

12TH ANNUAL MEETING OF ISMPP

SCIENTIFIC PLATFORM DEVELOPMENT: Bringing the Lexicon to Life

Gaylord National Harbor Resort & Convention Center
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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

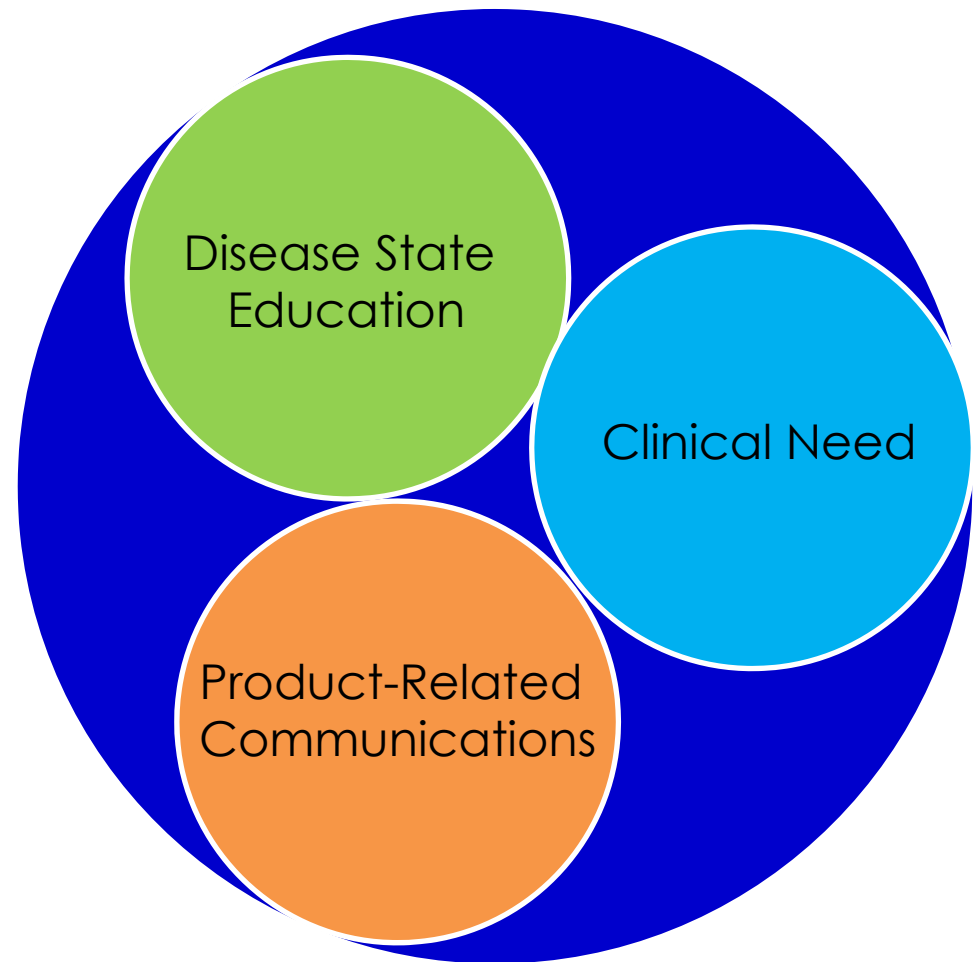


VALUE



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

SCIENTIFIC PLATFORM

Mind-sets • Concepts • Statements • References

COMMERCIAL

PUBLIC RELATIONS

MEDICAL COMMUNICATIONS

PUBLICATIONS

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



Scientific Platforms Can Serve Many Purposes

	Pubs	Medical	HEOR	MSL	Med Info
Relevant and consistent lexicon	✓	✓	✓	✓	✓
Discussion topics for medical experts	✓	✓	✓	✓	✓
Comprehensive reference repository	✓	✓	✓	✓	✓
Onboarding resource	✓	✓	✓	✓	✓
Prioritizes communication activities	✓			✓	
Prioritizes research efforts		✓	✓		
Identifies data gaps	✓	✓	✓		
Response letter content	✓	✓			✓



Explaining the Importance

How do you describe the value of a scientific platform to your colleagues in

- Clinical?
- HEOR?
- Commercial?
- Corporate?

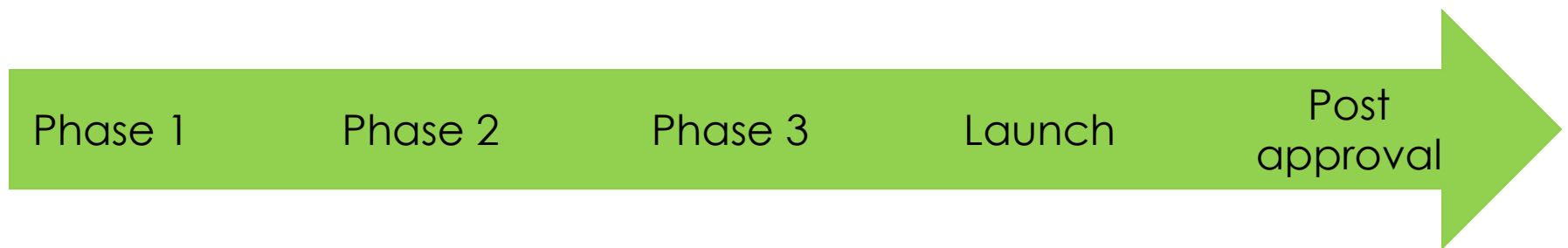
Can you provide a real-world example where it made a difference?



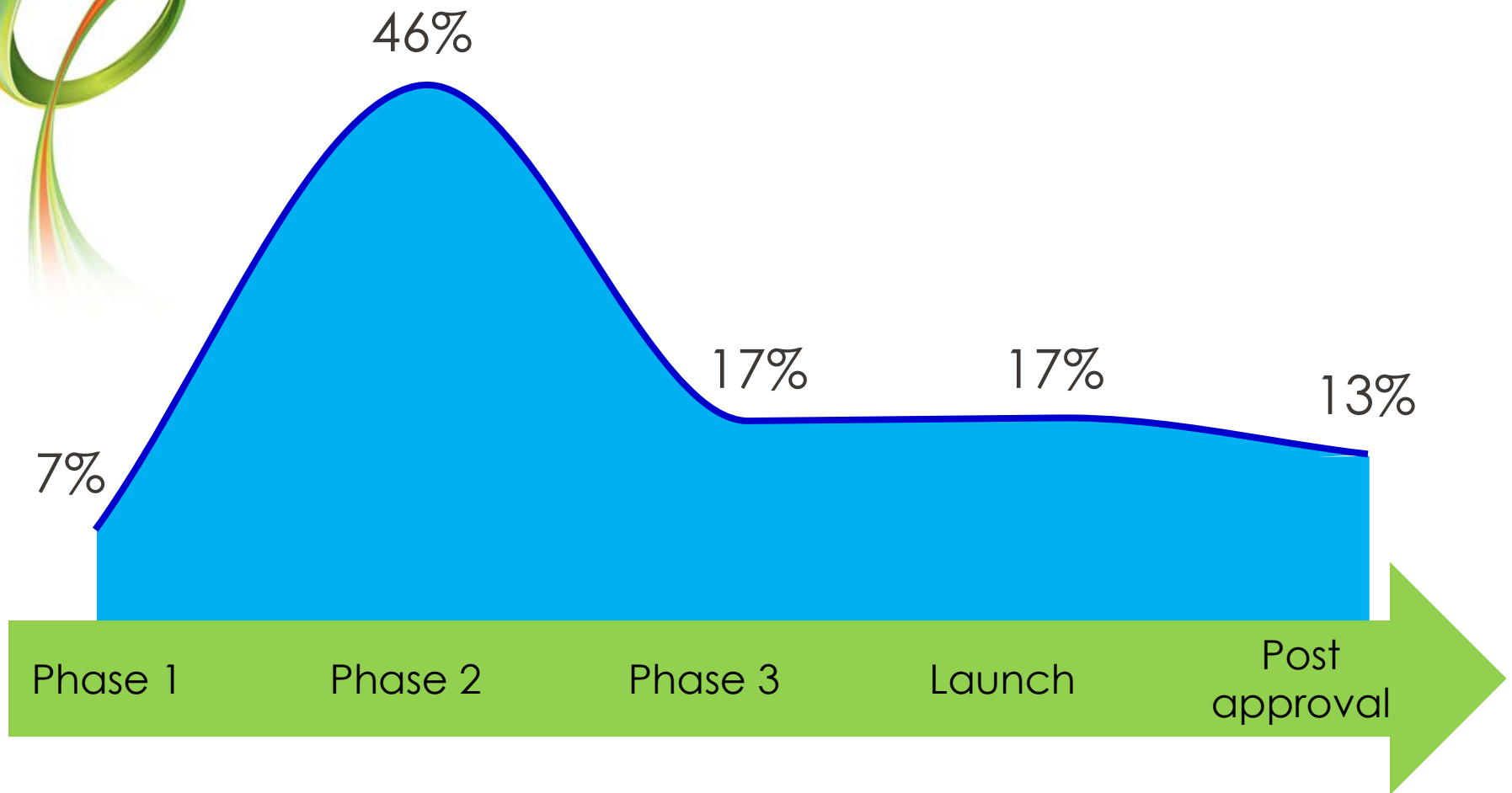
When Is the Best Time to Develop an Initial Platform?

Key Question

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



Directional Data Permits Platform Initiation





How Often Should the Platform Be Revisited?

New Data Milestone

- Pivotal data
- Key subanalysis

Major Change in Program

- Failure to meet key endpoint
- New indication

Shifts in Landscape

- Entry of new competitor
- Updated clinical guidelines



Types of Platforms



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



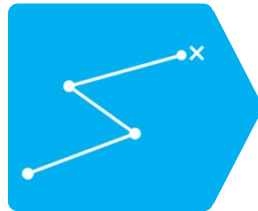
Best Practices Suggest Importance of Multistep Process

Immersion



- Literature review
- 1-1 interviews

Mapping



- Unmet needs
- Attribute map
- Mind-set shifts

Concepting



- Core concepts workshop

Supporting



- Scientific statements

Summarizing

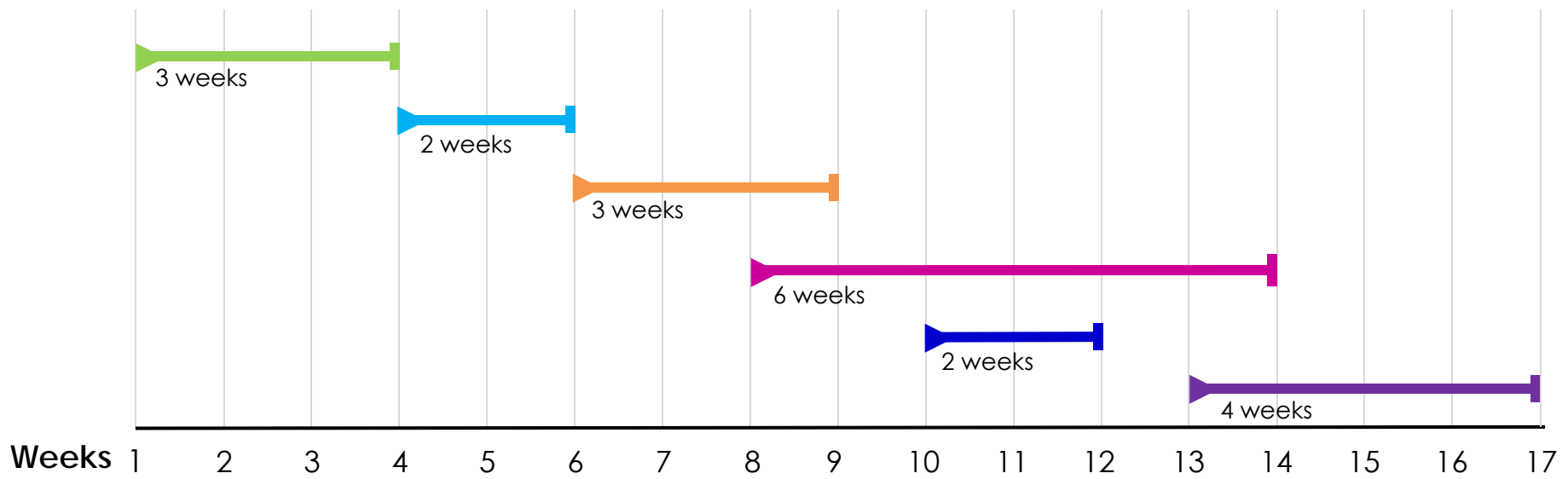


- Lexicon
- Elevator story

Vetting



- Expert feedback





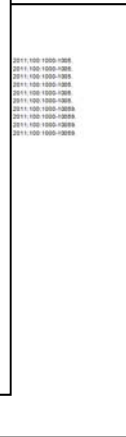
Vetting Platforms



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

If so

- Why?
- When?
- How?



Scientific Platform

Lexicon Elevator Story

[illegible]

Chapter 1 – Fundamentals of Disease			
Cells	Structure/function _____		
	Subcategory 1 _____		
	Subcategory 2 _____		
	Type _____		
	Type _____		
	Type with division categories _____		
	Type _____		
	Subcategory 3 _____		
	Type of mechanism _____		
	Type of resolution _____		
Measures of Quality _____			
	Category 1 _____		
	Category 2 _____		
	Category 3 and Options _____		
	Subcategories _____		
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Need for Consistency in Word Usage Should Be Considered

Lexicon
Elevator Story

Lexicon
✕

Word Choice	Category	Key Lexicon to Adopt	Evidence to Support	Additional Comments
Long-acting release	General			
Long-acting (vs once-daily)	Clinical			
Injectable	Pharmacology			
Parenteral	Safety			
Preparation	Adherence			
Product	Administration			
Formulation				
Maintenance				
Switch				
Loading dose				
Next generation				
Previous generation				
Regimen				
Monotherapy				
Self administration				
Minimal injection				
site reactions				
Mild ISRs				

For internal purposes only.
Company X

Section 1:
Medical Need

Section 2:
MOA and Properties

Section 3:
Clinical Evidence

Section 4:
Other Indications

Section 5:
Differentiation and Value

Section 6:
Technology Platform



Consistency in Communication



Where is the balance between focusing the platform on ideas vs just presenting data?

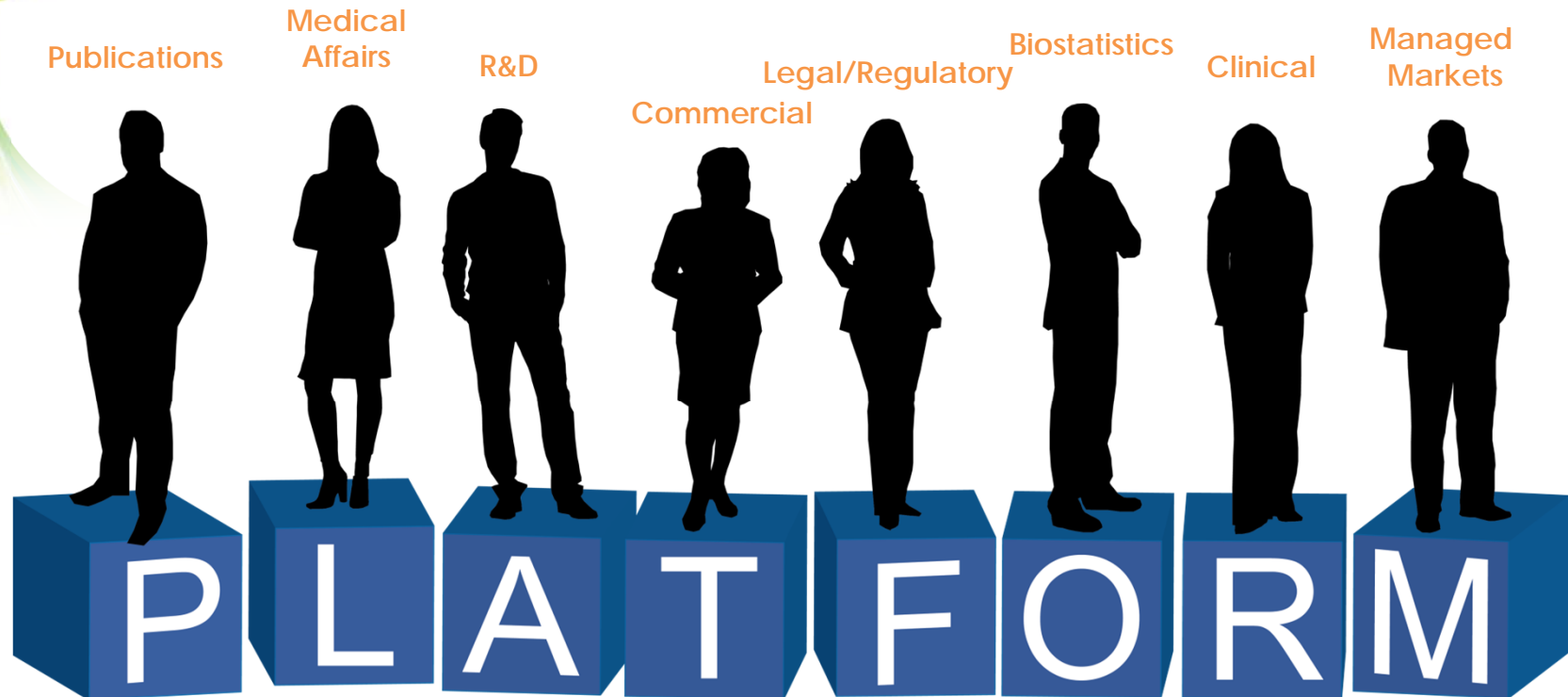
What are some of the challenges you have encountered in creating a lexicon and/or balancing it with author expectations?



ENSURING CROSS-FUNCTIONAL ALIGNMENT



Ensure Adequate Representation of Team Functions





Workshops Engage and Motivate Participants



Engagement



Alignment



Ownership



Role of Publication Professional



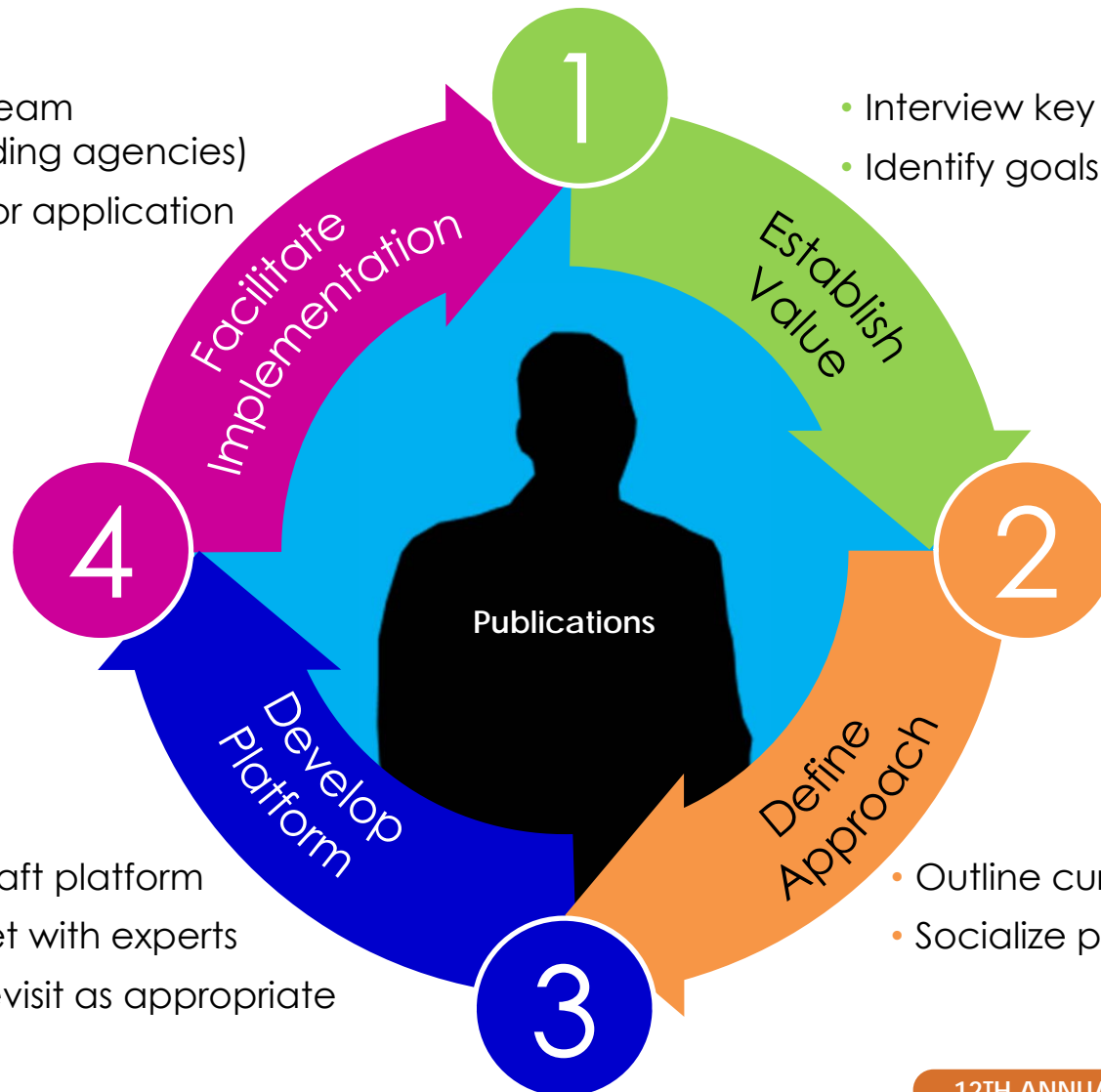
What is the role of the medical publication professional in the development of a scientific platform?

How have you ensured execution/implementation of the scientific platform? Ensured that it is a living document?

Key Takeaways for Development of Scientific Platforms

- Train team (including agencies)
- Monitor application

- Interview key stakeholders
- Identify goals and output





QUESTIONS?