



# Open Source Hardware, Exploring how Industry Regulation Affects Knowledge Commons Governance: An Exploratory Case Study

RESEARCH ARTICLE

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## ABSTRACT

Tools for clinical examination have not fundamentally evolved since the invention of the stethoscope by René Laennec in the nineteenth century. However, three decades ago, the medical community started to consider repurposing ultrasound scanners to improve physical examinations. A broad community of healthcare professionals trained in the new clinical examination paradigm could not be created due to the very high price of portable ultrasound scanners available on the market. In this paper, we study an Open-Source Hardware (OSH) community that aims to improve diagnosis in hospitals and medically underserved areas worldwide. They are designing an echo-stethoscope – a portable ultrasound scanner – that would be affordable in low and middle-income countries. The variety of expertise pooled to achieve this objective puts this knowledge common (KC) at the crossroads of open-source software (OSS), OSH, and medical communities. Unlike typical KC outcomes, an ultrasound probe is a physical object. Development and innovation in the physical world bring social dilemmas that the community has to overcome, restrictions in terms of openness, and in this case, unintended privatization. Our study uses the governing knowledge common framework (GKCF), a modified institutional analysis and development framework, to untangle the interactions between resources, participants, and governance structures.

Our research describes why and how the creation of a physical object subject to industry regulation influences the evolution and governance of the KC. We provide evidence that temporary privatization of the KC can be used as a way to protect and sustain a common during the industrialization phase. We also demonstrate how a portfolio of projects is an effective and resilient way to help the common survive this privatization step.

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## INTRODUCTION

Innovations in the medical field have been instrumental in improving public health and quality of life (WHO, 2010). Medical technologies (Medtech) help to prevent diseases, diagnose, and treat patients. However, Medtech innovations have not always been widely available and accessible to low and middle-income countries. Fragmented regulation (Bergsland, Elle, & Fosse, 2014; De Maria et al., 2018), high prices, and inadequate solutions for local markets (Malkin & von Oldenburg Beer, 2013) are the typical barriers hindering product adoption. According to the World Health Organization (WHO), in the cardiac disease field alone, more than two million patients die worldwide every year due to lack of access to an implantable cardiac defibrillator or pacemaker (Ochasi & Clark, 2015).

Access and distribution are two fundamental principles of the open-source movement. Initiated in the mid-80s, this movement paved the way for an open and collaborative approach to developing software. Groups of independent developers sharing similar interests gathered (Benkler, 2002, 2006; Benkler & Nissenbaum, 2006) to create open-source software communities. Today this practice has become a dominant way of producing critical software, such as operating systems for telephones and servers (Pearce, 2017).

With the emergence of 3D printing and fab-labs, open-source communities started to build tangible objects and made their designs freely available over the internet (Gibb & Abadie, 2014; Raasch, Herstatt, & Balka, 2009). This extension from purely digital to physical product development gave birth to a new form of product development and distribution; Open-Source Hardware (OSH), which *“is hardware whose source files are publicly available for anyone to use, remanufacture, redesign and resell”* (Gibb & Abadie, 2014, p. xiii).

OSH recently demonstrated its relevance in the medical field as an alternative way to provide technical solutions in the case of pandemics disrupting supply chains. It allowed decentralized production of respirators, visors, and spare parts as a rapid response to emergency needs (Maia Chagas, Molloy, Prieto-Godino, & Baden, 2020). Furthermore, making hardware design available under an open-source license allows anyone to contribute and improve the device, thus accelerating innovation at a fraction of the cost (Pandey & Vora, 2019; Pearce, 2015b; Williams, Gibb, & Weekly, 2012).

Open-source initiatives can be seen as community-powered projects that are often managed informally and aim to create and share a common knowledge (Coriat, 2011). They constitute a Knowledge Common (KC), a self-governed form of community created to produce and manage a particular type of resource: knowledge (Ostrom & Hess, 2007).

At first sight, OSH communities are very similar to OSS communities and other KCs. However, due to the extra constraints resulting from their interaction with the tangible world, they differ in many aspects (Ackermann, 2009; Beldiman Dana, 2018). This case study is located in the medical industry, an environment that is highly regulated to ensure patient safety. OSH Communities developing medical devices have to comply with stringent quality controls and audits (Abuhav, 2018), but this regulation has been designed for commercial enterprises and is inadequate for non-profit organizations or for informal institutional arrangements. As a result, these communities' efforts are frustrated and generate various social dilemmas the community has to overcome to achieve their goals.

Regulation has a substantial impact on these KCs governance and product development (Powell, 2012). With this case study, we intend to understand how KCs can adapt to industry regulations and ultimately place a product on the market.

We followed EchOpen, a community started in 2014, involving people interested in m-health and e-health devices worldwide. The project involves physicians who have fostered and developed the concept of echo-stethoscopy – the use of ultra-portable ultrasound imaging devices to enhance diagnosis during a clinical examination – for 30 years (Elezi, 2018). Their ambition is to build an affordable ultrasound probe and make it available in hospitals and medically underserved areas worldwide. They initiated a KC composed of more than 500 healthcare professionals, scholars, students, and engineers. We relied upon the governing knowledge common (GKC) framework (Frischmann, Madison, & Strandburg, 2014) to understand the evolution of this KC, a modified version of Elinor Ostrom and Charlotte Hess' institutional analysis and development framework adapted to knowledge as a resource. We gained insights into product development up to the industrialization stage, a stage that has potentially fatal implications for OSH projects and their community of volunteers in a regulated industry.

A legal entity must be accountable for manufacturing a device before it is allowed on the market for use on patients. In this case study, there was unintended privatization of the Common that was at odds with the commoners' expectations and which could have led to the end of the common. This study sheds light on mechanisms helping KCs survive regulation-driven privatization which goes against the open-source community's ethos. Moreover, through the lens of KCs, we provide guidance to anticipate and cope with the extra complexity OSH projects entail.

This paper describes the Open source movement's theoretical foundations, including both the well-established OSS and emerging OSH branches. We describe

why open-source models are an effective way to innovate in the medical device industry and pay particular attention to the regulatory framework of medical devices. It also introduces institutional arrangements used to produce and manage information or digital assets: the KC.

An exploratory case study is then presented following the Governing Knowledge Common framework approach, which describes how various stakeholders interact and govern the common to produce knowledge and overcome social dilemmas.

The final section elaborates on the findings, discusses limitations and potential ways forward for further research.

## BACKGROUND ON OPEN-SOURCE COMMUNITY AND GOVERNANCE OPEN MODELS AND COMMUNITIES

In the development of innovations, *openness* in exchange of information with external parties – companies (Chesbrough, 2003; Chesbrough & Appleyard, 2007), academia, or individuals (Benkler, 2002; Benkler & Nissenbaum, 2006) – is a powerful way to reduce development costs and accelerate innovation. The community studied here ranks high in openness using a metric developed by Bonvoisin & Mies – the ‘Open-o-Meter’ (Bonvoisin & Mies, 2018). This community coordinates volunteers’ efforts to design an affordable portable ultrasound probe with a smartphone app to visualize images. This OSH project is the congruence of a medical and a technical project in which anyone can study, modify, make, distribute, and sell the hardware/software based on that open design/code (Winter et al., 2019).

### GOVERNING OPEN SOURCE COMMUNITIES

The study of institutional arrangements to preserve shared resources started half a century ago with the seminal work of Elinor Ostrom. She described how a group of people could self-organize and create a Common to govern and preserve shared natural resources -Common Pool Resources (CPR) (Ostrom, 1990).

Starting in the early 1980s, a series of intellectual property rights laws and court rulings have progressively reduced the scope of ‘open access’ knowledge (Coriat & Orsi, 2002), for instance, software programs and living organisms have become patentable. Thus, emerging sectors such as Information Technologies and Pharmaceuticals have started to patent their innovations extensively. The legislator’s initial intent to stimulate innovation by creating an incentive for companies to invest in new technologies eventually became an obstacle to the creativity of many innovators and communities. This second enclosure movement (Boyle, 2003) invited scholars to extend the

concept of CPR to knowledge (Hess & Ostrom, 2003) and to various digital assets, fruits of the internet revolution (Benkler & Nissenbaum, 2006; Bollier & Pavlovich, 2008; Dedeurwaerdere et al., 2014; Laerhoven & Ostrom, 2007; Ostrom & Hess, 2007). Communities have become a central component of this decentralized production of digital assets, made possible by access to the internet and the reduction of transaction and replication costs (Benkler, 2006).

In this paper, we allude to open source communities or commons interchangeably. More precisely, a KC “*refers to the institutionalized community governance of the sharing and, in some cases, creation of information, science, knowledge, data, and other types of intellectual and cultural resources*” (Dedeurwaerdere et al., 2014). Knowledge is neither a well-bounded nor a straightforward concept; in this article, we consider knowledge as ideas, data, and information at any point in the wisdom hierarchy (Davenport & Prusak, 1998; Henry, 1974). To better describe the variability and complexity of knowledge and information as a resource, we extend the notion of knowledge to creative works (Ostrom & Hess, 2007).

In a Commons, knowledge is considered to be a shared resource to be enriched and maintained (Coriat, 2011). For example, communities combine their resources to provide public libraries (Shuhuai, Chen, Xingjun, Haiqing, & Jialin, 2009). The scientific community ‘stands on the shoulders of giants’ as it makes advances in complex problems that no person or organization could solve alone (Spier, 2002). In sum, when people collaborate to share and produce knowledge, they create a KC.

KC constitutes a compelling mode of production of information, knowledge (Coriat 2011), and innovation since there is virtually no limit to the number of participants in a common. It has proven to be a game-changer in the production and circulation of information while safeguarding innovators’ intellectual property (Allen & Potts, 2015, 2016; Potts, 2017). Furthermore, Frischmann, Madison, and Strandburg have shown that norms, community standards, and democratized participation is an effective way to govern intellectual resources even in the absence of traditional intellectual property (Frischmann et al., 2014). Scholars have described countless cases of virtual communities organized as commons that produce knowledge, in particular software (Hess, 2012; Ostrom & Hess, 2007; Schweik & English, 2012).

However, the technological landscape has changed, and innovations made the creation of physical products considerably more accessible to individuals, such as Arduino, Raspberry Pi, 3D printing, and fab labs. Community members now work together to build complex tangible objects. However, building objects ‘in the real world’ is not

as simple as writing a piece of code; extra constraints of the physical world will influence the KCs governance.

Scholars' understanding of open source community— as a KC – derives from the study of OSS communities. As OSH practice takes off (Pearce, 2017), it is crucial to assess the validity of our current models against the extra complexity brought by a product existing in the physical world.

## A BRIEF HISTORY OF THE OPEN-SOURCE MOVEMENT

The open-source movement started in the eighties with Richard Stallman (Stallman, 1985), an MIT engineer frustrated by a software program not answering his needs. He realized that he was not allowed to make minor modifications without infringing copyright laws. He created an innovative software license: the GNU General Public License (GPL) permitting modification, copy, and redistribution of software programs (Stallman, 1999; Stallman, Lessig, & Gay, 2002). This legal mechanism, known as *copyleft*, is the cornerstone of the open-source software community's global success. This robust system of licensing promotes and protects OSS innovations, although, as we will further explore, this licensing mechanism is not fully applicable to OSH (Ackermann, 2009).

The open-source approach has many virtues that scholars have analyzed over the past thirty years. It reduces project development costs (Gruber & Henkel, 2006; Schweik & English, 2012), brings innovation (Chesbrough, 2003; Schweik, Stepanov, & Grove, 2005), and products created by a voluntary, global collaboration of people are regularly shown to be superior to proprietary solutions (Benkler, 2016; Redlich & Moritz, 2019). It is no longer a question of knowing whether open source is a rational choice or an emerging trend (Carillo & Okoli, 2008). It has become a mainstream way of developing novel technology (Pearce, 2017), e.g., as of July 2019: 86% of smartphones rely on Linux as their operating system<sup>1</sup>.

## INTRODUCING OPEN SOURCE HARDWARE

The OSH movement is an extension of the OSS movement into the physical world (Raasch et al., 2009; Schweisfurth, Raasch, & Herstatt, 2011). The Open Source Hardware Association defines OSH as a tangible artifact “*machines, devices, or other physical things – whose design has been released to the public in such a way that anyone can make, modify, distribute, and use those things.*” (OSHWA, 2020 Website <http://www.oshwa.org/definition>). In summary, an OSH product is a physical artifact whose documentation is released under a license granting production and distribution rights to anyone. This documentation has to be sufficiently comprehensive to enable anyone to build the object and develop it further (Bonvoisin, Mies, Boujut, &

Stark, 2017). For a long time, it has been considered a means to develop “gadgets for hobbyists” (Hansen and Howard 2013). Unlike the products of software development projects, the products created by open hardware project communities are substantially more complex to organize and implement due to their tangible nature. They require a broader range of expertise and skills (Lerner & Tirole, 2004; Raasch et al., 2009), although technological evolutions such as 3D printing and fab labs in the last decade have helped to overcome some of these challenges.

The expected benefits of OSH are numerous: reduced cost of R&D, a faster innovation cycle, lower legal fees, better product quality, lower cost of repair, and an ethical bonus for the brand (Gibb & Abadie, 2014; Gibney, 2016). However, OSH is a relatively new movement, and the number of publications in the peer-reviewed literature is inevitably lower than the number of ongoing projects that are still in early phases (Pandey & Vora, 2019). The added value compared to the proprietary model is not yet fully understood (Huang, 2015). However, emerging literature tends to indicate that in the medical field, the return on investment is significant (Pearce, 2015a, 2015b).

## MEDICAL DEVICE REGULATION

Medtech projects have bloomed<sup>2</sup> in recent years (Pearce, 2017) thanks to increased access to 3D printing and fab labs (Niezen, Eslambolchilar, & Thimbleby, 2016). However, it is not clear how they tackle the challenges posed by the regulation of medical devices (EU, 2010). In regulated markets such as the US or EU, a medical device cannot be distributed legally without proving its safety, validated by a security clearance given by an appropriate regulatory body (Twomey, 2013). In Europe, this regulatory process is ruled by the Medical Device Directive (MDD) that described how organizations could obtain the CE mark— a guarantee that the device complies with the applicable rules and regulations is safe and efficacious for patients.

Existing literature usually assumes that companies, startups, or academic labs manufacture OSH devices (Li & Seering, 2019; Pandey & Vora, 2019). But the emergence of the OSH movement in the medical field led the Food and Drug Administration (FDA), in charge of medical device certification in the United States, to change their policies. For instance, FDA proposed flexibility for smartphone-based applications (FDA, 2013) and 3D printing (De Maria et al., 2018; FDA, 2018).

However, simplification of the regulation does not apply to sophisticated medical devices such as the ultrasound probe under study in this paper. An ultrasound probe is a class IIa medical device; it must be assembled by a specialized industrial partner that grants a CE mark after validation by the notified body. Moreover, regulators require that the

development and manufacture of medical devices follow quality management guidelines ISO 13485 (Abuhav, 2018).

In a KC, volunteers enrich the pool of knowledge when they can, when they want, without constraints or commitment. They cannot be held accountable for complying with regulation within a quality management framework; a community cannot have its product authorized for commercialization<sup>3</sup>.

Hence our research question: *How can Knowledge Commons adapt to industry regulations and place a product on the market?*

The KC we study in this paper faces severe challenges in complying with the regulation. We will pay particular attention to their self-transformation into a private entity without discouraging community volunteers or terminating the KC.

### PROTECTING OPEN-SOURCE HARDWARE

Contrary to widespread perception, KCs are not growing based on an absence of rights (Hess & Ostrom, 2007). Instead, they are prospering thanks to different types of rights, allowing fit for purpose use, modification, and distribution. They protect authors and innovators who choose to make their work available for free to retain their copyrights. However, copyright does not protect ideas -or objects-, it protects the expression of these ideas; for instance, schematics or documentation of these ideas -objects- (Ackermann, 2009). Hence, typical copyrights and licensing deriving from the OSS movement may not offer suitable protection of knowledge generated by KC in Open-Source Hardware (Marrali, 2014).

Usually, OSH projects are developed for a nascent or not existing market; therefore, the temptation for the third parties to free-ride the resource and enter these markets is low, protecting de facto the intellectual property of the innovation. In some cases, that could constitute “good enough” protection.

Another mechanism of protection is the patent. It is not part of OSH community ethos to patent; often perceived as an impediment to innovation (Bergsland et al., 2014; Chien, 2013). Compromises such as defensive publishing or patent pooling place the invention in the public domain to protect it (Beldiman Dana, 2018; Schultz & Urban, 2012). In the absence of suitable protection -open access to knowledge but with clear ownership- the Common could be in danger; typically, a free-rider could decide to patent the knowledge obtained from the community.

## EMPIRICAL ANALYSIS METHODOLOGY

The study of a KC is a complex exercise (Madison, Frischmann, & Strandburg, 2010) due to the dynamic

nature of institutional arrangements and the wide variety of commons (Hess, 2008). Hence, we relied on the last version of the institutional analysis and development framework, adapted to take into account specificities of knowledge as a shared resource (Frischmann et al., 2014; Ostrom & Hess, 2007). The GKCF supports the identification of various ‘building blocks’ that make up the governance of a common.

The first building block relates to the basic attributes of the KC, including resource characteristics, community members, goals and objectives, and rules-in-use.

The second is the ‘action arena’ where choices made are governed by ‘rules-in-use,’ and relevant stakeholders interact with one another to deal with the social dilemmas associated with sharing and sustaining of the resource.

The resulting pattern of interaction – how people interact with rules, resources, and one another – is described in **Figure 1** (Ostrom & Hess, 2007).

Furthermore, GKC provides a comprehensive approach to case study design and analysis, facilitating comparison with other cases to produce generalizable results.

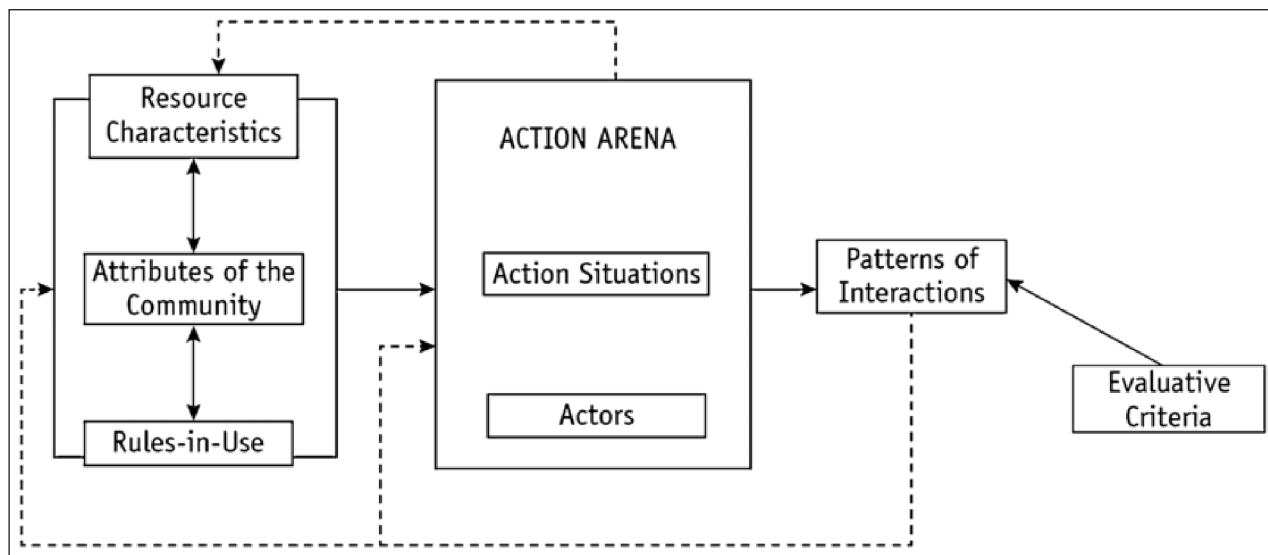
This exploratory case study approach is particularly relevant for analyzing changes and the reasons for them. Qualitative research is particularly adapted to our case, where our goal is to highlight the reasons for governance decisions within the KC (Yin 2010). We want to understand governance adjustments in response to social dilemmas arising in the development of an OSH medical device. An exploratory case study will allow us to gain an extensive and in-depth description of this social phenomenon (Merriam, 2009). We presume that these causal links are too complicated to be investigated by a survey or experiment. Moreover, we have no pre-determined outcome when asking ‘how’ or ‘what’ questions (Yin, 2014).

### Empirical setup and data collection

In January 2020, we had access to the EchOpen lab in the AP-HP premises in Paris for three days, where we conducted in-person semi-structured interviews and attended meetings as silent observers. The EchOpen team granted us access to internal documentation. Since it is a very open community, most of the content was freely available over the internet on their website or even on their Slack application – a digital workplace to organize team discussions and structure documents shared among members. This community information platform has been incredibly useful for coordinating with community members for internal document sharing. We were rapidly granted access to the development platform and became members within a few hours. We then proceeded to the archival analysis of internal documents, reports, and websites.

We first targeted core community members for an interview, since they are more knowledgeable in the





**Figure 1** Governing Knowledge Commons framework (Frischmann et al., 2014).

governance mechanisms at stake. Then, we expanded to occasional contributors in the medical or technical field. We conducted fourteen semi-structured interviews with the core members of the community: the CEO of echOpen, founding partners, seconded staff from the funding partner, medical doctors, and academics. The average interview length was between 45 and 90 minutes. The questions were inspired by the GKCF research questionnaire and were tailored to the context. Our questionnaire was designed in English, although informants were allowed to answer in French to improve the quality of their feedback. Quotations in this paper are in English; when translated from French, we asked informants to confirm that the translated quotation faithfully transcribed their opinion.

For triangulation purposes, we collected secondary data from publicly available documentation over the internet, on the community’s wiki, GitHub, website, and past newsletters.

For our data analysis, we transcribed more than three hundred pages of interviews, which represents approximately 18 hours of recordings in French and English. We designed our questionnaire to fill in the GKC framework; our coding was deductive, resulting in the minimization of coding bias.

In the next section, we use the GKC structure to describe the EchOpen environment and governance choices in light of the characteristics of the pooled resources.

**GOALS AND OBJECTIVES OF THE COMMON**

**Introducing a New Paradigm in Clinical Examination**

Echo-stethoscopy is the use of an ultra-portable ultrasound imaging or medical visualization tool to enhance the diagnostic orientation capabilities of health professionals during a clinical examination (Elezi, 2018). General practitioners, emergency physicians, specialists,

midwives, and nurses can improve their diagnostic abilities and work routines (Narula, Chandrashekhar, & Braunwald, 2018). More frequent and affordable imaging during clinical examination benefits patients but also taxpayers, thanks to a reduced number of complementary examinations and faster patient management. Emerging literature is starting to study how echographic imaging or insonation can improve physical examinations (Narula et al., 2018).

The primary objective of the community under study is the adoption of echo-stethoscopy as an innovative medical practice. The distribution of a large number of probes to physicians and a growing community of healthcare professionals is contributing to this objective. A not-for-profit (NFP) association supports the community, and one of its bylaws<sup>4</sup> clearly states the community’s goal:

*“Its purpose is to promote the general interest by the development of free software and open hardware projects which can benefit all and be reused or redeveloped by all, respecting norms and open standards, promoting virtuous digital practices, a free web, and guaranteeing the respect of personal data[...]more specifically in the field of health, by making accessible, open, affordable, and collaborative medical technologies, such as ultrasound imaging.”*

In this endeavor to change medical practice, conceiving an affordable and fit for purpose ultrasound probe is an essential part of the process. The mission statement further describes key deliverables:

*“Create a multidisciplinary community with a shared vision to create the first low-cost, open-source echosthoscope [...] document all the work done by*

*the community and make it available to all those who want to run a free, open and collaborative project.”*

EchOpen has a role in shaping the landscape of diagnosis and may well create a market that could attract private companies and create a virtuous circle. The business development manager states very clearly how they will assess and evaluate the progress of their mission:

*“The success factor is dissemination. So that we are able to [...]increase, develop the community. [...] One example is using this technology for veterinary purposes [...] disseminating even basic knowledge about ultrasound, about electronics, about everything, all subjects. For us, it is very important. [...]We [...] see us also as a platform developing knowledge about ultrasound, about echography, about medical imaging, about electronics, about software, et cetera.”*

Ultimately, with the dissemination of echo-stethoscopy as a metric to measure the success of the common, if a third party manufacturer reduced their prices to provide affordable probes, the echOpen mission would still be considered a success.

## COMMUNITY STAKEHOLDERS

This KC is the epicenter of various stakeholders' efforts. First and foremost, the founders, pioneers in the medical community who perceive echo-stethoscopy to be a giant leap forward for the practice of physical examination and diagnosis. Two of them are medical doctors at the Assistance Publique – Hôpitaux de Paris (AP-HP), one of which is specialized in radiology. The third founder is an open community and technology expert who has created numerous open data projects, including one dedicated to accelerating cancer research. They were rapidly joined by various software and hardware developers who wanted to help.

Along with them, a small group of very active volunteers started to dedicate an increasing amount of time to the project, close to a full-time equivalent. They joined the community highly motivated by the idea to build a low-cost medical device that could improve life of the poorest.

A software developer rapidly took the lead for the development of the smartphone app. Similarly, an electronics expert was appointed to take the lead for the electronic aspects of the probe. Likewise, an engineer was identified to integrate the probe's mechanical parts with the software and hardware.

A public health doctor joined the team to coordinate the pool of medical experts. Their role was to define the field of application of the echo-stethoscope, basically in which case the medical device is useful and how to interpret the

results displayed on the screen. Organs are targets, and the community is interested in identifying what visible signs of a potential pathology are.

A project manager and community manager joined the common to help coordinate the community. We will refer to this group of ten to twelve members as the core team.

In parallel, an increasing number of students, Universities, and engineering schools brought their research facilities and expertise to the common. An engineer from the core team observes:

*“I never imagined that I would be able to make a phone call or call on LIP6 experts to shed light on this or that communication issue. For example, some time ago, someone asked, “Do you have an expert who specializes in this or that communication protocol?” And we spent an hour discussing with that person in a meeting.”*

OSS projects can live and evolve during the early years of their development without physical infrastructure or external financing. However, the development of a physical artifact by the echOpen project required a commonplace to organize gatherings or meet-ups and, above all, a fully equipped lab to build and test prototypes. Thus in 2015, core team members created a French not-for-profit association to support the development of the project. The AP-HP made premises available and lent equipment and decommissioned ultrasound machines for reverse engineering. Later on in 2015, the Foundations Pierre Fabre and Sanofi Espoir brought financial resources and dedicated staff to support the project. In 2017, Altran signed a partnership with the association to provide pro bono consulting. Finally, in 2018, EchOpen joined the 'knowledge and innovation community' (KIC) of the European Institute of Innovation and Technology (EIT) called EIT Health. This program provides financial support and access to a vast network of academic institutions and consulting firms.

At a later stage, an industrial partner was involved in manufacturing the final version of the ultrasound probe, based on the community's prototype. The ultrasound probe is a class IIa non-invasive medical device<sup>5</sup>. The affixing of the CE mark by the designated manufacturer<sup>6</sup>, required for commercialization across the European market, is authorized by a Notified Body. An audit is conducted covering the conformity of the product's technical file and the manufacturer's quality system.

## RESOURCE CHARACTERISTICS

*“We do not really expect resources from the community[...] Any organization that is interested in contributing can provide resources”- Co-founder*

Several deliverables are needed to provide affordable echostethoscopes to healthcare professionals around the world successfully.

A low-cost ultrasound probe must be designed and produced, a smartphone app must be developed to visualize images received from the probe, a robust training program to ensure the probe is correctly used and images are understood correctly must be prepared, and finally, medical proof of the device's efficiency is required. These deliverables require a blend of specific skills provided by volunteers, pro bono consultants, freelancers, and pooled in the community.

The technical community's main objective is to design and deliver two work packages: the smartphone app and the low-cost ultrasound probe (Figure 2). The probe is a complex piece of hardware that transforms ultrasound waves sent into a patient's body into an electrical signal that is interpreted by the smartphone app, which reconstructs an image of the organ under investigation.

#### Business as Usual: Building an Open-Source App

The app transforms a smartphone into a visualization screen for the ultrasound probe. Building the app requires a broad range of expertise in software development and engineering skills, image processing, mobile apps, iOS, Android development, and low-level language programming. Developers interact online with the support of digital tools such as GitHub or Slack that facilitate code sharing and validation. They also meet during hackathons or other regular events.

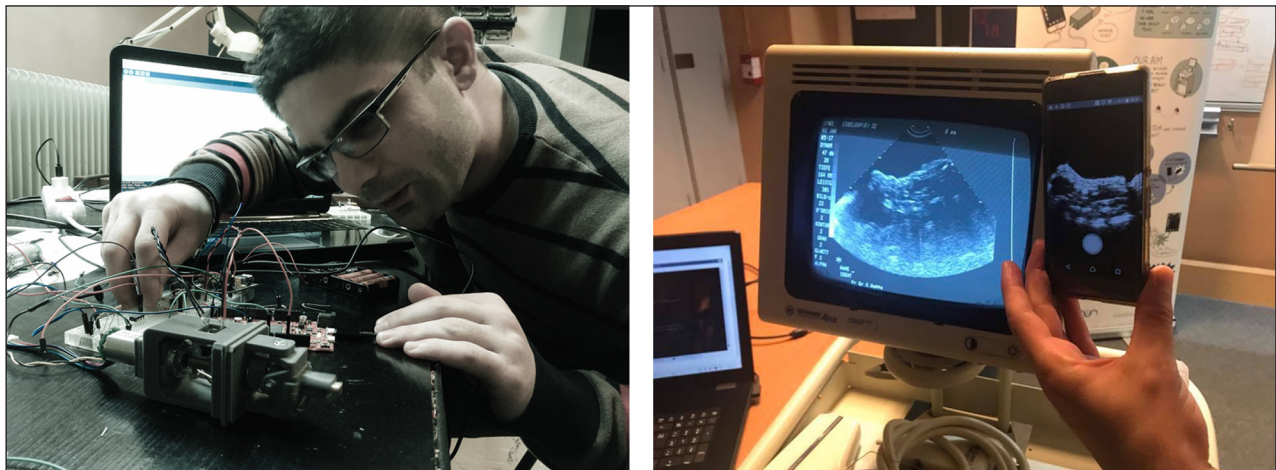
Physicians and engineers collaborate closely during the development of these two apps. The medical community was in charge of the specifications and validation, while the technical community worked on the development. As a purely intangible asset protected by copyright laws, the

code produced for the two prototypes is available on Github, fully accessible to the public. It is reusable under the BSD 3, a permissive license allowing unlimited redistribution for any purpose as long as the copyright and warranty disclaimer is not modified.

#### Welcome to the Tangible World: Building the Probe

The ultrasound probe work package is more challenging to execute, and having a large number of people involved in OSH design or development is a complicated endeavor (Boujut, Pourroy, Marin, Dai, & Richardot, 2019). The expertise needed is highly specific: acoustic, transducer and electronics experts are difficult to onboard (Lerner & Tirole, 2004). OSH projects require resources that are physical and subject to competition, as opposed to the purely digital resources of an OSS development project. A physical meeting place is needed to gather participants and build the prototypes. AP-HP lent a free lab where community members can come to work on prototypes. They have access to electronic equipment: oscilloscopes, electronic material, components, and a few prototypes. The relatively high cost of the prototype limited the number available for testing and development, turning community members into competitors; when someone works on a prototype, and others cannot:

*“Echopen lab is based at Hotel Dieu Hospital in Paris and is open to the public everyday. To come, a simple mail is needed. We developed a fully documented ultrasound technology kit divided into modules. Each module corresponds to a category such as a transducer, mechanics, analog electronics, digital electronics, signal analysis and software application, etc. to let anyone with skills in such areas to get involved in an inclusive manner.” – Introduction of EchOpen Welcome Kit*



**Figure 2** EchOpen Concept (picture on the left: the probe, picture on the right: the smartphone App) ©EchOpen.



Various academic institutions reinforced the technical community; amongst others, Lip6 Sorbonne specialized in onboard computers and in engineering EPFL or ULB. They brought direct access to their researchers' networks, labs, and equipment that echOpen could not afford. A founding member comments:

*“Any organization that is interested in contributing can provide resources. Opening their facilities, as we had with schools, universities, and research labs gets us free access to their materials, their equipment that we could not afford.”*

Physicians, radiologists, and healthcare professionals contributed to the specification of the probe, including the expected features, design, and size. Professional designers helped to optimize the form factor and the size of the probe. The community's ambition is to place a probe in every doctor's pocket, replacing its famous ancestor, the stethoscope. Thus the probe should be relatively small and able to fit in a shirt pocket. The documentation and design of the prototype probe are publicly available under a GPL 3 license<sup>7</sup> adapted to the hardware. However, this protection is partial and can easily be overcome with a few minor design modifications, potentially allowing third parties to patent it against the community to protect their market share. Hence, the community considered patenting some key elements of the device and make them available under an open license to secure subsequent open use and improvement.

## GOVERNING THE COMMON

### Rules-in-Use

The 'rules-in-use' are governance rules that explicitly deal with the conditions for the enrichment of shared resources; they may be formal or informal. Although the community is five years old, there are no formal governance rules to govern the project development. The only formal rules that we discovered were in the bylaws of the association, which describe membership and the organization of their governance. We identified consortium agreements that govern project interactions between funders and the echOpen association, which explicitly or implicitly push the association to work towards a specific objective. For instance, Sanofi Espoir would like to promote the use of the ultrasound probe for the benefit of children and maternal health.

There are a few informal rules that everyone follows: budget-related questions are the co-founder's responsibility, medical questions are dealt with by a group of doctors who are experts in the field, and software development is under the responsibility of the lead programmer. The decision-

making process is very collegial, with a strong need to establish a wide consensus within the core team. In case disagreements cannot be resolved during the week, they are brought to arbitration at the weekly meeting every Monday. A co-founder summarizes the dynamics of these arbitration meetings:

*“There is one tacit rule, only one: [...] the one who is doing the work is right.”*

### The Action Arenas

The *action arena* is the place governed by 'rules-in-use,' where relevant actors make choices and interact with one another to deal with social dilemmas associated with sharing and sustaining the resource. It is also the place where actors decide to make rules and norms applied to the Common that evolve to cope with emerging constraints.

The "raison d'être" of a KC is the enrichment and sharing of a resource (Coriat, 2011). The community makes choices in the action arena that are assessed against their evaluation criteria: to create knowledge and disseminate it.

### Privatization to comply with medical device regulation, a social dilemma

During project development, the echOpen community had to overcome various social dilemmas within the action arena. However, complying with medical industry regulation is probably the most challenging dilemma they had to resolve (Madison, Frischmann, & Strandburg, 2009).

A portable ultrasound device is considered as a medical device by the health regulatory authority in Europe<sup>8</sup>. Medical devices are grouped by *classes* designed to be representative of the level of risk associated with the intended use of the device. These classes are defined by a set of rules based on different criteria, such as the duration of contact with patients, the degree of invasiveness, and the part of the body affected by the use of the device<sup>9</sup>. Active devices intended for direct diagnosis or monitoring of vital physiological processes are in Class IIa. Devices at this level are considered to be low to medium risk products. They require authorization from regulatory bodies to be used on patients and commercialized worldwide; FDA in the United States and Australia Therapeutic Goods Administration (TGA) in Australia, for instance. EchOpen decided to obtain CE marking first due to their geographic location. Medical device manufacturing is controlled by certification of CE marking, following a conformity assessment process. The submitting organization, aka the manufacturer, must provide a technical compliance dossier and have it audited by a notified body. This certification authorizes<sup>10</sup> the usage of the medical device on patients and its commercialization within Europe.

The CE marking<sup>11</sup> has no legal jurisdiction in low and middle-income countries. However, health authorities generally recognize that the technical dossier and quality audits that have been implemented for the European Conformity Assessment process are sufficiently sound to demonstrate the device's safety and effectiveness. These generally constitute a very significant part of the requirements for importation, with some country-specific administrative procedures.

Securing the CE certification process is a critical success factor for the echOpen project. Although an association or a community can outsource the production of the device to an industrial manufacturer, it cannot fully comply with the registration dossier.

*“even if you are very highly engaged community, you will never attain CE marking for a medical device. When you have a community, even if [you] follow [a documentation process strictly], because you need to show the working contracts of the people [developing] the solution. When you have a community, you don't have a working contract, you don't have the resume[...] nothing has been put in place for a collaborative and even open project to achieve industrial goals. [...] a quality management system [...] cannot be on a voluntary basis.” – co-founder*

Community work can hardly be placed in a quality management system: internal standard operating procedures are vague or non-existent, the association has no employee who can be contractually held responsible for quality control. In sum, OSH communities cannot put a medical device on the market.

This brings the commoners to the main decision point in the community's development: in order to achieve the association's mission, the community decided to create a private company. That was a turning point in the development of this KC since the original intent was to stay informal, open, and not to become a company. A software developer observes the risk of enclosing the common:

*“You don't know what could happen on the way, that's always a risk [...] that you do not lose control of what you have done, that all the contributors that volunteered to do it, they [give] their works to a company that [...] make[s] money on the work of thousands of contributors because they host this thing or make it more accessible. That's super frustrating because, in the end, all these people that did it in their free time, they finally [have] been exploited.”*

The creation of a private company, in addition to the community, is a convenient way to scale up the development of the probe and to distribute it more rapidly. It becomes possible to approach venture capitalists with a business plan and seek extra funding, thus accelerating project delivery. In that sense, it fits with the objective of the common: “disseminating the tool” as a prerequisite to disseminating medical knowledge.

However, this move towards privatization has a substantial impact on the hardware community's governance and culture of openness. While working under the umbrella of the private organization, free communication and information sharing outside the private entity will be on hold.

The common is in danger if volunteers do not follow the new strategic direction, since commoners' commitment is vital for the survival of the community (Ostrom 1999). Commoners perceive privatization as going against the ethos of an open hardware community and may become demotivated by this unintended privatization.

This strategic direction must be understood and agreed by all to avoid the tragedy of the digital commons – underproduction or lack of maintenance that ends up killing a project (Schweik & English, 2007).

Therefore the volunteers' two main concerns have to be resolved to maintain the involvement of the project's various stakeholders:

- How to resume the KC after the ultrasound probe industrialization phase?
- How to secure the open-source nature of the knowledge produced by the common?

The private entity's role is to manufacture and sell the probe, but being able to resume the common after the manufacturing phase is a crucial part of the KC success. The community is the keystone of the product post-launch phase; members will develop the semiology, training material and become ambassadors of echo-stethoscopy. These crucial steps are instrumental in reaching a critical number of health professionals adopting this new medical practice and in triggering a snowball effect.

Hence to secure the *Open source destination of the community* and the *resuming of the common*, EchOpen has implemented a form of project portfolio management. A new, fully open source project is started, and volunteers are invited to participate while the core teams and suppliers are working on the manufacturing phase of the ultrasound probe. This new project is EchOlub Box (ELB), a standalone ‘do it yourself’ kit based on the open-source foundations of the ultrasound probe repurposed for educational ends. Students from schools and universities have access to a

bundle containing simple step-by-step documentation, hardware components, and ready-to-use software to install on a smartphone. Together, in class with their teacher, they can build an ultrasound emitter and conduct experiments. This kit contributes to knowledge dissemination, reinforces the community’s expertise in ultrasound technology, and is not subject to medical device regulation.

Meanwhile, the manufacturing of the ultrasound probe continues as a ‘closed project’ supported by consultants and suppliers. This project will remain closed and confidential until the development is completed and the probe available on the market. At that stage, all source code, schematics, and hardware design will be released into the public domain (Table 1). In the future, when developing a subsequent version of the probe, EchOpen will continue with this pattern of alternating open and closed project phases: initiating a new open project for Version 2 of the probe that will, in turn, be closed at the industrialization phase.

This agility of resources within a project portfolio helps to maintain momentum for the community members. It facilitates the Common resuming since it was not stopped but only focused on something else. Besides, commitment to publish source code and schematics under an open license, once the probe is available on the market, secures the open-source nature of the community. Thus, the involvement of commoners in the projects prevents the termination of the KC common.

These two critical governance decisions are the core solutions echOpen found to overcome regulatory-led dilemmas and to secure the future of the KC.

## DISCUSSION CONTRIBUTION

With this case study, we describe why and how the creation of a physical object subject to medical regulation influences the evolution and governance of a KC. We provide evidence that KCs, coupled with dynamic project portfolio management, are effective and resilient institutional arrangements in OSH project settings. KCs are flexible and scalable enough to protect and grow shared knowledge

throughout the development process of a medical device. This case opens a new area of research at the crossroads of regulated environments and open-source innovations, where partial privatization of the Common is a convenient way to achieve product development. The exploration of OSH fields subject to regulation is becoming increasingly relevant. Openness in hardware development helps build trust, is usually more reliable, and the reuse of standardized modules facilitates maintenance and training (Gibney, 2016; Niezen et al., 2016). Altogether, these benefits are particularly adapted to low- and middle-income countries, where medical equipment training and support are often suboptimal (World Health Organization, 1985; WHO, 2010).

OSH projects are also a means to lower product development costs, facilitate dissemination of innovation (Broumas, 2017), and accelerate mass adoption. KC-based projects also open doors to unexpected or unaffordable expertise. Nevertheless, they bring extra complexity in terms of governance compared to the classical closed model of product development – volunteers expect extensive transparency and consensus in decision-making (Ostrom, 1990). Moreover, regardless of their institutional arrangement, they cannot overcome regulatory barriers without staff and a legal entity.

### The fate of KCs in a regulated environment

In this case study, we have identified limitations to the scale-up and success of OSH projects. Regulation can impose constraints that an informal community cannot overcome in normal circumstances (Twomey, 2013) – although, during the COVID-19 pandemic, regulation has been adapted to allow usage of open-source hardware medical devices<sup>12</sup>. A class II or above project must fully comply with current medical device regulations to ensure patient safety. This regulation assumes the existence of a legal entity with staff or consultants to endorse the responsibility of device manufacturing, something a KC composed of volunteers cannot easily achieve.

Communities developing complex OSH projects in a regulated environment must anticipate the regulatory stage. They have to implement a quality management

ECHOPEN PROJECT PORTFOLIO					
		ECHOLAB BOX	PROBE V1	PROBE V2	PROBE V3
Project Timeline	T1	N/A	Open Project	N/A	N/A
	T2	Open Project	<b>Closed Project</b>	Open Project	N/A
	T3	Open Project	Open Project	<b>Closed Project</b>	Open Project
	T4	Open Project	Open Project	Open Project	<b>Closed Project</b>

Table 1 Project openness evolution – Own elaboration.

system early on and train volunteers to maintain it. It is hugely challenging, but unless they successfully do so, they will only be allowed to deliver a prototype and they will never realise their ambition – the production and distribution of a safe medical device.

Furthermore, the intellectual property of an OSH community is partially protected by the copyright mechanisms that made OSS so successful. Solely relying on open source licenses exposes the common to a significant risk that the community’s work would be patented against the community - in our case study to prevent the emergence of a low-cost actor in a nascent market. Defensive patents are a suitable protection, but require temporary restriction of information sharing within the community while a legal assessment is conducted.

Our first finding, although counter-intuitive at first sight, is that partial privatization of the Common is appropriate to protect the common’s work. In this case, privatization of intellectual property through the use of patents ensures the availability of an open license to the largest number of people and contributes to knowledge dissemination. Moreover, privatization is a proven solution for coping with regulation steps, guaranteeing that the community’s efforts will move from a functioning prototype to a market-ready product.

However, this privatization may well destroy the common, which leads us to our second finding.

**Going Private to avoid the End of the Common**

The tragedy of the digital commons is the underuse or under maintenance of the KC. And during privatization, this risk of terminating the common is high since development is kept confidential and is no longer available to the members.

Communities face two dilemmas when forced to stop their activities during temporary privatization. Firstly, they have to prevent the common from ending due to this unexpected transformation. Secondly, they have to reassure members that the common will eventually resume.

Our second finding is that a project portfolio management approach, which facilitates coordination and prioritization of tasks and resources across multiple projects

and multiple workstreams, prevented a fatal outcome. This type of project management also allows the dynamic assignment of volunteers from one project or work package to another, according to each project’s development stage. Moreover, it maintains momentum and involvement within the common. The involvement of volunteers in projects changes over time (*Table 2*), with more activity at the beginning and the end. As a consequence, commoners are motivated to work on several projects within an OSH Common. The variety of projects facilitates the reallocation of volunteers, previously working on an OSH project subject to heavy regulation, to purely open projects, thus keeping the community active, evolving, and mutually enriching.

**A New Field of Research for KC**

Contrary to a frequent misconception, a KC does not thrive in the absence of rights, quite the opposite is true (Hess & Ostrom, 2007); here we have a striking example of commoners agreeing to create a private legal entity to handle compliance aspects of medical device manufacturing. KCs have demonstrated their relevance and flexibility in the OSH environment, they bring the ability to dynamically adapt to evolving constraints while securing the long-term objective of enriching pooled knowledge. For open-source community members, openness is not only a means; it is also an end in itself. In that sense, KCs provide an *arena* where a consensus can progressively emerge to close down a fully open model and eventually resume it. As OSH projects multiply in the coming years, scholars will have tremendous opportunities to examine how these communities are evolving at the frontier of the digital and the tangible worlds.

**LIMITATIONS AND SUGGESTIONS FOR FUTURE RESEARCH**

This paper is a single case study, therefore, the conclusions of our findings will have to be corroborated by other work. The Medtech industry is highly regulated; further case studies in other regulated industries would undoubtedly improve the reliability of our findings. For instance, the impact of environmental regulations (RoHS<sup>13</sup>) or electromagnetic compatibility (USA’s Federal Communications Commission<sup>14</sup>)

		TIMELINE T1	TIMELINE T2	TIMELINE T3	TIMELINE T4
Volunteer involvement	Project 1	+	-	+	+
	Project 2		+	-	+
	Project 3			+	-
	Project 4				+

**Table 2** Volunteers dynamic involvement in the KC.



will most likely have a strong influence on the Commons' governance of other projects.

Our study was limited in time, so we did not witness the post-industrialization phase when the common resumed after the market launch. We could only record the intentions of the core team and the community; further research and a longitudinal case study on this KC would certainly bring valuable insights.

We witnessed that introducing a form of portfolio project management in a KC is an effective way to maintain momentum within a community. However, in our case study, only a handful of projects were managed in parallel. Further research is needed to understand the effect of breaking down the community into many sub-projects. The very existence of the KC could be endangered by potential divergence in the objectives of these subgroups. Besides, volunteers could lose interest in the project and leave the community.

### The medical device landscape

Theoretically, not-for-profit associations can manufacture medical devices with a CE marking. However, to the best of our knowledge, there is no such example and the literature is often very evasive on the regulatory question. This situation may change in the light of the recent COVID 19 crisis, which has shined the spotlight on the weaknesses of the “normal” way of validating medical devices built by communities. Regulators and communities have been able to respond to this emergency<sup>15</sup> situation as volunteers worldwide have gathered as communities to produce masks, ventilators or spare parts for medical equipment. Henceforth they will need to focus on longer-term collaboration to amend a system that has been designed for corporations and requires adjustment to support the blooming of OSH communities building medical innovations.

Open-Source Hardware is a fast-paced emerging practice. Additional work is needed to define standards, influence regulatory bodies, and provide guidance on effective governance mechanisms to embrace its potential fully. We hope our work will help future OSH communities to anticipate the necessary transformation they will face as they progress along their product development pipeline.

We invite academics to conduct a longitudinal study of the entire development pipeline to gain a comprehensive understanding of the long-term dynamics of an OSH KC. This paper covers only phases T1 and T2 of the timeline in **Table 1**, covering project development from inception to the end of the industrialization phase. During our investigations, we collected evidence that the KC will be instrumental in the launch and post-launch phase of the project (T3). For medical purposes, the community will collect data in order to be able to run clinical trials with the probe. Moreover, to help define how the probe should evolve in response to new needs, a user

innovation approach will be followed (Hippel & Krogh, 2003). This stage deserves a more in-depth analysis to understand the transformation of the commons membership from ‘commons-based peer production’ (Benkler & Nissenbaum, 2006) to ‘user-based innovation’ (Hippel & Krogh, 2003).

With this case study, we identified profound institutional changes, starting with the creation of a not-for-profit association and then later the birth of a private organization. These modifications raise a broader methodological question, how to study the evolution of KC over a long period (Strandburg, Frischmann, & Madison, 2017)?

Finally, we hope that using the GKC framework will allow the comparison and aggregation of case studies from different industries and knowledge domains to shed light on the underlying contextual reasons for any differences.

## NOTES

- <sup>1</sup> <https://www.idc.com/promo/smartphone-market-share/os>.
- <sup>2</sup> *Open MRI, open ecg, Bio nico, Raptor hand, Prosthetic hand, Robot hand*.
- <sup>3</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745>.
- <sup>4</sup> Echopen Bylaws, 2018.
- <sup>5</sup> Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.
- <sup>6</sup> The commercial entity who takes responsibility for the manufacture of the product and is designated on the label. It is not necessarily the same entity which physically ‘makes’ the product.
- <sup>7</sup> <https://www.tapr.org/ohl.html>.
- <sup>8</sup> Medical Device Directives (MDD): MDD 93/42/EEC; MDR 2017/745; AIMDD 90/385/EEC.
- <sup>9</sup> Medical Device Directives (MDD): MDD 93/42/EEC; MDR 2017/745.
- <sup>10</sup> Some member states require some other (administrative) steps such as registration with the national authority.
- <sup>11</sup> Like a clearance or approval from the FDA or another ‘major’ regulatory bodies.
- <sup>12</sup> <https://www.insideulifesciences.com/2020/03/23/mhra-issues-specification-for-a-rapidly-manufactured-ventilator-system-for-use-in-hospitals-during-the-covid-19-outbreak/>.
- <sup>13</sup> [http://ec.europa.eu/environment/waste/rohs\\_eee/legis\\_en.htm](http://ec.europa.eu/environment/waste/rohs_eee/legis_en.htm).
- <sup>14</sup> <https://www.fcc.gov/oet/ea/eameasurements.html>.
- <sup>15</sup> <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices>.


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## COMPETING INTERESTS

The author has no competing interests to declare.

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