Disclaimer

• The views and opinions expressed in this presentation are those of the presenters and do not necessarily reflect the opinions of our employer.

• The opinions do, however, reflect our research and professional efforts over the past 15 years.
Objectives

• Understand the value of and when to best develop a scientific platform

• Understand the process for developing a scientific platform and how medical publication professionals can contribute

• Be knowledgeable about how to develop a lexicon within the scientific platform and how best to carry through to associated medical publications
VALUE
What Is a Scientific Platform?

- Scientific story
- Prioritized communication points
- Based on available evidence and aspirational statements
- Developed to address the clinical needs of the audience in a consistent manner
The Scientific Platform Translates the Science

**CLINICAL DATA**
- CSRs
- NDA
- Guidelines
- Target product profile
- Peer-reviewed publications

**PUBLICATIONS**
- Abstracts
- Posters
- Oral presentations
- Primary manuscripts
- Secondary manuscripts

**MIND-SETS**
- Concepts
- Statements
- References

**COMMERCIAL**

**PUBLIC RELATIONS**

**MEDICAL COMMUNICATIONS**
Scientific Platforms Can Serve Many Purposes

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Pubs</th>
<th>Medical</th>
<th>HEOR</th>
<th>MSL</th>
<th>Med Info</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relevant and consistent lexicon</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Discussion topics for medical experts</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Comprehensive reference repository</td>
<td>✓</td>
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<td>Onboarding resource</td>
<td>✓</td>
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<tr>
<td>Prioritizes communication activities</td>
<td>✓</td>
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<td>Prioritizes research efforts</td>
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<td>Identifies data gaps</td>
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<tr>
<td>Response letter content</td>
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</table>
How do you describe the value of a scientific platform to your colleagues in
- Clinical?
- HEOR?
- Commercial?
- Corporate?

Can you provide a real-world example where it made a difference?
When Is the Best Time to Develop an Initial Platform?

**Key Question**
Are there sufficient data to suggest where the program is going?

Phase 1  Phase 2  Phase 3  Launch  Post approval
Directional Data Permits
Platform Initiation

- Phase 1: 7%
- Phase 2: 46%
- Phase 3: 17%
- Launch: 17%
- Post approval: 13%

12TH ANNUAL MEETING OF ISMPP
How Often Should the Platform Be Revisited?

<table>
<thead>
<tr>
<th>New Data Milestone</th>
<th>Major Change in Program</th>
<th>Shifts in Landscape</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Pivotal data</td>
<td>• Failure to meet key endpoint</td>
<td>• Entry of new competitor</td>
</tr>
<tr>
<td>• Key subanalysis</td>
<td>• New indication</td>
<td>• Updated clinical guidelines</td>
</tr>
</tbody>
</table>
When have you typically initiated a scientific platform?

Does the initiation timing vary on the basis of the type of platform (eg, disease state, product, HEOR)?
BUILDING A PLATFORM
Best Practices Suggest Importance of Multistep Process

- Literature review
- 1-1 interviews
- Unmet needs
- Attribute map
- Mind-set shifts
- Core concepts workshop
- Scientific statements
- Lexicon
- Elevator story
- Expert feedback
Vetting Platforms

Do you vet the platform and related scientific statements with external advisors?

If so
  – Why?
  – When?
  – How?
Deliverables Should Address Team Needs
Need for Consistency in Word Usage Should Be Considered
Where is the balance between focusing the platform on ideas vs just presenting data?

What are some of the challenges you have encountered in creating a lexicon and/or balancing it with author expectations?
ENSURING CROSS-FUNCTIONAL ALIGNMENT
Ensure Adequate Representation of Team Functions
Workshops Engage and Motivate Participants

Engagement
Alignment
Ownership
Role of Publication Professional

What is the role of the medical publication professional in the development of a scientific platform?

How have you ensured execution/implementation of the scientific platform? Ensured that it is a living document?
Key Takeaways for Development of Scientific Platforms

1. Interview key stakeholders
   - Identify goals and output

2. Establish Value
   - Outline current practices
   - Socialize process enhancements

3. Develop Platform
   - Draft platform
   - Vet with experts
   - Revisit as appropriate

4. Facilitate Implementation
   - Train team (including agencies)
   - Monitor application

Publications
QUESTIONS?