



Supporting Emerging Biopharma

Syneos Health R&D Advisory supports emerging Biopharma to deliver medicinal therapies to patients, nurture a culture of innovation and compliance, and build a platform for future growth and success.

Emerging Biopharma operate in a highly regulated and competitive landscape, with success hinging on agility, innovation and an often-limited number of therapeutic assets and resources. Indeed, as Biopharma are often 'building the runway as the plane comes into land' from Phase II through Commercialization, the timing of building and integrating high-quality capabilities (organizational structure, governance, compliance, processes, technology landscape and talent) across multiple functions is vital to streamlining Development and maximizing asset return on investment. As a Biopharma builds-out its organization and scales-up operations, we define three critical challenges on the journey to delivering medicines to patients.

Critical Challenges Facing Emerging Biopharma:



Timely Development Of Effective Late-Stage And Commercial Asset Strategies

To support maximization of asset value and to streamline Development, late-stage and go-to-market strategies must be developed early. This requires a proactive shift in focus beyond demonstrating scientific/clinical value, early and effective integration of nascent late-stage and Commercial functions into governance and asset development, and collaboration across an increasing set of stakeholders (functions and potential new partnerships).



Build-Out Of Organizational And Functional Capabilities To Execute Asset Strategies In A Compliant Manner

To support late stage Development, Commercialization and expanding operations, a Biopharma must effectively prioritize, invest in, resource and implement capability-building initiatives across multiple functions while maintaining quality & compliance. Timing, prioritization and seamless integration are critical. Furthermore, ensuring the appropriate level of structure for effective operations, whilst retaining flexibility to allow for speed, innovation and scalability is key.



Enabling Talent To Innovate In An Evolving Organization

Scale-up of operations and build-out of capabilities marks the beginning of an extended period of transformational change. The rapid influx of talent (e.g. Development and Commercial Leadership and Expert Practitioners) can dramatically shift company culture and ways of working. Initiatives must be prioritized and managed to increase immediate productivity, and reduce the resistance that can spread across an organization and disrupt team operations, innovation and potentially delay progress to market.



How Can We Help?



Developing Effective Late-Stage And Commercial Asset Strategies

Syneos Health R&D Advisory supports design and implementation of fit-for-purpose integrated Development Plan (iDP) frameworks across an organization. Furthermore, R&D Advisory supports program teams to develop effective cross-functional asset strategies through our robust approach to iDP creation.

Key Benefits

- Enhances cross-functional collaboration and alignment
- Supports integrated decision-making across the product lifecycle (e.g. indication prioritization, trial design)
- Enables a standardized and streamlined approach to product strategy definition across an organization
- Allows effective utilization of functional resources



Timely Build-Out Of Organizational And Functional Capabilities

Syneos Health R&D Advisory supports strategic deployment of fit-for-purpose capabilities across all R&D functions and throughout the asset lifecycle. Key support activities are highlighted below:

	Develop Target Product Profile (TPP)	Proof of Concept established	Product registration	Product lifecycle	
	EXPLORATORY	PRE-CLINICAL	EARLY DEVELOPMENT	LATE DEVELOPMENT	LIFECYCLE MANAGEMENT
R&D Strategy & Ops		Create and update integrated Development Plan for medicine(s) in development Support to the operating model design of development functions – vision, capabilities, processes, organizational structure, sizing, footprint and roadmap Design and implement digital strategy: assessment of technology landscape, recommendations for improvement, business case development, vendor selection, implementation support and building of digital assets (e.g. BMP, RPA)			
Drug Safety & PV			Create company safety strategy and operationalize safety capability	Create and embed PV QMS and SOPs	
Clinical Operations		Formalize sourcing strategy and vendor selection	Create company safety strategy and operationalize safety capability		
Regulatory Affairs		Create and operationalize data transparency and dissemination policy	Formalize and support MAA submission processes		
Medical Affairs		Operating model development, including organization design and sourcing strategy Definition of processes, including industry best practices Regulatory technology strategy, business case and implementation KOL mapping Stakeholder perception management and engagement strategy development Support to organizational and operating model design and implementation. Development of core processes and planning for insight generation, medical governance, written standards etc. Medical Affairs capability enhancement and training			
Q&C		Create and operationalize QMS, written standards, SOPs to support the organization's way of working at scale			

Key Benefits

- Establish robust, flexible and scalable functional capabilities to drive operational excellence and provide a platform for future growth
- Break down functional silos through synchronization and development of complementary capabilities



Enabling Talent To Innovate In An Evolving Organization

Syneos Health R&D Advisory designs and delivers holistic change management programs to support clients to prioritize and align multiple initiatives with executive strategies and embed an effective company culture.

Key Benefits

- Enhance culture, effective ways of working and behaviours to increase productivity, efficiency and innovation
- Attract, retain and develop the best talent
- Maximize the benefits for investments and improvement programs

Syneos Health R&D Advisory has a depth of experience and expertise in supporting emerging Biopharma in build-out of their organizations.

We look forward to continuing the conversation through release of our thinking on key challenges and best practices in this space in the near future!

“If you are interested in finding out more about our thinking or our services, please do not hesitate to get in contact.”



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