Streamlining and Improving the Global Publication Development Process to Align with Publication Best Practices

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BACKGROUND

Global Medical Publications Center of Excellence (CoE)

Focuses on the development of high-quality and timely medical publications

Mission

- To support the development of high-quality and timely medical publications that ensure clear, scientific communication of Bristol-Myers Squibb (BMS) data
- To distill, share, and apply publication best practices and to drive process improvements to ensure publications are developed with the highest degree of integrity, quality, and transparency, thus enabling the safe and appropriate use of BMS medicines
- To foster alignment of publication standards across therapeutic areas and between global and regional medical publication groups

Bristol-Myers Squibb Policy Documents

- Corporate Policy on Publications and Other Disclosures of BMS Information
- Corporate Directive on Scientific Publications
- Global Development and Medical Affairs Global Directive on Scientific Publications

Policy Documents Address GPP

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

- Based on guidelines established by ICMJE
- Applicable across R&D organizations
- Ensures accountability re: author selection and author involvement
- Ensures transparency through acknowledgment of all contributions and financial disclosure of conflicts-of-interest

The Issue

Internal stakeholders reported that the timeframe for publishing primary data was too long

- Primary manuscript development process averaged 130 business days
  - Based on a review of 12 manuscripts over a 4-year period

METHODS

- Overall Goal
  - Simplify the development of publications
  - Ensure alignment with external guidelines
- Internal task force created
  - Critically analyzed issues
  - Identified opportunities to streamline

Root Causes Identified

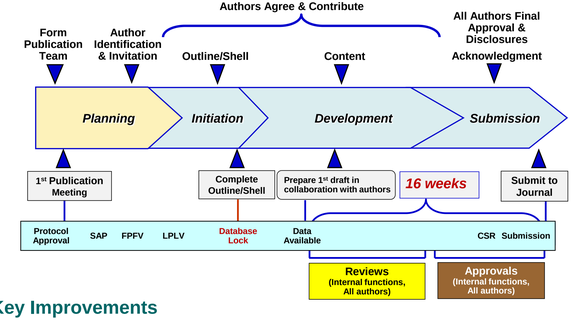
- **Accountability**
  - **Lack of a standard process**
  - **No clear decision-making model**
- **Review Process**
  - **Too many reviewers**
  - **Multiple reviews by same person**
  - **Multiple reviewers per function**
  - **Lack of clarity around reviewer's role**
- **Timelines**
  - **No rigor around timeline**
  - **Lack of timeline enforcement**
  - **Critical Path timeline too linear**
  - **Lagging collection of disclosure information**

RESULTS

Goals Achieved

- Increased process efficiency
  - Decreased the number of reviewers and number of reviews by each individual
  - Reduced publication development timeline to achieve publication of primary manuscript within "acceptable" timeframe
- Continued alignment with publication best practices
- Increased accountability to authors
  - Transparency
  - Efficient communication of BMS scientific information
  - GPP

Streamlined Manuscript Development Process



Key Improvements

- Manuscript development process follows ICMJE and Good Publication Practice (GPP) guidelines
  - Mandates authors' control over and responsibility for content
  - Ensures transparency at every step
- Implementation of a standard process for the development of primary manuscripts
  - Parallel development of primary manuscript and clinical study report improves efficiency and timeliness, with several key publication milestones achieved prior to database lock
  - Early identification of data analyses required for publication
- Process changes
  - Major input obtained early
    - Fosters early internal alignment
    - Accountability to authors with increased author responsibility for publication development
  - Reduced number of reviews and non-author reviews
    - Clarified reviewer roles
  - Maximum 1 reviewer per function

- **Outcome**: **Reduced review time for primary manuscripts by 40% – from 130 to 80 days**

Case Examples of Process Improvements

Case Example 1

- Primary phase 3 oncology study manuscript → submitted to major medical journal ~ 1 month from availability of validated data
  - Shell manuscript written and signed off by authors/authoring committee
  - Rapid dissemination of data to authoring committee after validation
  - Roles & responsibilities of internal reviewers identified at onset
  - Review teams included a maximum of 1 member per function (accountability with representative of the function)
    - Non-author involvement minimized

Case Example 2

- High-priority immunoscience manuscript → 8 weeks from content development to submission
  - Early engagement of publication steering committee (~ 4 months prior to database lock)
  - Authors and internal stakeholders aligned with timelines and committed to dedicate review time when needed
  - In collaboration with authors, early outline/shell publication prepared and reviewed
  - After database lock, 1st draft completed and reviewed by all authors and internal stakeholders within 4-5 weeks
  - Final draft reviewed, approved, and submitted in 3 weeks

Lessons Learned

- Establish review process
- Proactive planning
  - Awareness of timelines
  - Early alignment & setting of expectations
- Comment resolution completed at each step

Streamlined Process Improvements Applied to All Types of Publications

- Manuscripts, Abstracts, Congress presentations
  - Established streamlined processes and timelines
  - Early identification and involvement of external authors, especially Lead and Senior authors

Strategic Planning Steps Critical to Timely Publication Execution

✓	Process Step	Recommended Timing (No later than)
	Operational Planning kickoff	3 months prior to database lock for manuscripts
	Invite Lead & Senior Author	No later than -4 weeks prior to start
	Internal Alignment Kick-off Meeting	No later than -2 weeks prior to start
	Lead/Senior Author Kick-off Meeting	No later than -1 week prior to start
	Manuscript/Abstract/Presentation Development	START (based on date established during operational kickoff)

Implementation of Publication Management and Tracking System

- Improved publication planning globally
- Increased transparency of publication development
- Supports GPP
- Generates metrics to identify potential issues and bottlenecks

Increasing Awareness of Publication Best Practices

- Short videos about new processes rolled out company-wide on internal online portal
- Internal presentations (oral and poster) at company-sponsored symposia
- Creation of Global Medical Publications CoE brochure highlighting publications best practices (eg, ICMJE, GPP2) and BMS policies
- Development of company-wide workshops on Publication Best Practices
- Dedicated CoE Sharepoint website for dissemination of Publication Best Practices information
- Dedicated and well-informed members of the Global Medical Publications CoE serve as "ambassadors" to inform BMS Medical Staff outside the US about GPP

SUMMARY & CONCLUSIONS

- Improved process for publication development
  - Core steps identified and aligned with key study development timelines
  - Simplified review and approval process
    - Instilled more rigor around timelines via early strategic alignment and parallel development with clinical study report
    - Role clarification – standardized development and decision-making processes and clarified reviewer roles
    - Reduced number of reviews and non-author reviews
      - Maximum 1 reviewer per function
    - Reduced review time for primary manuscripts by 40% – from 130 to 80 days
- Increased awareness of Publication Best Practices
- Implemented publication management and tracking system

DISCLOSURES

- All authors are employees of Bristol-Myers Squibb

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Bristol-Myers Squibb