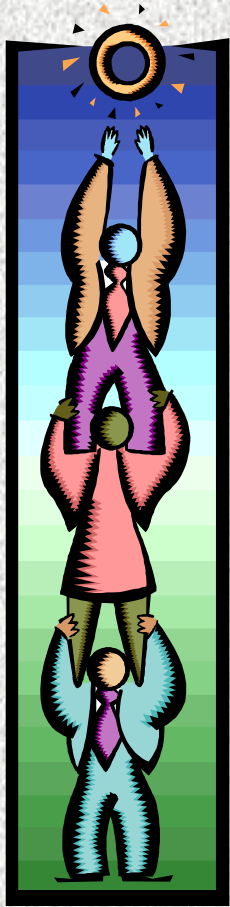


# **Relationships Between People and Technology in Regulatory Information Management: Tools and Techniques for Virtual Teams**

**Kevin B. Johnson, Ph.D.**

PharmaKnowledge Consulting

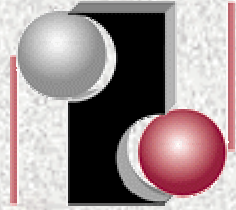
[www.pharmaknowledge.com](http://www.pharmaknowledge.com)



**“Coming together is a beginning.  
Keeping together is progress.  
Working together is success.”**

**Henry Ford**





# Protodigm Ltd.

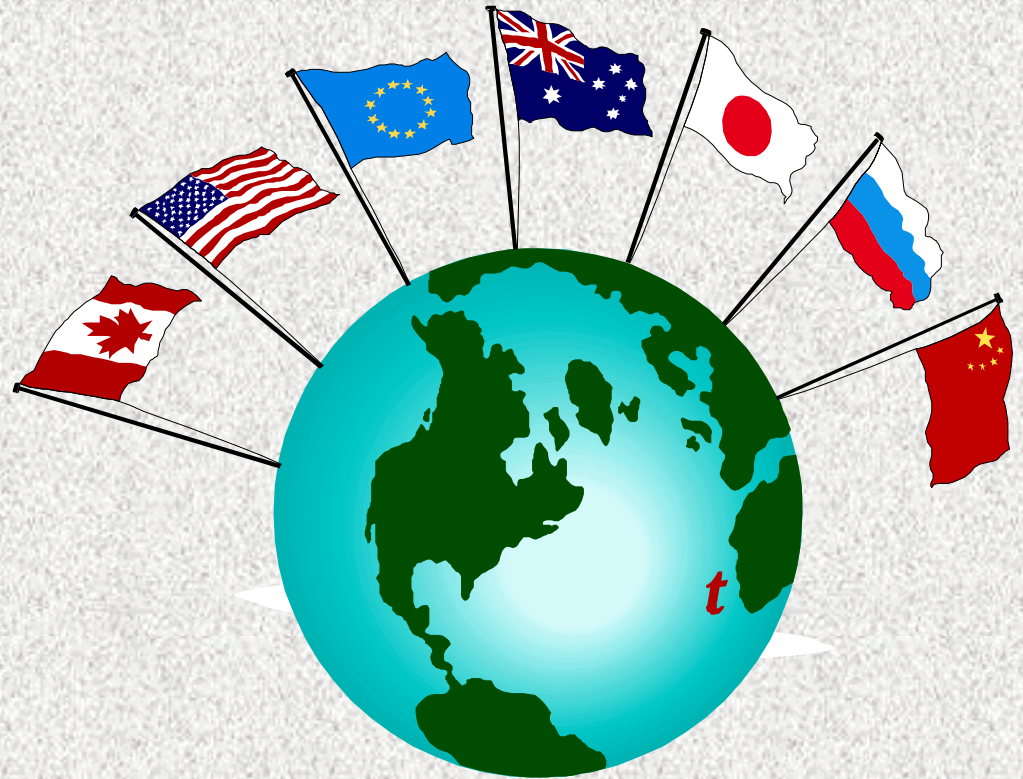
- **Created as a business prototype for a new paradigm by its parent, Hoffmann-La Roche**
- **“Driving strategic outsourcing to get medicines to market faster and more efficiently”**
- **Virtual development through innovative total outsourcing**

# The Tempium Project

- **Resurrected a terminated development program for CNS drug**
- **Initiated and completed Phase III studies**
- **Created virtual teams for clinical, nonclinical, CMC, and regulatory**
- **Goal: global regulatory submissions shortly after completion of Phase III studies**

# The virtual team

**27 users at  
15 sites in  
5 countries  
(US, Canada,  
UK, France,  
Switzerland)**



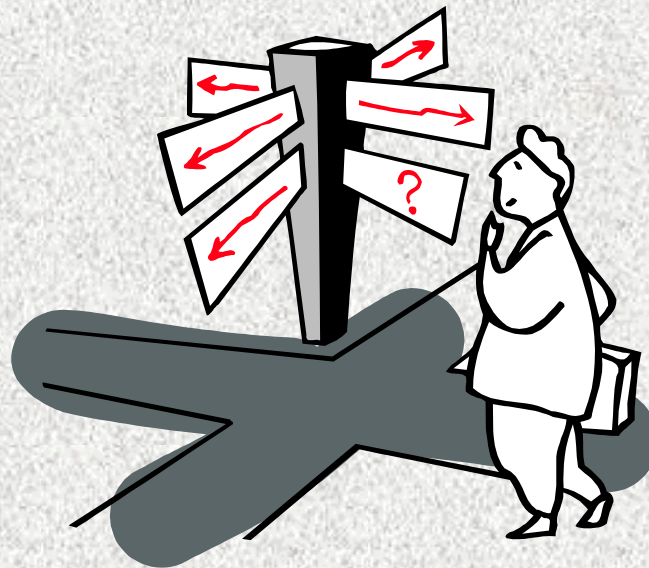
# Challenges...

- **Geographically Distributed**
- **Support/Infrastructure Diversity**
  - Individual consultants to multinational pharmaceutical company
- **Technologically Diverse**
  - Technophiles
  - Technophobes

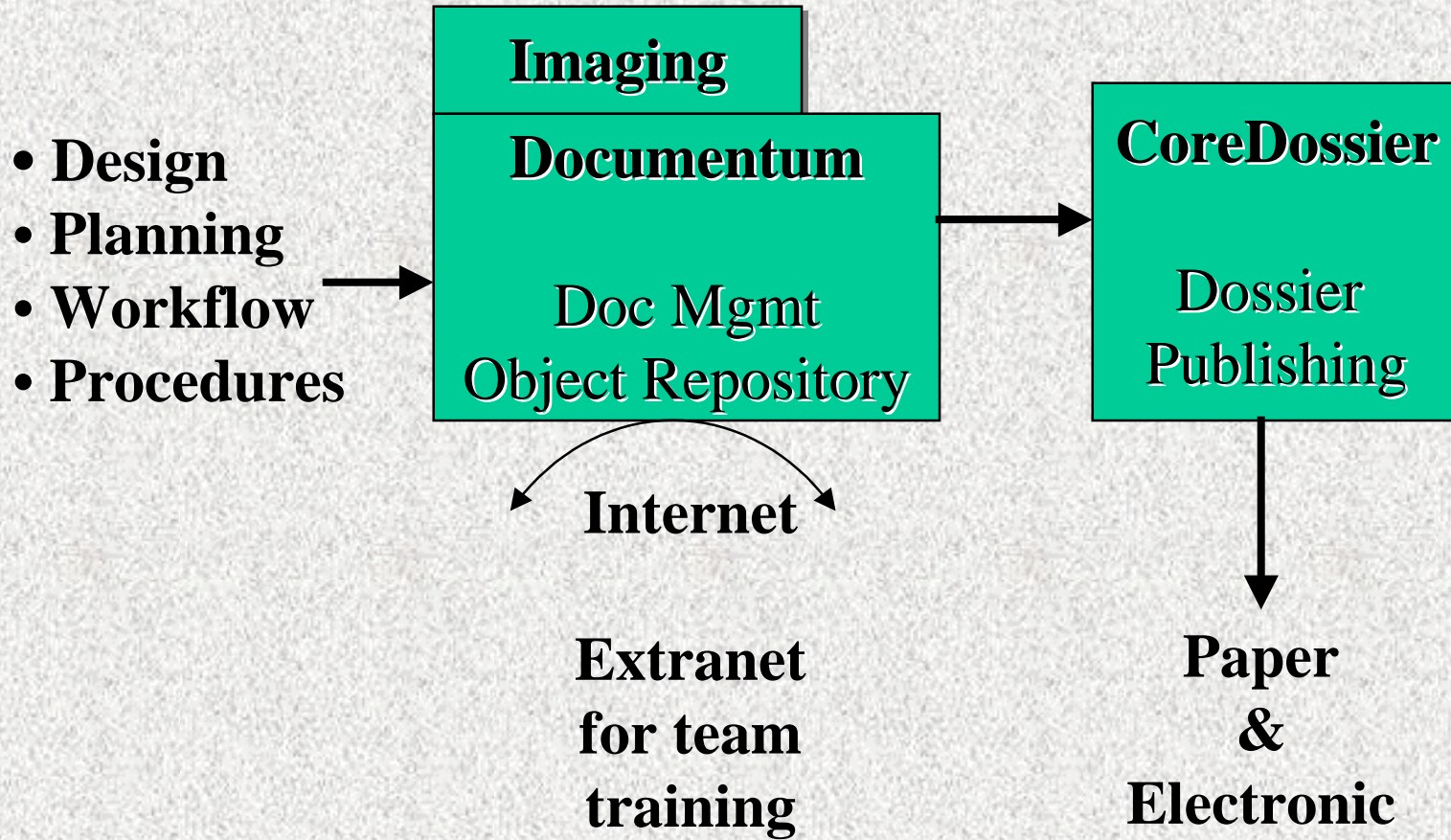


# Meeting challenges...

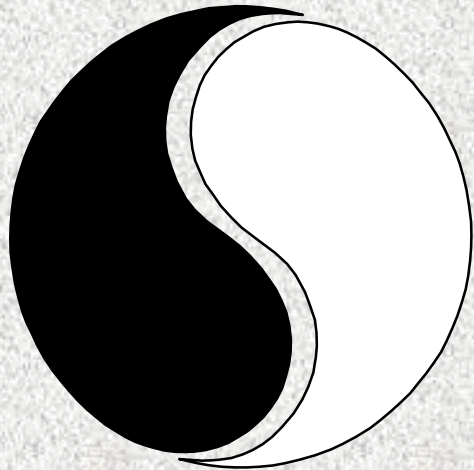
- IT infrastructure/tools
- Managing people-technology interfaces
- NDA development in a virtual team



# IT System - EDM, publishing, websites

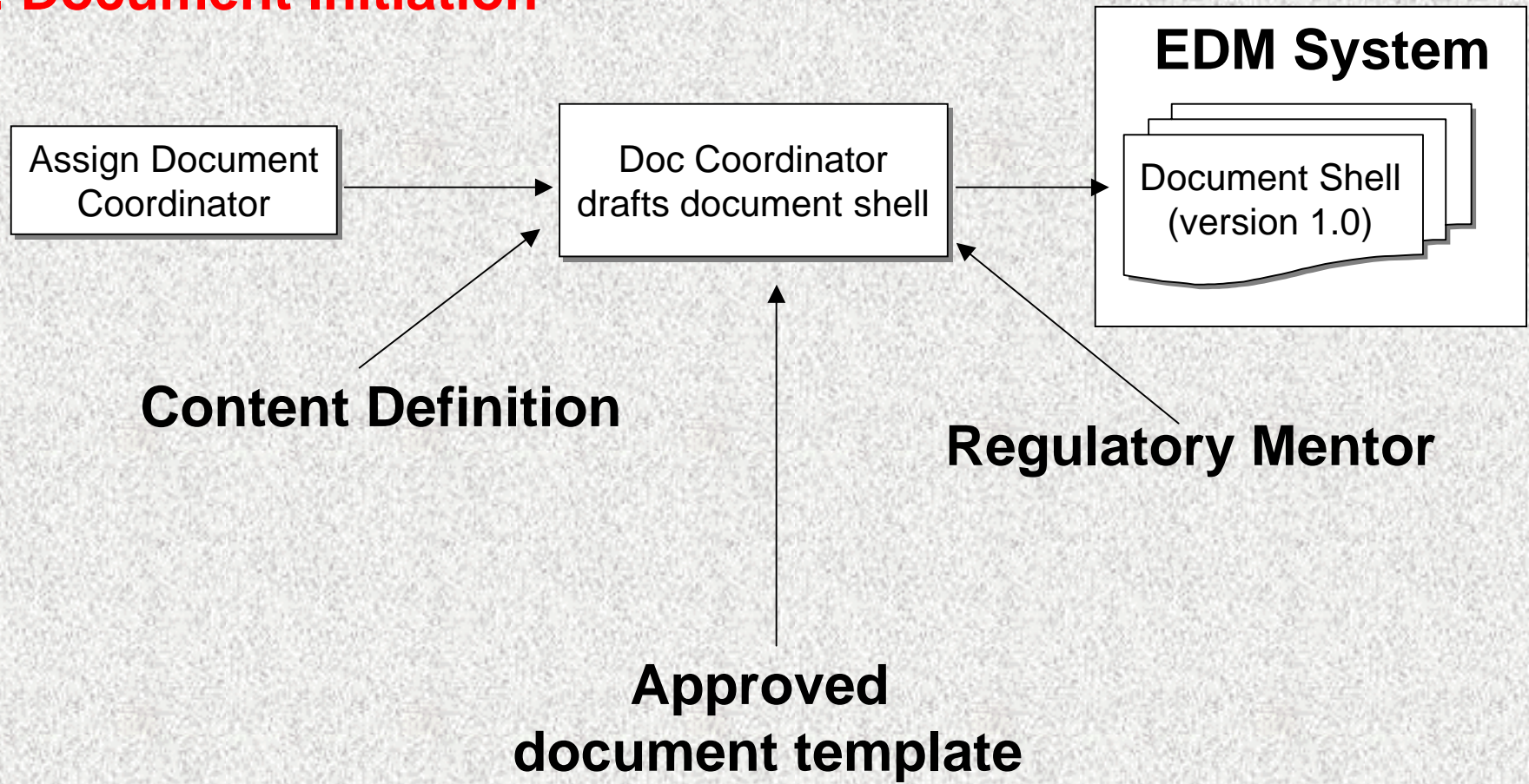


# Document Coordination

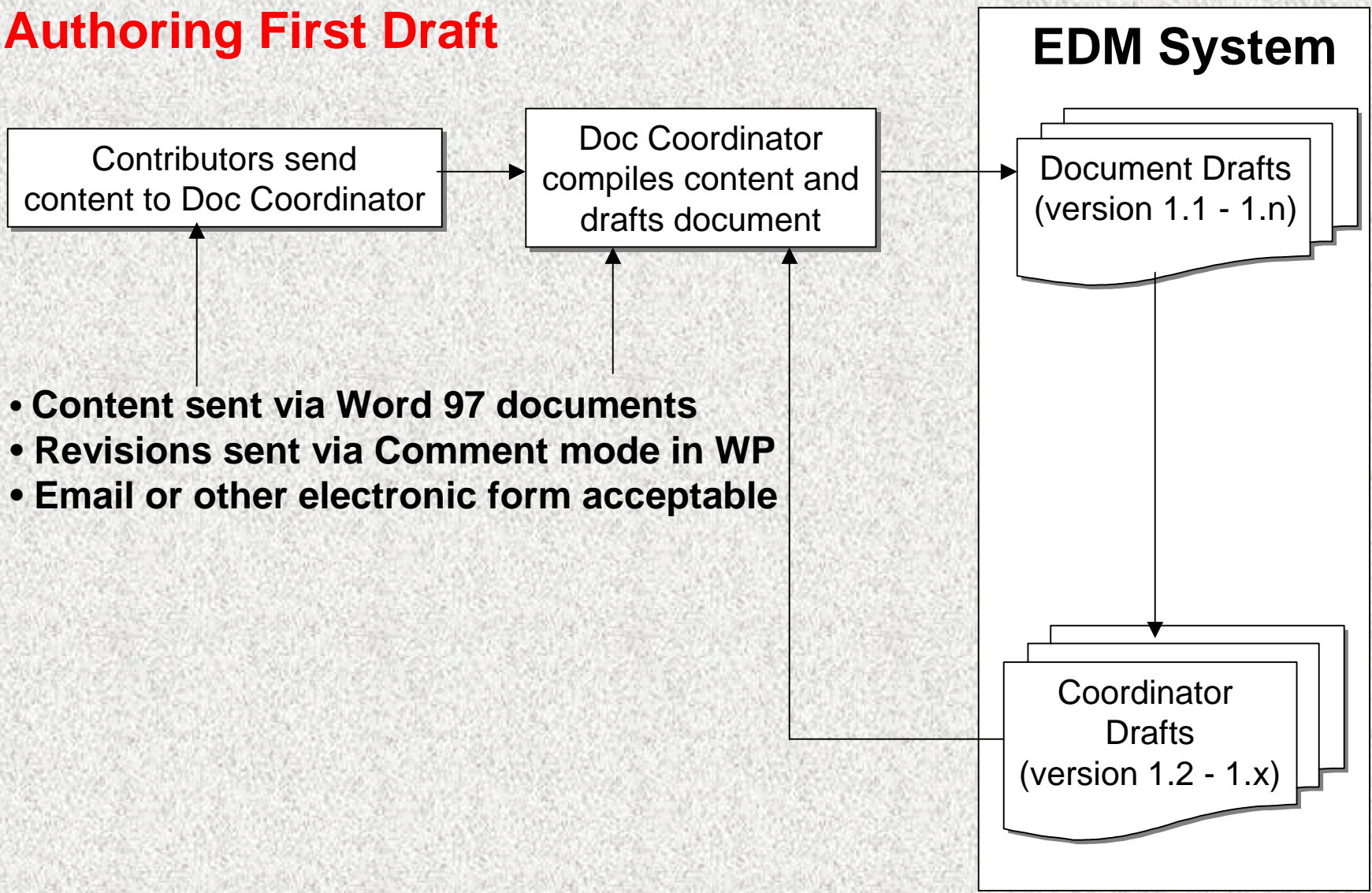


- **Balances EDM use with people constraints**
- **Allows for flexibility across EDM users**
- **Provides framework for authoring, review and finalization of documents within the EDM environment**

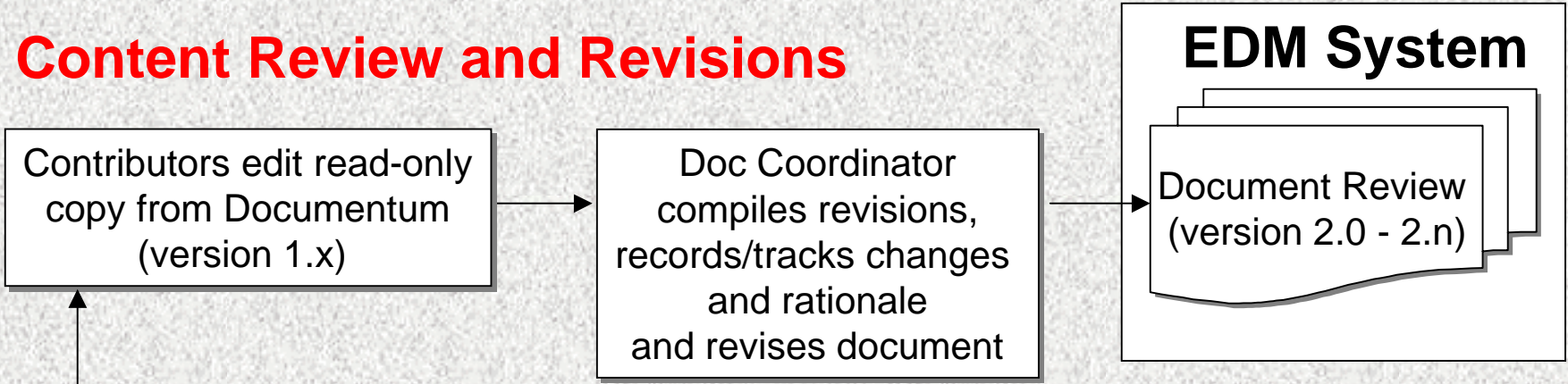
# 1. Document Initiation



## 2. Authoring First Draft



### 3. Content Review and Revisions

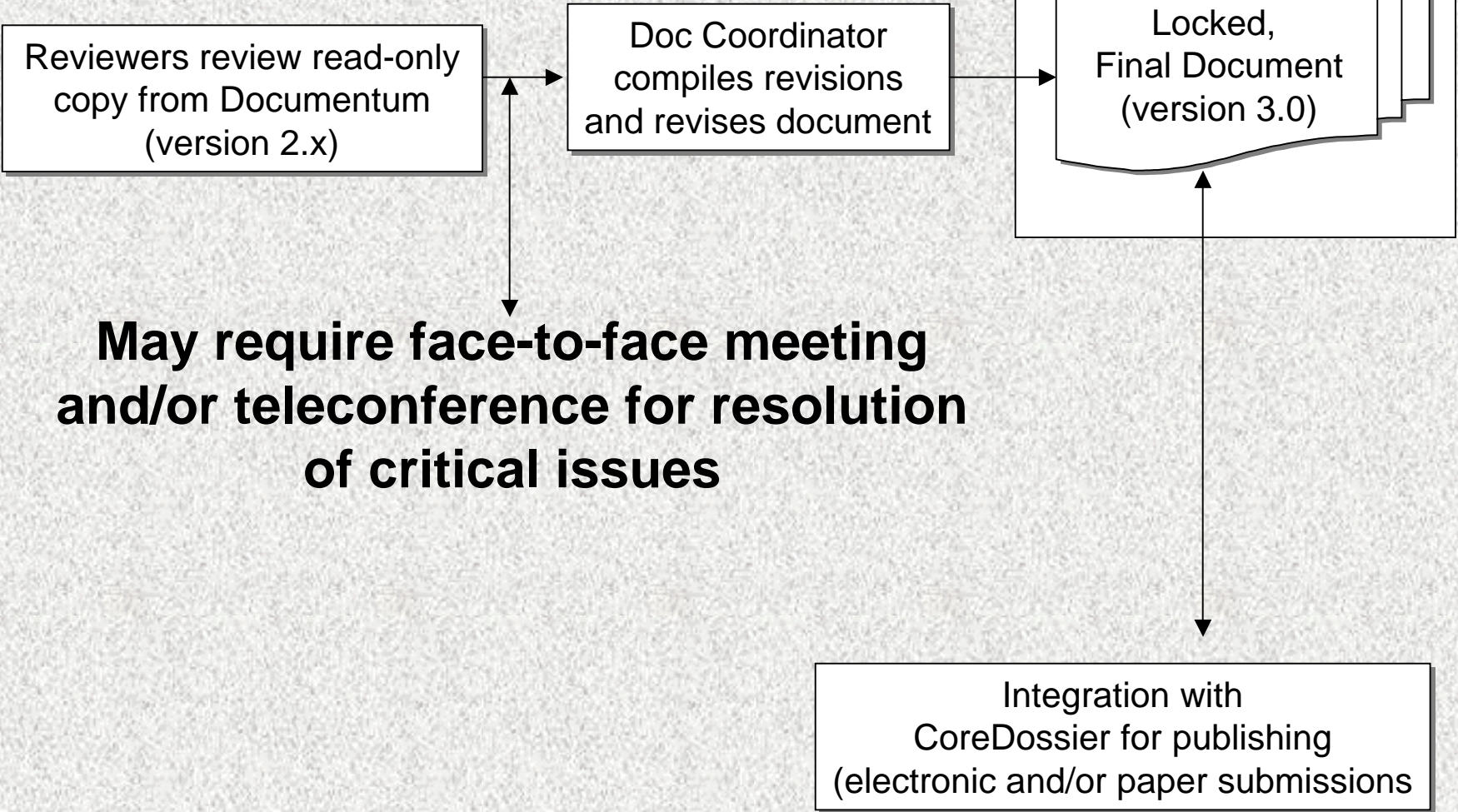


**Draft document only accessible through EDM**

**Reviewers can only access read-only copy**

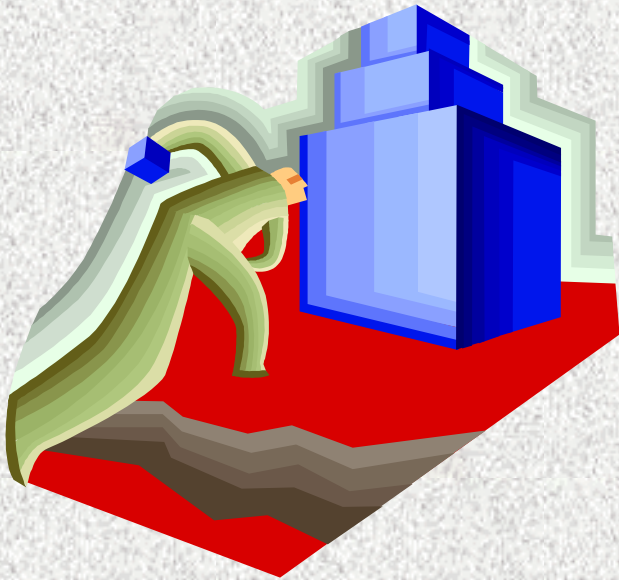
**Many types of reviews may be used**

# 4. High-Level Review and Finalization



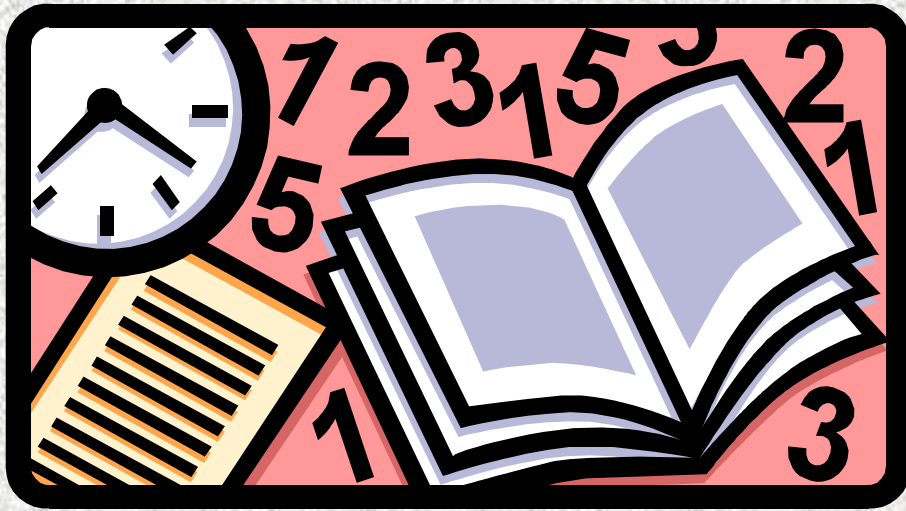
**May require face-to-face meeting and/or teleconference for resolution of critical issues**

# **NDA Planning and Document Preparation**



- **Phase I - Planning**
- **Phase II – Content Specs**
- **Phase III - Doc Production**
- **Phase IV – Publishing and Compilation**
- **Phase V - Evaluation**

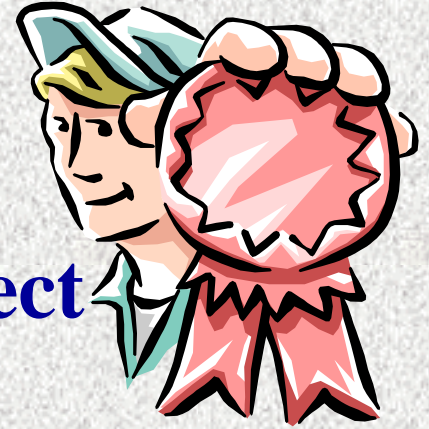
# Information Plan



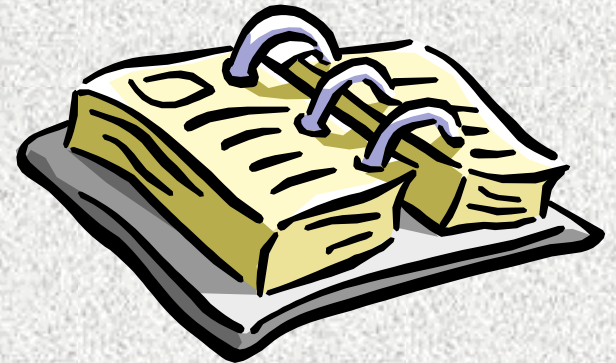
**“Focus the NDA  
towards the  
audience you  
seek...”**

- **Project Goals and Objectives**
- **Reviewer Profile and Analysis**
- **Documentation Strategy and Concerns**
- **Team Membership and Review Team**

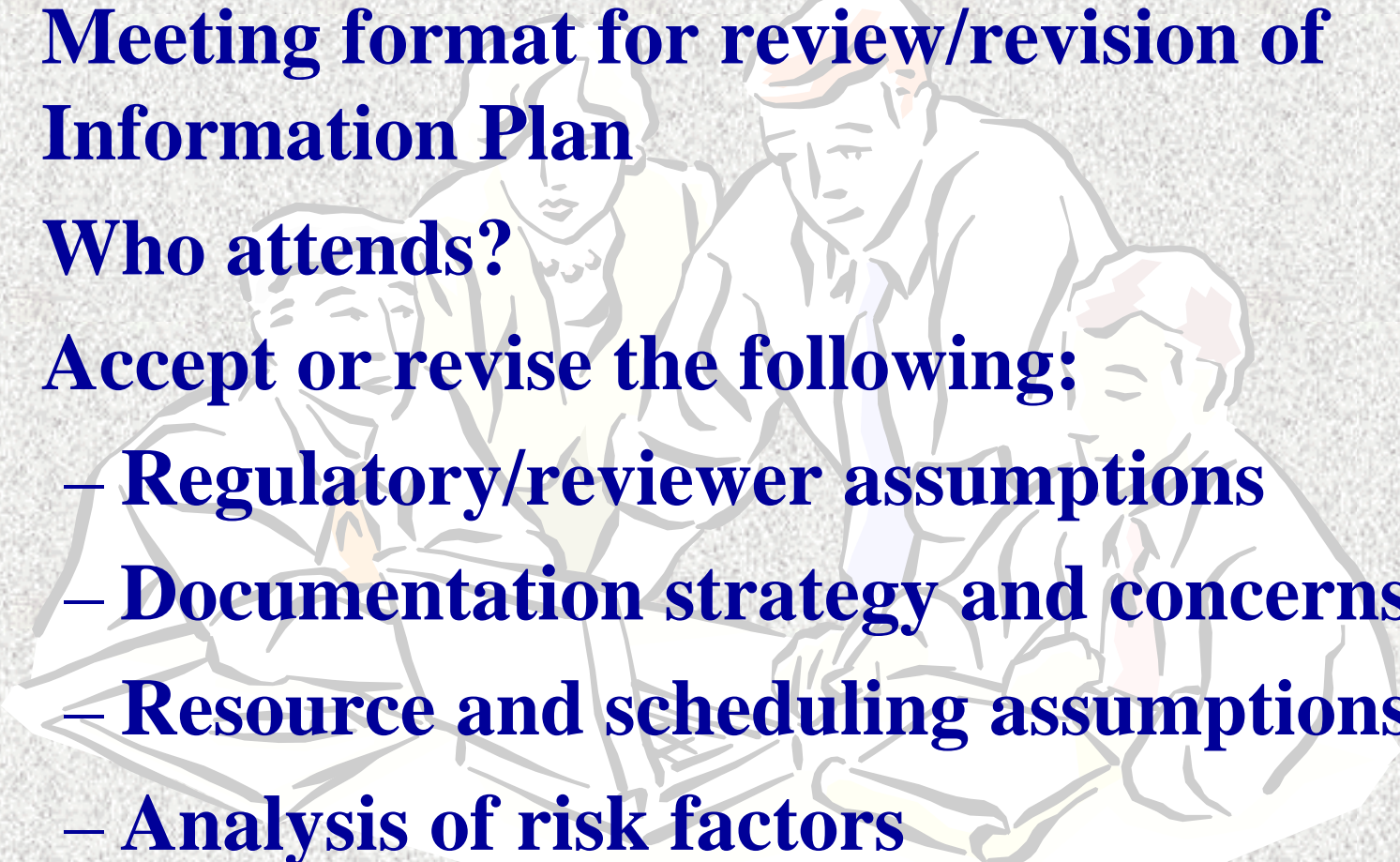
# NDA Project Plan



- **Scope and Complexity of Project**
  - Preliminary Resource Estimate
  - Identify Risk Factors and Develop Dependency Matrix
  - Definition of Quality Levels and Reassessment Schedule
- **Schedule of Milestones**
- **Preliminary Timeline**



# Phase I Review

- **Meeting format for review/revision of Information Plan**
  - **Who attends?**
  - **Accept or revise the following:**
    - **Regulatory/reviewer assumptions**
    - **Documentation strategy and concerns**
    - **Resource and scheduling assumptions**
    - **Analysis of risk factors**
- 
- A stylized illustration of four business professionals (two men and two women) sitting around a table, engaged in a meeting. They are looking at documents and laptops, suggesting a collaborative review process. The illustration is rendered in a light, sketchy style with some color highlights.

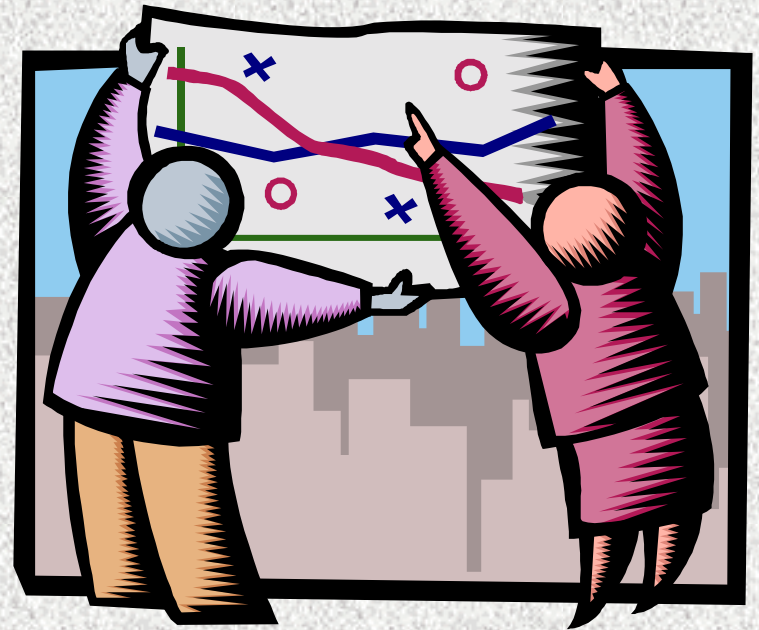
# Virtual Team Relationships in Phase I



- **Effective team-building**
- **Input from upper management and key individuals/departments**
- **Setting the stage for quality level and well-organized process**
- **Key role for regulatory in planning process**
- **Key role for project management in organizing teams and tasks**

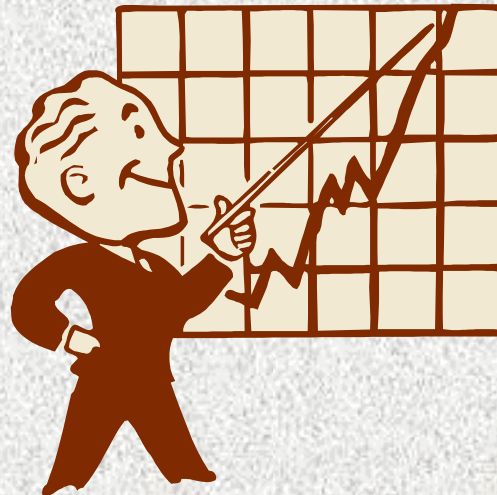
# Phase II: Content Specifications for High-Level Documents

- **PI/SmPC**
- **Application Summary**
- **Technical Summaries**
- **ISS**
- **ISE**
- **Risk/Benefit**
- **Clinical Study Reports**



# Project Tracking System and Progress Reporting

- **Master Document List with associated roles and responsibilities**
- **Progress reporting - real-time on project extranet**



# Project Standards/Templates

- **MS Word 97 as standard WP application**
- **Developed both general and specific (ISS template) templates for team use**



# **Document Management Procedures**

- **Define use of electronic document management system**
- **Who, what, where, when, how**
- **Document coordinator role**
- **Use of web-enabled Documentum for entire team**
- **Procedures for tracking status of documents**

# **Virtual Team Relationships in Phase II**

- **Overall messages...**
- **Content specs produced in team environment (prototyping) and reviewed concurrently, if culture accepts**
- **Role for vendor depending on selection of IT tools for doc management and publishing**

# Phase III - Document Production

- **Detailed Deliverables Table and Timeline**
- **Individual Document Production, Review and Finalization**

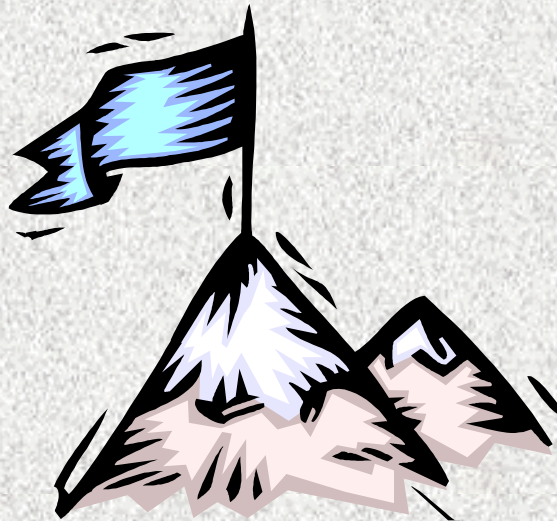


# **Virtual Team Relationships in Phase III**

- **Writing teams developed:**
  - **medical writers**
  - **regulatory**
  - **compilation experts/publishers/vendor teams**
  - **content providers**
- **Use content specs to develop documents**
- **Use IT infrastructure to streamline review and finalization (document coordination)**

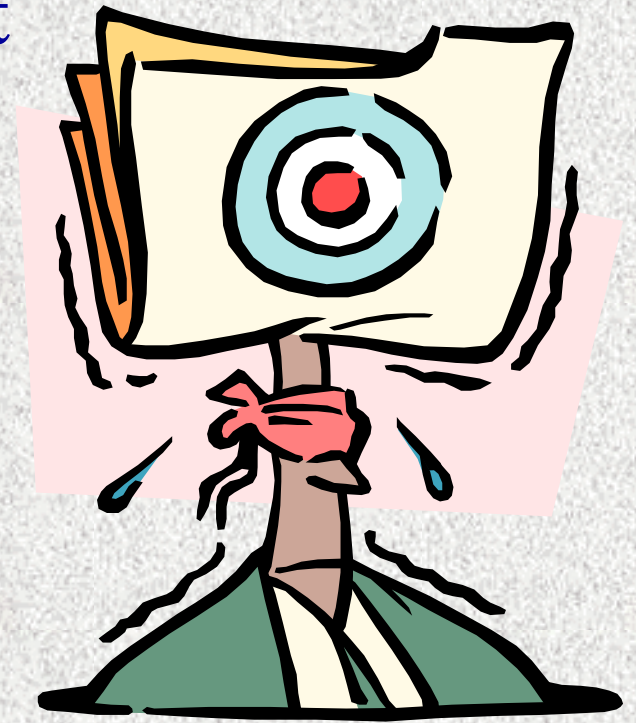
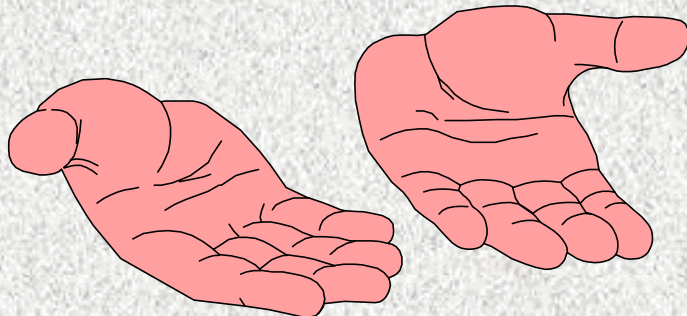
# Phase IV - Publishing and Compilation

- **Publication team takes over project**
- **Close relationship with vendor critical**
- **For global submissions, interactions with compilation teams occur here**



# Phase V - Evaluation

- **Project Completion Report**
- **Team and Project Evaluations**
- **Metric Calculations**
- **Feedback into “Best Practices”**



# Virtual Team Relationships in Phase V

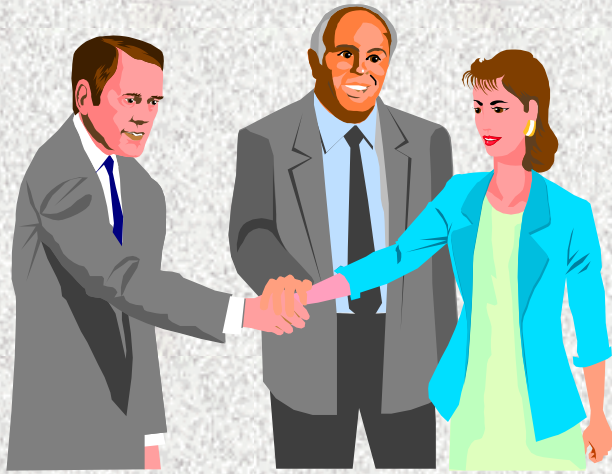
**One of the most critical steps, since this is  
where learning and knowledge gained  
can directly impact current and future  
projects**



# Virtual Team Relationships in Phase V

- Ideally, develop an environment where learning of best (and worst) practices are:
  - automatic,
  - highly interactive and provided to entire team,
  - rewarded by the culture, and
  - actively used for improvements





**“Synergy is the highest activity of life; it creates new untapped alternatives; it values and exploits the mental, emotional, and psychological differences between people.”**

**Stephen Covey**