

# **Bridging the Gap:** **Understanding and Implementing** **Gap Analyses**

Focus Area Working Group: Medical Strategy and Launch Excellence

# Presenters



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Next webinar in the series “Setting Strategic Objectives” will be in Sept 2023

<https://medicalaffairs.org/content-hub/>

# Educational Objectives

## **At the end of the session, you will be able to**

- Understand how to conduct gap analyses to identify needs or deficiencies within your medical plan
- Identify when gap analyses can be leveraged throughout the Medical Affairs strategic planning process
- Demonstrate how to apply results of gap analyses to effectively address needs



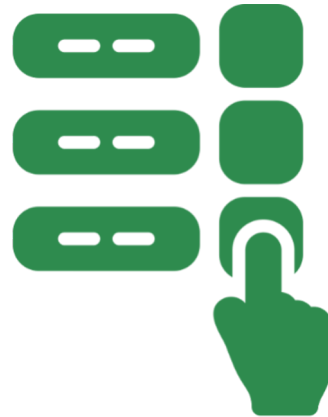
# What Is a Gap Analysis?

Leah Williams

# Polling Question

**Do you regularly perform gap analyses as part of your function in Medical Affairs?**

- A. Yes, annually
- B. Yes, as needed
- C. Yes, but not often
- D. No, not at all
- E. Not sure



# Situational Analysis: Understanding Where We Are Now

Strategy is never developed in a vacuum, so it is important to understand a product in the context of the therapeutic space and available treatment options





# Gap Analyses: A Strategic Planning Tool

- Systematic process of comparison
- Identifies deficiencies, needs, or improvements that may be required to reach a goal for a product in a specific therapy area
- Helps to understand current state vs desired state
- Helps determine what steps need to be taken
  - Internal analyses – gaps to address
  - External analyses – gaps to maximize
- Used in conjunction with other tools, such as SWOT or PEST analyses, as part of strategic planning

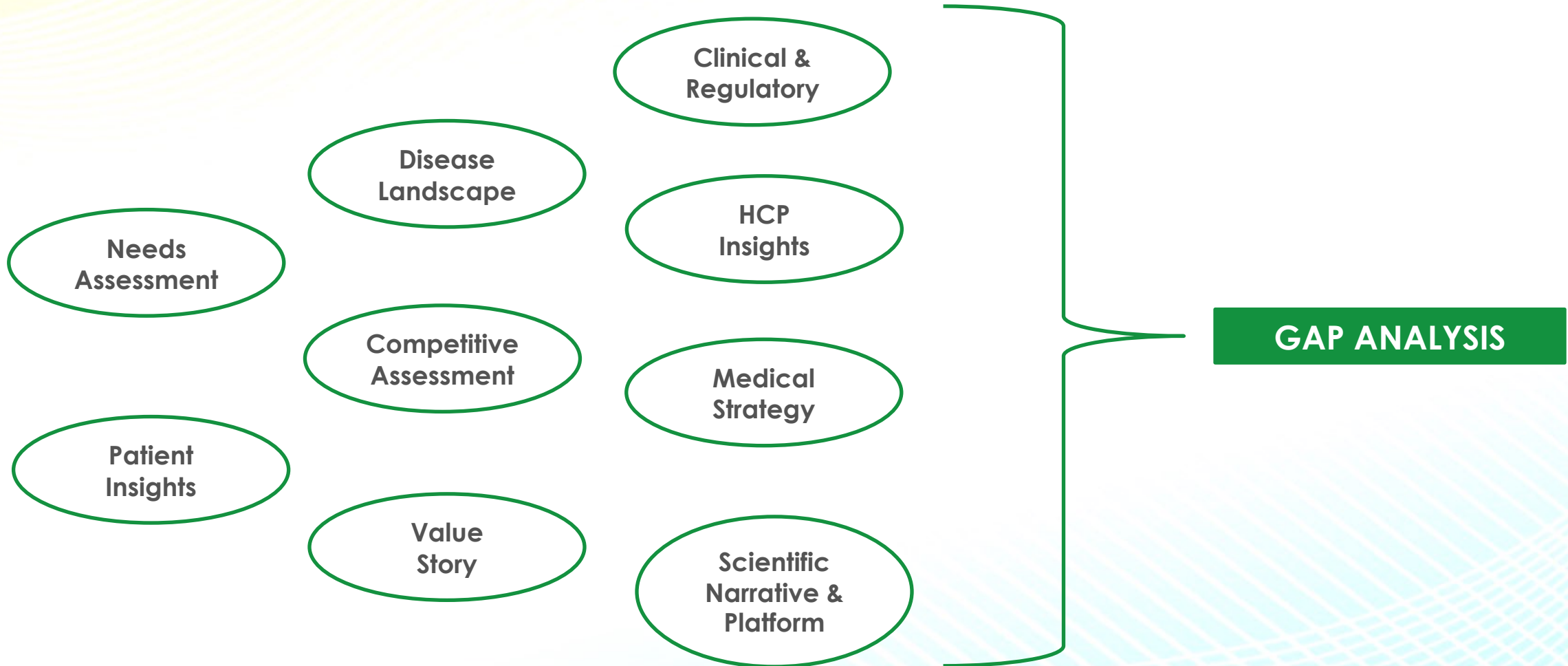
# Components of a Gap Analysis



Gaps need to be closed to move from the current situation to the desired situation

# Gap Identification

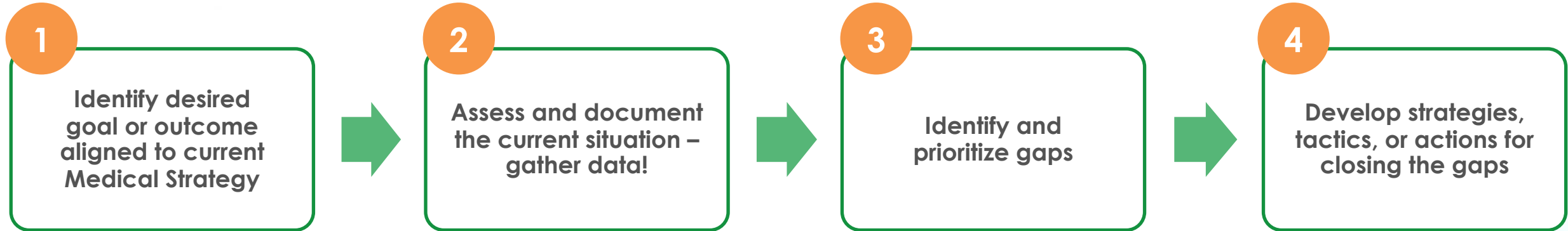
Gaps in evidence generation, interpretation, communication, and/or education



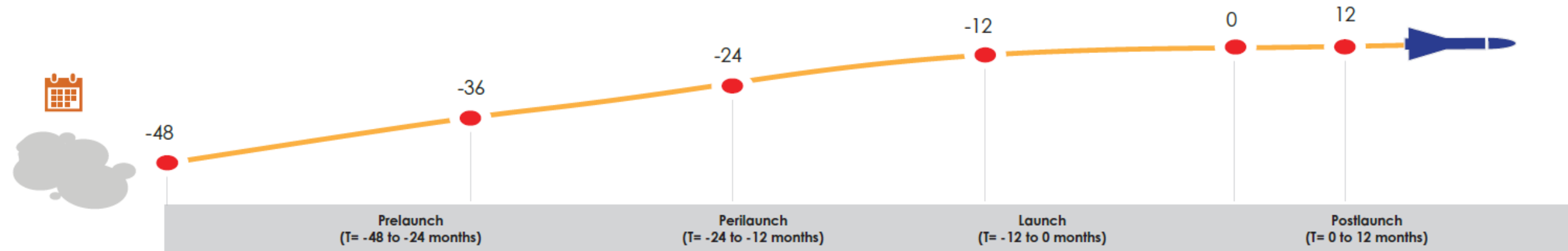


# Steps for Gap Analyses

## Four Basic Steps in Conducting a Gap Analysis



# When Are Gap Analyses Performed?



- ✓ **Part of a situational analysis during annual strategic planning**  
(eg. internal analyses prior to strategic objective setting; competitive assessments)
- ✓ **Tactical planning when creating annual strategic plan**
- ✓ **Clinical data gap analyses**
- ✓ **Scientific platform and messaging**
- ✓ **Publication planning**
- ✓ **Integrated evidence planning**
- ✓ **Others?**

# Case Examples: How to Execute Gap Analyses in Strategic Planning

Leah Williams, Jennifer Schwinn, & Amanda Henkel



# Minding the Gap: Examples

Example 1: **Tactical Planning**

Example 2: **Publication Planning**

Example 3: **Integrated Evidence Planning**

# Minding the Gap: Examples

Example 1: **Tactical Planning**

Example 2: Publication Planning

Example 3: Integrated Evidence Planning

# Components of a Gap Analysis



Gaps needs to be closed to move from the current situation to the desired situation



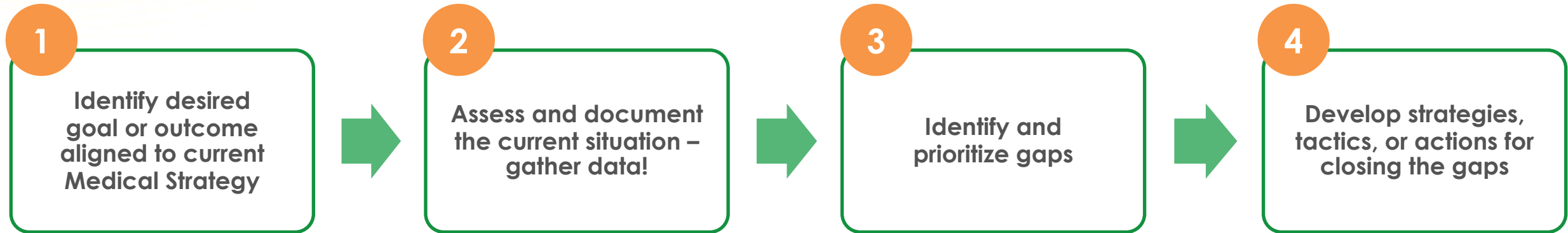
# Strategic Planning: Gap Analyses



- Formally identify potential gaps to address with the medical strategy and tactical planning phases
- Helps identify internal gaps in evidence generation, interpretation, communication, and/or education
  - New research questions/ideas
  - Product data or evidence needs
  - Education or communication needs by stakeholder
  - Other items to be addressed in tactical planning

# Steps for Gap Analyses

## Four Basic Steps in Conducting a Gap Analysis



**DESIRED GOAL:** Reassess the unmet needs and the potential generation, interpretation, communication, and/or educational gaps in the marketplace to help drive Medical Strategy development and help achieve the product vision

# Step 1: Identify Desired Goal

## Vision

- A broad overarching goal for a product that is typically used across functions

## Medical Objectives

- Concise statements that facilitate moving from the current situation to the desired goals

= Strategic Objective

## Strategic Medical Drivers

- Concise statements that are granular and support the associated medical objective
- Help facilitate translation of strategy into key tactics

= Key Drivers, Critical Success Factors

Product Y:

A mAb in a dermatology indication

VISION		
[Product Y] provides robust and lasting efficacy for individuals with the [inflammatory skin disease] with the convenience of a new treatment paradigm		
Medical Objectives		
1. Advance understanding of the disease course, burden, and unmet treatment needs of individuals with [dermatologic condition]	2. Communicate additional evidence, beyond the pivotal trial data, on the efficacy of Product Y in comparison to standard of care and current therapies for [dermatologic condition]	3. Partner with medical societies and key dermatologists in the field to advance understanding and update current guidelines on the treatment of [dermatologic condition]
Strategic Medical Drivers		
A. B. C. D.	A. B. C. D.	A. B. C. D.
<b>*Note*</b> If you are not starting from the beginning, look at the objectives you set the previous year – and look for opportunities to improve		



# Step 2: Assess and Document the Current Situation

## Current Situation: Medical SWOT

- Collaborative and structured approach to understanding where your product stands in the current environment and disease state – identifying both internal and external factors

It is a combination of:



Internal

Strengths and Weaknesses



External

Opportunities and Threats

# Example: SWOT Analysis

## Product Y:

A mAb in a dermatology indication

### Internal:

#### Product- or Company-Specific

#### Strengths (+)

- Infrequent dosing (convenience)
- Part of a portfolio of products
- Company is a scientific leader in dermatology
- First-in-class novel MoA
- Better efficacy vs standard of care in direct H2H studies
- No unexpected safety signals



#### Weaknesses (-)

- Delayed launch
- Not clinically differentiated
- Misperception of safety concern (driven by competitor messaging)



### External:

#### Market or Environment-Specific

#### Opportunities (+)

- Large unmet need and an expanding market
- Patient preference for less frequent dosing (helps them forget their disease)
- Patients want improved efficacy from treatment



#### Threats (-)

- Competitive market that is perception-driven
- Large competitor companies are well-established
- Price points are lowering due to biosimilars
- HCPs do not have desire to improve treatment goals (disconnect with patients)



# SWOT Guiding Strategy

Output will help guide medical and scientific strategy by answering key questions



How do we capitalize on or use each strength to differentiate?



How do we take advantage of each opportunity?



How do we overcome or stop each weakness?



How do we counter or defend against each threat?

Another tool, called a TOWS analysis, is an alternative approach that helps you make connections between each quadrant of the SWOT analysis to inform strategic actions



# Step 3: Identify Gaps (Workshop)

## Creating a Work Map

Current State	Unmet Need or Desired State	Gap	Action to Fill the Gap (Medical)
Patients want less frequent dosing, but HCPs believe current treatments are adequate	HCPs realize burden of disease on current treatment	<ul style="list-style-type: none"> <li><b>Evidence Generation Gap</b> – limited data on patient preferences</li> <li><b>Communication/Education Gap</b> – patient preferences and need for more convenient dosing to HCPs</li> </ul>	<ul style="list-style-type: none"> <li>Gain patient preference data (ie, improved efficacy, dosing, etc)</li> <li>Provide rationale for need to improve treatment outcomes grounded in patient benefits</li> </ul>
Efficacy is not optimal for all patients	HCPs redefine expectations of efficacy for all patients	<ul style="list-style-type: none"> <li><b>Evidence Generation Gap</b> – limited data on patient preferences</li> <li><b>Communication/Education Gap</b> – patient preferences on optimal efficacy - HCP</li> <li><b>Communication/Education Gap</b> – guidelines to redefine optimal efficacy in this group of patients</li> </ul>	<ul style="list-style-type: none"> <li>Focus communications, both patient and HCP, on greater efficacy with convenient dosing, in line with patient desires</li> <li>Ensure robust differentiation from all competitors (mechanistic and clinical)</li> <li>Work with medical societies and key KOLs to update guideline recommendations based on new MoA and key clinical data</li> </ul>
Misperceptions on safety due to competitor messaging	Limited misperceptions on safety concerns	<ul style="list-style-type: none"> <li><b>Evidence Generation and Interpretation Gap</b> – limited published information on novel MoA and reason to believe there would be no off-target effects</li> <li><b>Communications/Education Gap</b> – limited analyses published on safety beyond clinical trial</li> </ul>	<ul style="list-style-type: none"> <li>Pull together current literature on MoA</li> <li>Ensure robust differentiation from all competitors (mechanistic and clinical)</li> <li>Proactively communicate safety in context – answer the questions the competitors are posing and provide more</li> </ul>

**Collaboration with cross-functional team is critical!**

# Step 3: Prioritization (Workshop)

- Determine what to tackle
- What to consider
  - Biggest impact
  - Ease of execution
  - Timing restraints
  - Budgetary and resource restraints
- Rank the items of highest priority to guide medical strategy and place all other items into a parking lot for future consideration
  - High, medium, low

## Gap Prioritization

1. Evidence Generation Gap – limited data on patient preferences
2. Communication/Education Gap – patient preferences and need for more convenient dosing to HCPs

1. Communication/Education Gap – guidelines to redefine optimal efficacy in this group of patients
2. Evidence Generation Gap – limited data on patient preferences
3. Communication/Education Gap – patient preferences on optimal efficacy - HCP

1. Communications/Education Gap – limited analyses published on safety beyond clinical trial
2. Evidence Generation and Interpretation Gap – limited published information on novel MoA and reason to believe there would be no off-target effects

# Step 4: Develop Strategy, Drivers, Tactics to Close the Gap

## VISION

[Product Y] provides robust and lasting efficacy for individuals with [the inflammatory skin disease] with the convenience of a new treatment paradigm

### Medical Objectives

1. Advance understanding of the disease course, burden, and unmet treatment needs of individuals with [dermatologic condition]
2. Communicate additional evidence, beyond the pivotal trial data, on the efficacy of Product Y in comparison to standard of care and current therapies for [dermatologic condition]
3. Partner with medical societies and key dermatologists in the field to advance understanding and update current guidelines on the treatment of [dermatologic condition]

### Strategic Medical Drivers

- A. Bring together current knowledge of the new MoA and how it is differentiated from current classes of treatment  
B. Coordinate and publish patient and physician preferences in treatment of [dermatologic condition]
- A. Ensure robust differentiation from all competitors (mechanistic and clinical) through targeted educational programming  
B. Proactively communicate safety of Product Y in the context of standard of care
- A. Complete a KOL mapping and engagement exercise to support goals  
B. Support need for updated guidelines with Medical Societies (X, Y, & Z)

Transition from actions of gap analysis



# Strategy versus Tactics



**Medical Strategy**

- The **WHAT**
- The **WHY**

VS



**Tactical and  
Operational Plan**

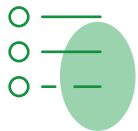
- **THE HOW**
- **THE WHO**

# REMINDER: Determine KPIs or Metrics

## Determining the Success of the Medical Plan



Outcomes-based metrics are needed to assess the impact of the medical strategic plan objectives



Goal-based metrics evaluate performance of efforts

- Analyze quantitative and qualitative metrics against key milestones and deliverables



Determine adjustments needed based on ongoing assessment

Table 1. Example quantitative and qualitative metrics in MA

QUALITATIVE METRIC	QUANTITATIVE METRIC
<ul style="list-style-type: none"><li>Internal and external customer feedback (eg, market research, surveys)</li><li>Insights captured from investigators, advisors, patients, and other external stakeholders that may inform medical strategy, clinical development, or other internal functions</li><li>Changes in formulary decisions or medical policy, or guidelines</li><li>External recognition<ul style="list-style-type: none"><li>Credibility for scientific information in therapeutic areas</li><li>News coverage</li><li>Social media coverage and/or reach</li><li>What credible KOLs and HCPs in the field are saying at congresses and in publications</li></ul></li><li>Sentiment analysis for altmetrics</li><li>Benchmarking to other companies</li></ul>	<ul style="list-style-type: none"><li>Number and type of MSL activities and engagements</li><li>Number of accepted publications</li><li>Number of symposia or educational opportunities supported</li><li>Number of conversations/interactions with KOLs</li><li>Number of formulary changes</li><li>Number of medical information requests</li><li>Patient or investigator recruitment</li><li>Number of investigator-initiated trials</li><li>Altmetrics (to measure publication impact)</li></ul>

HCP=healthcare professional; KOL=key opinion leader; MSL=medical science liaison.

KPI, key performance indicator. The Value of Medical Affairs. Defining Strategic Metrics to Demonstrate Impact. Envision Pharma Group. 2018. <https://epg-digital.com/u/MAPS2023MedAffairs>.

# Minding the Gap: Examples

Example 1: Tactical Planning

Example 2: **Publication Planning**

Example 3: Integrated Evidence Planning

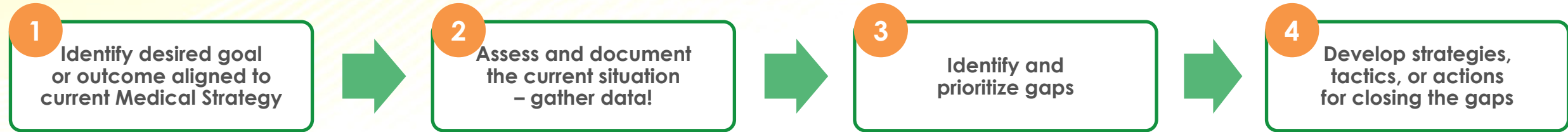


# Gap Analyses in Publication Planning

## **Purpose of publication gap analyses:**

- Identify evidence, education, or publication gaps
- Benchmark current trends in literature and/or competitive data dissemination
- Identify key target audiences and journals

# Publication Planning: Gap Analysis Process



## MEDICAL & PUBLICATION STRATEGY

- What are the strategic objectives for publications based on Medical Strategy and stakeholder needs?

## SITUATIONAL ANALYSIS

- What are the key insights from internal and external assessments for publications?
  - Disease
  - Product
  - Competitors
- What are the informational needs of the target audiences?

## GAP ANALYSIS

- What are the priority gaps, key opportunities, and issues to address?

## PUBLICATION PLAN DEVELOPMENT

- Do the current strategies need to be refined?
- What publications are needed? At what time? To what audience(s)?

# Publication Planning: Literature Search Process

## Examples

A

**Identify your objective(s)**

- Disease state and current treatment landscape
- Competitor benchmarking
- Specific endpoints or data

B

**Select search parameters**

- Keywords
- Drug names
- Field parameters
- Language

C

**Evaluate appropriate timeframe**

- Recent timeframe (past 3-5 years)
- Pre- and post-launch periods
- Historical

D

**Determine scope of search**

- Indexed, peer-reviewed articles
- Congress presentations
- Press releases



# A. Identify Your Objective(s)

## Having a clear objective informs subsequent steps

- **Disease state and current treatment landscape**
  - Knowledge or evidence gaps
  - Burden of disease
  - Unmet needs
  - Patient journey
  - Costs
- **Competitor benchmarking**
  - Pivotal data releases
  - Subanalyses and secondary publications
  - Target audience
  - Key messages
- **Specific endpoints or data**
  - Safety
  - Long-term extension data
  - Specific populations



# Develop Research Questions

Analyses to Consider	Potential Questions
Target audiences	Are we communicating to all relevant specialties?
Target journal	Are we targeting journals read by target audience?
Key data	Do we need publications focused on a specific endpoint or area of research? How does our plan benchmark against other drugs?
Target region	Should we support local language publications, or consider a broader range of journals? Are certain regions interested in specific data versus others?
Key messages	Is the literature sufficient to support our scientific narrative?

# B. Select Search Parameters

- **Keywords**
  - Indication
  - Disease terminology
  - Endpoints or populations of interest
- **Drug names**
  - Generic names
  - Molecule numbers
- **Field parameters**
  - Title
  - Title/abstract
  - Text word
  - MeSH term
- **Language**
  - English, non-English



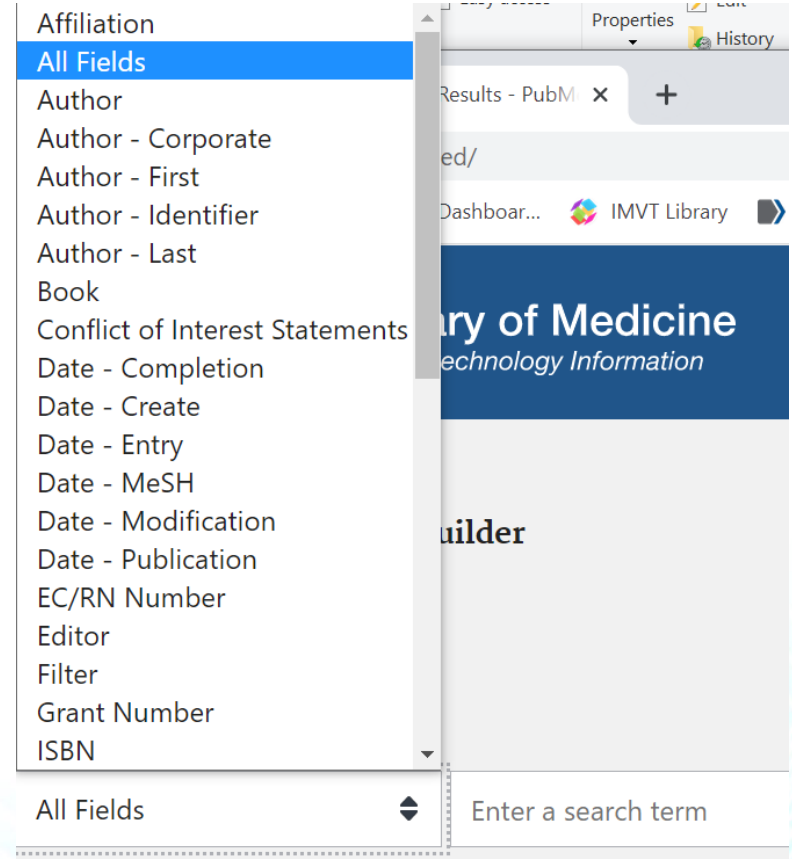
Embase



Cochrane  
Library

MeSH

Topic Searching in PubMed:  
Using the Medical Subject Headings





# C&D. Evaluate Appropriate Timeframe & Scope of Search

- **Consider your objective**

- Trends over time
- Current landscape
- Specific information (eg, competitor pivotal data)

- **Consider what is valuable**

- Broad versus specific
- Appropriate competitors considering current landscape
- Volume of findings

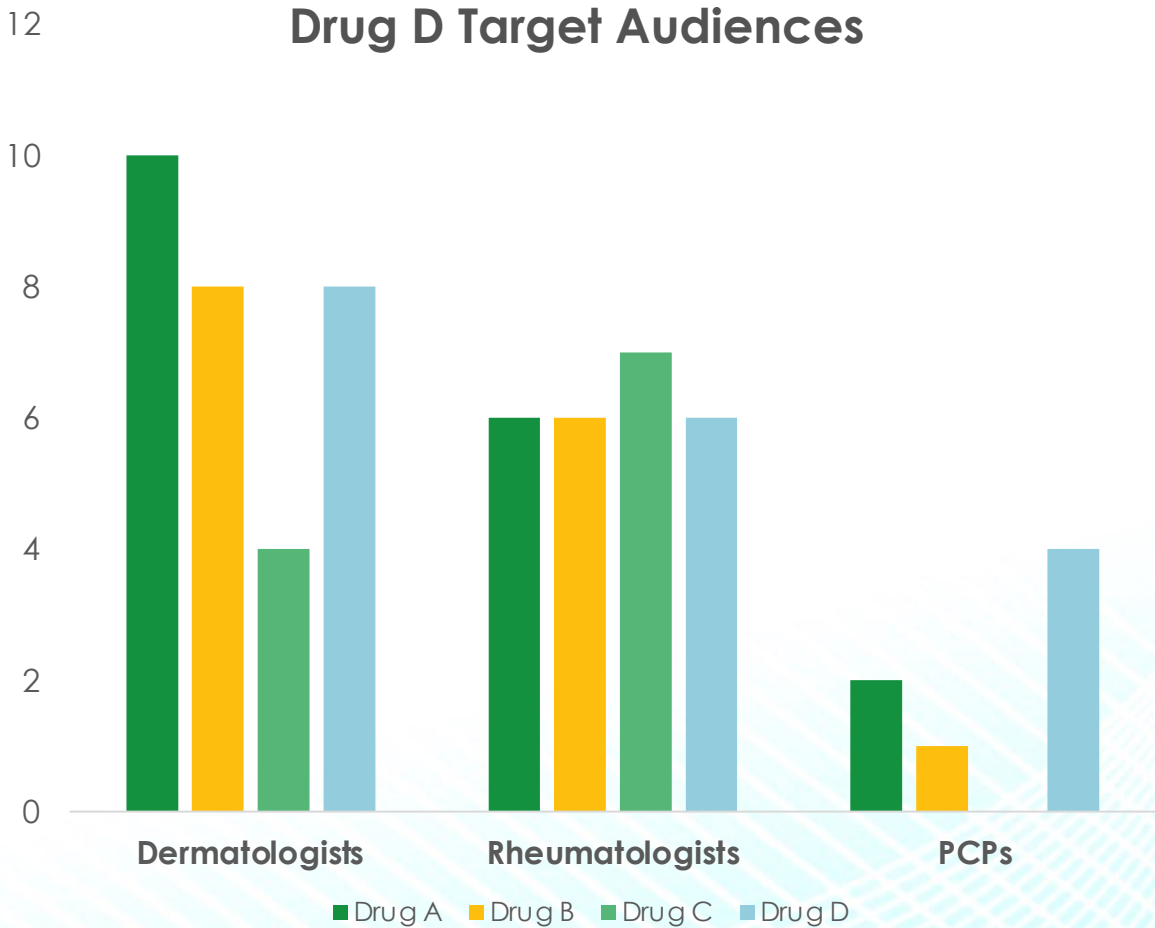
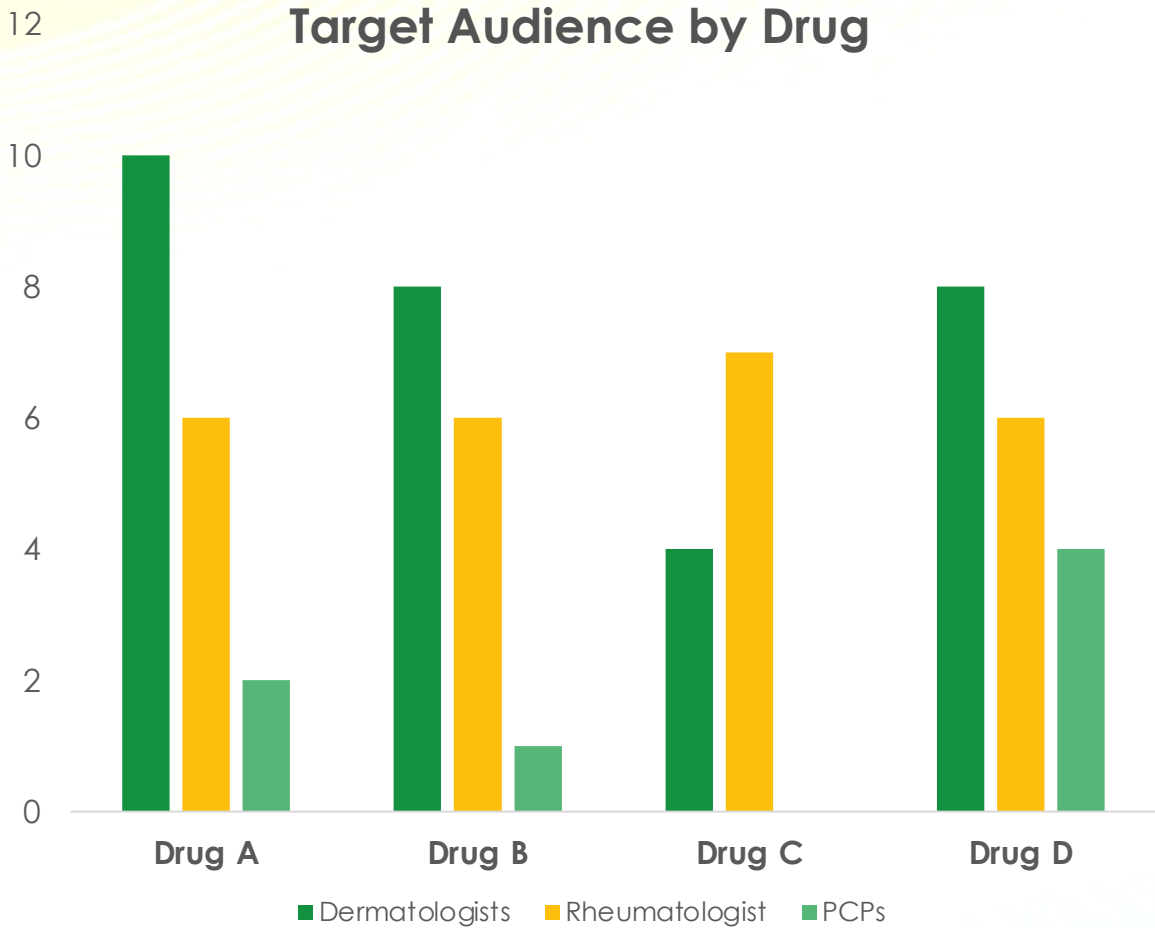
- **Consider the scope**

- Indexed, peer-review articles (eg, PubMed)
  - Fully published
- Congress publications
  - More recently released data
- Press releases
  - Prior to or in lieu of congress presentation

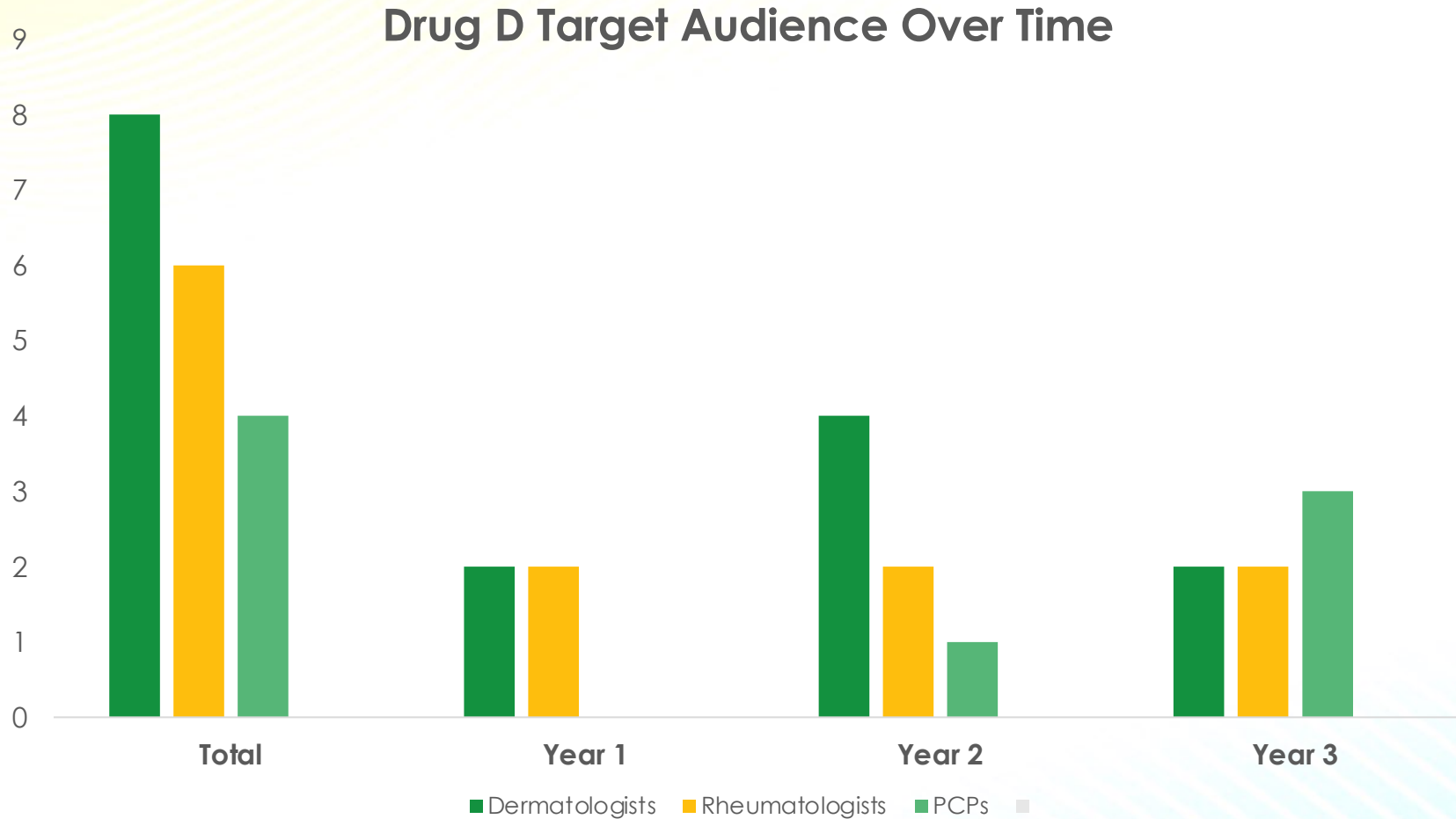
**How far back?**



# Example: Target Audience



# Example: Target Audience (cont'd)



Drug D has increased publications targeted to a primary care audience over time



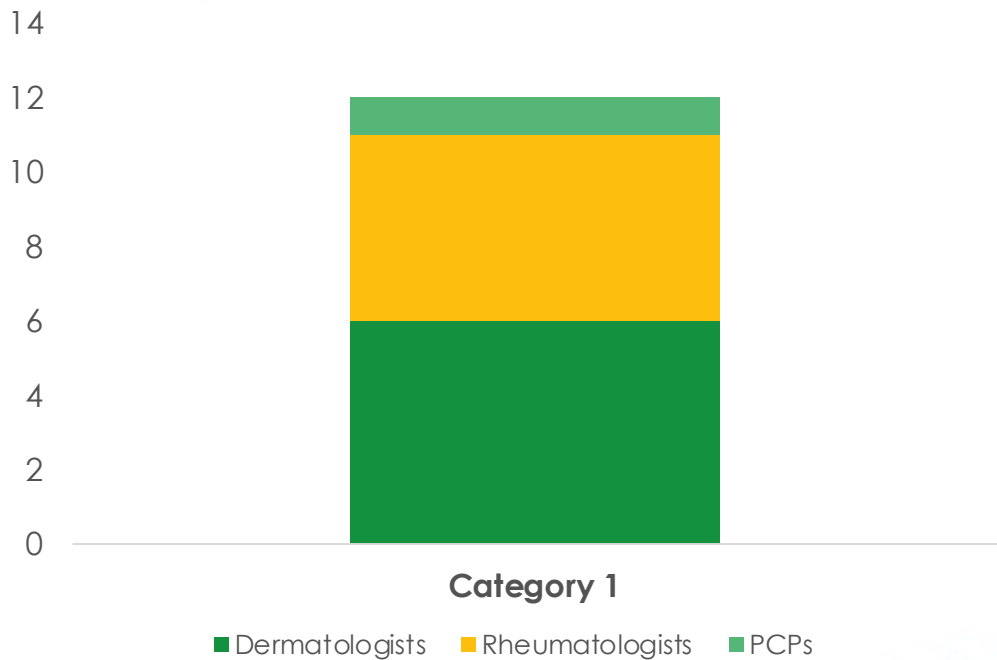
# Example: Target Audience (cont'd)

Drug D has increased publications targeted to a primary care audience

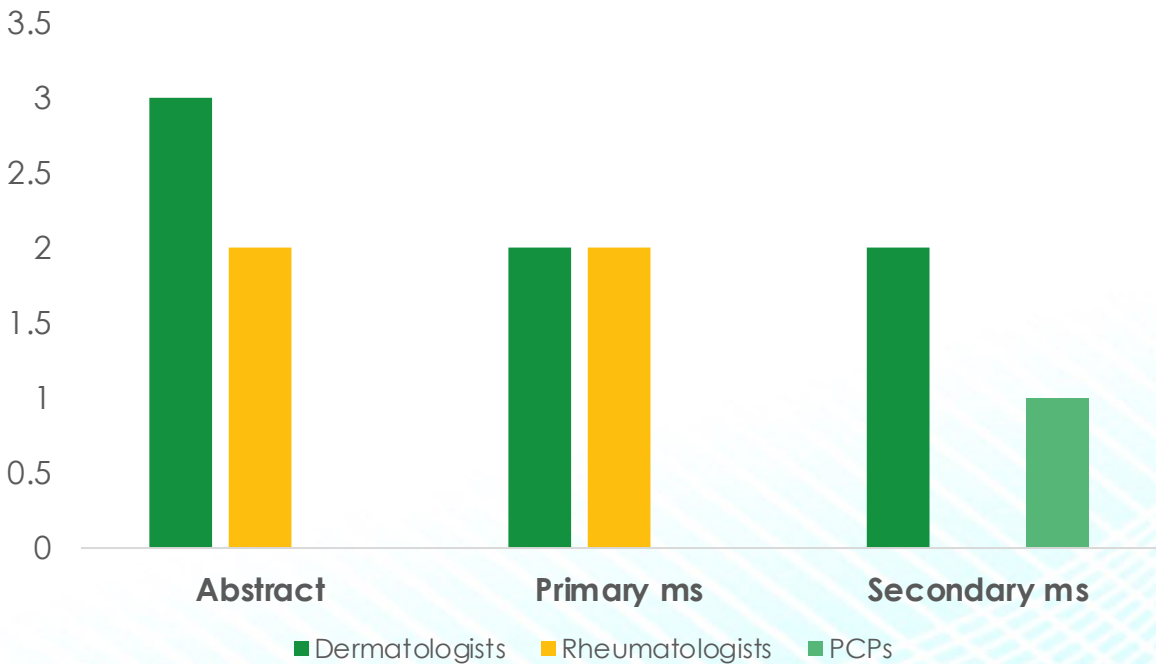


Is this a gap in our current plan?

By Target Audience



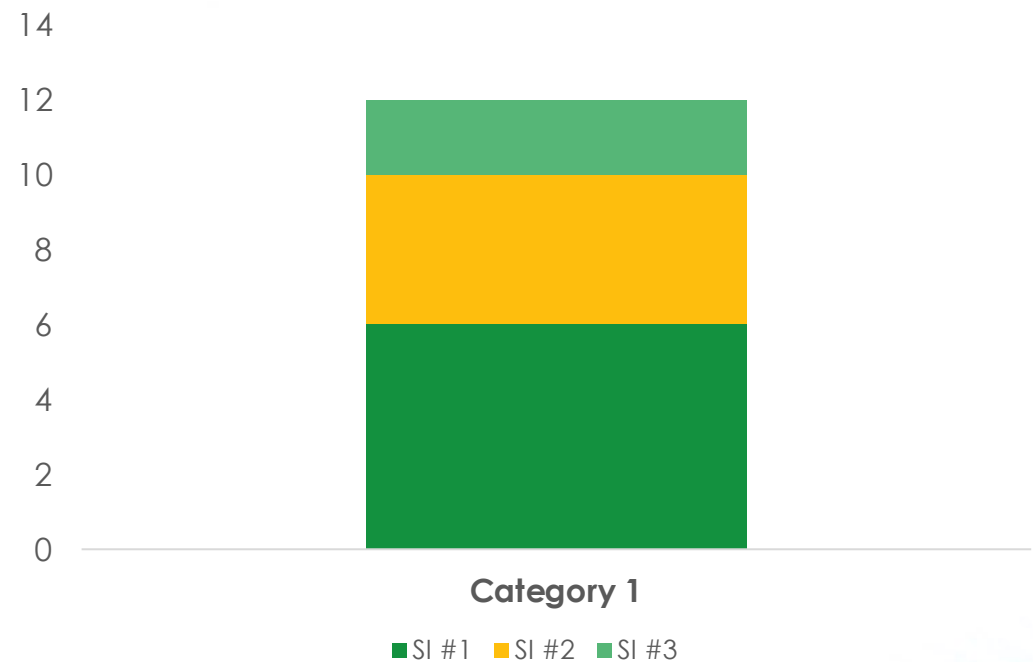
By Audience and Type



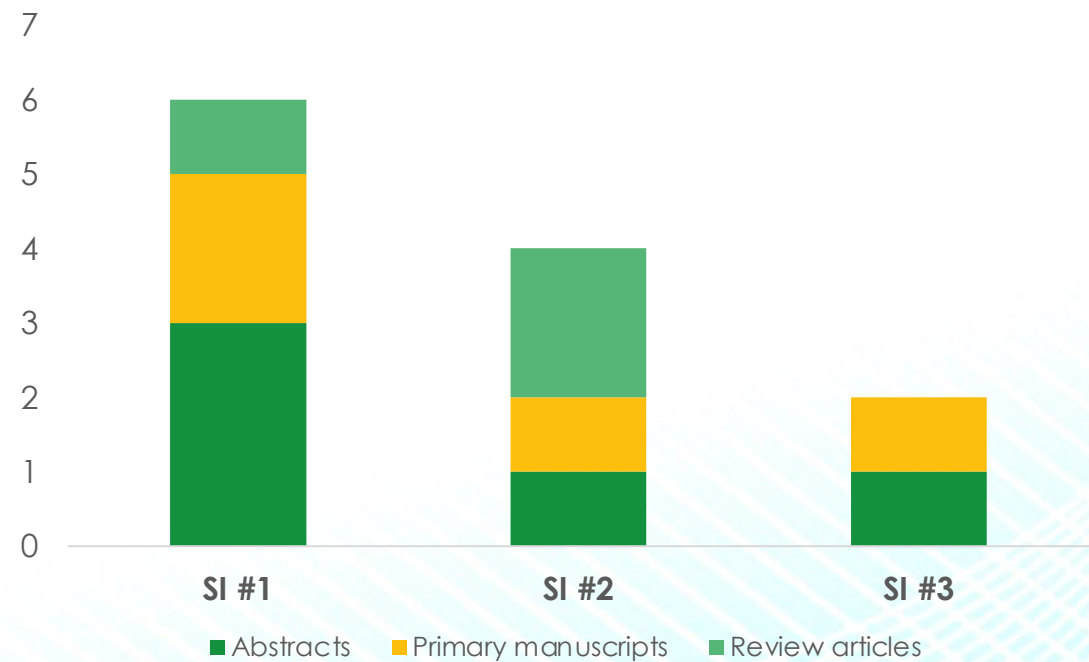
# Example: Analyzing the Plan

Consider changes as appropriate  
\*\*Remember to ensure that any decisions ladder up to Scientific Imperatives

By Scientific Imperative



By Scientific Imperative and Type



# Gap Identification Workboard

Gap identified	Gap type			Potential Opportunities to Address Gap (2020–2021)
	Pub	Data	Comm	
There is a lack of literature on the MoA in this therapeutic area	X			<ul style="list-style-type: none"> <li>Publish preclinical data, develop review article</li> </ul>
Misconception of safety profile			X	<ul style="list-style-type: none"> <li>Secondary manuscript with greater detail on safety events</li> </ul>
Lacking publications to the PCP audience compared with competitors	X			<ul style="list-style-type: none"> <li>Consider (1) encoring data presentations and/or (2) retargeting some manuscripts or developing a review article to PCP audience</li> </ul>
No literature on current unmet needs despite available treatment options	X			<ul style="list-style-type: none"> <li>Prioritize publishing patient preference data when available</li> </ul>
Lack of data in patient populations of interest compared with competitors		X		<ul style="list-style-type: none"> <li>Secondary analyses and subsequent presentation/publication</li> </ul>



# Apply the Findings

- Assess your current bibliography and publications plan
- Review findings with Publications Team and Steering Committee
- Build/revise your plan
  - Key topics
  - Audiences
  - Timelines and priorities
    - Align with the Integrated Evidence Plan
  - Alignment with scientific objectives

# Apply the Findings: Defining Your Plan

Pub type	Data source	Topline description	Communication points supported	Audience	Target congress/journal	Anticipated timing
<b>Manuscript</b>	Preclinical	Preclinical/MoA data	1A	Clin Pharm	G2C	Q1
<b>Review article</b>	Preclinical	Description of MoA and impact on MoD	1A	Derms	JAAD	Q2
<b>Abstract</b>	Phase 3	Safety deep-dive	3A	Derms	AAD	Q1
<b>Encore</b>	Phase 3	Safety deep-dive	3A	PCPs	ACP	Q1
<b>Manuscript</b>	Phase 3	Safety deep-dive	3A	Derms	BJD	Q2
<b>Review article</b>	Multiple	Efficacy, safety, dosing regimen	2A, 2B, 3A	PCPs	JAMA	Q3
<b>Manuscript</b>	HEOR *avail Q2	Patient unmet needs	2B, 2C	Derms	JAAD	Q3-4
<b>Abstract</b>	Phase 3 subanalysis	Efficacy/safety in [population of interest]	2A, 3A	Derms, Rheums	ACR	Q4
<b>Manuscript</b>	Phase 3 subanalysis	Efficacy/safety in [population of interest]	2A, 3A	Rheums	J Rheum	Q4

# When to Reassess Your Plan



LET'S  
RETHINK

- Annual planning
- New data releases
- Updated guidelines
- Regulatory events
- Medical insights



# Minding the Gap: Examples

Example 1: Tactical Planning

Example 2: Publication Planning

**Example 3: Integrated Evidence Planning**

# Integrated Evidence Plans: A Deeper Dive



- **Tracks evidence gaps** and associated evidence plans
- An internal **living document**
- Compiles **evidence by stakeholder needs**
- **Prioritizes evidence generation requirements** across functions, countries, and the product lifecycle

**Facilitates strategic decision-making to support the development, launch, and lifecycle of an asset**

# What Are the Benefits of an IEP?

## Internal stakeholders

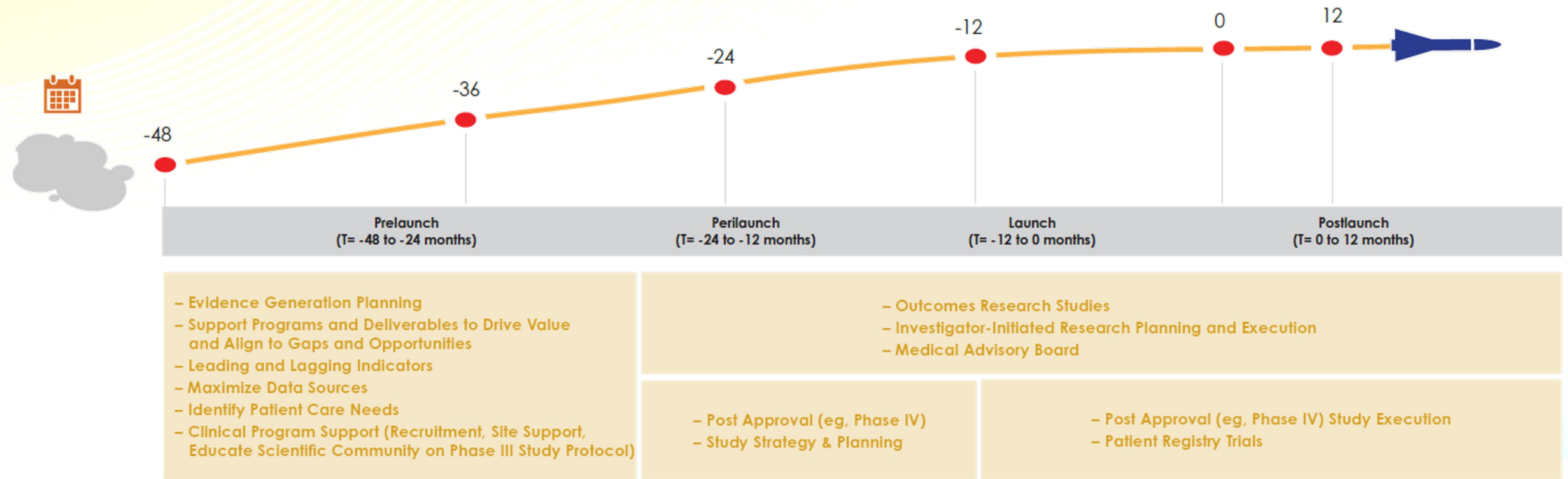
- ✓ Consistent framework & approach
- ✓ Prevents silos across the organization
- ✓ Efficient & effective resource utilization

## External stakeholders

- ✓ **Patients:** Needs, preferences, & experience
- ✓ **Regulators & payers:** Evidence to support access
- ✓ **HCPs:** Clinical adoption & optimal decision-making
- ✓ **All:** Product differentiation & comparative assessment



# When Should We Initiate an IEP?

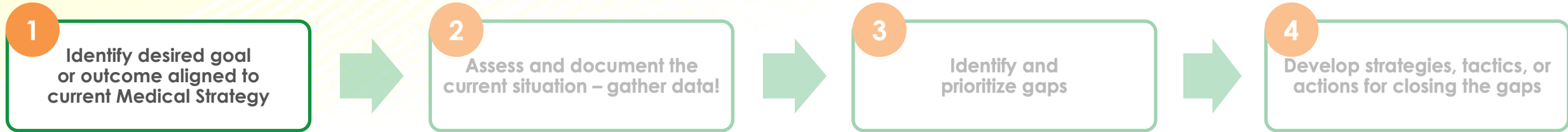


- Early initiation, ideally at Proof of Concept (no later than Phase 2)
- Can be considered as early as asset discovery/preclinical

# The Cross-functional IEP Process

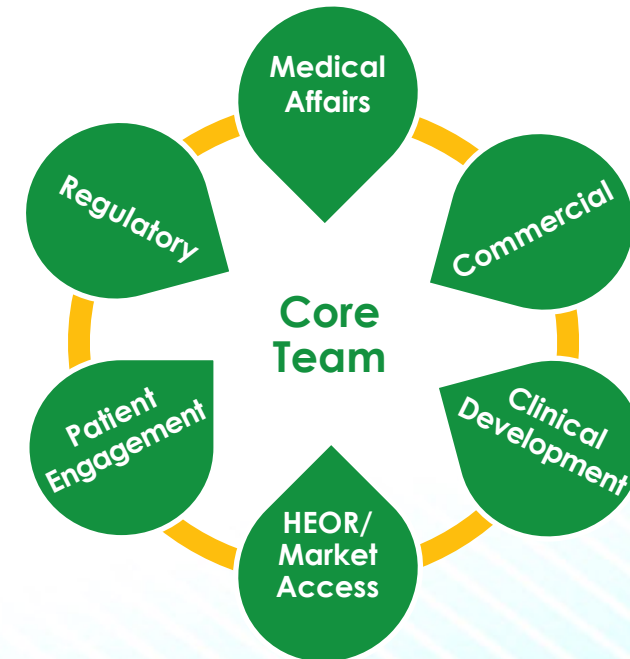


# Step 1: Set-Up and Collation



## Set-up and collation

- Establish core cross-functional team



## Broader regional/affiliate team

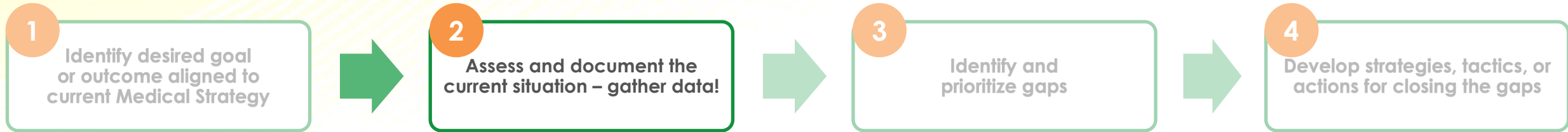
Medical Affairs

Market Access

Commercial



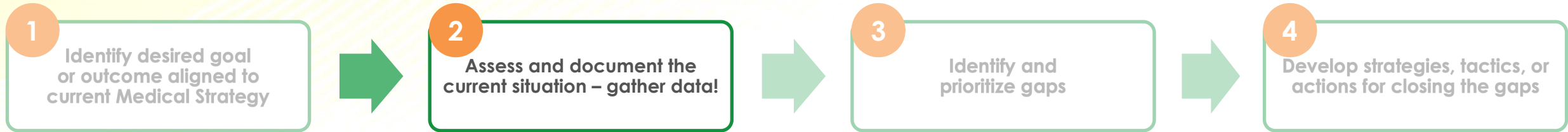
# Step 2: Assess and Document



## Set-up and collation

- Establish core cross-functional team
- **Collate and review relevant stimuli**
- **Stakeholder interviews**
- Develop and circulate gap template to regions

# Step 2: Assess and Document



## Set-up and collation

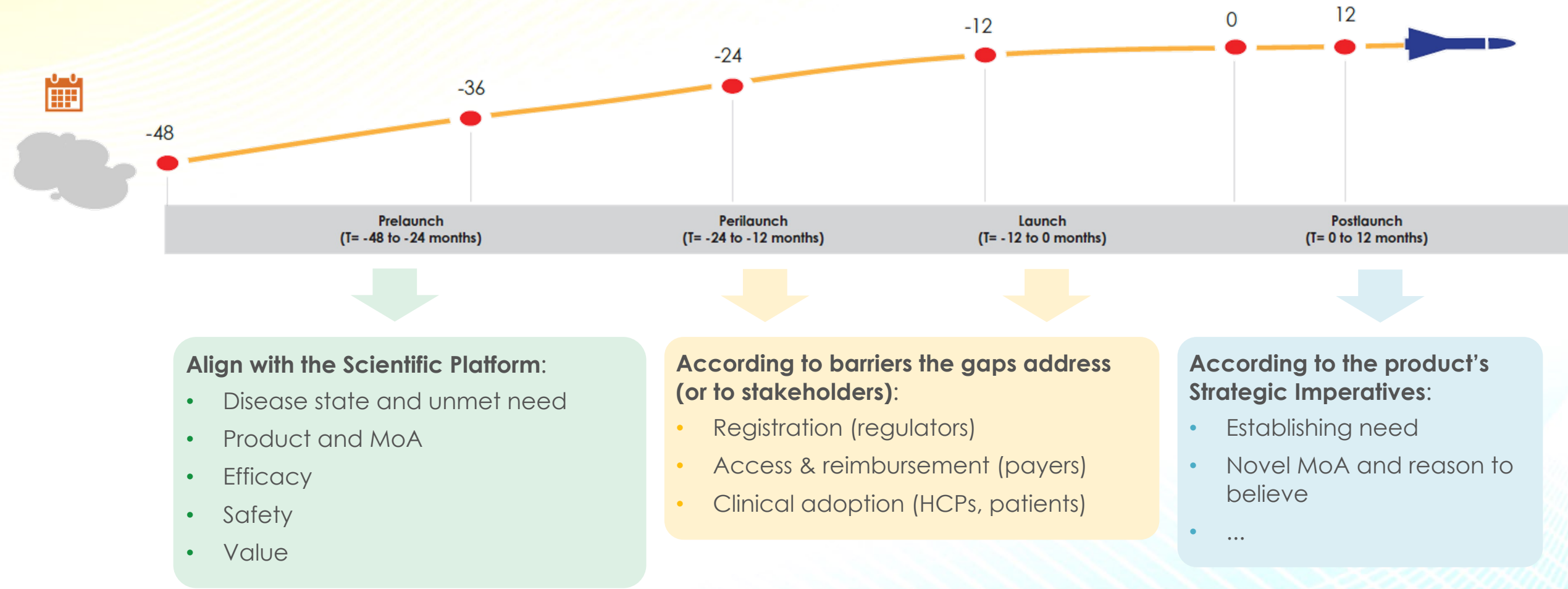
- Establish core cross-functional team
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- **Develop and circulate gap template to regions**

Gap category			Gap description Identification of evidence gaps		Target stakeholder (most impacted)					Additional comments or feedback
Gap type (program)	Category	Priority (ranking)	Gap description	Impact of the gap being closed	Target stakeholder	US	APAC	EU	LATAM	
1L	Clinical Adoption	High	1. Proof of durable skin clearance vs SOC	Increased uptake	HCPs, Payers	✓	✓	✓	✓	
1L, 2L	Access	Medium	2. Patient preference over other therapies	Supports differentiation and access	Patients	✓		✓		
1L	Clinical Adoption	High	3. Reduction in pruritus score	Improvement in QoL; increased clinical uptake	HCPs, Patients	✓	✓	✓	✓	
1L, 2L	Access	High	4. Limited data on novel MoA and reason to believe there would be no off-target effects	Supports differentiation and clinical uptake	HCPs, Payers	✓	✓	✓	✓	

Diagram illustrating the structure of the Gap template, with arrows indicating the flow of information into the table columns:

- Gap type (indication or setting)** points to the **Gap type (program)** column.
- Priority** points to the **Priority (ranking)** column.
- Impact of gap being closed** points to the **Impact of the gap being closed** column.
- Does the gap apply to key regions?** points to the regional columns (US, APAC, EU, LATAM).

# How Should Gaps Be Categorized?





# Identifying Gaps: Cross-Functional Team Input

Template can be broadened to also collect communications gaps, if desired

Gap category			Gap description Identification of evidence gaps		Target stakeholder (most impacted)						
Gap type (program)	Category	Priority (ranking)	Gap description	Impact of the gap being closed	Target stakeholder	US	APAC	EU	LATAM	Additional comments or feedback	
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1L, 2L	Access	Medium	2. Patient preference over other therapies	Supports differentiation and access	Patients	✓		✓			
1L	Clinical Adoption	High	3. Reduction in pruritus score	Improvement in QoL; increased clinical uptake	HCPs, Patients	✓	✓	✓	✓		
1L, 2L	Access	High	4. Limited data on novel MoA and reason to believe there would be no off-target effects	Supports differentiation and clinical uptake	HCPs, Payers	✓	✓	✓	✓		

| Gap type (indication or setting) | | Priority | Impact of gap being closed | | Does the gap apply to key regions? | | | | | |

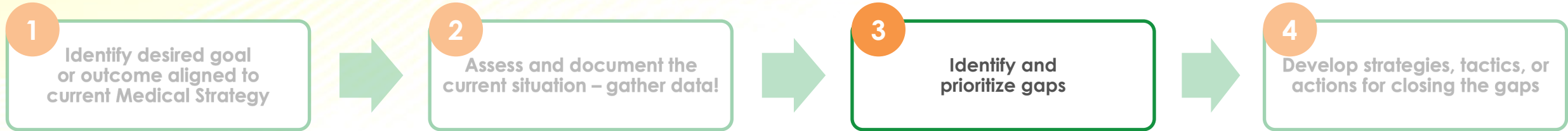
Gap type  
(indication  
or setting)

Priority

Impact of gap being closed

Does the gap apply  
to key regions?

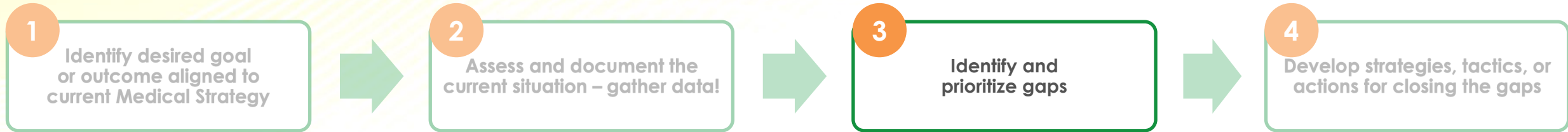
# Step 3: Identify and Prioritize the Gaps



## Identify and prioritize

- Assimilate gaps
- Preliminary prioritization
- Regional workshop(s) to align prioritization

# Step 3: Identify and Prioritize the Gaps



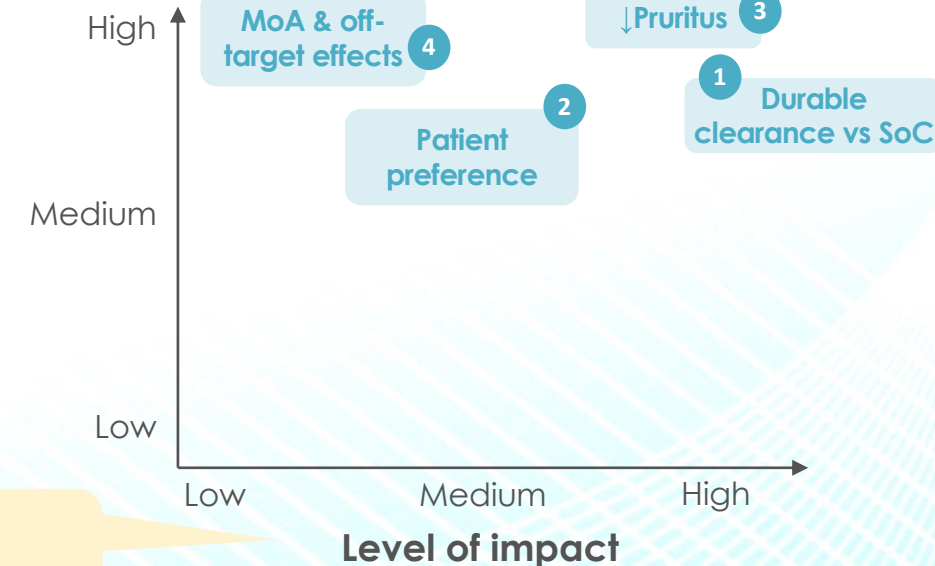
## Identify and prioritize

- Assimilate gaps
- Preliminary prioritization
- **Regional workshop(s) to align prioritization**

- Strategic alignment
- Duration of study
- Budget/resources

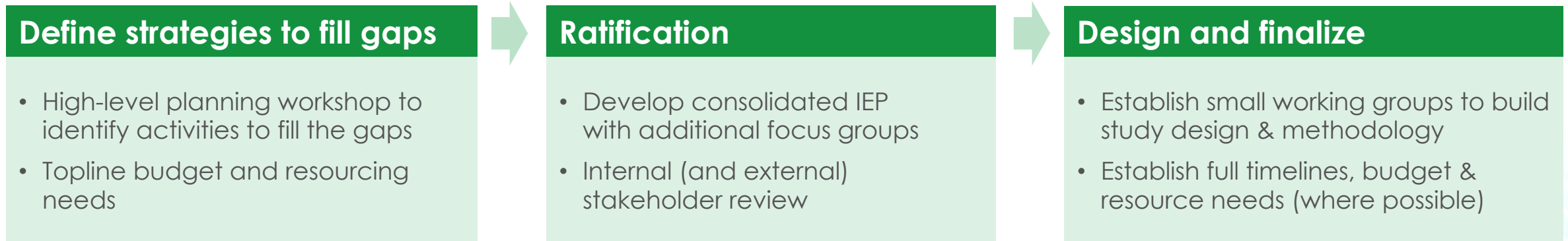
- Supports differentiation
- Relevance to stakeholder
- Size/number of markets impacted

## Feasibility

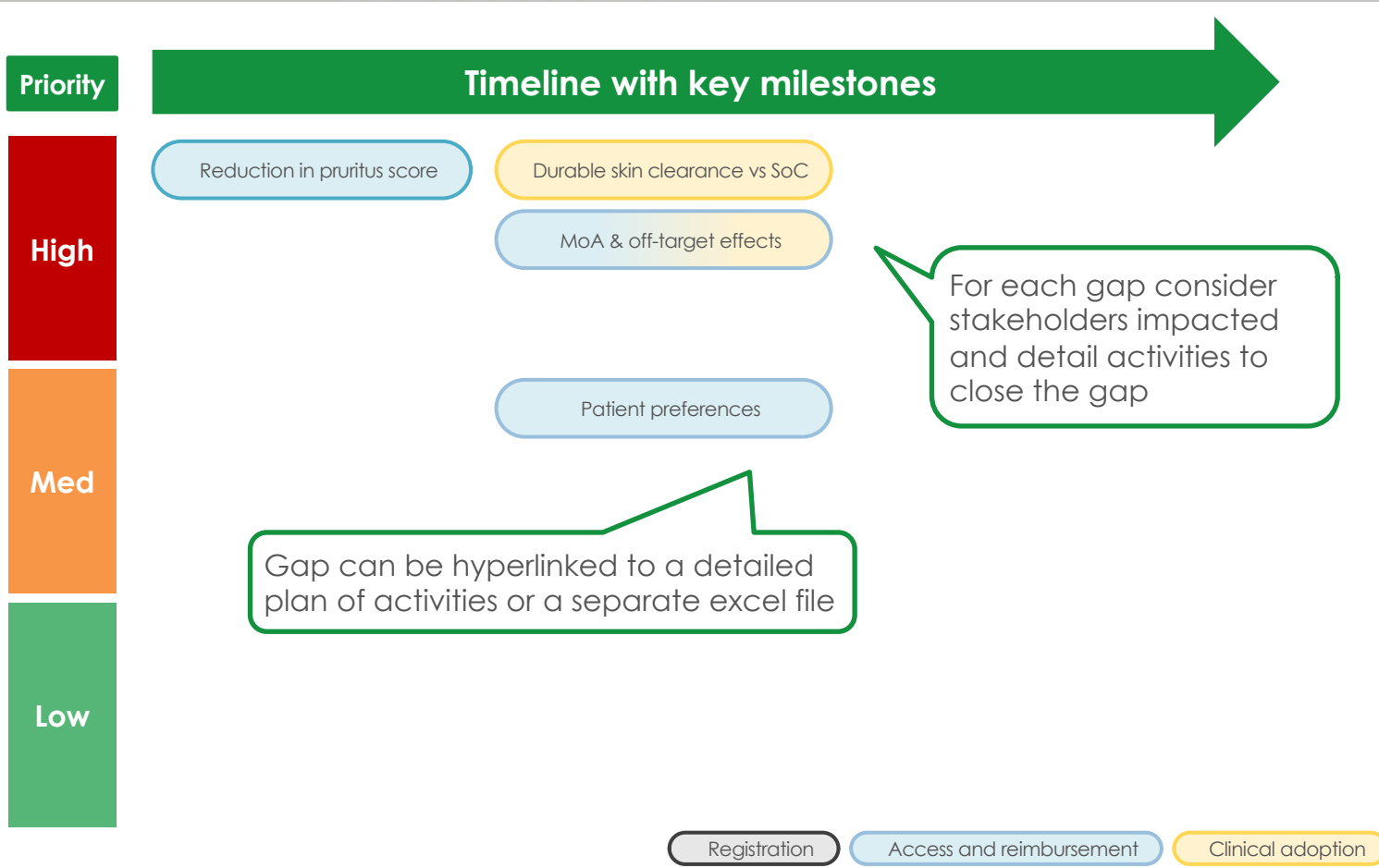




# Step 4: Develop Strategies & Tactics To Close the Gap



# The IEP Tracks Evidence Gaps and Associated Plans



**Disease state**

- Burden of disease

**MoA**

- MoA and off-target effects

**Efficacy**

- Proof of durable skin clearance vs SoC
- Reduction in pruritus score

**Safety**

- Gap 1
- Gap 2

**Value**

- Patient preference

**For priority gaps, include:**

- Activity type
- Completion date
- Functional owner
- Stakeholder targeted
- Estimated budget

# The IEP Is a Living Document for Cross-Functional Use

5

Link to publications and communications plan

6

Review and updates

Pub type	Data source	Top-line description	Communication points supported	Audience	Target congress / journal	Anticipated timing
Manuscript	Preclinical	Preclinical /MOA data	1A	Clin Pharm	G2C	Q1
Review article	Preclinical	Description of MOA and impact on MOD	1A	Dermis	JAAD	Q2
Abstract	Phase 3	Safety deep-dive	3A	Dermis	AAD	Q1
Encore	Phase 3	Safety deep-dive	3A	PCPs	ACP	Q1
Manuscript	Phase 3	Safety deep-dive	3A	Dermis	BJD	Q2
Review article	Multiple	Efficacy, safety, dosing regimen	2A, 2B, 3A	PCPs	JAMA	Q3
Manuscript	HEOR *avail Q2	Patient unmet needs	2B, 2C	Dermis	JAAD	Q3-4
Abstract	Ph3 subanalysis	Efficacy/safety in [population of interest]	2A, 3A	Dermis, Rheums	ACR	Q4
Manuscript	Ph3 subanalysis	Efficacy/safety in [population of interest]	2A, 3A	Rheums	J Rheum	Q4

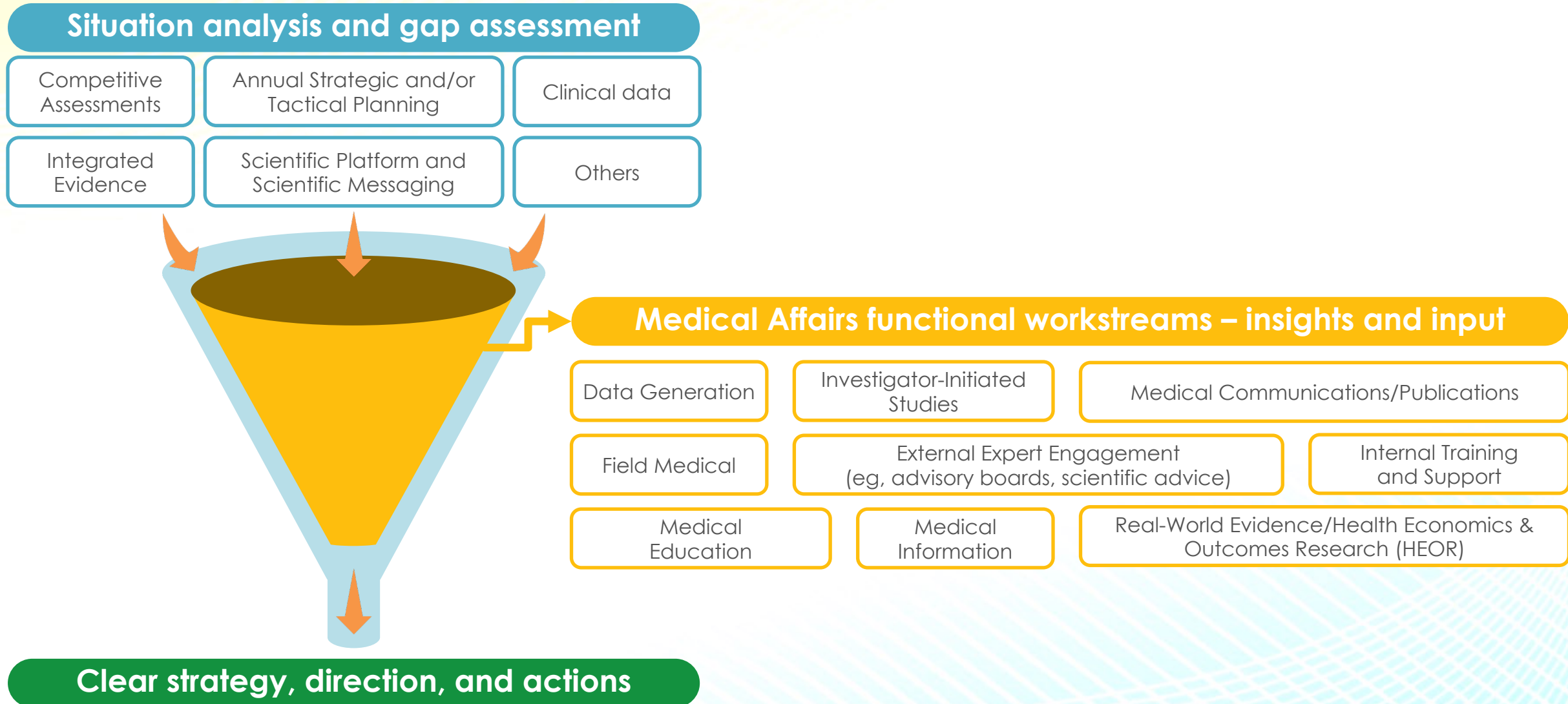
- How are you tracking against the gaps?
- Has the landscape evolved; do our plans need to change in light of this?
- Do any timelines need adjusting?
- Have new activities been initiated, or are new activities required?



# Why Are Gap Analyses Important in Strategic Planning?

Amanda Henkel

# Gap Analyses Should Not Be Done in a Vacuum



# Summary: Dos and Don'ts of Gap Analyses



## Things to DO

- ✓ **Ask specific questions** – define a purpose for your analysis
- ✓ Define a **strategy for information gathering** (ie, search strategy/research, format)
- ✓ Maintain a **consistent approach**
- ✓ **Organize information in a framework**
- ✓ **Provide interpretation** for analysis



## Things to AVOID

- × Have **vague needs**
- × Have too **narrow scope for source material** (eg, timeframe considerations, amount of material/data)
- × Conducting **tactics that are not aligned to your strategy or gaps**
- × **Working alone** – ensure you gain cross-functional team input



# Benefits and Limitations of a Gap Analyses

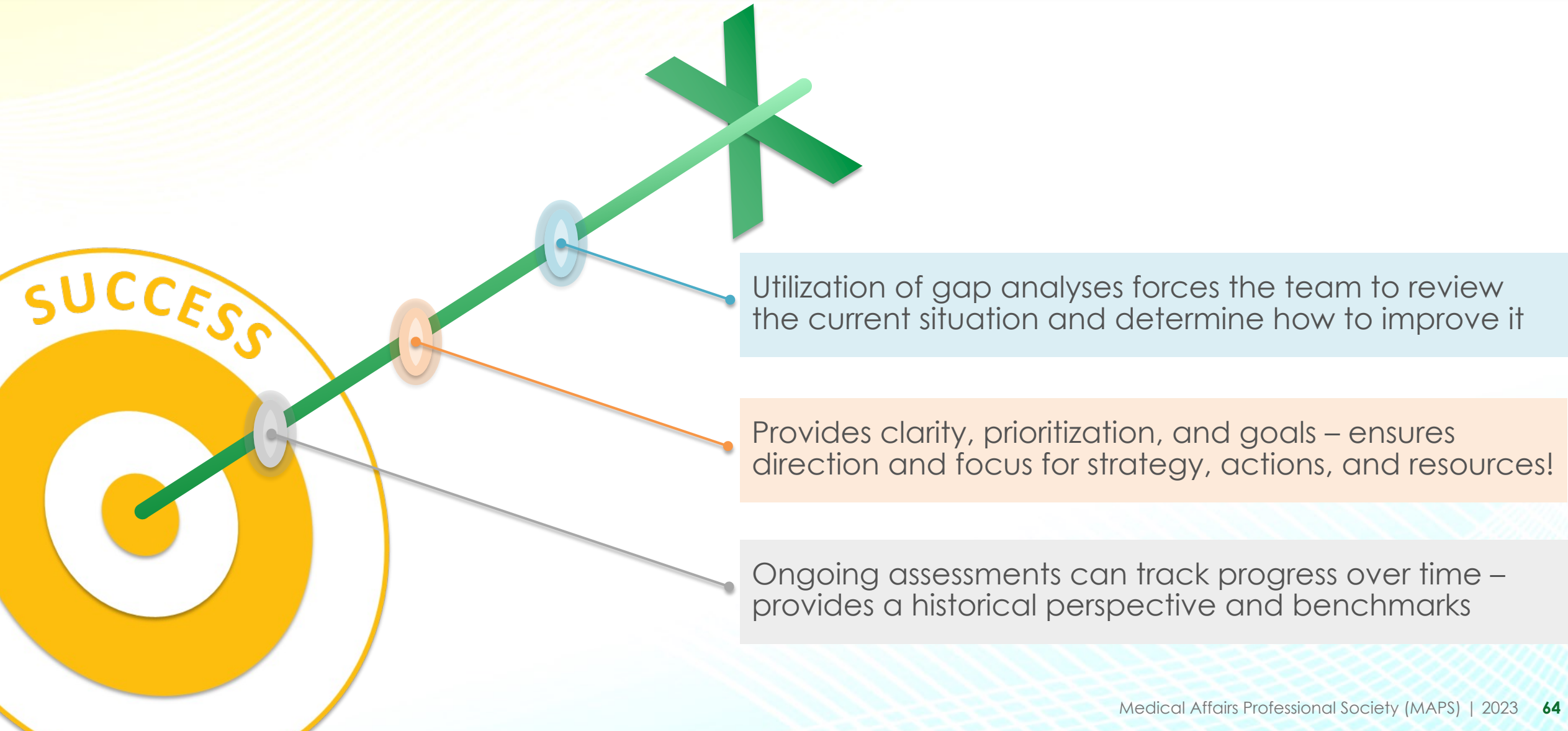


- Provides a comprehensive overview of what is being assessed (interpretation and depth)
- Helps to prioritize actions
- Provides a clear plan for strategic activities and informed decision-making



- Takes time (and cost) to conduct data collection and analysis
- Internal biases and level of knowledge may impact analysis
- Constantly changing landscapes may make gap analyses quickly obsolete

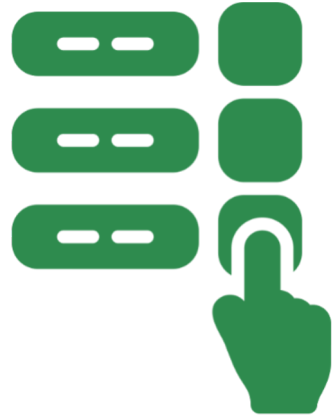
# What Does Good Look Like?



# Polling Question

**As a result of this webinar, what do you believe you will do differently?**

- A. Nothing
- B. Apply gap analyses for tactical planning only
- C. Apply gap analyses in different settings
- D. Work with my cross-functional team to complete gap analyses
- E. Devise a formal plan for updating and revising previously completed gap analyses
- F. Other





**Thank you!**  
Questions?