OPTIMIZING SCIENTIFIC VALUE: SMART AND SYSTEMATIC APPROACHES TO MEDICAL PUBLICATIONS

April 27–29, 2015
Hyatt Regency Crystal City
Arlington, VA, USA
ORAL PRESENTATIONS AND POSTER AWARDS

Jim Gurr, PhD, ISMPP CMPP™
Abstract Committee Chair

Scientific Publications
MedImmune
Thank you!

• 2015 Abstract Committee
  – Jim Gurr
  – Bhakti Kshatriya
  – Marc Eisenberg
  – Sharon Suntag
  – Holly Zoog
• Jennifer Ciafullo
Number of Abstract Submissions Continues to Increase

<table>
<thead>
<tr>
<th>Year</th>
<th>Submitted</th>
<th>Accepted</th>
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<tr>
<td>2009</td>
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<td>2013</td>
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<td>2014</td>
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<td>(76.6%)</td>
</tr>
<tr>
<td>2015</td>
<td>46</td>
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Value of ISMPP Research

ISMPP Research

Publications Best Practices

External Environment

Optimize Communication of results

Transparency

Efficiency

New media

Quality

Compliance

Better Informed Medical Decisions

Improved Patient Outcomes

Better Informed Medical Decisions

Improved Patient Outcomes
Abstract Evaluation Criteria

• Originality and innovation
• Organization and clarity of presentation
• Relevance to the field and/or the theme of the Annual Meeting
• Potential for improving/advancing service or practice
• Do the data support the research premise?

Opportunity for "provisional acceptance"
Oral Presentations

• Copyright Infringement: A Case Study
  – **Manon Boisclair**, Robert Matheis, Keisha Peters, Adriana Stan, Niina Nuottamo and Anna Georgieva

• Optimizing scientific poster production
  – **Joelle McCaslin**, Cindy Fung, Patrick Campbell, Kimberly Cushing, and Karen Pinette

• Monitoring adherence to Good Publication Practices (GPP): Insights from a global biopharmaceutical company
  – **Sonia A. Schweers**, Ann L. Davis, Brenda Connor, Susan A. Nastasee and Ananya Bhattacharya
COPYRIGHT INFRINGEMENT: A CASE STUDY

Manon Boisclair\textsuperscript{a}, Robert Matheis\textsuperscript{a}, Keisha Peters\textsuperscript{b}, Adriana Stan\textsuperscript{b}, Niina Nuottamo\textsuperscript{b}, and Anna Georgieva\textsuperscript{b}

\textsuperscript{a}Celgene Corporation, Summit, NJ, USA
\textsuperscript{b}Excerpta Medica, Amsterdam, The Netherlands
DISCLAIMERS

Please note that the views and opinions expressed in this presentation do not necessarily reflect those of Celgene Corporation, Excerpta Medica, or ISMPP.
Intellectual Property (IP)

• Includes 4 components:
Intellectual Property is Big Business

- Creates competitive advantage and barriers to entry
- Protects against copying
- Adds value
- Income stream/licensing
Three Basic Copyright Principles

1. What is copyright?
2. Copyright Protection and Infringement
3. Copyright Compliance
What is Copyright?

• A copyright exists when “original work of authorship is fixed in any tangible medium of expression”\(^1\)

• Copyright lasts 95 years from first publication or 120 years from creation, whichever is shorter\(^2\)

• Key Points: Copyright covers 7 different types of works and covers a bundle of different types of rights:
  – Right to copy
  – Right to distribute
  – Right to make derivative works
  – Right to perform
  – Right to display publicly

1. 17 U.S. Code § 102 - Subject matter of copyright: In general
Different Types of Copyrights

1. 17 U.S. Code § 102 - Subject matter of copyright: In general
Copyright infringement

• The use of works protected by copyright law without permission, infringing certain exclusive rights granted to the copyright holder, such as the right to reproduce, distribute, display or perform the protected work, or to make derivative works¹

• Congress abstracts and presentations (poster, oral) are protected under US federal copyright law²

2. http://scholarlycommunication.library.tamu.edu/scholarly-communication-issues/copyright/copyright-basic.html
Emergence of Copyrights

- Development of copyright laws followed the creation of the printing press circa 1450, and greatly expended over time to protect other medium of expression.

Origin Copyrights in the US (1787)

- **US Constitution** (Article I, Clause 8, Section 8)

- “The Congress shall have power to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”
Copyright Warning

The unauthorized reproduction or distribution of this copyrighted work is illegal. Criminal copyright infringement is investigated by federal law enforcement agencies and is punishable by up to 5 years in prison and a fine of $250,000.

Civil penalties: Up to $150,000 per work of “wilful” infringement

Consequences: Music Industry

• Pharrell Williams & Robin Thicke’s 2013 hit “Blurred Lines” infringed on Marvin Gaye’s “Got to Give it Up” copyright recorded in 1977

• On March 20th 2015, they were ordered to pay $7.4 million to Marvin Gaye’s family

Financial Times (March 20, 2015): www.ft.com
Case Study

• **Background:**
  
  – A pivotal trial was presented at an international congress (ASH)
Case Study

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  - The primary manuscript was submitted to NEJM and conditionally accepted
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  - One of the co-authors of the primary publication found a citation on PubMed referring to a supplement summarizing the data presented at ASH
Case Study

**Background:**

- A pivotal trial was presented at an international congress (ASH)
- The primary manuscript was submitted to NEJM and conditionally accepted
- One of the co-authors of the primary publication found a citation on PubMed referring to a supplement summarizing the data presented at ASH
- Someone had published a summary of the data presented, rendered a proprietary figure (Kaplan Meier curve), and published it in a supplement of a peer-reviewed journal
Case Study

• **Issue #1:**
  - Coverage in the supplement infringed copyrights related to the abstract from ASH\(^1\) and its publisher Blood\(^2\):
    - “No part of the publication may be reproduced, stored in a retrieval system, translated or transmitted in any form or by any means now or hereafter… without permission in writing from ASH, and the publisher.”

2. http://www.bloodjournal.org/page/rights-permissions
Case Study

• **Issue #2:**
  - The supplement released would have prevented the publication of the original primary article at great detriment to the NEJM, its co-authors and the company
  
  • **NEJM undertakes review of any manuscript with the understanding that neither the substance of the article nor any of its pictures or tables have been published or will be submitted for publication elsewhere. This restriction does not apply to abstracts published in connection with scientific meetings (Ingelfinger Rule)**¹

Case Study

- Remediation:
  1) Informed NEJM of the situation discovered as well as the remediation/action plan
Case Study

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  1) Informed NEJM of the situation discovered as well as the remediation/action plan
  2) Commissioned an external IP legal firm for their counsel and expertise
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  3) Subpoenas were issued to both the 3rd party author as well as the editor of the journal in which the supplement was published
     ✓ Mandated the withdrawal and retraction of the unauthorized and infringing publication
     ✓ Journal website de-activation (page, link, PDF)
Case Study

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4) Removal of the citation and entry in PubMed
Consequences of Infringement in Our Field

• Impact on journal reputation
• Relationship with journals
• Impact on congress reputation
• Intellectual property (including copyright)
• Data rights
• Confidentiality
Can Law Keep up With Technology and Individual Practices?

- Development of copyright laws followed the creation of the printing press\(^1\)

- Today’s information and communications technologies are **rapidly** challenging the intellectual property landscape\(^2\)

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The digital culture
Perception vs. Reality Concerning Copyright–Impact of Social Media

John Smith

#mmsm #ASCO14 - Lokhorst - Daratumumab - anti-CD38 PFS

Chicago, IL

Progression-Free Survival

The median PFS estimate in the 16 mg/kg is rather immature. The current median PFS in the 16 mg/kg group is 23 weeks which is also the longest follow-up of any patient in this cohort.
Perception vs. Reality Concerning Copyright- Impact of Social Media

• A picture is worth a thousand words,

• Important clinical data could be worth a NEJM paper,

• But when research is protected by copyright, it could be worth three words: **cease and desist**
Lessons Learned:

- **Personal Ethical Accountability:**
  - Awareness
  - Responsibility
  - Knowledge of copyrights related to congress material (abstract, poster, oral presentation)
  - Do not use unauthorized text, images, video
  - Request permission
  - In doubt- ask a copyright attorney
Lessons Learned:

• Author’s and Journals’ Responsibilities:
  – Knowledge about copyright
  – Accountability
  – Awareness of the possible presence of specific clinical data on social media
  – Due diligence- check for any prior publication
  – Respect of existing copyrights for congress material (Abstract and presentations)
KEEP CALM
BUT
Protect Your IP
Special Thanks To:

• My co-authors and collaborators
• Rebecca Goodman (Copyright attorney)
• Kerry Rothschild (Corporate attorney)
• Liz Arnold (Knowledge Center)
QUESTIONS?
BACK-UP SLIDES
# IP: Different Terms & Coverage

<table>
<thead>
<tr>
<th>Protected Interest</th>
<th>Trade Secret</th>
<th>Patents</th>
<th>Copyright</th>
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<td>Business Information</td>
<td>Functional Inventions</td>
<td>Expression embodied in a fixed medium</td>
<td>Consumer Recognition &amp; Goodwill</td>
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<td>New, useful, non-obvious, proper subject matter</td>
<td>Originality</td>
<td>Use in commerce</td>
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<td>Term</td>
<td>As long as it remains a secret</td>
<td>20 years from application date</td>
<td>For corporations, 95 years after publication</td>
<td>Indefinite, if trademark is used properly</td>
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<tr>
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<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>Conduct Prohibited</td>
<td>Misappropriation</td>
<td>Making, using, selling or offering to sell</td>
<td>Copying or substantially similar works</td>
<td>Creating a likelihood of confusion</td>
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<td>Prohibited</td>
<td>May be prohibited</td>
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<td>Compensatory and statutory damages; attorney fees</td>
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<tr>
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<td>$15-$25,000 (filing and attorney fees)</td>
<td>$45 filing fee</td>
<td>$275 per class</td>
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</table>
Elements to Keep in Mind in Pub Planning

• Journals with a Corporate Subscription:
  – **Reactive or Responsive Use Clause (RUC)**
    Allows for sending of single copies of articles in response to an **unsolicited** request (Med Info, MSL, etc)

• Journals- Open Access:
  – Does not always mean we can send a PDF
  – Each publisher/author establishes rights and permissions
Useful Links Related to Copyrights

Additional Resources Related to Copyrights:

- [http://copyright.com](http://copyright.com): Search by journal title, Check local licenses if applicable

- [http://creativecommons.org](http://creativecommons.org): Open access articles where author grants the permission

- Copyright Clearance Center Education page [http://www.copyright.com/content/cc3/en/toolbar/education/resources.html](http://www.copyright.com/content/cc3/en/toolbar/education/resources.html)

- Copyrightlaws.com (Lesley Ellen Harris) Resources page [http://www.copyrightlaws.com/resources/](http://www.copyrightlaws.com/resources/)
OPTIMIZING SCIENTIFIC POSTER PRODUCTION

Joelle McCaslin, Clare Baker, Cindy Fung, Patrick Campbell, Syeda Raji, Kimberly Cushing, and Karen Pinette

Biogen, Cambridge, MA, USA
Biogen International GmbH, Zug, Switzerland
DISCLOSURES

Joelle McCaslin, Clare Baker, Cindy Fung, Kimberly Cushing, and Karen Pinette are employees and stock owners of Biogen. Patrick Campbell, Syeda Raji are contractors for Biogen.

The views expressed in this presentation reflect the opinions of the authors and not those of Biogen.
PORTIONS HAVE BEEN PREVIOUSLY PRESENTED AT ISMPP-EU 2015

Introduction

• Posters are valuable educational tools and offer a unique medium for authors to engage a live audience at scientific and medical congresses.

• In order for a poster to have maximum impact, the content should be clear and concise, displaying the data in a visual manner and presenting well-written conclusions.

• However, posters can frequently contain a large amount of content and their layouts can vary in order to accommodate the dense content.
Complexity with Major Congresses

- Posters describing findings from Biogen led research efforts were being accepted by congresses in high numbers.
  - AAN 2014: 51 posters
  - CMSC 2014: 13 posters
  - EFNS-ENS 2014: 36 posters
  - ECTRIMS-ACTRIMS 2014: 52 posters
- Data stemmed from global, regional, and local publication plans.
- Represented 9 marketed products and development programs.
- Supported by 4 global agencies, HEOR vendors, in-house scientific writers, and several freelancers.
- Quality of our posters varied in the past.
Objective

Could we find a way to be **efficient** with production, **consistent** with our graphic elements, and **impactful** to our audience across all of these posters?

In order to more clearly communicate our scientific findings to congress attendees, we sought to:

1. Optimize poster production across agencies
2. Identify improvements to content development and graphic design elements
A modified process for poster production was developed.
Selection of posters evaluated and revised

Revised posters analyzed to enhance layout

Layout and pre-layout templates developed

Poster production guide created

Materials disseminated and process implemented across 4 congresses
Poster Design

**Identified Layout Weaknesses**

<table>
<thead>
<tr>
<th>long introductions</th>
<th>cramped study design</th>
<th>overcrowded figures</th>
<th>long and duplicative methods</th>
<th>difficult to navigate</th>
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</table>

11TH ANNUAL MEETING OF ISMPP
Word Count Reduction

**Introduction**
- 182 (1) - 104 (2) - 337 (3) - Avg. 230
- 42% reduction

**Methods & Objectives**
- 499 (1) - 246 (2) - 289 (3) - Avg. 416
- 54% reduction

**Results**
- 142 (1) - 126 (2) - 304 (3) - Avg. 250
- 10% reduction

**Conclusion**
- 133 (1) - 101 (2) - 220 (3) - Avg. 150
- 13% reduction

30% reduction overall
Room for Graphs and Tables

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<tr>
<th></th>
<th>Poster 1</th>
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<th>Poster 2</th>
<th></th>
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<td>5</td>
<td>5</td>
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Average

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<th>After</th>
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18% increase in the amount of space used for graphs and tables
Pre-Layout and Layout Templates

Recommendations for a 6’x4’ poster

- Total word count of 684
  - 134 words in Introduction
  - 195 in Methods
  - 226 in Results
  - 131 in Conclusions
- Total of 4 graphs and tables.
Poster Production Guide

“This document outlines the style and formatting requirements reflected in the poster templates provided. This is meant as a reference guide to address any questions that may arise during development.”

“To ultimately improve the communication of the scientific findings.”
## Process Coordination

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<th>Owner</th>
<th>Task Duration (days)</th>
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<td>Placeholder posters sent to IT to associate with individual QR code links</td>
<td>Pubs</td>
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<tr>
<td>Testing of link between QR code and placeholder poster</td>
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<td>QR codes forwarded to agencies to be included on layouts</td>
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In total 53 ECTRIMS posters passed through internal QC process
29 **Standard timeline**, 24 **Latecomers**
15 **in-house layout posters**
Implementation & Results

• Guidance documents were cascaded to global, regional, and local publication teams to enable aligned and consistent poster development.

• This new model for poster production was implemented across 4 major neurology congresses in 2014.

• A total of 174 posters passed through this new process. Attendance at the posters was high and feedback was positive, with two posters selected as semi-finalists for poster awards.

Refinement of the model occurred after each conference
Insights and Learnings

• Guidance Documents
  – Specifications and templates needed early
  – Detailed and clear style guides
  – “Foolproof” templates

• Quality Checks
  – Multiple levels of QC
  – Service to affiliates/regions
  – Allow time for corrections

• Technology Integration
  – Owning QR code creation and dissemination
  – Platform for transferring files
  – Research congress requirements in advance
  – Implications of new formats for presentations
Insights and Learnings

• Communication Channels
  – Poster identifiers across agencies and teams
  – Master Spreadsheet for tracking
  – Clear process owner and communication

• Production
  – Plan Ahead
  – Agreement and flexibility on timelines
  – Budget funds and time

• Logistics
  – Hanging & removal at the conference
  – Peace of mind from authors
  – Shipping them back to the company and to PIs as requested
  – Printing on site if needed
  – Supporting international congresses
Conclusions

Could we find a way to be efficient with production, consistent with our graphic elements, and impactful to our audience across all of these posters?

We created an optimized centralized process for poster development and a set of comprehensive guidance documents including pre-layout templates, congress specific layout templates, and a poster style guide, ultimately enhancing the quality of our posters for the scientific community at congresses.
THANK YOU & QUESTIONS?
MONITORING ADHERENCE TO GOOD PUBLICATION PRACTICES: INSIGHTS FROM A GLOBAL BIOPHARMACEUTICAL COMPANY

Sonia A. Schweers, Ann L. Davis, Brenda Connor, Susan A. Nastasee and Ananya Bhattacharya

Bristol-Myers Squibb
Medical Publications – Publication Policy and Education
Background

- Adherence to good publication practices (GPP) is critical to ensure the integrity and credibility of publications.

“Quality means doing it right when no one is looking” Henry Ford
Objectives

• Implement a new capability to monitor GPP adherence within a global biopharmaceutical company

• Identify solutions for common compliance challenges
Methods

• Develop monitoring strategy and plan
  – Identify GPP requirements to monitor

• Conduct baseline assessments
  – Gaps were defined as
    • Lack of or insufficient documentation
    • Deviation from publication development process

• Share results with teams and stakeholders with opportunity for clarification

• Identify root causes and recommend corrective and preventive actions
Ex-US Market Publications
GPP Gaps: Baseline

Market Publications with Gaps (n=10)

Root Causes:
- Inadequate understanding of requirements due to language barrier
- Ineffective oversight
- External author expectations
Improvements in GPP Compliance
Baseline vs. 6 Month Follow-up

Market Publications with Gaps

- **Author Acknowledgment**: Baseline (n=10) - 100%, Follow-up (n=6) - 0%
- **Author Review**: Baseline (n=10) - 50%, Follow-up (n=6) - 50%
- **Author Final Approvals**: Baseline (n=10) - 70%, Follow-up (n=6) - 10%
- **Disclosure in Publication**: Baseline (n=10) - 0%, Follow-up (n=6) - 0%
Corrective and Preventive Actions (CAPAs)

- Re-assessments in 2015
- Clarify requirements for documenting access to data for abstracts
- Establish oversight requirements
- Gap-focused
- Live, followed by knowledge checks
- Training materials specific to gap

- Update tool to align with SOPs and documentation requirements
- QC checklists at start and end of publication to facilitate oversight of documentation in tool
Solutions for Compliance Challenges

- Simplify when possible
- What is required? What must be documented?

- Tool must capture all the documentation requirements
- Use tool to add controls (i.e., checks)

- Establish training curriculum
- Training retention
Summary

• Implementation of a global publication monitoring program led to improved adherence to GPP

• The monitoring program raised awareness of
  – the requirements for compliant publication development, and
  – the importance of staying compliant to mitigate risk
QUESTIONS?
2015
POSTER AWARDS
Original Research – TIE!!!

Poster # 5

Clinical trials: do the patients get the thanks they deserve?
Radhika Bhatia and Barrie Anthony
Original Research – TIE!!!

• Poster #36

Professional medical writing support improves the quality of reporting of randomized controlled trials

William Gattrell,, Sally Hopewell, Kate Young, Stephen Lang, Paul Farrow, Richard White, Elizabeth Wager and Christopher Winchester
Best Practice

• Poster # 11

Current medical writing practices: Identifying the optimal model for cost-effective and timely publications

Susan Pacconi, Dan Bridges and Robert Matheis
Visual Communication

• Poster # 14

Publication contracting made simple
George Samman and Jessica Bowler
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April 27–29, 2015
Hyatt Regency Crystal City
Arlington, VA, USA