EXEMPLARY ALLIANCE, ORDINARY PRACTICES

HOW PARTNERSHIPS TO CREATE INNOVATIVE MEDICINES *SHOULD* WORK

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Preface

The statistics are daunting. Drug development has an overall failure rate of over 96%. It is especially acute for some of the most debilitating diseases where the biological mechanism that causes the disease state is not well understood.[1] Spreading that risk is part of the reason why most drugs are developed in partnership. In 2018, all 62 drugs approved by the FDA incorporated some aspect of partnership.[2]

Partnership may be common, but that doesn't mean it is practiced well. Research from the Association of Strategic Alliance Professionals indicates that success rates increase substantially when leading practices are utilized.[3] At first blush, good alliance practices seem to just make sense and of course, every good business person and collaborative scientist will naturally apply them. However, alliances are conceptually simple but operationally quite challenging. Consistently engaging in the behaviors and implementing the practices that help alliances be successful—and deliver life-changing medicines to patients—takes work.

AbbVie, a global biopharmaceutical giant, and BioArctic a research-intensive Swedish biopharmaceutical company engaged The Rhythm of Business to help them examine what they did right in a recently concluded research collaboration to develop antibodies (immunotherapy) based on promising science discovered by BioArctic that could stop or slow down the progression of the debilitating Parkinson's disease (PD). The partners wish to share their experiences so that both their companies and others may benefit. Their story—from initial contact through to a successful conclusion—follows.

[1]Hay, Thomas et al, Clinical development success rates for investigational drugs, *Nature Biotechnology,* 2014

[2]*Deloitte Touche Tohmatsu Limited, 2019 Global Life Sciences Outlook*

[3]Luvison, D, de Man, AP, Krijnen, A, Duysters, G. (2012) Digging into the 4th State of Alliance Management Study: The State of Alliances Past, Present, Future. Association of Strategic Alliance Professionals

The Making of a True Collaboration

At the September 2014 Parkinson's Congress in Stockholm, Sweden, Gunilla Osswald, CEO of BioArctic approached the AbbVie booth and asked whom she should talk with about her company's Parkinson's Disease program. She was directed to AbbVie's Europe-based search and evaluation team member who told her that BioArctic's program was too early for AbbVie to consider. "Come back when you've humanized the antibody," he said.

Fifteen months later, having successfully humanized the antibody, Osswald was meeting with AbbVie's search and evaluation lead for neuroscience at a partnering conference. Their meeting was supposed to be a brief 20 minutes. Layer-by-layer it became 90 minutes of scientific discovery. It was the first step in establishing a critical trust building foundation for what would become a successful collaboration on promising science to treat a disease with no known cure.

This partnership is as ordinary as it is exemplary. The partners did not implement breakthrough new practices. Rather, they consistently implemented proven alliance practices, adapting and innovating them for their specific context. What is exemplary is the discipline with which the practices were executed throughout the lifecycle of the alliance because they just made good business sense. Also unusual is the depth of the collaboration that developed because of the partners' intense focus on the goal and on practicing behaviors that build trust and respect, enabling the kind of transparency and honesty that innovatively addresses problems and challenges without egos or politics impeding progress.

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Design Before Deal

The period of time when partners are considering if they should work together is often referred to as deal-making. A more productive and value-creating approach to this "courtship" is to use it to design the collaboration with the desired outcome in mind. When you believe you have both the right partner and the right plan, the business elements of the partnership

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fall into place. Good alliances rest on strategic, operational, and cultural "fit" between the partners. AbbVie and BioArctic are very different companies, with different strategies, business models, and cultures. They found common ground in the science and in the patient-centric approach each of them had that drove the motivation to work together.

After the initial meeting—which was very much focused on the science—AbbVie's search and evaluation lead, who is a scientist, realized there was something there that he could bring forward for a potential alliance. He "rounded up a few key stakeholders, flying them to Germany—in the height of the holiday season. BioArctic also brought their key people." Other AbbVie staff who would have important roles in a potential collaboration were included via video conference. One of the BioArctic participants described it as "unlike any other big pharma meeting they had because all the key people were involved from the beginning." From this first big face-to-face meeting, the decision makers and the key people who would be responsible for the work of the collaboration were engaged, creating an agile platform for designing the future alliance.

The focus was on science at this meeting, just like the prior encounter between AbbVie's search and evaluation lead and Osswald. "The scientific exchange was very open. The stage of the asset was clear. We understood how they were approaching the open questions and it all made sense. Together we outlined the gaps in the program and identified how they could be addressed. There was a fair degree of alignment we could move forward." As AbbVie was assessing the science, BioArctic was sizing up AbbVie, as there were other suitors for the asset. "You should select the partner you think you can work with very well. Someone who will take your baby and make it work in the long run. They were committed to the Parkinson's patient and you could tell they saw us as very skilled in science and drug development."

Importantly, the open scientific exchange helped the partners get to know each other as people. The chemistry between them was obvious to all and partially manifest in their ability to listen to each other and understand what the other needed. According to a key BioArctic team member, "We felt they really wanted the asset. That's what we would want. A champion that will guide the project, especially in terms of their internal governance process. When we started to talk with the AbbVie team, it was their great [scientific] knowledge and ability to listen that helped build trust."

Creating Value for Patients and Partners

The meetings between the teams continued into 2016. They were actually working sessions, focused on building out the operating framework and workplan for what was now being referred to as "our program." The initial plan BioArctic presented was very streamlined. AbbVie had a vision and wanted a more ambitious plan. Time to patients with clinical trials and ultimately to market is essential in a competitive environment such as PD, so having a plan that would aggressively address the rate-limiting risks was essential. According to BioArctic, "We had a lot of iterations and the plan grew. It impressed us that they saw the scope of the plan could be expanded. We listened to them and accommodated their wishes. We showed knowledge and flexibility. That we could answer all of their questions, that impressed them."

As the plan was being developed, the functional leaders were working together designing the four specific "work packages" to achieve the overall plan. In many situations, this level of detail would have been left until after the diligence and agreement was complete and the alliance kicked off. There would often be new people involved at that point, requiring both knowledge transfer and building trust with the new members of the team. By conducting planning at the work package level with the people who would be responsible for executing the work before the specific alliance agreement was negotiated, the companies achieved three important value-creating outcomes:

1. They continued to build relationship and trust between the people who would be responsible for the work
2. They saved time that would have been lost in getting new functional teams up to speed had the design of the operating framework been left to after the agreement
3. Both parties had a better understanding of the time and resources required to complete the research

The third outcome meant that once the plan was complete and they moved to the finances behind the alliance, "Contracting and negotiations went smoothly." (Note that in the partners' view, negotiations only began *after* the alliance operating framework was developed.) In fact, getting to the economic model that would underpin the alliance was so straight forward that it was *negotiated over the phone.*

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The most important work at a kickoff is to ensure everyone is aligned on the North Star for the alliance.

According to AbbVie's business development lead who did the negotiating, "I did some work on the valuation and sent them a term sheet. They changed one number and made two other relatively minor edits. We negotiated the term sheet in about an hour over the phone. The next step was to draft the definitive agreement. We provided them with a draft and they came back with a relatively light markup. It took two sessions on the phone with me, Gunilla (BioArctic CEO Osswald) and our respective attorneys. It was maybe four hours in total. We never met in person."

The agreement was signed in September 2016, roughly nine months after the first big meeting in Germany. While that may not seem extraordinarily fast, when one considers that there were detailed workplans and established relationships in place, they were far ahead of where many alliances are in the same period of time.

The Alliance Kickoff Matters

Every alliance professional knows the adage, "Start it right or start it again in the midst of conflict and significant mistrust." The work during the alliance design, due diligence, and negotiating process got this alliance off to a good start. Indeed, the partners acted as if they were in an alliance from that first face-to-face meeting in Germany. Contrast this with the typical due diligence period where the companies are posturing to gain the best financial deal and you begin to understand why this alliance is exemplary.

The kickoff was a formal two-day session that brought together the full teams that would be working on the work packages. There were a number of new people, especially from AbbVie who were introduced to the collaboration at this point, so it was important to have the type of meeting that would help the teams achieve the same level of collaboration that had brought the partners to this stage.

Perhaps the most important work at a kickoff is to ensure everyone is aligned on the North Star for the alliance. The North Star is a representation of the value the alliance will bring to the patients and the partners. It guides decision making and resource allocation. It provides a rallying point when the pressures of organizational life distract. It is sometimes referred to as a mission statement. Regardless of the label, the importance cannot be overstated.

As the AbbVie project leader said, "The mission statement we agreed to at the kickoff of the collaboration captured the spirit of what we were trying to achieve. At every governance meeting thereafter we would remind everyone of it. I think this was one of the key reasons for our successful partnership. Every alliance should have a mutually agreed mission statement."

Getting to "Happy-Happy"

The synergy equation of 1+1=3 is an axiom of partnering, implying that the goal is to create value that cannot be achieved alone. BioArctic takes it a step further, looking to achieve the state of "happy-happy" with their partners. This very Swedish next generation of the classic win-win focuses on "satisfaction, relationship, the cooperation, and the future."[4] It is a way of getting to an agreement that is open, transparent, non-competitive, and assumes that each party gets what it wants by helping the other parties to the relationship get what they want. This "give and get logic" is the essence of collaboration; core to how to create, deliver, and capture true value in an alliance. As BioArctic's project leader explains, "It is important to listen to the partner and understand what they need to get to the happy-happy for the alliance."

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Moving into Operations

The design phase and the alliance kickoff meeting set the tone. The relationships and trust that were built, together with detailed workplans allowed the work package teams to immediately and effectively execute their plans. The high level of interaction between the partners continued into the operational phase. According to one of BioArctic's work package leaders, "This was different from other collaborations. You usually wait until formal governance meetings with senior management to share results. Here we could really share between scientist and disciplinary experts. We started with bi-weekly meetings then moved to every three weeks. But we would interact in between meetings, too." As a result, "When we came to the face-to-face meetings (the formal governance meeting) we had already talked through the issues and we are aligned."

The frequency contributed to openness and a safe environment to experiment and try out ideas. "We could talk about exciting data, even though data might be preliminary and required confirmation. We were setting up new methods so it was important to be really open." This sharing about how the research would be carried out occurred, even though BioArctic was the decision maker. They did not have to engage with

[4]Åge, Lars Johan, *Happy Happy*, Volante, 2020 (In Swedish, quote excerpted from www.grandagency.se/happy-happy)

Risk can be described as the potential events that will prevent the partnership from achieving its desired outcomes. A proactive risk identification and management strategy addresses risk transparently and directly.

AbbVie and AbbVie did not have to devote time and resources—but they both knew that a lesser degree of engagement would not get them to a successful outcome. "Even if we were the one to make the decision, we were keen to let them know what we were doing. It was important to let them know when studies failed. We wanted them to know we were listening and incorporated their ideas. We seldom made a decision to move forward without AbbVie's consent," explained one of the work package leaders. It is behaviors and actions like these that let a partner know they are being listened to, their needs considered, and that lead to happy-happy.

Tackling Challenges and Solving Problems Collaboratively

The strength of a partnership matters most when it is tested by challenges and problems. By definition, partnerships to advance science will run into their share of issues and potentially fail, no matter the level of trust, respect, and collaborative working between the partners. One of the most effective means to be prepared for these challenges is to have a proactive risk identification and management strategy and to address them transparently and directly.

Risk can be described as the potential events that will prevent the partnership from achieving its desired outcomes. AbbVie's alliance management initiated an internal meeting to identify the key risks to the potential in-license decision. At that meeting, it became clear that due to an evolution of the regulatory environment, a biomarker strategy was on the critical path to a favorable decision, but that had not been clearly communicated to BioArctic. At the next governance meeting it was discussed forthrightly. "After all, we can't hold our partner accountable for addressing a risk if they aren't aware of this risk!"

Shifting Priorities, Shifting Resources

During the discussion at the governance meeting, "It became clear the parties held different views of the deliverables in this area." Because of the strength of the relationship they were able to openly discuss AbbVie's need and BioArctic understood it. Equally, AbbVie understood that identifying a clinically translatable biomarker was a high hurdle—and that it had not been built into the development plan to the level of reliability now being requested.

According to the work package leader, "Gunilla (BioArctic CEO Osswald) said I would get the resources I needed." Researchers, including external support were shifted to the effort, although no additional funding was requested. "AbbVie understood we listened and would mitigate the risk for them with a really quick response—all of a sudden, they saw I had more

people." AbbVie did appreciate the effort – and also put additional resources to it that they were not required to. "Our partner did what we would have done and that is the best you can do." explained AbbVie.

The Picasso

Another key challenge the partners worked together to overcome was the CMC (chemical, manufacturing, controls) release of the drug substance to AbbVie from the third-party manufacturer BioArctic engaged. The process would be subject to an AbbVie quality audit—and the more the partners discussed it through a series of governance committee meetings and emails, the more it became apparent that the partners did not have the same understanding of the process.

A two-day, in-person meeting was scheduled to work it through. "It seemed like a lot of time, but it was what was needed. We came to an aligned understanding. The process was so complicated it came to be known as the 'Picasso or the New York subway map' within BioArctic." The quality audit of the process was successfully completed seven months after this meeting. "Getting the CMC teams from AbbVie and BioArctic together with AbbVie quality personnel was the turning point for understanding this very complex way forward." We wonder what it would take to achieve the same alignment today when face-to-face includes an Internet interface. Two days might not be enough.

We're the Barca Collaboration Team

In a successful collaboration an outsider that steps into a meeting cannot tell which company the meeting participants work for. This "one-team" or "entity" mindset informs thinking, behavior, and actions and is driven by the focus on the North Star of the alliance. The AbbVie-BioArctic alliance—known to the alliance team as the Barca Collaboration—understood and acted upon this principle. Even before they were officially partners, they referred to "our program." When introducing himself during a governance committee meeting, AbbVie's project lead said he worked for BioArctic! Indeed, he did—and BioArctic's project lead worked for AbbVie in addition to the companies that employed them because that mindset is needed to succeed.

The one-team mindset is invaluable when approaching third parties who become essential contributors to the alliance. AbbVie and BioArctic approached the CMC partner referred to above together to present a united front. They also approached a contract research organization (CRO) together so that they could design the best possible animal model of Parkinson's Disease.

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The one-team or entity mindset helps teams coalesce around their patient-focused purpose and ignore parochial considerations that distract from the mission. At the end of the day, patient-focused missions always serve the corporate interest. Importantly, they attract the best and brightest talent without whom missions are impossible to achieve. "Great teams are hard to find. I found one in the Barca Collaboration team," enthused one of the project leads.

The Golden Package Leads to the Payoff

For two years the partners had been following the workplan, advancing the science that they hoped would produce a game-changing treatment for Parkinson's Disease. For that to happen, AbbVie had to "opt-in" to license the antibodies for clinical development. If it decided not to, for any number of valid business or scientific reasons, BioArctic would need to go find another partner. If that rejection were to occur, it would cost them valuable time in both the exclusivity to the underlying intellectual property and in the competitive arena. It would result in devaluing the asset in the eyes of a new development partner. In October 2018 BioArctic delivered the "Golden Package" containing the fruits—all the data and deliverables—of the two years of work to AbbVie, which had 90 days to make a decision. Thanks to a proactive approach with much of the ground already laid, the review was quick and internal alignment secured. Within two weeks it informed BioArctic that it would exercise its license option bringing the alliance to a successful outcome.

Marshalling the Stakeholders

Decision making in a company the size of AbbVie can be complex. There are many stakeholders who need to align to make a licensing decision. In doing so, AbbVie would make a $50 million milestone payment to BioArctic and be committing to devoting additional people and money to the development of the asset. Having been at the forefront of many such opt-in decisions in a prior company, the head of AbbVie's alliance management started preparing stakeholders for the decision about a year before the actual decision point. "I knew that the option decision was not going to be straightforward. It is complex, with both legal and financial implications. I wanted to be sure we were doing this well. I started asking my key internal stakeholders what were the most important things they needed to see to enable a positive decision."

Equally, it was important that BioArctic understood what those stakeholders needed. "When I asked myself does our partner know what our highest priority is, I didn't think it was clear. I started having biweekly meetings with the [BioArctic] CEO sometime in January, in advance of the October decision. She heard us very clearly and quickly reorganized resources and started addressing our concerns. It eased the licensing decision."

By being proactive in identifying and communicating the requirements, the alliance leader engaged in perhaps the most important practice related to

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orchestrating opt-in decisions: mitigating the risk of an unfavorable decision. Afterall, despite the great collaboration and tremendous learning that occurred during the course of the research, the alliance would not be a success if the deliverables didn't include the critical elements that would convince her organization the asset was de-risked enough to invest further and take it to the next stage of development.

An Agile Decision Process

It was important that BioArctic understood the decision process that AbbVie would follow. Large companies have fairly rigid governance meeting timelines. As important as this alliance and the asset was to AbbVie, decisions about it would flow through normal channels and calendars. According to the AbbVie project lead, "We clearly set out the internal decision path and the different committees it would need to get support from. We were very transparent about it." It helped that many of the team at BioArctic had extensive experience working at big pharma and thus knew not only what to expect, but also how they could help facilitate the decision-making. "BioArctic did everything they could to prepare us. I would ask them to help me with the slides or ask a question, and within less than 24 hours I would have all the answers."

One of the deliverables included in the Golden Package was the documentation for the Investigative New Drug application or IND that would be filed with the US Food and Drug Administration (FDA). This would assemble all the data generated by the work package teams into one cohesive story demonstrating why AbbVie should be allowed to initiate clinical trials. A transition team was established to conduct the work. The first task was to align on a process. As with everything about the alliance to date, the focus was to be agile and to produce a high-quality document. In keeping with its emphasis on regular and robust communication, the project manager prepared a weekly email laying out who was on point for what for that week. This kept everyone aligned and continued the culture of accountability that developed over the course of the alliance. There were no proverbial balls dropped.

Of course, there were other components to the opt-in package. According to a member of that team, "We had to lay out all the deliverables and when AbbVie would receive them. Then we had to find a mechanism to transfer, track, and review them." A data room was established, so as soon as reports would come in, AbbVie had access to them. "We set up a process to review them right away. Everything was done in an agile way. There was no wasting time on bureaucratic process."

Educating the Decision Makers

In parallel to producing the opt-in package, the AbbVie members of the team developed a very clear plan for stakeholder management. Each key stakeholder was identified, along with what the ask would be of them and the documents they would be tasked with reviewing. Then the timing of setting up those reviews was carefully coordinated with when BioArctic would deliver the documents. It takes a lot of work to get leadership aligned—and it began well in advance of the decision with the regular consultation the head of alliance management engaged in with the key leaders. This was critical to bring them along and of course, hear and address their concerns.

In parallel to producing the opt-in package, the AbbVie members of the team developed a very clear plan for stakeholder management.

According to the senior AbbVie executive overseeing the project, "Throughout the alliance, every time we gave a report to senior leaders, a key element of the report would be how well the alliance was going. It gave them great confidence. With all the proactive listening, risk mitigation, and tremendous transparency about not just process, but what could and couldn't be known, or done, it is no wonder that, "By the time we got to the governance meeting, the decision had already been made." As one of the team members shared, "The team's recommendation was sufficient for the decision. That made us all feel good."

The Essential Element of Collaborative Leadership

For all the good alliance practices the collaboration benefited from, an essential element is the empowering collaborative leadership demonstrated by the BioArctic CEO, the project leads from both partners, AbbVie's head of alliance management, and its senior executive on the project. They worked together as one team with a singular objective—to present AbbVie with a good asset that it would opt-into licensing for development, creating the most direct pathway for the exciting science to one day reach patients in need. They were always willing to be straightforward, to ask the right questions, to listen to understand, to be accountable, and to demonstrate trustworthiness. Challenges were addressed proactively, always letting the science guide their decisions. Observing their leadership allowed the teams to perform at their best, setting an example for all to follow. Indeed, bad behavior on this alliance would have been so obvious as to be untenable. As one of the work package leaders said, "We brought out the best in each other."

In many opt-in situations, the potential licensor controls the situation, providing only periodic reports to the option holder, who doesn't assign resources to work on something that is not yet part of their portfolio. That

All of the resources committed and work done by AbbVie—its willingness to be a true partner to BioArctic—and BioArctic's commitment to do what was necessary to produce what AbbVie needed is a testament to a deep appreciation by leadership that collaboration produces better outcomes.

approach does not result in an asset that has been de-risked in the most impactful manner. It doesn't result in each partner learning from the other. All of the resources committed and work done by AbbVie—its willingness to be a true partner to BioArctic—and BioArctic's commitment to do what was necessary to produce what AbbVie needed is a testament to a deep appreciation by leadership that collaboration produces better outcomes.

For the team members, it was hard to let go. Once the opt-in decision was made, it became an AbbVie development program and BioArctic was no longer involved in the work. Letting go was described as "painful." Another team member summed it up, "I wish this collaboration could continue forever."

Key Takeaways

The partners embarked on this project with The Rhythm of Business to share their experience and their learning about how partnerships to develop innovative medicines *should* work, but too often don't. In our experience advising biopharmaceutical alliances for more than 20 years, less than optimal results occur because of leaders that don't know how—or won't—collaborate to lead by example. They consider transparency weakness, fear a loss of control, and never build sufficient trust to be confident that everyone is pulling in the same direction, confident that the biggest win comes from everyone winning—and that starts and ends with the patient.

The asset AbbVie licensed is currently 18 months into Phase One clinical trials. Whether or not a beneficial therapy results from this exemplary research collaboration will not be known for many years. What we can know at this point are five key practices *(See Figure 1 - Key Alliance Practices)* that got the alliance to a successful outcome that others can follow:

1. **Align on a Strategic Value Assumption –** Align strategically and scientifically around a robust value assumption and define the alliance's North Star.
2. **Plan to Execute –** Have an agreed development plan with milestones, actions, and owners prior to financial negotiations.
3. **Start it Right –** Take the time to have a comprehensive startup process. There is a saying among alliance professionals: "Start it right or start it again, after conflict and lack of trust."
4. **Meet Regularly and Often –** Create a one team mentality, sustained through frequent, regular meetings, together with leadership who communicates openly.
5. **Provide Transparency into Decision Making –** Understand and be transparent about the pathway to reach important decisions.

The partners embarked on this project with The Rhythm of Business to share their experience and their learning about how partnerships to develop innovative medicines should work, but too often don't.

The practices AbbVie and BioArctic followed to get to a successful outcome are core practices of the discipline of alliance management, but are not always followed. The trust the partners built and the collaborative behaviors they executed allowed the science to benefit from all the resources—human, financial, and otherwise—the partners brought to the table. That results in producing a win for the partners and the patients and a blueprint for others to follow.

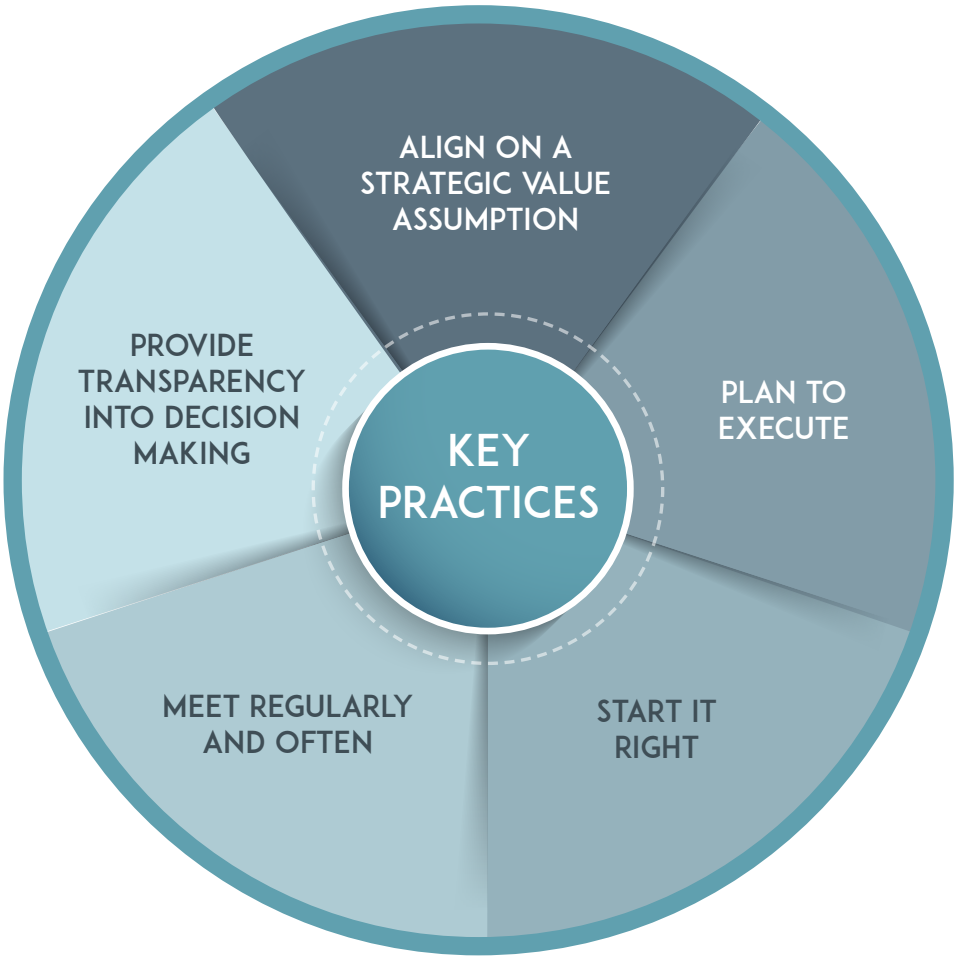

Figure 1 – Key Alliance Practices

About the Authors and The Rhythm of Business

Jan Twombly, CSAP and **Jeff Shuman, CSAP, PhD** are the principals of **The Rhythm of Business,** a consultancy and advisory firm with core expertise in partnering, strategic alliances, and collaboration. Since 1999 they have consulted globally and offered education and training to help organizations achieve higher levels of partnering and alliance success. They work with leaders to build and execute a collaborative leadership agenda, break down barriers, and drive consistently excellent alliance practice throughout an organization and its partnerships.

Twombly serves on the Board of Directors of the Association of Strategic Alliance Professionals as Chairman of the Editorial Committee. Shuman is also professor emeritus of management at Bentley University in Waltham, Massachusetts.

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