EVIDENCE GENERATION

Strategic Integrated Evidence Generation Planning: Company and Non-Company Sponsored Research

Guidance Document

EVIDENCE GENERATION

Acknowledgements

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Those named above contributed to Strategic Integrated Evidence Generation Planning Guidance Document in their personal capacity. The views expressed and guidance provided in this document and associated presentation are their own and do not necessarily represent the views of their named employers.

Using this guidance document

This resource is intended to provide Medical Affairs teams the rationale for strategic evidence generation planning, as well as tips and tools to support with plan development, and practical guidance for investigator-initiated studies

- 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

Questions addressed in this resource

- Why is strategic evidence generation planning important?
- How can an adaptive strategic evidence generation plan be developed?
- How can we ensure our evidence is meaningful for our stakeholders?
- How should evidence gaps be prioritized?
- How can we successfully implement investigator-initiated studies?
- From outputs to impact: How can the value of the evidence be measured?

Why is strategic evidence generation planning important?

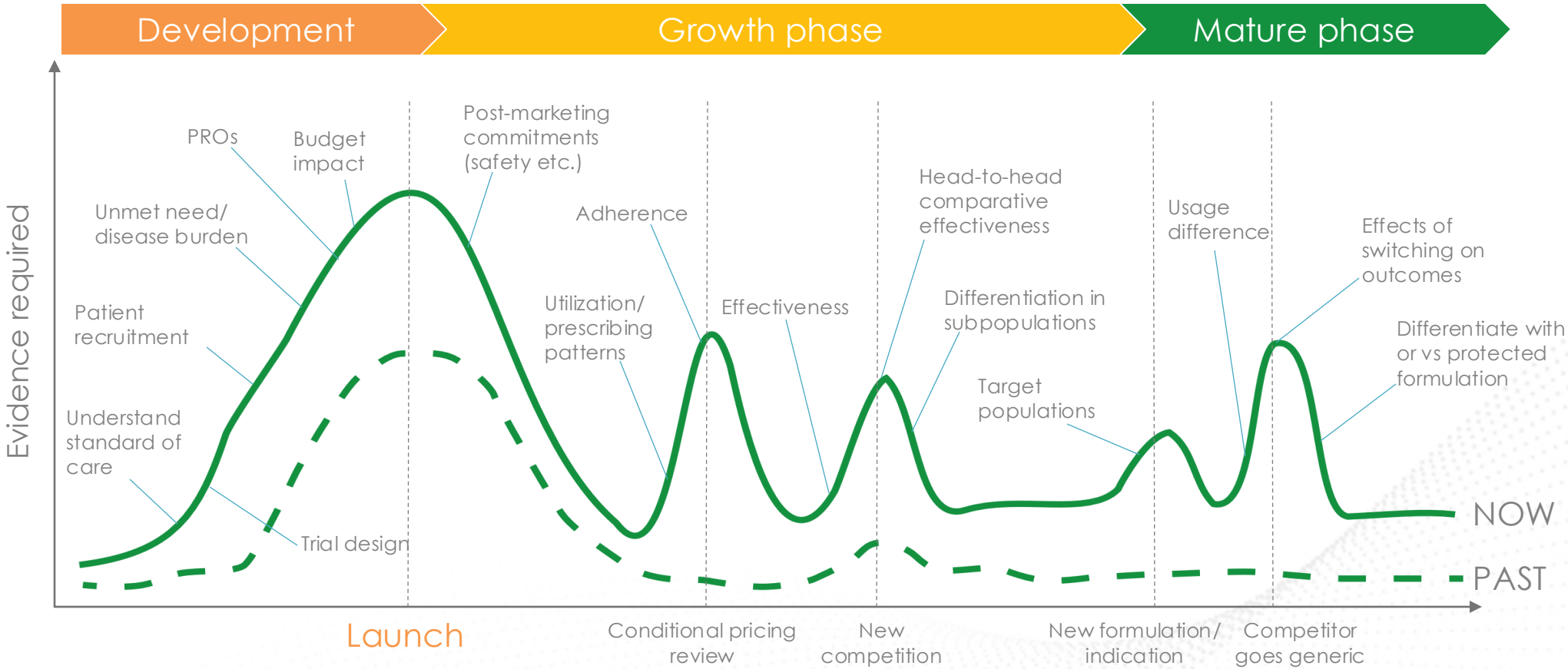
Having a future-looking, strategic approach to planning ensures meaningful evidence is available at the right time

Generating relevant and compelling evidence can be a lengthy and costly process, so it is essential that requirements are identified as early as possible and prioritized based on need and impact

- While the focus is commonly on approval and launch, changes in needs are to be expected, based on increasing understanding of the product, as well as competitive and environmental changes
- The likely expectations of key decision-makers for supporting evidence can be anticipated, based on team experience and ongoing insights capture
- While many needs can be predicted, plans should also be flexible and adaptable, and reviewed regularly to accommodate new expectations in a timely fashion

Ideally, planning should start ~3 years before data are expected to be needed

Evidence planning should consider the entire product journey, and reflect evolving stakeholder needs throughout its lifecycle



Adapted from EMA Adaptive Pathways Pilot Presentation at STAMP;
http://www.ema.europa.eu/docs/en_GB/document_library/Presentation/2015/11/WC500196727.pdf

Planning ensures evidence is available to each stakeholder when it is needed to inform decision making and improve patient outcomes

Development of evidence generation plans should reflect diverse needs across stakeholders

Patients
Understanding how treatments can enhance quality of life as part of shared decision-making

Policymakers
Better understanding of patient's unmet need can help with policy decision-making

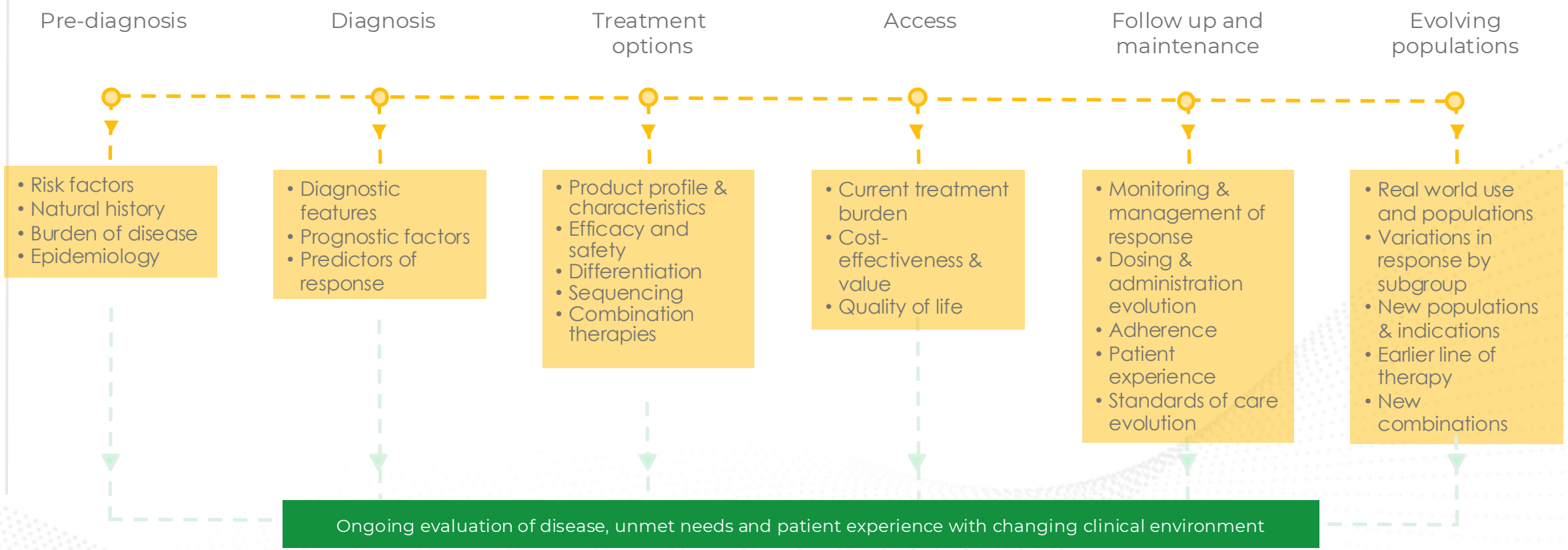
Payers
Varying regional and local requirements need to be considered in order to support successful reimbursement and access

Industry
Strategic evidence planning needed to support differentiated value propositions throughout the product lifecycle

HCPs
Increasing variety of treatment options is furthering the need for evidence to support treatment decision-making in order to optimize patient outcomes

Regulators
The rise of the expedited approval process, fast track and priority reviews is requiring further consideration of evidence beyond RCT; requirement for increased levels of evidence as products enter the market with lower evidence levels

A holistic view is needed to ensure that planning activities reflect the widest needs of stakeholders



Adapted from Integrated evidence generation: A paradigm shift in biopharma; McKinsey report, 2021

Effective planning allows goals to be achieved more quickly and maximizes the value of the evidence across audiences

Audience-centric

Plans should be insight-based and reflect the information needs of the audience, to ensure that evidence is generated that can make a real difference to clinical practice or patient outcomes, rather than being of scientific interest only

Strategically aligned

The evidence generation plan should be an integral part of the success of medical, market access and commercial plans, with prioritization of activities that optimizes timing and achievement of objectives – it should not be seen as a workstream independent of the overall portfolio plan

Transparent communications

The transparent communication and delivery of a plan that addresses both internal and external priorities helps to build confidence in the company's products and the wider organization, and increases differentiation from competitors

A fully integrated approach can yield evidence of greater value across all stakeholders

Regulators, payers, healthcare professionals, patients and care givers require ever-more information in order to inform decision making and optimize the experience of and outcomes with products, as well as to rationalize their use

An integrated evidence plan (IEP) creates a commonality of approach across the various cross-functional departments of an organization, ensuring that all perspectives and needs are considered as part of the planning process

Benefits of an integrated approach

- ✓ Strategic alignment across stakeholders and enhanced collaborations
- ✓ Avoids 'siloed thinking' and data gaps being missed
- ✓ Efficient use of resources through synergies built between individual initiatives
- ✓ Focuses effort on activities that will have the greatest impact, and enables alignment on research that should be said no to
- ✓ Ensures that cross-functional needs are met, and equal access to evidence regardless of function, budget or market size

With an in-depth understanding of the needs and priorities across internal and external stakeholders, medical affairs are best placed to lead integrated evidence planning

- Clinical development
- Market access
- HEOR
- Patient engagement
- Regulatory
- Commercial
- External healthcare community

MEDICAL AFFAIRS

EVIDENCE GENERATION

How can an adaptive strategic evidence generation plan be developed?

A comprehensive understanding of key influencers' expectations and industry standards allows for more complete planning

- Much of the focus of core evidence generation is to support regulatory and launch milestones, with plans reflective of industry norms and expectations
- The likely expectations of key decision-makers in terms of supporting evidence can be anticipated, based on experience and standardised timelines, and plans should ensure relevant data will be available at the right time and in the right format

1

APPROVAL

e.g. effectiveness across diverse patient populations, outside of RCT

2

ACCESS

e.g. budget impact for formulary committees

3

ADOPTION

e.g. scheduled updates of clinical guidelines

Plans should be based on an initial assessment of established needs of key internal as well as external stakeholders, and anticipated future requirements, based on the evolving 'story' for the product; gaining cross-functional input is an essential part of the process

Flexibility in an evidence-generation plan is essential to maintain its relevance

- While many needs can be predicted, situations can change, sometimes rapidly, and plans should not be viewed as fixed and simply requiring implementation
- Beyond evolving external factors, ongoing tracking of the impact and value of newly-generated evidence may also highlight areas where a refinement in approach is needed, either in terms of the data itself or the format of dissemination
- Ongoing monitoring of community insights and changing clinical and environmental situations, e.g. changing pressures from policy makers, will allow identification of any new needs and required reprioritisation of activities
- Having a process to ensure a two-way channel of communication with potential external partners to identify new data sources or ideas for both company and non-company sponsored research is key to accelerating knowledge advancement
- The validity and relevance of plans should be reviewed on a regular basis, and as new insights from across internal and external stakeholders are received, to ensure they remain strategically aligned

The success of an evidence-generation plan is not the delivery itself, but in the outcomes it achieves

Plans should accommodate the changing need for evidence, based on increased experience and evolving internal strategies

Increased exposure to a therapy or device, as well as identification of new audiences or stakeholders, may further expand the need for information and support

NEW REQUIREMENTS

With evolving knowledge of classes of therapies and devices, and the diseases they are used in, additional questions or requirements regarding the safety and optimal use of products from regulators, and guideline and formulary committees, may require further data or wider evidence generation at a local, regional or global level

NEW PARTNERSHIPS

Extensions or establishment of new relationships, e.g., with independent registries and with patient groups, may lead to access to new real world data sets or opportunities to generate evidence, including investor-initiated studies and patient surveys

NEW NEEDS

As therapies become more established across primary stakeholders, there may be interest in broadening use or communications to other specialties or disciplines, for which more tailored evidence is needed to optimize their understanding or application of the product within a new setting

Adaptations to approved plans should be made in a timely fashion, with revisions communicated to internal and external stakeholders to manage expectations

Regular evaluation of plans in the context of the evolving external environment is crucial

COMPETITIVE LANDSCAPE

- New mechanism of action or therapy that targets a broader or more specific population
- Clinical trial of an established therapy/device in a novel population
- Adverse event in a therapy or device with a similar MOA
- Product withdrawal

STANDARDS & GUIDELINES

- New screening modalities and policy updates, e.g. newborn screening
- Planned updates to guidelines
- HTA assessments
- Updates to ICD codes

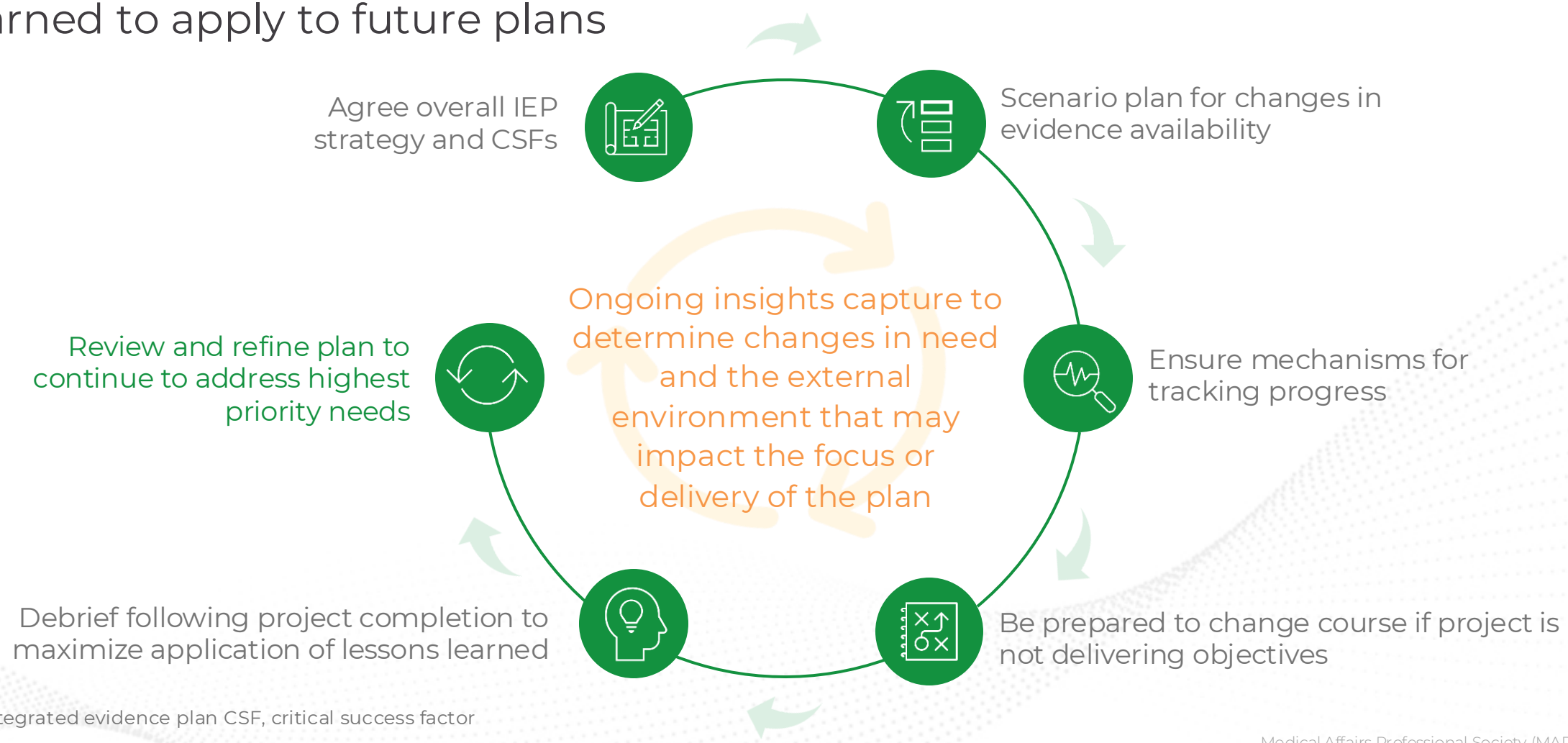
POLICY ENVIRONMENT

- Introduction or adaptation of federal policies
- New standards on pricing evidence
- Introduction of new gatekeeping by policy makers

INDEPENDENT RESEARCH OR VIEWS

- External expert generates new data that addresses a gap identified by the organization, or conflicts with established thinking
- New needs or concerns are raised by patients or healthcare professionals following more extensive experience of a product
- Changes to internal processes regarding external partnerships

IEPs should be built with adaptation in mind and enable mitigating strategies to be put in place when delays occur and lessons to be learned to apply to future plans



IEP; integrated evidence plan CSF, critical success factor

EVIDENCE GENERATION

How can we ensure our evidence is meaningful for our stakeholders?

Creating evidence of true value stems from asking the right questions

WHO: In order to develop an effective evidence generation plan, you need to have a comprehensive understanding of who the primary stakeholders are, as well as who else will value the information.

WHY: You should have a clear idea as to why the information will be of particular value to the target audience, and how it will affect their decisions or practice.

WHEN: Be as specific as possible regarding what particular information is needed and by when, to allow the most appropriate approach to be designed to ensure the evidence will be available at the right time

WHAT IF: Consider what the implications will be of not providing the identified evidence within the desired timeframe. Activities do not always go to plan, so it is important to you build an approach that can accommodate change.

Answering key questions: Who?

Internal colleagues

- Is there a need to evolve marketing messaging, e.g. a new competitive threat?
- Are teams struggling to respond effectively to queries encountered?
- Could success on a strategic imperative be made more likely with additional evidence?

Healthcare professionals

- Is there information that would help improve the use of the product and patient outcomes?
- Are there any gaps in terms of HCPs' understanding of patient needs and experience?
- Are there any within-label sub-populations that may benefit specifically from the product?
- Are there any new databases or registries that could provide potential new data sources?

Payers/regulators

- What information are payers likely to need to be convinced of the value of our product to practice?
- Are there specific local requirements to enable approval, access of adoption?

Patients/caregivers

- Is there evidence that could aid better compliance with treatment by patients and caregivers?
- Are patients views fully understood to enable shared decision making?

Answering key questions: Why?

Given the time, and financial and personnel investment required to generate evidence, it is of critical importance that it will be of significant clinical interest and/or patient benefit

- For internal teams, new data should enable your product to be differentiated from the competition to a greater extent, support teams to better communicate the benefits, or reinforce the commitment of the organisation to enhance understanding of a disease
- For healthcare professionals, valued evidence could be that which provides new insights that support better patient selection for a therapy, or sequencing or dose optimisation of treatment, or enhances knowledge of the disease or patients' experience of care
- For payers, any evidence to show how a specific approach is reducing disease burden in specific populations, including those not covered within standard RCTs, and where there are efficiencies in care provision associated with the product would be beneficial, and ensure access for the greatest number of patients who would benefit
- For patients and caregivers, evidence that would allow their views to be heard to a greater extent will help drive better experience and outcomes. Any data to support their ability to take a greater role in self-management would also be empowering

Consider whether a single study or activity could address multiple needs

Answering key questions: When?

- In order to identify when specific evidence is needed, you first need to consider what change you are looking to achieve
- Are you seeking to inform a belief or behaviour of a small number of individuals from one stakeholder groups, or the opinions and practice of many?
- Consider whether a single new piece of data, or an analysis of an established body of information, will be sufficient to achieve the change you are looking for or whether there will need to be other supporting initiatives required to achieve your goal
- Evaluate what insights you have that lead you to believe that the evidence you have identified will be sufficient to affect the change you are looking for in the desired timeframe
- Determine whether there is a specific sequencing in which the information is required in order to have the greatest impact

Answering key questions: What if?

- If you are not confident that your preferred method is likely to provide the evidence at the ideal time, consider alternative options
- Even if not as comprehensive, if other approaches will generate information of value
  in a shorter time, they should be explored with key stakeholders to select the most effective tactic
- Consider the overall investment, both financial and time, of different approaches, and determine what the most efficient mechanism is to address the evidence gap you have identified
- Assess whether you will be able to track your progress to addressing the knowledge gap in real time, gain early readouts and make adjustments to the process in real time, to improve the value of the evidence generated
- Consider what actions you will take if your method of generation does not provide the evidence you need to address the gap identified

Consider whether your organization is the best group to generate the evidence, or whether a lead by an independent institutions may be more appropriate

Understanding your external stakeholders enables you to focus on areas that will have the most impact

Once you have identified your primary and other audiences, it is important to determine what their baseline is, in terms of knowledge and belief, and what are their trusted sources of information that inform their views

- What do they need in order to fulfil their role in the process of approval, access, adoption and optimization of experience with your product?
- What is their baseline information, knowledge, belief and behaviour?
- What would they find compelling in terms of specific evidence to be available (including study design e.g., RCTs, IISs, RWE, HEOR)?
- What is your goal in terms of their target knowledge, information and belief/behaviour?
- How will you measure whether the evidence you have generated has addressed any gaps that existed?
- What partnerships are supported and enhanced (individual investigators, institutions or group of institutions) when considering research collaborations and IISs?

Start with the end in mind: The value of evidence generated can only be fully realised if it is available at the right time

Creating a comprehensive timeline for individual evidence generation activities is essential to determine the most appropriate approach to achieve the desired objectives

Key questions to consider as you develop your timeline

- [ ] In what timeframe will the evidence have greatest impact? Will our preferred choice of approach generate what is needed in time? Be realistic!
- [ ] What decision points and milestones will there be? Who are the primary internal and external stakeholders (e.g., IIS partnerships) and at what stages do they need to be involved?
- [ ] What activities are likely to compete for resources and time and at what stages? What bottlenecks are there expected to be? How can these be avoided?
- [ ] How frequently do we need to track our progress to identify if and why milestones are not being met? Who do we need to communicate progress to and at what stage?

EVIDENCE GENERATION

How should evidence gaps be prioritized?

Evidence generation can require a high degree of investment of time and resource, so it is important to focus on areas where a true need exists

There are common gaps in our knowledge in our understanding of mechanisms of disease and actions of therapies, even when the product has been on the market for some time; the importance of filling these gaps, however, can vary significantly

E.g. Why does a therapy work in some individuals and not others, when the disease markers and patient profiles are similar?

Why does a patient respond differently to two therapies with the same mechanism of action?

Valued evidence or completeness of knowledge?

Are you looking to better understand the patient profile?

Sub-analysis of patient population by mutation to determine the impact on disease course and treatment outcomes

VS.

Profiling specific mutations when it has been established that they do not affect clinical manifestations and treatment outcomes

Are you looking to differentiate from the competition?

Further PK-PD profiling to determine time course of receptor occupancy when unexpected efficacy/safety variations seen

VS.

Evaluation of receptor occupancy when no difference in clinical profile from competitor with same MOA is observed

Are you looking to improve the patient experience?

Collaboration with a patient organization to undertake a membership survey to understand current experience of care

VS.

Survey among HCPs as to current patient perspectives of care and ongoing unmet needs

When looking to prioritize research efforts, reviewing the patient journey is a key starting point

Our primary goal for all our activities is to improve patient outcomes

The focus of evidence generation, therefore, is to provide the awareness and information needed to enable early, appropriate decision-making regarding diagnostic strategies, management and patient and carer support

By considering the path a patient goes through from initial signs or symptoms or disease through to long-term maintenance or resolution, we can ensure that we are targeting knowledge gaps that are most meaningful

Patient perspectives should be sought in the generation of this journey. The pain points for a patient are likely very different than that of the clinician

What is the current experience for the patient?

Proactive screening or only on signs of disease?

Early signs & symptoms review or delayed presentation?

Diagnosis or mis-/delayed diagnosis?

Watch and wait, trial and error, or targeted treatment?

Holistic support or prescription-centered care?

Cycling through therapies or early long-term control or resolution?

Are there any challenges associated with day-to-day practice?

Prioritization should consider both the strategic advantages for the organization, as well as the short- and longer-term benefits for patient outcomes

- What are the elements within the journey where there is the greatest need for new information or education?
- Of these elements, what will have the greatest impact on outcomes?
- Are there any evidence needs that could be addressed more quickly, even if the overall impact is less?
- Will generating the evidence help to further build relationships with and across the community?

How will the new evidence improve…

Patient experience and outcome

Awareness of disease or presentation

Optimal initial treatment selection

Optimized access to appropriate treatment

Evidence does not have to mean initiation of new company-sponsored trials

- For many, addressing an evidence gap automatically means the generation of new primary trial data, commonly via Phase 4 studies
- Depending on the specific question, and timing requirements, this may not be the best course of action
- Consider whether there is a more creative or pragmatic approach to addressing identified needs, with data sources that already exist or are being generated
- Make sure you have also researched what evidence your stakeholder is actually looking for – don't make assumptions on what they will find compelling!

Evidence generation options
Registry analysis
EMR review
Meta-analyses
Ethnographic research
Post-hoc analyses
Investigator initiated research

Is new evidence truly needed, or could revisiting the way available information is communicated be an opportunity?

When feedback indicates a lack of confidence or awareness of a particular therapy or approach, consider whether it is truly due to a lack of data

Assess where you have taken your data and what the likely audience will have been

- Have communications have been focused on KOLs via congresses?
- Have publications all been in English, which might not be read by local HCPs?
- Where does your wider audience go to for information and how often do they go there?
- Do large data sets depersonalize the data and make it more difficult to visualize the individual patient?

Make it ‘real’, make it personal and make it simple

Make the patient ‘real’:

- Showcasing different patient profiles
- From local centers

Make the data personal

- Publish from local centers
- Consider HCPs beyond clinicians
- Local education roadshows

Make it simple to find and understand

- Publish in local language
- Consider more visual formats, e.g. infographics
- ‘Fish where the fish are’…place the data across channels already trusted by your audience

EVIDENCE GENERATION

How can we successfully implement investigator-initiated studies?

Investigator-initiated studies can help to advance knowledge of patient populations and response to management strategies of key importance to day-to-day practice

Investigator-initiated studies aim to generate data that address real-world scenarios. Depending on the study design, they can consider questions that clinicians face in their day-to-day practice, explore the mode of action of a particular treatment, contribute to regulatory approval, and inform future clinical trials

Why conduct an investigator-initiated study?

- Expand product knowledge and gain insight into usage in real-world clinical practice, to complement data reported in randomized controlled trials
- Gather additional safety data, and insights into real-world management processes
- Expand therapeutic area knowledge
- Explore potential new indications or patient populations not typically included in clinical trial settings
- Optimize use of available resources
- Expand networks of key external experts

Critical success factors

- Set clear internal and external roles and responsibilities at outset (e.g. RACI)
- Establish clear channels of communication, both internal and external
- Standardize processes, including data sharing, reporting and storage
- Establish a consistent review process
- Develop approaches that mitigate risk, and appropriate procedures should things not go to plan
- Build appropriate tools to support execution

See also: "*How to Engage External Research (Investigator-Initiated Research and Collaborative Research) – Practical Compliance Considerations*" (Presented by the MAPS Compliance Focus Area Working Group, 2021), https://medicalaffairs.org/wp-content/uploads/2021/10/SLIDES-MAPS-Webinar-IIR-Collabrative-Reseach-with-Appendix-Detail.pdf (Accessed February 2025)

Options outside of RCTs offer opportunities to enhance partnerships with external stakeholders, and optimize use of internal and external expertise and resources

Sponsored Trials

- All aspects of study design, protocol, site selection, and analysis are defined and managed by company
- Opportunity to ensure full strategic alignment, and direct value for the company
- Wide range of potential designs, including controlled trials, and real-world evidence

Research Collaboration

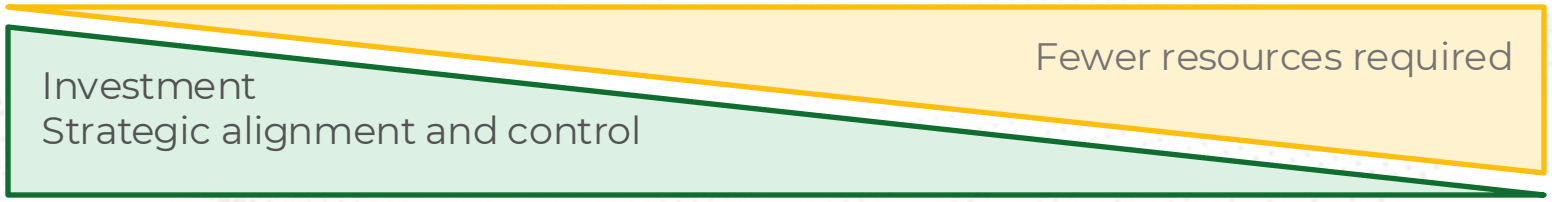
- Broadly equal contributions from company and partner, with joint work leveraging strengths and needs of each partner
- Potential to leverage external funding via partner

Investigator-Initiated

- Proposed by investigator, who is fully responsible for study design and conduct
- Investment ideally aligned with evidence-generation priorities
- Key considerations around compliance

Non-Interventional Design

- Real-World Observational Study
- HEOR
- Systematic Literature Review



A solid understanding of the benefits and challenges associated with investigator-initiated research helps with planning and implementation

Benefits

- Generate data in the real-world setting
- Applicable to the population where the study is conducted
- Assists in developing hospital/state/nation-specific policies
- Generates more safety data and aids in benefit-risk assessment, particularly if pragmatic trials are conducted as IISs
- Fewer commercial conflicts of interest
- Answer research questions for physicians in their daily practice

Challenges

- Lack of familiarity with research methodology required for study design development
- Lack of awareness about recent changes in regulatory guidelines in the specified country
- Staff attrition
- Formulating research question without confirming feasibility
- Inadequate planning of safety monitoring and attention to risk mitigation
- Disputes over data ownership

IISs should be for a legitimate research purpose, with scientific merit, to generate data on the effectiveness and safety of a drug in a real-world setting, or better understand the condition or patient population

Defining key roles and responsibilities across all internal and external stakeholders is key to ensuring the IIS is conducted in a safe and ethical manner, and meets legal and regulatory requirements

Internal

- Responsible for
  - Review of protocol, including medical/legal/regulatory
  - Review of protocol amendments as appropriate
  - Commits to providing requested support, e.g.:
    - Medicinal products
    - Material support
    - Financial support

Core team:
- Scientific lead
- Medical lead

Extended/ad hoc team:
- Biostats
- Scientific communications Quality lead
- Drug supply lead

External

- Sponsor/investigator
  - Develops study protocol and submits to pharma company for support
  - Assures review by and compliance with relevant IRB requirements and health authorities as required
  - Registers study in public database
  - Conducts study in line with agreed protocol and relevant GCP and local laws and regulations
  - Ensures patients provide informed consent and that their data and rights are protected
  - Maintains case reports and provides progress reports
  - Monitors and reports safety data
  - Submits protocol amendments
  - Reports and publishes study reports as appropriate

Agreeing and establishing a clear process between all stakeholders at the onset is key to setting up a successful partnership

1. Investigator/Sponsor initiates request for support

- High-level outline proposal
- Budget
- Protocol synopsis/full protocol
- Investigator's clinical credentials
  - Including documented clinical study experience
- Nature of support requested, e.g.:
  - Medicinal products
  - Material support
  - Financial support

2. Company reviews request

- Compliance with ICH-GCP (or local GCP regulations), and applicable laws, rules, guidelines and regulations
- Medical and/or scientific value of proposed study
- Alignment with global/local medical strategy
- Quality risk assessment (depending on risk and study design)

3. Company approves request

- Agreements drafted, agreed and executed by all parties, including investigator's institution as appropriate
- Agree frequency and format of communications
- Agree roles and responsibilities for study conduct including:
  - Documentation of safety reporting, local ethics approvals, registry in public database, and regulatory, legal and financial agreements
  - Drug supply and drug quality, and biomarker research agreements as appropriate
  - Agreement over data ownership and consideration of publication plan
- Agree oversight measures for ongoing evaluation and monitoring of study

4. Set-up agreed support

- Set-up study per Step 3, including:
  - Study oversight mechanisms
  - Drug supply mechanisms
  - Provision of medicinal product
  - Any biomarker analyses

Continuing the collaboration throughout the study duration helps ensure clarity, transparency and contributes to the success of the study

5. Ensure adequate monitoring of safety data

- Clear reporting process for AEs
- Clear roles and responsibilities for collection and reporting of safety data relating to company products
- As a minimum, inclusion of aggregated safety data within interim safety analysis and in final CSR

6. Study is conducted per protocol

- Company manages internal activities and provides agreed support
- Investigator conducts study per protocol
- Adequate two-way communication
- Review progress and performance against agreed contract
- Any deviations related to medicinal product managed and documented appropriately
- Any impact of identified risks analyzed, and action plan implemented as needed
- Protocol amendments developed as needed per as required in line with steps 2 and 3

7. Study is closed

- Ensure IIS is complete, and no patients are in follow-up
- Ensure all safety related activities are complete
- Complete statistical analyses
- Complete study close out processes per agreed plan
- Company requests final study deliverables and reviews internally
- Review, finalize and document final CSR

Common challenges associated with IISs can be mitigated through adequate planning ahead of requesting support

Lack of familiarity with research methodology required for study design development	• Investigators can attend training on good clinical practice and appropriate research methodology, and ensure study is designed around a well-defined research question, and adequately powered to validate study endpoints
Lack of awareness about recent changes in regulatory guidelines in the specified country	• Investigators should stay up to date on local regulatory situation and any changes that occur during study duration • They should be mindful of monitoring and timely reporting of safety events, especially in multi-site studies which may all need their own IRB mandate
Compliance with IRB requirements and/or ethics committees	• Engaging in dialogue with ethics committees may be of benefit when considering benefit-risk assessments
Study operational issues	• Studies that are run at centers with a dedicated clinical research/trials unit with appropriately trained staff who are able to develop and implement SOPs to address issues arising during study conduct are likely to have fewer operational issues that affect success
Management, analysis and publication of study data	• Investigators can develop their own skills in understanding and analysing biostats, or enlist the services of a third-party vendor to ensure adequate and timely management and analysis of data • Working with a dedicated medical writing vendor can aid timely and accurate submission and publication of study data

From outputs to impact: How can the value of the evidence be measured?

Measurement of success should consider not only creation of the evidence, but on wider processes and partnerships

- Generation of evidence can be a lengthy process, so having mechanisms that allow progress to be chartered, and interventions made when necessary, will increase the likelihood of achievement of objectives
- Where there is a variation from expectation, take the time to analyze why this is the case to determine if there are lessons that can be applied to future planning and projects
  - Could the reason for a negative variation have been predicted or prevented?
  - What effect will this have on other projects and partnerships?
  - What lessons can be applied to future plans?

Potential measures of plan progress and success
Willingness of internal and external partners to engage in collaboration analysis
Feedback from internal partners regarding the IEP development process
Turnaround time for review and feedback
Speed of updates to internal education resources
Feedback from internal and external stakeholders regarding the value of the evidence
Analysis of sentiment and practice

Cross-functional input will help to establish what a meaningful change would be, and may be required to support tracking of the impact of the evidence

To understand what impact your data has had, you need to understand your starting point (baseline) – what is the current level of knowledge or perception

Establish your baseline of current knowledge, beliefs and behaviors

- Recent market research across stakeholders across geographies
- Insights from local, regional and global cross-functional colleagues to determine commonalities and variances within or between countries, centers and specialists

Agree the target change the evidence will lead to

- Determine whether a single channel for presentation will lead to the desired change, or if multiple activities will need to combine together to achieve your target
- Consider any external factors that may influence change and whether your target or timescale are realistic or need to be flexible to accommodate such external forces
- Evaluate surrogate markers, e.g. guidelines or formulary changes, that have been identified as drivers of change

Define a tracking and measurement approach

- Ongoing insight capture allow for a real-time tracking of changes in perceptions, but a robust process needs to be in place to fully analyse the findings and understand a true trend appearing
- Active measurement allows for lessons to be learned across similar geographies, centers and stakeholders, and shared across the organization to accelerate change

Go beyond the metrics, to identify measures that provide an understanding of the impact of the plan

- A critical measure of success is that the evidence is available on time, which is a simple assessment – either it is or isn't
- While availability of the planned evidence is key, it should not be seen as the sole indicator of success
- Consider other measures that give a deeper understanding of the outcomes of activity, as well as its potential impact
- In the results chain, moving from delivering and output, through achieving an outcome to having a positive impact increases the value of the evidence for the organization
- Across study types, success can be measured across both data generative metrics and collaborative metrics that demonstrate the establishment of long-term external partnerships

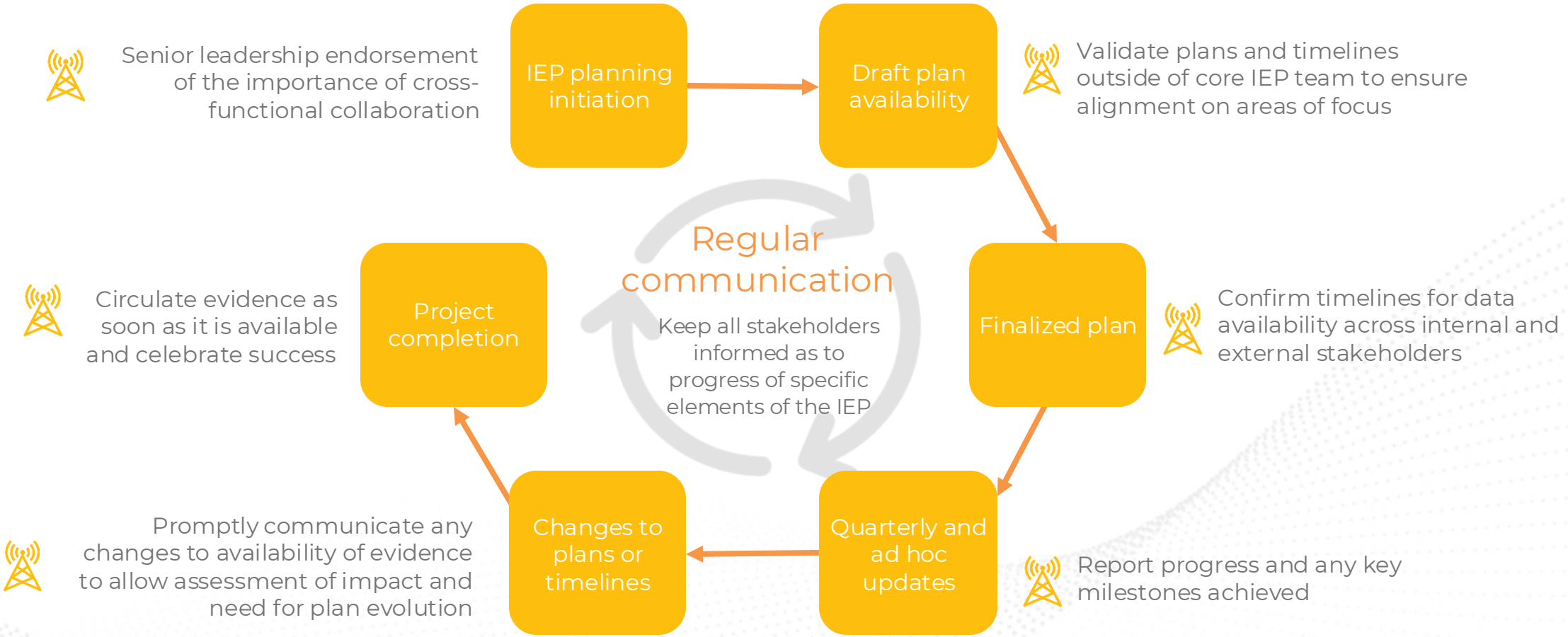
The results chain

Impact
The wider long-term change that the outcomes of the activities delivered contribute to, e.g. enhanced sequencing of therapies to improve outcomes

Outcome
The results of the activity delivered, including measures of quality, e.g. HCP targeted education was updated to include the evidence

Output
The volume or quantity of activity delivered; includes measures of productivity, e.g. the study was completed

Communication of progress and results builds support for and confidence in the IEP and the value of the approach



CSF, critical success factor

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