Opportunities for efficiency in R&D

Most firms face a challenge of improving returns on investment in pharma R&D. But as Hasini Wijesuriya explains, new ways of understanding patients, their behaviour and their optimum outcomes might unlock a new era of R&D efficiency.

KPMG Rethinking Life Sciences series offers insights and practical advice for leaders seeking agility, adaptability and innovation in business critical areas

Patients' impact on the pharma R&D process is often limited to specific interaction points, usually in the later stages of development. Now we're starting to see a desire to involve patients more widely and much earlier in the process – for example, in creating the Target Product Profile – rather than just design of marketing or delivery options.

This goes way beyond considering patient usage patterns, drug efficacy under different regimens or potential side-effects. We're entering a phase where patients' self-articulated needs; new availability of data about their lifestyles; and the evolution of both payer and regulator expectations are driving change.

The ROI challenge

Underlying this shift is an acute need to improve falling returns on investment (ROI) in R&D. The problem isn't unique to pharma. According to US research by Anne Marie Knott, a professor of strategy at Washington University, "the returns to companies' R&D spending have declined 65% over the past three decades."

Pharma's challenges around dwindling blockbuster drugs and narrowing opportunities in key clinical areas are well understood. Many firms cast a wide net, with more new molecular entities (NMEs) in development – which pushes R&D capacity to its limits. Combined with increasing timelines, the cost implications of additional requirements for late stage trials (such as outcome-based data) and investor pressure, the need to do more with less is getting stronger.

It's a financial imperative, too. As a 2016 study of R&D efficiency among leading pharma firms between 2006 and 2014 explained, "the challenge… is the rising expectations of investors for a reasonable ROI provided by a high number of new molecular entities (NMEs) launched to the major pharmaceutical markets. Although exceptions exist, the industry as a whole did not live up to these expectations, as the total number of NMEs commercialized in past years did not match with the extraordinarily high R&D costs."

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Better R&D across stakeholders

Injecting patient inputs further back in the process – to identify needs and target early research – could be a useful tactic, then. As patients become more empowered and better informed around the treatment development process, reaching out to them as part of that process could also yield valuable market opportunities.

(See our companion article on optimising relationships with patient associations.)

It could also potentially aid relations with regulators, who are increasingly eager to see patient needs reflected in development processes. Recently the European Medicines Agency decided to extend its pilot programme allowing patients to participate in The Committee for Medicinal Products for Human Use (CHMP) discussions on the medicines assessed, for example.

The dialogue has already shifted from "this is the right thing to do," to "patient centricity is key to understanding market access".

That's also true of payers. They want evidence that treatments address real-world problems and symptoms affecting patient lifestyles.

Demonstrating efficacy against notional tests is no longer enough. For example, muscular dystrophy has historically been evaluated against a "six-minute walk test", which is perfectly valid… except the majority of patients cannot walk at all. Re-casting research priorities around outcomes important to patients is critical to payers.

One option is to create translatable metrics that demonstrate impact, with clear guidelines for use, and including ones that are relevant across therapy areas or trial phases to maximize impact.

Internal champions advocating standard ways of working across the organisation also helps pharma companies leverage R&D across value chains.

Technology reveals all

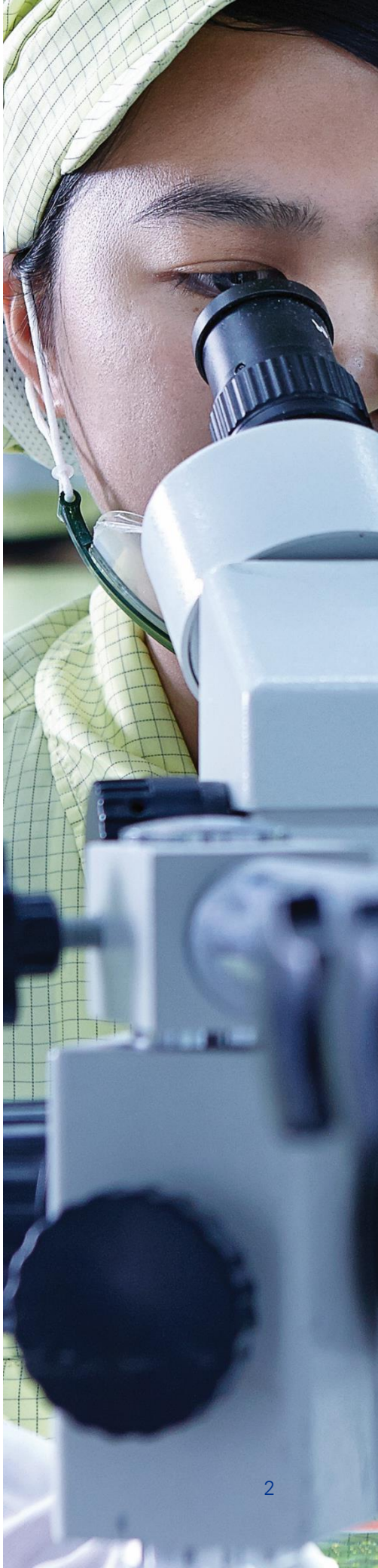
More sophisticated selection of patient end-points, then, helps focus upstream R&D on areas designed to deliver treatments that will gain acceptance in the field. Technology plays a critical role here – both in creating opportunities for patient "push" into the process, and passively pulling in patient data to shape R&D.

The rapid growth of app-powered patient communities is aiding the proactive "push" efforts. PatientsLikeMe, for example, has worked with several pharma companies to guide their R&D. Last year, a study into lung cancer on the site was funded by AstraZeneca and Roche's biotech arm Genentech.

This April, PatientsLikeMe announced a major tie-up with Shire, whose head of R&D Philip Vickers explained: "This will enable [us] to understand how disease impacts patients in their own environment and integrate data from multiple sources on a single platform. Our goal is to gather a more complete picture of the patient and caregiver experience that could potentially guide the development of new, more patient-centred treatments."

Other examples include Patients Know Best – which promotes its patient-controlled records-sharing system to both payers and professionals – and I Want Great Care, a rating and review site ideal for evaluating patient satisfaction.

This raw input is valuable – but there is a risk that the signal-to-noise ratio for upstream research will be intolerable. That's why the "pull" is also key.



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This comes from passive data collection around patient indicators and behaviours using "quantified self" technologies such as wearable technology; better data harvesting in clinical situations; and smarter analysis of all this data.

New technologies make it easier to address varied patient inputs, rather than snapshots from 'expert' or 'professional' patients.

We're already seeing some incredible potential in cognitive technologies such IBM's Watson and Google's Deep Mind for setting target profiles. Analysis of huge sets of patient data has already seen the successful resurrection of cancer treatment Olaparib, on which AstraZeneca (AZ) had previously written off a $285m R&D investment. AZ also has a long-standing relationship with WellPoint's data and analytics subsidiary HealthCore. They gather and analyse real-world evidence (RWE) in part to target R&D investment towards better management of chronic conditions.

Structural and cultural change

A deeper understanding of both desired patient outcomes and better analysis of the patient community in aggregate also ought to help optimise recruitment and retention for clinical trials.

That's partly about more sophisticated participant selection. But the type of patient data now available means researchers can also design trial logistics much more carefully, to ensure faster recruitment, minimal retention issues and compliance with trial regimens.

Patient centricity is increasingly important to both payer and regulator attitudes to new treatments – and pharma companies are going to be increasingly under pressure to demonstrate how that has been reflected, right the way from research prioritisation through to the final stages of the development process.

We've seen many pharma companies adapt to this new reality already – appointing "patient centricity officers" in their R&D function, for example. The challenge is also a cultural one. A board deciding to inject patient perspectives into R&D more aggressively is one thing – but whether this is adequately reflected and embraced by teams on the ground and in the lab is another.

A Chief Medical Affairs Officer at a large pharmaceutical company recently told KPMG "we want to focus on sustainable, pragmatic patient engagement over the long term. This is why we are going deep – selecting the right trials to initiate patient engagement. We need to ensure we don't stretch the R&D teams too much. Importantly, we also need to make sure we make a long term commitment to the patients."

There are legal, ethical and regulatory challenges to overcome. A top-down approach, with empowered leaders and a clear mandate to bring together expertise and develop guidelines, is a good place to start.

We meet with many pharma businesses that are asking when and how to step up their patient involvement in R&D, especially where molecules or marketable treatments are already well into the trials or market readiness process.

Nevertheless, the genie is out of the bottle. Patients have the tools and the desire to shape the way their treatments are developed; payers and commissioners are under pressure to demonstrate value for money and efficacy around those patient-reported outcomes.

Pharma that can react by placing patients more deeply at the heart of the R&D process should reap not only benefits for the people being treated – but also better ROI on their processes and improved investor relations, too.

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"To us, the only customer is the patient, and not the healthcare professional. Everyone else is a stakeholder" – Director, Patient Centricity in Clinical Operations, Large Pharmaceutical Company

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Our approach enables bespoke interventions to be designed and piloted; with the aim of partnering the patient across R&D in the long term

Baseline and agree on focus

Understand strategy and agree on focus:

- Understand current corporate and R&D strategy, goals and ambitions.
- Align internal stakeholders and decide on area(s) within R&D for initial focus, e.g. Research only, Clinical Trail design, R&D project progression etc.

Develop a baseline (interviews / review of client data):

- Current practices and policies on patient engagement, e.g. type / frequency and intended outputs.
- Current measurements and metrics for success (if available).

Agree on key point(s) of intervention:

- Identify initial points at which patient engagement initiatives can be improved or developed, e.g. defining priority projects during the Research phase

Research interventions

Secondary research to collate insights:

- Identify effective interventions from within and outside pharma.

Review interventions and create high level outlines:

- Use a pre-agreed set of criteria to assess interventions for best fit, e.g., capability and resource requirements, evidence of impact.

Align and agree on best-fit interventions for further development:

- Workshop to review interventions and select 1-2 best-fit.
- Wider testing internally to ensure validation and alignment.

Design intervention

Design interventions:

- Create details of interventions including: tools and methods of interaction, internal capabilities, ownership of outputs, contractual terms and conditions etc.

Develop patient profiles:

- Create detailed profiles of the patient(s) or groups to engage, e.g. individual patient, expert patient, carers, patient groups etc.
- Secondary research to identify a set of best-fit participants (if possible).

Assess partnering requirements:

- Review intervention and identify requirements for external partners, e.g. real-time monitoring, patient registries.
- Identify potential partnering options, e.g. IWantGreatCare, PatientsLikeMe, HealthiVibe etc.)

Plan pilot and metrics

Gap analysis:

- Identify key areas that may need strengthening internally.

Plan pilot:

- Create a plan for a pilot, e.g. capabilities, process or program management requirements etc.
- Highlight key considerations, e.g. ethical implications, non-promotional requirements, regulatory hurdles etc.
- Develop a set of validated metrics (e.g. through Delphi panel) to be tested as part of the pilot.

Develop plans for expansion:

- Create a roadmap highlighting timelines and milestones.
- Agree on a set of next steps for expansion of pilot to other trials / other parts of the R&D organization.

Hand over to client

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