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About the Centre for Regulatory Innovation

The Centre for Regulatory Innovation, launched in 2019, promotes a whole-of-government approach to regulatory experimentation to support innovation and competitiveness, and to help regulators and the regulatory system keep pace with technological advances.

Led out of the Treasury Board of Canada Secretariat's Regulatory Affairs Sector, the Centre for Regulatory Innovation provides support and expertise in regulatory innovation to industry and regulators.

About Nesta

<u>Nesta</u> is an innovation foundation. For us, innovation means turning bold ideas into reality and changing lives for the better. We use our expertise, skills and funding in areas where there are big challenges facing society.

Nesta is based in the UK and supported by a financial endowment. We work with partners around the globe to bring bold ideas to life to change the world for good.

About Science Practice

Science Practice is a research and design consultancy. Our Good Problems team works with funders to help them

identify and prioritise important problems and design effective innovation programmes.

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Regulators' Experimentation Toolkit

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OForeword

To support the Centre for Regulatory Innovation's mandate to facilitate regulatory experimentation, this toolkit was developed to provide Canadian regulators with a practical guide to identify, design, and carry out regulatory experiments.

Recognizing the novelty of regulatory experimentation, this toolkit provides a starting point for Canadian regulators to reference. Regulators are encouraged to seek out expert advisory services offered by the Centre for Regulatory Innovation to tailor guidance to their specific context.

While acting as a centralized coordinator, knowledge hub, and repository for lessons learned, the CRI leverages the perspectives and experiences of those inside and outside government to spur innovation and collaboration in the regulatory frameworks.







1 Introduction

Why regulatory experimentation?

A constant challenge for regulators of all kinds is the need to make decisions in contexts of **uncertainty**. This includes uncertainty about the environment within which the regulator is operating, and about the impact that its decisions will have on the environment. Innovation can be a particularly challenging source of uncertainty for regulators. New product or service innovations – or even entirely new categories of product or service½ – can push at the frontiers of existing regulation and have the potential for significant but unknown impacts, and the effects of changes to regulatory frameworks, policies, or mechanisms on innovation can be deeply uncertain.

Often, these uncertainties cannot be satisfactorily resolved through traditional approaches such as information gathering and consultations. For example, information about innovations can be particularly sparse, fragmented and contested or missing entirely relative to that available for more established technologies or practices. In other situations, it may be impossible to know which approach to a regulatory challenge is best if none of the most promising options under consideration have been tried in a similar context before, or indeed if the context is genuinely new and precedents offer little guidance.

Experimentation provides a way for regulators to reduce uncertainty and to inform regulatory decision-making in these circumstances. Experimentation can be a powerful approach to reducing uncertainty in a wide range of areas, but it is particularly relevant in relation to innovation where alternative courses of action, such as research and speaking with stakeholders, may be unavailable or unable to sufficiently satisfy a regulator's information needs. Being experimental is one principle regulators can adopt to become more 'anticipatory' in their approach to innovation.²

While experimentation is of course well established as a method in scientific research, and is also routinely used by many businesses to inform business decisions, adoption of experimentation by the regulatory community is still at an early stage. While regulatory sandboxes have become widely used (in particular among financial services regulators) to facilitate a particular category of experiment, regulatory experimentation has much broader potential applicability and utility to regulators than is currently being exploited. This Toolkit therefore starts with regulatory experimentation before turning to regulatory sandboxes as a special but important case.



What is a regulatory experiment?

A regulatory experiment is a test or trial of a new product, service, approach or process designed to generate evidence or information that can inform the design or administration of a regulatory regime. For example, a regulator might design an experiment to test the performance of a new licensing system versus an existing one, or to decide between alternative potential disclosure requirements for a new class of product by systematically comparing their performance. Regulatory experiments can happen inside or outside a regulatory sandbox, depending on what a regulator needs to experiment with.



What is a regulatory sandbox?

Over the past decade many regulators across the world have established regulatory sandboxes.⁴ Though this name is used widely, the purpose, design and implementation of regulatory sandboxes varies significantly across regulatory jurisdictions. For this Toolkit, we define a **regulatory sandbox** as a facility, created and controlled by a regulator, designed to allow the conduct of testing or experiments with novel products or processes prior to their full entry into the marketplace.

Key to this definition of a regulatory sandbox is the role played by industry, and specifically that the initiative for particular regulatory experiments comes from outside the regulator. By establishing a regulatory sandbox the regulator makes it easier and less costly for industry to propose and execute experiments, and provides a degree of certainty that experiments of a certain kind will be allowed.

Regulatory sandboxes involve partnership between regulators and industry and provide benefits to both that they may not otherwise be able to achieve. For industry, they offer a pathway for innovators to propose and safely run experiments with novel technologies subject to a regulator's approval and oversight. Often the purpose of a regulatory sandbox is described as being about reducing barriers to marketplace entry for innovative products and services. But they also provide valuable learning opportunities for regulators, notably about innovations falling within their regulatory remit and about the interplay between their regulation and innovator activity.

It follows from these definitions that regulatory experiments underlie, and are therefore in a significant sense 'prior' to, regulatory sandboxes. Regulators considering whether to establish a sandbox may therefore wish to first explore the principles and practice of regulatory experimentation more generally in order to inform specific sandbox design decisions.

About this toolkit

Who is it for?

The Regulators' Experimentation Toolkit is for any Canadian regulator interested in carrying out, facilitating, and learning from experiments.

This includes regulators interested in:

- Exploring new ways of regulating to develop a more proactive, anticipatory regulatory practice.
- Discovering, evidencing, and de-risking potential responses to regulatory challenges.
- Enabling, stimulating, or guiding industry and other stakeholders to advance innovation safely within new or existing regulatory frameworks.

How to use it

This toolkit contains guidance and tools to equip regulators with the practical knowledge needed to confidently undertake and facilitate regulatory experimentation.



Chapter 2: Regulatory experiments gives practical advice for identifying opportunities for experimentation, and for designing and running an experiment. Read this if you're interested in running a test or trial of a new product, service, approach or process in order to generate evidence or information to develop or amend regulations or regulatory administration.

• **Best for**: testing existing regulations to validate their appropriateness, obtaining information to inform the revision of these regulations or the development of new ones, or trying out potential processes to improve the administration of a regulatory regime.



Chapter 3: Regulatory sandboxes clarifies the concept of sandboxes and their relevance to regulators, and provides practical advice for implementation. Read this if you're interested in setting up a facility in which tests or experiments with novel products or processes can be safely implemented to provide both industry and regulators with learning opportunities.

• **Best for**: facilitating market-led innovation, engaging in industry-regulator dialogue, or building an understanding of an immature and emerging sector or innovation space.

Finally, at the end of this toolkit, you'll find a Resources and Glossary section with a glossary, references, and additional resources to support regulatory experimentation.

Regulatory experiments

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Part A: What is regulatory experimentation?

To 'experiment' means different things in different contexts by different practitioners. There are various approaches to what constitutes an experiment among policymakers, researchers, innovators and evaluation practitioners.

At its loosest, the term is sometimes used to mean 'trying out something new and seeing what happens' with little preconceived idea of what the outcomes of the experiment may be. Strict definitions, on the other hand, consider a process an experiment only if it generates evidence that meets very specific criteria or standards, and this usually requires having a clearer prior understanding of the possible outcomes of the experiment and how these will be interpreted.

To the Centre for Regulatory Innovation (CRI),

A regulatory experiment is a test or trial of a new **product**, **service**, **approach** or **process** designed to generate evidence or information that can inform the design or administration of a regulatory regime.

This definition can encompass both looser and stricter versions of experiments, but the unifying motivation is to generate evidence or information useful to a regulator.

Regulatory experiments and uncertainty

It is the norm rather than the exception that regulators must make decisions under uncertainty – about the environment within which they are operating, and about the impact that their actions will have on that environment. Uncertainty can impair the quality of decision-making (making it less likely that desired outcomes will be achieved), or even make it practically impossible to make an informed decision. Regulatory experimentation is one way regulators can generate evidence or information to reduce uncertainty, and to thereby establish a surer basis for their decisions and actions.



Innovation – particularly in the form of new products, services, processes and practices that develop in the market economy – often presents significant challenges to which regulators must respond. Innovation is also a significant source of uncertainty that problematizes regulatory decision-making. For instance, if a regulator is focused on developing regulatory responses to the actual or potential impacts of a specific innovation, it may face uncertainty related to:

- The development trajectory of the innovation the speed and shape of its development, adoption, and dissemination.
- The impact of current regulation or regulatory practice on the innovation's development trajectory.
- How the innovation will be (ab)used by producers and consumers.
- The emergence of new potential causes of harm from the innovation (personal, social, and environmental).
- Shifting public attitudes and values in relation to the innovation or the behaviour that it enables.
- Available options for regulating innovation types or trajectories.

Looking beyond the challenges in calibrating the regulatory response to a specific innovation, regulators taking action to enable or stimulate innovation in support of specific regulatory goals may face other kinds of uncertainty related to:

- Whether enough or the 'right kind' of innovation is emerging and gaining traction in a sector, and how to assess this.
- Identifying the drivers of or barriers to innovation and which regulatory options would best address these.
- How the marketplace will respond over time to regulatory actions, and what unintended consequences may result.
- The relevant determinants of success for potential regulatory actions.

To reduce or resolve uncertainty in these situations, regulators may find that more traditional approaches such as desk research and stakeholder consultations are inadequate. Information and evidence a regulator needs about innovations can be particularly sparse, fragmented and contested or even missing entirely relative to that available for more established technologies or practices. While regulatory experimentation can be a powerful approach to reducing uncertainty in a wide range of areas, it is particularly relevant for regulators grappling with innovation, where suitable alternative approaches may not be available.

What are the key characteristics of a regulatory experiment?

While there are many different experimental approaches available, all start by:

- Establishing a clear, carefully defined idea. intervention, or change to test or trial.
- · Specifying the learnings that are sought, and by
- Considering how these learnings could be applied in practice.

What differentiates a regulatory experiment from other experiments is that regulatory experiments generate information or evidence to support regulatory decision making, including decisions on regulatory design and regulatory administration.

A well-designed experiment has these characteristics:

- Prioritizes learning: generates information and evidence by systematically testing ideas.
- Tests or trials a defined learning objective or hypothesis.
- Clarifies the potential outcomes of the experiment and how these would be interpreted and acted on.
- Structure: a systematic process that allows learning to happen.
- Timelines: there are limits or checkpoints set from the start at which results are assessed and decisions made.

An experiment is not:

- Any initiative to provide supporting evidence for a decision that has already been made, where the outcome will not change the course of action taken.
- Any initiative without an established process for learning.





What can a regulator experiment with?

As stated in the definition, regulatory experiments may test or trial new products, services, approaches, or processes with the goal of building knowledge that can inform further action. In practice, a regulator might run an experiment with a regulated product or service, a new approach to regulating, or a policy or regulatory process.

A regulated product or service

This includes new technologies and business models that create regulatory uncertainty. These may be unregulated or prohibited in some way by existing regulation. An experiment might be designed to understand the implications of those innovations if they were used in the real world or assess how easy they would be to regulate using existing instruments.

Case study

Singapore Licensing Experimentation and Adaptation Programme

Innovation in Singapore's telemedicine sector led to the creation of services that were either not regulated or prohibited. These new services seemed to have benefits as well as risks, though neither were well understood. There was a need to better understand innovative telemedicine services to develop a new framework for regulating this service category.

In response, the Singapore Ministry of Health launched a **regulatory experiment**. The experiment was supported by a sandbox, which removed the prohibitions otherwise preventing the experiment. The experiment was designed to trial new and

innovative services in a safe and controlled environment to obtain information about the services benefits and risks while ensuring patient safety. Safety measures taken as part of the experiment included providing training for physicians in the safe use of telemedicine.

Comparing the telemedicine services trialed during the experiment to traditional services provided through the healthcare system has helped the Ministry of Health better understand the benefits and risks associated with telemedicine and to develop a new framework for regulating telemedicine.

Read more



A new approach to regulating

In some cases, regulators may want to trial a new type of approach to regulating (e.g. punitive versus cooperative) or a new version of a regulation under controlled conditions in order to monitor its effects. For example, regulators could test proposed regulations with a specific group of regulated entities to assess their effectiveness before being formally implemented.

Case study Open Banking in the UK and Europe

In the UK and Europe, a lack of effective competition in retail banking was leading to a lack of choice for consumers. At the same time, there was limited innovation in the products and services being offered by companies that did exist in the market. Policymakers recognized a need to address consumers' feeling of being 'locked in' to their current account provider through enabling easy and secure sharing of data with permissioned third parties.

To help address this problem, in the UK the Competition and Markets Authority set out to define and implement a common open banking standard that would apply across most of the UK retail banking sector. It did this by creating a new organization, Open Banking Limited, charged with working across all relevant stakeholders to accomplish this mission. Establishing open banking is itself a large scale experiment to test if enabling regulated financial service providers to securely access financial information across company

and institutional divides will deliver improvements in consumer choice, market competition, and innovation. In addition, through the Open Up Challenge, Open Banking Limited tested elements of the new infrastructure with select industry organizations by allowing them to build real but anonymized open banking data into their products and services before open banking launched in the market.

Open Banking Limited has iterated and improved the open banking standard over time, based on learnings from systematic engagement with a wide range of stakeholders with an interest in open banking, including through the Open Up Challenge. Open Banking Limited has also used metrics to inform these interactions, including data on patterns of usage of open banking infrastructure and consumer adoption of open banking-powered services.

Read more



A policy or regulatory process

This covers a broad range of activities. For example, a regulator could test different ways of consulting stakeholders on the design of new regulations, such as co-development, or it could run an experiment to understand if a new process for compliance or enforcement is better than the current procedures in place.

Case study

Global Financial Innovation Network

Emerging trends within financial services are increasingly global, but a complex regulatory landscape exists for companies and institutions looking to operate across multiple countries as each has its own regulatory framework. There is a need for both more efficient ways for innovative firms to interact with regulators and navigate between countries, and also an opportunity for greater cooperation between regulators to enable sharing of experience.

Building on positive feedback received to date from national-level sandboxes, e.g. the Financial

Conduct Authority's Regulatory Sandbox (see page 52), an international group of financial regulators and related organisations set up the Global Financial Innovation Network (GFIN) in 2019 to create a new framework for cooperation between financial services regulators on innovation-related topics. Although this network is relatively new, its activity is experimentation-oriented and has so far included a pilot of cross-border testing and regular member engagement.

Read more





What are the benefits of regulatory experimentation?

The core reason to undertake regulatory experimentation is to provide evidence or information to inform regulatory decision making. Experimentation can be used to complement other decision-supporting approaches such as research and evaluations. Regulatory experiments can be useful to regulators for several reasons:

- 1. They provide a structured approach to systematically generate high quality evidence to inform regulators' decisions. Experimentation provides a way in which valuable new information (e.g. how well a new regulatory approach works) can be generated through a structured process. Building a robust evidence base is an essential component of better regulation.
- 2. They are a powerful way to test alternative approaches and to identify potentially better approaches to achieving regulatory objectives. This might include new regulatory approaches (e.g. for a new technology, product or service) or improvements to existing regulatory approaches (e.g. to reduce the compliance burden without increasing compliance risk). Either way, experiments can help regulators find out if an intervention has any effect toward a goal.
- 3. Experiments help regulators to reduce the risk and uncertainty associated with a new regulatory approach prior to implementing it at scale. An experiment may be the only chance to observe, control and learn before a regulatory approach is fully implemented and may lead to irreversible consequences. This means experiments have a role to play in risk mitigation by identifying adverse effects of a proposed regulatory intervention.
- 4. Experiments allow policy makers and regulators to **generate information in a controlled and purposeful way**. Experiments allow for a much greater degree of control and more effective
 monitoring to isolate aspects of particular interest than would be possible through non-experimental
 observation in a 'real world' setting where there is greater complexity.
- 5. Experiments can generate information in complex, changing systems. They can be particularly useful in rapidly changing circumstances where previous research and theory may become quickly outdated or offer little guidance. This can be helpful in supporting optimization by identifying what works best or better.
- **6.** By building a more robust evidence base they **help to build consensus** around a particular regulatory option or issue that may otherwise be contested.



Integrating experimentation into regulatory culture

Knowing why and when to design and run an experiment is as important as knowing how to do so. If a regulator is to recognize the right opportunities for experimenting, then it needs to be open to exploration, trial and error, and validation. Taking on this mindset is also important when conducting experiments.

One key thing that can be challenging about putting experimentation into practice is that it requires a shift in what constitutes a successful outcome. Traditionally, organizations might feel that 'success' is when a policy or regulatory process, regulated object or regulation or piece of legislation 'works' at the end. But in reality, learning that something doesn't work is also extremely useful, and helps stop wasted resources and money on things that won't make a difference.

The Government of Canada has embraced this approach, specifically through its Experimentation direction for Deputy Heads in December 2016. This encourages departments to test new approaches to learn what works and what does not work using different experimentation methods, including:

- Deliberate, thoughtful, and ethical experimental design.
- Comparisons between interventions and base cases to capture evidence (e.g. randomized controlled trials, A/B testing, counterfactual experiments, baseline performance data, preand post-tests).
- Randomized assignment to test and control groups, whenever possible.
- Rigorous impact measurement and causality assessment.
- Transparent publication of positive, negative and neutral results.

The direction acknowledges that taking an experimentation-led approach requires:

Work environments that are conducive to experimentation, innovation and intelligent risk-taking so that public servants try new approaches and are not reprimanded for well-managed risks that fail to produce improvements, so long as lessons are captured and reflected in subsequent plans.

Practical steps that regulators can take to integrate experimentation into their ways of working include making a point of learning from failure, cultivating a learning mindset, acknowledging uncertainty, and getting buy-in.



Making a point of learning from failure

Failure is often associated with a regulation or intervention that has been implemented but has not been effective in achieving its goals, or it can refer to a regulation that has been designed but not fully implemented. However, in an experimental context, where the experiment had been robustly designed and carried out, both of these situations can be classed as a success if something new and valuable was learned that would improve the quality and efficacy of future interventions. When taking an experimental approach, good failure is an unavoidable part of the learning process, and bad failure is a preventable failure that doesn't result in new learning.

Cultivating a learning mindset

The underlying rationale behind any experiment should be to learn, build evidence and test what works. If a regulator starts from a place of just 'doing something new' rather than creating a structured plan for learning, it can be harder to capture the full benefits of experimentation since the underlying question and desired evidence haven't been built into the design from the start. Having a learning-focused mindset is critical, and is part of reframing those traditional notions of success and failure. Being open to uncertainty and testing out solutions can help build a culture that embraces learning. Below are some of the key traits of a learning organization that regulators can begin to adopt to help them on this journey.

Figure '	1:	Traits	of	a	learning	org	anization
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Open culture	Feedback loops	Intelligent failure	Adapting better practice	Common vision
Open to new ideas, open to constructive criticism, open to changing direction when something isn't working.	Purposeful user and employee feedback, post project reflection.	Use of Minimum Viable Product (MVP), prototypes, pilots, individual of team experiments. Collection and dissementation of lessons (good and bad).	Identifying what works in other organisations, departments and implementing fast.	Cultivation of a shared vision across all employees. See importance of role and connect the dots between departments.

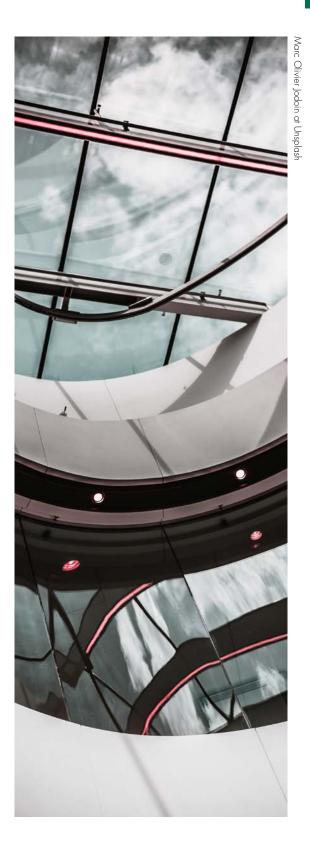
Acknowledging uncertainty

Sometimes, there will be uncertainty about the best approach to take to address a regulatory challenge. By generating evidence and information, experiments can play a role in resolving this. Throughout, it's best to be clear and open in acknowledging what is and isn't known, and why. The value of evidence is that it can help illuminate areas of uncertainty where there are not yet answers.

Getting buy-in

Finally, any shift in mindset or culture requires buy-in. Individuals can support this by taking on an experimental mindset. This could involve helping to make it safe and acceptable to not have ready answers at all times, and rather to know how to get evidence to improve decision-making through experimentation. It's also essential that peers and leadership understand what being open to experimentation means and why it is important. Understanding the benefits of regulatory experimentation (See What are the benefits of regulatory experimentation?) can help with this.

Regardless of how a regulator characterizes its current regulatory approach, to fully embrace regulatory experimentation, change may be needed at the level of individual mindset, attitudes, and habits – but also at the level of established functions and ways of working, and the wider environment in which the regulatory organization is situated. Individuals working within regulators can focus on identifying and acting on the concrete opportunities they have identified to support this wider shift, and recognize that integrating a more experimental orientation will take time, effort, and patience.





Part B: Is regulatory experimentation right for you?

Regulatory experiments can be helpful to regulators in need of data and information to support decision-making in situations where this might be difficult to obtain using other approaches. Like any approach, regulatory experimentation has its own strengths and weaknesses, and it will not be applicable to every challenge a regulator faces.

This section provides a checklist of considerations to help you determine whether regulatory experimentation is the right approach for your situation. Use it to determine if a regulatory experiment would help you to gather evidence to support a decision you are facing

1. Are you asking the right type of question?



Use this section to complete the **Research questions** section of the <u>Is regulatory</u> experimentation right for you? worksheet.

When thinking about what you want to find out, you need to ensure that the question you are asking can be answered using an experiment. There are many different types of questions that you might be interested in investigating. For example, you might be interested in strategic questions such as "What areas of regulatory policy should we focus our attention on?" You might be interested in descriptive questions such as "What are the key regulatory challenges that innovators are facing?" Equally, you might have process-related questions such as "Are our compliance mechanisms effective and appropriate?" These questions are all crucial for successful program design and evaluation, but not all of them require a regulatory experiment in order to reach an answer.



Experiments are best for answering questions around impact and a need for evidence

Did something work (i.e. have the desired impact)? And why? This is why in an experiment the research question is often framed as a hypothesis statement to be proved or disproved: "If we do this, then this will happen."

If the format of a hypothesis does not work for your context, you may instead wish to express what you hope to learn through a set of concrete learning objectives. Your experiment should enable you to generate knowledge to meet these objectives.

Before proceeding, check

Is there a clear question that needs to be answered that can be framed as a testable hypothesis or articulated as explicit learning objectives?



If YES, move on to 2. Can you generate evidence to answer your question?



| X | If NO, refine or reframe your question, or consider addressing your challenges through mechanisms other than regulatory experimentation, such as those listed in Comparing experiments to other approaches on page 24.



2. Can you generate evidence to answer your question?



Use this section to complete the Evidence and impact section of the <u>Is regulatory</u> experimentation right for you? worksheet.

Evidence needs

Once you have articulated a question in the form of a hypothesis or learning objectives, think about what evidence you would need to answer it. Then, consider what it would take to obtain this evidence.

- Is it feasible to run an experiment in this area?
- Are there any potential ethical issues associated with running an experiment in this area?
 For example:
 - > Can you in good conscience provide an intervention for one group in your experiment and not for the other if the intervention is likely to result in either benefit or harm?
 - What would be the consequences of rolling out a regulatory policy without having tested it, as through an experiment? Could doing so potentially result in harmful impacts?
- Would participant consent be required, and how could this be obtained?

Anticipating outcomes

Envision the possible outcomes from the experiment, and whether the results would answer your question sufficiently. Consider what would happen were you to prove your hypothesis, as well as what could happen if your experiment disproved it or produced an inconclusive result.

- How will you know whether and when you have answered your question?
- Is it possible that these results could be received quite differently by colleagues, leadership, innovators, wider industry, and the public?
- How might the experiment's outcomes be interpreted?
- Will all those interested in your question be satisfied that the experimental outcomes answer it?
- How will your results interact with related evidence that already exists in this field?

Think about how convincing your evidence will be, and the extent to which these results will be actionable.

Before proceeding, check

Can an experiment be designed that would provide evidence to answer your question?

If YES, move on to 3. Is experimentation needed, given other approaches?

🗶 If NO, consider other ways to gather evidence and/or support decision making in this area.



Is experimentation needed, given other approaches?



Use this section to complete the Other approaches section of the Is regulatory experimentation right for you? worksheet.

It's important to recognize good opportunities for experimentation. The case for experimenting is strong when there is:

- A high-stakes decision to be taken where the strength of evidence informing the decision is important (e.g. big budget, big downside risks).
- A lack of existing relevant evidence or experience to inform a decision.
- No strong theoretical basis for taking the decision.
- Time available; the decision does not need to be taken in a hurry (e.g. not a crisis situation).
- An opportunity for experimental outcomes to influence a decision (e.g. it is not purely a political decision).
- A context in which it is ethically appropriate to experiment.

Other approaches for supporting regulatory decision-making

Experiments are not the only way to gather evidence, arrive at answers to technical or strategic questions, or support complex decision-making processes. Before developing a plan to run a regulatory experiment, it's important to understand what other approaches are available and to consider the feasibility, cost, timing, robustness of evidence, speed/timeliness, and ethical/legal implications associated with each. Some of these approaches are listed below, with strengths and weaknesses highlighted.

Rely on existing individual, team, or institutional experience and views

This approach involves drawing on the experiential data you have.



Strengths

Not all decisions can be made with quantitative evidence. In such cases, this approach provides a very fast and low- or no-cost alternative to an experiment.



Weaknesses

Because it relies on one person's or group's point of view, it may be difficult to avoid bias, to build your case, and to gain wider support for your ideas.



Do desk research

Search for experimental evidence and case study insights in your own regulatory sector, or look for how those in other sectors have tackled similar questions. If others in very similar circumstances have already researched the options you are considering, then it may be redundant to experiment.



Strengths

If others have already tested different answers to the decision you are making, this approach can help you gather evidence quickly and at low cost.



Weaknesses

When making decisions around innovative products, services or approaches, keep in mind that relevant research may not exist yet.

Consult experts

Ask others with different specializations and perspectives on your area of interest to share their opinions or experiences. This could be obtained through interviews, via referrals to additional resources, or by commissioning analyses.



Strengths

Asking those who may already have answers for you is low-cost and sensible if relevant expertise exists.



Weaknesses

When making decisions around innovative products, services or approaches, keep in mind that relevant expertise may be difficult to identify or access. Bias may be a risk, and experts may not be best-placed to consult on public experiences and perceptions.

Consult the public and other stakeholders

Consulting the public can help you understand how their priorities, perceptions, and preferences may contribute to your response, or how different responses are likely to be received.



Strengths

In some cases, the public may be able to easily intuit likely outcomes or have direct experience of these, which may diminish or eliminate your need to experiment.



Weaknesses

Though it depends on the breadth of the consultation, this approach may be costly and timeconsuming. It may also require augmentation with desk research and/or expert views.



Implement, then evaluate

It is unethical to experiment when a political situation requires decisive and timely action. Otherwise, when a highly likely course of action or best decision exists, it may be best to implement at scale and then evaluate.



Strengths

This approach still provides opportunities to learn by doing, and to improve over the course of implementation or following evaluation.



Weaknesses

Implementing an untested solution risks revealing a bad decision. Implementing at scale may be slow and encounter unanticipated barriers or growth in scope.

Monitor, assess, and revisit

Another approach is to 'wait and see' by monitoring the relevant regulatory space, assessing it, and revisiting it to consider intervening at a later date.



Strengths

If a highly likely course of action or best decision exists but is not yet identified, and the cost and potential risks of delayed action or inaction are low, taking more time to observe and assess the situation as it unfolds can make sense.



Weaknesses

If a decision is urgent and important, inaction or delayed action is unethical, as this risks a solution arriving 'too late' to provide benefit or prevent negative consequences.

Comparing experiments to other approaches

To better understand each potential approach you are considering, write down the advantages and disadvantages that each affords in terms of feasibility, cost, timing, robustness of evidence, speed/timeliness, and ethical/legal implications. Then, compare each option to taking a regulatory experiment approach: which is better suited to tackling your challenges? Could multiple approaches be combined to support your decision-making?



For example, given that research will often be less expensive and resource-intensive than designing and running an experiment, it may make sense to invest in research before deciding to experiment. On the other hand, if the specific question you need to answer has not been investigated before, or not in similar contexts to your own, collecting information from existing sources may not be as helpful. Consider whether similar or related experiments have been run already by other regulators or in academic settings. What were their results? Are their results sufficient for you to rely on?



See the **Other approaches** section of the **Is regulatory experimentation right for you?** worksheet for a suggested format to make this comparison.

Before proceeding, check

After considering other approaches, are you confident that at this point in your exploration, a regulatory experiment is the best way to obtain the information you are seeking?

If YES, move on to 4. Do you have the time and resources needed to experiment?

X If NO, consider scoping out the most promising alternative approaches available to you.



Heyla Gostechie at Unsplash



4. Do you have the time and resources needed to experiment?



Use this section to complete the **Resources** section of the <u>Is regulatory experimentation</u> right for you? worksheet.

Time

Running a regulatory experiment can take time, but this time investment may result in higher-quality evidence. Before considering an experimental approach further, think about how quickly you need an answer to your question, and how likely it is that an experiment will get you this information by the time you need to act on it.

- Would any of the other approaches you have considered provide you with information more quickly?
- On the other hand, is an experiment more likely to give you enough and quality evidence to proceed with and influence further action?
- If you must trade off time against confidence, which is your priority?

People

Experiments also require people. For example, designated or additional staff may be needed to coordinate implementation, and specialists may need to be brought in to support experimental design, evidence gathering, and analysis.

- What skill sets are already represented on your team, and what capacity do you have?
- What competing priorities would have to be balanced in order to take on the work associated with running an experiment?
- Consider future staffing costs as well. For example, how might an experiment reduce administrative costs over the long term?

Funding

Given the time and people they require, experiments may also need funding. Establish what budgetary constraints you are working within, and how these interact with timelines. Importantly, you should also consider the potential costs and impacts of not experimenting.

- Which future scenarios are possible if you experiment, and which are not?
- What implications would each of these scenarios have for the public, industry, and your regulatory organization?
- Consider the risks and costs associated with implementing at scale based on alternative approaches, versus testing through an experiment first.



Different scales, different requirements

Also keep in mind that experiments can vary in scale and resource requirements. For example, smaller-scale experiments could include testing different communications strategies or different regulatory intake processes, and could be carried out by existing staff working in relevant policy and program areas.

Before proceeding, check

Do you have the time and resources (both people and funding) to carry out an experiment at the scale you envision, or is there potential to develop a strong case for directing time and resources toward this? You may want to revisit this question after reviewing the information in Part C: Which type of experiment should you use?



✓ If YES, continue by exploring the different experimental designs in Part C.



| If NO, consider how alternative approaches could support your learning, or how an experimental approach could be broken down into smaller components to work with existing deadlines and budgetary restrictions.



Part C: Which type of experiment should you use?



Use the following sections to complete the **Experimental design** section of the **Is regulatory experimentation right for you?** worksheet.

Experiments can be run in different ways. There are three core types of experimental design:

Randomized experiments

Often considered the 'gold standard' of experiments, these experiments separate participants into a treatment group which receives an intervention and a control group which doesn't in order to understand the impact of the intervention. These groups are randomly assigned to ensure there is no bias in how they are allocated.

Non-randomized and quasi-experimental designs

Randomization isn't always possible, and in these types of experiments a comparison group is created using statistical models to ensure it is as similar to the treatment group as possible. The treatment group receives the intervention and the comparison group doesn't, and the results are compared.

Pre-post experiments

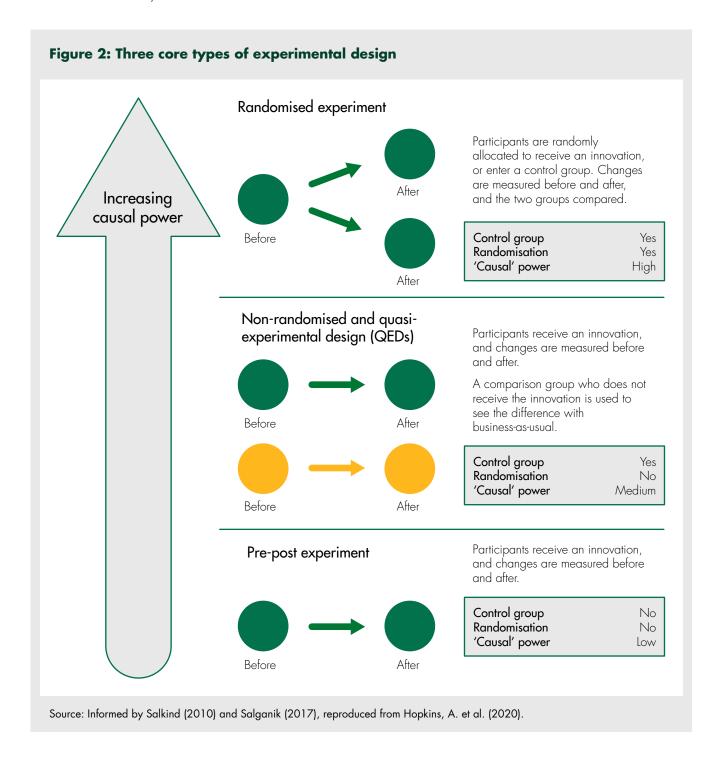
If there is no way to create a comparison group, the same group can be measured before and after receiving an intervention.

In their own way, each of these approaches aims to create what's called the counterfactual, an estimation of what would have happened if the experiment hadn't taken place. This in turn influences the causal power (a clear link between the intervention and the changes observed) that can be inferred or established as a result of the experiment, with a randomized experiment giving high causal power and a pre-post experiment low causal power.

Note that because experimentation is still a relatively new approach within regulatory practice, there are not yet many examples of regulatory experiments that match these categories exactly as they are described. While establishing a counterfactual is best practice, not all regulatory experiments may do this. However, any type of well-designed experiment has the potential to help regulators improve the rigour and efficiency of their evidence and insight-gathering activities. While a randomized experiment will always give experimenters the highest causal power, both non-randomized/quasi-experimental designs and pre-post experiments are good options for regulators and in some cases may be more feasible to implement.



The next section introduces each of the designs to provide an understanding of when you could use each and why.





Randomized experiments

Randomized experiments aim to test an intervention by investigating what difference it has made. They do this through an experiment group (also called a treatment or intervention group) and a control group; this means that some participants in the experiment receive an intervention, while others do not. By comparing results for the groups, you can get a clear sense of the intervention's impact.



> Can show with a high degree of certainty that an intervention is or isn't responsible for changes seen during the experiment.

Cons

- > In many circumstances it will be very difficult for regulators to carry out fully randomized experiments.
- Can be resource intensive depending on scale.

How they work

Randomized experiments allocate the control and experiment groups by chance. This is where the strength of their design lies, in their ability to reduce what is technically termed selection bias. Selection bias results from the experiment and control groups being fundamentally different in some (often unobservable) way – and will skew results.

When a sample is large enough, random allocation will even out any differences between the control and experiment groups, to create a fair comparison. A large enough sample size and similarity between the groups also means both groups will be exposed to any other influencing factors, called confounders. This means any change can be reliably attributed to the intervention, demonstrating a strong connection between a cause (the intervention being testing) and an effect (the desired outcome). This is what is referred to as causal inference.



Randomized experiments are used widely in evaluating the effectiveness of medical treatments and educational programs, but so far, they have been much less frequently used in the regulatory realm. In many instances, randomization may be difficult in a regulatory context. For example, in most situations, it would be impossible to randomize who has to comply to a set of regulations to evaluate its impact.

Ethics of experimentation

A key criticism of randomized experiments is that it is unethical to withhold an intervention from a control group for the purpose of testing its effect when this intervention has the potential to benefit all people involved in a study. In other words, if it is unknown whether the intervention works or has potential to result in detrimental outcomes, it may be ethically acceptable to randomize. On the other hand, if an intervention is known to work based on previous randomized experiments or other evidence (not just theory or assumptions), it is ethically

unacceptable to randomize. Wherever there are sensitivities, ethical approval should be sought from the appropriate ethics committee.

For more information, see:

Hopkins, A., Breckon, J. & Lawrence, J. 2020. 'The Experimenter's Inventory: A catalogue of experiments for decision-makers and professionals.' Alliance for Useful Evidence, Nesta, London. Available: www.alliance4usefulevidence.org/ publication/the-experimenters-inventory

When to use

There are lots of instances where randomized experiments, such as A/B tests (which are described below), can be used by regulators. For example, randomized experiments could also be used to test and evaluate:

- Different interventions or approaches to interactions with industry (e.g. how advice centres
 provide information or support, such as general guidance versus workshops versus online
 support).
- Alternative compliance mechanisms (e.g. new digital systems).
- Inspection (e.g. effect of timing or use of new technologies from predictive analytics to drones), or
- Improved methods for post-market surveillance of critical products and services.



If you need to establish the impact of a specified intervention but you cannot feasibly or ethically conduct a randomized experiment, you may want to consider a quasi-experimental design or non-random experiment.

Case study

A/B tests and Health Canada's Consumer Product Safety Program

A/B tests are a type of randomized experiment often used to test small tweaks in design or implementation, often online. An A/B test is a simple way of finding out what users prefer. Sometimes called 'messaging trials', they randomly assign a particular design or communications strategy, such as the wording of a letter or the header of a website, to different groups of users. Experimenters can then compare response rates to see what was most effective. A/B tests are used in business all the time, and as 'nudges' to improve the design and delivery of services.

For example, Health Canada's Consumer Product Safety Program partnered with Experimentation Works to run an A/B test and determine if changes in language and presentation could successfully encourage users to complete the cosmetic or consumer incident report form. The experiment showed that making the landing page more user-focused played an important role in encouraging users to access the incident report form.





Non-randomized and quasi-experimental designs

Random assignment of an intervention is not always possible, particularly for regulators. In these cases, experimenters need another way to control for other sources of change or influence (the confounders), i.e., they need a way to ensure that change they observe is due to the intervention being tested, and not anything else. Non-randomized experiments, sometimes called quasiexperimental designs, provide ways of identifying a counterfactual without assigning a control group.



Pros

- Very useful where randomization isn't possible.
- > Several different ways of generating a comparison group depending on the context.



- Requires some statistical expertise to run. Where this does not exist in-house, support could be brought in.
- > Can be complicated in design and evaluation, so regulators may need to bring in external expertise.
- Not as robust as randomization.

How they work

Instead of assigning a control group, quasi-experimental designs or non-randomized experiments specify a comparison group. This comparison group is critical for establishing with some certainty (though not as much certainty as randomized experiments) that the intervention being tested has or has not led to the changes observed during the experiment. The comparison group becomes the counterfactual that can be compared to the intervention group.

The comparison group therefore needs to be as similar as possible to the intervention group in any characteristics that might be relevant to the test, e.g. company size, type, structure, previous interactions with the regulator, etc. To do this where randomization is not possible, quasi-experimental and non-randomized approaches use statistical models to identify the right participants to include in the comparison group.

If the experiment is not designed well, there is a risk that the comparison group won't be similar enough. If this happens, it can introduce bias into the experiment, which may distort the results, e.g., if organizations have to apply to be in an intervention group and those who do not apply remain in a comparison group, then those who opted in could potentially have a more flexible mindset or greater capacity for change than those who did not.



When to use

Most types of regulatory intervention could be tested through this method and it would be a useful way to test the impact of innovative regulatory methods or new forms of public engagement.

If you need to establish the impact of a specified intervention but you cannot feasibly or ethically conduct a randomized experiment, you may want to consider a quasi-experimental design or non-random experiment.

Pre-post experiments

Unlike randomized experiments or quasi-experimental designs and non-randomized experiments, pre-post experiments do not compare across different groups. Instead, they compare one group of participants before and after an intervention to see what has changed.



- Good for feasibility testing at the early stages of shaping a new idea.
- > Useful when aiming to probe and discover, to shape hypotheses that can be tested more rigorously later. Pre-post experiments build on background research and problem definition, helping design better interventions and experiments to test them.
- Require less long-term investment, generally quicker and iterative in nature.



Cons

> Without a proper control or comparison group, it can be hard to discern whether or not the intervention being trialled is responsible for any changes observed. Not as robust as randomization.

How they work

In pre-post experiments, the 'before' state, or baseline, becomes the de-facto counterfactual. Because of this focus on only one group, causal inference does become an issue: without a control or comparison group it's hard to know if any change after the intervention is introduced was really caused by it, or by another factor affecting the group in question.

However, pre-post experiments are useful where regulators are either not yet in the position to develop and run a more robustly designed experiment or where it simply may not be possible to implement another experimental approach. Many initial regulatory experiments might fall into this category, and over time, further experiments may move up to the more rigorous levels.



When to use

Pre-post tests are those where measurements about outcomes for a group receiving an intervention are taken before (pre) and after (post) the intervention takes place. These could be used when a regulatory intervention is going to be carried out but its implementation cannot be randomized and there is no equivalent group for comparison.

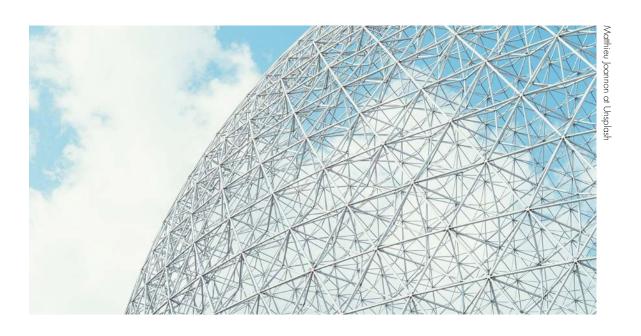
Alternatively, a regulator may still be at the early stages of developing an intervention and wants to find out more before moving to the more rigorous levels of experimentation. A pre-post experiment is helpful for this type of feasibility testing at the early stages of shaping a new idea when looking at how something could work and getting a better idea of what will be involved.

If you need to show a change over time to evaluate whether an intervention has been successful or not, and to what degree, consider a pre-post experiment.

For a more detailed breakdown of these specific methods and how to use them, see:

Hopkins, A., Breckon, J. & Lawrence, J. 2020. 'The Experimenter's Inventory: A catalogue of experiments for decision-makers and professionals.' Alliance for Useful Evidence, Nesta, London. Available: www.alliance4usefulevidence.org/publication/the-experimenters-inventory

Edovald, T. Firpo, T. & Roberts, I. 2016. 'Running randomized controlled trials in innovation, entrepreneurship and growth: An introductory guide.' Innovation Growth Lab, Nesta, London. Available: www.nesta.org.uk/toolkit/running-randomised-controlled-trials-in-innovation-entrepreneurship-and-growth





Part D: Designing and running an experiment

This section of the guide provides an overview of the practical steps you'll need to consider regardless of the type of experiment you'd like to run. We also include references to other practical resources where you can get more in-depth information.

Before you begin: ingredients for a successful experiment

As we've seen, there are a variety of different forms an experiment can take. Despite these distinct methodologies, all types of experiment require the same essential ingredients to be successful:

· A problem worth experimenting with

As we've covered in Part B: Is regulatory experimentation right for you?, experiments are useful when you have a clear question that you believe you can test through an experimental design. Doing the work up front to make sure you're asking the right question is essential.

A hypothesis to be tested or learning objectives to be fulfilled

The hypothesis is a statement that sets out the expected outcome that is being tested through the experiment. For example, a hypothesis in the context of financial regulation could be "if we enable more open banking, then it will create better competition and choice for consumers." The hypothesis is important for laying out the scope of the experiment and defining its focus. It should also help you identify your metrics – what you are going to measure to understand if the outcomes are being achieved? Thinking about metrics will also be important if you opt to define learning objectives instead of a hypothesis.

A counterfactual or baseline for comparison

To understand the impact of an experiment, ideally you need to be able to compare it to what would have happened if it hadn't taken place. Your counterfactual is an estimation of this, and is generated either by your control or comparison group – or, in a pre-post experiment, where you compare only one group before and after the experiment, you need to collect baseline metrics before you begin.

Monitoring and evaluation

While monitoring looks at 'what' changes have occurred since the beginning of the experiment, evaluation looks at 'whether' the hypothesis has been confirmed or the learning objectives have been reached. In other words, has the intervention met its objectives and why. You'll need to develop a plan for how you will analyze both.

A plan to apply the learning in practice

An experiment will only be useful if you're able to act on the results, so before you even begin you'll want to have a good idea of what action you'll take from the learnings.



Case study

Ofgem consumer engagement trials

Ofgem, the UK's regulator for the electricity and downstream natural gas markets, undertook a three-year research programme to understand whether behaviour change interventions could prompt consumers who had not switched energy tariffs for years to do so. Over the course of ten experimental trials involving 1.1 million energy consumers, 94,00 ended up switching, which resulted in total combined savings of £21.3 million.

A problem worth experimenting with

Ofgem, whose remit includes ensuring that the energy market is working for all consumers, noticed that consumers in the UK energy market were not switching to energy providers offering the best prices for them. They wondered: What interventions work in increasing consumer engagement?

A hypothesis to be tested or learning objectives to be fulfilled

Ofgem's hypothesis was that removing hassle and simplifying the switching process – by notifying consumers with a personalized list of three providers offering cheaper tariffs – consumers would be encouraged to switch energy providers. To understand whether this outcome was achieved,

Ofgem decided to measure the proportion of consumers switching who received the notification, versus those who did not.

A counterfactual or baseline for comparison

In this case, the counterfactual or baseline for comparison was the group of usual energy consumers who did not receive a letter. Whether consumers were in the treatment versus the control group was randomised.

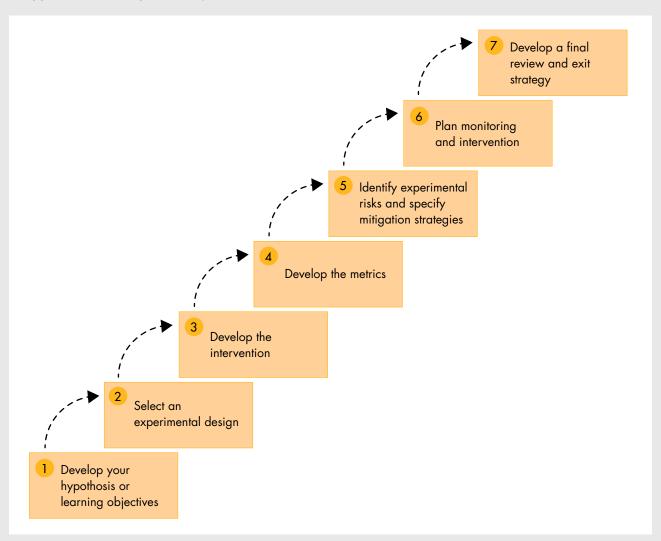
A plan to apply the learning in practice

Through this experimentation, Ofgem learned that the interventions they tested were effective. The letters and emails they sent out notifying consumers of cheaper alternatives did encourage consumers to switch providers to achieve these tariffs. However, Ofgem did not have a clear plan in place to act on these results. In the current environment, long-term implementation of these changes would need to be done by energy companies – a difficult barrier to overcome. Unfortunately, this means that no design or administrative change has been made to the regulatory regime that existed before the experiment was conducted.





To help you design and run an experiment that integrates all of these ingredients, this guide suggests the following seven steps:





1. Develop your hypothesis or learning objectives



Use this section to complete the **Problem** and **Hypothesis** sections of the **Running an experiment** worksheet.

To develop your hypothesis or learning objectives, you need to first clarify the problem, and then propose your hypothesis or learning objectives based on this understanding.

Clarify the problem and your need for evidence

Before you start to think about running an experiment, it's important to put in the work to clearly define the problem you're trying to address and understand how it is experienced by people. This will help you to narrow down what you would like to test, and ensure you are testing the right thing. What evidence or information do you need to support decisions or actions to address the problem at hand?

Clarify how you will apply learnings in practice

An experiment is only useful if you're able to act on the results. Before starting, you should be clear on how you'll apply what you learned. How will it inform the design or administration of a regulatory regime? If you can see no clear way to act, it might not be the right thing to be experimenting on at that moment. Once you have the evidence or information from your experiment, how will you use it? To get buy in for making decisions or taking action from the results of your experiment, you'll need a strong rationale. Being clear on this 'so what?' of your experiment will help convince others of the need to act.

At this stage, activities you should think about include:

Problem framing

Thinking about your problem from different perspectives, or framings, to see if you uncover new insights from looking at it in a different light.

• User and stakeholder research

Gathering the perspectives from a range of potential users or stakeholders will help inform the problem and what might be effective to tackle it.

Evidence mapping

Exploring existing evidence and research around what works will also help you to identify missing evidence needed to take action or make a decision.

Systems mapping

Doing a systems mapping exercise can help you to understand what else might be affecting your problem and where it might be most useful to intervene.

Solutions mapping

Looking at existing solutions, e.g., from other domains, can help spark ideas of what might be transferrable or possible in your own domain.



For more details on these methods and others, see:

Quaggiotto, G., Leurs, B., & Christiansen, J. 2018. 'Exploring the unobvious: six principles to establish experimental practices.' Nesta, London. Posted on blog February 4, 2018. <u>www.nesta.org.uk/blog/exploring-unobvious-six-principles-establish-experimental-practices</u>

Develop your hypothesis or learning objectives

In this early exploratory phase, you might find you have multiple questions you could investigate through research that could each provide evidence to help you formulate next steps to address the regulatory challenge you've identified. A hypothesis is a statement setting out the claim that you want to test through your experiment. Your experiment may find evidence to support the claim, or it may not. This claim is likely to be about the option or options you are considering for addressing the regulatory challenge you are facing.

You may find it helpful to express the hypothesis you want to test in the form of an if/then statement, for example: "If we were to do X, then we expect Y to happen as a result." The purpose of the experiment in this case would be to seek evidence to support this hypothesis.

Proposing a hypothesis can be tricky. If you cannot express what you want to learn from your experiment in the form of a hypothesis, you can alternatively clarify the information you are seeking to obtain from the experiment as 'learning objectives'. In this case, it may be helpful to think of the success of the experiment being defined by whether this learning is acquired (or not) through the experiment, rather than the specific result of the experiment. Developing a theory of change $^{\circ}$ or logic model 10 may be helpful in supporting this route.

Socialize to gather feedback

At this stage, sharing your hypothesis or learning objectives is a good way to validate your experiment idea with other people, such as colleagues, subject matter experts, innovators, or stakeholders, to build your understanding. Proposing a hypothesis or learning objectives requires you to focus your questioning and formulate this into a 'prototype' – something visible or tangible that you are able to share with others to get feedback in order to improve and refine it. 11



2. Select an experimental design



Use this section to complete the **Plan** section of the **<u>Running an experiment</u>** worksheet.

Once you've developed your hypothesis or learning objectives, think about which type of experimental design is right for your situation. The three core types of experimental design are randomised experiments, non-randomized and quasi-experimental designs and pre-post experiments. Part C: Which type of experiment should you use describes each of these design options and when to use each.

Defining your sample

A key step in the design of an experiment involves estimating how many participants you need to ensure that the hypothesis can be assessed. An experiment with too few participants is called 'underpowered', meaning that it lacks the statistical power (i.e. the ability to detect a certain impact) to answer the research questions.

Sample size calculations in the design stage are based on a number of assumptions. The most important one regards the expected effect size, i.e. a measure of the difference in outcomes you anticipate the intervention will cause. More specifically, it is common to consider the minimum detectable effect size (MDES), which is the smallest true effect size that has a good chance of being found to be statistically significant. The more participants take part in the study, the smaller the effect it will be able to detect.

Often, however, resource constraints will dictate how many participants can be recruited into the trial. For instance, there might only be enough budget to provide the intervention to 100 companies. In these cases, another calculation, known as the power calculation, is carried out instead to estimate the probability that a trial with the specified number of participants will detect a statistically significant intervention effect of a certain size.

There are a number of techniques to estimate how large a sample size will be sufficient, and wherever possible it is preferable to involve a statistician for these purposes.



3. Develop the intervention



Use this section to complete the Plan section of the $\underline{Running\ an\ experiment}$ worksheet.

Identify implementers and key stakeholders, and specify roles

Understand who will need to be involved in carrying out this regulatory experiment from within the regulatory organization and its close circle of collaborators. Define roles and responsibilities for each.

Engage with the public, industry, other regulators, and other jurisdictions

Involving relevant stakeholders at all stages of the experimentation design and implementation helps to ensure that it runs smoothly, is fit-for-purpose, and is able to feedback into decision-making. For some groups, you'll want their direct input into your design. For others, you'll want to keep them informed to build engagement and support for the experiment's outcomes.

Specify your experiment design

Elaborate on how the experimental design you selected will be applied to your context, including what you will test or set out to learn (hypothesis or learning objectives), how you will establish a counterfactual if relevant, and where the experiment will take place.

Ensure the right resource

Setting up and running an experiment will take time, so you need to make sure you have the capacity to be able to do it well. You'll also want to think about the different capabilities you'll need. For example, you might want support on how to select and measure your metrics. Or if you're looking at running a quasi or randomized experiment, you'll likely need statistical expertise to make sure it is set up in a robust way. You'll also need to think about the different data, information or tools you'll need access to in order to run your experiment. How can you gain access to these? Who are the 'gatekeepers' at any stage of your experiment and do you have the right relationships in place? Who else do you need to bring on board?

Define when the experiment ends

Experiments should have an unambiguous structure: fixed timelines, limits and checkpoints are established for assessing results and making decisions.



Anticipate risks of harm to people and environment

Consider the ways in which running your experiment could inadvertently cause harm to people and the environment as it is carried out. How likely are these and how impactful would they be?

Consider existing safeguards and the need for a regulatory exemption

Before proceeding with an experiment, it is important to clarify what is and isn't possible under existing legislation. Depending on the focus of your experiment, you might need a regulatory exemption or other permissions to run your experiment. If existing authorities are not sufficient, legislative change may be needed to enable a sandbox. Government departments should reach out to their legal teams to ensure they have the proper legal authorities and for options on how to achieve exemptions, waivers and/or legislative change should any be required.

Consider whether your organization has the regulatory flexibility to grant any required permission for your group to run experiments. Will exemption or permission be possible to get? How might this affect the timeframe? Consider that any exemptions or waivers will be limited in time and scope. You'll need to factor all this into the design of your experiment.

Experimentation and exemption clauses

In some cases, existing exemption powers and processes may not be sufficient for or suited to enabling the regulatory flexibility required for an experiment. Experimentation clauses can address this gap in authorities.

Experimentation clauses are legislative provisions permitting temporary exemptions from legislative or regulatory requirements for the purpose of regulatory experimentation. These clauses will often allow for setting limits in time and scope for any exemptions

issued, and for prescribing additional conditions specific to an experiment.

Departments may or may not already have experimentation clauses in their Acts or Regulations. Incorporating an experimentation clause would require a legislative or regulatory amendment. Regulators can consult with their legal teams to identify options.

For related discussion, see Is regulatory flexibility possible? in Chapter 3: Regulatory sandboxes.



4. Develop the metrics



Use this section to complete the **Plan** section anticipate the **Results** section of the **Running** an **experiment** worksheet.

After determining the evidence you're looking for, you'll also need to decide on the metric – how are you going to measure whether the expected change has happened or not? The choice of metrics is crucial in an experiment and will be guided by the hypothesis or learning objectives.

What makes a good metric?

Relevant

Does it align with what you're trying to achieve?

Measurable

Can you define it? Is it something you can objectively measure? Are you able to capture the data, in the timeframe?

Replicable

Would it produce the same findings when measured again under the same conditions?

Actionable

Can you do something with the data? Will it help you make decisions?

Understandable

Can it be easily understood? Does it require a lot of context?

For example, in the <u>Ofgem case study</u>, the key metric was the proportion of consumers switching who received the signposting versus those who did not receive this signposting.

Planning your data collection

You'll have decided on your metrics during the design of your experiment. Throughout its duration, you'll be collecting this evidence, and so you need a defined plan for how and when this will be gathered. All groups should have their data collected at the same time and under the same conditions. If you're running a pre-post experiment, you'll need to capture baseline data before the experiment begins so that you can make your comparison afterwards.



Use the following questions to plan your data collection based on each metric.

Metric	Metric description	
Data source What? Where?	Data collection strategy Who? When? How?	Data analysis strategy Who? When? How?
Guiding questions: • What data are you gathering? • Where will you source the data from?	Guiding questions: • Who will collect the data? • When are the different points at which data will need to be collected? • How will you collect the data – for example through questionnaires, expert assessment or other methods?	Guiding questions: • Who will complete the data analysis and do they have the right skills? • When will the analysis take place, including the final and any intermediate analysis? • How will the data be analysed and used to prove or disprove the hypothesis, or to yield the learning sought?

5. Identify experimental risks and specify mitigation strategies

Specify the type of learning risk you are willing to take on

An experiment shouldn't be shut down just because it is considered risky in the sense of not proving your hypothesis to be correct, or not achieving the expected outcome; if the experiment will help you to learn what you want to then taking on some 'learning risk' is usually helpful. Because of the confines of an experiment, you're also able to take on some of this type of risk in a controlled, considered way. You'll need to consider in your specific context what type of learning risks you're willing to take on, and how much. Openly communicating that you're taking an experimental approach and framing your activities around learning can also help manage concerns around reputational risk.

Create a mitigation plan for potential risks to the experiment

This is where it's time to think through everything that could hinder your experiment as a project and prevent you from achieving your learning objectives. This could include poor project management or poor design of your experiment. Could funding or resourcing change? If so, would there still be a way to ensure something valuable is learned from the experiment?



6. Plan monitoring and reflection



Use this section to complete the **Plan** section and anticipate the **Insights** and **Next experiment** sections of the **Running an experiment** worksheet.

If you're testing a new product or service it might become quickly apparent that it isn't having the desired outcome. This is why it can be helpful to build in 'stage gate' moments for reflection, so that you can see when an experiment isn't achieving the desired outcomes and be ready to readjust or close it down. This doesn't mean that the experiment has 'failed'. Rather, it means you're learning quickly without spending too many resources.

Concluding an experiment



Use this section to anticipate the Reflections sections of the **Running an experiment** worksheet.

Results evaluation

Once you reach the end of your experiment, you'll need to allow the time and space needed for analyzing the results and developing your learnings. It's vital that your reporting of the experiment is transparent and includes all results, not only those that might be statistically significant or convenient (this means including outliers and excluded data and rationale for exclusion). It should also include how the experiment was designed, analyzed and interpreted. You should also think about whether you should plan for impact evaluation beyond the life of experiment. Will there be any longer-term impacts on those who participated in the experiment?

Sharing data and insights

An important part of any experiment is sharing the data and insights you have collected. This could include both sharing insights to support decision making and sharing information as part of broader stakeholder management. Think about the different stakeholders and audiences you want to reach. What is the best way to share this information with them? For anyone involved in decision making, what do they need to know to help guide them?

Process evaluation

As well as thinking about the impact of the experiment, it's also valuable to reflect on the process of running the experiment: were you able to obtain and analyze the data needed to test your hypothesis or learning objective? This will help you learn and pinpoint things you could improve next time. Define times for reflection and process evaluation, and ask yourselves questions such as what about the experimentation process made gathering learning easier or harder?



Sharing experience

Just as you will share the impact of the experiment, you should also share your experience about the process. Make a plan to document and share your insights, thinking about who would benefit from this learning? How can you best reach them with this learning? What relevant platforms and media exist?

Planning your exit

When the experiment ends, or when participants exit the experiment before then, regulators may need an exit strategy to manage the transition of participants from the treatment to the business-as-usual state. In cases where an experiment finds the alternative requirements tested were highly beneficial, the exit strategy could include measures to mitigate participant expectations around future wider-scale implementation of these, or broaden the rollout of these new requirements rapidly.

Final evaluation output

A final evaluation output should be produced for the experiment as a whole. This review should provide an impact evaluation that assesses the extent to which the experiment achieved its aims of validating a hypothesis or achieving learning objectives. It should also include general insights gained, process evaluation notes, lessons learned and follow-up actions. This may include planned adaptations to existing regulatory advice and processes, a proposal for adapting relevant regulations through further consultation, or recommendations for how to run a better experiment in future.





3

Regulatory sandboxes

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Part A: What is a regulatory sandbox?

In Chapter 2: Regulatory experiments, this toolkit describes when and how a regulator may consider taking an experimental approach. Regulators can use experiments as ways of testing or trialing new products, services, approaches, or processes. A well-designed experiment can help a regulator generate evidence or information that can inform the design or administration of a regulatory regime.

In other situations, rather than initiating a stand-alone experiment itself, regulators may want to facilitate experimentation and information-gathering activities in cooperation with third parties. This is particularly relevant for innovative products and services being developed by third parties, where there is uncertainty around how an innovation will interact with and impact people, existing markets, and regulation in the 'real world'. Innovative products or services may pose challenges for regulators because they may not fit easily within existing regulation, it may be unclear how regulation applies or they may even present a radical challenge to the regulatory framework. In these situations, both innovator and regulator will have an interest in generating evidence and information about how an innovation will work in a 'real world' context (e.g. with real users, or in a realistic physical environment).

Setting up a **regulatory sandbox** is one way regulators can facilitate these experimentation and information gathering activities.

A regulatory sandbox is a facility, created and controlled by a regulator, designed to allow the conduct of testing or experiments with novel products or processes prior to their full entry into the marketplace.

Regulatory sandboxes began emerging in the 2010s in financial services, with the sandbox concept borrowed from the world of computing. They provide a framework to enable industry and regulators to undertake and learn from experiments. To industry they offer access to testing in something approximating a real world environment, but usually in a limited regulatory subsector, for a limited period of time, and within a safely circumscribed space that a regulator can adequately supervise. In this way, regulatory sandboxes also allow regulators to "advance regulation through proactive regulatory learning" and in doing so, help them gather knowledge to "find the best means to regulate innovations based on real-world evidence" in order to respond to challenges related to uncertainty and disruption or to develop new regulatory policies. 12

Regulatory sandboxes vary in their practical implementation across jurisdictions, reflecting differences in regulatory objectives, legislative contexts, and other factors. Different sandbox models may vary in particular in the extent to which they permit regulatory waivers or other kinds



of regulatory flexibility for new products or services, in the processes they follow for approving experiments and enabling them to be carried out, and in any feedback loops to the regulatory decision-making process.

Despite these differences, the primary motivations for establishing a regulatory sandbox are widely shared between regulators. These motivations are to:

1. Support marketplace innovation

By reducing regulatory barriers to market entry.

2. Contribute to regulatory learning

By providing opportunities to investigate the public value, risks, and regulatory implications associated with innovations that are developing at regulatory frontiers, and to understand how regulation might need to adapt or develop.

The types of experiment that take place within sandboxes can also vary, though in practice they tend to be exploratory experiments, often using a pre-post experimental design rather than more rigorous designs involving randomisation (see Chapter 2: What is regulatory experimentation for detail on different experimental designs). This reflects the fact that the priority for innovators participating in sandboxes is to trial their innovations with real customers rather than to test specific hypotheses to the highest standards of evidence; and the regulator's priority in implementing a sandbox is typically to gather more qualitative, observational data across a range of innovations.

By allowing testing of new products and services, a regulatory sandbox can help support market-led innovation, giving innovators a way to overcome uncertainties related to both innovation viability and regulatory compliance before investing in all necessary regulatory approvals for market access. A sandbox can also provide a venue for industry stakeholders to provide feedback to regulators on existing or proposed regulations. Finally, a regulatory sandbox can also help a regulator to gather knowledge about an emerging sector or class of innovation and to inform or even trial regulatory responses to these, possibly as a precursor to dedicated regulatory experiments.

Regulatory sandboxes versus testbeds, living labs and similar initiatives

The term regulatory sandbox is used in practice to refer to a range of different kinds of initiative. Other terms, such as 'testbeds', 'living labs', 'innovation spaces' or 'real-life experiments' are also frequently used to refer to similar (and overlapping) approaches to allowing the testing of innovations in more or less 'real world' settings. Key differences may relate to how close to 'real world' the setting provided is, whether the approach is focussed on a particular technology or use case or is more open, and the scope of regulatory flexibility offered.

Our definition of 'regulatory sandbox' set out above is consistent with different design choices, but emphasizes the regulator's motivation in establishing the sandbox. To avoid confusion when engaging with other stakeholders, clarity is vital. It is important to confirm what you mean when talking about your proposed regulatory sandbox as others may hold different assumptions about what is or isn't meant by a regulatory sandbox, testbed, etc.

What are the benefits of regulatory sandboxes?

The main reasons to set up a regulatory sandbox are to support marketplace innovation and contribute to regulatory learning. Once established, regulatory sandboxes can be beneficial for several reasons.

Benefits for regulators can include:

Greater market and innovation insight

Engagement with innovative businesses allows regulators to stay up to date with a changing market, the evolving needs of businesses and recent technological developments. A sandbox can help regulators understand the regulatory implications of emerging ideas based on direct experience and quantitative metrics rather than on opinions (e.g. from subject matter experts, advice centres, or industry engagement) giving them better foresight for future innovations.

Insights to inform long-term policymaking and development of new regulations

Sandboxes are time-limited, controlled, observable environments where gathering information in 'real-world' environments is possible. The data, evidence and resulting insights from experiments conducted within sandboxes can be valuable to regulators through either directly or indirectly shaping regulatory policy and the development of new regulatory frameworks.

Early intervention supports consumer, public and environmental protection

A sandbox provides time-limited regulatory flexibility while ensuring appropriate safeguards and increased monitoring are in place throughout the testing phase. Existing rules and regulatory uncertainty can prevent safe and valuable innovations from reaching the market, so it is useful to have a mechanism that creates some flexibility while allowing for the improvement of safety and protection standards. This is particularly important in cases where the regulatory situation may be unclear or uncertain and meaningful legislation is yet to be created. By working closely with businesses as they develop their innovations, the regulator can better understand potential risks (and opportunities), guiding businesses to ensure new products or services are aligned with regulatory expectations and do not cause any form of obvious harm. Innovators who have been through sandboxes have expressed greater respect for the regulator and their aims and have said that participation led them to adopt better practices which will help them ensure compliance in the future.







Benefits for innovators can include:

Quicker entry to market

Moving from application to licencing/approval and then participation in a sandbox can happen very quickly (sometimes in a matter of weeks). Insights from the sandbox allow regulators to better tailor regulatory support for new products, services and business models, in some cases helping innovators to reach the market sooner.

Reduced regulatory uncertainty

Participation in a sandbox can provide innovators with a greater level of regulatory understanding and certainty. This is particularly valuable for small or new businesses with fewer resources to invest in legal advice than larger companies. Where regulatory agencies take a more hands-on approach during the sandbox, communication has greatly improved between regulators and innovators on an ongoing basis. By getting to know regulators, innovators also gain access to channels through which they can share feedback. Through advice centres, innovation hubs and other forms of regulatory support, lessons learned through a sandbox will also benefit other companies seeking to develop similar products or services.

Investor and market confidence

Regulatory sandboxes can have a significant influence on the growth of investment in an emerging area. Investors and other market stakeholders may have higher confidence in innovations and innovators that participate in a sandbox and receive regulatory approval, many of which may otherwise be seen as unviable. For example, evidence has shown that by removing regulatory uncertainty, sandboxes have likely played a vital role in increasing venture capital investment in the fintech ecosystem.

Which sectors use regulatory sandboxes?

The regulatory sandbox model is extremely versatile and adaptable. Since emerging in financial services regulation they have spread to many other regulated sectors of the economy. To illustrate the diverse settings in which sandboxes have been established, and the different models adopted, selected examples are described below.

Fintech

There are fintech sandboxes in over 50 countries. In Canada, the Canadian Securities Administrators (CSA) set up the CSA Regulatory Sandbox to support fintech businesses seeking to offer innovative products, services and applications in Canada. It allows firms to register and/or obtain exemptive relief from securities laws requirements, under a faster and more flexible process than through a standard application, in order to test their products, services and applications throughout the Canadian market on a time limited basis.



Around the world, fintech sandboxes are experimenting with several different technologies, including distributed ledger technologies, biometric authentication, robo-advisers, soft-tokens and remote account opening.

Case study Financial Conduct Authority in the UK

Problem

One of the central aims of the UK's Financial Conduct Authority (FCA) is to protect consumers. It is also interested in encouraging innovation, as long as this is to the benefit of consumers.

Solution

To balance these interests, in 2016 the FCA established the world's first regulatory sandbox for the financial sector. The FCA's regulatory sandbox allows businesses to test innovations with real consumers in a controlled environment. Innovations must either be regulated activities or support regulated activities in the UK financial services market, must be genuine innovations with a clear need for testing in the sandbox, and present a benefit for consumers.

How it works

The sandbox accepts applications on a cohort basis. Firms can propose any innovation they think would benefit from access to the sandbox, as long as it meets the eligibility criteria (see Eligibility criteria for the Financial Conduct Authority's sandbox (UK)). When the FCA opens calls for a sandbox cohort, it often identifies problems it is particularly interested in addressing through innovation. For example, when seeking applications for Cohort 7 in late 2020, although this was not an entry requirement the FCA expressed interest

in business, product, and service innovations to "detect and prevent fraud and scams, support the financial resilience of vulnerable consumers", and "improve access to finance for small and medium sized enterprises." It also mentioned an interest in proposals for innovations to help address consequences of coronavirus.

Once accepted to the sandbox, innovators gain access to regulatory expertise from the FCA, and access to regulatory flexibility. This includes restricted authorization to test specified ideas, informal advice related to regulatory implications of an innovation, waivers and modifications to FCA rules (within the FCA's regulatory jurisdiction) or "no enforcement action" letters to facilitate testing, and individual guidance to interpret requirements to facilitate responsible testing.

Impact

As of early 2021, the FCA has accepted six cohorts of approximately 20 innovations each for testing through the sandbox, with applications for a seventh having recently closed. The FCA estimates that participation in the regulatory sandbox reduces the time it takes for innovations to reach the market by 33 per cent, and of innovators that participated in the first sandbox cohort, 30 per cent succeeded in attracting investment. 13, 14

Read more



Health

A growing number of sandboxes have emerged in the health and care sector such as Singapore's Licensing Experimentation and Adaptation Program, ¹⁵ the UK's Care and Quality Commission sandbox, ¹⁶ Jersey's Digital Health Sandbox, ¹⁷ and proposals in Malaysia. ¹⁸

These initiatives have predominantly focused on digital innovations, such as digital triage, or alternative approaches to service provision (e.g. telemedicine and mobile medicine services).

Energy

Energy focused regulatory sandboxes are being developed or run in a number of countries, including the United Kingdom, Canada, Singapore and Germany. These sandboxes have somewhat different emphases and are run by entities with differing regulatory remits but are all testing new types of energy infrastructure (e.g. battery technology) or new types of service provision.

For example, the Ontario Energy Board's sandbox¹⁹ is designed to support innovators to run experiments in order to test new ideas, products, services, and business models in the electricity and natural gas sectors. Specifically, it is looking to assist utilities and other companies interested in innovative energy-related projects that show clear potential for benefit to consumers, whether in the form of long-term economic efficiencies, cost performance improvement, service enhancements or other ways.

In the UK, the energy regulator Ofgem's Energy Regulation Sandbox has "desirability characteristics" for sandbox participants that relate to "the impacts (good and bad) you expect your innovation to have on consumers, decarbonisation, the energy networks and markets."²⁰

Transport

There are a number of regulatory sandboxes within the mobility sector, especially around mobility on demand (MOD) solutions and connected and autonomous vehicles (CAV). Since the live-testing of mobility innovations emerged simultaneously with, but independent of, regulatory sandboxes, initiatives in this space are often described as living labs or testbeds.

These initiatives tend to take the form of large-scale public-private partnerships with the joint involvement of actors from government, industry and academia. Notable examples include the Catalonia Living Lab,²¹ the Singapore Autonomous Vehicle Initiative,²² GoMentum Station²³ in the US or the Austrian government's efforts around connected and automated mobility.²⁴



Case study

Land Transport Authority in Singapore

Problem

In Singapore, the Land Transport Authority (LTA) is tasked with addressing current and anticipated transport needs through exploring the use of new technologies.

Solution

The LTA plays a crucial role in building and supporting an entire ecosystem around autonomous mobility. Its live-testing initiative is helping to realize a broader objective of meeting some of Singapore's unique challenges around increasing travel demand, shortage of labour, land constraints and an ageing population. It is helping do this through the testing of autonomous vehicles, bicycle- and e-scooter-sharing services and other technologies.

How it works

In general, innovators can apply to test their innovations in relevant sandboxes that have been established. Trials can take place if they are approved by the LTA, beginning in more constrained zones and then expanding to larger areas if they pass safety tests designed to give regulators oversight. The LTA engages community-level leaders ahead of anticipated sandbox activity in their constituencies.

Impact

The LTA has been able to work with innovators to test autonomous vehicles, bicycle- and e-scooter-sharing services, and other technologies while developing relevant regulation dynamically over time.

Read more

Data

A few sandboxes have started to emerge to address uncertainties around the use of personal data as new data regulations come into force. These initiatives are cross-sectoral by definition because such questions arise in almost every domain.

The beta-phase regulatory sandbox developed by the UK Information Commissioner's Office, ²⁵ is open to organizations of any type that deal with challenges around the use of personal data, such as sharing or data protection impact assessment. The Singapore Infocomm Media Development Authority's Data Collaborative Program²⁶ offers funding as well as a sandbox environment and targets companies that seek to offer a data-sharing platform as a service.



Part B: Is a regulatory sandbox right for you?

Before setting up your own regulatory sandbox, use this checklist of considerations to determine whether this approach is right given your context and needs, and those of your stakeholders.

1. Is regulatory flexibility possible?



Use this section to complete the **Regulatory flexibility** section of the <u>ls a sandbox right for</u> you? worksheet.

Before deciding to set up a regulatory sandbox, it is important to clarify what is and isn't possible under existing legislation (e.g. whether an exemption from a legislative or regulatory provision can be issued to enable a sandbox, or whether some form of waiver can be provided). In some cases, sandboxes may require exemptions from multiple regulations that may be administered at different levels of government. Ensuring that all regulatory exemptions required have been identified and can be secured is an important early step in determining if the proposed sandbox is possible.

Any exemptions or waivers would be limited in time and scope. If existing authorities are not sufficient, legislative change may be needed to enable a sandbox. Government departments may wish to reach out to their legal teams for options on how to achieve exemptions, waivers and/or legislative change.

Case study

Remotely Piloted Aircraft Systems (RPAS) with Transport Canada

Drone technology is widely available in professional and consumer markets. However, the absence of a regulatory framework is limiting innovation and economic opportunity within this space. There is a need for greater understanding of the technology, its capabilities, and its potential applications in order to bring regulation into alignment with this technology.

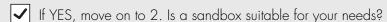
Transport Canada responded to this problem by creating a regulatory sandbox for implementing pilot projects to develop Canadian expertise and experience in drones in the aviation and technology industries. These pilots have allowed the regulator to provide online and accessible services to Canadians, and to make timely and iterative amendments to the Canadian Aviation Regulations.



For additional discussion on experimentation and exemption clauses, see **Experimentation and exemption clauses** in **Chapter 2: Regulatory Experiments**.

Before proceeding, check

Does existing legislation permit you to establish a sandbox?



X If NO, consider proposing an experimentation clause, exemption, or waiver.

2. Is a sandbox suitable for your needs?



Use this section to complete the **Problem** section of the <u>Is a sandbox right for you?</u> worksheet.

Regulators use several different starting points or justifications for developing a regulatory sandbox. These broadly fit into three categories:

- 1. Sandboxes can be used as a novel way of meeting statutory objectives and mandates, such as environmental protection or promoting competition. The sandbox is a way to explore whether existing regulations still support the regulator's mandate as new products, services or business models enter the market, and allows the regulator to oversee the testing of innovations that might deliver public value or even support their mandate.
- 2. The need to understand and regulate an emerging area is another key driver. This could be an area that is currently unregulated or an area of innovation that is currently prohibited by existing regulation.
- 3. Regulatory modernization and a broader push to reduce regulatory burden is sometimes used as an additional justification in combination with the others above.

Sandboxes are mainly useful where new products, services or business models are already starting to emerge, but their potential impacts on regulation, society and the economy are unclear. These products or technologies don't need to be particularly mature, but there does need to be a relatively high level of innovative activity for a sandbox to be valuable. Autonomous vehicles are not yet fully mature but there has been a great deal of innovation in this area and regulatory sandboxes have proven to be a valuable way to begin resolving regulatory uncertainty through testing.



Understanding what's happening in your sector

Developing a research base on the kinds of innovation that might be emerging in your sector, where this innovation is coming from (startups vs incumbents, from within or outside the sector) and the kinds of barriers innovators are struggling with will help you assess how useful a sandbox might be. Sandboxes are resource intensive and it is not advisable to go ahead without first completing detailed background research and wider industry engagement. In many cases, setting up an advice centre or creating better mechanisms through which the regulator can engage directly with innovators will be enough to resolve any reported regulatory issues.

Non-regulatory barriers

In deciding whether to pursue a regulatory sandbox, it is also important to remember that many non-regulatory barriers to innovation also exist. These tend to be sector specific and historical (e.g. complex system or market relationships prevent new ideas from flourishing). A regulatory sandbox will not be able to help innovators overcome these kinds of barriers and care should be taken in communicating what the sandbox can and can't do. 27

Regulatory capture

As sandboxes are typically small, often reaching tens of companies per year, there may be some concern around the extent to which participating businesses are able to influence future regulatory decisions unduly to favour their business model. This influence would count as an example of 'regulatory capture'.

Regulators have addressed this risk in two main ways:

 Any insights gained through the sandbox are used to help the regulator improve the services and support they offer to all regulated entities.

- However, to maximize these benefits the regulator will need to have other processes in place, such as open advice centres and clear communication strategies.
- Any proposed adaptations to existing regulations or the creation of a new regulatory framework will be informed by wider stakeholder consultations and other standard processes, as well as insights gathered from the sandbox. In this way, the sandbox provides valuable additional learning that complements other well established ways of working.

Before proceeding, check

Does existing legislation permit you to establish a sandbox?



✓ If YES, move on to 3. Have you spoken to industry, innovators or the public?



| X | If NO, analyse the consequences and root causes of the problem you are trying to address, what needs to change to overcome these, and whether other experimental mechanisms in the Experimentation section could be used instead.



3. Have you spoken to industry, innovators or the public?



Use this section to complete the **Stakeholders** section of the **Is a sandbox right for you?** worksheet.

Your sandbox needs to meet your needs as a regulator (the focus of Part B2 in this chapter), but its success will also depend crucially on how stakeholders respond to it. Stakeholders include in particular the industry players and innovators that you hope will participate in the sandbox, but also the consumers who may be directly involved or indirectly affected. Stakeholder engagement will enable you to test your assumptions and hypotheses about the sandbox, and in particular to establish that a sandbox is perceived as useful and necessary and will meet a significant need of industry and innovators, and that it will command the consent of consumers; and it can inform the design of the sandbox to ensure that it will meet both your own and stakeholders' needs.

At this stage, when deciding whether or not to set up a sandbox, you should consider which stakeholder groups to engage and specifically who within them, the benefits of engaging them, the risks of not doing so, and what you want to learn from your engagement with them. Stakeholder groups you may want to consider include:

- Industry: Incumbent players, startups, SMEs, innovators and non-traditional players.
- Other government departments and regulators (local municipal, provincial/territorial and federal level).
- Civil society organizations and the public (may be more relevant at a later stage, once a sandbox design is ready to be proposed).

Once you have identified your priority stakeholders, you can design out the best way of engaging them. Informally holding conversations with key industry stakeholders and innovators may support decision-making by helping to identify non-regulator perspectives on regulatory and wider industry challenges, and by testing out the high level sandbox idea. Introducing others to the concept of a sandbox and observing how it is received can help keep decision-making aligned with industry needs, interests, expectations, readiness, and appetite. Networking, attending existing industry meetings, and engaging in one-to-one conversations with key industry representatives can provide opportunities for a regulator to surface industry frustrations, concerns, desires, and ideas. It can also present opportunities to soundboard an early-stage sandbox concept before committing to a particular approach to design and implementation.

This engagement is best conducted on an ongoing basis to stay in step with evolving needs, interests, challenges, and uncertainties. Staying aware of current conversations relevant to a potential sandbox project can help to understand the benefit it could have and how it could be positioned in relation to interested actors.



Before proceeding, check

Have you tested the concept of a sandbox with key stakeholders who have an interest in the regulatory challenges this approach could address?



✓ If YES, move on to 4. To what extent are you focused on regulatory change?



X If NO, map the range of stakeholders who could give insight into whether and how a sandbox could help address their needs.

To what extent are you focused on regulatory change?



Use this section to complete the Regulatory change section of the Is a sandbox right for you? worksheet.

A key distinction between sandbox initiatives is the extent to which they include the potential for (or focus on) regulatory adaptation. Although this is not the norm for sandboxes, some have had the explicit aim of developing a new set of regulations by a fixed date. An example of one such sandbox was the Singapore Ministry of Health's licensing Experimentation and Adaptation Program.²⁸

If this is an objective for your sandbox, it will most likely have implications for how your sandbox is executed and marketed. For example, the sandbox is more likely to be time-limited (rather than operating on a rolling, open timetable) and there is more likely to be a well-defined set of innovators or industry participants whose participation in the sandbox is particularly important. In these circumstances the regulator will likely want to use the sandbox to collect data on specific metrics or indicators to inform decision-making. To do this, it is recommended that the regulator consider using the guidance from Chapter 2: Regulatory experiments to help design the experimental aspect of the sandbox to meet its learning objectives. Also, the regulator should decide whether and how to communicate these learnings.

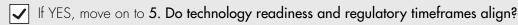
Most sandboxes leave open the possibility of regulatory change, but in practice the resulting changes tend to be to regulatory guidance rather than the regulation itself. For example, the Hong Kong Monetary Authority (HKMA) updated its supervisory guidance on biometric authentication and remote account onboarding in light of tests conducted by banks participating in the sandbox 29

Proposed regulatory changes will have to go through a drafting and consultation process, which takes time. Regulators may need to exercise caution when outlining the extent to which regulatory change is possible (or even necessary) with companies who might be pushing for regulatory change through a sandbox.



Before proceeding, check

Have you defined the aim, if any, of your sandbox in relation to regulatory change?



If NO, revisit the results of your stakeholder engagement to understand expectations around and appetite for regulatory change and consult with colleagues and leadership to understand potential to enact change.

5. Do technology readiness and regulatory timeframes align?



Use this section to complete the Technology readiness and regulatory timeframes section of the Is a sandbox right for you? worksheet.

Where regulatory change is an explicit aim of the sandbox, careful consideration should be given to the maturity or market readiness of the innovations being tested, the scale of regulatory uncertainty and the feasibility of regulatory change within a reasonable timeframe.

In instances where technologies, products or services are ready to be deployed but testing in a sandbox won't completely overcome key areas of regulatory uncertainty, or it is clear regulatory change can't happen in a timeframe that would benefit the innovations being tested, a sandbox will struggle to serve the needs of both regulators and innovators.

An extreme example would be the use of gene drive technology to manage disease vectors like mosquitos. Gene drives are a genetic engineering technology that propagates a set of genes throughout a population. While the technology is ready to use, extensive legal and ethical uncertainties exist. This is partly because its potential impacts are unclear but also because using it requires political and values-based judgements to be made. Even if live testing could overcome key legal, regulatory and ethical questions (though it would not be advisable as its effects on a population could be irreversible), the process for developing new laws or regulations would likely not be done in a timeframe that would benefit a company's investment in that technology.

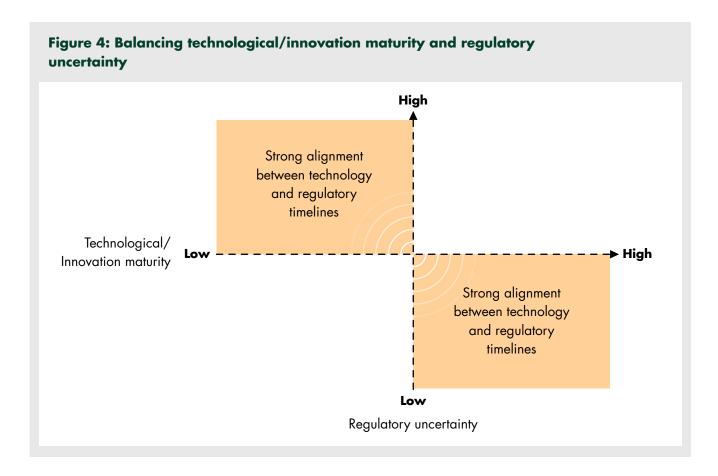
Comparing technology readiness or innovation maturity with levels of regulatory uncertainty is a valuable way of assessing how far a particular sandbox can support the needs of both regulators and innovators.



Achieving this balance is much easier where:

- There is a high degree of regulatory uncertainty but innovations are still immature. The
 technology and regulation develop simultaneously so by the time the innovation is ready to be
 deployed, adequate regulations are in place. Connected and Autonomous Vehicle test beds have
 taken this approach to technology and policy development.
- 2. Products and services are market ready and there is little regulatory uncertainty to deal with.

 Even if changes to regulations are needed, they are light touch, straightforward and can be processed quickly. For example, the Licensing Experimentation and Adaptation Program run by the Singapore Ministry of Health has provided a defined timeline for regulatory change linked to its sandbox for market ready telemedicine products and services.



Before proceeding, check

Are you confident that the level of regulatory uncertainty you hope to resolve is aligned with technology readiness or innovation maturity?

✓ If YES, move on to 6. How much inherent risk does running a sandbox present?

If NO, establish the level of uncertainty from a regulatory perspective, and engage with technical expertise to establish the maturity of a technology or innovation market.



6. How much inherent risk does running a sandbox present?



Use this section to complete the **Risks** section of the <u>Is a sandbox right for you?</u> worksheet.

Sandboxes imply a different approach to risk management from that of other activities undertaken by regulators. On the one hand, sandboxes typically entail new risks, because they allow the testing of innovative products and services without a track record in (close to) real-life situations. On the other, the regulator can devise bespoke requirements for participants in a sandbox and will typically be dedicating significant supervisory resources to the sandbox. The net result is not that the regulator needs to accept a higher level of risk in running a sandbox, but it does demand a different and deliberate approach to risk management.

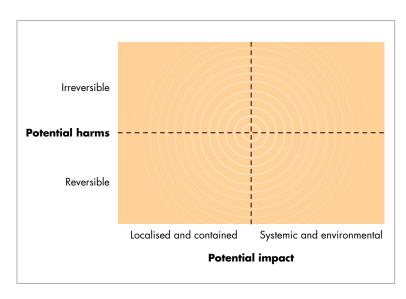
To date, sandboxes have mainly been used in sectors or with innovations that carry relatively few risks or where risk can be tightly controlled. This may mean that the benefits of the sandbox approach are not being fully exploited.

If they are designed with the right safeguards, sandboxes are a good way to manage these risks within a controlled environment. Certain innovations or sectors are inherently more risky than others and in others public perception of risk may be as important as the actual risk involved with testing new products, services or business models (see point 3). Where the potential for harm is greater, or public perception of risk is important, a more controlled testing environment would be needed. In these situations there is a tradeoff between real world fidelity and control. In practice this might look very different to the usual sandbox model adopted by many regulators.

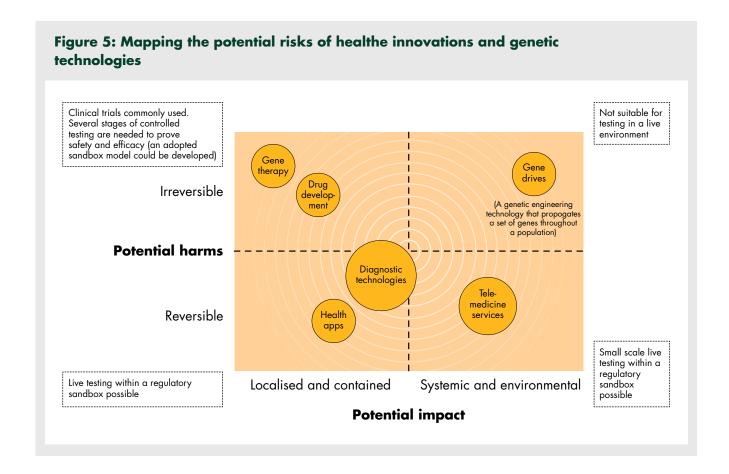
A sandbox model with several stages could be developed for high risk areas. In a process similar to clinical trials, each stage would allow the innovation to be tested in a more realistic environment only if it had passed certain evidence and safety requirements in a previous testing stage.

Mapping potential harms and impacts

Before developing a sandbox, you will want to have as clear a sense as possible of the potential risks involved in testing different innovations and put adequate safeguards in place to mitigate any risks. Mapping the types of technologies, use cases or areas of innovation you are interested in onto the axes below can help identify whether a sandbox is a feasible approach. Beneath this is shown an illustrative example that maps different kinds of medical innovations on these axes and the potential implications for testing these innovations in a regulatory sandbox.







Before proceeding, check

Do you have a clear sense of the potential risks involved in testing different innovations, and have you specified safeguards to mitigate these?

✓ If YES, move on to 7. Will regulatory cooperation be needed?

If NO, map the potential risks, including harms and impacts, of the innovations and technologies you plan to test in your sandbox.



7. Will regulatory cooperation be needed?



Use this section to complete the **regulatory cooperation** section of the <u>Is a sandbox right</u> for you? worksheet.

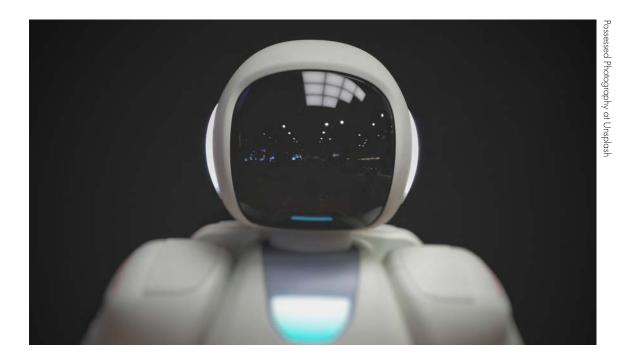
Sandboxes often require, or may benefit from, collaboration among various federal regulators or among municipal, provincial/territorial and federal authorities to achieve their goals. This may be because a particular area of innovation cuts across departmental mandates (e.g. data or digital enabled services have emerged in virtually every sector) or because testing requires more than one authority to cooperate (e.g. a product may be regulated at a federal level but needs to be physically tested in a particular region or city, or regulatory flexibility may require approval from different agencies). Such regulatory cooperation can be especially important when working in innovative industry sectors that are evolving rapidly, which can be the sectors that will benefit most from regulatory sandboxes.

International cooperation to pool resources and share learnings may also be relevant (e.g. when regulating the financial services and other sectors that operate across borders). Try to identify if there are other regulators, in Canada or internationally, who may be impacted by your sandbox idea and reach out to them in advance.

This is especially important when looking to establish a sandbox in industry sectors that are developing rapidly. Cooperating with different jurisdictions at an early stage can start the harmonization of data, information and findings. Cooperation can also create an economic incentive for outside firms to adapt to the findings from the experiments.

Regulatory cooperation could occur through coordinating advice and support to sandbox participants with a second regulator, or the sandbox could be designed and delivered as a joint undertaking. If your sandbox could benefit from regulatory cooperation, engage your regulatory counterparts early to investigate the shared benefits as well as the likely practical challenges in working together.

Building in early agreement with the parties identified can improve the scope of impact and the possible results that could be achieved through a joint sandbox. When facing challenges in identifying, contacting, or obtaining buy-in from impacted or key regulators, you can seek advice and support from the CRI and the Regulatory Cooperation team (see box below) to help address these issues and determine whether a regulatory sandbox is right for you.



The Regulatory Cooperation team in the Regulatory Affairs Sector

The process of regulatory cooperation is supported by the Regulatory Cooperation team in the Treasury Board of Canada Secretariat's Regulatory Affairs Sector (RAS). This team works together with federal regulators to ensure that regulations reflect the environment in which the regulated parties operate. Regulatory cooperation is an important factor in determining the success of a regulation because it ensures that Canadian regulations are well-suited for a global market.

The team can leverage its network of experts and representatives to help you make meaningful connections that amplify your impact.

If you would like to take advantage of the services offered by the Regulatory Cooperation team, please contact: rcd-dcmr@tbs-sct.gc.ca

Before proceeding, check

Have you identified whether there are other regulators whose jurisdictions may be impacted by your sandbox?



✓ If YES, move on to 8. Do you have access to the necessary resources?



| If NO, you could conduct interviews with key stakeholders, particularly innovators, to understand the other regulators they interface with.



Do you have access to the necessary 8. resources?



Use this section to complete the Resources section of the Is a sandbox right for you? worksheet.

Running an effective sandbox is resource intensive. It is easy to underestimate the potential cost and staff time required. Resource intensive activities include:

- Engagement with potential and actual sandbox participants
- Design and development steps (e.g. creating custom testing arrangements, securing approvals for regulatory flexibility)
- Monitoring, evaluation and ongoing engagement (this may mean a dedicated contact person for each innovation being tested)

Before developing a sandbox, it is important to ensure you have the capacity and resources needed across the whole project lifecycle. You will need to decide what level of engagement you want (and are able) to have with potential and actual sandbox participants, and whether this is consistent with your objectives and approach to risk. Sandboxes typically solicit considerable interest from innovators, even where the functionality offered by the sandbox is not really what the innovator needs.

A more engaged approach is more likely to create better outcomes for innovators participating in the sandbox and possibly for the regulator. Limiting the size of the sandbox (e.g. number of innovations or companies participating) can help limit the required resource commitment and is advisable when starting a sandbox.

A somewhat more hands-off approach is possible. For example, participation in the Hong Kong Monetary Authority's (HKMA) Fintech Supervisory Sandbox 2.0 is not tied to any strict eligibility criteria. There are no reporting obligations or mandatory minimum requirements beyond ensuring safety and consumer protection. There is no dedicated contact person during the testing period and the interaction between the regulator and the bank is mostly limited to the creation of the testing arrangements.

Before proceeding, check

Have you determined existing capacity and estimated additional resource needs for designing and running your sandbox?



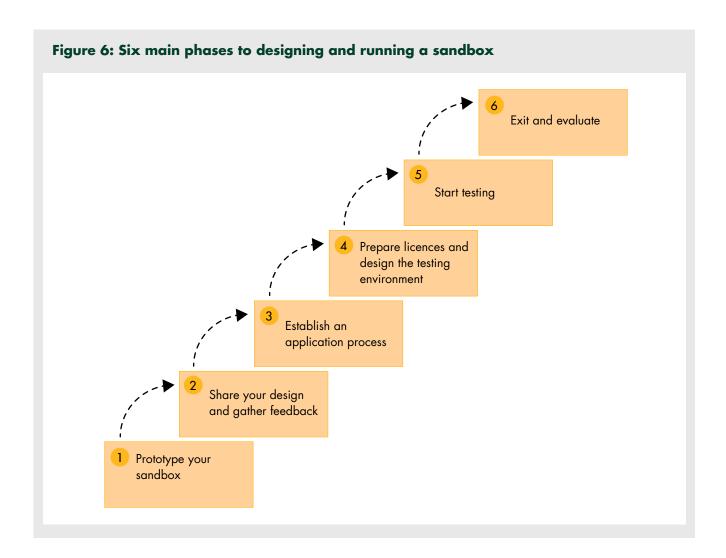
✓ If YES, move on to Part C. Designing and running a sandbox.



| If NO, understand opportunities and constraints in your ability to access resources, and determine how these may enable, limit, or prevent your vision from taking shape.



Part C: Designing and running a sandbox



1. Prototype your sandbox

Once you have run through the checklist of considerations in Part B: Is a sandbox right for you? and decided a sandbox is a good fit for your regulatory context and needs, you can begin to design your own. This process begins with creating an initial sandbox design proposal – a first version, or 'prototype' of the sandbox that explains the essentials of what it will do and how it will work.



To create your prototype, begin by identifying stakeholder needs and learning from other sandbox implementations in Canada and elsewhere and from any stakeholder engagement to date, before defining aims and objectives, specifying design parameters, determining resource requirements, and anticipating and mitigating risks.

Identify key stakeholder needs

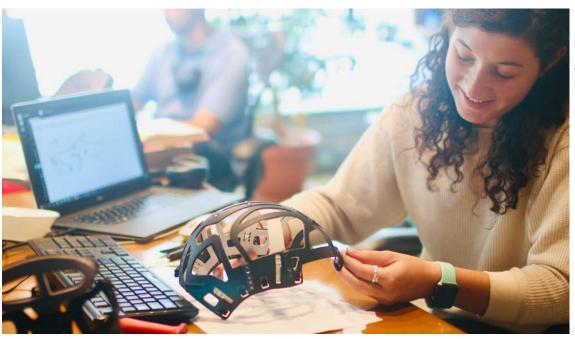


Use this section to complete the **Identify key stakeholder needs** section of the **Regulatory** sandbox canvas.

Clarify the aims and goals of your sandbox by identifying how it could address the needs, interests, challenges, and uncertainties surfaced through ongoing informal engagement with key stakeholders, particularly industry and innovators, and extract key points indicating stakeholder needs and challenges.

You should have already engaged with industry, innovators, and the public to help you determine whether a sandbox is right for you (see Have you spoken to industry, innovators or the public?
In Part B). If you have, consider whether there is a need to speak with more or different types of people at this stage. If you have already conducted extensive engagement with relevant groups, you may be able to revisit the insights you previously gathered to extract key ideas and perspectives that should inform your sandbox design.

Your understanding of stakeholder needs, interests, and challenges will evolve over time, and documenting it should be seen as an iterative activity. Expect your insights to specify, change, or expand in detail over the course of your design process.



ool Inc. at Unsplash



Map stakeholder involvement

Identifying stakeholder needs can help you understand who would be involved in a sandbox and how their roles would interact. One way of further clarifying this is to conduct a stakeholder mapping exercise (see Sandbox stakeholders in practice: autonomous delivery robots in Hamburg for an example). Who are the core stakeholders, who might be active or occasional participants and who is part of the surrounding environment?

Sandbox stakeholders in practice: autonomous delivery robots in Hamburg

Core stakeholders

- The delivery company Hermes Germany GmbH is the applicant
- The Hamburg Authority for Home Affairs and Sports and its traffic division is the relevant authority (supervisory and control function)
- These are the main two stakeholders establishing and running the regulatory sandbox.

Active participants

- Starship Technologies supplies the autonomous supply robot
- TÜV Hanse and HVD insurance
- The Hamburg Authority for Economy, Transport and Innovation (set up contacts and cooperation between the relevant administration and Hermes)

Occasional participants

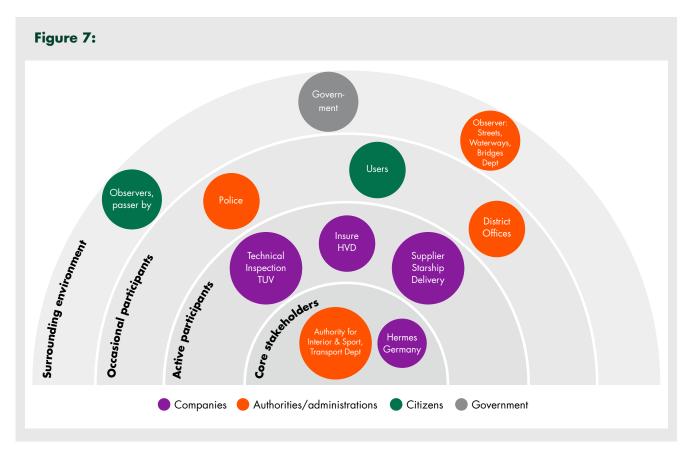
 The district offices are involved with regards to safety issues and can prohibit the implementation of the test.

- The police, which are also the road traffic authority in Hamburg
- Various police departments are to register and report accidents.
- Users of the service

Surrounding environment

- The Streets, Bridges and Waterways Department is observing the tests and attends the information meetings.
- Beyond the city of Hamburg, other policy bodies are interested in the regulatory sandbox (e.g. the approach taken and results achieved are discussed in the Joint Conference of the Transport and Road Construction Directors-General).
- All the passers-by who encounter the delivery robot are part of the surrounding environment.





Learn from similar solutions



Use this section to complete the **Lateral inspiration** section of the **Regulatory sandbox** canvas.

Consider whether other regulators have dealt with similar challenges to those you are aiming to address, and whether they have used a sandbox or related mechanism to develop a regulatory response.

This could include conducting desk research to review case studies or press releases describing sandbox activities or reaching out to networks of relevant contacts. Relevant insights may come from:

- Regulators working with the same regulatory sectors but in different jurisdictions.
- Regulators working in similar jurisdictions but with different regulatory sectors, or
- Any regulator addressing challenges of a similar nature.

Learning from existing examples can help expedite your design process by giving you models on which to base your design. This can put you a step ahead of where you'd be if you were to work entirely independently, without these references. It can also help you spot decision points where your design needs to be adapted, or potential pitfalls where other solutions failed or performed differently than what you are aiming for.





Define aims and objectives



Use this section to complete the **Define aims and objectives** section of the **Regulatory** sandbox canvas.

Before developing the practical elements of a sandbox, you want to clearly define both your primary and secondary goals. This will help you to shape what the sandbox looks like in practice, focus your resources and think about how you'll carry out your evaluation.

You'll have a much clearer picture of what these should be from your earlier engagement, and as far as possible goals should be developed in collaboration with your key stakeholders. It is good practice to try and reach a consensus on common aims and to put these in writing for clarity, as differing expectations can have a negative impact on the perceived value of the sandbox. Having clarity around the goals will also help with the sandbox evaluation.

Most sandboxes have goals that fit into one or more of these three categories:

- 1. To assess the real life regulatory and market implications of new technologies, products, services or business models.
- 2. To develop and test a new regulatory framework or new regulations that cover a previously unregulated or prohibited area.
- **3.** To support innovation in aid of wider policy goals (e.g. regional policy goals, promotion of sustainable mobility or development of a new industry) where the regulator is beginning to play an innovation catalyst role. In this case, the sandbox is likely to be one part of a larger initiative.



Case study

Singapore Autonomous Vehicle Initiative

Sandboxes can be one part of a set of regulatory (and broader policy) initiatives aiming to achieve broader or longer term strategic policy objectives that may cut across the responsibilities of multiple agencies.

The Singapore Autonomous Vehicle Initiative (SAVI)³⁰ is an ambitious example of this approach in practice. Its aim is to provide a technology platform for the research and development and sandboxing of AV technology solutions. These efforts form parts of Singapore's broader strategy towards attaining a sustainable transport ecosystem, which seeks to reduce reliance on private transport through ridesharing and mobility on demand.

Problem

In Singapore, policymakers saw potential for autonomous vehicles (AVs) to contribute to addressing challenges associated with travel demand and land as well as labour constraints faced by its transport systems. However, they also recognized a need to address risks associated with safety, privacy, cybersecurity, and liability, and the development of a specialized industry before AVs could be put into widespread use.

Solution

Singapore's Land Transport Authority (LTA) initiated the Singapore Autonomous Vehicle Initiative (SAVI) in partnership with the national Agency for Science, Technology and Research (A*STAR).

How it works

In this arrangement, the LTA takes the role of regulator while A*STAR oversees research and development, planning and coordinating research, and the sandbox operations. The SAVI partnership provides an opportunity to develop innovative approaches to regulation in parallel with technology development. SAVI has provided policymakers with an opportunity to proactively test the technical implementation and safety of emerging technologies through a series of trials, and to develop a regulatory framework based on the ensuing learnings.

Impact

Developing this initial regulatory framework has allowed SAVI to expand testing capacity accordingly, and this expansion continues to provide further opportunities to strengthen and specify regulation as rollout of AV technologies in Singapore increases.

Read more



Specify design parameters



Use this section to complete the **Design**, **implementation** and **delivery** section of the **Regulatory sandbox canvas**.

Starting with a 'beta'

If you are developing a sandbox for the first time, it can be helpful to begin with a beta version that has a set start and end date and only includes a small group of participants (no more than six or seven). This will help you to understand how the sandbox will work in practice and iron out any issues before opening it up to a wider group.

Determine resource requirements



Use this section to complete the Current assets and processes and Core team sections of the Regulatory sandbox canvas.

Once you have defined aims and objectives and specified design parameters, it's important to specify what resources will be required to fulfill these.

Taking a broad understanding of resources, you may want to consider:

- Infrastructure, including physical and/or digital.
- Data and data preparation (e.g. data scrubbing or anonymization).
- Subject matter experts (e.g. those who can provide technology, innovation, stakeholder engagement, or evaluation advice).
- Operational capabilities (e.g. in communications, legal, or IT).
- Support for sandbox participants (e.g. for training and onboarding, in-kind support).

Of the resources required to support your proposed sandbox, determine a) what you already have access to, and b) what you still need – and how you could access this.

Develop an evidence and insights strategy



Use this section to complete the Monitoring and measurement and Reflection and Learning sections of the Regulatory sandbox canvas.

Sandboxes provide a significant learning opportunity for regulators and other stakeholders, but without a deliberate approach to capture, disseminate and use learning this opportunity can be missed. As part of designing your prototype, make a plan to ensure this learning will have the greatest possible impact. This plan should include a strategy for handling both formal evidence and informal insights.



Evidence

Collecting evidence will mean planning data collection and analysis, and also ensuring the interpretation and dissemination of results will reach those who need to know about it and support their further action. This will include planning monitoring and evaluation: indicators of success and failure, metrics, and reporting responsibilities. Guidance in Chapter 2: Regulatory experiments on different approaches to developing metrics and gathering evidence in regulatory experiments will help you to identify an appropriate approach.

Insights

Documenting insights as they emerge, and after the sandbox completes, is also important to ensure a wider community of interest can benefit from what is learned. Planning to capture insights can include designating reflection points, developing continuous feedback mechanisms, and making an influencing strategy.

Above all, ensure you have a clear understanding of the learning opportunities your sandbox will afford, and also of how these learnings will inform changes to future regulatory action and policy, and influence wider changes in the regulatory sector.

Anticipate and mitigate risks



Use this section to complete the **Risk mitigation** section of the **Regulatory sandbox** canvas.

Looking back at the sandbox prototype you have designed, determine what potential risks could be involved in implementing it, and what could be done to manage and mitigate those risks or to respond if needed.

- Refer to the previous section How much inherent risk does testing running a sandbox. present? What potential harms and impacts have you identified?
- What safeguards will you put in place to reduce risk?
- What strategies and resources will be available to you should you need to address risks?

Finally, consider the maturity of your regulatory organization's current appetite for risk. How does the proposed sandbox relate to this? Will any shifts in mindset be required?

For more information on this topic, you may find it useful to refer to:

Care, E., Anderson, H. & Lloyd, J. 2020. 'Reframing Risk: How to adopt new mindsets around risk that enable innovation.' Nesta, London. Available: media.nesta.org.uk/documents/ Reframing_Risk.pdf



2. Share your design and gather feedback



Use this section to complete the **Leadership**, **Relationships with stakeholders**, and Engagement and communication sections of the **Regulatory sandbox canvas**.

Once you've established your sandbox goals with key stakeholders, it's a good idea to share these for wider, more formal consultation with any broader sectors or actors who may not have been involved in earlier, informal engagement activities. This will also help to gauge wider interest and start to communicate your intentions. At this stage, the aim of engagement should be to validate the proposed sandbox idea, anticipate its impact, and understand the features it would require.

Engaging with industry and innovators

Engaging with industry and innovator stakeholders is a critical step in assessing how useful a regulatory sandbox might be. But it is also necessary to inform the sandbox's scope and focus and to ensure there is adequate alignment between regulator and industry on the purpose and functionality of the sandbox. Lessons from several initiatives show how easy it is for a significant mismatch to occur in the way regulators may seek to support businesses and what those businesses actually want or need to successfully bring their innovations to market.

When engaging with industry, you may want to get stakeholders' opinions on:

- Their motivations for participating in a sandbox.
- The kind of support that is offered and what is possible during the testing phase.
- The extent to which regulatory change is an explicit possibility or aim.
- What is and isn't eligible for testing.
- How easy it is to recruit users (participation doesn't guarantee that an innovation can be tested, some business to business (B2B) products and services have struggled to recruit users for testing, even with the regulator's help).

Open, transparent and meaningful engagement with industry and innovators will not only help ensure the sandbox reflects the users' needs, but it also demonstrates the regulator is making a genuine commitment to supporting innovation.

Engaging with the public

The public are another key but often overlooked stakeholder. In most cases, testing will directly or indirectly impact the public in several ways. Where individuals are direct participants in a test, for example, as a customer or user, they will likely need to provide their consent and you may wish to understand how individuals will think about this decision and what kind of information they will need in order to take it. In other circumstances explicit consent may not be required but you may want a more general understanding of likely public attitudes to the sandbox and to the kinds of test that may take place in the sandbox.

When deciding if public engagement at this stage is essential for deciding whether to proceed with a sandbox, and if so of what kind, consider the legitimate concerns or interests that members



of the public may have, whether they directly or indirectly engaged in sandbox experiments, and the potential for negative impacts on consumers.

Case study Lithuanian Central Bank

A good model is the process through which the Lithuanian Central Bank set up a blockchain sandbox. The bank conducted a thorough assessment of the technological feasibility and benefits of the concept of a blockchain sandbox. It also took an iterative approach to developing the sandbox, first piloting it at a small scale before rolling it out for wider participation.

Throughout the process they had continuous discussions with platform service providers and interested fintech companies. While this level of prior engagement is costly and time-consuming, in this case it helped to ensure that the sandbox was fit for purpose for all those involved.

Read more

At this stage, you may want to consider working with stakeholders to:

- Iterate on the proposed sandbox model through a collaborative co-design or consultative scoping process.
- Understand which of multiple sandbox design options they prefer.
- Gain a better understanding of the conditions 'on the ground' and how the proposed sandbox would impact people in practice.

To help raise awareness of the sandbox among a wide range of potential applicants, you should carry out dedicated communication activities. This is particularly important if you're interested in engaging with non-traditional players. Trade press, other publications and industry representative bodies can be helpful mediums to help reach your target audiences.

3. Establish an application process

Some sandboxes are run over defined periods and engage several cohorts of innovators, while others have an open, ongoing application process.

The defined approach allows regulators to better manage resources and adapt each iteration of the sandbox, while the open approach allows firms to engage with the regulator at any time when they are ready to test an idea.

During this stage, regulators often provide informal advice to applicants on what they might need to consider when completing applications, explain the eligibility and assessment criteria and what is required from applicants.



You should be very clear in the way you communicate timelines and your expectations of the innovators looking to participate. Innovators may also need to demonstrate that they are able to make any necessary partnerships or secure clients before entering the testing space. Before accepting participants into the sandbox, you should perform additional due diligence on the companies applying.

Eligibility criteria

Potential participants in regulatory sandboxes are typically required to submit applications that are judged on specific eligibility criteria. Eligibility criteria will depend on the scope and focus of the initiative but generally will cover five points:

Is the innovation and/or firm in scope?
Scope might cover jurisdictional considerations (e.g. which country and sector the innovation is intended for) and more specific questions around things like the technology being used or the innovations intended use cases. Applicants may be asked to provide information on things such as who the customers would be, how it will make money and the markets that the innovator wants to operate in.
Is the product, service or business model innovative?
Innovativeness is a difficult attribute to quantify. When determining how genuinely innovative a proposal is, regulators have tended to apply a low bar, at least in the beta stages of a sandbox. In practice, they tend to simply try to confirm nothing like this already exists in the market. Expert opinion may also be used to identify genuinely innovative products and services.
Is there a clear potential for public or consumer benefit?
Public benefit may be interpreted broadly. Assessment is usually based on quantitative measures (e.g. how many people benefit) and qualitative predictions (e.g. how much will they benefit). This is also an opportunity to ask participants what they think the impacts of their innovation might be and why they think it is a good idea.
Is testing necessary? What barriers does the innovation face?
This question seeks to clarify if the innovation easily fits within the existing regulatory framework and how important sandbox testing is to achieving market access. Where it is an incumbent firm putting in an application, they may be required to explain why they have not been able to resolve the issues without sandbox support.
Is the innovator ready to test?
Participants must demonstrate that they have a clearly developed plan for testing (e.g. clear objectives, parameters and success criteria), are ready to participate in the sandbox and are able to put the necessary safeguards in place.



Table 1: Eligibility criteria for the Financial Conduct Authority's sandbox (UK)

These are the criteria against which we will make decisions regarding applicants for testing in the sandbox.

Criteria	Key question	Positive indicators	Negative indicators
Is the firm in scope?	Is the firm looking to deliver innovation which is either regulated business or supports business in the UK financial services market?	 Innovation appears to be intended for the UK market. The firm's relevant activity is regulated by the FCA or is intended for firms regulated by the FCA. 	 Innovation does not appear to be intended for use UK market. The firm's relevant activity is not within the scope of the FCA's regulatory regime or intended for FCA regulated firms.
ls it genuine innovation?	 Is the innovation groundbreaking or constitutes a significantly different offering in the marketplace? 	 Desk research produces few or no comparable offerings already established on the market. Internal experts believe that it constitutes a genuinely innovative technology/approach/product or service. Step-change in scale. 	 There are numerous examples of similar offerings already established on the market. Internal expertise believes it is not particularly innovative. It looks like artificial product differentation.
Is there a consumer benefit?	Does the innovation offer a good prospect of identifiable benefit to consumers (either directly or via heightened competition)?	 The innovation is likely to lead to a better deal for consumers directly or indirectly e.g. through higher quality services or lower price due to enhanced efficiency. The business has identified any possible consumer risks and proposed mitigation. The innovation will promote effective competition. 	 Likely detrimental impact on consumers, markets or the financial system. It looks designed to circumvent regulatory or fiscal obligations.
Is there a need for a sandbox?	Does the business have a genuine need to test the innovation on real customers and in the FCA sandbox?	 The innovationdoes not easily fit the existing regulatory framework, thus making it difficult or costly to get the innovation to market. There is a clear need for a sandbox tool in order to test this product in a live envirionment. The business has no alternative means of engaging with the FCA or achieving the testing objective. The full authorisation process would be too costly/burdensome for the purposes of a short test of the viability of a perticular innovation. 	 Live testing is not necessary to answer the question that the firm is seeking to answer (to achieve the testing objective). The firm is able to undertake the test easily without the support of the FCA. A dedicated supervisor or the Innovation Hub could answer the query.
Is the firm ready for testing?	Is the business ready to test their innovation in a live environment?	 Testing plans are well developed with clear objectives, parameters and success criteria. Some testing has been conducted to date. The firm has the tools and resources required to enable testing in the sandbox. The firm has sufficient safeguards in place to protect customers and is able to provide appropriate redress if required. 	 Unclear objectives for testing and/or plans for testing are underdeveloped. Little to no testing has been conducted on the innovation to date. The firm does not have the required resources available to conduct the sandbox test. The proposed customer safeguards are inadequate and/or appropriate redress cannot be provided by the firm.



4. Prepare regulatory exemptions and design the testing environment

As the regulator, you'll work closely with eligible innovators to design each testing environment and secure any necessary exemptions. This is done on a case-by-case basis and will cover all specific details related to testing, including:

- Where the innovation will be tested (some sandboxes, like those testing drones, may offer physical testing in an appropriate space such as designated air space away from towns or cities).
- The scale of testing (e.g. how many).
- The main goals being pursued by the innovator.
- Any necessary safeguards.

This preparation phase is usually quite intensive, particularly as it is usually best to issue any required regulatory exemption as quickly as feasible in order to minimize uncertainty and waiting time for sandbox participants (which are often commercial organisations subject to commercial pressures). To develop the testing agreements and exemptions usually requires a few dedicated staff over this period.

Getting agreement on the terms of the sandbox

It is important to develop a contract or other type of agreement with each participant that outlines the terms of the sandbox. The following items should be confirmed and written into the agreement before you begin the sandbox:

Key Performance Indicators (KPIs)

At this stage, you will ask participants to identify any Key Performance Indicators (KPIs) related to their business objectives (e.g. customer satisfaction), while also working with you to identify other key outcomes that need to be assessed (e.g. environmental impacts in the form of emissions).

Data collection

In order to measure these outcomes, participants and regulators need to identify what kind of data is needed, how this will be collected and by whom. Participants will be expected to provide data through reports, e.g., on the number of complaints or safety-related incidents, and to share raw data where possible.

Time period

If the time limit of each test hasn't been established by the overall design of the sandbox or by the wording of an exemption clause, you will want to confirm this with each participant depending on what they are testing. The time available for testing varies significantly and can be anything from eight to ten weeks to several years. Longer testing arrangements tend to be used to investigate less mature technologies such as autonomous vehicles.



Responsibilities and procedures

Each agreement should also include stipulations on responsibilities and procedures over the course of testing (e.g. how often the innovator will need to share information and in what form) and what should happen if a particular incident should occur (i.e. how and when the test would be stopped). Risk and impact assessments should be done upfront and can help identify areas that will need closer monitoring by the regulator or its agents.

Check in frequency

You should also arrange regular, informal meetings with participants to identify areas of potential concern before issues arise.

Before testing begins, other relevant stakeholders should be consulted and together regulators and innovators should disclose the nature of products and services to any customers or members of the public that will be involved or affected during the testing phase.

Addressing any concerns

It is important to address any issues or concerns prior to starting the sandbox. If you and the applicant are unable to agree upon a feasible sandbox plan, or if you have concerns about how the plans are progressing, or if there are certain requirements that the applicant is unable to meet, then either you as the regulator or the applicant can terminate participation at any time. Your agreement should also include an exit plan to avoid disruption at the end of the sandbox or if the participant should exit part way through the testing phase.

Statement of regulatory comfort

Some regulators offer a statement of regulatory compliance or comfort as part of sandbox participation. This statement is agreed on a case-by-case basis and will aim to provide information about the compliance of a company's product or service with respect to the relevant regulation and legislation. This statement will only apply to the product or service as it was in the sandbox and on the basis of the information provided during testing. Regulators have the right to revoke this confirmation based on future legal or market developments.



5. Start testing

Data and information collection should begin as soon as the testing phase begins, with any baseline data being collected prior to testing. Where resources allow, regulators often appoint a dedicated contact person for each participant. Throughout the testing phase, innovators are expected to communicate and share data with the regulator and bring attention to any issues as soon as they arise. The mechanisms for doing this will have been agreed in the previous phase. You should aim to record information in a standardized way so lessons and insights can be compared.

Informal steers

Throughout the sandbox, regulators will usually provide informal advice and steers.

This could include:

- Iterative informal advice and steers on risk mitigation at design stage.
- Informal supervision of product or service testing.
- Processing design walkthroughs step-by-step walkthroughs of proposed processing activity leading to informal advice.

Monitoring progress

The amount of monitoring you need to do will be specific to each organization's sandbox plan and will depend on the level of risk involved in the development of the product or service. High-risk plans will require more frequent monitoring. For example, meetings or reporting could be done weekly, monthly, on an ad hoc basis, whether in person or online.





6. Exit and evaluate

Evaluating the products and services being tested

At the end of the testing phase, you should create a final evaluation report for each product or service included in the sandbox using any data and/or qualitative information collected by both you as the regulator and the participants. The evaluation should use the parameters set out at the start of the sandbox to assess the outcomes of each test.

This report should summarize the process and key activities that were undertaken as well as cover key questions such as:

- The viability/acceptability of the innovation under existing regulations.
- Its potential public value.
- Potential areas of risk.
- Where further uncertainties may exist.

Where the products, services or business models being tested are 'market ready', it will be easier to answer questions around regulatory compliance and provide a statement of compliance or comfort if appropriate to do so based on the outcomes of testing. Depending on the length of the testing phase and amount of data available, these evaluation reports can take anywhere from a matter of weeks to a few months to complete.

Exit strategies for participants

Participants will have been required to prepare an exit strategy before they are able to participate. As an outcome from the sandbox the regulator may wish to set out for participants (where applicable) pathways to becoming fully authorized. In some cases, this will simply mean releasing a statement of regulatory comfort.

Evaluating the sandbox

A separate evaluation report should also be produced for the sandbox as a whole. This evaluation should provide transparent and objective information on the following:

- A narrative describing the objectives, timing, location and type of participants.
- The extent to which the sandbox has achieved its aims.
- Additional outcomes.
- General insights gained, and
- Follow up actions.

Follow-up actions could include planned adaptations to existing regulatory advice and processes or a proposal for adapting relevant regulations through further consultation.



Clearly articulated goals are a fundamental starting point for effective evaluation. In some cases – particularly for complex, larger-scale sandboxes or where the regulator wants to employ a rigorous experimental methodology – it will be valuable to commission an independent evaluator, such as a consultancy, NGO or academic institution, in order to benefit from deeper methodological knowledge and experience.

Where possible, the default approach should be to openly and transparently share reports, insights and any data collected as part of the testing process, if it is in a form that is safe to share. Currently, very few sandbox operators have systematic evaluation measures or performance indicators in place and few openly publish (or even record) detailed findings.

Extracting wider value from the sandbox

The insights you gain from running from the sandbox will often be of benefit to those beyond the sandbox too, so you should make sure you have strategies in place to share and take action from the learning. For example:

- Share the insights, learnings and outcomes in a transparent manner.
- Use sandbox insights to provide improved regulatory advice and support (e.g. through online resources, updated informal guidance or dedicated advice centres).

Standardizing any information collected and publishing all data and reports in a transparent manner can also benefit other regulators and parts of government. Sandboxes provide a unique opportunity for regulators to build expertise in new technologies and emerging products as well as critical market intelligence on where that innovation is coming from and what impacts it might have.

Ultimately, it is our hope that the increased use of regulatory experimentation via sandboxes will lead to enhanced regulatory modernization and innovation throughout the Government of Canada.





E Annex

Glossary

Causal inference

Reliably demonstrating a connection between an intervention and an effect (an observable change). This results in strong evidence that the intervention is responsible for a certain outcome.

Causal power

The extent to which an experiment can approximate the counterfactual by establishing a clear link between the intervention and any impacts that are observed. Since randomized experiments get closest to approximating the counterfactual, they have the highest causal power while pre-post experiments have the lowest causal power.

Comparison group

When randomly assigning participants to either a treatment or control group is not possible or ethical, nonrandomized experiments or quasi-experimental designs can instead use statistical models to define a comparison group that is as similar to the treatment group as possible, but is not exposed to the intervention. The comparison group is then compared with the treatment group.

Confounders

Factors other than an intervention that participants in an experiment might be exposed to. An experiment must have enough participants (i.e., a large enough sample size) and enough similarity between the control or comparison and treatment groups to ensure that the likelihood of exposure to any of these other influencing factors is equal across the groups. If not, these

confounders might result in observable differences in the results of the groups being compared, which could make it more difficult or impossible to understand whether the intervention has had an effect or not.

Control group

In a randomized experiment, participants are randomly assigned to either the treatment group or the control group. The control group is the one that does not receive the intervention (product, service, approach, policy, or process) that is being tested.

Counterfactual

In an experiment, this can be understood as an estimation of what would have happened to a treatment group if the experiment hadn't taken place and they hadn't been exposed to an intervention. As it's not possible to observe this directly, experiments are designed to approximate this as closely as possible by establishing a control group in a randomized experiment, a comparison group in a non-randomized experiment, or, in the case of a pre-post experiment, observing a baseline.

Innovation

The process by which new ideas turn into practical value in the world: new products, services, or ways of doing things.

Innovator

An individual or organization developing innovation.

Minimum detectable effect size (MDES)

The smallest true effect size that has a good chance of being found to be statistically significant.

Power calculation

An estimate of the probability that a trial with a specified number of participants will detect a statistically significant intervention effect of a certain size.

Prototype

A prototype is a draft manifestation of a concept or idea that makes it tangible, shareable, and testable. Depending on the concept or idea that needs testing, this could be anything from a drawing, a hypothesis, a written description of a program, a diagram of a process, a scale model, a rehearsal or dry run, or a demonstrator technology before it has been produced at scale. Prototypes provide a basis for further development to improve a concept or idea before it takes its final form.

Regulatory experimentation

A regulatory experiment is a test or trial of a new product, service, approach or process designed to generate evidence or information that can inform the design or administration of a regulatory regime.

Regulatory sandbox

A regulatory sandbox is a facility, created and controlled by a regulator, designed to allow the conduct of testing or experiments with novel products or processes prior to their full entry into the marketplace.

Selection bias

If participants in an experiment are assigned to an experimental group (treatment, control, or comparison) based on factors that make this group distinct from the other experimental group, then this can result in selection bias. For example, if a regulator was looking to measure the effect of an opt-in program, it might conclude that the program had an effect because the outcomes for the participants opting in and those not opting in could look quite different. However, the participants who proactively signed up could be more motivated or distinct from the control or comparison group in other ways, so it might be these factors that account for the difference between the groups rather than the intervention.

Treatment group

Also known as the 'intervention' group, this designates the participants in an experiment who are exposed to the product or service, new approach to regulating, or policy or regulatory process that is being tested.

Suggested resources

Experimentation Works

An initiative led by Treasury Board Secretariat to build the capacity of public servants in experimentation skills and practice. It applies a unique learning-bydoing model that supports and showcases small-scale experiments in the open. You can find more information about Experimentation Works at: www.canada.ca/en/government/publicservice/modernizing/experimentation-works.html

Worksheets

is regulatory exper	imentation right for you?	This tool will help you assess whether regulatory experimentation is the right approach for addressing your regulatory challenges.							
Research questions									
What questions are you trying to answer?		What hypotheses could you test to answer these que	stions?						
Evidence and impact									
What evidence do you need?	How will you get it?	What results are possible?	Likely outcomes based on results?						
		Support hypothesis							
		Do not support hypothesis							
		Inconclusive							
	<u>i</u>	<u> </u>	<u> </u>						

Regulators' Experimentation Toolkit • Annex: Worksheets Is regulatory experimentation right for you? - continued Other approaches Resources Approach What resources do you have? What resources do you need? Pros Cons Potential What would this help What would be difficult Could this replace Time you do/learn? to do/learn? or complement an experiment? People Funding **Experimental design** What would your experiment look like as... A randomized experiment? A non-randomized/quasi-experimental design? A pre-post experiment?

Running an exp	Running an experiment				This tool will help you to plan and evaluate an experiment by articulating your hypothesis, planning how you will collect your data and reflecting on the results.			
Set-up								
Problem								
What is the problem you are trying to solve?				What situation do you want to change?				
Hypothesis								
		·		• • • • • • • • • • • • • • • • • • • •				
What evidence or information do you nee support decisions to address the problem?		What is the claim that you wan experiment?	it to test through your	What learning do y experiment?	ou want to acquire through the	How wil gain?	ll you use the evidence or learning you	
		<u> </u>						
lf				Then				
pl.				:				
Plan							<u></u>	
Which type of experimental design is How will you set up and run the right for your situation? Experiment?		Who will be involve	ed?	Which metrics will you use? Ho you going to collect data?	w are	Have you created a monitoring and reflection plan with appropriate stagegates?		
							•	

Running an experiment - continued

Reflection: Results evaluation

Results	Results insights		Next steps				Sharing results	
What data did you collect?	What did the	Given this, what did you learn from your experiment?		What will you do next?	What changes do you need to make?	What are gaps or assumptions you have to test?	Who do you	How can you best share these results and learning?

Reflection: Process evaluation

Were you able to collect : Were you able to complete : Were the right stakeholders Did the experiment help : What changes would : Who do you need/want to : How can you best s	Process			Process insights	Next steps	Sharing 'what worked'	
the data planned? Why or why not? the experiment on time and on budget? the data planned? Why or why not? the experiment on time and on budget? the experiment on time and on budget? but the experiment in the you prove/disprove your hypothesis or help you achieve your learning objective? but the experiment on time and on budget? why not? but the experiment in the you make to a future experiment? the experiment on time and on budget? why prove/disprove your hypothesis or help you achieve your learning objective? with a byour learning about this learning? this learning? why not? why prove/disprove your hypothesis or help you achieve your learning objective?	the data planned? Why or	ny or : the experiment on time and	Were the right stakeholders involved?	hypothesis or help you achieve		the experimentation process	How can you best share this learning?

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Is a sandbox right for you?

This tool will help you assess whether a regulatory sandbox is the right approach for addressing your regulatory challenges.

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Kego	latory	ш			7

Affordances	
What does current legislation	allow

Constraints

What doesn't current legislation allow?

What needs to change?

Which constraints need to be overcome?

How could we change it?

How could we overcome constraints?

Problem			Engaging stakeholders			
What is the problem? Who does it affect and how?	Why is it a problem? What is causing it?	Why does it need solving now?	How would a sandbox solve this problem?	Stakeholder (individual or category)	Needs and interests	Sandbox benefits sought

To what extent do you aim to create or revise

Regulatory change

regulations based on sandbox learnings?

Is a sandbox right	for you? - continued			
Technology readiness and	d regulatory timeframes			
Technology maturity		High Low	Regulatory uncertainty	High Low
Risks			Regulatory cooperation	
Potential harms	Potential impacts	How to mitigate?	Are other regulatory sectors impacted? e.g. those	Are other regulatory jurisdictions impacted? e.g.
Irreversible	Localized/contained		covering related technologies	countries, provinces/territories, municipalities
Reversible	Systemic/environmental			
Resources			······	
What would a small-scale, hands-c	off version of the sandbox look like? \	What resources would be needed?	What would a large-scale, hands-on version of the sc	andbox look like? What resources would be needed?

Capture your initial thoughts about a regulatory innovation. Discuss key decisions with your team and stakeholders to test out your thinking



Regulatory sandbox canvas

What is the name or working title of your project?

Strategy

Addressing key stakeholder needs	Lateral inspiration	Current assets and processes	Define aims and objectives
What are the specific unmet needs (business, regulatory, policy, etc.) that your sandbox will aim to address?	What do you know about the innovations emerging in relevant areas? • Who are the stakeholders involved?	What capabilities exist in your organisation?	What is your primary focus?
What are the key areas of regulatory uncertainty and how will your sandbox aim to address them?	> Where do they originate (in/out of sector?)		
	> How are they disrupting existing regulatory frameworks?		
What benefits do you aim to achieve for industry? Innovators? Regulators? Citizens?	› Could they have public value?	What barriers exist in your organisation?	Are you interested in a broad range of innovations or specific technologies and use cases?
How will you ensure buy-in from these stakeholders to your approach?	> Do they present potential risks?		
	> What barriers do they face?		



Regulatory sandbox canvas – continued 1

Setting up the sandbox					
Engagement and communication Risk mitigation		Design, implementation and delivery			
Engagement and communication What data did you collect?	Risk mitigation What are the potential risks involved?	How will you mitigate those risks?	Design, implementation and delive How will you design the sandbox? What tools, techniques and approaches might you use?	ry What is the time horizon for your proposed change?	What is the budget for your sandbox? • Where will the funding come from?
					• How will it be leveraged?



Regulatory sandbox canvas - continued 2

Setting up your team					
Core team	Leadership	Relationships with stakeholders			
What skills, sector knowledge and relationship brokerage do you need on your team?	Do you have political and regulatory buy-in?	Which innovators and organisations will be involved in the sandbox?			
Monitoring and measurement	Reflection and learning				
Impact	Failure	Knowledge capture			
What are your indicators for success? How will you measure impact?	What does failure look like? How will you measure failure?	How will you ensure that the knowledge created in the sandbox informs future regulatory action and policy?			

Endnotes

Click on endnote number to go back to source page

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