

TOWARD THE "NEW NORMAL" AFTER COVID-19 – A POST-TRANSITION ECONOMY PERSPECTIVE

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Editors

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7. Challenges for innovation cooperation in the biopharmaceutical industry during the Covid-19 pandemic¹



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Abstract

Purpose: This chapter seeks to verify the development of new partnerships and R&D alliances in the biopharmaceutical industry during the Covid-19 pandemic, but also to present the related challenges for innovation cooperation.

Design/methodology/approach: The main method applied in this research was scientific study, meaning that the study applied descriptive, comparative, documentation, and desk research methods, along with deductive and inductive forecasting.

Findings: The text presents new partnerships undertaken by biopharma companies (in and outside the industry) in order to face the pandemic and to discover and deliver a new vaccine for SARS-CoV-2 to the market. Moreover, the chapter describes the research projects in the European Union focused on the Covid-19 pandemic defeating. Thanks to more flexible and open cooperation, companies will greatly support the possibility to defeat the Covid-19 pandemic faster.

Practical Implications: We should consider that due to the current situation caused by the Covid-19 pandemic, the cooperation of companies and all entities in the biopharmaceutical R&D innovation ecosystem is even more challenging than before. Moreover, we should re-

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member that the organizational fluidity of open innovation initiatives and multiparty relations increases the complexity of alliance management. The use of an open innovation model can significantly hasten the production process of new drugs and vaccines.

Originality and value: Biopharma-university alliances can significantly increase the likelihood of creating better medical therapies for patients. Results of such cooperation enable a number of innovative projects, given the significant pressure on innovativeness and challenges caused by the pandemic. Using the latest IT technologies will allow physicians to even better monitor, diagnose, and care for patients with a focus on the patient-centered approach.

Keywords: COVID-19 pandemic, innovation cooperation, open innovation, R&D alliances, patient care.

7.1. Introduction

The main aim of the chapter is to verify the development of new partnerships and R&D alliances in the biopharmaceutical industry during the Covid-19 pandemic. The author will present new partnerships undertaken by biopharma companies (in and outside the industry) in order to face the pandemic and discover and deliver a new vaccine for SARS-CoV-2 to the market. We should remember that due to the current situation caused by pandemic, the cooperation of companies and all entities in the whole biopharmaceutical R&D innovation ecosystem is even more challenging than before the Covid-19 pandemic. Biopharma-university alliances can significantly increase the likelihood of creating better medical therapy for patients. In addition to partnerships within the industry, biopharma companies establish relationships with universities or research institutes as well as more often cross-industry alliances and public-private partnerships. This cooperation enables several innovative projects and allows significant synergy effects, given significant pressures on innovativeness and challenges caused by the pandemic.

7.2. Development of modes of cooperation in the biopharmaceutical industry

Biopharmaceutical (pharma and biotech) companies have developed cooperation with universities for many years. At the beginning, it was mainly focused on individual projects, from small research projects to large clinical trials. Later, the companies developed alliances with individual academic institutions, including a wider range of cooperation through research programs, clinical trials, and translational research. Companies also increasingly began to use different models of R&D alliances, from individual links in research projects to multilateral agreements involving multiple research projects, including various models for

open innovation (Chesbrough, 2003). According to the latest definition by Chesbrough, open innovation is “a distributed innovation process based on purposively managed knowledge flows across organizational boundaries, using pecuniary and non-pecuniary mechanisms in line with each organization’s business model” (Chesbrough & Bogers, 2014, p. 17). This concept can be developed in bilateral and multilateral alliances. In comparison to traditional alliances, the open innovation model is more dynamic because partners in an alliance are not identified in the conventional, purposeful way. Cooperation is focused more on the exchange of knowledge and ideas during the period preceding the creation of the alliance. The main purpose of open innovation alliances is to support the free flow of knowledge and ideas leading to the creation of partnerships aimed not only at joint innovation but also risk and profit sharing (Wilks & Prothmann 2012). The results of research on open innovation show how firms manage both the inflows and outflows of knowledge and how they seek partners and innovations (Culpan, 2014; West, 2014; Chesbrough, 2019). We can also observe how companies in specific industries (like biopharma) use the model of open innovation to establish open innovation alliances not only with firms from the same or other industry but also with universities, individuals, communities, and other organizations (Wilks & Prothmann, 2012; Deloitte, 2017). We should consider that the organizational fluidity of open innovation initiatives and multiparty relations increase the complexity in the alliance management. The use of open innovation model can significantly speed up the production process of new drugs and vaccines, which are in demand on the market because of Covid-19 pandemic (Chesbrough, 2020b). More interdisciplinary academic teams can also accelerate and support this process (Wilks & Prothmann, 2012). Open innovation was implemented by companies in several ways, including innovations for users, crowdsourcing, the creation of joint development alliances, and through building innovative ecosystems (Deloitte, 2017; Hanson, 2015; Puślecki, 2015, 2016; Puślecki & Staszków, 2015; Wilks & Prothmann, 2012).

7.3. Characterizing the biopharmaceutical R&D innovation ecosystem

Innovation cooperation developed in biopharmaceutical R&D ecosystem enables important scientific breakthroughs in novel diagnostic technologies and the definition of molecular targets for the development of personalized medicines. These advances impact the current development of new drugs during the Covid-19 pandemic and improve health care. Biopharmaceutical companies involved in cooperation can develop targeted therapies and drugs needed to treat serious diseases and unmet medical needs (Gomes-Casseres, 2014; Deloitte, 2017, Chesbrough, 2020a)

and have better innovation cooperation performance (Trąpczyński, Puślecki, & Staszaków 2018). The biopharmaceutical R&D ecosystem is composed of a varied group of stakeholders (Figure 1), which makes it possible for them to achieve together what would be difficult for individual entities.

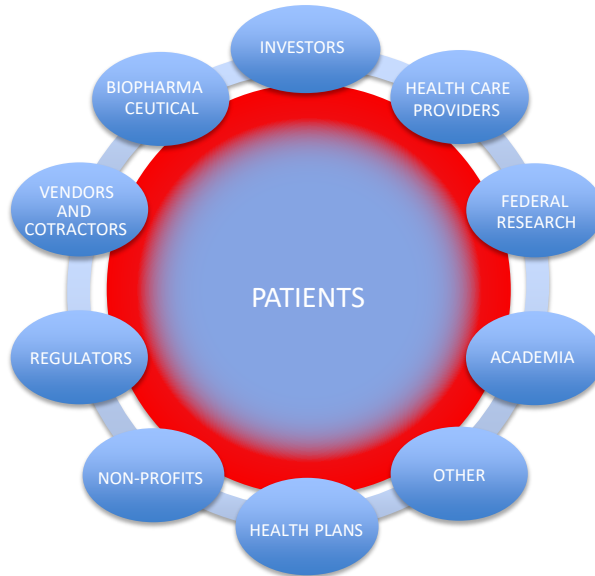


Figure 1. Illustrative biopharmaceutical R&D innovation ecosystem

Source: Own elaboration of (Deloitte, 2017, p. 11).

In the R&D ecosystem biopharma companies are responsible for two functions: they are contributors and integrators of the ecosystem. They gather diverse stakeholders offering distinct characteristics and contributions with a common goal of improving patient health outcomes. Patients are positioned as the hub of the ecosystem, as both key participants in driving *patient-centered innovation* and recipients of the value created as a result of cooperation in the ecosystem (Deloitte, 2017).

7.4. Growing diversification of partnership models and approaches in R&D cooperation: Covid-19 vaccines and research projects

When analyzing examples of partnerships in biopharmaceutical industry, we observe different modes of cooperation: R&D alliances, open innovation alliances,

public-private partnerships, consortia, pharma-university alliances, cross-industry alliances (especially with the IT industry), along with different entities involved in cooperation such as governments, universities, research institutes, foundations, funds, banks, and other organizations. As multiparty alliances, these partnerships require even greater competencies and skills of alliance, managers and appropriate alliance management tools. Thanks to significant synergy effects, participation in an R&D innovation ecosystem gives its partners access to huge innovative potential and more market opportunities, which helps them to innovate, accelerate growth, and expand into new promising markets (Fraser, 2014; Burke, 2020; De Man, 2018, 2020; De Man & Luvinson, 2019; De Man, Koene, & Ars, 2019).

Taking into consideration current challenges impacting the biopharmaceutical R&D environment – the Covid-19 pandemic – the development of collaborative relationships can help partners to obtain scientific and technological advances and offer new innovations like new vaccines and drug to patients faster (Table 1). Like drugs, potential vaccines must pass through stages of clinical trials. It is very important for their safety, even during the Covid-19 pandemic. Currently, scientists are testing 50 candidate vaccines in clinical trials on people. Additional 150 candidate vaccines are in preclinical development, including animal and laboratory testing. In China and Russia, six vaccines received limited or early approval (before the completion of phase 3 clinical trials), which raised concerns about their safety (Healthline, 2020).

Table 1. Selected ongoing Covid-19 vaccine projects

Name/Partners	Description	Results
Moderna/ National Institutes of Health	The company began testing its two-dose messenger RNA (mRNA) vaccine in March 2020 in phase 1 clinical trial to promising results. In late July 2020, Moderna began phase 3 clinical trials of the vaccine.	In mid-November 2020, Moderna officials reported that their vaccine achieved the effective rate of 94 percent in initial phase 3 trial results. Experts said more testing and more information is needed.
Pfizer / BioNTech / Fosun Pharma	Drugmaker Pfizer teamed up with the German biotech company BioNTech and Chinese drugmaker Fosun Pharma to develop a two-dose mRNA vaccine.	On November 9, 2020 the company announced that its vaccine had been more than 90 percent effective in clinical trial participants. A few days later, company officials announced they were applying for an emergency use authorization from the FDA for their vaccine. It was the first regulatory approval in the United States for a Covid-19 vaccine. The officials said the vaccine could be available to high-risk groups as early as mid-December 2020.

Table 1 cont.

Name/Partners	Description	Results
Johnson & Johnson	Drugmaker Johnson & Johnson announced in late July 2020 that it began a phase 1–2 trial in people after their adenovirus vaccine had shown promising results when used on monkeys.	In mid-November, Johnson & Johnson officials said they expected their vaccine to be ready for FDA approval by February 2021.
AstraZeneca/ the University of Oxford	A phase 1 clinical trial at the University of Oxford began in late April. The vaccine is based on a chimpanzee adenovirus, which shuttles coronavirus proteins into cells.	In August 2020, AstraZeneca began phase 3 trials in Brazil, South Africa, and the USA. These trials were halted in September when a study volunteer developed a rare spinal inflammatory disorder called transverse myelitis. The trials were restarted a week later in Brazil and the United Kingdom. In late October, the FDA authorized the US trial to resume. In mid-November 2020, company officials said their vaccine had produced a strong immune response in a clinical trial that involved people over the age of 70.
Sanofi / GSK / TranslateBio	Drugmaker Sanofi pursues two vaccines. The company is working with drugmaker GSK on a vaccine based on proteins from the coronavirus. When combined with another compound, called an adjuvant, the proteins elicit an immune response.	They expect results from a phase 2 trial in early December 2020, after which they will begin a phase 3 study. Sanofi is also working with biotech company Translate Bio to develop an mRNA vaccine. They expect to start clinical trials in December 2020.
CanSino Biologics	Scientists at this Chinese company are also working on a potential vaccine that uses an adenovirus known as Ad5 to carry coronavirus proteins into cells.	The Chinese military approved the vaccine in June 2020, allowing the vaccine to be given to its armed forces. In August, the company began phase 3 trials in Pakistan, Saudi Arabia, and Russia.
Gamaleya Research Institute	This Russian institute developed a vaccine that includes two adenoviruses, Ad5 and Ad26.	Russian officials said the vaccine received a “conditional registration certificate.” Results of a phase 1–2 trial found that the vaccine elicited an immune response with mild side effects. Phase 3 trials are currently under way in Russia, Belarus, the United Arab Emirates, and India.
Beijing Institute of Biological Products / Sinopharm	Sinopharm is testing a second inactivated virus vaccine developed by Beijing Institute of Biological Products.	Phase 3 trials began in June 2020 in the UAE and in September 2020 in Argentina. In September 2020, the UAE approved the vaccine for use on health care workers even before the results of the phase 3 trials.
Sinovac Biotech	This Chinese company launched phase 3 trials of its inactivated virus vaccine in Brazil in July, Indonesia in August, and Turkey in September 2020.	In August 2020, the Chinese government issued emergency approval for the vaccine for use on high-risk groups.

Source: Own elaboration based on (Healthline, 2020).

Due to the challenges caused by Covid-19 pandemic we can also observe the development of new research projects on coronavirus diagnostics and treatments financed by the Innovative Medicines Initiative (IMI) with the total amount of EUR 72 mln (IMI, 2020) but also by the European Commission (2020). Until September 2020, the EU already invested EUR 458.9 mln from Horizon 2020 in 103 research projects specifically targeting the Covid-19 pandemic, also including partners from the Central and Eastern Europe (CEE) region (Table 2).

Table 2. Selected research projects on coronavirus diagnostics and treatments and vaccines including also partners from the CEE region

Acronym/ Title	Description	Project coordinator	Partners	Funding body
PREPAREDNESS AND RESPONSE				
I-MOVE-Covid-19: Multidisciplinary European network for research, prevention and control of the Covid-19 Pandemic	To obtain epidemiological, clinical and virological information on coronavirus and infected patients through the I-MOVE surveillance network spanning 11 countries.	Epiconcept (FR)	25 partners: Albania , Germany, Spain (5), France (5), Ireland, Lithuania , Netherlands (2), Portugal (2), Romania , Sweden, UK (5)	Horizon 2020
HERoS: Health Emergency Response in Interconnected Systems	To improve the effectiveness and efficiency of the response to coronavirus outbreak by providing guidelines for improved crisis governance.	Svenskhandelshögskolan (FI)	11 partners: France, Finland (2), Italy, Netherlands (2), Poland (3) , UK, US	Horizon 2020
EXSCALATE4CoV: EXaScale smart platform against pathogens for the coronavirus	To exploit powerful computing resources to identify molecules capable of targeting coronavirus and develop an effective tool to counter future pandemics.	Dompéfarmaceutici (IT)	18 partners: Belgium, Switzerland (2), Germany (2), Spain, Italy (10), Poland , Sweden	Horizon 2020
DIAGNOSTICS				
Covid-RED: Covid-19 infections – remote early detection	The project will combine expertise in clinical epidemiology with digital devices (such as wearables and mobile apps) to rapidly and reliably detect Covid-19 cases so that they can be prioritized for testing.	Universitair Medisch Centrum Utrecht, The Netherlands	9 partners from Denmark, Lithuania , the Netherlands, Switzerland, UK	Innovative Medicines Initiative (IMI)

Table 2 cont.

Acronym/ Title	Description	Project coordinator	Partners	Funding body
DRAGON: Rapid and secure AI-imaging-based diagnosis, stratification, follow-up, and preparedness for coronavirus pandemics	The project will apply artificial intelligence and machine learning to deliver a decision support system for improved and more rapid diagnosis of Covid-19 and prognosis. Citizens and patients will be involved in the development of the system.	Oncoradiomics, Belgium	21 partners from Belgium, China, Italy, the Netherlands, Switzerland, UK	IMI
RAPID-Covid: Robust automation and point of care identification of Covid	While the world focuses on Covid-19, other infectious diseases with similar symptoms continue to circulate. The RAPID-Covid project aims to develop a diagnostic test that can simultaneously detect SARS-CoV-2 as well as 30 other common respiratory bacteria and viruses.	GeneFirst Limited, UK	5 partners from France, Slovenia , Spain, UK	IMI
CoronaDX: Three Rapid Diagnostic tests (Point-of-Care) for Covid-19 coronavirus, improving pandemic preparedness, public health and socio-economic benefits	To deliver three complementary diagnostic tools, including one point-of-care diagnostic that can be used with minimal training	Danmarks Tekniske Universitet (DK)	8 partners: Austria, China (2), Denmark (2), Italy (2), Sweden	Horizon 2020
TREATMENT				
CARE: Corona accelerated R&D in Europe	The goal is to deliver treatments for the current Covid-19 outbreak as well as future coronavirus outbreaks. To do this, they will identify candidates among existing drugs that could be effective as treatments for the Covid-19 pandemic (drug repurposing), and develop new drugs specially designed to tackle the SARS-CoV-2 virus.	Institut National de la Santé et de la Recherche Médicale (INSERM), France	36 partners from Belgium, China, Denmark, France, Germany, the Netherlands, Poland , Spain, Switzerland, UK, US	IMI
SCORE: Swift Coronavirus therapeutics Response	To develop a combination of anti-viral treatments for patients infected with the coronavirus.	Academisch Ziekenhuis Leiden (NL)	10 partners: Belgium (3), Switzerland, Germany (2), France (2), Netherlands (2)	Horizon 2020

Table 2 cont.

Acronym/ Title	Description	Project coordinator	Partners	Funding body
MANCO: Monoclonal Antibodies against 2019–New Coronavirus	To develop and evaluate monoclonal antibodies as treatments against coronavirus.	Erasmus Universitair Medisch Centrum Rotterdam (NL)	8 partners: Germany, Spain, France (2), Netherlands (4)	Horizon 2020
VACCINES				
OPENCORONA: Rapid therapy development through Open Coronavirus Vaccine Platform	To develop a vaccine that can also be used as a therapy against the coronavirus using a DNA vaccine platform.	Karolinska Institutet (SE)	7 partners: Germany, Italy, Sweden (5)	Horizon 2020
Prevent-nCoV: Prevention of 2019 nCoV infection through development and clinical testing of a novel Virus Like Particle (VLP) vaccine	To develop and evaluate a potential vaccine that uses virus-like particles to expose coronavirus proteins to the immune system	Københavns Universitet (DK)	6 partners: Germany, Denmark (3), Netherlands (2)	Horizon 2020

Source: Own elaboration based on (IMI, 2020; European Commission, 2020).

These research projects focus on the development of diagnostics, treatments, vaccines, epidemiology, preparedness, and response to outbreaks, socioeconomics, production, and digital technologies, but also the infrastructures and data resources that enable this research. The involvement of many different partners in innovating cooperation, including biopharmaceutical companies and academia, can contribute to the faster overcoming of challenges related to the Covid-19 pandemic.

7.5. Conclusions

Biopharmaceutical companies involved in innovation cooperation with academic institutions – especially in the model of open innovation alliances – can significantly reduce the risk and cost of research, use the resources, competencies, technology, and knowledge from partners, and thus easier respond to changes in the dynamic environment and most of all, quickly launch new biotechnology or pharmaceutical products (new vaccines and drugs), along with better diagnostics and treatment of patients that are now desired because of the Covid-19 pandemic.

Stopping the growing pandemic requires speed, agility, and cooperation. Openness mobilizes knowledge from many different places, making science

progress and accelerating our progress in the fight against the disease. Openness unleashes a volunteer army of scientists working in their own facilities, in different time zones, and in different countries. Openness uses human capital available in the world to fight the disease, but it also utilizes access to already existing physical capital (such as factories and equipment) to begin the rapid testing of possible solutions. Open innovation can speed up action. More than 50 vaccine candidates under consideration are already approved drugs for other medical uses (being repurposed). This means that the baseline safe dosage levels for any candidate in humans have already been established. This allows for testing to begin in the middle of the normal drug development process, with phase 1 of clinical trials safety protocols already completed. Making all relevant medical research available at the same time in a machine-readable form allows for rapid learning by anyone who wants to look at it, which enables scientists around the world to contribute to the fight against the pandemic (Chesbrough, 2020a, b).

Nevertheless, finding a vaccine is not enough. We must think about logistic issues regarding the transport of vaccines (mRNA vaccine) in proper temperature and about the distribution and delivery of vaccines to millions of people. Mass vaccination is a giant logistics operation. Some airlines (Air France-KLM) prepare Covid-19 vaccines airlift in order to deliver the vaccines in the right way, by using dry ice. Openness could help here as well: we may learn from each other and use good practices, which could be further applied by other airlines in the vaccines' delivery.

Companies must be more open to cooperation (Chesbrough, 2020a, 2020b.), change their business models (Puślecki, 2020; Chesbrough, 2020b), and use local potential and partners to develop better therapies for patients in times of the pandemic, e.g. the use of ECMO to support patients with Covid-19 (Czekajlo, Dabrowski, Puslecki, Drozd, & Szarpak, 2020). Moreover, we should consider whether the pandemic brings a decrease or an increase in cooperation between companies. The answer is not clear cut. It seems that in the long run, the consequence of the pandemic on some companies will be the increased interest in the development of cooperative behavior. The challenges of the Covid-19 pandemic may become a development opportunity and have a positive impact on R&D and pro-innovation activities. The crisis caused by pandemic shows that companies have real opportunities to contribute to social welfare and, by acting so, they can obtain the economic benefits of such actions (Gorynia & Jankowska, 2020).

The Covid-19 pandemic contributed to the development of new strategic partnerships in the biopharmaceutical industry, also in the open model (open innovation alliances). Additionally, we observe the involvement of many companies from biopharma in cooperation with IT companies in order to develop diagnostic tools using the latest technologies: IoT, AI, Machine Learning, and Blockchain,

along with the progressive digitalization of health care such as telemedicine, med-Health, and digitalHealth. Since the end of the 1980s, the world has seen more and more non-equity R&D alliances in the biopharmaceutical industry (Puślecki, 2012), which provide greater flexibility in the selection and possible change of partners, and they also enable a faster change of technology than traditional equity alliances. This trend is also visible in Central and Eastern Europe (CEE). The results of quantitative research conducted within research grant entitled “Analysis of Open Innovation Alliances and Strategic Partnerships in the Biopharmaceutical Industry in Poland and CEE countries” show that over 80% of companies from the biopharmaceutical industry from 18 CEE countries carried out mainly R&D non-equity alliances in the development of innovation cooperation in years 2015–2017. Thanks to more flexible cooperation and business models, it will be possible to defeat the coronavirus pandemic faster.

The “new normal” after Covid-19 will be different, we will be different, richer in knowledge and experience from the current coronavirus, which will allow us to prepare for future pandemics through better care for our health, faster diagnoses, and better treatments. Having vaccines for the current coronavirus will make it easier to work on possible new drugs and vaccines in the event of future pandemics as part of expanded R&D innovation ecosystems and the involvement of many partners in the cooperation. Using the latest IT technologies will make it be possible to even better monitor, diagnose (DigitalHealth), and care for patients with focus on the patient-centered approach: “Good ideas can come from anywhere, making openness is an imperative in these times of crisis. Global public health simply works better – and faster – when we open up” (Chesbrough, 2020b, p. 413). Through our involvement in cooperation, the evolution of our pandemic-induced behavior, we can further contribute to the building of the common good (Thaler, 2015; Mruk, 2018).

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Part II

CHALLENGES FOR BUSINESS SECTORS AND INDUSTRIES

1. Internal substitution in the tourism market: Effects of the Covid-19 pandemic (*Agnieszka Niezgoda, Ewa Markiewicz, Klaudyna Kowalska*) <https://doi.org/10.18559/978-83-8211-061-6/III>
2. Effects of the Covid-19 pandemic on sport, video game, and tourism industry: Sentiment analysis of press, Internet articles and Twitter data (*Łukasz Bryl, Justyna Majewska, Szymon Truskolaski*) <https://doi.org/10.18559/978-83-8211-061-6/II2>
3. Goods road transport sector facing pandemic crisis (*Piotr Banaszyk, Sylwia Konecka, Anna Maryniak*) <https://doi.org/10.18559/978-83-8211-061-6/II3>
4. The Polish logistics real estate market as a link in international supply chains during the Covid-19 crisis (*Waldemar Budner*) <https://doi.org/10.18559/978-83-8211-061-6/II4>
5. Covid-19 disruption of European agri-food markets: The case of Poland (*Magdalena Śliwińska, Rafał Śliwiński*) <https://doi.org/10.18559/978-83-8211-061-6/II5>

6. Consumer acceptance of AR technology in e-commerce in the light of the Covid-19 pandemic: A conceptual perspective (*Małgorzata Bartosik-Purgat, Tomasz Grzegorzczak, Wiktoria Rakowska*) <https://doi.org/10.18559/978-83-8211-061-6/II6>
7. Challenges for innovation co-operation in the biopharmaceutical industry during the Covid-19 pandemic (*Lukasz Puślecki*) <https://doi.org/10.18559/978-83-8211-061-6/II7>

Part III

CHALLENGES FOR COMPANIES

1. The adoption of Industry 4.0 solutions as a remedy against the pandemic crisis—the case of Polish companies (*Barbara Jankowska, Ewa Mińska-Struzik*) <https://doi.org/10.18559/978-83-8211-061-6/III1>
2. Future competences in times of an economic crisis (*Anna Łupicka*) <https://doi.org/10.18559/978-83-8211-061-6/III2>
3. The impact of the crisis on the maintenance of sustainable development initiatives: A comparative analysis of local and international companies (*Lukasz Małys*) <https://doi.org/10.18559/978-83-8211-061-6/III3>
4. Women's entrepreneurship in the Covid-19 pandemic (*Alicja Hadryś*) <https://doi.org/10.18559/978-83-8211-061-6/III4>
5. Challenges in currency derivatives management in the OTC market in Poland during the Covid-19 pandemic (*Piotr Wybieralski*) <https://doi.org/10.18559/978-83-8211-061-6/III5>
6. Donation crowdfunding as a source of relief for small businesses (*Marcin Wieczerzycki*) <https://doi.org/10.18559/978-83-8211-061-6/III6>