


# Optimizing Workflows

Getting the most from your CMS

Presented by Ed Tripp

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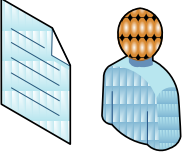
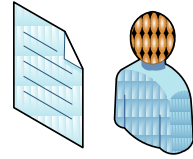
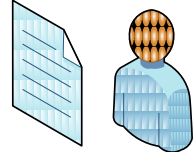

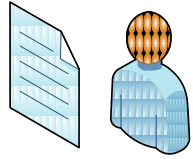
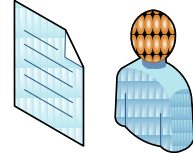



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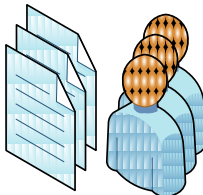

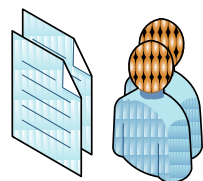
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# The Unfilled Promise

## Days for Paper Process

1	2	3	4	5	6	7	8
Reviewer 1		Reviewer 2	Reviewer 3	Edit	Approver 1	Approver 2	File
							

## Days for Electronic Workflow

1	2	3	4
Reviewers 1,2 and 3		Edit	Approvers 1 and 2
			

**The Promise:**  
by implementing electronic workflows we could cut review and approval times by 50% or more!

# Reality Check

**Business Processes do not always follow the “Happy Path!”**

But this is just a minor edit!

Mary no longer works here!

But this is an exception!

I always wait until everyone else signs before I sign it.

Joe is traveling and won't be back for two weeks.

This is not how we do it in an emergency!

I have not taken my training yet!

# Examine from different perspectives

## Document

- Do all documents need to follow the same process – break down by type
- Can some documents simply be promoted after inspection
- Do you route multiple documents together
- Carefully select what notifications will be sent to users

## Process

- Are there special processes for emergencies
- Are there special processes for minor edits
- What are ALL the roles involved (editors, word processors, other specialists)
- Are approvals based on document revision or content revision
- Are approval requirements by function or individual
- How do you handle proxies and delegation
- Who can add signatories
- Does everyone have access in all work locations
- Do people outside the company participate in review or approval

# Carefully define the lifecycle for each document type

## Consider Document Types

- Labeling
- Correspondence
- Submission documents
- Data sets
- Templates
- Compiled publications
- Virtual Documents

## Lifecycle Questions

- Do you have a state to indicate editing vs. authoring?
- Do you use annotations?
- Do you retain drafts after approval?
- Do you retain annotations?
- Do you have an obsolete state separate from a prior version or superseded state?
- Do you indicate when a document has been reviewed?

## Key points to Consider

Identify and include all stakeholders. Lack of buy in can kill a good system.

Ask “Why” and don’t accept, “We’ve always done it this way.”

Use the opportunity to redesign your process. Automate a bad process produces more bad faster!

Test user interface with HTML or other easy to change formats

Run a proof of concept with stakeholders (it does not have to be computer based)

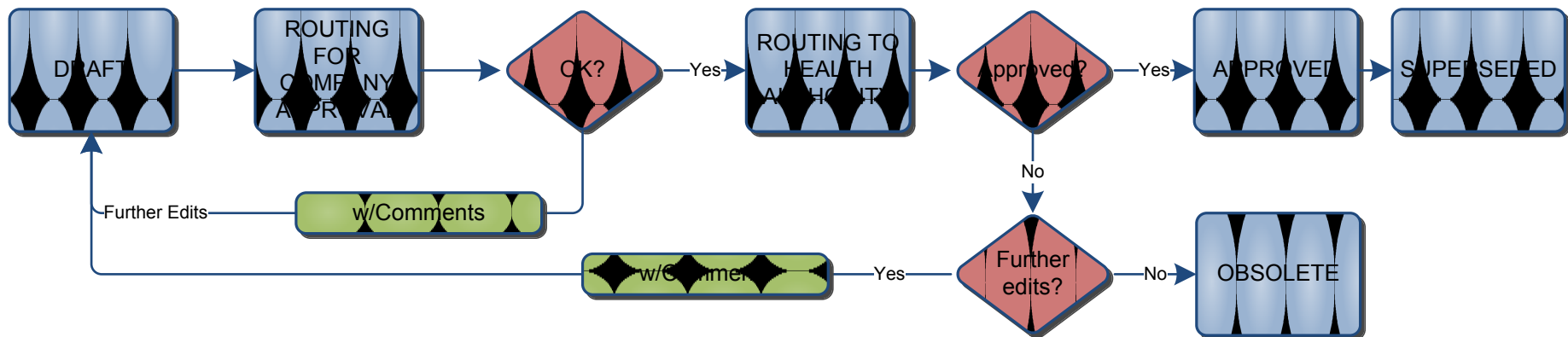
# Manual Proof of Concept





# State and Workflow for Labels

Labels present a unique opportunity since they require internal approval to be sent to the Health Authority, but approval by the Health Authority to reach a final approved state



States noted in ALL CAPS

# Forms Based Workflows

The use of a forms based approach allows the establishment of workflow rules based on answers to questions and data about the change

rules based on answers to questions and data about the change


5

### CR Properties





1. Priority of Change

High  
 Medium  
 Low

2. Target Closure Date

01/12/2011 

3. Related CRs

CR 3910

4. Will Regulatory Affairs approval be required for this Change Request?


Yes  
 No

5. Type of Change

Document ▼

### CR Properties

- Description and Rationale
- CR Approvers
- Workflow Documents
- Summary



# Routing Controlled by Data

Because Regulatory Affairs Approval was checked an approval route is added. This was predefined to be a serial routing when the form was created.

This was predefined to be a serial routing when the form was created.

**Simple Change Request Workflow Summary**

<b>CR Approval</b> <span style="float: right;">1</span>
<ul style="list-style-type: none"><li>CR Approvers is not blank</li></ul>
Erin Riley <span style="float: right;">• CR Approvers : CR Approvers</span>

<b>Regulatory</b> <span style="float: right;">2</span>
<ul style="list-style-type: none"><li>RA Needed is Yes</li></ul>
David Follmer <span style="float: right;">• Priority of Change is not High</span>

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# Provides Reviewers/Approvers Intuitive Interface

Workflow recipients can view, compare, annotate, delegate and take action from a single user friendly form base interface.

How a single user friendly form base interface:

**CR-000091**

Title : CR-000091  
Modified By : qdmpradm  
Creation Date : Mon Jan 10 19:48:38 GMT 2011  
Status : Draft  
CR Initiator : QMD Test 010

Supporting Documents

- Typical Controlled Document Requirements v1.0.pdf
- Typical Controlled Document Requirements v2.0.pdf

Workflow Documents

- 90.C-0196
- CR-000091

**Form Actions**

- View Versions
- Annotate
- Copy
- Edit
- Change Owner
- On Hold
- Add Supporting Documents

**Workflow Actions**

- View Audit Log
- View Approvers

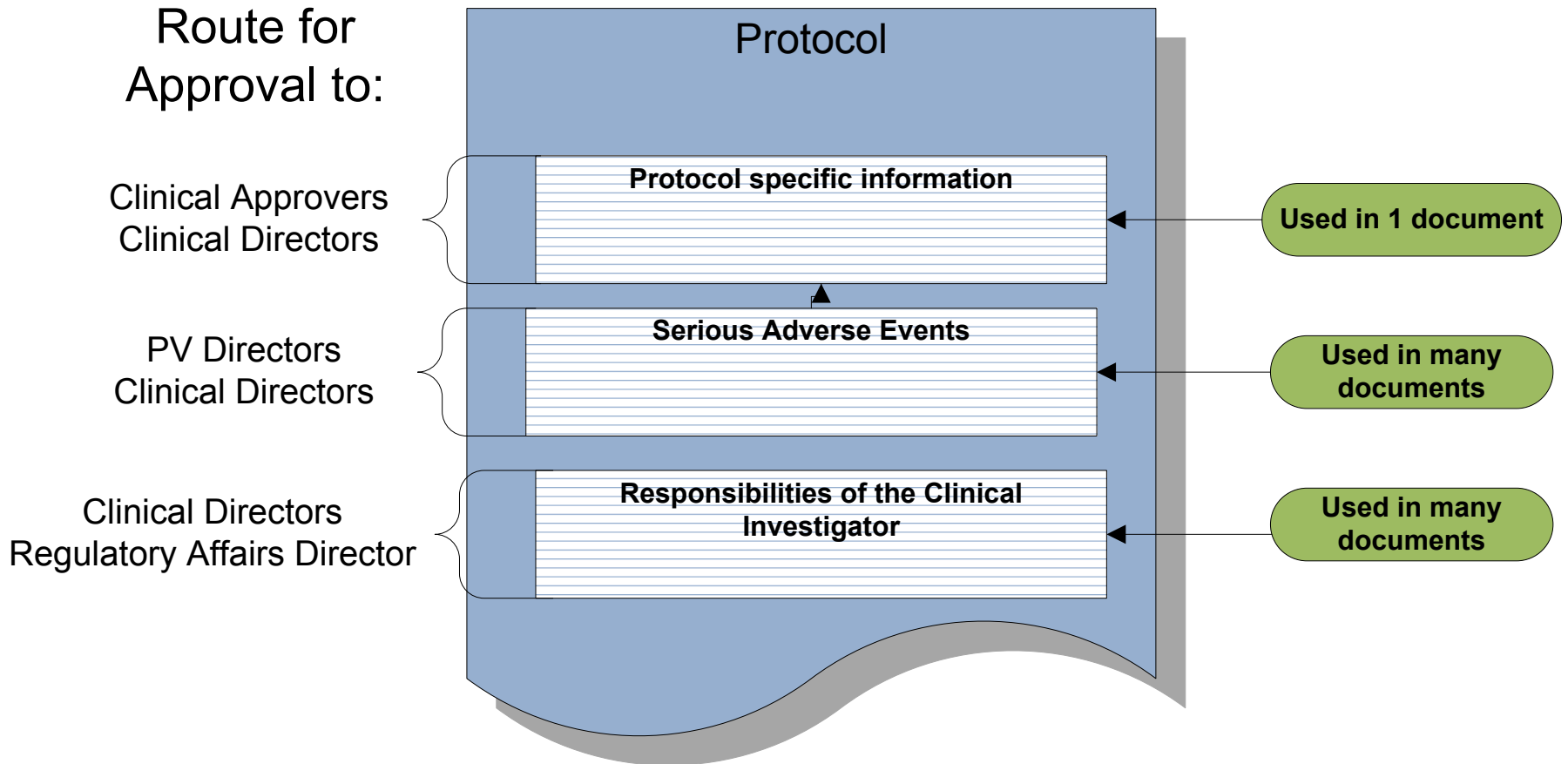
**Typical Controlled D...**

Rank	Requirement Text	
2	The system shall clear out the following property values when creating a new document by copying an existing document: document number.	2
2	The system shall copy the document content, but not the PDF rendition, when creating a new document by copying an existing document: document number.	2
1	The system shall require a user to enter required properties when checking in a document.	1
1	The system shall prevent the user from updating the system assigned version number.	1
2	The system shall automatically assign the user who creates the document as the author of the document.	2
1	The system shall allow the following groups to create a new document: [list groups].	1
3	The system shall automatically set the following properties when creating a document: [list properties].	3
1	The system shall allow the following groups of users to delete draft versions of documents [list groups].	1
2	The system shall allow the following groups of users to import documents: [list groups].	2
1	The system shall automatically attach a lifecycle based on the selected document type.	1
1	The system shall prohibit users from making changes to the document or change request without checking it out.	1
1	The system shall prohibit users from checking out a Document that is currently in a workflow.	1
1	The system shall automatically generate a PDF rendition upon checkin.	1
1	The system shall full-text index all rendered documents.	1
2	The system shall prevent a user from checking out a previous major and minor version of a document (i.e. prevent branching).	2
1	The system shall allow a user to update document property values during check-in.	1
1	The system shall not allow a user to modify a read-only document property.	1

**2.1.4 Document Review**

Rank	Requirement Text
1	The system shall allow a parallel review of a document by all applicable reviewers.
1	The system shall allow a document to be routed to one or more reviewers.
1	The system will route a PDF rendition of the document in the review workflow.
1	The system will generate an email notification for those reviewers selected in the review workflow.

# Managing Content not Documents



Thoroughly examine processes for special use cases

Look at each document type and group by common process

Craft lifecycles based on document type requirements

Use forms based workflows to dynamically adjust routing and participation

Move toward managing content rather than documents to improve reuse and productivity