ASTRAZENECA
Fighting a Global Pandemic

CHALLENGE:
From Lab to Jab at Light Speed

As COVID-19 spread throughout the world in the spring of 2020, AstraZeneca recognized the need for an effective COVID-19 vaccine to defeat the virus. In April 2020 AstraZeneca joined forces with the University of Oxford to make a meaningful difference and save lives. This landmark partnership brought together world-class expertise in vaccinology with AstraZeneca's ability to deliver a global solution at scale.

AstraZeneca's research partners at Oxford University had demonstrated an immune response in preclinical studies and some encouraging early clinical results that provided a basis for confidence that a vaccine could be rapidly developed.

AstraZeneca's proven manufacturing capability and global supply chain would enable rapid progress from the research lab to the development of a highly effective vaccine, with a favorable safety profile that could be administered around the world.

AstraZeneca and Oxford University pledged to provide the vaccine on a not-for-profit basis. This commitment to broad and equitable access ensured that the vaccine would be available at cost during the pandemic, and accessible to low-income countries after the pandemic subsides. To be successful, however, AstraZeneca would have to make every dollar count.
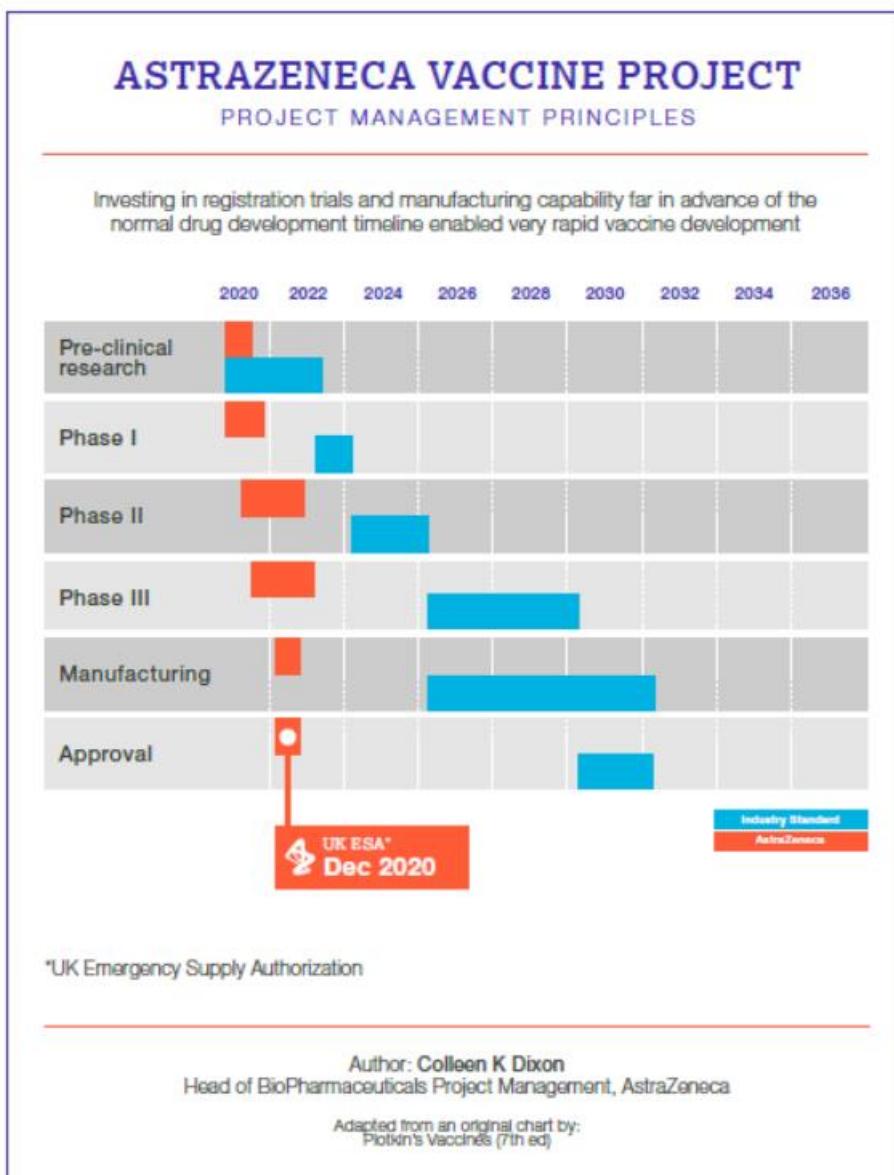
AstraZeneca is a global bio-pharmaceutical company headquartered in Cambridge, England, with revenues of $26.6 billion (2020).

Key Results
As of July 2021, AstraZeneca has released 1 billion doses for supply to 170 countries.

CONTEXT:
Risk, Complexity, and Visibility

From the moment AstraZeneca publicly announced a vaccine partnership with Oxford University on April 30, 2020, the process it undertook was unlike that for any other technology it had developed in the past, with vastly more uncertainty, complexity, and visibility.

ASTRAZENECA VACCINE PROJECT
PROJECT MANAGEMENT PRINCIPLES

Investing in registration trials and manufacturing capability far in advance of the normal drug development timeline enabled very rapid vaccine development

	2020	2022	2024	2026	2028	2030	2032	2034	2036
Pre-clinical research									
Phase I									
Phase II									
Phase III									
Manufacturing									
Approval									

Industry Standard
AstraZeneca

UK ESA*
Dec 2020

*UK Emergency Supply Authorization

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Adapted from an original chart by:
Plotkin's Vaccines (7th ed)

Risk

The uncertainties and reputation risks inherent in the vaccine project were significant. The need for speed demanded large, simultaneous investments in the Phase 3 clinical program for emergency use authorization by regulatory bodies such as the US Food and Drug Administration (FDA) as well as the setup of manufacturing capacity around the globe. These investments typically would have taken place after years of work and risk mitigation rather than within weeks of seeing initial clinical results in Phase 2.

The company had to dedicate resources and top talent to the project without compromising the rest of its portfolio. It was keenly aware of the reputational risk associated with delivering a vaccine on a global scale at unprecedented speed. The risk management process would also require close, frequent contact between project and senior leadership teams.

Complexity

The need to move quickly drove the project's complexity. Due to the accelerated timeline of the vaccine project, AstraZeneca had to manage clinical trials while simultaneously ramping up manufacturing capacity. The project's complexity also increased with every new customer. The primary customers were governments seeking to immunize their populations, and each government brought its own regulatory requirements and compliance framework to the table, adding to the contracting and compliance challenge.

Visibility

The global need for the vaccine gave this project a prominence unlike any other for drug development—there were universal pressures. "It's a fishbowl to the nth degree to be on a project like this, where you literally have presidents of governments calling and asking, 'When am I getting my vaccines?'" said Colleen Dixon, Head of Biopharmaceutical Project Management. "We were working out loud on a global scale."

PROJECT MANAGEMENT:
Building from the Ground Up

As AstraZeneca's Global Project and Portfolio Management function prepared to undertake the project, **it quickly identified three gaps**:
1) internal project managers experienced in vaccine development,
2) project management processes fit for moving at the speed the vaccine project required, and
3) an internal government contracting organization that could support the project.

Before addressing these gaps, though, it needed the project management infrastructure necessary to address the unique challenges of this project.

Establishing a PMO
The first step was to create a project management office (PMO). Prior to COVID, the AstraZeneca R&D unit did not have a PMO because the types of projects it managed didn't require the capabilities of a dedicated office. The vaccine project was a different story.

PMI's *[A Guide to the Project Management Body of Knowledge](#)* **(PMBOK® Guide) provided the framework for the creation of the PMO**. "We literally pulled out the PMBOK and said, 'What kind of PMO are we going to deploy next week? What are the control elements that a typical PMO would have, and which ones do we most need on this one?'" Dixon said. "We couldn't build a PMO that would take two years because we had to do it in a week."

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> *- Colleen Dixon*

Given the time pressure, Dixon's team prioritized four key roles for the PMO:

1) *Integration of schedule and budget*. This included adapting the enterprise system to support billing for a US government contract and setting up cost codes for time entry.

2) *Contract management*. This provided a centralized resource for team members and functional owners who needed to understand the relevant terms and conditions of contracts with different governments and entities.

3) *Team process guidance*. The PMO developed guidance and training for team members on ways of working on various government contracts, including considerations ranging from time entry to client confidentiality.

4) *Risk management*. This enabled the team to understand and manage key risks to the project and the business.

The ability to rely on the PMBOK® Guide framework relieved the project management team of having to design the PMO from scratch. It also served as a source of credibility that Dixon could lean on in conversations with senior leaders: "'We have a control framework, and it's based on the PMBOK, and this is how other companies do it. It's the right way to do it.'"

Staffing the Project

The next challenge was to staff the PMO. Hiring externally would have taken time that the project didn't have, so Dixon started her search internally, looking for people within her existing team of 80 project managers, as well as people outside the team with relevant experience in their careers. Drawing on her knowledge of their backgrounds and on feedback from others across the company, Dixon staffed the vaccine team with people who had worked on government contracts or vaccine projects in the past. One person, for example, had worked for a company that helped other drug manufacturers secure government contracts, and another had worked on government contracts for a company AstraZeneca had acquired.

"The PMO put the structure and resources in place to allow the technical teams to focus on the deliverables in the midst of great complexity, a pandemic and under extreme pressure."
- Tonya Viillafana, Infection Global Franchise Head

But one critical capability that Dixon couldn't find internally was project management experience in *both* vaccine development and government contracting. So she decided to hire from the outside, and with the cooperation of HR, was able to onboard a new project manager in a week, despite the challenges of recruiting during the pandemic.

Focusing the Project Manager's Role
Dixon hired Tina Guina, who previously had worked at the US government's Biomedical Advanced Research and Development Authority (BARDA), to serve as the lead R&D global project manager for the vaccine project.

The project manager, however, would have to play a different role than in a typical AstraZeneca R&D project. On those projects, the project manager would often serve as a relationship manager with the external partner or customer, negotiating the contract with support from the project staff while also managing the project. But the vaccine project was too big, complex, and risky for the project manager to have such a broad role. The US government contract alone was so big that the responsibilities had to be divided. The newly created PMO proved invaluable for easing the project manager's responsibilities in contract management, schedule and budget integration, compliance, and risk management, enabling her to focus primarily on the efforts of the project team.

Scaling to Meet Government Requirements
Working with government contracts of this size and scope called for project management deliverables that were not standard practice for AstraZeneca R&D projects. A typical drug project schedule might track a few hundred topline tasks, with responsibility delegated to sub-teams to manage at greater levels of detail. Contracts of this size and scope required a master schedule, which in turn demanded bringing in a person with this experience to kickstart the process. The budgeting process was similarly unfamiliar: most R&D project budgets were developed at a high level from the top down. Government contracts often require a bottom-up approach with significantly more detail.

The answer was to establish the government contract management function within the PMO. "It was essential to have a separate office that could enable the focus on contract deliverables rather than running the project and managing the team, because it really takes a different mindset," said Guina.

Having so many government clients also meant satisfying stringent regulatory requirements across multiple jurisdictions. While the project adapted for speed where it could, **the one area in which it could not cut corners was quality** in either the clinical trials or manufacturing. "We had to achieve this using all our standards of quality and complying with our quality systems and satisfying regulatory bodies around the world," said Dixon. **"We underwent that intense scrutiny at light speed."**

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> *- Tina Guina*

LESSON LEARNED:
Adapt, Adapt, Adapt

Adaptability was the core project management challenge. At every step, **the project faced changing circumstances as governments across the globe lined up** to become customers. For example, the US government initially planned to issue the contract through BARDA, but given the sheer size of the agreement, elected to move the contract to the Department of Defense (DOD), which had significantly more experience with procurements of this size.

"We had to totally rework a different contract with a different group of people," Dixon said. "It was ultimately a good switch because of the DOD's capabilities, but it was hard to be in the middle of the negotiation and have to start over."

As the project acquired increasing numbers of government customers, it also had to secure agreements with contract manufacturing organizations (CMOs) in various geographies to ensure that it would have the necessary production capability. There was no time for hesitation since other vaccine projects would be seeking manufacturing capacity as well. "We were grabbing CMOs as best we could," said Guina. "Under this immense pressure, the speed was incredible."

While the team worked 24/7, its commitment to the mission, which was shared throughout the company, served as an essential motivator.

But knowing *when* to adapt was important too. "There's also a fine line between how much adaptability there should be, how much adaptability is actually feasible, and deciding when it's ok to let go," said Guina. "It's the goal for the project manager to know when to push, when to pull, when to work offline with somebody, and when to try to pull a team together to discuss things. To manage things appropriately without a breakdown is a question mark every day."

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