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Towards an Experimental Governance Framework for Emerging Technologies

Chapter 2: Interpreting The Present

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How can we make experimentation the norm when building policy in emerging tech?

Open Loop and Demos Helsinki reflect on past experimental governance initiatives, assess the ones being currently used, and imagine what a holistic, inclusive experimental governance framework for the regulation of emerging technologies could look like.

Reflect to reimagine

The nature and scope of changes and the impact emanating from emerging technologies, like AI and machine learning, can be difficult to shape, anticipate and identify.

And the same thing can be said about the downstream effects of laws and regulations governing those technologies. References to experimentation are already being made in national AI strategies and in calls for regulatory sandbox approaches to the deployment of emerging technologies.

Yet how can we more systematically harness the potential of experimentation- to test and assess impacts in the development and deployment of technology and regulation, but also to foster openness and mutual trust through an inclusive, holistic governance framework?

Reflection #1

What would it take for testing and experimenting to become a go-to regulatory approach in tech governance, embedded in the different stages of policy and lawmaking processes?

Reflection #2

How can governments, technology companies, academia and civil society start engaging collaboratively in experimenting with regulation in tech?

Reflection #3

How can experiments in building policy and regulation foster open, trustworthy and evidence-based policies for emerging technologies?

Key Messages

- In the second chapter, a set of case study analysis on the design, development, or deployment of a range of new and emerging technologies is performed in order to assess their governance implications. To do so, a robust experimental governance framework, based on the core principle of experimental governance and the shifts identified in the first chapter, is leveraged. This results in a framework made of three elements:
  - i) anticipatory governance
  - ii) stakeholder-inclusive governance
  - iii) holistic governance
- The robust experimental governance framework identifies the following for each of its elements: i) a tentative definition and ii) a list of governance approaches and tools to help identify their practical relevance.
  - Governance approaches refer to the instruments linked to contemporary experimental governance of emerging technologies (i.e., regulatory sandboxes, testbeds, and policy prototyping) and form the main focus of the analysis.
  - Governance tools refer to the methodologies linked to the three components. That is, they identify concrete solutions through which anticipation, inclusion, and holism can be put into practice to develop a more robust experimental governance framework.
- The insights emerging from the analysis can be grouped based on each governance approach:
  - Regulatory sandboxes are shown to be capable of advancing elements of both anticipatory and stakeholder-inclusive governance. Nonetheless, they seem to hinder the potential for holistic experimentation due to their excessive focus on compliance with existing laws (see Case Study 1). This seems to be changing as we start observing the use of regulatory sandboxes to inform future policies and update existing ones (see Case Study 2).

- Testbeds are shown to be capable of promoting stakeholder-inclusive governance and, to a degree, anticipatory governance, thanks to their ability to promote experimentation through collaboration among different actors (see Case Study 3). However, they are characterized by different degrees of intensity, diversity, and quality, depending on the collaboration they are able to foster. This is a challenge that prevents the scalability of these approaches beyond the local level (see Case Study 4).

- Finally, policy prototyping methodologies are shown to be conducive to a holistic governance approach. Interestingly, policy prototyping approaches can also yield fruitful results in terms of anticipation and stakeholder-inclusiveness (see Case Study 5). However, their potential cannot be scaled up if the overarching legislative landscape in which the regulation is enacted is not also taken into account. This is why a virtuous combination of multiple governance tools linked to all the key stages of the policy process seems key to success (see Case Study 6).

- The journey towards the consolidation of an experimental approach for the governance of emerging technologies that is also anticipatory, stakeholder-inclusive, and holistic is still a long one. However, we are already seeing early but promising signs of change that, taken together, point towards the development of a robust experimental governance framework. To achieve the latter, however, three gaps need to be addressed first:

  - **A cultural gap:** the lack of enabling conditions for stakeholders to engage in governance

  - **An operative gap:** the limitations that impede current policy approaches from moving forward

  - **A governance gap:** the lack of arenas for multi-stakeholder collective action

- Based on this analysis, the third chapter aims to better understand and investigate how to address these gaps to foster the development of a robust experimental governance framework for emerging technologies.

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Content

01

Introduction: Framing Chapter 2

Emerging technologies, including AI, are posing great challenges to our societies. Widespread skepticism and doubt about the development and deployment of this technology in a responsible way, about its use for the common good, and about the realistic possibilities for AI stakeholders to work together around these goals looms over our collective future. In the first chapter, two major issues were identified, which render the act of governing emerging technologies particularly challenging.

- On the one hand, the so-called Collingridge dilemma identifies an apparent trade-off between the possibility to control technology development and that to foresee its eventual effects early enough in the innovation process.[1] As such, it shows how contemporary challenges affecting emerging technologies are not new but instead a recurrent feature of the dynamics that characterize "socio-technical transitions" at large (such as industrial revolutions in the past).[2]

- On the other hand, the Collingridge dilemma is aggravated further by the current decline in the level of trust towards and societal legitimacy of many emerging technologies – e.g., autonomous cars.[3] Indeed, while new technologies typically gain trust from users through the resolution of societal problems, their societal legitimacy can become increasingly questioned in several circumstances. For example, when prior regulatory frameworks do not match the pace of technology or when societal fears around technology exceed the promises of rewards, they preclude the maximization of its benefits or fail to minimize its harms as a result.[4]

Combined, these two issues pose a formidable challenge for the governance of emerging technologies and socio-technical transitions at large. To overcome this, this report tackles one key question: How can technology developers *and* policymakers address and ultimately solve this challenge?

As a promising and potential solution, the report explores experimental governance as a potential way forward for the effective governance of emerging technologies. The premise behind this approach is that the development of technology and policy should neither be seen as linear processes nor as separate activities, but instead as a continuous loop. Together, the development of technology and policy should entail two goals: one, the possibility of continuously testing the mutual effects that technology and policy have on each other – that is, both *before* and *after* their definitive enactment and, two, the possibility

1 Collingridge, 1980 2 Freeman & Louça, 2001 3 Stilgoe, 2020 4 Frewer, 1999, pp. 569–574

for the actors that develop them to imagine and implement new strategies for shared decision-making.[5] In this context, the first chapter argued that experimental governance has the potential to do so and hence overcome the Collingridge dilemma in two respects:

- First, as a way to acknowledge and intentionally embed the iterative nature of the decision-making processes behind innovation into the ways through which emerging technologies are governed

- Second, as a way to provide a common ground for multiple stakeholders to come together and jointly assess the potential implications of both technology and policy development

As such, experimental governance has the potential to enable stakeholders to achieve both goals. The core principle behind experimental governance – i.e., experimentalism – can in fact be interpreted as "a recursive process of provisional goal-setting and revision based on learning from comparison of alternative approaches."[6] As such, it provides a strategy to design governance processes that are constantly evolving and open for revision and, thus, reflect the dynamic and evolutionary nature of the technologies themselves. Moreover, experimentalism is not new, and there are many historical examples proving how it can be applied to policy dilemmas such as the one faced in this context.

Following this analysis, the first chapter identified three "families" of approaches – each illustrating a way through which experimental governance has been interpreted and applied during the last century – and assessed their capability to provide solutions to the challenges we're facing. As a result, three key shifts have been defined, the fulfilment of which would be critical for the future of governing emerging technologies.

- Experimental lawmaking aims to embed experimentation into policy implementation by codifying it directly into pieces of law (i.e., legal documents approved by elected officials) as well as into pieces of regulation that stem from these (e.g., as formulated by executive agencies). This has been done through tools such as sunset clauses, experimental legislation, and pilot projects. Experimental lawmaking showcases how greater adaptability can be embedded into rules that have been traditionally framed as rigid and definitive. Yet, their actual uptake in policy practice has been slow and tendentially past the unfolding of critical innovation processes. To address this gap, a shift **from outpaced to anticipatory** lawmaking is needed.

- Experimental policymaking aims to embed experimentation at the core of the policy process: that is, decision-making and evaluation. To do so, experimental and impact evaluation techniques are used in order to test, learn, and improve a given policy before its eventual translation into law – e.g., by means of randomized experiments, quasi-experimental experiments, and pre-experiments. Experimental policymaking, as such, results in a wealth of techniques that provide strong methodological clarity to policy decisions. Yet, the data derived from these techniques and their interpretation have been subjected to intense politicization in very complex and uncertain environments (think Covid-19), at times leading to stark controversy. As such, they've rarely been leveraged to provide a common ground for stakeholders

5 Sarewitz, 2011 6 Sabel, & Zeitlin, 2012. p. 170

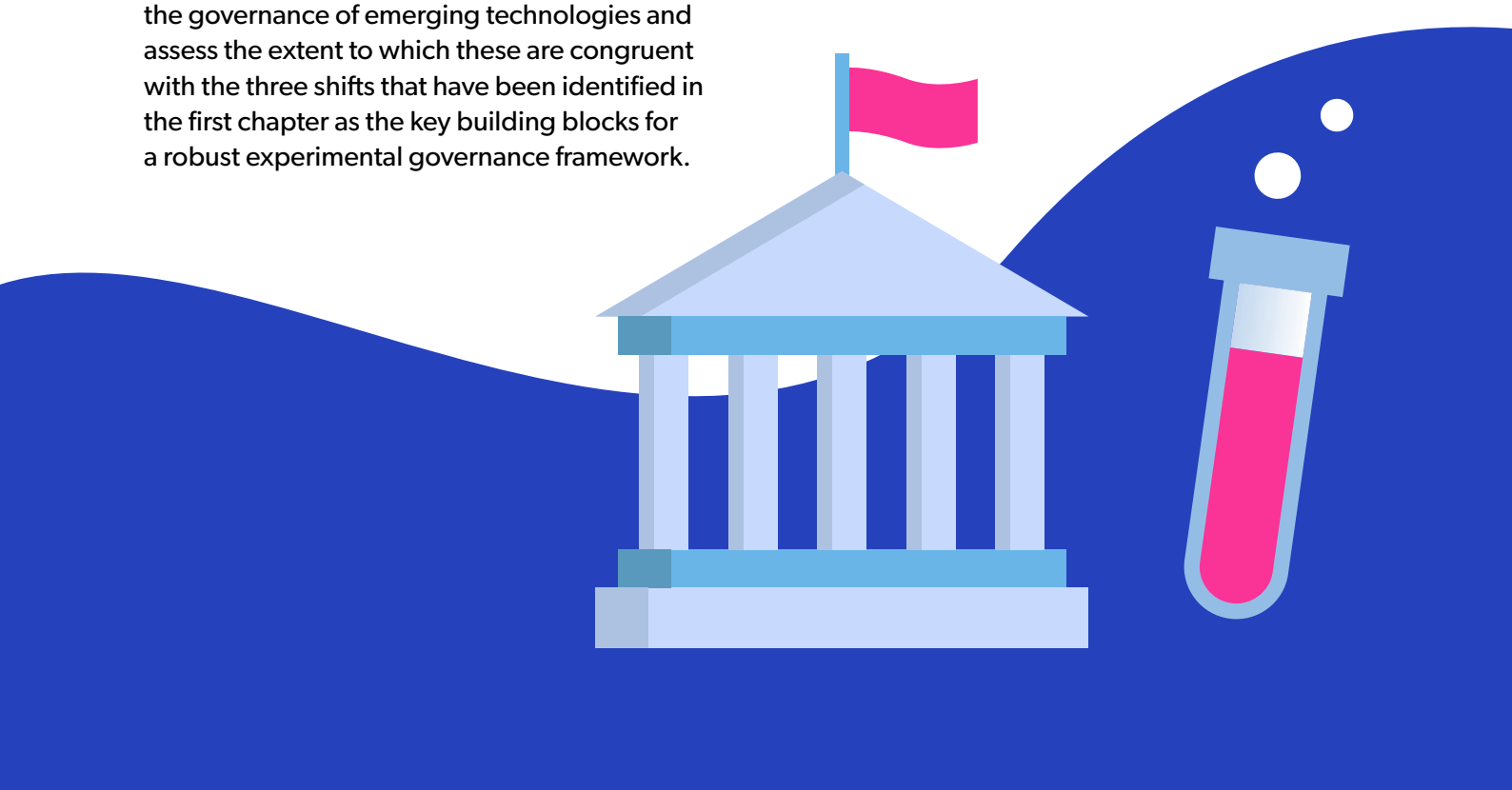
to convene on joint problem-solving. To address this gap, a shift **from top-down to stakeholder-inclusive** policymaking is needed.

- Finally, experimental design aims to embed experimentation into policy formulation. To do so, conventional ways in which the public sector frames public issues and ideates their solutions are challenged – notably, by increasing the openness and transparency of such processes via tools such as prototypes and challenge prizes. As such, experimental design shows that policy can be framed, formulated, and developed more inclusively than it has ever been. Yet, it has not managed to upscale its relevance from secluded units (such as policy labs) to the core of government. To address this gap, a shift **from piecemeal to holistic** design is needed.

Based on this analysis, the goal of the second chapter is to leverage the insights acquired from the past to interpret the present: i.e., determine the current state of the art in experimental governance of emerging technologies. The goal is to analyze the range of policy tools that are being deployed by policymakers worldwide in the governance of emerging technologies and assess the extent to which these are congruent with the three shifts that have been identified in the first chapter as the key building blocks for a robust experimental governance framework.

As a result, this chapter aims to identify both best practices and potential ways forward to improve current ways of governing emerging technologies through experimentation. In doing so, this research aims to foster a more open and transparent conversation among all the relevant stakeholders involved, one which might nurture reciprocal trust and cooperation in developing technology and policy with a view on societal progress.

The second section provides a robust experimental governance framework based on the three shifts previously identified (i.e. anticipatory, stakeholder-inclusive, and holistic governance). The third section identifies and analyses a selected number of case studies from the fields of AI and emerging technologies at large by leveraging the aforementioned framework. The fourth section uncovers the key gaps, best practices, and ways forward that emerge from this analysis. Lastly, the fifth section summarizes the results of the report and provides three takeaways that represent prompts for steering the development of a robust experimental governance framework for emerging technologies.



02

A framework for interpreting the present

In this second background report, six case studies concerning the design, development, or deployment of emerging technologies – such as data processing techniques, medical software, drones, and robotics – are explored in order to assess their governance implications. To do so, a framework based on the core principle of experimental governance and the shifts seen in the first chapter is leveraged. These are as follows:

- From outpaced to anticipatory governance
- From top-down to stakeholder-inclusive governance
- From piecemeal to holistic governance

While building on the original results of our research, the proposed robust experimental governance framework shows analogies with the work developed by academic scholars, the OECD, and World Economic Forum. To contextualize the framework within contemporary academic and policy debate, this section illustrates how it draws on such insights and provides a brief overview on the current consensus emerging from these debates about current gaps and ways forward in the field.

On the one hand, much of the contemporary academic debate revolves around the notion of "Responsible Innovation," defined by leading Science and Technology Studies scholar René von Schomberg as "a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the acceptability, sustainability and societal desirability of the innovation process and its products."[7] Based on this concept, contemporary scholars such as Stilgoe, Owen, and Macnaghten proposed four "characteristics [...] which can be heuristically helpful for governance": i.e., reflexivity, anticipation, inclusion, and responsiveness.[8] Notably, these bear a close resemblance to the core principle and the three shifts identified in the framework.[9]

On the other hand, the contemporary policy debate moves from the assumption that, to deal with the Collingridge dilemma, the governance of emerging technologies must expand its focus "from managing the risks of technological products to managing the innovation process itself: who, when, what and how."[10] For the OECD, this shift is motivated both by "regulatory challenges brought by emerging technologies" and by a need to ensure that "the innovation that can power economic growth and solve the world's most pressing social and environmental challenges is not held back by regulations designed for the past."[11] This resonates with the analysis conducted by the WEF, which advocates for "a more agile, flexible approach to regulation" as key to upend the rigidity of existing regulatory models as well as a way to embed anticipation and inclusion into them.[12] In this context, the OECD has also identified three "imperatives" for a "process-based approach" to the governance of emerging technologies: i.e., anticipation, inclusion, and directionality.[13] Once more, these have strong analogies with the overall rationale of the proposed framework, if not even help us specify its content.[14]

Drawing on the insights emerging from the consensus briefly summarized above, the remainder of this section outlines the main characteristics of the framework by providing for each of its elements: i) a tentative definition and ii) a list of governance approaches and tools to help identify their practical relevance.[15]

7 von Schomberg, 2011, p. 1570 **8** Ibid [7], Stilgoe, 2013, p. 1570. **9** Pairings across the four dimensions can be identified as follows: (i) reflexivity as experimental governance; (ii) anticipation as anticipatory g.; (iii) inclusion as stakeholder-inclusive g.; and (iv) responsiveness as holistic g. **10** OECD, 2019. **11** OECD, 2021 **12** WEF, 2020 **13** Ibid [7]. **14** Pairings across the three imperatives can be defined as follows: (i) anticipation as anticipatory governance; (ii) inclusion as stakeholder-inclusive governance; and (iii) directionality as holistic governance. **15** The list of related governance approaches and tools is drawn from Stilgoe, Owen, & Macnaghten, 2013 and integrated via own research of the authors.

A synthetic overview of the robust experimental governance framework is shown in Figure 1, where the relationship between the core principle of experimental governance and the three shifts – or framework **components** – is shown and linked to many instruments and methodologies. These are distinguished among governance approaches and governance tools.

- **Governance approaches** are the instruments linked to experimental governance. They provide the main focus of the analysis given in the remainder of this chapter and represent the starting point for the exploration of contemporary governance of emerging technologies and, hypothetically, how it could be improved by means of anticipation, stakeholder-inclusiveness, and holism.

- **Governance tools**, on the other hand, are the methodologies that are linked to the three components. They identify solutions through which anticipatory, inclusive, and holistic governance can be put into practice, and represent potential pathways to integrate contemporary experimental governance approaches.

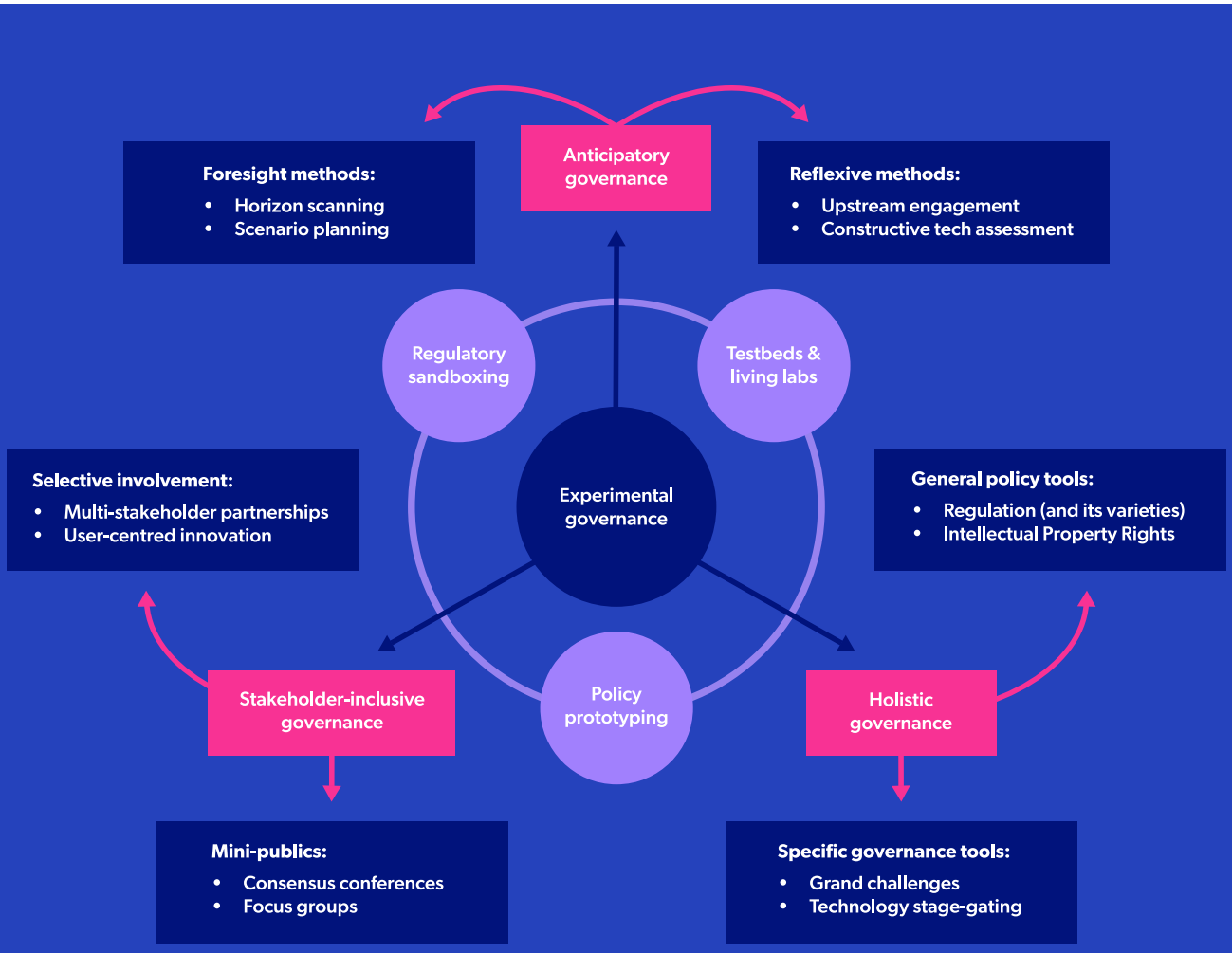


Figure 1. Robust experimental governance framework: A visual representation

2.1. Core principle: Experimental governance

The core principle of our framework provides the bedrock for a new approach for governing emerging technologies. This report defines experimental governance as a mode of governance based on a recursive process of provisional goal-setting and learning-oriented revision through different tools and approaches.[16] This report explores how experimental governance can transform the ways in which collective decisions are designed and implemented *both* in regards to emerging technologies *and* to the rules that govern them. In this context, the value that experimental governance can bring is twofold:

- On the one hand, experimentalism suggests that testing hypotheses based on the potential effects of emerging technologies in society *and* those of policy on innovation *before* and *after* their enactment can help validate or rebut their effectiveness. As such, these results can inform the choices made throughout the policy process.

- On the other hand, experimentalism also incorporates elements of reflexivity. That is, it helps each stakeholder with "holding a mirror up to one's own activities, commitments and assumptions" to become "aware of the limits of knowledge" and of the variety of framings through which an issue can be tackled.[17]

However, while there are several governance tools that incorporate reflexivity in the development of emerging technologies (e.g., ethical technology assessments[18] and codes of conduct[19]) these usually neither address the rules governing them nor incorporate experimentation as such. In this respect, regulatory sandboxes[20], testbeds[21], and policy prototyping[22] are the key exceptions that are explored in the next section of this chapter in order to understand how the experimental governance of emerging technologies can be realized in practice.

16 Sabel & Zeitlin, 2012 p. 170. See also Wolfe, 2018 **17** Ibid [11], p. 1571 **18** Swierstra, Stemerding & Boenink, 2009, pp. 119–138
19 von Schomberg, 2013, pp. 51–74 **20** Ranchordas, 2021 **21** Engels, Wentland & Pfotenhauer, 2019, p.2 **22** Singapore and AI Act Andrade & Kontschieder, 2021; Andrade, 2022; Andrade & Zarra, 2022

Approach	Definition	Example
Regulatory sandboxes	Environments where developers and businesses can experiment with their products, services, business models and delivery mechanisms, in a «safe space» that sometimes (but not always) waives legal requirements, under the conducive oversight of a regulatory authority.[23] [24] A repository of recent regulatory sandbox initiatives can be found here.[25]	The Ministry of Health in Singapore's Licensing Experimentation and Adaptation Programme (LEAP) was launched in 2018. LEAP enabled healthcare providers to trial new services in close partnership with the Ministry, allowing the creation of regulations which are 'fit-for-purpose'. For instance, the Ministry generated rules for the safety of clinical procedures, data protection and other relevant areas relating to telemedicine.[26]
Testbeds	"Controlled experimental spaces that facilitate […] hypothesis testing under presumably realistic conditions"[27]	Sidewalk Labs, owned by the same company as Google, was granted permission in 2017 to develop Toronto's waterfront and turn it into testing space for innovative urban space technologies. The district would adopt self-driving buses, new traffic control technologies, innovative housing, amongst other technologies, with the end of creating more environmentally friendly and technologically advanced cities. The city would remove regulations to allow for these innovations.[28]
Policy prototyping	A nascent methodology aimed at testing "the efficacy of a policy by first implementing it in a controlled environment"[29]	The EU's Automated Decision Impact Assessment (ADIA) included the design of a policy prototyping programme which was four weeks long and was accompanied by a draft prototype law. Ten European AI companies took part in the prototype test, which sought to evaluate AI policy. It found that policy prototyping is effective in creating stakeholder collaboration, allowing them to experiment and develop new technologies and their regulation.[30]

Table 1. Experimental governance approaches: Definitions and examples

23 Financial Conduct Authority, 2015 **24** The legal definition, good practices and lessons learned of regulatory sandboxes is currently evolving, especially with their proposed role in the EU AI Act. For an overview of regulatory sandboxes in the EU AI Act and other jurisdictions, see Truby et al., 2022, p. 270 **25** World Bank, 2020 **26** Attrey, Lesher, & Lomax, 2020, p.11 **27** Ibid [21], p. 2 **28** Hook, 2017 **29** Ibid [22], p. 17 **30** Ibid [22]

The first chapter illustrated how the particular features of experimentalism might address the challenges posed by the Collingridge dilemma: first, by providing room for iteration and evaluation of technology and policy; second, by providing room for open multi-stakeholder collaboration. Yet, it has also been shown how past ways of implementing experimentalism into governance – i.e., through lawmaking, policymaking, and design – suffered from relevant limitations.[31] Completing the robust experimental governance framework, the following paragraphs elaborate the content of the three shifts pursued in response to those limits, and identify related governance approaches that help specify them in practice.

2.2. First component: Anticipatory governance

The first component entails a move from outpaced to anticipatory governance. In general terms, the concept of anticipation prompts technology developers and policymakers to ask "what if" questions based on what is known, likely, plausible, and possible.[32] As such, it requires tools to embed into governance systematic ways to *predict* future opportunities and risks (which reifies them by setting shared expectations around identified scenarios) and ways to ensure *participation* into shaping them (which allows multiple actors to be involved in the generation and exploration of such scenarios). On this basis, anticipatory governance has been defined as a "capacity extended throughout society [….] to manage emerging […] technologies while such management is still possible" – that is, to shape their purpose and prevent its risks in the early phases of technology and policy development.[33]

With respect to emerging technologies, anticipatory governance tools can be found both in foresight tools – e.g., horizon scanning[34] or scenario planning[35] – as well as in future scoping methods that are based on the discussion of desirable futures – e.g., upstream public engagements[36] or constructive technology assessments.[37] Yet, there is no clear established approach for how such tools could deal with the laws that govern emerging technologies. Moreover, there is no clear blueprint for how anticipation can be matched with experimentation.[38]

31 See this report's Chapter 1, Section 4 **32** Ravetz, 1997, pp. 533–539 **33** Guston, 2014, pp. 218–242 **34** Amanatidou et al., 2012, pp. 208–221 **35** Robinson, 2009, pp. 1222–1239 **36** Wilson & Willis, 2004 **37** Rip, Misa, & Schot, 1995) **38** For an interesting but understudied example, see Ramos, 2017, pp. 107–118

Tool	Definition	Example
Horizon scanning	A methodical exploration of potential future situations associated with the object of study. It has scope to explore issues at the fringes of present expectations as well as known lasting phenomena and weak signals. It serves to alert policymakers of potential issues and create potential solutions.[39]	For example, in Singapore, a national horizon scanning initiative took place under the Risk Assessment and Horizon Scanning program. This created a system that collects and understands data in order to discover emerging issues that might affect Singapore.[40]
Scenario planning	This serves to describe, assess, and evaluate potential alternative futures or present how complex processes might play out.[41]	For example, a nanotechnology research organization, called Frontiers, used scenario planning to inform workshops with stakeholders. This hoped to improve the understanding of problems, viewpoints, and dynamics to improve future plans.[42]
Upstream public engagements	This approach advocates for public dialogue to be incorporated early within the development of science and technology. This is opposed to leaving public engagement until later in the development process, where the public might hold back a technology's application due to skepticism.[43]	The UK Government sponsored an initiative called "GM Nation?", which sought to understand public opinion on genetically modified crops. This included facilitating a discussion amongst 250 people in Harrogate, UK, who were asked their thoughts on genetically modified crops. The initiative discovered huge public uncertainty about the technology.[44]
Constructive technology assessments	This approach focuses on the design and implementation of technologies, rather than assessing their impact. It seeks to methodically strengthen the cooperative nature of technology production and the integration of regulators and improve the discussion and learning around technologies.[45]	The approach was used by the Dutch government to enhance digital skills and new digital development in Amsterdam in the 1990s. During the project, citizens tested e-mail and internet technologies to improve their abilities and provide information for developers.[46]

Table 2. Anticipatory governance tools: Definitions and examples

39 Ibid [33] **40** Chong et al., 2007 **41** Ibid [34] **42** Ibid [35], p. 1223 **43** Ibid [35] **44** Ibid [35] **45** Ibid [36] **46** Schot, & Rip, 1997, p. 254

2.3. Second component: Stakeholder-inclusive governance

The second component entails a move from top-down to stakeholder-inclusive governance. The goal of stakeholder-inclusive governance is to ensure that the voices of all societal actors affected by the uses and exposed to the effects of emerging technologies are heard and able to shape key decisions informing their development.[47] Yet, not all forms of inclusion are the same. Depending on the framing of the dialogue, the act of including more and diverse voices in governing emerging technologies can range from effective – e.g., when decision making is informed or influenced by the outcomes of such a dialogue – to tokenistic – e.g., when dialogue is instrumentally exploited only to increase the legitimacy of expert authority.[48] To prevent the latter outcome, it is key to ensure that multi-stakeholder dialogue is proceduralized by paying close attention to at least three components that can help ensure its effectiveness: (i) intensity – i.e., how early and how recurrently actors are consulted; (ii) diversity – i.e., who is represented and how diverse the group is; and (iii) quality – i.e., the gravity, continuity, and impact of the discussion.[49]

Moving from the theory to the practice of stakeholder-inclusive governance, its tools can be grouped in two sets. The first refers to mini-publics: small-group public dialogues that feed into decision-making by means such as consensus conferences, citizens' juries, and focus groups.[50] The second is more diversified and aims at widening the inputs of and ways of delivering governance while maintaining centralized decision-making at its core – e.g., via focused multi-stakeholder partnerships,[51] inclusion of lay members in advisory bodies,[52] or "user-centred" and "open innovation" methodologies.[53] Compared to anticipatory governance, these tools show the ability of the stakeholder-inclusive governance to address both technology and policy. Yet, it remains unclear how they could fit within a robust experimental governance framework. On the one hand, public consultation seems to be gradually paving its way into relevant policy processes. For example, the EU has adopted this process in creating its AI White paper.[54] Further, the OECD expounds the improvements to "transparency, efficiency and effectiveness of regulation" that public consultations bring.[55] In practice, the tool has been used by the OECD in the development of tax policy relating to digitalization. On the other hand, it is still to be seen whether exercises like the ones that are mentioned here can be deemed truly experimental in nature or are in fact initial tokenistic attempts to provide preconceived decisions with forms of external validation.

47 Stirling, 2008, pp. 262–294 **48** Irwin, 2006, pp. 299–330 **49** Callon, Lascoumes, & Barthe, 2009 **50** Goodin & Dryzek, 2006, pp. 219–244 **51** Bäckstrand, 2006, pp. 290–306 **52** Brown, 2002, pp. 369–385 **53** von Hippel, 1976, pp. 212–239 and Chesbrough, 2003 **54** European Commission, 2020. **55** OECD, n.d.

Tool	Definition	Example
Mini-publics	Relatively small groups of people are brought together to discuss issues. The groups must be sufficiently small to allow for meaningful discussion and often consider representation carefully. Mini-publics can include consensus conferences, citizens' juries, and focus groups.[56]	AmericaSpeaks organizes events that include a representative group of 500-5000 people. At the events, moderated group discussions happen between roughly ten people. The outcomes of these discussions are collected on computers, which sort the discussions based on themes and information. Also, publications are created by stakeholders to help inform the debates. For example, an AmericaSpeaks event took place after 9/11 about rebuilding Manhattan.[57]
Public-private partnerships	Collaborative networks of multi-sectoral organizations, which combine their facilities and knowledge bases and share risks in order to solve collective problems. They can encourage innovation and systemic solutions. There may be costs associated with reconciling organizations with different values and institutional processes.[58]	Founded in 2008, the World Economic Forum's New Vision for Agriculture, Grow Africa and Grow Asia is an ongoing collaboration between regulators, food suppliers, and civil society. It aims to make food supply chains and consumption more environmentally sustainable, secure and economically successful.[59]
User-centred innovation	A development process in which the users of an instrument play the primary role in creating, prototyping, and testing the instrument, as opposed to instrument manufacturers.[60]	Students at Stanford University created a successful prototype of a nuclear magnetic resonance instrument, which was quickly developed into a market model by the Varian engineering company in 1954.[61]
Open innovation	An approach that encourages the use of ideas from internal and external sources for developing new technologies. In this sense, emerging technologies are licensed to external operators. This helps ensure that good ideas are not neglected due to a closed business model.[62]	Intel has always adopted an open innovation model. It has used outside innovation to its advantage by quickly moving it in-house to follow market trends fast. It also invests in small technology companies, allowing them further access to innovative technologies.[63]

Table 3. Stakeholder-inclusive governance tools: Definitions and examples

56 Ibid [47] **57** Ibid [47], 224. **58** Stibbe & Prescott, 2016, pp. 1-3 **59** Ibid [55], p. 2 **60** Ibid [50] **61** Ibid [50], p. 225 **62** Ibid [50] **63** Ibid [50]

2.4. Third component: Holistic governance

Lastly, the third component entails a move from piecemeal to holistic governance: i.e., a governance approach that is capable of embracing the various stages of both technology development *and* policymaking processes, looking at them in their entirety. On the one hand, the shift to holistic experimental governance is prompted by the fact that – as seen in the previous chapter – most experimental design practices have been left at the margins of governance systems.[64] On the other, it also stems from the recognition that the governance of emerging technologies demands better approaches to reduce the intrinsic uncertainty related to the effects of both technology development and regulatory practices, while still demanding greater alignment between the goals of both technology and policy.[65] To do so effectively, it is key to devise governance processes that help diverse stakeholders – such as public, private, and civic – navigate such uncertainty by facilitating a stronger alignment of the overall direction and purpose of both innovation and policy and strengthening it by means of holistic experimentation.[66]

In this respect, despite strong innovation in the last decade (e.g., adaptive, outcome-based, risk-based, or collaborative approaches[67]), traditional regulatory management tools – such as regulatory impact assessment, stakeholder engagement, or ex-post evaluation – have largely been insufficient in ensuring that such alignment is nurtured.[68] To be clear, ongoing efforts at the European level show that policymakers are starting to leverage tools and mechanisms that can help them enable the purposeful governance of emerging technologies *before* and *after* the implementation of a given policy – as shown, for example, by the new Better Regulation guidelines.[69] However, it is still to be seen how these tools will be implemented in practice; whether they will be enough to permeate the whole policy process; and whether they can be integrated with the tools and approaches that, as seen in the report, can be key to governing emerging technologies. With respect to emerging technologies, holistic mechanisms of governance can also be found in lesser known but promising tools such as grand challenges,[70] strategic niche management,[71] and technology stage-gating.[72] These are capable of addressing both technology and policy through a more agile understanding of decision-making processes that encompass the entirety of their development. In addition, some of them also enable the fast iteration of both technology and policy, thus demonstrating the value and usefulness of how policy experimentation could and should be integrated in such a governance approach.[73]

64 Lewis, McGann & Blomkamp, 2020, pp. 111–130 **65** Ibid [19] **66** te Kulve, & Rip, 2011, pp. 699–714 **67** Eggers, Turley, & Kishnani, 2018 **68** Ibid [10], Chapter 1, Key findings **69** European Commission, 2021 **70** Kuhlmann & Rip, 201, pp. 448–454 **71** Schot & Geels, 2008, pp. 537–554 **72** Högman & Johannesson, 2013, pp. 264–287 **73** See e.g. use of stage-gating in Fuchs, 2010, pp. 1133–1147

Tool	Definition	Example
Grand challenges	Grand-scale and unrestricted missions, which involve innovation that relates to a diverse range of actors and dynamics in the socio-economic system.[74] The approach is ambitious in scale. Without clearly defined end goals, it is potentially hard to determine the success of these missions.	The Bill and Melinda Gates Foundation has an agenda to improve public health and develop countries, while orchestrating a network of governments and companies to help these challenges.[75]
Strategic niche management	An approach that creates safe spaces for the cooperative development of new technological niches and their uses and regulation. This is thought to ensure technological innovation is sustainable.[76]	In 1998, a European Union project used strategic niche management within its Environment and Climate RTD program. Scholars investigated new transport developments in European cities.
Technological stage-gating	A management model for product development, typically involving five stages: scoping, business case, development, testing, and launch.[78]	Companies in Sweden have implemented a form of the model to great effect. It was found out that different companies varied specific features of the model in its application, such as the number of gates.[79]

Table 4. Holistic governance tools: Definitions and examples

Before moving to the next section, Table 5 (on the next page) provides a comprehensive overview of the key contents of the robust experimental governance framework; i.e., a definition and a set of governance approaches and tools for its core principle and three components. In this sense, it is key to note that, while each tool has been assigned to specific components for readability and illustrative purposes, some of them may also serve the purpose of other components. Moreover, given the broad conceptual array of the framework, each shortlist of approaches and tools is not meant to be complete and definitive but rather an attempt to exemplify the potential connection between different streams of governance theory and practice and experimental governance. While this section attempts to provide shortlists that are as exhaustive as possible, further research and additions are welcomed.

74 Ibid [67], p. 450 **75** Ibid [67], p. 451 **76** Schot & Geels, 2008, pp. 537–554 **77** Ibid [73], p. 551 **78** Högman. & Johannesson, 2013, pp. 264–287 **79** Ibid [75], p. 284

Core principle	Definition	Governance approaches
Experimental governance	A recursive approach to the design and implementation of collective decisions based on the iterative review and learning from their effects.	**Experimental lawmaking:** • (e.g.) Regulatory sandboxes **Experimental policymaking:** • (e.g.) Testbeds and living labs **Experimental design:** • (e.g.) Policy prototyping

Component	Definition	Governance tools
Anticipatory governance	A mode of governance that aims to leverage a variety of inputs to manage emerging technologies while it is still possible to do so.	**Foresight methods:** • Horizon planning • Scenario planning **Future scoping methods:** • Upstream public engagement • Constructive technology assessments
Stakeholder-inclusive governance	A mode of governance that aims to ensure that the voices of all societal actors affected by emerging technologies are heard and able to inform their actual development.	**Mini-publics:** • Consensus conferences • Citizens' juries • Focus groups **Selective involvement:** • Public-private partnerships • Lay membership in expert bodies • User-centred or open innovation
Holistic governance	A mode of governance that is capable of embracing both key technology development and policymaking processes as a whole rather than separate, and throughout the different stages of the policy process.	**Regulation policy:** • Adaptive and risk-based regulation • Performance-based regulation • Self- and co-regulation **Governance mechanisms:** • Societal grand challenges • Strategic niche management • Technology stage gating

Table 5. Robust experimental governance framework: A comprehensive overview

03

Interpreting contemporary governance of emerging technologies

This section presents major examples that have characterized the experimental governance of emerging technologies during the last decade. Such examples are drawn from existing applications of the three governance approaches that have been illustrated in the previous section on the principle of experimental governance: i.e., regulatory sandboxes, testbeds, and policy prototyping. At their core, these approaches are characterized by their capacity to embed experimentalism across different stages of the policy process. However, the ways in which they have been designed and implemented so far have been rather disparate and have only rarely addressed both technology and policy in an anticipatory, stakeholder-inclusive, and holistic fashion. For this reason, the present analysis concentrates on whether and how the six relevant case studies from across the world have been able to integrate these dimensions in their design and implementation. As such, by leveraging the insights from this analysis, the chapter aims to uncover gaps, best practices, and ways forward towards the development of a robust experimental governance framework for emerging technologies.

In order to do so, the analysis presents two case studies for each of the three components in the framework – anticipatory, stakeholder-inclusive, and holistic governance – hence presenting a total of six case studies. To facilitate their comparability, these are organized according to four main elements: context, approach, outcomes, and assessment. For the sake of analytical convenience, each subset of case studies presented for the three components leverages one experimental approach, such that anticipatory governance is explored by means of regulatory sandboxes, stakeholder-inclusive governance by testbeds, and holistic governance by policy prototyping. At the same time, the following two caveats are worth mentioning:

- The first caveat is that, as pointed out above for governance tools, the three governance approaches may (and in fact do) serve various components of the framework at the same time. As such, while the analysis of the three governance approaches goes hand in hand with that of the three shifts, a relationship among components and approaches is not necessarily implied in this analysis.

- The second caveat is that, while the previous section highlighted how different components can be translated into concrete governance tools, these are purposely not leveraged in this analysis. This is due to the fact that no case study has been found that foresees a purposeful integration between the three governance approaches and governance tools. As such, the latter are meant to provide more of an ideal benchmark for how to proactively foster anticipation, inclusion, and holism in experimental governance, rather than as tools for analysis.

3.1. Towards anticipatory governance

The goal behind anticipatory governance is to embed into the policy process new ways to predict future opportunities and risks related to technology development as well as to ensure broader participation in shaping them.[80] Keeping this goal in mind, the recent development of regulatory sandboxes that targeted groundbreaking AI applications as well as their development processes can illustrate interesting insights – as well as challenges – for how to do so in practice.

For example, Malta's Digital Innovation Authority (MDIA) developed a Technology Assurance Sandbox that aims to ensure that newly emerging technologies leveraging data are designed and implemented while considering the potential issues that might arise during their subsequent adoption and diffusion. As a result, the certification released by the MDIA provides a guarantee to external investors and stakeholders that the innovative products and services being developed through the sandbox are aligned with the relevant international standards (see Case study 1).[81]

Another relevant example is Colombia, where the national Superintendence of Industry and Commerce (SIC) built a sandbox focused on advancing "privacy by design and by default." The goal is to provide public and private companies with a space where they can both develop innovative AI-based products and strengthen their compliance with existing data privacy laws. The main outcomes of this process include not only the creation of AI products that are respectful of individual rights but also the opportunity for key regulatory authorities to grasp the characteristics of recent technology advances and elaborate new suggestions on how to adjust or adapt national laws accordingly (see Case study 2).[82]

On the one hand, these two case studies illustrate how regulatory sandboxes can anticipate compliance issues and mitigate infringement risks that are related to emerging technologies by assessing the efforts made by developers in the first place. On the other hand, they only provide initial evidence for how to embed stakeholder-inclusiveness and holism within them. With respect to stakeholder-inclusiveness, they favor participation only within the strict rules predefined by the sandbox. With respect to holism, they assess the implications of technology development without explicitly considering those stemming from policy – which is taken "for granted." As a result, part of their potential is lost in favor of a more conservative goal – that of ensuring compliance with existing regulation. Overall, the case studies mentioned above still show promising developments with respect to both dimensions – e.g., in terms of their efforts to include multiple stakeholders' views in the design phase of the sandbox and in the search for opportunities to update existing regulations in light of new learnings. However, the road for systematizing these practices and making the most of them is yet to be explored.

80 Here is an example of how one framework component can feed into another **81** Malta Digital Innovation Authority, 2022 **82** Superintendence of Industry and Commerce, 2021

Case study 1: Malta

MDIA's Technology Assurance Sandbox

Context

Malta Digital Innovation Authority (MDIA) was established in 2018 with the goal of setting and enforcing standards that ensure compliance with international obligations and of becoming a centre of excellence for technological innovation. The Technology Assurance Sandbox (TAS) is its flagship program.

Approach

MDIA's TAS aims to provide start-ups and small businesses with a custom journey experience for the development of innovative technologies. The journey consists of a two-year residency, composed of three key phases. First, the standard onboarding phase requires applicants to submit a business plan, a residency plan, and a technological blueprint to MDIA, which then assesses whether the proposal is suitable for residency. Applicants must also identify a Technical Officer (ensuring data protection compliance in the residency) and a System Auditor (conducting technical assessments). Then, the monitored residency phase provides personalized access to two functions: (i) the iterative assessment of technology development as performed by the System Auditor and (ii) eased change management procedures, for technical or administrative hurdles. Lastly, once all technical assessments have been done to the satisfaction of the System Auditor and MDIA, the standard off-boarding phase concludes with the exit of the applicant from the TAS and the publication of the end results on the Authority registry. The overall process is supported by the setup of a forensic node whose purpose is to maintain an audit log of the system's operations and transactions, hence supporting potential system audits or requests for information regarding legal compliance and the operational behavior of the system.

Outcomes	After a defined number of assessments, applicants can obtain full MDIA certification, indicating that the solution provides technological assurance for stakeholders such as investors and end users. Technological assurance is determined on the basis of control objectives that are aligned with international standards (including EU regulation), hence making the solution more trustworthy in the eyes of both potential investors and users.
Assessment	MDIA's TAS ensures that newly emerging technologies leveraging data are designed and implemented while considering the potential issues that might arise during implementation – e.g., failing to meet data protection standards. Moreover, the way in which MDIA's services are provided allow a high degree of customization, with the residency in the TAS being phased in a manner that is appropriate for the needs of each particular Applicant. Nonetheless, MDIA's sandbox does not allow for the iterative experimentation and assessment of the effects of established regulation, hence limiting the possibilities for the development of both holistic and stakeholder-inclusive governance.

Case study 2: Colombia

SIC's Regulatory Sandbox

Context

In 2019, Colombia's Superintendence of Industry and Commerce (SIC) published two key documents: (i) a policy brief concerning the use of personal data processing for e-commerce, marketing and (ii) advertising purposes and a set of guidelines to operationalize accountability in the international transfers of personal data. In 2020, these work streams fed into the publication of a document focused on a new sandbox adopting a "privacy by design and by default" approach in AI projects. After its release, the document was opened up for consultation from stakeholders.

Approach

The privacy by design and by default regulatory sandbox carried out by SIC aims to offer national and international companies, from the public and private sectors, an experimental space where they can strengthen compliance with data privacy laws and mitigate infringement risks. As such, the sandbox supports companies in structuring the design of AI projects involving personal data processing through customized advisory and guidance. Following the 2019 guidelines mentioned above, the sandbox entails that Privacy Impact Assessments (PIAs) are performed collaboratively prior to the design and development of AI projects. The results of PIAs and the measures for risk mitigation that emerge from the assessment (e.g., guarantees, security measures, software design, technology, and mechanisms) are then implemented into the sandbox. Once at the development stage, the identification of feasible solutions is then initiated in collaboration with SIC's office of the Deputy Superintendent for the Protection of Personal Data, who supports the process by means of providing feedback, recommendations, and observations.

Outcomes

The intended outcomes of SIC's regulatory sandbox include: (i) the adequate processing of personal data as an essential component of the design and implementation of AI projects; (ii) the establishment of criteria and procedures that can facilitate compliance with current regulation on personal data processing; and (iii) the creation of AI products that are respectful of individual rights and in accordance with the regulations that relate to their processing. In addition to those, the SIC also mentions the possibility of leveraging the regulatory sandbox to elaborate new suggestions or even recommendations to adjust, correct, or adapt Colombian regulations in the light of emerging technological advances. Most importantly, it also mentions the primary objective of consolidating a preventive and proactive approach to the protection of human rights within AI projects.

Assessment

In this case study, organizational accountability and human rights protection are put at centre stage. The approach sets an interesting process to foster trust in public as well as private organizations that are willing to join the sandbox and therefore commit to the privacy by design and by default principles proposed by the SIC. Additionally, the collaboration between authorities and companies reduces information asymmetry in a way that, while participating organizations may gain access to knowledge on privacy by design and by default tools, regulators are also able to make more informed decisions along the way. As such, at least in theory, the sandbox can contribute both to reinforcing compliance with existing regulations and informing new regulations – an element that also feeds into the development of a holistic governance approach to emerging technologies.

3.2. Towards stakeholder-inclusive governance

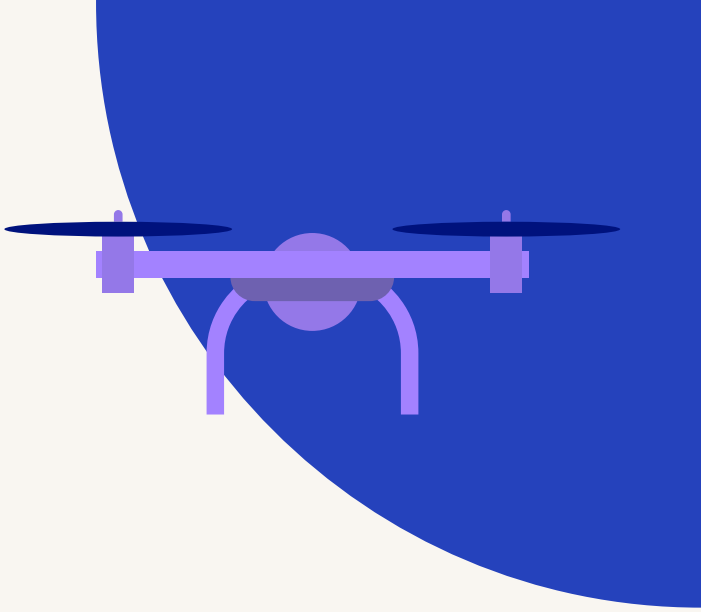
The goal of stakeholder-inclusive governance is to embed into decision-making processes effective, non-tokenistic multi-stakeholder dialogue on three grounds: (i) intensity – i.e., how early and how recurrently in the process actors are consulted; (ii) diversity – i.e., who is represented and how diverse the group is; and (iii) quality – i.e., the gravity, continuity, and impact of the discussion.[83] With respect to this goal, the increasing use of testbeds that target several emerging technologies provides interesting insights also with respect to AI governance.

While not a case of testbedding per se, the approach adopted by the Rwandan Civil Aviation Authority (RCAA) to improve blood delivery in hardly accessible rural areas allowed them to test different ways to design and develop both emerging drone technology *and* its related regulation. Crucially, what enabled the adoption of this approach was the intentional effort to convene the right stakeholders at the same table, ranging from a US-based start-up to the Rwandan Ministry of Health, and from a newly created Drone Advisory Council (DAC) to the World Economic Forum (see Case study 3).[84]

Overall, the two testbeds illustrated here prove how new solutions for achieving common understanding and promoting a participatory culture to clearly identified local challenges can help promote collaboration among stakeholders and nurture mutual trust. Moreover, it is evident how – while not necessarily communicated as such (as in the case of Rwanda) – experimentation is very much at the core of testbedding. The experimentation element is present in how these two testbeds enabled different stakeholders to test out their assumptions about what works within a real-life context and assess the results together. At the same time, while the two case studies show a high quality of the dialogue, they both present different degrees of diversity (narrower in Rwanda and wider in Melbourne) and a relatively low intensity. In addition, while the Rwanda case successfully led to the definition of innovative rules, it remains to be seen if and how "pure" testbeds – such as the one promoted in Melbourne – are able to effectively promote lasting regulatory innovation on a permanent basis.

Instead, the case of Melbourne provides an example of a testbed focused on a wide range of emerging technologies – such as 5G or the Internet of Things. By pushing the ambition of stakeholder-inclusiveness beyond the multi-stakeholder approach adopted in Rwanda, Melbourne leveraged the testbed as a tool for strategic experimentation with an ever-growing number of local and national industry partners and as a platform to promote citizen engagement at the urban scale. Devising many types of experimentation tools – e.g., challenges, pilots, and trials – the approach helped consolidate a more innovative environment by providing (i) room for broad collaboration; (ii) new rules and procedures for experimenting with emerging technologies; and (iii) innovative connections between the digital and physical space (see Case study 4).[85]

83 Ibid [46] 84 WEF, 2018 85 Participate Melbourne, n.d.



Case study 3: Rwanda

RCAA's Multi-stake-holder Approach to Drone Regulation

Context

In 2016, the Government of Rwanda partnered with the US-based drone start-up Zipline to improve the delivery of blood in hardly accessible areas of rural Rwanda. Prior to the partnership, the complexity of Rwandan regulations for private and public unmanned aircraft operations reached stalemate in terms of leveraging new technologies to advance delivery operations.

Approach

In 2018, the Rwandan Civil Aviation Authority (RCAA) partnered with the Ministry of Health, the national Drone Advisory Council (DAC), and the World Economic Forum Centre for the Fourth Industrial Revolution to overcome key regulatory bottlenecks, foster a new ecosystem for unmanned operations, and expand on opportunities to benefit from drones while mitigating potential risks to other participants. As a result of the partnership of the Ministry of Health with DAC and Zipline, a number of performance-based regulations[86] were devised in order to allow regulated parties to select the process or tools that are best suited to achieve the key objective while also ensuring compliance with different risk and safety profiles.

86 NB: As shown in Table 4, performance-based regulation is a governance tool classified as conducive to holistic governance. In the context of this case study, indeed, its use provides an example of how different methods – such as performance based regulation and public-private partnerships – can be combined to ensure a robust governance approach to emerging technologies.

In addition, measures for community outreach and engagement were devised so as to ensure that public acceptance of new technologies was achieved and public concerns about the use of technology were mitigated. As a result, regulated parties were able to find more consensual, cost-effective, and efficient solutions for the goals and outcomes mutually agreed upon between the regulators and the regulated community.

Outcomes

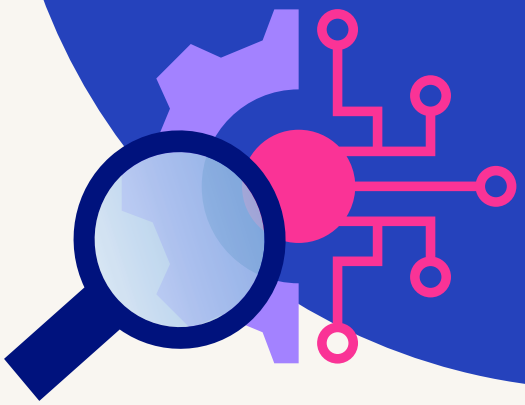
Trust and accountability between the regulator and regulated community were established through new governance structures – such as cross-ministerial councils and public–private forums. In turn, the ensuing collaboration enabled the local drone ecosystem to flourish while still maintaining safety. As an end result, the approach led to the broader societal adoption and scaling of the drone delivery technology, hence feeding into the expansion of blood delivery to 95% of the country.

Assessment

The RCAA case proves that increased mutual understanding between the parties that are involved in the innovation process was key to ensure both technology deployment and its adherence to societal purposes. To succeed, new goals, guidelines, and standards had to be clearly identified and agreed upon by all stakeholders and measured accurately. While the collaboration methodology did not explicitly leverage experimentation as a policy principle nor as an implementation strategy, the versatility of the approach adopted for determining, verifying, and monitoring compliance was key in lowering administrative costs without predetermining the actual outcome of the technology development process.

Case study 4: Australia

Melbourne's Emerging Technology Testbed



Context

In 2018, the City of Melbourne established a testbed to explore the opportunities, challenges, and impacts of new and emerging technologies in a real-world urban context. Alongside expanding their understanding of how to apply emerging tech in the city and their potential benefits and risks for the community, the data insights accumulated from it were also expected to inform the municipality's decision-making process on matters of efficiency, comfort, inclusiveness, and equity.

Approach

The City of Melbourne leveraged the testbed as a tool for collaborative, strategic and transparent testing of the opportunities and impacts of new technologies. The process involved 26 local and national industry partners, who were invited to pitch their responses to three key issues: (i) public space connectivity – e.g. for 5G; (ii) strategic data collection on city activity – e.g., for IoT; and (iii) improving the experiences of living, working and playing in the city – e.g., urban technology hardware. The proposed responses were tested through challenges (i.e., innovation-pitch competitions addressing city issues), pilots (i.e., collaborative projects focused on the explorative application of emerging technologies), and trials (i.e., large-scale experimental implementations leveraging relevant industry collaborations).

The groundwork prior to their implementation required investment in data capture and analysis; establishing new partnerships for permission to enable experimentation; and facilitating community and industry engagement in order to prompt idea and innovation sharing.

Outcomes

Among the projects developed, there are *Data In The Park* (focusing on using sensors to understand how citizens live in the public space and can contribute to shape it) and *Reimagining the City* (inviting all stakeholders to propose new ideas on how to bring life back to the city and to establish new ways to realize these ideas). In turn, the establishment of these projects helps consolidate the three core elements of the testbed: (i) room for collaboration – i.e., collective effort to co-create new guidelines for the governance of issues concerning emerging technologies; (ii) novel rules and procedures – i.e., as the outcome of such co-creation and of the testing of their own effects; and (iii) innovative connections between the digital and physical space – e.g., by new delivery channels, data platforms, communication networks, and physical sensors.

Assessment

The City of Melbourne testbed promotes a participatory culture for the governance of emerging technologies in a real-world urban context while also nurturing trust among stakeholders. Moreover, the data accumulated in real-time assists informed decision-making and lowers information asymmetries between public organizations, private companies, and citizens. Looking forward, the City of Melbourne is now exploring new ways for the community to orient the testbed activity; promote transparency to the process; and find new ways to communicate tech and data use to the community. The pilots present many applications for real-world experimentation, hence potentially increasing public awareness and trust in emerging tech. Overall, while the testbed does not address the issue of how to build iterative regulation per se, it ensures that the purpose behind its definition follows commonly agreed objectives.

3.3. Towards holistic governance

Lastly, the goal of holistic governance is to embed within the policy process new ways to enable positive synergies between technology and policy throughout the policy process – i.e., from technology ideation and policy design to technology assessment and policy evaluation. With respect to this goal, new policy prototyping methodologies that aim at fostering the development of novel governance processes for emerging AI applications constitute a key source of inspiration.

One example of a similar approach can be found in the United States, where the Food and Drug Administration (FDA) developed a methodology that enables the holistic evaluation and monitoring of software as medical device (SaMDs) products that are increasingly used in the health sector (from pre-market development to post-market performance) as well as the development of new regulatory approaches that are suited for these emerging technologies. Named "Total Product Lifecycle," the approach was based on a Software Precertification Program that has been previously prototyped by the FDA in a real-life setting. Its purpose was to provide developers with tailored and less burdensome regulations based on their own ability to iterate and update their products to the required safety and effectiveness standards as soon as new issues arise after market distribution. As such, the approach allowed the FDA both to promote a culture of trust and transparency among developer organizations and to verify the safety of products in post-market developments (see Case study 5).[87]

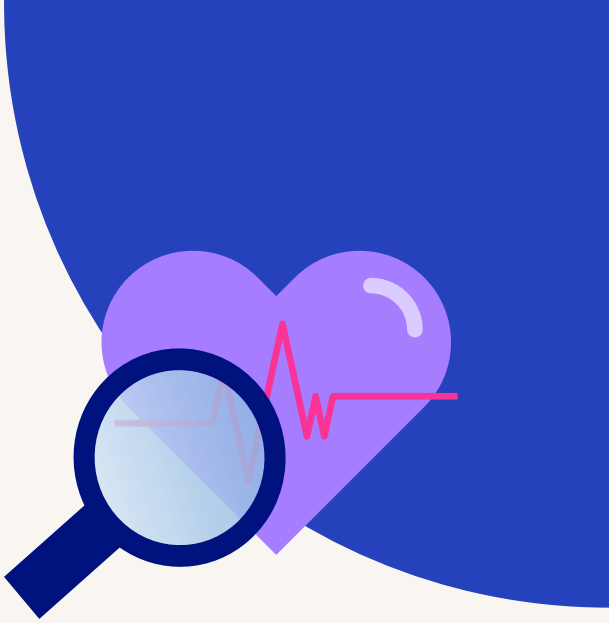
Besides FDA's approach, Singapore's Ministry of Health provides another interesting example of how to develop, test, and iterate policy along with the development of another set of emerging technologies: the use of robots and autonomous systems in long-term care (LTC). To explore their potential, the Ministry leveraged, along with substantial funding, three sets of tools: (i) new spaces for collaborative experimentation with industry players – e.g., through a new Centre for Healthcare Assistive and Robotics Technology (CHARTS); (ii) the involvement of governmental bodies – e.g., the Housing Development Board – to develop real-life pilots; and (iii) regulatory innovations – e.g., the Robotics Middleware Framework, acting as a guideline for organizations to co-create smart health systems solutions. By doing so, the Ministry maintained a flexible approach to decision-making while steering the innovation process in a holistic fashion – i.e., throughout the policy process. While the road to broad adoption of such technology is still long, the approach succeeded in fostering the local ecosystem's experimental spirits as well as in paving the way for a more flexible regulatory framework (see Case Study 6).[88]

Despite their diversity, the two case studies share one common feature: both illustrate the potential of mechanisms that are capable of ensuring the synergy of parallel technology development and policy processes. The FDA's TPLC approach proved the need to ensure that emerging technologies align with societal needs well beyond initial regulatory approval, and adapt regulatory and legislative frameworks to a changing industry context. Singapore's systemic approach, instead, made a powerful case for evaluating the experimental character of any given governance system beyond regulation, as well as for leveraging multiple governance tools in order to ensure that the system covers both technology and policy development from beginning to end.

87 Food & Drug Administration, 2022 **88** Tan & Taeihagh, 2021, pp. 211–231

Case study 5: United States

FDA's Total Product Lifecycle Approach



Context

Among the goals observed by its mandate, the US FDA has set the objective of advancing public health by helping speed innovations that can make medical products safer, more effective, and more affordable. In this context, the rise of software as a medical device (SaMD) during the last decade promises to enhance the ways in which health systems treat, diagnose, cure, mitigate, or prevent disease and other conditions.

Approach

From 2017 to 2022, the FDA's Total Product Lifecycle approach (TPLC) aimed to enable the evaluation and monitoring of a software product from pre-market development to post-market performance, thus providing users with continued demonstration of the excellence and trustworthiness of the product and the company producing it. In order to do so, the TPLC approach consisted of a methodology for the revision of the FDA's internal policy process towards greater agility and experimentation. Moving from the premise that the existing framework was not well suited to the faster cycles of innovation and the speed of change needed to fit industry evolution, the TPLC approach was developed on the basis of a pilot – the Software Precertification (Pre-Cert) Pilot Program. The Pre-Cert first looked at the technology developer through "retrospective testing" of its own trustworthiness (i.e., based on SaMD regulatory submissions previously reviewed) as well as the "prospective testing" of its products' (i.e., based on voluntary product submissions to innovative assessment pathways). Its goal was to

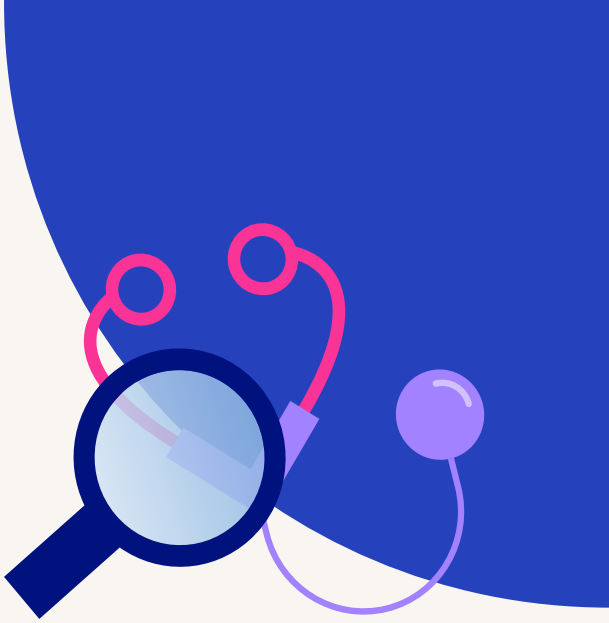
provide a reasonable assurance of safety and effectiveness of new products when compared with the traditional regulatory paradigm – and ways to amend and improve products if issues with their public use arise – while at the same time retaining flexibility within how the regulatory framework could be implemented, assessed, and revised to fit the changing technological context. As such, the Pilot Program aimed to embed experimentation into the FDA's policy process, e.g., in terms of policy formulation (by leveraging evidence to understand gaps and needs in the existing regulatory framework), decision-making (by informing its decisions based on case-by-case analysis), implementation (by observing how the new products interact with the existing regulatory framework), and evaluation (by formulating original proposals for amending it).

Outcomes

On the one hand, the Pilot helped the FDA better understand the practices that companies use in designing, developing, and managing digital health products and infer from those lessons for developing a more agile and flexible policy process. On the other hand, it also showed major limitations in the FDA's existing statutory authorities that limited its ability to pilot the TPLC approach with a broader sample of devices and better target its implementation to sets of apt technologies. As a result, in 2022, the end of the 5-year pilot resulted in the publication of a report identifying key recommendations for legislative change and authority that would be necessary to support the development and implementation of a new, holistic regulatory paradigm.

Assessment

The FDA case provides a two-faced account of the possibilities and difficulties that pertain to the advancement of holistic governance. Indeed, the TPLC approach (and the Pre-Cert Pilot Program that tested its potential) showed that valuable insights can be gained by an integral revision of the agency's policy process that aims to interweave technology and policy development on the basis of experimentation – notably, while also providing room for anticipation and inclusion. At the same time, it also showed a need for broader reform in the legislative context surrounding the agency's activity as critical to help both the public and private stakeholders not only make the most of a holistic governance approach but also enable its upscaling in the first place.



Case study 6: Singapore

Ministry of Health's Systemic Piloting Approach

Context

In the last decade, Singapore has experienced an unprecedented increase in population ageing, while its old-age support ratio has declined substantially and the downward trend is expected to continue. This does not bode well for the country's labor force and economy in the long run. As Singapore's demographic structure transitions to one with an older profile, this means the demand for long-term care (LTC) services and the associated public spending will increase as well. To this end, the Singapore government's Ministry of Health (MOH) explored the adoption, deployment, and development of robots and autonomous systems in LTC.

Approach

From 2014 to today, the MOH launched various initiatives to advance the development and deployment of robots and autonomous systems in the LTC and health sector at large. From an institutional perspective, the National Health Innovation Centre (NHIC) and the Centre for Healthcare Assistive and Robotics Technology (CHARTS) were established to support innovative healthcare technology development and implement it. To embed experimentalism into policy formulation, a number of design and living labs were created to facilitate collaboration across a diverse range of industries and sectors. The experimental approach was extended to policy decision-making and evaluation – with the MOH, for example, collaborating with actors such as the Housing Development Board (HDB) to roll out pilot projects from 2016 onwards (e.g., installing elderly monitoring systems within public housing structures occupied by lone elderly residents).

Finally, as the program pilots yielded new results, the experimental governance approach was also translated into policy implementation – e.g., via tools such as the Robotics Middleware Framework (RMF) for healthcare, which was launched in 2018. In this perspective, the RMF served both as a framework for the adoption and integration of technology systems within and beyond healthcare and as a guideline for organizations to co-create along with public entities smart health systems solutions.

Outcomes

By leveraging a plethora of governance tools and approaches scattered throughout the policy process, the Singapore government's Ministry of Health managed to spur a comprehensive pathway for the adoption, deployment, and development of robotics and autonomous systems in LTC. To do so, the MOH betted on sustained collaboration with the private sector as well as continuous experimentation throughout the phases of both technology and policy development. As a result, the country has become a global forerunner in the development of such industry and developed a regulatory framework that is both flexible enough to foster innovation while at the same time, focus on the respect of ethical safeguards and priorities.

Assessment

The Singapore case shows how effective governance goes beyond issues of regulation and addresses the need for continuous experimentation around both the essential processes and purposes of technology and policy. In this case, through the leadership and facilitation of the MOH, the government accomplished two paramount innovations linked to the development of a holistic governance approach: On the one hand, it crafted new capacity for collaboration and experimentation by establishing a new set of national innovation centres; on the other, it devised an integral "pathway for experimentation" around such new structures by leveraging multiple governance tools – such as design and living labs, public–private partnerships that revolved around pilots, as well as regulatory frameworks based on increased flexibility. While not mentioning grand challenges nor strategic niche management, the emerging approach presents elements of both holistic tools – hence showing the potential that a holistic approach to the governance of emerging technologies can have.

04

Uncovering gaps and ways forward for governance and technology

The six case studies illustrated in the previous section highlight how different experimental approaches – e.g., regulatory sandboxes, testbeds, and policy prototyping methodologies – are leveraged in the landscape of contemporary governance of emerging technologies. As a result, this analysis accumulated a number of initial insights into whether and how they can help show what a robust experimental governance framework might look like in practice.

- First, the analysis showcased how prominent examples of regulatory sandboxes are now advancing elements of anticipatory governance by establishing arenas in which innovators can deal with compliance issues and mitigate infringement risks related to their use of emerging technologies. By doing so, they also demonstrate how private stakeholders can engage with regulation at the early phases of their own innovation process – so as to embed greater stakeholder-inclusiveness within them, as Malta did (see Case Study 1). Yet, sandboxes tended to narrow down their experimental potential by limiting the participation of stakeholders and decision-making only to the phase of policy implementation – i.e., when the regulatory framework has already been defined – hence failing to address the entirety of the policy process. In this perspective, the natural step forward for regulatory sandboxing seems to be finding ways to leverage their potential in order to inform future policies and update existing ones; a step now attempted, for example, in Colombia (see Case Study 2).

- Second, the analysis assessed the ability of contemporary testbeds to promote a stakeholder-inclusive governance approach by showing how they may help advance collaboration and mutual trust among public, private, and societal actors by means of experimentation. The case of Rwanda, for example, illustrated how their approach can not only succeed in doing so by leveraging complementary capabilities all over the steps of policy formulation and decision-making but also result in more agile and anticipatory regulatory frameworks (see Case Study 3). Yet, it has also been shown how different implementation strategies can lend multi-stakeholder dialogue up to different degrees of intensity, diversity, and quality. In this respect, the challenge of scalability provides a key obstacle for testbedding: arguably, a reason explaining why best practices can be found at a local level – as in Melbourne (see Case Study 4).

- Third, the analysis also explored how innovative methodologies closely related to the emerging approach of policy prototyping can also help foster a holistic governance approach: i.e., by ensuring new synergies between technology and policy throughout the policy process. Interestingly, policy prototyping approaches can yield fruitful results also in terms of anticipation and stakeholder-inclusiveness – such as seen in the USA (see Case Study 5). At the same time, their potential cannot be scaled up if the overarching legislative landscape where regulation is enacted and experimented with is not also taken into account: in other words, if the shift from piecemeal to a holistic experimentalism is not accomplished. In this respect, a virtuous combination of multiple governance tools linked to all the key stages of the policy process seems to provide the most interesting results – such as in the case of Singapore, where a mix of design labs, policy pilots, and adaptive regulation paved the way for the growth of a new industry (see Case Study 6).

Overall, two insights stand out from this analysis. On the one hand, the journey towards the consolidation of an experimental approach for the governance of emerging technologies that is also anticipatory, stakeholder-inclusive, and holistic is still a long one. On the other, however, examples from around the world seems to present early but promising signs of change – initial developments that can help researchers, practitioners, and policymakers identify next steps and move forward in the exploration of how to build a robust experimental governance framework.

In an attempt to understand how to pursue such a direction, the second event behind this initiative convened a group of 28 global experts to discuss the key challenges faced by the field of AI governance that we should acknowledge before moving on. As a result of this joint assessment, three gaps have been identified – as well as related ways forward – that might help advance a robust experimental governance framework for emerging technologies. These are: (i) a capacity gap; (ii) a policy gap; and (iii) a governance gap.

First, the cultural gap refers to the lack of essential preconditions that would enable all the relevant stakeholders to take part in this conversation fruitfully. Currently, the field is ridden with an uneven distribution of technology-related expertise across public, private, and societal stakeholders; a lack of terminological clarity about experimental approaches and tools now being developed; and an institutional culture beware of

experimentation. To address these challenges, there are at least three ways forward:

1. **Nurture stronger capacities across the ecosystem**
2. **Develop a common vocabulary around experimentation**
3. **Overcome the fear of failure by fostering a culture of experimentation**

Second, the operative gap refers to the limitations that prevent current policy approaches from advancing anticipation, stakeholder-inclusiveness, and holism. These are highlighted in the assessment performed above and concern the lack of means to exploit the full experimental potential of regulatory sandboxes as means to upend regulation and not only enforce compliance; the lack of means to facilitate the inclusion of stakeholder early enough within policy experimental processes; and the lack of attention to the potential for designing more comprehensive policy mixes (rather than focusing of single tools) to ensure that the whole of the policy process feeds into the development of an experimental governance approach. Accordingly, this calls for pursuing the following ways forward:

4. **Scope the potential for regulatory sandboxing to experiment with regulation**
5. **Explore ways to include stakeholders in designing experimental approaches**
6. **Design comprehensive policy portfolios rather than standalone policy tools**

Third, the governance gap refers to the challenges that – beyond the distinctive features of different policy approaches – hinder the very possibility for collective action by eroding mutual trust among stakeholders. These include the low degree of openness, transparency, and consideration of ethical issues that characterize recent policy experimentations in both the public and private sector, and the need to address it by assigning clearer "mandates" and administrative mechanisms for distributed governance; the lack of intentional attempts at promoting collaboration between them; and the absence of arenas and mechanisms for the joint elaboration of premises, methods, goals, and purposes behind experimentation. The persistence of these challenges demand action on at least three grounds:

7. **Ensure the allocation of accountability behind experimentation**
8. **Approach collaboration as an integral principle of experimentation**
9. **Provide room for joint discussion of the purpose behind experimentation**

05

From interpreting the present to shaping the future

The goal of this second background report was that of leveraging the insights acquired from the past to interpret the present: i.e., the state of the art in the experimental governance of emerging technologies. To do so, we analysed a wide range of case studies that helped us put under the limelight different tools currently deployed for such purposes across the five continents. Based on this, we then briefly assessed the extent to which they feed into or challenge the three shifts for which we identified a need in the first report: from outpaced to anticipatory; from top-down to stakeholder-inclusive; and from piecemeal to holistic. As a result, we identified both a selection of best practices and potential ways forward to improve current ways of governing emerging technologies. Crucially, these relate to three main gaps that should be taken into account while paving the way for further developments: (i) a capacity gap; (ii) a policy gap; and (iii) a governance gap. Now, our goal is to figure out how to address them.

In the third and last step of this initiative, we will reconvene and prompt our group of global experts for a Community Workshop: an opportunity for joint sensemaking, exploration and co-creation of a future model of experimental governance. In this event, we will generate a number of ideas and devise how to test them in practice based on the learnings from previous phases. As a result, we hope to ignite the debate on the governance of emerging technologies, and come up with bold, innovative solutions to the current impasse of technology and society.

Before moving from the analysis of the present to the future of experimental governance of emerging technologies, this chapter concludes with three key takeaways that underpin the further development of a robust experimental governance framework. As in the first chapter, these takeaways also serve two purposes: on the one hand, prompt interested actors to join the debate; on the other, steer the further exploration of future experimental governance towards a more robust and consolidated framework.

TAKEAWAY 1: There is a dire need for a tighter connection between technology development, policy making, and society. Effective governance of emerging technologies promotes their alignment by leveraging stakeholders' input in scoping desired goals for policy; gaining insights on technological possibilities; and preempting flaws in the design and implementation of both.

TAKEAWAY 2: By providing room for the iterative accumulation of knowledge and revision of both policy and technology, experimentalist approaches can be leveraged to induce transformative change that prioritises societal progress.

TAKEAWAY 3: Ensuring accountability of the public, private and societal actors involved in the deployment of experimental governance approaches is a key precondition for the effective governance of emerging technologies.

06

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