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All Change for Pharma and Biotech Partnerships

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Partnerships in R&D

Over the recent past there has been an increasing reliance on partnering to strengthen R&D. We believe that this trend will continue and accelerate.

Organisations developing new medicines need to:

- Understand how sector, environmental and global healthcare trends are driving and influencing change.
- Understand the range of possible alliances and partnerships and their implications.
- Develop new skills and capabilities to capitalise on the opportunities presented.
- Develop different and more flexible decision making and organisational structures to enable full advantage to be taken from partnering.

In the not very distant past, big pharma and biotech worked largely on the principle that in-house and do-it-yourself was best...and with some good reasons. This approach ensured an accessible and growing expertise in key areas of interest; there was certainty about standards and it was relatively easy to change direction or speed as needed. Confounding the picture, relationships with regulators and statutory bodies were predominantly at arm's length and often somewhat adversarial.

Innovation has been another driver for the formation of partnerships. Small units, whether within larger companies, spin-offs or stand-alone organisations have been recognised as offering greater opportunities for innovation. However, by their very nature these smaller units need to collaborate in order to navigate the pathway from research, through development, to commercialisation.

However, the scale, cost and complexity of bringing new medicines to patients are rendering this model untenable. We are moving inexorably from a go-it-alone model to an alliance and partnership model. What does this mean for the future research-driven organisation?

A Plurality of Partnerships in Pharma

Partnering is not new to the pharmaceutical industry. For example, to enable market access, Western-based companies first formed alliances with Japanese national companies at least 30 to 40 years ago. What is new is the scale, breadth and changing nature of partnering.

In our view this will continue because of three key trends:

- The market is increasingly patient-driven. Better informed patients want cures, not treatments. This means the product is not enough - increasingly pharma will be paid for outcomes, not efficacy.
- Healthcare is increasingly cost-constrained, meaning that value-for-money assessment will drive new forms of collaboration.
- Science and technology is becoming more diversified, meaning R&D will need a wider and more multi-disciplinary skills base and will continue to expand in non-traditional countries.

The impact of these trends is already becoming clearer in a number of ways.

"The cost of developing drugs have increased tenfold over the past three decades…from £125M in the 1970s to £1.2bn today reflecting a shift toward more challenging scientific therapies and risk aversion by regulators,"

Andrew Jack, Financial Times, December 2012

Customer & Supplier Relationships

Contract Houses have supplied services to the industry for many years based on a supplier / purchaser relationship, with each side not quite trusting the motives or capabilities of the other. But strategic partnerships are now becoming the new normal. Merck Serono recently announced a 5 year clinical development partnership with Quintiles, whereas Eli Lilly has formed a 10 year, $1.6Bn services agreement with Covance.

Research & Discovery Partnerships

The limited productivity of in-house research coupled with the difficulty of finding new targets has led to numerous early stage partnerships, characterised by significant payments for performance (and, potentially, longer term mergers / acquisitions). Such recently announced partnerships include AstraZeneca's partnership with Oxford Biomarkers for the development of biomarkers for the big pharma's oncology portfolio. Additionally, The University of Dundee recently joined the Division of Signal Transduction Therapy (DSTT) consortium of six major pharmaceutical companies to focus on cell signalling research to speed the process of new drug development.

Development Partnerships

Major companies have joined forces to develop products jointly, so taking advantage of shared costs and enabling exploitation of each partner's particular expertise. For example, Merck is conducting joint clinical trials with Bristol-Myers Squibb on their respective hepatitis C drugs. More unusual alliances include GlaxoSmithKline's tie up with automotive engineering firm McLaren, with the aim of improving general levels of research innovation.

Commercialisation Partnerships

This is not a novel concept. For many years, companies have formed partnerships or alliances to exploit a particular commercialisation expertise or geographical presence. However, few commercialisation approaches have been as comprehensive as Novo Nordisk's quest to "defeat diabetes".

"There are a number of benefits for 'Big Pharma' for establishing [company to company] partnerships. First, they can shave two years off a program by forming a strategic alliance with a biotech, rather than starting the program themselves. Second, they can invest in what they do best."

Dr. Mark Varney, CEO, Cortex Pharmaceuticals. Life Science Leader, January 2013

In 2001, the company launched a global initiative called DAWN (Diabetes Attitude, Wishes and Needs), in conjunction with the International Diabetes Federation, to provide "psychosocial support" for patients with diabetes. Since then it has gradually increased its reach. For example, the company now operates a "National Changing Diabetes" programme in 66 countries, through which it provides training for medical staff, free blood sugar screening services, support for diabetes patient organisations and equipment for diabetes clinics, as well as working with governments to improve the diagnosis and treatment of the disease.

Healthcare Provider / Industry Partnerships

Despite, or perhaps because of, initially hesitant approaches there are now strengthening and mutually beneficial partnerships developing between healthcare providers and the industry. A survey undertaken last year highlighted that nearly 90% of NHS commissioning influencers with experience of an NHS / industry joint working or partnership project would consider doing it again to improve patient care. Furthermore, over 80% reported that they saw it as a means to achieve cost efficiencies or redesign clinical services in a priority area[1].

Other examples of a more open and healthy partnership approach include joint training sessions, for example those developed by the Parenteral Drug Association with the US Food and Drug Administration and the European Medicines Agency, on pharmaceutical regulation and quality management.

Though perhaps not partnerships in the traditional sense, performance based risk-sharing arrangements (PBRSAs) have been instituted by a number of authorities. PBSRAs involve a plan by which the performance of a product is tracked in a defined patient population over a specified period of time and the amount or level of reimbursement is based on the health and cost outcomes achieved[2]. Examples include the Australian authorities linking the price of bosentan for pulmonary arterial hypertension to patient survival, and the introduction of Aricept for mild-to-moderate Alzheimer's, where the UK funded 12 weeks of treatment for patients. In return, the manufacturers provided a full rebate for "treatment failures", defined as a continuing decline in cognitive function.

1. Improving patient care and service efficiencies through partnership working, http://www.pmsociety.org.uk/article/new-evidence-confirms-nhs-industry-partnerships-improve-patient-care-and-cost-efficiencies#sthash.2Rb8n6Lc.On8piuyZ.dpuf

2. Performance-Based Risk-Sharing Arrangements—Good Practices for Design, Implementation, and Evaluation: Report of the ISPOR Good Practices for Performance-Based Risk-Sharing Arrangements Task Force. Garrison L.P. et al. 2013 Value in Health; 16, 703-729

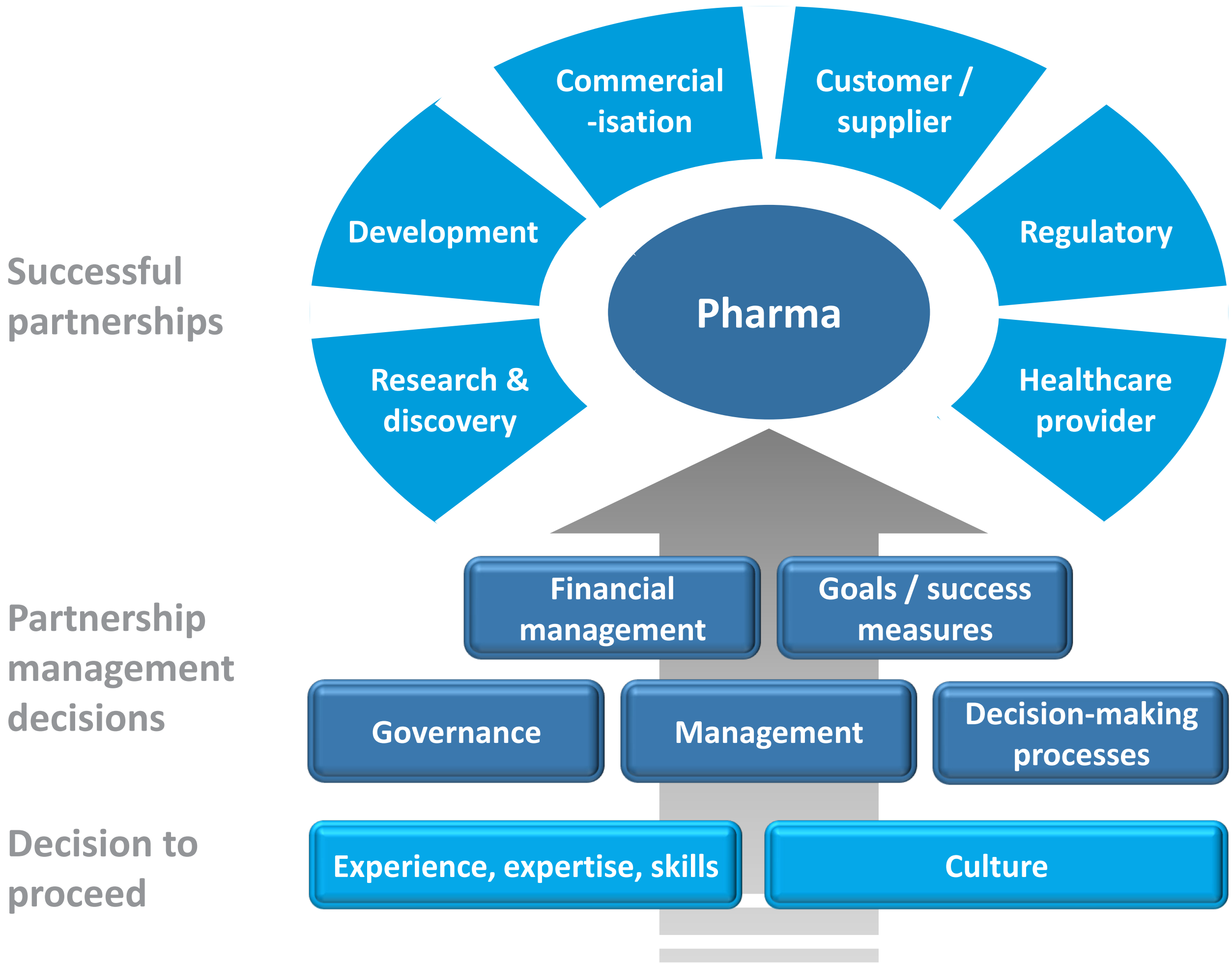

Figure 1: The different types of successful pharma partnerships.

"A good alliance is an investment in relationships, and it is important to ensure that there is a true cultural fit to complement the necessary technical fit".

Garry Menzel, EVP
Regulus Therapeutics Ltd.
Bioentrepreneur, February 2012.

Similarly, in Germany, Roche reached an agreement with several statutory health insurance schemes which allowed Avastin to be co-administered with paclitaxel to test patient survival in both metastatic breast cancer and metastatic renal cell carcinoma. Under the terms of the deal, Roche agreed to provide full or partial reimbursement for cases in which the treatment exceeded a specific total dosage over a certain period of time. In the meantime, the Avastin + paclitaxel combination would have the opportunity to be tested in the real-world environment.

Industry / Regulatory Partnerships

In 2009, Eli Lilly partnered with Rozdravnadzor (the Russian equivalent of the US FDA) to train that body in international manufacturing standards. At a European level, the Innovative Medicines Initiative, a public-private partnership between the European Union and European Federation of Pharma Industries and Associations, has a budget of €2 billion to support joint projects in areas such as safety, education and training. This initiative includes not only payers and industry but also patient organisations, academia and regulatory agencies.

Early Decisions Define Partnership Success

But before dashing in, it is important to realise that in any partnership arrangement there are a host of issues to be decided – and most of them need to be resolved before commitment. The points below highlight some of those issues, and whilst they may not all apply to every partnership; some points will apply to all.

The Partnership Decision

The first question is who to partner with? Sometimes the answer will be obvious, there may be no choice. Where there is a choice, a number of factors need to be considered including:

- Experience, expertise and skills – Experienced partners will have mastered the key partnering skills for example the ability to create trust, to resolve conflict and to create and manage change, plus the ability to develop approaches which maximise joint value. Without these and related skills, partnerships are doomed to failure. It is equally important to be clear on expectations of other expertise that each of the partners will bring to the table – particular scientific specialisms or capabilities for example.
- Culture – exemplified by your organisation's style in decision-making. Do you approach decisions consensually, or do you have

a more directive approach, and how will your partner's style match your preferences? Is the management style hands-off or close supervision? You need to understand if you can recognise and reconcile any differences, because if you cannot, there is trouble ahead.

Managing and Running the Partnership

Even with a limited choice of partners, governance and management practices can make or break a deal. It is essential that these are agreed very early in the relationship:

- Governance – How will a joint governance body operate, who will chair, and is there to be equal representation from all parties? What information will governance require to do their job, who will provide it, and how will it be generated? What sort of reporting is required?
- Management – Will there be a single manager of any partnership, how will they be selected, and what skills will be needed? What authority will the manager have? How will partnership teams be set up, who will be on them, and what will be their roles?
- Decision-making processes - how will decisions be made, which decisions need to be made jointly, which can be made by individual partners, and who will be responsible? Is there a clear escalation process for any issue? It is particularly important, given the complexity of interests and stakeholders, that those partnership arrangements have robust decision-making processes that are agreed to upfront by all parties and adhered to.
- Financial management – how will costs be shared (and on what basis will cost be decided), how will returns be divided, and how will investment be managed?
- Goals and success measures – Are goals and objectives clear? Who will deliver what? Are plans jointly developed and agreed? Are success measures and frequency of assessment agreed –do these include team and governance performance, value delivered and process effectiveness and efficiency?

Planning for failure

Whilst planning for success is essential, accomplished partners are aware that things can go wrong....and sometimes terminally wrong. For this reason it is vital that termination provision is included in the initial agreement. This needs to cover performance failure (failure to meet goals, failure to provide agreed resource etc.) as well as termination because the project failed – it just did not work despite everyone's best efforts. There is no shame in suggesting things might go badly!

Phenestra enables key decision-makers in Life Sciences to master the complexity of developing and commercialising new products.

We provide expertise across 5 vital disciplines to help you develop your decision-making capabilities:

- Portfolio Optimisation
- Managing Partnerships
- Horizon Scanning
- Lifecycle Management
- Marketing Excellence

Contact details
For more information or to arrange further discussion please contact Phenestra Ltd.

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Partnership is a Given, Success is Not

We believe that partnering and alliance creation and management will increasingly underpin successful product delivery in the pharmaceutical industry.

This has profound implications for both R&D and commercial functions, including:

- Scientific capability will not be enough. Scientists will increasingly engage with partners and will drive alliances, so need support in such decision-making. Organisations will need to develop a cadre of partnering savvy scientists and managers with new and broader skills and expertise.
- New decision-making practices and structures will need to be developed. Individual organisations will need to be prepared to cede responsibility to joint committees, whilst R&D roles and responsibilities from senior management downward will change.
- New metrics will be needed to determine the value of new potential partnerships and evaluate the performance of existing ones. Partnership efficiency and effectiveness will be an important component of value delivery, so deciding on appropriate performance indicators will be vital.
- Organisations will need to develop a more flexible approach to product development. “That’s the way we do it here” will not work. Building cross-organisational trust and a common vision will be key to success, which means that hard decisions will sometimes need to be made about internal structure, process or personnel.

Whilst the underpinning science and technology forming the foundation of the pharmaceutical industry will continue to move forward and offer huge opportunity, capitalising on that opportunity through effective partnership requires a significantly increased focus on relationship and organisational management.

Pursuing active partnerships across multiple areas has become an absolute necessity for the successful growth of big pharma and biotech alike. Making the right decisions around who to partner with, when and why has therefore become a critical marker of success for the industry.