated time consuming steps affecting process cycle time and error rate
    - Time with respect to complete entry of CRFs into database

Experimental Observations

A. For In-house/organization's current method of CRFs data entry:

- Labour intensive workflow
- Error prone
- Multiple QC cycles
- Manual query handling
- Weeks in data entry and transfer

B. Improved/enhanced CRF data entry process developed by using Lean Six Sigma

- Dedicated project team involved
- Almost error free within 0.2% acceptance margin of SOP
- Less QC activity with more accuracy
- Less cycle time

Outcome and Conclusion

Reduction of greater than 70% in cycle time and errors while CRF Data Entry

Eliminating waste and duplication + Improve and redesign workflow/processes

=

Better and efficient workflow/processes

The ‘X’ Factor

Daiichi-Sankyo

Focusing on Output Measures is something to look in a rear view mirror.

Cocktail…!

I hope this presentation helped you to strengthen your faith on Lean Six Sigma…!

If you QUALIFY; then you will get a BONUS

Thank you!

Contact –

Pramod Wable

+44 (0) 7872442090

pjwable@gmail.com

Useful Reading –

- **The Lean Six Sigma Pocket Toolbook: A Quick Reference Guide to 70 Tools for Improving Quality and Speed**
  by Michael L. George, John Maxey, David T. Rowlands, Malcolm Upton

- **The Lean Six Sigma Black Belt Handbook: Tools and Methods for Process Acceleration**
  by Frank Voehl, H. James Harrington, Chuck Mignosa, Rich Charron

- **Velocity: Combining Lean, Six Sigma and the Theory of Constraints to Achieve Breakthrough Performance- A Business Novel**
  by Dee Jacob, Suzan Bergland, Jeff Cox

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/