While not an everyday occurrence, product transitions between alliance partners can be enormously complex. For Eli Lilly and Company, a recent product transfer project included many considerations: regulatory and clinical trial approvals, manufacturing and supply chain continuity, and commercial responsibilities—along with the simultaneous requirement of ensuring uninterrupted patient care. Based on that experience and many others, this article describes how thorough planning is critical to the successful transition of a globally marketed asset to an alliance partner, regardless of industry.

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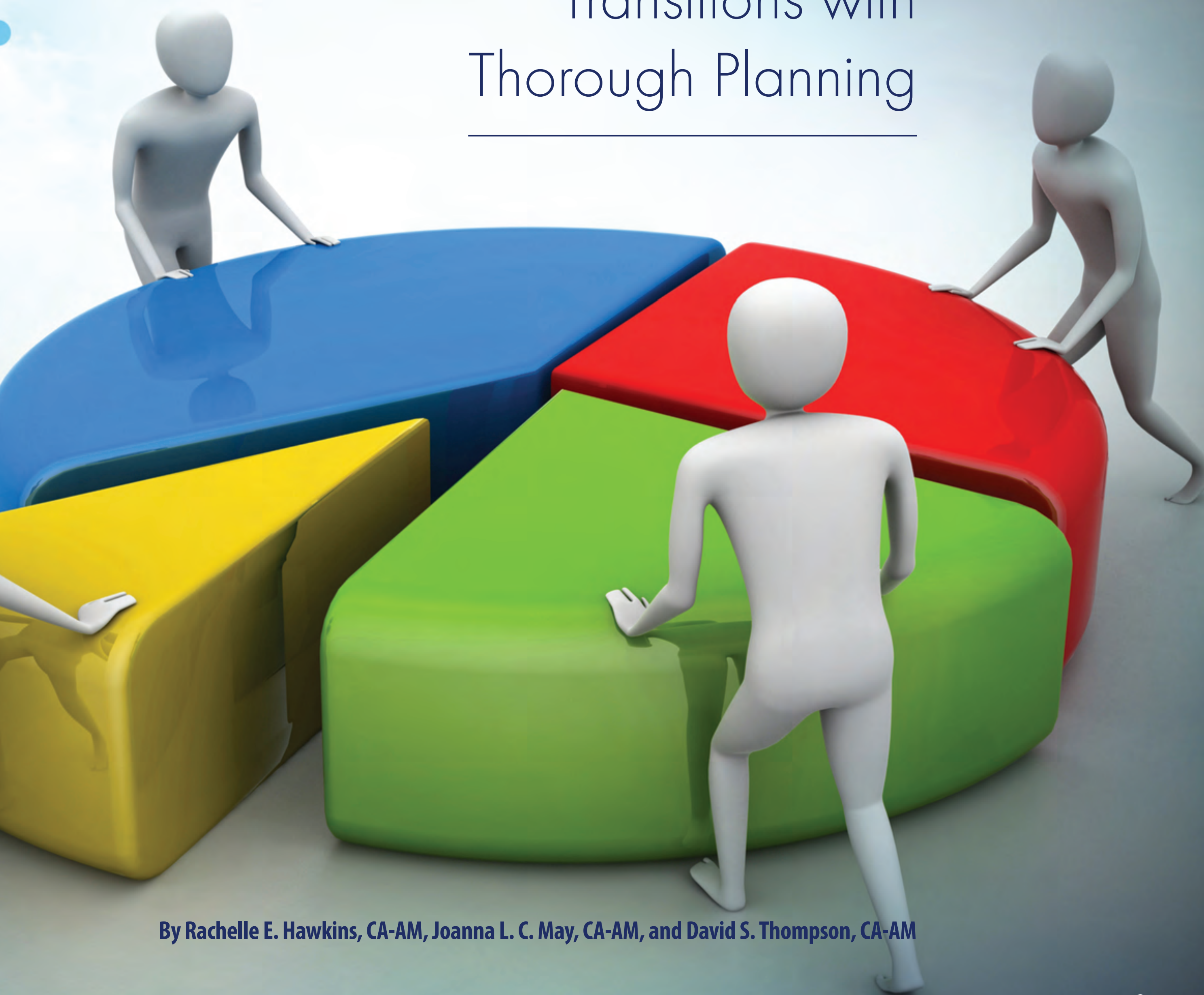
Major Moves:

Simplify Alliance Product Transitions with Thorough Planning



By Rachelle E. Hawkins, CA-AM, Joanna L. C. May, CA-AM, and David S. Thompson, CA-AM

Transitioning a globally marketed asset to another company is a massive undertaking. While our company's experience is in the pharmaceutical industry, a successful product transfer in any two firms requires the consideration of several key aspects: legal rights and ramifications, operational alternatives, external events (both expected and unexpected), and commercial continuity, just to name a few.

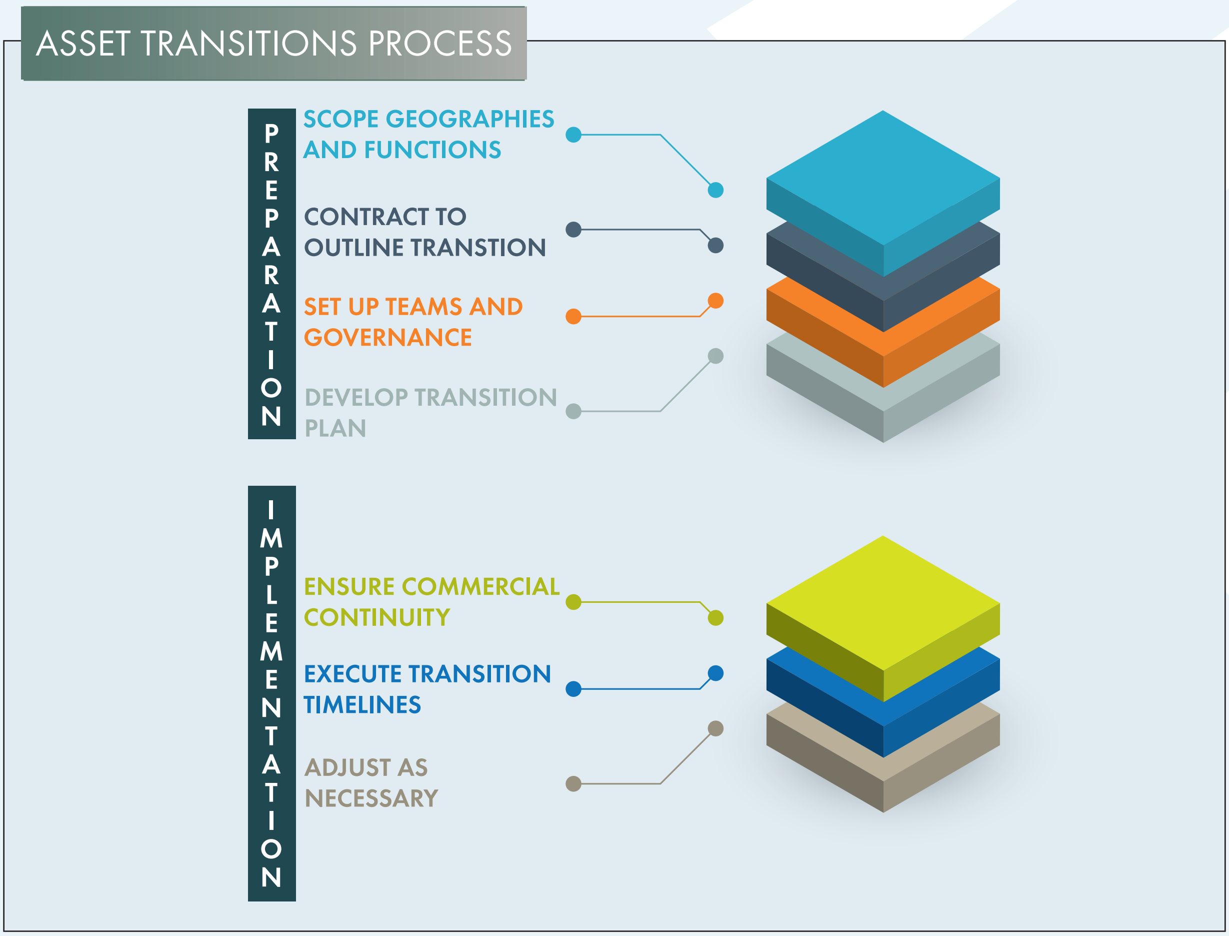
In many ways, the global transition of an asset is like the sale or purchase of a home. First, the buyer and seller do extensive work before agreeing on terms and signing a contract. The current owner makes arrangements to remove all belongings, turn off services, and secure cleaning services in a timely and orderly manner as mutually agreed. The new owner researches and determines the most efficient way to contract for local services, arranging for water, power, gas, and other services to be turned on or transferred in an orderly fashion. Similarly, the transition of a global asset necessitates both wide-ranging evaluation and careful attention to detail.

As with the sale of a home, the foundation of a successful transition is a sound legal contract. It is unlikely that every eventuality will be addressed—in fact, prolonging negotiations with the goal of including "everything" is usually impossible or unwise. However, the contract should address the main areas of business risk, legal uncertainty, and potential misalignment; provide for additional development on specific topics and details; and identify a process to handle unforeseen scenarios.

A contract should always cover the scope of the transition, commercial continuity from the asset owner to the buyer, and the definition of legal rights and obligations of each party during the transition. Importantly, the contract should specifically address the ongoing, commercially reasonable efforts of both parties, and how profits and losses will be handled during the transition.

Scope It Out

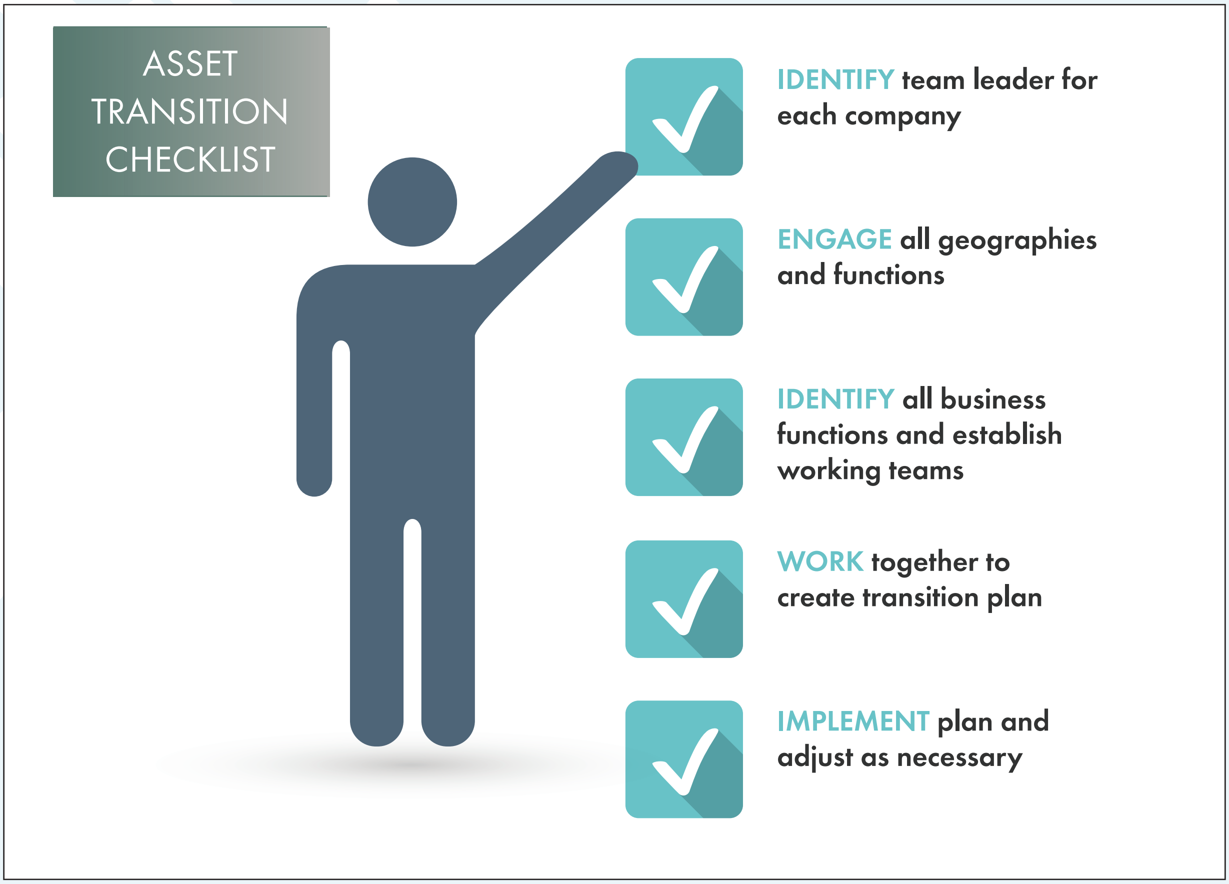
When negotiating the transition's scope, be ruthlessly thorough in assessing which geographies and functions will be included. Whenever possible, seek input from



functional and regional team members in developing a transition plan. Maintaining the appropriate level of confidentiality during negotiations is important, but be sure to involve enough team members to create a workable plan.

If the transition will be holistic—both global and enterprise-wide—consider how to address gaps between the parties. If the receiving party has no presence or interest in a certain market or activity, how will that aspect be transitioned? Will the receiving party develop or acquire such a presence? Will it partner or contract to obtain the presence? If so, by what time? How long would all of that take? And if that plan is not achieved, what are the rights and obligations of the asset owner?

The transition should also include a formal governance structure between the parties. This structure serves several functions: it provides the framework for a decision process, a way to monitor progress, a source of accountability for collaboration, and a means to resolve disagreements. A holistic transition warrants a robust governance structure, much like an active partnership would. Working teams or subcommittees support the governance process and execute the work of the transition; they may be cross-company or internal to each party. As the transition progresses, the company receiving the product may take more of a lead role in governance administration, including organizing and chairing governance meetings.

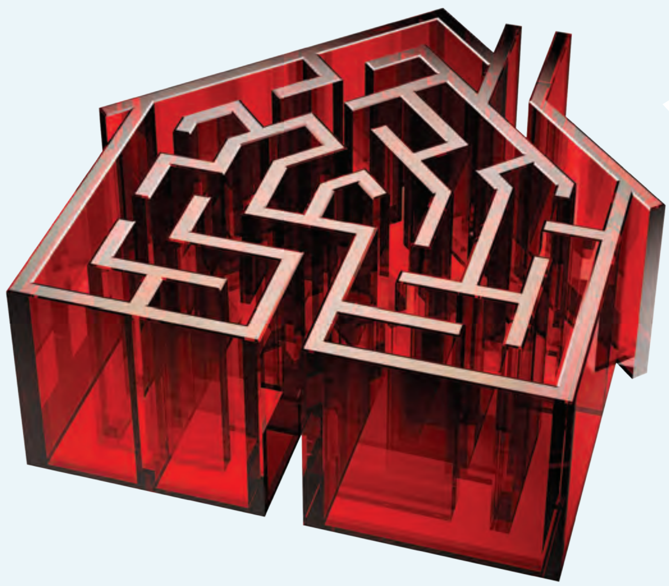


If the receiving party needs further time to develop a presence or expertise, the asset owner should consider that in good faith. In such cases, the receiving party should consider financially compensating and indemnifying the asset owner for supportive activities which are extensive.

Maintain Continuity

Given its critical role in the transition, commercial continuity requires clear and thorough negotiation up front. Commercial continuity includes market strategy, marketing and sales operations, payer relationships, and supply and distribution. When negotiating, keep this guiding principle in mind: a balanced, positive outcome benefits all parties—including customers—and should be achieved whenever possible. Achieving operational continuity through the transition requires a focused and sustained effort by both parties.

> Like buying or selling a home, product transfers between alliance partners can be enormously complex, as Lilly has learned through experience. Regardless of industry, thorough planning is critical to the successful transition of a globally marketed asset to an alliance partner.



Within this category are critical decisions regarding the timing of the transfer of commercial responsibility. It is wise to align this transfer for all countries globally on a single date or to align on a country-by-country basis with the date of marketing authorization transfer. Each scenario has associated legal uncertainties and business risks. In either scenario, it is advisable to align financial incentives with the commercially responsible party.

If all commercial responsibility transitions globally on a single date, financial processes will be streamlined and any desired commercial strategy changes can be implemented simultaneously, along with any other operational duties such as call center management. In this scenario, there will be a misalignment between legal rights and obligations under the transition contract and regulatory rights and obligations. This must be resolved clearly with regulatory agencies and contractually between the parties; indemnification should be provided as appropriate.

If commercial responsibility transitions on a market-by-market basis, timed with marketing authorization transfer, this helps align the legal rights and obligations under the transition contract with the regulatory lead responsibilities. Other duties, such as management of patient safety information, responses to medical inquiries, and financial processes will likely become more complex. Until all markets have transitioned, each party will likely be required to maintain infrastructure at a corporate level to support these functions.

Build and Lead the Team

Once both companies have agreed on roles and responsibilities and the appropriate legal structure is in place, it is time to build the transition team. Both parties should staff at a level sufficient to support a major effort, not a sideline project. It is important to identify specific core team members who are focused only on the transition and who will be supported by extended team members. Be sure to maximize the involvement of solid leaders and team members who have familiarity with the asset and those who were involved in developing the contract.

Each party should name a transition leader to guide the internal team and coordinate inter-company activities. This transition leader should be capable of making decisions on internal transition priorities and the transition approach. A project manager can be named to provide process structure, including overall coordination and metrics.

The transition leaders and working teams also need to define communication pathways within and between the parties. Often, internal teams agree on the approach and boundaries regarding a certain topic, and the expert functional or regional team member works through the issue with the other party. Team members should take care to keep company leadership, functions, and geographies updated on transition progress, timelines, and issues.

Dig into the Details

For the next part of our discussion, let's return to the home buying analogy. Because buyers typically have not actually lived in the house they are looking to buy, they must put significant time and effort into familiarizing themselves with the structure and its intricacies. Likewise, the alliance company that will be on the receiving end of the transfer must thoroughly plan to assimilate all of the product's associated processes in a seamless manner.

In product transfer situations, the bulk of this effort is put forth by a variety of working teams, the membership of which will vary depending on the type of transition and the industry or geography involved. While many of our comments are specific to pharmaceuticals, the principles can apply across industries.

If we again assume a broad, holistic transition, in a pharmaceutical context, working team members should be included from regulatory, manufacturing and supply chain, research and development, clinical trial operations, medical affairs, patient safety, product complaints, call centers, finance, legal, marketing, quality, information technology, and pricing. Other industries may need to include recruiting, procurement, facilities management, or community outreach.

Our own recent transition of globally marketed pharmaceutical assets to a partner required particularly detailed coordination in several key functions, and our experience produced generalizable conclusions, especially in the regulatory, supply chain, and legal areas. Overall, it became obvious that because regulations and internal company processes are optimized to support a marketed product, both firms must work differently—both together and internally—to enable a smooth transition from one company to another.

Another facet covered by our transition was product supply to the patient, which has to remain continuous during what may be an extended regulatory review for marketing authorization transfer. Some markets require that import licenses be approved before the receiving party can import additional product. Further still, some markets may not allow either party to import product once the application to transfer marketing authorization is submitted, creating a supply "blackout period" that must be accounted for in advance. In another twist, certain markets reference other countries' marketing authorizations and will not approve changes until the reference country has done so. Careful coordination and anticipation of such local requirements goes a long way toward reducing the uncertainty associated with any transition.

Ongoing clinical trials also must be managed closely, and it is beneficial to transition this activity as soon as possible. As with marketing authorizations, clinical trial transfers must be managed in coordination with several parties including clinical research organizations, clinical trial material management teams, and local regulatory teams. In many cases, contracts must be assigned to the receiving party, and clinical trial records must be transferred for relevant ongoing and completed trials. Patient privacy must be maintained throughout this process, which may be lengthy.

The technical transfer of manufacturing capabilities may also be necessary. Given the length of time it often takes, this set of tasks should be clearly outlined early in the transition process. Any technical transfer activities should be carefully coordinated with regulatory and supply chain management to ensure continuous supply.

And not surprisingly, system and data transfers are inevitable in a transition. Team members should assess early on which information must be transferred and coordinate with IT to develop a robust plan. Having an IT team member on the transition team can be invaluable, especially in the scoping and planning stages. IT also can provide consistency and expertise in transferring data in accordance with relevant laws and internal policies. All team members should collaborate to ensure that any system cutovers are managed with care and without disruption to the ongoing business. Transfer of paper records may also be necessary.

Looking across the entire process, transitioning a globally marketed asset to another company is complex, and each project should be approached with care and planning. With appropriate up-front effort, a large transition can be executed with success. By prioritizing the most important aspects—legal uncertainty, operational complexity, and commercial continuity—a strong team can achieve an effective transition. ■

BUILDING YOUR ASSET TRANSFER TEAMS