



# Business Adaptive Strategies in Crisis: the Case of Pfizer's COVID-19 Vaccine

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Dissertation submitted in partial fulfilment of requirements for the MSc in  
Strategy, Entrepreneurship, and Impact, at the Universidade Católica  
Portuguesa, January 3<sup>rd</sup>, 2023.

### **Abstract**

This dissertation examines the adaptive strategies that Pfizer Inc. deployed in 2020 during the COVID-19 pandemic to develop its COVID-19 vaccine in less than a year; the dissertation provides a means for bachelors and masters business students to connect business strategy management theory to a real-world business case. Along with the case, instructors have a theoretical discussion section and teaching note to teach a comprehensive lesson on business adaptive strategies in crisis.

Evidence was collected from dozens of sources (from Pfizer, journals, newspapers, press statements, etc.) to construct this dissertation case and theoretical section. The case primarily focuses on how Pfizer parallelized a normally sequential vaccine development process in conjunction with BioNTech. Pfizer took two essential parts of vaccine development: (1) research and development and (2) large scale manufacturing and performed them at the same. Management strategy theory in vertical integration, strategic responses to crisis, resource-based view, and dynamic capabilities helps match a theoretical view to Pfizer's strategy to develop a vaccine during the COVID-19 pandemic.

Thanks to Pfizer's innovative and agile strategy to the COVID-19 pandemic situation, the company was prepared to properly deploy their internal capabilities and resources to establish a new vaccine platform that had never been scaled for commercial sale. The company relied upon its strong control over its supply chain and spent extra resources to bring the COVID-19 vaccine first to the market.

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**Keywords:** mRNA, resources, dynamic capabilities, innovation, strategy, crisis, adaptation, pharmaceutical, manufacturing

### **Resumo**

Esta dissertação examina as estratégias adaptativas que a Pfizer Inc. implantou em 2020 durante a pandemia de COVID-19 para desenvolver sua vacina COVID-19; a dissertação fornece um meio para estudantes de negócios conectarem a teoria de gestão de estratégia a um caso de negócios do mundo real. Juntamente com o caso, os instrutores têm uma seção de discussão teórica e notas de ensino para ministrar uma aula abrangente sobre estratégias adaptativas de negócios em crise.

As evidências foram coletadas de dezenas de fontes (da Pfizer, periódicos, jornais, etc.) para construir este caso de dissertação e seção teórica. O caso se concentra principalmente como a Pfizer paralelizou um processo de desenvolvimento de vacina normalmente sequencial em conjunto com a BioNTech. A Pfizer mudou duas partes essenciais do desenvolvimento da vacina: (1) pesquisa e desenvolvimento e (2) fabricação em larga escala e as executou ao mesmo tempo. A teoria da estratégia de gestão em integração vertical, respostas estratégicas à crise, visão baseada em recursos e capacidades dinâmicas ajudam a combinar uma visão teórica com a estratégia da Pfizer para desenvolver uma vacina durante a pandemia de COVID-19.

Graças à estratégia inovadora e ágil da Pfizer para a situação de pandemia, a empresa estava preparada para implantar adequadamente suas capacidades e recursos internos para estabelecer uma nova plataforma de vacina usando tecnologia que nunca havia sido dimensionada comercialmente. A empresa dependeu do seu forte controle sobre sua cadeia de suprimentos e gastou recursos extras para trazer a vacina COVID-19 primeiro ao mercado.

**Título:** Estratégias de Adaptação Empresarial em Crise: o Caso da Vacina COVID-19 da Pfizer

**Autor:** Benjamin South

**Palavras-chave:** mRNA, recursos, capacidades dinâmicas, inovação, estratégia, crise, adaptação, farmacêutica, fabricação

### **Acknowledgments**

I would like to first thank professor Nuno Cardeal for his help on how to frame and create a proper dissertation. His insights were essential in order to deliver a quality final product. I would like to also thank all of my professors at Católica Lisbon SBE, as the academic rigor of Católica's Masters program has been very well fostered by these individuals. I have learned a lot during my time at Católica, and it has given me many keys to succeed as a young professional anywhere in the world.

Thank you to my friends and colleagues from Católica SBE for being good companions and pushing high standards to succeed. I would like to give a big thank you to my parents, as they made it possible for me to even attend this school; they have always supported my chosen path to study, live, work, and explore in Western Europe. I'm very thankful for all of my family and the hardworking characteristics they have instilled in me.

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### **Key Abbreviations**

CEO – Chief Executive Officer
CMA – Conditional marketing authorization
DNA – Deoxyribonucleic acid
EMA – European Medicines Agency
EU – European Union
EUA – Emergency Use Authorization
FDA – Food and Drug Administration (of the United States of America)
mRNA – Messenger ribonucleic acid
RBV – Resource-based View
SEC – Securities and Exchange Commission
UK – United Kingdom
USA – United States of America
WHO – World Health Organization
VRIO – Valuable, Rare, Inimitable, and Organization
YoY – Year-over-year

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## 1. Theoretical Background

### 1.1 Vertical integration

According to her 1985 article “Vertical Integration and Corporate Strategy”, Harrigan defines vertical integration as “a way of increasing a firm’s value-added margins for a particular chain of processing from ultraraw materials to ultimate consumers” (Harrigan p.398, 1985). The chain of processing she is referring to is in the supply chain. Refer to **figure 1** below for a generic supply chain.



Figure 1. Supply chain; own source.

Firms can control different parts of this chain; a firm can vertically integrate upstream or downstream within the supply chain. Upstream refers to the activities closer to raw materials and their production. Downstream refers to the activities closer to distribution and sale of the end-product to the consumer. Vertical integration upstream is called backward integration. Vertical integration downstream is called forward integration. In opposition to vertical integration, a firm can be horizontally integrated. This means a firm expands upon the same level of the supply chain; for example, a car manufacturer buys the manufacturing plants of a competitor.

Firms employ vertical integration for a variety of reasons, and these considerations may be dependent on the industry in which they operate. Refer to the **table 1** below for some advantages and disadvantages of vertical integration, as written in Harrigan’s 1984 paper, “Formulating Vertical Integration Strategies”.

Table 1

Some Advantages and Disadvantages of Vertical Integration

<b>Advantages</b>	<b>Disadvantages</b>
<i>Internal benefits</i>	<i>Internal costs</i>
Integration economies reduce costs by eliminating steps, reducing duplicate	Need for overhead to coordinate vertical integration increased costs

overhead, and cutting costs (technology dependent)	
Improved coordination of activities reduces inventorying and other costs	Burden of excess capacity from unevenly balanced minimum efficient scale plants (technology dependent)
Avoid time-consuming tasks, such as price shopping, communicating design details, or negotiating contracts	Poorly organized vertically integrated firms do not enjoy synergies that compensate for bigger costs
<i>Competitive benefits</i>	<i>Competitive dangers</i>
Avoid foreclosure to inputs, services, or markets	Obsolete processes may be perpetuated
Improved marketing or technological intelligence	Creates mobility (or exit) barriers
Superior control of firm's economic environment (market power)	Lose access to information from suppliers or distributors
Synergies could be created by coordinating vertical activities skillfully	Synergies created through vertical integration may be overrated

Source: Harrigan, Kathryn Rudie. "Formulating Vertical Integration Strategies." *Academy of Management Review*. Vol. 9, no. 4, 1984, p. 639.

When developing a strategy to vertically integrate, firms primarily acquire or internally develop their "*supplying or distributing units*" to increase their control/strength in the market (Harrigan p. 638, 1984). Harrigan outlines the main decisions that entail the dimensions of verticalization in her "Formulating Vertical Integration Strategies" paper:

1) "*breadth of integrated activities*": wherein "*broad*" integration means conducting "*many upstream or downstream tasks in-house*" and "*narrow*" integration means conducting "*few vertically related tasks*" (Harrigan p.641, 1984).

(2) "*stages of integrated activity*": wherein a firm engages in "*many*" or "*few*" stages along the supply chain depending on the overall count of stages that are vertically integrated (Harrigan p.641, 1984).

(3) "*degree of internal transfers*": classified by "*full integration*", "*tapered integration*", and "*nonintegration*". The classifications refer to the "*proportion*" of resources "*transferred*"

*internally*” between the different supply chain stages, meaning wholly, partly, or not at all (Harrigan p.641, 1984).

(4) “*form of ownership*”: wherein a stage is “*wholly-owned*” by the firm if the stage is 100% owned by equity, or “*quasi-integration*” if the firm partly owns the stage through “*joint ventures, franchise, [or] minority equity investments*” (Harrigan p.646, 1984).

It is hard to give a definitive rule to how a vertical integration strategy will result financially or with synergy creation, as it can depend on the specific industry and competitive environment in which a company operates (Harrigan p.535, 1986). Still, some vertical integration strategies can be “*more appropriate than others*” when “*favorable conditions which the firm can exploit are present*” (Harrigan p.554, 1986).

## **1.2 Strategic Responses to Crisis**

In the 21<sup>st</sup> century and couple decades leading up to it, business firms have had to continuously deal with crisis. Whether this be war, economic, or natural disaster, firms have had to adapt their decision making and strategies in order to deal with sudden environmental shock (Wenzel, et al. p.8, 2020). Previous crisis responses from firms give an indication for current day managers how to react to crises, such as the COVID-19 pandemic.

Wenzel et al.’s 2020 paper, “Strategic Responses to Crisis” published at the onset of the COVID-19 pandemic, helped define different types of strategic responses that firms take during crises that are “*sudden, unexpected, and massively disruptive*” (Wenzel et al. p.8, 2020). They reviewed 13 papers from the Strategic Management Science journal that gave empirical evidence on firms’ responses to crisis. In the review of this literature, they identified four types of strategic responses: “*retrenchment, persevering, innovating, and exit*” (Wenzel et al. p.7, 2020). The different strategic responses are not necessarily exclusive of one another. The paper matches “*time horizon*” effects that may result from each strategic response.

To begin, with “*retrenchment*”, the authors refer to this as “*cost-cutting measures that potentially reduce the scope of a firm’s business activities*” (Wenzel et al. p.9, 2020). This is a common

response to crisis which can help mitigate a decrease of revenues in the short term (and one that may even be necessary at first), but may lead to negative long-term effects as retrenchment can cause “*irrecoverable damages such as the loss of synergies*” (Wenzel et al. p.9, 2020) through the divestiture of assets or other cost reduction measures.

With “*persevering*”, the firm facing a crisis attempts to preserve the status quo of their normal activities (Wenzel et al. p.9, 2020). This strategy is dependent upon “*slack resources, both internally and externally*” that are available to managers at the time of the crisis, so that they do not have to commit to “*strategic renewal*” too early on. Persevering strategy can help firms during crisis in the medium run, but the authors note the firm could run into trouble trying to sustain this response long-term, as internal and external resources would eventually be exhausted (Wenzel et al. p.11, 2020).

The next strategic response to crisis is “*innovating*”. Innovating refers to “*conducting strategic renewal*” wherein a firm will widen their scope of activities to a different sector (Reymen et al. p.369, 2015), capitalize upon strong centralized corporate governance, or even acquire a different firm (Wenzel et al. p.11, 2020). The transformative impact of crisis on society and business environments provokes a “*mode of reflection that allows managers and employees to transcend the boundaries of what they believe is thinkable and feasible*” (Wenzel et al. p.13, 2020). Crises can forever change the landscape of business environments (especially during crises that last a long period of time), so innovating is a necessary strategic crisis response for long term corporate sustainability due to the need for additional revenue streams (Wenzel et al. p.13, 2020).

The final strategic response, “*exit*”, is where firms exit a particular business during crisis. This is a strategic response wherein the exit preempts what would be a forced exit because of economic shock factors (Wenzel et al. p.12, 2020). Exit strategy can be done at any time, and does not necessarily imply “*the end of the road*” for the firm as it may lead to “*strategic renewal*” by freeing up resources for future ventures (Wenzel et al. p.13, 2020).

### **1.3 Resource-based View**

JB Barney laid the beginning foundations for the Resource-based view in the 1986 and 1991. Barney argues that strategic decisions that garner greater than normal returns should not solely be sourced from a firm's environmental analysis; rather, strategic choices should "*flow mainly from the analysis of its unique skills and capabilities*" (Barney p.1231, 1986). Later in 1991, Barney built a theoretical model in order to "*understand sources of sustained competitive advantage*"; to begin, Barney creates a framework that assumes firm resources "*may be heterogeneous and immobile*" (Barney p.105, 1991). Heterogenous and immobile firm resources can have the potential to provide sustainable competitive advantage when they have four attributes: value, rareness, imperfect imitability, and substitutability. This framework was improved upon in 1995

From these foundations, Barney built a different framework in 1995. Barney crafted his framework first through the lens of the SWOT framework; the SWOT framework identifies four areas a firm must pay head to understand its sources of competitive advantage: strengths and weaknesses (internal considerations) and opportunities and threats (external considerations). In opposition to Michael Porter's Five Forces, which focuses upon external analysis and market forces, Barney argues that firms need to make a conscious evaluation of their internal attributes to understand their competitive advantage. As an example, Barney mentions that firms can be in poor or unfavorable environments and still gain competitive advantage. These internal attributes that Barney identifies are resources and capabilities including the financial, physical, human, and organizational resources of a firm.

A firm's manager should address four points to ensure whether their resources and capabilities provide sustained competitive advantage. These qualities of resources must all be present, in the following order, to create sustained competitive advantage:

- (1) These resources must be "*valuable*", wherein these "*resources and capabilities add value by enabling to exploit opportunities and/or neutralize threats*" (Barney p.50, 1995).

Firm's resources can be valuable in separate ways; these opportunities and threats refer to the external environment a firm is in.

- (2) A firm's resources and capabilities must be "*rare*", meaning many other competing firms should not possess this resource (Barney p.52, 1995). Resources can be valuable, but common; these types of resources are unlikely to give competitive advantage for the controlling firm (Barney p.52, 1995).
- (3) Resources should be "*inimitable*" to give competitive advantage to the controlling firm. This means that the resources will give a "*cost disadvantage*" to any firms that imitate the resources and capabilities (Barney p.53, 1995). This imitation can be done by duplication and substitution. Below are reasons a firm's resources may give a cost disadvantage to the copying firm:
- a. The firm's special history was integral in creating the inimitable resource.
  - b. The firm made many "*small decisions*" to develop, nurture, and exploit these resources that are hard to replicate over the long term (Barney p.54, 1995).
  - c. These resources may be rooted in social complexity wherein they are developed from "*reputation, trust, friendship, teamwork and culture*" (Barney p.55, 1995).
- (4) A firm must be "*organized*" to properly "*exploit its resources and capabilities*" (Barney p.56, 1995). Barney notes "*complementary resources*" like compensation policies and reporting structure help exploit these resources and capabilities for sustained competitive advantage (Barney p.56, 1995).

Firms can look forward to gain sustained competitive advantage from their resources and capabilities that meet all four of these aspects (i.e. resources that are 'VRIO')

#### **1.4 Dynamic capabilities**

Originally introduced by Teece et al. in 1997, the dynamic capabilities concept has become very popular in the management science field and other disciplines. The dynamic capabilities framework expounded upon the Resource-based view of the firm proposed by Barney in 1986 and 1991. Teece and his colleagues put forth the dynamic capabilities framework to fill a "*gap*" (Barreto p.259, 2010). This gap is that the RBV is "*static*" in nature, and cannot accurately "*explain firms' competitive advantage in changing environments*" (Barreto p.259, 2010).

In 2010, Barreto proposed a systematic construct and formal definition of dynamic capabilities: “[a] dynamic capability is the firm’s potential to systematically solve problems, formed by its propensity to sense opportunities and threats, to make timely and market-oriented decisions, and to change its resource base” (Barreto p.271, 2010).

His definition helps capture the complexity and depth of a large body of research into a multidimensional matrix to aid future management research and development of the dynamic capabilities’ framework. Barreto asserts that all variables inside of this definition should be considered together, as “no dimension alone can represent the construct” (Barreto p.271, 2010). Notably, the definition does not make a direct connection to firm’s performance. Barreto prefers instead to use the more inclusive word “potential” (Barreto p.273, 2010), as the wide range of literature developed on this topic of performance is difficult to unify.

Barreto’s construct helps unify varying concepts in management literature of dynamic capabilities’ nature, specific role, relevant context, creation and development mechanisms, heterogeneity assumptions, outcomes, and purpose. These are the same elements and key theoretical points that Teece et al. built their original dynamic capabilities framework around in 1997.

In management research, the “nature” of dynamic capabilities “have been defined as abilities, capacities, processes, and routines” (Barreto p.260, 2010). Barreto states that the challenges for this aspect of the construct are to be “more specific” so the area of study is not too generalist and to allow a continuum of dynamic capability to account for real-world grey area of firms’ internal makeup (Barreto p.270, 2010).

The “specific role” of dynamic capabilities concerns “changes in resources, capabilities, operating routines, or one combination of these” (Barreto p.270, 2010). Other “specific roles” have been proposed, like “decision-making abilities or the ability to sense opportunities and threats” (Barreto p.270, 2010). Barreto states that the challenge for this specific role aspect of the construct is to integrate both these proposals together.

The “*relevant context*” of dynamic capabilities, and one of particular importance to consider, is “*regarding the kind of external environments that are relevant*” (Barreto p.261, 2010).

Researchers are divided between linking dynamic capabilities (and to what degree) to “*highly dynamic*”, “*moderately dynamic*”, or in “*more stable*” environments (Barreto p.270, 2010).

In management research literature, the “*creation and development mechanisms*” of dynamic capabilities mainly focus around “*learning mechanisms*” within the “*evolutionary economics perspective*” (Barreto p.262, 2010).

The “*heterogeneity assumptions*” of dynamic capabilities diverge between those who ascribe dynamic capabilities as “*firm specific and unique*”, following the RBV basis of the framework, and those that state that dynamic capabilities “*exhibit commonalities across firms*” (Barreto p.263, 2010). The challenge here is how to integrate these two points and still explain dynamic capabilities influence “*on performance or competitive advantage*” (Barreto p.270, 2010).

The “*outcomes*” of dynamic capabilities are contested between those who link their existence in a firm with the firm’s performance like Teece et al. in 1997 and those who do not attest for a “*compulsory and direct link*” between the two (Barreto p.263, 2010).

The “*purpose*” of dynamic capabilities is not included by all researchers in their definitions (Barret p.270-271, 2020). Those who include a purpose in their definition contest whether there should be “*a specific purpose (e.g., ‘to address rapidly changing environments’) ... or any purpose (e.g., doing something ‘purposefully’) will do*” (Barreto p.271, 2010).

Teece, in 2007, proposed a framework for dynamic capabilities (see **figure 2**) -- constituting three classes of dynamic capabilities and their corresponding microfoundations -- that firms can utilize to gain “*enterprise-level competitive advantage*” in environments characterized by “*rapid (technological) change*” (Teece p.1341, 2007).



Figure 2. Foundations of dynamic capabilities and business performance; Teece, David. “Explicating Dynamic Capabilities: The Nature and Microfoundations of (Sustainable) Enterprise Performance.” *Strategic Management Journal*, Vol. 18, 2007, p. 1342.

A firm can gain “*enterprise-level competitive advantage*” when it can “*explicate*” the three dynamic capabilities in Teece’s 2007 framework:

- (1) Sensing: meaning “*spot the opportunity to earn economic profits*” (Teece p.1347, 2007).
- (2) Seizing: meaning “*make the decisions and institute the disciplines to execute on that opportunity*” (Teece p.1347, 2007).
- (3) “*Managing Threats/Transforming*”: meaning “*stay agile so as to continuously refresh the foundations of its early success, thereby generating economic surpluses over time*” (Teece p.1347, 2007).

Underpinning these dynamic capabilities are their respective microfoundations or “*the distinct skills, processes, procedures, organizational structures, decision rules, and disciplines*” of an enterprise (Teece p.1319, 2007). Overall, “*entrepreneurial management*” is at the center of the dynamic capabilities concept, as “*[d]ynamic capability is a meta-competence that transcends operational competence. It enables firms not just to invent but also to innovate profitably*” (Teece p.1344, 2007).

### **1.5 Vaccine Science and mRNA**

As vaccines are the focus of this dissertation, background information should be given on how they work. Vaccines are injected into a patient in order to fight against infections by training the recipient’s immune system to fight against a specific pathogen (Bourla p.19, 2022). Traditional vaccines usually utilize “*weakened, dead, or noninfectious parts of these pathogens*”; the recipient’s immune system will identify them and engage its immunal defenses (antibodies and

T-cells) to combat them (Bourla p.20, 2022). Afterward, the body will be prepared to fight against the disease when it arrives.

Check the **exhibit 4** in the appendix for an in-depth explanation of the vaccine technology and the required clinical and regulatory checks needed to develop a vaccine in normal circumstances. This can give the reader a baseline understanding of how vaccine clinical testing is completed.

## **2. Pfizer COVID-19 Vaccine Case**

Table 2

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### **2.1 Introduction**

At the end of 2019, Chinese scientists identified a virus that would soon be known as the Sars-2-Coronavirus. This infectious respiratory influenza virus would ravage the world and cause millions of deaths and infections.

Hospitals and healthcare systems were the most overloaded entity all across the world because of the rapid spread of the virus. Preventative measures like lockdowns and social distancing were employed to prevent infection, but health providers were looking for solutions to reduce casualties from the virus. Pharmaceutical companies across the world quickly understood, along with supplying essential medical equipment and preventative medicine, that a vaccine had to be developed to help.

When the WHO pronounced a global pandemic on March 11th, 2020, major pharmaceutical corporations across the world had already started their respective quests to make a COVID-19 vaccine. Given the wide spread and magnitude of coronavirus infections, the scale-up production of such a vaccine would require resources, coordination, and speed unlike any other known in the history of healthcare. Billions of vaccines were necessary in order to help quell this pandemic and drive widespread immunity.

In less than a year, Pfizer would develop their ‘Comirnaty’ COVID-19 vaccine and achieve their first emergency approval to sell it in the UK on December 2<sup>nd</sup>, 2020.<sup>1</sup> What follows is an incredible story of manufacturing, scientific development, logistical finesse, and regulatory collaboration on a global scale. The lessons herein focus on parallelizing the sequential conventional process of vaccine development into something extraordinary. Pfizer’s internal

capabilities and ability to deploy its company's resources across different geographies proved essential to complete the COVID-19 vaccine development project called, 'Operation Lightspeed'. The implications of this impressive feat signal new possibilities for public and private collaboration and even scientific and manufacturing innovation.

## **2.2 Company overview**

According to Pfizer's "Company Timeline" on the about section of their website, Pfizer is a pharmaceutical company that was founded in Brooklyn, New York, United States of America in 1849 by Charles Pfizer and his cousin Charles Erhart.<sup>2</sup> At the time, the company was called Charles Pfizer & Company. In 1882, the company began to expand its footprint west of the Mississippi River, in the wake of American expansion. In 1900, the company initiated a "seven-day-a-week production schedule" and became the world's leading producer of Vitamin C the very same year.<sup>2</sup> Later, in 1944, the company became the largest producer in the world of penicillin. The company started to operate in many different territories in 1951, namely Belgium, Brazil, Canada, Cuba, England, Mexico, Panama, and Puerto Rico. Pfizer's international employee count increased to over 7,000 by 1957.

Pfizer crossed a billion dollars in yearly revenue by 1972. The company is still well known for its pharmaceutical drugs that were released in 1992 like Zoloft (depression medication), Norvasc (for treatment of angina and hypertension), and Zithromax (for skin and respiratory infections), and later, Viagra which was launched in 1998.<sup>2</sup>

Pfizer began an aggressive acquisition and investment strategy in the 2000s; the company bought Warner-Lambert, an American pharmaceutical company, for \$90.2 billion.<sup>3</sup> Later, in 2003, the company bought Swedish pharmaceutical company, Pharmacia, for \$60 billion.<sup>4</sup> Pfizer was already the world's largest drug company before the acquisition of Pharmacia.<sup>4</sup> With these acquisitions Pfizer bolstered its drug product folder with blockbuster drug products Lipitor (cholesterol drug) and Celebrex (arthritis drug) from each company respectively. Starting in 2008, Pfizer's Chairman and CEO at the time, Jeff Kindler, steered the company to "smaller operating units designed to enhance innovation and accountability, while drawing upon the advantages of Pfizer's scale and resources".<sup>2</sup>

By 2020, Pfizer had about 88,300 employees and 43 manufacturing sites and was selling its products in over 125 countries.<sup>6</sup> According to the company’s 2019 10-k (a comprehensive annual report publicly traded companies in the USA file with the SEC), the majority of the company’s revenues come from biopharmaceutical products that it manufactures and sells. The company engages in research and development, manufacturing, and distribution of their products.<sup>6</sup>

Pfizer’s 2019 revenue counted \$51,750 million, contributed to by three distinct operating business segments: Biopharmaceutical, Upjohn, and Consumer Healthcare. The revenue percentage by operating segment and geography can be seen in **figure 3**.

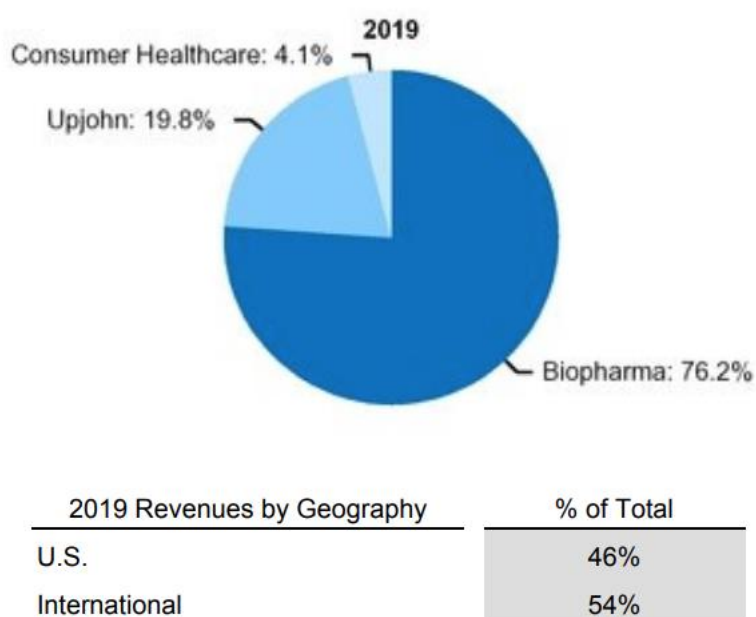


Figure 3. Pfizer Inc. 2019 revenues by operating segment and geography source; “Pfizer Inc. Form 10-K for the Fiscal Year Ended December 31, 2019.” *EDGAR*. Securities and Exchange Commission, 2020.

Biopharmaceutical products include Internal Medicine, Oncology, Hospital, Vaccines, Inflammation and Immunology, and rare disease products (refer to **exhibit 1** for more detailed information).<sup>6</sup> Upjohn products are “primarily off-patent branded and generic medicines”, like

key products Lipitor and Viagra.<sup>6</sup> Consumer healthcare includes products like cold and influenza medication.

The reader should not forget that Pfizer is not just a vaccine manufacturer; of its \$51,750 million revenue in 2019, \$6,504 million was from vaccine product sales (12.6%).<sup>6</sup> Of which, \$5,847 million was from one vaccine product, Prevnar. The largest product category out of Pfizer's biopharma products in 2019 was internal medicine, counting \$9,119 million.<sup>6</sup> The company's revenue streams are diversified across various product offerings.

### **2.3 Key Vaccine Developers and Regulatory Environment**

Before entering Pfizer's situation, the stage must be set for the regulatory and competitive environment. The urgent need for a vaccine greatly influenced the involvement and willingness of nations and state institutions to allow clinical testing on a quicker timeline. The coronavirus pandemic situation warped the environment of traditional product development in the pharmaceutical industry, specifically with vaccines. Governments and state agencies were willing to go the extra mile to speed up the timeline of clinical testing and regulatory approval. These entities still wanted vaccine development to be done in a safe, effective manner, even if the vaccine would be a key solution in the fight against COVID-19.

Many firms went to task to make vaccines (based on different technology and developed in different geographies). The fastest to market were the state sponsored/owned vaccines, namely deployed by Russia and China. Their story is outside the scope of this case, as this case focuses upon the development of a drug product by a publicly traded company; their development is a clear indicator that there was a need for quick vaccine development throughout the world.

Previously, the fastest vaccine developed in the world was the mumps vaccine, developed in the wake of the second World War.<sup>7</sup> The mumps vaccine was developed in four years. In comparison, by the end of 2020, two COVID-19 vaccines had been developed in less than a year and approved for emergency use authorization. These were the Moderna and Pfizer vaccines. For reference, by December 22nd, 2020, 52 vaccine candidates made it to clinical trials (in the United

States) and only 13 made it to phase 3 (the final phase before approval). At the end of 2020, Moderna's and Pfizer's vaccines were approved by regulators in the USA, Canada, and the UK.<sup>8</sup>

To give a look into the future, the first four vaccines developed by private companies are as follows: Pfizer, Moderna, AstraZeneca, and Johnson & Johnson as they were the quickest to the commercial market. AstraZeneca and Johnson & Johnson developed vaccines on traditional platforms (called "Adenoviral vector vaccines").<sup>9</sup> Pfizer and Moderna decided to produce their vaccine on the mRNA platform, a vaccine platform on which no product had ever before been sold to customers at that time. What's more, Moderna had never put a drug to market, and Pfizer had never developed an mRNA vaccine outside of lab research.

The emergence of these vaccines gives context that Pfizer was not the sole player in this industry, and other players were attempting their own vaccine products. Still, pharmaceutical firms vying for government contracts and supplies such as glass for vaccine vials made it an incredibly competitive atmosphere. In addition to these tangible considerations are the high stakes reputation considerations if any vaccine were to fail for any of these big pharmaceutical companies.

#### **2.4 Choosing a Vaccine Platform and Partner**

With the onset of the coronavirus, Pfizer's executive leadership came together to meet March 4<sup>th</sup> 2020.<sup>10</sup> The CEO of Pfizer, Albert Bourla, called them together. Bourla had just been promoted from COO to CEO of Pfizer just 15 months prior.<sup>11</sup> The company was going through a reorganization at the time, where more funds were being diverted to Research and Development, and less being sent for marketing and administration.<sup>12</sup>

Albert Bourla had his team together to discuss the reorganization, but also in order set some priorities for Pfizer in response to the coronavirus. Of chief concern, Pfizer had to ensure their workers throughout the world were safe, all while anticipating the dip in demand the company was sure to face caused by lockdowns and other exogenous shocks.<sup>13</sup> Two days prior on March 2<sup>nd</sup>, Mikael Dolsten, Pfizer's head of Research and Development, verbally committed to make a vaccine along with other preventative medicine to United States President Donald Trump.<sup>14</sup>

The company had developed vaccines in the past, but still had one very important decision to make before launching development: the choice of vaccine platform to utilize.

In his 2022 book describing how the vaccine was developed, *Moonshot*, Albert Bourla wrote that his most difficult decision was to use the mRNA vaccine platform, as Pfizer already had many different proved vaccine products and manufacturing methods.<sup>15</sup> What's more, this vaccine would need to be developed for billions of people; scaling this technology was of particular importance. Even though the technology has never been scaled before, Mikael Dolsten and his team urged Bourla to use the technology.<sup>15</sup>

As Pfizer had never developed this technology before, they would need a partner to provide the mRNA vaccine technology. Pfizer had previously worked on mRNA vaccine research with a German biotechnical company, BioNTech. BioNTech was founded by two Turkish scientists in 2008 in Germany. Pfizer and BioNTech had already worked together before: in August of 2018 the companies agreed upon a multi-year R&D agreement to develop mRNA vaccines for the flu.<sup>5</sup> Pfizer gave BioNTech a \$50 million upfront payment for this work agreement, which also gave BioNTech the chance to be paid up to \$325 million for development and sales volume milestones across worldwide sales. Also, Pfizer purchased 169,670 shares from BioNTech for \$50 million in the third quarter of 2018.<sup>27</sup>

On March 1<sup>st</sup>, Ugur Sahin (the CEO of BioNTech) proposed a vaccine collaboration in a call with Kathrin Jansen, the vaccine-research chief at Pfizer.<sup>16</sup> One week later, after the push from Mikael Dolsten and the rest of the vaccine teams, Albert Bourla agreed to using the mRNA vaccine platform, and to working with BioNTech.<sup>16</sup> The companies reached a verbal agreement on March 13<sup>th</sup> to develop a mRNA based vaccine.<sup>17</sup> In the interest of speed, the two company CEOs agreed to begin working together before all official agreements were signed.

According to Albert Bourla, the very next day, on March 14<sup>th</sup> 2020, the two companies held a conference call “to discuss candidate antigens, toxicology study plans, first in-human clinical trial plans, regulatory interactions, and manufacturing schedules”.<sup>18</sup> They started to develop

contingency plans if any of the companies' sites went down during the pandemic. The two teams agreed on a basic plan and would later have daily meetings following this conference call to continue collaboration.<sup>18</sup>

With collaboration in motion, the companies agreed to a letter of intent on March 17<sup>th</sup> 2020 concerning the “co-development and distribution” for a mRNA COVID-19 vaccine.<sup>19</sup> Along with this letter of intent, the companies had already “executed a Material Transfer and Collaboration Agreement” to permit work together to begin right away.<sup>19</sup> The letter of intent stated that the two firms agreed to “utilize multiple research and development sites from both companies” to push forward an expedited development of BioNTech’s “potential first-in-class COVID-19 mRNA vaccine program, BNT162”.<sup>19</sup> Clinical testing was aimed to start at the end of April 2020.

After further discussions between the company’s lawyers and managers, the two companies signed an official collaboration agreement on April 9<sup>th</sup>, 2020 to develop BioNTech’s COVID-19 vaccine program together.<sup>20</sup> The agreement was not as comprehensive as vaccine development project would normally be (normally, official manufacturing and commercial agreements would be finalized as well). The companies agreed, upon future regulatory approval, that BioNTech would own commercialization rights of the vaccine in German and Turkey (and tangentially China, Hong Kong, Macau, and Taiwan, as BioNTech already made an agreement to commercialize any potential vaccine with China). Pfizer would own commercialization rights for the rest of the world.<sup>18, 20</sup>

Furthermore, BioNTech would “provide clinical supply” of its different vaccine candidates from its “mRNA manufacturing facilities in Europe”.<sup>20</sup> Pfizer would contribute its “global vaccine clinical research and development, regulatory, manufacturing and distribution infrastructure and capabilities”.<sup>20</sup> The effort of scaling up the manufacturing capacity of this eventual mRNA candidate would be shared at risk and worked on jointly by BioNTech and Pfizer.<sup>20</sup>

Pfizer gave an upfront payment to BioNTech of \$185 million “including a cash payment of \$72 million and an equity investment of \$113 million”.<sup>20</sup> This equity investment brought Pfizer’s ownership of BioNTech to about 2.3%.<sup>18</sup> According to the agreement, BioNTech would “be

eligible to receive future milestone payments of up to \$563 million for a potential total consideration of \$748 million”.<sup>20</sup>

The companies would equally pay development costs. Still, Pfizer would “fund 100 percent of the development costs, and BioNTech will repay Pfizer its 50 percent share of these costs during the commercialization of the vaccine”.<sup>20</sup> If the project failed, Pfizer would take on all of the loss.<sup>18</sup> The companies didn’t sign any further written agreement until a commercial agreement in January 2021. Pfizer and BioNTech relied upon the letter of intent and collaboration agreement for the rest of 2020.<sup>21</sup>

There are two elements involved with a vaccine being created from idea all the way to the point of being injected into a patient’s arm. (1) The development of the vaccine, which involves three phases of clinical studies to determine its efficacy. (2) The manufacturing and shipping of the vaccine. Typically, during this process, these two activities are completed sequentially, but Albert Bourla of Pfizer decided to complete these two activities in parallel with the goal of having a vaccine ready by October of 2020.<sup>22</sup>

### **2.5 Vaccine Candidate Testing and Approval**

Now that a partner was chosen, and consequently, the technology platform for the vaccine was selected, Pfizer had to identify “an optimal vaccine candidate and testing in clinical trials on an expedited timeline”.<sup>23</sup> BioNTech had already made 20 different mRNA vaccine formulations when the structure of the virus was first publicized in January 2020 by Chinese scientists.<sup>16</sup>

Using the constructs that BioNTech had created, the company began to identify a proper candidate. Before starting clinical trials, both BioNTech and Pfizer conducted pre-clinical trials to collect the necessary data to present to regulators.<sup>16</sup> This pre-clinical testing was done in test tubes to examine different dosing levels and to look for “molecular signs of effectiveness and safety. BioNTech also tested the candidates in mice”.<sup>16</sup> The researchers narrowed down the 20 candidates to 16, and “[i]n April, they filed their plans for testing a candidate with regulators, but the paperwork was littered with holes for data they would need to fill in”.<sup>16</sup> In all of the clinical

trials to come, Pfizer “sent the U.S. Food and Drug Administration updated batches of data almost daily”.<sup>16</sup>

Typically, vaccines are tested on a longer timeline, but given the pandemic situation, this was not possible. Regulatory bodies supported and even encouraged accelerated clinical trials. The Paul-Ehrlich Institut, a federal research institution agency and regulator for vaccines and biomedicines in Germany, gives a brief description of this possibility: “In general, phase 1 (vaccine safety) and 2 (dose finding, vaccination schedule) clinical trails can be combined and combined phase 2/3 trials are recommended to determine safety and efficacy”.<sup>24</sup>

BioNTech launched the testing of four different vaccine candidates on April 22, 2020 in Germany<sup>25, 26</sup> and later on May 5<sup>th</sup> Pfizer did the same in the United States.<sup>27</sup> Both programs tested the four different vaccine candidates in approximately 200 healthy adults aged 18-55 in Germany and up to 360 adults aged 18-85. These clinical tests were conducted with the goal of comparing the different candidates at ranging levels of dosage.<sup>28</sup> After the initial clinical results of these tests were examined, two standout favorites out of the four were chosen; these two received fast track designation by the FDA on July 13<sup>th</sup>, 2020.<sup>29</sup> The FDA describes fast track designation as: “a process designed to facilitate the development, and expedite the review, of new drugs and vaccines that are intended to treat or prevent serious conditions that have the potential to address an unmet medical need”.<sup>29</sup> It was during this test that Pfizer and BioNTech decided on 2 separate doses for their COVID-19 vaccine.

Of these two lead candidates, early predictions from Pfizer leaned toward one being the anticipated candidate for a combined Phase 2 and Phase 3 trial, but the second candidate was showing more “reactogenicity in both younger and older participants in the phase 1 studies”.<sup>23</sup> Based on these data, the team decided on July 27, 2020 to proceed with the second candidate for the phase 2/3 study.<sup>23</sup>

Phase 3, the largest and most important test, was designed to give conclusive results as fast as possible.<sup>30</sup> Pfizer alone was responsible for conducting the phase 3 trial.<sup>26</sup> In order for the vaccine to be approved by the United States regulatory body, the FDA, the vaccine candidate needed to

exceed at least 50 percent efficacy. To obtain the Emergency Use Authorization in the United States, the FDA usually wants two months of phase 3 data and six months of data for full approval.<sup>30</sup>

Pfizer had to go big on the scale of this clinical testing to receive results as quickly as possible. Between July 27 and November 14, 44,548 persons aged 16 or older underwent the process in 152 sites worldwide: of which 130 were in the United States, 1 in Argentina, 2 in Brazil, 4 in South Africa, 6 in Germany and 9 in Turkey. 21,720 people received the vaccine and 21,728 participants received a placebo.<sup>31</sup>

The rapid spread of the virus made it possible to test at such magnitude. Pfizer selected research sites in areas where there were higher infection rates to ensure a better test environment. Vaccine testing is jeopardized if test participants have low infection rates as there will be less participants who become infected, and thus a smaller sample size to confirm the vaccine's effectiveness is available.<sup>30</sup>

But Pfizer ran into an issue: infection rates were changing over time, and they had to consider these infection rates all across their different research sites. When a certain city or county had a large number of COVID-19 infections, it would react with measures to reduce the rate of infection. In contrast, areas with low COVID-19 infections would relax measures, and the infection rate would then rise afterward. Pfizer epidemiologists developed an algorithm to account for this variation and fluctuation in infections; it predicted which areas in the world would have higher COVID-19 rates during certain periods of time. So, “[t]he research team would then try to open investigation sites accordingly, so that by the time the participants had received their second doses, the chances of high disease burden would be greater”.<sup>32</sup>

Pfizer's scientific and regulatory efforts paid off in November 2020 after two months of the phase 2/3 study. On November 18th, 2020 Pfizer and BioNTech concluded their phase 2/3 study of the COVID-19 vaccine, meeting their efficacy requirements.<sup>33</sup> Soon after, on November 20th, they submitted their Emergency Use Authorization Request to the United States FDA.<sup>34</sup>

Approvals wrang out through the western world: the UK was the first to authorize the vaccine on December 2nd, 2020.<sup>1</sup> Later, on December 11th, the FDA in the United States granted the companies the first COVID-19 vaccine Emergency Use Authorization in the United States.<sup>35</sup> On December 21st, 2020, the EU authorized Pfizer's vaccine in the European Union.<sup>36</sup>

Vaccine research and development was only one piece of the puzzle to get the Comirnaty vaccine from idea to a patient's arm. Of equal importance were the manufacturing and shipping considerations that went into the vaccine's development.

## **2.6 Manufacturing**

Pfizer's COVID-19 vaccine manufacturing development took place along the same time frame as the clinical development of the vaccine and was essential to the Emergency Use Authorization that Pfizer received in the USA, EU, and elsewhere. Albert Bourla described Mike McDermott's (head of manufacturing for Pfizer) plan while the company was preparing for clinical trials and beyond: "while the lab would prepare the vaccine candidates to be tested in Phase 1 and Phase 2 studies, the manufacturing teams would start working to scale up the manufacturing process even without knowing which candidate would be eventually selected".<sup>37</sup> Albert Bourla knew that this would result "in a much bigger expenditure of resources" than normal.<sup>38</sup>

What's more, in order to be ready to manufacture at scale any one of the four different vaccine candidates, Pfizer would have to procure raw materials for each, even before committing to a single one. Their biggest challenge was "that there were was no industrial production, anywhere in the world, of any mRNA product (medicine or vaccine)", so the value chains of this product were not yet established.<sup>37</sup> Until this point, Pfizer had only produced mRNA at small scale in laboratories for research purposes. Mike McDermott and the rest of the manufacturing team "would have to invent, design, and order new industrial formulation equipment that didn't currently exist".<sup>37</sup>

Up until the COVID pandemic, Pfizer's total vaccine production counted 200 million doses per year, including Prevnar, its biggest seller. Prevnar was Pfizer's largest-volume vaccine in its history and it took ten years to reach that level of production.<sup>38</sup> To reach the scale of yearly dose

production Bourla was looking for, the manufacturing team would need to double Pfizer's vaccine production per year to 400 million doses in only nine months.<sup>38</sup> What's more, the CEO set the goal for the company to produce 100 million COVID-19 vaccine doses by the end of 2020.<sup>16</sup> The manufacturing team under Mike McDermott gave Bourla the estimation of \$850 million to complete their part of production. Bourla granted this figure.<sup>38</sup>

Bourla created a centralized project team for the vaccine development. The team would meet in one-hour twice weekly meetings between Pfizer's leadership, including key decision makers like Kathrin Jansen and Mike McDermott. These meetings were designed to be free flowing for in-the-moment decision making to be more agile.<sup>16</sup>

Pfizer chose three sites in the United States and one in Belgium to be the main supply chain for its COVID-19 vaccine. See **figure 4** for the USA sites on a map with all other Pfizer sites. The first site was in St. Louis, Missouri, where the original DNA 'instructions' for the mRNA drug product are created. The second site, in Andover, Massachusetts, manufactured the mRNA drug substance from this DNA template for the mRNA vaccine. This drug substance was purified and then shipped to one of two "sterile injectable manufacturing" sites: in the United States, in Kalamazoo, Michigan and in Europe, in Puurs, Belgium.<sup>39</sup> There, the mRNA drug substance was mixed with other raw materials to create the final product. The vaccine was put into a vial and then packaged and labeled, ready for shipping. The vaccines were mainly stored at these final locations. **Exhibit 2** goes more in depth on the scientific manufacturing process. To be safe, the company instituted a redundant supply chain, where it ensured at least two different manufacturing sites performed each step of the manufacturing process.<sup>39</sup> Albert Bourla ensured this step to avoid any supply chain shocks related to export restrictions, or any downturn in production capability in one side of the redundant supply chain.<sup>39</sup>



Figure 4. Scaling for success; “Scaling-Up to Manufacture a Potential COVID-19 Vaccine.” Pfizer Inc., November 2020. [cdn.pfizer.com/pfizercom/2020-11/Scaling-Up%20to%20Manufacture.%20a%20Potential%20COVID-19%20Vaccine.pdf](https://cdn.pfizer.com/pfizercom/2020-11/Scaling-Up%20to%20Manufacture.%20a%20Potential%20COVID-19%20Vaccine.pdf).

Though Pfizer was the main driver for the manufacture of this vaccine, BioNTech made moves to secure its own capacity in the future as well. Later, in September 17<sup>th</sup> 2020, BioNTech acquired a biologic drug production facility in Marburg, Germany from pharmaceutical company Novartis to secure vaccine production capacity at 750 million doses per year.<sup>26</sup> The company signed an agreement with a contract manufacturer Siegfried in Hameln, Germany to package and fill the vaccine. The German government gave BioNTech a subsidy of about \$440 million to expand manufacturing in BioNTech’s home country of Germany.<sup>26</sup> Pfizer took no money from federal grants or subsidies, as it wished to exert as much control as possible over its side of production.<sup>40</sup>

## **2.7 Scaling-up and Developing the mRNA Vaccine Process**

Before even establishing a supply chain, the mRNA manufacturing process needed to be developed in Pfizer’s labs to prepare manufacture at scale; Pfizer leveraged heavily upon its already strong manufacturing network and extensive history with developing other types of drug products in the past. Conventional procurement methods and even shipping techniques could not be employed because of the incredibly short timeline set to develop this new mRNA vaccine technology.

Pfizer leveraged its expertise in its Gene Therapy Program production processes to develop technology for the different vaccine candidates. A mRNA process-development team was tasked with first transferring the knowledge on how to develop mRNA production at scale to Pfizer development labs in St. Louis, with the ultimate goal of process scale-up to commercial scale in Andover.<sup>41</sup> This team in St. Louis worked closely with Pfizer's Vaccine Research Development team in Pfizer Pearl River, New York, and the BioNTech development team in Mainz, Germany, to achieve this.<sup>41</sup>

Pfizer didn't have time to purchase all new equipment to ensure this manufacturing process was possible, as it would take too long to purchase, be received, and eventually integrate into their manufacturing system to test. The company reorganized sections of space in its St. Louis site, and later its other sites, to house this equipment.

The company had to find a means to use the equipment it currently had. Pfizer ventured to employ the technique of single-use equipment that it utilized in previous manufacturing-scale up development. This single-use equipment was discarded after a catch and didn't have to be cleaned, "so both development and manufacturing equipment could be turned around quickly".<sup>41</sup> These single use 'bioreactors' were used to test and establish the manufacturing process and later in the commercial-scale production (of a larger volume) in Andover, Massachusetts for mRNA drug substance in vitro transcription. Essentially, these bioreactors were used to make the mRNA synthetically from the DNA template developed in St. Louis.

In some occasions, Pfizer even used its corporate aviation team to expedite the timeline of shipping critical supplies to its manufacturing network during this process, as domestic and international flights during the pandemic were severely reduced.<sup>42</sup>

## **2.8 Materials**

To feed the process of the vaccine development, the vaccine would need an abundance of materials to produce at scale. The company created a "cross-functional team dedicated to developing raw material sourcing strategies".<sup>43</sup> The team decided to order incredibly large amounts of raw materials before assurance that a particular candidate would be pursued. This also

meant the team would have to anticipate materials need in the future, so they would need to work with their suppliers and vendors closely.<sup>44</sup>

Albert Bourla noted that because of protectionist policies from suppliers in different countries, Pfizer's raw material sourcing and scaling goals were threatened. Some countries would block Pfizer's access to materials necessary to the vaccine's development, and Pfizer's redundant supply chain proved to be useful. These materials included glass vials and stoppers to cap the vaccine vials.<sup>39</sup>

The biggest bottleneck in obtaining the raw materials would be 'lipid nanoparticles' (the material that incases the mRNA drug product). These lipids are made chemically, and they had never been used at this scale in other vaccines.<sup>45</sup> Pfizer's solution was to take matters into its own hands and build its own capacity; the company started to produce their own lipids to ensure they would have the necessary raw materials outside of the ones supplied by third-parties. Pfizer modified a plant in Groton, Connecticut and eventually a Kalamazoo manufacturing site as well to produce its own lipids, securing capacity for millions of vaccine doses.<sup>46</sup>

## **2.9 Shipping**

With the vaccine science assured and the capacity to create millions of doses achieved, the whole operation would still be useless if patients and health administrators couldn't receive the vaccine. Another hurdle that had to be jumped was the storage methods of the mRNA vaccine. mRNA vaccines have a fragile structure within, and because of this had to be stored and shipped at a temperature of -75 degrees Celsius. Once more, like with the manufacturing, shipping a mRNA vaccine at this temperature at scale had never been done.<sup>47</sup>

Before these vaccines were shipped off, they had to be stored. In their plant in Michigan, Pfizer retrofitted the space to include freezers, measuring in total the size of an American football field (about 110 meters). This plant could hold 100 million doses at a time. Three other plants underwent this retrofit, so Pfizer's worldwide storage capacity counted 400 million doses.<sup>48</sup>

Pfizer utilized a pilot idea it had developed before the pandemic to solve this super cold transportation challenge in any corner of the globe. The company skipped the testing phase and immediately used it. Its description: “[t]he shipper, about the size of a carry-on suitcase, weighed about seventy-five pounds. It carried a minimum of one tray of vaccine vials and as many as five trays. Each tray had 195 vials, 6 doses per vial. So a single shipper could carry as many as 5,850 doses”.<sup>47</sup>

Pfizer exerted exceptional control over its supply chain shipping. Each box was fitted with a tracking device, whether this device was being transported by land, sea, or air. The tracker collected data in real time, so the company could always have a status update on any shipping method. This meant the information related to any shipped vaccine box could be tracked, regardless of the company that was transporting the vaccines for Pfizer.<sup>49</sup>

Margert Kennan, an English woman of the age of 91, received the first emergency use authorization COVID-19 vaccine (Pfizer’s Comirnaty vaccine) on December 8<sup>th</sup> 2020, at University Hospital in the Midlands of England, north of London.<sup>50, 51</sup>

## **2.10 Future Outlook**

It was estimated, that the Comirnaty vaccine “contributed to averting almost 9 million symptomatic cases, 700,000 hospitalizations, and over 110,000 deaths” in the first year it was given to patients.<sup>52</sup> In 2021 and beyond, Pfizer (and other pharmaceutical companies) had to react to a new COVID reality; much of the world’s population had been infected, so new studies would need to be instituted to “optimize booster vaccination strategies to continually offer all patients well-tolerated protection from severe COVID-19”.<sup>52</sup> The company was hopeful that it could carry over the lessons of innovative scientific collaboration and development with the broader scientific community for vaccine development projects in the future.<sup>52</sup>

According to Pfizer’s and BioNTech’s top research scientists, Pfizer’s achievement of ‘Lightspeed’ approval of the Comirnaty vaccine in less than 11 months showed “a practical demonstration that RNA-based vaccines... are a major new tool to combat pandemics and other infectious disease outbreaks” and that a combined and shortened regulatory approval sequence

(phase 1/2/3) can be useful model to combat “other infectious diseases of medical importance”.<sup>53</sup> But even with this speed, the company was only able to produce about 50 million vaccines doses by end of year 2020, half of Albert Bourla’s original goal.<sup>16</sup>

Furthermore, Pfizer demonstrated how a novel vaccine technology (mRNA) can be developed with speed, considering “a sufficient investment of resources”.<sup>53</sup> The lessons learned during Pfizer’s quick (and massive) scale up of new vaccine production methods can enable the company to adapt quickly to new mRNA constructs for any potential variant COVID-19 strains.<sup>54</sup>

Pfizer had to overcome shipping and logistical difficulties to reach their patients – as mRNA vaccines had to be transported in super cold containers. The real time data collecting techniques the company developed gave incredible logistical visibility, allowing quick reaction to correct shipping flaws when they arose.<sup>55</sup> In the end, this logistical innovation could be useful when the company pursues any novel mRNA technology.<sup>55</sup>

By the 25<sup>th</sup> of February, 2021 -- the day Pfizer delivered its year-ended 2020 10-k to the SEC in the United States – the Comirnaty vaccines was given a “CMA, EUA or temporary authorization in more than 50 countries worldwide”.<sup>56</sup> For 2021, the company agreed to supply the U.S. government 200 million doses, the EU 300 million doses, the Japanese government 144 million doses, and COVID-19 Vaccines Global Access (COVAX) 40 million doses.<sup>56</sup> The FDA accepted full authorization of Pfizer’s vaccine on August 23<sup>rd</sup>, 2021.<sup>57</sup>

The company achieved an incredible wind fall with this one vaccine product. In the year ended 2020, Pfizer had \$41,651 million in biopharmaceutical product revenue. In the year-ended 2021, Pfizer had \$81,288 million in biopharmaceutical product revenue (a 95.2% YoY increase). The Comirnaty vaccine counted \$36,781 million in revenue in 2021.<sup>58</sup> Refer to **exhibit 3** for Pfizer’s and some other COVID-19 vaccine makers’ related financial data for vaccine sales and overall revenue.

It will be important to pay attention to the revenue streams that Pfizer will have in the future. SO called, ‘vaccine hesitancy’ has already rendered some portion of consumers unwilling to take

vaccines. Vaccines in general have become a partly politicized topic and their role and public perception could affect their future demand. Pfizer's incredible Comirnaty vaccine development gives great insight into future vaccine development, regulatory and private company collaboration, scientific discovery, and even the determination of human beings when their backs are against the wall.

### **2.11 Case Endnote Citations**

- 1: (“Regulatory approval”)
- 2: (“About”)
- 3: (Peterson, 2000)
- 4: (Frank and Hensley, 2002)
- 5: (“Pfizer 2020 Annual Review”)
- 6: (“Pfizer Inc. Form 10-k for the Fiscal Year Ended December 31, 2019”, 2020)
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- 10: (Bourla p.13, 2022)
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- 13: (Bourla p.16, 2022)
- 14: (Bourla p.5, 2022)
- 15: (Bourla p.18, 2022)
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- 17: (Bourla p.26, 2022)
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- 19: (“Pfizer and BioNTech to Co-develop”, 2020)
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- 22: (Bourla p.31, 2020)
- 23: (Lewis et al. p.3, 2022)
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- 25: (“BioNTech and Pfizer announce regulatory approval”, 2020)
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- 31: (Polack et al. p.2606, 2020)
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- 40: (Rowland, 2021)
- 41: (Thorn et al. p.3, 2022)
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- 43: (Thorn et al. p.2, 2022)
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- 45: (Bourla p.90, 2022)
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- 47: (Bourla p.94, 2022)
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- 49: (Bourla p.95, 2022)
- 50: (“I'm so happy': first person to get fully-tested COVID-19 shot”, 2020)
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- 52: (Lewisa et al. p.8, 2022)
- 53: (Polack et al. p.2613, 2020)
- 54: (Thorn et al. p.1, 2022)
- 55: (Bourla p.96, 2022)
- 56: (“Pfizer Inc. Form 10-k for the Fiscal Year Ended December 31, 2020”, 2021)
- 57: (“FDA Approves First COVID-19 Vaccine”, 2021)
- 58: (“Pfizer Inc. Form 10-k for the Fiscal Year Ended December 31, 2021”, 2022)

### **3. Teaching Note**

#### **3.1 Case Synopsis**

Beginning in 2020, the COVID-19 pandemic caused an urgent need for vaccine solutions all across the world, so a large volume of vaccines was needed. Usually, vaccine development takes years to approve and then sell, but governments and private companies across the world were willing to take extra measures to get vaccines to market. This meant private companies needed to expend extra resources, government regulators accepting testing data on a rolling basis, and scientists taking innovative approaches to vaccine development.

Pfizer was well poised to make a COVID-19 vaccine. The company owns many different biopharmaceutical product lines, has strong control of its value chain, and has many different manufacturing plants across the world to rely upon for production scale-up. Still, the company had never reached vaccine development production above 200 million doses per year. What's more, Pfizer chose mRNA vaccine technology for its COVID-19 vaccine; mRNA drug products have never been sold before in the world, and Pfizer did not own any mRNA vaccine technology itself.

Pfizer chose a German biotechnical company, BioNTech, to partner on this vaccine development effort. In a nutshell, BioNTech would provide the vaccine technology, and Pfizer the manufacturing and distribution know-how. The two companies would share the profits, and Pfizer would pay 100% of the development costs. BioNTech would later pay its 50% of development cost after the vaccine was approved.

Pfizer took two sequential processes of vaccine development (1) research and clinical testing and (2) manufacturing and scale-up into one parallel process. The company completed research and clinical testing in less than a year with the help of BioNTech, testing multiple candidates on a very quick timeline. During the same time frame, the company leveraged upon its extensive manufacturing network, experience in other drug scale-up manufacturing techniques, aggressive procurement strategy, and innovative distribution methods to deliver a vaccine across the world.

Pfizer was rewarded handsomely for its efforts, as the company increased its revenue year-over-year from 2020 to 2021 by almost 100%. Even with a new vaccine technology, Pfizer was able to leverage its global network and product knowledge to be the first private company to receive an emergency approval from health agencies in the world. This case provides a wide-lens view of the most important factors of Pfizer's 2020 COVID-19 vaccine development.

### **3.2 Pedagogical Objectives**

This case is suitable for bachelors and masters business management students; the subject matter can be most relevant to students studying strategy or innovation, and even with business students pursuing a career in the pharmaceutical industry. This case and its corresponding questions can be used to understand Pfizer's strategic response to the COVID-19 pandemic; Pfizer's actions can give broader insight into how a company can utilize its capabilities and resources to respond to a crisis like the COVID-19 pandemic.

The following questions test students' skills in applying tenets of management theory into real world situations. Students are encouraged to utilize frameworks based in management theory related to the following concepts: vertical integration, dynamic capabilities, strategic responses to crisis, and resource-based view.

### **3.3 Suggested Questions**

3.3.1: How can you describe Pfizer's vertical integration strategy during the development of the COVID-19 vaccine? What are some advantages and disadvantages of this strategy?

3.3.2: Did Pfizer exploit dynamic capabilities when developing their COVID-19 vaccine? Can Pfizer's COVID-19 vaccine success be explained by exploiting dynamic capabilities?

3.3.3: What were the key elements of Pfizer's vaccine development that were affected by the COVID-19 pandemic? How did Pfizer react, in the context of the pandemic, to exploit these key elements?

3.3.4: What resources of Pfizer's are VRIO? Will Pfizer's resources provide sustained competitive advantage for their firm?

### **3.4 Analysis and Discussion**

In this section, words that are italicized are key terms that are used in the theoretical discussion section of this dissertation. These words provide key markers that an instructor can look for when evaluating the verbal or written responses to the following questions. The following answers are not the only way to approach these questions, but they give a representation how to integrate the relevant management theory to the evidence in the case.

#### **3.4.1 Vertical Integration Question**

Utilizing the dimensions of Harrigan's framework in her 1985 article "Vertical Integration and Corporate Strategy" one can outline Pfizer's vertical integration strategy during the development of the COVID-19 vaccine. Pfizer is a mature company with many different product lines and three different operating segments; the company has control over many stages of the supply chain *vertically* and has, in the past, acquired similar companies to expand their supply chain *horizontally*. The speedy and voluminous development of the COVID-19 vaccine can in part be attributed to this supply chain strength and control. Since the company deals in pharmaceutical development it must also possess scientific knowledge and technological prowess.

The company engages in many aspects of the supply chain (herein ordered from upstream to downstream stages): research and development, manufacturing, and distribution of their products. The company operates in *many stages* of integration, given this spread. During the COVID pandemic, the company integrated more *upstream* activities when it started to develop lipid nano particles in-house, essential to creating the vaccine product, that it usually bought from a third party. This upstream integration helped the firm internally because it could then avoid negotiating contracts, thus saving time and giving the firm more control over the vaccine's necessary raw materials. Still, the company would have to dedicate increased capital expenditures to ensure this vertical control.

Pfizer's *breadth of integrated activities* cannot be described as *broad*, as in many cases the firm utilizes outsourcing/agreements to complete tasks in the stages of the COVID-19 vaccine supply chain. The only stage of the supply chain that the firm conducts majority activities inhouse is with manufacturing. Otherwise, in the case of the vaccine, the firm has *narrow integration* in the following supply chain stages: research and development (Pfizer 'acquired' the mRNA technology that was created by BioNTech and Pfizer conducted pre-clinical and post clinical trials up to phase 3 in conjunction with BioNTech) and raw materials (it procured most of its supplies from third parties). As a result, the company does not have to expend resources to coordinate all the activities in its supply chain, such as raw materials inventory and clinical testing during development.

In terms of the company's *degree of internal transfers* in the vaccine supply chain, the company has *full integration* of the resources that are transferred internally between the different stages of the vaccine supply chain. The Comirnaty vaccine was manufactured and sold solely by Pfizer and BioNTech. Pfizer did not sell any raw materials that it manufactured (like lipids) nor develop any COVID-19 vaccine technology / manufacture COVID-19 vaccines / provide distribution services for other companies. Overall, though scientific knowledge can be shared publicly, Pfizer's competencies and capabilities were not used to benefit other COVID-19 vaccine developers and their products.

Pfizer's *form of ownership* is *quasi-integration* as the different steps of the COVID-19 vaccine supply chain were made in conjunction with BioNTech on a collaboration agreement. Though the property and plant to develop the vaccine at scale are owned by Pfizer, the end-goal and profit sharing between Pfizer and BioNTech indicate this is *quasi-integration*. Pfizer and BioNTech's collaboration agreement underpinned this profit sharing. Still, though the companies split profits of the vaccine sales 50/50, Pfizer had to cover at risk 100% of the initial development costs for both companies.

### 3.4.2 Dynamic Capabilities Question

In line with the framework that Teece developed in 2007, Pfizer exploited three dynamic capabilities: sensing, seizing, and managing threats/transforming when developing their COVID-

19 vaccine. Pfizer had to adopt an entrepreneurial mindset to develop their COVID-19 vaccine; Pfizer's procurement, manufacturing, and management teams were encouraged to buy materials without guarantee they would be expended, innovate processes for a completely new product, and to coordinate across the world in a 'any means necessary' manner that was in no means business as usual.

Pfizer achieved the first dynamic capability of *sensing* when developing their vaccine. Pfizer has a history of acquiring and developing successful products in the biopharmaceutical market. The company had already been working on mRNA vaccine technology with BioNTech before the pandemic had arrived. The company already had a stake in BioNTech before this pandemic had started, so it recognized such worthwhile technology in its external environment; Pfizer had already tested this mRNA technology in the laboratory before the pandemic thanks to this agreement.

Pfizer achieved a second dynamic capability of *seizing* when it decided to use mRNA technology for their COVID-19 vaccine. This was the most difficult decision to make for Pfizer's CEO, Albert Bourla, in the first days of the vaccine development. Pfizer already had technology it could have utilized for vaccine development, but the vaccine development team made the conscious decision to work on mRNA technology, even if they would have to develop such new technology at scale. This decision was possible because the company had worked on so many different drug constructs before, and it had an incredible network of assets to leverage upon when the time came (e.g. incredible manufacturing infrastructure across the world, top-flight scientific know-how, intellectual property of manufacturing techniques).

Pfizer achieved a third dynamic capability with *transformative activities*. The company was able to bolster the output of raw materials necessary to make the vaccine; wherein, the company started to be their own supplier of lipid nanoparticles that were short in supply. What's more, in order to develop the capacity necessary for 10s of millions of vaccines, the company had to make space for mRNA vaccine development equipment in its manufacturing sites. Also, the company used one of its manufacturing sites in St. Louis, USA to be the testing ground to scale its new mRNA manufacturing platform. The company even transferred this knowledge to other

manufacturing plants (namely Andover), showing that Pfizer's knowledge management was transferrable across company sites.

In regards to the *performance* aspect of Pfizer's vaccine development: the dynamic capabilities mentioned above were essential in developing the vaccine. It is clear that Pfizer made incredible windfall on this vaccine, contributing largely to their year over year revenue increase from 2020 to 2021 of almost 100%. Sensing, seizing, and transformative activities were not only essential to make their vaccine, but they were essential to make the vaccine with speed.

It is not evident to what extent these dynamic capabilities can be delineated from the *relevant context* of the COVID-19 pandemic. The external environment made for a special scenario, especially for vaccine clinical testing, as regulators like the FDA and EMA permitted fast-tracked clinical trials and rolling submissions of data. All of the first companies to get the COVID-19 vaccine to the consumer market (Pfizer, Moderna, Johnson & Johnson, AstraZeneca) were privy to this sort of advantage; still, only Pfizer developed a new mRNA vaccine technology while managing its other product lines and operating segments (of which made up a much larger segment than its vaccine business). Moderna – the other vaccine maker who brought a mRNA COVID vaccine to market -- worked solely in mRNA pharmaceutical product development, and did not have such an extensive product line and operating segments like Pfizer. For this reason, *heterogeneity* of dynamic capabilities can be assumed in Pfizer's scenario, as the make-up of their company and product lines completely differs to Moderna's.

In regard to linking these three dynamic capabilities to *outcomes*, it is also not so clear in this case. Success is certainly an outcome in Pfizer's case, but a direct empirical link to revenue is difficult to quantify. There existed an almost inelastic demand for COVID-19 vaccines at the time -- any successful regulatory approval to sell a vaccine was bound to produce high revenues (as evidenced by the four competitors Pfizer, Moderna, Johnson & Johnson, and AstraZeneca). What's more, such a quick development of a vaccine may not have even been possible without the worldwide rate of infection. The pandemic was a perfect storm to create innovative techniques and reveal dynamic capabilities given the external environment, but direct links are hard to define.

### 3.4.3 Strategic Responses to Crisis Question

Given that the COVID-19 was a global health crisis, all of Pfizer's operating segments were impacted, since it is a pharmaceutical company with a diverse range of healthcare and pharmaceutical products. In terms of the vaccine, Pfizer had to develop a vaccine quickly, as it was an essential element to help quell the pandemic. Speed was the main determinate of how Pfizer changed its normal vaccine development processes.

Pfizer employed an aggressive strategy to deal with the pandemic; following the theoretical outline that Wenzel et. al consolidated in their 2020 article "Strategic Responses to Crisis", Pfizer's strategy required temporary increased resource expenditure and development of innovative processes to deliver a novel vaccine quickly during the COVID-19 crisis.

Pfizer sought to *persevere* and keep the status quo of its firm; the company did not divest any of its products. In a sense, this was not even possible, as in normal circumstances the sale of a product line would take a long time and a lot of resources to execute. Even though they had to develop the vaccine on an expedited timeline, Pfizer still had to meet regulatory standards and practice rigorous scientific methods to support evidence of efficacy in their COVID-19 vaccine. In Pfizer's original deal with BioNTech, the company would cover 100% of the development costs. Ultimately, Pfizer had to persevere and ensure scientific quality or else they risked reputation damage and the full cost of development if they were to fail on their project.

Pfizer had to stockpile resources from their suppliers at risk, as the supply chain was not ensured with the rise of stock restrictions from third-parties and other competitors vying for the same raw materials. Like the procurement team, the manufacturing team had to spend extra resources to ensure the supply chain was ready to go when Pfizer decided on a final vaccine candidate to pursue. Overall, the company had to use slack resources to ensure product quality and to parallelize the steps of clinical testing and development of their vaccine.

Pfizer's managers and workers had to act in a way that was even beyond what they thought was possible. The company had to *innovate* its manufacturing, materials procurement, clinical testing, and shipping methods to deliver a new technology, at scale, in an incredibly short time frame.

Even though the quickest vaccine ever, the mumps vaccine, took four years to be developed and get to market, this COVID-19 vaccine would have to be done in less than a year in order to reach Albert Bourla's demands of launch in 2020. What's more, Pfizer would have to double the capacity of their vaccine manufacturing in less than a year to reach the CEO's demands of vaccine doses. The key element in all of this was speed, as it allowed Pfizer to take innovative measures to deliver on an mRNA vaccine.

Pfizer had to retrofit equipment and knowledge it already had for other drug products -- for example, within its Gene Therapy Program production process -- to develop the mRNA vaccine production technique at scale. Pfizer innovated and made a new manufacturing process for mRNA vaccines by first testing its techniques in its St. Louis manufacturing site (all while collaborating with other entities across the world). The company then transferred this knowledge to its Andover site. There was no time to buy and integrate new manufacturing equipment; the company utilized the space of current manufacturing sites to make the space for this new equipment.

The company also had to innovate on its shipping techniques to successfully deliver its precious cargo to its customers. Since the vaccine needed to be shipped at super cold temperatures, the company leveraged a prototype for the shipping method. This prototype had never been produced at scale, but it helped pioneer a new mRNA drug product shipping technique for the company. What's more, this innovation advanced the company's product shipping quality control, thanks to the super cold shipping box's "live-tracking" feature. This system gave the company another system to utilize in the future, another tangential benefit caused by the conditions of the pandemic.

Overall, Pfizer was able to capitalize on its infrastructure and know-how in other drug development to scale mRNA technology. Speed was the most important overall factors, and as

more people died and were infected, the more direly a vaccine was needed. The requirement for speed caused Pfizer to turn certain vaccine development activities that were normally sequential into a parallel process (requiring higher resource expenditure), and it necessitated innovative manufacturing and shipping techniques.

#### 3.4.4 Resource Based View Question

Utilizing the VRIO framework that Barney created in 1995, one can analyze the aspects of Pfizer's resources and capabilities that can provide sustained competitive advantage for the firm. This internal analysis can show what types of resources Pfizer used to exploit opportunities and prevent threats in its external environment when developing the vaccine.

Some resources that Pfizer has that are *valuable*, *rare*, *inimitable*, and *organized* within their firm are: different drug products they have developed, and the manufacturing scale-up process associated with each, the ability to create their own raw materials in-house, and the strong manufacturing network the company has.

We will list the associated reasoning that each of these resources are VRIO, starting with Pfizer's drug product portfolio and associated manufacturing scale-up process:

- (1) This resource is *valuable* because Pfizer's manufacturing process scale-up it has done in other products has allowed to sell these products at scale and garner a lot of revenue.
- (2) This resource is *rare* because it is uncommon for a firm to have so many different types of products that it can leverage upon.
- (3) This resource is *inimitable* as another firm would have to dedicate an incredible amount of capital expenditures to reach to this amount of drug products. Pfizer has a head start on this strategy, as it acquired Pharmacia and Warner-Lambert for their drug products. Pfizer has a very long history of drug development, and this would be difficult for any competitor to replicate at the wide range that Pfizer has.
- (4) This resource is usable inside of Pfizer's *organization* as the firm focuses on developing (or acquiring) a wide range of pharmaceutical products; the firm can integrate new technology into its existing systems thanks to its expertise in many different drug product areas.

To continue, with the ability to create their own raw materials in house (like the lipids that are necessary to make the mRNA vaccine):

- (1) This resource is *valuable* as the firm can bypass the bottleneck of suppliers controlling a limited supply of raw materials necessary to make the vaccine.
- (2) This resource is *rare* as not many pharmaceutical firms can venture into separate manufacturing disciplines outside of their current operating procedure.
- (3) This resource is *imitable* as a competitor would have to acquire property and equipment, or even separate business lines in order to create raw materials like the lipids.
- (4) This resource can be exploited in Pfizer's *organization* as it already had in place the supply chain to take raw materials like the lipids to make part of the vaccine drug product, so it could handle transferring these raw materials in-house.

Finally, with Pfizer's extensive manufacturing network:

- (1) This resource is *valuable* because it allows Pfizer to produce the large volume of drug products that it needs.
- (2) This resource is *rare* because not many companies have a worldwide manufacturing network nor make agreements with other partners. What's more, Pfizer is able to make redundant supply chains in its manufacturing network.
- (3) This resource is *inimitable* as it has taken a long time for Pfizer to develop this manufacturing network. A competitor would have to purchase a large-scale network, and would have to develop the know-how to do establish a manufacturing supply chain.
- (4) This resource can be exploited by Pfizer's *organization* as it has a long history of manufacturing and know-how within the company. Part of the company's success is thanks to its manufacturing prowess that it developed early on its history. With time, the company developed the capability to handle this extensive network.

Since the vaccine development is done on such a short timeline, further analysis may be required to understand whether this competitive advantage can be sustained across several years. Some of the resources that were exploited to develop the new mRNA technology at scale are indicative of resources and capabilities that can provide sustained competitive advantage to Pfizer. The case of

Pfizer's vaccine can only give a window into this aspect of sustained competitive advantage. The situation of the coronavirus pandemic made a vaccine of utmost importance, so the 'normal' considerations for product development were not present. None the less, Pfizer was ready for this opportunity and relied heavily on its resources and capabilities that were valuable, rare, inimitable, and able to be properly exploited in its organization.

As a simple logical exercise, one can examine the revenue gained from Pfizer's Comirnaty vaccine compared to its competitor Moderna. Pfizer sold \$36.7 billion in 2021 in its COVID-19 vaccine. Moderna sold \$17.6 billion. Both companies used mRNA vaccine technology for their COVID-19 vaccine. Moderna only works on mRNA drug products and Pfizer works on a wide range of biopharmaceutical products. Compared to a company that solely works on this new technology, Pfizer was able to exploit some of its resources and internal capabilities in order to eclipse the sales of Modern's vaccine; whether this be thanks to their manufacturing scale-up know-how with different drug products, extensive manufacturing network, or the ability to create their own raw materials in house, it is evident that Pfizer has internal capabilities that have the potential to provide competitive advantage over the long run compared to its competitors.

### **3.5 Limitations and Conclusion**

Pfizer's incredible effort gives indication that mature companies can be innovative in product lines that are not its main focus to great benefit for the firm. Pfizer was prepared to exploit its resources and capabilities to produce a vaccine solution to the coronavirus pandemic quickly. Future managers can learn from Pfizer's actions, to show that an entrepreneurial mindset (the one needed to exploit dynamic capabilities) is very much useful in a mature company.

In order to move quickly the company had to mobilize and innovate in many different parts of its value chain (i.e. manufacturing, research, shipping, etc.). The company was able to capitalize upon its past product history and know-how to develop an innovative drug platform rapidly.

The COVID-19 pandemic is a very unique situation, and the specific environmental scenario that allowed this incredibly short vaccine development timeline to be possible may not be replicated again. Even so, crisis situations can give unique insights to a company's strategy to exploit its

resources and capabilities. The disruptive nature of exogenous shocks can even be a boon for certain companies, wherein the company focuses only upon what can be successful, and even takes risks to do so.

Pfizer's coronavirus vaccine development is a lesson in pushing the limits of conventional 'procedure' to circumnavigate time limit thresholds. Conventional procedure may be helpful in properly developing a product or new technology, but managers can do more, and even more faster, when uncertain situations arise. A company that has resources and capabilities that develop sustained competitive advantage can hope, and even expect, to rely upon these resources and capabilities when a crisis situation arises.

This case has discussed extensively how Pfizer developed its vaccine. Still, the case has some limitations in regard to the granularity of information. First, this case has been created entirely with secondary data, as no interviews were conducted with current Pfizer employees by the case writer. This case does not explore in depth the strategic and operational role of BioNTech in the COVID-19 vaccine development. Though the details of the collaboration agreement are outlined, the involvement of BioNTech on an operational level are not described in detail.

The scope of this case does not consider the pricing strategy related with the vaccine; given the case focuses on strategic management this consideration was foregone, as it does not completely pertain to the theoretical focus at hand. The author of this case chose to focus primarily on Pfizer's operations in the United States, as he is American; for this reason, the full picture of Pfizer's activities in Europe were not given as much focus.

Students who want to learn beyond the scope of this case should study management science literature in strategic alliance formation, strategic procurement, and corporate governance in multinational corporations. Overall, students should examine how the theory and examples written herein could be applied to other firms during future crises to expand upon their critical thinking skills.

## Appendix

### Exhibit 1

#### PFIZER BIOPHARMACEUTICALS GROUP (BIOPHARMA)

The key therapeutic areas comprising our Biopharma business segment include:

<i>Therapeutic Area</i>	<i>Description</i>	<i>Key Products</i>
<b>Internal Medicine</b>	Includes innovative brands from two therapeutic areas, Cardiovascular Metabolic and Pain, as well as regional brands.	Eliquis, Chantix/Champix and Premarin family
<b>Oncology</b>	Includes innovative oncology brands of biologics, small molecules, immunotherapies, and biosimilars across a wide range of cancers.	Ibrance, Sutent, Xtandi, Xalkori, Inlyta and Braftovi + Mektovi
<b>Hospital</b>	Includes our global portfolio of sterile injectable and anti-infective medicines, as well as Pfizer CentreOne, our contract manufacturing and active pharmaceutical ingredient sales operation.	Sulperazon, Medrol, Vfend and Zithromax
<b>Vaccines</b>	Includes innovative vaccines brands across all ages—infants, adolescents and adults—in pneumococcal disease, Meningococcal disease and tick-borne encephalitis, with a pipeline focus on healthcare-acquired infections and maternal health.	Prevnar 13/Prevenar 13 (pediatric/adult), FSME-IMMUN, Nimenrix and Trumenba
<b>Inflammation and Immunology</b>	Includes innovative brands and biosimilars for chronic immune and inflammatory diseases.	Xeljanz, Enbrel (outside the U.S. and Canada), Inflectra and Eucrisa
<b>Rare Disease</b>	Includes innovative brands for a number of therapeutic areas with rare diseases, including amyloidosis, hemophilia, and endocrine diseases.	Vyndaquel/Vyndamax, BeneFIX, Genotropin and Refacto AF/Xyntha

Exhibit 1. Pfizer Inc. key biopharmaceutical products by therapeutic area; “Pfizer Inc. Form 10-K for the Fiscal Year Ended December 31, 2019.” *EDGAR*. Securities and Exchange Commission, 2020,

## Exhibit 2

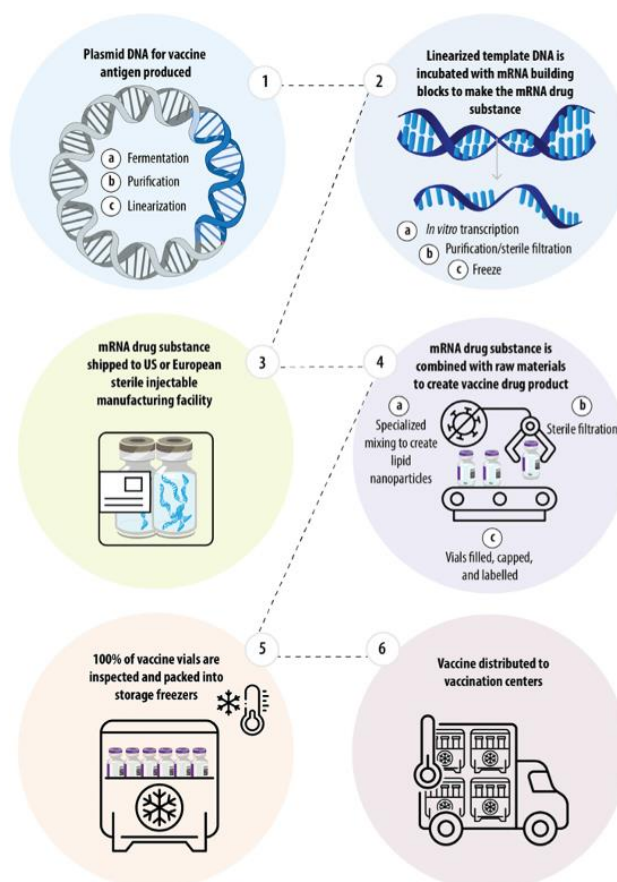


Exhibit 2: Steps in the manufacturing of the mRNA drug substance and vaccine drug product; Lewisa, Lavinia M., et al. “The Race to Develop the Pfizer-BioNTech COVID-19 Vaccine: From the Pharmaceutical Scientists’ Perspective.” *Journal of Pharmaceutical Sciences*, 2022, p. 6.

## Exhibit 3

Company	Revenue 2020 (millions)	Revenue 2021 (millions)	Revenue YoY Growth	2021 COVID Vaccine Revenue (millions)	Net Income 2020 (millions)	Net Income 2021 (millions)	Net Income YoY Growth
Pfizer	\$41,651	\$81,288	95.3%	\$36,781	\$9,159	\$21,979	140%
Moderna	\$803	\$18,471	2,200%	\$17,675	(\$747)	\$12,202	1,733%
Johnson & Johnson	\$82,584	\$93,775	13.5%	\$2,358	\$15,363	\$23,062	13.5%
AstraZeneca	\$26,617	\$37,417	41%	\$4,002	\$3,144	\$115	(96.3%)

Exhibit 3. Financial information from first COVID-19 vaccine makers to consumer market; “Pfizer Inc. Form 10-K for the Fiscal Year Ended December 31, 2021.” *EDGAR*. Securities and Exchange Commission, 2022.; “Moderna, Inc. Form 10-k for the Fiscal Year Ended December 31, 2021.” *EDGAR*. Securities and Exchange Commission, 2022.; “Johnson & Johnson, Form 10-k for the Fiscal Year Ended December 31, 2021.” *EDGAR*. Securities and Exchange Commission, 2022.; “AstraZeneca Annual Report & Form 20-F Information 2021.” *AstraZeneca*, 2022.

#### **Exhibit 4**

##### **Vaccine Science and mRNA**

As vaccines are the focus of this thesis, background information should be given on how they work. Vaccines are injected into a patient to fight against infections by training the recipient’s immune system to fight against a specific pathogen (Bourla p.19, 2022). Traditional vaccines usually utilize “weakened, dead, or noninfectious parts of these pathogens”; the recipient’s immune system will identify them and engage its immune defenses (antibodies and T-cells) to combat them (Bourla p.20, 2022). Afterward, the body will be prepared to fight against the disease when it arrives.

The vaccine described in this case, a novel mRNA vaccine, is of a different technology. mRNA vaccines do not contain the aforementioned parts of a pathogen (Bourla p.20, 2022). Rather, when the injected mRNA reaches the organism’s cells, it teaches the cell to “make its own vaccine” (Bourla p.20, 2022). mRNA gives the instructions to the body on how to create “proteins that are part of a pathogen’s construct” (Bourla p.20, 2022). Ribosomes within the vaccine recipient’s cells start producing these proteins by “reading the mRNA”; in turn, the immune system will identify these proteins and enact an immune response that will protect the vaccine recipient from the real pathogens if they come along (Bourla p.20, 2022).

To back up even further, mRNA stands for messenger ribonucleic acid. mRNA complements the DNA (deoxyribonucleic acid) in our genes. DNA “holds all the information required for the body to form and function” (Bourla p.18, 2022). This DNA information houses the instructions how to produce a protein, for example (Bourla p.18, 2022). When the body needs to produce this protein,

“it will copy these instructions on an mRNA molecule and send it to an organelle called a ribosome, which will move along the mRNA, read its instructions, and produce the hormone” (Bourla p.18, 2022). Thus is the same means that mRNA vaccines work, but the mRNA is introduced within a vaccine.

mRNA molecules are fragile and cannot deliver their instructions to a vaccine recipient’s cells without help; enter, lipid nanoparticles (Thorn et al. p.4, 2022). Lipid nanoparticles are the vehicle in which mRNA’s ride in an mRNA vaccine. The synthetic mRNA is incased by lipid nanoparticles to “aid the delivery into the cells to enable the downstream effect of encoding for the spike protein to generate an immune response” (Thorn et al. p.4, 2022). These lipid nanoparticles play a big part in the materials needed to develop Pfizer and BioNTech’s vaccine, and their procurement and production end up being one of the manufacturing bottlenecks in this case.

mRNA vaccine development can be done quickly, but in order for the vaccine to remain stable while being shipped it needs to be kept at super cold temperatures (Bourla p.25, 2022). This creates a logistical difficulty for a company that makes an mRNA vaccine, as any number of doses will need to be kept at super cold temperatures; this is not to mention delivering these vaccines to places in the world where there does not exist infrastructure for this type of logistics. This consideration will become a part of the success of Pfizer in the case.

There are different types of mRNA vaccine technology, but their specific makeup goes beyond the scope of this case. Though Pfizer’s COVID-19 mRNA vaccine was the first mRNA vaccine to ever hit the market, the technology was in development sometime before. mRNA was discovered in 1961 (Dolgin p.323, 2021) In late 1987, a scientist developed the idea that mRNA could be incased in a fatty lipid and then be potentially used as a drug (the same sort of method that current novel mRNA vaccines utilize to transport the mRNA to the recipient’s cells) (Dolgin p.319, 2021). The first mRNA vaccines were tested in 1993 (Dolgin p.323, 2021). The two companies that primarily worked on mRNA medicine and technology, BioNTech and Moderna, were founded in 2008 and 2010 respectively. These companies would develop the mRNA technology in vaccines that would revolutionize the vaccine world.

## Vaccine Development and Regulatory Approval

Typically, vaccine development and clinical study follows a linear, and long, path. This benchmark can help envision why COVID-19 vaccine development is so exceptional. Average vaccine development usually takes years. There are two major regulators that we will consider during this case study and thesis: the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA). These are the regulators to whom major vaccine providers must give clinical data, and receive approval, in order to sell their product in the USA and EU markets respectively.

In the **figure 5** below, the European Medicines Agency illustrates the typical development path of a vaccine. Note how the path is by and large sequential. In the **figure 6** shown below, the FDA vaccine approval process follows a similar sequential path:

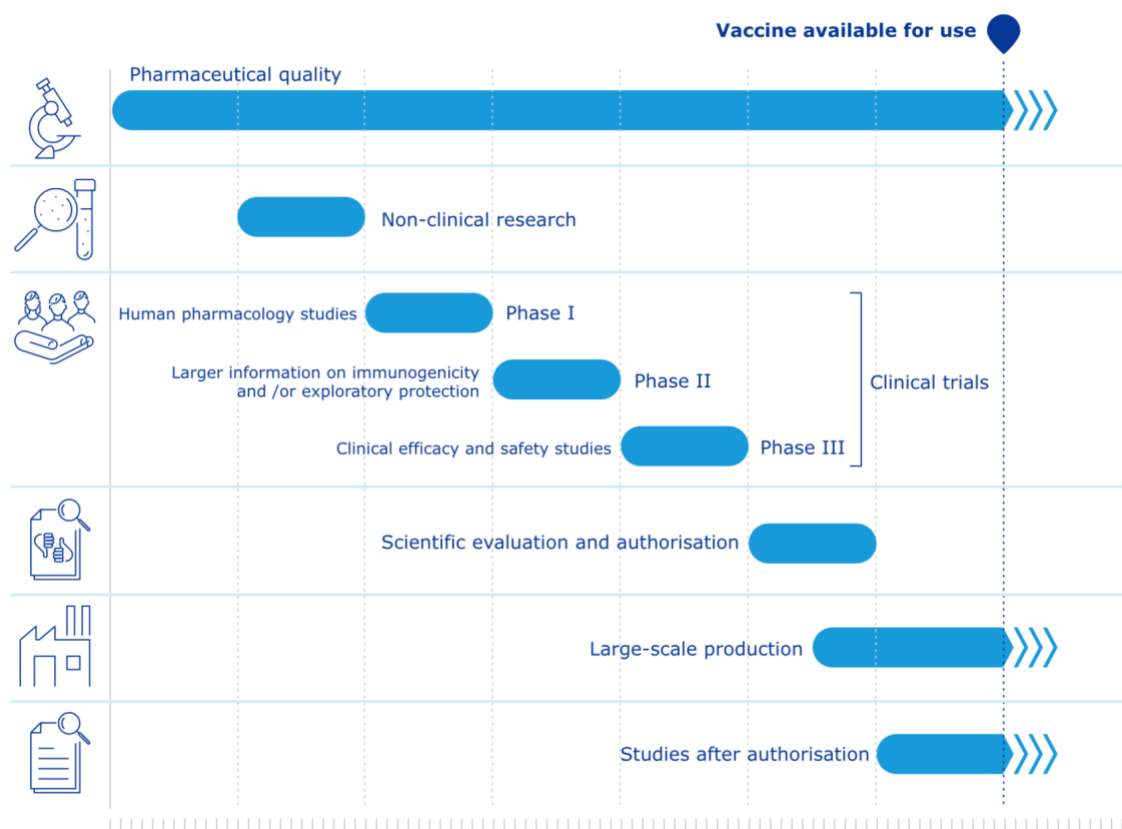


Figure 5. Indicative timelines for COVID-19 vaccines compared with standard vaccines – Standard vaccines; Glanville, Daniel. “COVID-19 Vaccines: Development, Evaluation, Approval and Monitoring - European Medicines Agency.” *European Medicines Agency*, 27 Oct. 2020.



Figure 6. Vaccine development process; FDA. “Vaccine Development – 101.” U.S. Food & Drug Administration, 20 November 2020.

In both processes (EMA and FDA), before clinical trials (Phase 1, 2, and 3) even start, preparation, research, and other types of scientific tests must be completed with the potential vaccine. In the beginning, research is conducted to test the possibility of a certain vaccine candidate and observe whether it will have a practical application (on an infectious disease, for example) (“Vaccine Development – 101”, 2022). These preliminary tests are usually done on animals. Next, in the pre-clinical phase, vaccines are tested in animals in order to test whether the vaccine is safe and could potentially work on humans (“Vaccine Development – 101”, 2022).

To reach clinical studies, firms must give the results of the pre-clinical tests, visibility to the type of manufacturing techniques that made the vaccine, and information regarding the quality of the vaccine to the FDA. After analysis of this information, the FDA can allow the company to test this vaccine candidate in humans. These three clinical phases are usually sequential, but it is not out of the ordinary for clinical trials to overlap (“Vaccine Development – 101”, 2022).

Phase 1 helps determine the safety of the vaccine in (usually) 20-100 healthy volunteers and to determine whether the vaccine can “induce an immune response” in the test subjects (“Vaccine Development – 101”, 2022). When there are no safety concerns for Phase 1, Phase 2 tests include more test volunteers (hundreds this time) to try various dosages of the vaccine, to understand

more short-term safety concerns or risks related to the vaccine, and to understand the vaccine's ability to produce an immune response. This phase usually includes a placebo group (a group in which there is no active ingredient in what is administered to the volunteer) to compare the two groups ("Vaccine Development – 101", 2022).

In Phase 3, the vaccine is given to thousands of volunteers to understand the efficacy and safety of the vaccine, and to observe whether any side effects could have been missed in the first phases. This phase includes more participants, and tests again against a control group. To understand the efficacy of the vaccine: "the number of cases of disease in the vaccinated group is compared to the number in the control group to see whether the vaccine reduces the incidence of disease" ("Vaccine Development – 101", 2022).

The navigation of these regulatory procedures, not to mention the manufacturing component of this development, gives credence to why the vaccine development process is so laborious for a pharmaceutical company. Out of the three clinical phases, the phase 3 studies cost the most to conduct, and are the most critical for a pharmaceutical company to receive regulatory approval (Bourla p.32, 2022). When phase 3 studies are finished, the regulatory group of the pharmaceutical company will prepare all of the data for the regulators' approval; this effort is enormous as these regulatory applications count thousands of pages, the data must be accuracy controlled, and the time dedication to produce such a report is huge (Bourla p.33, 2022). At the same time as this is being done, materials and even specialized equipment must be ordered to prepare the production of the vaccine; if the vaccine must use specialized equipment to be produced, the capital expenditures associated with acquiring and installing this equipment count hundreds of millions of dollars (Bourla p.34, 2022).

After regulatory approval is sent to the FDA after the completion of Phase 3, the participants in this study and others are continuously tracked and studied in Phase 4 to track the long-term effects/safety of the vaccine product.

### **The Special Regulatory Situation During COVID**

Major regulatory agencies across the world understood the exceptional situation of the coronavirus pandemic and acted accordingly. In the case of the United States of America, the FDA states that in abnormal “public health emergencies” such as the coronavirus pandemic, vaccine development processes can be “atypical or expedited” (“Vaccine Development – 101”, 2022). In response to the pandemic, the federal (USA) government can unite “government agencies, international counterparts, academia, nonprofit organizations and pharmaceutical companies to develop a coordinated strategy for prioritizing and speeding development of the most promising treatments and vaccines” (“Vaccine Development – 101”, 2022). What’s more, the federal (USA) government can even, at its own risk, make investments to aid manufacturing capacity to help speed up the process of development (“Vaccine Development – 101”, 2022).

Along with this extra push by many of the pharmaceutical firm’s stakeholders during development, the vaccine maker can request an Emergency Use Authorization to the FDA “to facilitate the availability and use of their vaccine during this time” (“Vaccine Development – 101”, 2022). What’s more, adaptive trial designs can be followed to “expedite clinical trial decisions based on preliminary results derived from earlier trials and, in some cases, from the same trial” to speed along clinical vaccine development and even decrease the size and duration of clinical trials to identify an effect, if it is actually present (“Vaccine Development – 101”, 2022).

To aid in the visual understanding of this ‘parallelizing’ that is done with vaccine development during a pressing time like COVID, please refer to **figure 7** below, made by the EMA. Please compare the infographic with the first one above to observe the ‘parallelized’ difference.

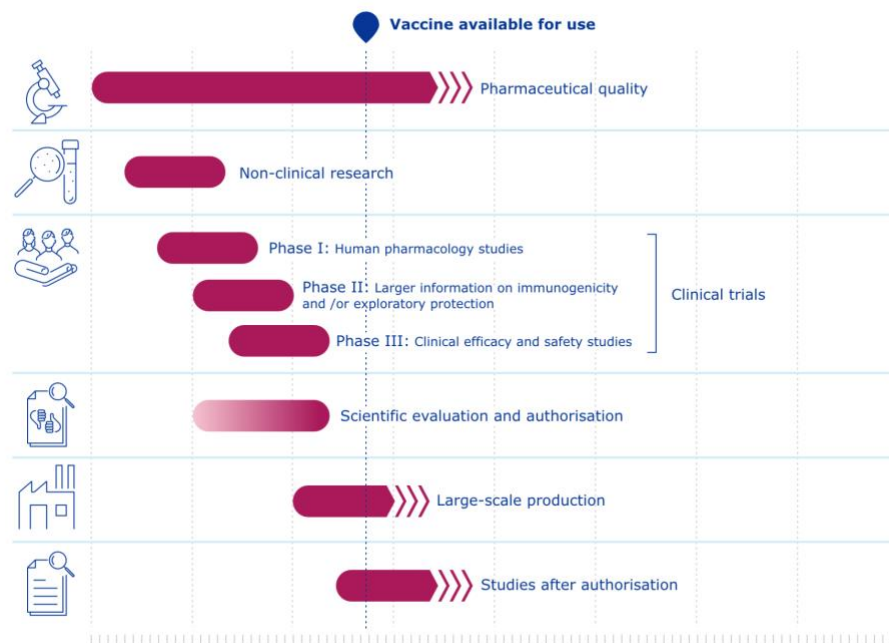


Figure 7. Indicative timelines for COVID-19 vaccines compared with standard vaccines – COVID-19 vaccines; Glanville, Daniel. “COVID-19 Vaccines: Development, Evaluation, Approval and Monitoring - European Medicines Agency.” *European Medicines Agency*, 27 Oct. 2020.

Part of what makes this reduced timeline possible is the rolling review of clinical data for COVID-19 vaccines. Regulators can take this data on a rolling basis, due to the unique need for COVID vaccines. **Figure 8** below from the EMA illustrates this.

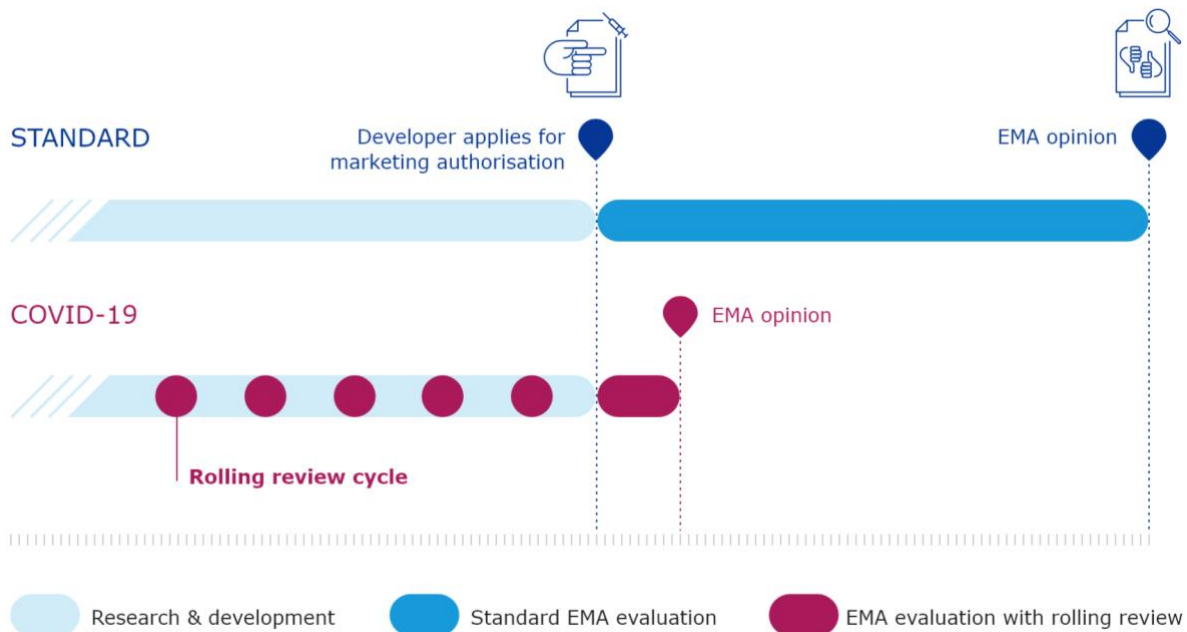


Figure 8. Standard evaluation process compared with rolling review of COVID-19 vaccines; Glanville, Daniel. “COVID-19 Vaccines: Development, Evaluation, Approval and Monitoring - European Medicines Agency.” *European Medicines Agency*, 27 Oct. 2020.

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