



A Practical Approach to Managing Knowledge

*Making Knowledge Flow in
Merck's Manufacturing Division*

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NASA Knowledge 2020

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A Rich History of Scientific Achievement Impacting Society



1898 – Small Pox vaccine in US

1899 – Merck Manual Established (physician's bible)

1933 – Vitamin B12 discovery

1936 – Vitamin B1 synthesis

1944 – Streptomycin discovery for TB, Cortisone synthesis for pain

1958 – First children's safety cap

1963-69 – First Vaccines for Measles, Mumps & Rubella *

1971 – MMR – first live vaccine trio*

1975 – SINEMET – Parkinson treatment

1985 – Imipenem (drug resistant infections)

1987 – Lovastatin - first statin for cardiovascular disease

1995 – World Bank Program to distribute MECTIZAN for River Blindness

1996 – CRIXIVAN – for HIV/AIDS

2006 – JANUVIA for type II diabetes

2006 – Gardasil – Human Papilloma Virus (99% efficacy)

2007 – Isentress – antiretroviral for HIV

2014 – Keytruda – FDA approval, breakthrough Anti-PD1 mAB for Melanoma

Today: Working on a cure for Hepatitis C, and much more

** Maurice Hilleman
credited with
saving more lives
than any other
medical scientist
in the 20th century*



Today's Merck

- **Merck** is a global healthcare leader working to help the world 'Be Well'
 - In business since 1851, currently operating in 140 countries with approximately 73,000 employees
 - Pharmaceuticals, Vaccines, Biologics, Consumer Care, Animal Health
 - 2013 revenue: \$44 billion
- **Merck Manufacturing Division (MMD)** manufactures a majority of Merck's products through a global manufacturing network
- **Global Science, Technology & Commercialization (GSTC)** is an MMD function responsible for the late stage development, commercialization and life-cycle support of Merck products
 - GSTC is a large and diverse organization located at over 50 sites, in over 20 countries around the world

With Growing Pressures... the need for knowledge flow came in to focus...



Growing network, complexity

- Globalization
- Externalization
- In- & Out-licensing
- Market pressures
- M&A

Insufficient knowledge capture

- Explicit knowledge
- Tacit knowledge



Past “KM” failures

- KM = IT
- Lack of processes, culture, sponsorship



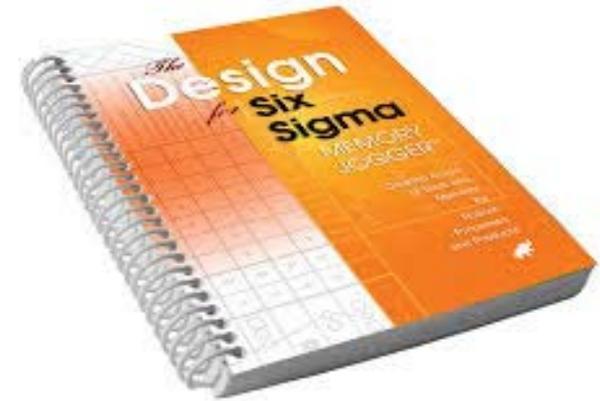
Increased Expectations & Opportunity

- Quality by Design
- Regulatory bodies

Taking the first step...



APQC® +



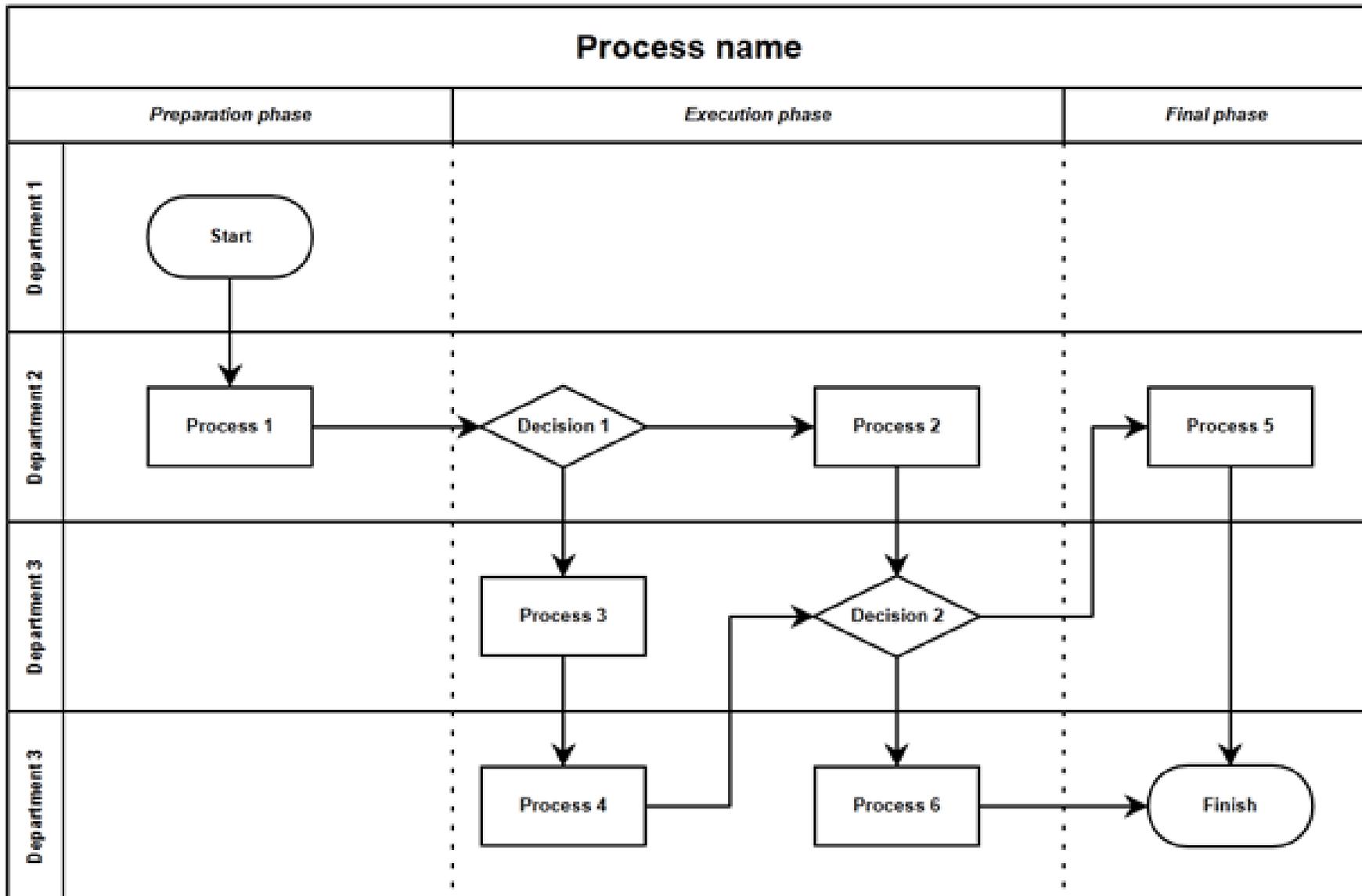
Build a **strategy** that would:

- Create alignment, set direction and concentrate resources
- Help us define and make choices such as tacit vs explicit
- Enable us to learn by doing
- Help us **think big, start small...but start**

It All Starts with 'The Work'

Using a knowledge map to identify needs

Process is illustrative only



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Using a knowledge map to identify needs

Process is illustrative only

		Process Step	Knowledge Needed	Created By	Used By	Explicit or Tacit	Where is it	Flow	Impact	Gap / Opportunity
Department 1	A	Early Risk Assessment	API Engineering	Pharm Engineering	Explicit	Document Repository	Green	Red	None	
					Tacit	Partially captured on RA	Yellow	Red	Rationale not consistently captured	
Department 2	B	Safe operating conditions	Safety Eng	API Engineering	Explicit	Document Repository	Yellow	Red	Not sure which is latest version	
Department 3	C	Summary of lab development	Analytical	Registration Team	Explicit	Local team work space	Red	Red	No standard repository	
	D	Performance of similar product	Manufacturing	Development	Tacit	Local, at manufacturing sites	Yellow	Yellow	Limited access to SMEs and no standard expectations for reporting	
Department 3	E	Knowledge on powder processing	Pharm Engineering, Manufacturing	Manufacturing	Tacit	Unknown	Red	Yellow	No formal SME listing identified	

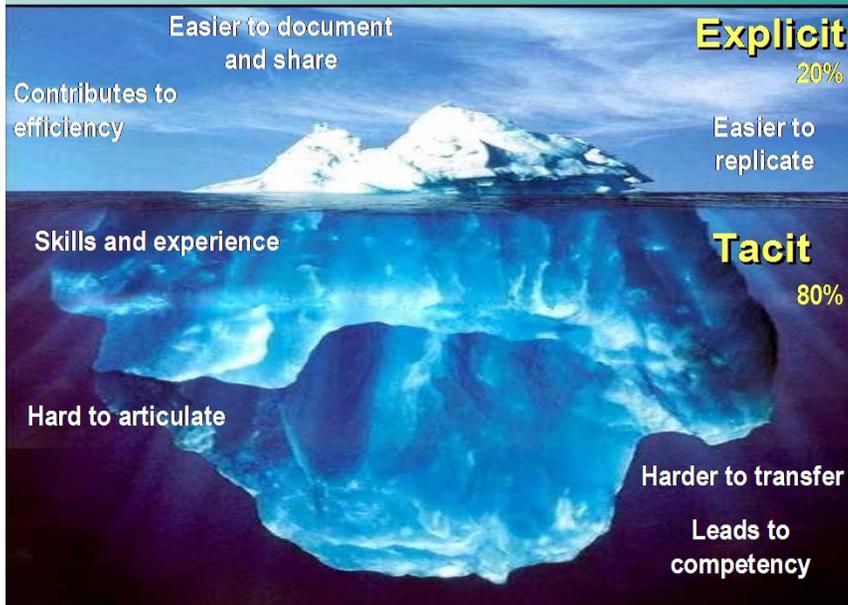
It All Starts with 'The Work'

Using a knowledge map to identify needs

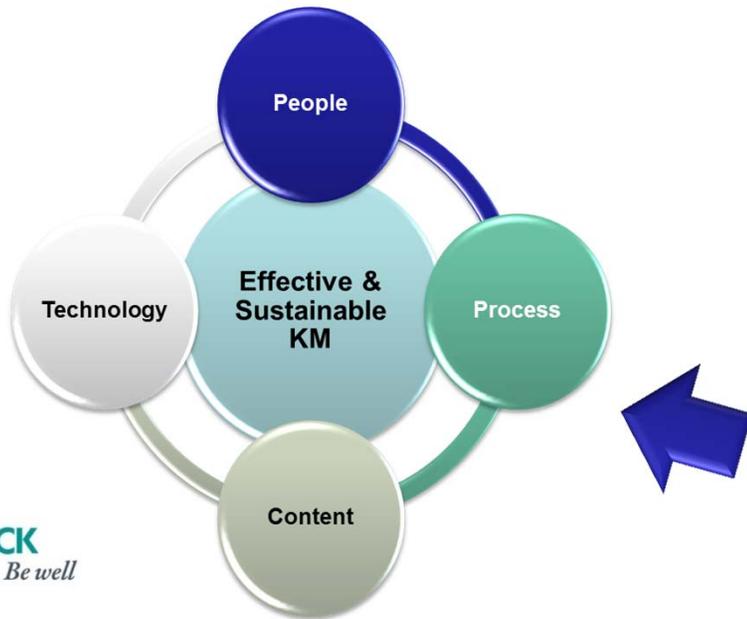
Process is illustrative only



Guiding Principles

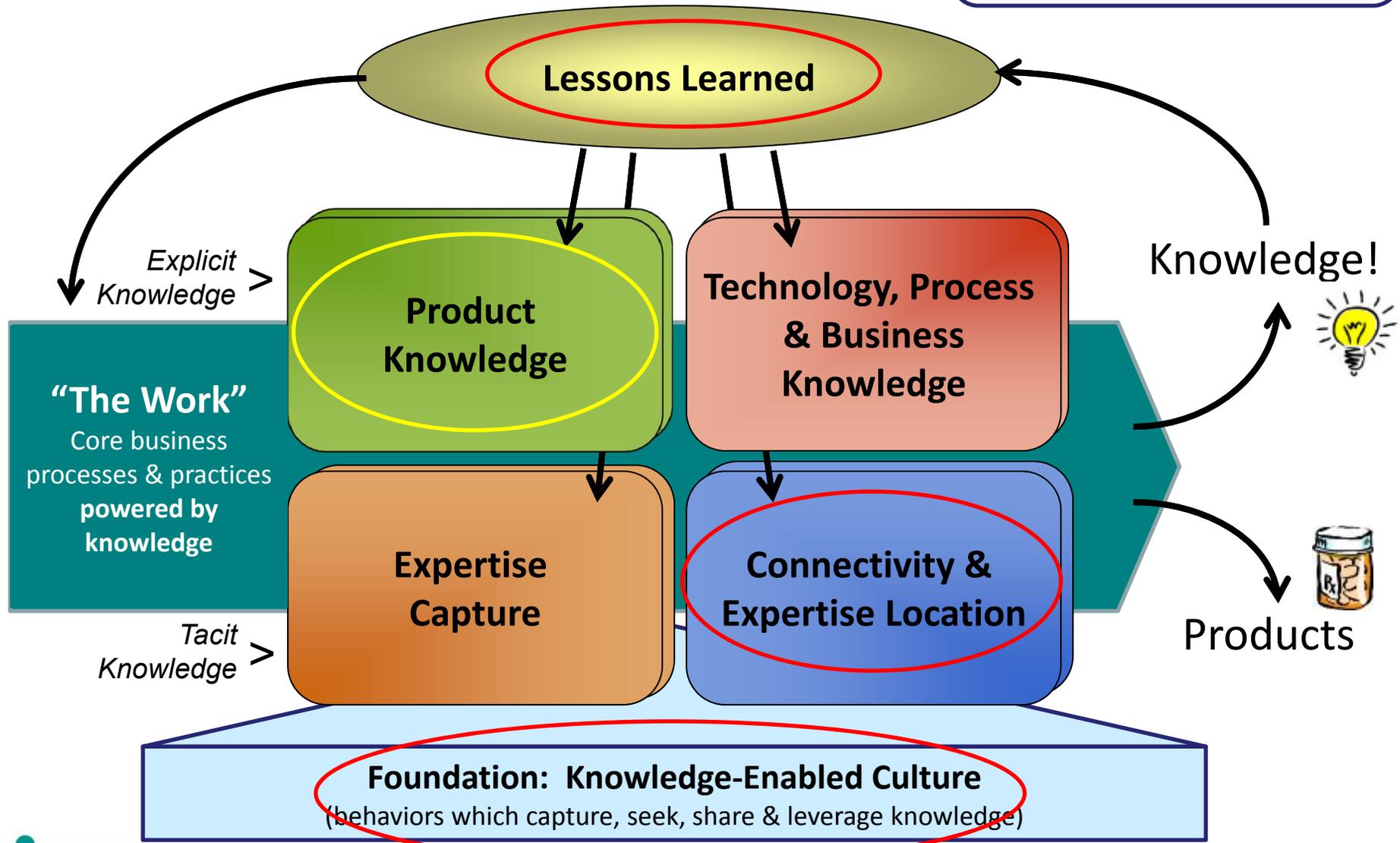


credit: APQC



Merck Knowledge Ecosystem

*“Knowledge knows no organizational boundaries... it is **boundaryless**”*



The VTN is...Connectivity!



Analytical Science & Technology



Applied Statistics & Experimental Design



Automation



Best Practices for Cleaning



Biologics & Sterile Processing



Data Modernization



Excipients



Engineering



Packaging



Proactive Process Analysis



Process Modeling



Powders Processing



Process & Environmental Safety



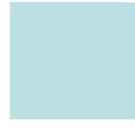
Robotic Automation



Health, Wellness & Fitness



Medical Devices



Learning Tools & Technology



Global Change Management



RLMS



Quality by Design



Single Use Network



Stability



Substitution & Biopharmaceuticals



Technical Challenges and Solutions in Emerging Markets



Technology Transfer Improvement



Women's Health & Specialty Products



Women in Science and Engineering

VTN Enables the POWER of the NETWORK

“Have you seen...?”
“Does anyone know...?”
“What else should we try...?”
“How would you...?”



“Did you consider...”
“You should talk to...”
“When that happened to us, we...”
“Here is the link to...”

The NETWORK

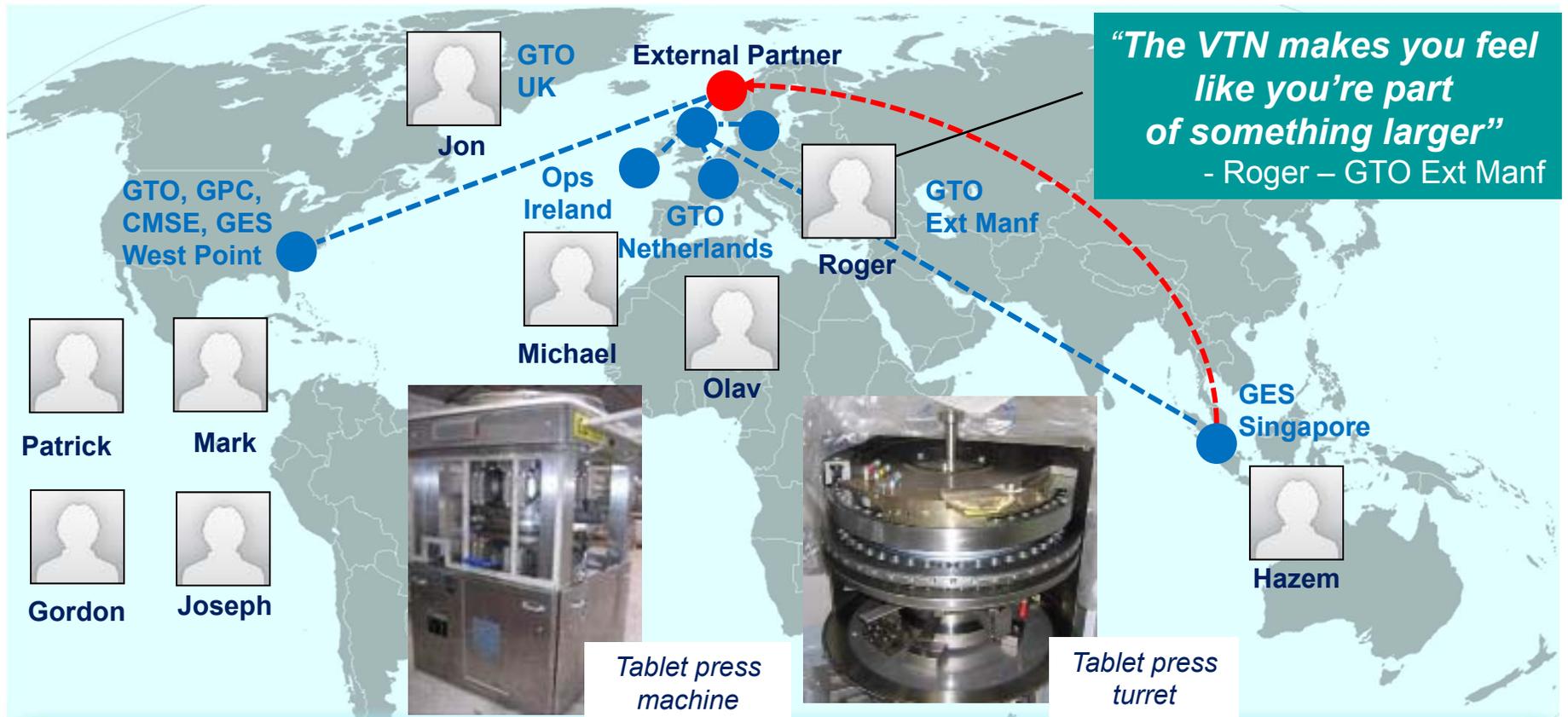
- 27 Communities
- 4k members
- 1000 questions in 2013, 3100 responses
- 40% ex-US membership
- Countless new connections established

The IMPACT

- 50% hidden expertise
- 81% increased engagement
- No need to go “up and over”
- Tens of millions in business benefit from improved connectivity & collaboration
- 2014 winner: *Workplace Leadership*

What this looks like in action: Success Story

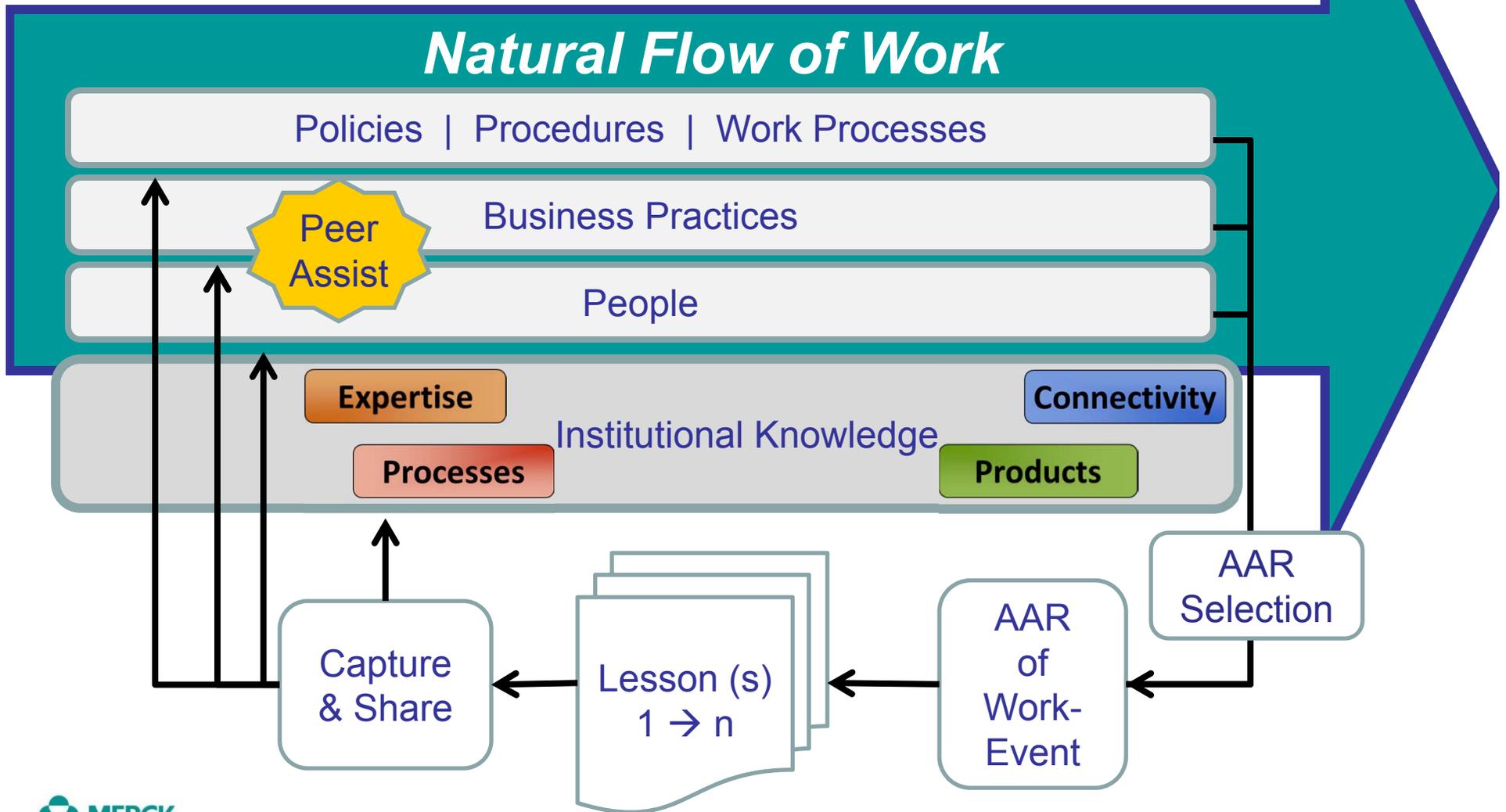
\$3MM and 20 weeks saved when our global network leveraged *Tier Process*, *VTN* and *Compression Technology Platform* to ensure reliable, cost-effective Supply of a Key Product



- ❖ Our global network engaged rapidly to locate a spare turret in Singapore within 1 business day to replace a damaged turret used for a Key Product in the UK
 - ❖ Operational in 4 weeks versus 24 weeks for new turret from vendor
 - ❖ Direct benefits plus great credibility building with partner, enhanced relationship for the future

MMD Lessons Learned System

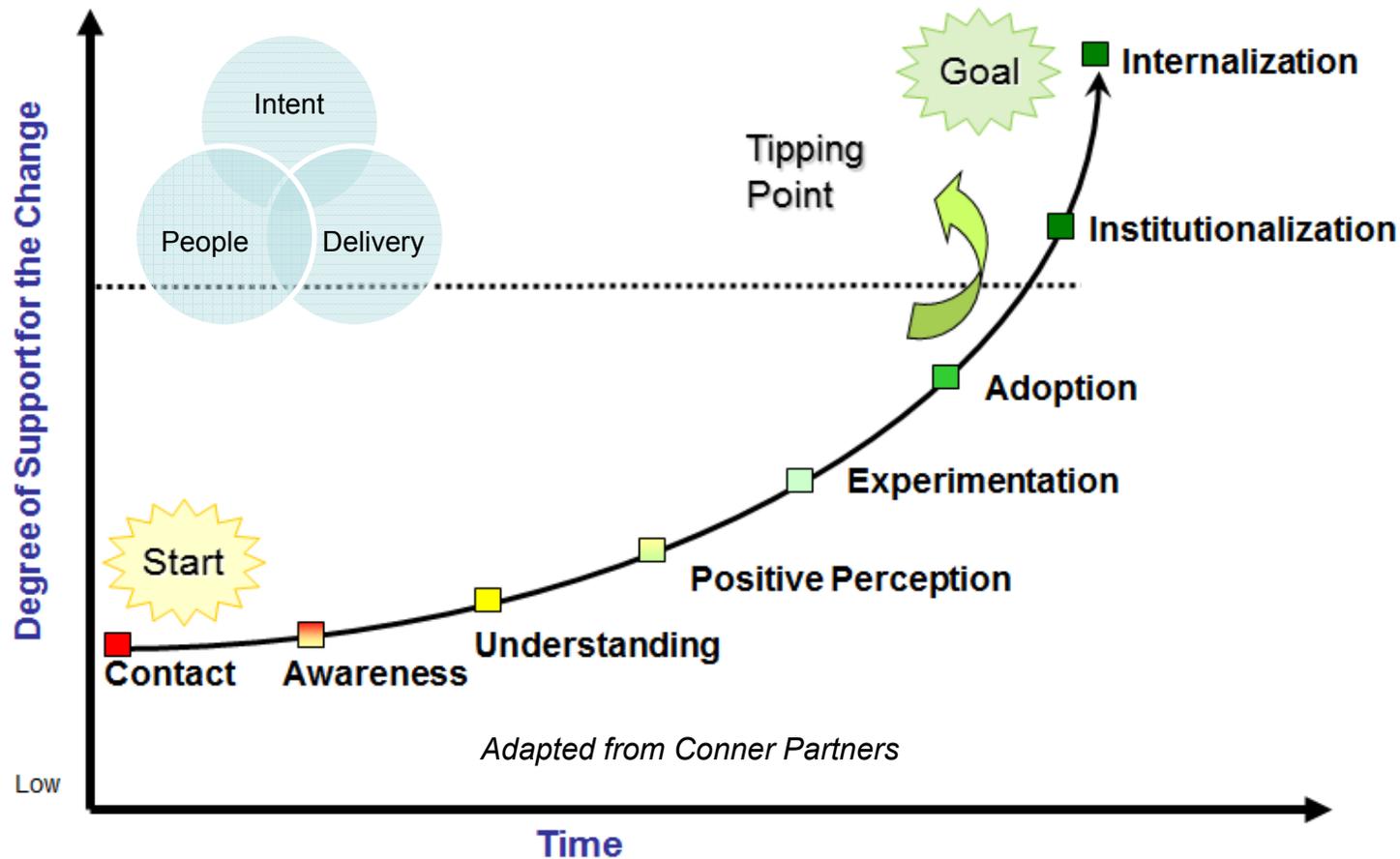
Generalized Life of a Lesson



Key Change Execution Concepts

*blending social technologies for success**

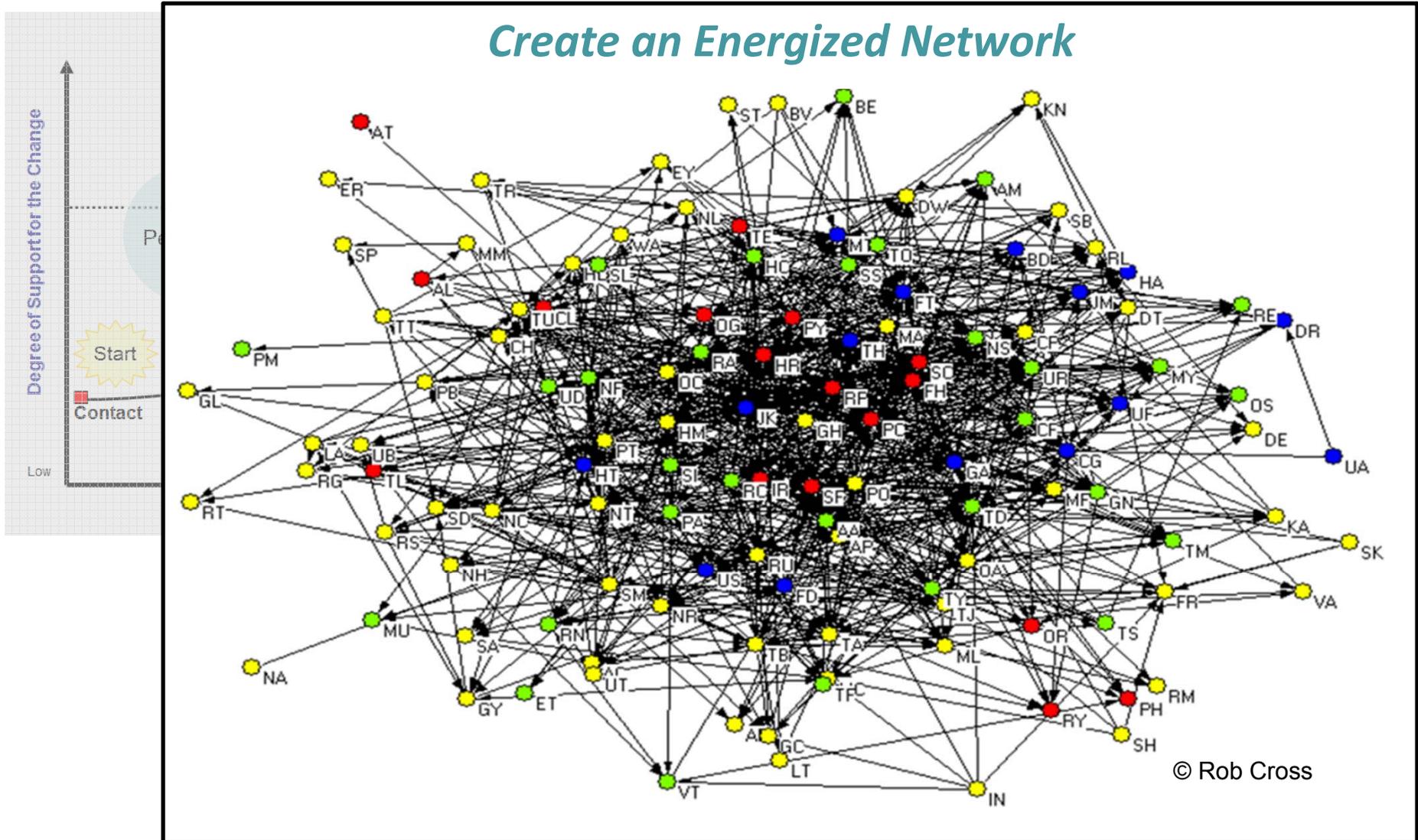
Structured Methodology (CEM)



Key Change Execution Concepts

*blending social technologies for success**

Create an Energized Network

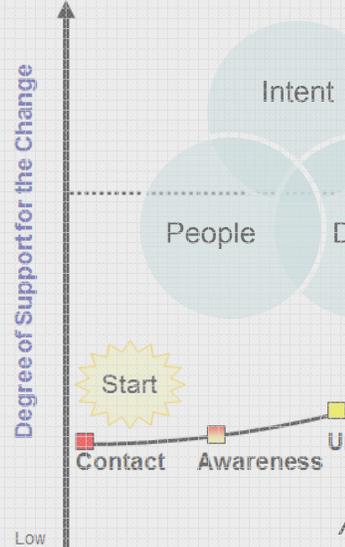


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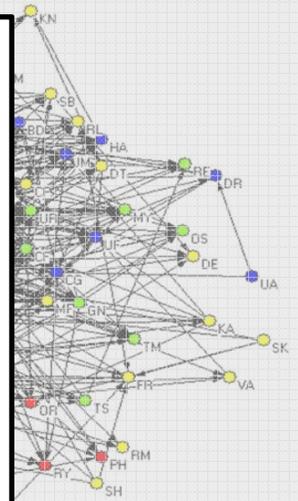


Behaviors are Critical

Ensuring people have the right:

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- Direction
- Competence
- Opportunity
- Motivation



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Key Change Execution Concepts

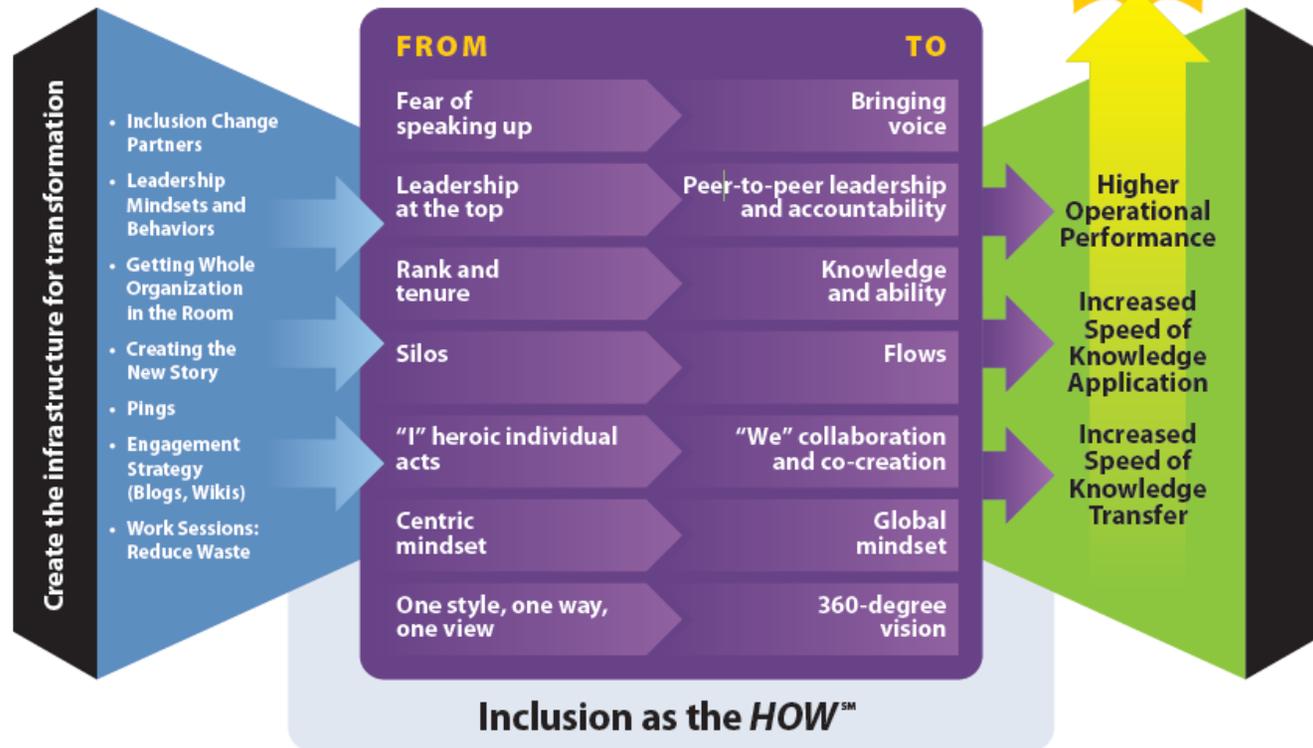
*blending social technologies for success**

Structured Methodology (CEM)

Create an Energized Network

Tap into Culture

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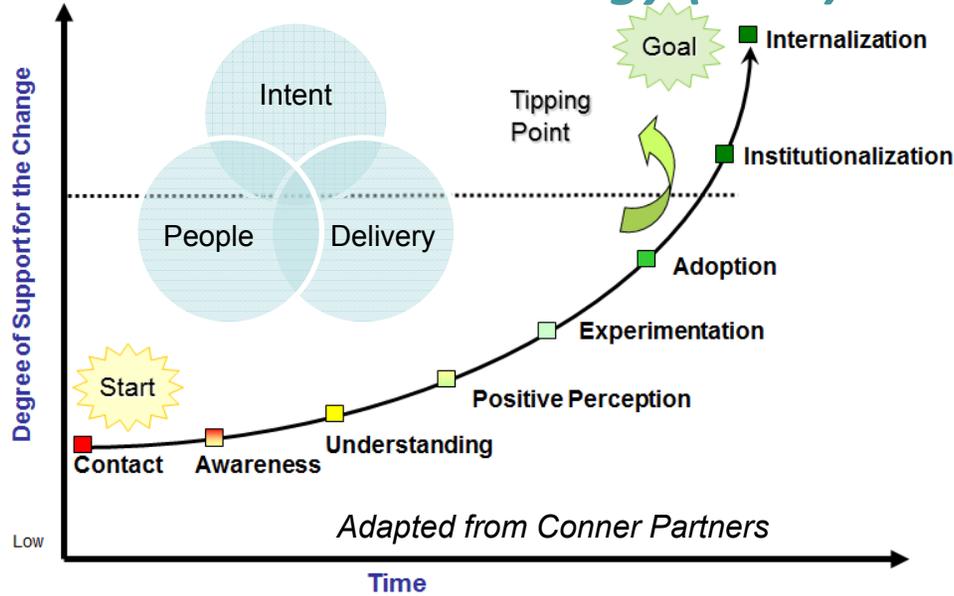
critical

the right:

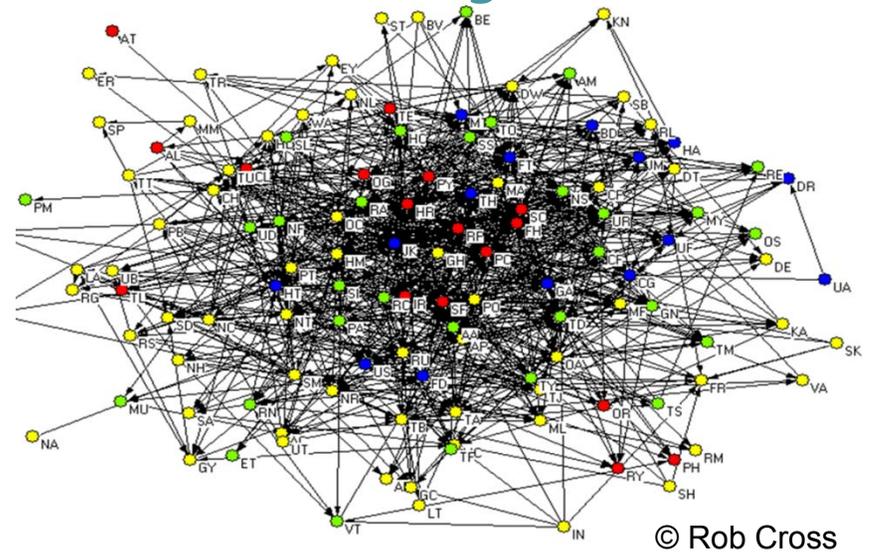
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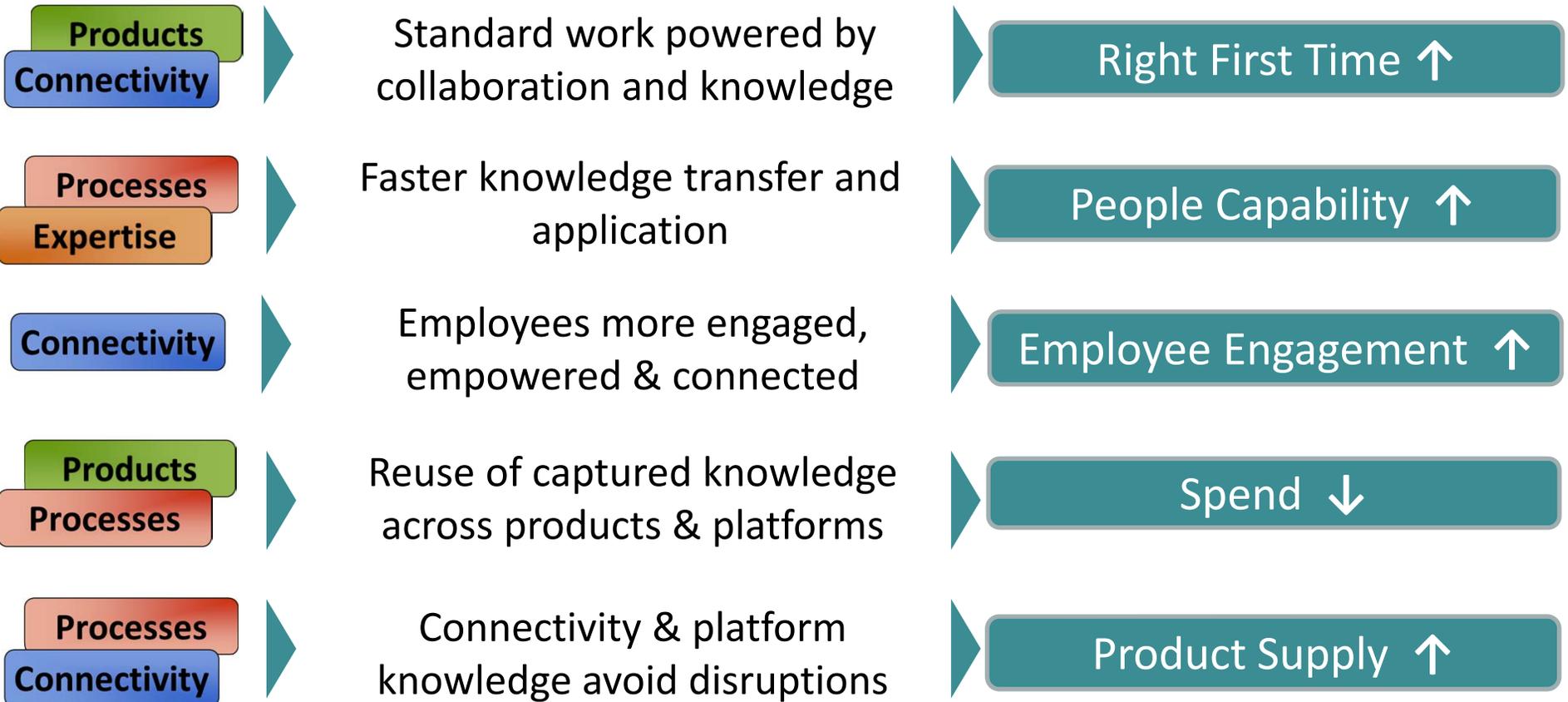
*R. D. Guenard, M.J. Lipa, S. Bruno and J. Katz, "Enabling a New Way of Working through Inclusion and Social Media: A Case Study", *OD Practitioner*, 45(4), 2013

Improved Knowledge Flow = Improved KPI's

Capability...

Which Enables...

Which Drives...

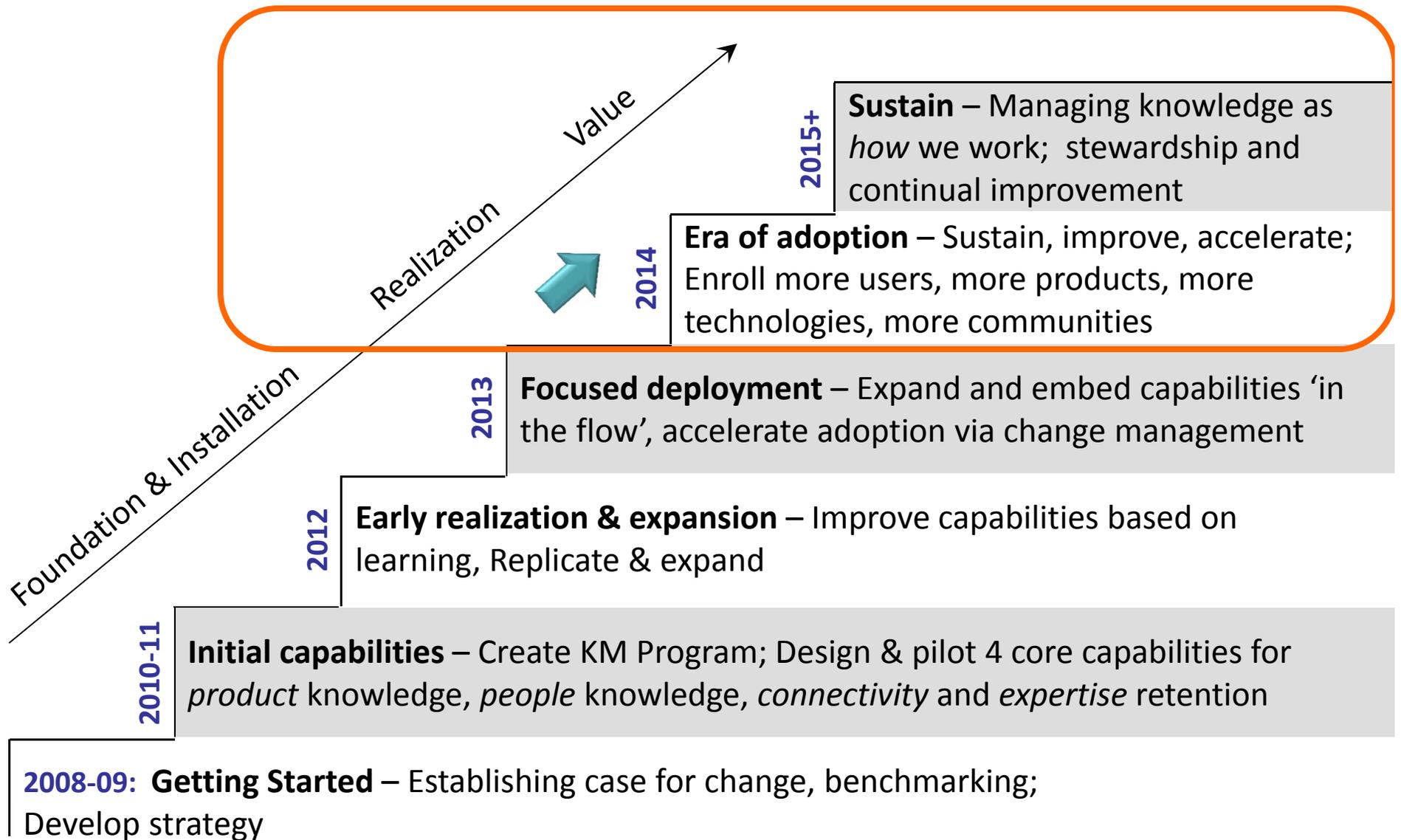


Key Lessons from our Journey

- **Sponsorship, sponsorship, sponsorship**
- **Alignment** with business priorities
- **Framework:** People, Process, Content, Technology
- Embed KM **'in the flow'**
- **Stewardship, stewardship, stewardship**
- **Tell the new story**



Roadmap of our Journey



The Road Ahead



Challenges

- Getting **everyone in the pool**
- Creating and maintaining k-behaviors in a **shrinking environment**
- Many still **see as an initiative**
- **Change capacity**
- Articulating **business value**

Opportunities

- **Operationalize** in the flow of daily work
- Link to our **organizational performance goals**
- **Opportunistically** grow to deliver value to Merck
 - Build KM into new processes
 - Scope of knowledge and served population
 - New knowledge capabilities

With Special Thanks to...

- Dr. Michael Thien
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- Anando Chowdhury
- David Vossen
- GSTC Leadership Team
- MMD KM CoE Team
- APQC

and many fellow KM practitioners!



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For more details, see ISPE Pharmaceutical Engineering (Nov/Dec 2013, Vol 33 #6):

A Practical Approach to Managing Knowledge –

A Case Study of the Evolution of Knowledge Management (KM) at Merck

How to Reach Us

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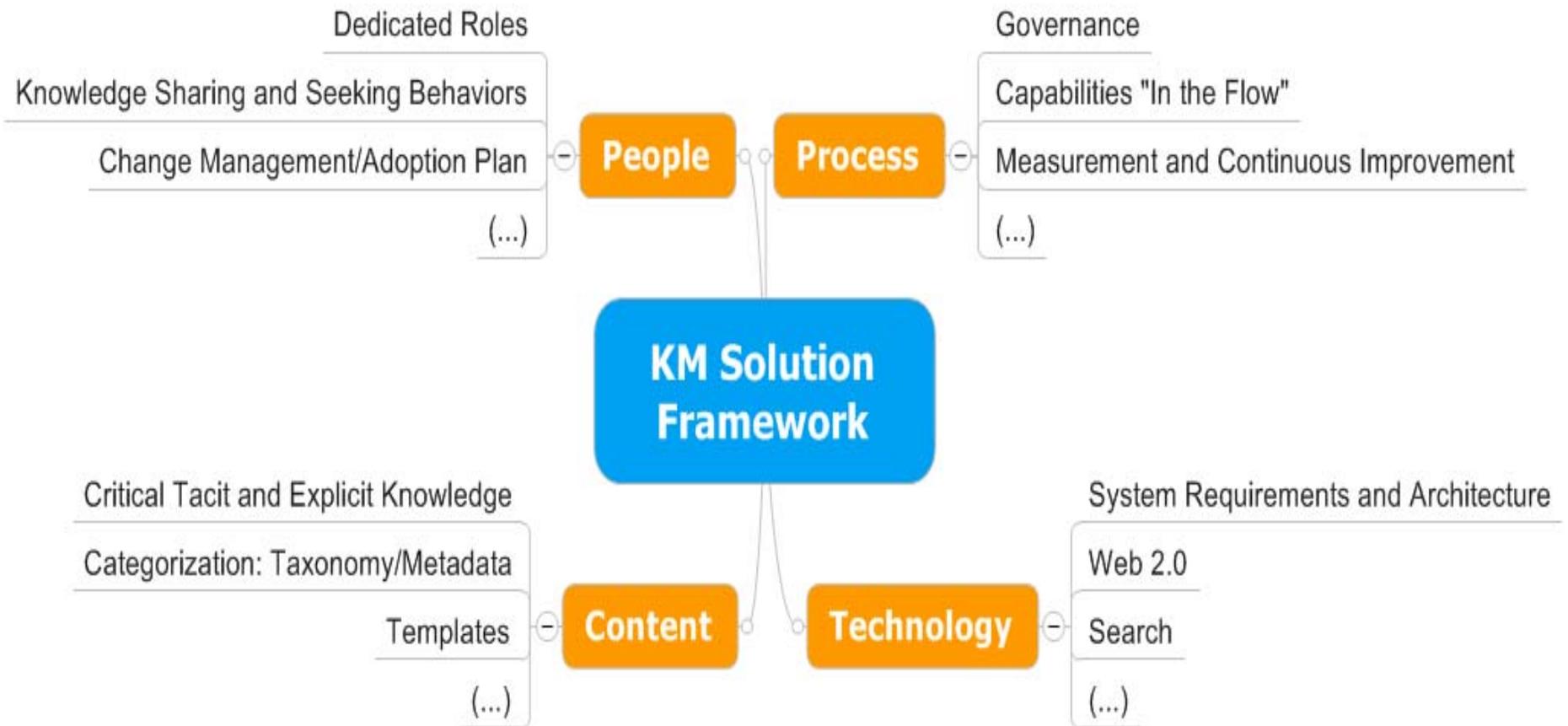
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Extras

Our Framework in Action



What is Design for Six Sigma?

“Did the strategy deliver?”

- Control & monitoring plan
- Measure & sustain
- **Improved business KPIs**

“What is the desired future state & steps to achieve?”

- **Strategic Plan**, including:
 - Principles, program, pilots
- **3 Year Roadmap**

“How does knowledge *flow* now?”

- Knowledge maps
- **Business case**

“What are the goals of improved knowledge *flow*?”

- Charter effort, establish team
- Anecdotal evidence, baseline performance
- **Link to business strategy**

“What knowledge is most important to Merck’s mission?”

- Voice of the Business
- Benchmarking
- **Link to specific business KPIs**

IMPROVE!



What are the attributes of a transformational change?

Strategy Execution is applied when the change is transformational.

INDICATORS OF TRANSFORMATIONAL CHANGE	INDICATORS OF NON-TRANSFORMATIONAL CHANGE
Intent driven; designed from the future (leap; innovate)	Designed from the current state (improvement)
Modifies behaviors, beliefs, and assumptions	Modifies methods, systems, and behaviors
No right answer; many right answers	Clear direction
Designed with a customer focus	Designed with a process focus
Different, unrecognizable, challenging	Familiar, improvement, better
A significant number of changes required across a large span of the organization	Fewer changes required and/or a smaller span of the organization affected
Major disruption of people's expectations	Minor disruption of people's expectations
Planned from an outcome perspective	Planned from a start point
Multiple interdependent components to integrate	More linear path
High shift to the politics of the organization	Minimal change to existing politics
A significant number of people will be unwilling or unable to complete the journey	A small number of people will be unwilling or unable to complete the journey

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