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Maximising value in early development

Selecting product candidates with the highest probability of success and applying rigorous risk-based management in development maximises the value of biopharmaceutical products and increases speed to the clinic and registration.



The situation

Due to the high costs for product development, few small and medium sized pharmaceutical companies will take their product to the market on their own. Therefore, the goal is often to develop the product to a stage where partnering becomes feasible. However, the aim should be to add as much value as possible to the product during early development, as this will maximize the likelihood of a successful deal with a corporate partner and provide alternative exit opportunities for the company.

The longer-term goal for any product is commercialization and the perceived risks and success probabilities will strongly influence the selection criteria of a corporate partner. This seems obvious, but it is sometimes neglected by biotech companies whose goal is to accelerate the product towards the first key milestone: start of clinical development.

Commercialization of a product requires regulatory approval, issued by the respective competent authority and companies should make use of an integrated regulatory strategy throughout product development to meet this long-term goal. An integrated regulatory strategy maps out the anticipated development pathway for the product considering requirements in each global region. Identification of critical activities, milestones and decision points as well as risk management tools that support the efficient advancement of a product towards gaining regulatory approval in each region, are integral parts of the approach.

Is an early development strategy really needed?

Defining the path towards critical milestones and its timely execution while balancing risks and resources is a key strategic focus for small to medium enterprises. Integrating project specific development strategies and the respective milestone deliverables in the overall corporate objectives provides a strategic roadmap to valuable exit points and allows acceleration of high value projects.

Such a regulatory strategy can optimise the efficiency of product development and prevent any unnecessary backward steps. Its risk based approach is also sufficiently flexible to allow for future changes in the regulatory environment.

Developing a global regulatory strategy is an important value driver of a product as it enables a global approach to maximise return on investment. Although regulatory harmonisation is proceeding through the ICH process, there remain many differences owing mainly to the legislative basis in the respective jurisdictions. These differences must be considered at all stages of development to optimally achieve registration in all regions of interest.

When looking for partnering opportunities, corporate partners will inevitably wish to develop a product for as broad a market as possible and therefore, differentiated products that satisfy the requirements of the major regulatory authorities in all relevant regions will be more attractive. Such products will also maximise the opportunity for gaining additional funding and provide attractive exit opportunities for SMEs.

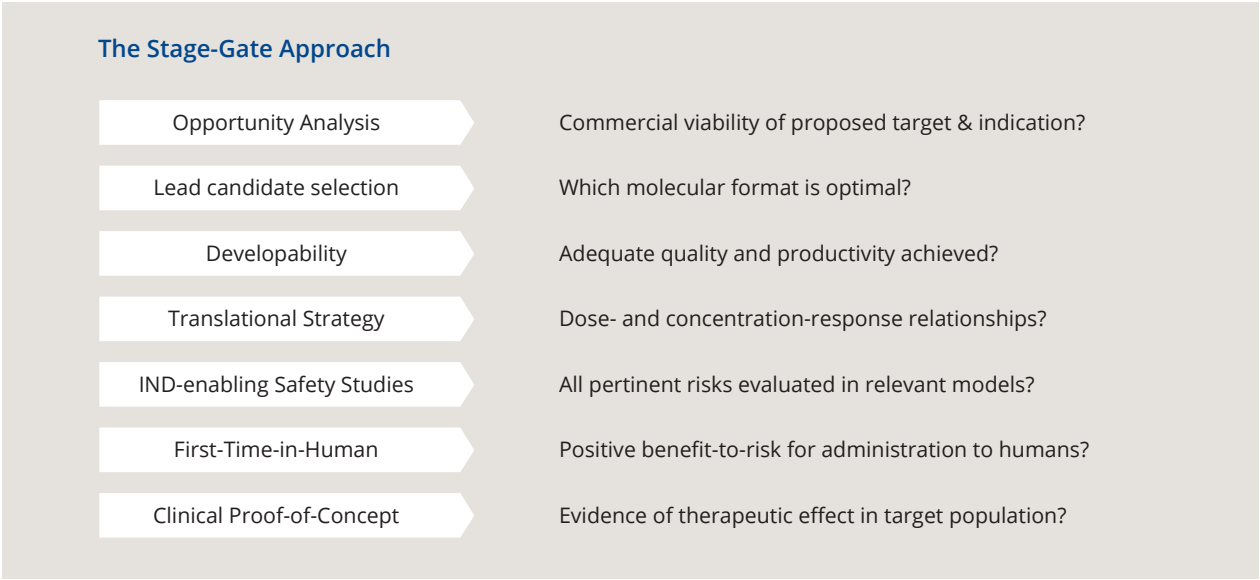
Implementing a global and value-driven perspective in early-stage development is a key driver in positioning the product towards successful global approval and commercialization.

When to start?

Defining a Target Product Profile for the potential drug candidate is a great starting point to delineate an early development strategy.

Go/No-Go criteria as well as milestones and deliverables can be mapped out as part of a stage-gate approach.

Figure 1: Stage-Gates for Early Development.



Where to start?

Starting from the available data (in-house and external), a stage-gate approach can be applied using critical input and assessment of alternative routes for product development. This results in a clear and acceptable product profile that allows proactive mitigation of challenges and gaps. In addition, an early assessment of benefit/risk can be conducted which is further developed through the development life cycle. Consistent, clear product messages, identification of supporting data and the identification of common (core) requirements will result in a core dossier for the EU and US. This will in turn achieve acceleration of development timelines, focussing of resources and increasing the value of the product.

Strategy bit by bit

NDA's expert team can help develop your strategic roadmap to critical milestones that maximize the value of your projects and provide you with a choice of exit opportunities (e.g. partnering, licensing, M&A, IPO etc.).

We can be your strategic partner, helping you build a credible business plan that reflects the value potential of your assets. We can also evaluate your financing requirements (scenarios, costs etc.) and lay out a product development road-map from value proposition to end-customer. We provide support to examine assets, resources and perform gap analysis, map competencies, chart work-packages (discovery, development, commercial) and define resource requirements.

Support building R&D processes and the project structure

In order to facilitate execution of the integrated development strategy, we can support the set-up of your R&D governance (e.g. project management, portfolio management), and provide technical and strategic input in product valuation, risk assessment/mitigation and prioritization. We can continue this support during partnering and due diligence.

Conclusion

Defining an early development strategy and implementing it into an overall strategic roadmap is a very valuable component of overall product development.

This roadmap encompasses the scientific and clinical pull to generate products that fulfil unmet clinical needs and provide benefit to patients. The roadmap also provides the regulatory push to successfully navigate regulatory requirements for product approval and to generate a dossier supporting favourable pricing reimbursement discussions. The endpoint is the maximised commercial value for a potential drug product to a partner, licensor or acquirer. This in turn maximises the corporate value through the achievements of value inflection milestones and provides potential for corporate financing and exit strategies.

The NDA Group approach

Combining NDA's experiences from working across multiple regions and multiple sets of requirements allows us to support companies all the way through the translational stages of product development and throughout the product lifecycle.

We will help you to define integrated project deliverables and input data for informed decisions at critical stages of product development to prioritise your development activities, identify resource and investment needs, resulting in added commercial value and minimised regulatory risk.