HOW GAP ANALYSIS AND PUBLICATION PLANNING CAN INCREASE YOUR CHANCES OF PUBLICATION SUCCESS

**Moderator:** Andrew Sakko, PhD, ISMPP CMPP™

**Presenters:** Jake Burrell, PhD, ISMPP CMPP™
Eric Chi-Wang Yu, PhD, ISMPP CMPP™

June 20-21, 2016
ISMPP WOULD LIKE TO THANK . . .

. . . the following Titanium and Platinum Corporate Sponsors for their ongoing support of the Society:

- Amgen
- AstraZeneca
- Biogen
- Bristol-Myers Squibb
- Caudex
- CHC Group
- Complete Healthvization
- CMC
- MedErgy
- MedThink SciCom
- Pfizer
To optimize your ISMPP U webinar experience today, please:

- Turn up the volume of your computer speakers
- Use the fastest internet connection available to you
- Use a hardwire connection if available
- If you experience audio problems, please consider switching to a different browser (eg, Chrome vs Internet Explorer)
• ISMPP (not-for-profit)
  – > 1300 members
  – Write, plan, edit, publish, peer-review, research . . .

• Education
  – Webinars (Asia-Pacific, international)
  – Conferences, including in the Asia-Pacific region

• International certification
  – ISMPP Certified Medical Publication Professional™ (CMPP)
    • Next application deadline = 1 August 2016
    • Testing centres = 62 in Asia-Pacific region!
    • Increasing ISMPP CMPP™ professionals in Asia-Pacific region
Join your colleagues – join ISMPP!

FIND OUT MORE…
www.ismpp.org
• **GPP3 Presentation at APAME 2016 in Bangkok, Thailand!**
A GPP3 presentation will be held at The Asia Pacific Association of Medical Journal Editors Convention (APAME 2016) on **27 August**. Additional details can be found on their website [www.apame2016.com](http://www.apame2016.com)

• **Plan Ahead** – ISMPP is looking to host another AP meeting in 3Q 2017 in Tokyo, Japan. Contact [apmeeting@ismpp.org](mailto:apmeeting@ismpp.org) for more information.

• **REMINDER** to enter credits earned at the 12th Annual Meeting Presentations from the 12th Annual Meeting are archived in the ISMPP Archives ([www.ismpp.org/annual-meeting-archive](http://www.ismpp.org/annual-meeting-archive))
Renew your ISMPP membership today and take advantage of great benefits like monthly ISMPP Us!

Visit www.ismpp.org to renew today!
BECOME AN ISMPP CMPP™!

• We are proud to now have over 1,000 CMPPs!
• Applications are being accepted for the September 2016 exam
  – Deadline to submit – 1 August 2016
• Are you a 2011 ISMPP CMPP™?
  – This is your LAST chance to recertify via exam
  – Deadline to apply for recertification by CE credit – 30 September 2016
• Contact cmpp@ismpp.org with any questions. We’re here to help!
QUESTIONS...

- Questions will be addressed at the end of the webinar.
- To ask a question, please type your query into the Q&A box
  - To ensure anonymity and that all panelists receive your question, please choose the drop down box option, "Hosts, Presenters and Panelists." Otherwise, all audience members will be able to see your submitted question
  - Because of the nature of this presentation, we may not be able to respond to all questions about research by faculty on whom we are reporting, but we will be happy to reach out to them later with your queries

NOTE: Make sure you send your question to "Host, Presenter and Panelists"
• Information presented reflects the personal knowledge and opinion of the presenters and does not represent the position of their current or past employers or the position of ISMPP
SPEAKER PROFILES

- **Jake Burrell**, PhD, ISMPP CMPP™, was awarded his PhD on oncology from the Institute of Cancer Research in London. He began his career in medical communications at MeditechMedia in London, where he worked with a range of top-20 Pharma companies across a range of therapy areas including oncology, virology, and haematology. He speaks fluent Chinese and has worked in Shanghai for over 3 years, where he is currently the Business Director of Adelphi. Jake is an ISMPP Certified Medical Publication Professional™ (CMPP) and is a member of ISMPP’s Asia-Pacific Education Taskforce.
SPEAKER PROFILES

• Eric Chi-Wang Yu, PhD, ISMPP CMPP™, is Medical Publication Manager at Shanghai Roche Pharmaceuticals, Ltd, based in Shanghai, China. Eric is responsible for overseeing publication processes and development of publication plans, comprising publication strategy and tactics for Roche China. Eric holds his PhD in molecular pathology from University of California in San Diego, USA. He is an ISMPP Certified Medical Publication Professional™ (CMPP) and a member of ISMPP’s Asia-Pacific Advisory Committee.
GAP ANALYSIS: HOW TO PLAN YOUR RESEARCH LIKE A PUBLICATION PROFESSIONAL

Jake Burrell, PhD, ISMPP CMPP™
Business Director, Adelphi
DISCLOSURES

• Financial
  - Employee of Adelphi (we provide scientific communication services to for-profit clients in China)

• Non-financial
  - ISMPP Asia-Pacific Education Task Force Member
TODAY’S TOPICS

- What is a gap analysis?
- What role can gap analysis play in the publication process?
- How do you perform a gap analysis?
Section 1

WHAT IS A GAP ANALYSIS?
HIGH IMPACT RESEARCH TARGETS A KNOWLEDGE GAP
WHAT IS THE AIM OF A PUBLICATION/SCIENTIFIC GAP ANALYSIS?

1. Identify **key topics** related to a therapy or intervention within a certain therapy area
2. Characterise how **broadly and deeply** these topics are covered

Gaps = missing or limited information
### WHAT CAN WE DO WITH A GAP ANALYSIS?

- Increase the clinical impact of research questions and ideas
- Compare research activity for different treatment strategies and find missing evidence
- Identify new clinical research ideas
- See what other researchers have already published
- Determine the key audiences for communicating research
Publication activity can be analysed by quantitative or qualitative analysis.

**Quantitative**
- Numbers and volumes
- Relatively fast to generate data
- Can create graphs for direct comparison

**Qualitative**
- Looks at scientific messages, themes, quality of evidence (study design, endpoints)
- More time consuming
EXAMPLE GAP ANALYSIS OUTPUTS

Identify audiences

Identify relative volume

Identify relative focus
• Global publications focused on hypertension, angina and chronic heart failure in humans on Pubmed.com
• Significant gap in number of Concor (bisoprolol) publication – opportunity!
WHAT ROLE CAN GAP ANALYSIS PLAY IN THE PUBLICATION PROCESS?
Publication is the final step of research.

Research is the first step of publication.
GAP ANALYSIS FOR RESEARCH PLANNING

Clinical problem/ question

Gap analysis

Knowledge gaps

Research trends

Publication gaps

Audience gaps

Identify study aim

Study design

Journal selection
WHAT CAN GO WRONG WITHOUT A CLEAR STUDY AIM AND STRONG DESIGN?

- Example: data mining of Chinese patient data from several large clinical trials

  - Standardise and clean data
  - Run many multivariate analyses
  - Look for significant associations between variables
  - Publish the significant findings

  - Gap analysis
  - Identify knowledge gaps and formulate study aims
  - Standardise and clean data
  - Run targeted multivariate analyses
  - Investigate pre-selected variables
  - Publish the scientific story even if the results are not statistically significant

- What about non-significant associations?
- Are the significant results clinically meaningful?
Section 3

HOW DO YOU DO A GAP ANALYSIS?
# GAP ANALYSIS PROCESS

<table>
<thead>
<tr>
<th>Step</th>
<th>Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1</td>
<td>Identify the focus areas (potential gaps)</td>
</tr>
<tr>
<td>Step 2</td>
<td>Determine a meaningful timeframe</td>
</tr>
<tr>
<td>Step 3</td>
<td>Identify the information sources</td>
</tr>
<tr>
<td>Step 4</td>
<td>Define the search parameters</td>
</tr>
<tr>
<td>Step 5</td>
<td>Select format for gap analysis output</td>
</tr>
<tr>
<td>Step 6</td>
<td>Conduct the search</td>
</tr>
<tr>
<td>Step 7</td>
<td>Organise and prioritise results to identify trends</td>
</tr>
</tbody>
</table>

Finucane, S. Conducting a Gap Analysis for a Medical Publication Plan. AMWA Journal. 2014;29(3)
## GAP ANALYSIS PROCESS

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Identify the focus areas (potential gaps)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 2</td>
<td>Determine a meaningful timeframe</td>
</tr>
<tr>
<td>Step 3</td>
<td>Identify the information sources</td>
</tr>
<tr>
<td>Step 4</td>
<td>Define the search parameters</td>
</tr>
<tr>
<td>Step 5</td>
<td>Select format for gap analysis output</td>
</tr>
<tr>
<td>Step 6</td>
<td>Conduct the search</td>
</tr>
<tr>
<td>Step 7</td>
<td>Organise and prioritise results to identify trends</td>
</tr>
</tbody>
</table>

Finucane, S. Conducting a Gap Analysis for a Medical Publication Plan. AMWA Journal. 2014;29(3)
STEP 1 – IDENTIFY FOCUS AREAS (1)

- A gap analysis should have a defined and limited aim
- Define the aim with a broad question addressing some of the potential gaps

**Potential gaps**

- Volume
- Audiences
- Types of studies
- Timing
- Therapeutic indications
- Scientific messages
- Quality of data
- Clinical trials
- Etc.
Example questions:

- What was the volume of publications reporting efficacy of Treatment A in Chinese patients between 2005 and 2016?
- What types of treatment regimens have been explored for neoadjuvant treatment of rectal cancer?
- What types of biomarkers have been investigated for response of DLBLC patients to R-CHOP treatment from 2005 to 2016?
## GAP ANALYSIS PROCESS

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Identify the focus areas (potential gaps)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step 2</strong></td>
<td>Determine a meaningful timeframe</td>
</tr>
<tr>
<td>Step 3</td>
<td>Identify the information sources</td>
</tr>
<tr>
<td>Step 4</td>
<td>Define the search parameters</td>
</tr>
<tr>
<td>Step 5</td>
<td>Select format for gap analysis output</td>
</tr>
<tr>
<td>Step 6</td>
<td>Conduct the search</td>
</tr>
<tr>
<td>Step 7</td>
<td>Organise and prioritise results to identify trends</td>
</tr>
</tbody>
</table>

Finucane, S. Conducting a Gap Analysis for a Medical Publication Plan. AMWA Journal. 2014;29(3)
STEP 2 – DETERMINE A MEANINGFUL TIMEFRAME

- Examine the literature published over a meaningful time window
- Search for trends over this time to predict future activities
- What time window is most suitable? This depends on the question
  - 1 year?
  - 5 years?
  - 10 years?
<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1</td>
<td>Identify the focus areas (potential gaps)</td>
</tr>
<tr>
<td>Step 2</td>
<td>Determine a meaningful timeframe</td>
</tr>
<tr>
<td>Step 3</td>
<td>Identify the information sources</td>
</tr>
<tr>
<td>Step 4</td>
<td>Define the search parameters</td>
</tr>
<tr>
<td>Step 5</td>
<td>Select format for gap analysis output</td>
</tr>
<tr>
<td>Step 6</td>
<td>Conduct the search</td>
</tr>
<tr>
<td>Step 7</td>
<td>Organise and prioritise results to identify trends</td>
</tr>
</tbody>
</table>

Finucane, S. Conducting a Gap Analysis for a Medical Publication Plan. AMWA Journal. 2014;29(3)
STEP 3 – INFORMATION SOURCES

- **Indexed journals**
  - Public databases (PubMed, Cochrane Library)
  - Commercial databases (Ovid, EMBASE, Web of Science)

- **Congress literature**
  - Abstracts, posters and presentations
  - Online databases from scientific meetings, journal supplements

- **Clinical trials databases**
  - i.e. clinicaltrials.gov
GAP ANALYSIS PROCESS

Step 1
• Identify the focus areas (potential gaps)

Step 2
• Determine a meaningful timeframe

Step 3
• Identify the information sources

Step 4
• Define the search parameters

Step 5
• Select format for gap analysis output

Step 6
• Conduct the search

Step 7
• Organise and prioritise results to identify trends

Finucane, S. Conducting a Gap Analysis for a Medical Publication Plan. AMWA Journal. 2014;29(3)
STEP 4 – SEARCH PARAMETERS (1)

- A gap analysis might include several sets of search terms
  - treatment-specific, disease-specific, patient-related etc.
- Identify the search terms (key words) based on the focus of the analysis
  - Drug name and alternative/similar drug names
  - Therapy area or disease target (prostate cancer, HER2)
  - Type of treatment (class of drug)
  - Any data of interest (quality of life, overall survival)
  - Other key words i.e. biomarker names
STEP 4 – SEARCH PARAMETERS (2)

- Set limits to filter unwanted results
  - Search fields for the keywords (e.g. title, abstracts, articles with free full-text)
  - Geographical location of the study
  - Types of articles (clinical trials, case reports, reviews, etc.)
  - Study population (pediatric, elderly, etc.)
  - Date of publication
EXAMPLE: BREAST CANCER

- Scenario: Your hospital has a large database of triple negative breast cancer patients and you plan to do a retrospective study.
- Possible gap analysis search terms:
  - Breast cancer
  - Triple negative
  - Prognosis
  - Chemotherapy
  - Neoadjuvant
  - Platinum
  - Taxane
  - Timeframe: 2010-present?
  - Retrospective
  - Radiotherapy
## GAP ANALYSIS PROCESS

<table>
<thead>
<tr>
<th>Step 1</th>
<th>• Identify the focus areas (potential gaps)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 2</td>
<td>• Determine a meaningful timeframe</td>
</tr>
<tr>
<td>Step 3</td>
<td>• Identify the information sources</td>
</tr>
<tr>
<td>Step 4</td>
<td>• Define the search parameters</td>
</tr>
<tr>
<td>Step 5</td>
<td>• Select format for gap analysis output</td>
</tr>
<tr>
<td>Step 6</td>
<td>• Conduct the search</td>
</tr>
<tr>
<td>Step 7</td>
<td>• Organise and prioritise results to identify trends</td>
</tr>
</tbody>
</table>

Finucane, S. Conducting a Gap Analysis for a Medical Publication Plan. AMWA Journal. 2014;29(3)
GAP ANALYSIS PROCESS

Step 1 • Identify the focus areas (potential gaps)

Step 2 • Determine a meaningful timeframe

Step 3 • Identify the information sources

Step 4 • Define the search parameters

Step 5 • Select format for gap analysis output

Step 6 • Conduct the search

Step 7 • Organize and prioritize results to identify trends

Finucane, S. Conducting a Gap Analysis for a Medical Publication Plan. AMWA Journal. 2014;29(3)
• Trends about publication coverage should become apparent from the results
• The results can be turned into research aims and publication targets to help fill knowledge gaps
  – What data to focus on, what type of study to conduct (RCT, observational, data mining etc.) audiences, journals, meetings, timing
• A gap analysis will help maximize the impact of a publication related to a specific topic
• Chronic Myeloid Leukemia, 2005-present, survival versus quality of life
• Chronic Myeloid Leukemia, 2005-present, non-interventional/observational versus RCT versus retrospective

<table>
<thead>
<tr>
<th></th>
<th>Non-interventional/observational</th>
<th>RCT</th>
<th>Retrospective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global</td>
<td>26</td>
<td>74</td>
<td>162</td>
</tr>
<tr>
<td>China</td>
<td>1</td>
<td>1</td>
<td>12</td>
</tr>
</tbody>
</table>

Number of publications

- Survival: 1200
- Quality of life: 100
INTERPRETATION OF RESULTS: CHOOSING STUDY ENDPOINTS AND STUDY TYPE

- Chronic Myeloid Leukemia, 2005-present, survival versus quality of life

- Chronic Myeloid Leukemia, 2005-present, non-interventional/observational versus RCT versus retrospective

- These basic results suggest that QoL for patients with chronic myeloid leukemia is a knowledge and publication gap
- An observational study of QoL may be an appropriate study design
- Retrospective studies seem to be common in this therapy area

<table>
<thead>
<tr>
<th></th>
<th>Interventional/observational</th>
<th>China</th>
<th>Global</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Survival</td>
<td>26</td>
<td>1</td>
<td>74</td>
<td>162</td>
</tr>
<tr>
<td>Quality of life</td>
<td>1</td>
<td>1</td>
<td>12</td>
<td>12</td>
</tr>
</tbody>
</table>
INTERPRETATION OF RESULTS: EXPLORING A THERAPY AREA (1)

- Search terms: lymphoma, BCL2, BCL6, MYC, between 2000 and 2015
- An increasing number of publications addressing these terms, especially 2010-present
Chemotherapy versus prognosis versus biomarkers for lymphoma 2010-present?

Mining deeper can reveal further gaps
SUMMARY

- High impact research and publications usually target a specific knowledge gap
- Research and publication are part of the same process
- Gap analyses can help generate clear research and publication aims which target a specific knowledge gap
THANK YOU!
PUBLICATION STRATEGY IN PRODUCT LIFE CYCLE MANAGEMENT

Eric Yu 余志宏, PhD, ISMPP CMPP™
Medical Publication Manager, Roche
• I am a full-time employee of Shanghai Roche Pharmaceuticals Ltd.

• I am a member of ISMPP and a ISMPP Certified Medical Publications Professional (CMPP)

• I serve on ISMPP Asia-Pacific Advisory Committee and ISMPP Asia-Pacific Education Taskforce

• The views expressed in this presentation are my personal opinions and do not represent those of my employer
WHAT “PUBLICATION” ARE WE TALKING ABOUT?

**Congresses**
- Abstract
- Poster
- Oral presentation

**Journals**
- Manuscript
  - Original research
  - Review
- Case study
- Letter to the editor

Peer-reviewed
PUBLICATIONS ARE EVIDENCE TO INFORM DECISION MAKING

Industry
Medical Communication Agency
Publisher
Academia

Regulatory agency
Patient organization
Public/News media
Commit to Publish

- Joint Position on the Publication of Clinical Trial Results in the Scientific Literature¹
  - Results of all sponsored clinical trials should be published
  - Timely submission of primary manuscript

- Principles for Responsible Clinical Trial Data Sharing Our Commitment to Patients and Researchers²

MAJOR PUBLICATION GUIDANCE
MILESTONES

1999 GPP drafted
2000 AMWA taskforce set up
2001 PhRMA guidelines published
2002 AMWA position statement
2003 GPP published
2004 ICMJE trial registration requirements
2005 EMWA guidelines published
2006 CSE integrity white paper
2007 FDAAA passed
2008 GPP2 published
2009 ISMPP Updated Code of Ethics published
2010 GPP for medical communications agencies updated
2011 ICMJE Uniform Requirements Updated
2013 The Sunshine Act
2014 ISMPP Updated Code of Ethics published
2015 GPP3 published

Adapted from Wager E. Update on Guidelines for Medical Writers and Publication Planners. April 2011. www.KeywordPharma.com
WHY PUBLICATION PLANNING?

Right Data
Right Time
Right Audience

- Higher transparency
- Better prioritization
- Necessary resources allocation
- Foster collaboration and strengthen operations
PUBLICATION PLANNING – “3 RIGHTS”

Publication Strategy

Publication Tactics

Right Data
- Data available
- Educational needs

Right Time
- Product/Study milestones

Right Audience
- Target audience

Good Publication Practice
OVERVIEW OF PUBLICATION PLANNING PROCESS

Clinical Development Plan

Medical Plan

Knowledge gap summary
  • Medical Information query
  • Advisory Board input

Annual Business Plan

Scientific Statements

Publication gap summary
  • Competitor literature landscape

Other team publication plans
  • HEOR
  • Global publication plans

Publication Strategy
+ Publication Tactics

Publication Plan
  ➢ Life cycle management
  ➢ Medical strategy
PUBLICATION OBJECTIVES
EVOLVE ACROSS LIFECYCLE

Key scientific statement 1

Early-phase

Mode of action
Defining the value and need for new therapy
Disease burden

Core-phase
Safety and efficacy

On-market
Life cycle: New indications
HEOR
Real world data

TAE community 1
TAEs community 2
TAE community 3

Physicians
Regulators
Nurses
Payers
WHAT MESSAGE A PUBLICATION CAN DELIVER?

- Create awareness of an educational gap of a new product
- Introduce new approaches to treating or monitoring a disease
- Inform on relevant characteristics of your product:
  - Efficacy, safety, quality of life, cost, usage, etc.
- Generate an evidence base for a new drug
- Generate evidence to support other scientific communication activities
  - Safety and efficacy in other population, and of other regimen
- Generate an evidence base for reimbursement
Deliver individual publications on a strategy
CLOSING THE “GAP” BETWEEN GLOBAL AND LOCAL PUB PLANS

Local market knowledge

• Language
• Different stake holders
• Different clinical practices/standards
• Product life cycle disparity
• …etc.
THANK YOU!
To ask a question, please type your query into the Q&A box.

To ensure anonymity, before sending please choose the drop-down box option, "Hosts, Presenters and Panelists." Otherwise, ALL audience members will be able to see your submitted question.
Asia Pacific Educational Task Force 2016

- Julie Newman (Co-Chair)
- Tim Collinson (Co-Chair)
- Andrew Sakko (Secretary)
- Jake Burrell
- Martine Docking
- Rebecca Lew

- Lin Lin
- Kalyan Pulipaka
- Bruce Shao
- Kanaka Sridharan
- Aya Tokaji
- Eric Yu
UPCOMING ISMPP Us

• **July 2016**
  • **Topic**: Congress Presentations -- Insider Perspective

• **September 2016**
  • **Topic**: Patient-Reported Outcomes and the Patient Perspective
  • **APET ISMPP U Topic**: Understanding Encores and Translations
THANK YOU FOR ATTENDING!

We hope you enjoyed today's presentation!

We will be providing a link to the survey via email. **Please take a moment to click on the link and fill out the survey**, so your valuable feedback can be used to develop future educational offerings.