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Health Solutions

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Creating a Successful Global Value Dossier

The power of knowledge.
The value of understanding.

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Key Learning Objectives

- Learn how to develop and incorporate value messages and supporting evidence into a Global Value Dossier that will demonstrate your product's value to a variety of stakeholders.
- Understand the process for developing an accessible and usable GVD that addresses the stakeholders' needs.
- Learn how to use a GVD to support development of local submissions.
- Choose among the variety of platforms for communicating GVD evidence
- Review best practices for successful GVD development.

Creating Product Value Messages

Stephanie Barrows
Senior Director
Market Access and
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What are Value Messages?

The value the product offers to the stakeholders

Provide concise description of the product

Which comes first –
the Value Message or the data?

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Generating value messages

Sample Value Messages

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Chronic Disease

Disease Burden

- PsA is a chronic, progressive, and debilitating condition that causes joint pain and damage as well as skin and nail disease.
- Patients experience severe complications and sequelae from invasive meningococcal disease.

Clinical Value – Efficacy

- Novel oral inhibitor for PsA that has a faster onset of action and likely more sustainable long-term efficacy.
- Demonstrated non-inferior efficacy and safety to the standard of care for PsA.
- Demonstrates robust bactericidal activity against epidemiologically diverse strains of Neisseria meningitidis in adolescents and young adults.

Oncology

Disease Burden

- Lung cancer has a high mortality burden and is the leading cause of cancer deaths worldwide.
- Symptoms of cough, shortness of breath, and fatigue impact patient HRQOL.
- The advanced stages of NSCLC and toxicities related to treatment result in significant decrement in health-state utilities.

Clinical Value – Efficacy

- Significantly improves PFS compared with platinum-based chemotherapy in previously untreated patients with advanced nonsquamous NSCLC.
- Demonstrated numerical improvement (not statistically significant) in overall survival compared with platinum-based chemotherapy.

Sample Value Messages

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Chronic Disease

Humanistic Value

- Leads to a significantly greater improvement from baseline in emotional functioning, physical functioning, role functioning, and social functioning.

Economic Value

- With a price [X%] lower than TNFis and comparable safety and efficacy, Product X offers opportunities for budget savings.

Oncology

Humanistic Value

- Associated with a significantly longer time to deterioration in the symptoms of pain in chest, dyspnea, or cough (composite endpoint) compared with platinum-based chemotherapy in previously untreated patients.

Economic Value

- Provides cost-effective benefits based on cost per life-year gained (cost/LYG) and cost per quality-adjusted life-year (cost/QALY).
- Treating advanced NSCLC patients could lead to a decrease in total cost of administration and monitoring in advanced NSCLC.

Helpful Tips for Creating Value Messages

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Start early to define product value messages.

Understand the **added value** of the product in relation to the competitors—differentiation.

Interact with entire product team to gain consensus

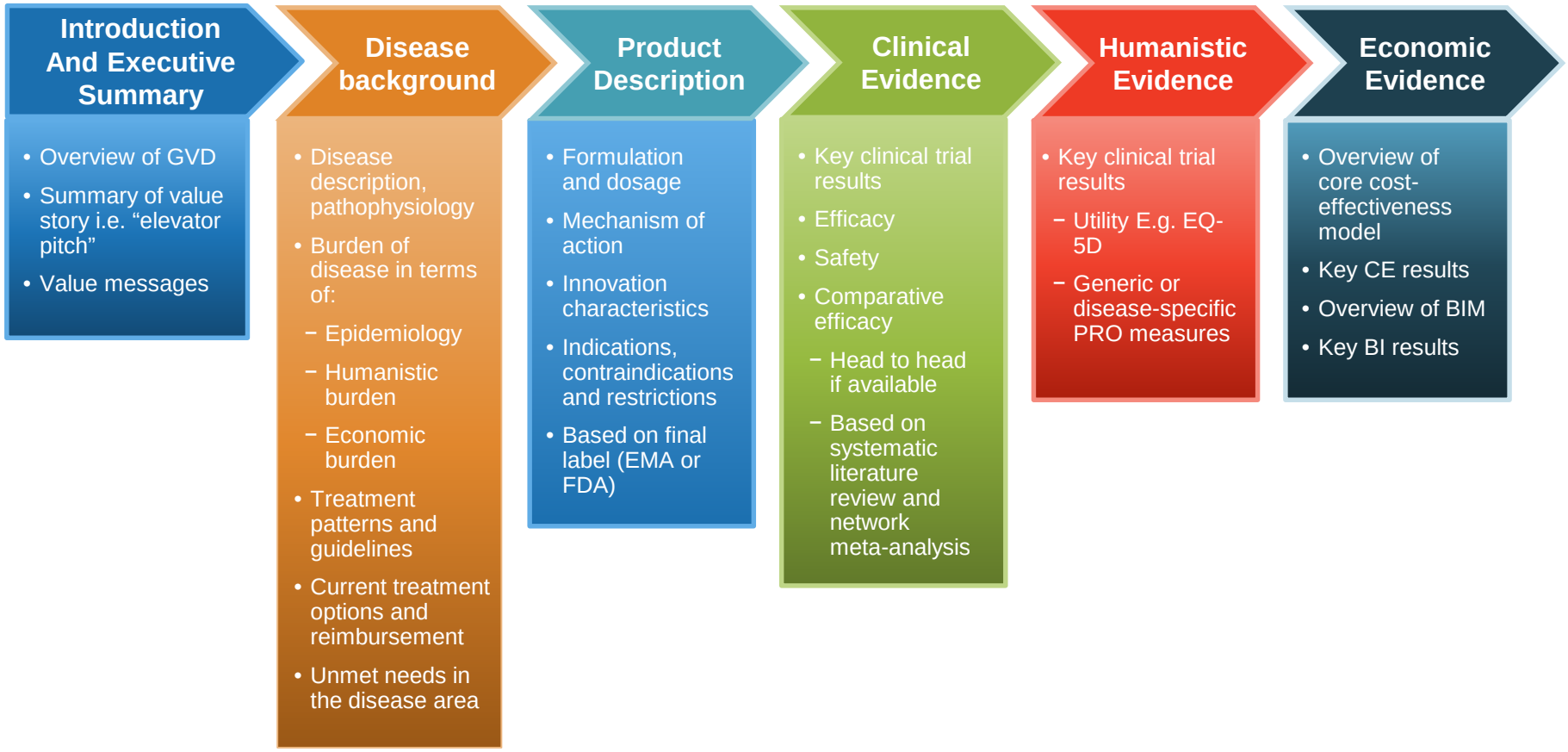
Creation of background messages and product value messages is an **iterative process**.

GVD Process and Format

Caroline Ling
Senior Director
Market Access and
Outcomes Strategy

GVD Content to Meet Needs Across Markets

- Usually include the following sections of relevance to many HTA markets



Evidence Taken from a Range of Robust Sources

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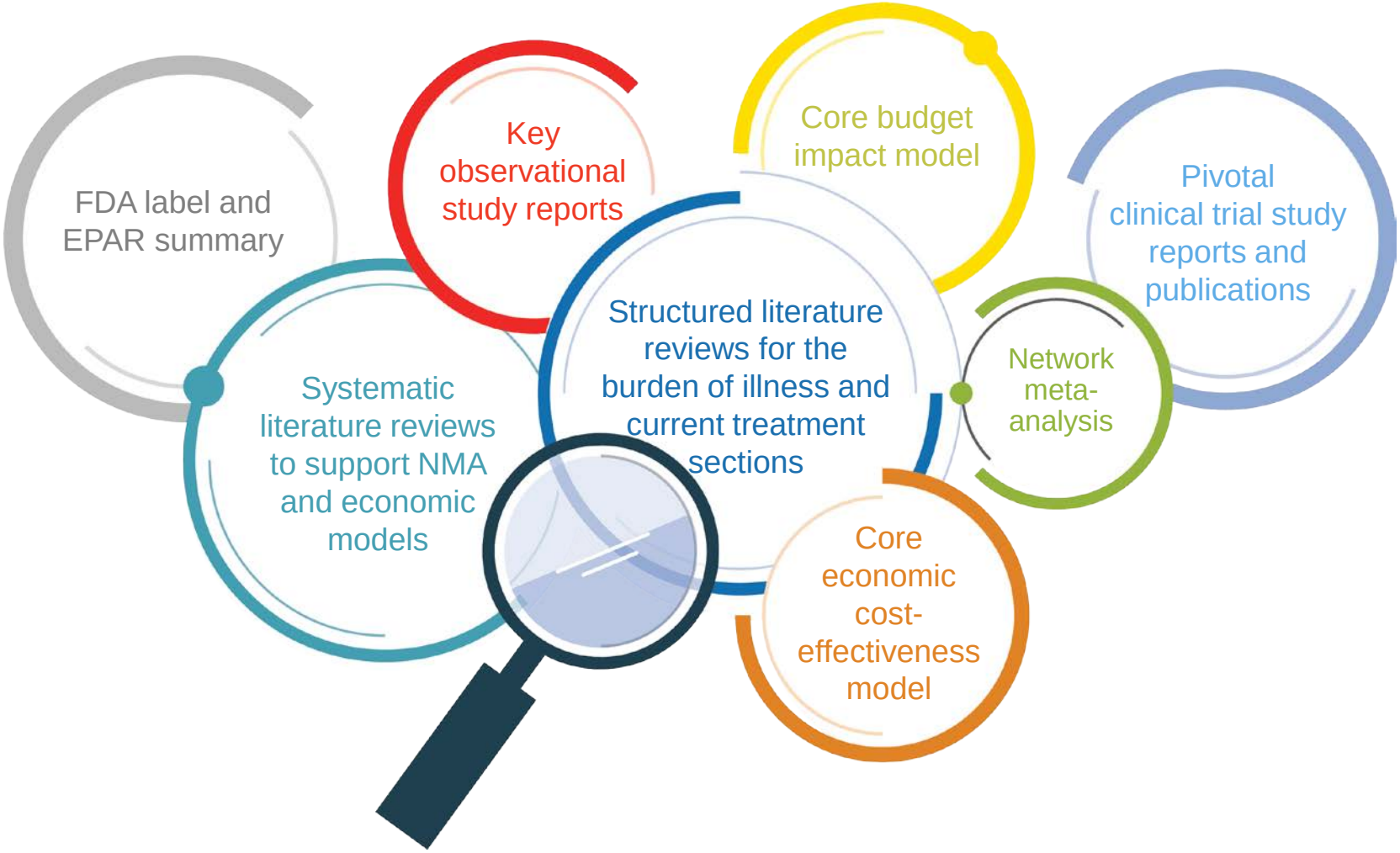
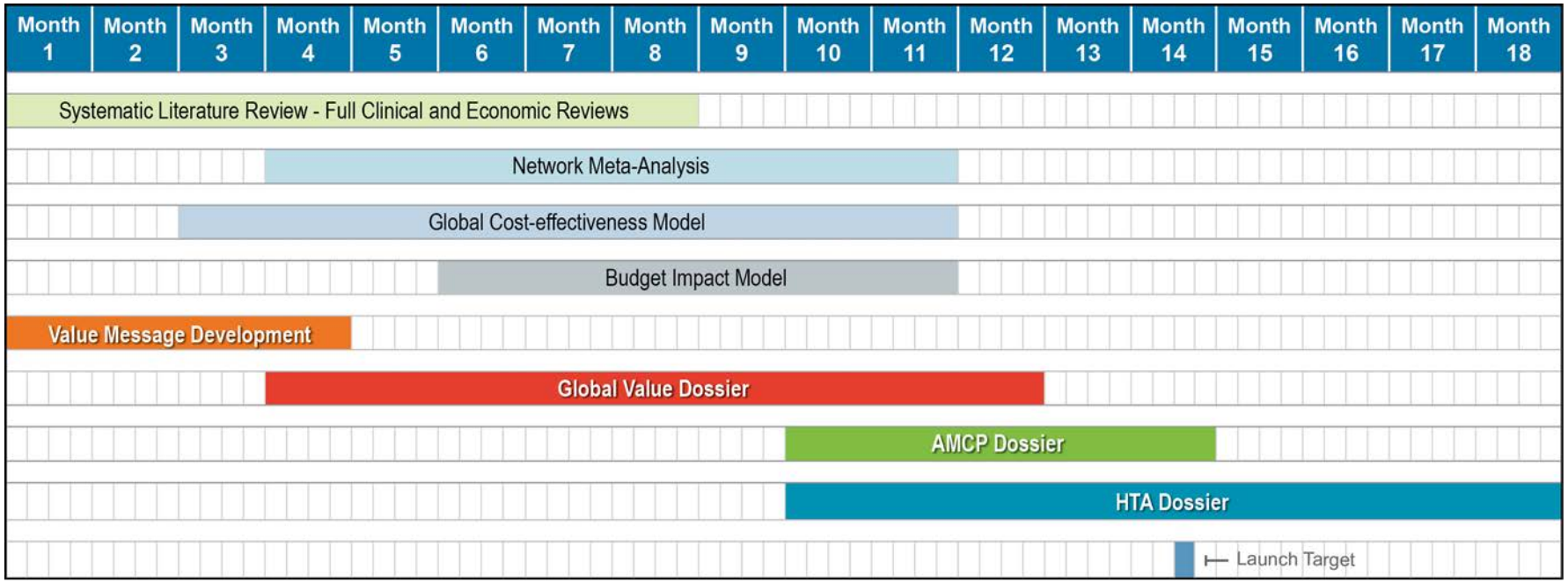


Develop in Sections as Data Become Available

- Disease burden sections can be developed early
  - Peer-reviewed literature (based on structured literature)
  - Authoritative national/international sources
  - Build the unmet need, economic and humanistic burden of disease, and competitor gap analysis
  - Include information from key markets, others will need to identify local data
- Product value will be based primarily on outcomes of pivotal studies
  - Product labels (FDA and EMA) will be important to include in the Product Description Section when they are available

Supplemental Evidence Generation and Local Requirements Must Be Factored Into Timeline



Example only

Dossier updates

- It is important for the end-users that dossiers and associated materials are up-to-date

Plan for updates, particularly around any major anticipated changes
• Label wording
• Publication of new data - New burden of disease studies - New product data(clinical studies, RWE, economic analyses)
• Changing competitor landscape - Adding new comparators - Amending unmet needs to reflect the new landscape

Process for updates
• Update literature search
• Provide internal publications in development / recently published
• Liaise with your team for additional evidence that should be included
• Consider the approval/sign-off required: - Has the internal team changed? - Does the new evidence have wider implications for other dossier sections? - Does only new information need to be approved?

Coordination of a GVD with Local Submissions

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Use of the GVD is Likely to Vary Between Markets

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Larger markets with specific HTA requirements

- GVD provides the most value to:
  - Give affiliates a robust value story and strategy to guide their local discussions
  - Bring the local team up to speed on a new disease or product
  - Provide background information on the disease and product to include in dossiers
  - Identify availability of key clinical data, although CSR used as the source
- GVD should be available when local markets start planning their submission, at launch is too late

Smaller markets with more flexible HTA requirements

- GVD provides the most value to:
  - Provide background information on the disease and product to include in dossiers
  - Provide clinical data in support of the product
  - Provide example presentations of economic data for base case market
  - Will still need to tailor country-specific aspects
- Likely to copy or translate GVD text directly to populate dossier template

Global GVD Providing for Local Needs

What the Global GVD brings
• Value story and messages
• Unmet needs
• Burden of disease
• Current treatment options
• Product description
• Key clinical trial results
• Comparative efficacy (head-to-head)
• Systematic literature reviews
• Network meta-analyses
• Standard and disease-specific PROs

Need for country-specific data
• Epidemiology
• Standard of care – important for clinical and economic considerations in terms of comparator / reference drugs
• Treatment guidelines
• Economic burden
• SLRs and NMAs conducted to country standards
• Adaptation of economic model(s)

Key Success Factors to Maximize the Use of the GVD in Local HTA Submissions

- Seek input from key affiliates
- Evidence feeding into the GVD should adhere to country-specific HTA guidelines
- Highlight clearly the country-specific information
- Highlight where further local information needs to be gathered
- Provide links to relevant associated information stored on your intranet and that will be relevant for local submissions

Example: United Kingdom

- Specific requirements for different regions, and for Ireland

Considerations

- In England, NICE aims to issue guidance around the time of marketing authorisation
  - Decision on timing of submission to other HTA groups varies
  - GVD must be available early to be used as basis of NICE submission
- NICE template has minimal scope for setting the scene or telling a story so submission writers may need to be creative with the burden of disease and unmet need elements of the GVD
- Clinical data may be taken from GVD and adapted to NICE template
- Specific NICE requirements for systematic literature review, network meta-analysis, cost-effectiveness and budget impact models
  - If England not used as base case in GVD, likely that local affiliate will need to start these early

NICE = National Institute of Health and Care Excellence

Example: the US, AMCP format for Formulary Submissions

- Intended for use by manufacturers responding to requests to support reimbursement or formulary placement for a new product or indication
  - Version 4.0 launched in April 2016 (www.amcp.org/FormatV4)
- Are areas of overlap between a typical GVD and the AMCP format
  - Section 1: Executive Summary
  - Section 2: Product Information and Disease Description
  - Section 3: Clinical Evidence
  - Section 4: Economic Value and Modeling Report
  - Section 5: Additional Supporting evidence

Considerations
• General information such as disease description, guidelines and HTA information can be taken from GVD • Specific format requirements (e.g., clinical trial summaries and evidence tables) often require additional information/updates beyond the GVD content • US-specific elements include: label, epidemiology, burden and economic value • Consult with AMCP dossier team to determine strategy for US submission and best supporting evidence

AMCP = Academy of Managed Care Pharmacy

Web-based GVD Presentation Platforms

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(Europe)

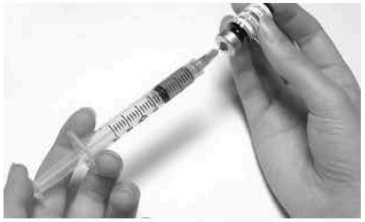
Web-based Global Value Dossier Definition

A presentation tool that allows for enhanced user navigation and customisation versus standard documents and slides

Annatar®

Annatar is a monoclonal antibody (a man-made version of an immune system protein) that targets EGFR. When combined with chemotherapy, Annatar is an effective first-line treatment in people with advanced squamous cell NSCLC.

Key Value Messages



Clinical Value

Annatar has proven efficacy and safety established in the ANNA clinical trial program.

Humanistic Value

Annatar decreased disease-related symptoms, including cough, shortness of breath, and chest pain, in 80% of patients.

Economic Value

Annatar is cost-effective compared with standard of care in the treatment of NSCLC based on a US economic model.

Clinical Value

Annatar® has proven efficacy and safety established in the ANNA clinical trial program

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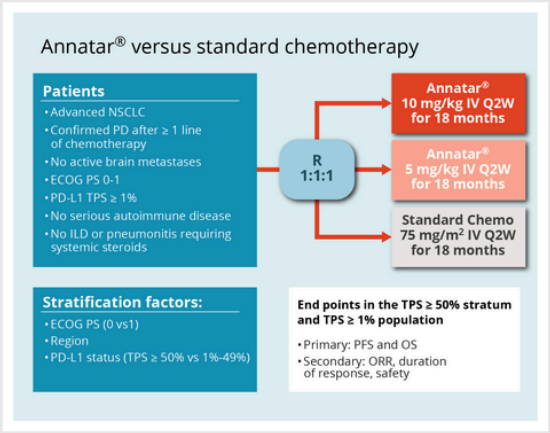

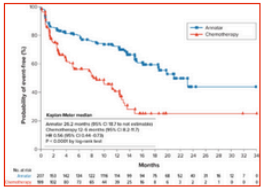

Annatar has a favourable tolerability profile with similar rates of adverse events to standard chemotherapy

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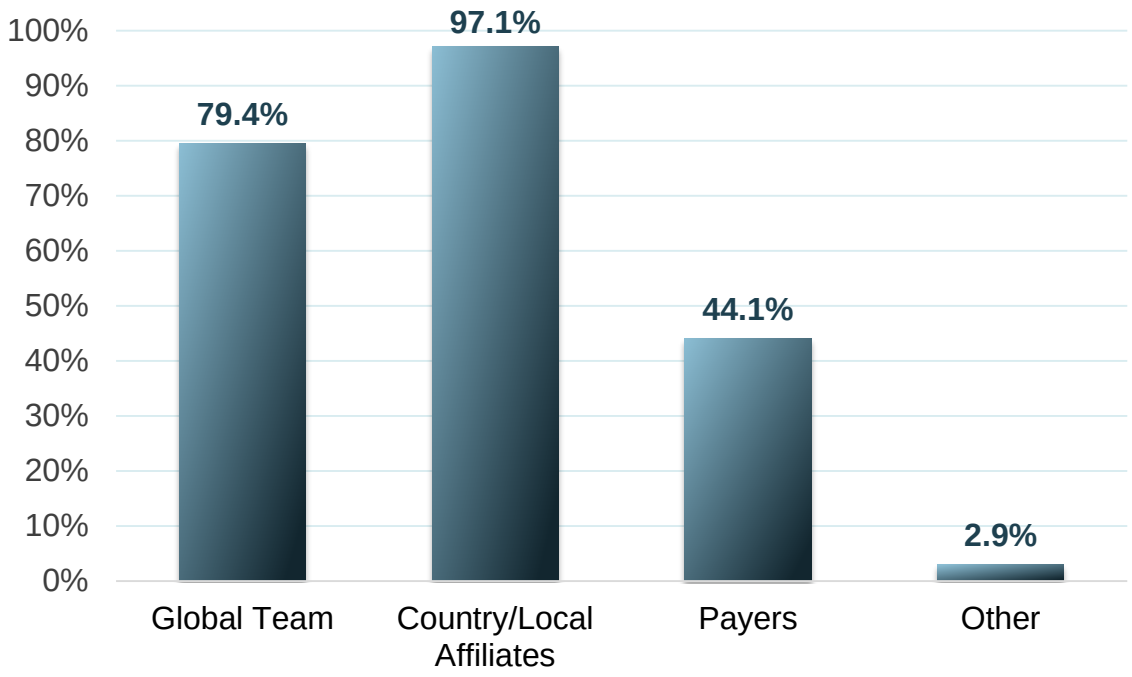
Annatar significantly improves overall survival in patients with advanced NSCLC compared with standard care

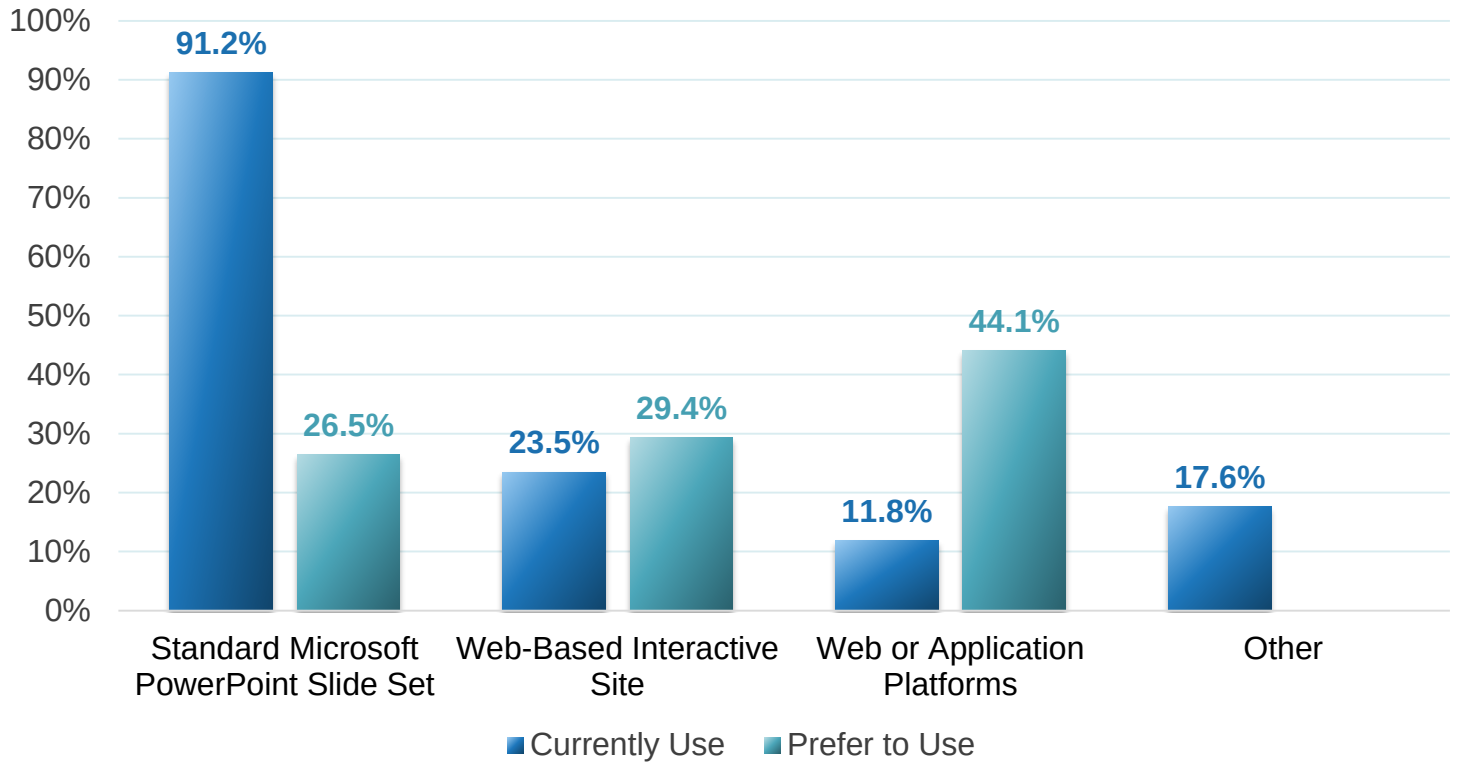
Audiences for GVDs - *On-line survey*

- Majority of respondents are using GVDs with **country/local affiliates** (n=33, 97.1%) and the **global team** (n=27, 79.4%)
- 44.1% use GVDs with **payers**



Current Practices and Preferences

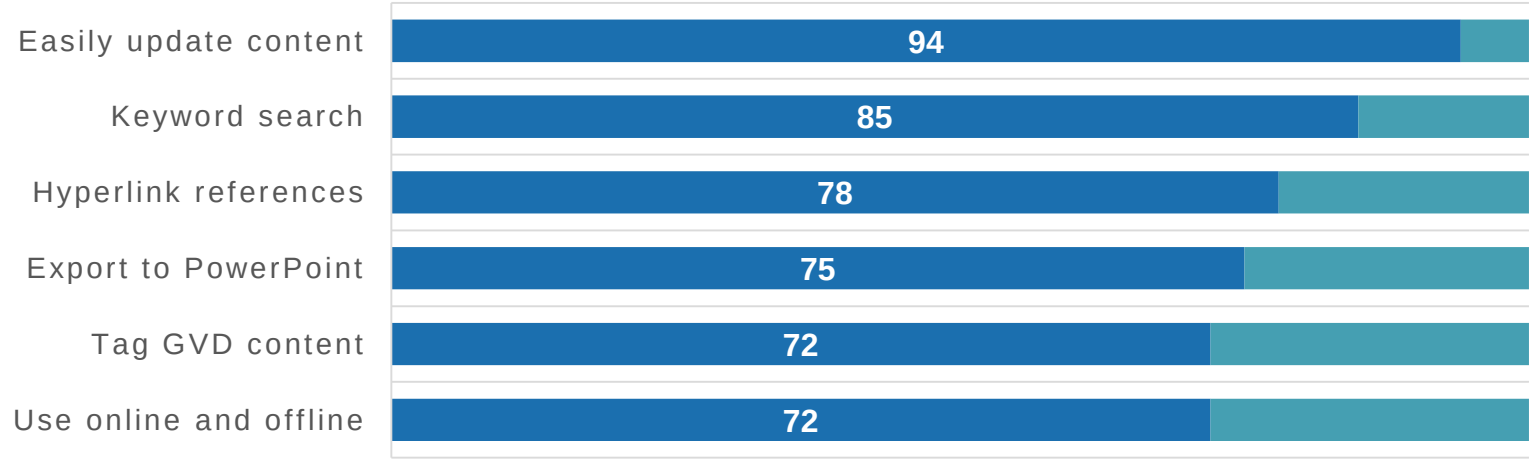
- Despite **almost all** (91.2%) respondents **currently using** a Microsoft **PowerPoint** slide set format for their GVDs, it is **not preferred** (26.5%) compared to **web-based formats** (73.5% prefer)
  - Represents a **gap** between the status quo and client preferences



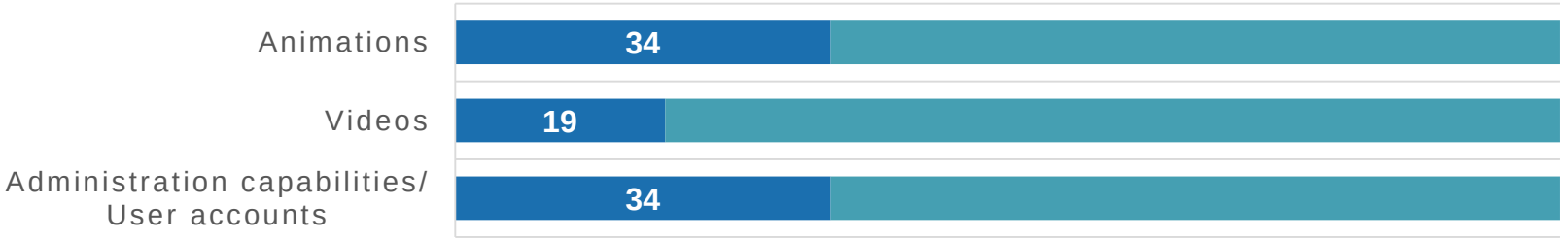
Desired GVD Platform Features

- 13 of 20 suggested features were endorsed as being needed by >50% of survey respondents.

Most needed:



Least needed:



Best Practices for GVDs

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Best Practices for GVDs

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Plan ahead
~9-12 months prior to launch

Know your internal stakeholders

Establish a timeline and regular communications

Formalize GVD Structure

Best Practices for GVDs *(cont.)*

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Consider the web-based platform

Establish editorial, content and QC review processes

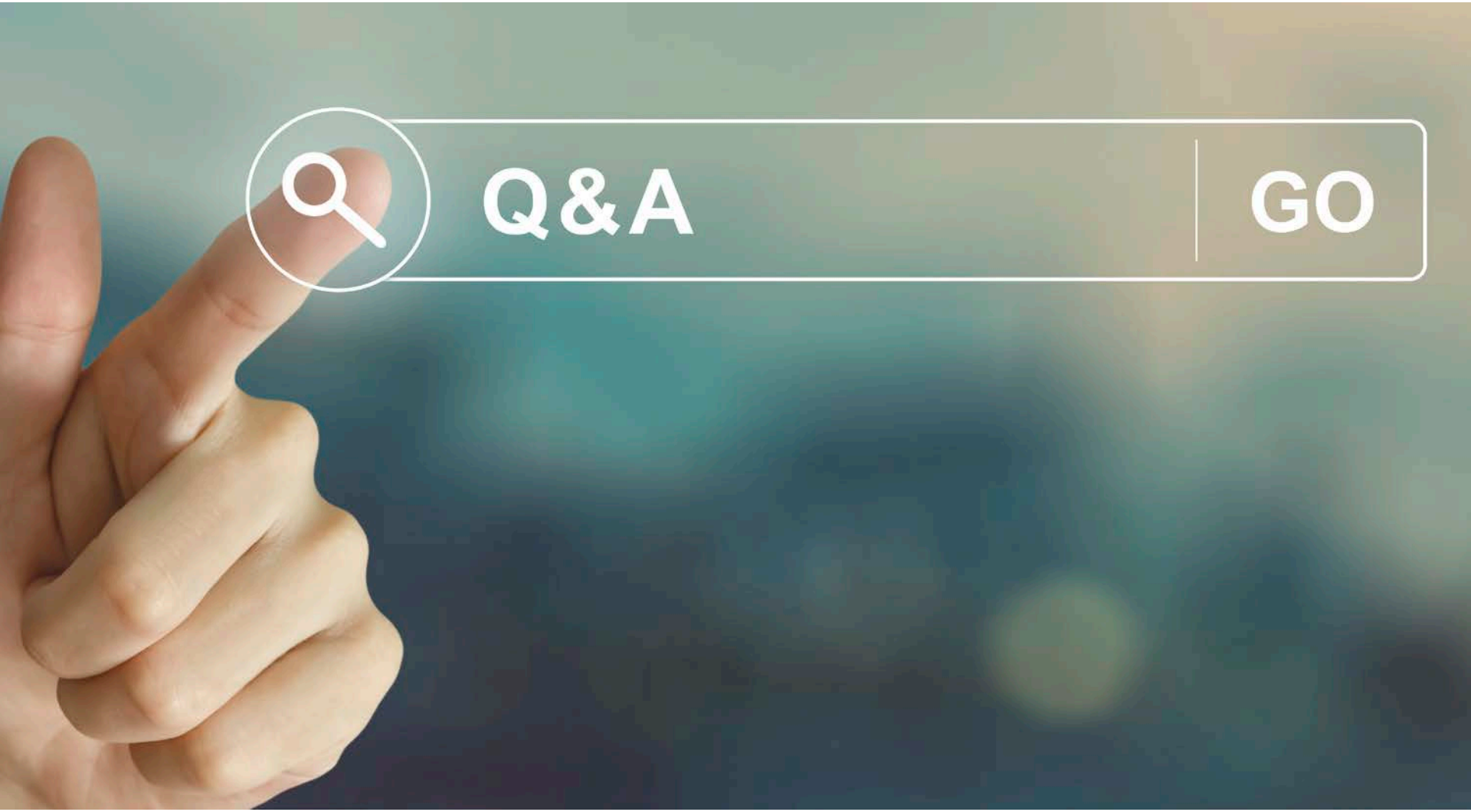
Select best evidence

Provide consolidated comments on drafts to dossier writers

Best Practices for GVDs *(cont.)*

Plan for rollout and training for country affiliates

Develop a plan for periodically updating the dossier



Generating knowledge and providing greater understanding so that you - and those who regulate, pay for, prescribe, and use your products - can make better decisions.

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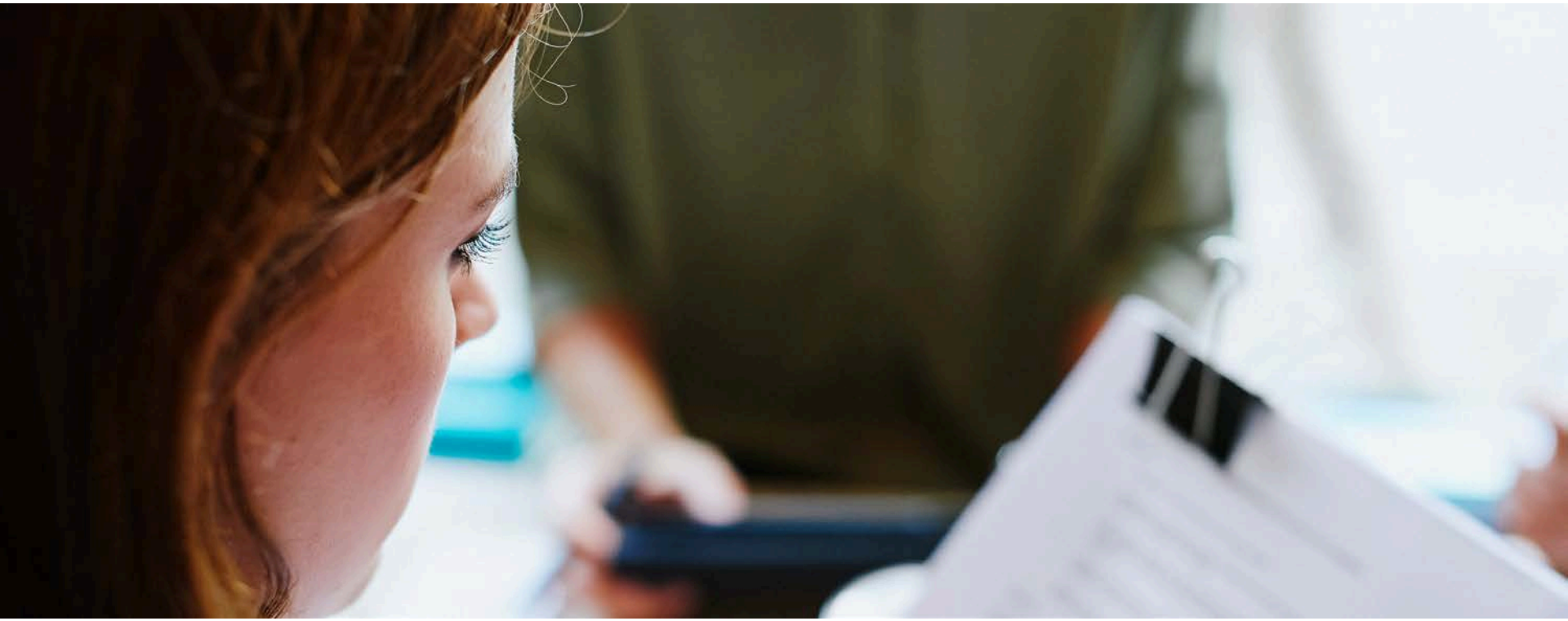

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