WHITE PAPER

Patient Services

Six Strategies for Optimizing Cross-Functional Collaboration Between Compliance and Access

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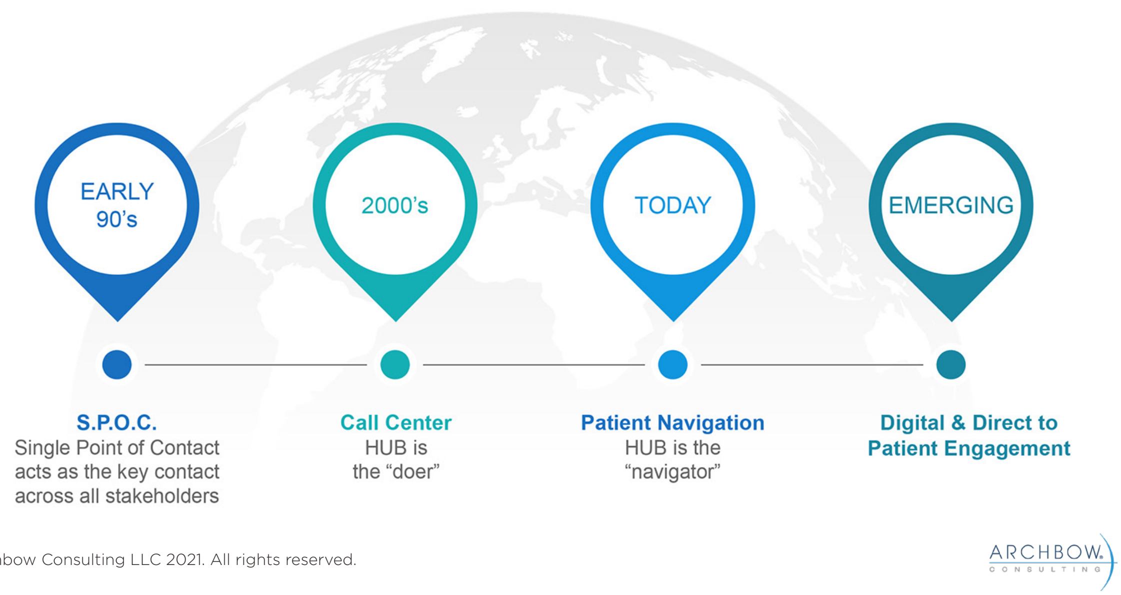
In the pharmaceutical industry, patient services and compliance teams work together, with an eye toward creating robust patient support programs. At some companies, these functions collaborate from the early stages of a product launch, uncovering customer needs and creating an outstanding patient journey. At other organizations, the relationship between Patient Services and Compliance can be more complicated.

To learn more about how leading organizations promote better collaboration, communication, and patient outcomes, **Justine Hughes, Vice President, Archbow Consulting,** spoke with four industry experts from compliance and patient services:

- **Laurie Hughes,** Head of U.S. Patient Services, Biogen
- **Rahul Khara, PharmD,** Vice President, Legal and Chief Compliance Officer, Acceleron Pharma Inc.
- **Terence Milton, JD,** Director, Ethics & Compliance, Managed Healthcare Services and Consumer Experience, Eli Lilly and Company
- **Michael Sanders,** Market Access Strategy Lead, Orphan and Rare Disease, UCB

Figure 1: Evolution of Patient Support Program



Patient Support Program Models Have Evolved

As the pharmaceutical industry has shifted from launching simple, small-molecule drugs to more complex, large-molecule therapies, the nature of patient support programs has changed.

- In the 1990s, companies used a single point of contact that acted as the key contact across all stakeholders.
- In the 2000s, the hub and call center model emerged. The patient support services "hub" was responsible for all the front- and back-end actions needed to support patients.

Today, the industry has shifted to a patient navigation model. Patients are responsible for taking action, but the hub drives the journey. Companies are also adopting more digital and direct-to-patient engagement approaches for their patient support programs. Looking ahead, technology may drive the patient experience more than human interactions.

Patient support programs offer a full suite of services to support stakeholder needs. Organizations and brands typically customize these services to meet their unique requirements.

Figure 2: Examples of Patient Support Program Services

For the execution of patient support programs, many pharmaceutical companies turn to external vendors for help. Most programs fall into one of the following categories:

1. **Fully outsourced approach.** All touchpoints with patients, healthcare providers, and payers are outsourced. The pharmaceutical company leverages the expertise of third-party partners to optimize the patient experience, learn from industry best practices, and mine data to support continuous improvement. With an outsourced patient support program model, it is easy to scale services for new indications, new products, and a growing patient base.

2. **Hybrid approach.** The pharmaceutical company insources critical customer touchpoints with patients and healthcare providers to ensure the quality and consistency of relationships. Back-end operations, data analysis, and other support functions are outsourced to third-party vendors. The patient services team ensures seamless communication between internal and external teams and optimizes the complete patient experience.

3. **Insourced approach.** The pharmaceutical company builds all the internal resources and capabilities needed to fully support the therapeutic journey with patients, healthcare providers, and payers. This approach offers tight control over staffing, data monitoring, and issues management, as well as the quality and consistency of customer interactions.

Six Strategies to Promote Collaboration

The panelists shared six strategies that pharmaceutical companies can use to promote more productive collaboration between their patient services and compliance teams, with a goal of delivering more effective patient support programs:

Strategy 1: Involve Compliance and Legal Early in Patient Support Program Design

Sometimes, brand teams develop program ideas for patient services departments to operationalize. However, program design, execution, and oversight tend to go more smoothly when patient services engages early with legal and compliance. This allows teams to align on program intent and establish the appropriate guardrails.

"People need to understand that this is a journey. As companies build out patient support programs, Ethics, Compliance, and Legal are all learning. The sooner Patient Services brings us in, the sooner we understand what they're trying to accomplish and we can actually help with program development," explained Terence Milton from Eli Lilly.

In addition to Legal and Compliance, Patient Services should not overlook privacy teams. As Michael Sanders from UCB noted, "Depending on the services and the types of patient engagements that you want to deliver, you may need a great privacy partner to help develop programs for the market." In small companies, the Chief Compliance Officer may also be responsible for privacy. In larger organizations, however, the functions may be siloed.

Savvy patient services teams recognize that Compliance, Legal, and Privacy aren't just approvers of patient support program plans; they are co-creators on the journey. One best practice is to hold a roundtable meeting where the brand team reviews patient support program information with colleagues from Compliance, Legal, and Privacy.

This collaborative approach, however, can take a considerable amount of time. It is crucial to discuss early on what resources will be required to operationalize a patient support program. Rahul Khara from Acceleron commented, "I love the idea of being a co-creator. All along the way, Compliance and Legal are learning, not just ingesting information. The learning process takes time, however, and that can only be achieved if teams are brought in early."

Strategy 2: Establish Data Governance Practices to Protect Patient Data

Patient services teams tend to think that more data is always better. Whenever a company deals with provider and patient data, however, questions must be answered about how and where data is housed and who has access to it.

With patient-level data, privacy concerns immediately come to mind. The California Consumer Protection Act, for example, requires companies to delete data upon request. In addition, brand teams will want access to certain datasets, but they can only use aggregated data. These types of issues must be discussed before data transfer occurs. One solution is to establish a data governance board or committee. "Once a product's launched, there will be extraordinary interest in the data flowing into the company. Unless you have an organized approach for storing and disseminating it, you could get into trouble," noted Biogen's Laurie Hughes.

Looking beyond privacy, organizations must continually reevaluate and update their data strategies. As Dr. Khara explained, "One pitfall that manufacturers fall into is designing the patient support program up front, deciding what data they need, and then never revisiting how they use the data. Data acquisition and usage shouldn't be a 'set it and forget it' kind of mentality."

Strategy 3: Implement Patient Support Program Services to Meet Company Needs, Not Simply to Imitate Competitors

The right patient support programs are based on the brand, disease state, program goals, and the company's risk tolerance. Simply because a competitor is using a certain type of patient support program service doesn't mean that your company should automatically follow suit. Before deciding on program components, it is often helpful to take a step back and ask what problem the team is trying to solve.

Both commercial and compliance teams, however, agree that it is good to stay abreast of industry developments. Technological and digital innovation are pushing pharmaceutical companies into new territories.

"One of the challenges for highly regulated industries like pharmaceuticals is that patients are consumers. The digital engagement they have with other sectors sets their expectations for everything they purchase or use. It's important to stretch our thinking about what we offer. When our commercial team collaborates with compliance and legal partners, we've found it helpful to ask how we might best do something, rather than stating that we are going to implement a certain program," said Mr. Sanders.

Dr. Khara encouraged patient support services teams to share industry intelligence with their legal and compliance counterparts. "It's good to hear what's going on in the industry. From a compliance perspective, we like to understand what's happening and perform our due diligence," he said.

Strategy 4: Leverage Technology to Enhance the Patient Experience

To date, technology adoption in patient support programs has been on the low end, compared to other industries. This may be due to a variety of factors ranging from company risk tolerance to IT infrastructure and the degree of outsourcing that an organization uses.

As Mr. Milton noted, "The pandemic thrust all of us into the virtual technology world. I think this will accelerate technology adoption, but it depends on the type of patient support program that you're running and the vendors that you're working with."

As teams incorporate technology into patient support programs, it is best to focus on enhancing the patient experience and not disrupting existing workflows. Mr. Sanders observed, "If a technology creates a better experience for patients or providers, the adoption will be high. I think usability is one of the things that gets in the way of new technologies coming to market."

Strategy 5: Monitor Third-Party Risk When Using a Hybrid Patient Support Program Model

Over the last two to three years, pharmaceutical companies have leaned toward hybrid patient support programs. As Laurie Hughes noted, "Hybrids are here to stay. Whenever you launch a product and anticipate a surge, it's critical that you have the bandwidth to handle it. Having good partners that can staff up or down helps us to manage the problem of over-hiring or under-hiring internally."

While the hybrid approach has many benefits, it also introduces third-party risk into programs. From a legal and compliance perspective, controlling these risks and overseeing internal FTEs are very different activities. In a hybrid environment, teams must address both of these areas simultaneously.

"The risks of the hybrid model aren't new, but they are additive. In addition, new risks may arise if internal and external people are interacting in new ways and using different data flows. Teams need to account for things like this. Early engagement with Legal and Compliance can help," said Dr. Khara.

Quarterly business reviews with vendors are another way to monitor quality and manage risk. These meetings ensure that vendor performance is in alignment with the company's requirements and risk levels.

Mr. Sanders observed that hybrid patient support program models aren't well-suited for every product. "Vendors are traditionally better at off-the-shelf services that treat every patient similarly, rather than personalized or customized approaches. With smaller disease states, patient support services tend to be higher touch. Many companies are pulling those program elements in-house, so they have greater control over the services," he said.

Strategy 6: Consider How Innovation Can Drive the Patient Journey

In some cases, vendors have developed innovations to support the patient journey. Examples include electronic benefit verification (EBV) and electronic prior authorization (EPA).

When it comes to customer-facing technology services, however, most innovation that enhances the patient experience is driven by pharmaceutical companies. This is particularly true for higher-touch therapeutic areas like orphan drugs, rare disease drugs, and oncolytics.

As pharmaceutical manufacturers consider whether they need to develop innovations in-house, it can be helpful to engage with patient services consultants.

Laurie Hughes noted, "Brand team members are very familiar with patient services vendors that operate hubs and provide patient services operations. When they prepare to launch a brand or product, they come to it with preconceived notions. There are several vendors, however, that are true consultants. They bring value to the table when we design programs because they are very objective."

Conclusion

There is a distinct difference between outstanding patient support programs and less effective programs. A defining characteristic of successful programs is the level of cross-functional collaboration. By following the six strategies discussed, pharmaceutical companies can improve collaboration, enhance the patient experience, better protect patient data, reduce risk, improve compliance—and improve the overall patient support program and patient journey.

ABOUT ARCHBOW CONSULTING

Archbow Consulting helps pharma and biotech companies design, build, and optimize product distribution and patient access strategies. Archbow was founded by industry veterans to meet a need in the marketplace for consulting options that offer diverse real-world experience, are able to leverage deep connections across the industry, and can also provide actionable strategic guidance.

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