

The fast response of academic spinoffs to unexpected societal and economic challenges. Lessons from the COVID19 pandemic crisis

*Original*

The fast response of academic spinoffs to unexpected societal and economic challenges. Lessons from the COVID19 pandemic crisis / Battaglia, Daniele; Paolucci, Emilio; Ughetto, Elisa. - In: R & D MANAGEMENT. - ISSN 0033-6807. - ELETTRONICO. - 51:2(2021), pp. 169-182. [10.1111/radm.12444]

*Availability:*

This version is available at: 11583/2853755 since: 2022-03-14T15:59:32Z

*Publisher:*

Wiley

*Published*

DOI:10.1111/radm.12444

*Terms of use:*

openAccess

This article is made available under terms and conditions as specified in the corresponding bibliographic description in the repository

*Publisher copyright*

Wiley postprint/Author's Accepted Manuscript

This is the peer reviewed version of the above quoted article, which has been published in final form at <http://dx.doi.org/10.1111/radm.12444>. This article may be used for non-commercial purposes in accordance with Wiley Terms and Conditions for Use of Self-Archived Versions.

(Article begins on next page)

# The fast response of academic spinoffs to unexpected societal and economic challenges. Lessons from the COVID-19 pandemic crisis.

*Daniele Battaglia, Emilio Paolucci and Elisa Ughetto*

*Accepted manuscript at R&D Management*

## Abstract

The rapid emergence of the COVID-19 crisis has challenged both private and public firms, requiring them to reshape their internal processes and external linkages in the fight against the virus, but also to survive the disrupting economic impact of the pandemic on their activities. Academic spinoffs have not been exempted from these dynamics. In this paper, we present and discuss a case study of an academic spinoff, Omnidermal, which has developed a new, efficient and easy-to-realize emergency life support machine for use in intensive and sub-intensive care units.

This case, apart from offering information on the best practices of how spinoffs may contribute socially to the fight against COVID-19 and – more in general – against other exogenous shocks, also provides insights on their stages of development, evolution patterns and ability to define new solutions. The case shows that when the market needs are clear to a firm (as in the case of medical devices during the COVID-19 crisis), the “legacy competences and practices” of spinoffs (i.e., technical competences and work practices) can be fully exploited to compress the development time and to realize products demanded by the market. We also identify access to a network as being an essential boundary condition for this process.

These results introduce an alternative scope for academic spinoffs. Given the “legacy competences and practices” they are able to develop, they are ideal candidates to respond to the societal and economic challenges posed by a crisis over short periods of time. On the basis of these insights, we draw a series of implications for practitioners, policy makers and academics.

**Keywords:** Academic spinoff; Academic entrepreneurship; University spinoff; Spinoff development; Spinoff growth; Technology transfer; University; COVID-19

## 1. Introduction

The recent global shock caused by the rapid diffusion of COVID-19 has challenged businesses all over the world (Bartik et al., 2020; Saglietto et al., 2020), with dramatic consequences on many industrial segments (e.g., the temporary shutdown of firms, resource constraints to perform R&D activities, a reduction of the consumers’ willingness to buy new products or to adopt new innovations). Spinoffs have been affected dramatically by the pandemic outbreak: new challenges for their current business models have emerged, and have endangered their consolidation, growth and survival.

Previous research on academic spinoffs underlined that their growth occurs through a process that is mainly technology-push, that is, moving from basic research to market commercialization (Vohora et al., 2004). Despite the validity of this process, the adaptation of a new technology to the market has often been recognized to be lengthy and to rarely generate sustainable returns (Mathisen and Rasmussen, 2019). In this article, we complement this view by emphasizing how this technology-push process is instrumental in creating

a baseline of capabilities that enable academic spinoffs to quickly address new opportunities that emerge on the market later on. In particular, we show that academic spinoffs can adapt to changing external conditions by recombining previously acquired competences and knowledge, in order to promptly exploit new and sudden market opportunities, thus moving their development model from a technology-push to a market-pull one.

We develop this idea by presenting a case study of an Italian academic spinoff – Omnidermal – whose business was impacted directly by the COVID-19 outbreak, and which reacted to the threats imposed by the pandemic by exploiting new emerging business opportunities. Before the pandemic outbreak, Omnidermal was developing an artificial intelligence (AI)-based device (WoundViewer) for the assessment and monitoring of ulcers. With the advent of the COVID-19 emergency, the company converted a traditional Auxiliary Manual Breathing Unit (AMBU) device into an automated ventilator (Automatic Breathing Unit, ABU) to sustain the breathing deficiencies of COVID-19 patients who need hospitalization in intensive and sub-intensive care units (ICUs and SICUs).

This case study is of particular relevance for three main reasons. First, it outlines how academic spinoffs are able to react to exogenous shocks (like the one induced by the COVID-19 crisis) to reshape their business models and quickly provide solutions aimed at tackling society's needs. More specifically, the case shows how some “legacy competences and practices” that the company developed prior to the COVID-19 advent have been particularly effective in facing issues created by the COVID-19 pandemic and leveraging on the needs that the crisis created. An interesting result concerns the time that was required to develop the new product. Although the technological development and the search for a target market for WoundViewer required several years, the ABU prototype was developed in about 15 days. This evidence indicates that the spinoff was able to leverage on settled practices and competences and to recombine and redeploy them for the development of a new product.

Second, the case illustrates how COVID-19 has represented an exogenous “shock” for spinoffs (especially for those operating in the med-tech industry), forcing them to overcome the dictates imposed by the technology push development path highlighted by the previous literature (Vohora et al., 2004; Mathisen and Rasmussen, 2019). This technology-push process, which is often characterized by slowness and uncertainty, is frequently advocated to be an essential condition for the growth of academic spinoffs, as it

allows them to acquire sufficient market capabilities to understand market needs and improve the market fit of their product/s (van Geenhuizen and Soetanto, 2009). The case considered here shows how spinoffs can quickly reconfigure their business models, starting from the market needs (and not necessarily from technological development, as predicted by the technology-push development model) in order to seize new market opportunities and move toward a market-pull development model. In particular, the case reveals how Omnidermal was able to do so by leveraging on a set of prior legacies (i.e. technical competencies and work practices) and on the access to a network of consolidated partnerships.

Third, the Omnidermal case provides some key insights on the societal impact of science commercialization (Fini et al., 2018). While previous literature has underlined a lack of understanding on “how scientific research may lead to improved economic and societal impacts through science commercialization” (Fini et al., 2018: 5), our case study illustrates how the competences developed within academic spinoffs for the conversion of a scientific knowledge into a product can be recombined and used to generate new products able to solve critical societal challenges.

The remainder of the paper is organized as follows. We present our theoretical background in Section 2. Section 3 presents the methodology that was followed. Section 4 illustrates the Omnidermal case, which is then discussed in detail in Section 5. Section 6 concludes with some recommendations for policy makers and for future research.

## **2. Theoretical background**

### ***2.1 Academic spinoff development: stage model of growth, technology and market capabilities.***

The primary objectives of a spinoff, as for other entrepreneurial businesses, is to ensure the stable growth of the firm in order to survive and make profits, at least in the long term (Chiesa and Piccaluga, 2000). In order to do so, academic spinoffs work to bring scientific knowledge originating from university labs onto the market (Mustar et al., 2006). Their target is to develop research-based inventions (RBIs) into successful products to be sold on the market or, alternatively, into reliable technologies to be licensed out to larger incumbents (Mathisen and Rasmussen, 2019).

According to the literature, academic spinoff development is a process that occurs in five distinct phases (Vohora et al., 2004). The first three phases anticipate the formal establishment of the spinoff, while the last two phases occur ex-post to its founding. In the first phase, spinoffs typically focus on the development of a single technology resulting from university research. At this stage, nothing more than an invention (not even tested through a prototype) exists. In phase two, the research team generally receives valuable insights on the possible avenues for a commercial exploitation of the RBI, thanks to collaborations with the technology transfer office (TTO) or an external stakeholder (Algieri et al., 2013). This opportunity framing phase anticipates the pre-organization phase, in which the team undertakes strategic decisions for the future of the company, such as the amount of resources and the kind of knowledge that has to be acquired (Vohora et al., 2004).

The main obligations of formally setting up the company and start-up operations are accomplished between the third and the fourth phases. In phase four, spinoffs implement the early stages of their strategic planning, by continuously acquiring and integrating resources and knowledge to serve customers with a valuable product. The final phase, known as the “sustainable return phase”, is characterized by the definition of a precise business model to serve customers. Operations are put in place, customers are served, and the spinoff is a functioning company that attempts to scale the market.

Along the process outlined above, a spinoff has to develop both technological and market capabilities. Technological capabilities are idiosyncratic to the entrepreneurial team (Huynh et al., 2017) and can easily be improved over time. Market capabilities are instead more critical, because they require time and investments (van Geenhuizen and Soetanto, 2009; Hayter, 2011) and affect the survival and success of a spinoff (Abbate and Cesaroni, 2017). A correct understanding of the customers’ needs and market requirements is pivotal to increase a product-market fit or, more generally, to develop alternative business models to serve prospective customers (Clausen and Rasmussen, 2013).

In this stylized view of the evolution of an academic spinoff, each phase is characterized by the willingness of the firm to achieve a satisfactory product-market fit (Wright et al., 2012), which is realized through heavy investments of the available internal resources in technological developments and market

exploration activities.<sup>1</sup> The subsequent success and survival of an academic spinoff largely depends upon its capability to build connections (Prokop et al., 2019): with investors (who provide both financial resources and guidance in market exploration), with external entrepreneurs (who have the necessary business skills to explore the market) and with TTOs (in order to protect and market their RBIs).

A less linear position has been proposed by Lubik and colleagues (2013). While Vohora's model presents the development path of spinoffs as a technology-push process that linearly moves from the scientific discovery to the product commercialization, Lubik et al. (2013) propose a more articulated configuration. They argue that spinoffs undergo a series of development loops (e.g. in the upstream activities, as R&D, or in the downstream activities, as the marketing), which are activated by partners fuelling resources in each step. It follows that some partnerships (e.g. those with other spinoffs and those with academic institutions) are oriented toward the acquisition and development of technical capabilities, while others toward the acquisition of more exploratory capabilities in downstream activities.

## ***2.2 How academic spinoffs cope with the emergence of a sudden crisis: challenges and responses.***

The sudden diffusion of the coronavirus 2 (SARS-CoV-2) acute respiratory syndrome in 2019 and 2020 (Zhu et al., 2020) has challenged the growth and survival of many businesses (Bartik et al., 2020; Kuckertz et al., 2020). It has been observed that organizations are largely unprepared to face and respond to crises (Crandall et al., 2010). During crises, businesses are subject to turbulences that challenge their organizational structures, as well as the routines and capabilities they originally developed (Williams et al., 2017). Some businesses may put in place contingency plans in an attempt to anticipate the emergence of a crisis and its direct consequences, but this is quite rare in small entrepreneurial settings (Yamakawa and Cardon, 2017). Crises are therefore more severe for small entrepreneurial firms, who suffer from structural liabilities (e.g., liability of smallness, liability of newness), which in turn limit their prompt response to external shocks that challenge their current operations (Devece et al., 2016).

---

<sup>1</sup> It should be noted that founders of academic spinoffs usually develop a technology and then identify a commercial application. The contextual identification of a market opportunity with the development of a technology is very rare and has been proved only under particular circumstances, as when spinoff are created by star scientists (Thomas et al., 2020).

Entrepreneurial self-efficacy and resilience have been highlighted as crucial factors that may favour business growth under adverse conditions (Bullough et al., 2014). Resilience in fact triggers entrepreneurial intentions, which favor the recovery and transformations of businesses (Korber and McNaughton, 2018). In the context of the earthquake that occurred in Emilia Romagna (Italy) in 2012, Martinelli and colleagues (2018) showed that both dynamic capabilities and social capital were instrumental to the emergence and reinforcement of organizational resilience. The authors identified five capabilities that were necessary to overcome external shocks: i) the capability to reconfigure the existing resource base; ii) the capability to utilize and deploy the already available resources in new situations; iii) the capability to understand and forecast the environmental evolution; iv) the capability to learn from experimentation or through external resources; v) the capability to exploit long-term relationships linked to the personal network of entrepreneurs.

Despite these advancements, it is not clear how firms cope with uncertainty and potential adversities when a crisis occurs, especially when its emergence is sudden and impossible to anticipate, as in the case of COVID-19. This theme is even more compelling for entrepreneurial firms and for spinoffs in particular, as the financial resources they advocate are constrained and can only sustain activities for a limited period of time. More importantly, when spinoffs only concentrate on product-market fit (Vohora et al., 2004) and customer searches, they are rarely ready to change the focus of their business in response to environmental shocks that may suddenly change the competitive landscape and the priorities and preferences of their customers.

### **3. Methodology**

In this paper, we rely on a single case study design. We developed the case study by building on different sources of information. First, we collected material about the company and its products (i.e. WoundViewer and ABU) from the spinoff website and publicly available newspaper articles. We then complemented this information with the personal knowledge of one of the authors, who has been an advisor of the company since it was first set up. We used this preliminary information to identify the key themes necessary to guide the semi-structured interviews we then conducted with the founders. All three authors conducted a first round of interviews (lasting 1 hour) with one of the founders on April 19<sup>th</sup> 2020 <sup>2</sup>. At this

---

<sup>2</sup> The interview was conducted online, by means of a cloud-based team collaboration software (Microsoft Teams) and was recorded. Although high methodological standards of case study research recommend performing interviews face-to-face (e.g., Yin, 2017), we were prevented from doing so due to the lockdown measures in the authors and interviewees' country.

stage, we also asked spinoff founders to provide us with further confidential material, such as technical reports and other reserved documents. We proceeded to triangulate all the information as follows. Two of the three authors independently wrote a narrative of the case study, and the third author put together elements from the two cases in one final narrative. When any inconsistencies emerged, cross validation was performed with the spinoff team. On May 3<sup>rd</sup> and August 18<sup>th</sup>, 2020, we performed a second and third round of interviews with the other two founders of the company (each lasting 40 minutes). We first asked updates about the project and then investigated in detail some of the crucial aspects that emerged from the data triangulation. We then integrated the narrative with the new information, and we sent it to the entrepreneurs for a final cross-validation.

#### **4. The Omnidermal case**

According to our framework, we can divide the case into two different stages: before and after the outbreak of the COVID-19 pandemic. The first stage lasted around 3 years, and in that period Omnidermal's development patterns largely reflected Vohora et al.'s (2004) framework. The second stage, which started with the spread of the COVID-19 pandemic, prompted the company to stop testing its original Woundviewer product with hospitals and with other potential customers, and induced a change in its product-market offer in order to deal with this change.

##### **4.1 The story**

Omnidermal Biomedics was founded in 2017 by three Post Doc researchers (with a background in the biomedical field) as a spin-off of the Politecnico di Torino (henceforth, PoliTo), a technical university located in the north-west of Italy. Two founders have a background in Biomedical Engineering and one in Management Engineering. After graduation, two of them went on to obtain a PhD, at the Houston Methodist Research Institute (Houston, Texas) and at PoliTo, respectively, where they specialized in the development of implantable medical devices for drug delivery and in the development of artificial intelligence algorithms; the third cofounder worked for 18 months at the PoliTo TTO.

The long-term objective of the spin-off was to provide doctors and healthcare workers in the field of angiology, vascular and general surgery with a diagnostic tool - based on artificial intelligence - to optimize the treatment of patients through the use of accurate and objective data. To design a new solution to certain



existing medical problems, the founders leveraged on both the knowledge acquired during their PhD and the experience developed in hospitals. Since the inception of the spinoff, the team has invested in improving the scope of available competences. The first decision was to apply their theoretical knowledge about artificial intelligence to “precision and predictive medicine”; the second was to develop new competences on the main clinical protocols at an international level. Two founders also strengthened their managerial competences by obtaining an MBA degree. In 2017, the spinoff received from PoliTo a Proof of Concept (PoC) grant (€50 k) and started its activity, with the founders frequently travelling abroad in order to complete the development of their technology.

In 2018, the company received a first round of financing from a business angel and began to activate partnership agreements with a large software company that provides IT services and software to hospitals and for domiciliary assistance. It also consolidated the partnership with the partners that provided fundamental technical, scientific, legal and commercial support to the company’s activities<sup>3</sup>. Its Board of Advisors, composed of specialists and professionals from various fields, facilitated contact with the medical device industry.

The first product the company developed was WoundViewer (in collaboration with international and national scientific institutions). This is an AI-based device that was designed by “doctors for doctors”, which automatically provides the operator with all the essential clinical parameters to assess and monitor the pathological condition of skin ulcers. The device processes images and generates an objective, quantitative and standardized evaluation of a wound (i.e. tissue segmentation, ulcer classification, and precise values of an area, as well as the volume and depth of a wound), and promptly alerts healthcare professionals in the case of any deterioration in the conditions. Thanks to the potential of the WoundViewer technology, the President of the Italian Republic (Sergio Mattarella) awarded Omnidermal the “Premio Leonardo Biomedics 2018”.

In 2019, Omnidermal collected funds for around USD 700k from an industrial investor (PBL) and started performing on-field PoCs of WoundViewer with selected hospitals. The immediate effects were the

---

<sup>3</sup> The Politecnico di Torino, the Technische Universität Dresden (Germany) and the Collège des Ingénieurs are the university partners. The technical partners are AIUC (The Italian Association of skin ulcers), who were involved in the realization of the WoundViewer device, Corley srl, who were engaged in the high quality and safety standards in the data protection and management of clinical data field and Pegaso srl, who participated in the design of the devices.

development of new capabilities regarding the testing of products and a more robust reputation. The industrial investor also helped them internalize new competencies, in terms of manufacturing and the certification process. At the beginning of 2020, the spinoff was completing several tests with various potential customers.

The outbreak of the COVID-19 pandemic interrupted such a cycle of development since it was simply impossible for the hospitals to continue running these tests. Suddenly, the company entered a new stage of development, and the founders started thinking about how to positively contribute toward the current crisis by adapting the spinoff's capabilities to the new situation.

The reputation and the contacts developed in the past two years with hospitals helped the three co-founders understand that there was an urgent need for a large-scale production of ventilators. The fact that the incumbents in the ventilator industry were unable to satisfy the sudden rise in demand (i.e. the incumbents did not develop new products and they were not able to increase their output) worsened the shortage. The pandemic stopped international supply chains, and made it almost impossible to obtain a supply of ventilator components.

Such constraints immediately became clear to the Omnidermal team. They understood the necessity of a radical redesign of the concept of automated ventilators, and their experience led to the idea of transforming an already available manual ventilator into an automatic one at limited costs. Collaboration with doctors in different hospitals helped them to refine the idea and quickly define the requirements of a new product.

The new ABU is a transformation of a traditional AMBU device- which can be found onboard ambulances- into a real ventilator by using both flow and pressure sensors and a high precision electronic feedback system. The device is able to automate the process of forced ventilation and assisted ventilation. The device is also able to insert a continuous positive pressure flow for CPAP (Continuous Positive Airway Pressure), it can adjust FiO<sub>2</sub>, via an oxygen mixer or a Venturi valve, and can be connected to an oxygen-enriched air tank. The device allows the following clinical parameters to be electronically monitored: PEEP pressure (end-expiratory pressure that is applied to a patient when ventilated with invasive or non-invasive mechanical support), Peak pressure (Maximum airway pressure reached during insufflation), Air flow (Volume of air passing through a duct in the time unit), Tidal volume (Volume of air entering or leaving the respiratory system during each normal respiratory cycle), Respiratory frequency, Inhalation/expiration ratio,

Pressure Trigger, Flow Trigger and Backup ventilation. High precision sensors monitor the functioning of the ABU, guarantee security, and alert the operator if necessary.

The strength of the device resides in its intrinsic simplicity and efficiency (it can be produced quickly, and with no bottleneck in sourcing; it costs one third of the price of traditional ventilators), and has shown great flexibility in the management of ICU patients (both incoming and outgoing). Apart from guaranteeing ventilation for patients who are waiting for a standard ventilator in an ICU, it can also be used to allow extubated patients (weaning post ARDS - Acute respiratory distress syndrome) to restore normal breathing. By reducing the paucity of ventilators available for ICUs, it also lowers the ethical dilemmas that doctors have to face about which patients should be treated with ventilators and which patients should be left to die (Bazerman, M. H. Bernhard et al., 2020). The ability of the ABU device to face the COVID-19 emergency has led the company to become eligible for a national grant from Invitalia of €1M.

From a technical standpoint, the architecture of the new ABU product was a radical shift with respect to the previous product already developed by the firm (i.e. WoundViewer). Despite its lower complexity (the dominant components are hard rather than soft), the set of competences required to develop it was similar to WoundViewer<sup>4</sup>. Conversely, the new market dynamics connected with the ABU represented a radical shift for the company with respect to the past: under the pressure of the pandemic, the demand of the market immediately became clear, customers were ready to collaborate (without the intervention of any intermediary) and cofounders had to learn immediately about the requirements of the new application domain.

## **4.2 Key traits from the case**

The Omnidermal case is informative on how academic spinoffs may leverage on what we name as “legacy competences and practices” to quickly develop new products in emergency circumstances, forcing firms to rethink their activities, but with clearer market needs. We define “legacy competences and practices” as the set of capabilities that are deployed by the spinoff within a specific product-market domain and that are

---

<sup>4</sup> The only relevant difference is that while the ABU product required the inclusion of some software features to regulate its functioning to constantly change the air-flow according to the health conditions of patients, it did not require the development of AI algorithm, as in the WoundViewer.

redeployed and leveraged within an adjacent product-market domain in the future. These are competences and practices that the firm already has and that uses to reconfigure and reposition itself within a new product-market domain. In other words, they serve as a “bridge” from an already developed business model to a new one.

The innovation of Omnidermal was grounded on known scientific principles but, in order to be effectively implemented, the founders had to acquire and recombine pieces of knowledge from different domains. The team did not only identify the architecture of the new solution, but also adopted some existing components (which could easily be supplied) and in-house developed the more specific mechanical components as well as the control software (on the basis of known and tested algorithms already existing in software libraries). This case illustrates the four main competences and practices that prompted the development of the ABU device, which can be grouped into two macro-categories: technical competences and work practices (illustrated in Table 1).

As far as the **technical competence** domain is concerned, the Omnidermal case highlighted how “technology know-how” and “on-site testing capabilities” were decisive for the quick development of the ABU product. **Technology know-how** refers to the capability of academic spinoffs to develop and accumulate competences which can rapidly be redeployed in adjacent technological domains. This was possible for Omnidermal, thanks to the founders’ accumulated expertise (e.g. the software know-how was decisive in quickly developing the product - see quotes AS1, AS2 and AS3 in Table 1). Moreover, the knowledge gained from WoundViewer made the new ABU product relatively easy to develop from a technological point of view [see quote AS3]. **On-site testing capabilities**, instead, refer to the ability to quickly test products and to learn from the users’ feedbacks. For example, the quick identification of critical aspects (“fast failing”) [see quote NA4] was of primary importance in engaging with doctors and in running tests in hospitals. In addition, prior experience in on-site testing led the team to focus on the validation of certain key core features, without wasting time on developing those of negligible value [see quote AS5].

With reference to the **work practices**, the Omnidermal case highlighted two distinct practices that were decisive in their ability to quickly address the market with the ABU product: agile mindset and agile working. Such practices were decisive in the development and commercialization of the ABU device, as they

helped gain both flexibility and speed not only in managing the project, but also in addressing and entering the new market. **Agile mindset** refers to the capability of a firm to promptly identify product-market opportunities and to rethink current business models accordingly. This work practice was crucial for Omnidermal to identify the emerging ventilator market [see quote AS6]. **Agile working**, instead, refers to the capabilities of a team to organize work activities in non-standard situations. The ABU was fully developed during the lockdown period in Italy, which severely limited contact between people. In this complex situation, the team was able to leverage on previous agile work practices, implemented in the past while working between the USA and Italy [see quote AS7]. The founders remarked that the team had acquired the skills to manage meetings via Skype and to take complex decisions in just a few hours even without working closely on a physical artefact. This capability was central to speeding up the ideation of the ABU ventilator, which took about 15 days [see quote AS8].

The expeditious development of the device was also possible (and probably boosted) as a result of the **access to a network** of partners and resources outside the firm's boundaries that allowed to coordinate and speed up manufacturing, certification and commercialization stages [see quotes NA1, NA2, NA3, NA4 and NA5]. In fact, Omnidermal was able to leverage on the key partners from the existing network of the firm and to exploit their knowledge to accelerate the development, testing and commercialization of the ABU. For instance, the joint work with PBL allowed Omnidermal to resolve quickly technical challenges in designing the ABU and in accessing the hospital networks. One of the key insights emerging from the interviews was that without the benefits from the network, the firm would have reached the same results but later. Similarly, the access to a network of investors allowed the entrepreneurs to become eligible for a national grant from Invitalia of €1M and to move toward a new idea very soon after the outbreak of the Covid-19.

If the access to a network has been a key aspect in speeding up the development of the ABU product, the role of the parent university of Omnidermal (i.e. PoliTo) has been quite different and extremely important at the beginning of the life of the spinoff. In fact, PoliTo provided: i) support to the spinoff for filing patents; ii) access to an initial Proof of Concept grant (necessary to further improve the WoundViewer); iii) education and legal support in setting the contracts with external counterparts, as well as in developing testing and certification competences. However, concerning the transition from the WoundViewer product to the ABU product, the university did not formally provide support, as the time span in which the transformation occurred

was very short. Interviews revealed that some informal consulting with a few PoliTo's professors occurred and that the spinoff benefited from the reputation deriving from its affiliation with the university.

[Insert Table 1 here]

Table 2 summarizes the ABU development steps and shows how Omnidermal managed the recombination of accumulated competences according to mechanisms that are able to bridge very diverse domains of knowledge, spanning from scientific research to manufacturing processes.

[Insert Table 2 here]

## 5. Discussion and conclusions

Drawing on the insights of the case, Figure 2 illustrates a model on the linkage between academic spinoffs' possession of "legacy competences and practices", the instrumental role played by network access and a quick development of a new product in emergency conditions.

[Insert Figure 2 here]

The Omnidermal case is representative of how academic spinoffs can leverage on "legacy competences and practices" (that are in excess to what is needed for running "routine" activities) to continue operations during a crisis, and on how they can identify and implement innovations in response to social and economic threats. It also sheds light on how spinoffs can outperform other organizations in solving new problems, by effectively connecting several and "distant" domains of knowledge in just a few days<sup>5</sup>.

---

<sup>5</sup> Other companies followed a similar approach to the one by Omnidermal:

- During March 2020, a research team from MIT developed an old project from Stanford University that was thought as an open source contribution from the university to companies active in this field.
- The University of Minnesota certified a ventilator with the FDA (under the UEA- Emergency Use Authorization-rule for emergency) on April 15th. A team from the university, with the help of external members, adapted the initial prototype based on an assortment of available machinery components to a custom slider-crank mechanism, which enabled to control how oxygen is delivered to patients.
- On April 30th 2020, the FDA approved a high-pressure ventilator developed by NASA engineers at the Jet Propulsion Laboratory (JPL) and tailored to treat coronavirus patients to free up the limited supply of ventilators.
- On May 5th 2020, an Italian team (MVM) obtained the FDA certification (under the UEA rule) for a ventilator based on a different principle. The team includes research centers and universities.
- Lungpacer Medical Inc, a spinoff from Simon Fraser University, received on May 4th 2020 the EUA clearance by the FDA, paving the way for the immediate use of its Diaphragmatic Pacing Therapy System.

Although some of the crucial capabilities and competences we have identified are not completely new to the literature (e.g. technology competences; Clarysse, Wright, and Van de Velde, 2011), we introduce some original key features that academic spinoffs can leverage on to renew their businesses (or open up new opportunities) in emergency contexts. First, our study recalls that it is important for academic spinoffs to nurture the development and the accumulation of a wide set of capabilities (e.g. technological, testing, manufacturing, etc.) (Fontes, 2005) in order to fuel their innovation process. Second, our results show the importance of testing a spinoff's product/s in a real environment. The literature on PoCs has identified them as being a tool that favours Technology Transfer from universities to industry (Munari et al., 2017). This case pushes toward the idea that PoCs are needed to quickly exploit new product-market opportunities and test them with the customers (rather than being used to refine products to fit the market). Indeed, the capability of Omnidermal to develop a PoC with hospitals in just a few days and to validate its results was crucial to compress the time from concept to development of the ABU device.

An important aspect concerns the specific trait that “legacy competences and practices” have in the context of academic spinoffs to promote the quick redeployment from a product-market domain to another one in order to solve an urgent societal problem. While both technical capabilities and agile practices can be common to different kind of firms (i.e. academic spinoffs, start-ups or incumbent firms), their development within academic spinoffs has been undoubtedly different when compared to other types of organizations. For instance, technical capabilities are quite dispersed and integration is difficult for large firms (Zander, 1998) or they are in the hands of few people with technical competences in start-ups. Instead, in academic spinoffs they tend to be concentrated in the hands of people also in charge of marketing/commercialization tasks. The Omnidermal case has shown that the possession of technical capabilities (in excess to what is needed to perform routine activities) by few people in charge of marketing tasks has been crucial to quickly adapt the spinoff's competences to a new product-market domain (from WoundViewer to the new ABU device). Similarly, the agile working practices found a favourable environment for developing new routines within the team, thanks to the small size of the company.

Our results uncover a few further aspects that appear to have been overlooked in prior studies. The first one refers to the reiteration of the work practices acquired along the development of past products. The

second relates to the crucial role played by the access to an external network as a facilitator of the development of a new product in a short time window (Rasmussen et al., 2011). The third refers to the fact that the spinoff adapted to the sudden change in the market environment more quickly than other firms.<sup>6</sup> This quick response was favoured by: i) its small size; ii) its flexibility in the work practices; iii) the previous technological capabilities developed within the field and iv) the access to the local network.

At a more general level, the case of Omnidermal further highlights the importance and the relevance of academic spinoffs in terms of societal impacts (Fini et al., 2018). While we have primarily stressed the internal mechanisms leading spinoffs to address a specific opportunity emerging on the market (through the development of a new product), the case study sheds light on the pathways that they can undertake to grow and thus provide benefits at large to society. For instance, even if many academic spinoffs may not bring a high economic impact as they remain small and often fail (Blumenthal, 1997), their products may provide substantial benefits at a societal level, as the ABU device did.

### **5.1 Policy and managerial implications**

Our case study has implications for policy and management. The quick development of the ABU product by Omnidermal seems to suggest a new role for academic spinoffs. Previous literature has underlined how the achievement of satisfactory results (in terms of growth) still represents a difficult target for many academic spinoffs. Policy initiatives aimed at increasing the number of academic spinoffs have led to a reduction of their overall quality and potential impact (Fini et al., 2017). Moreover, the returns to investments often emerge only in the very long period rather than in the short run (Vincett, 2010). The limits to spinoff growth and success are often associated with their limited market knowledge and to an intense allocation of internal resources to develop further technological capabilities.

Our case study shows that academic spinoffs are a precious source of technological competences accumulated over the years and of valuable work practices that allow them to use and recombine extant knowledge. In other words, the insights from the Omnidermal case suggest that academic spinoffs may play a new role in the current entrepreneurial landscape. They can become organizations that are able to recombine

---

<sup>6</sup> We thank an anonymous reviewer for suggesting this point.



accumulated competences and knowledge in order to develop articulated solutions to complex problems under strong time constraints. On the basis of these arguments, it seems important for policy makers to favor the accumulation and development of legacy competences, not only when spinoffs are founded, but more importantly when crisis periods emerge. We suggest that policymakers should sustain the development and survival of spinoffs with small amounts of money in ordinary periods; larger amounts of funds should instead be invested during periods of crisis. Similarly, as network access is important for academic spinoffs to quickly develop new products, policymaking should foster new forms of collaborations.

The current policies in Italy (e.g. the so-called Ministerial Decree “Cura Italia”) were not designed specifically to support academic spinoffs, although several other examples of academic spinoffs, apart from Ominidermal, have emerged and introduced new solutions to fight the COVID-19 crisis (e.g. see Sybilla Biotech<sup>7</sup>). We thus strongly advocate the rapid adoption of such measures.

Our study suggests that academic spinoffs are organizations that are able to access, internalize and recombine competences and knowledge from different scientific domains. Previous literature suggested the acquisition of market capabilities and market knowledge (van Geenhuizen and Soetanto, 2009) to be crucial for their development. We contend that the five phases identified in prior studies (Vohora et al., 2004) are instrumental in acquiring the set of capabilities and competences necessary to address grand challenges which may, in particular, emerge during periods of crisis. Our study remarks the importance of boundary spanning and network capabilities in spinoffs, as they provide access to the networks and ecosystems that are necessary for the acquisition of resources (both financial and operational). In addition, this study has uncovered the importance of the work practices put in place by spinoffs. On the one hand, these are instrumental in recognizing and quickly addressing business opportunities that are made available on the market. On the other hand, they allow the team to collaborate and quickly escalate new business opportunities.

## **5.2 Future research and limitations**

This research leaves ample room for further research and insightful debates on the possibility of reconsidering the linear stage model of spinoff growth and development (Vohora et al., 2004), which is based

---

<sup>7</sup> [https://www.adnkronos.com/soldi/economia/2020/04/29/coronavirus-spin-off-italiana-sibylla-trova-nuovi-bersagli-per-farmaci\\_9wBD6IUWMUM5sLTjzB7xeM.html](https://www.adnkronos.com/soldi/economia/2020/04/29/coronavirus-spin-off-italiana-sibylla-trova-nuovi-bersagli-per-farmaci_9wBD6IUWMUM5sLTjzB7xeM.html)

on a technology-push model. Besides extending and providing more nuances on the insights we have introduced with this study, future research could attempt to extend our understanding of the “legacy competences and capabilities” of academic spinoffs in shifting their development model from a technology-push toward a market-pull configuration.

A key point worth of further investigation is related to the role that ecosystems play in the long run to assist spinoffs in their development path in turbulent times (as during the Covid-19). Previous research has shown that ecosystems play a key role in favouring the creation and successful development of spinoffs (Novotny et al., 2020). While for the case we presented the time occurred between the idea and the development of the ABU product was limited and it did not allow ecosystems to reconfigure and boost the commercialization of the ABU, we realize that different situations could have emerged in different contexts. Therefore, we strongly encourage further research on this topic.

Our work is not free of limitations. The study was designed as a quick response to the current COVID-19 crisis and suffers from limited opportunities to extend our intuitions to other contexts in order to verify their applicability. However, this is a field of scientific interest that displays great research potential. We acknowledge that Omnidermal is a med-tech spinoff that had to reconfigure its business during a medical crisis. We would like to stimulate future research toward the exploration of similar patterns in other domains that have been affected to a great extent by this sudden crisis, - for instance - the whole manufacturing industry.

## 6. References

- Abbate, T., Cesaroni, F. (2017) The (needed?) market orientation of academic spin-off firms. *International Journal of Entrepreneurship and Innovation Management*, **21**, 395–421. <https://doi.org/10.1504/IJEIM.2017.085690>
- Algieri, B., Aquino, A., Succurro, M. (2013) Technology transfer offices and academic spin-off creation: The case of Italy. *Journal of Technology Transfer*, **38**, 382–400. <https://doi.org/10.1007/s10961-011-9241-8>
- How Are Small Businesses Adjusting to COVID-19? Early Evidence from a Survey* (2020, Cambridge, MA). 2020. Ed. Bartik, A., Bertrand, M., Cullen, Z., Glaeser, E., Luca, M., Stanton, C. Cambridge, MA,
- Bazerman, M. H. Bernhard, R., Greene, J., Huang, K., Barak-Corren, N. (2020) How should we allocate scarce medical resources?. *Harvard Business Review*, 2020
- Blumenthal, D. (1997) Withholding Research Results in Academic Life Science. *JAMA*, **277**, 1224. <https://doi.org/10.1001/jama.1997.03540390054035>
- Bullough, A., Renko, M., Myatt, T. (2014) Danger Zone Entrepreneurs: The Importance of Resilience and Self-Efficacy for Entrepreneurial Intentions. *Entrepreneurship Theory and Practice*, **38**, 473–499. <https://doi.org/10.1111/etap.12006>

- Chiesa, V., Piccaluga, A. (2000) Exploitation and diffusion of public research: the case of academic spin-off companies in Italy. *R&D Management*, **30**, 329–340. <https://doi.org/10.1111/1467-9310.00187>
- Clarysse, B., Wright, M., Van de Velde, E. (2011) Entrepreneurial Origin, Technological Knowledge, and the Growth of Spin-Off Companies. *Journal of Management Studies*, **48**, 1420–1442. <https://doi.org/10.1111/j.1467-6486.2010.00991.x>
- Clausen, T.H., Rasmussen, E. (2013) Parallel business models and the innovativeness of research-based spin-off ventures. *Journal of Technology Transfer*, **38**, 836–849. <https://doi.org/10.1007/s10961-012-9294-3>
- Crandall, W.R., Parnell, J.A., Spillan, J.E. (2010) *Crisis Management in the New Strategy Landscape*. Thousand Oaks, CA: Sage Publications.
- Devece, C., Peris-Ortiz, M., Rueda-Armengot, C. (2016) Entrepreneurship during economic crisis: Success factors and paths to failure. *Journal of Business Research*, **69**, 5366–5370. <https://doi.org/10.1016/j.jbusres.2016.04.139>
- Fini, R., Fu, K., Mathisen, M.T., Rasmussen, E., Wright, M. (2017) Institutional determinants of university spin-off quantity and quality: a longitudinal, multilevel, cross-country study. *Small Business Economics*, **48**, 361–391. <https://doi.org/10.1007/s11187-016-9779-9>
- Fini, R., Rasmussen, E., Siegel, D., Wiklund, J. (2018) Rethinking the commercialization of public science: From entrepreneurial outcomes to societal impacts. *Academy of Management Perspectives*, **32**, 4–20. <https://doi.org/10.5465/amp.2017.0206>
- Fontes, M. (2005) The process of transformation of scientific and technological knowledge into economic value conducted by biotechnology spin-offs. *Technovation*, **25**, 339–347. <https://doi.org/10.1016/j.technovation.2003.08.004>
- van Geenhuizen, M., Soetanto, D.P. (2009) Academic spin-offs at different ages: A case study in search of key obstacles to growth. *Technovation*, **29**, 671–681. <https://doi.org/10.1016/j.technovation.2009.05.009>
- Hayter, C.S. (2011) In search of the profit-maximizing actor: Motivations and definitions of success from nascent academic entrepreneurs. *Journal of Technology Transfer*, **36**, 340–352. <https://doi.org/10.1007/s10961-010-9196-1>
- Huynh, T., Patton, D., Arias-Aranda, D., Molina-Fernández, L.M. (2017) University spin-off's performance: Capabilities and networks of founding teams at creation phase. *Journal of Business Research*, **78**, 10–22. <https://doi.org/10.1016/j.jbusres.2017.04.015>
- Korber, S., McNaughton, R.B. (2018) Resilience and entrepreneurship: a systematic literature review. *International Journal of Entrepreneurial Behaviour and Research*, **24**, 1129–1154. <https://doi.org/10.1108/IJEBR-10-2016-0356>
- Kuckertz, A., Brändle, L., Gaudig, A., Hinderer, S., Morales Reyes, C.A., Prochotta, A., Steinbrink, K.M., Berger, E.S.C. (2020) Startups in times of crisis – A rapid response to the COVID-19 pandemic. *Journal of Business Venturing Insights*, **13**, e00169. <https://doi.org/10.1016/j.jbvi.2020.e00169>
- Lubik, S., Garnsey, E., Minshall, T., Platts, K. (2013) Value creation from the innovation environment: partnership strategies in university spin-outs. *R&D Management*, **43**, 136–150. <https://doi.org/10.1111/radm.12006>
- Martinelli, E., Tagliazucchi, G., Marchi, G. (2018) The resilient retail entrepreneur: dynamic capabilities for facing natural disasters. *International Journal of Entrepreneurial Behaviour and Research*, **24**, 1222–1243. <https://doi.org/10.1108/IJEBR-11-2016-0386>
- Mathisen, M.T., Rasmussen, E. (2019) The development, growth, and performance of university spin-offs: a critical review. *Journal of Technology Transfer*, **44**, 1891–1938. <https://doi.org/10.1007/s10961-018-09714-9>
- Mustar, P., Renault, M., Colombo, M.G., Piva, E., Fontes, M., Lockett, A., Wright, M., Clarysse, B., Moray,

- N. (2006) Conceptualising the heterogeneity of research-based spin-offs: A multi-dimensional taxonomy. *Research Policy*, **35**, 289–308. <https://doi.org/10.1016/j.respol.2005.11.001>
- Novotny, A., Rasmussen, E., Clausen, T., Wiklund, J. (2020) *Research Handbook on Start-Up Incubation Ecosystems*. s.l.: Edward Elgar Publishing.
- Prokop, D., Huggins, R., Bristow, G. (2019) The survival of academic spinoff companies: An empirical study of key determinants. *International Small Business Journal: Researching Entrepreneurship*, **37**, 502–535. <https://doi.org/10.1177/0266242619833540>
- Rasmussen, E., Mosey, S., Wright, M. (2011) The Evolution of Entrepreneurial Competencies: A Longitudinal Study of University Spin-Off Venture Emergence. *Journal of Management Studies*, **48**, 1314–1345. <https://doi.org/10.1111/j.1467-6486.2010.00995.x>
- Saglietto, A., D’Ascenzo, F., Zoccai, G.B., De Ferrari, G.M. (2020) COVID-19 in Europe: the Italian lesson. *The Lancet*, **395**, 1110–1111. [https://doi.org/10.1016/S0140-6736\(20\)30690-5](https://doi.org/10.1016/S0140-6736(20)30690-5)
- Thomas, V.J., Bliemel, M., Shippam-Brett, C., Maine, E. (2020) Endowing university spin-offs pre-formation: Entrepreneurial capabilities for scientist-entrepreneurs. *Technovation*, May. 2020, 102153. <https://doi.org/10.1016/j.technovation.2020.102153>
- Vincett, P.S. (2010) The economic impacts of academic spin-off companies, and their implications for public policy. *Research Policy*, **39**, 736–747. <https://doi.org/10.1016/j.respol.2010.02.001>
- Vohora, A., Wright, M., Lockett, A. (2004) Critical junctures in the development of university high-tech spinout companies. *Research Policy*, **33**, 147–175. [https://doi.org/10.1016/S0048-7333\(03\)00107-0](https://doi.org/10.1016/S0048-7333(03)00107-0)
- Williams, T.A., Gruber, D.A., Sutcliffe, K.M., Shepherd, D.A., Zhao, E.Y. (2017) Organizational response to adversity: Fusing crisis management and resilience research streams. *Academy of Management Annals*, **11**, 733–769. <https://doi.org/10.5465/annals.2015.0134>
- Wright, M., Clarysse, B., Mosey, S. (2012) Strategic entrepreneurship, resource orchestration and growing spin-offs from universities. *Technology Analysis and Strategic Management*, **24**, 911–927. <https://doi.org/10.1080/09537325.2012.718665>
- Yamakawa, Y., Cardon, M.S. (2017) How prior investments of time, money, and employee hires influence time to exit a distressed venture, and the extent to which contingency planning helps. *Journal of Business Venturing*, **32**, 1–17. <https://doi.org/10.1016/j.jbusvent.2016.10.002>
- Yin, R.K. (2017) *Case study research and applications : design and methods*. Sixth edition London: SAGE.
- Zander, I. (1998) The evolution of technological capabilities in the multinational corporation - Dispersion, duplication and potential advantages from multinationality. *Research Policy*, **27**, 17–35. [https://doi.org/10.1016/S0048-7333\(97\)00068-1](https://doi.org/10.1016/S0048-7333(97)00068-1)
- Zhu, N., Zhang, D., Wang, W., Li, X., Yang, B., Song, J., Zhao, X., Huang, B., Shi, W., Lu, R., Niu, P., Zhan, F., Ma, X., Wang, D., Xu, W., Wu, G., Gao, G.F., Tan, W. (2020) A novel coronavirus from patients with pneumonia in China, 2019. *New England Journal of Medicine*, **382**, 727–733. <https://doi.org/10.1056/NEJMoa2001017>

## 7. Appendix.

### Semi-structured interview script

19<sup>th</sup> April 2020

- Could you please introduce us to the most important projects in your company? What is the main product you developed since now?
  - Which have been the crucial steps in its development?
  - Can you please give us a timeline of such steps?
- How the Covid-19 outbreak had an impact on the development of your project?
- How did you come up with the idea of turning your efforts toward the development of the ABU product? How did you manage to develop and test the first prototype?
- Can you please describe us the ABU unit, how it works and how it has been accepted by potential customers?
- Which have been the main steps for the development of the ABU product?
- Which have been the key persons/institutions which helped your team in developing the ABU product?
- What have been the lessons you learned from the development and commercialization of WoundViewer and you carried in the development of the ABU product? Were the reputation and the network developed with Woundviewer important?
- Did you already have all the technical capabilities required to develop the product?
- How did you organize your work activity in these turbulent times? What was critical in managing complex technical development in such a short period of time?
- What are the next steps you expect to face for the development of your product?
- According to you, is there any point we missed during our interview?

May 3<sup>rd</sup> and August 18<sup>th</sup>, 2020

- What happened in the last 3 months in terms of ABU product development?
- What were the main obstacles faced that influenced the development of the product?

## 8. Figures

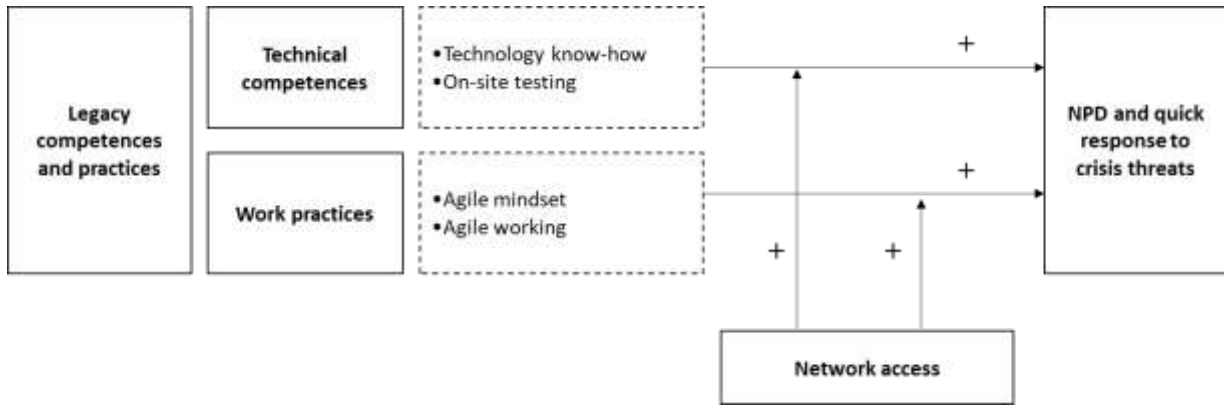
Figure 1

The ABU developed by Omnidermal



**Figure 2**

An emerging model of how legacy competences and practices can be leveraged on by academic spinoffs to quickly develop new products.



**9. Tables**

**Table 1.**

**Emerging themes from the case study**

Main themes	Exemplary quotes	
	Academic spinoff context	Network access
<b>Technology competences</b>	<ul style="list-style-type: none"> <li>• “Although our device may seem easy to realize, it combines two different elements of increasing complexity: hardware and software. Even though the hardware is pretty easy (it is just made of two mechanical pilers used to clamp a balloon), the software is much more critical, since if it is not able to correctly read and process the health parameters of patients, they will die.” [AS1]</li> <li>• “Our competences have been instrumental in developing the software and, partially, the hardware of the device” [AS2]</li> <li>• “It has been easy for us to design the new product, as ventilators are relatively easier to design than our core product.” (i.e. Woundviewer) [AS3]</li> </ul>	<ul style="list-style-type: none"> <li>• “Jacopo, Filippo and a technician from PBL designed the ventilator and quickly understood that they could make automatic an AMBU balloon.” [NA1]</li> <li>• “They defined the technical specs and validated them on the market through a series of quick calls to doctors and anaesthetists in order to confirm their impressions on what hospitals needed. [NA2]</li> <li>• “The automation is managed completely by PBL, who gave us the opportunity to manufacture the product by leveraging on their previous knowledge.” [NA3]</li> </ul>

<p><b>On-site testing</b></p>	<ul style="list-style-type: none"> <li>• <i>“We received the first positive results from tests in hospitals and then we quickly moved on to achieve all the necessary certifications” [AS4]</i></li> <li>• <i>When we tested the product, we avoided the errors we had made in the past: we trusted doctors much more, and we speeded up the process in order to achieve a working product, albeit not the “coolest” on the market”. [AS5]</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>“Mr. Serventi (PBL) put all his experience at our service, and taught us how to fast fail and quickly test our product on the market” [NA4]</i></li> </ul>
<p><b>Agile mindset</b></p>	<ul style="list-style-type: none"> <li>• <i>“We asked ourselves: “What can we do now that our project has been stopped? How can we mitigate the risk?”. We immediately understood COVID was an opportunity for us to consolidate our brand on the market in a different way. We then decided to develop a new product for the same customers we already had.” [AS6]</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>“At the beginning, we made some calls to the investor. Jacopo and the guy brainstormed some B-plans and the idea of the ventilator came out.” [NA5]</i></li> </ul>
<p><b>Agile working</b></p>	<ul style="list-style-type: none"> <li>• <i>We were not worried about working at distance during the lockdown. We can say it is a routine we have since the beginning of our collaboration. [AS7]</i></li> <li>• <i>Being able to work at a distance from each other was a key asset in this period. The possibility of taking decisions in just a few moments, in spite of the great distances, was especially important.[...] We are accustomed to this way of working as we implemented this process at the beginning of our entrepreneurial experience when some of us were here in Italy and others in the USA.” [AS8]</i></li> </ul>	

**Table 2.****ABU development steps and accumulated competences used to sustain its development**

<b>Date</b>	<b>Stage of development</b>	<b>Available competences applied at each stage</b>
March 13-14	Idea Development	<ul style="list-style-type: none"> <li>- Basic scientific knowledge about the medical needs and medical equipment</li> <li>- Selection and recombination of the technologies</li> <li>- Access to existing results of academic research</li> </ul>
March 15-22	Development of the first version of ABU	<ul style="list-style-type: none"> <li>- System integration of different components and software acquired from the parent company (which makes fully automatic machines for pharmaceutical applications).</li> <li>- Design for manufacturing (with selection of standard off-the-shelf components)</li> <li>- Selection and adaptation of the software and control algorithms</li> </ul>
March 22-23	Initial medical tests	<ul style="list-style-type: none"> <li>- Design of PoCs according to the medical protocols</li> <li>- Debugging of the control software and its algorithms</li> <li>- Reputation with hospitals</li> <li>- Compliance with the existing codes and standards</li> </ul>
March 23	Application to the “Invitalia” call for the industrial development of technologies to fight COVID-19	<ul style="list-style-type: none"> <li>- In-house manufacturing of the new components (based on PBL)</li> <li>- Engineering of the products to scale up quantities</li> <li>- Ability to identify and supply off-the-shelf components</li> <li>- Compliance of the production system</li> </ul>
March 23	Certification process starts (CEI 62142; ISO 60601; ISO 80601) <sup>8</sup>	<ul style="list-style-type: none"> <li>- Knowledge about the certification process, the required tests, and other technical requirements</li> </ul>
March 24-30	Development of the second ABU version	<ul style="list-style-type: none"> <li>- Same as the one used to create the first ABU version</li> <li>- Ability to manage the results of the initial tests and suggestions from doctors</li> </ul>
April 1-8	Advanced tests in intensive care units in hospitals (Gemelli - Rome, Mauriziano - Turin, Castel San Giovanni - Piacenza, Bellaria - Bologna, Valduce – Como)	<ul style="list-style-type: none"> <li>- Design of the tests according to the medical protocols</li> <li>- Debugging of the control software and its algorithms</li> <li>- Reputation with hospitals</li> <li>- Compliance with the existing codes and standards</li> </ul>
April 15	Commercial development starts (RFQ received from potential worldwide customers)	<ul style="list-style-type: none"> <li>- Management of RFQ and contracts</li> <li>- Costing of the final product</li> <li>- Certification process</li> </ul>
April 19	€1M grant from Invitalia (public funds)	<ul style="list-style-type: none"> <li>- Ability to identify a new product</li> <li>- Scientific background and a proven Proof of Concept</li> <li>- Manufacturing capabilities</li> <li>- Reputation</li> </ul>
April 21	Testing at the Ram Bam hospital of Haifa (Israel)	<ul style="list-style-type: none"> <li>- Design of the tests according to the medical protocols</li> <li>- Debugging of the control software and its algorithms</li> <li>- Reputation with hospital</li> <li>- Compliance with the existing codes and standards</li> </ul>
June 12	First reply from the certification agency (IMQ); request to implement minor	<ul style="list-style-type: none"> <li>- Technical competences needed to run tests and to adapt product characteristics to technical standards</li> <li>- Update of certification documents</li> </ul>

<sup>8</sup> The device is currently under certification; both the hardware and software components are under certification. Commercialization cannot start until the certification process has been completed.



	technical adjustments of the product (expected termination of the process: September 2020)	
July 31	First batches produced (components of the ABU)	<ul style="list-style-type: none"> <li>- Product engineering (in parallel with certification activities).</li> <li>- In-house manufacturing of the new components (based on PBL)</li> </ul>