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CREATING CONVERGENCE SPACES

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Collaborative Platforms for Emerging Technology: Creating Convergence Spaces

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Governments, together with partners in industry and civil society, are developing experimental forms of collaborative platforms to provide better linkages between research and innovation, and to promote the development and use of emerging technology. This report analyses 33 case studies from key fields of emerging technology – genomics, advanced materials and engineering biology – and finds that collaborative platforms are most effective when they act as "convergence spaces" for the fusion of diverse disciplines, actors and technology. It also shows how governance mechanisms shape platform operations and act as policy levers for ordering what amounts to a common pool resource: they aim to maximise tangible and intangible value, realise sustainability models, foment collaboration, and promote technological integration. After presenting cross-cutting and comparative findings on key components of governance, the report concludes with policy implications for the design of existing and future collaborative platforms.

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Keywords: collaborative platforms, convergence space, genomics, biobanks, advanced materials, engineering biology, governance, innovation policy, science and technology

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- "Collaborative platforms for personalized health: realizing the potential of genomics and biobanks", held in Stockholm, Sweden, in September 2019
- "Collaborative platforms for innovation in advanced materials", held in Braga, Portugal, in November 2019
- "Workshop on Collaborative Platforms for Advancing Engineering Biology: Focus on the COVID-19 Pandemic", hosted virtually by the United States in July 2020

The work also benefitted from discussions in the 9th, 10th and 11th BNCT plenary meetings, as well as the work of three Steering Groups that guided each technology work stream.

Two companion reports in Project One deepen the analysis and discussion in genomics and biobanks (Garden, Hawkins and Winickoff, $2021_{[1]}$) as well as advanced materials (Kreiling, Robinson and Winickoff, $2020_{[2]}$).

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Executive Summary

Collaborative platforms are organisational arrangements around shared resources – material, digital or both – for technological development and diffusion. These platforms work across the private and public sector to manage, co-ordinate, and catalyse innovation. Many governments, along with partners in industry and civil society, are developing experimental forms of these collaborative platforms to provide better linkages between research and innovation, and to promote the development and use of emerging technology.

New kinds of collaborative platforms are arising in response to a number of key trends in policy, technology and the structures of innovation; first, the movement towards missionoriented approaches to STI policy; second, the penetration of digitalisation into research and development systems; third, the movement towards more open and participatory modes of knowledge production such as "co-creation".

These developments make it an opportune time to collect, analyse evidence and report on OECD countries' policy practices. The 33 case studies analysed here originate from key fields of emerging technology – genomics, advanced materials and engineering biology. Collaborative platforms in these three technology areas offer both technology specific and more generalised insights about policies for building and managing these resources critical for the development of emerging technology.

Cross-cutting findings are detailed in the report. The cases reveal, for instance how novel organisational arrangements enable different partners to work jointly in new ways resulting in the acceleration of research and innovation; how digitalisation carries significant potential for enhancing the value of collaborative platforms and is driving the development of new configurations; and how longevity of collaborative platforms depends on the creation of diverse kinds of tangible and intangible value.

Collaborative Platforms as "Convergence spaces"

The empirical cases and their analysis showed that collaborative platforms are most effective when they act as "convergence spaces" – loci for the assemblage of diverse disciplines, actors and technology. These convergence spaces:

- Synthesise traditional *disciplines*. They must both attract and train scientific staff with expertise across many disciplines to complement the respective skillsets of platform actors;
- Assemble *diverse actors* who can contract around access to resources, current discoveries, and downstream inventions. Further, they have the potential to deepen understanding across the science, technology and society.
- Drive the convergence of *technologies* and the production of new ones. For example, digital technologies are enabling the automation of platform activities to increase their efficiency and speed, whether in production or lab technologies, and new digital tools are created in the process.

Bringing together these diverse elements, collaborative platforms are able to produce new kinds of value in the form of products, technologies, and training.

Specific governance mechanisms - e.g. funding models, access rules, ownership/IP, regulation, engagement, standards – shape platform operations and function as policy levers for ordering what amounts to a common pool resource. These levers can help

optimise platforms for particular purposes, and ideally aim to maximise tangible and intangible value, realise sustainability models, foment collaboration, and promote technological integration. They can also enhance the cyclical creation of value, where data, knowledge, skills – i.e. different forms of value – return back to the platform.

Policy implications for the design of collaborative platforms

The convergence space as both a descriptive and normative model leads to the following design considerations for existing and future collaborative platforms for emerging technologies.

1. Build sustainability models that encourage interaction over revenue or IP generation

Platform developers should consider designing access and IP policies that maximise the use of its resources and interaction. For example, fee-based mechanisms should differentiate between kinds of private sector actors, large and small. Standardised access procedures can avoid delays and lower bureaucratic barriers. Platforms should ideally seek to build intangible value like skills and education through training programs, and provide adequate job security despite project-based funding to avoid "brain drain".

2. Leverage collaborative platforms as vehicles to drive mission-oriented innovation policy.

Collaborative platforms can help implement missions and mission-oriented policies by serving as a hub to align and coordinate diverse actors and to drive the development of emerging technologies. Many grand challenges cannot be achieved by platforms within a single country, and there are therefore often great potential gains for international collaboration. Thus, governments should consider directly supporting activities of platform actors across borders.

3. Activate mechanisms which enable different actors to convene and innovate jointly.

Standards coordinate users and are therefore prerequisites for platform use and access. In setting standards, the use and promotion of industry consensus, rather than top-down approaches, may help avoid fragmentation that can result from too many standards. If collaborative platform are to act as hubs for ecosystem growth or its creation, built-in flexibility is required so that platform dynamics can occur, such as changes in platform actors.

4. Realise the potential of digitalisation in convergence.

Digitalisation can accelerate convergence and the inclusivity of platforms. Platform should consider investing in strong data management systems to produce high quality databases. Access to data improves platform attractiveness, but platforms need clarity about rights of control and use. Sustainable data infrastructures require long-term investment and clear incentives for individual researchers and companies to share data with provisions to protect their interest.

5. Catalyse the interaction of technology and society.

Collaborative platforms can help deepen the engagement of the broader society with emerging technologies. They are positioned to convene stakeholders and publics to discuss goals, expectations and concerns around emerging technologies. These activities can feed into the potential formation of research questions within the collaborative platform, generating trust and trustworthiness in sociotechnical projects.

1. Introduction

This report aims to improve emerging technology policy. Many governments, along with partners in industry, start-ups, and civil society are developing experimental forms of "collaborative platforms" to nurture emerging technologies and to provide better linkages between research and innovation (Gawer, 2014_[3]; Katz and Shapiro, 1994_[4]). Collaborative platforms can be defined as organisational arrangements around shared resources – material, digital or both – for technological development and diffusion. Drawing on a definition by Gawer (2014_[5]), this report focuses on organisations or partnerships of organisations that bring together and co-ordinate actors from at least two different sectors – academia and industry, often involving actors from civil society – who can innovate and compete. For emerging technologies, markets may not yet be fully in place, and thus collaborative platforms also will have an impact at pre-competitive stages of technology and play a role in shaping markets.

There are strong reasons for governments to invest in collaborative platforms for emerging technology. Government involvement in collaborative platforms can de-risk investment in emerging technologies. Further, they are often more flexible than national regulatory frameworks when it comes to setting technical standards for the application of technology and regulating associated risks. Ultimately these platforms can enable emerging technologies to contribute to society and environmental sustainability.

From a theoretical point of view, spillovers from R&D¹ suggest that major market failures are at play in financial markets for emerging technologies. The rationale for public involvement in collaborative platforms is especially strong in areas where emerging technologies have a general purpose, i.e. they enable complementary innovations in application sectors (Bresnahan and Trajtenberg, 1995_[6]). Furthermore, collaborative platforms often aim to develop business models around products, services, and/or technologies that provide the foundation upon which outside actors – often large firms and start-ups, can build further complementary innovations and potentially generate network effects (Box 1).

Box 1. Network effects

Although collaborative platforms differ from technology or industry, they also seek to benefit from network effects. These result from the more users who adopt the platform, the more valuable the platform becomes to the owner and to the users because of growing access to the network of users (Gawer and Cusumano, $2008_{[7]}$)

Network effects. Increased usage of a platform leads to a direct increase in the value of that platform to its users. The value of a platform increases exponentially 2^N in proportion to the number N of its users (Reed, $2001_{[8]}$)

Two-sided markets. Two-sided network effects arise when the utility of users in one group (side A) depends on the number of other users in other groups (side B) (e.g. companies that advertise on the platform, or group A, to target consumers – group B) (Rochet and Tirole, 2003_[9]).

New kinds of collaborative platforms are arising in response to a number of key trends. First, the movement towards mission-oriented approaches to STI policy is arguably

¹ Benefits of emerging technologies that accrue to others than the originating firm due to e.g. follow-up innovation.

pushing countries to pay more attention to mechanisms like collaborative platforms to aid industrial translation, including with respect to emerging technologies. Second, the penetration of digitalisation into research and development systems has disrupted the models and scope of collaboration, leading to changes in what is even meant by a platform, to the enhancement of network effects therein. Third, perhaps in response to these other factors, there has been shift of national and international research and development programmes to more open and participatory modes. These developments in innovation policy reflect a growing awareness of the creative potential of being more inclusive not only in reaping the benefits but also along the process of innovation itself.

These STI policy developments underscore a need to re-examine the governance arrangements underlying collaborative platforms, especially in areas of key and emerging technology. Critical questions face governments that wish to design collaborative platforms across key governance dimensions, e.g. sustainability models, access to shared assets, openness, intellectual property, and standards. Furthermore, the roles of digitalisation and convergence, specific technology at hand, and international collaboration need to be better understood.

1.1. Key components of governance – an analytical framework

A policy analysis of collaborative platforms can be aided by a framework for understanding the relevant components and levers of governance that help determine the operations, behaviours, and efficacy of the initiative. From its broadest angle, drawing on Bevir $(2013_{[10]})$ and Delmas and Young $(2009_{[11]})$, platform governance refers to the formal and informal rules through which partnerships organise their operations.

A useful framework to study the governance of collaborative partnerships is provided by the Nobel Laureate economist, Elinor Ostrom. Her theory addresses the problem of how to sustainably manage common pool resources, and helps illustrate the ways in which different governance mechanisms can be effective. Partnerships should clearly delimit common-pool resources, define platform members, provide easy conflict resolution mechanisms between members, and link collaboration to wider systems (Ostrom, 2010[17]).

In the field of emerging technologies, governance often involves both governmental and private actors, and new forms of "collaborative governance" guarantee broader involvement in decision making that goes beyond mere consultation (Bevir, $2009_{[12]}$). Their participatory modes, including civil society consultation, make them adaptive to social needs and ethical challenges. Governance embraces flexible approaches that are adapted to technological change (Kuhlmann, Stegmaier and Konrad, $2019_{[13]}$). In the context of emerging technologies, the concept of governance has evolved in response to high uncertainty (Folke et al., $2005_{[14]}$), risk (Baldwin and Woodard, $2009_{[15]}$), and complexity (Hasselman, $2016_{[16]}$).

Governments that wish to design collaborative platforms across key governance dimensions face critical questions, including

- How to find the right sustainability models to achieve goals, including value creation, data access and intellectual property (IP).
- How to facilitate collaboration, including across jurisdictions.
- How to harness digitalisation and Artificial Intelligence (AI)

While governance is a concern for policy, evidence on the role of governance of collaborative partnerships in emerging technologies is rare. One notable exception is a

study by Hatchuel, Le Masson and Weil ($2009_{[17]}$), which analysed collaborative platforms in biomaterials, microelectronics, aeronautics, and biotechnology. Platforms in these emerging technologies do not fit into the design prescriptions for industry platforms. Platform-wide rules are often practiced with substantial leeway for the platform owners to interpret the rules. Further, collaborative platforms do not follow a specific strategy, but develop alternative strategies – reflecting the diversity of actors involved and their interests.

With regard to collaborative platforms, critical governance issues relate to (1) their sustainability model including funding and access provisions, (2) collaboration factors, and (3) digitalisation. These are discussed in turn.

1.1.1. Sustainability models and value creation

Today, many platforms need to be self-sustaining, which means to have a viable model for funding and access. A sustainable model of public-private partnerships needs to be collaborative and reconcile public and private interests. Often, they receive government funds, but are required to draw on additional income from industry (Jacobides, Knudsen and Augier, 2006_[18]). A sustainable model, like a business model, describes the purpose of the platform such as e.g. creating value for partners; promoting open access; development of technology; and delivery of products, services, and standards. A good sustainability model helps to identify target users and/or customers and outlines processes to deliver the objectives, and seeks to reconcile conflicting objectives.

Value creation. To create value, collaborative platforms depend on complementary inputs made by loosely interconnected, yet independent actors. Platforms then draw their value from joint ownership over these assets, which can take various forms, including IP, standards, or the control of complementary assets that are key for the operation of a platform (Jacobides, Knudsen and Augier, 2006^[18]). Governance choices surrounding value creation include (i) who has decision rights over assets, IP, and data; (ii) who has access to these assets, and (iii) who can derive revenues from their commercialisation.

Platforms at pre-commercial stages tend to provide wider access to data, which is of high value for research. Platforms also provide important sharing functions for data, contributing to the development of standards and ontologies (OECD, 2017^[19]). More mature stages of technology will see platforms where commercialisation and financial objectives come to the fore. Services for data analysis or testing services are common business services of platforms.

IP, *Licensing and access fees*. IP and licensing conditions arrange for access to or ownership of assets that arise from platform activities or that are stored in platforms and are thus a key source of their value. The way in which IP and licensing policies are set-up in collaborative platforms influences their collaboration potential and indicates their emphases on discoveries or commercialisation. In other words, whether the platform focuses on exploration or exploitation which is also reflected in technology readiness levels that the platform targets.

There are trade-offs associated with open and closed platforms (Eisenmann, Parker and Van Alstyne, $2011_{[20]}$). Openness can spur complementary innovation around the platform (Gawer and Cusumano, $2008_{[7]}$). Adding access to third parties can increase the appeal of the platform (Gawer and Henderson, $2007_{[21]}$). On the other hand, more closed forms of platforms, characterised by strong ownership rights, provide more room to capture value for the platform owners. If the public owns the platform, it can benefit from returns on investment, which can finance public goods.

The boundaries between restricted access and openness are often fluid, with ownership models ranging from proprietary models, models with favourable licensing terms for third

parties, to open standards and open source (West, 2003_[22]). Moreover, market forces tend to push collaborative platforms over time towards hybrid licensing forms, as characterised by central control over platform technology and shared responsibility for serving users (Eisenmann, 2008_[23]).

1.1.2. Collaboration

There are different governance arrangements aiming to coordinate, align and connect partners within collaborative platforms.

Coordination. An early key challenge for collaborative endeavours is co-ordination, without which joint value creation is not possible. The governance tools to do so range from top-down control by platform owners (e.g. restriction of access) to informal coordination between equal partners in a loose network. Informal coordination takes place via standardisation and the propagation of social roles and values (Gawer and Cusumano, $2002_{[24]}$)). While in industry platforms, coordination is achieved through design templates and standardization (Gawer and Cusumano, $2014_{[25]}$), platform ecosystems rely more on coordination through rules and values (Huber, Kude and Dibbern, $2017_{[26]}$).

Standards. Standards support and are constitutive of collaboration and interoperability of platforms. A technical standard is an established norm or a legal requirement that provides a technical specification for a repeatable technical task, process or product. Platforms are often organised around technical standards, which allows external players to use the platform for their own products and services. They enable quality improvement, reproducibility and reliability of business operations and processes, and often entail high-level technical principles for entire industries. Standards also deliver competitive advantage and are at the core of network effects (Katz and Shapiro, $1985_{[27]}$) – as they create compatible technical system that are widely used by others, provide minimum quality and safety (Akerlof, $1970_{[28]}$) and enhance consume and investor confidence.

Platforms themselves can engage in standard setting exercises, bring together different actors around complex issues surrounding emerging technologies (West, 2003_[22]). Relying on standards, application program interfaces (APIs) have emerged in the digital realm to promote inter-operability of different databases. APIs are standardised interfaces that facilitate interoperability between different databases. For instance, using an API, a researcher can discover what type of information is contained in a single library. There are different functions of APIs, including data use, search, access and interoperability.

Collaborative platforms can bridge national regulatory boundaries by setting internationally agreed standards surrounding the use of emerging technologies, and provide guidance for risks associated with their application. Collaborative arrangements can be more flexible than state regulation (Ansell and Gash, 2007[32]; Folke et al., 2005[13]). In the context of emerging technologies, where change is fast and often unpredictable, platform-based models are flexible arrangements to spur data sharing, and discuss norms around the use of converging technologies. They support the development of markets and play a role in shaping them (Gawer, 2014[5]).

International contexts. The business plan of a collaborative platform should clearly describe the management of scientific activities, finances, data and commercialisation, as well as regulate financial responsibilities of the funders. OECD work (2017_[29]) analysed business plans of international research infrastructures. Another aspect is that connecting across multiple jurisdictions requires different kinds of collaboration (Edelman, 2015_[30]; Cosens, 2013_[31]). Collaboration and data sharing across national boundaries faces several difficulties due to different perspectives, disparate geography on ethical and legal issues. Common frameworks need to set out common practices of research and data sharing

(OECD, 2017_[19]). This includes development of information technologies to promote discoverability of data and sharing, and promotion of regulatory approaches – in close coordination with policy makers, industry, and often civil society if privacy is at stake. Policy can support public-private partnerships by providing guiding principles on ethical, legal and IT related matters.

Box 2. European Technology Platforms – example of international platform governance

The European Technology Platforms, cross-country arrangements that bring partners from industry, science, government and civil society to develop research agendas and innovation roadmaps around emerging technologies. There is also increasing recognition of European Technology Platforms for international co-operation to address global challenges, such as sustainable development.

A Steering Group is responsible for the strategy, implementation and operation of the Platform. This includes i) defining roles and responsibilities of partners, ii) compliance with platform mission, iii) launch of joint activities, iv) and representation of partners, including in the European framework programme Horizon 2020.

1.1.3. Digitalisation

The digitalisation of research and development systems has disrupted the modes and capacities of collaboration, restructuring what is even meant by a platform in the first instance, enhancing the potential platform and network effects therein. This penetration of the digital has given rise to the synergistic effects of "convergence" where combination and recombination can result in completely new ideas, methods and outputs (OECD, 2014).

Digital technologies. Digital technologies are driving convergence in medical fields (OECD, $2019_{[32]}$; Guellec and Paunov, $2018_{[33]}$). The use of digital devices in combination with medical technologies is now common in clinical research, where the line between therapeutic and non-therapeutic applications is blurring (Garden and Winickoff, $2018_{[34]}$). Digital devices can perform many medical tasks and support disease prevention and therapy, potentially leading to new technologies.

The impressive role of Artificial Intelligence (AI) and big data go well beyond the field of genomics and personalised medicine. In synthetic biology and nanomaterial research, for instance, cloud-based platforms (so-called cloud laboratories) use machine-learning techniques to enable the analysis of hundreds of terabytes of data collectively to build models and refine designs (e.g. DARPA Synergistic Discovery and Design program). Moreover, as firms in digitalised industries have trouble to acquire ownership of IP and standards, they switch to open, collaborative forms of innovation (Teece, 2018_[35])

Data management. A new element of the governance of collaborative platforms in the digital age is data management. This includes a data access policy that specifies privileged access for certain types of users such as e.g. non-commercial, academic researchers, SMEs, or other for-profit partners. It should clearly set out how data is processed, stored, and made accessible for users. Access can be granted to different types of data, and policies should be put in place to guarantee confidentiality of sensitive information. Inter-operability with other data systems is important to increase data availability and optimise resources and costs. And finally, sustainable funding should be provided for open access (OECD, 2017_[29]).

1.2. Study design: Focus on three technological areas

Building on prior work at the OECD and in academia, this study aims to support policy makers and innovators to realise the potential of emerging technologies through well-designed collaborative platforms. The fields of genomics for personalised health, advanced materials and engineering biology are of high interest to governments. Thus, this study analyses multiple case studies with examples of collaborative platforms within each of these three technological fields to identify trends and best practices. The case studies both within and across these three technological areas are diverse, but present some common traits across many of the institutional facets listed above. This project aims to support the development of policy-relevant knowledge in each of the three technological fields, as well as for collaborative platforms as a whole.

1.2.1. Genomics and biobanks for personalised health

Novel approaches to personalised medicine are being built into innovation and health systems. Government investment and cross-sectoral collaboration have been key drivers for the translation of shared R&D assets and common-pool resources such as genomic, neurological, and phenotypic data as well as collections of bio-specimens into clinical practice. National and international genomic initiatives are at the heart of the development and use of personalised medicine. Public-private partnerships are supporting transformative change in research and health-care while simultaneously addressing issues around implementation, sustainability, and wider adoption.

Biobanks and assemblages of health data have become institutionalised in many countries for some years. The mix of technology, actors, and policy in personalised medicine has opened new questions about: the best practices to public-private partnerships and sharing of large volumes of genomic data; the definition of value and the potential new "currency of innovation" (data versus products and IP); and, the impact of recent technological developments (e.g., artificial intelligence,) on the integration of genomic research and general health-information in personalised medicine. Policy analysis might also open pathways to responsible and effective sharing of genomic, epidemiological, and clinical data and facilitate evidence-based personalised medicine.

1.2.2. Advanced materials

Advanced materials promise revolutionary changes in multiple industrial sectors. Historically it has taken 15 to 20 years from laboratory discovery of new nanomaterials to their deployment in products. Governments, along with partners in the private sector, are developing new kinds of collaborative spaces and common resources in the field of advanced materials to provide better linkage between research and technology commercialisation. Systematic methods for accelerated materials discovery and development are still in early stages in the new digital era. Experts in the field imagine the need for collaborative platforms to enable the convergence of a diverse range of fields, such as materials data science and informatics, design optimisation, digital materials and metadata, sensors and automation, and measurement and validation sciences; and to allow the research enterprise to better engage with the private sector.

Collaborative platforms that support advanced materials, especially with a focus on nanoand converging- technologies, include user facilities that provide access to fabrication and characterisation tools, databases, test-beds, and pilot plants. Collaborative platforms are also instruments for establishing common standards, ontologies and regulation. These platforms range from tools that support basic research to prototypes and early production. They are expected to become sustainable by making their facilities and services accessible

to industry at fair costs and by attracting a community of users, investors and other stakeholders.

1.2.3. Engineering biology

The field of engineering biology is making significant strides, but the development of applications that will deliver real societal impacts could be enhanced through public policy, including through the support of new collaborative platforms such as biofoundries. These are highly automated facilities that allow the co-ordinated use of laboratory robots which helps to de-risk, decrease costs, and speed up innovation in biotechnology. Biofoundries are based on information infrastructures that enable programming robots and other equipment to follow detailed, complex workflows (Chao et al., 2017_[36]).

Distributed networks of public research infrastructure provide access to data and specimen, and digital platforms are in place for sequence curation and for design tools. Much could be learned by comparing and linking such programmes together in analysis and potentially in practice.

Key policy questions are: (1) how can collaborative platforms in engineering biology help de-risk, decrease costs, and speed up innovation? (2) What policies would allow the field to expand to enable a broader community of innovators to commercialise new, value-added and sustainable bio-based products?

1.2.4. Common questions

Working across these three technology areas, the following report will attempt to answer these three policy questions:

- What kind of governance arrangements and practices can generate value of different kinds and build sustainability?
- Can collaboration around common knowledge resources including international –be deepened through policy design?
- In what ways are key trends in technology, such as digitalisation and the use of AI, and trends in society, e.g. mission-orientation of policy, affecting the goals and functions of collaborative platforms?

The study collected information from collaborative platforms in three selected technological areas (see section 1.2) to compare and contrast policy challenges. Using the key governance components of collaborative platforms (see section 1.1) as an analytical framework, a Steering Group for each technology area that consisted of subject matter experts gathered data and empirical examples, as summarised in Figure 1.

Figure 1 Study design: looking at a set of governance components across three technology areas



Source: developed by report authors

2. The landscape of collaborative platforms in different technology areas

Collaborative platforms exist in different technology fields. In line with the study design (Figure 1), this work focuses on collaborative platforms in three technology areas. The Annexes I-III present the respective technology fields and collaborative platforms therein in some detail: Collaborative platforms in genomics and biobanks for personalised health (Annex I); Collaborative platforms in advanced materials (Annex II); Collaborative platforms in engineering biology (Annex II). The following sections provide an overview of the landscape of collaborative platforms by technology area.

The empirical basis for analysis are a total of 32 case studies of collaborative platforms in these three technology fields. (Table 1).

Technology field	Case study title Country	
Genomics and biobanking	BBMRI-ERIC	EU
	ClinVar and ClinGen, two National Institutes of Health (NIH)	USA
	Plan France Medicine Genomique 2025 (PFMG 2025)	France
	Initiative on Rare and Undiagnosed Disease (IRUD)	Japan
	Genomic Medicine Sweden	Sweden
	Korea National Bio Big Data Project	Korea
	Maccabi Healthcare Services, The Israeli National Biobank for Research and Psifas	Israel
	Genomics England	UK
	Global Alliance for Genomics and Health (GA4GH)	International
	ELIXIR	EU
Advanced materials	Austrian Smart Systems Integration Research Centre (ASSIC)	Austria
	Polymer Competence Centre Leoben (PCCL)	Austria
	Materials for Clean Fuels Challenge Program	Canada

Table 1. Summary overview of all 32 empirical case studies

	European Pilot Production Network (EPPN)	European Commission
	Innovation test bed for lightweight embedded electronics (LEE BED)	European Commission
	Nanotechnology Platform Japan (NPF)	Japan
	International Iberian Nanotechnology Laboratory (INL)	Portugal
	Collaborative laboratories (CoLABs)	Portugal
	University of Texas at Austin - Portugal Program	Portugal
	Nano-Convergence 2020 Program	Korea
	Materials Design Platform	Korea
	National Nanotechnology Coordinated Infrastructure (NNCI)	United States of America
Engineering biology	Concordia Genome Foundry (CGF) Lab for Metabolic Systems Engineering (MSE) The Biofoundry at UBC (TBU)	Canada
	Toulouse White Biotechnology (TWB)	France
	Microbial Resource Research Infrastructure (MIRRI) ²	Italy
	Smart Cell Project	Japan
	Singapore infrastructure for engineering biology	Singapore
	Seven synthetic biology research centres (SBRCs) and five biofoundries	United Kingdom
	Agile Biofoundry (ABF)	United States
	Engineering Biology Research Consortium (EBRC)	

Source: The case studies originate from the work of three steering groups; more information on the cases can be found in respective 'empirical case studies' sections in Annex I, II and III.

2.1. Characterising collaborative platforms - unique features and platform types

The characteristics of collaborative platforms reflect the challenges of the technology field that they are part of. These are influencing factors in the collaborative platform's environment that translate into collaborative platform characteristics in the respective technology field.

This section sheds light on these characteristics, notably the unique features, as well as different platform types in which organisational arrangements exist around shared resources for technological development and diffusion. This creates the ground for the comparison of collaborative platforms across technology areas in section 3.

2.1.1. Genomics: the centrality of personal data, networks and trust

Human biobanks and genetic research databases are structured resources that include human biological materials and/or information generated from their analysis and extensive associated information (OECD, 2009_[37]). Genomic and biobank collaborative platforms enable the sharing of collected genomic, clinical and related data among researchers, industry, clinicians and other stakeholders, allowing the wider use of data in order to optimise scientific, economic and social value.

Two forms of collaborative platform in this context prevail: either a single collection of genomic and health data that seeks to bring partners to use and exploit it, or a broader networks of such resources that share data and samples among themselves and with third parties. An example is Plan France Medicine Genomique 2025 that sets out to create a network of 12 genome sequencing platforms across France. Similarly, Genomic Medicine

Sweden is a nation-wide networked collaborative platform in Sweden, headed by 14 partners from regional healthcare and universities.

Collaborative platforms in genomics and biobanks are currently experiencing a wave of new policy challenges related to technological and institutional change:

- The steady increase of computational power as well as new kinds of machine learning are opening new scientific models around even greater assemblages of diverse personal data. Platforms that can collect and organise large amounts of data have taken on greater scientific and economic value.
- Systems of clinical care seek to tailor treatments based on genotype
- The push towards greater international linkage has resulted in new forms of institutional collaboration.

It is a dynamic time for genomic databases and biobanks. There have never been so many large-scale, national and international projects and attempts to sequence at the population scale, to integrate genomic data into healthcare systems, and to link genomics initiatives together in larger networks of health data and biological samples (Dubow and Marjanovic, $2016_{[38]}$). At least 14 countries have invested over USD 4 billion in establishing national genomic-medicine initiatives (Stark et al., $2019_{[39]}$). The IQVIA Institute for Human Data Science has identified 187 genomic initiatives globally of which half are US based and close to one fifth in Europe (Aitken, $2020_{[40]}$). Building and sustaining scientific, economic, and social value in this context is a defining challenge across many genomic and biobank collaborative platforms.

There are two dynamics that are pushing an array of new policy issues to the fore. First, a confluence of developments offer an increased understanding of genotype-phenotype associations for more effective therapies and diagnostics: whole genome sequencing (WGS), the digitalisation of health evidence and lifestyle indicators, combined with AI-driven innovation (Caulfield and Murdoch, 2017_[41]; Robinson, 2012_[42]; Tam et al., 2019_[43]; Thorogood et al., 2019_[44]). However, these developments have heightened concerns around data integration, the return of individual genomic results to participants, workforce development, and cost effectiveness (Minari, Brothers and Morrison, 2018_[45]; Stark et al., 2019_[39]; Yehia and Eng, 2019_[46]).

Second, in terms of institutional change, many genomic and biobank collaborative platforms are seeking forms of sustainability less dependent on public funds, more frequently targeting public-private business models (Ciaburri, Napolitano and Bravo, 2017_[47]; Livesey, 2019_[48]; Rao et al., 2019_[49]). At play are different aspects of sustainability that operate with different economies of value, from financial models of investment inputs and knowledge outputs to social models built on trust (Andry et al., 2017_[50]). Engaging in greater involvement with the private sector, platform executives must manage and uphold a complex social contract that entails mutual responsibilities across participants, publics, and research institutions.

Actors leading the platform may come from the government, civil society or the private sector which results in three kinds of platforms (Table 2). Most platforms that focus on the development of diagnostics and individualized treatment through large-scale genomic sequencing techniques, are government led initiatives and have either a public or non-profit status. Fully private sector collaborative platforms are rare in genomics and biobanking. The strategy of companies is instead to build genomic and bio-sample repositories, or partner with public sector initiatives. An example of the former is the Geisinger MyCode Community Health Initiative which offers an integrated biobank and electronic health record infrastructure for research use by the company and its collaborators.

Platform type	Short description
Government-led initiatives	Set up by countries as public or non-profit initiatives. Initiatives have differing levels of involvement of and rules for collaborating with civil society, and private sector entities. They often set the number of sequenced genomes or patients to collect and encourage public engagement and participation to achieve the goal, and establish infrastructure to collect, analyse, and share data.
Civil society-driven initiatives	Often seek to leverage the power of networks to address particular challenges or issues. Such networks link platforms and key stakeholders with expertise to establish frameworks and standards. Two exemplars are the Global Alliance for Genomics & Health (GA4GH) and ELIXIR, which recently engaged in a strategic partnership for the development of technical standards and regulatory frameworks to facilitate responsible sharing of genomic data between countries and institutions.
Private sector research initiative	The pharmaceutical industry and biotech companies have been driving the integration of genetic genomic information into the discovery and development process for novel therapies, vaccines, and diagnostics. Examples of private sector initiatives include The Geisinger MyCode Community Health Initiative, launched in 2007, offers an integrated biobank and electronic health record (EHR) infrastructure for research use by Geisinger and collaborators.

Table 2. Three kinds of platforms in genomics and biobanks

Source: Based on case study analysis

A unique feature of collaborative platforms in genomics is that human research participants play a critical role to help structure the entire terrain of collaboration. Consequently, civil society initiatives are often set up as networks to link platforms and key stakeholders to address particular challenges or issues. For example, the Global Alliance for Genomics & Health (GA4GH) and ELIXIR formed a strategic partnership to develop technical standards and regulatory frameworks to facilitate responsible sharing of genomic data between countries and institutions.

An idiosyncratic platform framework condition is the regulatory approval process in the healthcare field that influences the business model of collaborative platforms in the field of genomics and biobanks. In fact, a lengthy and expensive regulatory approval process in healthcare systems is not conducive for disruptive innovations that may have great potential to improve patient outcomes. In these cases, the research and development of the innovation is only one part of the equation as integrating them e.g. in clinical care is a complex process. This means for collaborative platforms that the translation of the innovation into use needs to be an integral component of platform activities.

For the analysis and the mining of data in collaborative platforms in genomics and biobanks, an approach used is "federated learning". This is also a machine learning technique that works across decentralised devices and does not require the exchange of local data samples. In contrast to centralised approaches which require the upload of data, the model is sent to the data which allows searchers to run analyses over genomic data in a more unified and seamless way. Security breaches and privacy issues are less likely to occur because the data is never accessible all at once or by a single actor but rather scattered nodes in a network. This means that no party has a complete view of the entire dataset, but individual models can be trained with the parts of the data that are required in the respective case.

2.1.2. Advanced materials: the centrality of technology readiness

Novel and improved materials are a key resource for the development of new technologies and new consumer products. They also are likely to help drive additive manufacturing, and mass customisation. However, historically it has taken 15 to 20 years from laboratory discovery of new materials to their deployment in products.

The field of advanced materials is experiencing an acceleration of materials discovery and development which has been enabled by advances in scientific instrumentation, computing and predictive computational methods for material structure and properties, and data analytics. Increasing the rate of discovery and development of new and improved materials is key to enhancing product development and facilitating mass customisation based on emerging technologies such as 3D printing. Nevertheless a number of challenges face modern material sciences. These include:

- the need for significant data infrastructure: global scale management of material data scalable data repositories and data curation strategies;
- lack of coordination, redundancy and/or dispersion of instrumentation and technical skills;
- the need for interdisciplinary research, development and training;
- lack of ecosystems that can help build new supply chains.

In the face of these challenges, governments are currently experimenting with the creation of shared digital and physical infrastructures and access to technology and services. Such "collaborative platforms" for advanced materials are being built in hopes of addressing some of these challenges and of advancing the field. They aim to facilitate connections between the supply and demand sides of technological markets, pooling resources that otherwise may not be readily available, removing redundancy, co-locating instrumentation and technical skills, coordinating value chains to power new product development and nurture nascent industries, influencing and driving technical standards. These collaborative platforms are expected to become sustainable by making their facilities and services accessible to industry at fair costs and by attracting a community of users, investors and other stakeholders.

Collaborative platforms for advanced materials facilitate major changes in multiple industrial sectors and to increase the rate of discovery and development of new materials. By acting as focal points of communication with the public about respective technologies and their potential application in day-to-day life, collaborative platforms are not only tools for developing and improving scientific culture and awareness in society but also for addressing societal challenges.

Collaborative platforms are diverse and involve different types of stakeholders, different mixes of public and private actors and may focus on catalysing activities at different market stages. As an important mechanism for innovation in the area of advanced materials technologies, they can allow materials research institutions to better engage with the private sector and society at large.

The 12 case studies show a broad diversity in terms of technological readiness and sustainability models among platform examples. Their analysis resulted in the identification of three platform types (see Table 3). These are rather ideal types as none of the twelve case studies showed solely characteristics of only one platform type. Still, the platform types are distinct as they focus on different aims and objectives.

Platform type	Short description
Research-intensive user facilities	With the aim to advance advanced materials R&D, these collaborative platforms focus on making the most of technical expertise, leveraging resources to acquire, maintain, and upgrade high-end equipment, as well as developing, constructing and implementing new instruments.
Commercialisation-focused clusters and networks	The collaborative platforms focus on transforming a technology into a product on the market. This means their activities are to bring together relevant stakeholders to commercialise a novel material (or family of materials) and connect the supply side of advanced material development with the demand side of technology markets
Digital-focused platforms	Virtual in nature, they are a rapidly evolving emergent platform type as they aims to address challenges in modern material sciences today: enable the global scale management of material data, provide infrastructure for the accumulation of data, facilitate the design of scalable data repositories and drive data curation strategies.

Table 3. Three kinds of platforms in advanced materials

Source: Based on case study analysis

The extent to which these ideal types are present in the respective platform is reflected in the unique type mix of each empirical platform example in the field. All case studies had elements of at least two platform types. For example, the Materials for Clean Fuels Challenge Program in Canada which focuses on materials research, on the one hand, and has also components of digital platform activities. Similarly, the Korean Materials Design Platforms also has components of these two platform types. In this case, however, the collaborative platform is a virtual research space in itself that promotes new materials development with advanced tools based on both virtual experiments and computations. Other platforms are commercialisation focused with a smaller focus on research (ASSIC, PCCL and LEE BED), or showing elements of all three ideal platform types. An example of the latter is the National Nanotechnology Coordinated Infrastructure (NNCI) in the United States, a network of user facilities that focuses primarily on fundamental research, but also focuses to a lesser extent on commercialisation and has digital elements.

2.1.3. Engineering biology: the biofoundry and other platforms

The origins of engineering biology are in the synthetic biology concept that emerged in the early years of this century, and is still in a period of intense research with relatively low levels of commercialisation. The discipline aims to turn biotechnology into an engineering discipline, harnessing biological processes to act as a platform technology across a wide range of key economic sectors. As part of its goal, the discipline seeks to increase reproducibility to enable the quantitative precision required for modern manufacturing. Standards, automation, and machine learning are key to the success of this approach. It is an approach applicable to both research and industrial production. Engineering biology has many bottlenecks that make progress slow. A fundamental need is for low-cost gene synthesis technology that can then unleash the combined power of genomics (DNA reading) with DNA synthesis (DNA writing).

The new form of biology being created – digital biology – relies on making biotechnology into an engineering discipline rather than a science discipline. Biological complexity makes this an enormous task. Modern biotechnology lacks many of the hallmarks of modern engineering-based manufacturing, such as orthogonality (independence), interoperability (for example, like the standardised USB port) and separation of design from manufacture.

For industry however, there are various forms of risk associated with investing in engineering biology in the absence of public policy support. Technological risks at this stage still rely on basic research and applied research solutions best suited to public research. In other words, gearing up with large investments in, say, an ethanol production company is fraught with financial risk.

In addition to financial risks there are other disadvantages stemming from the policy arena. First, despite much increased visibility of the term "bioeconomy", much of the public support still targets traditional bioeconomy sectors. Few countries are focussing their efforts on building an advanced bioeconomy with biotechnologies and digital technologies at the heart of it. Second, as demonstrated very recently, fossil industries are continuing to grow despite over two decades of climate policy. Thus private industry might justifiably be nervous about high-risk engineering biology investments. National governments and international bodies have to make a long-term commitment to sustainable manufacturing with biomass and biotechnologies as the enablers. Other challenges include:

- The risk that society at large will reject advanced synthetic or engineering biology technologies on safety or moral grounds, especially if the products are for human consumption.
- Producing a new generation of biologists with skills outside traditional wet laboratory skills that also encompass skills in digital technologies.
- Uncertainties about real greenhouse gas emissions savings and other (as yet uncertain and un-harmonised) sustainability criteria. Bio-based products are often declared to be more sustainable than fossil equivalents, but that has to be proven.

In addition to these broad challenges, those focussing on successful commercialisation in the field are being addressed by collaborative arrangements, so-called collaborative platforms in engineering biology. They set out to achieve the following

- supplying a workforce of trained scientists and engineers in engineering biology
- lowering costs of R&D for firms trying to commercialise new technologies
- sharpening standards
- reducing regulatory uncertainty

Collaborative infrastructures exist on the national and international level. An example of the former is the Synthetic Biology Leadership Council in the United Kingdom and of the latter the Engineering Biology Research Consortium, a non-profit, public-private partnership based in the United States. A total of 10 case studies were identified and analysed, resulting in the identification of four kinds of infrastructures (Table 4).

Table 4. Four kinds of platforms in engineering biology

Platform infrastructure	Short description
Biofoundry	A highly automated facility that focus on experimental design, using laboratory robots to perform specific tasks following a 4-stage cycle: design, built, test, learn. They exist at individual institutions or are part of a national network, and may be distributed enterprise that operates as a collaboration.
Biological research centres (BRC)	BRCs play an important role as collaborative platforms in engineering biology. They are repositories of the living cells, genomes of organism, and information relating to heredity and the functions of biological systems as well as service providers
Human capital infrastructures	These kinds of infrastructures bring together experts from different sectors in society to form a community and work jointly on tasks which would be out with the realm of each stakeholder's individual line of work. A case in point are the development and monitoring of industry roadmaps.

Demonstrator-scale facilities	Infrastructure between pilot and full-scale production. Case study analysis showed that they are not very present in the field of engineering biology today. A notable exception is the Toulouse White Biotechnology (TWB), a mixed service unit of three large French research bodies. TWB bridges the gap between public research and pre-industrial development in industrial biotechnology and is thus a
	pre-industrial development in industrial biotechnology and is thus a pre-industrial demonstrator.

Source: Based on case study analysis

To explore the role of collaborative platforms in the engineering biology in the context of the Covid-19 pandemic, a workshop was held in July 2020. It highlighted that engineering biology infrastructures are in their infancy, but the COVID-19 pandemic may represent the "coming of age" of the discipline if the on-paper advantages of the approach can be translated into practical successes. Structured in three sessions, each focused on an area in which governments could improve on the preparedness for future pandemics: biofoundries (see Box 3), engineering biology research roadmaps and distributed biorefineries.

Typically engineering biology roadmaps are written on the presumption of a continuing period of "business as usual", often out to 10 or 30 years in the future and are not typically written to respond to sudden change, like the outbreak of the pandemic. This presents an opportunity for policy makers to write future engineering biology roadmaps embracing the possibility of future pandemics. Critically the issue will be the ability to mobilise large resources rapidly. The two roadmaps described at the workshop were quite different in nature. The Engineering Biology Research Consortium (EBRC), founded in the United States, produced a research roadmap relevant to both industry and policy makers. The Australia synthetic biology roadmap, produced by the Australian Council of Learned Academies (ACOLA), identified the areas of strength that synthetic biology infrastructure in Australia can enhance and provided an outlook for synthetic biology in Australia until 2030.

Both presentations on distributed biorefineries were quite clear about the difficulties to scale-up bioprocesses, a subject that has been described widely. One presentation looked at the economies of unit scale and how biotherapeutics and diagnostics production models are very different from fossil-derived production and the other one offered that increased productivity for biomanufacturing is a combination of strain engineering and the bioprocess itself e.g. the separation and purification of bioproducts post-fermentation. Given the high value and low production volume of these products, perhaps this approach could be transformative in scale-up of production for future pandemics.

Box 3. The role of biofoundries in the COVID-19 Pandemic

Various existing non-commercial biofoundries offer an integrated infrastructure including automated high-throughput (HT) equipment to enable the prototyping of biological testing standards and developing liquid-handling workflows needed for diagnostic testing of SARS-CoV-2. Equally the biofoundry can be applied to the design of certain types of vaccine. In the workshop, two examples of public biofoundries were described – the United States Department of Energy Agile Biofoundry (ABF) and the University of Edinburgh Genome Foundry (EGF).

The ABF capabilities are now being offered to companies to help develop new SARS-CoV-2 therapeutics and diagnostics for both research and scale-up. Research efforts

include computational protein modelling to understand structures of COVID-19 targets. Scale-up has frequently been recognised as a major inhibitor for biomanufacturing, and the DBTL cycle of the biofoundry is hoped to drastically reduce the time-to-market for bioproducts. The core purpose of scale-up of the ABF is being used in industry projects for: cell-free technology for antibody manufacturing; CRISPR enzymes for rapid SARS-CoV-2 testing, and; proteases to improve nutrition for elderly patients.

The EGF can offer various services for the pandemic: stratification of patients based on their SARS-CoV-2 exposure status; analysis of the longevity of the immune response and prediction of the re-infection rate; assessment of vaccine efficacy and informing design, and; further development of the platform for future rapid responses.

Source: OECD research based on the virtual Workshop on Collaborative Platforms for Advancing Engineering Biology: Focus on the COVID-19 Pandemic, July 29, 2020.

2.2. Ontology of collaborative platforms

Collaborative platforms can be described in terms of a set of key characteristics which can help in comparing platforms and their salient aspects (see Figure 2). These categories and aspects, derive from the discussion of unique features and platform types of the case study examples presented in the previous section.

Public-private actor mix. Partnerships for emerging technologies involve research institutions, universities, and industry. The public-private mix describes the extent to which these actors are involved.

Closed versus open membership. Platform might grant exclusive access to member/partner organisation that pay membership fees, or they might be open to third parties, such as small firms that can get access to the services provided by platforms for monetary compensation.

Centralised versus decentralised networks. Members of partnerships can be located in a single site or distributed across multiple sites. Centralised partnerships are organised around a central leading institution or firm that decides about access to platform services. Decentralised partnerships exist where looser networks of autonomous actors collaborate, potentially across national jurisdictions.³

Pre-commercial stage versus commercialisation stage. A platform can move from precommercial to commercial stage, or cover both stages simultaneously. Using case studies in aeronautics, biomaterials, biotechnology, and microelectronics sectors, Hatchuel et al. (2009_[51]) show that collaborative platforms differ from private platforms in that their business models evolve with maturity of the underlying technology.

At pre-commercial stages of technologies, collaborative platforms help de-risking investment. Governments often provide stable, long-term funding for emerging technologies at this stage, where innovations are complex and costly and where economic outcomes are yet uncertain (e.g. genetic platforms for precision medicine) (Jessop-Fabre and Sonnenschein, 2019_[52]; Crowley and Gusella, 2009_[53]).

In the commercialisation stage, collaborative platforms deliver standardisation, demonstration and testing services for its members. They encourage innovation and

³ Innovation ecosystems are another example of decentralised partnerships and have the form of large companies, start-ups and SMEs, investors, universities and other research organisations, regulators and society.

commercialisation of enabling technologies by developing business models (Dattee, Alexy and Autio, $2018_{[54]}$).



Figure 2 Summary of collaborative platforms characteristics

Source: created by report authors

Maturity of the technology. The potential of collaborative platforms for commercialisation will depend on the maturity of the technology. New emerging technologies are characterised by uncertainty with regard to their potential applications, while mature technologies are rather ready for application.

3. Comparative analysis of the technology areas

The empirical examples in the previous sections⁴ display a high institutional diversity of collaborative platforms in the three investigated technology areas. Various institutional forms of collaborative platforms are apparent: research-intensive user facilities, commercialisation-focused clusters and networks and digital-focused platforms in advanced materials; biofoundries, resource centres and demonstrators in the field of engineering biology; and biobanks and genomic initiatives at governmental health system level, in the public, non-profit or private sector, and networked initiatives.

It is evident, therefore, that collaborative platforms in the three investigated technology areas offer distinct insights. Nevertheless, a detailed comparative analysis across governance elements as outlined in the analytical framework (see section 1.1) yields relevant insights across the spectrum of platforms.

3.1. Sustainability models and value creation

Collaborative platforms use different approaches to sustain themselves and create value from their activities. They fall broadly into four categories: funding, access, ownership and the creation of social value.

⁴ More information on the cases can be found in respective 'empirical case studies' sections in Annex I, II and III

3.1.1. Funding models

Most collaborative platforms require continuous investment from a mix of the public and private sectors as they are forms of infrastructure often developed due to perceived insufficient private investment. For one thing, platforms based largely on fees from memberships or the use of equipment find it difficult to put money aside for large investments. This can be required for the initial set-up but also maintenance, staffing and other cost that arise during its operations. Some collaborative platforms in the field of engineering biology and advanced materials face the challenge to maintain the stream of funding over the course of the platform's lifetime.

Funding based on public, private or a combination of sources is the most common in collaborative platforms in the fields of engineering biology and advanced materials. In fact, platform-funding models are evolving overall to become less dependent on public financing. However, in some fields with a strong public interest, such as genomics, they still depend primarily on government and charitable research funding. In the ideal case, a virtuous mix of public and private investments are complementary and generate both tangible commercial value but also intangible value. Using the analogy of "the last mile" (Figure 3), public investment enables the establishment of the core infrastructures of the platforms whereas private investment tailors the product development and other unique innovation activities on the platform.



Figure 3 Last mile analogy to the public-private mix of platform financing

Source: Presentation by Nathan Hillson, Lawrence Berkeley National Laboratory, on 29 July 2020, adapted from Lyft

The mixture and feasibility of financing mechanisms depends on the level of technology readiness that the respective platform targets. Public financing of mid to high technology readiness can become problematic if there are strong rules against the distortion of competition. In a transnational setting, however, research and innovation funding operates under different legal frameworks. For example, the European Pilot Production Network (EPPN) in the field of advanced materials supports individual piloting activities with public financing because of this transnational nature of the platform.

Platform financing is linked with power -- institutions that are funding collaborative platforms play an important role in deciding which stakeholders can participate and get access to the platform. In the field of genomics biobank, funders structure the forms of public participation in the governance of the resource. Platforms in the engineering biology context suggest that platforms funders can broaden the scope of stakeholders so that more

views points are considered. This links with decisions on the mechanisms who grant access to platforms resources that are discussed next.

3.1.2. Access to platform resources - data and facilities

Governing access is a central issue in all three technology areas. Collaborative platforms might be considered what Hess and Ostrom (2007_[55]) have called "toll goods", i.e. resources whose use by one party does not compromise others but beneficiaries can be (easily) excluded. For toll goods, designing access is critical for questions not only of funding generation but also for increasing the inherent value of the resource. For example, selective access to platform resources is important because collaborative platforms are dealing with equipment and data that require expertise and can be of sensitive content, such as healthcare information in the fields of genomics. Hence, a trusted environment with own identifiers in virtual data centre(s) is vital in which genomic, clinical and diagnostic imaging data as well as samples of blood and tumours are made available for commercial and non-commercial research

In some contexts, platform actors articulated the aspiration that platforms, through the right access provisions, had the ability to "democratise science". In practice, access policies tend to conform to one of two models, either a membership model or an open access model. The former requires an initial or recurring membership fee; the latter has a fee-for-use of facilities or platform data. These fees can be a barrier for some stakeholders to participate in a collaborative platform which became apparent in the context of collaborative platforms in advanced materials and engineering biology. Thus, the recommendation emerged that platforms should differentiate with their fees between different kind of private sector actors, such as SMEs and large companies, and public research organisations.

A formalised policy that streamlines the access process can help avoid unwanted consequences such as long project delays -- due to negotiations between the legal departments of companies and the public infrastructure management – as well as perceived high bureaucratic barriers. The latter might deter SMEs or other smaller potential platform actors, a concern that was raised in both Austrian case studies in the field of advanced materials and was highlighted in collaborative platforms in engineering biology. In the field of genomics, Genomic England standardised its participation agreement and created a dedicated body – the Access Review Committee –that governs who can use the platform and its resources.

The geographic location of physical facilities raises important design considerations for platform access. In fact, researchers and experts may need to be on-site to use equipment and other resources which usually involves accommodation and living costs. To enable access and participation in platform activities, the International Iberian Nanotechnology Laboratory (INL) in the field of advanced materials, for example, has short-term accommodation facilities at its premises. Depending on the type of access required, connecting to equipment remotely could be a possibility to address the issue of geographic location, such as in the case of the Nanotechnology Platform Japan. Offering remote connectivity requires digitalisation of the platform which is discussed in section 3.3.

3.1.3. Ownership – IP and licensing

The terms of the contracts that grant access to a collaborative platform often also set out ownership of IP rights. These contractual provisions may concern prohibitions on patenting of upstream technologies to avoid restrictions on further research and development in the technological field, licensing requirements to advance the purpose of the collaborative platform or the right of first refusal. A case in point are the Collaborative Research and Development Agreements (CRADAs) which the Agile BioFoundry in the United States puts in place when companies send their researchers to work at the Agile BioFoundry, the industrial partner generally has a right of first refusal to an exclusive license. Alternatively, access contracts can stipulate that any IP resulting from the collaboration will be held by the platform. The default of the Research England Participation Agreement is that ownership of results from the research conducted with the data from the platform stays with the platform unless IP is assigned to an institution for commercialisation. Therefore, it is important to analyse IP and licensing arrangements that govern not only access but also ownership of assets that are created or deployed in collaborative platforms.

The analysis across the three technology areas resulted in the finding that either the platform or its individual members are the lead party to govern ownership and IP rights. Box 4 presents four approaches in collaborative platforms to govern ownership and IP rights.

Box 4. Approaches to govern ownership and IP rights in collaborative platforms

1. Platforms own IP

Platforms are owners of the IP resulting from platform activities. This is the case in the two Austrian COMET centres (Competence Centre for Excellent Technologies) in the field of advanced materials where the IP belongs to the platform unless otherwise stated. General IPR conditions, regulated in COMET-Agreement, serve as a basis for more detailed IPR regulations that are part of cooperation agreements on a project basis. IPR belongs to the Centre ASSIC, unless otherwise stated. General practice in company projects is that they get the right of first refusal and in projects that involve only research institutions, IPR are shared among the involved parties.

2. Bayh-Dole model: IP held and transferred by the parent research institution

In the absence of a platform-wide IP policy, IP rights rest with platform actors. Examples from North America follow this approach; the sites of the National Nanotechnology Coordinated Infrastructure (NNCI) in the Unites States adopt IP policies of their parent university because there is no network-wide IP policy. In the case of the United States, IP is usually assigned to the university or research institution under the so-called Bayh-Dole Act.⁵ In Canada, all three universities that plan to create a future network of biofoundries work under their university's IP policy through their University Industry Liaison Office.

3. IP policy depends on platform use

The IP policy depends on the use of the platform or the project type. This is the case in collaborative platforms in the field of engineering biology. For example, the Toulouse White Biotechnology (TWB) distinguishes in their IP approaches between early-stage projects, public-private projects and industrial contracts. In early-stage projects, TWB has the right to valorise the IP with external partners after a 6-months priority period for members. Partners in public-private projects own IP according to their investments. Regarding contracts with industrial partners, if research collaborations result in IP, then the industrial partner has the right to decide in return for paying the full project cost and an eventual success fee in case of commercial exploitation of the results.

4. Collaboration agreements determine IP rights

⁵ Bayh-Dole Act of 1980 as enacted through Public Law 96-517 (96th Congress, United States).

Members decide about IP right on the level of the respective collaboration that takes place thanks to the platform. This is the case in the European Pilot Plant Network (EPPN). The platform members who decide to work together make arrangements on the individual-level of the collaboration. Still, technology of the digital platform of the EPPN itself which is the tool connecting the members belongs to the EPPN consortium and EPPN owns the data gathered from the use of the digital EPPN platform

Source: OECD

The leveraging of publicly owned IP is the sole purpose of some collaborative platforms. This is the case, for example, of the Korean Nano-convergence platform in advanced materials. It sets out to link and provide support to companies that wish to commercialise nano convergence technologies with public sector research institutes or universities that hold patented technologies in the field which have the potential to be turned into a commercial product.

Ethical concerns about the role of IP are particular issues raised in the field of genomics and biobanks. Some platforms have sought to engage research participants in dialogue about the dispensation of IP rights, which is good practice for ensuring transparency and building trust in the governance system.

In terms of licensing, the downstream impact of policies and conditions often remains uncertain due to the time lag between the imposition of licensing conditions, and the ultimate clinical or industry use the technology outcome from industry. Empirical examples of platforms in genomics and biobanks have suggested regular reviews of licensing terms and a flexibility approach to adjust to the needs of all platform actors.

3.1.4. Social value – partners' trust, training and workforce development

Collaborative platforms bring different kinds of stakeholders together which is essential for the creation of social value that manifests in the development of human and social capital. Both are difficult to assess and capture in normal platform metrics and they are dynamic managerial capabilities, according to the Oslo Manual (Dattee, Alexy and Autio, 2018_[54])(OECD/Eurostat 2019). The importance of social value for the platforms' sustainability and their impact became evident in the analysis of collaborative platforms especially in the genomics area.

Social capital is also referred to as "goodwill derived from relationships" (Dattee, Alexy and Autio, 2018, p. 109_[54]) and results from the creation of inter-personal relationships, networks and trust between platform stakeholders who collaborate in joint projects. This intangible, relational value can manifest in a shared sense of identity, norms and values for the different platform actors. It may result in the establishment of long-term networks and partnerships which may extend beyond the scope of the respective technology platforms. This was reported from the collaborative platforms in advanced materials, ASSIC and PCCL, in Austria.

Human capital are competencies, knowledge and skills created in training and workforce development efforts that set out to build, resulting in value for the individual (researcher, technician, engineer etc.) that can be translated to economic value further down the line. For example, the development of human capital is a key objective of the Collaborative Laboratories (CoLabs) in Portugal that create scientific jobs and offer skill-building classes, e.g. to PhD students to build capacity to fulfil these jobs one day. Moreover, training and educational programs for students or technical staff are common in collaborative platforms for advanced materials, such as NPF in Japan or NNCI in the United States.

A stable base of core staff that works at the respective platforms is essential, however fluctuations of staff are not uncommon and can cause a "brain drain" which can significantly weaken the potential of collaborative platforms. A reason are short-term research staff contracts that are quite common due to project-based funding (OECD, $2017_{[29]}$).

3.2. Collaboration

Collaboration is an integral part of research and innovation activities in engineering biology, advanced materials and genomics and biobanks. In all three technology areas, novel organisational arrangements enable different partners to work jointly in new ways resulting in the acceleration of research and innovation. The four aspects crucial in this regard - standards, ecosystems perspective, international platforms and missions – are key for understanding collaboration in this context.

3.2.1. Standards

Collaborative platforms have a two-way relation with standards: on the one hand, they play a key role in the development and testing of standards and, on the other hand, they depend on standards to ensure interoperability. In all three technology areas, sound functioning of platforms require such interoperability. Platform actors must communicate using complex packages of tools, data, and software emanating both from academia and industry. If technical components are incompatible because of different standards or the lack thereof, operation and work flow processes can be adversely affected and collaboration stymied.

In field of advanced materials, technical standards are considered as a form of market infrastructure, necessary for quality control, interoperability and to support regulation. Similarly, in engineering biology, technical standards that automate methods, describe and assemble components and document the performance of engineered microbial strains have a high priority. An example in this regard is the Singapore synthetic biology community which mainly collaborates on technical standards with overseas collaborators.

The field of genomics illustrates the potential dangers of too many rules. There, there is a real danger that too many standards may introduce potential conflict and fragmentation. In fact, formal standards may not always be necessary or desirable. For example, in the field of genomics and biobanks, it was highlighted that, industry consensus can serve to ensure that research and collaboration is possible and not hindered.

Standards can be an access qualification to ensure interoperability and the smooth operation of collaborative platforms. For example, adherence to a minimal level of quality assurance measures and commitment to implementing a quality management system following appropriate international standards can be a requirement to participate in platform activities, as is the case for mBRCs to become MIRRI-ERIC partners in engineering biology. In doing so, collaborative platforms can also shape markets by fostering standards, regulation and good practices. An example in this regard is the development of the 3D printing technology led by the private sector in the field of advanced materials in the context of additive manufacturing.

Standard setting is linked to the funding of collaborative platforms. A lack of long-term funding commitments can lead to a reluctance to set standards on data formatting across universities, an issue identified in the field of advanced materials.

3.2.2. Ecosystems

Collaborative platform can seed and catalyse ecosystems that they are part of or they themselves can have ecosystem-like properties. On the latter, platform stakeholders and innovation ecosystem actors share the same elements: a shared notion of value, complementarity and mutualistic relationships. The concept of an "innovation ecosystem" (Jacobides et al. 2018) was useful during the analysis of collaborative platforms in the three technology areas to understand their purpose and how they operate, but also what environment they are trying to create around them.

Ecosystems emerged quite differently across the collaborative platforms analysed in three technology areas. In a number of engineering biology platforms, collaborative platforms are seen as hubs for ecosystem growth whereas the Materials for Clean Fuels Challenge Program in Canada is designed as an ecosystem builder by supporting funding and network creation, integrating and coordinating platform activities. Examples on the former are the Agile Biofoundry in the United States and the TWB in France which both have the function to develop a growing ecosystem of biotechnology and engineering biology on the regional or national level. In genomics and biobanks the ecosystem perspective is rather mobilised in the context of population genomics (PopGen) to differentiate between the building blocks and the overall system-level of analysis. PopGen is a logic model to identify the key inputs and activities required to deliver an effective population genomics programme.

3.2.3. International platforms

There are fewer collaborative platforms that are operating transnationally because they are facing various challenges:

- cultural differences may lead to variations in standards, laws and regulations across national systems resulting in the need to harmonise diverse approaches, e.g. using higher-level standards or meta-standards
- different approaches to privacy or ethical issues, such as consent. A reason that was brought forward in the context of genomics.
- public funding from governments that prioritises national actors to collaborate

Thus, it is not surprising that the majority of empirical examples from the three technology areas are platforms that act on the national or regional level. Still, the analysis of the empirical examples in the three technology areas showed that collaborative platforms across national borders are present and can be strong. In the field of engineering biology, notably iGem and GBA, are prime examples where public funding streams were dedicated specifically to building international partnerships and ecosystems. Examples of international collaborative platforms in the field of advanced materials are from the European Commission (EPPN&LEE BED) and Portugal (University of Texas at Austin - Portugal Program).

Collaborative platforms can bridge national regulatory boundaries by setting internationally agreed standards surrounding the use of emerging technologies, and provide guidance for risks associated with their application. Supporting Ansell and Gash (2007) and Folke et al. (2005), collaborative arrangements seek and can develop more flexible governance standards than, e.g., state regulation. Supporting Gawer (2014), in the context of emerging technologies, where change is fast and often unpredictable, platform-based models are flexible arrangements to spur data sharing, and discuss norms around the use of converging technologies.

3.2.4. Missions

The creation of suitable mechanisms to operationalise mission-oriented research and innovation policies (MOIPs) and challenge-driven approaches is a key issue for STI policy and organizations today (Larrue, 2021_[56]). MOIPs are tailored to address well-defined, but solution-neutral objectives. These measures possibly span different stages of the innovation cycle from research to demonstration and market deployment, mix supply-push and demand-pull instruments, and cut across various policy fields (Larrue, 2021_[56]). Collaborative platforms can be an important vehicle to enable the implementation of missions and MOIPs: they present a type of R&D organisation that could be highly responsive to sharply drawn societal goals. The issues addressed may vary depending on the technology area. In advanced materials the creation of a circular economy or taking up the lack of key resources and plastic disposal; in genomics and biobanks to addressing unmet public health needs, reducing unnecessary interventions and health costs, improving testing and diagnosis of diseases or achieving better health outcomes by personalising treatment options; addressing sustainability in engineering biology.

Two concreate examples of collaborative platforms to implement clearly defined missions in order to address societal challenges related to either the medical field or climate change are the Genomics Health Futures Mission in Australia and the Materials for Clean Fuels Challenge Program in Canada. Both have in common that they:

- set out to create collaborative platforms to support the development and use of technology which seem crucial to policy makers for the years to come
- focus on advancing basic research in high-risk, high-reward technologies
- provide research funding in competitive grants
- recently launched government programs in the fields of genomics and advanced materials with 10 and 7-years duration respectively

The Genomics Health Futures Mission in Australia runs from 2018–28 and aims to improve testing and diagnosis for many diseases, help personalise treatment options to better target and improve health outcomes, and reduce unnecessary interventions and health costs. Launched in early 2020, the Materials for Clean Fuels Challenge Program in Canada provides an integrating and coordinating role, as well as supports funding and networks in order to harmonize the different efforts towards defined greenhouse gas (GHG) emissions reduction objectives.

3.3. Digitalisation

Digitalisation carries significant potential for enhancing the value of collaborative platforms and is, indeed, driving the development of new kinds of collaborative platforms. The availability of large amounts of data in digital format is facilitating data sharing and access across the globe. Moreover, it allows for the delocalisation of a wealth of platform activities and diminishes geographical barriers, resulting in more network-type collaborative platforms. Hence, collaborative platforms can become a tool for inclusiveness, enabling new user groups to participate in platform activities, even if they could have not produced such knowledge by themselves.

The important role that digitalisation is playing for collaborative platforms is exemplified by the emergence of a third type of platform in the advanced materials field, a so-called "digital-focused platform". It mobilizes digital data on materials and may also include AI to support material design and development. In doing so, it cuts across traditional platform types in advanced materials, i.e. research-intensive user facilities and commercialisation-

focused clusters and networks, is virtual in nature, but still has a range of infrastructural requirements. In engineering biology, digitalisation has helped give birth to the biofoundry, and its advantages for the speed-up of design-build-test-learn cycles at the core of engineering practice.

There are a number of prerequisites to leverage the potential of digital technologies and for data sharing to occur in collaborative platforms. Based on the empirical examples from the collaborative platforms in the three analysed technology areas, the following sections shed light on these important issues by focussing on data management and the role of digital technologies in collaborative platforms.

3.3.1. Data management

Data plays a pivotal role in collaborative platforms whether they are physical or virtual structures. Data management concerns the sharing and protection of data, its importance varies across the examples of collaborative platforms in all three technologies. It is of outmost importance in collaborative platforms where data is the primary resource, currency of value and object of collaboration. This is often the case in the field of genomics and biobanks.

The genomics and biobanks cases illustrate that for some platforms, especially in health, research can only advance with access to a large quantity of data yet provisions need to be in place to protect the interests of the patients or participants whose data is shared. In terms of data protection, the General Data Protection Regulation (GDPR) is an important set of rules in the European Union regulating access. Implemented in May 2018, it sets out to give individuals control over their personal data and unifies the regulation within the EU and the European Economic Area (EEA). The respect for and protection of the privacy of patients and study participants is a point that is particularly important to the governance of collaborative platforms in genomics

For data sharing to work in collaborative platforms, expertise, money, incentives and standard-setting are required. Collaborative platforms in advanced materials and genomics pointed out that the conditions for these factors to be in place include long-term funding, good data quality and clarity on data property, particularly in digital-focused collaborative platforms. In fact, among the key challenges are the lack of incentives for companies to do so, the cost associated with building and maintain respective infrastructures and expertise of platform staff. Moreover, even if funding agencies force the sharing of data, this does no guarantee the quality of data.

Interoperability was signalled by participants across the three areas, in workshops and written responses, as a critical challenge for leveraging the power of digitalisation. Indeed, interoperability is a prerequisite for data sharing and requires compatible data formats, data integrity and expertise in data handling. The latter is closely related to the point about the custodian, the party responsible for storing, keeping and making the data available. In the ecosystem of a collaborative platform, this can be considered a service that is provided to the platform stakeholders which has a cost. Thus, clarifying who takes care of this task and who pays for it are important considerations when setting up a collaborative platform.

3.3.2. Digital technologies

Collaborative platforms in all three technology areas mentioned that advances in digital technologies, specifically AI, machine learning and cloud computing offer both opportunities and challenges; these vectors of change are reshaping the modes of working, sources of value, and the very future of collaborative platforms.

Cloud computing is playing an important role in collaborative platforms in the fields of genomics and biobanks in three areas today: First, platform users can remotely access and analyse vast data sets available in existing data archives. Second, collaboration on large amounts of shared data becomes possible. Third, computing resources can be scaled according to the data analyses needs of researchers, thus money wasted less often on idle moments. Examples of projects that rely on cloud computing are the Cancer Genomics Cloud (CGC), Pilots and the Encyclopaedia of DNA Elements (ENCODE and Model Organism ENCODE (modENCODE)) as well as the Pan-Cancer Analysis of Whole Genomes (PCAWG).

AI and machine learning are techniques well suited to mine the large data sets that have opened up new avenues and efficiencies of research in the three areas of technology. For example, for the Edinburgh Genome Foundry in engineering biology, these techniques are vital to design experiments when predicting outcomes of different experimental scenarios. Similarly, in genomics and biobanks, the use of AI and machine learning are increasingly leveraged to generate and analyse large volumes of data. Moreover, AI promises to be a crucial enabler for a more efficient use of data in collaborative platforms. Thus, AIsupported materials design and development was cited as a new and important stream of work in collaborative platforms for advanced materials. For example a key pillar in the Canadian Materials for Clean Fuels Challenge Programme is that AI tools are expected to heavily augment the materials development and R&D in general at the National Research Council of Canada in the future.

The ascendancy of digital tools in many collaborative platforms has culminated in fully digital platforms, such as the Korean Material Design Platform. It is at the leading edge of a new paradigm in materials research that conducts (sub) atomic level simulation and realises new gains and modalities through rapidly increase computing power and the development of efficient computation methods. However, despite these promising avenues for research and innovation in the future, the barrier for advanced computational research is high today which arises from the theoretical and numerical complexities and the requirement for high performance computing environments.

4. Collaborative platforms as convergence spaces

The empirical cases and their analysis make it clear that collaborative platforms are at their most valuable when they operate as "convergence spaces" – physical and/or material loci that bring together diverse elements: actors, disciplines, and technology. In doing so, they are able to produce new kinds of value, products, technologies, and training. The governance levers in the analytical framework (see section 1.1) can help optimise these convergence spaces for particular purposes, seeking to maximise tangible and intangible value, realise sustainability models, foment collaboration, and promote technological integration. Ultimately outputs like new knowledge, approaches and partnerships can feed back into the platform, enhancing its value.

This study therefore reveals that the definition of convergence as it was deployed in section one may not fully reflect the diverse work of the collaborative platforms. Roco et al. (2013, p. xiii_[57]) have produced a definition of convergence that is more apt, explaining that

Convergence [...pertains to ...] the escalating and transformative interaction among seemingly distinct scientific disciplines, technologies, communities, and domains of human activity to achieve mutual compatibility, synergism, and integration, and through this process to create added value and branch out into emerging areas to meet shared goals.

The convergence of disciplines, technologies and actors does not occur in isolation. Thus, it depends, e.g., on transdisciplinarity, the integration of knowledge from different science disciplines and (non-academic) stakeholder communities (OECD, $2020_{[58]}$) and also processes of "co-creation," in which actors engage in joint knowledge production across industry, research and even civil society. Adding technology convergence to these elements, collaborative platforms can create the powerful synergies necessary to enable innovation. The following paragraphs disentangle the different kinds of convergence that come together at a collaborative platform assembling a convergence space.

4.1. Convergence of disciplines

The convergence of scientific disciplines goes hand in hand with the growth in demand for interdisciplinary research (OECD 2020). The US National Academies (2014_[59]) defines convergence in terms of combining disciplines to create new fields. In other words, it comprises

the merging of ideas, approaches, and technologies from widely diverse fields of knowledge at a high level of integration. [This constitutes] one crucial strategy for solving complex problems and addressing complex intellectual questions under emerging disciplines (p.20)

Convergence resulting in the creation of new fields demands a new kind of interdisciplinary workforce and training for the 21st century. It also requires attracting scientific staff with expertise across many disciplines to complement the respective skillsets of platform actors, e.g. to enable them to use platform equipment, as cases in engineering biology and advanced materials illustrate. Concretely, this is the case in the NNCI in the United States that not only offers leading-edge fabrication and characterization tools and instrumentation but also scientific expertise that spans a wide variety of disciplines related to nanoscale science, engineering, and technology. The stakeholders that contribute to a collaborative platform have different expertise and may work jointly on the development of new knowledge. In engineering biology, a new industrial paradigm called "digital biology" is evolving which is breaking the boundaries between traditional biotechnologies and IT/computer programming. It will require a new generation of biologists with expertise to

navigate both fields in the future with skills in traditional wet laboratory work and digital technologies.

The interdisciplinary knowledge and skills required for research development in platforms underlines the convergence at the heart of many collaborative platforms. The success of automation, for instance, depends not only on the configuration of suitable hard- and software but also on the necessary interdisciplinary skill levels of platform staff. This will result in a future workforce that is able to participate in platform activities, as platform user or staff.

The convergence entailed by collaborative platforms, therefore, puts new demands on the training systems. Broadening the curricula of formal higher education to include more/adjacent disciplines is a solution proposed to address these demands. For example, in the field of engineering biology, there are calls to include in the training of biotechnology employees engineering and business skills. Interdisciplinary approaches to education and training were also raised at the discussion of collaborative platforms in advanced materials. In addition to formal education, calls for more training outside higher education and rather as "lifelong learning" were echoed in both technology areas. Examples from the field of engineering biology include continuous professional development (CPD) in Italy and some innovative initiatives including the "4-day MBA" in the UK. Similarly, when reporting about its engineering biology platform, Singapore noted that the inclusion of engineering biology modules in more traditional undergraduate courses, such as biomedical sciences, chemical engineering and biochemistry is an approach used to build required capacities.

4.2. Convergence of actors

Collaborative platforms, almost by definition, are convergence spaces for public and private actors in the business of discovering and marketing new knowledge. They provide places where diverse actors can interact, co-create new knowledge, and generally cooperate. They present a trading zone where parties can contract around access to resources, current discoveries, and downstream inventions. Motivations to use or contribute to platform activities depends on the value proposition for individual actors. While a private sector actor will tend to seek monetary benefits accruing in the short or long term, partners from the public sector are more likely aim to build infrastructure for longer-term knowledge or skill force development. In the field of genomics and biobanks, for instance, universities are often involved in the initial development, whereas companies and public-private partnerships play the key role in commercialising the technology.

Breaking down the barriers between science and publics is both a function and strength of collaborative platforms: that is, they have the potential to build interested publics through engagement and communication. A case in point is the National Nanotechnology Coordinated Infrastructure (NNCI) in the United States that engages with the public through a range of channels, such as seminars and symposia, a radio series, community events and a traveling museum exhibit. In additional, the NNCI runs educational programs including classroom visits, teacher workshops and the dissemination of teaching resources.

Interactions can be mutually beneficial and serve to increase the reflexivity of the enterprise, as illustrated by the Scale Travels Initiative by the International Iberian Nanotechnology Laboratory (INL) in Portugal. At its launch in 2015, the initiative set out to stimulate reflection and debate on societal, ethical, cultural and other impacts of nanotechnology by mobilising the arts in various ways. This resulted in an artist in residence programmes where artists embed themselves in the life of the laboratory and engage with researchers to stimulate reflection on nanotechnology research and society. The public can see the pieces in local exhibitions. In the field of engineering biology,

societal engagement is seen as a potential means to prevent mistakes with communication around genetically modified organisms (GMOs) in the past by mobilising scientists, technologists, practitioners and policy makers to work closely with biofoundry operators and the public.

Platforms for health innovation, including those build around biobanks and genomics databases, require close partnerships with patient populations. Cases in the study show how the sustainability of such platforms ultimately depends on the maintenance of a social contract with the public. This is because the public has a two-fold role in the research endeavour of these platforms: on the one hand, the work with patients and their data is the lifeblood of the platform; on the other hand, the society may take-up the benefits of outcomes from platform activities. Thus, there are important considerations to be made for the protection of public interests, the creation of transparent and accountable governance structures, data security and privacy and continued engagement and dialogue about commercial involvement in research.

4.3. Convergence of technologies

Collaborative platforms are also spaces both for the convergence of technologies and, thereby, the assembly new ones. Digitalisation is a key driver of this convergence. Digital technologies are enabling the automation of platform activities to increase their efficiency and speed, whether in production technologies or lab technologies. The convergence of digital technologies in collaborative platforms is exemplified in the materials research by Information Integration Initiatives (MI2I) at the National Institute for Materials Science of Japan. The driver of the MI2I platform is a high-throughput materials development method based on data science where data mining, machine learning and AI are combined. Digitalisation also facilitates the assembly of actors to engage in group work.

Engineering biology presents a strong example of how platforms can galvanise a virtuous convergence of technologies to produce not only new technologies, but new products, new ways of working, and a novel scientific paradigm. Biofoundry platforms represent the latest evolution of "digital biology", the on-going convergence of biology, robotics, IT and machine learning. The ability to carry out complex workflows with relatively little human intervention, and to iterate the design-build-test-learn cycle greatly increases the speed at which optimal designs can be created. This is heralding the arrival of engineering biology as a discipline of engineering. As such, the reproducibility and reliability required for modern manufacturing is being approached. A future vision of manufacturing could be the convergence of automated synthetic chemistry with automated synthetic biology, aided massively by projects that are sequencing the DNA of an increasing number of life forms. Thus combining the known biology (genomics) with the new biology (biofoundries) with automated chemistry fuelled by green energy may be the ultimate convergence of sustainable manufacturing technologies.
4.4. The convergence model of collaborative platforms

Using the broader definitions cited above, collaborative platforms leverage the generative potential of convergence. Taken together the above findings, this section proposes a model that conceptualises these platforms as "convergence spaces", building on the insights about the different forms of collaborative platforms and characteristics (see section 2) and their comparison (section 3). Key elements of the model include:

Figure 4 Conceptual model – collaborative platforms as convergence spaces



Source: developed by report authors

- **Convergence space**. Physical and digital sites where disciplines, technologies and actors come together and interact resulting in different kinds of creative output, whether new data, information, knowledge, discoveries, skills, public communication, etc.
- **Governance components**. Mechanisms to order platform operations, e.g. funding model, access rules, ownership/IP, engagement, standards. They are levers for shaping the convergence space.
- Cyclical value creation. It is a feature of collaborative platforms that they can be designed such that data knowledge, skills i.e. different forms of value return back to the platform thereby entering a virtuous cycle and enhancing the tangible and/or intangible value of the resource or infrastructure.
- **Drivers.** Digitalisation and societal challenges can function as drivers for the formation and operation of collaborative platforms. The former is rather an enabling factor and the later mobilises actor to address urgent issues such as climate change, pandemic response etc.

In the case of networked platforms, the model of collaborative platforms as convergence spaces expands in that the individual platforms get linked with others in a network. This means concretely that a central, national- or regional-oriented platforms build together a network of convergence spaces which are of virtual nature (see Figure 5). Examples are biofoundries in the United States and Singapore, or GA4GH in the genomics case, or the National Nanotechnology Initiative.



Figure 5 Collaborative platforms as convergence spaces - a networked model

Cases from the three technology areas reveal how convergence is not only leading to their creation, but also operating throughout the platform's existence. In other words, it can be considered the underlying process that leads to the creation of the platform and remains essential to the platform over the course of its lifetime.

5. Design considerations: building collaborative platforms as convergence spaces

Those wishing to create collaborative platforms that operate as productive convergence spaces might take into account the following design considerations.

Build sustainability models that encourage interaction over revenue or IP generation. All collaborative platforms exist over a specific period of time and should ensure that their activities create value of tangible and intangible nature. To do that, the following aspects need to be considered during the design of collaborative platforms:

- The platform funding model links to its sustainability and needs to cover their operational expenses, as well as maintenance and other larger irregular expenses. User fees can cover the former, but this needs to be complemented with investment on the latter.
- Define access and IP policies that enable platform actors to interact and use its resources: Fee-based mechanisms should differentiate between the kind of private sector actors, such as SMEs and large companies, and public research organisations. Deploying standard access procedures is a good practice to avoid delays and high bureaucratic barriers. Physical facilities can offer short-term accommodation for experts and researchers to enable on-site access and participation in platform activities.

Source: developed by report authors

- Manage the innovation activities of platform actors with suitable managerial tools. After the recruitment of partners and/or staff, this is an important step for the establishment of platform-specific work practices, such as the use of roadmaps or logic models.
- Encourage training, education and a stable platform workforce. A good platform practice is to ensure the development of skills by offering training and educational programs for students, researchers or technical staff platform staff, and to provide adequate job security despite project-based funding to avoid "brain drain".

Leverage collaborative platforms as vehicles to drive mission-oriented innovation policy.

- Consider designing collaborative platforms for the implementation of missions and mission-oriented policies. The greatest societal challenges today require solutions from innovative or newly developed technologies. Collaborative platforms can act as vehicle to drive their development and diffusion. This requires the willingness to provide funding for research on high-risk/high-reward technologies.
- Collaborative platforms have the capacity to drive mission-driven research and development in part through their diverse coordinating functions e.g. ordering the relations of diverse partners through property and access rules, and addressing technical and normative interoperability.

Activate mechanisms which enable different actors to convene and innovate jointly.

- Promote and support standard-setting. Standards have a strong coordination function, and are prerequisites for platform use and access, and thus standard-setting is good practice to ensure compatibility and the smooth operation of collaborative platforms. The use and promotion of industry consensus, rather than top-down approaches, may help avoid fragmentation that can result from too many standards.
- Aim to anchor the development of innovation ecosystems. If collaborative platform are to act as hubs for ecosystem growth or its creation, built-in flexibility is required so that platform dynamics can occur, such as changes in platform actors.
- Stimulate the activities of platform actors across borders. Many grand challenges cannot be achieved by platforms within the borders of a single country, and there are often great potential gains for international collaboration. Governments should consider directly supporting such endeavours.

Realise the potential of digitalisation in convergence. Digitalisation can enable collaborative platforms in all three technology areas. It can accelerate the convergence of actors, technologies and disciplines in collaborative platforms and can make them more inclusive by diminishing geographical barriers. In order to realise the potential of digitalisation in this context:

- Promote access to data which improves platform attractiveness, but be clear about rights of control and use that are entailed in the use of the platform.
- Invest in strong data management systems. Transform data provided by researchers into a standardised data format when building high quality databases and ensure that the collaborative platform uses compatible data formats and that it has expertise in data handling. Support labour-intensive and costly data quality assurance and data curation processes as well as data management that concerns the sharing and protection of data

- Build sustainable data infrastructures based on long-term investments with incentives for individual researchers and companies to share data to such platforms via funding mechanisms
- Put provisions in place that protect the interest of those that are sharing data, particularly in cases of sensitive data such as from patients or study participants
- Co-build data analysis tools using data science and informatics methods e.g. to find the relationship of structure and property/function or optimum materials
- Leverage the potential of emerging digital technologies, notably cloud computing for the remote access of data as well as AI and machine learning for the generation and efficient use of data in collaborative platforms

Catalyse the interaction of technology and society. Collaborative platforms can help deepen the engagement of the broader society with emerging technologies. In that context, the societal engagement of collaborative platforms with actors outside its innovation activities is becoming increasingly important. Maintaining levels of public involvement and engagement over the platform lifetime can build the mutual trust and social contract that needs to support the enterprise.

Therefore, platforms need to be designed to foster these interactions, e.g. to:

- Communicate with and engage diverse publics about the potential opportunities as well as challenges of emerging technologies. A good practice is the use of different channels with a mix of on-site and digital information diffusion via seminars and symposia, podcast series, community events and an interactive museum exhibit
- Run programmes that inform the public about platform activities and their outcomes and findings. This could consist in interactive classroom visits, teacher workshops and the dissemination of teaching resources
- Solicit input on public attitudes, hopes, expectations and concerns about emerging technologies, and use this to feed into the potential formation of research questions within the collaborative platform.
- Host programs which allow for interactions with local actors in its immediate geographical realm. This pertains to physical infrastructures and sets out to increase visibility and transparency on platform activities. A good practice is to have residence schemes, e.g. for artists, to enable observation and reflection on the platform activities from different perspectives. A side effect is that platform actors come into contact and learn to communicate their work with outside audiences.

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Annex I: Collaborative platforms in genomics and biobanks for personalised health

Empirical case studies

This part of the report is based upon data collected from 10 case studies (Table 5).

Table 5	Case study	vexamples of	collaborative	platforms in o	penomics and	biobanking
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Country	Case study title	Short description
EU	BBMRI-ERIC	The Biobanking and BioMolecular resources Research Infrastructure–European Research Infrastructure Consortium (BBMRI-ERIC), an umbrella organization for biobanking in Europe, was founded in 2013 to provide a focal point for biobanking activities in Europe and to provide fair access to quality-controlled human biological samples and associated data for cross-biobanking research. BBMRI-ERIC currently includes 20 countries and one international organisation, making it one of the largest European research infrastructure. Provides a gateway for access to the collections, expertise and services of the European research community, ensuring coordination and efficiency, and new services and better access for users. As existing biobanks have a strong national character and background, BBMRI-ERIC uses a distributed hub-and-spoke structure.
USA	ClinVar and ClinGen, two National Institutes of Health (NIH)	ClinVar and ClinGen, two NIH-funded resources, have formed a partnership to improve our knowledge of clinically relevant genomic variation. This partnership includes efforts in data sharing, data archiving, and collaborative curation to characterize and disseminate the clinical relevance of genomic variation. ClinGen establishes partnerships with the non-profit sector and CSOs (e.g. the Association for Clinical Genomic Science (ACGS), and the American Society of Hematology (ASH)) and with companies (e.g. Genomenon, a genomic health IT company, and Concert Genetics a technology company dedicated to enhancing the transparency and efficiency of genetic testing for clinicians, hospitals, laboratories and health insurers) to build an authoritative central resource that defines the clinical relevance of genes and variants for use in precision medicine and research.
France	Plan France Medicine Genomique 2025 (PFMG 2025)	PFMG 2025 aims to construct a network of 12 genome sequencing platforms with territorial coverage across France. The Centre de référence, d'innovation, d'expertise et de transfert (CRefIX) was established as a multi-institutional unit between Inserm (National Institute of Health and Medical Research), CEA (Alternative Energies and Atomic Energy Commissions), and Inria (National Research Institute for the Digital Sciences). The objective of CRefIX is to set reference standards, to manage implementation of those standards in PFMG 2025, and to promote innovation and collaboration with the industrial sector (Aviesan, 2019). CRefIX also works on standardization of conditions regarding new indications for genomic medicine, protocols for sequencing platforms, and collaborates with CAD (National Centre for Intensive Calculation) and COFRAC (French Accreditation Committee).
Japan	Initiative on Rare and Undiagnosed Disease (IRUD)	The Initiative on Rare and Undiagnosed Diseases (IRUD), was established in 2015, and is and coordinated by the Japan Agency for Medical Research and Development (AMED). The initiative has encouraged collaboration between paediatric and adult research consortia, with a focus on (1) reaching out to potential participating institutions and co-ordinating them as the 'All-Japan' diagnosis system for those who are currently undiagnosed; (2) developing globally compatible databases and identifying data-sharing opportunities; and (3) accelerating research and development in the field of rare and undiagnosed diseases (Adachi et al. 2017). An important focus is on interoperability of the data, and the IRUD Exchange data platform is interoperable with diverse Japanese and foreign platforms. In addition, AMED aims to integrate aggregated data managed by the Ministry of Health Labor and Welfare of Japan to construct rich data.
Sweden	Genomic Medicine Sweden	Genomic Medicine Sweden (GMS) is a publicly funded nation-wide networked collaborative platform, headed by 14 partners from regional healthcare and universities. Collaboration with the private sector is of key importance for GMS, and industry has been involved from an early stage in the design of the infrastructure. A focus on opportunities and challenges for collaborations between public healthcare and industry in Sweden has led to the initiation of collaborative projects between GMS and specific private sector partners. An important precondition to industry collaboration is a mutual understanding that the ability to access and utilize health care data within GMS and its regional health authority partners is dependent on resolving the legal, ethical, and social aspects of data sharing.
Korea	Korea National Bio Big Data Project	The Korea National Bio Big Data Project is carried out by a consortium of several institutes, with three playing a key role with respect to bio samples and data: the Korea Centers for Disease Control and Prevention (KCDC), which is under the Ministry of Health and Welfare, the Korea Research Institute of

		Bioscience and Biotechnology (KRIBB) and the Korea Institute of Science and Technology Information (KISTI), both of which are under the Ministry of Science and ICT.
		Three types of data are collected for rare disease patients—(1) blood and urine samples, (2) clinical data such as general information, family history, diagnosis results, family history, treatment history, and follow- up monitoring information, and (3) genomic data. Both the clinical and the genomic data from this project are shared among the project consortium member institutes—KCDC, KRIBB, and KISTI. KISTI will construct a Clinical Interpretation Research Network (CIRN), which is based on a closed system among KCDC, KRIBB, and KISTI. External researchers access the virtual research environment provided by CIRN, which will accommodate access requests after consideration of research ethics and computing resource demand.
Israel	Maccabi Healthcare Services, The Israeli National Biobank for Research and Psifas (Israel)	MHS is creating the Tipa Biobank, a population-based biobank in Israel. MHS is the second largest healthcare provider in Israel, serving 2.3 million members, which constitutes a representative quarter of the Israeli population, and has electronic health records which form a longitudinal history of many patients throughout their entire lives. The Tipa Biobank collects a wide variety of samples and links with electronic health records data in a de-identified manner for broad research use. The uniqueness of the Tipa Biobank is that the collection of samples is repeated from the same patients throughout their lives, therefore creating a "biological health record" which can be used for development of early detection tests and liquid biopsy development. Maccabi has recruited over 122 000 members.
		The Israeli National Biobank for Research (MIDGAM) was established to promote academic research and biomedical industry in Israel. MIDGAM is funded by several governmental ministries and agencies and operates under the supervision of the Chief Scientist of the Israel Ministry of health. Since 2014, samples and annotated demographic and clinical data have been collected, processed and stored in several medical centers. The medical centers report to MIDGAM HQ, which handles investigator requests and operates a database, quality control measures, scientific and regulatory counselling services and price lists.
		Psifas is Israel's National Precision Medicine Initiative, a research oriented project, designed to collect health data and biological samples from hundreds of thousands of Israeli Donors. Psifas will collect biosamples as well as clinical data from electronic medical records and questionnaires, genomic data and continuous physiological data utilising devices. The information obtained will create a national research framework and virtual research environment.
UK	Genomics England	Genomics England collaborates with stakeholders including governmental initiatives, hospitals and universities. Genomics England was originally established to administer the 100 000 Genomes Project, which was launched in 2012 to catalyse the uptake of genomic medicine for the benefit of UK National Health Service (NHS) patients and research, with the involvement of over 130 NHS partner institutions across the UK, delivering a total of 125 000 whole genomes from approximately 85 000 patients and unaffected relatives. Following the completion of the project in 2018, Genomics England is now leading the expansion of the project with further genomic sequencing and increased integration of genomic medicine into the NHS. Genomics England also is focused on developing capabilities in sequencing, data storage, ethics and public engagement.
International	Global Alliance for Genomics and Health (GA4GH)	GA4GH is an international, non-profit alliance formed in 2013 to accelerate the potential of research and medicine to advance human health. GA4GH brings together more than 500 leading organisations from healthcare, research, patient advocacy, life science, and information technology to create frameworks and standards that enable responsible, voluntary, and secure sharing of genomic and health-related data. Twenty-three real world genomic data initiatives have signed on as GA4GH Driver Projects to help guide GA4GH's development efforts and pilot GA4GH tools. All GA4GH work builds upon the 'Framework for Responsible Sharing of Genomic and Health-Related Data', a guidance document founded on the human right to benefit from the advances of science.
EU	ELIXIR	ELIXIR is an intergovernmental organisation that brings together life science resources from across Europe, with the goal of coordinating these resources so that they form a single infrastructure. ^[1] ELIXIR is developing a local/ federated European Genome-phenome Archive (EGA), as a secure storage for sensitive human sequence and sequence-related data. ^[2] The EGA provides a service for the permanent archiving and distribution of personally identifiable genetic and phenotypic data resulting from biomedical research projects. EGA allows authorised users to search sequenced material, patient samples stored in biobanks, and the metadata around patients (their illnesses, treatments, outcomes). It also queries national search engines on behalf of the users. The Federated EGA extends and generalises the system of access authorisation and secure data transfer developed in the EGA. It aims to provide a framework for the secure submission, archiving, dissemination and analysis of human biomedical data across Europe.

Typology of genomic and biobank collaborative platforms

Although there is no single model for genomic and biobank collaborative platforms, three main models can be discerned: government initiatives, civil society initiatives, private sector initiatives (see Table 2 in section 2.1.1). Platforms often overlap these categories, but the typology is nonetheless useful for understanding the structures and operation of genomic and biobank collaborative platforms. A collaborative platform may be constituted by a single collection of genomic and health data that seeks to bring partners to use and exploit it, but it also refers to broader networks of such resources that share data and biospecimens among themselves and with third parties.

Government initiatives

Government-led initiatives can be wholly public, wholly non-profit or mixed. Government led initiatives often set the number of sequenced genomes or patients to collect and encourage public engagement and participation to achieve the goal, and establish infrastructure to collect, analyse, and share data. Most genomic and biobank collaborative platforms focus on the development of diagnostics and individualized treatment through large-scale genomic sequencing. Initiatives vary insofar as how they engage with partners in civil society, private sector, or research entities.

Initiatives differ in the type of data (e.g. genomic data, clinical data, electronic health care records) that they aim to collect, the way to store collected data (e.g. virtual storage, central repository), and the way to share curated data (e.g. differing levels of restriction on access). In addition, participant consent processes vary, as do the nature and extent of collaboration internationally, and with the private sector.

An important challenge for these types of initiatives centres on long-term funding. Where the research infrastructure is funded through public research funding, funding cycles are often perilously short to produce outcomes, and without the renewal of funding, the outcomes of a project risk being lost. Moreover, the resources involved in applying for renewal of funding are significant and the focus of the project can be diverted away from core research aims. Where collaborative platforms are supported predominantly through fixed term government and grant funding, they are vulnerable to changes in government policy, changes in funding structures or fragmented funding.

Networked and civil society initiatives

Civil society initiatives in genomics and biobanking often seek to leverage the power of networks to address particular challenges or issues. Such networks link platforms and key stakeholders with expertise to establish frameworks and standards. Two exemplars are the Global Alliance for Genomics & Health (GA4GH) and ELIXIR, which recently engaged in a strategic partnership for the development of technical standards and regulatory frameworks to facilitate responsible sharing of genomic data between countries and institutions.⁶

Some projects are heterogeneous networks of governance and non-government entities. The pan-European Biobanking and BioMolecular resources Research Infrastructure-European Research Infrastructure Consortium (BBMRI-ERIC)⁷ is a research infrastructure that enables responsible health innovation between academic research, biobanks, industry, and patients (Van Ommen et al., 2015_[60]). BBMRI-ERIC currently includes 20 countries

⁶ https://elixir-europe.org/news/elixir-and-ga4gh-expand-collaboration

⁷ <u>https://www.bbmri-eric.eu/about/</u>

and one international organisation, making it one of the largest European research infrastructures.

Private sector research initiatives

The pharmaceutical industry and biotech companies have been driving the integration of genetic genomic information into the discovery and development process for novel therapies, vaccines, and diagnostics. Examples of private sector initiatives include Based in a large private not-for-profit healthcare provider in the US, the Geisinger MyCode Community Health Initiative8 was launched in 2007. This initiative offers an integrated biobank and electronic health record (EHR) infrastructure for research use by Geisinger and collaborators (Carey et al., 2016_[61]). In another example, the Foundation Medicine, established in 2010, offers tissue-based genomic testing and more than 400 000 patient profiles to inform strategies in cancer therapy.

Collaborative platforms developed entirely by the private sector are rare in genomics and biobanking. Companies instead tend to build their own genomic and bio-sample repositories, or partner with public sector initiatives (Stark et al., 2019_[39]). They may wish to partner with collaborative platforms for access to data, and in such cases may be treated similarly to other public sector entities accessing or contributing data, or may access the platform on differential terms (for example pricing). In addition, companies are developing tools and techniques to interface with and supplement analytical capacity of existing collaborative platforms. The interaction of the platform and private companies depends on the legal structure of the platform, and the contractual relationship between the parties, and these vary greatly. Some platforms form a strong collaborative relationship with a number of commercial partners, and integrate those particular commercial partners more closely into the structure of the platform.

Trends in technology – novel digital technologies

Advances in digital technologies are enabling changes in the field and reconfiguring the value of data. Cloud computing and AI are influential technological developments, enabling sharing, mining and value creation in new ways. Accordingly, platforms that can collect and organise large amounts of data are able to take on greater scientific and economic value. The use of these technologies has increased the complexity of the regulatory and governance frameworks against which collaborative platforms develop.

Cloud computing

Cloud computing has advanced greatly in recent years (OECD, 2019_[62]), and is "a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources ... that can be rapidly provisioned and released with minimal management effort or service provider interaction" (Mell and Grance, 2011_[63]). It therefore allows the central aggregation of data from federated collaborative projects, and the accessing of that data from a single source by project collaborators and other investigators. In genomics, cloud computing is significant in two areas. Cloud computing enables the reanalysis of vast data sets available in existing data archives and it has permitted collaborations on large amounts of shared data. The distributed nature of the cloud facilitates collaboration through enabling collaborative and distributed computing efforts, such as in the International Cancer Genome Consortium (Langmead and Nellore, 2018_[64]).

⁸ <u>https://www.geisinger.org/mycode</u>

Cloud computing provides elastic and flexible computational services which enable genomic and biobank initiatives to scale their computation resources according to the amount of genomic analyses researchers need to deploy, with no money spent on idle compute resources. Furthermore, as the cloud computing market becomes increasingly competitive, cloud-based computing resources and storage will become significantly cheaper than existing solutions. Moreover, cloud computing promotes both reproducibility and global access (Langmead and Nellore, 2018_[64]).

AI and machine learning

AI and machine learning can enable the generation and analysis of large volumes of data and facilitate new and efficient tools of genomic analysis (Williams et al., $2018_{[65]}$; Raza, $2020_{[66]}$). With developments in computational power and techniques, AI can be used to analyse different types of information from multiple sources, discern patterns and links, and draw conclusions. AI is therefore becoming an indispensable tool for working with large amounts of data in health settings (OECD, $2019_{[67]}$). While most current applications of AI in genomics are in the research phase, it is also beginning to have relevance in the clinical setting (Raza, $2020_{[66]}$).

Effective AI requires large amounts of high quality data in useable form. Collaborative platforms are an ideal aggregator of such data, and AI has clear potential to be an important tool within the collaborative platform environment. The closer integration of AI specialists with genomics specialists will improve the power of AI in relation to genomics, and new partnerships and public and private sector collaboration will be important for developing expertise and high quality outputs (Zhou and Troyanskaya, 2015_[68]).

An increasing number of genomics AI applications have been developed, with universities often involved in the initial development, and companies and public-private partnerships commercialising the technology. For example, DeepSEA, developed at Princeton, predicts chromatin states and evaluates variants associated to diseases (Zhou and Troyanskaya, 2015_[68]). Face2Gene employs a facial image analysis framework to detect genetic syndromes from patient facial features (Gurovich et al., 2019_[69]). Named DeepGestalt, this framework uses computer vision and deep-learning algorithms trained on thousands of patient cases from a phenotype-genotype database

Although these digital technologies offer important opportunities for genomic and biobank collaborative platforms, they also present significant challenges around stability, continuity and resilience, as well as ethical, legal and social issues (Tamminen, 2015_{[701}). Particular issues relate to questions of privacy, fairness and transparency in relation to the use of AI (Vayena, Blasimme and Cohen, 2018[71]; Morley and Floridi, 2020[72]; Hall and Ordish, 2020[73]). It is well known that traditional genomics research carries privacy concerns, but the use of AI on health data could raise different risks for research participants in the future. When an AI algorithm trains on poorly representative data sets, biased algorithms may compromise fairness. These risks of bias necessitate the development of best practices in order to recognise and minimise downstream effects (Vayena, Blasimme and Cohen, 2018_[71]). AI also raises other ethical and legal questions. A lack of transparency in research methods and diagnosis may be problematic for the application of traditional legal and regulatory principles in biomedicine (Vayena, Blasimme and Cohen, 2018_[71]; Morley and Floridi, 2020[72]). Impacts beyond the level of risks for individuals, to broader risks at the group, institutional, and societal levels warrants a more overarching analysis of the risks of AI (Morley and Floridi, 2020^[72]).

The application of novel digital technologies to genomics data linkable to other data sources, such as through social media platforms, raises an extra layer of complexity (Nuffield Council on Bioethics, 2019_[74]; Williams et al., 2018_[75]), and may implicate actors who are not traditionally included in existing governance frameworks.

Enhancing the value of data through collaboration: challenges and opportunities

Data is the primary currency of value in genomics and biobanking. Large datasets are vital to realise the potential of genomics research, and linking datasets helps to avoid duplication and waste of resources. The costs of sequencing have dramatically decreased over the past ten years (Wetterstrand, 2019_[76]; Schwarze et al., 2019_[77]; Schwarze et al., 2018_[78]) and the increasing proportion of genome sequencing occurring in healthcare presents both opportunities and challenges for research and for the advance of personalised medicine (Birney, Vamathevan and Goodhand, 2017_[79]).

At the same time, the nature of personal health and genomic data gives rise to important challenges in the establishment and continued operation of collaborative platforms for genomics and biobanking. Their sustainability will therefore depend on balancing a number of interests in the control, access and linkage of data, with key issues around privacy and data protection, fragmentation and interoperability, standards and federated learning.

Privacy and data protection

Collaborative platforms in genomics and biobanking deal in sensitive personal data about identifiable individuals, with significant privacy and data protection implications (Mitchell et al., 2020_[80]). Genetic privacy is a multifaceted topic, with a complex web of regulation (Clayton et al., 2019_[81]; Pormeister, 2018_[82]). Two particular aspects of genomic data complicate questions of privacy and data protection. First, genomic information relates not only to the person from whom the information was obtained, but also to their family members. Second, genomic information is detailed and inherently identifiable (Erlich et al., 2018_[83]; Homer et al., 2008_[84]; Lin, Owen and Altman, 2004_[85]; McGuire et al., 2011_[86]), and genomic data can never be truly anonymised because each person's genetic code is unique. Even if anonymization were technically feasible, in many cases it is impossible in the context of the design of the collaborative platform, taking into account the need for ongoing linkage to medical records, gathering future data, or obligations to recontact or follow up participants.

Although technical solutions are important to protect privacy (Bonomi, Huang and Ohno-Machado, $2020_{[87]}$), they must be used in combination with robust governance mechanisms, which are key to the protection of privacy (OECD, $2013_{[88]}$; OECD, $2016_{[89]}$)Respect for and protection of the privacy of participants is fundamental to the governance of collaborative platforms, and the governance and data sharing policies of platforms must set out the ways in which privacy is protected.

The General Data Protection Regulation (GDPR) is a particularly important development in the regulation of privacy, and although an EU instrument, has implications internationally. Other countries also have their own approaches to data protection regulation. Data protection laws serve an important purpose in protecting privacy, but the burdens of compliance with these regulations can be significant, and attention to these questions by collaborative platforms is vital.

Responses at the institutional level also address privacy challenges. The GA4GH Framework for Responsible Sharing of Genomic and Health-Related Data provides guidance for sharing human genomic and health-related data, by reference to the right to privacy, and is supplemented by a Data Privacy and Security Policy. GA4GH has developed a beneficial three stage privacy test, which considers the data's sensitivity, the

potential harm resulting from possible re-identification of the data, and the expectations of individuals with respect to the sharing of that data (Dyke, Dove and Knoppers, 2016_[90]).

Fragmentation and interoperability

Fragmented data present major challenges for realising the scientific and commercial value of collaborative platforms. Data is fragmented when it is generated and stored in isolated and inaccessible environments, and is in silo by type, disease, country, institution, and sector, complicating data accessibility and collaboration. Transferring data from one environment to another is no longer feasible as it leads to long transfer times, increases storage costs (as data is held in multiple places) and presents significant regulatory and privacy challenges. Achieving interoperability of datasets is challenging, hindered by differing technical approaches, regulatory regimes and approaches to governance worldwide. Overlapping and divergent international regulations are an important and time-consuming obstacle to smooth data flows. Attention to these questions, and whether regulation appropriately balances the importance of participant protection against the risks and the drawbacks of compliance must continue.

The role of standards

Standards help to promote interoperability. These may be formal standards, but where formal standardisation does not exist, or is not necessary or desirable, a degree of industry consensus can serve to ensure that research and collaboration is not obstructed. Working towards developing consensus to build standards at an early stage is important, as is building consensus with the full range of stakeholders, including policymakers, public and private sector researchers, industry (in the full range of areas involved, including pharma, diagnostics, AI and data science) and, importantly, the public and research participants. As genomics is a truly global endeavour, input from all nations, not only the west, is essential. Although international standards have the potential to promote interoperability, too many standards can introduce potential conflict and further fragmentation. Standards for genomic platforms proliferate, and the majority are voluntary standards, guidelines or codes of practice. In these cases, meta-standards, or higher-level standards might be useful in harmonising diverse approaches. For instance, as of February 2020, GA4GH has produced 15 standards, including application programming interfaces, data models, schemas, and ontologies.

Balancing pluralism and harmonisation

Some degree of variation in laws and regulations across national systems and among platforms is inevitable and may be desirable, as local context is important in the design of effective governance (Gibbons, 2009_[91]; Kaye, 2011_[92]). Legal regimes are specific to each jurisdiction, and local arrangements for ethical governance and the contractual bases of individual projects are necessary. Where there is a power imbalance and where there has been a history of exploitation, such as where research is conducted in resource limited settings, extra attention to inequalities is important, to guard against and provide redress for exploitative research practices (TRUST Equitable Research Partnerships, 2019_[93]; Staunton and de Vries, 2020_[94]). Moreover, local and regional differences in approaches to ethical issues, including in areas such as consent, in light of histories of exploitative research, may need to be accommodated. The challenge is to recognise and accommodate local variation, whilst also designing a system which permits sufficient standardisation at a high level to enable interoperability.

Federated learning

Federated data analysis allows researchers to abstract analysis on top of secure multi-party computation systems, addressing problems with data quantity and fragmented datasets and helping to ensure genetic data privacy and compliance. Federated data analysis means that data effectively never moves. It enables the training of a single model when the data is scattered nodes in a network, never accessible all at once or by a single actor. It can train a model that accounts for all the data, often exhibits comparable accuracy to the full-availability case, yet preserves privacy in individual nodes by never requiring raw data to be pooled, shared or otherwise aggregated. Federated learning works by sending the model to the data, instead of bringing the data to the model, and allows researchers to run analyses over genomic data in a more unified and seamless way, bringing their own data and tools to effectively mine and analyse this data. Both public and private sector entities are developing tools to enable federated data analysis. Imagia (Canada) and Lifebit (UK) are two companies developing federated learning tools which are integrating with public sector collaborative platforms in this area.

Federation helps to effectively minimise potential threats and data compliance breaches. Because no party has a complete view of the entire dataset, there is reduced probability of leaks due to security and privacy failures. Because federation requires broad, reciprocal data access methods that respect the national processes and patient consents of each dataset, there are both technical and legal and policy obstacles to federation. Moreover, in order that maximum value can be extracted from analysis of the data in question, the data must be stored according to FAIR principles – it must be findable, accessible, interoperable and reusable (Corpas et al., 2018_[95]).

Sustainability of collaborative platforms - economic, social and legal dimensions

Collaborative platforms are in a period of transition, from publicly-funded research infrastructures, to increasing interface with industry, integration with clinical healthcare and focus on clinically useful outputs. Platforms involve varied stakeholders across the range of research - the public, participants and patients, clinical and research staff, industry, funders, government and policymakers – all with different conceptions of value. A company will be seeking to generate monetary profits. However, patients and governments value the outputs of research differently, and this value can be difficult to capture in traditional economic assessments. Robust assessment of, and evaluation of the value to different stakeholders of the benefits of innovations in genomics is important (Ginsburg and Phillips, $2018_{[96]}$).

Economic dimensions

To date, most collaborative platforms have relied heavily on government and charitable research funding. Their future financial sustainability may be addressed to some extent by a cost-recouping business model, if it enables self-funding in the long term. Ultimately, sustainable business models in this field depend on translating innovations into use, but integrating such innovations into clinical care is a complex process, which depends not only the research and development of the innovation, but also on a lengthy and expensive regulatory approval process. Different types of innovative outputs, including therapeutic products, diagnostics and algorithms, have different manners of development, different paths to market. Disruptive innovations may have great potential to improve healthcare for patients, but healthcare systems can be slow to adopt innovations which do not fit within

existing care pathways. All these factors complicate the development of business models for biobanks and genomic databases.

Figure 6 Schematic of diverse value propositions of collaborative platforms



Source: Illumina, Inc.

The social contract

Collaborative platforms in genomics and biobanking retain a strong public character and mandate due to the collective demands of this type of research. These collaborative platforms depend on the involvement of patients and the wider public, who contribute the primary resources of the platform. Moreover, public funding also underpins many platforms. The role of the public in this research endeavour, the ways in which the public should be protected, and benefit from the research, and maintaining levels of public involvement and engagement in the research and are all important questions for the sustainability of collaborative platforms in this field.

For these reasons, some have posited that there is a form of "social contract" underpinning genomics research (Lucassen, Montgomery and Parker, $2016_{[97]}$). This implies that for stakeholders in the common enterprise, each party has important rights that must be respected, but also that each owes each other responsibilities, with the combination of reciprocal rights and obligations enabling the enterprise to operate fairly and effectively for mutual benefit. The social contract in relation to genomics and biobanking can be conceived of as including three interrelated elements: reciprocity, altruism and solidarity, which feed into all levels of public involvement (Ipsos MORI, 2019_[98]).

The maintenance of this social contract depends on trust. People will only actively take up the benefits that will come from data-driven innovation, and will only participate in the research needed for these developments to progress if they have inherent trust in them (Chalmers and Nicol, 2004_[99]; Caulfield, Borry and Gottweis, 2014_[100]). There are many

factors key to maintaining public trust in the research endeavour, but some of the most relevant in the genomic and biobanking collaborative platform environment include transparent and accountable governance structures, data security and privacy and continued engagement and dialogue about commercial involvement in research.

Intellectual property (IP) considerations

Business models in biomedical research and innovation are closely tied to IP rights, and IP frameworks will become increasingly important as research projects develop and outputs mature. IP rights arising from research using collaborative platform data is contentious, for reasons closely tied to questions of the social contract and trust discussed above. The ownership of IP rights depends on the terms of the contracts through which access to the collaborative platform is granted. In many cases it may be appropriate for those accessing the platform to own the IP on inventions generated from the data, as they are best placed to develop it effectively. For example, The Israeli National Biobank for Research (MIDGAM) formally waives any IP rights, or ownership pertaining to inventions based on materials supplied by MIDGAM. In contrast, the default position of the Genomics England Participation Agreement is that Genomics England owns the results of non-commercial research, with the purpose of ensuring that collaborative research is available to future users. Genomics England will assign IP to an institution or other user for commercialisation but will retain an interest to help ensure that the invention is available for future NHS use (at an appropriate cost).

Collaborative platforms can limit or control the use of IP rights through contractual provisions in two important respects: firstly, prohibitions on patenting of upstream technologies which have the potential to inappropriately restrict further research and development in the technological field; and secondly requirements as to terms of licensing to advance the purpose of the collaborative platform. Collaborative platforms are in a position to prevent, through contractual terms of access, patents of this nature. Horizon scanning and a regular assessment of the risks of technologies in the field will permit appropriately specific and clear prohibitions.

Secondly, restrictions or positive obligations as to the licensing of IP arising from the platform have the potential to advance public access to the technology in question. Some important attempts to formulate the principles for licensing genomic IP and to seek to harmonise high level policies and practices have been made by key bodies, including funders, academic and professional associations and policymakers (OECD, 2006_[101]; The Department of Health and Human Services National Institutes of Health, 2005_[102]; Aymé, Matthijs and Soini, 2008_[103]). However, the downstream impact of licensing policies and conditions often remains uncertain, at least partly due to the long time lag between the imposition of the conditions, and the ultimate clinical use of the outcome of the research. Flexibility, and regular reviews of licensing terms can help to address problematic effects.

Box 5. Genomics England, United Kingdom IP Policies

The Genomics England IP Policy builds on the core aims of ensuring patient benefit, supporting research, enabling industrial collaborations and maintaining public trust and confidence. Genomics England collects genomic, clinical and diagnostic imaging data, and samples of blood and tumours, and stores and shares curated data with own identifiers in the virtual data centre(s). Data is made available through a Trusted Research Environment for commercial and non-commercial research. Access to the data is governed by the Access Review Committee and requires users and their institutions

to agree to the Participation Agreement and Rules. This includes expectations on the researcher and their institution around information governance, acceptable uses, and the approach to collaboration, publications and IP rights.

For Genomics England, a set of broad IP principles address the need to recognise the level of public investment in the project and the need to address future access of the NHS to inventions and discoveries in any licensing agreements. The NHS institutions contributing samples agreed to assign ownership of the samples and genomic data to Genomics England to manage on behalf of the nation.

The Participation Agreement also sets out a default position that Genomics England owns the results of non-commercial research. This was intended to ensure that any collaborative research in the trusted research environment would be available to future users. Much of the research is collaborative, across different disease- or method-related "domains" and often involves additional work to curate, tag and refine the complex genomic and phenotypic data. Genomics will not seek to own any pre-existing IP and it will also assign IP to an institution or other user if they wish to commercialise, but will retain an interest to help ensure that the invention is available for future NHS use at an appropriate cost.

Although IP rights are private rights, in this field, there is a significant public interest in access to innovation. Attempts by collaborative platforms to use such IP conditions to advance the purpose of the platform should be encouraged. Collaborative platforms, serving as the interface between the public and private sector in genomic medicine, are well placed to advance the field of IP in this way, and they can employ innovative and creative policies. Additionally, and importantly, collaborative platforms are also well placed to assess and monitor the impact of their policies on downstream access and availability. As the gatekeeper to information, they have sufficient bargaining power to implement these principles – and they have the imperative to do so, to safeguard the participants, and further develop and advance existing governance frameworks.

Policy implications and the role of good governance

Governance is key to the successful operation of collaborative platforms in genomics and biobanking, and can be an effective means to address the policy challenges identified in this report. Collaborative platforms invest significant time and effort in the terms of their governance structures. Governance involves the decision making processes and procedures by which people organise themselves to achieve defined goals. Governance can have multiple layers, and there is both internal governance (for example of individual projects or companies) and external governance (legal frameworks, regulatory bodies). Governance structures – including accountable frameworks, oversight boards, committees and participatory processes -- can help mediate tensions and make decisions in accountable ways.

Addressing novel digital technologies

The greater use of AI and machine learning approaches in research, the existing focus on the accountability of data stewards for misuse of the data will be less effective to address harms. Instead, the difficulty will be to ensure that outcomes of data use are fair and ethical. Governance frameworks therefore need to continue to adapt in this respect. The harms and benefits of new technologies should be monitored, and governance frameworks adapted accordingly. Due regard to the potential for bias, and the development of best practices for recognizing and minimizing the downstream effects of biased training data sets are necessary. Moreover, questions of explicability, liability and privacy in the AI context must be recognised and addressed.

Mitigating data fragmentation and lack of interoperability

Mitigating data fragmentation and enhancing interoperability could be achieved through standardisation and regulatory alignment. Here collaborative platforms could serve as a model for the development and testing of processes and standards in, for example, information technology networking, quality management, pubic deliberation, commercial strategies, education and training, and approaches to responsible innovation (Chalmers et al., 2016_[104]).

Federated data analysis shows great promise for enabling effective and productive collaboration for platforms. This functionality may address problems with data quantity, distributed and fragmented data sets and help ensure genetic data privacy and compliance. However, further work towards international consensus, standard setting and harmonisation is necessary to ensure that the promises of federation are realised.

Balancing interests through governance

Collaborative platforms feature interests that must be balanced. First, in the healthcare context the security and privacy of participant and patient data should be at the heart of governance frameworks but the privacy and security of data must be balanced against the need for data fluidity and secondary use. Second, local or national interests, e.g. those of healthcare or universities may conflict with global interests, e.g. those of international researchers or pharmaceutical companies. Third, the interests of sharing findings or benefits with the original data generator may conflict with downstream revenues and indeed there is evidence that the public is concerned about the need to prioritise public benefit over profit in biomedical research (MORI for Wellcome Trust, 2016_[105]).

Governance frameworks can help mediate differing and conflicting interests of various stakeholders. Some governance structures are attempting to ensure that ethical and lawful research is supported through accountable decision making. The Genomics England case and others show how governance is starting to address these tensions in a transparent fashion, enabling opportunities arising from the changing nature of collaborative platforms. Good governance of the translational research process is especially important in relation to the involvement of commercial entities: indeed, research demonstrates that enhanced involvement of the public and data subjects in the governance of health data inspires trust and confidence in health data access (Bell, 2020_[106]; Nuffield Council on Bioethics, 2015_[107]).

Intellectual property

Collaborative platforms, serving as the interface between the public and private sector in genomic medicine, are well placed to develop innovative and creative licensing policies. Attempts by collaborative platforms to use licensing and contractual conditions for IP rights to advance the public purpose of the platform should be encouraged. For instance, IP policies and practices need to be consistent with existing governance frameworks, and governance frameworks need to be open to commercialisation of downstream research. Moreover, collaborative platforms should monitor the impact of licensing and IP policies on translation into clinical use and access.

Regulatory harmonisation

In a large collaboration, involving public and private entities, perhaps across a number of countries, there is often great complexity in the governing frameworks themselves, with multiple regulatory regimes overlapping, each with their own different objectives (Kaye et al., $2012_{[108]}$). Attention to these questions, and whether regulation appropriately balances the importance of privacy protection against the risks and the drawbacks of compliance must continue.

Regulatory harmonisation creates efficiencies. Nevertheless, due to cultural differences, some variation in standards, laws and regulations across national systems and among platforms is inevitable and may be desirable: there is a need to recognise the importance of context in designing effective governance. In these cases, meta-standards, or higher-level standards might be useful in harmonising diverse approaches.

The Social Contract, trust and participatory governance

The roles of public funding, research participants, researchers and licensees of the genomics enterprise make up a form of "social contract" that carries mutual responsibilities: each party has ethical claims that must be respected, but each owes each other certain duties. The combination of reciprocal rights and obligations are likely to enable the enterprise to operate fairly and effectively for mutual benefit. The sustainability of collaborative platforms depends on the maintenance of this "social contract".

Transparent and inclusive governance frameworks and public engagement can help define terms of the social contract, resolve tensions therein, and promote the value of collaborative platforms in genomics. There is for example, a need to support ongoing dialogue about the role of research partnerships between public and private sectors. Participant engagement underpins trust in the research, and helps to maintain levels of participation in the research, as well as improve its relevance and utility. Trust in genomics research is essential for the success of collaborative platforms in this field.

Annex II: Collaborative platforms in advanced materials

Further to the information provided in section 2.1.2, this annex presents insights from the analysis of contributions from six countries and the European Commission. It begins by providing an overview of twelve empirical case studies and the observation of different platform types. The next part highlights the platform characteristics that were discerned during cross-case analysis, they focus on the platforms' approach to create and capture value, balance funding and access, manage ownership and IP, catalyse innovation ecosystems, setting of standers and building human and social capital. Thereafter, three key trends are discussed that shape the nature and operation of collaborative platforms for advanced materials. The section concludes with implications for platform actors.

Empirical case studies

The diversity of collaborative platforms for advanced materials becomes apparent in the analysis of the twelve case studies from six countries and the European Commission which is outlined in the section that follow. Table 6 provides a general overview of the twelve case study contributions and provides a short description of each.

Country	Case study title	Short description
Austria	Austrian Smart Systems Integration Research Centre (ASSIC)	A so-called Competence Centre for Excellent Technologies (COMET), focusing on applied research in the field of intelligent system integration of micro- and nanoelectronics components, employing 103 scientists (131 employees in total. The partners cover the whole technological value chain and are in total 15 from industry (both SMEs and large industrial companies) and ten scientific (six are international). The contribution of the industry partners (= 40%) has to be paid in cash, whereas scientific partners can contribute up to 100% with in-kind activities. ASSIC is funded by two federal ministries and a regional government entity. Total costs have been amounting to EU 38.8 million for the first two funding period (2015-2018 + 2018-2022).
Austria	Polymer Competence Centre Leoben (PCCL)	With 110 employees from 14 different nations, PCCL is currently the leading Austrian "centre of excellence" for cooperative research in the fields of polymer engineering and sciences. It is a so-called COMET centre, just as ASSIC, and has 18 scientific and 45 industrial partners (23 are international). Financed through the national COMET-programme for eight years (40%-55% public funding) and at least 5% by scientific partners, and 40% by companies. The infrastructure of PCCL is set up to be complementary and used mutually. Whereby all other partners can use it, with an hourly cost. There is a strong collaboration, especially between long-term partners. PCCL fosters interdisciplinary teams which cover the whole value chain - ranging from materials, to production, and up to recycling – and broad technology readiness spectrum along the entire value chain of polymers between science and industry.
Canada	Materials for Clean Fuels Challenge Program	Launched in early 2020, it is a 7-year \$57m collaborative mission-driven research program aimed to develop technology to decarbonize Canada's oil & gas and petrochemical sectors. The program seeks to develop high-risk, high-reward technologies at a rather low readiness towards prototype and demonstration. It brings together Canada's national labs at the National Research Council (NRC) with academic and SME partners. About 65% of the funds are NRC contributions to the projects including labor, facility, and operating costs whereas 35% are grants & contributions to academics or SMEs. Projects are

Table 6. Overview of case studies

		selected through a combination of directed calls and an open call competition. The commercialization by Canadian companies and access to Canadian end-users will be a general objectives and data ownership and sharing is negotiated on a project-by-project basis.
European Commission	European Pilot Production Network (EPPN)	A network of over 170 pilot productions in 19 European countries. It was created to boost the European competitiveness through the exploitation of the existing pilot line production facilities across Europe in the area of nanotechnology and advanced material technologies. The overall aim of the platform is to enable SME's and industry to get connected with state-of-the-art infrastructure and services to bring new technology developments faster to the market. Funding of almost EUR1m is provided for three years by Horizon 2020. After the end of public financing the platform aims at being financially sustainable. The technology of the digital platform itself (i.e. the connecting tool) belongs to the EPPN consortium and IPR and licensing arrangements are made on individual basis between the members of the platform who decide to work together.
European Commission	Innovation test bed for lightweight embedded electronics (LEE BED)	An Open Innovation Test Bed (OITB) created to de-risk and accelerate the development and manufacturing of nanomaterials and lightweight embedded electronics for the benefit of European industry. It is a four-year project that started at the beginning of 2019 and receives Horizon 2020 funding of about EUR10m. Unifying the entire value chain from raw materials to embedded electrical components, tailored solutions for European entrepreneurs, start-ups, SMEs and large enterprises are provided with the main objective of going from concept to prototype within six months. Unique to LEE-BED is the development of tailored services, including technical, business, patent mapping, safety and life-cycle analysis modelling.
Japan	Nanotechnology Platform Japan (NPF)	A user facility network started in 2012 as a ten-year national program. Today, about 350 researchers are involved and 250 technical staff are directly employed at this national nanotechnology platform for academia and industry. It consists of 25 research institutes including universities and national laboratories in Japan. NPF's total activity cost is about 5 billion yen, of which 2.5 billion yen is covered by the expenditure from the constituent research institutes, 1.0 billion yen by the usage fee for their technical services, and 1.5 billion yen by the funding money from the national project. The price of the equipment usage and technical staff's support fee differs depending on whether users make their research content open or not. NPF has its own programs of schooling and training for students and technical staffs using NPF facilities, and exchanging information and networking for younger researchers.
Portugal	International Iberian Nanotechnology Laboratory (INL)	An autonomous intergovernmental institution with international laboratory status that also has a start- up program and incubating facilities for hire. Located in Braga in the North of Portugal, it gathers today 430 people from 42 countries and different science backgrounds, working in 22 research groups in six general areas. Founded by the governments of Portugal and Spain to perform interdisciplinary research, deploy and articulate nanotechnology for the benefit of society, scientific activities at INL began in 2010. The research programme comprises four strategic fields of application of nanoscience and nanotechnology: Food and Environment monitoring, ICT, Renewable Energy and Health. The INL has developed partnerships with higher education institutions and industry transferring knowledge, generating employment and training specialized professionals. IP is regulated by agreements case by case.
Portugal	Collaborative laboratories (CoLABs)	Non-profit private associations or companies that are to foster knowledge transfer to the economy and society. Another goal is to create skilled and scientific jobs in Portugal, both directly and indirectly, by implementing research and innovation agendas geared at creating economic and social value. Moreover, education and training of technical and scientific staff are central components. CoLABs may include companies, non-corporate R&I organizations, Higher Education Institutions (through their R&D Units), Technological Interface Centers and other intermediate or interface institutions, business associations, other public administration organizations, and other partners within the productive, social or cultural fabric. No associate, partner or shareholder may hold less than 5% or more than 49% of the assets or share capital. Among the 26 CoLABs approved, two are focused on specific applications of advanced materials.
Portugal	University of Texas at Austin - Portugal Program	A partnership program in Science and Technology between the Portuguese Foundation of Science and Technology (FCT) and the University of Texas at Austin (UT Austin), supported by the Ministry of Science, Technology, and Higher Education in close collaboration with the Council of Rectors of the Portuguese Universities (CRUP). The program seeks to stimulate and reinforce the effective collaboration among researchers, faculty, students and companies through collaborative R&D projects and high-level education and training opportunities, while promoting and enabling the multidisciplinary network between Portugal and Austin. Launched in 2007, the partnership was renewed in 2018, towards a new decade until 2030. The program activity focus in five Areas: Advanced Computing, Medical Physics, Nanotechnologies, Space-Earth Interactions and Technology and Innovation and Entrepreneurship.

Korea	Nano-Convergence 2020 Program	A collaborate program of the Ministry of Science and ICT (MSIT) and Ministry of Trade, Industry and Energy (MOTIE) for the creation of new products and markets in the early stage. The aim is to commercialise patented nanotechnology in the public sector (universities, research institutes) by combining with market demand in the private sector, leading to new innovations in the field of nano-convergence technology. Launched in September 2012, the planned outcomes when terminating at end of 2020: global star products having large share in the global market (4 cases), companies successfully commercialising the target products (15 cases), basic nanotechnology converged with other technologies (40 cases), and nano-convergence technology globally acceptable (4 cases). For the nine-year program period from 2012 to 2020, the total budget was KRW 208.7 billion, thereof 69% from the government and 31% from the private sector.
Korea	Materials Design Platform	The materials design platforms provide virtual research spaces to accelerate nanotechnology industrialization, and promote new materials development with advanced tools based on both experiments and computations. There are three materials design platforms: NANO FAB for nano-device simulations, iBAT for Li ion battery materials design, and qCat for materials design for catalysis applications. The platforms have been developed with close collaborations among multiple government-funded laboratories, universities, and companies. The platforms operate as a core infrastructure for generating, collecting, managing, and utilizing materials research data for big data applications. They are part of the national Korean R&D Data Infrastructure by the Korean government, initiated in 2017, to promote sharing and utilization of research data generated and accumulated nationwide so that scientific breakthrough in materials development is feasible by data-driven research and development.
United States of America	National Nanotechnology Coordinated Infrastructure (NNCI)	A network of user facilities funded by the National Science Foundation (NSF) to provide access to nanofabrication and characterization facilities. The NNCI sites are located across the country and involve a total of 29 university and partner organizations, providing collectively access to 69 facilities with over 2000 tools. NSF provides a total of \$81 million USD to support 16 NNCI sites and a coordinating office (2015-2020). Individual sites may also have funding from their institutions and/or localities and also collect user fees. Researchers from universities, industry and government have access is to leading-edge fabrication and characterization tools, instrumentation, as well as scientific expertise that spans a wide variety of disciplines related to nanoscale science, engineering, and technology. Education and workforce development is a critical component of the NNCI and each site adopts IP policies of their parent university.

Source: Short summary of case studies that are in the annex of the report "Collaborative platforms for innovation in advanced materials" (Kreiling, Robinson and Winickoff, 2020[2])

Platform types

The analysis of the empirical case evidence resulted in the finding that the characteristics of platforms for advanced materials differ, depending on the platform type. Moreover, the kinds of goals and platform attributes of collaborative platforms for advanced materials were largely similar for platforms of the same archetype. Table 7 provides an overview of the two "classical" platform types and the emergent form of digital-focused platforms (Type 3).

Table 7. Overview of platform types

Category	Title/label	Features
Type 1	Research-intensive user facilities	aim: further the R&D on advanced materials (rather low technology readiness; co- location of scientific and technological supports for the development of advanced materials)
		 objectives: leverage resources to acquire, maintain, and upgrade high-end equipment make most of technical expertise development, construction and implementation of new instruments

Туре 2	Commercialisation- focused clusters and networks	aim: transform a technology into a product on the market (rather high technology readiness; develop and commercialize advanced material enabled products)
		 objectives: connect the supply side of advanced material development with the demand side of technology markets bring together relevant stakeholders to commercialise a novel material (or family of materials)
Type 3	Digital-focused platforms	emergent platform type; rapidly evolving and virtual in nature
		aim: address challenges in modern material sciences today
		objectives: • enable the global scale management of material data • provide infrastructure for the accumulation of data • facilitate the design of scalable data repositories • drive data curation strategies

Source: Based on analysis of case studies.

Type 1 (Research-intensive user facilities) platforms are heavily focused on research and development (R&D) and are often capital intensive technical facilities which require large investments in infrastructure and technical staff. They are characterised by a co-location of instruments, infrastructure and skilled personnel, and are based on a "user facility" business model. Value creation is linked to creating and circulating knowledge, jobs, workforce qualification or economic development.

Research intensive user facilities can be one large physical facility with widespread access for regional, national and potentially also international actors, or be networked to provide national infrastructures with a centralized user gateway, guiding potential users to appropriate facilities. An example of the former is the Iberian International Nanotechnology Laboratory (INL) in Portugal whereas examples of the latter are the National Nanotechnology Coordinated Infrastructure (NNCI) in the US and the Nanotechnology Platform Japan (see case study overviews in Table 6).

Type 2 (Commercialization-focused clusters, consortia and networks) platforms are market-oriented with a strong demand-pull, but focused on building collective advantage between public and private actors. Since advanced materials are often a component of a technology product or device, it is not uncommon that Type 2 platforms have a large network of private sector partners stretching from highly specialized technology firms to large consumer market focused firms. An example is the Austrian Smart Systems Integration Research Centre (ASSIC, see Table 6) which fosters cooperation between leading Austrian industrial actors and research institutes as well as international partners along the whole technological value chain and has 15 industrial partners and 10 academic research partners.

The range of technology readiness that Type 2 platforms cover varies. Compared to Type 1 platforms, they tend to focus at more advanced technology development with a strong view towards developing products. The innovation test bed for lightweight embedded electronics (LEE BED, see Table 6) is an example of a Type 2 platform that covers technologies of different readiness stages. It focuses on accelerating potential supply side material options into various markets that would benefit from light-weight embedded electronics.

Type 3 (Digital-focused) platforms are rapidly evolving in light of the global digitalisation trend which influences not only the way how collaborative platforms are managed. Collaborative platforms in this context offer opportunities to address challenges in modern materials science today such as the global scale management of material data, infrastructure for the accumulation of data, the design of scalable data repositories and data curation

strategies. Virtual in nature, they none-the-less have a range of infrastructural requirements and raise issues of security and privacy.

These platforms range from online repositories of data on material properties curated databases as a resource to artificial intelligence driven material design and development. Examples in this context are the Korean Materials Design Platform which is expected to largely influence the way in which research data are produced, managed and shared among researchers in Korea, as well as the Canadian Materials for Clean Fuels Challenge Programm which fosters AI-accelerated materials discovery (see both cases in Table 6). Still, systematic methods for accelerated materials discovery and development are in early stages in the new digital era.

Applying these ideal platform types to the twelve case studies resulted in the observation that most collaborative platforms for advanced materials consist of a mix of elements from different types. The resulting "Type mix" for each case study is indicated approximatively in Figure 7. Three grey shades are used to show: Type 1 (research-intensive) in light grey, Type 2 (commercialisation-focused) in medium grey and Type 3 (digital-focused) in dark grey.

Figure 7. Case studies and archetype mix



Country	Name	Type mix
Austria	Austrian Smart Systems Integration Research Centre (ASSIC)	
Austria	Polymer Competence Centre Leoben (PCCL)	
Canada	Materials for Clean Fuels Challenge Program	
European Commission	European Pilot Production Network (EPPN)	
European Commission	Innovation test bed for lightweight embedded electronics (LEE BED)	
Japan	Nanotechnology Platform Japan (NPF)	
Portugal	International Iberian Nanotechnology Laboratory (INL)	
Portugal	Collaborative laboratories (CoLABs)	
Portugal	University of Texas at Austin - Portugal Program	
Korea	Nano-Convergence 2020 Program	
Korea	Materials Design Platform	
USA	National Nanotechnology Coordinated Infrastructure (NNCI)	

Source: Based on discussions in the Advanced Materials Steering Group.

Characteristics of collaborative platforms for advanced materials

The diversity of collaborative platforms for advanced materials becomes apparent when analysing the empirical case study contributions according to differing platform characteristics. Three interrelated elements of the business models of collaborative platforms take central importance: funding structures, access models, and intellectual property. These elements represent policy choices and levers for building and sustaining diverse kinds of value. In addition to these rather "internal" aspects, the facilitation of

collaboration and standard-setting are platform characteristics with an outward facing character. Each of the above elements is outlined in the sections that follow.

Value creation and capture

A business model describes the design or architecture of the mechanisms to create, deliver and capture value employed by an organization (Teece, $2010_{[109]}$). A business model perspective provides an approach to the question how platforms create, support and sustain value. Even though the components of respective business models vary as much as the structure, goals and objectives of the collaborative platforms themselves, they have in common that their value can be of tangible and intangible nature. The former relates to employment creation and pecuniary components, and the latter to public goods, services and expertise.

There is not one model of value creation and capture for collaborative platforms, but this differs depending on the prevalence of the platform types. The analysis of the case studies showed that in collaborative platforms with a focus at higher technology readiness and product development, i.e. Type 2 components, value creation mainly consists in the development of IP or the creation of new products and perhaps firms. This is the case in the University of Texas at Austin - Portugal Program (see Table 6), for example, in which scientists and companies in Portugal engage with the institutions in Texas in multidisciplinary research and technology transfer and commercialisation.

For Type 1, platform value creation is linked to creating and disseminating knowledge, jobs, workforce qualification, training or economic development which are also a form of intangible value. The National Nanotechnology Coordinated Infrastructure (NNCI) in the Unites States (see Table 6) is an example of a Type 1 platform which not only provides access to tools, staff expertise and facilities but also uses network resources to support education, outreach and programs on ethical and societal implications of nanotechnology.

Balancing funding and access

There are some challenges with regards to access which can have to do with the funding model deployed. For example, the Austrian cases (see Table 6) point out the fact that fees can be a barrier for participation of some stakeholders, especially for SMEs or academic units. The special challenges for SMEs was echoed in the Japanese case, opening up the question of whether SME-specific access should be developed to encourage use of Type 1 platforms and participation in Type 2 platforms.

The way access to a collaborative platform is handled varies. In general, it can be divided into two models: (1) membership and (2) open access models. Both impose fees, either for membership or fee-for-use which can be a barrier for platform participation for some stakeholders. In addition, potential users of platform resources and infrastructure can be subject to an evaluation.

In addition to the fees, collaborative platforms are financed by public, private or a combination of sources. The mixture and feasibility of financing mechanisms is dependent on the technology readiness that the platform targets. While public funds are generally used for activities with low technology readiness, collaborative platforms that target more advanced technology stages focus on creating technologies for the market, therefore it is much easier to capitalize on investments. In fact, public financing of technologies with rather high readines become problematic in some national contexts where there may be a policy to not distort competition. A counter example to this is the European Pilot Production Network (EPPN, see Table 6). In this example, individual piloting activities are

benefiting from public financing, highlighting that in a transnational setting, research and innovation funding operates under different legal frameworks.

Another challenge, particularly for Type 1 platforms, is the geographical location of the facilities which may also be a barrier to participation, since using the facilities usually involves accommodation and living costs. Some sites have solved this problem by incorporating short-term accommodation facilities within the premises, such as in the International Iberian Nanotechnology Laboratory (INL, see Table 6).

Managing ownership and IP

From SMEs to larger firms, participants must see value in using the platform and mechanisms must be found to encourage participation and investment. IP is not only a core aspect for the implementation and running of a collaborative platform, but also a form of value creation. The analysis of the twelve case studies (see Table 6), shows a striking similarity in IP policy. This can be summarised as "what I create is mine, what you create is yours and what we create together is ours".

The implementation of the IP policy, in terms of ownership and access fees, differs across the platforms. They range from site-specific IP policies in Type 1 platforms, such as the NNCI where the ownership of specific IP may depend on several factors governed by the host university policy, to platforms which were created to actively leverage publicly owned IP, like the Korean Nano-convergence platform which has contributed to a number of commercial products, and platforms where the IP belongs to them unless otherwise stated, as in the case of the two Austrian case studies (see further information on cases in Table 6).

Catalyse innovation ecosystems

Collaborative platforms drive and coordinate systems of stakeholders that may be beyond individual projects and contractual relationships with the specific platform. These systems of stakeholders might operate in the same field, follow the same rules and play specific discrete roles, constituting what might be referred to as "innovation ecosystems" (Jacobides, Cennamo and Gawer, 2018_[110]). The ecosystem concept helps to understand what platforms are and how they operate, but also what environment they are trying to create around them.

The "glue" that binds actors together in innovation ecosystems is the same that unites platform stakeholders: a shared notion of value, complementarity of ecosystem members and mutualistic relationships. The analysis of the case studies revealed that a collaborative platform for advanced materials can seed and catalyse ecosystems that they are part of, or they themselves can have ecosystem-like properties, such as elements which are mutually enhancing and that operate in concerted way. For example the Materials for Clean Fuels Challenge Program in Canada is designed as an ecosystem builder: it provides an integrating and coordinating role, as well as supports funding and networks in order to harmonize the different efforts towards defined greenhouse gas (GHG) emissions reduction objectives. In doing so, it does not only catalyses an innovation ecosystem, but drives it towards a specific societal mission.

Standard-setting

Collaborative platforms for advanced materials development play a key role in the development and testing of standards in their various forms. This means that they can shape markets by fostering standards, regulation and good practices. Technical standards, for

example, constitute a form of market infrastructures as they are necessary for quality control, interoperability and to support regulation.

The lack of long-term funding commitments emerged as a reason for the reluctance to set standards on data formatting across universities from the case study analysis. A related issue is the question who drives data standardisation. There are prominent examples, such as the generic 3D file format suited for additive manufacturing which was made freely available (Robinson, Lagnau and Boon, $2019_{[111]}$), where the private sector drove this development.

However, there are also instances, such as in the case of data sharing, where the lack of incentives for companies to do so is among the key challenges, together with expertise and cost. The case study from the Nanotechnology Platform Japan (see Table 6) exemplifies how governments could play a vital role by linking public funding with data sharing. Even if funding agencies force the sharing of data, there is no guarantee of data quality.

Build human and social capital

An important aspect of collaborative platforms for advanced materials are the stakeholders they brings together. In fact, their activities contribute to the development of human and social capital. The former refers to building competencies, knowledge and skills which ultimately create value for the individual and can be translated to economic value whereas the latter focuses on the inter-personal relationships, networks and trust that is created between platform stakeholders who collaborate in joint projects.

Case study analysis reveals different aspects of these multifaceted concepts. The development of human capital is an essential objective of the Collaborative Laboratories in Portugal by creating skilled and scientific jobs. Moreover, training and educational programs for students or technical staff are common in collaborative platforms for advanced materials, such as NPF in Japan or NNCI in the United States.

Interpersonal relationships which are fostered by collaborative platforms, through joined projects can manifest in a shared sense of identity, norms and values for the different actors. This intangible, relational value may even extend beyond the scope of the respective technology platforms and result in the establishment of long-term networks and partnerships, as it was reported from ASSIC and PCCL in Austria.

Trends

There are three key trends that are shaping the nature, operation, impact and policy support of collaborative platforms for advanced materials. These trends present both challenges and opportunities for leveraging collaborative platforms to enable advanced materials.

- <u>Technology convergence</u> has resulted in new ideas, methods and outputs of collaborative platforms for advanced materials. Concretely, convergence is a multidimensional concept that stands for the integration of research, industry and societal actors which bring differing expertise to the platform, the transformation of knowledge across technology development stages and the multiple science and technology disciplines required to successfully deliver platform projects. Triggering new ideas, methods and outputs of collaborative platforms for advanced materials, convergence should be enhanced to drive innovation.
- <u>Intersections with society</u> are gaining importance, which manifests in societal engagement, on the one hand, and mission-oriented platform programs, on the other hand. The former are reciprocal exchanges in the form of education and training,

aimed not only at internal platform staff and next generation scientists, but also in terms of educating the wider public about platform activities and technology insights. Challenge-driven or mission-oriented research and innovation policies may become an important part of the global policy mix. In this context, collaborative platforms for advanced materials are an important vehicle to enable the "implementation" of missions. This is becoming a key issue for STI policy and for organizations wishing to apply mission-oriented approaches to address societal challenges such as creating a circular economy, addressing the lack of key resources and plastic disposal.

• <u>Digitalisation</u> of collaborative platforms for advanced materials has been an emerging trend, it has not only been cutting across traditional platform types, i.e. research-intensive user facilities and commercialisation-focused clusters and networks, but also resulted in the emergence of a third Type "digital-focused platforms". The change that digitalisation brings about for collaborative platforms is a double-edged sword: on the one hand, it can improve access to data, thus making platforms more attractive and inclusive because of the ability to reach new user groups. On the other hand, expertise, money, incentives and standard setting are required for data sharing to work which requires long-term funding, good data quality and clarity on data property in digital-focused collaborative platforms.

Realising the potential of digitalisation in the field of advanced materials will require:

- building high quality databases, which requires a common format for the data and the metadata and transforming these data provided by researchers into the standardised data format.
- creating incentives for individual researchers to provide data to such platforms.
- co-building data analysis tools using data science and informatics methods to find the relationship of materials structure and property/function, and to find optimum materials

Implications for platform actors

The findings from this section on collaborative platforms for advanced materials carry important implications for governments, platform actors and founders which are grouped thematically:

Access, funding and standards

- 1. Governments developing governance models for collaborative platforms should actively consider funding structures, access models, and intellectual property as the key policy levers for building and sustaining different kinds of value.
- 2. Platform creators should clearly set-out the platform funding and its planned endof-life, so that it is clear from the start if it is subject to a finite end, such as the case in programs and projects, or an upfront commitment to a business model for platform sustainability.
- 3. The suitability of a platform access model either by membership or open access depends on the platforms business model and the kind of engagement of actors sought with the platform. An open-access model e.g. with a fee-for-usage provides users with flexibility and can be a means to make datasets and algorithms readily available for the community to use and further develop. However, depending on the platform type and the nature of its infrastructure, this might not always be the best solution.

- 4. SME-specific access needs to be considered to encourage use of Type 1 platforms and participation in Type 2 platforms.
- 5. Governments and funders should incentivise the use and development of standards, for example by conditioning funding on the deployment standard data formats. While this would contribute to ensuring data compatibility and improve the conditions for data sharing, it necessitates quality assurance and clarification of data property in platforms.

Value creation and innovation ecosystems

- 1. Governments can use collaborative platforms of different kinds as powerful vehicle for the generation of intangible value related to the creation and circulation of knowledge, the creation of jobs, the development of workforce qualification or economic development.
- 2. Governments should use IP policies and workforce provisions in collaborative platforms to help seed local innovation ecosystems and to create value chains and expand workforce opportunities.
- 3. Individual platform actors who come together with a shared notion of value should capitalise on the mutualistic relationships with other platform actors and profit from their complementarity which enables value creation beyond the ability of an individual actor alone. Moreover, joint platform activities create intangible relational value which may extend beyond the scope of the respective technology platform and result in cooperation between certain partners outside the platforms.
- 4. Platform creators who set out to achieve a specific mission with the respective platform could explicitly design it to act as ecosystem builder, so that it integrates and coordinates platform activities in pursuit of the overall aim and ensure that it drives all platform efforts.
- 5. The management of technology platforms needs to ensure that the platform develops human capital. This concerns platform actors, e.g. by building skills in workforce development programs and training researchers at different career stages, as well the wider public by education on nanotechnology and its application to real-world issues.

Convergence

- 1. Governments could use collaborative platforms to drive a process of convergence, a promising vehicle for innovative approaches and materials' development, by making them nodes where new or added value is created by combining scientific disciplines or key enabling technologies.
- 2. Platform actors can drive innovation in the advanced materials field using platforms as mechanism for the convergence of disciplines, stages of technologies and diverse actors. In fact, the development of nanotechnology itself has grown out of a convergence of different disciplines with a common language.

Intersection with society

1. Governments could develop collaborative platforms as physical or virtual spaces where technical communities come together with the broader society for mutual exchange and learning.
- 2. Platform founders and funders should consider creating mechanisms for societal engagement and societal relevance. On the former, by the platform up for contributions from actors, such as artists or citizens which would have otherwise remained outside the platform and on the latter by designing mission-oriented platforms to address societal challenges.
- 3. Platform management should develop intramural and extramural programmes to communicate with the broader society, through e.g., putting humanists in residence, offering tours of facilities to students and clubs, student internships, and engaging broader society in public spaces like science museums.

Digitalisation and digital platforms

- 1. Technology platforms can be a means to realise the potential of digitalisation in the field of advanced materials by
 - promoting access to data which improves platform attractiveness and requires expertise, investments and incentives and standard setting
 - transforming data provided by researchers into a standardised data format when building high quality databases
 - fostering standard setting for data sharing by providing long-term funding commitments and support labour-intensive and costly data quality assurance and data curation processes
 - creating incentives for individual researchers and companies to share data to such platforms via funding mechanisms
 - co-building data analysis tools using data science and informatics methods to find the relationship of materials structure and property/function, and to find optimum materials
- 2. Realising the promise of digital platforms for material development necessitates data standardisation, management, and curation for digital transformation. High quality data management and use will enable researchers and innovators to find relationships between structure and property/function of materials from potentially large databases of materials.

Platform lifetime

- 1. At platform creation, platform management needs to ensure a clear understanding of all partners and platform stakeholders by clarifying rules for collaboration up front.
- 2. Throughout the existence of Type 2, commercialisation-focused collaborative platforms, the platform management needs to be attentive to pre-competitive forms of collaboration to bridge gaps in product development, etc.

Annex III: Collaborative platforms in engineering biology

The "public biofoundry" – explored below -- and other platforms found in this annex attempt to address some of these challenges for realising the promise of engineering biology and other biotechnology. The case studies reflect a high diversity of approaches to building and managing collaborative platforms, but certain themes emerge. These include a focus on "converge", structuring public-private collaboration and access, developing intellectual property and licensing approaches, and generating skills and education.

Diversity of platform structures

Biofoundries

At the core of an investigation of platforms in the field of engineering biology is the "biofoundry". Biofoundries are highly automated facilities that comprise the extensive and coordinated use of laboratory robots that are programmed to perform specific tasks according to a workflow, including liquid handling, genetic assembly, and characterisation functions. Biofoundries are based on information infrastructures that allow the robots and other equipment within the biofoundries to be programmed to follow detailed, complex workflows. The combination of bio design tools (BioCAD) and biofoundries is producing the digital biology that could revolutionise the manufacture of many of the sought-after bio-based products of the bioeconomy, such as chemicals and advanced materials.

Pathway analysis Pathway bot modification Paths assembly for modification Paths assembly for modification Baic research centres Pathway selection design Path way bot modification Paths assembly for modification Baic research centres Kot modification Screening Machine learning Combinatorial selection Baic research centres Biofoundry Natytical Screening Machine learning Screening Machine learning Biofoundry

 Machine learning
 Image: Comparison of the biofoundry
 Image: Comparison of the biofoundry

 Biofoundry
 Analytical
 Bioprocesses e.g. biopharma, biorefineries breweries,

 Note: The iterative Design-Build-Test-Learn (DBTL) cycle forms the core of the biofoundry. Biofoundries

perform design DNA parts through computations methods, assemble those parts, prototyping and testing performance of designs in living cells. These are followed the application of machine learning tools to inform the design process. Iterations of the DBTL cycle result in genetic designs that aim to fulfil the design specifications. A feature of the biofoundry approach consistent with modern manufacturing is that the site of the design (the biofoundry) can be totally separated from the site of manufacturing (typically the biorefinery). Source: OECD research.

Figure 8 Overview of the processes in a biofoundry

5.1.1. Biological resource centres

Subsequent to the earlier OECD work, the microbiology community followed up with the Global Biological Resource Centre Network demonstration project, which focussed on collections of living microorganisms. European member states in the European Strategy Forum for Research Infrastructures (ESFRI) accepted the pan-European research infrastructure Microbial Resources Research Infrastructure (MIRRI) on to their roadmap for 2010 and its preparatory phase began in late 2012 (Smith, McCluskey and Stackebrandt, 2014_[112]).

Distributed infrastructures

While collaborative platforms in engineering biology can draw actors to a centralised physical infrastructure like a biofoundry, they can also consist of a network of either heterogeneous or homogeneous institutions that creates a form of cluster or ecosystem which, when assembled, contribute to a shared capacity in engineering biology often in a national context. This type of distributed platform characterises the Agile Biofoundry in the United States as well as the distributed engineering biology system in the United Kingdom and Singapore.

Human capital infrastructures

These can represent the top researchers in the field along with other stakeholders such as industry and societal representatives. Governments may wish to fund such infrastructures to act as independent advisory bodies that can perform a variety of functions that would not be within the domain of researchers alone e.g. writing industry roadmaps, and ensuring that milestones and targets are met according to the timetable rolled out by a roadmap. Examples are the Engineering Biology Research Consortium (international) and the Synthetic Biology Leadership Council (United Kingdom).

Empirical case studies

As is apparent, the types of infrastructure represented in this annex are diverse. Among the nine platforms described below, Italy features a transnational network of microbial biological resource centres (mBRCs). The United Kingdom describes a national engineering biology network of basic research centres, biofoundries and a technology translation centre. The United States Agile Biofoundry (ABF) is a single infrastructure designed for academic and industrial collaborations. Japan describes a distributed research programme, not a physical infrastructure. The Engineering Biology Research Consortium (EBRC) is also not a physical infrastructure. These differences will manifest in the descriptions of the infrastructures below.

Table 8 Examples of collaborative platforms in engineering biology

Country	Platforms name/s	Short description						
Canada	Concordia Genome Foundry (CGF) Lab for Metabolic Systems Engineering (MSE)	Canada is at the crossroads in its support for platforms and infrastructures that accelerate commercialisation of engineering biology. Existing capacity is relatively nascent but a vision has been put forward by three universities to create a future network of biofoundries. Founded in 2016, the CGF works on automating workflows for testing and cell design through multiple iterations in line with its vision to create a fully integrated design, build, and test process. MSE works primarily on the metabolism of microbes applied to making chemicals for environmental and manufacturing use. It was established in 2006 within the Department of Chemical Engineering and Applied Chemistry. Its procedures for testing and cell design have not yet been automated and						
		it has already industry partners.						

	The Biofoundry at UBC (TBU)	TBU works closely with industry partners and employs approximately 10 people who are largely graduate and co-op students. It uses metabolic and enzyme engineering towards the design and development of next-generation, green chemical processes for the manufacture of cleaner fuels, superior therapeutics and novel materials.
France	Toulouse White Biotechnology (TWB)	The pre-industrial demonstrator TWB was created in 2012 with a EUR 20 million Agence Nationale de la Recherche (ANR) grant. Located in Toulouse, it is a mixed service unit managed by INRA under the joint administrative control of INRA /INSA /CNRS. It is a unique public - private consortium that gathers 50 members from public research, institution, industry, start-up and investor communities. TWB bridges the gap between public research and pre-industrial development in industrial biotechnology: it develops innovative and sustainable routes from renewable feedstocks by de-risking and fast-tracking research and innovation along an ethical approach. It designs its own, original, highly automated equipment, and has built several platforms: some are specialised such as strain engineering, fermentation and process development while others are transverse, supporting the activities across the organisation such as analytics. TWB had 90 employees at the end of 2018 and generated EUR 35 million+ industry contracts and hosts six start-ups.
Italy	Microbial Resource Research Infrastructure (MIRRI) ⁹	MIRRI aims at obtaining the legal status of European Research Infrastructure Consortium (MIRRI- ERIC) in 2020. MIRRI-ERIC will comprise 41 microbial Biological Resource Centres (mBRCs) from 10 different countries. The mission of MIRRI-ERIC is to serve Bioscience and Bioindustry by offering users from academia, governmental laboratories and the private sector access to a portfolio of mBRC's services, expertise, education and training. MIRRI-ERIC will gather biological resources and outstanding expertise in microbiology as the users of MIRRI-ERIC will be (a) seeking resources from mBRCs for research, (b) requesting deposition of microbes into mBRCs and (c) requesting services that are based on the unique expertise in mBRCs. The statutory seat of MIRRI-ERIC will be hosted by the University of Minho, Braga, Portugal. The Central Coordinating Unit (CCU) will employ five staff members to coordinate the activities of the participating mBRCs under MIRRI- ERIC. This CCU will be partly located in Braga, partly in Paterna, Spain where the IT-officer and the Collaborative Working Environment (CWE, described below) will be hosted.
Japan	Smart Cell Project	In 2016, the Ministry of Economy, Trade and Industry (METI) created the project "Development of Highly Functional Product Production Technology Using Plants and Other Organisms", in short the "Smart Cell Project". It is owned by a funding agency New Energy and Industrial Technology Development Organization (NEDO) and consists of approximately 30 organisations with about half by universities and the rest by private companies. Between 2016 and 2020, research on plant and microbe has been carried out with various objectives with total sum of 16 to 24 million USD/year for 5 years. Among the large number of universities and industries involved, one of the most notable platforms established is located in Kobe University where technology in relation to engineering biology is developed ranging from long-chain DNA synthesis technology to new genome editing technology. It aims to fully automate DNA synthesis technology or metabolome analysis technology developed in the project.
Singapore	Singapore infrastructure for engineering biology	Key components are mainly situated in universities and research institutes, many are funded by the Agency for Science, Technology and Research (A*STAR), such as the Bioinformatics Institute (BII) that manages the A*STAR Natural Product Library (NPL) or the Metabolic Engineering Research Laboratory (MERL) that focuses on engineering microbial cell factories capable of producing high-value chemicals. Moreover, the Biotransformation innovation platform is a research initiative under the Food and Consumer (FNC) cluster in A*STAR which focuses on the development of novel sustainable biotechnology for the production of high value-added specialty chemical ingredients for the food, nutrition and consumer care sectors. Additional key infrastructures are research groups at Nanyang Technological University (NTU) and SynCTI, a cross-faculty research centre working on different areas of synthetic biology, including biomanufacturing, living therapeutics, biosensors, bioremediation, synthetic genomics, at the National University of Singapore (NUS). In addition Temasek Lifesciences Laboratory (TLL) is a research institute with the capability and infrastructure for synthetic biology research and the Singapore Institute of Technology (SIT) has the infrastructure and capability to train students for bioprocess in the areas of biopharma and food technology.
United Kingdom	Seven synthetic biology research centres (SBRCs) and five biofoundries	The overall vision of the UK infrastructure for synthetic biology is to work within the UK's synthetic biology innovation and academic ecosystem to create a highly interconnected UK innovation cluster. Five biofoundries at Earlham Institute, University of Edinburgh, Imperial College London, University of Liverpool and University of Manchester were funded in 2014. The SBRCs have different research emphases: developing new tools and methods for plant synthetic biology (OpenPlant), biomolecular design and engineering aspects of synthetic biology (BrisSynBio), fine and speciality chemicals production (SYNBIOCHEM), engineering bacteria to make industrially-useful products from C1-feedstocks (SynBio Nottingham), developing next-generation synthetic biology tools and systems, biosynthetic pathways, synthetic communities of microbes, and plant-microbe interactions (Warwick

⁹ More information, see online at: <u>https://www.mirri.org</u>

		WISB), build expertise in cell engineering tool generation, whole-cell modelling, computer-assisted design and construction of DNA (Edinburgh Mammalian Synthetic Biology Centre) and developing platform technology for synthetic biology (IC-CSynB at Imperial College).
United States	Agile Biofoundry (ABF) Engineering Biology Research Consortium (EBRC)	Established in 2016, the ABF deploys the collective skills, expertise, and experience of scientists, engineers, and technical staff from eight national laboratories of the U.S. Department of Energy's (DOE). The overall goal of the ABF is to enable US biorefineries to achieve 50% reductions in time to bioprocess scale-up – as compared to the current average of around 10 years – by establishing a distributed biofoundry that will "productionise" engineering biology. The ABF is a public infrastructure investment that increases industrial competitiveness and enables new opportunities for private sector growth and jobs. EBRC sets out to advance pre-competitive research in engineering biology through cross-sector coordination between industry, academia, and government. It is a non-profit, public-private partnership whose consortium members showcase their research in engineering biology, identify pressing challenges and opportunities in research and application, and articulate research roadmaps and programmes to address these challenges and opportunities. EBRC is comprised of 'Individual' and 'Institutional' members who represent diverse perspectives of the engineering biology research community.

Relative importance of policy aspects

Case study analysis

A dedicated analysis with quantitative and qualitative components was conducted to better understand the importance of different governance issues in the respective case studies. Assuming that the number of words dedicated to the answer for each issue is a measure of its importance, the reasoning followed that the greater its word count in the case study, the higher the importance of the issue.

To derive the top policy issues, the first step was to calculate the relative number of words per issue compared to the total word count for each case study. Next, the issues were ranked by a score. This means that for example if a case study devoted 20% of its total answer to the "access" issue, the score for access would be a 20. Thereafter, the top five issues from each case study received a score of 1 (lower) to five (upper) points and were colour coded accordingly.

As shown in Table 9, the structured analysis revealed the top five issues which case studies focused mostly on: "convergence", "public-private collaboration", "access" and "skills/education" (third equal) and "other". The category "other" was rather broad and did not converge around any single issue which makes further analyses difficult. Hence the following sections will concentrate on these top four issues.

	Percent of country answer devoted to the issue								
Issue	CA	FR	IT	JP	SG	UK	US ABF	US EBRC	Total score
Convergence	4	9.5	14.9	6.1	22.8	19.8	12.3	16.4	27
Funding	11.2	4.8	6.1	4.5	4.6	5.2	10.4	4.1	7
Access	6.4	20.4	5.8	2.6	6.4	19	6.3	7.7	13
IP	1.7	4.8	4.6	9.2			5.8	2.3	4
Data	9.6	0.4	6.4	3.8			3.5	1.2	3
Public-private collaboration	2.9	9.8	11.3	8.5	5	4.4	15	31.5	15
Skills/education	16.5	9.9	6.7	2.5	6.3	9.1	4.9	5.2	13
Standardisation	1.4	2.5	6.7	2.6	7.6	6.9	6.4	6.6	8
Measures of activity	2.4	11.7	6.4	5.9	3.2	4.3	7.1	3.5	8
Stage of commercialisation	7	6.4	8.5	4.9	2.6	5	8.7	4.6	7
Safety/regulation	11.5	3.7	5.6	1.9	8.9	6.8	3.3	4.8	7
Other	0	2.4	4.7	21.5	20.4	12.2	5.5	0	12

Table 9. Ranking the importance of issues by word count

Note: For further analysis, the top five issues are colour-coded

red = most important, green = second, yellow = third, blue = fourth, brown = fifth.

For the total score, red is assigned five points, green four, yellow three, blue two and brown one. Note that the numbers in the final column are therefore not percentages.

Countries are listed alphabetically by ISO two-letter country code.

Convergence

While attempts in the past to perfect production strains for industrial bioprocesses have often been unsuccessful, it is now that emerging biotechnologies are starting to mature and real convergence with digital technologies can be considered feasible. Convergence was the most important issue to arise from the case studies; four of the eight examples in Table 9 had convergence as the top issue, and seven of eight had convergence in the top five issues. The case studies articulated the meaning of convergence differently, revealing different and valid interpretations of convergence.

Singapore described convergence in terms of the convergence of appropriate research stakeholders, and "... efforts to bring together experts in achieving a common goal." France took a similar interpretation, describing convergence in terms of technology readiness, with Toulouse White Biotechnology (TWB) "...developing new technologies for rapid development of bioprocesses and moving R&D projects along the pathway to higher technology readiness." From the technology convergence viewpoint, France kept to this theme of convergence as public-private interaction as TWB "...integrates both in-house and external (partners") capabilities to deploy a full continuum of expertise..."

In its interpretation of convergence, Italy described how bioprocess "...relies on the availability of well characterised (a full set of metadata including genome information)..." Still within the convergence issue, Italy raised an important point regarding reproducibility within life sciences research. For the Microbial Resource Research Infrastructure (MIRRI), an important part of the mission is to combat the "...irreproducibility of life science research and the consequent waste of public money through the provision of quality-controlled, contamination-free, reliable, reproducible, biological resources by mBRCs [microbial Biological Resource Centres]..." And in its description of convergence, Japan noted the "elemental technologies of Design-Build-Test-Learn including dry smart cell design system" – elements of digital science – "...and wet high-throughput synthesis, analysis, evaluation technology)."

In engineering biology, convergence reaches its zenith in the biofoundry, but Italy raises an issue that should be very high up on the priorities for policy makers - biological resource centres should be an integral part of the engineering biology ecosystem. Biodiscovery is in its infancy but critical events are taking place that will cement it within the engineering biology remit. For example, the Earth Biogenome project¹⁰ aims to sequence every known eukaryote. The work of MIRRI-ERIC complements this with biodiscovery within the microorganisms, an essential pool of genetic diversity with many differences from the eukaryotes.

In its description of the MIRRI case study, Italy may, unwittingly or otherwise, have described a hitherto unexplored form of convergence in biotechnology and engineering biology in policy communities – the convergence of natural biodiscovery with the industrial processes of engineering biology, through very distinct forms of public-private infrastructure. In such a convergence, it would be a matter of routine for biofoundries to interact with BRCs for the creation of new products. In other words, the BRCs act as the curators of natural life forms, and the biofoundries are the birth place of new life forms.

The UK had a broad-ranging interpretation of convergence. This manifested in considering roles of people with the appropriate skills and education to blur the boundaries between wet biological sciences with digital technologies. The biofoundries are also seen as critical infrastructure on the path to convergence. That same view is sharply focussed in the US case study on the Agile Biofoundry (ABF) "…laboratory automation, process engineering, and machine learning/artificial intelligence, as well as other facets of the computational sciences…", all fundamental enablers of the ABF modus operandi. Similarly, the US EBRC, as a network infrastructure, continues to "…strengthen research, development, and innovation in biotechnology, the biological sciences, and the convergence of biology, engineering, and the information sciences".

Collaboration

Public-private collaboration and access

The platform case studies show clearly that publicly funded infrastructure – such as facilities and funding programmes – have difficulty delivering value effectively without the private sector, even within the scope of "pre-competitive" infrastructure. However, public-private collaboration goes beyond a public funder and the private sector. Additional stakeholders are often key, including those that identify themselves with ethical and societal issues.

Public-private collaboration and access are treated together here as they bear strong relation to each other. In fact, they were discussed with almost the same level of importance across the case studies (see Table 9). Some draw a distinction between the two issues in that access describes the stakeholders that perform projects within the infrastructure. This is very evident from the clear description of the mechanisms by which public and private actors can perform projects under different forms of agreement within the US Agile Biofoundry. These agreements are then further elaborated under "Intellectual property terms".

An older infrastructure is the Toulouse White Biotechnology in France, which also has a formalised access policy that has proven very effective to streamline the access process to avoid at least two unwanted consequences:

¹⁰ <u>https://www.earthbiogenome.org/</u>

- 6. Long project delays before commencement can occur as protracted negotiations have to take place between the legal departments of companies and the public infrastructure management.
- 7. A perception can arise that there are high bureaucratic barriers that disfavour the engagement of SMEs, resulting in lost opportunities.

It is highly recommended that policy makers make structured collaboration agreements based on full economic cost and IP, but with different terms for private sector actors, such as SMEs or large companies, and public research organisations.

Public-private collaboration can also refer to wider communities of stakeholders. For example, whilst the existing infrastructure in Canada is much more focussed on academic actors, the proposed infrastructure in the case study will "...support research by academic users as well as industry and NGO users".

The wider community of stakeholders demonstrated by the TWB case study from France, where stakeholders consider "...common socio-economic issues (academic centres, local authorities, large companies, SMEs, start-up companies, clusters, investors)." Perhaps more than any other case study, there is a strong ethical context in the public-private collaboration entry for TWB, with a formalised approach to ethical considerations.

The UK devotes considerable attention to these wider aspects of public-private collaboration, perhaps as a consequence of work done earlier for the UK synthetic biology roadmap, and the inclusion of social scientists in its synthetic biology leadership council (SBLC). The UK used the term "responsible research and innovation" (RRI) in the case study. It is interesting to note that "responsible" was rarely mentioned in other case studies in the same context.

In the United States, the Department of Energy enabled collaborations through a mechanism called a "Directed Funding Opportunity" (DFO) which provided funding for an industry competition at the Agile BioFoundry. Companies proposed a number of possible projects to be executed at the Agile BioFoundry with those government funds. At the first DFO in 2017, industry proposals totalled over four times the available funding which showed the promise and value of the Agile BioFoundry. Through this public private partnership, it is expected that the Agile BioFoundry will develop new tools, technologies and expertise that will benefit future collaborations.

Intellectual property, licensing and collaborative research provision

TWB in France negotiated a consortium agreement with three administrative bodies (INRA/INSA/CNRS) and members from the private sector that contains pre-negotiated terms related to confidentiality, IP rights and license terms for three main types of projects:

- 1. Early-stage projects that generate technologies as the basis of tomorrow's products/processes: the relevant administrative body owns the IP and TWB members have a 6-month priority access; beyond this, TWB can valorise the IP with external partners.
- 2. Public/private projects that can attract public funding: IP is shared between partners according to their investments and license terms are on an *ad hoc* basis.
- **3.** Industrial contracts that are either research collaborations (with IP generated) or simply services (with a priori no IP generated) between TWB and industry partners. In the former case, the industry partner is the solely decides on IP protection and valorisation; in return, it pays the project full costs and commits to pay success fees in case of commercial exploitation of the results (within a range from 1 to 3 times

the overall project costs and with instalments based on commercialisation milestones – it can be more for TWB non-members).

Collaborative Research and Development Agreements (CRADAs) and Strategic Partnership Programs (SPPs) are mechanisms for industry collaboration with the Agile BioFoundry in the United States. CRADAs often involve larger scope collaborations including integrated process steps across subsets of the eight national laboratories and offer industry partners the opportunity to embed their researchers at the Agile BioFoundry. With a CRADA, IP ownership follows inventorship, with the industrial partner generally having a right of first refusal to an exclusive license to Agile BioFoundry (co-invented intellectual property in specific field(s) of use). In most cases, industrial partners are expected to pay full-cost recovery for all Agile BioFoundry National Laboratory work performed under the scope of the project's work. Under SPPs, collaborations tend to be smaller engagements where the Agile BioFoundry performs a specific task (e.g., targeted proteomics analysis) for the industry partner. SPPs may be very attractive to industry, as the industrial partner retains all IP rights derived from the work performed.

All three groups in Canada currently work based on their university's IP policy through their University Industry Liaison Office. In Singapore, The SynBioNet biofoundries will not acquire IP. All IP will be held by the platform users.

In Germany, IP, licensing and collaborative research provision are currently being put in place. It is clear that all IP will stay with the client and several material and non-material "fire walls" will be effective in order to ensure that this applies at all times. There has to be a collaboration agreement in place for every single customer / utilisation of the infrastructure. By having a public entity run the facility, the IP-protection of the customer shall be further ensured.

International partnerships

Some countries have specific public funding streams dedicated to building international partnerships, and previously the OECD has reported how publicly-funded clusters play a similar role further downstream of research (OECD, 2018_[113]). Growing these relationships at research level can have spill-over effects later when higher levels of commercialisation occur and international trade is spurred. Singapore noted that some of their students that took part in competitions by the iGEM Foundation later joined or formed biotechnology companies. Exposure at iGEM has been strongly implicated in building networks which can be deliberately formalised. The iGEM foundation also created a an online platform where "…community members can maintain an online presence and connect with others who have gone through this shared experience."

Another directly significant international partnership is the recently formed Global Biofoundry Alliance (GBA) (Hillson et al., 2019_[114]), with representation in Asia, Australia, Europe and North America. The UK SynbiTECH conferences are partnering events primarily showcasing the development of the synthetic biology industry in the United Kingdom and internationally.

In conclusion, ecosystems building and partnering have been strong motivators for the engineering biology actors to form international partnerships.

The roles of standards

Standards can be viewed as an agreed way of doing something, or a consensus of good practice at any time, developed through rigorous testing and the distilled wisdom of experts in the field. They can be very specific, such as regarding a particular type of process or product (e.g. Bluetooth, or, more general, such as management or quality control practices).

Lacking uptake of standards may be explained by a misconception by some that standards are primarily about regulation and compliance. In fact, standards can facilitate trade, provide a framework for achieving economies, efficiencies and interoperability, and enhance consumer protection and confidence.

Standards in various forms are needed in the engineering biology field. Given the growing number of tools and techniques, interoperability will become increasingly important. Technical standards are of high priority that automate methods, the description and assembly of components, and documentation of the performance of engineered microbial strains. De Lorenzo and Schmidt (2018_[115]) argued that the adoption of standards will accelerate the transition to a future with advanced bioeconomy, driven by bio-based manufacturing.

At present, the microbial biological resource centres (mBRCs) partners of MIRRI-ERIC have reached various levels of quality management implementation. To become MIRRI-ERIC partners, all mBRCs must ensure a minimal level of Quality Assurance measures and commit to implement a quality management system following appropriate international standards. In case an mBRC does not have a certified or accredited quality management system in place, this mBRC must demonstrate compliance with a number of defined minimal criteria. MIRRI-ERIC will use checklists and/or external audits to evaluate the knowledge, competence and experience of the mBRCs. MIRRI-ERIC will encourage, advice on and assist with the implementation of ISO 9001 requirements by these partners in a 2 to 3 year timeframe. In order to stay informed about and to influence on the development of new relevant international standards, MIRRI-ERIC has applied to become liaison with the ISO/Technical Committee 276/working group 2 (voting pending). The scope of this ISO TC is the standardisation in the field of biotechnology processes.

The Singapore synthetic biology community mainly collaborates with overseas collaborators on technical standards, for example, on the development of two technical standards - SBOL and DICOM-SB. Currently, the NUS biofoundry is also participating in various Global Biofoundry Alliance (GBA) working groups such as the metrology and software working groups to develop standards in measurement and software. NUS SynCTI has recently started to develop experimental standards and metrology protocols for synthetic biology, working with the GBA metrology working groups.

Broadening stakeholder engagement in infrastructure funding

As engineering biology applications become more entrenched in future markets, the representative organisations will become increasingly visible to the public. To prevent mistakes with communication around genetically modified organisms of the past, scientists, technologists, practitioners and policy makers need to work closely with biofoundry operators and the public to shape and guide this future (A Dixon, C Curach and Pretorius, 2020_[116]).

Marris and Calvert (2019_[117]) warned of the possibility that roadmaps can end up representing a narrow range of participants who are "closely associated with current developments in the field and are seeking to attract resources." They felt that the UK synthetic biology roadmap contributed to solidifying existing framings of synthetic biology as a driver of jobs and economic growth, but took lesser account of other framings such as responsible research and innovation (RRI). It is a matter for funding agencies to broaden the stakeholder scope to consider more viewpoints, and to gather an accurate picture of the societal good from funding infrastructures,

Value creation

Skills and education

In the collected case studies, the issue of "skills and education" is among the top issues overall, it was accorded the same level of attention as "access" (see Table 9). The topic is strongly connected to convergence because there is a need for a new type of biological scientist with the ability to work across traditional biotechnologies and IT/computer programming. This is at the heart of digital biology as a new industrial paradigm. For example, Canada notes in its case study the need for specific training in robotics as workflows become increasingly automated.

Countries mentioned the need for broader skillsets in their case studies. Some focused on PhD-trained researchers and others on university education from undergraduate modules to dedicated Master degrees. This is consistent with the development of new master degrees in "bioeconomy", and there are roles for engineering biology infrastructures in meeting these new education needs. For example, TWB is to contribute to a new Master in bioeconomy to be offered by INSA (Institut National des Sciences Appliquées) Toulouse.

It may be too early for complete undergraduate degrees in engineering/synthetic biology, but Singapore noted the inclusion of engineering biology modules in more traditional undergraduate courses, such as biomedical sciences, chemical engineering and biochemistry.

There is also a need for training programmes outside of higher education. For example, Italy mentioned continuous professional development (CPD), and some innovative initiatives were discussed by the UK, including the "4-day MBA" offered by Imperial College. The latter is designed to provide a rapid introduction to the key elements of business practice that are needed to establish and grow a new company and assuming no prior knowledge of engineering biology. As many of the engineering biology companies are young and small, this could also be an important mechanism to fill management gaps without taking managers away from their desks for long periods.

A broad range of actors has a role to play, including foundations and community colleges. For example, the international competition by the iGEM Foundation has been very successful in attracting the interest of undergraduate students in synthetic biology. Moreover, its graduates now number tens of thousands and many go on to engage the private sector in some capacity. Singapore noted that some of their iGEM graduates have gone on to PhD programmes in synthetic biology and are now being employed in biotechnology-related companies and universities. The cases study of the EBRC from the US mentioned the involvement of community colleges, where education can be tailored to workforce as well as academic needs. The community colleges can also broaden the catchment of the engineering biology community, but are often absent from discussions of educational needs of this field.

In summary, skills and educational needs are seen as important to this young industry. As identified by Delebecque and Philp $(2019_{[118]})$, they span technician level diploma programmes to PhD, and then the business skills courses such as the mini-MBA. Given the predominance of research in engineering biology, PhD-level training still often dominates. However, there is a definite need for cross- and inter-disciplinary training in modern PhD programmes as the skillsets required of a growing industry are very different from the skillset of a typical PhD programme. This need was recognised decades ago in the United States (Griffiths, 1995_[119]) and policy makers need to take action to educate this new breed of biotechnology employees with more engineering and business skills embedded in their formal education.

Ecosystems and smart specialisation

The case study from France showed that the TWB has been seen as a key motivator for the development of a growing ecosystem of biotechnology and engineering biology around Toulouse. In fact, a smart specialisation analysis across France in 2015 identified two specialisations of interest for Toulouse: industrial biotechnologies for the recovery of renewable carbon, and territorialised agri-food innovation which are both a perfect match for a bioeconomy (Peltier, $2014_{[120]}$). Two strengths of Midi-Pyrénées area identified were research excellence and a dense network of transfer and support structures. Thus, in TWB, this public investment can be seen to be succeeding.

By acting as a hub for ecosystem growth, the Agile Biofoundry in the United States is fulfilling the same function. Also Japan reported in its case study"...spinoff companies to support the platform" under "other", which is effectively saying the same thing – the collaborative platform has a function in growing the ecosystem.

The MIRRI-ERIC case study from Italy, reported plans that it will have its own research lines and programmes to produce results that speed up the process to commercialisation. An aspect of this is the value that research results can have in generating other income streams, particularly research grants, leading to new avenues of investigation. This can offset slow growth through the primary services offered. Previous experience with microbial culture collections has shown the need for novel funding mechanisms to stabilise a business (Smith, McCluskey and Stackebrandt, 2014_[112]). This provides vital services to the life sciences community which has long been a problem, such as the financial challenge of developing Biological Resource Centres (OECD, 2001_[121]).

Policy implications

It is of great interest to public funding bodies how much private investment is leveraged from the initial public investment. Whilst extremely important, there are caveats to this performance indicator which need to be considered such as the time horizon of the investment and its timing. A physical engineering biology platform will be needed in the longer term. The inflow of private investments may come much later than the initial public investment. Thus other metrics, such as patents, job creation and academic output, notably publications, should also be included.

The biofoundry is an essential infrastructure in a sustainable bioeconomy today, as biobased products are often portrayed as sustainable alternatives to fossil products. In light of the lack of international agreement on what sustainability metrics are or how to measure them, life cycle analysis (LCA) for new projects/products at the planning stage may become a higher priority KPI in future.

Political continuity is important when private ecosystems are constructed from a public nucleus which shows that governments are willing to engage long-term. This is what is meant by the term "long tail" funding of research in the UK. Thus building biofoundries should also be accompanied by long-term research funding in the public sector. Ultimately the need for traditional biotechnology laboratories could fade as more of the routine work is taken over by machines and automation (The Economist, 2018_[122]). Governments should be mindful of the gap period until that goal is achieved.

Advice on assessing the effectiveness of collaborative platforms in engineering biology is difficult given the absence of appropriate tools for quantitative assessment. This should be borne in mind when setting up engineering biology platforms. In any case, assessment criteria by the public funders should be agreed with the operating staff to ensure that the criteria are measurable and transparent.

As a general rule, there is a lack of tools to make an informed choice of the best publicprivate collaboration model to determine the effectiveness of using this mechanism in solving socially significant problems. When sustainability is a criterion for funding, then the lack of clarity on what sustainability actually means makes the problem more complex. There is a developing literature on toolkits to address this. For example, Anopchenko et al. (2019_[123]) created and tested a multi-criteria modelling toolkit for the choice of mechanism in relation to managing sustainable development projects. Yale Insights offers general advice to try to navigate the many pitfalls that can beset PPPs¹¹.

The point is important as companies have to know what to expect from a project at an engineering biology platform. Post-project arrangements such as licensing and IP rights vary greatly according to technology readiness. The Bio-based Industries Joint Undertaking (BBI JU) in Europe pays attention to technology readiness for project selection. Proposals to BBI JU should clearly state the starting and end technology readiness of the key technology or technologies targeted in the project¹². It should be obvious, but not always is, that the project proposal should enable the technology or system to achieve the end readiness level within the project timeframe.

There remains the risk that society at large will reject advanced synthetic or engineering biology technologies on safety or moral grounds, especially if the products are for human consumption. The efforts invested by governments in biosafety and biosecurity should be continuous to alleviate public concerns, while not being so onerous as to stymy innovation.

¹¹ <u>https://insights.som.yale.edu/insights/how-do-you-build-effective-public-private-partnerships</u>

¹² <u>https://www.bbi-europe.eu/sites/default/files/bbi-ju-awp-2019.pdf</u>