MAPS Medical® Affairs Professional Society

Welcome!

Optimizing Clinical Development Plans Through Earlier Integration of Medical Affairs

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- The following faculty and planning members do disclose financial relationships – *Klein, Yee, and Elassal*

Meeting Overview

#	Section Topic	Est. Time
1	*Benefits of Earlier Integration of Medical Affairs to Support Clinical Development*	~25 min
2	*Challenges for Greater Medical Affairs Involvement in Early Product Life Cycle Initiatives*	~10 min
3	*Opportunities to Drive Growth of Medical Affairs Earlier in Clinical Development*	~20 min
4	*Conclusion / Q&A*	~5 min

MA makes a significant impact throughout the product life cycle, however, involvement in early pre-launch phases has historically been more limited

Product Life Cycle	Historical Role of MA*
Discovery/ Preclinical	Lower
Phase I	Lower
Phase II	Moderate
Phase III	High
Registration and Launch	High
Post Launch	High

*Despite the **growing need for** Medical Affairs initiatives throughout the product life cycle, there is a **gap** in leveraging Medical Affairs in an **early pre-launch environment***

***However, inclusion of Medical Affairs** in this time period can **inform key decisions** in R&D / clinical development, leveraging **medical insights** from key stakeholders*

Abbreviations: MA – Medical Affairs, R&D – Research and Development, HCP – Healthcare Professional. **Sources:** *In the Thick of it: Medical Affairs, Strategic Partner to Other Functions

Section 1: *Benefits of Earlier Integration of Medical Affairs to Support Clinical Development*

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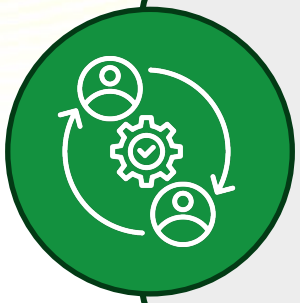

What factors have signaled the need for greater Medical Affairs involvement earlier in R&D / clinical development initiatives?

Please submit your responses to the question and responses will begin to populate on the screen

Abbreviations: R&D – Research and Development.

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What factors have signaled the need for greater Medical Affairs involvement earlier in R&D / clinical development initiatives?

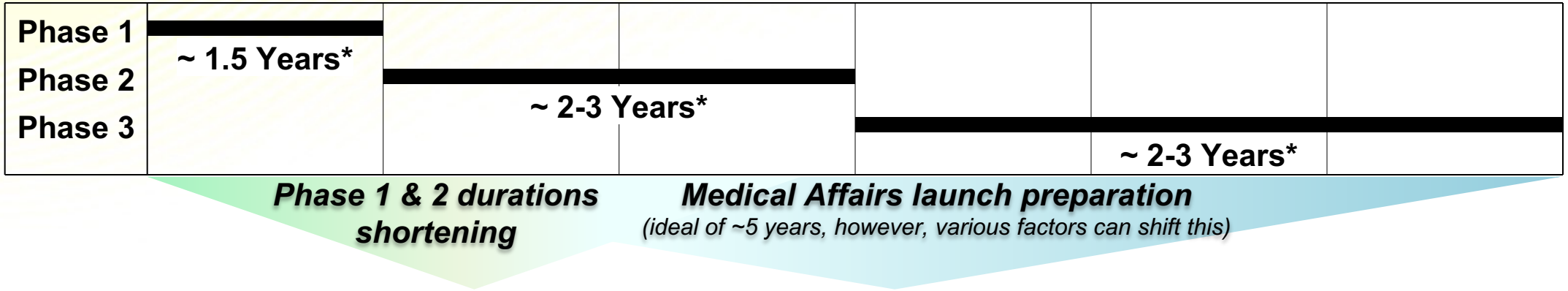
There are several key changes in the pharmaceutical landscape driving the need for Medical Affairs involvement earlier in the product life cycle

Key Drivers Signaling the Need for Greater MA Involvement in R&D

Increased Specialized Care	• Complex innovations and individualization of treatment (e.g., gene therapy, biomarkers, rare diseases etc.)
Health Equity Regulations for Clinical Trials	• Legislation requiring demographic and geographic diversity in clinical trial patient populations (i.e., FDORA diversity provisions)
Opportunity for RWE Utilization to Inform Label	• Increased FDA willingness to accept RWE to support regulatory approvals (i.e., FDA labels / indications)
Integration of Digital Health Tools	• Emergence of novel digital tools creates opportunities for use in clinical trials and RWE (e.g., digital biomarker tools, telehealth, wearables, predictive AI tools etc.)
Increased Evidence Burden	• Increasingly competitive product landscapes and HTA requirements drive greater need for robust evidence collection • Increased need to balance HEOR selection of PROs measures with needs of key stakeholders (e.g., regulatory bodies, HTA, patients, payers etc.)

Abbreviations: MA – Medical Affairs, R&D – Research and Development, RWE – Real World Evidence, AI – Artificial Intelligence, HTA – Health Technology Assessment, PROs – Patient Reported Outcomes .

Shorter durations of Phase 1 & 2, specifically in oncology and rare diseases, warrant earlier integration of MA given launch preparation time required



The duration of Phase 1 and Phase 2 clinical trials is shortening for a variety of reasons:

- **Expedited pathways**
- Clinical program **design strategies** *(e.g., utilization of predictive biomarkers, RWE, single arm trials, combined phases, AI integration etc.)*
- Generally **shorter durations** for **biologics**, **orphan drugs**, and **specialty drugs**

*~70-80% of new launches in recent years receive an expedited pathway**

*~The majority of new drug launches are specialty medicines**

The earlier integration of Medical Affairs is crucial in ensuring adequate time to prepare for and optimize product launches even in the context of shortening clinical trial durations

Abbreviations: MA – Medical Affairs, RWE – Real World Evidence, AI – Artificial Intelligence. ***Sources**: Citeline Trialtrove Clinical Trial Durations by Phase (March 28, 2014 – March 28, 2024), New Drugs Approved in 2021, A Review of Approaches for the Management of Specialty Pharmaceuticals in the United States

While ideal launch preparation time is ~5 years, various factors exist that drive involvement of Medical Affairs earlier versus later in the product life cycle

Situational Drivers Impacting Timing of Medical Affairs Involvement		Scenario Driving Earlier MA Involvement	Scenario Driving Traditional MA Involvement Timeline
External Market Factors	***Disease Awareness***	**Low**	**High**
	Reimbursement Pathways	**No Precedence**	**Established**
	Existing Research *(i.e., Natural History Study)*	**Limited**	**Robust**
	Mechanism of Action	**Novel** *(i.e., education required)*	**Commercialized**
	Patient Community Engagement and PAG Status	**Needs to be Developed**	**Patients Highly Engaged**
Organizational Factors	***Identification / Relationships with Appropriate Experts*** *(e.g., CoEs, KOLs, etc.)*	**Limited**	**Established**
	Status of Medical Affairs Infrastructure *(e.g., CRM, Med Info call center etc.)*	**Needs to be built** *(i.e., smaller biotech company)*	**Established** *(i.e., larger pharmaceutical company)*

Abbreviations: CRM – Customer Relationship Management, MoA – Mechanism of Action, CoE – Center of Excellence, PAG – Patient Advocacy Group

Section 1: *Benefits of Earlier Integration of Medical Affairs to Support Clinical Development*

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What role does Medical Affairs play in R&D / clinical development?

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Abbreviations: R&D – Research and Development.

What role does Medical Affairs play in R&D / clinical development?

There is opportunity for Medical Affairs to be utilized in a series of critical areas across the product life cycle, particularly in an early pre-launch context

Need for Higher Involvement — Lower Need for Involvement

Key Initiatives	Life Cycle Phase: Discovery / Preclinical	Pre-Launch (Phase I, II, III)	Registration & Launch	Post-Launch
Key Stakeholder Identification & Engagement				
Medical Insights Gathering *(e.g., PROs measures, TPP development etc.)*				
Patient Journey				
Scientific Narrative Development				
Developing RWE				
Integrating Complimentary Digital Tools				
Launch Preparation				

Abbreviations: RWE – Real World Evidence, TPP – Target Product Profile.

Medical insights gathering is a crucial role in discovery and preclinical phases, driven by efforts of Medical Affairs

Key Stakeholder Identification & Engagement
(e.g., providers, patients, payers, policymakers etc.)

Medical Insights
and development of…

The Patient Journey

Disease Landscape & Situational Analysis
(e.g., unmet need, care pathways, SoC, evolving guidelines, emerging competitive landscape overview, natural history / BoD etc.)

Expanded Access Program
(i.e., compassionate use decisions)

Target Product Profiles *(TPPs)*

Clinical Trials
(e.g., appropriate comparators, relevant endpoints such as PROs etc.)

Lifecycle Management & ISTs
(i.e., new indication identification)

Additional details on following slides

Medical Affairs medical insights gathering can be leveraged to optimize organizational-level decision making prior to significant investment in a product

Abbreviations: MA – Medical Affairs, SOC – Standard of Care, BoD – Burden of Disease.

Medical Affairs plays a critical role in informing development of clinical trials that are meaningful to key stakeholders

Development and Support of Clinical Trials includes…

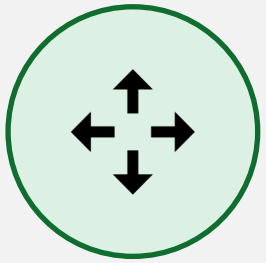
Trial Design Decisions			*Enrollment*	*Facilitation*
Appropriate Comparators	**Clinically Relevant Diagnostic Tools and Scores**	**Meaningful Endpoints** *(e.g., selection of PROs, value for regulatory approval vs. HTA/Reimbursement etc.)*	**Trial Site & Population Diversity** *(i.e., managing PI relationships to facilitate diverse patient recruitment)*	**Patient Monitoring Through Digital Technology**

Medical Affairs can inform decisions on clinical trial design and enrollment to prepare for medical adoption of a new therapeutic

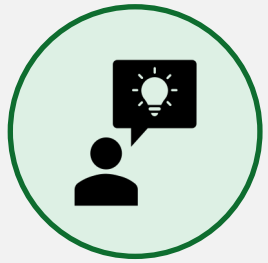
Abbreviations: HTA – Health Technology Assessment, PI – Principal Investigator.

Medical Affairs engagement with key stakeholders is critical to inform the initial TPP and adjustments that may be required over time

Support in **TPP development** involves…



Ensuring Differentiation versus SoC and Emerging Competitors



Gaining Key Stakeholder Perspectives to Ensure Relevance *(e.g., meaningful endpoints, preferred RoA, indications, etc.)*

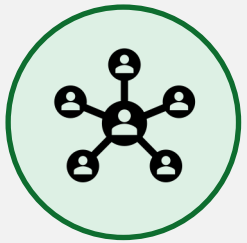
Medical Affairs knowledge of landscape and connections with key stakeholders provide a critical channel for informed understanding on relevant elements to drive successful product launch

Abbreviations: TPP – Target Product Profile, SoC – Standard of Care, RoA – Route of Administration, MA – Medical Affairs, CDP - Comprehensive Drug Development Plan

Medical Affairs plays an important role in developing and understanding the patient journey

Medical Affairs can enhance the **Patient Journey** by…

Partnering with Patient Associations



Developing Patient-Centric Services / Shaping Support Programs

Identifying Meaningful Health Outcomes Across Stakeholders
(e.g., input on trials, ensuring PROs are feasible for patients, ensuring value to health insurers and HTA organizations)

Experiences with patients in the field allows for Medical Affairs personnel to foster a deep understanding of the patient journey and identify strategies to optimize it

Abbreviations: MA – Medical Affairs, HTA – Health Technology Assessment

Development of RWE is increasingly valuable to inform regulatory and payer decision making, driven by responsibilities of Medical Affairs

Medical Affairs identifies **evidence gaps to address** in order to **demonstrate value and differentiation**, including…

Developing a Relevant Scientific Narrative

Creating an Integrated Evidence Plan *(IEP) (across R&D, MA, HEOR, commercial)*

Ensuring RWE plan fulfills both key stakeholder & organizational needs *(key stakeholders: HCPs, patients, payers, policymakers)*

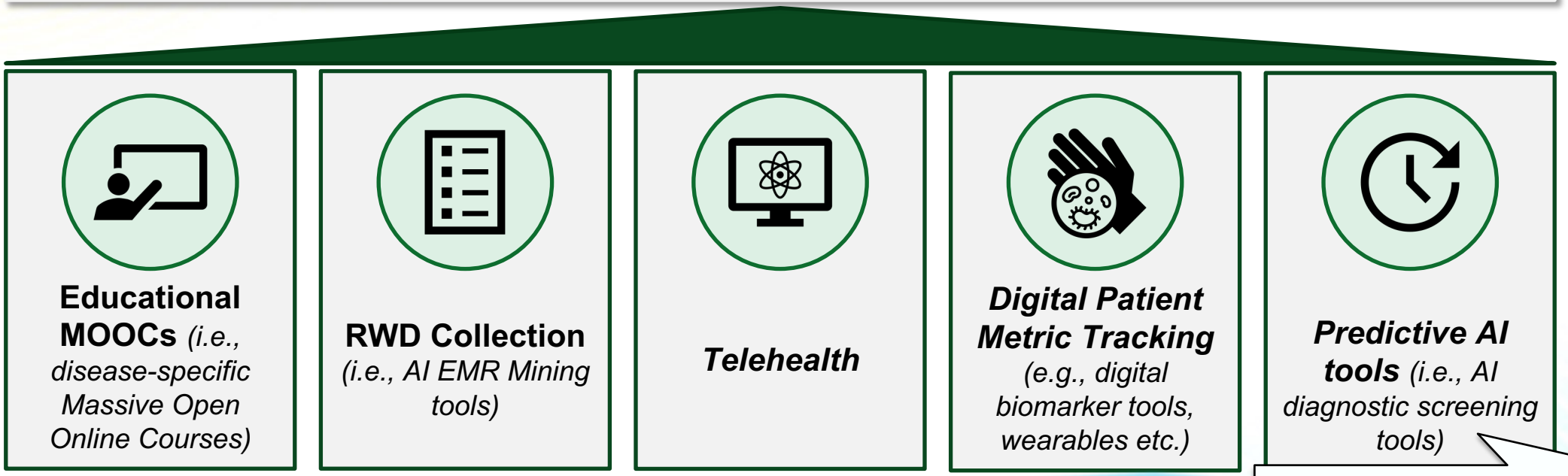
Ensuring that RCT data and RWE data are complimentary

- *RWE development is key to ensuring robust data collection that can be utilized in time for regulatory and payer decision-making processes*
- *Increasing sources of data exist (i.e., healthcare claims data, EHR, biomarker data, genomics data, and unstructured data like mobile health solutions, wearables and social media) and AI allows analysis of unstructured data not previously possible*

Abbreviations: RWE - Real World Evidence, IEP – Integrated Evidence Plan, HPC – Healthcare Professional, RCT – Randomized Clinical Trial, HEOR - Health Economics and Outcomes Research.

Integration of digital tools is a critical area for Medical Affairs to drive success of pre-launch processes

Integration of complimentary digital tools in the form of…



- *44% of life sciences professionals use / experiment with AI with 94% expecting to increase use within the next two years**
- *By 2025, 13% of oncologists will be from the baby boomer generation, with 87% from younger generations, shifting a general preference towards multichannel and remote engagement.**

Note: *Utilization of innovative AI tools requires medical* ***insights gathering*** *on* ***institutional experience with AI*** *implementation and insights into the* ***presence / influence of AI governing bodies*** *within institutions*

Abbreviations: MOOCs - Massive Open Online Courses, RWE - Real World Evidence, AI - Artificial Intelligence, EMR – Electronic Medical Record. ***Source**: Pharma Medical Affairs: A Blueprint for Future.

Section 2: *Challenges for Greater Medical Affairs Involvement in Early Product Life Cycle Initiatives*

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What challenges preclude greater involvement of Medical Affairs in early product life cycle initiatives?

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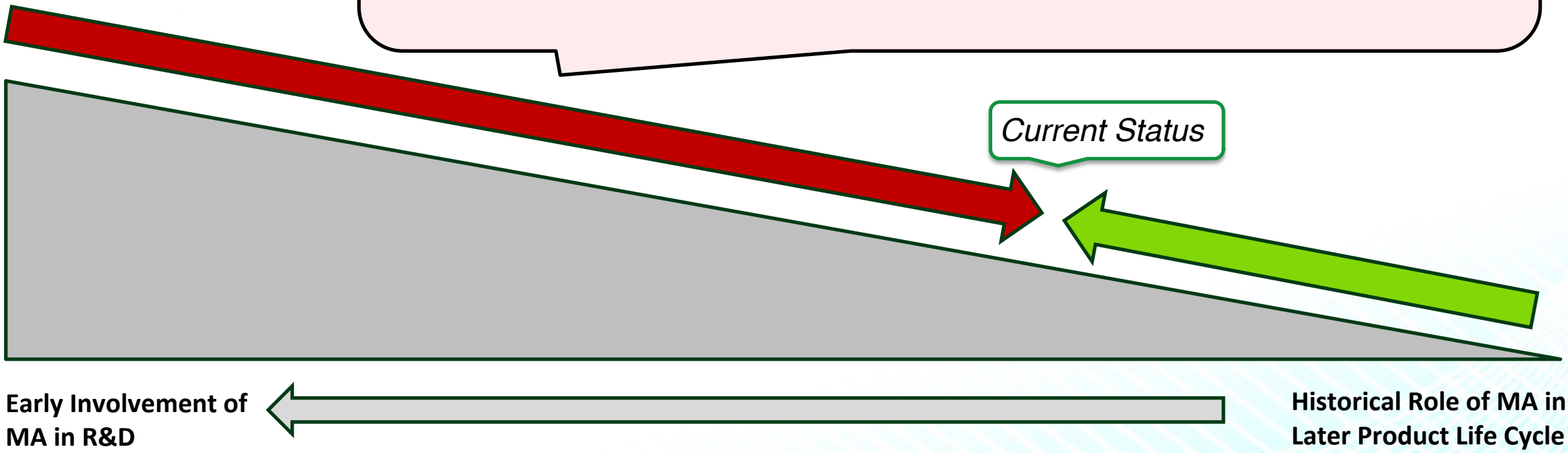
Abbreviation: MA – Medical Affairs.

What challenges preclude greater involvement of Medical Affairs in early product life cycle initiatives?

Institutional budget limitations and the ability to quantify the value preclude earlier involvement of Medical Affairs

Key Challenges to Early Involvement of Medical Affairs:

- Institutional budgets limitations
- Difficulty capturing metrics to quantify the success of MA initiatives



Abbreviations: MA – Medical Affairs, R&D – Research and Development.

Section 3: *Opportunities to Drive Growth of Medical Affairs Earlier in R&D / Clinical Development*

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What can be done to support earlier involvement of Medical Affairs in R&D / Clinical Development?

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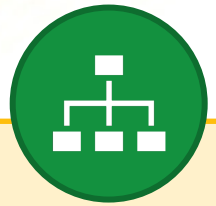
Abbreviation: MA – Medical Affairs.

What can be done to support earlier involvement of Medical Affairs in R&D / Clinical Development?

A variety of opportunities exist to drive towards greater involvement of Medical Affairs in the product life cycle, notably R&D / clinical development

Communicating the Value of Medical Affairs

- **There needs to be a Medical Affairs value narrative that both defines the role and communicates the impact that early involvement of Medical Affairs has** (e.g., RWE collection expediting regulatory approvals, stakeholder relationships facilitating guideline integration, patient insights driving towards more patient-centric care, establishment of measurable KPIs etc.)
- **The Medical Affairs value narrative can be further enhanced though the encouragement of skills development**
  - Robust education on skills (i.e., data analytics) to match the changing landscape (i.e., implementation of novel digital tools) is crucial in maximizing the value of a Medical Affairs role



Cross-Functional Governance, Processes, and Structure Considerations

- **After communicating the value of Medical Affairs, it is crucial to create clear structure around R&D / clinical development and Medical Affairs.** This includes determining cross-functional governance and having clear processes / structures in place to drive towards successful implementation of the role (e.g., clear involvement timelines, specific deliverable plans etc.)
- **In order to solidify clear structure of the role, establishing partnerships with key stakeholders is crucial in ensuring the presence of a champion / advocate**

Measuring the Impact of Medical Affairs

- **Alignment upon key metrics to track the impact of Medical Affairs on organizational success is crucial to the earlier involvement of Medical Affairs** (e.g., metrics tracking diversity in clinical trial sites and participants, metrics tracking approval timelines with RWE utilization, etc.)

Abbreviation: RWE – Real World Evidence, MA – Medical Affairs, KPI – Key Performance Indicator.

While MA is underutilized in R&D / clinical development due to key challenges, opportunities exist to educate on need for an expanded role

Historical MA Involvement → **Current Status** → **Barriers to Growth of MA** → **Desired Future Status**

Given **shifts in the pharmaceutical landscape**, it is more important than ever to leverage Medical Affairs in **R&D / clinical development** phases to drive towards greater organizational success

Limited involvement of Medical Affairs in a pre-launch setting is driven by institutional **budget limitations** and **difficulty capturing metrics** to quantify the success of Medical Affairs initiatives

Communicating the value and **measuring the impact** of Medical Affairs are critical to drive greater adoption of Medical Affairs across the product lifecycle journey

Abbreviation: MA – Medical Affairs.

Q&A / Conclusion

Thank you for your time today!

For Discussion: Are there any final questions / comments from the group?