Translational balance

By C. Simone Fishburn, Executive Editor

Different mindsets, motives and mandates have blocked the progress of companies and academics in forming deals to move discoveries from academia to industry. The solution is a balancing act that engages scientists in the partnerships, imposes a realistic view of the risk and, if necessary, trades value for the ability to execute.

Those were the conclusions of a panel of leaders from translational centers across Europe and the U.S. that met last month at the BIO-Europe conference to discuss issues surrounding the commercialization of therapeutics and diagnostics from universities and other academic organizations. The conference was organized by **EBD Group** and the **Biotechnology Industry Organization** (BIO).

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The five panelists represented technology transfer divisions or translational units allied with specific universities. Translational units are on the rise—they take discovery-stage projects from the allied university's labs and perform additional preclinical experiments to build a package that can be commercialized.

The panelists' institutions were **MRC Technology** (MRCT), **Max Planck Innovation GmbH**, the **Institute of Science and Technology Austria**, the **Broad Institute of MIT and Harvard** and the **Cluster for Individualized Immune Intervention** (Ci3), an organization that connects partners from pharma, biotech and academia.

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Managing mindsets

Rainer Wessel, executive board member at Ci3, said that a common problem he sees is the gap between the researchers' view of their programs' status and what pharmas actually require. "You talk to people from universities, very often they have a good paper. They think that's already 90% of the picture to getting a good deal done"

However, that is rarely the case, and the data produced by academic labs usually do not contain much of the preclinical validation that pharmas want to see.

According to Wessel, the goal is to make both sides understand each other's reading of the situation.

One solution, he said, is to create working groups containing research scientists and representatives from commercial and other organizations. For example, one of Ci3's members, **TRON**—the translational unit at the **University Medical Center of the Johannes Gutenberg University Mainz**—created a working group with the Cancer Immunotherapy Consortium (CIC) of the **Cancer Research Institute** and the individual project partners that focused on a personalized medicine program dealing with RNA-based cancer vaccines.

In that case, the regulatory requirements were complex, and the working group provided the scientists with expertise on what would be needed to advance their compounds to the clinic.

Dieter Link, senior licensing and patent manager at Max Planck Innovation—the technology transfer arm of the **Max Planck Society**—said that the Society's approach was to create a dedicated unit, the **Lead Discovery Center GmbH** (LDC), to serve as an interface between academia and industry because it wanted to allow the Max Planck Institutes to continue to focus on basic research.

The LDC is staffed by Ph.D. scientists with experience in biopharmaceutical development whose role is to take discovery-stage projects into early development and generate commercially viable programs.

Although LDC's original plan was to perform screening assays, early pharmacology and preliminary animal models to bring projects to a stage at which they could be licensed, it turned out that pharmas were interested in collaborating even earlier, Link said. That led to a strategy of forming framework agreements between the LDC and pharmas to create joint project pipelines and work on hit-to-lead development together.

Whereas Wessel said that TRON takes a similar approach and believes that having scientists from both sides of an industry-academia partnership is the best way to advance a project, Issi Rozen—director of strategic alliances at the Broad Institute—said that his team takes a different view.

"We believe that if there is work we can do at the Broad that a partner cannot do, it should stay in-house. If we think we are the best party to do the work scientifically, we keep it in," he said.

"The moment we believe an outside partner can do as good or better job, we just spin it out," he added. The decision on when to partner is dependent "on who can deliver the most value to the technology."

The panelists agreed that one of the biggest challenges is dealing with the delays and drawn-out time lines that often are involved in getting agreements in place.

Egenhard Link, head of technology transfer at the Institute of Science and Technology Austria, said that taking a long view is important because the deal time line can be slowed down by unrelated events at an interested company.

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For example, in his previous work in patent and licensing at Max Planck Innovation, a gene therapy technology for renewing vision in blind people sparked interest from a pharma that rapidly kicked off negotiations. However, an acquisition by the pharma of a small biotech, followed by a job promotion for the business development head, slowed down the negotiation for about nine months. In that situation, there was little his team could do to accelerate the process, but the delay was not a sign of dwindling interest by the pharma, Link said.

Wessel noted that although there are few global rules for speeding up the process, academic organizations should focus on identifying a strong champion in the partner company because "large corporations are also driven by individuals."

Michael Dalrymple, director of business development at MRCT, said that deals can be done in the space of six to eight weeks when there's a will, and the time the process takes often boils down to how flexible the parties are in moving from their starting points.

In addition, he said, it is often not the money part of the deal that holds up the process. "The heads of terms [agreements] generally just deal with the financial terms. And what the lawyers get their heads around are things like warranties and liabilities and so on. These are the things that, in my view, take the most time," he said.

He added that warranties and liabilities are also intrinsic to the legal systems that operate in different countries, which can complicate negotiations between international parties.

Rozen thinks that the key is for business development leaders on both sides "to control the lawyers."

"The lawyers' job is to protect institutions from any possible risk. So if there's a 0.1% chance of some risk, the lawyer will say there's a problem here" and the process can get hung up over a single word that one side cannot accept, he said. "So somebody needs to make a call here on how important that word is. And unless the business development team can assume some risk, the deal would take forever."

He added that accepting risk is part of his role. "When there's risk that we can accept, we should accept the risk. When there's a risk that pharma can accept, they should accept the risk. Because without that, without controlling the lawyers, it's just an impossible job."

Not about the money

One significant factor affecting the deal-making process is that business development professionals have different perspectives and mandates depending on whether they come from pharmas, biotechs or academia.

Dalrymple said that they are not bottom-line driven at MRCT because their sole mission is to see the products of their research translate to treatments.

"I think therein lies the difference," he said. "I have no shareholders to keep happy, no investors to keep happy. However, I do want to see my organization deliver patient benefit."

Rozen noted that earlier in his career when he worked in pharma, his role was to constantly look for in-licensing or M&A opportunities. "I remember being very suspicious of every opportunity I looked at."

He added that when he moved to a venture-backed startup with a single asset, the angle was slightly different. There, his role was to try and get as much money as possible, with an exclusive focus on that one opportunity. "I knew every detail about my technology, and all I had to do was maximize the value."

By contrast, he said, "At the Broad, I know nothing about most of my technology because I have hundreds of them. And the mandate is very different."

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Although the Broad Institute "likes value," its focus is to maximize the chances of a program moving forward, Rozen said. "When I look for partnerships, unless we believe the party at the other side of the table has high science and can take the program forward, we will not move the program to them, even if the offer is more generous."

He added, "If we think a second offer has a better scientific organization, we will trade value for the ability to move a program forward."

For example, he said, the Broad Institute had a flood of interest in the gene-editing CRISPR (clustered, regularly interspaced short palindromic repeats) technology that was partly invented there. Although many pharmas approached the institute, it chose not to partner with pharmas but to start a new venture-backed entity, **Editas Medicine**.

Rozen said that in forming Editas, "We got a team who think about the technology 100% of the time, versus if you gave it to pharma, they would think about it 2% or 5% of the time."

The institute's priority was to find a way to maximize the therapeutic potential of the technology. For that reason it was willing to pass up the possibility of having greater revenue sooner in favor of an avenue that promised a greater ability to execute.

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COMPANIES AND INSTITUTIONS

Biotechnology Industry Organization, Washington, D.C.
Broad Institute of MIT and Harvard, Cambridge, Mass.
Cancer Research Institute, New York, N.Y.
Cluster for Individualized Immune Intervention, Mainz, Germany
EBD Group, Munich, Germany
Editas Medicine, Cambridge, Mass.
Institute of Science and Technology Austria, Vienna, Austria
Lead Discovery Center GmbH, Dortmund, Germany
Max Planck Innovation GmbH, Munich, Germany
Max Planck Society, Munich, Germany
MRC Technology, London, U.K.
TRON, Mainz, Germany
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