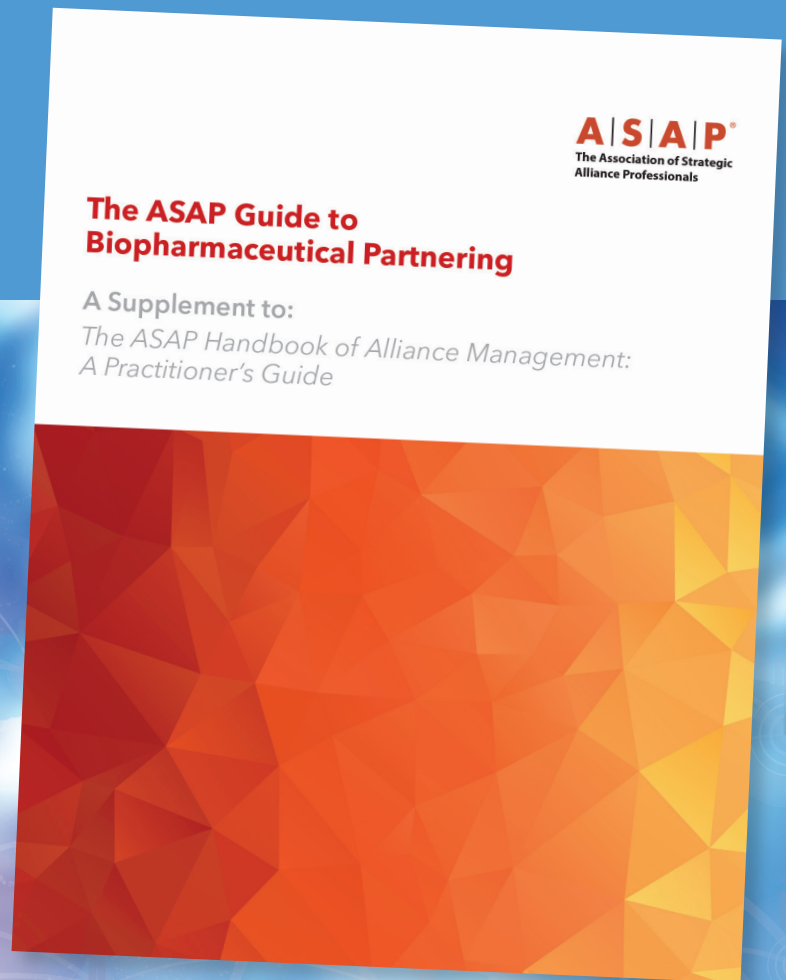


The ASAP Guide to Biopharmaceutical Partnering

A Supplement to:

*The ASAP Handbook of Alliance Management:
A Practitioner's Guide*



ASAP
The Association of Strategic
Alliance Professionals

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Biopharma Partnering in a Rapidly Changing World

In a complex, challenging industry where creating a product and getting it to consumers takes considerable investments of time and money—and where less than 12 percent of drug candidates even make it to the first phase of clinical trials—no one company can go it alone. Partnering is a must in biopharma, which means that expert guidance on best practices in partnering and alliances is also necessary.

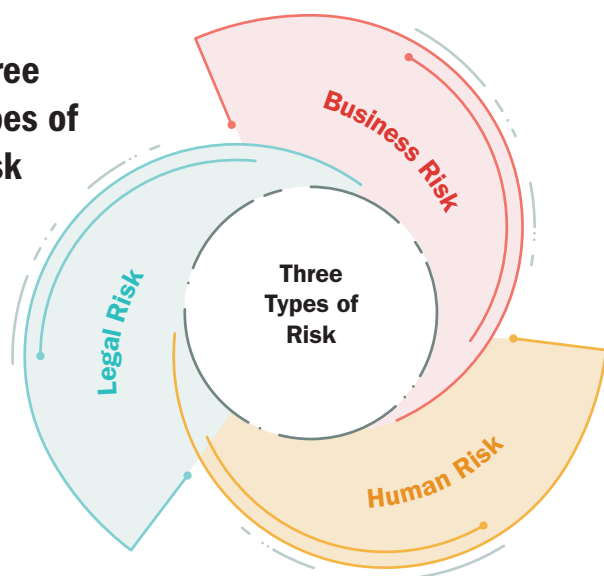
So where to turn for help?

The ASAP Guide to Biopharmaceutical Partnering is your go-to source. This updated supplement to *The ASAP Handbook of Alliance Management* contains a wealth of new partnering insights gleaned from interviews with numerous alliance leaders, executives, and consultants working in biopharma. It covers partnerships in all phases of the alliance life cycle, from deal negotiations to kickoff to governance and eventual wind-down and termination—as well as all the stages of the asset or product life cycle: discovery, development, and commercialization alliances.

In addition, it features coverage of

- The important role of alliance managers in minimizing risk and maximizing value creation
- Alliance metrics, tools, and dashboards
- The new frontier of digital health partnerships
- The biopharma ecosystem: academia, clinical collaborations, CROs, CMOs, and more
- Alignment, orchestration, and influencing: key activities for alliance managers
- Alliance professionals as strategic thinkers, leaders, and “diplomatic ninjas”

Three Types of Risk



Encompassing all three risks—business, human, and legal risk or uncertainty—is what might be called “regulatory risk,” or the risk associated with the all-important effort in development alliances to achieve the goal of registering a drug with the FDA (US), EMA (EU), NICE (UK), or other regulatory bodies around the world. In any asset-based product alliance, there is nothing more critical than achieving the goal of drug registration, so anything that hinders or delays the achievement of that goal becomes a risk: in time, cost (billions of dollars), and otherwise. Minimizing these risks means that both parties in an alliance must work together and work with regulatory authorities at all times, staying focused on the goal of drug registration. Otherwise, alliance failure—and failure to come out with a registered drug—can be the result.

“From a business [risk] standpoint, we need to understand all the therapeutic areas, need to have a depth of experience in the science so we understand what risks may arise from our partnerships. Legal risk: we’re expected to know and understand the contract, inside and out, so we can support teams to manage legal issues that surface in partnerships or agreements that need to evolve. And then obviously the human risk is the most fun, because you bring two companies together—we all have different cultures, approaches, and people, so our [alliance management] group should be the experts on how we manage differences between companies and the people involved. Having an element of really knowing how people interact and collaborate, deal with conflict, and so forth. Our group should be a one-stop shop for all things human, business, and legal risk associated with partnerships.”



Order your copy of the supplement today! Visit theasap.org

Maximizing Value Creation

How do alliance managers maximize value creation? First, by minimizing risk in all kinds of ways—arguably, nearly everything they do is in the service of managing and minimizing risk—and making sure the alliance moves forward smoothly and efficiently (wringing out inefficiencies). Second, alliance managers:

- Work constantly to **realize the intended value** of the deal
- Seek to **expand the value** of the alliance by facilitating life cycle management activities
- **Ensure that milestones and revenue targets are met** and the alliance stays on track
- **Monitor both companies' financial and other obligations** under the alliance agreement and ensure compliance
- **Think strategically** about how to generate new opportunities with the partner



“The value is really left to the client to determine. It’s a really important concept. When I hear people talking about, ‘We’re going to go talk to the client about the value we create,’ I think that’s kind of a backwards way of doing it. They should be talking to you about the value you create because they feel it, they can see it. Before alliance management, after alliance management. ‘Gosh, I never want to do without alliance management again!’”

Managing Risk During Wind-down and Termination

	Human Risk	Business Risk	Legal Uncertainty
Transition/Termination	<p>Off-boarding</p> <p>Cross company transition meeting</p> <p>Engagement guidelines for transition period</p> <p>Celebrating performance & team success</p>	<p>Leveraging existent governance for transition</p> <p>Staging transition activities</p> <p>Re-evaluating processes e.g. finance</p>	<p>Document retention processes observed</p> <p>Final amendments/side letters</p> <p>Ongoing responsibilities</p> <p>Local legal obligations</p>

courtesy Steve Twait, AstraZeneca, and Ron McRae, Janssen Biotech Inc.



“The role itself is always the same: you would be looking for additional sources of value, risk mitigation opportunities, how to make sure things are not going off the rails. Those are your guiding forces, but you do that in the three buckets of alliance management activity we know so well: governance, relationship management, contract management. You’re always doing elements of that, but sometimes you’re doing more or less depending on who is on your team and the state of the collaboration.”



The latest word in **Biopharma partnering**

The ASAP Guide to Biopharmaceutical Partnering is a supplement and update to the *ASAP Handbook of Alliance Management*, and represents the latest and most advanced thinking on leading, managing, guiding, and deriving revenue from alliances in every stage of the biopharma asset life cycle and throughout the biopharma ecosystem.

Building on the shared insights, published research, and real-world, in-the-trenches experiences of numerous ASAP members and the broader community of biopharma alliance management practitioners, **The ASAP Guide to Biopharmaceutical Partnering** explores the challenges, changes, and opportunities of a complex biopharma landscape marked by pharma companies large and small, academic research institutions, clinical collaborations, contract research, sales, and manufacturing organizations, and increasingly, big tech companies and smaller tech startups seeking to capitalize on the emerging field of digital health.

This supplement provides a deep dive into such critical areas as:

- ▶ Biopharma alliances at different stages in the alliance life cycle
- ▶ Managing alliances from deal negotiations to term sheet to contract to execution—and beyond
- ▶ The importance of proper alliance kickoff and launch
- ▶ Alliances as entities—and alliance managers as orchestrators, navigators, and strategists
- ▶ Governance, alignment, and influencing without authority
- ▶ Alliance wind-down, termination, and divestiture
- ▶ Integration of alliances acquired via M&A activity
- ▶ Academia and pharma
- ▶ Project managers, program managers, and alliance management
- ▶ Specific issues that arise in discovery, development, and commercialization alliances
- ▶ What to expect on the digital horizon: where biopharma meets tech
- ▶ The evolving role of biopharma alliance management

The ASAP Guide to Biopharmaceutical Partnering features:

- ▶ Frameworks, checklists, guidelines, and important activities for biopharma alliance managers
- ▶ Alliance metrics, dashboards, and other tools
- ▶ Essential qualities of today's biopharma alliance professionals
- ▶ Key questions for alliance managers at various decision points
- ▶ Glossary of terms
- ▶ Suggestions for further reading
- ▶ Fillable online worksheets and forms

“**The ASAP Guide to Biopharmaceutical Partnering** is a long-awaited update of and supplement to our original *Handbook of Alliance Management*, specifically tailored to the needs of biopharma practitioners and reflecting their concerns. Like many other industries, biopharma is complex and changing rapidly as it now partners with information technology and other industries, but at the same time it has its own unique challenges and issues. So we reached out to a wide range of ASAP members and others from biopharma—respected alliance leaders and executives, successful consultants, and more—to gather and synthesize the best thinking and the most useful insights for our membership and our community of practitioners. Along with our new update for the IT field, we're very pleased and excited to add this supplement to our growing storehouse of helpful and thought-provoking content for our ASAP member community.”

—**Michael Leonetti, CSAP, President and CEO**
Association of Strategic Alliance Professionals

The ASAP Guide to Biopharmaceutical Partnering

should be required reading for anyone who is embarking on or transitioning into an alliance management role in biopharma, and contains numerous insights that will aid more experienced practitioners as well.

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