

Commercial and R&D: Value Lost in Translation?



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Aligning R&D activities with commercial realities is an issue as old as the pharmaceutical industry itself. The importance of a commercial perspective in R&D is increasing as the downward pressure on drug prices and limitations on market access from private and public payers continue to increase. This is particularly pressing in areas where medicines do not offer differentiated advantages over existing treatments. In parallel, as pharmaceutical organisations have become more complex, regions have become more fragmented, and organisational functions have become larger, it has become increasingly difficult to ensure integrated and holistic commercially-oriented behaviour in R&D. Our experience is that this causes significant frustration in both R&D and Commercial functions, not to mention unrealised value creation. In this Novasecta Note we explore the R&D-Commercial interface and what can be done to improve it.

Introduction

Every year, the pharmaceutical industry spends in the region of \$140 billion in the pursuit of innovation, yet productivity has fallen consistently over the last 60 years. Much has been made of this decline, with Scannell et al. proposing Eroom's Law – "the number of new U.S. Food and Drug Administration (FDA)-approved drugs per billion U.S. dollars of R&D

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spending in the drug industry has halved approximately every nine years since 1950, in inflation-adjusted terms” (Nature Reviews Drug Discovery 11, 191-200, March 2012). Regardless of where one stands on the productivity debate, most will agree that opportunities for improvement exist within any R&D organisation, and internal effectiveness is paramount to preventing the already-high cost from soaring out of control. In this Novasecta Note, we ask how can pharmaceutical companies ensure that the increasingly expensive costs of drug development will result in assets that get patients, physicians, and payers excited?

Novasecta believes that improvements can be made by actively fostering better relationships between the right Commercial and the right R&D colleagues. Solidly connecting the R&D organisation to the realities of the market and customers can seed the development of products that will meet stakeholder needs in the future. This requires persistence and patience: it is as much a people issue as it is a technical issue, and as such delivering impactful change requires appropriate effort, focus, and a long-term perspective.

A Conversation Culture

Despite significant investments and substantial experimentation with different R&D models, the delivery from R&D of value-enhancing products that are commercially successful remains inconsistent. That is not to say that reorganisations or operational excellence initiatives lack merit – they can, of course, add value. It is simply that these approaches often fail to address the underlying problem: the culture and ethos of the organisation. How do the people who make up the company interact with one another, seek input from colleagues, and approach decision-making?

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In our experience, critical decisions are often left unaddressed until a development checkpoint is reached. While these milestones are necessary for good governance, they should never become the sole forums for decision-making. Rather, major milestone gates should serve to ratify decisions made by an on-going series of conversations between the people with the relevant expertise and perspectives, armed with relevant commercial and scientific data and insight. This will create an organisational understanding of the end-to-end process of R&D and commercialisation and, crucially, bring that understanding to day-to-day decision-making.

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Speaking the Same Language

It is possible to create better commercial instincts and capabilities for decision-making in any R&D organisation. This involves bringing clear commercial thinking into the process at the very early stages, well before clinical proof of concept. Importantly, this dialogue must flow in both directions, for commercial functions to understand the R&D process and future assets.

Across the pharmaceutical industry, many intelligent and well-intentioned employees operate in systems that consign them to generate sub-optimal outcomes. Insight into the commercialisation process and deep corporate knowledge of payers, regulators, clinicians, and patients is lost in translation between the often highly diverse and somewhat disconnected market-facing functions where these insights are captured, and the R&D organisation that must apply them to capture future value.

Commercially-Oriented R&D

In our experience, commercially oriented R&D requires three core enablers:

<p>Leadership & Governance</p>	<p>Develop a common Company language to describe the external environment, so that two-way dialogue between Commercial and R&D colleagues can take place.</p> <p>Ensure that a common understanding of customer needs is agreed jointly, so that it can be reflected in the R&D decision-making process.</p>
<p>Processes</p>	<p>Design a methodology that makes customer-facing function accountable for providing insights into the R&D process.</p> <p>Make clear choices about who should do what and when, and set accountabilities and high expectations for individuals and teams.</p>
<p>People & Culture</p>	<p>Align the whole organisation behind a clearly articulated vision for commercially-orientated R&D</p> <p>Leverage 'methodology' and 'translation' to promote beliefs, values, and attitudes that support commercial curiosity.</p> <p>Invest in building and reinforcing a company culture that supports the long term mission of value creation in R&D</p>

These enablers are deliberately focused on people, process and capabilities; as we have found these are the ultimate keys to success. Deep knowledge of, and existing relationships with, external stakeholders is the foundation. To unlock the power of this knowledge, companies must systematically translate and incorporate the explicit and implicit knowledge into the thinking and decision-making processes of the organisation. This way, sizable investments can generate outcomes that are relevant to, and valued by, the market place.

In time, organisations can be evolved to make better choices related to both R&D and commercialisation. R&D can be better enabled to generate more products of value, while commercial functions can be afforded the time necessary for optimal launch planning. There are many benefits from making the effort to understand one another.