# Scientific Communication Platforms
## *Best Practices for Medical Affairs*

# Acknowledgments

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# Practical Tools and Insights

- This presentation is intended to serve as a tool for scientific communication platform guidance and recommendations to Medical Affairs professionals

- The **Scientific Communication Platforms—Best Practices for Medical Affairs** presentation provides a basis for development of platforms, but it does not cover all situations or organizational requirements

- The recommendations provided should be tailored to the individual organization, product, and treatment landscape

- The views and information provided do not reflect the position or views of any one individual or company

# Rationale and Purpose

# Scientific Foundation for Communication

## How does the platform help?

- Ensures accurate, consistent language and referencing through communication activities, supporting a unified narrative to specific external audiences (eg, physicians, payers, providers)

- Highlights existing data gaps and informs future evidence requirements (eg, prospective data sets, post hoc analyses)

- Accommodates regulatory and cultural differences among regions

- Can be used as an internal training tool

- Evolves with the product/franchise, competitive landscape, and clinical and regulatory environments
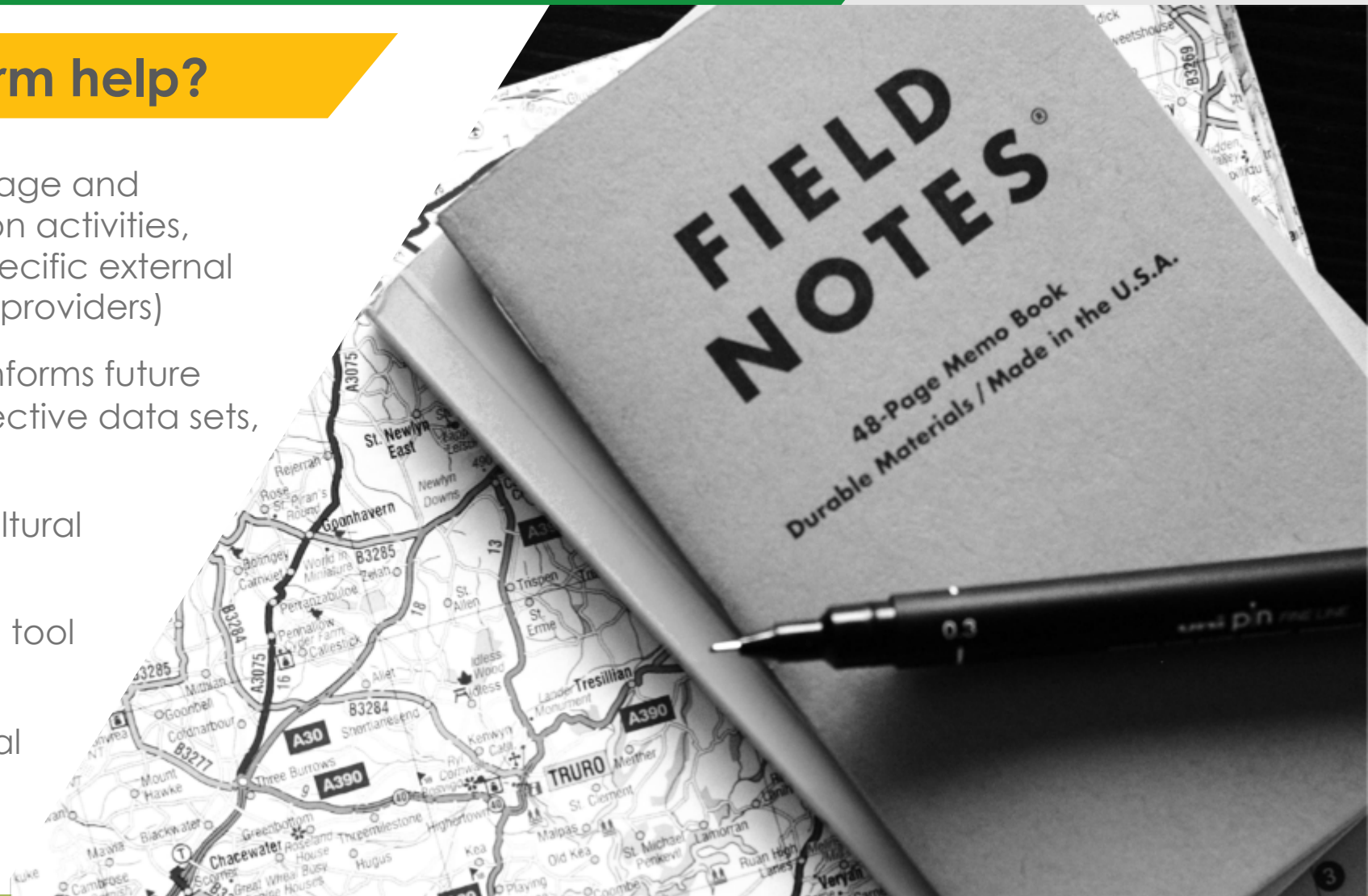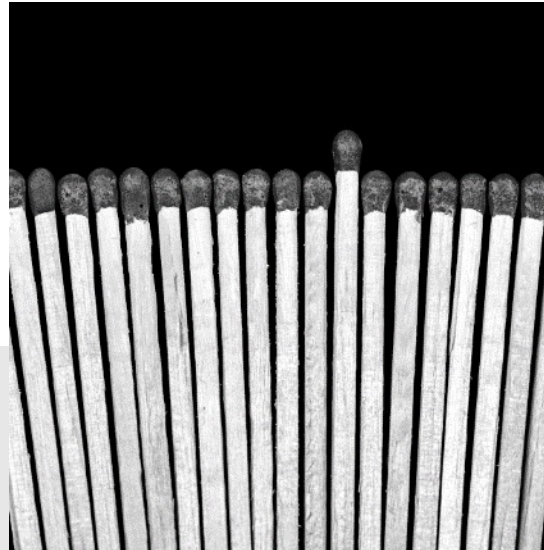
# Scientific Communication Platform Delivers 3 Primary Benefits



### Foundation

Ensures that content is well supported and grounded in scientific evidence



### Alignment

Provides internal alignment on communication approach across all functional areas
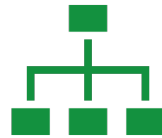


### Efficiency

Assists in prioritization and improves efficiency upon implementation

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# The Scientific Communication Platform Can Include Several Distinct Components

## Communication objectives

Prioritized set of objectives that address key educational gaps and opportunities

## Scientific statements

Hierarchically organized, standardized, scientifically accurate statements that describe the disease state and product

## Scientific summary

Short, high-level summary of scientific statements that provides a clear overview of key narrative elements

## Lexicon

Common vocabulary for communications that maintains accuracy and integrity while providing guidance on specific language and terminology

Best practice is to include all 4 components; however, selection of components depends on organizational dynamics and company-specific needs

# Scientific Communication Platform Supports Needs Across Functional Teams

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BY Medical Affairs Professionals

## Clinical

- Clinical development plan
- Evidence-generation priorities
- Scientific statements
- Investigator meetings

## Medical Affairs

- Medical Affairs plans
- Publication and congress plans
- Field medical resources
- Medical Information resources (SRDs, FAQs)
- Training and education

## HEOR

- Health outcomes development plan
- Evidence-generation priorities
- Value messages
- Managed care dossiers
- Publication plan

## Commercial[a]

- Brand message platform
- Supporting evidence
- Thought leader and HCP engagement plans
- Speaker training

## Corporate Communications

- Press release planning and key topics
- Investor presentations
- Digital and social media

FAQ, frequently asked question; SRD, standard response document.

[a]If the platform will be used to support commercial communication needs, the Commercial team needs to be properly engaged in the development process.

# Section Summary: Misperceptions on Rationale and Purpose

**1** **Is a scientific communication platform (SCP) an externally facing document that contains approved statements to be used verbatim?**

An SCP is an internal strategic document that provides the foundation for medical communications with external audiences

**2** **Can a single functional team develop an SCP?**

An SCP is a resource that should be developed and vetted by a cross-functional group of internal stakeholders

**3** **Should an SCP serve as a compendium of all data and references associated with a product or disease state?**

An SCP should be composed of concise, prioritized scientific statements with the critical supporting references

**4** **Is an SCP a static resource?**

An SCP is a living document that should be regularly updated to ensure continued relevance throughout the product's life cycle and landscape evolution

# Draft Process for Development of a Scientific Communication Platform



**STEP 1**
Define vision and identify gaps

**STEP 2**
Draft and prioritize communication objectives

**STEP 3**
Develop primary and secondary statements

**STEP 4**
Platform workshop

**STEP 5**
Finalize platform

**STEP 6**
Training and rollout

Although platform development generally requires 5 months, training and rollout can require an additional 1 to 3 months depending on scope (eg, global vs single country) and size of extended team

# Determine the Destination

# Determine the Destination

**STEP 1**
Define vision and identify gaps

**STEP 2**
Draft and prioritize communication objectives

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# Questions to Consider Before Initiating Platform Development

**1**    What challenges do you hope to address with the platform?

**2**    Who will use this information (internal audience)?
With whom are they communicating (external audience)?

**3**    What is a platform in the view of the team?

**4**    Will the platform focus on a product,
a disease state, or a portfolio?

**5**    Who should be involved in developing and/or
reviewing the platform?

**6**    Where is the program in its life cycle?

**7**    How often do you anticipate updating
the platform?

# Identify Core Planning Team With Adequate Representation of Team Functions



Preclinical and Clinical

Commercial

HEOR

Medical Affairs

Biostatistics

Managed Markets

Corporate Communications

Patient Advocacy/ Government Affairs

# Define Goals and Needs for Development With Core Team



Ensure stakeholder alignment on definition and vision

Determine potential uses and preferred output

Establish process

Define team's roles and responsibilities

Including a project brief in the team kickoff meeting request will help attendees focus

# Define Goals and Needs for Development With Core Team (cont)

Ensure stakeholder alignment on definition and vision

Identify internal stakeholders, develop discussion guide, and conduct interviews

Review and audit internal materials
- Strategic documents
- Regulatory submissions
- Publications
- Commercial materials
- Clinical trial information
- Conference materials

Develop executive summary of key learnings

Including external thought leaders in the information-seeking process can ensure an unbiased understanding of the situation

# Define Goals and Needs for Development With Core Team (cont)

**Determine potential uses and preferred output**

Determine primary external audiences for deliverables that platform will support

- Physicians
- Policy makers
- Patients
- Payers
- Providers

Determine final format based on organizational needs
- Ease of use and updates? Security? Search functionality? Interactivity?

Although interactive PowerPoint decks and PDFs are common formats, some companies utilize Web-based platforms for ease of updates and enhanced version control

# Define Goals and Needs for Development With Core Team (cont)

Establish process

Determine need for landscape analysis
- Platform should be based on defined medical gaps

Set key milestones
- Communication objectives
- Draft of primary and secondary statements
- Workshop
- Vet full draft

Develop timelines for completion

# Define Goals and Needs for Development With Core Team (cont)

**Define team's roles and responsibilities**

Who will draft and help prioritize communication objectives?

Who will review drafts of primary and secondary statements?

Who will participate in planning the platform workshop and develop its materials?

# Communication Objectives Align With Medical Strategy and Direct Medical Communications

## Overarching Medical Strategy
Provides overall strategy for program and asset with which all supporting materials should align

## Communication Objectives
Summarize key educational gaps and opportunities aligned with overarching medical strategy

## Publication Objectives
Guide development of proactive, targeted medical communications aligned with strategic imperatives

**HIV example**

Create and disseminate scientific information supporting the clinical importance of new treatment options to overcome HIV resistance

Define unmet need in heavily treatment-experienced patients with HIV-1 infection

Characterize the population of heavily treatment-experienced patients with HIV-1 infection, highlighting prevalence of resistance mutations, lack of available active regimens, and importance of tolerability and adherence

**Cystic fibrosis example**

Provide appropriate information on existing and new data supporting the clinical value of appropriate patient identification in cystic fibrosis (CF)

Characterize biomarkers that may guide optimal treatment selection in CF

Educate on emerging biomarkers in patients with CF

💡 In general, platforms should focus on ≤5 objectives of greatest relevance to the product and consider longer-term needs (eg, market access)

# Working Session Can Help Core Team Prioritize Communication Objectives

## STEP 1

Core team members to fill out note cards with proposed communication objectives

## STEP 2

Note cards placed on wall for team consideration

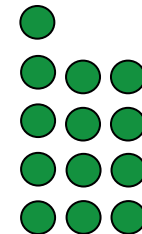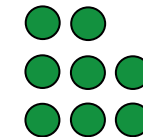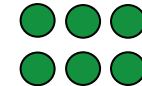## STEP 3
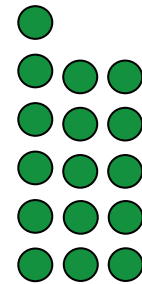
Full team to prioritize identified objectives

### Communication Objective Note Card Template

**Topic**

**Objective:** Short phrase, no more than 1 sentence

**Region:** Is this objective specific to a certain region?

### Example of prioritization exercise

| Diagnosis and treatment | Product | Diagnosis and treatment | Diagnosis and treatment | Clinical efficacy and safety | Mechanism of disease | Diagnosis and treatment |
|---|---|---|---|---|---|---|
| Differential diagnosis | Educate on receptor  Global | Current treatments and gaps | Need to treat and exclude comorbid conditions | Broadly educate on phase 2 data | Pathology of advanced disease | Guidelines for diagnostic workup |

# Chart the Course

# Chart the Course

| STEP 1 | STEP 2 | STEP 3 | STEP 4 | STEP 5 | STEP 6 |
|--------|--------|--------|--------|--------|--------|
| Define vision and identify gaps | Draft and prioritize communication objectives | Develop primary and secondary statements | Platform workshop | Finalize platform | Training and rollout |

# Pillars Are Composed of Grouped Information on Key Story Elements

## Example pillars

| Unmet need | Mechanism of disease | Diagnosis and treatment | Pharmacological characteristics | Clinical evidence | Real-world evidence | Value story |
|---|---|---|---|---|---|---|
| • Epidemiology<br>• Patient population<br>• Burden of disease | • Anatomy<br>• Physiology<br>• Pathogenesis | • Diagnostic criteria and testing<br>• Clinical guidelines<br>• Treatment landscape<br>• Pipeline | • Mechanism of action<br>• PK/PD<br>• Formulation<br>• Dosing and administration | • Safety<br>• Efficacy<br>• Patient-reported outcomes | • Outcomes research<br>• Postapproval efficacy and safety<br>• Noninterventional research<br>• Patient registries | • Health economic models<br>• Affordability evidence<br>• Comparative effectiveness |

Work with your core team to customize pillar topics on the basis of individual program needs and insights gathered during earlier planning stages (eg, communication objective prioritization, learnings from stakeholder interviews and internal document audit)

**Click button for more information**

How does stage in life cycle inform focus of platform pillars?

HEOR, health economics and outcomes research; PD, pharmacodynamics; PK, pharmacokinetics.

# Platforms Organize Scientific Statements Under Pillars

```
                        Product strategy
```

| Unmet need | Disease burden | Mechanism of action | Efficacy | Safety | PK/Dosing | Administration/ Handling | Value |
|---|---|---|---|---|---|---|---|

## Scientific statements

**1. Primary statements**
Define the overarching direction of each section

**1.1. Secondary statements**
Make up the individual components of the story for each primary statement

**1.1.1 Tertiary statements**
Support each secondary statement with scientific data
Serve as a reference tool and a mechanism for gap identification

PK, pharmacokinetics.

- In general, a platform should include no more than 6 pillars
- Each pillar generally includes 3 to 7 secondary statements
- Statements that represent existing data gaps are labeled as aspirational
- Platform should contain a collection of the most relevant references needed to support scientific statements; it is not a repository for all available references related to a given topic

# If Appropriate, Draft Scientific Summaries

- A scientific summary (also known as an elevator story) is a short series of scientific statements (usually 3-5) that provides a clear overview of key story elements from the platform

- Critical elements for inclusion can be identified using a prioritization exercise

- Summaries can be individualized according to specific audience needs (eg, community oncologist, nurse, payer) or length of typical audience interactions (eg, 1-2 bullets vs 5-6 bullets)

**Example summary for diabetologists[a]**

- In patients with type 2 diabetes mellitus (T2DM), weight reductions of 5% can improve glycemic control, decrease the risk of long-term diabetes complications, and reduce cardiovascular risk factors

- Glucagon-like peptide 1 (GLP-1) receptor agonists have been shown to be effective in reducing A1C, have a low risk of hypoglycemia, and are associated with reductions in weight and blood pressure

- Consistent with ADA treatment guidelines recommending weight loss–promoting or weight-neutral antihyperglycemic drugs for diabetes where possible, GLP-1 receptor agonist treatment may provide clinical benefits for patients with T2DM as monotherapy or in combination with insulin

[a]Content adapted from Apovian et al. *Adv Ther*. 2019;36:44-58.

# Vet Draft Materials With Core Team in Preparation for Workshop

Forward or present draft materials, including primary and secondary statements for each pillar and scientific summary, to core team members for their guidance (may require multiple iterations or interactions to ensure alignment)

Collate comments and incorporate feedback to ensure alignment

Conduct workshop or working sessions with key stakeholders across departments

On the basis of their involvement, core team could serve as workshop breakout group or working session facilitators

Travel Together

# Travel Together

| STEP 1 | STEP 2 | STEP 3 | STEP 4 | STEP 5 | STEP 6 |
|---|---|---|---|---|---|
| Define vision and identify gaps | Draft and prioritize communication objectives | Develop primary and secondary statements | Platform workshop | Finalize platform | Training and rollout |

# Planning Considerations for a Successful Workshop

## Who will attend?

- Skilled facilitator(s) and 12 to 18 participants, although platform scope and stage in life cycle guide final number of attendees
- Cross-functional representation

## What are the objectives for the workshop?

- Confirm expectations and roles
- Set near-term communication objectives
- Gain alignment on the framework and flow of platform primary and secondary statements
- Refine scientific summary

## How will the working sessions be structured?

- Full group or breakout groups
- Work mats to capture the output of the working sessions

## Where will the meeting be held?

- Select a venue that encourages in-person attendance (significantly increases engagement and value of participation)

If an in-person meeting is not possible, specific accommodations are needed to ensure remote attendee engagement (eg, virtual breakout sessions)

# Workshop Agenda Requires Sufficient Time Allocation for Audience Engagement

| Time | Topic | Objective |
|------|-------|-----------|
| 9:00 AM–9:15 AM | Welcome, introductions, and meeting objectives | Set the tone |
| 9:15 AM–10:00 AM | Progress update | Convey insights and learnings |
| 10:00 AM–10:15 AM | Platform structure | Confirm the pillars |
| 10:15 AM–12:15 PM | Working session 1<br>Pillars and statements | Gain alignment (part 1) |
| 12:15 PM–1:00 PM | Lunch | Refresh and refuel |
| 1:00 PM–2:30 PM | Working session 2<br>Pillars and statements | Gain alignment (part 2) |
| 2:30 PM–3:15 PM | Working session 3<br>Developing scientific summaries | Establish targeted summaries |
| 3:15 PM–3:45 PM | Working session 4<br>Lexicon | Review words to use and words to avoid |
| 3:45 PM–4:00 PM | Summary and action items | Set expectations |

TOTAL: 7 HOURS

# Considerations For Working Sessions

- Inclusion of specific working sessions should be tailored to the needs of each team

- Prioritize efforts according to scope and timing

- Allow approximately 1 hour per pillar

- If there is a limited time frame (eg, 3-4 hours), consider using breakout sessions with regroups to maximize efficiency or reduce scope
  – For example, breakout sessions may allow simultaneous review of multiple pillars

- Offline channels can be used to obtain feedback for some objectives (eg, evidence-generation prioritization)

- Recap learnings and action items at conclusion

# Objectives for Working Sessions on Pillars

**Pillars**

- Do the pillars represent the most relevant categories of information?
- Do they need to be reorganized?

**Primary statements**

- Are the statements comprehensive?
- Do they need rewording?

**Secondary statements**

- Are the statements comprehensive?
- Should anything be combined, deleted, or added?
- Are there key terms that require further discussion?
- Do they reflect the landscape (eg, how MOA differs from other drugs in the same indication)?

**Example work mat**

| Pillar #1 |
|---|
| Primary statement |

| Secondary statement #1 | Secondary statement #2 | Secondary statement #3 | Secondary statement #4 |
|---|---|---|---|

Notes:
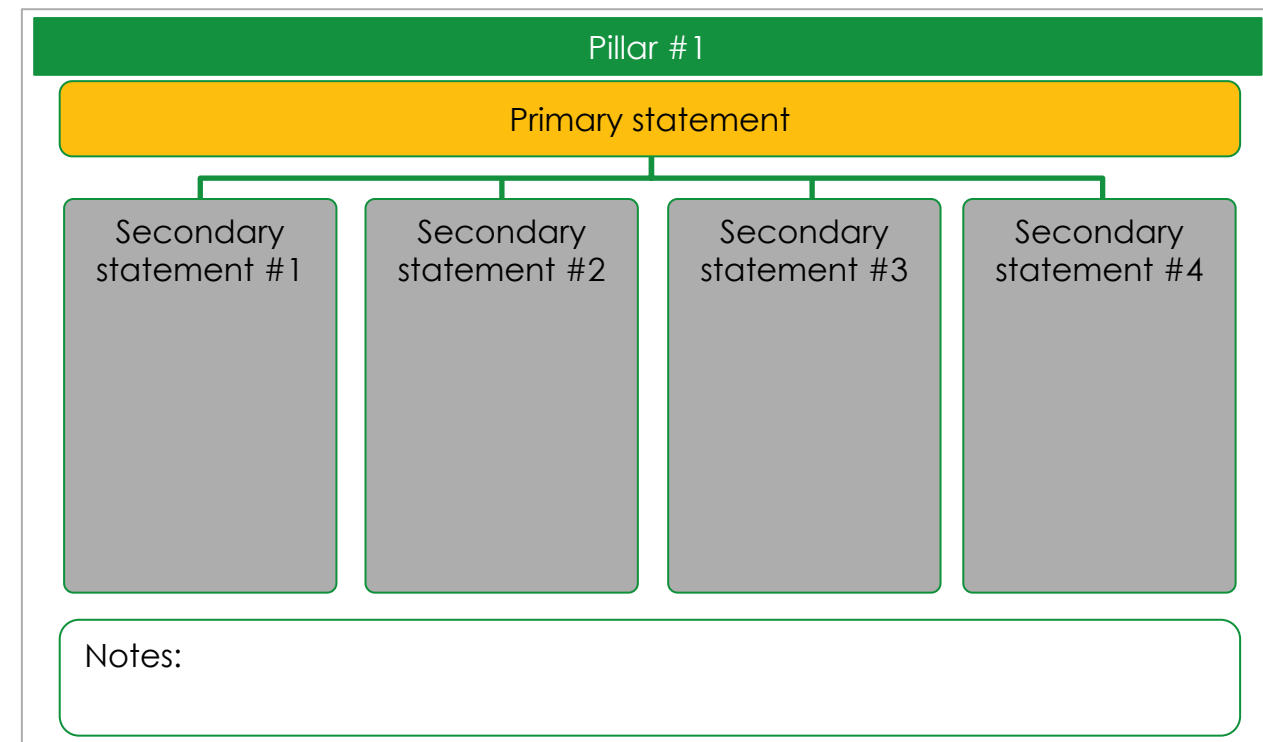
Attendees can physically mark up the work mats and capture comments and ideas in the blank space or highlight key terminology

# Considerations for Working Sessions to Evaluate Platform Statements

## Full group

All attendees work together through each pillar

### Advantages

- Pillars are viewed in sequence
- All attendees hear each other's comments directly
- Potential for increased alignment

### Disadvantages

- Less time overall per pillar
- Potential for conversation to be dominated by a few vocal individuals

## Small group

Groups rotate through each pillar in small teams, layering feedback on efforts of prior teams

### Advantages

- Ensures that contributions from all team members are captured
- Allows more time for discussion of each pillar

### Disadvantages

- Pillars are not viewed sequentially
- Internal lead for each pillar does not review other pillars

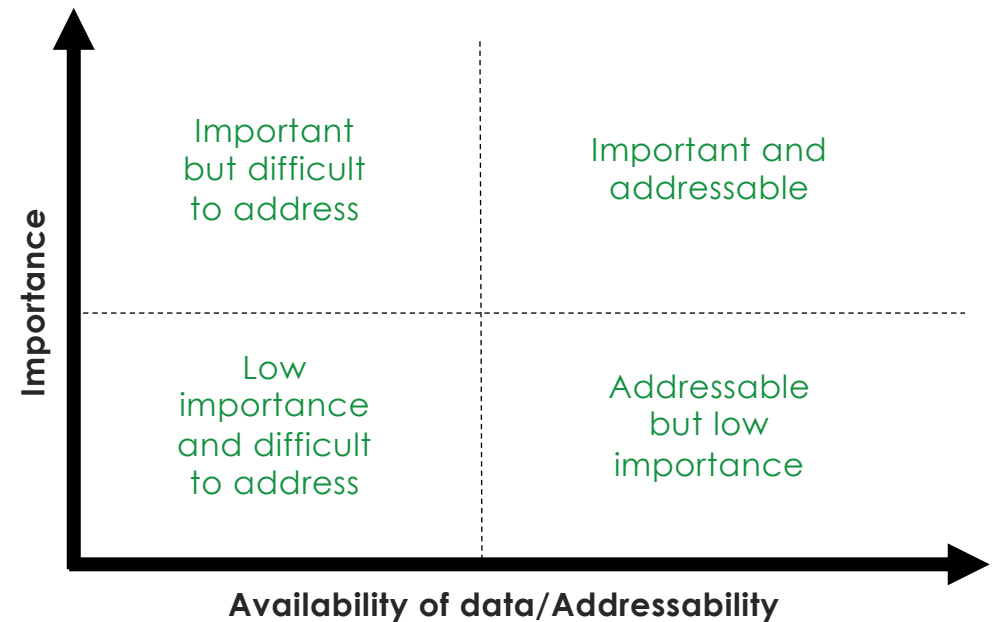Medical Affairs Professional Society | 2019

Level of alignment, available time, number of attendees, and unique personalities on your individual team can guide use of full- or small-group working sessions to evaluate statements

# Prioritization Session Can Help Gain Alignment on Product-Specific Needs

## Potential use cases

- **Evidence generation needs** can be prioritized on the basis of ease of acquiring data (considers time and resources) and importance for supporting communications objectives

  - A representative from biostatistics may be key to determine the feasibility of specific analyses

- **Product attributes** can be prioritized to identify the most effective points of emphasis for platform statements

## Example work mat

Importance (vertical axis) / Availability of data/Addressability (horizontal axis)

- Important but difficult to address (top left)
- Important and addressable (top right)
- Low importance and difficult to address (bottom left)
- Addressable but low importance (bottom right)

Attendees write concepts or topics on note cards and place them on the work mat according to the importance and addressability of the concept

# Slides or Worksheets Can Be Used to Solicit Feedback on Key Topics for Scientific Summaries

**Draft summary for diabetologists[a]**

- In patients with type 2 diabetes mellitus (T2DM), weight reductions of 5% can improve glycemic control, decrease the risk of long-term diabetes complications, and reduce cardiovascular risk factors
- Despite the known benefits of moderate weight loss in patients with type 2 diabetes mellitus (T2DM), many patients remain over-titrated on basal insulin regimens, resulting in hypoglycemia and weight gain
- Glucagon-like peptide 1 (GLP-1) receptor agonists have been shown to be effective in reducing A1C, have a low risk of hypoglycemia, and are associated with reductions in weight and blood pressure
- Consistent with ADA treatment guidelines recommending weight loss–promoting or weight-neutral antihyperglycemic drugs for diabetes where possible, GLP-1 receptor agonist treatment may provide clinical benefits for patients with T2DM as monotherapy or in combination with insulin

**Worksheet**
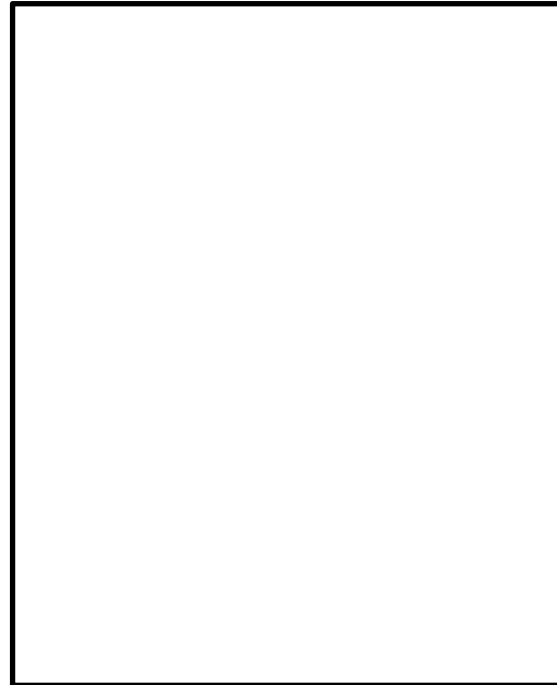
- Capture key topics live on screen during the session
- Do not focus on wordsmithing because the polished draft can be developed after the meeting

**Tailored summaries may be needed to address educational gaps relevant to specific audiences (eg, community practitioners)**

[a]Content adapted from Apovian et al. *Adv Ther*. 2019;36:44-58.

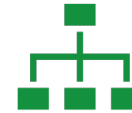# Optional Exercise Can Support Consistent Use of Key Terminology

| | WORDS TO USE | WORDS NOT TO USE | RATIONALE |
|---|---|---|---|
| **Example** | Next generation | Second generation | Next generation emphasizes that mechanism is different from current approaches, implying a bigger change than second generation |
| | | | |
| | | | |
| | | | |
| | | | |

- Goal is to develop a common vocabulary for scientific and medical communications, as well as downstream commercial and global communication plans, that maintains scientific accuracy and integrity while providing clear, helpful suggestions on styling and language

- For publications, final approval of all scientific communications, descriptors, and language is at the discretion of the authors

# Learnings From Workshop Guide Development of Comprehensive Platform

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- Develop executive summary to capture key learnings

- Integrate workshop learnings and develop full draft, including primary, secondary, and tertiary statements, for each pillar

- Distribute in Word format for team review to facilitate tracking and collating comments

- Integrate comments and transfer content to layout or upload into Web-based portal

**Click button for more information**

**When should external reviewers be used to evaluate the platform?**

# Share Your Story

# Share Your Story



| STEP 1 | STEP 2 | STEP 3 | STEP 4 | STEP 5 | STEP 6 |
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| Define vision and identify gaps | Draft and prioritize communication objectives | Develop primary and secondary statements | Platform workshop | Finalize platform | Training and rollout |

# Rollout and Training Current Team Members

## 1
### Key stakeholders in rollout and training

- Functional leads?
- Regional leads?
- MSLs?
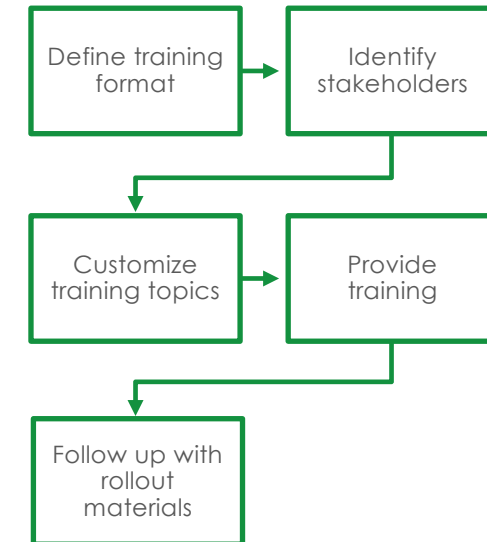- Medical Information?
- Commercial?
- PR?

## 2
### Effective format for training

- Workshop?
- Seminar?
- Teleconference?
- Training videos?
- Training modules?
- Language(s)?

## 3
### Process for training

Define training format → Identify stakeholders

Customize training topics → Provide training

Follow up with rollout materials

💡 **Global training programs should assess needs and preferences of regions/countries**

Chari and Shanthanelson. Presented at: Medical Affairs Professional Society Annual Meeting; February 25-27, 2018; Miami, FL.

# Ongoing Training

## Who needs ongoing training?

- What types of new employees?
- Which agency partners?
- Do platform updates require broad retraining?

## What format should be used for ongoing training that is both effective and efficient?

- Videos?
- Best practice slide deck?
- Training modules?

## Who should be responsible for providing the training?

- Medical Affairs lead?
- Publications team?
- Training team?
- Prerecorded training?

💡 Leadership video highlighting importance and value of platforms can encourage use

Chari and Shanthanelson. Presented at: Medical Affairs Professional Society Annual Meeting; February 25-27, 2018; Miami, FL.

# Determine Optimal Approach to Monitor Uptake and Use Across Functional Team

| Category | Internal document audits | Literature analyses | Web-based metrics[a] |
|---|:---:|:---:|:---:|
| Communication points addressed (eg, key points covered in publications or field medical resources) | ✓ | ✓ | |
| Consistency of disease state or product descriptions (eg, consistency of statements in publications, press releases, or educational materials) | ✓ | ✓ | |
| Lexicon consistency | ✓ | ✓ | |
| Pages visited most frequently | | | ✓ |
| Most commonly requested references/resources | | | ✓ |

💡 Lack of consistency in platform use could represent an opportunity for retraining

[a]Only applies for Web-based platforms.
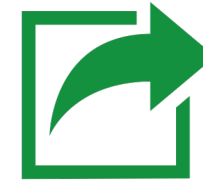
# Platforms Are Living Documents

### New data

- Pivotal data
- Key subanalysis
- Publication alerts
- Key congresses

### Major change in program

- Failure to meet key endpoint
- New indication
- Shift in priorities

### Shift in landscape

- Entry of new competitor
- Updated clinical guidelines

Prospectively identify triggers for platform updates with the core team. If an update is needed, reconvene the core group to determine scope of potential changes, process for implementation, and how changes will be communicated to the broader team to ensure version control

# Key Takeaways From Scientific Communication Platform Development

## Scientific Communication Platform Development Process

### Step 1: Define vision for scientific communication platform and identify gaps

- ☐ Establish vision for platform and understanding of its value
- ☐ Identify core team that adequately represents a range of functions; define roles and responsibilities
- ☐ Identify platform audiences, potential uses, and preferred output
- ☐ Communicate overall development process, key milestones, and associated timing
- ☐ Conduct internal stakeholder discussions to gain insight into the product, patient population, and indications
- ☐ Gather and review key internal documents and materials from the public domain for insights into overall strategy, available data, and lexicon
- ☐ Assess need for external interviews or literature analyses to further inform unmet educational needs

### Scientific Communication Platform Development Process (detailed checklist)

**Step 1: Define vision for scientific communication platform and identify gaps**
- ☐ Establish vision for platform and understanding of its value
- ☐ Identify core team that adequately represents a range of functions; define roles and responsibilities
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- ☐ Communicate overall development process, key milestones, and associated timing
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**Step 2: Draft and prioritize communication objectives**
- ☐ Leverage learnings from internal stakeholder discussions and insights from materials to identify communication objectives and core pillars that reflect program needs
- ☐ If needed, conduct a working session with core team to prioritize communication objectives

**Step 3: Develop primary and secondary statements**
- ☐ Develop primary and secondary statements aligned with current and planned data availability
- ☐ Develop scientific summaries tailored to necessary key audiences, if appropriate
- ☐ Vet draft materials with core team prior to platform workshop

**Step 4: Scientific communication platform workshop**
- ☐ Identify workshop objectives that are clear, actionable, and aligned with overall strategic objectives
- ☐ Select workshop venue and approach that optimize active participation
- ☐ Identify workshop exercises that efficiently address objectives while maximizing engagement
- ☐ Develop executive summary to capture key learnings

**Step 5: Finalize platform**
- ☐ Integrate learnings from workshop into full draft of platform
- ☐ Route draft platform to internal team in Microsoft Word format to facilitate tracking and collation of comments
- ☐ Determine need to validate platform with external scientific leaders
- ☐ Package all components into preferred final format

**Step 6: Training and rollout**
- ☐ Create rollout and training materials that facilitate onboarding while defining a process for ongoing training
- ☐ Monitor ongoing communications for uptake and use of platform across functional teams
- ☐ Maintain visibility and awareness of platform to address gaps in uptake and use
- ☐ Establish approach for updating platform and define landscape events that trigger an update

- Systematic, well-vetted process for development
  - Foundation for consistency in medical communications across organizational functions

- A high-level checklist can provide a brief overview of the process and function as a reminder of steps to be taken

Chari and Parker. Presented at: 10th Annual Center for Business Intelligence Publication Planning Meeting; December 11-12, 2014; Philadelphia, PA.

# Frequently Asked Questions

# Stage in Life Cycle Can Inform Focus of Platform Pillars

| Early development (phase 1 or 2) | Phase 3 (preapproval) | Postapproval |
| --- | --- | --- |

**Early development**
Emphasis on setting the stage
(eg, mechanism of disease)

**Common topics**
- Unmet need
- Epidemiology and patient population
- Mechanism of disease
- Mechanism of action
- Dose-ranging studies in patient population
- Efficacy, safety, real-world evidence, HEOR, and value; may include aspirational statements

**Phase 3 and beyond**
Emphasis on communicating the clinical benefit and value
(eg, pivotal trials demonstrating efficacy and safety)

**Common topics**
- Pivotal trials demonstrating efficacy and safety
- Patient-reported outcomes
- Patient subpopulations (eg, hepatic impairment)
- Real-world evidence and HEOR
- Value

Certain pillars may evolve as data are acquired or as program needs change

- MOA: first-in-class MOA could be focus early in life cycle, but as understanding of MOA is established, the MOA could be simplified; MOA could also be revisited on the basis of new learnings in the field

- Clinical evidence: efficacy and safety could be a single pillar early in life cycle, but, as data are acquired, they may need to be separated into separate pillars

# When Should External Reviewers Evaluate the Scientific Communication Platform?

External reviewers can evaluate credibility of the platform and may be especially useful in situations when

- The treatment landscape is crowded

- The effects of emerging scientific evidence on treatment decisions are uncertain

- Moving into a new therapeutic area

**One-on-one engagement**
Facilitates focused discussion

**Surveys**
Allow reviewers to provide feedback at their convenience; virtual feedback tools enhance efficiency and participation

**Phone interviews**
Allow engagement with remote reviewers

**Advisory boards**
Encourage robust discussion and facilitate real-time resolution of differing viewpoints

**Web conferencing**
Provides many of the benefits of an advisory board with fewer logistical and scheduling considerations

When determining the optimal approach, consider

- Geographic representation

- Audiences (eg, oncologists, nurses, specialists, payers)

- Number for each audience

When planning external validation of a platform, leverage existing educational engagements (eg, planned clinical study groups and scientific information exchanges) whenever possible