R&D MANAGEMENT

When nothing is certain, anything is possible: open innovation and lean approach at MVM

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Using a participatory observation approach, this paper aims at exploring how public and private organizations have collaborated in response to the COVID-19 pandemic. We examine the case of Mechanical Ventilator Milano (MVM), an international project with over 250 contributors and partners; this project aimed to achieve the challenging goal of designing and realizing a mechanical ventilator for mass production in about 6 weeks. The project received the Emergency Use Authorization granted by the U.S. Food and Drug Administration. The MVM ventilator is a reliable, fail-safe, and easy-to-operate mechanical ventilator that can be produced quickly at a large-scale, based on the readily available parts. The success of the MVM case is unique as it adopts open innovation practices to generate technology innovation, in addition to a lean perspective. Through the MVM project description, this study offers a framework that explains the interplay between open innovation and lean approach, highlighting the different internal and external forces and types of collaborations, and offering fine-grained insights into the role of universities as platforms of multidisciplinary knowledge. This framework might serve as a basis for future theoretical and empirical research, providing practitioners with new best practices that are essential when facing a severe crisis like COVID-19.

1. Introduction

At the beginning of 2020, the new virus COVID-19 spread worldwide at an unprecedented pace. Both firms and governments were affected, wherein the former was suffering economically due to the lockdown, whereas the latter was struggling to flatten the pandemic curve and preserve the National Health Services from collapse. During the pandemic, approximately 30% of hospitalized patients with COVID-19 required mechanical ventilation (Ferguson et al., 2020), and global demand was estimated to rise exponentially to a peak of 880,000 more ventilators (GlobalData, 2020). Hospitals worldwide required more ventilators, but scaling up the production was more complicated than it might seem. Ventilator manufacturing companies boosted their production; however, they could not afford a growth of 500% due to limited capacity to expand their relatively small plants and their supply chains, which were likely to run into shortages to meet the demand (World Economic Forum, 2020). The only hope was focusing on innovative projects capable of changing the pandemic route (The Economist, 2020).

In this paper, we investigate how both public and private organizations have successfully cooperated to respond effectively to the COVID-19 emergency related to the scarcity of ventilators. In the specifics, we explore the case of the Mechanical Ventilator Milano (MVM), an international research project composed of more than 250 researchers including a Physics Nobel laureate. MVM was closely cooperating with firms and medical staff to produce reliable and easy-to-operate mechanical ventilators built on readily available parts in approximately six weeks. On May 2, 2020, the MVM received the Emergency Use Authorization granted by the U.S. Food and Drug Administration (FDA), paving the way for mass production.

The success of MVM is not only related to excellence in basic research or the profuse sacrifice and enthusiasm among collaborators but also related to a virtuous interplay between open innovation and lean approach. Recently, Chesbrough (2020) highlighted that openness is essential to recover quickly from COVID-19. Since his seminal work in 2003, innovation scholars and practitioners have been consolidating the role of open innovation as a best practice for firms to adapt rapidly to external changes and to succeed in the marketplace (Leiblein et al., 2018). Open innovation, with its outside-in and inside-out knowledge flows across an organization's boundaries, fosters innovation and competitive advantage (Chesgrough and Bogers, 2014). Although a plethora of research focuses on how firms leverage universities' basic knowledge in their open innovation practices (Perkmann et al., 2013, 2021), less is still known about what dynamics occur when universities open their boundaries to a broad range of private actors and how the collaboration network is managed.

Moreover, the literature on lean research is more recent. The pioneering idea of Ries (2011, 2017) highlights the motives of failure in new ventures and the limits of traditional thinking when applied to startups. The lean perspective favors experimentation over elaborate planning, and user evaluation and feedback over intuition (Blank, 2013). In doing so, the lean approach can be an advantage from both the inbound and outbound knowledge paths of open innovation to make an organization's experimentation more effective.

Finally, Chesbrough and Tucci (2020) specified how open innovation could benefit from lean practices, highlighting the need for more research to explore this connection. In this work, we provide a framework that depicts the interplay between open innovation and lean approach, unveiling the distinct internal and external forces and types of collaborations, and providing fine-grained insights into the role of universities as platforms of multidisciplinary knowledge.

2. Literature background

Open innovation has often been perceived as the panacea to organizational issues related to the innovation process, especially to accelerate things (Chesbrough, 2020). The concept of open innovation, initially introduced by Chesbrough (2003), has been defined as 'a distributed innovation process based on purposively managed knowledge flows across boundaries' (Chesbrough and Bogers, 2014, p. 17). These knowledge flows can follow a dual path leading to outside-in (inbound) and inside-out (outbound) open innovation, and their combination allows organizations to involve a broad multiplicity of actors, further fostering the innovation process.

Existing research on open innovation has primarily focused on the outside-in path characterized by opening up an organization's boundaries to external inputs and contributions, such as acquisitions, collaborations, or sourcing (i.e., Chesbrough, 2003; Dahlander and Gann, 2010); these external inputs are determined by the adoption of specific business models (Chesbrough and Bogers, 2014). Additionally, in the inside-out type of open innovation, an organization's ideas venture outside its boundaries and merge with other firms' business models (Arora et al., 2001). Nevertheless, the business model has often to be discovered to bring the idea onto the market, as it might differ from the organization's existing one (Chesbrough and Bogers, 2014). Bogers (2011) connects the processes of outside-in and inside-out open innovation to develop or commercialize an innovation collaboratively. Collaboration might occur between firms (Di Guardo and Harrigan, 2016), or it might involve users and customers collaborating with the firm to create knowledge for an innovation process (Chesbrough and Bogers, 2014; Piller and West, 2014; Tucci et al., 2016).

The onslaught of the COVID-19 pandemic has boosted open innovation more than ever, involving firms and research institutions and leading them to experience innovation opportunities through and beyond the crisis per se (Chesbrough, 2020; Dahlander and Wallin, 2020). Moreover, open innovation has emerged as a critical aspect to cope with uncertainty in lean times (Chesbrough and Garman, 2009; Bogers et al., 2018).

The 'lean philosophy' has its roots in the manufacturing field; it is known as a systematic method for waste minimization in the manufacturing process (Womack and Jones, 1997). Nevertheless, since the seminal idea of Blank (2003) and subsequent development of Ries (2011, 2017), the lean perspective (known as the lean startup) has been steadily gaining popularity, especially over the past few years. Different from lean manufacturing, the essence of the new 'lean' thinking is related to the notion of experimentation (Contigiani and Levinthal, 2019; Camuffo et al., 2020).

Nowadays, the lean approach is revolutionizing how managers think about strategy and innovation. This method is used to launch several new ventures and product innovations. In addition, established firms are struggling to adopt lean practices to boost their innovation efforts, although with different levels of success.

More specifically, the lean approach is a scientific and hypothesis-driven approach wherein a vision or business idea is translated into falsifiable hypotheses subsequently tested through a series of minimum viable products (MVPs). MVP refers to the development of a product with a minimum set of features/requirements capable of satisfying the potential users, to avoid wasting resources in creating undesired products. As such, the lean approach is more than a theoretical inquiry; it refers to the realization of a first product capable of entering commercialization (Ries, 2011). Once the first MVP is realized, running several tests is crucial to generate validated learning by introducing a real product to real customers and gauging their reactions (Ries, 2011). The evaluation of the MVP tests can lead to three distinct directions: (a) persevere with the business idea if the MVP validates the hypotheses, (b) pivot changes in some business model elements as feedback suggests higher opportunities elsewhere while maintaining others, or (c) perish, that means MVP test rejects the hypothesis and no relevant pivot is identified (Eisenmann et al., 2012). After all key hypotheses have been validated and the 'build-measure-learn' feedback loop is concluded via the realization of a product that meets customers' needs, the product–market fit is achieved (Ries, 2011; Blank, 2013). Importantly, Bocken and Snihur (2019) argued that the lean approach should be exclusively conceived in terms of not only iterative experimentation but also business model conception, as novel business models could emerge by jointly cooperating with customers, partners, and stakeholders.

Recently, Chesbrough and Tucci (2020) highlighted how open innovation could benefit from lean practices, focusing on the interplay between them. Both open innovation and lean approach are conceived as a crucial set of toolkits for executives to accelerate the innovation process. On one hand, the lean approach contributes to open innovation by providing practical suggestions about the experimentation of potential new business models. On the other hand, open innovation contributes to lean perspective by combining and balancing inside-out and outside-in knowledge flows while generating a flow of activities aimed at eliminating 'waste'. In line with these considerations, we will develop a framework that captures both open innovation and 'lean' phenomena, highlighting the various internal and external forces, distinguishing the types of collaborations and their distinct role, and investigating how universities can serve as platforms of multidisciplinary knowledge.

3. Methodology

The exploratory nature of our research prompted us to adopt a qualitative case study for a more in-depth understanding of how organizations and communities react to respond promptly to a severe emergency, thereby analyzing the phenomenon in its complexity and within its real context (Lee et al., 2007; Yin, 2009). This study builds upon participatory observation because of the direct involvement of coauthors in the project since the earliest steps (Bryman, 2016). Although participation in the project is still ongoing, in this paper, we focus on the timeframe that goes from project initiation to the realization of a certified product granted by the U.S. FDA.

We used a triangulation principle of data collection and analysis (Yin, 2009) to build robust evidence based on the case study. The coauthors participated in all project meetings that functioned online due to lockdown in several countries. These reflective practices and observations helped achieve a better comprehension of the process on a step-by-step basis and to capture the constraints and challenges faced by collaborators and project leads. We also obtained access to emails, drafts, and comments on the publication's earliest version of the product design, by monitoring news releases and social media. In this way, we closely followed the overall flow of the project from its start and prosecution, encompassing milestones and practical issues of designing and realizing the MVM ventilator.

4. The case of MVM

The MVM project aimed to create a reliable, fail-safe, and easy-to-operate mechanical ventilator that can be produced quickly, at a large-scale, based on readily available parts. It is a contemporary interpretation of the Manley ventilator, a mechanical device created in 1961 by Roger Manley (1961) based on 'the possibility of using the pressure of gases from the anesthetic machine as the motive power'. Observing the same principle of simplicity, the main difference between the two is the use of electrically driven pneumatic valves in MVM instead of mechanical switches to ease the large-scale production. Besides this, several other characteristics, make the MVM ventilator an extremely innovative product, as summarized in Table 1.

The MVM project was developed by an international research group involving universities and research centers worldwide, all of whom were working under the Global Argon Dark Matter (GADM) Collaboration. GADM focused on the study of the universe's invisible components; the study was led by Professor Cristiano Galbiati (Princeton University and Gran Sasso Science Institute). Owing to the

Table 1. Key innovative characteristics of the MVM and description

Innovative characteristics	Description
Simplicity of operation	The MVM requires only oxygen (or medical air) and electricity, and it can be operated with simple instructions
Reduced number of components	The MVM consists of electromechanical valves, a flow meter, an oxygen therapy humidifier, pressure and oxygen sensors, manual valves, and tubes for medical use. The electronic control system is connected directly to the valves and sensors. In addition, management software is implemented
	The role of the 'human interface' is played by an LCD screen touchpad capable of displaying the patient's vital signs and send them to medical staff. The backup power supply for the system control is provided by a VDC battery
Ease of supply	The parts necessary for the MVM construction have been selected from those available globally across countries. The use of standardized parts eases the mass production and large-scale assembly of the device. The MVM is easy-to-assemble; the necessary small clear set of instructions is available. The software is open-source and available for customization by end-users
Reduced costs	The estimated total cost of the MVM components ranges between €4,000 and –€5,000. The price of existing ventilators is around €30,000
Easy to install	The device only requires a connection to a line of oxygen under pressure and a standard AC power supply (220 or 110 V); this feature makes it possible not only to be used in clinics with a centralized system supply of oxygen and air (COVID-19 hospitals or COVID-19 care areas in general hospitals) but also used for home care and in ambulances
Customization	The development of specific algorithms allows MVM to operate in different ventilation modes, both independent and patient-assisted. The operating parameters can be adjusted by the operator using a simple one user interface. This interface involves the use of a software that will increase the graphic interface's versatility and offer customizable settings to the individual patient, with the possibility of remote control of device parameters
Reliability	The MVM is designed to be easily repairable by replacing the individual parts that may not work
Limited oxygen consumption	Oxygen consumption with this device does not exceed 6 LPM

Source: Galbiati et al. (2020).

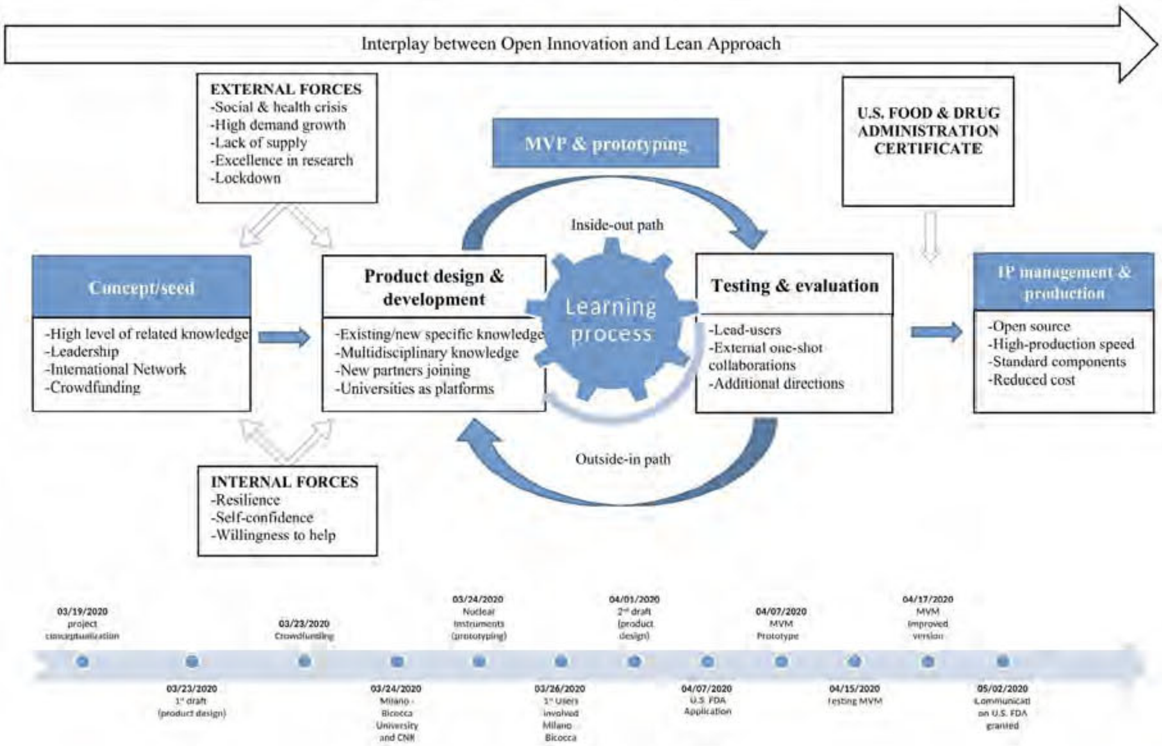

Figure 1. Framework of the interplay between open innovation and lean approach and timeline of the MVM project

efforts undertaken by the research network of a group of scientists, the brilliant initial idea for the MVM was developed. Under the leadership of Professor Galbiati, the collaboration for the MVM project realization expanded rapidly to include more than 250 collaborators in nine countries following an open innovation approach (see the list at https://mvm.care/who-we-are-en/).

Moreover, it took the MVM interdisciplinary research team slightly more than one month to identify whether the product was viable or not and develop a certified product (https://www.fda.gov/media/136528/download), owing to the collaborations. As mentioned by an engineer involved in the collaboration, if the project had followed the standard procedures adopted by companies regarding general planning, product design, development, and testing, it would have probably required around a couple of years to complete. The MVM case is valuable and interesting owing to the openness to generate technology innovation and the adoption of a lean perspective that allowed the achievement of such a challenging goal.

In the succeeding section, we will demonstrate the interplay between open innovation and lean approach during different development stages identified in the MVM project and key elements that have characterized them. Figure 1 depicts the overall process configuration and outlines three distinct phases: (1) concept generation, (2) MVP and prototyping, and (3) intellectual property (IP) management and production.

5. Interplay between open innovation and lean approach

5.1. Concept generation phase

According to Cristiano Galbiati, spokesperson for the GADM Collaboration and MVM project, 'when, from the inception of the diffusion of the pandemic in Italy, it became clear that many patients were going to need *respiratory assistance*, we decided to make our *knowledge* and ability to *cooperate* to build a new, powerful yet *safe*, *accessible*, and *easy-to-replicate* ventilator'.

Several external forces drove the decision to start the MVM challenge. In early March 2020, the pandemic crisis started in Italy; however, it soon became a threat to many other countries. In particular, the healthcare system of the Lombardy region, the area most affected by the virus in Italy, was extremely strained. The number of infected people requiring ventilators surpassed the number of machines available.

On March 19, 2020, while in lockdown for the COVID-19 virus in Milan, Professor Galbiati, other members of the GADM project, and supporters from the Gran Sasso Science Institute and the National Institute of Nuclear Physics decided to combine their specialized knowledge on gas handling systems and complex control systems to design and develop a new ventilator. The high expertise of the team members in nuclear and particle physics was crucial from the earliest steps of idea generation. In a few days, on March 23, 2020, the group published an open-access paper that describes the product design; this paper immediately became a platform for discussion (Galbiati et al., 2020).

When nothing was certain, everything was made possible by the profuse willingness to help, commitment, and spirit of resilience of researchers. 'Every researcher or firm I called replied saying, how can I help?', said the MVM project lead. Working in an international environment can be stimulating, but working to save lives gives a stronger motivation to act and react. This was particularly true, at the time, for researchers and companies operating in the Lombardy area, where the virus killed more than 15,000 people since the beginning of May, 2020. Professor Arthur McDonald, a Physics Nobel laureate, stated 'for me, it has been wonderful to work with an international team covering such a broad range of expertise, working extremely hard to save lives in these difficult times. Everyone is very happy that their talents can make a difference, a true humanitarian spirit'. The internal factors described above, played a determinant role to trigger the spark and to go from 'having an idea in mind' to 'realizing the said idea'.

The role of far-sighted vision and leadership and network was evident throughout all phases; however, it was particularly salient in the earliest steps. Without clear guidance from the beginning, enthusiasm, and the capability to attract partners and collaborators, accomplishing the challenging goals that the critical situation required would have been difficult. Gabriele Cogliati, President and CEO of Elemaster S.p.a. Electronic Technologies, a key partner, stated 'we responded with enthusiasm to the request of collaboration received from the international scientific community coordinated by Professor Cristiano Galbiati and Professor Arthur McDonald'.

The project initiated without any funding. Collaborators used their resources to contribute to the project in an attempt to respond promptly to the pandemic. On March 27, 2020, a crowdfunding initiative, managed by Foundation Aria—a nonprofit foundation whose main objective is to promote innovation and economic growth in depressed areas—was set up to achieve the first goal of €30,000 to produce the first test units in a rapid interval.

As depicted in Figure 1, the main elements in this first step were as follows: high level related knowledge of scientists and researchers involved in the initial project; Professor Galbiati's leadership and vision to recognize an opportunity and gather people and companies; the international network of the GADM; the specific geographical area at the heart of the infection that allowed the team to stay in close contact with end-users and physicians who treat the effects of the virus on the lungs; and the ability to start a crowdfunding project quickly to finance the first step of prototyping.

5.2. *MVP and prototyping phase*

The lean approach predominantly emerged in the MVP and prototyping phase. Realizing a product that is unable to tackle the pandemic on time would have meant not only a huge waste of resources but also the loss of human lives. Being lean means following a quick and responsive development, which differs from the more traditional product development whose phases occur linearly requiring a long time before a project is completed.

As depicted in Figure 1, the MVM project went through a virtuous cycle of continuous and proactive learning that involved product design and development, and its testing and evaluation. The timeline (Figure 1) shows some critical events that occurred during the project. On March 26, 2020, a team of physicians from Milano-Bicocca University, who are directly involved in treating patients with COVID-19, provided the first feedback on the MVM concept. The first MVP was built on March 28, 2020, owing to the collaborative efforts undertaken by Elemaster S.p.a. The prototype was tested and immediately improved, activating the learning process and the process of pivoting continued. On April 15, 2020, the third generation of MVM was tested in the Milano-Bicocca Medicine Department and San Gerardo Hospital in Monza. On May 2, 2020, the sixth prototype version received the U.S. FDA certificate. Moreover, the degree of openness depended on the new resources required to build a new prototype that can address the needs of end-users. After evaluating the requirements of end-users, the team could promptly identify collaborators able to contribute to the project for facilitating the product development cycle. During the six concluded cycles, the number and range of collaborators have grown exponentially, raising the coordination costs of managing complex activities combined with strict time constraints. A strong leadership was prominent in the initiative's success.

When collaborating with universities, firms might choose to either cooperate or contract, depending on the strategic importance of the project (Cassiman et al., 2010). In the MVM case, we observed that universities behave similarly: they can choose between growing the collaboration network for partners who could contribute to the project on an ongoing basis and only having one-shot collaborations.

In the MVM case, the project leaders drove the whole initiative without any involvement of the Technology Transfer Offices as universities involved acted only through their researchers who freely contributed to the project. The primary motivation was related to the lack of time that hinders the initiation of regular (and formalized) technology transfer procedures. In addition, MVM did not use any existing technology patented by universities that would have required the involvement of Technology Transfer Offices.

Partnerships in the MVP and prototyping phase involved researchers of the University of Milan and the National Institute of Nuclear Physics. Immediately after, on March 24, 2020, a team of physicists led by Professor Giuseppe Gorini (Milano-Bicocca University) joined the program. Professor Giuseppe Gorini then began to coordinate with the Italian network of firms and researchers involved, the National Research Council and STIIMA, and ISTP institutes in Milan with two teams on product design and experimentation. The aim of this partnership primarily regarded the experimentation of some ideas that came out during the GADM project that were suitable to the ventilator's technology. The role of Milano-Bicocca University became increasingly crucial not only because of the outstanding specialized knowledge and expertise but also for its capabilities of being a platform of multidisciplinary knowledge, such as physics, medicine, mechanical engineering, control unit programming, and environmental engineering among others. Researchers from the following universities were also involved: the University of Brescia, closely collaborating with the National Research Council, the University of Bergamo that contributed to the software development, the University of Pavia for the sensor system improvement, the University of Insubria for the MVM testing, and the University of Cagliari that focused on the innovation management process. The collaboration expanded rapidly and internationally. It included three national laboratories in Canada, namely, the Fermilab, the Princeton Plasma Physics Laboratory, two of the Department of Energy's national laboratories in the United States, and CNRS-IN2P3 and CIEMAT in Europe.

Italian firms were the core contributors to the project especially in developing an industrialized prototype viable to the market. At this point, the move to an industrialized design was not trivial; without this crucial achievement, a product for mass production cannot be created. This activity involved Elemaster S.p.a., AZ Pneumatica S.r.l., Saturn Magnetic S.r.l., Bell Power Europe S.r.l., and Nuclear Instruments S.r.l. Notably, all contributors gave their full support and contributed without any monetary reward. Specifically, Elemaster S.p.a., put at disposal a full-time team of more than 40 specialists involved in project management, engineering design, and process technology control, as well as printed circuit board development and production. Additionally, Nuclear Instruments S.r.l., a small company equipped with specialized knowledge, was fundamental for developing the electronic part of the device from an industrial viewpoint, enabling the product certifiability and compliance with the European, Canadian, and U.S. regulations for mass production.

Users were central not only in the prototype evaluation following a lean approach but also in offering concrete suggestions on how to improve and adapt the MVM to patients affected by COVID-19. Indeed, lead users strongly characterized the MVM case. For instance, Milano-Bicocca University involved two affiliated professors, namely, Professor Bellani and Professor Foti, who were working in the COVID-19 intensive care unit of San Gerardo Hospital. Doctors observed that recovering from COVID-19 could take several weeks, and during the COVID-19 treatment, the oxygen flow intensity should not remain the same during the overall phase; at the beginning, it should be higher, and then lower. Taking this aspect into consideration, the first prototype and others that followed could improve significantly. Moreover, doctors provided insightful comments on the first draft of the paper on product design and offered suggestions about a user-friendly interface to be operated by nonspecialized personnel. 'Building on our specific knowledge about the COVID-19 disease, we are contributing to making MVM a customized product', said Professor Bellani.

Furthermore, the lean approach aims at minimizing all inefficiencies in production and manufacturing, including wasting time on unproductive meetings (Morgan and Liker, 2006; Flores et al., 2017; Chesbrough and Tucci, 2020). In the MVM case, teams have set schedules to monitor the achievement of specific intermediate goals and to update about emerging news, considering the number of participants when deciding the meeting duration. All meetings ran online due to lockdown; this can also be considered a new way of organization modality for project development. These dynamics highlight how lean and agility converged.

The outside-in path of open innovation during the testing phase was not characterized by the entrance of new partners but by the temporary occurrence of one-shot collaborations and additional directions and suggestions from several institutions. For instance, to produce a safe device, the performance of the sensors' technology must be improved significantly. A team of Ferrari engineers made fundamental recommendations during this phase. Key suggestions arrived from the Decarbonization & Environmental R&D department of ENI S.p.a. Besides, the MVM had to specify the detailed measurement of the organic substances emitted by the ventilator, Milano-Bicocca University contacted an affiliated researcher specialized in environmental chemistry who could perform the test, owing to efforts of an external collaborator, the SRA firm in Lombardy that borrowed the device in collaboration with scientists at Pisa University who gave specific instructions for its correct use. In addition, to facilitate the final design's rapid certification, suggestions provided by Health Canada, the U.S. Air Force, the U.S. FDA, and the Italian National Institute of Health and the Technical Scientific Committee of the Civil Protection Department became necessary.

As Figure 1 depicts, in this step, the interplay between existing and new specific knowledge, a multidisciplinary approach, and the role of universities as platforms (especially Milano-Bicocca University), with the active involvement of lead users and experts on one-shot collaborations, could reduce 'waste' in the generation processes of MVM. In this specific case, 'waste' is relatively easy to define as inefficiencies in the manufacturing process, rework due to failed addressing of malfunctioning problems, and in general, a waste of time.

5.3. *IP management and production phase*

The latest MVM prototype version was designed to meet the requirements of a ventilator in the simplest way possible. The MVM project's ultimate goal was to enable the largest possible diffusion of a ventilator optimized for the care and recovery of patients with COVID-19. The rapidity of the necessary development cycle mandated the development to be performed in an open-source format. The conceptual design was immediately placed in the open domain by publishing a paper on the arxiv.org pre-print server[1] to prevent the establishment of proprietary IP and/or preventing attempts at malicious patenting.

The MVM Collaboration decided not to patent or copyright any intellectual property rights concerning the MVM. Instead, it focused on making such intellectual property available in open-source to encourage other scientists and engineers at universities, national laboratories, and scientific foundations to freely contribute their work pro bono to advance the MVM testing and creation of the necessary documentation. The first document on MVM was published on March 23, 2020; the document highlighted developmental efforts undertaken by a critical mass of researchers from universities and laboratories worldwide.

In May 2020, the MVM Collaboration was approaching the completion of its paper's one last version to be released, and the perimeter of the information to become publicly available was carefully gauged to protect the MVM Collaboration and Foundation Aria from any legal liabilities that may stem from attempts of constructing MVM from unqualified groups. Thus, the information to be publicly disclosed was limited to the conceptual design, main components' characterization, and core of the results obtained, that is, the demonstration that MVM's simple design indeed achieves full conformity to the strict requirements of ISO regulation. The public domain information was licensed under the open license based on the CERN Open Hardware License (CERN-OHL) type 'P' (Permissive) v2.0 (the 'MVM CERN License'). CERN-OHL is a reputed open hardware license; it governs the use, copying, modification, and conveying of covered source and products, including the making of products. The license was granted by Foundation Aria as the licensor, which is applicable worldwide without time limitation.

CERN-OHL makes it possible for any qualified company in any country to manufacture the product without worrying about infringing intellectual property rights. Additional disclaimers accompanying the open license clarify any potential manufacturer's specific responsibilities, such as determining and endorsing the detailed construction drawings, obtaining the certifications required for use in healthcare settings by patients, and bearing the burden of all related legal liabilities. Manufacturing firms are also responsible for maintenance.

MVM Collaboration and Foundation Aria could decline any legal responsibility in the actual project implementation and in its use in healthcare settings, and acceptance of these terms was one necessary element of the MVM open licensing. Foundation Aria acting on behalf of the MVM Collaboration could reserve the right to deny the open licensing to subjects patently unqualified to build MVM implementations that meet all safety and performance requirements. The MVM Collaboration and the Foundation Aria could also foster tight cooperation among companies licensed to build MVM implementations.

Finally, the production on a large-scale basis was fostered by the MVM's intrinsic characteristic as an innovative product. MVM was inspired by the 1961 technology's simplicity, improved with a modern approach, and adapted to the customer's current needs. Existing modern ventilators are based on a relatively early technology from the 1990s, which has become more and more sophisticated via incremental innovations. Moreover, the use of standardized off-the-shelf components readily available in different countries is fundamental for gearing up the mass production and lowering the production cost. The customization feature and limited oxygen consumption can positively contribute to the entry of MVM in the existing and new markets and futhermore, govern their growth.

5.4. *MVM challenges*

The MVM Collaboration faced multiple challenges during the MVM realization stages (refer to Table 2). In the concept generation phase, at the onset of the COVID-19 pandemic, the most important challenge was responding promptly to the worldwide need for ventilators. Professor Galbiati, the project leader, first recognized the opportunity of using mechanical ventilators with a fluidics system and envisioned bringing a reliable, fail-safe, and easy-to-operate mechanical ventilator to any patient with COVID-19. As mentioned in the previous sections, resilience and the willingness to help were vital to the MVM project initiation and its further development.

Although setting the vision spontaneously came in the MVM case, translating it into something concrete was demanding. The high level of related knowledge and excellence in the research allowed the realization of the first MVM conceptualization and the overcoming of the freedom-to-operate analysis, a crucial concern when dealing with an open-source IP. Thus, given the lack of time, to avoid existing IP violations, every researcher (within their area of expertise) had to ensure that the parts used to make MVM were not protected. A critical aspect worthy of note regards the role of self-confidence that characterized researchers and the project leader's international reputation and network; these elements fostered the active and rapid involvement of collaborators. Raising funds in

Table 2. Challenges faced by MVM Collaboration and how these challenges were overcome

Phase	Challenges faced	How these challenges were overcome
Concept/seed	Respond promptly to the dramatic need for mechanical ventilators during the COVID-19 pandemic	Vision to recognize an opportunity Resilience and willingness to help
	Translate the vision into MVM: the first conceptualization	High level of related knowledge Excellence in research Self-confidence
	First collaborators' involvement	Project lead reputation and international network
	Freedom-to-operate analysis	Standard device parts selected
	Funding	Crowdsourcing
	Lockdown	Use of new technologies to ease communication
MVP and prototyping	Multidisciplinary and specific knowledge required	University as a platform New partners joining One-shot collaborations
	User testing	Users' involvement (physicians of Monza Hospital) Lead users
	Coordination	Strong leadership Strong commitment of all participants
	Time constraints	Speed up response time and learning process
	Movement limitations due to the lockdown	Involvement of private and public partners located in the Lombardy region (for instance, Elemaster S.p.a and Monza Hospital)
IP management and production	Decision of the IP protection level	CERN Open Hardware license
	Product liability	Manufacturing firms are responsible for manufacturing and maintenance

a short time was also essential to sustain early MVP costs, making the crowdfunding initiative helpful at this stage. The complexity and urgency of the initiative required continuous communication among all members and constant updates with the project leader, all made possible by the use of new technologies and platforms.

The MVP and prototyping phase are characterized by challenges mostly related to building a product with the right features for addressing current needs of hospitals – in other words, achieving produc–market fit. The COVID-19 emergency required the MVM team to accelerate the process of developing, neglecting somehow efforts to define a well-designed business model. In such a situation, it can be considered rational to keep the focus of team members on achieving product–market fit quickly. Lead users can be easily recognized in this step. Moreover, during the whole process, bringing together multidisciplinary and specific knowledge on ventilators was fundamental, and this was conducted, owing to the role of universities as platforms, new public, and private organizations joining the project, and less stable collaborations that can be configured as one-shot ones. The fast development of MVM increased the scope of partnerships and the number of people involved, thereby exponentially increasing the coordination costs at the same time; a robust leadership combined with a general commitment of all participants was essential to the MVM success. Time constraints, although present throughout the whole project, became a key challenge in this phase as it regards critical aspects related to learning. The general lockdown brought movement limitations, thus, to proceed with the different series of MVPs, the partners chosen (i.e., Elemaster S.p.a. and Monza Hospital) were located in the same region, the Lombardy region. Elemaster S.p.a. made significant contributions to the MVM development, including software and hardware; the company finally desires to manufacture and sell MVM defining its specific business model, coherent with the open-source nature of the MVM design.

The decision of the IP protection level became salient in the IP management and production phase. MVM Collaboration decided to disclose MVM information under the open license of CERN-OHL. According to CERN-OHL terms,[2] the licensor has 'no liability for direct, indirect, special, incidental, consequential, exemplary, punitive or other damages of any character including, without limitation, procurement of substitute goods or services, […] however, caused and on any theory of contract, warranty, tort (including negligence), product liability […]'. Therefore, the licensor is free and unharmed from any product liability, including claims by third-parties concerning such use.

The case of MVM is a remarkable case showing precisely how the combination of open innovation and lean approach significantly affects the innovation process by fostering innovative outcomes. The analysis of this case allows to identify a set of key challenges and describe the practices the research group adopted to overcome them.

6. Implications and conclusion

In this paper, we exposed the case of MVM as a new paradigm in open innovation research and a best practice in the management field. In this vein, several lessons and managerial implications are noteworthy. First, Chesbrough and Tucci (2020) argued that a lean approach contributes to the inside-out open innovation also via the generation of general-purpose technologies. Similarly, we showed how open innovation and lean approach could benefit from their conjoint adoption, equipping managers with a new toolset to explore opportunities for radical innovation. Second, to respond rapidly to the severe COVID-19 threat, iterative experimentation and feedback on a minimally viable product were determinant. Although the practitioner-oriented research stream argued that experimentation is a core component for new ventures (Ries, 2017), in the MVM case, we provided insights into the challenges and success of experimentation also conducted by established organizations. Third, combining open innovation and lean models required additional efforts for project leaders. By studying the MVM challenges, we learned that appropriate leadership, coordination, and commitment are essential for an efficient learning process and for adjusting the directionality and speeding up these activities.

Additionally, this study provides implications for public organizations. First, public organizations, including universities and research institutes, are characterized by a high degree of formalization that contributes to organizational rigidity, which, in turn, hinders the rapid response to external environmental changes. Considering our direct observation, public sector policies should stimulate initiatives aimed at introducing a lean philosophy in organizations to increase their agility and efficiency. Second, we showed the importance of being lean in an open innovation context, both to recognize and explore new opportunities. In this perspective, public organizations should train researchers and employees to learn how to master open innovation and lean tools effectively. Last, establishing a strong relationship with companies and the community was a contributing factor for the MVM project. Nowadays, universities with their Technology Transfer Offices are engaging in activities that aim to enhance knowledge transfer. However, their activities predominantly rely on the inside-out path of open innovation; in addition, more effort should be made on fostering the outside-in path and identifying effective incentives to attract private firms.

To conclude, we believe that our framework and exploration of open innovation and lean models might serve as a stimulus for future theoretical and empirical research in an attempt to better understand the interplay between the phenomena. Technology innovation scholars and practitioners would welcome future research to enlarge and deepen the scope of this study, also focusing on contexts characterized by nonemergency conditions.

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Notes

[1]The paper is available at https://arxiv.org/abs/2003.10405.

[2]CERN Open Hardware Licence Version 2 – Permissive.

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