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HOMA BAHRAMI
STUART EVANS

Flexibility at Genentech: Developing Versatile Domain Experts and Deploying Flexible Resources at One U.S. Medical Affairs Unit

The reality is that we need to be prepared for success, and we need to be prepared for failure. Planning for failure will be as important as planning for success.

—MAURICIO SILVA DE LIMA, VICE PRESIDENT, U.S. MEDICAL AFFAIRS - SPECTRUM, GENENTECH

In June 2013, Mauricio Silva de Lima, M.D., Ph.D., had just arrived in South San Francisco from Brazil to take over as Vice President of a newly formed Medical Unit (MU) in U.S. Medical Affairs at Genentech. Silva de Lima, who had joined the pharmaceutical industry a decade earlier after a career as a psychiatrist and professor, was preparing to lead the new MU, which had been formed as a result of a company-wide reorganization of the medical affairs function. This MU would be responsible for two new therapeutic areas—cardiovascular-metabolism and neuroscience—as well as a number of established products.[1]

Silva de Lima had earlier worked in Sao Paulo at Roche, Genentech's parent company. Founded in 1976, Genentech was acquired by Roche and became a wholly owned member of the Roche Group in 2009. Genentech is a leading biotechnology company that discovers, develops, manufactures, and commercializes medicines to treat patients with serious or life-threatening

[1] Established products are medicines that have been on the market for some time, that Genentech has, in most cases, stopped actively promoting. Because these drugs remain available to patients, Genentech must continue to support them for safety and regulatory reasons. Established products can be from any therapeutic area. Several criteria are used to determine when a medicine shifts into the established product category, and the amount of time a medicine has been on the market before it is considered an established product varies.

Berkeley-Haas Senior Lecturer Homa Bahrami and Professor Stuart Evans of Carnegie Mellon University prepared this case study with Case Writer Elizabeth Whalen as the basis for class discussion rather than to illustrate either effective or ineffective handling of an administrative situation.

medical conditions. It has approximately 12,000 employees in the United States[2] and focuses primarily on five therapeutic areas: oncology, immunology, metabolism, neuroscience, and infectious diseases.[3]

Two weeks after Silva de Lima arrived at Genentech, he received an internal communication about one of the cardiovascular-metabolism products the new MU was supporting. "It was a negative result in a phase three trial, and the company realized there was no benefit for patients," he said. (See Exhibit 1 for an overview of the studies conducted at different phases.) "It was a tough decision because of the investments the company had made, but it was the right decision for patients. We needed to focus on other areas where we have promising molecules in development."

That meant terminating the program for the last of the major cardiovascular-metabolism molecules[4] that Genentech had in development. In anticipation of a positive result, the company and the healthcare community had invested substantial resources to understand the molecule's potential benefits. The big question for Silva de Lima became "'What [am I] going to do now?' This decision affected all the people I was just starting to work with."

Many of the employees working on the program were highly trained scientists with advanced degrees. Through their training and experience, these employees had developed deep domain expertise in their specialties. When a program is terminated, the domain expert generally moves to a different role in a new group but continues to focus on the same or a similar therapeutic area.

Program terminations are not unusual in a pharmaceutical company, but they are typically balanced by successful drug launches. Across Genentech this balance had persisted, but the new MU was working on a number of programs targeted at disease states with high unmet need but low probability of success. As a result, the MU had gone through multiple program terminations without counterbalancing launches.

Medical Affairs does not determine which programs are terminated; that decision is made based on data from clinical trials and other related factors. This particular program termination resulted in the new MU needing to shrink, and over the next few weeks, a number of employees were displaced. Although some were able to find another position in the company, others had to leave the organization. Silva de Lima recognized that, under the traditional model, his new team would likely again face the challenge of terminating and re-distributing employees with highly specialized expertise. "We're always exploring new therapeutic areas. Those can change tomorrow," he said. "So we started having conversations about 'What can we do? How can we develop a different model?'"

Medical Affairs: A Knowledge Hub

At Genentech, the product development group[5] typically curtails work on a molecule once it gains U.S. Food and Drug Administration (FDA) approval and is launched into the marketplace as a medicine. In anticipation of a potential drug approval, the commercial group begins working on marketing campaigns in advance of that drug's launch, often referred to as L0, and continues

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[2] Source: Genentech website: http://www.gene.com/media/company-information/fast-facts
[3] Source: Genentech website: http://www.gene.com/media/company-information/backgrounder
[4] For the purposes of this case study, "molecule" refers to a substance before it is approved and launched as a medicine. "Medicine" refers to a substance that has been approved and is available to patients.
[5] Product development is essentially analogous to research and development.

until the company decides that the drug should be designated an Established Product.

The lifecycle of a molecule/medicine is a continuum, so the responsibilities of Product Development, Commercial, and Medial Affairs overlap somewhat, and the three groups interact on a regular basis. "The focus for Medical Affairs is to help physicians and patients make more informed decisions for therapies within the disease areas we're supporting," explained Jennifer Hertz, Ph.D., head of business operations for the MU.

A molecule is studied for a specific group of patients in a phase three trial. Such trials use carefully defined inclusion and exclusion criteria. The objective is to understand, as clearly as possible, how effective the molecule is, what risks it may present, and which patients would benefit from it.

However, once medicines are launched, physicians may have patients who could benefit from them but don't exactly fit the profile of the subjects studied in a phase three trial. Physicians and patients then need to determine if the medicine makes sense, and to do that, they need additional information.

Medical Affairs works to anticipate, identify, and close knowledge gaps between how the molecule is studied before launch and how the medicine is used in the broader population. Gaps may relate to safety, efficacy, dosage, and long-term impacts, as well as other topics such as concomitant medicines. For example, patients may already be taking another medicine, and they need to know how the medicines might interact. Other key gaps relate to how a medicine impacts a patient's health in practical terms, such as a reduction in the number of days before he or she can return to work, or on the patient's quality of life.

"Medical Affairs is about conducting research to generate and analyze clinical and scientific data, educating physicians and other healthcare professionals, and generally helping the medical community to better understand who is the right patient for the right drug," explained Susan Begelman, M.D., group medical director for the MU.

Medical Affairs's responsibilities begin before L0 and continue through the designation of a drug as an Established Product. "It's always debatable: at what L-minus [years] should Medical Affairs participate in an organization? How far L-plus should Medical Affairs make large investments?" Hertz said. Regardless of the exact timing, Medical Affairs works to understand critical gaps, conduct research to fill the gaps, and educate healthcare providers, payers, and patients about the results of its research so that those groups can make more informed decisions.

In many cases, that research takes the form of post-marketing studies, conducted by Medical Affairs. In other cases, Medical Affairs collaborates with external groups, such as universities and medical societies, that are also working to understand how a medicine works for patients. Medical Affairs reviews research proposals to assess rigor, and it provides financial support for those studies likely to provide useful information.

The group goes beyond providing financial support to external groups. "We're collaborating with intellectual capital and acting as thought partners in these projects," noted Diana Slowiejko, Pharm.D., Ph.D. As Senior Medical Science Director, Scientific Collaborations, she works to "define where we should be prioritizing, who we should be collaborating and interacting with."

"It's always a two-way dialogue," elaborated Hertz. "We try to think about what we can do differently with the molecules we're trying to launch, even in small ways, that could have a big

impact on our understanding and use of medicines when they get launched." Identifying potential high-impact levers requires thorough understanding of patients as well as effective communication of that information to other parts of Genentech.

For example, the development group may be about to start a study on a molecule in one of the MU's therapeutic areas. Through interactions with the medical community, Medical Affairs can give insights into how the development group could design its study to improve patient adherence. Or, Medical Affairs may suggest additional tests be included in the phase three trial that could help address potentially critical questions prior to launch.

"And there could be cost savings later because you don't have to do an extra study. You could already answer those key questions before the molecule moves to Medical Affairs," noted Vinita Adkar, finance partner to the MU.

Medical Affairs also has field employees, medical science liaisons (MSLs) who cover specific territories and specific molecules; MSLs make up approximately half the group in this MU. MSLs have Ph.D.s, M.D.s, Pharm.D.s, or the equivalent qualifications, and receive some of the most rigorous training of all Genentech employees because they primarily interact with external groups and health care professionals.

They disseminate scientific information within the medical community in an objective way. "By doing that, MSLs increase the level of confidence physicians have in how they make clinical decisions," said Nina Malik, Pharm.D., director of MSLs for the MU.

MSLs also collect related information. For example, if the company is exploring a new disease area, MSLs will undertake research into the medical and patient community, its current activities and priorities, and communicate the findings to Genentech's medical teams to help guide strategy.

"One of our most important partners is the commercial part of the organization because we also want to understand what their business strategy and alignment is for the overall product," said Begelman. The insights Medical Affairs gathers help allocate resources to efficiently address potential scientific and knowledge gaps.

A New Team, a New Leader, a New Name

In response to the program termination in June 2013, Silva de Lima and his senior leadership team (SLT)[6] began preparing for an offsite meeting slated for September 2013. They talked about developing a new model that would accommodate program terminations and other changes in a more flexible way. Silva de Lima asked the team to think about ways to engage the entire MU, which by then numbered approximately 50 people. Together, the group decided to take a bottoms-up approach: rather than dictating how the model would change, the SLT would discuss the challenge and listen to everyone's input.

The evening before the offsite started, Silva de Lima and the rest of the MU were joined at dinner by those employees who worked on the impacted program, including those who had transitioned

[6] The SLT included Adkar, Begelman, Hertz, Malik, Slowiejko, Mandy Sodhi, Ph.D., therapeutic area lead, Spectrum, Immunology, and Ophthalmology, and Elaine Yu, M.S., Pharm.D, head of health economics and outcomes research for the MU.

into other roles within Genentech and those who were about to leave the company.

"We decided that would be a way to recognize their contributions and to celebrate failure, in a way," Silva de Lima said. "That's easy to say, but difficult to make real, and to make people believe it."

He wanted to remind the group of Genentech's ultimate goal, which could sometimes be lost amidst the day-to-day activities of a pharmaceutical company. He also wanted to thank these team members for the way they had fought for patients. "We're not here to launch, launch, launch," Silva de Lima told them. "We're here to develop medicines for patients, for ourselves, for our families, so great job."

The next morning, the offsite continued for the team members who would continue working in Silva de Lima's group; they gathered to begin mapping their future and did so in a positive atmosphere. "People felt like that was a respectful way to say goodbye," said Hertz. "They respected the organization, Mauricio, and the team and were ready to take what we had and make it work."

Silva de Lima began the day by telling the team about a quote he had recently found by Alan Kay: "The best way to predict the future is to invent it," and then said, "If you are concerned about your future, go out there and invent it. I'm making you accountable for your own future, and if we develop a smart business model, if we develop the right work environment, the right mindset, and the right set of skills, that will allow for efficient flexibility."

He wanted to avoid broadcasting an unrealistically optimistic perspective on the pipeline, so he didn't try to persuade the team that another successful launch was certain or imminent, nor did he suggest that people who harbored doubts about the pipeline should leave the team. "Instead, I said, 'Listen, there is a risk. The reality is we need to be prepared for success, and we need to be prepared for failure. Planning for failure will be as important as planning for success.'" Indeed, Silva de Lima explained, "uncertainty is not the exception but rather the way it is in this type of business."

The group was starting essentially from scratch. "We were all brand new to this MU and told, 'Here are your roles,'" said Hertz. "'It's the same structure as the other MUs,[7] but you're smaller, so you'll get fewer resources. Go. And, by the way, you're covering a wide spread of stuff.' We said, 'OK, we have to figure out a strategy that will work well for us.'"

At the offsite, the group decided to focus on its mission, values, and core competencies rather than the group's structure or individual roles. It wanted to develop a way of working that would allow people to grow across the unit if a program was terminated rather than have to transfer to a different group or lose their job.

Team members also got to know each other, and Silva de Lima, better. "I think the team was trying to figure out who Mauricio was, how many things he was going to change, and what his attitude was going to be," said Sodhi. "I remember being in the hallway and saying, 'Wow, he really is genuine and he really does care what happens to me.' And even though he was brand new and didn't know anybody, he trusted Nina and Susan at that time to do what was best. I have seen other leaders who said, 'I need this and this to happen,' but he trusted them from the get go.

[7] Other MUs within Genentech cover other therapeutic areas.

He was a really great listener."

Silva de Lima's leadership style took some getting used to. "It was very different for the majority of people to have a leader come in and say, 'You guys figure it out,'" said Hertz. "It looked passive, as if maybe he didn't know what to do. We had to realize that, if he wanted to, he could immediately make the decisions. He wanted us to work as a team and be very collaborative and figure it out."

Although Silva de Lima recognized his new team expected him to describe his plans right away, he resisted. First, he wanted to understand the people, the stakeholders, the challenges, and the business dynamics. Gradually, through a series of conversations, he began to see a clear, complete picture of the new MU and the role it would play within U.S. Medical Affairs and Genentech as a whole.

After the offsite, the next question became how to make the concept of flexibility operational for the MU. But first, the group needed a name. Team members submitted ideas, and the group eventually selected "Spectrum" to denote flexibility in both therapeutic areas and employees. The group was preparing to support therapeutic areas new to Genentech in addition to neuroscience and established products; it also contained a diverse set of individuals and planned to cultivate flexibility within those people.

Next, the SLT used the information collected at the offsite to define the MU's unique values: agility, spirited, partnership, innovative thinking, resilience, and entrepreneurial. The team abbreviated these values with the acronym ASPIRE, with "flexibility" as a foundational anchor.

Flexibility would mean cross-training scientists who had spent years developing expert knowledge in a specific therapeutic area, a factor especially relevant to this MU because it supports molecules in therapeutic areas that are new to Genentech. The concept of cross training was also new to Genentech's Medical Affairs organization.

"We operate very differently compared to our Commercial colleagues," said Begelman. "A good marketer can market anything. By nature, they're flexible; they move around all the time. By nature in Medical Affairs, we are not flexible. There's an inherent rationale why we lack ease with flexibility."

Spectrum faced many questions about the feasibility of a new approach. One early concern expressed by company leadership focused on the idea that people might end up working on molecules for which they weren't the ideal fit because of a perceived mismatch between their expertise and the molecule. "We challenged that," Silva de Lima said. "Because it depends. Once you have a strong medical science foundation, you can learn the science specifics in a new therapeutic area. The mindset is the big thing."

Connecting with external stakeholders is also key to success in Medical Affairs, and building relationships with expert leaders in a new therapeutic area takes time. However, Spectrum countered this argument by pointing out that new employees, who may already have the relevant subject-matter expertise, also need time to build relationships or become familiar with new territories.

Defining—and Re-defining—Flexibility

As the team began developing a new, more flexible model, it faced a number of questions. It spent time discussing flexibility, what it would mean for each team member, and its impact on resource deployment.

The group also set specific goals for itself. Said Hertz: "To establish a culture that's dynamic and effective, to make sure we evolve as a community together to create credibility, demonstrate integrity, establish a positive reputation, and see if we can serve as a change agent within U.S. Medical Affairs." To achieve these goals, the leadership team took a collaborative approach. Two to three people acted as leads for each goal and worked across the leadership team and across Genentech to understand how best to achieve them. The leadership team would then meet to discuss progress and offer support.

"It was unclear what those goals really meant early on," said Hertz. "It was ever evolving. But organizations want to know exactly what a goal is, exactly what the deliverable is going to be, exactly the timing. We couldn't specify [these] early on."

The question of how to communicate its decisions was a central topic of discussion. Spectrum had to clearly articulate its new strategy to Genentech's senior leadership team. This meant the team had to specify clear metrics and concrete criteria for resource-allocation decisions. "That is hard to do when it's strategic. It's not easy to measure," added Hertz.

The group itself was also evolving. To help facilitate Spectrum's transition, the SLT engaged Peggy Nagae, partner and consultant at Anderson & Rust Consulting. At the beginning of her involvement, she observed: "They were a team of leaders rather than a leadership team. I find that often happens because people are passionate about the work they do. Therefore, when a decision needed to be made that focused on Spectrum as a whole, a lot of times there was no distinction between taking off the functional hat and putting on the Spectrum leadership hat."

Nagae coached the SLT, on a group and individual basis, to define shared goals and to build relationships through effective communication. The SLT defined an ideal scene that captured the shared goals and tracked progress on a regular basis. The group also practiced giving feedback in a way that assumed positive intent and avoided acting on assumptions. Instead, team members asked questions to understand what led others to their conclusions and explained their own thought processes.

A New Model

Medicines typically go through several stages prior to approval and launch. Spectrum's involvement often begins to ramp up once a molecule has reached phase three clinical trials. At that point, the group needs team members who can learn about the molecule and the therapeutic area, identify the key health care professionals and entities (such as medical societies, collaborative groups, and academic organizations) in the field, and build effective relationships.

The Medical Affairs Group is engaged during various stages of a medicine's life cycle, including pre-launch, peri-launch (which includes the actual launch), growth, late lifecycle, and maturity. The level of involvement necessary to support each stage varies but is generally highest in peri-launch and growth.

Once a medicine reaches maturity, the group's involvement changes. Established products

generally require little, if any, de novo research. Instead, Spectrum provides safety and scientific information for label updates when necessary and answers requests from external groups.

Before developing its flexible model, Spectrum used to invest a moderate amount of resources during the early stage to gain sufficient knowledge about the molecule. The time commitment was reduced through the pre-launch, and increased through peri-launch and growth phases. Once the medicine reached the late stage, investments would be substantially reduced. (See Exhibit 2.)

Silva de Lima believed a new investment curve would lay the foundation for Spectrum's future and worked with Hertz and Adkar to develop the concept. Hertz translated the concept into visual depictions and led the SLT's collaborative model-refinement process.

To be truly flexible, Spectrum had to prepare for various scenarios. Traditionally, Medical Affairs determined when to begin forming teams and planning for molecule support based on the estimated launch date. Today, Spectrum uses a set of criteria to help make those determinations. One criterion is the probability of technical success (PTS), a metric often used within Genentech and Roche; however, Spectrum applied this metric in a new way to objectively assess the optimal allocation of people and resources. In general, Spectrum now allocates a relatively small amount of resources to molecules in the early stage. The goal is to free up resources for programs in the pre-launch phase. The higher the PTS, the more is invested early on, and the lower the probability, the more caution is exercised.

Funding the molecules based on clear risk assessment criteria increases financial flexibility and resource deployment. High-risk programs receive the minimum level of required funding. Key milestone accomplishments dictate financial decisions and maximize investment value. This model differs from the traditional one where programs are fully funded and, if terminated, the funds are subsequently reallocated.

This model also differs from the financial allocation process in other parts of Genentech. Adkar, who worked as a finance partner for the product development group before joining Medical Affairs two years ago, observed: "Product Development will obviously invest in high- and low-risk projects, but they have a larger committed spend. They can't just turn off the spigot, so it's not possible to be as nimble. In Medical Affairs, at certain stages of the lifecycle, it is possible." The commercial arm of Genentech is typically able to curtail spend very quickly. Medical Affairs fits between the two in terms of flexibility.

As a result of this shift, the first part of the investment curve has flattened. Hertz explained: "The key word is 'maintain.' If we're going to spend a little early on, we don't want to then drop it because it's like starting over." By keeping the level of support for a molecule essentially the same in the initial phase, Spectrum can prepare for next steps without over-investing. It can, for example, build key relationships so that when it needs to conduct a study, it has already identified key gaps and external groups. (See Exhibit 3.)

This approach challenged the conventional wisdom about the timing of Medical Affairs's involvement with a molecule. "It was common practice to rely on approximately L-minus two years as a guide," said Hertz. "There's the idea that 'It's this period of time, and it's an on-and-off switch.' It just can't work that way. That's really not going to be helpful for a number of our molecules. We needed to do something different, to look and do some minimal planning so that we can be prepared. At the same time, people think you have to plan the whole world. We've got to plan just enough to know so that when it comes to that point, that trigger, we are set and ready to go."

Spectrum also worked on assessing priorities by surveying projects and identifying those with the most impact. It prepared for program terminations by thinking carefully about risk. Some questions the group wrestled with included: Where do we take risks? What information do we use to inform that risk-taking behavior? How much is enough for now? When is more better? If a program is terminated, what is our backup plan for what to do with our people and other resources?

Before joining Genentech, Begelman had worked on a project that was cancelled, and it was clear no contingency planning had been put in place. Management appeared paralyzed. She realized that teams are often better at scenario planning for the best possible outcomes than for negative results. After all, if a group doesn't believe its program has a good chance of success, investing in it seems illogical. "But I think for many leaders, if they're really good leaders, what keeps them up at night is the 'What if the negative [or the worst case] happens?'" she explained.

However, the model needed to do more than simply re-allocate resources when circumstances changed. A strategy was essential, both as a way to plan for the future and to communicate critical decisions.

Spectrum's strategy was designed to be flexible and proactive; it identified a range of projects for team members who had worked on discontinued programs. For example, team members could work on programs with longer phase three trials or on molecules licensed from another company. These in-license programs are often already in the pre-launch stage and require employees to come up the learning curve quickly.

Program terminations also affect Spectrum's collaborations with external groups. In the wake of a prior program termination elsewhere within Genentech, those leading the relevant collaborations had shut them down. "It was a cliff," said Slowiejko. "Genentech has such a robust portfolio that we might not have something two years away in that space, but we could have something five years away. Then you have to re-establish some of the credibility you had [already] built."

Therefore, Slowiejko now works to maintain relationships over the long term, despite program terminations. However, the level of involvement does evolve over time. For example, if Genentech is no longer able to support certain activities, this message is clearly communicated to the relevant external groups.

Slowiejko also adopts a holistic approach to external collaboration. She has widened her focus beyond the short term and a specific molecule. Spectrum's goal is to benefit the patients by identifying low-risk opportunities for high impact. In addition, Slowiejko has been preparing to ramp up external collaborations when necessary by putting together a framework for addressing new therapeutic areas. First, a team assembles and considers several questions. What do we know about this therapeutic area? What, if any, research is necessary? What do we know about the external entities' perspectives? Who are the key stakeholders? It then determines an early-stage communication strategy. "I think putting that on paper has been very helpful, and has helped get buy-in from leadership," Slowiejko explained. "Right now, we're the only medical unit [in U.S. Medical Affairs at Genentech] that has this model formalized."

Mapping Core Competencies to the Molecule/Medicine Lifecycle

Another aspect of Spectrum's flexible model is the use of what can be characterized as "relay teams." The same people do not necessarily move through the lifecycle with the molecule. In the earlier stages of Medical Affairs's involvement with a molecule, different experts handle the work; as the molecule progresses through peri-launch, growth, and the early part of the late lifecycle stage, new teams are formed and the work is handed over. As the medicine becomes an established product, new experts, as needed, are deployed for handling the task. Teams grow and shrink in size accordingly.

To implement its flexible model, Spectrum tailored Roche's ten core competencies and mapped them to each stage of the lifecycle. Those that are key to each stage vary significantly. (See Exhibit 4.)

Important competencies during the early stage include business, change management, and innovation expertise; decision making is of medium importance, and technical expertise is of low importance.
During the middle stages, decision making and technical expertise are critical, while business and change management expertise are viewed as relatively less important. As a medicine transitions into the established product state, it's important to have individuals with business expertise as well as innovation and decision-making skills.

"Early on, we need individuals who understand the process," said Hertz. "That's more important than understanding the disease area. That's why we put 'technical expertise' as low. The majority of the people we need early on are those who understand what is needed to get a molecule moving into the middle stage. [Then], a share of the team needs to understand the process, but others need to join who can become or already are experts in the disease area. [Later], it's the transition back to individuals on the established products team. We need some technical expertise to understand the history, but we don't need somebody who's extremely versed in that therapeutic area or medicine. We really need people who understand what's required for medicines in the established area and the support they need."

For example, people working on the established products team need to understand how to respond to requests and questions from the FDA, physicians, and patient groups. By this stage, the information necessary to answer many of these questions has already been gathered, but analysis is still necessary.

Cross-Training Domain Experts

To facilitate transitions and prepare for potential program terminations, the Spectrum team began a cross-training initiative. In the traditional medical affairs model, responsibilities and training materials are largely separated by therapeutic area. Spectrum now gives all its team members the opportunity to be trained on all the molecules it has in its pipeline.

A primary tool supporting this initiative is a single pipeline slide deck that covers all the group's therapeutic areas. This deck gives everyone, particularly MSLs who are responsible for addressing questions in the field, an understanding of Spectrum's entire portfolio. All MSLs, no matter which therapeutic area they support, are then able to answer high-level questions about the pipeline. The MSLs covering one therapeutic area are not expected to be experts in all the other areas, but they should have enough knowledge to answer basic questions or to know who would

be able to answer a more complex question.

Cross-training nurtures flexibility by increasing MSLs' capacity to accommodate program terminations and other changes. If, at some point in the future, MSLs want to move into other therapeutic areas, they will have a higher likelihood of doing so successfully.

The fact that MSLs work remotely presents its own challenges. "Sometimes the field is a little disconnected, so when operational models change, it doesn't immediately affect the team," said Malik. "They feel things are different, but they don't know why. Most of it is happening more at the headquarters level, from the standpoint of processes or divisions of competencies. I don't think that immediately [after the flexible model was implemented] people in the field really understood what was happening in terms of the change."

It took some time for MSLs to see the value of the cross-training initiative. Although the training gave MSLs a more comprehensive picture of Spectrum's programs, it didn't change how MSLs did their jobs. In addition to the offsite in September 2013, Spectrum held a series of additional offsites that helped reinforce the changes for the MSLs. Malik also works to engage the MSLs by involving them in strategic decisions and enabling them to drive implementation.

She frequently communicates Spectrum's values, using specific examples. "You have to live it and if people are struggling, you have to identify it and say, 'You're challenged by this,' so it becomes real," Malik said. She incorporates the importance of agility, resilience, and innovative thinking in one-on-one conversations with MSLs, at meetings and in training sessions. She will discuss the importance of looking to the future and thinking about the competencies that will be necessary to succeed. "That's similar to what they'd have in any job, but I think we put it in the framework, making sure they're developing the competencies that are required to be flexible, and that flexibility is important in their career," she continued.

When a program is terminated, she reminds MSLs of the holistic training they've received as well as the emphasis Spectrum places on resilience. For Malik, transparency supports resilience. Talking openly about risks as a team helps people handle failures more effectively and gives them an opportunity to be part of the business solution.

Finding the Right Fit

Not everyone is likely to thrive in a flexible environment. Scientists who have spent years developing domain expertise in a specific field may be passionate about that subject matter and less interested in a different therapeutic area. Long, specialized training cycles may also lead people to believe that taking on a new domain is not feasible. That mindset is prevalent in many scientific fields and also fairly common at Genentech.

"I've had a couple of people from my team recently move onto other great roles in the company," said Begelman. "And it's interesting because I got feedback from others asking, 'What's going on? What's wrong?' instead of 'How wonderful that they're [being flexible].'"

Assessing the candidate's flex "fit" is crucial because flexibility needs to make sense for both Genentech and the individual. Therefore, the SLT takes the interview process seriously. Before interviewing candidates, the SLT divides up the task so that each team member can focus on a core competence during interviews. The goal is to ensure that key competencies, as well as the candidate's attitude towards flexibility, can be thoroughly explored.

Begelman also likes to explore a candidate's attitude towards risk and "failure."

"So what are the small wins for you and how do you weather that storm [if a molecule is not successfully launched]? I try to get at the person's risk-taking mindset. I ask a lot about mistakes or errors and lessons learned and how they've managed through that. I ask about projects; if it didn't go well, why not, and what did you learn?"

Begelman has also adjusted her own mindset. Her medical training is in the cardiovascular field, and she practiced in that area for several years. Before joining Genentech, she had worked in the same field at another pharmaceutical company, and had continued that focus after joining Genentech in 2008. The June 2013 program termination left Medical Affairs without any cardiovascular programs, so she re-evaluated her own motivation; she asked herself whether specialized therapeutic expertise or the opportunity to craft strategy across multiple therapeutic areas energized her more. She chose the latter.

The Spectrum team also evaluates candidates by understanding their comfort level with volatility, uncertainty, complexity, and ambiguity (VUCA). People with higher tolerance for VUCA are more likely to shift from one program to another. Those with lower VUCA tolerance levels tend to feel frustrated and lost when programs they've worked on for years are terminated.

Yet, candidates also need to demonstrate an engaged spirit. "At Spectrum, they value everybody's opinion, so you have to be courageous enough to speak up and share yours," said Sodhi. "If you can't do that, it's not a place for you."

Early Tests and Positive Results

The flexible program was put to the test early on. While the group was developing the initiative, another program was terminated, yet Spectrum retained nearly every employee who was willing to be flexible. (One person eventually left to pursue a passion for a different therapeutic area.) Shortly thereafter, just as a new employee joined the group to take a role on a different project, the new position was eliminated, and the new team member's responsibilities were re-defined. The employee successfully transitioned in part because of the focus on flexibility during the interview.

These early tests enabled the Spectrum Team the opportunity to demonstrate the potential of its new model. "We were able to practice what we preached, and people were able to witness how we did it," said Begelman.

The SLT also compared the termination and its impact to the group's expectations, using that feedback to continue and iterate the model. As the flexible model was evolving, the Spectrum Team set out to educate its key stakeholders. "The idea of flexibility was challenged in every situation in a very positive way," said Silva de Lima. "I don't know how many times I re-presented the same slides—quite a few times, to the head of Medical Affairs, to the CEO—always with something new. One of the good things was that, as we were adapting, we had more to share, more than just a concept."

Codifying and documenting the model was essential for effective communication. "We talk about it a lot because we lived it, but we had to put this on paper. Otherwise, what is the model? We've solved a problem, but we haven't put down what it looks like," said Slowiejko.

Over time, the team became more confident in its communications to upper management. Early

on, Spectrum's SLT was facing a barrage of questions, but now it's able to anticipate what the organization needs to know and craft its message as needed. The SLT has also learned that, in some cases, over-communication is important, especially for conversations about shifting resources.

The trust the SLT built early on contributed to the quality of these communications. "You could tell the SLT members really supported each other and liked each other," said Nagae. "And that showed up in front of the room. That communicates in unspoken ways."

In 2014, Roche engaged an external consulting firm to conduct a company-wide Global Employee Opinion Survey (GEOS) to measure employee engagement; for many questions, direct comparisons can be made between data specific to Spectrum and that from an aggregated set of other global pharmaceutical companies.

The results show the impacts of Spectrum's efforts.[8] Overall engagement, a high-level measure of positive employee perceptions and attitudes, was 88 percent among Spectrum employees compared to 63 percent among employees at the other global pharmaceutical companies surveyed. The GEOS also measured engagement with a range of additional, specific questions.

For example, it asked respondents whether they agreed with the statement, "Given the opportunity, I tell others great things about working here." Among Spectrum employees, strong agreement was nearly unanimous at 95 percent; 69 percent of employees from other companies expressed strong agreement.

Spectrum also outscored other companies by wide margins in the areas of employee motivation, learning and development, and management effectiveness. Eighty-six percent of Spectrum employees agreed that "this organization motivates me to contribute more than is normally required to complete my work," compared to 58 percent of employees from other companies. Eighty-nine percent of Spectrum employees agreed that "my learning and development is strongly supported," compared to 58 percent of employees from other companies. And, 84 percent of Spectrum employees agreed that "my manager provides the support I need to succeed," compared to 68 percent of employees from comparison companies.

Furthermore, 71 percent of Spectrum employees agreed that "major change initiatives are well managed and help us to deliver better performance."[9]

Members of Spectrum's SLT believe the flexible model will continue to provide benefits as the group expands its scope. Earlier in her career at Genentech, Slowiejko had gone through a program termination in the cardiovascular therapeutic area and subsequently shifted her focus to metabolism, where she worked on molecules related to diabetes. Although the two therapeutic areas differed somewhat, there was also a fair amount of overlap. But when the news came of the program termination in June 2013, she wasn't sure what she would do. Over time, however, her experience has changed.

"I've moved across four different therapeutic areas in two years," said Slowiejko. "This model, it's almost therapeutic-area agnostic in many ways. You do have to quickly learn, but you can use the model in any new therapeutic area."

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[8] The response rate of Spectrum employees was 92 percent.
[9] No comparison data was available for this question.

Surveying the Strategic Landscape and Measuring Engagement

External collaborations are critical for the medical affairs function, yet it is challenging to measure their impact. Often, collaborations are forged based on who shows up first; this is another area where a flexible framework for assessing potential opportunities and risks can be critical for success.

Before joining Spectrum, Slowiejko also worked in scientific collaborations; in that position, she stepped back and set out to better understand how different groups inside and outside Genentech manage collaborations. She conducted research on a broad set of organizations, including other pharmaceutical companies and large nonprofits, such as the Bill and Melinda Gates Foundation, to look for resource-allocation models.

Over the past year, she has extended that research by carefully considering how to measure success in building collaborations. The simplest method is to count the number of engagements, but this approach leaves out valuable information, so she has created an engagement index. The index monitors the number of engagements, their impact, and eventual outcomes.

The index segments "engagement" into four categories: *introductory meetings* in which Spectrum establishes initial contact with an external group; *participation as part of a group* (often an arrangement in which Spectrum would join a council, including others working in the same therapeutic area); *meaningful scientific exchange* (including engagement in serious conversations about a specific collaboration or providing new information on all phases of clinical trials); and *execution on a specific collaboration*, when Spectrum works with the external group as a co-initiator instead of simply providing financial support for a project that's already in the works.

Engagements in each category are assigned points. The weighting for each category increases at an accelerating rate as the type of engagement deepens. For example, those in the first category may receive one point each, while those in the fourth category may receive 50 points each.

"Our goal isn't necessarily to get everyone to the fourth stage because we can't do collaborations with every organization," Slowiejko explained. "And right now, I'm not concerned about the total number, but going from 2015 to 2016, I would expect us to be two- to three-fold higher in terms of what our goals are. And in fact, we looked at what we're planning on doing this year, what our objectives were, and it came out at about two-and-a-half times. It's a way to try to start putting together some kind of measurement around what success looks like."

The impact of those engagements will be determined over time. Slowiejko plans to use what she learns to better assess potential partnerships in advance. Her goal is to develop concrete criteria that would help Spectrum identify ideal opportunities. She uses scenario planning as she evaluates potential engagements. A key goal is to find the right balance between engaging too aggressively too soon and developing the trust necessary to move collaboration to the highest level.

Slowiejko is still working to define that balance. "But you have to think about that because the worst thing to do is be fully engaged and all of a sudden just walk away," she said. "That's very frustrating. The organizations remember that, even if you come back five, six, or seven years later."

Building and Maintaining Spirit

As Spectrum continues to leverage its flexible model, the SLT continues to reinforce the 'S' in ASPIRE: Spirited, which can be difficult in the face of program terminations. When people work extremely hard on a program that ends abruptly, they can feel as though their work produced nothing of value.

Begelman challenges that idea in two ways. For projects that have been terminated, she talks about how much Spectrum has learned that will be applied in the future. For projects that succeed, she emphasizes how past work, including work on terminated programs, has contributed to that success. "Many of the people may have moved on to other roles or left the company, but people have long memories. They may know who worked on that previous project. They may have worked on it," Begelman said.

She also exercises caution when communicating about the scenarios Spectrum's SLT considers. Although there is much value in thinking about and planning for potentially negative outcomes, discussing those in detail can send the "wrong" message—that the SLT doesn't truly believe in the project. That can, in turn, demotivate the team.

For instance, when Spectrum employees ask her why the team isn't larger or why it isn't taking on every project, she reiterates that the SLT is planning for success but also prepared for challenges. If she's asked, "When can I hire another person?" she'll often respond with, "Let's achieve milestone 'X' and then we'll talk about it."

Throughout the development and implementation of the new flexible model, Spectrum continued to celebrate team members' efforts. "There are a number of things you don't control, so whenever possible, I like to recognize the effort before the outcome," said Silva de Lima. "Because if people believe 'Either I deliver a result or I won't be successful,' then they won't take risks."

Other aspects of Silva de Lima's leadership style helped build trust and strengthen the group's spirit, observed Nagae, including his big-picture perspective, his relationship-oriented approach, and his ability to support people without micromanaging them. "When you have that, you have the ingredients for an entrepreneurial spirit. If there was another leader who was rigid and had to have precedence, I think it would have been much more challenging."

Also key was the SLT's dual focus on achieving its goal and doing so in a team-focused way. "It's the 'what' and the 'how' of leadership," Nagae continued. "What" refers to the goal and "how" to the way it's pursued. The SLT incorporated both and avoided sacrificing one for another. "How we work together, how we talk with one another—emotional intelligence says that can make the deciding difference on whether something works or fails."

Moving Forward

In January 2016, Silva de Lima became the leader of Medical Affairs for Roche in Europe, an assignment that will take him to Roche's headquarters in Basel, Switzerland. He plans to take the lessons learned from Spectrum while articulating his own leadership style. "When people ask me, 'What are you going to do?' I am going to say, 'You have to be prepared because, in the next few weeks, I am going to listen rather than tell you what to do. I will be talking to people, I will be asking questions.'"

As Silva de Lima reflects on his experiences leading Spectrum, he notes the power of constructively challenging his team. Intelligent people need to be stretched on a regular basis in order to remain engaged. Over-stressing the team can lead to problems, but challenges are key to engagement. "In many situations, we thought, 'Gosh this is crazy, how are you going to do it?' But really smart people, they need that."

Silva de Lima recognizes he'll encounter a more established culture in Europe and will face additional challenges: "People are afraid of change exactly because of the likelihood of failure. You can say, 'Change will be great, no reason to feel bad about it,' but we all feel threatened in some way by change."

Stepping into Silva de Lima's role is Begelman, who will lead Spectrum as it grows and evolves to support multiple molecules that are now shifting into launch mode. She is thinking about how to maintain the flexible culture as new people join the team, especially when they were not part of the group that helped shape its new approach. Another challenge is how to demonstrate the benefits of flexibility in an organization that is steeped in the merits of deep domain expertise. She would like talented scientists to think about flexibility in the context of their own career development in a "VUCA" world characterized by fluidity and uncertainty.

Case Discussion Questions

1. When the new MU formed, what were the critical challenges facing Mauricio Silva de Lima and his SLT?

2. At that time, what considerations did Silva de Lima and his SLT need to balance?

3. Evaluate the initiatives Silva de Lima and his SLT implemented. What are the benefits? What are the potential downsides? Which initiative is likely to have the most impact? Why?

4. What are the potential barriers to the continued success of Spectrum's flexible model?

5. In hindsight, what do you think the Spectrum team should have done differently?

6. The Spectrum team used a number of internal metrics to help it plan and allocate resources. What criteria and metrics, from any industry, could be used to support product launches and growth strategies?

7. What are the lessons of this case for leaders in other knowledge-based organizations that want to become more flexible?

8. What should Silva de Lima do next as he assumes his new role as the head of the European medical affairs group?

9. What should Begelman do next as the new head of Spectrum?

Exhibit 1 Clinical Trial Phases

Clinical trials are conducted in a series of steps, called phases. Each phase is designed to answer a separate research question.

Phase I: Researchers test a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.

Phase II: The drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.

Phase III: The drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.

Phase IV: Studies are done after the drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use.

Source: Quoted directly from https://www.nlm.nih.gov/services/ctphases.html

Exhibit 2 Spectrum's Original Investment Model

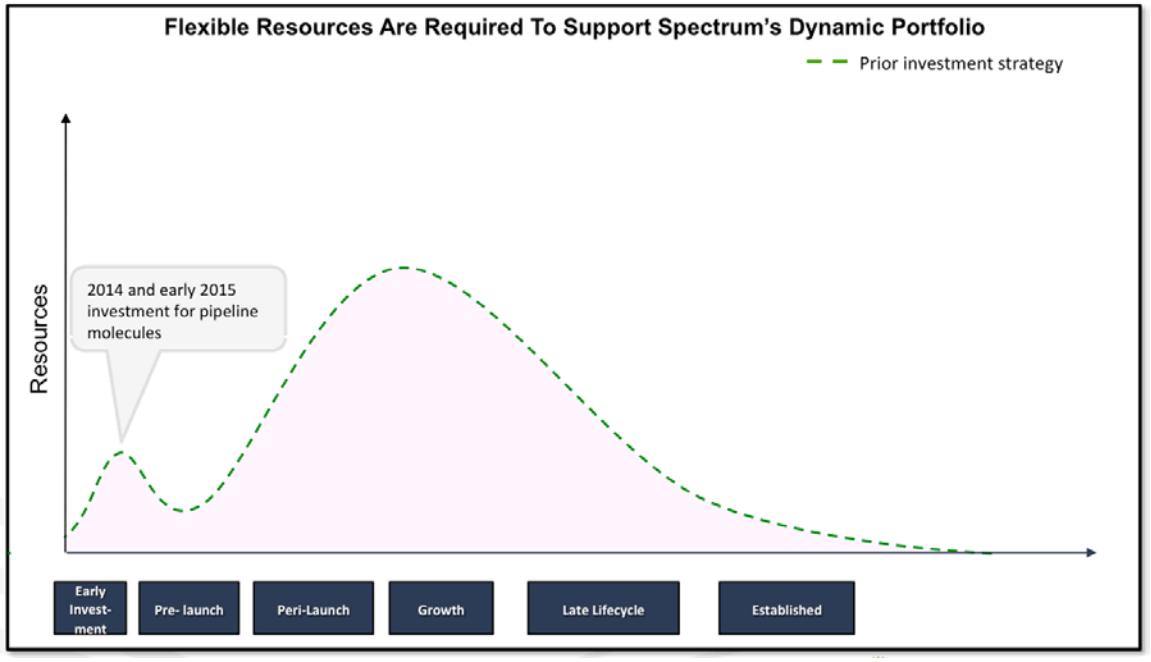

Exhibit 3 Spectrum's Flexible Investment Model

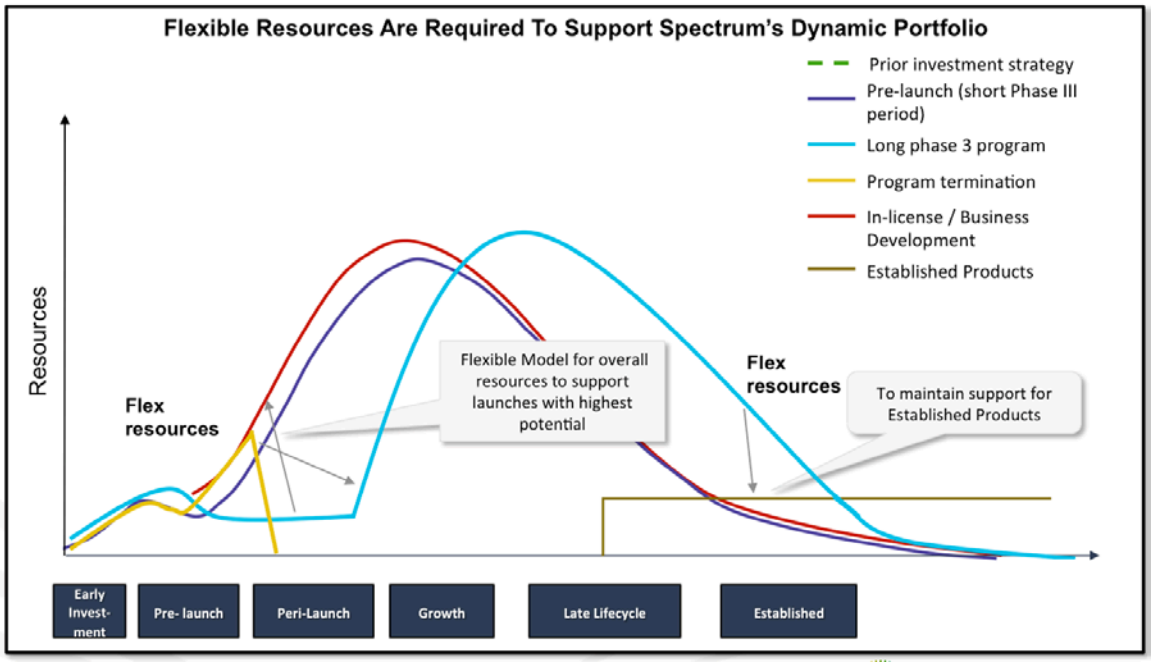

Exhibit 4 Spectrum's Mapping of Key Core Competencies to the Molecule/Medicine Lifecycle