Clinical Knowledge Management: Scenarios
Overview of Tool

Scenarios are fictionalized examples that illustrate how knowledge management (KM) could address common clinical development issues within a particular organization.

PURPOSE:
Assist in building sponsorship for and understanding of KM (change management)

Each slide covers different areas of clinical development to assist in tailoring the message.

Intended to allow selection of relevant slides for different purposes and audiences.

• These scenarios may be customized by presenters to reflect actual instances experienced within their organization

Not intended to be a “how-to” guide for what KM solution to use for a given scenario nor how to design a particular solution.

• For more detailed information on individual KM tools see CKM Reference and Tool Guide
Overview of Tool

Each scenario is presented in four parts:

1. **Scenario Description**
2. **Business Impact**
3. **KM Solutions**
4. **KM Benefits**

Note that similar types of KM solutions apply in many different scenarios.

An integrated and overarching KM program enables consistent design and implementation of solutions to address multiple needs.

Other solutions, such as business processes and systems, can help address these scenarios, but the focus in this tool is on potential KM approaches and benefits.
List of Scenarios

1. Company Acquisition & Organizational Changes
2. Knowledge Sharing Across Teams
3. CAPA Knowledge Sharing Across Projects and Sites
4. Tailoring of Training & Delivery to Needs
5. Clinical Supply Shipping/Import Requirements
6. Investigator Site Selection
7. Clinical Site Monitoring
8. Regulatory Submission & Review
9. Regulatory Intelligence for Clinical Trials
10. Protocol Standardization
11. Data Management & Supported Systems
12. Data Management & Supported Systems – Interactive Response System (IXRS)
13. Electronic Trial Master File (eTMF) Inspection Readiness
14. Summary/Conclusion
Clinical Knowledge Management: Company Acquisition & Organizational Changes

**Scenario**

Company X acquires Company Y.

Departments & site locations are consolidated, including establishment of a new corporate headquarters. Not all staff relocate.

- Organizational changes
- Departure of known SMEs* & experienced staff
- New people in new roles
- Legacy processes & technology systems combined or changed

**Business Impact**

- Time spent learning new roles & systems
- Delays in finding new SMEs
- Knowledge gaps
  - Not all content in legacy systems is accessible

**KM Solutions**

Effective onboarding program for new people in roles.

Timely off-boarding of key departing experts for knowledge transfer.

Site-wide content management system created with defined business process for transfer of system ownership & access privileges.

**KM Benefits**

New people consistently trained in rapid time to competency.

Expertise & critical knowledge captured & effectively transferred.

Continuity of access to easily searchable and up-to-date content.
Clinical Knowledge Management: Knowledge Sharing Across Teams

**Scenario**

Company identifies multiple drug candidates with unique mechanism to address high unmet medical need. Different teams develop each clinical candidate but don’t share knowledge.

- Company culture doesn’t promote cross-team sharing
- Different teams use different systems for information storage
- Learnings from prior program executions are not documented or not accessible
- Key staff depart during development

**Business Impact**

Development issues and rework result from failure to apply key relevant knowledge (current and/or prior), including expertise.

Company’s product was delayed to market and patients did not have access to needed medicines.

**KM Solutions**

Leaders promote culture of knowledge seeking and sharing behaviors.

Content management systems with broad access & search capabilities capture knowledge across all clinical programs.

Timely off-boarding procedures capture knowledge from staff departing projects.

**KM Benefits**

Development teams learn from each other and previous issues are not repeated.

Teams are aware of, have access to and apply relevant prior knowledge.

Continuity of access to easily searchable up-to-date content.

Expertise & knowledge are captured & available to team when key members depart - no knowledge gaps.
Clinical Knowledge Management: CAPA Knowledge Sharing Across Projects & Sites

**Scenario**

Many Corrective Action Preventive Action (CAPA) plans are developed and executed within clinical development. Similar audit/inspection observations across different projects or at multiple sites result in repetitive CAPAs.

- Different CAPA coordinators/owners use different systems for CAPA storage
- Process for CAPA development does not include seeking knowledge on similar issues or prior CAPAs
- Learnings from prior Root Cause Analyses (RCAs) are not captured or shared

**Business Impact**

Prior issues and observations are repeated on different projects and/or at different sites.

Time is spent creating CAPAs to address issues or observations for which root cause has been previously determined and relevant CAPA’s exist.

Delays in CAPA creation and/or ineffective action plans may impact study timelines & result in delays in regulatory approvals.

**KM Solutions**

Issue investigation and CAPA creation process steps include consistent classification of quality issues and searching for previous, related CAPA’s.

- CAPAs are stored, categorized and available to relevant staff via a content management system with search capabilities that include issue and observation key words.
- Community of Practice is established to provide access to experts and best practices for CAPA creation, execution & management.

**KM Benefits**

Aggregate analysis of recurring issues or observation trends creates new knowledge about process dysfunctions and drives effective actions for process improvements.

- CAPAs are developed utilizing most current best practices and effective plans learned from prior experience.
- Number of CAPAs may be reduced.
- CAPA modifications during execution are minimized and less time is needed to complete CAPAs.
## Clinical Knowledge Management: Tailoring of Training & Delivery To Needs

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<td><strong>Periodic mandatory refresher training is typically:</strong>&lt;br&gt;  - Required for all employees (E) regardless of current level of knowledge competency&lt;br&gt;  - Consumes time (T) that could be spent on core business activities versus repeat training&lt;br&gt;  - Incurs costs (C) of employee salary during training time&lt;br&gt; Company training time total spend (S)&lt;br&gt;  - $E \times T \times C = S$</td>
<td><strong>Cost of time spent on repeating training for knowledge already acquired.</strong>&lt;br&gt; People who already have that knowledge (or do not currently need it) feel frustrated by time wasted.</td>
<td><strong>Training/e-learning modules are managed in a library and each includes a preliminary knowledge assessment that triggers non-participation or different modules.</strong>&lt;br&gt; Training/e-learning content is customized to required knowledge level based on current competency level or function.</td>
<td><strong>Advance confirmation of competency saves time and resources.</strong>&lt;br&gt; By training the right people on the right level at the right time, peoples’ motivation is not impacted.</td>
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Clinical Knowledge Management: Regulatory Submission & Review

Scenario

Lack of knowledge sharing across teams of regulatory review Q&A.

Team A submits Phase III CTA to a local regulatory agency in country Z.

- Phase I & II studies were completed by different teams
- Team A receives questions from regulatory agency
- Similar questions were answered for earlier studies

Business Impact

- Time spent finding information and members of previous teams
- Later phase filings don’t address similar issues adequately
- Regulatory agencies receive inconsistent responses to similar queries
- Lack of awareness of past experience with a specific agency
- Re-work and longer timelines for resource commitment

KM Solutions

Knowledge sharing across team boundaries.

After Action Reviews.

Capture of regulatory Q&A in a searchable content management system.

Sharing of Lessons Learned through a Community of Practice.

KM Benefits

- Fewer findings in regulatory review
- Less time spent reinventing wheel
- Breakdown of team silos
- Avoid study delays and additional costs
- Fast regulatory approvals
- Process improvement
**Clinical Knowledge Management:**

**Regulatory Intelligence for Clinical Trials**

### Scenario

Specific local regulatory requirements for clinical trials and submissions have changed, are not known or easily accessed.

Program plans & timelines do not include all requirements, such as:

- Regional submission to ethics committee
- Timing for approvals (site, country, EC & health authorities, national vs. VHP*)

Clinical trial recruitment delays are due to:

- Informed consent forms, protocol approvals, translation of documents into local language

Budget is not adequate to cover certain local requirements:

- Compassionate use studies
- Lifelong meds for certain study patients

* EU Voluntary Harmonization Procedure

### Business Impact

- Time spent determining local requirements
- Delays in program timelines if all requirements are not initially met
- Lack of budget to cover all clinical trial requirements

### KM Solutions

Communities of Practice for sharing experience and interacting with SMEs (or local contacts) on regulations in different countries.

Content management (centralized database) for searching and finding applicable regulatory requirements across sites & countries.

### KM Benefits

Understand country expectations up front.

Quicker setup time for studies.

Rapid preparation of program plans that consider all current, applicable regulatory requirements.

No program timeline delays due to not meeting local regulatory requirements.

Clinical program budgets cover all pre- and post-market requirements.
Scenario

Teams A and B are working on two protocols for the same compound in oncology for two different studies at different times and the protocols are not shared

- A couple of safety parameters are monitored in protocol A but not B
- Some procedures for performing lab tests and for disease assessments are inconsistent in the two protocols
- Teams’ experience in this therapeutic area varies

Business Impact

- Time spent searching for information on other protocols
- Protocols for compound are not standardized
- Difficulties are experienced in analyzing pooled data

KM Solutions

Sharing knowledge across teams.

Content management with associated technology (search library of standard templates and previous protocol examples, study procedures, disease assessments).

Protocol template with standard sections that is updated to reflect lessons learned across therapeutic areas & includes product/study specific requirements.

Community of Practice for capturing and sharing best practices for protocols.

KM Benefits

- Easy access to knowledge and subject experts
- Standardized protocol
- Less time spent searching for solutions
- Avoid delays and protocol amendments
- Less queries from regulatory, sites and study personnel
- Fast regulatory approvals
# Clinical Knowledge Management: Clinical Supply Shipping/Import Requirements

## Scenario

Documentation requirements for clinical supply shipments vary in different countries and regulations for custom clearance continue to evolve.

Incomplete knowledge of current requirements can lead to clinical supplies held up in transit and not at sites to meet timelines.

## Business Impact

- Additional staff time spent in responding to missing documentation and/or custom issues
- Delays in study starts
- Interruptions in supply continuity that negatively impact a long term clinical study
- Delays in overall project timeline (study approvals and/or filings)

## KM Solutions

Business Process/SOP that includes job role/responsibility to maintain current requirements database.

Content management system containing searchable, up-to-date regulatory process and documentation expectations (including templates) with access for all teams and programs.

Connection with experts (both central and in-country) to ask questions and understand current best practices.

## KM Benefits

No delays experienced on receipt of clinical supplies due to shipping or custom issues.

Risks to study timelines due to clinical supply arrival on-site minimized.
**Clinical Knowledge Management: Investigator Site Selection**

**Scenario**

Clinical trial planning requires careful selection of qualified investigator sites and site staff. Without access to prior knowledge of a particular site:

- Opportunities to select a high-performing site for a new study may be missed
- A site with past study execution issues could be used again without proactive actions taken to enhance past performance

**Business Impact**

Lack of timely and informed decision making in site selection. Study timelines & data quality potentially compromised.

Added time spent locating & onboarding a new investigator site where a qualified & capable site is already known to exist

Additional company resources are spent to manage/correct/mitigate repeat quality issues already experienced by other project teams using same site.

Added resources (= increased cost) to manage site.

**KM Solutions**

Content management & technology for searching of qualified investigators/sites by therapeutic area & previous assessments.

Lessons learned from past experience (prior monitoring, audit, inspection history) with a site captured and made available for other teams to leverage.

SME locator; ability to quickly identify internal key contacts with prior experience with a site.

**KM Benefits**

Efficient study planning; no need to “re-invent the wheel”.

Timely study start up. Minimize risks to study timelines and inspection outcomes.

Avoid need to deploy unplanned resources during course of study to re-train site and correct issues.
Clinical Knowledge Management: Clinical Site Monitoring

Scenario
CRA missed reporting the following issues in a study during a site monitoring visit:
- AEs were not captured in eCRF
- Inclusion/exclusion violations and other protocol violations were not identified in a timely manner
- Informed consent was not obtained properly
- Monitoring plan was not developed appropriately

Business Impact
- Data is not accurate and reliable.
- Issues are not identified in a timely manner. Preventive and corrective actions are not taken.
- Increased time spent by central team to cover for lack in monitoring oversight
- There may be major regulatory findings during inspection.
- Filing may not be accepted by Regulatory Agency due to issues related to data quality and study procedures.

KM Solutions
Content management for access to monitoring business process(es), regulatory guidelines, plan creation (template), storage, maintenance and results.
Capture and search monitoring results for lessons learned related to monitoring issues identified in other studies.
Consistent training modules & mentoring provided to CRAs.

KM Benefits
- Improve monitoring quality
- Ensure data quality and adherence to the protocol
- Minimize risk of regulatory findings
**Clinical Knowledge Management: Data Management and Supported Systems**

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| Different study teams, even within the same therapeutic area and working on the same compound, separately develop study-specific protocols and data capture, review & management tools. Electronic CRF (e-CRF) modules are developed without leveraging modules already available. | • Inconsistencies in protocol execution for similar studies  
• Direct comparison of data across studies is compromised  
• Difficulty making informed decisions  
• Delays and wasted effort in creating tools already created by other teams  
• Failure to learn from past successes & mistakes |

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| Sharing lessons learned & best practices through. Communities of Practice (consult/access to experts on tools, peer review). Creation of standardized data modules. Content management (searchable library of standard data modules/forms/templates). | • Harmonized approaches for data capture and analysis  
• Improved efficiencies  
• Reduction in “noise” in decision making  
• Expertise & knowledge captured & effectively transferred; best practices incorporated into standard practice  
• Shift in culture from reactive to proactive |
Clinical Knowledge Management: 
Data Management and Supported Systems

Scenario

Setup of Interactive Response System (IXRS) differs among studies for the same compound, e.g.,
- What to consider for randomization
- Re-supply of IMP
- Complicated administration
- Different doses

Business Impact

- Inconsistencies in protocol execution for similar studies
- Direct comparison of data across studies is compromised
- Difficulty making informed decisions
- Delays and wasted effort in creating separate IXRS’s

KM Solutions

Sharing knowledge and lessons learned & best practices through Communities of Practice (consult/access to experts on tools).

Content management (searchable library of IXRS forms/templates).

KM Benefits

Ability to make decisions based on knowledge from related studies.

Expertise & knowledge captured & effectively transferred.

Best practices incorporated into standard practice.
Clinical Knowledge Management: **Electronic Trial Master File (e-TMF) Inspection Readiness**

### Scenario

The eTMF is not up to date due to the following reasons:

- Relevant contributors do not all have system access
- Late submission/filing of critical clinical documents
- Misfiling due to lack of training and unclear filing instructions (naming conventions, table of content etc.)
- System is not user-friendly (slow, complicated)

### Business Impact

The eTMF is not inspection ready; this could result in inspection findings.

The eTMF is not reliable as a content management system by other users; study teams make use of shadow files which increases the risk of multiple records, incomplete filing, and inconsistent documentation.

Additional resources and costs are needed to clean up and reconcile the eTMF.

### KM Solutions

Leaders mandate use of eTMF as official content management system and ensure adequate resources for real-time entry and quality oversight.

Lessons learned related to timely access management and correct filing are captured & shared with users.

Network/Communities share knowledge and best practices to continuously improve eTMF business processes.

### KM Benefits

eTMF is up-to-date and inspection-ready at all times.

Study team members have all information/documentation at hand in a central place.

Less costs and resources at study end for reconciliation activities.

Easier handovers when study team members leave the team.
Scenarios illustrate the benefits of:

• Sharing knowledge across teams, sites & programs
• Capturing knowledge
• Searching for prior lessons learned and best practices (minimize repeat issues)
• Connecting with experts

Knowledge management can help connect people to knowledge and to each other through a combination of approaches:

• Sponsorship of a culture that promotes knowledge seeking and sharing
• Content management for storing and organizing knowledge in a searchable and accessible manner
• Communities of Practice for networking with experts to share existing knowledge and best practices
• Lessons learned processes to assist in capturing knowledge from experience
• Onboarding and off-boarding processes for assuring the transition of knowledge between/among people