Clinical Knowledge Management (CKM) and Tool Guide
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Introduction to the CKM Reference and Tool Guide

This Guide has been created to help clinical development organizations, whether a team, department or organization as a whole, recognize what types of tools and resources are available and would potentially be useful in the development, maintenance and continuous improvement of a Clinical Knowledge Management (CKM) strategy and program.

The Guide provides brief, high-level descriptions of Knowledge Management (KM) tools with references to practical applications. This tool also provides a list of selected, general resources such as KM websites, professional associations & publications, that might help with KM implementation.

It is intended to be used as an initial resource and reference to help increase level of CKM understanding and is not intended to represent the ultimate source of CKM knowledge resources nor as a “how to” guide for use of the suggested tools.
Introduction to the CKM Reference and Tool Guide

To help users determine what types of CMK tools or resources would be applicable during the various stages of a CKM Program lifecycle, the search function is structured based on visual aids which can be navigated via different views as described in the TransCelerate Manuscript:

- KM In Action – Knowledge Lifecycle
- CKM Framework
- Steps For Development of a CKM Program

Note that similar types of KM tools may appear when the user selects different combinations of categories during a search. This Reference and Tool Guide does not describe specific CKM tools developed by the TransCelerate CKM workstream.

Before using the CKM Reference Tool Guide it is important that you have read the TransCelerate CKM manuscript. This will help in the interpretation of the search results and their possible purpose.

Tools and resources developed by TransCelerate can be found at:

http://www.transceleratebiopharmainc.com/initiatives/quality-management-system/

Link to the sharepoint where member companies can access other tools.
KM in action
– Knowledge Lifecycle
Know what knowledge exists, where to look for it and how to quickly find it

Capture knowledge in a consistent and searchable manner

Know who the experts are and how to contact them for advice

Connect readily across boundaries of teams, functions and geographies

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

IDENTIFY

- Best Practices
- Communities of Practice, Centers of Excellence
- Content Management: Document Repositories, Portals, Wikis
- Expertise Location
- KM Maturity Models
- Knowledge Mapping
- Offboarding
- Onboarding
- Storytelling, Case studies

CAPTURE

- Best Practices
- Communities of Practice, Centers of Excellence
- Content Management: Document Repositories, Portals, Wikis
- Lessons Learned, After Action Review, Milestone Review
- Offboarding

STRUCTURE

- Content Management: Document Repositories, Portals, Wikis
- Search-enablers: Enterprise search
- Search-enablers: Faceted search
- Search-enablers: Taxonomy, Metadata/keyword, Folksonomy

VALUE

- Best Practices
- Knowledge Mapping
- Lessons Learned, After Action Review, Milestone Review
- Offboarding
- Onboarding
- Storytelling, Case studies

LEVERAGE

- Best Practices
- Communities of Practice, Centers of Excellence
- Content Management: Document Repositories, Portals, Wikis
- Expertise Location
- KM Maturity Models
- Lessons Learned, After Action Review, Milestone Review

SHARE

- Best Practices
- Communities of Practice, Centers of Excellence
- Content Management: Document Repositories, Portals, Wikis
- Expertise Location
- Lessons Learned, After Action Review, Milestone Review
- Offboarding
- Onboarding
- Role Mentoring, Apprenticeships
- Storytelling, Case studies
TransCelerate’s Clinical Knowledge Management Framework
TransCelerate’s Knowledge Management Framework

Knowedge Management

People
- KM Specific roles
- Training, teaching, mentoring
- Change management roles

Business Process
- Integration of KM in business processes
- Governance
- Measurement
- Change management

Content
- Tacit & explicit knowledge
- Taxonomy & metadata
- Templates & tools

Technology
- Data Storage
- Document repositories
- Team sites
- Networking software
- Search capabilities

Continuous Improvement
- Flexibility
- Knowledge-driven learning and improvement

Culture
- Leadership commitment
- Promotes knowledge seeking and exchange

Adapted from O’Dell and Hubert, 2011.
## Tools for Category

### CULTURE
- Best Practices
- Communities of Practice, Centers of Excellence
- Expertise Location
- Lessons Learned, After Action Review, Milestone Review
- Offboarding
- Onboarding
- Role Mentoring, Apprenticeships
- Storytelling, Case studies

### CONTINUOUS IMPROVEMENT
- Best Practices
- KM Maturity Models
- Knowledge Mapping
- Lessons Learned, After Action Review, Milestone Review
- Offboarding
- Storytelling, Case studies

### PEOPLE
- Best Practices
- Communities of Practice, Centers of Excellence
- Expertise Location
- Lessons Learned, After Action Review, Milestone Review
- Offboarding
- Onboarding
- Role Mentoring, Apprenticeships
- Storytelling, Case studies

### BUSINESS PROCESS
- Best Practices
- KM Maturity Models
- Knowledge Mapping
- Lessons Learned, After Action Review, Milestone Review
- Onboarding
- Role Mentoring, Apprenticeships
- Storytelling, Case studies

### CONTENT
- Content Management: Document Repositories, Portals, Wikis
- Search-enablers: Enterprise search
- Search-enablers: Faceted search
- Search-enablers: Taxonomy, Metadata/keyword, Folksonomy

### TECHNOLOGY
- Content Management: Document Repositories, Portals, Wikis
- Search-enablers: Enterprise search
- Search-enablers: Faceted search
- Search-enablers: Taxonomy, Metadata/keyword, Folksonomy
Steps for Development and Sustain of a CKM Framework
Steps for Development and Sustain of a CKM Framework

Think big, start small. And most importantly – Start!

1. Understand the Knowledge Needs
2. Assess Opportunity
3. Design and Implement Solutions
4. Improve and Sustain
Step 1: Understand the Knowledge Needs

**Actions to Take:**

1. Identify most critical information and knowledge needed by the organization
2. Understand the challenges and risks related to knowledge gaps
3. Assess KM behaviors of the organization

**Outcome:**

Areas of critical knowledge needs in key business processes are identified for more detailed assessment in Step 2

Identify the critical knowledge necessary to drive optimal outcomes tailored to organizational needs
Step 2: Assess Opportunities

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

Actions to Take:

1. Identify current gaps in the availability of specific knowledge needed to support key business processes
2. Prioritize opportunities based on business needs
3. Propose business case and pilot projects to relevant governance body for approval

Outcome:

Business case and pilot(s) are endorsed by governance body
Step 3: Design and Implement

Define and deploy mechanisms to enable and improve knowledge access and sharing

**Actions to Take:**

1. Select relevant KM approach(es) to address the types of knowledge to be managed
2. Design Clinical KM solutions/tools
3. Develop training plan and training materials
4. Communicate training and implementation plans to users
5. Deliver training to users
6. Deploy Clinical KM solutions/tools
7. Support users
8. Define measures for assessing use and effectiveness

**Outcome:**

CKM Solutions/Tools implemented with user support system in place
Step 4: Improve and Sustain

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

Actions to Take:

1. Establish ongoing oversight and business processes for Clinical KM Program maintenance and improvement
2. Update and/or expand Clinical KM Strategy and Program based on evolving business needs
3. Define and implement business-related measures for assessment of Clinical KM performance
4. Develop approaches for reinforcement and recognition of Clinical KM successes

Outcome:

CKM Program and Strategy established with mechanisms in place for ongoing oversight and feedback on performance
Tools for Category

1. UNDERSTAND THE KNOWLEDGE NEEDS

- KM Maturity Models
- Knowledge Mapping
- Lessons Learned, After Action Review, Milestone Review
- Offboarding
- Onboarding
- Storytelling, Case studies

2. ASSESS OPPORTUNITY

- KM Maturity Models
- Lessons Learned, After Action Review, Milestone Review
- Offboarding
- Onboarding

3. DESIGN AND IMPLEMENT SOLUTIONS

- Best Practices
- Communities of Practice, Centers of Excellence
- Content Management: Document Repositories, Portals, Wikis
- Expertise Location
- KM Maturity Models
- Lessons Learned, After Action Review, Milestone Review
- Offboarding
- Onboarding
- Role Mentoring, Apprenticeships
- Search-enablers: Enterprise search
- Search-enablers: Faceted search
- Search-enablers: Taxonomy, Metadata/keyword, Folksonomy

4. IMPROVE AND SUSTAIN

- Best Practices
- Communities of Practice, Centers of Excellence
- Content Management: Document Repositories, Portals, Wikis
- Expertise Location
- KM Maturity Models
- Lessons Learned, After Action Review, Milestone Review
- Offboarding
- Onboarding
- Role Mentoring, Apprenticeships
- Storytelling, Case studies
Tool Descriptions
Best Practices

Description:
Methods or techniques that have been generally accepted as superior to any alternatives because they produce superior results and/or have become the standard way of doing things. Use of best practices, which are continually improved through experience and lessons learned, drives consistency in execution within an organization and improves productivity and efficiency. A commitment to using the best practices in any field is a commitment to using all the existing knowledge and technology at one's disposal to ensure success.

References:
As best practices vary and depend on each individual company's circumstances and stage of maturity, no references are provided.
Communities of Practice, Centers of Excellence

Description:
Groups of interested individuals come together (face-to-face or virtually) to share a common area of expertise, search for solutions to common problems, and/or learn from one another. Facilitate the flow of knowledge across boundaries in geography, function, team, etc. Each community is centered around a topic of importance to the business, particularly where expertise is not widely available.

References:

Expert Location

Description:
Identify experts in specific areas and make it easy for employees to find them, regardless of geographic and departmental boundaries. Possible approaches include on-line directories, searchable profiles, social networking, mining of e-mail topic frequency, scientific publications & patents, etc.

References:
Content Management: Document Repositories, Portals, Wikis

Description:
One-stop-shopping for content that provides single authoritative instance of a file (vs. duplicate files with different versions in multiple locations); access to a central repository (vs. proliferation of storage repositories); and enables search by standardizing the naming conventions for similar content. The lifecycle of document repositories/portals includes:

• **Author** – creation & updating, version control
• **Review** – validation/vetting of content & placement
• **Administration** – controlled access (permissions), standardization rules, archiving
• **User** – receives alerts for new content & changes to existing

References:
Enterprise Content Management. Enablers of Effectiveness. APQC. August 26, 2014.
https://www.apqc.org/search/apachesolr_search/Enterpris%20Content%20Management.%20Enablers%20of%20Effectiveness
Description:
An assessment of knowledge management capability levels across multiple dimensions that provides a measurement of KM program status versus a maturity scale. Evaluates the gaps/areas for improvement and capabilities that need to be focused on to achieve goals. Provides a framework to measure the progress of a KM program against an external benchmark and helps determine next steps toward reaching the desired maturity level.

References:
Knowledge Mapping

Description:
A knowledge map identifies business-critical knowledge, sources, flows, gaps, barriers and dependencies using a visual representation of the knowledge of an organization or underlying a business process. Evaluate the knowledge flow, quality and business impact. Also useful for new employee training & personnel changes.

References:

**Description:**

Employees formally discuss, capture and share what they learned at established points or upon completion/resolution of a project or issue. A narrative account of an actual experience includes:

- **Context:** What was expected to happen?
- **Facts:** What actually happened?
- **Root Cause Analysis:** Why were there differences?
- **Recommendations:** What can be learned? Where else is this applicable?

A lesson can highlight positive or negative experiences, reinforce standard procedures, or inform best practices. A lesson is not "learned" until it results in a change in behavior and that change produces the predicted results.

**References:**

Offboarding

Description:
A process of capturing the explicit and tacit knowledge held by selected/experienced employees or experts in their field with critical knowledge not captured elsewhere, who are transitioning out of an organization. Develop strategies to successfully transfer the knowledge focusing on how they approach, analyze and solve problems. Offboarding process includes project wrap-ups, sharing and extracting the knowledge from a departing employee. Some approaches include make a plan, motivate the expert, create apprenticeships, emphasize team learning, document selectively, focus on the relationship, create offboarding checklist, etc.

References:

Onboarding

Description:
The process through which new employees acquire the necessary baseline knowledge, skills, and behaviors to become effective within the organization. Common approaches used in this process include formal meetings, lectures, videos, printed materials, or computer-based orientations to introduce newcomers to their new jobs, organizations and culture.

References:
https://en.wikipedia.org/wiki/Onboarding
Role Mentoring, Apprenticeships

Description:
Transfer of knowledge from experienced to newer employees with the goal of shortening time to competency and improving learning curves.

References:
Workplace Mentoring: Study Overview. APQC. April 21, 2016.  
https://www.apqc.org/search/apachesolr_search/Workplace%20Mentoring%3A%20Study%20Overview
Description:
Stories make abstract concepts concrete, easier to understand, and demonstrate best practices and/or lessons learned, including how KM practices can be applied plus the resulting benefits. This approach helps to bridge generational gaps and communicate important information about an organization. It also helps to foster engagement in a KM program and illustrate cultural behaviors that enable KM.

References:
Search-enablers: Enterprise Search

Description:
Enterprise Search: Single unified interface with capability to search multiple data sources in both intranet and internet, and provide results based on high relevance and semantic knowledge. Search queries and results can be shared and re-used. Limitations include return of results only from storage repositories to which the user has access and the content is not always reviewed or validated.

References:
As these are designed individually to address the needs of each organization, no references are provided.
Search-enablers: Faceted Search

**Description:**
Faceted Search: information classification structure consisting of a series of "facets" or dimensions according to which objects can be categorized, such as by location or subject.

Each facet is typically defined by a taxonomy. An item is classified by selecting the appropriate term from each relevant facet taxonomy. Commonly constructed as an aid for organizing and finding information. It can be used as a guide to Web-site navigation and search. It has more power than a single taxonomy because it supports different ways of classifying information. Multi-faceted navigation reflects the different perspectives of end-users. An illustrative example of search for study protocol dimensions: document type=protocol; therapeutic area; product; study phase; etc.

**References:**
As these are designed individually to address the needs of each organization, no references are provided.
Description:

Word(s) that describe a given knowledge item are often used to find it within a content management system. Taxonomy categorizes knowledge under consistent headings that enable search using the heading name. Additional detail that can be used in searching is provided by metadata: keywords that further describe specific knowledge items. Folksonomies may also be used through user generated tags.

References:


http://www.cs.nott.ac.uk/~pszdap/network/previous%20works/hops%20etc/understanding%20concept%20of%20knowledge%20leakage/km.pdf
General Knowledge Management (KM) Resources
## General Knowledge Management (KM) Resources

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<tr>
<td><strong>APQC: The American Productivity &amp; Quality Center</strong></td>
<td>APQC is a member-based nonprofit professional KM Organization. It is an authority in benchmarking, best practices, process and performance improvement, and knowledge management. APQC partners with more than 500 member organizations worldwide in all industries.</td>
<td><a href="http://www.apqc.org">www.apqc.org</a></td>
</tr>
<tr>
<td><strong>Electronic Journal of Knowledge Management</strong></td>
<td>The Electronic Journal of Knowledge Management (EJKM) publishes research on topics relevant to the study, implementation and management of knowledge management and intellectual capital and other related fields of study. The journal contributes to the development of both theory and practice in the field of knowledge management. The journal accepts academically robust papers, topical articles, communications, book reviews and case studies that contribute to the area of research in, and practice of knowledge management.</td>
<td><a href="http://www.ejkm.com/main.html">http://www.ejkm.com/main.html</a></td>
</tr>
<tr>
<td><strong>Emerald Insight/Journal of Knowledge Management</strong></td>
<td>Journal of Knowledge Management is an online journal covering subject areas of HR &amp; Organizational Behaviour, Information &amp; Knowledge Management.</td>
<td><a href="http://www.emeraldinsight.com/journal/jkm">http://www.emeraldinsight.com/journal/jkm</a></td>
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<tr>
<td><strong>Harvard Business Review</strong></td>
<td>Harvard Business Review (HBR) is a general management magazine published by Harvard Business Publishing, a wholly owned subsidiary of Harvard University. HBR's articles cover a wide range of topics that are relevant to different industries, management functions, and geographic locations. These focus on such areas as leadership, organizational change, negotiation, strategy, operations, marketing, finance, and managing people. Articles on knowledge management are published occasionally and are useful.</td>
<td><a href="https://hbr.org/">https://hbr.org/</a></td>
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<tr>
<td><strong>Journal of Information &amp; Knowledge Management</strong></td>
<td>Journal of Information &amp; Knowledge Management (JIKM) is a refereed journal published quarterly by World Scientific and dedicated to the exchange of the latest research and practical information in the field of information processing and knowledge management. The journal publishes original research and case studies by academic, business and government contributors on all aspects of information processing, information management, knowledge management, tools, techniques and technologies, knowledge creation and sharing, best practices, policies and guidelines.</td>
<td><a href="http://www.worldscientific.com/worldscinet/jikm">http://www.worldscientific.com/worldscinet/jikm</a></td>
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<tr>
<td><strong>KM World</strong></td>
<td>KMWorld is a publisher, conference organizer, and information provider serving the knowledge management, content management, and document management markets. KMWorld also offers a number of special publications that will help identify sources for KM tools and hosts an ongoing series of web events on the latest trends and best practices in knowledge management.</td>
<td><a href="http://www.kmworld.com">http://www.kmworld.com</a></td>
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<tr>
<td><strong>KMT (Knowledge Management Tools, An Educational KM Site)</strong></td>
<td>A knowledge management site covering the theories, frameworks, models, tools, and supporting disciplines that are relevant to both the student and the practitioner. The goal of this site is to provide a comprehensive overview of knowledge management by examining its objectives, scope, strategy, best practices, knowledge management tools, and so on.</td>
<td><a href="http://www.knowledgemangement-tools.net">http://www.knowledgemangement-tools.net</a></td>
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<td><strong>Knoco Ltd</strong></td>
<td>Knoco are knowledge management consultants helping organizations of any size to deliver tangible business value from their knowledge; by designing knowledge management strategies and frameworks, delivering knowledge management initiatives, and providing essential knowledge management toolkits. By working with world leaders in knowledge management over the past 20 years, Knoco helps clients in any sector improve performance and increase profitability through KM.</td>
<td><a href="http://www.knoco.com">http://www.knoco.com</a></td>
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<tr>
<td><strong>LinkedIn Community group for Knowledge Management</strong></td>
<td>LinkedIn is the international social network, specializing in professional and business dealings.</td>
<td><a href="https://www.linkedin.com">https://www.linkedin.com</a></td>
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Selection of Publications
supportive for Clinical Knowledge Management (CKM) framework implementation,
sustaining and improvement

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<tr>
<th>Reference</th>
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<tr>
<td>O’Dell C, Hubert C. The New Edge in Knowledge. John Wiley and Sons publication. 2011.</td>
<td>In this book the authors reveal emerging best practices and proven strategies for creating and sustaining a successful KM program. Using examples from leading companies, the authors explore the latest issues in KM and share practical tools and real-world advice on putting KM to work for the organization.</td>
<td><a href="http://www.newedgeinknowledge.com">www.newedgeinknowledge.com</a></td>
</tr>
<tr>
<td>Davenport TH, De Long DW, Beers MC. Successful Knowledge Management Projects. Sloan Management Review. Winter 1998; 39, 2; ABI/INFORM Global, pg. 43</td>
<td>Paper summarizes investigations on 31 knowledge management projects in wide range from R&amp;D to sale to production in 24 companies (9 in HP). Eight characteristics common for successful knowledge management projects were identified. Also some differences between success factors for knowledge management projects and other initiatives like data management or information were discussed</td>
<td><a href="https://www.researchgate.net/profile/Thomas_Davenport2/publication/200045855_Building_Successful_Knowledge_Management_Projects/links/53db93a40cf216e421e4210bf847.pdf">https://www.researchgate.net/profile/Thomas_Davenport2/publication/200045855_Building_Successful_Knowledge_Management_Projects/links/53db93a40cf216e421e4210bf847.pdf</a></td>
</tr>
<tr>
<td>Meeker-O’Connell A, Sam LM, Bergamo N, Little JA. TransCelerate’s Clinical Quality Management System: From a Vision to a Conceptual Framework. DIA TIRS. May 30, 2016</td>
<td>This article chronicles the evolution of a TransCelerate paper describing a proposed clinical QMS conceptual framework and reviews feedback from varied global clinical trial stakeholders during socialization of the concept paper. The article also describes TransCelerate’s efforts to work with regulators to persuade Health Authorities to issue harmonized guidance on this important topic and reviews ongoing work to develop additional tools and resources that may support organizations in evaluating whether and how they might translate the conceptual framework principles into practice.</td>
<td><a href="http://dij.sagepub.com/content/early/2016/05/30/2168479016651300?paperToc">http://dij.sagepub.com/content/early/2016/05/30/2168479016651300?paperToc</a></td>
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## Selection of Publications

.supportive for Clinical Knowledge Management (CKM) framework implementation, sustaining and improvement

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<tr>
<td><strong>Denning S. How Do You Change An Organizational Culture? Forbes. Jul 23, 2011</strong></td>
<td>World Bank case: Paper describes different strategies and efforts to change the World Bank from the small organization to what it is today. As it is presented, the most fruitful success strategy was to begin with leadership tools, cement the change in place with management tools, such as role definitions, measurement and control systems, and use the pure power tools as a last resort. An informative diagram of leadership, management and power tools is provided.</td>
<td><a href="http://www.forbes.com/sites/stevedenning/2011/07/23/how-do-you-change-an-organizational-culture/">http://www.forbes.com/sites/stevedenning/2011/07/23/how-do-you-change-an-organizational-culture/</a></td>
</tr>
<tr>
<td><strong>Katzenbach JR, Steffen I, Kronley C. Cultural Change That Sticks. Harvard Business Review. July–August 2012</strong></td>
<td>Aetna case: Paper presents the story of how to change the culture building the new strategy on cultural strengths and engaging personnel. It advises to match strategy with the culture; focus on a few critical shifts in behavior; honor the strengths of existing culture; integrate formal and informal interventions; measure and monitor cultural evolution; treat cultural intervention as the first resort. Coherence among culture, strategic intent, and performance priorities can make the whole organization more attractive to both employees and customers.</td>
<td><a href="https://hbr.org/2012/07/cultural-change-that-sticks">https://hbr.org/2012/07/cultural-change-that-sticks</a></td>
</tr>
<tr>
<td><strong>Murray A. How to Change Your Organization’s Culture. Adapted in part from “The Wall Street Journal Guide to Management”. Published by Harper Business.</strong></td>
<td>Tips: Start the change process with people who have disproportionate influence in the organization; look for ways to get people to experience the harsh realities that make change necessary; look for ways to redistribute resources toward “hot spots” – activities that require few resources but result in large change.</td>
<td><a href="http://guides.wsj.com/management/innovation/how-to-change-your-organizations-culture/">http://guides.wsj.com/management/innovation/how-to-change-your-organizations-culture/</a></td>
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Have Questions Based on Our Guide?

Visit http://www.transceleratebiopharmainc.com/assets/quality-management-system-assets/ to provide your feedback