

IND Applications: A Case Study of Document Development from the Medical Writing Perspective

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Introduction

- CRO awarded 3 IND submission projects for a US sponsor
 - 3 similar drugs
 - Similar indications (acute and/or chronic pain)
 - Similar regulatory pathways
- Timeframe of approximately 6 months



Medical Writing Focus

- Scope
 - Phase 2 and phase 3 studies
 - 19 deliverables (3 IBs, 10 synopses, 6 protocols)
- Goals
 - Provide clear, consistent documents for inclusion in the IND submissions
 - Meet or exceed the regulatory submission deadlines



Management

- Medical Writing Project Manager (MWPM) assigned
- Responsibilities
 - Maintain timelines for all MW deliverables
 - Ensure milestones met
 - Coordinate meetings and activities for the sponsor and the CRO teams
 - Write and conduct Quality Control (QC) reviews, as needed



Organization (1)

- Verified the regulatory requirements
 - IBs for each of the 3 drugs
 - Protocols for
 - Phase 2 proof-of-concept studies
 - Phase 3 pivotal studies
 - Synopses for
 - Phase 3 chronic pain study (1 drug)
 - Phase 3 open-label safety studies
 - Indications for each of these studies



Organization (2)

- Clarified MWPM role with Regulatory Affairs (RA)
 - Oversee MW document development in parallel with IND activities by RA
 - Act as the primary sponsor contact for MW deliverables
 - Ensure that RA was included in all pertinent communications with the sponsor and team



Organization (3)

- Identified key team members
 - CRO
 - Regulatory Affairs
 - Product Development
 - Medical Affairs
 - Biostatistics
 - Clinical Trials Management
 - Sponsor
 - Clinical Development Lead and Specialist



Organization (4)

- Determined the most efficient and user-friendly
 - Document storage location on the MW server
 - Folder naming and organization system
 - Drug → Document Type → Indication → Version*
 - Individual document naming conventions
 - (Sponsor's Name)_Protocol #_Document Type_ Draft/Final
_Version #_Date*
 - Email subject line contents



Strategic Planning (1)

- Consulted with RA to determine sponsor's goals for submission dates
- Determined which documents could be developed concurrently and which would be written sequentially
- Created timelines for each document



Strategic Planning (2)

- Evaluated MW resources for availability for estimated project duration
 - Identified MW lead for each program
 - Assigned 2 to 4 MWs to work across programs



Strategic Planning (3)

- Developed sponsor-specific document templates with style guide
 - Key components (eg, level of detail)
 - Style issues (AMA, 10th Edition)
 - Study participants – “subject” vs. “patient”
 - Reference to product – “study drug”, etc.
 - Specific drug name
 - Punctuation – serial commas, etc.



Communication (1)

At program initiation -

- Organized frequent interaction with teams (MW, other departments, and sponsor)
- Designed a 1-page overview that identified
 - Drug program
 - Document type
 - Study indication, protocol # (synopses/protocols)
 - Version/date and current status



Communication (2)

Overview of Medical Writing Deliverables

15 Mar 2010

	Documents	Study	Version	Current Status
Drug 1	IB		Final v2.0 (20Jan10)	Signatures on file; PDF with signature page sent to sponsor 22Jan10.
	Synopses	phase 2 acute pain	Final v1.0 (30Oct09)	Signatures on file; PDF with signature page sent to sponsor 10Nov09.
		phase 3 acute pain	Final v1.0 (30Oct09)	Signatures on file; PDF with signature page sent to sponsor 10Nov09.
		Open label	Final v1.0 (30Nov09)	Signatures on file; PDF with signature page sent to sponsor 03Dec09.
	Protocols	phase 2 acute pain	Draft v1.0 (08Mar10)	Sent to sponsor 08Mar10; comments due 19Mar10
		phase 3 acute pain	Draft v0.1 (10Mar10)	Internal CRO review started 10Mar10; due to sponsor 19Mar10
Drug 2	IB		Final v2.0 (20Jan10)	Signatures on file; PDF with signature page sent to sponsor 22Jan10.
	Synopses	phase 2 acute pain	Final v1.0 (25Jan10)	Signatures on file; PDF with signature page sent to sponsor 29Jan10.
		phase 3 acute pain	Draft v2.0 (10Mar10)	Sent to sponsor 11Mar10; comments due 22Mar10
		phase 3 chronic pain	Draft v1.0 (08Mar10)	Sent to sponsor 08Mar10; comments due 19Mar10
		Open label		Pending
	Protocols	phase 2 acute pain		Pending
	phase 3 acute pain		Pending	
Drug 3	IB		Final v1.0 (26Jan10)	Signatures on file; PDF with signature page sent to sponsor 05Feb10.
	Synopses	phase 2 acute pain		Pending
		phase 3 chronic pain		Pending
		Open label		Pending
	Protocols	phase 2 acute pain		Pending
	phase 3 chronic pain		Pending	



Communication (3)

Drug 1	Documents	Study	Version	Current Status
	IB		Final v2.0 (20Jan10)	Signatures on file; PDF with signature page sent to sponsor 22Jan10.
	Synopses	phase 2 acute pain	Final v1.0 (30Oct09)	Signatures on file; PDF with signature page sent to sponsor 10Nov09.
		phase 3 acute pain	Final v1.0 (30Oct09)	Signatures on file; PDF with signature page sent to sponsor 10Nov09.
		Open label	Final v1.0 (30Nov09)	Signatures on file; PDF with signature page sent to sponsor 03Dec09.
	Protocols	phase 2 acute pain	Draft v1.0 (08Mar10)	Sent to sponsor 08Mar10; comments due 19Mar10
	phase 3 acute pain	Draft v0.1 (10Mar10)	Internal CRO review started 10Mar10; due to sponsor 19Mar10	



Communication (4)

Throughout the program –

- Monitored progress of each deliverable
- Updated overview document frequently
 - Provided accurate, “real-time” information essential to keep teams on track
 - Forwarded to CRO team and sponsor weekly



Communication (5)

- Regulatory Affairs
 - Clarified IND issues
- Biostatistics
 - Addressed statistical project expectations
- Product Development/Clinical Trials Mgmt.
 - Assessed feasibility of study designs/procedures
- Medical Affairs
 - Provided medical perspective



Communication (6)

- Provided ongoing guidance to sponsor about project expectations
- Oversaw and coordinated the writing, review, and delivery of documents
- Met regularly (daily at times) with MW team for updates and input



Challenges

1. Program modifications
2. Change in sponsor's study lead
3. Submission priority changes due to manufacturing issues



Response – Program Modifications

- Documents written both concurrently and sequentially
- Diligently monitored changes
- Proactively confirmed whether changes in one program document affected the corresponding document in other programs
- Questioned whether changes affected other parts of a document (eg, statistics)



Response – Change in Sponsor Lead

- Efficiently provided important study information to the new sponsor lead
 - Described the project organization and communication patterns
 - Reviewed prior decisions
 - Discussed pending issues
- Virtually seamless transition



Response – Priority Changes

- Remained flexible
- Adjusted internal strategies across all departments to meet new priorities
- Early organization, strategic planning, and communication led to
 - Maintaining continuity
 - Providing timely document delivery



Case Study Results

- Effective management led to
 - Cohesive partnership with sponsor
 - Effective collaboration
 - Timely submissions
- Positive feedback received from
 - Sponsor
 - Department leaders at CRO



Medical Writer – Important Team Member

- Successfully manage complex programs
 - Meticulous organization
 - Strategic planning
 - Clear communication
- Establish positive, effective partnerships
 - Delivering high-quality documents
 - Meeting project milestones
 - Adjusting priorities when strategies change
 - Contributing MW expertise



Thank you!

Questions?

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