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From Technology-Transfer to Know-How Interchange

The Role of Academic-Industrial Collaborations in Innovative Drug Discovery

By joining forces and complementing expertise, benefits for both partners – pharma industry and academia – can be realised.

Photo: Bayer Schering Pharma

The importance of drug discovery alliances between pharmaceutical industry and academic institutions is growing and gaining momentum due to increasing "needs" on both sides. Thereby the types of partnership are changing and novel models on how to collaborate are being explored. One key aspect is how to generate value for both partners out of these joint efforts.

The pharmaceutical industry is currently facing major challenges. The block buster model seems to be outdated as most of the low hanging fruits have been exploited. This is exacerbated by the fact that there is increased pressure on pricing due to the need to reduce health care spending. In addition, the industry has to overcome the R&D challenge: On average it takes ten to twelve years and investments of approximately one Billion US Dollar to launch a new drug whereby most of the costs (up to 75%) are attributable to failures. Due to the introduction of novel technologies in the "omics" area and increasing safety requirements imposed by regulatory authorities, R&D costs have risen steadily. On the other hand, the number of New Medical Entities (NMEs) approved by the regulatory authorities is declining. This puts pressure on the R&D organisations to generate new approaches to developing novel and innovative drugs (Danner et al. 2009).

The main reasons for failures in drug development, in addition to economic aspects, are safety concerns and lack of efficacy. To avoid late failures the early drug discovery process has to be improved. This means to advance the understanding of disease mechanisms, to develop more predicitive animal models and to identify predicitive biomarkers and stratification markers to allow early clinical Proof of Concept and patient stratification.

This, however, cannot be addressed by industry alone and partnerships at various levels are important in meeting this challenge. New, more flexible ways of interaction between the different stakeholders (pharmaceutical industry, biotech, academia) need to be established. The current paper addresses the role of academic-industrial collaborations in the drug discovery process. The research presented is the result of in-depth qualitative interviews with twelve former and current leaders and/or heads of partnering functions from eight major pharmaceutical and biotech companies, directors from five scientific organisations and a group of ten young group leaders in academic institutes.

Why are collaborations established?

One goal of our research was to investigate the reasons why collaborations between pharmaceutical industry and academic institutes are set up. As a result it can be concluded that the main driver for pharmaceutical industry to collaborate with academic institutes is to foster innovation in drug discovery and development. Access to novel ideas, specific expert know-how on disease biology/pathophysiology or pathways, targets, technologies or animal models are the drivers in initiating partnerships with academia. In particular in the evaluation of new emerging fields, such as cancer stem cell research or in the identification of novel biologics, partnerships with academia play an important role. Outsourcing or provision of services is not the focus in collaborations between industry and academia. On the other hand, the study revealed that academia is interested in testing and validating their hypotheses (e.g. targets, disease models), translating their ideas into innovation, gaining access to company specific technologies and know-how in drug discovery and obtaining additional funding (either direct funding from industry or via consortia).

Strategic importance of collaborations is increasing

All the experts interviewed stressed the increasing strategic importance of collaborations between industry and academia which is supported by recent findings (Melese et al. 2009). Scientists at public institutions are more and more interested in field-testing their ideas and translating their ideas into innovative products. This is also reflected by the fact that many academic screening centres have been established, mainly financed by public funding (such as the NIH Roadmap Initiative for Molecular Libraries). In addition, governments are pushing publicly funded research organisations to foster the translation of research results to products (such as formulated in the Hightech Strategy of the Federal Ministry of Education and Research, Germany). On the other hand, industry needs exchange with academia to gain additional expertise to foster innovative research and drug discovery programs. In Figure 1 the benefits for both partners are summarized.

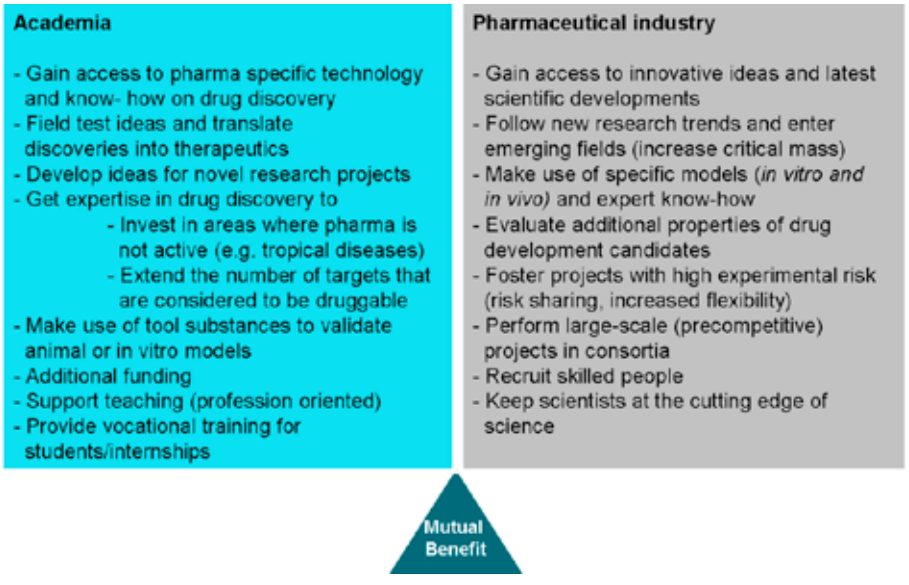

Figure 1: Benefits of industrial-academic collaborations.

Partnerships between industry and academia: current trends

Our research revealed that the current trend in collaborations with academia points towards strategic partnerships and alliances (Figure 2). Outsourcing or mere sponsorship is no longer

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seen as a successful basis for innovation creating collaborations. Real partnerships based on extensive exchange of know-how and joint research approaches with joint project teams are increasing. Individual project based collaborations still exist to address specific questions, but the importance of partnerships between entire organisations or larger units (as e.g. networks or competence clusters) is increasing. Novel risk and reward sharing models between industry and research organisations are evaluated leading from individual problem-solving approaches to long-term dialogues addressing major challenges in drug discovery. The goal is not just to foster the one-dimensional transfer of results from academia to industry, but to establish dynamic multidimensional networks (from technology transfer to know-how interchange) leading to novel and innovative ideas triggered by intensive interactions, combining complementary skills and expertise. Such models have been highly successful in the development of novel technologies in other industries. For example FEI, the world leader in electron optics and focused ion beam technologies, is developing its novel microscopes together (in joint teams) with their customers, i.e. academic groups at internationally renowned research institutes. Another example is given by the Dutch company Philips. In recent years Philips transformed its research facilities in the Netherlands from a fully owned research institute to a high tech campus, consisting of a network of small companies, academic research institutes and Philips research labs (MiPlaza). This setting fosters multiple interactions and provides fertile ground for innovation.

Recent examples of novel “risk and reward“ sharing as well as highly interactive networks in pharmaceutical industry are provided by the foundation of the “Academic Incubator” between the University of Cambridge and GSK and the strategic alliance set up by the German Cancer Research Centre and Bayer Schering Pharma. In both examples joint teams have been established to discover and develop innovative drugs, which have been selected by joint committees. These are pioneering approaches to collaboration, as both partners not only contribute know-how and expertise but also bear financial risks, for which the academic partner is compensated in the case of success. Other types of risk-sharing approaches are consortia between industry and academia supported by public funding (e.g. EU or national funds). One example is the recently established Innovative Medicines Initiative (www.imi-europe.org), a unique public-private partnership between the European Community and the European Federation of Pharmaceutical Industries and Associations (EFPIA). The initiative aims to remove major bottlenecks in drug development by promoting precompetitive research. The focus of the initiative is to develop predictive models and techniques to improve the safety and efficacy of new medicines. These efforts are underpinned by a knowledge management as well as an education and training program aiming to improve the flow of information at different phases of the drug development process. These challenges will be addressed in major joint consortia between industry and academic groups consisting of 10 to 15 pharmaceutical companies as well as 10 to 20 academic partners. The public funding of one billion Euros goes exclusively to the public partner while the pharmaceutical companies have committed to contribute to the initiative “in kind” in a volume of at least another billion Euros.

Keywords
innovation
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trends in industrial-academic collaborations
key success factors for collaborations

Challenges in academic-industrial collaborations

Analysing the interaction between pharmaceutical industry and academia also revealed a number of differences between both partners resulting in challenges for the partnership (Table 1). The main differences between pharmaceutical industry and academia can be attributed to different goals, drivers as well as expectations of stakeholders. Whereas the role of academia is to generate and disseminate knowledge, industry has to convert knowledge into products and generate profit. Accordingly, different types of people are attracted to the two organizations, resulting in cultural differences and operational tensions in partnerships. On the other hand,

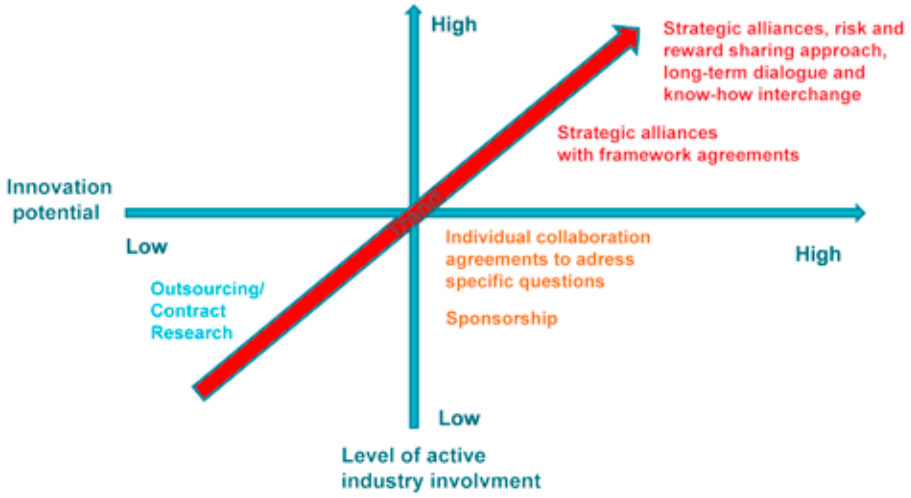

Figure 2: Trends in collaborations between pharmaceutical industry and academia. The trend points from individual agreements to "risk and reward" sharing strategic alliances with interactive multidimensional networks, from "technology transfer" to "know-how interchange".

governments expect universities and research centres to contribute to the growth of local economies and to facilitate the creation of products from ideas. In addition to different goals and motives, organisational barriers have been identified that need to be overcome (Table 2). Know-how and expertise provided by academic institutions is often not structured or presented in a tailored manner to industry. Company licensing offices are flooded with offers that do not address the particular needs of the company. Here industry has to improve communication and clearly define what it needs. This, however, is often hindered by concerns regarding confidentiality. Other obstacles are operational barriers on both sides. Whereas in large companies hierarchical structures often result in complex and often time-consuming decision making, academic institutions still need to improve management capabilities e.g. for contract negotiations, interface and collaboration management. In addition, appreciation of funding from industry is lower compared to public grants (e.g. from NIH or German Research Foundation). Furthermore, unclear frameworks from governments make it difficult for academic institutions to judge how far they can go in partnerships without compromising the universities legal status, autonomy or funding.

Trends are changing from 'individual problem solving-collaborations' to 'long-term risk and reward sharing alliances' and from 'technology transfer' to 'know-how interchange'.

Key success factors in academic-industrial collaborations

Within this study Key Success Factors (KSFs) fostering the establishment and management of successful relationships were defined. Successful collaborations are defined as relationships that deliver value to the organisations relative to alternative investments. Value, according to Zella King (pers. Comm.) is defined as "benefits generated (such as benefits for patients and revenue from novel or improved products/drugs) less costs (time, money, resources, opportunity costs)". As a result of the analysis KSFs were identified which were consolidated in the RESOLVE model (Figure 3).

In addition to the scientific expertise provided on both sides, the establishment of a trusting relationship was seen as the most important success factor in collaborations. Therefore, it is worthwhile investing significantly in the establishment of a solid and robust relationship, especially at the beginning of a joint venture. Teambuilding efforts as well as regular meetings are options to meet this challenge.

Another key success factor is the level of strategic fit. As depicted in Table 2 the drivers and goals for academia and industry are often different. Therefore, transparency of each partner's

Differences	Challenges	Academia	Pharmaceutical industry
Cultural differences	– Different types of people attracted – Different cultures exist	Guided by scientific interest and findings	Guided by overarching organisational goals to develop new therapeutics
Strategic tensions	Different goals and drivers	– Generating and disseminating scientific knowledge – Make original discoveries and contribute to society by translating scientific finding into products – Get financial support – Publish data	– Converting knowledge to products – Make medicine and generate profit – Get external expertise – Maintain competitive advantages
Operational tensions	Timelines and objectives are different	– More long-term orientation – More flexibletimelines – Wishes to keep IP Rights	– Focused on project objectives – Strict timelines – Wishes to get proprietaryposition/ freedom to operate
Learning challenges	Different value of contributions of partners	Underestimate complexity to be addressed in drug development (timelines and challenges that have to be overcome)	See initial idea only as first step in drug development
Communication challenges	Meaning of words differ and are not clearly defined	e.g. Translational research is regarded as the transfer of results from basic research to early development	e.g. Translational research is regarded as clinical proof of concept in humans
Commitment	Commitment to different stakeholders	Committed to society to generate and disseminate knowledge and to educate students	Committed to society, patients and shareholders to generate medicine and value

Table 1: Differences observed between academia and pharmaceutical industry

Academia	Industry
Know-how and expertise provided by academic institutes is not bundled and presented in a tailored manner to industry	"Needs" are not clearly communicated
Operational flexibility and processes need to be improved (e.g. contract negotiations)	Decision making is complex (large decision making unit) and usually takes a long time
Appreciation or value of industry funding is not equal to public funding	Concerns to spread confidential information hinder open communication
Frameworks for collaborations are ambiguous – It is unclear how far partnerships between industry and academic institutes can reach in order not to compromise the legal status and autonomy of the research institute	Strategic reorientations may influence collaborations and may lead to terminations

Table 2: Organisational barriers for academia-industry relationships

goals is an essential prerequisite for value-generating relationships. In order to create added value the skills and expertise also have to be complementary. This point is often underestimated, as the selection of partners in most cases follows purely scientific criteria. Professional operational management forms another pillar of the relationship. This poses a challenge mainly for academic institutions and could easily be overcome by introducing project management training for group leaders and senior scientists. The willingness to learn from each other provides the

basis for a long-term and successful dialogue. Both partners have to be open to learn and to overcome established paradigms and beliefs. Industry has to be prepared to go down new paths and academia has to learn more about drug discovery and the required standards.

The fourth success criterion relies on open, honest and timely communication to avoid conflicts resulting from miscommunication. If conflicts appear, clear mechanisms for conflict resolution (e.g. mediation by project leader, steering committees) must be in place. However, none of these factors alone is sufficient if real commitment and enthusiasm is lacking. Commitment to build a value generating alliance is required at all hierarchical levels involved – from the scientists at the bench to top management. The model is supported by the findings of King (2008) highlighting effective interface management and efficient knowledge production as a prerequisite for value generating alliances.

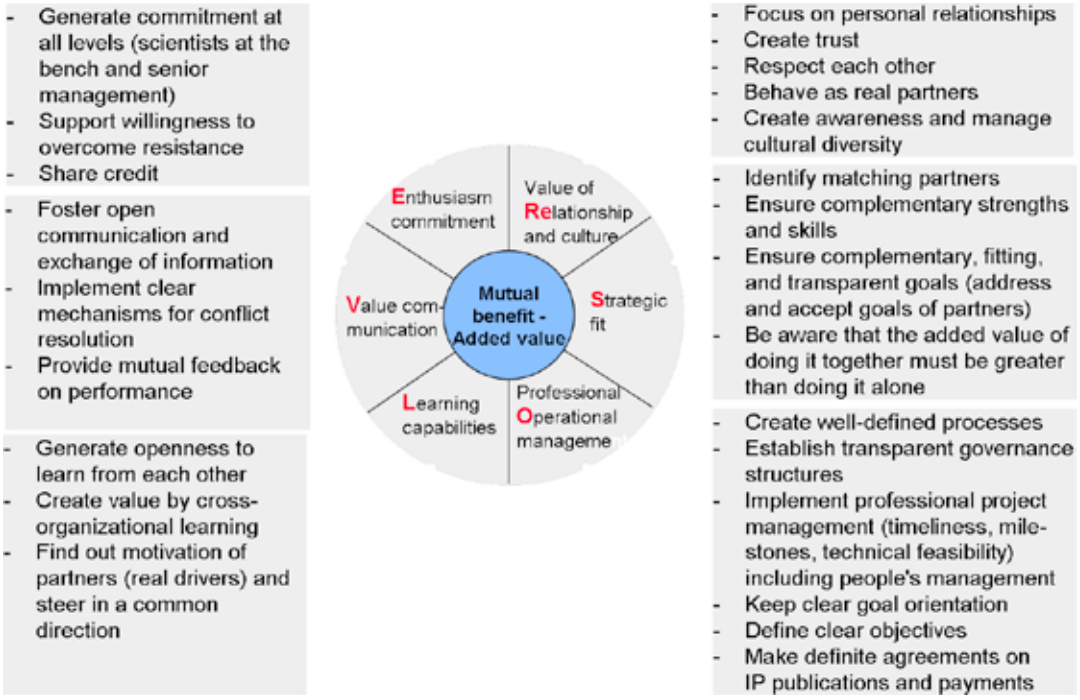

Figure 3: RESOLVE Model – Key Success Factors to generate value by collaboration management.

Based on the RESOLVE model, a check list has been created summarizing critical aspects that have to be considered when initiating collaborations (Table 3). To make sure that these Key Success Factors are taken into account for larger alliances a professional alliance management should be in place – both in academia and industry. Together with the investigators the alliance manager should take care of the project management, the communication, the stakeholder management and take measures to promote the relationship and create a trustful environment for the alliance.

How to overcome organizational barriers

As depicted in Table 2 not only differences between industry and academia resulting from distinct strategic goals and cultures have to be overcome, but also organizational barriers. Academic institutions need to professionalize their approach to finding matching partners and their ability to manage academic-industrial alliances. On the other hand, industry needs to become faster in its decision making and more open in providing relevant information to academic partners, as this exchange of know-how and data forms the basis for further innovation. In recent

Summary

Die Zusammenarbeit zwischen Pharmaindustrie und Wissenschaft in Bezug auf die Entwicklung neuer Medikamente wird immer wichtiger. Dabei verändert sich die Art der Kooperation von einem eindimensionalen Technologietransfer hin zu einem mehrdimensionalen Austausch von Know-how. Um die Partnerschaften zu optimieren, wurde das RESOLVE Model entwickelt, welches Schlüsselfaktoren für eine erfolgreiche Zusammenarbeit von Industrie und Wissenschaft zusammenfasst.

1.) Identifying matching partners
Do the partners fit together?
Do they share the same values? Is there a cultural fit?
Is there a willingness to respect and support each other?

2.) Strategic fit
What are the expectations of the partners and the respective goals?
Can the expectations with respect to scientific quality and expertise be provided by the partner?
What do the partners want to get out of the collaboration?
Will the goals fit together?
Do the partners provide complementary skills and expertise?

3.) Operational management
Who is in the driver seat for the collaboration, on a management level and on an operational level?
Will there be a single interface for effective collaboration management?
Have clear agreements been made before the start of the collaboration regarding objectives at each site, timelines, publication strategy, IP rights (who owns what?), budget, decision processes, conflict management?
Have all stakeholders been involved in the agreement and do they support it?

4.) Learning capability
Is there a willingness and interest to learn from each other?
What programmes can be initiated to foster cross-organisational learning (e.g. exchange programmes, seminars)?
Can specific training be offerend for members of the alliances (skill and competency building)?

5.) Communication
How is the communication culture of the partner?
How will timely communication be ensured?
How can an efficient and satisfactory exchange of information be ensured (e.g. regular meetings, communication platforms)?
Are conflict management conflict escalation measurements in place?

6.) Commitment
Are all stakeholders committed to the collaboration (from scientist at the bench to senior management)?
What can be done to overcome resistance and to motivate the people involved?
Will the credit of the collaboration be shared? What's in for each partner?

Table 3: Check list for initiation of joint projects

years pharmaceutical industry has been very restrictive in its provision of information which may prevent the influx of novel ideas and therefore hinder innovation. On the other hand, IP secures the competitive advantage within the pharmaceutical industry. Therefore, a balance between exchange of information and securing competitive advantage has to be found. Measures to overcome these barriers are summarized in Table 4.

Conclusion and recommendations

Novel collaborative models are currently being developed due to increasing "needs" on both sides: Whereas scientists at public institutions are more and more interested in field-testing and

Academic institutes:

- professionalize the process to find matching partners
- professionalize contract and collaboration management by efficient operational structures (alliance management)
- set appropriate incentives (by funding and reward systems) to translate research into products and foster collaborations with industry
- provide incentives (financial/emotional) to enter collaborations with industry

Governments:

- provide clear frameworks for collaboration between industry and public funded research organizations (how far can they go without compromising autonomy?)
- provide incentives for industry-academia collaborations

Industry:

- improve communication and define its requirements and interests clearly
- improve transparency (provision and exchange of information, generation of dialogue platforms) and the speed of decision making
- set up respective operational structures to promote collaborative efforts and provide incentives for partnership approaches with academic institutes as a measure to foster innovation

Table 4: Measures to overcome organisational barriers between pharmaceutical industry and academia

validating their ideas and hypotheses, industry – due to the productivity gap – needs to foster innovation and broaden expertise in an efficient and flexible manner. By joining forces and complementing expertise, benefits for both partners can be realised.

Trends are changing from "individual problem solving-collaborations" to "long-term risk and reward sharing alliances" and from "technology transfer" to "know-how interchange". To generate value out of these collaborative efforts the following aspects should be taken into account:

1. To overcome differences between pharmaceutical industry and public research institutes, key success factors summarized in the RESOLVE model should be taken into account and professional alliance management should be implemented in academia and industry.
2. The ability to identify partners with complementary skills, expertise and objectives is the key to generating value. Partnerships encouraging multilevel dialogue will only bear fruit if partners provide complementary skills and compatible objectives. Only if the "value of doing things together exceeds the value of doing it alone" will collaborations be successful in the long-term. Therefore, both partners should invest time and effort to identify partners that match best.
3. Appropriate incentives and rewards to foster collaborations between industry and academia are a prerequisite for successful relationships. If an organisation (company or public institute) values joint efforts with financial and emotional rewards this promotes the willingness and motivation of people to become engaged in research alliances.
4. The bundling of know-how in academia in interdisciplinary competence clusters or (virtual) centres not only promotes innovation and new scientific findings, but also facilitates interaction with industry if professionally managed interfaces are provided.

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