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Reflections on the effectiveness of IEPs in 2025

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REFLECTIONS ON THE EFFECTIVENESS OF IEPs IN 2025

The need for integrated evidence planning is well recognized across the industry and many companies have invested in design and implementation of Integrated Evidence Generation Plans (IEPs). However, implementing the process and plan does not necessarily result in timely generation of high-quality evidence, and many companies still experience challenges in unlocking the true value of IEP.

The broader operating model must be aligned and supportive of a truly integrated approach. We propose four key areas that are particularly important in this regard:



1. Processes must drive early, integrated, cross-functional thinking and continue to serve the needs of the organisation...

IEPs start with an evidence gap analysis based on an 'outside in' assessment of the anticipated evidence needs of external stakeholders. The cross-functional thinking and discussion must start here to avoid a modular approach to the whole exercise where different functions are responsible for different 'sections', or worse, where extracts from various functional plans are used to create an 'integrated' plan. Besides any de-duplication, the most tangible value that will then flow from this is a cross-functional discussion on the best ways of generating the evidence required e.g. whether end points should be added or amended to meet the needs of different stakeholders in different markets, or whether different modalities would be more appropriate. Additionally, the valuable scenario planning and optionality that is required can only be meaningfully discussed if all participants have been fully involved from the start. These dynamic group discussions

are naturally easier in person, and certainly for priority assets, the value of face-to-face workshops to brainstorm and challenge options and scenarios cannot be overestimated.

The IEP process must serve the needs of the team rather than the team being slaves to the process. The process must therefore also allow for strategic pivots to critical changes that may occur outside the annual cycle (e.g. key programme decision points or data readouts, external competitor data, external regulatory changes). With appropriate governance, teams can then plan and deliver meaningful evidence in an agile and timely manner without having to initiate the full process or wait for the next cycle.

2. Hierarchy of strategic plans must be established and governance structures aligned...

While the hierarchy of strategic plans will change across the lifecycle, the IEP is generally a strategic plan which flows from TPP, TVP,



asset, launch or brand ambition (for an indication), and the evidence generation tactics are then detailed in downstream functional plans. The governance model across the company needs to reinforce this hierarchy by defining at what point strategies are approved, plans signed off or budgets allocated. In many companies the alignment of IEP approvals and budget approvals remains challenging e.g. development plans are often approved, or resourcing and budgets for an RWE platform are approved ahead of the IEPs being signed off. In some instances, this is a result of the longer development studies fitting into the context of a new IEP ecosystem, but often it is because the design of the process does not extend to the TA and above TA governance committees e.g. portfolio management boards. Hence the sequence of approvals is sometimes contrary to the hierarchy of the plans.

While Life Cycle Management (LCM) from proof of concept (PoC) to end of life cycle is not a new concept, many companies are still not adequately advanced in the seamless flow between TA strategies, LCM plans for an asset or product, the development or brand plan, and the IEPs for indications within those assets and products.

Lastly, an effective IEP is the natural starting point for an integrated scientific communication plan (ISCP), which should lay out an effective strategy and plan to communicate the evidence. The link between IEP and ISCP is not always as seamless as it could be to realize the value of the evidence.

3. Once IEP accountability & responsibility are set, resources must be validated, including facilitator and project management support...

Although leadership of the IEP along the lifecycle is often a contentious issue in the design of the process, it is ultimately intuitive. The main obstacle is more often nervousness about what is meant by 'Accountable' and 'Responsible'. Given that there is an 'IEP Lead'

– usually the Global Development Project Lead (GPL) up until the P3 studies are underway before transitioning to the Global Medical Lead (GML) – the question is more about the responsibilities within that construct.

Different leads will have different strengths but credibility, trust, respect, and ability to understand and, where necessary challenge the opinions of the team members, are critical. However, the need for effective facilitation is often overlooked. If the IEP Lead is interacting and managing stakeholders within and between the various meetings, then project management and facilitation support are essential. This support is often provided from central groups or from external vendors. The former can lead to under-resourcing, and both can occasionally default to generic facilitators who cannot interact at the level of detail required. Regardless of where they come from, an effective project manager and facilitator who can prepare teams and materials ahead of workshops, as well as driving towards outputs, makes a significant contribution.

4. AI, digitisation, and information platforms must be considered as early as possible and should align with plan hierarchy...

Digitisation of the planning landscape is an ongoing discussion in many companies. While there are many applications and tools that enable digitisation of tactics (MS Project and Smart Sheets are basic examples), the challenge is to ensure consistency and flow through of strategic elements. This requires structured content management as well as clear understanding and articulation of the flow of strategy between the different plans. Crucially, this exercise does not lend itself to an isolated initiative or a small pilot on selected plans, as by definition it needs to incorporate the entire ecosystem of plans.

The digitization we are referring to here is largely automation of information management and transfer of content, not production of



insights or strategic content via methods like generative AI. Additionally, in a hybrid working environment, production of IEPs will most likely rely on some use of interactive tools (e.g. whiteboards, prioritization modelling and matrices). Digitizing these tools into the overarching IEP workflow will further enable the process.

Finally, a challenge that many companies still struggle with is the use of the IEP for different

audiences. While asset teams may find a more detailed document useful for their day-to-day discussions, the same format is not ideal for review or presentation. Developing the IEP in a digital space allows content to be extracted for different audiences and purposes quickly and allows reviewers and above-indication decision makers visibility across IEPs.

Conclusion

IEPs are an essential element of any planning ecosystem, but once the process is in place the organisation should focus on ensuring that the broader operating model reinforces the overall purpose of an integrated approach to evidence generation.

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