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Reflections on integrated evidence generation planning

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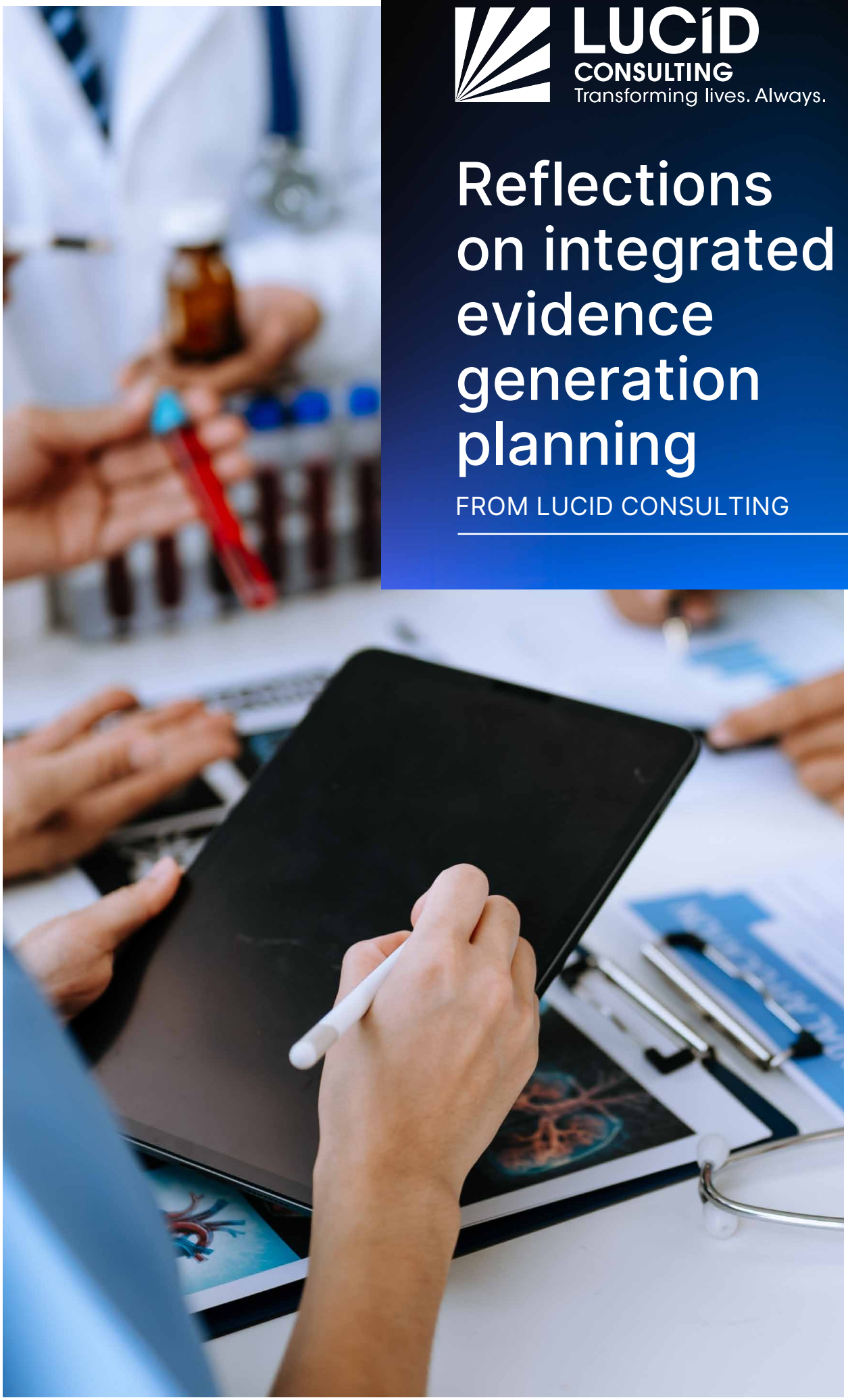

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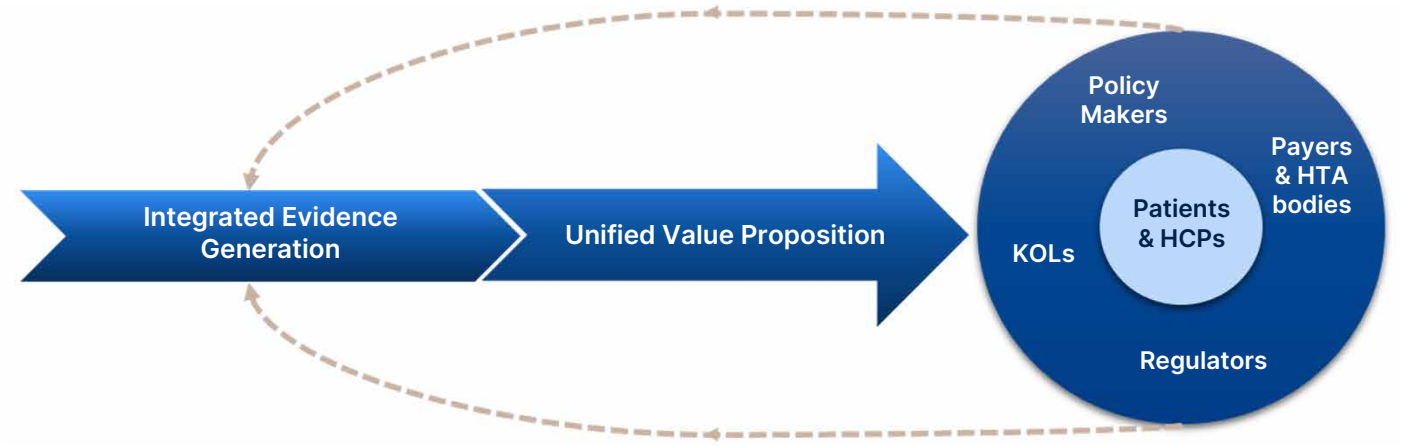
REFLECTIONS ON **INTEGRATED EVIDENCE** GENERATION PLANNING

Delivering robust evidence to external stakeholders at the appropriate time along the continuum of development and commercialisation of a medicine has never been more important. Furthermore, meeting the evidence requirements of a broadening network of heterogeneous and geographically specific external stakeholders has never been more challenging. An integrated approach to the identification and prioritisation of evidence requirements is now essential, as is the ability to optimise the generation of that evidence with regards to both modalities and end points.

Starting with the customer in mind, companies must take an integrated approach to providing robust and timely evidence to support a unified value proposition to external stakeholders (see below):



Integrated approaches to evidence generation planning have become more common, with the extent of integration spanning from 'integrated real-world evidence (RWE) plans' through to fully integrated Evidence Generation Plans (iEGPs). Of 10 pharmaceutical companies we interviewed, 8 have put in place a central process to drive a more integrated approach to evidence strategy and planning at an asset or indication level.

While the concept of integrated evidence generation planning is broadly understood and increasingly adopted across the industry, there are several more subtle challenges that may prevent full realisation of benefits. To maximise the impact of an iEGP, and ultimately ensure that evidence is generated in the most effective and timely way, with efficient allocation of resources, it is important to optimise both design and implementation of an iEGP initiative. From our experience in designing and implementing iEGPs with several companies, our key recommendations are as follows:

- Ensure early alignment on how the iEGP documents will be used on a day-to-day basis
- Define the relationship of the iEGP to other plans and processes early on
- Build alignment and understanding on responsibility and leadership of the iEGP
- Define fit-for-purpose governance and budgeting mechanisms
- Carefully select asset teams for initial implementation
- Ensure clear responsibility for information and document management.

Ensure early alignment on how the iEGP documents will be used

While asset teams will use frameworks to drive their thinking and discussions, and work towards the completion of an iEGP template, there is often also a realisation that different audiences and different settings will require different materials. For example, a 10-page Word document may not be suitable as a pre-read or presentation to a funding body, but may well be the most useful format for a scientific review body. Hence, in order to avoid digression of content and duplication of work, early consideration must be given to how the iEGP documents will be used and maintained, and ultimately how the content will effectively and efficiently serve the purposes of the different audiences. In addition, teams will often benefit from a catalogue of previous discussions and decisions made in order to create institutional memory as opposed to relying on individuals.

Define the relationship of the iEGP to other plans and processes early on

In the absence of an iEGP, evidence generation planning is typically fragmented across functional, regional and local plans. Assessing where aspects of evidence generation planning currently occur when designing the iEGP process helps to eliminate duplication and determine appropriate integration points. One of the key elements that must often be addressed is ensuring that a robust Target Product Profile (TPP) and Target Value Proposition (TVP) are in place, and are articulated in a consistent way, so that the iEGP is oriented around achieving these. Difficulties in implementing iEGP often arise where there is no clear mapping of the relationship (including sequencing and hierarchy) of the iEGP to these and other plans, such as development plans, brand plans and functional plans.

Build alignment and understanding on responsibility and leadership of the iEGP

Nobody would argue against an integrated approach to evidence generation... until trade-offs need to be made and strategies need to be deprioritised. While 'leadership' of the iEGP is often a contentious discussion, it is less so after adequate time is invested in understanding the meaning of leadership, accountability and responsibility in this context. A cross-functional approach requires a leader, but this does not necessarily mean unilateral decision making. What is more important is the ability to facilitate and lead the team through a lens which primarily considers external stakeholders, their needs, and appropriate evidence generation options to address those needs, including modalities and end-points. Shifting the focus to facilitation of team discussion and integration of cross-functional inputs enables the iEGP lead to take responsibility for driving alignment on the evidence generation strategy. While iEGP teams should be empowered to make collective decisions, escalation mechanisms are in place where conflicting positions cannot be resolved, and these can and should be used before plans are finalised and budgets are allocated.

Approaches to iEGP leadership differ - some companies have a single asset lead responsible for the iEGP throughout the lifecycle, whereas in others the responsibility evolves from a Development Lead through to a Medical Affairs Lead (or Medical Affairs joint with Commercial) as the asset moves through the lifecycle.

Effective management of the handover is required in the latter model, usually around the start of Phase III. Regardless of functional alignment, the iEGP lead must encourage active contribution from all team members and drive a mindset of 'asset first' to integrate around key external stakeholder evidence needs and collaborate on how best to generate the evidence required.

Define fit-for-purpose governance and budgeting mechanisms

At the start of an iEGP design initiative, governance and budgeting are often considered in an over-simplistic and linear way, on the basis that the plan will work in a similar way to functional plans. While approval and budgeting should not be overcomplicated, we must acknowledge that:

- Governance is a broad term and needs to be defined precisely within the context of the discussion i.e. does it refer to scientific approval, Medical Governance, budget approval or all of the above?
- Budgeting is generally complex at this level and the team responsible for designing the iEGP process may not be the appropriate team to design the budgeting process around the iEGP
- There are several levels of budget approval to be considered, from an individual study, to the holistic set of evidence generation activities executed across functions for an individual asset, to evidence generation activities across a therapy area, to budget allocation across the entire portfolio
- It is very unlikely that all of the budget approvals mentioned will happen in a linear and sequential manner, especially when the necessary scientific approval at various steps is intertwined with financial approval and resource allocation.

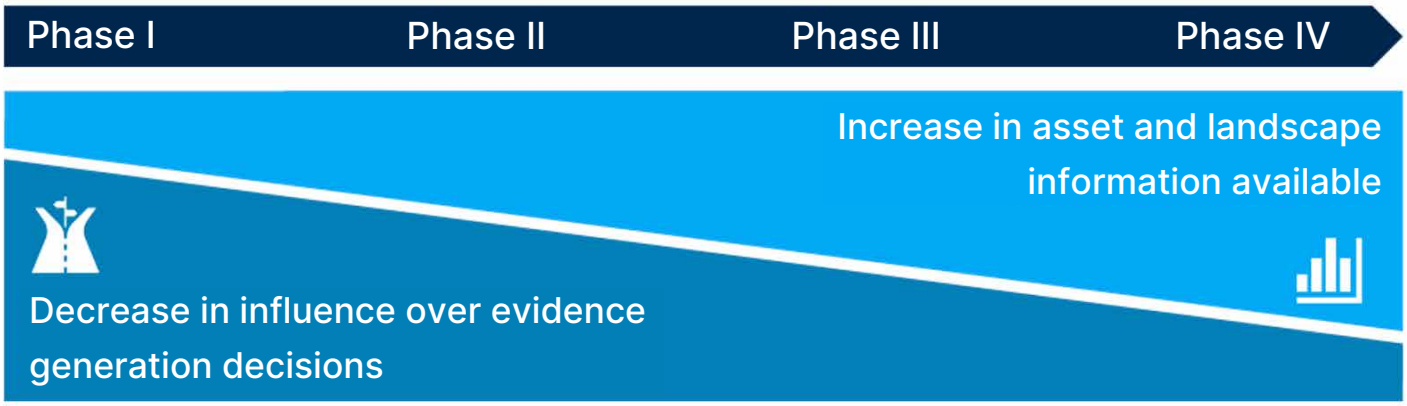
Each company will have its own landscape in which to work, but a first step is to acknowledge what approvals are required, and which stakeholders can meaningfully provide input to those approvals. The subsequent challenge is to keep the process as simple as possible, using existing governance bodies where possible and appropriate.

Additionally, in a world where data is clearly a competitive advantage, and the use of external data vendors and solution providers is a necessity, a longer-term data strategy is often required across a therapy area and then across the portfolio. While this does not initially need to complicate the governance and budgeting discussions for the iEGP initiative, it is worth bearing in mind, especially where specialist cross-portfolio data and analytics capabilities are also being developed, or where there is a focus on buying or building longitudinal data sets.

Carefully select asset teams for initial implementation

When selecting asset teams for initial implementation of the iEGP, key factors to consider include:

- **Asset lifecycle stage:** It is often beneficial to implement the iEGP initially with a combination of assets earlier and later in the lifecycle:



Despite unknown factors and evidence needs for early lifecycle assets (e.g., Phase I), the iEGP process provides an opportunity for early cross-functional asset discussion and decision making, enabling iterative development of a robust evidence generation strategy and initiation of longer-term evidence generation tactics (e.g. those that require development of longitudinal datasets). Assets later in the lifecycle are able to build a more comprehensive iEGP, since more is known about the asset and the wider landscape, but there is a risk that key evidence generation decisions have already been made, reducing the impact of the iEGP.

- **Asset prioritisation:** Investment in developing a robust iEGP is likely to have greater benefit with high priority assets and can contribute to wider visibility within the organisation.
- **Asset team performance:** Initial implementation with high performing teams, including iEGP leads with the leadership skills to effectively facilitate the iEGP process, helps to create best practice examples to demonstrate 'what good looks like' during wider iEGP roll-out.

Ensure clear responsibility for information and document management

While teams will initially manage documents in functional shared areas, more advanced information and document management is essential to enhance long term sustainability of the iEGP. Besides the obvious need to enable parallel review and manage version control, challenges will occur in managing changes to related documents that need to be reflected in the iEGP, such as changes to a TVP or brand plan. Without structured content management, and other fit-for-purpose information management capability, duplication of effort and currency of information are likely to remain a challenge.

Conclusion

While integrated evidence generation planning has become more common across the industry, some companies have implemented it more effectively than others. Rather than only focusing on KPIs to assess effectiveness after implementation, there are several factors that can be addressed early on during design and implementation to significantly improve the effectiveness and uptake of a more integrated approach to evidence generation. This will ultimately contribute to a company's ability to bring medicines to patients faster.

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About Lucid Consulting

Lucid Consulting is the consulting division in Lucid Group focused solely on the life sciences industry. We bring a combination of deep health & life sciences expertise with the capabilities, discipline and resources of a leading management consulting firm. Our consulting teams have worked extensively in R&D and Medical Affairs. We continue to focus on emerging trends, needs and best practices across the industry.