Publication Best Practices: An 8-Step Approach to Quality and Compliance

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The Agency Perspective

- Support the client
- Advise the client on best practices
- Protect the science
- Educate
- Empower HCPs
Imperatives

• Publications must
  – Address unmet scientific and clinical education needs
  – Identify knowledge gaps
  – Help HCPs improve clinical outcomes
Aspirations

• Publications should
  – Support Brand pillars and critical success factors
  – Highlight product attributes and their place in therapy
  – Differentiate scientific and clinical identity
  – Support all phases of brand life-cycle management
  – Deliver consistent messages
  – Establish and nurture thought leader relationships
“A method of accomplishing a business function or process considered superior to all other known methods.”
Why are they necessary in publications?

Consistent, compliant, and precise manuscript development processes create high-quality, need-based publications that deter unnecessary and unwanted oversight and minimize risk exposure to companies.
8 Steps for Pub Plans

1. Sound, compliant strategic development
2. Think CME
3. Understand regulatory landscape
4. Consider the drivers of strategic direction
5. Compliant tactical implementation
6. Transparent manuscript submission
7. Rapid respond to journal feedback
8. Monitoring affect of deployed publication
Step 1

Strategy
Strategy is based in ongoing evaluation

Strategic Development (identifies need)

Analysis Phase (ongoing evolution)

Execution Process (provides value)
Strategic Communication Phases

2006 – 2011

– Building Awareness

2007
– Interest and Evaluation

2008
– Preparing the Marketplace for Launch and Establishing Product’s Place in Therapy

2009 – 2010

2010–11

2012–13

Preclinical Articles

Phase I Publications and Abstracts/Posters

Phase II Publications and Abstracts/Posters

Phase III Publications and Abstracts/Posters

Phase IV Research & Development (R&D)

Derivative and Review Publications

Journal Supplements

Case Studies

Marketing Communications

Other Publications/Vehicles

Maximizing Trial Data

Multiple deliverable types ensure optimal reach of messages

- Abstracts
- Posters
- Podium Presentations
- White Papers
- Clinical Trial/Pivotal Data
- Primary Publications
  - Review Manuscripts
  - Rapid Communications
  - Academic Journal Web casts/Pod casts
  - Secondary Analyses
  - Journal Supplements
Step 2

Think About What Publication Planners Have Learned From the CME Experience?
Key Learnings

• Like CME, publications should
  – Serve unmet medical education need
  – Address known clinical/educational gaps
  – Focus on improving clinical outcomes
  – Be transparent, compliant, and of high quality
Goals

• Align publication need and developmental process with the need and process that led to discovery and development of the compound in the first place

• Publications should be seen as an extension of the scientific process, not an adjunct
Step 3

Understand and Appreciate the Regulatory Landscape
A Lot of Direction

Publication Process

- FDAAA
- ICMJE
- PhRMA
- EMWA
- WAME
- TIPPA
- AMWA
- ISMPP
A Lot of Direction!

- FDAAA
- WAME
- ICMJE
- EMWA
- AMWA
- PhRMA
- TIPPA
- ISMPP
Common Elements of Multiple Guidance

- Publish primary data acknowledging negative and positive trial results
- Support separation between marketing and medical affairs
- Maintain fair balance in all publications
- Acknowledge all medical writers/editors and their role in the publication
- Be aware of COI
- Recognize that “more” publications may not be in the best interest of patients
  - Strive for quality of publications over quantity
Step 4
Consider the Drivers of Strategic Direction
Voices of Multiple Stakeholders

- Medical (researchers and authors) Marketing, Sales, MSLs, KOLs, etc.
- Support Evidence-based Medicine
  - Identify ways to measure clinical impact
  - Close the communication and feedback loop by talking with everyone who interfaces with HCPs
Step 5

Tactical Implementation
Make Strategic Vision an Actionable Plan

- Tactics should be developed around brand-critical milestones
  - Launch date
  - Congresses and symposia
  - New data availability
  - Formulation of treatment guidelines
  - Brand/Therapeutic/Market-specific events
Author ID and Recruitment

Author Identification

Vetting Process

• Literature Search of Publications
• Analysis of CV
• Affiliation
  – Academic medical centers
  – Journals
• Experience
• Appreciation for the publications process
Author ID and Recruitment

Author Identification

Author Outreach

- Liaison approaches author with opportunity to develop manuscript
- What is appropriate author interaction?
  - An open discussion of the topic and educational need
  - A brainstorming session led by the author to define the article content
- What isn’t?
  - A “content discussion” driven by sponsor or agency
  - Discussion focused more on honoraria than science
Author ID and Recruitment

- Author Identification
- Author Outreach
- Author Feedback

- Is author capable?
  - Is author willing to participate per best practices?
  - Does author agree that there is unmet medical/scientific need in this area and that educational tactics are necessary?
  - If yes, proceed
Author ID and Recruitment

- Author Identification
  - Author Outreach
    - Author Feedback
      - PROCEED?
        - NO
        - YES
Author ID and Recruitment

Author Identification

Author Outreach

Author Feedback

PROCEED?

NO

YES

Author Contracting

- Clearly Stated Objective of Educational Publication Tactic
- Terms Dictate Manuscript Development Timeline
- Honoraria (if any)
  - Primary Papers- No
    - Usually determined before study initiation
    - Obligation to publish
  - Posters - No
  - Review Papers- Maybe
    - Honoraria considerations based on FMV
    - Opinion leader/author tier
    - Standards of author's academic affiliation
Author ID and Recruitment

- Author Identification
- Author Outreach
- Author Feedback
- PROCEED?
  - NO
  - YES
- Author Contracting
- Manuscript Development

- Kick-off participants
  - Author
  - Author liaison
  - Tactical team leader
  - Medical writer
Goals and Objectives at Project Kick-off

- Agreement with medical writer, medical affairs, strategic team on roles and responsibilities in manuscript development
- Seek author direction on
  - Target audience and journal
  - Clinical/scientific objectives
  - Specific content
Manuscript Development

Draft Outline Development

- Completed by Medical Writer (or Author)
- Review of Draft Outline
  - Author
  - Author liaison
  - Tactical team leader
  - Recommendations/comments by team members vetted by author
  - Author has veto of any recommendations/comments
  - Integration of author-approved comments into outline
Manuscript Development

- Recommendations/comments by team members vetted by author
  - Author(s) has veto power over any recommendations/comment
  - Integration of author-approved comments into outline
Manuscript Development

- Manuscript: Draft 1
  - Completed by medical writer
  - Review of draft 1 - manuscript
    - Author
    - Author liaison
    - Tactical team leader
  - Recommendations/comments by team members vetted by author
    - Author has veto of any recommendations/comments
    - Integration of author-approved comments into draft
Manuscript Development

- Draft Outline Development
- Author Review
- Manuscript: Draft 2

**Recommendations/comments by team members vetted by author**
- Author has veto of any recommendations/comments
- Integration of author-approved comments into draft 2

- Completed by medical writer
- Review of draft 2 - manuscript
  - Author
  - Author liaison
  - Client medical affairs lead
  - Tactical team leader
Manuscript Development

1. Draft Outline Development
2. Author Review
3. Manuscript: Draft 1
4. Final Draft Review
5. Submission
Step 6

Manuscript Submission
Submitted by Author

- Agency may assist author in development of manuscript submission package
- Submission subject to standards/processes defined by journal
- Not Submitted by Third Party (agency does not submit)
Step 7

Acceptance or Rejection
Acceptance Without Comment

Cue crickets.
Acceptance or Rejection

Acceptance With Comments

- Author responsible for addressing comments
  - Author liaison/agency medical director, client medical affairs, medical writer may assist in addressing comments at author’s explicit direction
  - Author responsible for resubmission
    - Agency may assist in development of resubmission package
Acceptance or Rejection

Rejection

• Author is responsible for selection of alternate journal
• Agency may assist author in reformatting manuscript to comply with alternate journals standards and requirements
• Author is responsible for second submission
Step 8
Publication
Impact Analysis

- Letters to the Editor
- Congress/Booth Dialogue
- Market Monitoring Reports
- Citation Tracker
- HCP Comments via Sales Force Feedback
- HCP Comments via MSL Feedback
8 Steps and Results

1. Strategic Vision  →  An effective plan
2. Think CME  →  Serve unmet need
3. Regulatory Landscape  →  Compliant
4. Multiple Stakeholders  →  Everyone is happy
5. Compliant Implementation  →  Improves acceptance
6. Transparent Submission  →  Honesty
7. Journal Feedback  →  Makes the paper better
8. Impact Analysis  →  Refines future strategy
Summary

- Best Practices consistent with standards that are compliant, transparent, and need based protect the industry from invasive, unnecessary regulation and protect the science by creating educational tools that advance clinical care.