European Research Studies Journal
Volume XXIV, Issue 2, 2021

pp. 294-313

Trade-Offs Occurring in the Process of Commercialization of SARS-CoV-2 Test in a Narrow Window of Opportunity

Submitted 10/03/21, 1st revision 11/04/21, 2nd revision 02/05/21, accepted 20/05/21

Urszula Mikiewicz[1], Miroslaw Moroz[2]

Abstract:

Purpose: *The aim of the paper is to assess the choices made within the trade-offs specific for the commercialization of a biomedical product in the circumstances of a narrow window of opportunity.*
Design/methodology/Approach: *The analysis of the literature on this subject revealed a research gap in the analysis of the trade-offs occurring during R&D works in the process of the development and commercialization of a biomedical product in the circumstances of a narrow window of opportunity for market introduction. For the sake of capturing the dynamic specificity of the innovation process and its comprehensive presentation, the authors decided to use the case study method.*
Findings: *The results of the research suggest that focusing on one factor (time) is possible when mobilising the entire potential of the enterprise, but ultimately it does not have to translate into faster launch of serial production and taking advantage of the window of opportunity. Research shows that excessive simplifications in the area of innovation process management lead to the need to re-implement some stages of the R&D works.*
Practical Implications: *Conclusions from the analysis of trade-offs can help managers in making key decisions within the innovative process under time pressure.*
Originality/Value: *Despite the time pressure, it is advisable to follow the main principles of conducting the research process, in particular, defining milestones in advance, exercising critical approach to formulating assumptions, taking care of good communication between R&D discipline teams, making at least a preliminary trade-off calculation.*

Keywords: *Biomedical product, innovation process, trade-off relation, SARS-CoV-2 testing.*

JEL classification: *O31, O32, L65, D22.*

Paper Type: *Research Case Study.*

Acknowledgement: *The project is financed by the Ministry of Science and Higher Education in Poland under the programme "Regional Initiative of Excellence" 2019 - 2022 project number 015/RID/2018/19 total funding amount 10 721 040,00 PLN.*

[1]*Wroclaw University of Economics and Business, Wroclaw, Poland, http://orcid.org/0000-0003-2276-5402, urszula.mikiewicz@ue.wroc.pl*
[2]*Wroclaw University of Economics and Business, Wroclaw, Poland, http://orcid.org/0000-0002-1439-9097, miroslaw.moroz@ue.wroc.pl*

1. Introduction

The SARS-CoV-2 coronavirus pandemic has rapidly changed the global socio-economic situation (Grima *et al.,* 2020; Khan *et al.,* 2020). Governments are trying to counter the negative consequences of the COVID-19 pandemic by using two types of strategies, mitigation or suppression, or a combination of both. Regardless of the adopted strategy to deal with the pandemic, the basic approach is testing the population for the presence of the SARS-CoV-2 coronavirus. Testing addresses the question of the percentage of the population infected with the pathogen and is the key information determining further activities. However, the novelty of the pathogen created an urgent need to develop effective tests for SARS-CoV-2. Many companies have undertaken R&D activities to develop and produce a coronavirus test.

A characteristic feature of the innovation process in question is a strong time pressure. There are two reasons for it. First, there is a race to save as many potential victims of the pathogen as possible. Testing is the basis of proper diagnosis and, subsequently, of the eligibility for vaccination. Secondly, according to the authors' knowledge, over 1000 companies have commenced R&D works regarding the commercialization of the SARS-CoV-2 test. This obviously has a positive effect on the search for and use of new solutions to beat the competition. And there is a lot at stake. By definition, a pandemic is of global nature. The development and implementation into serial production of a test providing accuracy, reliability, rapid diagnosis and low unit costs will determine the market position and financial results of the test manufacturer.

As a result, innovative works are carried out with the narrow window of opportunity in mind. Such circumstances occur when the demand for the product grows rapidly and at the same time many competing companies take up the challenge of its development. In this situation, each company tries to implement solutions that will speed up R&D and production activities. A natural solution, commonly implemented in such situation, involves improvement in the area of management. However, organizational changes in the R&D process make it necessary to redefine the trade-offs in terms of the test commercialization time, incorporated features/parameters (product functionality) and the costs of research. Giving priority to the time factor results in changes in the trade-offs between the above three factors. In the new circumstances, the question of the final effects of the commercialization process needs to be considered anew.

The aim of the article is to assess the choices made within the trade-offs specific for the commercialization of a biomedical product in the circumstances of a narrow window of opportunity. The analysis of the literature on this subject revealed a research gap in the analysis of the trade-offs occurring during R&D works in the process of the development and commercialization of a biomedical product in the circumstances of a narrow window of opportunity for market introduction. For the

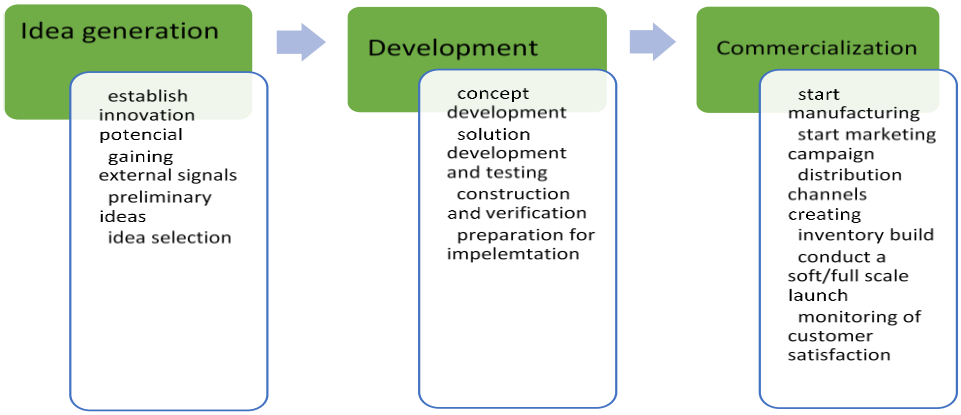
sake of capturing the dynamic specificity of the innovation process and its comprehensive presentation, the authors decided to use the case study method.

2. Acceleration of the Innovation Process

Innovation constitutes a mainstream interest of the technical, economic and social sciences (Acosta *et al.*, 2016; Saunila, 2020). Novelty is the focal point of innovation. According to the guidelines of the "Oslo Manual", a novelty can manifest itself in the form of a product, a process within a given entity, marketing and organization of basic (production, service, commercial) as well as management processes, including the business model (Oslo Manual, 2018).

The innovation process aims at effective commercialization of the innovation and its acceptance by the buyers/users. The innovation process takes place in several phases, starting with the creation of the appropriate potential in the organization, and ending with commercialization. Figure 1 shows a general scheme of creation and commercialization.

Figure 1. *General scheme of the innovation process*



Source: *Frederiksen and Knudsen, 2017.*

Time-to-market is important for the effectiveness of commercialization. Going through all the phases of the innovation process to develop a solution that meets the assumptions takes time. On the other hand, there is an optimal time frame for introducing a given product to the market - the window of opportunity (Kim and Kang, 2019; Messica and Mehrez, 2002). If the commercialization comes too late, it may destroy the chances of success - competitors who released the product earlier have already acquired customers, buyers do not want to pay a premium price for another similar product, and finally, in the case of cyclical branches, the demand may quickly disappear. In the event of late market entry, there is a risk that the

regulator might alter the requirements and another time-consuming prototype change will be necessary.

On the other hand, releasing an innovation too quickly may involve offering buyers a product that is not fully developed and does not meet all their requirements despite the hype. It may also happen that the product does not meet the expectations of the customers at all due to its low quality or safety issues. In this respect, another risk is an over-proportional increase in innovative process expenditure, consisting in the allocation of additional personnel, new resources, etc., which, in turn, will hamper the economic profitability of the project. There is also a risk that the involvement of a significant part of the company personnel in a given project will result in the slowdown/abandonment of all other research and development activities that could, at least theoretically, result in the development of a more groundbreaking solution. The window of opportunity is relatively small when (Bayus, 1997):

- Product lifetimes are short
- The time to peak sales is small
- Average product margins are sharply declining over time.

The window of opportunity is created by three groups of factors: those related to scientific and technological progress (knowledge and technology), changes in demand, and guidelines and regulations of government agencies (Kim and Kang, 2019). New opportunities for creating innovation appear in result of changes related to the level of knowledge and the possibility of using particular raw materials, materials, solutions or systems in a new, more efficient or unprecedented way. Examples include such industries as ICT, biotechnology and aviation.

The group of factors related to demand strongly urges enterprises towards faster time-to-market. Today, more and more customers want their preferences to be met immediately. This aspect also involves rapidly changing fashions or trends, price pressure and shortening of the product life cycle. The demand for the products of a particular company is also related to the level of competition in a given sector. The panacea may be to launch products onto the market faster. In this perspective, innovation is one of the instruments of competition and maintaining a competitive advantage.

The third group of factors are regulations and restrictions imposed by the authorities. A classic example is the automotive industry, which, due to growing environmental protection guidelines, has to develop new versions of engines with lower emissions of harmful gases. The aforementioned COVID-19 pandemic also brought about many regulatory changes, forcing companies to implement various types of innovation in terms of distribution, production methods, work organization, etc. Taking the above factors into account, it becomes natural to strive for the acceleration of the innovation process. However, the question is how to do this. The literature on the subject provides the following ways to boost efforts on the creation

and commercialization of innovations (Calantone and Benedetto, 2000; Cooper, 2019; Parthasarthy and Hammond, 2002):

- Formulating realistic assumptions across all phases of the innovation process, available resources, market information, etc.
- Reducing product complexity – determination of a minimum set of functionalities on the basis of MVP concept (Minimum Viable Product)
- Sharp, early, and fact-based product definition (Unique Selling Proposition)
- Iterative, spiral development – build, test, feedback, and revise
- Parallel and concurrent processing of innovation process phases
- Involving (potential) users of a given solution in providing feedback and assessing their usefulness as soon as possible at every stage of the innovation process
- Implementing agile management methods
- Improving communication between R&D - production - marketing teams by defining the rules and using ICT tools
- Increasing the motivation for creativity/performance of R&D - production - marketing teams by establishing a bonus scheme, incentive program, participation in ownership (shares) or decision making.
- Implementing a participatory style of management
- In economically justified cases, redundancy of human resources and other assets, including cooperation with other entities.

The acceleration of the innovation process - although desirable - is associated with certain types of risk. When deciding to accelerate work on a new solution, it is necessary to perform a profit and loss calculation every time. In this context, the following trade-offs are enumerated (Bayus, 1997):

- too early release of the product vs. unused opportunities
- time-to-market vs. development cost
- time-to-market vs. product features.

The above-mentioned dilemmas create a space for making decisions regarding actions accelerating the commercialization of innovations. However, the right choice is not at all obvious during the process, due to incomplete information and the emotional commitment of the decision maker.

3. Research Methods

3.1 Research Gap

A review of literature databases showed that the analysis of balancing various factors within specific trade-offs is a popular subject of scientific research on innovation. In particular, the studies focused on trade-offs within national systems of

innovation, intellectual rights, mergers and acquisitions, and business models (Cohen *et al.*, 1996; Kim, 2017; Roin, 2014; Weigelt and Sarkar, 2012).

The above sources refer to all business activities and are not limited to a single industry. Taking biomedical products into account, a search of literature databases revealed few sources (Angus, 2020; Corso and Gastaldi, 2010; Ehlers, 2011; Hirch, 2016). By applying an additional time pressure filter and taking advantage of the emerging window of opportunity, to the best of the authors' knowledge, only two papers deal with the trade-off of too fast versus too late market introduction. Corso and Castaldi (2010) analyzed the relationship between effective exploitation and flexible exploration as a result of the use of information and communication technologies in the healthcare sector. The authors based their analysis on empirical research. In turn, the work of Angus (2020) addressed the issues of optimizing the trade-off between learning time and commencing operation in the circumstances of the COVID-19 pandemic (Angus, 2020). The work subscribes to the mainstream of theoretical and postulative considerations.

In view of the above, the authors identified a research gap in the analysis of the trade-offs occurring during R&D works in the process of the development and commercialization of a biomedical product in the circumstances of a narrow window of opportunity for market introduction. Such a situation occurs in the event of a pandemic. This is when the need to develop and launch life and health saving biomedical products as quickly as possible is clearly visible. However, in terms of the current competitive situation, shortening the time to commercialization appears to be a more universal objective after mobilizing the R&D process. However, shortening the time has various consequences for research and production that deserve further exploration.

3.2 The Research Problem, the Purpose of the Study and the Research Method

On the basis of the identified research gap, augmented by the current pandemic circumstances, the authors formulated the following research problem: how the imperative of shortening the time needed to create a test for the presence of SARS-CoV-2 virus affected the course and effects of the product commercialization process in terms of the production launch time, costs and product features. The research problem relates to three typical trade-offs occurring in the course of research and development activities (Bayus, 1997):

- Too early release of the product vs. unused opportunities,
- Time-to-market vs. development cost,
- Time-to-market vs. product features.

The aim of the paper is to assess the choices made within the trade-offs specific for the commercialization of a biomedical product in the circumstances of a narrow window of opportunity.

Research questions that need to be asked to achieve the set aim of the work, and thus to explore and clarify the research problem are as follows:

1. What are the reasons for shortening the time of effective commercialization of the SARS-CoV-2 test?
2. What is the course of the commercialization process in the case of the SARS-CoV-2 test compared to the commercialization of the influenza test in the business under investigation?
3. What are the effects of the commercialization process in the case of the SARS-CoV-2 test compared to the commercialization of the influenza test in the business under investigation?
4. What do the trade-offs encountered during the commercialization of the SARS-CoV-2 test look like?
5. What are the effects of the choices made by the management of the business under investigation as part of trade-offs (time of production commencement, costs and product functions)?

The case study method was used for the research purposes. The rationale for selecting such a method was to match the nature of the research problem. The idiographic approach facilitates capturing of the research problem in all its dynamic complexity, which is appropriate for this research area. The case study method facilitates:

- Taking into account the context/specificity of a given organization and its environment (Coughlan and Coghlan, 2016)
- Adopting a broad view of the constantly changing, dynamic processes (Corallo, 2007)
- Obtaining an in-depth answer to the questions "how", "what", "in what way" (Yin, 2017), which constitute the focus of this study.

3.3 Research Techniques and Design

The conducted analysis is based on the knowledge made available by the management of company under investigation (PF company) relating to the processes of developing tests that detect viruses or bacteria in the body. The article analyses the trade-offs taking place during the commercialization of the SARS-CoV-2 coronavirus test.

The research was conducted in December 2020 and January 2021. The research was conducted using semi-structured interview and participant observation contributed by one of the authors. The interlocutors were the PF company CEO and R&D manager. The applied method of selecting interlocutors was dictated by their knowledge of various aspects of R&D work performed when developing the SARS-CoV-2 test.

The interlocutors were interviewed three times - the answers from the previous stage were analyzed by the authors, and the acquired knowledge regarding the course and effects of the coronavirus test implementation was used to formulate additional, more detailed questions. The interview conducted in this way provided us with a fairly detailed insight into the company's activities and better understanding of the problem.

4. The Conditions and the Process of Implementation and Commercialization of the SARS-CoV-2 Test

Antigen tests have become the most promising type of tests for SARS-CoV-2, due to short waiting time to obtain the result, simple method of smear collection, and its affordability compared to other types of tests. The size of the market, not only institutional (clinics, HEDs, offices, airports, etc.), but also commercial (tests performed on individual orders of private persons and companies) ensured business success. Hence, many companies have taken up the challenge of developing a rapid antigen test.

The decision to start work on the development of a diagnostic test for the detection of COVID-19 required the company to introduce changes on many levels of the its operation, due to time constraints resulting from the "window of opportunity". The imperative of shortening the time needed to develop the SARS-CoV-2 virus test resulted in the need to implement improvements in the company.

The company’s objective was to have a finished product – a COVID-19 ready for marketing authorization in June 2020, i.e., 5 months after the commencement of work. The sales was estimated at 70 thousand items by the end of 2020. In order to achieve this goal, changes were introduced, both in the research and development (design) and production areas.

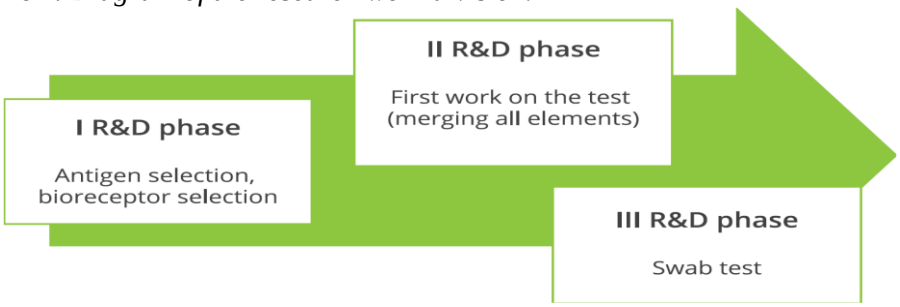
4.1 Introducing Improvements in the Research and Development (Design) Area

The company has divided the research and development activities into three phases, similar to ones used in the case of the influenza test:

- R&D Phase I - antigen selection and bioreceptor selection,
- R&D Phase II - initial work on the test and integration of all test elements (chemical, electronic, IT and biotechnological),
- R&D Phase III - smear testing.

The company benefited from the experience gained while working on the influenza virus test. Assuming that the SARS-Cov-2 virus is similar to the influenza virus, the time needed for the commercialization process and the necessary resources were estimated. This is shown in Figure 2.

Figure 2. *Diagram of the research work division.*



Source: *Own study.*

At the beginning of the development process, improvements were implemented in particular research and development phases, as shown in Figure 3.

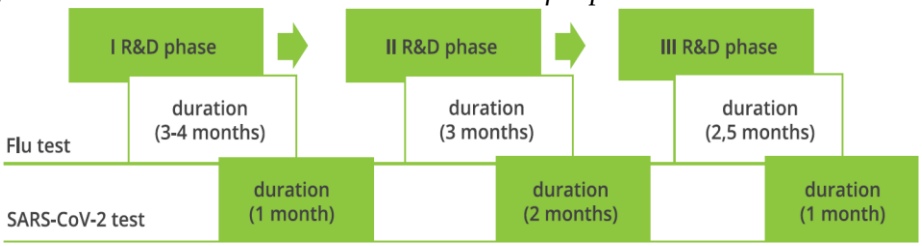
Figure 3. *Improvements introduced in respective phases of the research.*

R&D Phase I	R&D Phase II	R&D Phase III
•cooperation with other research centres working with the SARS-CoV-2 virus in the **scope of protein selection** •skipping checkpoints (e.g. checking the interaction with protein using ELISA test) •commencement of phase II without obtaining the results of all the performed analyses	•making use of the existing influenza diagnostic platform to identify the SARS-CoV-2 virus •skipping checkpoints •omitting indirect analyses, making decisions with account being taken of the risks associated with the lack of some data/analysis results regarding effectiveness	•cooperation with external laboratories in respect of obtaining as many samples as possible •the third phase activities began in the middle of the second phase

Source: *Own study.*

Thanks to the implemented improvements, the duration of the research stage was significantly reduced (to 4 months), as shown in Figure 4.

Figure 4. *Time saved thanks to the introduction of improvements in the R&D area.*



Source: *Own study.*

The implemented improvements were associated with a number of risks that the company had to accept in order to optimize the entire test development process and maintain the assumed time limits.

In Phase I, the possible risks were associated with the following activities:

- incorrect antigen choice – inability to find an appropriate bioreceptor,
- missing results of analyses – risk of selecting non-specific bioreceptors, i.e., selecting an inappropriate biofilm layer, causing non-specificity or low sensitivity of the test.

The following potential risks were identified in Phase II:

- incorrect selection of the diagnostic platform – the company used the existing influenza diagnostic platform (owned by the company),
- inability to test various reaction conditions, with the risk of selecting non-specific conditions and, in consequence, test failure.

In phase III, the possible risk was related to the lack of control over the obtained samples, which could make the verification of the test effectiveness difficult or significantly prolonged. The company estimated the possibility of occurrence of risks in the R&D area as follows in Table 1.

Table 1. *Estimation of the risks in R&D area.*

Event	Probability of occurrence (%)
incorrect antigen selection	10
non-specific bioreceptor selection	50
incorrect diagnostic platform selection	10
non-specific conditions selection	60

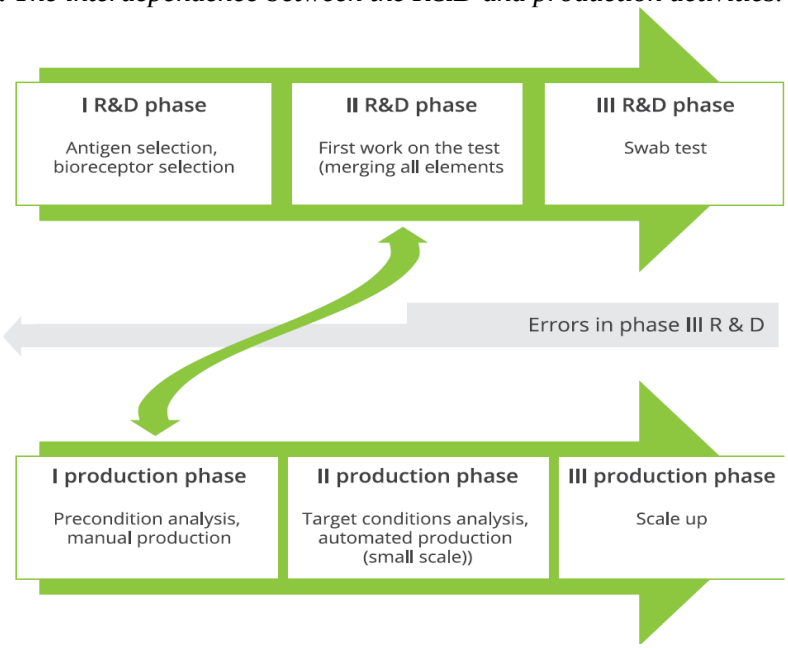
Source: *Own study.*

The company identified the greatest risks in the area of (1) non-specific bioreceptor selection, i.e. the selection of an inadequate biofilm layer at the earlier stages of research and development resulting in non-specificity or low sensitivity of the test, and (2) non-specific conditions selection, i.e. the selection of inappropriate conditions of the detection reaction (e.g., buffer, pH, concentration of individual components, reaction time). Under poorly selected conditions, the detection reaction is not visible or non-specific interactions occur, which negatively affects the sensitivity and specificity of the test.

4.2 Improvements in the Production Area

Due to the adopted timeframe, the company was conducting the research and production activities simultaneously. The interdependence between the R&D and production activities is presented in Figure 5.

Figure 5. *The interdependence between the R&D and production activities.*

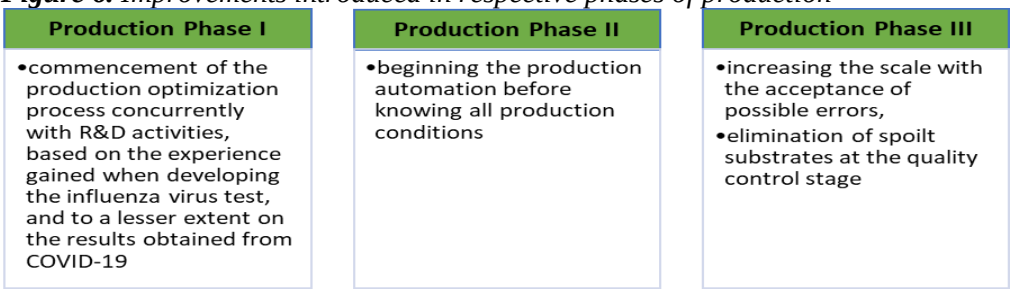


Source: *Own study.*

The link between the second R&D phase and the first production phase consisted in the commencement of production line testing in R&D Phase II, resulting in a significant acceleration of the process. The production line testing consisted in small-scale production with the selection of various parameters followed by the verification of the correctness of the introduced modifications, the stability over time and reactivity to positive and negative samples. In addition, the company had to accept the risk of occurrence of errors in the third R&D phase and the related consequences in the form of the need to go back with the entire process, both the research phase (return to phase I and II, respectively) and production phase (return to phase I and II, respectively). The improvements that the company introduced in the production area are shown in Figure 6.

Thanks to the introduced improvements, the Company shortened the overall research and production process to 8 months. After 5 months, the product was ready for registration at the Polish Office for Registration of Medical Devices and Biocidal Products, and it took the company 3 more months to scale up production, i.e., increase the number of manufactured tests.

Figure 6. *Improvements introduced in respective phases of production*



Source: *Own study.*

The process of implementing fast production was burdened with many risks. The most serious risk was related to the potential necessity of modifying the entire process, if it had ultimately turned out that some element of the final product had not functioned properly. Another risk was related to the possible occurrence of "waste products", i.e. tests that did not pass the quality control due to damage (e.g., scratches) that would prevent proper bioreceptor attachment and to the instability of the final product. The company estimated the possibility of occurrence of risks in the production area (Table 2).

Table 2. *Estimation of the risks in the production area*

Event	Probability of occurrence (%)
Waste products	100
Instability of the finished product	30
Problems production scale up	50
Occurrence of unexpected reaction/processes in the course of production	40
Lack of process repeatability	30

Source: *Own study.*

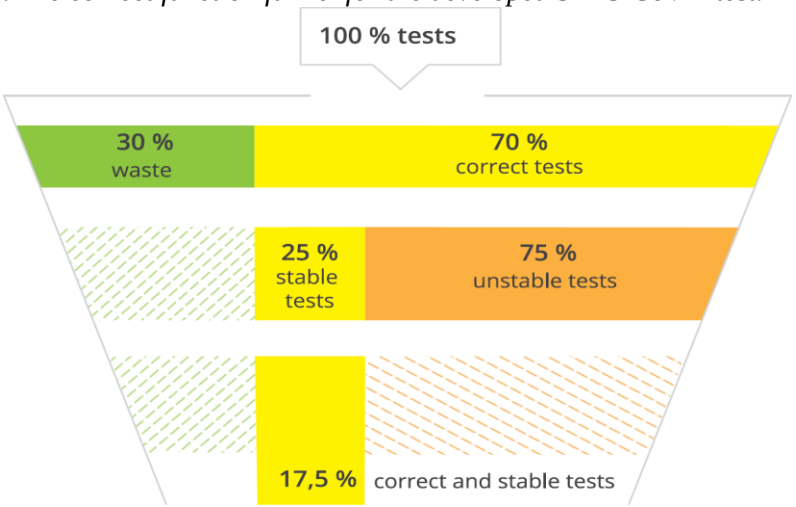
4.3 Financial Costs of Implementing Improvements

The imperative to shorten the time of development has significant financial consequences. When conducting works simultaneously, working intuitively, and starting activities based on incomplete research results, one should take into account the increase in the costs of individual phases, which directly affects the profitability of the entire process. The most risky and costly changes introduced by the company in the process of the COVID-19 test commercialization included:

- focus on production rescaling, which resulted in the occurrence of a significant percentage of "waste products", i.e. tests that did not pass quality control,
- time optimization when assessing the stability of the finished product - the impact of the production process on product stability was not fully verified,
- skipping checkpoints (milestones/verifiers),
- overtime, which significantly contributed to the increase in the value of payroll (by 50% on average).

The consequences of the introduced improvements in terms of the functional test percentage are shown in Figure 7.

Figure 7. *The correct function funnel for the developed SARS-CoV-2 test.*



Source: *Own study.*

At the production stage, 30% of the tests were not saleable due to poor product quality in terms of accuracy. Of the properly functioning products, 75% turned out to be unstable, which also made them unfit for sale. Stable, full value tests were those that had not been damaged and had passed positive verification in terms of measurement repeatability.

In the process of risk assessment, the company accurately predicted the occurrence of "waste products", while maintaining the stability of products turned out to be the biggest problem. Due to the lack of full verification of the impact of the production process on the product stability, only 17.5% of the tests turned out to be full-value, stable and saleable products. Undoubtedly, the lack of product stability influenced the entire commercialization process of the COVID-19 tests.

The imperative of reducing the time to develop the COVID-19 test certainly left its mark on the entire commercialization process. Significant acceleration of the research and production process resulted in the lack of full commercialization

understood as the introduction of the product onto the market and execution of sales plans. This is illustrated by the following data:

- 17.5% – full value, stable tests with repeatable parameters
- 1200 – the number of tests sold (against the assumed 70,000 items)
- disproportionately high costs incurred in the test development and production.

Finally, due to the problems related to instability of the product, the company decided to take the production process back to the product scaling stage. Taught by experience, the company allocated more time to repeat this process and plans to introduce the product to the market in over 5 months.

5. Discussion

The company's decision to accelerate the work on the development of the COVID-19 test should be considered in terms of time, costs and risk taken. However, to make the analysis and evaluation more complete, Table 3 summarizes the effects of commercialization of the SARS-CoV-2 test and the influenza test. The influenza virus test is the company's flagship product, successfully commercialized.

Table 3. *Comparison of the key features of the influenza test and the COVID-19 test*

Features	Influenza test	COVID-19 test
The costs of production (in arbitrary cost units) include R&D and production areas	2	1
Development time (R&D and production)	36 months	8 months
Number of employees involved	30	30
Full commercialization	yes	no

Source: *Own study.*

Due to the market conditions (raging pandemic and the emphasis on developing the test quickly), as well as the unknown nature of the SARS-CoV-2 virus, the company did not see the possibility of determining realistic and rational levels of checkpoints, and then imposing them as a condition for progressing with further activities. Up to a certain point in the course of work on the SARS-CoV-2 test, it seemed that the experience gained during the commercialization of the previous product, the influenza test, was working.

However, more or less in the middle of the R&D works, it turned out that there were more and more problems with the sensitivity and repeatability of the test, a large

percentage of invalid tests, and sales after commercialization, which was much lower than planned. Therefore, despite the implementation of the respective phases of the research and production processes in accordance with the schedule, less than 18% share of full value products warrants negative assessment of abandoning the sequential method of product implementation and strict control of subsequent stages of the research process. Greater focus on research results, control at the completion of milestones phases, and maintaining a time buffer between phases would help avoid problems that occurred at the later stages of the process. Each research process requires concentration and diligence. Disregarding these requirements results in the accumulation of errors and, consequently, accepting a significant probability that the ultimate result will not be consistent with the assumptions.

Another important issue is that the management mistakenly assumed that the research process established for SARS-CoV-2 would be essentially analogous to that for the influenza virus. This assumption was based on the assignment of both pathogens to the virus family. The analysis shows that the new virus turned out to be much more difficult at the detection stage, more unpredictable and, consequently, posed a much greater challenge for researchers in the first R&D phase. SARS-CoV-2 is a new pathogen, the research on which has began relatively recently - it will take time and a series of in-depth studies to gain more knowledge about its testing. Adding a very innovative and therefore also complicated technology (electronic layer) that was used for the SARS-CoV-2 virus, it can be concluded that following the research pathway used in the case of the previously developed influenza test too closely turned out to be illusionary and also contributed to deficiencies in the stability of the SARS-CoV-2 test. As a consequence, the company had to go back to the first R&D phase and gave itself another month to refine the test.

When analyzing the temporal aspect of the COVID-19 test commercialization, it should be stated that, thanks to the introduced improvements, the company registered the product with The Office for the Registration of Medicinal Products, Medical Devices and Biocidal Products at the scheduled time. So, formally, it achieved its main objective. However, if we take into account the low percentage of stable tests, it turns out that the objective of accelerating the work was not really achieved, because it took months to refine the test. As a result, sales levels were not achieved in line with the adopted schedule.

In terms of costs, the Company incurred huge expenses due to the pace of the process: a very large percentage of "waste products" (30%) at the quality control stage and a huge percentage of defective products due to their instability (70%). This directly influenced the sales of products - out of the assumed 70 thousand items, the Company sold 1,200 items of the product (1.71% of the plan).

Secondly, the nominal cost of production of the influenza test is twice as high as COVID-19 test, mainly due to the much longer research and development stage (36 months vs. 8 months), which generated much higher salary costs. The COVID-19

test was based on the knowledge previously acquired during the work on the influenza virus test and the process of its development took 8 months (R&D works plus the production scaling process). Nevertheless, on the basis of the monthly costs, the COVID-19 test development turned out to be much more expensive compared to the commercialization of the flu test. The average monthly cost for the SARS-CoV-2 test was 1/8 of the arbitrary cost unit, while for the flu test it was 1/18 of the arbitrary cost unit, which means twice higher monthly costs. Thus, the company incurred over-proportional expenses to commercialize only a partially reproducible test, focusing (prioritizing) on shortening the time to commercialization.

The company generally correctly identified the catalogue of risks related to the launch of the new test onto the market, noticing the dangers at various stages of the research and production processes (see Tables 1 and 2). However, at the beginning of the new project, the risk of achieving sufficient stability of the SARS-CoV-2 test was underestimated, being set at 30%. Meanwhile, this risk materialized in 75% of the produced tests. From a biological point of view, the reproducibility of the bioreceptor response is difficult to achieve, as seen in the previous work on the influenza test. Here, too, the adopted assumption of the similarity between the detection of influenza virus and SARS-CoV-2 as well as the biosensor response has left its mark.

The high level of risk associated with innovative projects became even higher due to the acceleration of research works and manifested itself in the form of a non-fully functional finished product, resulting in the need to continue work on a fully reproducible test for SARS-CoV-2. Conducting innovative activities in the circumstances of a perceived "window of opportunity" fully revealed the typical trade-offs:

- too early release of the product vs unused opportunities
- time-to-market vs development cost
- time-to-market vs product features.

Thanks to the mobilization of the research and production personnel, organizational improvements, the use of previous experience from developing the influenza test, the involvement of significant financial capital, and above all, the conviction of the company's management that the window of opportunity related to the launch of serial production of the SARS-CoV-2 test would close quickly - the time of development of the COVID-19 test was shortened to 8 months. The time to develop the company's second test was reduced significantly – by 77%, with the same structure and size of R&D staff. At the same time, the average monthly cost of developing and launching the SARS-CoV-2 test was twice (225%) the cost of developing the influenza test. Thus, the time-to-market vs development cost dilemma in the analyzed case indicates a relatively small increase in time benefits compared to expenses.

The results for the next trade-off, time-to-market vs. product features, are similarly unfavorable. Due to the lack of repeatability (18% share of stable tests in overall production), it should be concluded that the acceleration of commercialization had a negative impact on the features of the finished product. Despite the official registration of the COVID-19 test with the competent authority, the company has been continuing work on the test in order to scale up the production.

Seizing the window of opportunity initially appeared to be the main motivator for making the efforts to accelerate R&D activities. The company's management correctly identified the growing competition in the scope of development and subsequent production of SARS-CoV-2 tests. The time of launching the test on the market is associated with gaining a competitive advantage on the first mover basis. However, the desire to "fit into" the window of opportunity and overtake rivals overshadowed the critical assessment of test preparation for serial production. As a result, the company has to keep refining the product in the coming months, and during this time more tests are appearing on the market (FindDX, 2020).

The company commercialized too quickly (although the benefit of the formal registration of the SARS-CoV-2 test should be noted) and at this stage it is not obtaining any market or financial benefits, and even has to provide extra funds on additional R&D works. Thus, the analyzed case shows that there is indeed a strong complementary effect between starting the production of a new product too quickly and too slowly. If it is not possible to control the entire innovation process, this trade-off translates into no benefits, signaling that a better solution could be to enter the market later with a refined product, even in the face of a narrow "window of opportunity".

6. Summary

From a cognitive point of view, the analyzed commercialization of the SARS-CoV-2 test is an interesting study of the use of the emerging window of opportunity, if there is an objective (forced by social and economic needs) need to accelerate work on a new product, and on the other hand, if there is a previously proven potential for effective implementation of innovation. In such circumstances, the mobilization of human and financial resources takes place, organizational and management improvements are applied, and the managers conduct the project with great determination, striving for the fastest possible market success. However, in line with theoretical assumptions, when the window of opportunity is short, the enterprises unavoidably face the trade-offs associated with the optimization of time, cost, risk and the moment of product launch (Bayus, 1997).

As the analyzed case study shows, the benefits of quick product development and serial production launch may be disproportionately small in such conditions compared to the expected market effects (market share, building brand awareness, competitive position), financial (profits, costs) and the necessity to refine the product

functionality. Despite the time pressure, it is advisable to follow the main principles of conducting the research process, in particular, defining milestones in advance, exercising critical approach to formulating assumptions, taking care of good communication between R&D discipline teams, making at least a preliminary trade-off calculation.

There is an opinion expressed in the literature on the subject that quality can be sacrificed at the altar of accelerating R&D work on biotechnological products (Linton and Xu, 2021). However, as the analyzed case shows, there is a minimum product functionality below which a positive commercialization effect cannot be expected. Only after exceeding this limit can the functions of the product be modified. In the case of a medical test - the quality of the device is primarily related to the repeatability of measurement, which the company did not manage to ensure to a sufficient degree. The above conclusions are consistent with the Minimum Viable Product concept and suggest its wider adoption in the biotechnology industry (Still, 2017).

The case study presented here indicates that despite the feeling of strong (and objectively present) urgency to launch serial production of the SARS-CoV-2 test, it is necessary to precisely define the features/parameters of the finished product and to control the behavior of the above elements throughout the commercialization process. The problem is that it must be done at the very beginning of product development process, largely without full awareness of the effects that can be achieved. However, as this example shows, without defining the functionality more precisely, decision-makers may focus on a single factor (time to commercialization, to the detriment of other aspects (cost, features). And this, in turn, ultimately led to the need to improve the COVID-19 test, thus eliminating the chances of commercializing the product within the window of opportunity and at the same time generating a considerable cost increase. Further investments necessary in the process of increasing the stability of the test and the growing number of competitors successfully commercializing their SARS-CoV-2 tests will most likely delay successful commercialization.

In the end of this paper, it is worth mentioning the limitations that the authors encountered in the research process. The basic limitation is related to the adopted method of case study analysis. Although this decision was made consciously regarding the nature of the analyzed phenomena (grasping the dynamic and situational innovation processes in *statu nascendi*), it translates directly into the limited possibility of generalizing the conclusions.

Another limitation concerns the local context of the conducted research. The analyzed company is located in Poland, and the office registering medical products operates in accordance with the Polish law. This raises issues of specific organizational culture and organizational behavior.

The research that is worth undertaking in the future is to conduct studies on the trade-off effects occurring in the process of commercialization of biomedical products using a wider sample. Another promising direction of research is conducting longitudinal studies analyzing the company in terms of the degree of improvement of innovation processes, increase in the substantive and management competences, and proficiency in trade-off calculation.

References:

Acosta, B., Acosta, M., Espinoza, B. 2016. Understanding innovation based on company optics: interpretation mistakes on the types of innovation developed. RAI Revista de Administração e Inovação, 13(4), 295-304. https://doi.org/10.1016/j.rai.2016.03.006.

Angus, D.C. 2020. Optimizing the Trade-off Between Learning and Doing in a Pandemic. Jama, 323(19), 1895-1896. https://doi.org/10.1001/jama.2020.4984.

Bayus, B.L. 1997. Speed-to-Market and New Product Performance Trade-offs. Journal of Product Innovation Management, 14(6), 485-497. https://doi.org/10.1016/S0737-6782(97)00062-3.

Calantone, R.J., Benedetto, C.A.D. 2000. Performance and time to market: accelerating cycle time with overlapping stages. IEEE Transactions on Engineering Management 47(2), 232-244. https://doi.org/10.1109/17.846790.

Cohen, M.A., Eliashberg, J., Ho, T.H. 1996. New Product Development: The Performance and Time-to-Market Tradeoff. Management Science, 42(2), 157-306. https://doi.org/10.1287/mnsc.42.2.173.

Cooper, R.G. 2019.The drivers of success in new-product development. Industrial Marketing Management, 76, 36-47. https://doi.org/10.1016/j.indmarman.2018.07.005.

Corallo, A. 2007. The Business Ecosystem as a Multiple Dynamic Network, in: Corallo, A., Passiante, G., Prencipe, A. (Ed.), The digital business ecosystem. Edward Elgar Publishing, Cheltenham.

Corso, M., Gastaldi, L. 2010. Managing ICT-driven Innovations to Overcome the Exploitation-Exploration Trade-off: A Multiple and Collaborative Research Methodology in the Italian Health Care Industry. 11th Int. CINet Conference "Practicing Innovation in Times of Discontinuity", Zürich (CH), 5-17. https://www.researchgate.net/publication/232708764_Managing_ICT-driven_Innovations_to_Overcome_the_Exploitation-Exploration_Trade-off_A_Multiple_and_Collaborative_Research_Methodology_in_the_Italian_Health_Care_Industry.

Coughlan, P., Coghlan D. 2016. Action research, in: C. Karlsson (Ed.), Research methods for operations management, 2nd ed. Routledge, New York.

Ehlers, R.U. 2011. Cost-Benefit, Risk and Trade-Off Analysis of Regulation, in: Ehlers R.U. (Ed.), Regulation of Biological Control Agents. Springer, Dordrecht, 139-153. https://doi.org/10.1007/978-90-481-3664-3_6.

FindDX, 2020. SARS-CoV-2 diagnostic pipeline. https://www.finddx.org/covid-19/pipeline/.

Frederiksen, M.H., Knudsen, M.P. 2017. From Creative Ideas to Innovation Performance: The Role of Assessment Criteria. Creativity and Innovation Management, 26(1), 60-74. https://doi.org/10.1111/caim.12204.

Grima, S., Dalli Gonzi, R., Thalassinos, I.E. 2020. The Impact of COVID-19 on Malta and its Economy and Sustainable Strategies. Available at SSRN: https://ssrn.com/abstract=3644833,

Hirsch, G., Trusheim, M., Cobbs, E., Bala, M., Garner, S., Hartman, D., Isaacs, K., Lumpkin, M., Lim, R., Oye, K., Pezalla, E., Saltonstall, P., Selker, H. 2016. Adaptive Biomedical Innovation: Evolving Our Global System to Sustainably and Safely Bring New Medicines to Patients in Need. Clinical Pharmacology & Therapeutics, 100(6), 685-698. https://doi.org/10.1002/cpt.509.

Khan, S., Rabbani, R.M., Thalassinos, I.E., Atif, M. 2020. Corona Virus Pandemic Paving Ways to Next Generation of Learning and Teaching: Futuristic Cloud Based Educational Model. Available at SSRN: https://ssrn.com/abstract=3669832.

Kim, J.Y., Kang, S.H. 2019. Windows of Opportunity, Capability, and Catch-up: The Chinese Game Industry. Journal of Contemporary Asia, 51(1), 132-156. https://doi.org/10.1080/00472336.2019.1656761.

Kim, Y. 2017. The effect of process management on different types of innovations: An analytical modeling approach. European Journal of Operational Research, 262(2), 771-779. https://doi.org/10.1016/j.ejor.2017.03.064.

Lehrer, M., Nell, P., Gärber, L. 2009. A national systems view of university entrepreneurialism: Inferences from comparison of the German and US experience. Research Policy, 38(2), 268-280. https://doi.org/10.1016/j.respol.2008.11.007.

Linton, J.D., Xu, W. 2021. Understanding and Managing the Biotechnology Valley of Death. Trends in Biotechnology 39(2), 107-110. https://doi.org/10.1016/j.tibtech.2020.06.013.

Messica A., Mehrez A. 2002. Time-to-market, window of opportunity, and salvageability of a new product development. Managerial and Decision Economics. 23(6), 371-378. https://doi.org/10.1002/mde.1074.

Oslo Manual. 2018. Guidelines for Collecting, Reporting and Using Data on Innovation, 4th Edition, The Measurement of Scientific, Technological and Innovation Activities. OECD Publishing, Paris/Eurostat, Luxembourg. https://doi.org/10.1787/9789264304604-en.

Parthasarthy, R., Hammond, J. 2002. Product innovation input and outcome: moderating effects of the innovation process. Journal of Engineering and Technology Management, 19(1), 75-91. https://doi.org/10.1016/S0923-4748(01)00047-9.

Roin, B.N. 2014. The Case for Tailoring Patent Awards Based on the Time-to-Market of Inventions. UCLA Law Review, 61, 672. http://dx.doi.org/10.2139/ssrn.2235354.

Saunila, M. 2020. Innovation capability in SMEs: A systematic review of the literature. Journal of Innovation & Knowledge, 5, 260-265. https://doi.org/10.1016/j.jik.2019.11.002.

Still, K. 2017. Accelerating Research Innovation by Adopting the Lean Startup Paradigm. Technology Innovation Management Review, 7(5), 32-43. http://doi.org/10.22215/timreview/1075.

Weigelt, C., Sarkar, M.B. 2012. Performance implications of outsourcing for technological innovations: managing the efficiency and adaptability trade-off. Strategic Management Journal, 33(2), 189-216. https://doi.org/10.1002/smj.951.

Yin, R.K. 2017. Case Study Research and Applications: Design and Methods. sixth ed. Sage publications, Los Angeles.