

#### ROCHE'S PHARMA PARTNERING PROCESS INVOLVES:

- Alignment with appropriate partners
- Deal structuring that works for both parties
- Alliance management beyond the deal

# COLLABORATE TO GENERATE

The world of medicine is constantly changing and pharma companies need to be innovative to ensure continued growth. Forming an alliance is one solution, and a well-designed partnering strategy is essential for success, writes Peter Hug, Roche Pharma Partnering.



#### Author

Peter Hug is global head of Roche Pharma Partnering. He joined Roche Pharmaceuticals, Switzerland in 1983, in the pharma marketing department. Since then he has worked in the company's offices in Canada as assistant product manager, Greece as head of pharma, Uruguay as general manager and Germany as head of diagnostics. He returned to the Swiss office as general manager in 1996, and became general manager of the Spanish office in 2001.

At Roche, the core of the R&D model is a recognition that no company has a monopoly on innovation. This means looking to a company's own R&D as well as external alliances for new innovations to complement the product pipeline. Collaboration is therefore an integral part of Roche's culture and a well-designed partnering strategy is essential for its continued growth.

#### Process and philosophy

Roche Pharma Partnering was formed in 2001 as a department dedicated to building a network of world-class alliances. The aim is to strengthen Roche's portfolio and to transform scientific innovation into medicines that make a difference to patients' lives. To achieve this, Roche has developed a partnering strategy that governs the process of creating partnerships, and examines how to build strong relationships that nurture productive collaborations over the long term.

The process includes alignment with appropriate partners, deal structuring that works for both parties and alliance management beyond the deal. The philosophy ensures that Roche's core values of respect, autonomy, flexibility, accessibility and long-term vision are reflected in all its partnerships.

#### Innovation network

Collaboration is inherent to Roche and its experience in this area helps shape its future partnering strategy. The structure of the Roche Group is built on collaboration through a unique innovation network consisting of the Roche Pharmaceuticals and Diagnostics divisions, together with group companies Genentech and Chugai. Integrated into this structure is a global network of around 80 external partners.

Figure 1. Transforming deals into marketed products

Product	Partners
Viracept	Agouron
Avastin	Genentech
Herceptin	Genentech
MabThera	Genentech
Tarceva	OSI
Kytril	SmithKline Beecham
Fuzeon	Trimeris
Tamiflu	Gilead

Roche's collaboration with Genentech is perhaps the most well-known long-standing relationship in the industry. Roche was an early investor in Genentech and gained the majority stake in 1990. Since then, Genentech has grown to be a major force in biotechnology and the partnership has brought leading oncology drugs, such as Avastin, Herceptin and MabThera/Rituxan, to the market.

Chugai is a more recent addition to the Roche Group, having joined in 2002. This has also been a pivotal relationship, introducing Chugai products such as Actemra to global markets beyond Japan, while bringing Roche Group products such as Herceptin and MabThera/Rituxan to patients in Japan.

A key element of these collaborations is the operational independence each company enjoys. Creativity and productivity is best achieved when both parties operate autonomously, while also collaborating, pooling expertise and sharing success.

This arm's length approach has become a hallmark of Roche's partnering strategy and is offered to all its partners. Together, Roche and its partners have brought a significant number of innovative compounds to its pipeline, as well as products to the benefit of patients (see Figure 1). Wood Mackenzie has ranked Roche as a leader in this area, having brought eight partnered compounds to the market, including Tamiflu with Gilead, Tarceva with OSI and Fuzeon with Trimeris, in addition to Roche's portfolio of Genentech products.

**Creativity and productivity is best achieved when both parties operate autonomously, while pooling expertise and sharing success.**

### Identifying partners

In building the network of partners, Pharma Partnering follows a process of 'want, find, get, manage'. The 'want' is a strategic decision based on science and business needs, while 'find' is an external search for the 'want'. Roche encourages unsolicited contact from biotechs, but Pharma Partnering's team of finders is also dedicated to proactive outreach. Finders bring prospective partnerships to Pharma Partnering for assessment based on three criteria:

- Strategic fit
- Scientific merit
- Financial feasibility

For strategic fit, Roche evaluates whether the new project will complement its expertise in R&D or commercialisation. New partnerships should support internal research around Roche's main therapeutic areas, or may also focus on innovative technologies. Scientific merit determines if a new project will provide patients with an improved, safer, more efficacious, differentiated treatment.

Roche takes a long-sighted view of innovation and welcomes exciting concepts in the research phase. Its early investment in monoclonal antibodies is a good example of this – when the general perception was doubtful over the potential of biologics as medicines, Roche maintained its belief in the field and initiated collaborations with Genentech and other companies such as Genmab. Roche has maintained these collaborations and they have helped it to the forefront of therapeutic antibodies.

**Figure 2. New models for partnering: Roche-Aspreva – an indication-splitting alliance**

- The asset: CellCept, Roche's franchise leader in transplantation
- The deal: Apreva receives a licence for development and commercialisation in underserved autoimmune indications

**'The Roche-Aspreva alliance represents a sought-after answer in addressing the pharmaceutical needs of patients with less common diseases.'**

**Frederick Frank, vice chairman, Lehman Bros**

### Creative deals

The third stage in Pharma Partnering's process of creating partnerships is 'get'. This refers to the structuring of deals, tailoring the terms to meet the needs of each partner. Roche recognises there is no single formula that fits every case. Such flexibility has given Pharma Partnering extensive experience in creative deal-making, and Roche builds on its experience to select and combine successful elements for future partnerships.

The deal with Aspreva is one example (see Figure 2). This is a breakthrough indication-splitting partnership designed to bring innovative medicines to a wider patient population: Aspreva is dedicating its research strength in lupus and other autoimmune diseases to extend the benefits of Roche's leading transplant drug CellCept. This structure has proven to be productive – Roche and Aspreva have successfully brought CellCept to phase 3 clinical development in lupus, an indication that has not had a new therapy for over 30 years. The Lupus Foundation of America has recognised the contribution of this partnership in making a positive long-term commitment to improving the lives of the millions of patients with autoimmune diseases.

### Long-term relationships

R&D is a lengthy and challenging process. A long-term perspective with effective alliance management is essential to maximise the potential of a partnership. Consistent with the overall partnering strategy, Roche also has a clear structure and philosophy that drives alliance management.

Functionally, alliance directors act as the interface between Roche and the partner. They are assigned at the deal-making stage to ensure that both Roche and its partners have a clear understanding of each other's needs at the outset. Beyond the deal, the same alliance director remains with the partner as the sole point of contact for the entire Roche team assigned to the collaboration – from the scientists to lifecycle leaders to the highest levels of the organisation's management. The philosophy of alliance management is to empower a partner, to ensure that momentum is not lost in the continued

**Figure 3. Building long-term partnerships: how the Roche-Evotec relationship evolved**

- 2001** Chemical library (extended 2002)
- 2002** HERG agreement (renewed 2003, 2004, 2005)
- 2003** Lead optimisation Roche cancer target  
Licence Roche's NMDA portfolio  
Technology analysis for diagnostics
- 2004** Broad chemistry collaboration
- 2005** Evotec licenses Roche's GABA agonist
- 2006** Evotec licenses Roche's MAO-B components

'Roche has always been a reliable partner that has strongly supported our strategic development.'

**John Kemp, vice president of R&D, Evotec**

development of the asset, and to build a relationship on trust and respect.

Evotec is one such alliance that has evolved from a technology deal for chemical libraries to a true strategic alliance (see Figure 3). In five years, Roche has entered over ten licence transactions, spanning both in-licensing and asset management. Cooperation now takes place on

many levels, from building chemistry libraries to assay development, lead optimisation and out-licensing of drug candidates from Roche to Evotec.

The philosophy of alliance management is to empower a partner and to build a relationship on trust and respect.

**Partnership evolution**

Today, Roche has over 80 active alliances; tomorrow, it hopes to welcome more innovative partners into its network. As these alliances grow, exploring new and evolving trends in medicine, Roche will reassess and adapt its partnering strategy according to the changing environment. However, the company philosophy will remain constant – to build enduring relationships based on respect, autonomy, flexibility and long-term vision. With its partners and colleagues, Roche aims to continue moving forward, transforming scientific innovation into medicines that make a difference to patients' lives. **END**

**EXCEL LIFE SCIENCES**  
experience you can trust

**SITE MANAGEMENT**  
Excel Life Sciences, a US-based India-focused pharmaceutical research organization, has an extensive network and domain knowledge, enabling biopharmaceutical companies to complete clinical development and expedite FDA approvals.

- ★ Over 80 years of Domain expertise in clinical drug development
- ★ Over 45 years experience in obtaining approvals from the Ministry of Health
- ★ Over 30 years experience in biometrics and data management

**DATA MANAGEMENT**

**TRAINING**

**PHARMACEUTICAL CONSULTING**

Durham	Los Angeles	Delhi (India)
Dr. Vijai Kumar	Shiva Swami	Dr. Sauren Das
Tel: +1 919 597 8040	Tel: +1 310 804 5502	Tel: +91 9810255630
Vijai@ExcelLifeSciences.com	Shiva@ExcelLifeSciences.com	Sauren@ExcelLifeSciences.com