Clinical Knowledge Management: Executive Overview
Currently there are challenges that prevent organizations from realizing the full value of knowledge:

- Document repositories difficult to navigate/not user friendly
- Information is siloed
- Users don’t have access to the right information
- Knowledge leaves when people leave
- Experts are not well-identified/not easy to find them
- Information not available at the click of a button
- New knowledge is not effectively disseminated
- Best practices not captured/shared
Knowledge is “Information in Action” - using knowledge proactively to improve performance or decision making

Potential State

When KM is in practice, people across an organization will...

- Extracting optimal value from Knowledge
- Opportunities for competitive advantage
- Minimization of risk
- Easy access to the right knowledge and the right people
- Improved decision making
- Improved organizational performance: Growth in productivity and profit margins

1 McKinsey Global Institute (MGI) research: the state of digitization in sectors across the U.S. economy
## Challenges

- Do not know where/how to find information
- Inefficient search engine technology/poor results
- Information distributed across multiple locations and systems
- Illogical organization of content
- Ineffective tagging (labeling) when contributing content
- Content not easily usable

## Consequences

45% of users surveyed found it difficult to search for and find the information they needed\(^1\)

Inability to easily find information leads to 16% lost time on a weekly basis or $5M annually, based on industry studies\(^2\)

## Opportunities with KM

- Know what knowledge exists, where to look for it and how to quickly find it
- Capture knowledge in a consistent and searchable manner

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\(^1\) Source: KM Survey of TransCelerate member companies - Sept 2015
\(^2\) International Data Corporation (IDC’s) Unlocking the Hidden Value of Information Survey, Dec 2013 - 2155 organizations surveyed
Organizations can leverage KM solutions to learn from prior experiences and drive strategic decisions

**Issues Caused by Lack of Knowledge Sharing or Resource Availability**

- Wasted time due to re-work
- Repeat issues
- Poorly informed decisions
- Ineffective KM with external parties
- Delays in study/program timeline
- Higher costs
- Over emphasis on training for CAPA remediation
- Repeat audit/inspection findings

**Use of past lessons learned results in**

- Reduced risk of:
  - Repeat inspection / audit findings
  - Protocol amendments
  - Study delays
- Less redundancy / not reinventing the wheel
- Reduced loss of institutional knowledge
- Shared insights and improved collaboration

**Opportunities with KM**

Share lessons learned so new work always starts using current best practice

Proactively implement and use insights to minimize risk

Source: KM Survey of TransCelerate member companies - Sept 2015 (survey conducted on blinded basis)
In a globally distributed organization it is important to be able to find the right people or experts

<table>
<thead>
<tr>
<th>Challenges and Impact</th>
<th>Potential State</th>
<th>Opportunities with KM</th>
</tr>
</thead>
<tbody>
<tr>
<td>No systematic approach to easily identify experts</td>
<td>Knowledge experts are readily identifiable and easily accessible</td>
<td><strong>Know who the experts are and how to contact them for advice</strong></td>
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<tr>
<td>After Action Reviews (AAR) not held / not effective</td>
<td>Timely conduct of After Action Reviews: insights in the minds of individuals help others learn</td>
<td><strong>Connect readily across boundaries of teams, functions and geographies</strong></td>
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<tr>
<td>People networks either don’t exist or knowledge is not shared through them</td>
<td>People go to their networks when faced with complex / abstract challenges</td>
<td></td>
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</tbody>
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**Costly lost opportunities:**
- Wasted time / milestones missed
- Ineffective sharing of insights
- Non-optimal decision making
- Errors repeated due to not knowing about insights
Strong support & engagement from leadership and a knowledge seeking & sharing culture are critical for success

Main reasons why KM fails:

• Lack of strong sponsorship of the KM program by leadership
• Lack of reinforcement of desired behaviors
• Misconception that KM technology alone is sufficient
A proposed solution: a Clinical KM Program across Clinical Development or selected areas based on the CKM framework

Clinical Knowledge Management Framework

Example:
Embedding KM into process flows - either by presenting content or providing links to:

- SOPs, templates, Job Aides
- Names of experts for that process
- Links to related training
- Search capability for related content
- Links to relevant data/trends or insights
- Discussion board to the relevant Disease Area community

Adapted from O’Dell and Hubert, 2011
Effective KM connects the right people to the right information/expertise at the right time, which positively impacts the business.

Implementation of an effective knowledge management program enables avoidance of costs, which can add up to significant annual savings.

Sample benefits:

- **EXTENDING PROJECT TEAM**
  - 1-6 months
  - ~$650k - $12M

- **CRISIS TEAMS**
  - $100k-$144k for each team
  - >$10M

- **AMENDMENTS**
  - 25% avoidable
  - ~$5M (excl. Phase 1)

- **IMPROVED & MOTIVATED WORKFORCE**
  - Significant impact for organizations

THE KEY IS:

“Think big, start small – but start!”

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1 Source: Blinded estimates from a TransCelerate Member Company
What might the next steps be for an organization to “get started”?

**Understand the Knowledge Needs**
Identify the critical knowledge necessary to drive optimal outcomes tailored to organizational needs.

**Assess Opportunity**
Understand where improvement of knowledge flow may provide opportunity for enhanced execution to improve critical business outcomes.

**Design and Implement Solutions**
Define and deploy mechanisms to enable and improve knowledge access and sharing.

**Improve and Sustain**
Assess performance against anticipated outcomes and adjust as necessary. Assess opportunities for continuous improvement to sustain the framework over time.