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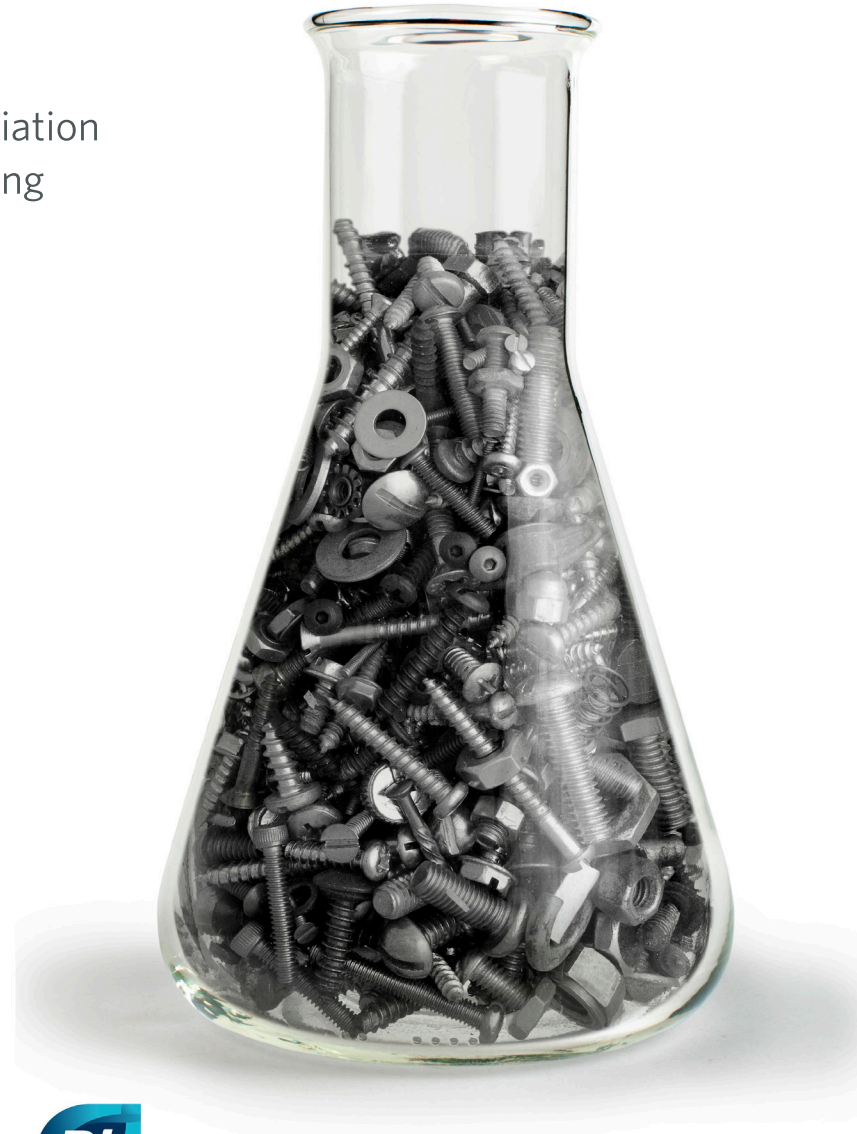
The Nuts & Bolts of Due Diligence in Biopharma Partnering

Based on a web panel discussion presented by ShareVault in association with BIO, LES and Pullan Consulting



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Licensing Executives Society
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Bio
Biotechnology
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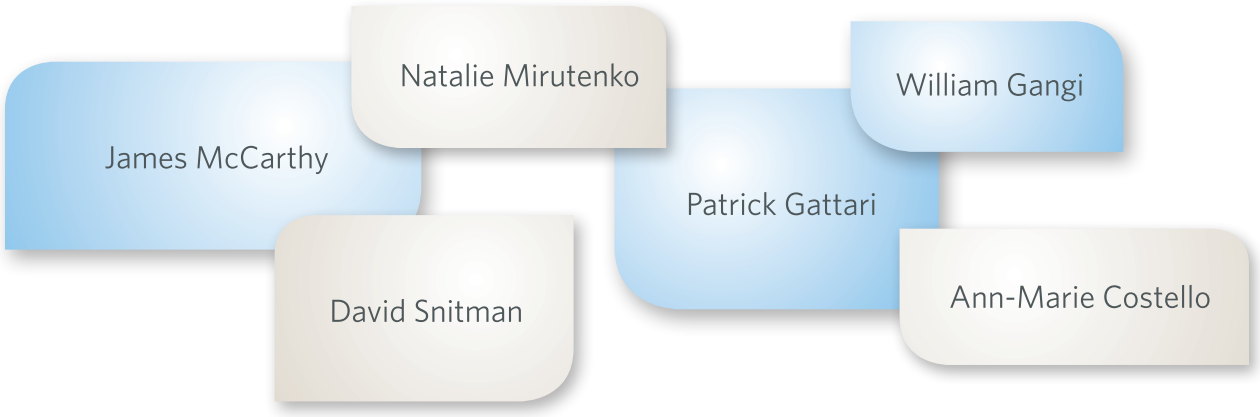
Often biotech companies seeking to out-license or in-license a drug candidate or other asset, or otherwise partner with another biopharmaceutical company are unfamiliar with the due diligence process. They may be unfamiliar with what large pharma expects when entering into due diligence or uncertain about the best ways to stage information that is disclosed to a potential partner.

To avoid costly mistakes and recognize potential problems, biotech licensing and pharmaceutical business development consultant Linda Pullan invited six experts in the field of biopharma partnering due diligence to sit down and discuss best practices for conducting due diligence that results in successful long-term partnerships. **That discussion resulted in the following conversation:**



Linda Pullan: What is due diligence from a big company perspective?

Natalie Mirutenko: At Takeda the due diligence process first focuses on the critical issues identified during the confidential review. We avoid wasting time on routine and less important issues and on deals that typically wouldn't progress to the negotiation stage. This is typically followed by a thorough technical evaluation and includes an overall **risks/benefits assessment that supports the business case and the resulting deal terms**. As part of the diligence process the diligence team is responsible for developing a risk mitigation strategy. These are insights and creative ideas on how Takeda can create value for the partner and us as well as manage the risk associated with the asset.

Linda: When do you do due diligence?

William Gangi: At Shire full due diligence is performed after a new opportunity has been identified internally. There's a small group that conducts an "early assessment" on the opportunity to evaluate whether it's a strategic fit for the company. They identify the key issues that would require further evaluation and also a high-level estimate of the size of the opportunity, which could range from a simple peak revenue, to perhaps even an initial valuation if there's a term sheet that's required prior to due diligence. We stage the process so all those opportunities are evaluated first by an **early assessment** team and then there's a small **governing body** that decides whether or not it warrants going into **full due diligence** given the amount of resources that we would likely expend on it.

Strategic Fit?

- ✓ **Early Assessment Evaluation**
- ✓ **Governing Body Decision**
- ✓ **Full Due Diligence**

Linda: Natalie, is that consistent with your processes at Takeda? What steps generally precede the start of due diligence?

Natalie: Yes, we also have a **staged approach** toward asset evaluation. For us, diligence really starts with the execution of the CDA and the process of sharing confidential information between parties for a potential business transaction. During this confidential review our triage team evaluates the opportunities and does a more in-depth evaluation and looks at the scientific merit of the asset.

We will go as far as completing a regulatory assessment in terms of how registrable this asset is. Depending on the stage of the asset, we may ask the commercial team to evaluate it vis-å-vis a TPP or look at a preliminary market assessment for the reimbursability of the asset. All this comes into our preliminary risk assessment in which it really touches on those four or five key parameters.

Linda: Natalie, would you explain what a TPP is?

Natalie: TPP is a Total Product Profile. Each asset that we evaluate has a profile that we develop which basically evaluates its safety, efficacy, mechanism of action, commercial status, where it is in development, who the potential competitors are, and how the asset compares to competitors for a particular treatment paradigm.

Linda: William, what about your team members? How are they organized?

William: The short answer is, it really depends. Our teams are really fit for purpose. So, the membership of our teams will differ depending on the opportunity, the stage of development of the target and the geographic scope of the opportunity. We also try to stage the diligence. We start the process by only focusing on the key issues or the potential **"show stoppers" identified in Early Assessment** and include only key relevant functional representatives. In that way we limit the resources until the risks are more fully understood and ultimately deemed accessible.

But generally speaking, each team always has a Due Diligence lead and a Due Diligence Program Manager to manage and drive the process. The Core Team are the key contributors to the valuation and provide input to the development plan and the associated expected costs of that development plan. The **Core Team might include clinical development, clinical operations, regulatory, commercial (which includes commercial assessment, and marketing or access & reimbursement), CMC and manufacturing.** Someone from the business development team to manage the transaction is also on the Core Team so that they are kept abreast of what the team is coming up with which ultimately helps inform them later on with the transaction. And, of course, we also have finance and resourcing to help manage the valuation process.

But, that being said, the Core Team could be expanded, and most of the time **is expanded, to fully evaluate the risks and opportunities**. The Expanded Team would include representatives from IP and clinical pharmacology, TK, toxicology, likely biostatisticians, as well as a legal representative.

So, there's a number of different representatives that may be involved depending on the complexity of the deal, the target, or whether or not we are familiar with the mechanism of action, and sometimes we will even hire external consultants when we realize internal expertise is not available. And finally, as the deal moves closer and closer to getting done, we'll involve an integration planning team to help ensure a smooth transition after the deal is completed.

Linda: What about the order of due diligence versus a term sheet?

William: Sometimes the target company will require a non-binding term sheet in order to enter full due diligence. In that case, the Early Assessment team has to be expanded in order to develop a high-level revenue forecast. This normally involves more team members so we can really flesh out a valuation to determine, given a certain number of assumptions, whether the deal would make sense for us.

Linda: Natalie, is it typical to have a term sheet before you start formal diligence or is it the exception?

Natalie: A few years ago, I would have said it is the exception. In today's day and age, given the competitive nature of business development and the need for good assets, I think it's becoming more and more a standard. Quite often, if there's a hot asset, the company will have a process that necessitates a term sheet before they open up the diligence room. It's their way to eliminate the tire kickers, so they only get those companies that truly see the value and appreciate the asset at the same level of the parent company.

"In today's day and age, given the competitive nature of business development and the need for good assets, I think it's becoming more and more a standard."

Linda: What about a small company perspective on diligence?

James (Jim) McCarthy: There is a scenario that often comes up when very small companies are involved, where they do not have a diligence function or an experienced staff that has been through the process before. Frequently, in these scenarios, they wind up getting into a situation where they do not really know where to begin. Sometimes smaller companies are still acting like they are in the partnering stage rather than, as Natalie mentioned, providing the type of information that people need for decision-making purposes. We have to start with a discussion about the "scenario objectives," with some basic discussion about framework, criteria, assumptions, information needs and timing for that information.

David Snitman: From a small company's perspective, part of our challenge is managing the number of companies and trying to structure the process as much as possible. What we're striving for is managing the process so we have a launch date for initiating partnering discussions and figuring out who we're going to target to ensure that we don't go too large and that we're focusing on the companies that have the best strategic fit for us. Then we try to create a competitive process where we try to manage that process as much as possible through a competitive atmosphere that moves as quickly as possible. We have all of the data available, but we try to take control of the process and move it quickly. If you can find a way to move quickly, you get the right company involved in the process and get higher value.

Linda: What about controlling information sharing?

Jim: During today's competitive environment and product opportunities, we have to keep in mind that many times the people who do not end up being the eventual partner might end up being your competition. In that regard, I think there is more of a filtering of the information that is shared and when it is shared, as opposed to all the due diligence information being provided to everyone all at once. There is more of a triage of information that parties need at different steps of their process in order to make a decision on whether to go forward or not. Because companies often have a staged gate process for their decision-making, I think it is fair to ask people what information they need, at what stage, to make decisions for moving forward.

Linda: What are the key questions asked and answered during due diligence and how does that differ from an early stage opportunity versus a late stage opportunity?

Natalie: Everything begins with an accurate understanding of 'what you need to know' and 'critical issues or questions' and how they will impact the value of an opportunity. The diligence focus changes with each opportunity and transaction. Each opportunity is unique; **the checklist changes to suit the specific transaction**. Staging Due Diligence aims to make the process as efficient and effective as possible. Timeliness and accuracy are essential because the team has limited time to get the answers and information needed. Through our Working Checklist we identify data or information gaps, value drivers and deal breakers. These checklists allow us to interpret and integrate the findings and determine how this asset creates value for Takeda.

> **"With the identified risks we develop a mitigation strategy, confirm/validate assumptions and develop a more robust set of financial projections related to both the product as well as the deal being envisioned."**

Linda: William, do you do it differently if it's an acquisition versus a license?

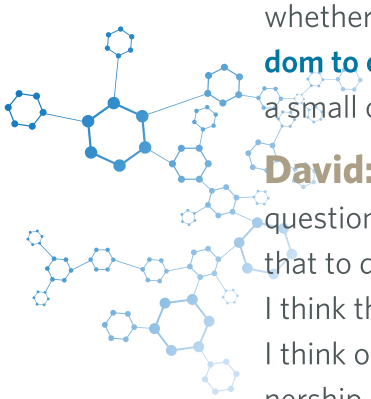
William: Certainly there are differences. With licensing we may only have to conduct due diligence on the product or the technology we're interested in, whereas for acquisitions there is that component, but then there are additional factors that we would evaluate such as **finance and tax, legal, corporate governance and compliance, HR** and many other aspects that you don't have to evaluate when only looking at a licensing agreement. And, with regards to integration, it's much simpler with a licensing agreement. It's typically just an R&D to R&D transfer, but for an acquisition we have to think about **the people, the facilities and the products**. The process for acquisitions also differs specifically with regards to the level of rigor of confidentiality employed depending on whether the target is a private versus a public company. Typically for **public M&As the teams are much smaller to ensure confidentiality**. There are potential SEC issues with including people who don't need to know.

Linda: What are the key questions from a legal perspective?

Patrick Gattari: My initial focus is identifying and understanding the asset that is being transferred or sold. From there I gain an understanding of what IP covers that asset. If there's a wide portfolio we need to identify the key patents that cover that asset or assets. Once those things are identified we move on to determining the **strength of the IP** and whether it will hold up in the face of any kind of challenge that might arise against it. Once you understand what the asset is, you have to ask if there's **freedom to operate** around it. Are there going to be challenges when the product is marketed? So, freedom to operate and the strength of the portfolio that's covering the asset are really the key issues. Finally, there are sometimes issues around whether the company actually owns the asset. There might be **co-owners** or an improper **chain of title on assignments**.

Linda: From a small company perspective, when does this IP sharing happen and how does it happen? Do you share information only from IP attorney to IP attorney? What are the sensitivities?

Patrick: From a small company perspective, certainly most of the time they'll have some patents that everyone can see publicly. So the question comes down to: when do you share that non-public information? Generally that's done after a CDA is in place and **usually there's no problem providing provisional patent applications that have been filed** or docket reports that show the complete portfolio, including non-public information. Some of the stuff that gets a little dicey is whether or not you're going to share **opinions about patentability or about freedom to operate**. Those are legal opinions and, in general, when I'm representing a small company, **I don't share documents I've created about the opinion**.



David: We really focus the discussion between lawyers, so a lot of times this question comes up on a conference call or in a general setting and I always defer that to discussion between counsel. We do not share our freedom to operate and I think that's something that should be done by the party that's looking to acquire. I think one of the critical questions that comes up in doing a small molecule partnership is the structure of the small molecule—composition of matter and that claim. When you're dealing with a lot of companies that are doing due diligence the likelihood that one of them is going to be your partner in the future is very

small. So, what we do is we will **share the structure through a third party** CDA where we set up a third party of their choosing, typically a chemist, to evaluate the structure from a chemistry point of view and also isolate either an attorney or a third party attorney to give an opinion of the patentability of the structure. Once we get past the term sheet stage, that's when it starts to make sense to share that structure.

Linda: Is this a point of sensitivity for others? To see structures or not see structures?

Natalie: We will often use a third party to evaluate the molecule in order to get an unbiased assessment. This process precludes contamination internally and it lends some objectivity to that evaluation.

Patrick: Whether or not it's a structure or some other type of technology during the diligence process you don't want to let the other party know exactly what the asset is. There have been cases when a third party does the evaluation and I've had access to that information, but my client has not.

Linda: Ann-Marie, let's talk about the human side of things. What should companies think of as the key questions for the human element during these transactions?

Ann-Marie Costelloe: The human side of these transactions is often ignored or pushed to the side. But even though the energy is dissipated broadly, the fact is that the two-legged assets achieved the value created and it's that value that you've got to understand and retain in order to propel the company forward. If small, the whole company can be consumed by the due diligence process. Many people might be quite excited by the proposal and see it as a way to move their career forward. In an acquisition or ongoing collaboration, it's important to evaluate employees and examine what they can deliver as well as the culture of the company and whether they can deliver the value they say they can. Who will do that? The organization that is acquiring that company should take the time to examine whether the target company's vision is congruent with their own.

What is the culture of the company? What can they deliver? What is their vision?

A significant enemy in all mergers is ambiguity. The potential buyer will wonder who they will be able to retain and the employees of the acquired company will want to know if this is a long-term solution for them. So, **you build and create value by reducing ambiguity**. Do as much of an assessment as is practical at the due diligence level as well as through the post integration level. Once you understand the human dimension there will be greater alignment between the intentions and hopes of the acquirer and the people on the ground in the target organization.

Linda: Dave, on the small company side, what you're doing in part is assessing the potential partner and whether you can work with these people. Talk a little bit about that.

David: Typically following a CDA, we'll put together a general overview presentation, and our scientists will make a presentation to their scientists. During that process **we're evaluating the level of interest, the amount of work they've done, the questions, the insights and trying to get a feel for how this would work**. The next questions we need answered are how are they going to develop it? What is their development plan? Are they committed to put more than one indication into development? Are they interested in a backup program? In the agreement itself we would typically ask for a three-year rolling clinical development plan. One of the key elements here is how do you know if they're diligently pursuing this opportunity? The term "commercially reasonable effort" has been watered down to such an extent that it really has no teeth. What we look for is a commitment to a plan and hopefully our participation in that plan. It's that interaction during discussions where you can evaluate your potential partner's level of interest and their commitment.

Development plan?

One indication?

Backup program?

Linda: How does a potential licensor prepare for formal due diligence?

Jim: There is a big difference between whether it is an acquisition or a licensing agreement. A licensing agreement can be quite simple. It may not even require face-to-face meetings. An acquisition, on the other hand, requires a much deeper dive where teams from both sides meet as part of the due diligence process.

Linda: What is the role of the data room?

Jim: I like to think of a data room as an organized system for the due diligence process. The purpose of the data is to facilitate the sharing of information that people need for their decision-making process. It is a matter of managing the information, providing access to it and controlling who gets to see what and when. The data room ends up being a core tool for the secure transfer of the due diligence information that is essential for decision-making.

Linda: How do you go about choosing a data room and what are the challenges?

David: One of the challenges is that it's expensive. At Array we had six or seven data rooms for different projects going at the same time. Initially everyone who was looking at the data room needed to download something from the internet, there were problems with different servers, so we switched to one that made it easy for the other company to gain access, but it does get expensive and you have to manage that. I come from a period of time when there weren't data rooms and you would have to bring people in and go through notebooks over the course of two or three days. That limited our ability to interact with multiple potential partners. Today you can have a half dozen people in a data room at the same time and it creates an incredible efficiency. One of the things we've found that's helpful is putting a concierge in place that helps the potential partner find what they're looking for. This should be someone who has gone through the due diligence process, created data rooms in the past and understands where different pieces of information are, because it's a huge amount of data. It's important that this is not a person who answers questions about the data, but a person that can help them locate the data, kind of like a librarian. But the data room has really become invaluable.

"One of the things we've found that's helpful is putting a conceirge in place that helps the potential partner find what they're looking for."

Linda: Do you structure the data room by function?

David: **We structure the data room by functional areas** within the company —toxicology, regulatory, pharmacology, DMPK, CMC, clinical pharmacology,

general biology, etc.—and it depends on the stage of the program. For a clinical program you're uploading documents that were probably part of the clinical filing. One of the challenges if you're in the middle of a Phase II trial is determining how much of the clinical information you include because at this time all the queries on the trial are not completed so, although interesting, the data may be incomplete. There's always a challenge determining whether that data is valid or not. That's one of the challenges of dealing with clinical trials that are in process. You want to get the data out there and you want to be transparent to your potential partner, but there certainly are caveats surrounding the credibility of that data and whether all the queries have been answered.

Jim: Getting back to the initial question about selecting a data room provider. I think one of the best testimonies we have had in knowing that we had chosen a good provider were the comments that came from the other side. I had one transaction where the legal group from the other side was trying to access some information and they were new to this data room provider. But there was a 24/7 help line and at 11 o'clock at night they found someone who answered the phone and was able to help them with their question. They appreciated that we used this provider and I am happy to say that it was ShareVault.

Linda: Ann-Marie, how do you assess company culture? What's the process?

Ann-Marie: Let's define culture first. It's basically the way people behave around each other and towards the market in the struggle to succeed. It's individual and counter party personalities and how they interact. It's very similar to a marriage. In the business world it's two cultures getting together with the same assumptions and anticipation. In the marriage scenario you may be anticipating that you and your spouse will earn enough to live in comfort. In the business case the anticipation may be that a merger will allow you to thrive in Asia. The human dimension is central to this. **What we're really looking for is a culture that will facilitate the growth that the acquiring company is looking for.** Some cultures act like brakes and everything comes to a stop. And speed is everything when you have integration. Often this involves issues of trust and not fully understanding the value proposition. **The target company has to remember that what happens during the due diligence process will impact post merger.** So they need to be

discussing their value and finding champions in the acquiring organization and making sure that they're educating, helping and assisting in any way they can. It's not enough to merely provide the acquiring company with comprehensive due diligence materials. It's also important to determine that the two companies can work well together. Are they going to configure themselves in such a way that it adds value to both sides? The difficulty arises when people have conflicting agendas and assumptions. The due diligence process should focus on integration prior to the merger. If integration is not a primary focus then trust issues can occur and create difficulties.

Linda: What should a recipient of diligence expect as a process of interaction after formal diligence has begun?

Natalie: Takeda begins shaping the relationship at the very first meeting with the potential partner. Our BD goal and our goal are to be transparent and keep the potential partner informed during every step of the process. We try to communicate on a weekly basis and provide feedback on where we are in the process, what our findings are, what our concerns are. This level of communication is important because it builds trust. **Trust is critical because it makes it easier to discuss and structure a deal concept to satisfy both partners** and to create a strategic objective. Trust is the most important element that can make a deal successful. Nothing is ever perfect and there are always issues that arise, but if you develop that trust and transparency it's a lot easier to resolve those issues when they arise.

"Trust is the most important element that can make a deal successful."

Linda: David, how does the recipient manage the interactions? Who is on your team and what do you expect of them?

David: What we try to do is identify within Array the key people with the basic understanding of these functions. Then we align them with their counterparts and have them form a relationship with their counterparts so there's trust between the two. Usually that happens around critical questions such as when you have some DMPK issue that needs to be dealt with and explained or the data needs to be re-analyzed. It's finding the right person, not always the best scientist, but the person who really understands the issue and can create a rapport with another

scientist. It's important to understand your team members and their capabilities and ensure that they are matched well with their counterparts.

Linda: William, what is happening behind the scenes at the big pharma during the diligence process? How does this fit with valuation and negotiations?

William: During the diligence process we're focused on aligning the key stakeholders across the functions and among senior management. There's not only cross-functional alignment with the team itself to **align on the assumptions and the risks and the opportunities but also with building the development plan, estimating all the costs and resources and revenues and ultimately working toward a valuation**. Following that will be the inevitable governance reviews to ensure that senior management is in line with our recommendations for doing the deal and then eventually the terms of the deal. This can sometimes be frustrating to a smaller company where they're wondering what's going on in the background, but we try to keep the target company in the loop with where we are and how long it's going to take.

Linda: How does a small company move things along?

David: The way to move things along is to have multiple parties interested so the partner is always asking, "Where am I?" The challenge when you have only one company interested is to be patient. That company's management team might only meet every quarter. But that can change if you have multiple parties interested. Now you've created competition and that can speed the process along.

Linda: What happens at the end of the formal due diligence process? Whether it goes well or stops without a deal being struck?

Natalie: At Takeda we have a variety of governances. The diligence team and each line function present their findings and recommendations to a therapeutic area or region. Assuming we have alignment with our internal stakeholder in the therapeutic area and they approve our valuation, then business development presents the business case and the risk mitigation strategy to governance portfolio review committee for approval of terms. Then we quickly communicate those terms to the potential partner. On the flip side, if the therapeutic area or

the portfolio review committee doesn't approve the terms, we will also notify the partner immediately and end the process by destroying all confidential materials that we've obtained.

Linda: William, how many deals end up failing? What are the odds for diligence?

William: I think it's fair to say that approximately **65 to 70 percent of the new opportunities that get through the early assessment stage of due diligence ultimately are killed at some point during due diligence**.

Linda: Do you let the other side know why?

William: Sure. We normally provide feedback to the target company to let them know why we're not moving forward with the deal. That could range from anything like at the moment it's not a good strategic fit for the company or there's not enough data for us to feel comfortable, or the timing is not working out. But in many cases the answer is not necessarily a "No" but a "No yet." So, we could very well be working with that company again in the future when more data is available.

Linda: How long does this all take? What's a reasonable expectation for the formal process of due diligence?

William: It certainly depends on the complexity of the product or the technology, but I would say anywhere from **six weeks to three months**.

Linda: What are the biggest challenges for big pharma in the diligence process?

Natalie: For big pharma, it's getting alignment with the internal processes and the governances on the asset. It takes time. Sometimes these committees meet monthly or twice a month, and it's critical to get on the schedule in order to present the business case. Full diligence requires a development plan with internal and external development costs, timelines and commercial assessments and all of this takes time to develop. Sometimes you look to external sources to provide you with key opinion leaders to align the risks and the attractiveness of the deal and that takes time. So to be nimble and responsive and to be transparent Takeda has developed standard templates and stacked-based tools, to help accelerate some of those diligence and business case processes, but nevertheless it still takes time.

Linda: A perceived aspect of big pharma is conservatism. So, is a single "no" a deal killer? If one person says "no," is it over?

William: Sometimes, but not often. **Most of the time, it becomes death by a thousand cuts.** Whereby the total combined risks across all of the functions that have identified risks ultimately will make the overall opportunity less attractive. But teams are made up of people with different personalities and sometimes one person on the team may try to convince the rest of the team that something in particular is a deal breaker. But in my experience, I think in most cases some of those risks can be mitigated. An IP attorney may say that their base case for exclusivity is only four or five years versus an optimistic case of twelve years which has a low probability of happening. This risk could possibly be mitigated through the deal structure by perhaps limiting the upfront payment to the target but have attractive milestone and royalty payments based on each year of exclusivity that the company goes beyond the base case. That being said, freedom to operate could be a deal killer. At the end of the day, it has to do with risk tolerance, which may be different between companies. Some companies may not want to take on risks or the costs of a protracted litigation—the freedom to operate may kill the deal right there. Others may want to take that risk.

"At the end of the day, it has to do with risk tolerance, which may be different between companies."

Patrick: Most of the time if there's a potential litigation or threat of litigation that's going to kill the deal. Unfortunately, that's the way it is. And now we have IP rights and other things that are involved that also create potential deal killers.

Jim: It's also important to find people in organizations who interact across companies and develop champions, because that whole process of making a decision on a deal is complex. Sometimes it's a "no," but sometimes it's a matter that no one has said "yes." **So if there are no champions advocating for the deal, it could create a situation where no one really has to say "no."** There simply is no champion to say "yes." In that situation, it is a decision by default.

Linda: How often does big pharma turn to Material Transfer Agreements (MTAs) to get comfortable with risk?

Natalie: Our discovery group implements them quite often, especially when it's a novel target or a target that is extremely strategic and we want to have a better understanding of the early data, such as potency and selectivity. In those cases we will ask for an internal assessment, so it's quite common during early-stage opportunities.

Linda: David, from the perspective of doing many deals over the years from the receiving side what have you learned and what have you changed?

David: When you're inside the company you have this feeling like you are invincible and the people within your organization are convinced that this product is going to be successful. On the outside you have people that are scrutinizing the product. **It's very important to listen to the potential partners and look for common themes and ensure that your internal people who are answering these questions are taking them seriously and not discounting them.** It's important that when you see a common theme among the people evaluating the product that you go to that extra level by perhaps having an outside evaluation of risk and not just assume that your team is telling you the facts, because they believe in the product and may not be looking at it objectively. As a business development person you have to listen to both sides and ensure that you're building the case based on fact and getting as much outside cooperation to ensure that your potential partner is getting a comprehensive view of your data. It's also important to move the process along as quickly as possible, and the best way to do that is to make sure that you have more than one company involved in the process. The way to be successful at that is to do your homework and know how your product fits within other company's portfolios. Have they had a failure in the past? Do they have a hole in their pipeline? Are they calling on doctors who could potentially be selling this product? Look at the whole picture and make sure you're creating as much competition as possible.

"The way to be successful at that is to do your homework and know how your product fits within other company's portfolios."

About the Panelists

Linda Pullan, Ph.D., Pullan Consulting

Linda offers biotech and pharmaceutical companies consulting in all aspects of partnering. Linda has a Ph.D. in Biochemistry, a B.S. in Chemistry and more than twenty years of drug industry experience. Linda has worked on many deals, from in-licensing to out-licensing and a few acquitions. Linda publishes a free monthly newsletter, Pullan's Pieces.

James A. McCarthy, C.L.P., M.B.A. Corporate and Business Development, Alliance Management, CorpDev Ventures

Jim has thirty years of life sciences professional experiences. His background includes a twenty-five year career with Bristol-Myers Squibb and Eli Lilly & Company, and over fifteen years in international corporate business development and licensing roles. These efforts included projects and deals in over 30 countries with over 80 completed agreements across a range of transactions valued in excess of $1 Billion. He holds an M.B.A. from Indiana University, a B.S. in Physical Therapy from SUNY Upstate Medical Center, is a recipient of the Certified Licensing Professional (C.L.P.) designation, and is the past Chair of the Licensing Executive Society USA/Canada, Life Sciences Sector.

Natalie Mirutenko, Ph.D., Transaction and Due Diligence Senior Director for the Center of External Innovation at Takeda

Natalie is an accomplished biopharmaceutical Business Development professional with a strong track record of results oriented achievements in technology, company, and product licensing and acquisition. She has over 35 years of diversified biopharmaceutical experience, with scientific, financial, strategic and business perspective. Her extensive experience also includes leading scientific assessment, due diligence and deal valuation, negotiation and execution with a genuine passion for seeking out new business opportunities and creative deal structures. She is an Immunologist by training and is an accomplished business executive with 35 years of business development, licensing and drug development experience.

David L. Snitman, Ph.D., DL Snitman Inc.
Former C.O.O., Array Biopharma Inc.
David is a partner in a biotech business development-consulting agency, DL Snitman Inc. He is a Co-founder of Array Biopharma and had served as Chief Operating Officer and Vice President of Business Development from 1998 to 2015. During his tenure at Array he led over a dozen partnering deals, providing more than $600M in non-dilutive capital. He served as a member of the Board of Directors from May 1998 to October 2012. Prior to forming Array, David held various positions with Amgen Inc. since 1981, including Associate Director, New Products and Technology and Manager of Amgen's Boulder research facility. David received a B.S. in chemistry from Northeastern University and obtained a Ph.D. in the synthesis of natural products from the University of Colorado. He was an NIH Postdoctoral Fellow at the Massachusetts Institute of Technology.

Patrick Gattari, J.D., Partner, McDonnell Boehnen Hulbert & Berghoff LLP
Patrick's practice focuses on patent prosecution and technology licensing, with emphasis in biotechnology, pharmaceuticals, diagnostics and medical devices. His 20-plus years of practice has emphasized patent portfolio management and the licensing, acquisition, and sale of intellectual property. Prior to joining MBHB, Patrick was patent counsel at Dade Behring, Inc. (now Siemens Healthcare Diagnostics). Early in his career, he worked for Abbott Laboratories in a variety of positions focusing on the development and production of pharmaceuticals and diagnostic products.

Ann-Marie Costelloe, AFBPsS, Chartered Organization Psychologist
Executive Consultant, Somerville Partners
With over 20 years of organizational development consulting with organizations, teams and individuals, Ann-Marie directly contributes to financial success by customizing solutions to assist leaders increase employee engagement and contributions, align strategy and tactics and elevate performance across the business. Ann-Marie also provides due diligence assessments of target management teams for VC and PE firms.

William Gangi, M.S., M.B.A.,
Director, Due Diligence Program Manager (Corporate Development), Shire
William currently serves as a Director, Due Diligence Program Manager within the Corporate Development department at Shire. He has 20 years of drug development, commercialization and strategic operations experience within the biopharmaceutical industry. He received a B.S. and M.S. in Biology from St. John's University and a M.B.A. from The Kellogg School of Management at Northwestern University.

About BIO

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With almost two decades of experience in the biotechnology, pharmaceutical, medical technology and life science technology sectors, the Trout Group offers its clients the knowledge base needed to clarify investment themes and leverage key relationships for increased exposure to the proper audience. The firm's global reach extends through a network of offices in New York, Boston, San Francisco, London, and Shanghai with contacts in all major financial centers, helping clients to connect with the right investors. For more information, visit www.bio.org.

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