PUBLICATIONS PLANNING

Michael G. Baker, Ph.D.

President & Principal, Samorn Biosciences
Session Objectives

+ Strategic development and execution of a publication plan, including:
  + Conference presentations (posters/slide decks)
  + Journal articles

+ At the end of this roundtable session, you should be able to:
  + Identify key publications to support medical communication & brand strategies
  + Overcome the challenges of working with busy authors
  + Leverage skill sets of communication agencies and medical writers
  + Appropriately target conferences and journals
  + Ensure timely release of publications to disseminate important messages
What is it?

+ **Strictly**, publications are peer-reviewed journal articles

+ **However**, publications may include:
  + Conference abstracts, posters, and presentations
  + Educational (unbranded) and advertorial (branded*) journal inserts
  + Books, chapters

+ A publication plan is a strategic/tactical document developed and executed by Medical or Clinical Affairs, with cross-functional input

*Advertising and promotional documents are the responsibility of the Commercial team, and in the US are subject to FDA DDMAC (Division of Drug Marketing, Advertising, and Communications) rules and regulations*
Why does it matter?

+ Publication planning ensures that health care professionals are convinced of the scientific validity and value of their products
+ Presentation via profession conferences and manuscript publications communicates:
  - Efficacy of the product
  - Safety of the product
  - Brand awareness
+ Planning is typically overseen by Medical or Clinical Affairs professionals
Getting the information out

The number of medical journals and articles has been increasing exponentially since 1750.

- In 2016, there were 1.5+ million articles published in 65,000+ journals.
- There are 2,000+ medical conferences held each year.
- Electronic media expands the reach of journals and conferences.
What is the return of investment (ROI)?

+ Virtually all biopharmaceutical companies with a marketed product invest in publishing
+ Why?
  + Lends scientific credibility to a product’s efficacy and safety claims
  + Expands the supportable messages that can be conveyed by the sales team
  + Proven to be a relatively low-cost form of product ‘advertising’ on a $ per exposure basis
What is the ROI? (continued)

+ Typical costs:

  - **Journal article**
    - $20,000 - $30,000

  - **Poster**
    - $10,000 - $15,000

+ Exposure to a single article or poster can be in the 1,000s to 10,000s, and likely includes the most influential users of your (future) product.
Where to start?

1. Define
   - product profile
   - target market
   - competitor landscape

2. Identify
   - primary audience
   - secondary audience

3. Perform
   - search for existing publications on the product or within the drug class
   - gap analysis of key messages in public domain

4. List
   - potential topics for new publications
   - ideal time frames for new messages to go public

5. Define
   - ideal time frames for new messages to go public
How to document the plan

+ In addition to documenting the aforementioned, establish an operational plan:

1. **Strategic team: internal staff +/- consultant(s)**
2. **Medical writing and biostatistical support**
3. **Preparation and communication support (journals, conferences)**
4. **Lead author(s) identification**

+ Estimate budget
Example of a publication plan (with outsourced support)

**PLAN**
- Determine data availability and significance
- Target audience
- Determine potential journals and/or conferences
- Strategize based on data timelines

**COLLABORATE**
- Weekly status update calls
- On-site visits
- Content review

**SUBMIT**
- Write proposals to confirm journal interest
- Follow Good Publication Practices
- Abide by submission requirements

**PROMOTE**
- Pre-publication
- At the point of publication
- Post-publication
Creating a journal article matrix

<table>
<thead>
<tr>
<th>Publication Topic</th>
<th>Target Submission Date</th>
<th>Target Publication Date</th>
<th>Target Journal</th>
<th>Proposed Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Overview</td>
<td>Sep-2019</td>
<td>Mar-2020</td>
<td>NEJM</td>
<td>Smith</td>
</tr>
<tr>
<td>Safety Review</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PK Study</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase 3 Study</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elderly Patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Satisfaction</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost Study</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients with Hepatic Impairment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pediatric Patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Creating a professional conference matrix

<table>
<thead>
<tr>
<th>Conference</th>
<th>Dates</th>
<th>Location</th>
<th>Abstract Due Date</th>
<th>Topic/Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASRA</td>
<td>5/2 – 5/5/2020</td>
<td>Boston, MA</td>
<td>10/1/2019</td>
<td>Safety &amp; Tolerability/Jones</td>
</tr>
<tr>
<td>ACS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AAOS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASPAN</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SAGES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASCRS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NASS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Part 2: Tackling FAQ’s
How do you identify key topics?

**Context:**
- Key topics are dependent on:
  - Status of product life cycle
  - Competitor landscape
  - Gaps in public messages
  - Need for scientific credibility
  - Promotional strategies

**Recommended approach:**
- Reach out to key opinion leaders
- Perform competitive intelligence on publications
- Take into account potential label expansion
What should you expect from authors?

Context:
+ Authors must contribute substantially to the publication
+ Contributions should follow ICMJE Uniform Requirements for Manuscripts Submitted to Biomedical Journals

Recommended approach:
+ Don’t forget that most authors welcome writing and biostatistical support
+ At minimum, provide the manuscript outline to authors
+ Ensure that authors support key messages – if not, consider alternative author
+ Expect author contributions to be the rate-limiting step
How do you leverage professional skill sets?

Context:
+ Typically, a minimum of 4 types of professionals will be needed for hands-on work:
  + MDs
  + Medical writers
  + Biostatisticians
  + Formatters/graphic designers

Recommended approach:
+ There are 3 approaches:
  + In-house team: for company with ongoing publication needs
  + Outsourced team
  + Intermediate: in-house head of publications (project management only); remaining tasks outsourced

  + Identify internal review and approval teams
How do you decide which journal to target?

Context:
+ Journals have different prestige ‘tiers’ based on impact factor
+ These ‘tiers’ are correlated with the difficulty of getting a submission accepted

Recommended approach:
+ Weigh the likelihood of acceptance against:
  + Journal audience (specifically)
  + Impact factor
  + Time frame to publish
What time frames to anticipate (conferences)

Context:
+ Time from submission to acceptance is concrete

Recommended approach:
+ Remember to check abstract due dates (may be up to a year in advance)
What time frames to anticipate (journals)

**Context:**
- Time from submission to acceptance is highly variable

**Recommended approach:**
- Expect a minimum of 4-6 months from initial submission to printed publication
- An epub may be available in advance
- Commercial and Medical Affairs teams will determine the number of reprints to be ordered
How do you set corporate expectations?

**Context:**
- If corporate leadership team is unfamiliar with the publication process, they are likely to underestimate time frames and costs.

**Recommended approach:**
- Formally present publication plan with budget.
- Update the plan and budget appropriately (if needed).
- Convey updates to the plan.
- Convey ROI while setting realistic expectations (i.e. time frames, per-item costs).
Request for publication plan template

+ Contact Michael G. Baker at mbaker@samornbiosciences.com