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Enhancing R&D processes in the age of precision medicine

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Introduction

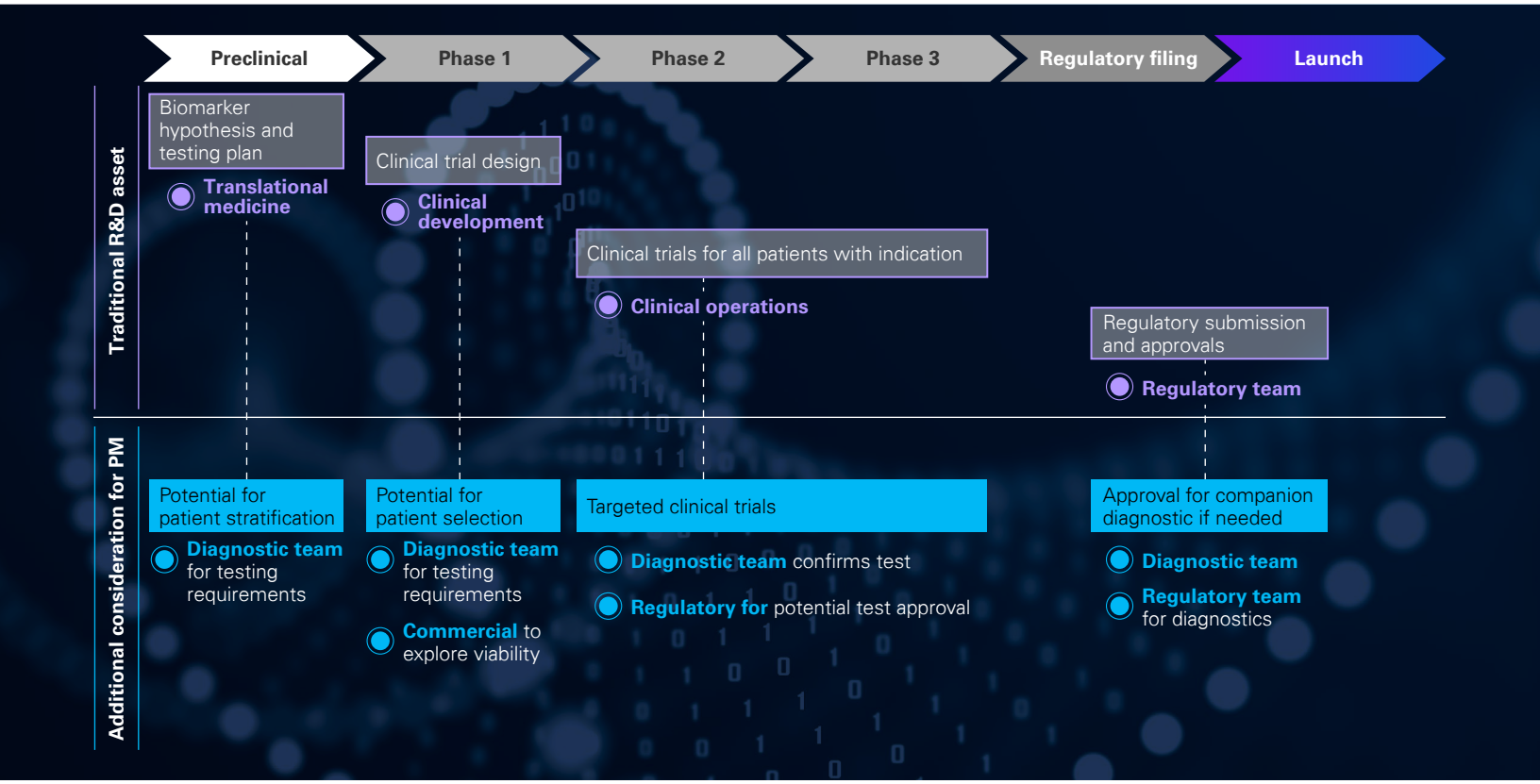
The life sciences industry has transitioned to an increasingly targeted approach to solution development, with precision medicine-based (PM) drugs and devices taking center stage to generate the most impactful interventions for patients and the most differentiated value for suppliers. Precision medicine therapeutics are biomarker driven and will therefore require some kind of diagnostic test to identify appropriate patients for specific therapies. As such, they add an additional layer of complexity to the classic drug development process and require close co-ordination of various teams within the R&D organization, as well as with external partners. However, organizational siloes and other dynamics within and between teams can often mean that avoidable mistakes are made during development of precision medicines, to the detriment of the development program. Instituting safeguards and structure to break down those silos is paramount to any successful precision medicine program.

What is precision medicine?

A medical model that customizes medical decisions, treatments, practices, and/or products to a subgroup of patients versus a one-drug-fits-all model using tools such as molecular diagnostics, imaging, and analytics. In PM, diagnostic testing is often employed for screening patients, selecting appropriate and optimal therapies, and monitoring patient outcomes based on the context of a patient's genetic information or other biomarker.

The cross-organizational R&D process for PM requires additional assessments versus the traditional development model

The traditional R&D model involves a sequential handover of decisions and assessments from one function to another across preclinical, clinical, and launch. In the age of PM, as soon as there is an indication of a potential patient stratification, cross-functional consultation is critical to confirm both the scientific and commercial viability of the asset and ensure early strategic planning for launch.



Key decision points for PM R&D

Confirming PM:

Would the asset's clinical program benefit from a biomarker-driven approach for patient selection/stratification?

Confirming diagnostic requirements in trials:

Should diagnostics be used to identify/stratify/select eligible patients for pivotal trials?

Confirming need for a companion or complementary diagnostic:

Are regulators likely to require use of a specific companion diagnostic to identify patients eligible for the treatment once marketed, or will a complementary diagnostic be appropriate?

What challenges do R&D teams face today impacting PM asset development?

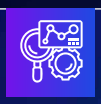
Challenge	Details	Impact on PM R&D
Unclear division of responsibilities and duplication of efforts	This is especially prevalent during the transition between the translational medicine and diagnostic teams from early to late development when a patient selection biomarker becomes a diagnostic.	Inefficient and delayed selection of partners for diagnostic testing
Lack of critical functional representation at key R&D decision points	Functions such as diagnostics, commercial, regulatory, and data science are not represented in a consistent manner in key early development decisions. Critical functional expertise can also lie with external partners—inefficiencies in their inclusion in development decision-making can impair the thinking and development of the full team.	Development of products with lower probability of commercial/regulatory success
Limited transparent knowledge sharing between functions	Development teams or individual functions are siloed with limited sharing of best practices, methodologies, and inputs to support end-to-end R&D decisions.	Prolonged development timeline as best practices/ challenges are not incorporated for future products
Lack of an integrated end-to-end guide for PM asset tracking	The multiple touch points, decisions, and analysis between different organizations and functions means there is a lack of a single source of truth to track current and upcoming development projects.	Delayed institutionalization of PM asset R&D
Limited maturity and targeted use of data science and analytics	Data science teams are currently reactive rather than proactive and only support with isolated function-specific initiatives.	Missing out on avenues for acceleration/innovation using next-generation testing and insights

How to move forward with your PM R&D strategy

Standardized assessment criteria

Develop a set of key questions and inputs required across R&D functions to inform decision-making for potential PM programs. This includes a set of criteria to determine the likelihood a program will require a diagnostic based on scientific, clinical, technical, regulatory, commercial, and financial inputs. Criteria are assessed at various interventions pretrial IND and should be revisited as new information is obtained through early phase studies. The criteria allow for a clear, replicable approach across indications/therapeutic areas to determine a program's need for a diagnostic that accounts for cross-functional perspectives. It provides for a single source of truth on which to base diagnostic decisions, driving transparency and efficient decision-making.

Data-driven approaches

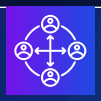


Integrate data science (DS) and informatics across asset development to enable and strengthen biomarker/diagnostic strategies. Enhancing R&D functions' knowledge of DS and informatics skill sets is a critical first step to best leverage and embed DS platforms and tools into development processes. Strategic incorporation of DS and informatics teams in early development forums provides for opportunities to identify unique use cases and applications of DS technologies. Diagnostic assessment criteria inputs, validation of novel/surrogate endpoints, real-time analysis of study data to evolve biomarker hypothesis and testing plans, and machine-learning algorithms as diagnostic tools are just some of the activities led by DS and informatics teams critical to inform PM R&D.

Forums and stage gates

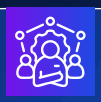
Facilitate new cross-function (and possibly cross-organization) R&D forums in early development. This can help to assess biomarker hypothesis and testing plans as well as results of diagnostic assessment criteria to ensure functions (e.g., translational medicine, clinical, diagnostics) are working with the same information toward aligned-upon objectives. Cross-function R&D forums in later phases of development provide opportunities to pressure-test biomarker hypothesis and testing plans to ensure they reflect earlier-phase learnings. They can also help to align on reverse translation plans to convert patient clinical trial experiences into hypotheses for discovery teams to test. The establishment of a diagnostic go/no-go stage gate (often between early and late development) reinforces a decision on whether a program will require a diagnostic in sufficient time for diagnostic development. Charters and guidelines for the new forums and stage gates provide clarity on functional roles and responsibilities while streamlining agendas.

Collaborative ways of working



Elevating levels of collaboration across R&D functions is integral to the success of PM programs. Implementation of formal and informal ways of working across R&D functions aims to optimize opportunities for cross-function input in an efficient manner. For example, defining triggers in early development for when a diagnostics team member should be brought on to the program based on the results of the diagnostic assessment criteria ensures there is diagnostic expertise on the team when needed. Conversely, it limits inefficiencies and bandwidth concerns by strategically bringing on the right team members/expertise at the right time.

Change management



Ensure messaging from senior leadership down that cultivates a collaborative environment and that stresses the importance that PM can drive an organizational mindset shift. Key change champions across R&D functions and PM playbooks/resources further aim to guide and reinforce changes required to support innovative precision medicine approaches.

Conclusion

The complexities of cross-discipline effort, parallel work, and additional decision points required for development of PMs require R&D teams to align on standardized assessment criteria for assessing potential PM programs. These teams must also embrace and embed data science and analytics across the R&D PM process and create cross-function R&D forums to ensure the right stakeholders are involved in key decisions and that there is clear delineation in roles and responsibilities. Above all, open, honest, and transparent collaboration within and between internal teams as well as with external organizations is essential. Remember that senior leaders must drive the change management that will allow the new future of medicine to flourish.

HOW KPMG can help

KPMG works across the PM ecosystem with biopharma, diagnostics, and life science tools companies, as well as with laboratories and academic medical centers. Our team supports clients in:

Strategy. Underpinned by our in-depth market studies and deep sector knowledge, we offer a full suite of strategic offerings, all with a global strategic focus with local level insight, customization, and execution.

Operations. KPMG helps organizations design and align operating models with business strategy, positioning the mid- and back-office functions of PM organizations for the best patient results and the overall commercial success of our clients.

Deals. We support corporate and private clients across the deal continuum, from front-end ideation and planning, to commercial, financial, and operational due diligence, and through integration and separation.

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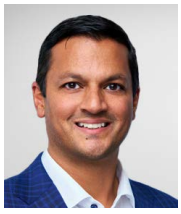

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Recommended reading:

2025 Healthcare and Life Sciences Investment Outlook:
Smart optimism to smart diligence

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