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Regulatory Sandbox: Health RegLab Design Elements

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Abstract

Regulatory Sandboxes are becoming more and more popular to drive an agile government agenda. They help policymakers deal with the uncertainty of new technologies and plan for the intended and unintended impact of these new technologies in the market and on the public. Nevertheless, the information on how to design a sandbox and its results are not very transparently presented. This paper presents a synthesis of the state-of-impact and focuses on best practices for developing a health regulatory sandbox. The focus is on the UAE, and the paper provides recommendations on how to develop a regulatory Sandbox for Health.

Keywords: sandbox, RegLab, experimentation, agile policy, agile government, health policy, sandbox design

1.0 Rethinking the Innovation-Commercialization Regulatory Environment

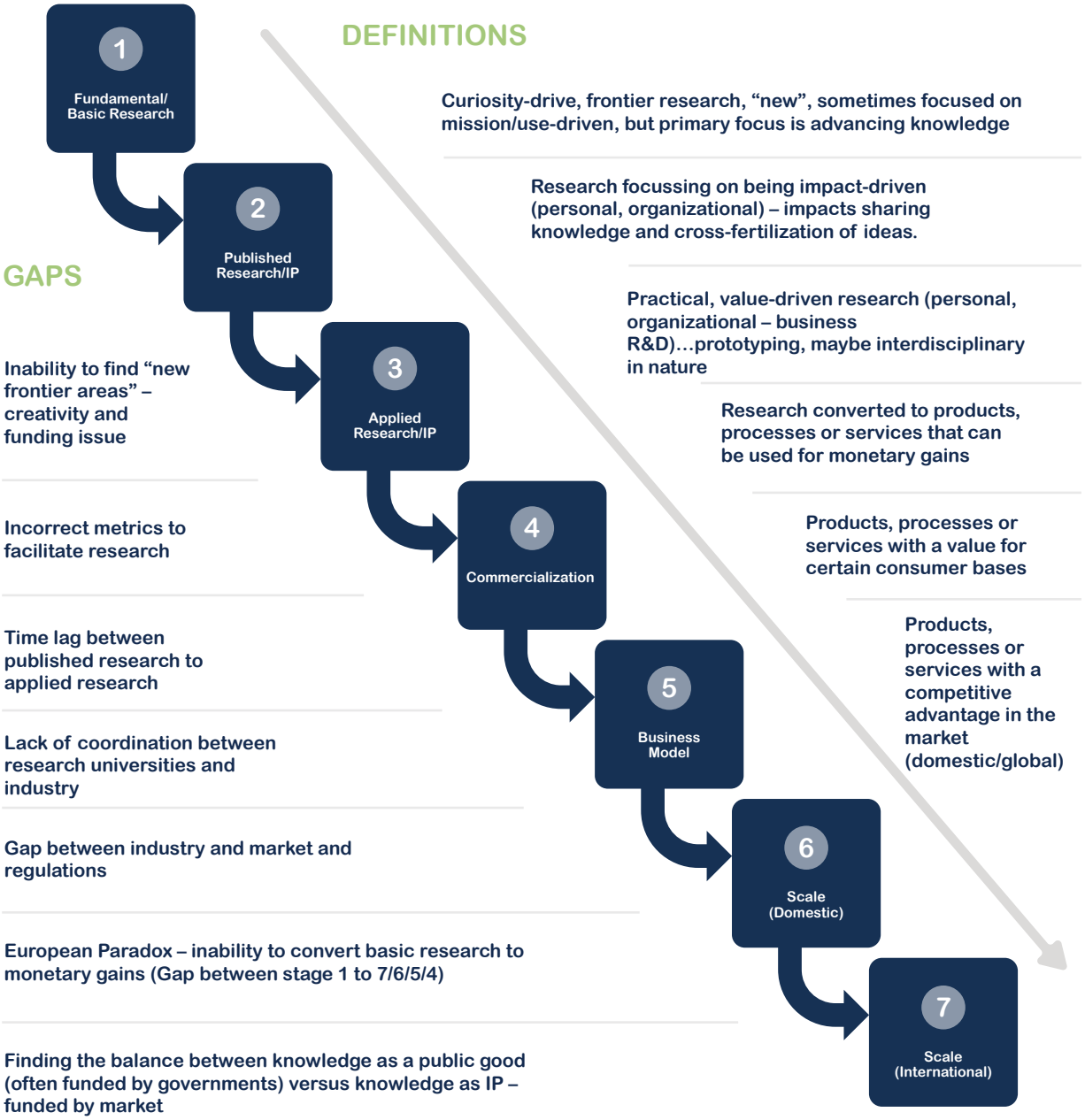
In today's world, the concept of innovation is one that is being embraced in schools, organizations, and governments. Innovation is defined as: (the aspiration of individuals, private institutions, and governments to achieve development by generating creative ideas and introducing new products, services, and operations that improve the overall quality of life (Prime Minister's Office at the UAE Ministry of Cabinet Affairs, 2015). The Fourth Industrial Revolution (4IR) age has resulted in exponential innovations - not just in quantity but in the level of disruptions. For example, in the field of AI, it is estimated that since 1956, over 1.6 million scientific articles and 340,000 patent applications have been filed, a majority since 2011, totaling 47% of total scientific publications as of mid-2018 (WIPO, 2019). This is but one field; when you look at genetics, clean energy, advanced material sciences, autonomous vehicles, space exploration, the rapid proliferation of innovation brings with it regulation challenges. There are time lags from knowledge to knowledge dissemination - in AI, for example, patents have a ten-year lag to scientific publications (except deep learning) (WIPO, 2019: 47). The next gap is basic research to applied research.

Challenges for governments are often to harness the advantages of R&D and basic research - the so-called 'translational research,' which allows for commercialization. Commercialization can take 10-20 years or more from basic research based on a long-term Swedish study (Elg and Staffan, 2011), and then global scaling. While applied research may seem as more economically productive and seem like a policy thrust area, scientists disagree in terms of its impact, believing it to be barrow sighted and counterproductive, killing creativity (Levin, 2019; UNESCO, 2015). In a counter-study by the US National Science Foundation (NSF) to the claims of US Department of Defense's Hindsight study which found that weapons research was applied after about 20 years, they found that the weapons research actually originated in research conceptualized 50 years back (Arnold and Giarracca, 2012: 27). Access to frontier research is critical for basic research and new technology developments (Iaria, Schwarz, and Waldinge, 2018).

Governments play an essential role in the innovation continuum (See Exhibit 1). Though the research-innovation continuum is presented as a linear model (courtesy of Vannevar Bush (1945), U.S. Office of Scientific Research and Development), it is rarely linear in practice. The various types of research, its impact metrics, and the economic value expectations are inter-related, suggesting that the policies being developed today will affect the future. Where governments can help, in addition to funding, is to encourage basic research and technology spillovers between research, experimentation, and

applied usage. Although exact figures of basic research funding at the private sector are not available, it is suggested that it is less than applied research and decreasing; this supports the argument that it should be driven by governments, as knowledge is a public good (see Arnold and Giarracca, 2012). Many examples cite the importance of basic research. In the advanced material sciences, it came about as a specialized field from semiconductor research, or the field of genomics arose as an outcome of selective breeding (Ibid, Brooks, 1994), showing that innovations arise out of existing stock of knowledge (basic research).

Exhibit 1: Innovation Continuum



Source: Authors

From a research paper to a product idea or prototype to a marketable product, it takes considerable time and investment of resources. This process may require different knowledge capacities and an ecosystem of players. The policies that governments put in place at this stage may either enhance or impede the exploitation of a research idea.

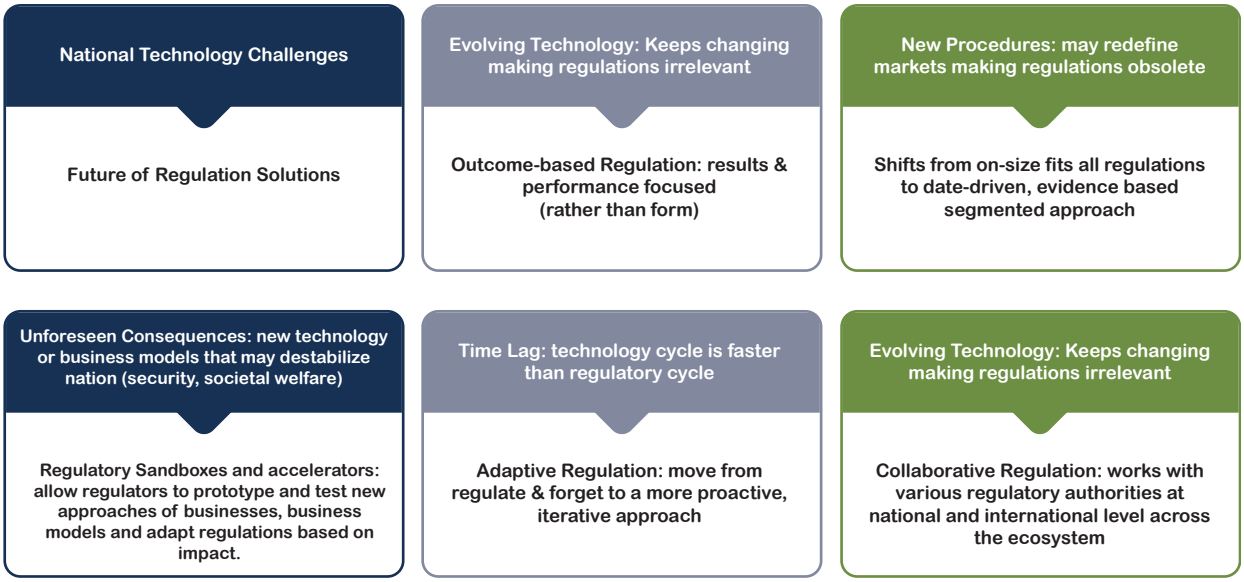
In the context of the Fourth Industrial Revolution (4IR), the time to scale globally has decreased drastically. If the radio took 75 years to reach 50 million users, Pokémon Go just took 19 days (WEF, 2018). Because of the lack of a linear relationship in innovation, the lagged effects, and the unpredictability of societal impact, governments need considerable strategic intelligence. It is estimated by Deloitte (Eggers et al., 2018) that once policies are created, they are not changed 68% of the time. Taking the example of the USA, where there are more than 70 federal regulatory agencies, it was estimated that each year over 3,500 new rules and regulations were introduced, with 4,000 pending during the Obama administration (Congressional Record, 2011: 18539). This regulatory environment highlights the dilemma of managing innovations without stifling them due to too much rigidness and complexity. On the other hand, it is a government's responsibility to identify new regulatory opportunities or improvements as the public can be encouraged to participate and co-create or even co-endorse. In South Korea, through the public petition system (www.sinmungo.go.kr and www.better.go.kr), Koreans and companies are invited to petition for improvements in regulation.

As the Clinton Administration put it (Office of Management and Budget, 1997: 10): "[R]egulations (like other instruments of government policy) have enormous potential for both good and harm. Well-chosen and carefully crafted regulations can protect consumers from dangerous products and ensure they have information to make informed choices. Such regulations can limit pollution, increase worker safety, discourage unfair business practices, and contribute in many other ways to a safer, healthier, more productive, and more equitable society. Excessive or poorly designed regulations, by contrast, can cause confusion and delay, give rise to unreasonable compliance costs in the form of capital investments, labor, and on-going paperwork, retard innovation, reduce productivity, and accidentally distort private incentives. The only way we know how to distinguish between regulations that do good and those that do harm is through careful assessment and evaluation of their benefits and costs. Such analysis can also often be used to redesign harmful regulations, so they produce more good than harm and redesign good regulations, so they produce even more net benefits."

Regulations need to be proactive in a world of unpredictability. There are five types of regulations to be considered: outcome-based regulation, risk-weighted regulation, regulatory sandbox, adaptive regulation, and collaborative regulation (Deloitte, Eggers, Turley, and Kishani, 2018) (see Exhibit 2). This paper focuses on the Regulatory Sandbox, which focuses on applied research and commercialization to encourage speed to market. The rapid pace of innovation, the scale of innovations (especially technology-based innovations), and the low predictability of possible risks make this an ideal solution for regulators to learn, watch and adapt to create new regulations. The regulatory sandbox is

also critical as technologies like AI are becoming more critical within national strategies.

Exhibit 2: Types of Regulatory Solutions for the Future



Source: Adapted from Deloitte Centre for Government Insights (Eggers, Turley, and Kishani, 2018)

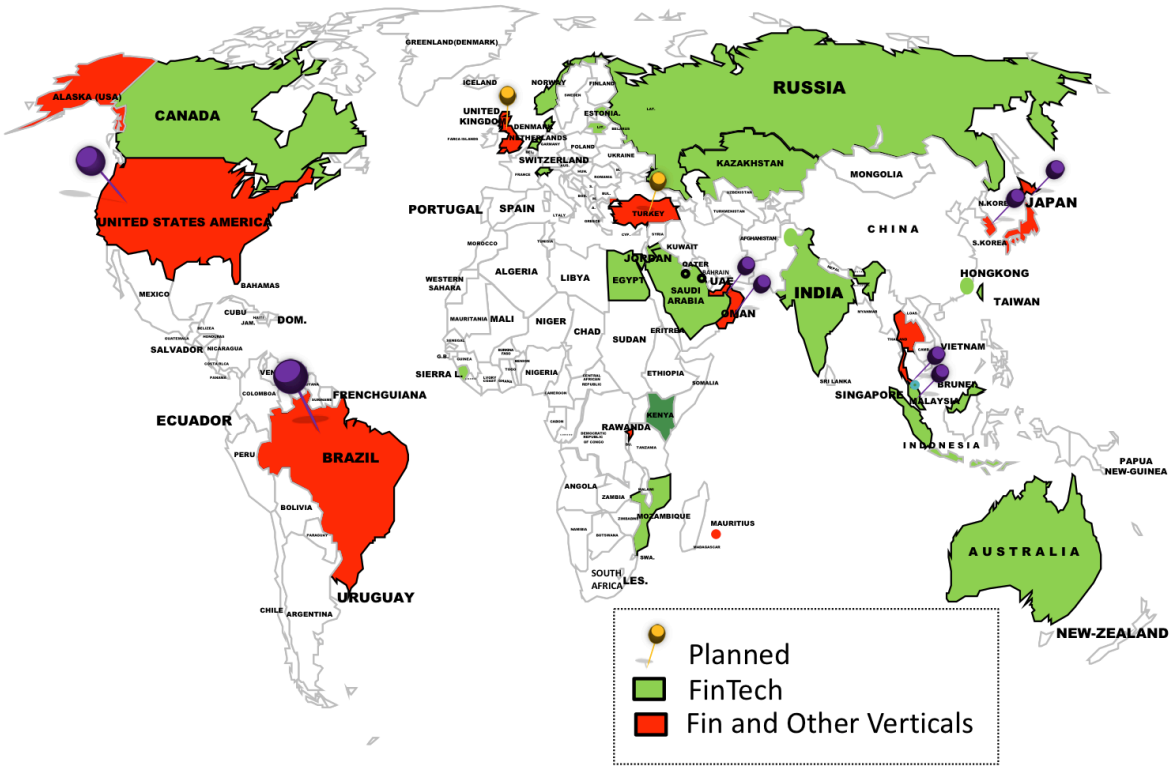
2.0 Sandboxing

Sandboxing is a framework that allows new technologies or products to be tested in a contained environment to test product viabilities in real-world settings, test regulatory boundaries, and consumer and market reactions to the same. Because there are boundary conditions, the risk is minimized, and the emphasis is on feedback and learning. This allows regulators an opportunity to "identify, understand, adapt, and respond to these disruptive new products and services in a timely and appropriate fashion" (Arner, 2017). In short, sandboxes, Test, and Learn or Regulatory Labs (RegLabs) function as small scale experiments (Wechsler et al., 2018). As a concept, this has been growing since 2012, albeit still mainly focusing on the Fintech sector (Ibid).

The U.S. Consumer Financial Protection Bureau introduced the first sandbox-like framework in 2012 under the name Project Catalyst (CFPB 2016). The UK is credited with assigning the name 'regulatory sandbox' when it introduced the same in 2014 for fintech. The Financial Conduct Authority's sandbox has been credited for supporting over 700 firms by increasing their speed to market by 40% vis a vis with the regulator's standard authorization time; this has been validated by the market as the first cohort has 80% of the

firms still operational, and the batch has received £135 million in equity funding (Perry, 2019). Since then, there has been an explosion of the concept of regulatory sandboxes (See Exhibit 3).

Exhibit 3: Global State of Regulatory Sandbox (2014-2020)



Source: Authors

2.1 Advantages of Sandboxes

The most significant advantage for governments has been to understand new technologies and their impact (positively and negatively) on the consumer, market, and governing environment. It can help focus national strategies - for example, Bank of Thailand focused on QR codes to drive cross border payments or Singapore's use of APIs for banking. It allows regulators to focus on the "what needs to be done to solve a problem" rather than the "how" according to the OECD 2018 Round Table on Sustainable Development (Hedegaard, 2018). It sends a signal to the market that the government wants to be proactive. Yet, it allows the public to know that they are cautious to ensure their safety (for example, see the European Banking Authority, 2017).

2.2 Disadvantages of Sandbox

Sandboxes may not be a party to the bulk of innovations changing the technology landscape. In their study sample on regulatory sandboxes, innovation hubs accepted on average 170 applications and accelerators accepted 23. Meanwhile, regulatory sandboxes averaged just 13 applications (Jenik, Duff, and Montefort, 2019). Further, the scale of growth may require cross-border testing, and so governments must work on partnerships. For example, access to Global Financial Innovation Network (GFIN). There is no standardisation of what works or does not work (International Monetary Fund, 2017). There is little evidence of the changes in regulations sandboxes bring though that was the primary reason they were formed (Jenik, Duff and Montefort, 2019). Suchitra Nair, director in the EMEA Centre for Regulatory Strategy at Deloitte, says, "I don't think it has lowered the barriers. What the sandbox has done is to create an environment where they tailor the barriers to address the specific risks and volumes of business the innovative firm wants to experiment with, with all the legal protections for consumers. I think it's made a positive contribution to the fintech landscape in the UK" (Perry, 2019). Finally, sandboxes are failing to target excluded or underserved segments of the population like the base of the pyramid (Jenik, Duff and Montefort, 2019) or for specific needs (FCA, 2017).

2.3: Sandbox Verticals

The majority of sandboxes are in the industry verticals like Fintech, but this can overlap with biometrics, health, or retail. A few countries are trying to extend the concept of sandboxing to other verticals to spearhead industry vitalization (see Exhibit 4). The countries with live or upcoming sandboxes (other than fintech) are Japan, Malaysia, Singapore, South Korea, Oman, UAE, Mauritius, UK, Brazil, and USA. However, the detailed processes or learnings in these new initiatives are not yet easily available.

Exhibit 4: A Snapshot of Various Government Regulatory Sandbox

Country	Type of Regulatory Sandbox (Finance)	Type of Regulatory Sandbox (Other)
Asia		
Brunei	2017: Autoriti Monetari Brunei Darussalam (AMBD). AMBD formally issued the FinTech Regulatory Sandbox Guidelines, which aims to aid in the development of FinTech companies in Brunei Darussalam through the creation of regulatory sandboxes.	NA

China	2019: Beijing Fangshan District has announced a regulatory sandbox, 10 more cities planned	
Hong Kong	2016: The Fintech Supervisory Sandbox under the Hong Kong Monetary Authority - two themes: Securities and Futures Commission & Insurance Authority. (live) 2019: Hong Kong's Securities and Futures Commission (SFC) adopt "sandbox" for crypto exchanges in the Asian financial hub. (live)	NA
India	2019: The Reserve Bank of India (RBI) issued a FinTech (RBI Regulatory Sandbox). And a Regulatory Sandbox under The Insurance Regulatory and Development Authority of India. (IRDAI) (live)	NA
Indonesia	2017: Regulatory Sandbox under Bank Indonesia - 6 months trial - 1 year to apply for full licensing (live)	NA
Japan	Included	2018 Japan Economic Revitalization Bureau under The Government of Japan (demonstrations of innovative technologies and business models) (live)
Malaysia	2016: Financial Technology Regulatory Sandbox Framework by Bank Negara Malaysia and Ministry of Finance (live) Focus: (1) preserve trust to safeguard the resilience and integrity of payment systems (2) to apply proportionate regulation to effectively manage risk, whilst not stifling innovation; (3) to enable connectivity through collaboration towards greater standardisation and interoperability; and (4) to promote efficiency and innovation through greater competition. (live) (1year pilot)	2018: National Regulatory Sandbox (Ministry of Finance Malaysia and facilitated by the National Strategic Unit, Futurise Centre and MaGIC) (live) - agriculture, biotechnology, building, education, energy, finance, food & beverages, green tech, healthcare, hospitality, sports, telecommunication, tourism, waste management, (live) (9 month pilot)
Singapore	Monetary Authority of Singapore (Sandbox and Sandbox Express) - the sandbox is not funded by MoH. So far only for telemedicine (as of 31 December, 2019)	2018 Ministry of Health - Licensing Experimentation and Adaptation Programme (LEAP) - care and business models like telemedicine, mobile medicine,

South Korea	2019 Financial Services Commission (live) - example was Robo Advisor Test Bed Center hosted by KOSCOM (mainly owned by Korea Exchange) (live)	2019 - Five Sandbox Acts focusing on Ex Ante authorisation and Ex Post regulations - seven zones digital health, smart wellness, e-mobility, smart security, next generation battery recycling, blockchain, autonomous driving (live)
Taiwan	2018: Financial Supervisory Commission. The Act on Financial Technology Innovations and Experiments promulgated on 31 January 2018 and took effect on 30 April 2018, paving the way for the sandbox. (live)	NA
Thailand	2016: Bank of Thailand: includes KYC, biometric solutions for identity (live)	2019: Under the National Broadcasting and Telecommunications Commission (the "NBTC") for technology testing for businesses and in preparation for the adoption of 5G technologies (live)
Turkey	Plans a Blockchain Regulatory Sandbox	
Middle-East North Africa		
Bahrain	2017: (The Central Bank of Bahrain) (live)	NA
Egypt	2019: The Central Bank of Egypt introduced in 2019 the Innovations Financial Technology Application Lab (sandbox)	NA
Jordan	2018 (The Central Bank of Jordan) (live) Many objectives including job creation. (9 month pilot) (live)	NA
KSA	2019: (The Saudi Arabian Monetary Authority (SAMA)) (live)	NA
Kuwait	2019: Central Bank of Kuwait (12 months) (live)	NA
Oman	2017: Central Bank of Bahrain 9 months with 3 month extension	2019 (Blockchain - The Information Technology Authority (ITA) of Oman)

UAE	2016: At Emirate level & Cross Border: Financial Services Regulatory Authority (FSRA) of Abu Dhabi Global Markets (ADGM) ASEAN Financial Innovation Network (AFIN), an entity located in Singapore. (live) 2017: Dubai Financial Services Authority (DFSA) introduced in 2017 the Innovation-Testing License (live)	2019 Reg Lab (live)
Africa		
Kenya	2018: CMA's Regulatory Sandbox Program 12 months (live)	NA
Mauritius	National Regulatory Sandbox (Financial Service Commission) (live)	2016 Regulatory Sandbox License (Economic Development Board) (live)
Mozambique	2018 Mozambique Regulatory Sandbox (Central Bank) (live)	NA
	Europe	NA
Rwanda	included	2017: Under Rwanda Utilities Regulatory Authority (RURA) includes telecommunication, utilities and fintech (Two years)
Sierra Leone	2018 Bank of Sierra Leone (live) - the initial objective was to increase BSL's understanding of emerging technologies and support. Evidence based approaches to regulations that advance the goals of Financial Inclusion, Financial stability, Integrity and Consumer Protection (1 year pilot) (live)	NA
Europe		
Denmark	2019: Danish Financial Supervisory Authority 6months (live)	NA
Estonia	2019: The European Bank for Reconstruction and Development (EBRD) and Estonia Ministry of Finance and the country's Financial Services Authority	NA
EU regional sandbox	Proposed - published report in 2019	

Kazakastan	2019 Fintech Lab under Astana International Financial Centre (live)	NA
Lithuania	2018: Bank of Lithuania (central bank), the Board of the Bank of Lithuania (live)	NA
Netherlands	De Nederlandische Bank	NA
Norway	2019 Ministry of Finance (MoF)	NA
Russia	2018: Central Bank of The Russian Federation	NA
Switzerland	Swiss Financial Market Supervisory Authority	NA
UK	Financial Conduct Authority's Regulatory Sandbox 2014 (Project Innovate) & 2017 Financial Conduct Authority's Regulatory Sandbox	2019 Proposed Industry Sandbox. The Health Data Research UK Sandbox under Digital Innovation Hub Programme.
America		
Brazil	Included	2019 - MoE, The Central Bank, the Securities Commission and Superintendent of Private Insurance (new technologies)
Canada	2017: Ontario Securities Commission (OSC) announced the launch of OSC LaunchPad, (live)	NA
USA	2012 Project Catalyst- Consumer Financial Protection Bureau	2018 United States is piloting a sand-box approach for unmanned aerial systems (UAS). The Department of Transportation's Federal Aviation Administration has chosen 10 public-private partnerships to test UAS.
Australia		
Australia	Australian Securities and Investments Commission (ASIC) and the Ontario Securities Commission (OSC) (1 year statutory waiver)	NA

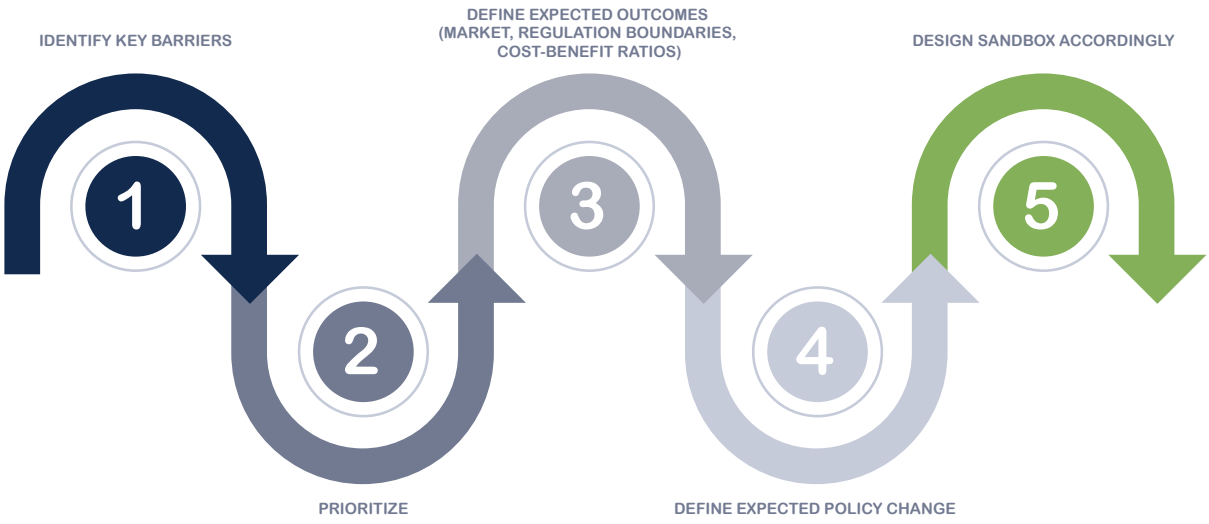
Source: Authors

3.0 The Health Regulatory Sandbox

Singapore was one of the first countries to introduce a Sandbox in health in 2018, focusing on specific business models like telemedicine and mobile medicine. South Korea has a Sandbox Act focusing on both Ex Ante authorization and Ex Post regulations, linking health (digital health and smart wellness) to specific economic zones. The UK Sandbox is a non-profit organization, backed by ten funders: British Heart Association, Chief Scientist office Scotland, Engineering and Physical Sciences Research Council, Economic and Social Research Council, Health and Care Research Wales, Health and Social Care Research and Development Division, Northern Ireland, The Medical Research Council, The National Institute for Health Research, Wellcome, and UK Research and Innovation. It has a collaboration of 22 universities. Their initial pilot chooses seven test cases: all of them using big data. All the industry sandboxes are not specific enough. In fintech, for cross-border sandboxes, there is the GNIF, but it is unknown if there is such an association for health. Looking at the UK initiative, the depth of national collaboration seems a strong foundation for success.

Health is a broad industry area, subject to many formal and informal regulatory bodies. Often these areas have no clear standards or guidelines for policymakers. For example, telemedicine has no universally accepted standards (World Health Organization, 2010; Poultney. N., 2014). Because of its complexity, policymakers need to narrow down the areas of focus for the health sandbox using a model prescribed by IMF (2017) (See Exhibit 5). This area of focus would be the starting point for a government regulator in designing a sandbox.

Exhibit 5: Steps Prior to Designing a Sandbox Vertical



Source: Authors (adapted from IMF, 2017)

It is crucial to notice the complexity of the market. The health market has both formal and informal regulatory authorities. A formal regulatory authority can be at both the international and national levels. A formal regulatory authority has the power to veto or restrict permission for a product or service entry into a market and inflict punishments and give rewards. Punishments can be criminal prosecutions for even unintended effects. The sandbox must have guidelines on levels of protection for the public but also levels of immunity for the sandbox participant.

An informal regulatory authority can influence a government's decisions on the acceptance of products and services. At the global level, the World Health Organization is a key driver at the inter-governmental level. However, there are other heavy-weight players like the Global Fund, Bill & Melinda Gates Foundation, and Gavi, the Vaccine Alliance. In terms of regulatory authorities, you have the FDA for certifying drugs and, WHO for endorsing vaccines. As multiple industries collide, big data, and AI become more common, there may be more challenges involved. In 2019, South Korea began to revise the Bioethics and Safety Act and the Brain Research Promotion Act to facilitate the sandbox.

The starting point is a baseline to see if the sandbox has the prerequisites to make it functional. For example, in health big data, important factors for effective healthcare are data heterogeneity, data protection, analytical flows in analyzing data, and appropriate infrastructures for data storage (Peek, Holmes and Sun, 2014).

Another key issue for sandbox regulators is defining expected outcomes. Most regulatory sandboxes are focused on markets (growth and impact on public). Frontier-innovations are highly complex, having complex back-end operations have policy implications. For example, a platform company is more than an app, it has a data privacy impact (needs big data to improve), it may have security issues as they store data on the cloud, and the country may have issues on local data being exported out; perhaps they product is built on the assumption the existing data is free (Google maps) which may impact the industry if this assumption is wrong; and finally it may unintendedly make existing regulations for the entrenched industry unfair (if Airbnb brokers "rooms" should they have the same regulations and standards as hotel 'rooms"?

This step also needs to define roles of regulators and the required expertise and the customer safeguards. From a regulatory point of view, developing a sandbox needs clarity on regulatory objectives, which can be to ensure greater regulatory flexibility, gain greater insight into regularity clarity, or assess the suitability of regulations (EY, 2017). Some of the customer safeguards to be considered are (Ibid):

1. The boundary or safeguards: trial period, number of customers, type of customer, exit strategy, a transition plan for full deployment
2. customer protection measures: client onboarding requirements, disclosure requirements (test and compensation), dispute resolution process (indemnity insurance, etc.)
3. risk management process: systems stability, privacy, cybersecurity, organizational competence,

For the public, the disruption to the legacy systems may highlight complex problems we do not have easy legal answers for. In 2017, Alexa was involved in a murder trial, and Amazon invoked the First Amendment's free speech protection (Sauer, 2017). Could Alexa be called a material witness in a murder investigation? Should Amazon have access to private conversations? Here the big question was that the data being collected and privacy. The crux of that matter is AI often uses big data, and this volume of data gets collected without personal permission. These technologies are ubiquitously available, and we often do not realize the inherent red flags. This case is just one example. Autonomous cars bring out issues of liability in case of an accident; genome therapy opens up a grey area of what is deemed as essential, and the consequences of that knowledge? The list goes on and on. Some of this cannot be discussed without a range of stakeholders representing multiple interests if the policy or regulation at the end of the sandbox needs to be fair and robust. Hence the period of "trial" or "pilots" should not only be speed to market but to understand the impact, especially if the regulatory body does have the ability for adaptive regulations (refer back to Exhibit 2).

The OECD recommends that these outcome-based evaluations can focus on four areas (and they need not be mutually exclusive) (Coglianese, 2012) (see Exhibit 6). Suggestions need to look at all four quadrants need - goals and attributions. Treatment goals are problem specific to reduce the problem or improve the outcome. Other value could look at spillovers like reducing side-effects or costs. Attributional goals gather support for casual linkages between treatment and indicators. Non-attributional goals focus on assessing the level of the indicators against other benchmarks. In the non-attributional goals, governments may want to assess the innovation metrics, and this could include both input and output indicators at both qualitative and quantitative levels. The government would benefit from a multi-stakeholder approach to managing projects like this as the consequences, and side effects may not be easy to see, but have potential far-reaching consequences.

Exhibit 6: Outcome-based evaluations

		Indicators	
		Treatment goals	Other values
Attribution	Non-attributional	Assesses level of the problem that the treatment was designed to address against other time periods or jurisdictions, "acceptable" levels, or decision maker goals.	Assesses level of other valued conditions (e.g., costs, time demands, side effects) other time periods or jurisdictions, "acceptable" levels, or decision maker goals.
	Attributional	Assesses the amount of improvement or the deterioration in the problem that the treatment actually caused.	Assesses the amount of improvement or the deterioration in other valued conditions (e.g., costs, time demands, side effects) that the treatment actually caused.

Source: Coglianese (2012)

Boundaries of the sandbox may be the type of products/ impact areas, types of organizations that can apply for the sandbox, or level of co-creation (for example, UAE RegLab asks for 5+partners). The period for the pilot, period to register for licensing, conditions of licensing, and licensing waiver should be based on the industry, the risk to the public, and the impact on public goods.

Various models of sandboxes exist, and it is clear it must serve the individual country's needs. There can be tiered registration with funding, coaching opportunities (like Indonesia and Singapore). In the case of Singapore, a sandbox is the final stage of a regulatory process before launching in the marketplace. In some cases, the focus is on managing multiple verticals like South Korea, which also has specific test zones. In some cases, countries also a regulatory waiver in a constrained environment for a specific period of time like Australia. All entities going through a Health Sandbox in Singapore have a logo attached to them saying "In a regulatory sandbox with Ministry of Health, Singapore" to ensure maximum transparency. To encourage scale, UAE RegLab requires at least 10+ global partnerships to source the best experiments.

3.1: The UAE and Health

The UAE has introduced a range of initiatives to promote innovation in the healthcare sector that aim to develop pharmaceuticals, biotechnology, life sciences, and telemedicine (Government.ae, 2019). These initiatives are in parallel with the Fifty-Year Charter of Sheikh Mohammed bin Rashid Al Maktoum, Vice President, Prime Minister and Ruler of Dubai, which aims to provide a doctor for each citizen (Government. ae, 2019b). The UAE RegLab launched in January 2019 in partnership with Dubai Future Foundation, under a federal law issued in 2018 authorizing the UAE Cabinet to grant temporary licenses for the testing and vetting of innovations that utilize future technologies and its applications such as Artificial Intelligence (AI). It aims to create a reliable and transparent legislative environment, introduce new or develop existing legislation, regulate advanced technological products and applications in support of Vision 2021 and UAE Centennial 2071 Plan. At the federal level, the UAE telemedicine sector got a boost in 2014 when it was first launched in Abu Dhabi, and Dubai launched it in 2019.

The healthcare space has a lot of exciting initiatives at the emirate level but not enough details. For example, in December 2019, the emirate of Abu Dhabi recently announced an initiative for a Genome Program under the Department of Health, but it is not an open initiative. In 2019, the Dubai Ministry of Health and Prevention partnered with Dhoner Health to use blockchain for organ donors (Trueman,2019). At the emirate-level, there are planned initiatives like the Dubai Health Authority's Innovation Hub and the Abu Dhabi's Plug and Play health accelerator with Abu Dhabi Department of Health (DOH) and Abu Dhabi Global. At the time of writing this paper (December 2019), there were no policies on a sandbox for health.

4.0 Steps in Designing a Sandbox

There are three key considerations for the final design of the sandbox are illustrated in Exhibit 7. They are (1) the mandate and objectives (scope), (2) governance, and (3) operations. Once policy regulators have assessed the information collected that were outlined in the processes outlined in Exhibit 5 and 6, they can move to the next stage Exhibit 7. This will feed into the sandbox blueprint - what the participants see and what happens behind the scenes as the sandbox regulators manage the innovation.

Exhibit 7: Regulatory Sandbox Design Framework

MANDATE & OBJECTIVES (SCOPE)	GOVERNANCE	OPERATIONS
What is the moral mandate of the regulator?	Who operates the sandbox?	Who can participate in the sandbox (eligibility and evaluation criteria)?
What is the legal mandate of the regulator?	Do they have the qualifications for making informed decisions?	What can happen in the sandbox (boundary conditions)?
What are the regulatory and policy objectives?	What information is needed for an informed decision and how is it collected?	What is the process?
What is the boundary conditions?	How is this information shared both internally and externally?	What is the reporting mechanism for collecting data needed for evaluation? (reports and reporting)?
What are the national objectives?	How is the learning communicated for future learnings?	What happens when the sandbox concludes? (exit procedures)?
What are market objectives?	How transparent is the process of “experimentation”?	How is the feedback loop for policy interventions captured?
What are the public value objectives?	How are risks minimized?	How do ensure that the human subjects of the experiment are adequately compensated from the discontinuation? Or from the adverse risks?
What are the global citizenship objectives?	How do you ensure fairness of the process for choosing participants of the sandbox?	How do you ensure the liability of the participants admitted to the sandbox is restricted post experiment if they stayed within the boundary conditions outlined by the sandbox regulators?
What are the cross-border objectives (internationally)?	Is the cost of participation communicated clearly (fees, any other binding requirements)?	

Source: Authors, adapted substantially from Crane et al. (2018)

The sandbox blueprint will vary depending on the type of sandbox, the verticals, the customer type, the complexity of the innovations, the level of regulations put in place in anticipation of this, the market support, and the level of impact on the publics.

4.1: Mandate, Objective and Scope

The mandate will inform the objectives and scope. There are three levels to be embraced here in terms of objectives - and they will still have to answer the questions posed in Exhibit 7.

4.1.1 Objectives: There are three primary objectives.

(a) The Global Health Value objectives: Here, the higher objectives are based on global citizenship. Sustainable Development Goals may be one objective, but there may be other issues the country is committed to.

(b) National Public Health Value objectives: Nations need to prioritize health issues based on their populations. The UAE is a unique population with 85% expatriates, and being a key tourist hub, it necessitates the need for resilient health systems. The pubic value being created has spillovers with global health, and hence policymakers can look at the dual objective of the same.

(c) Regulatory objectives: here, the objective maybe to adopt, introduce new regulations, or fine-tune older regulations. In short, the polices for responsible health innovation must address the value domains related to population, health system, economic, organizational, and environmental (Pacifico Silva, Lehoux, Miller, et al., 2018). For example, in the UAE, the regulations of focus are data privacy and data sharing laws (this may need to be extended to look at biodata), BioEthics, Ethical Research practices, data storage laws, AI policies etc.

4.1.2 Scope:

The main aim of the sandboxing, is to provide a place for innovative companies to test their new technology product and showcases benefits to the government and hence find common solutions to ease regulatory burdens that exist. This process requires the country to describe the boundary conditions of the type of products or services they will be willing to experiment with. For example, one way to categorize health products for testing is depicted in Exhibit 8. Each category will require its own set of pre-conditions, objectives, and safeguards to be clearly stated as sandbox criteria.

Exhibit 8: Health Categories for Testing

	Category 1	Category 2	Category 3
Categories	Health related (on equipment)	Health related process (apps, management process)	Health related based on people
Predictive Analytics	Hospital equipment tracking/breakdown	Manpower management Chat bots (depression counselling etc) Blockchain (health records/ payment)	Predicting Future Disease (genomics) Precision medicine Telemedicine
Invasive Technologies (examples)	Robotics (pharma) Genetic DNA kits 3-D printers (prosthetics)	Using wearables/videos/ social media to gather information for health	Cochlear Implants for children (see Humphries et al, 2012)
New Frontiers (examples)	Tissue growth equipment	Robotic care	3D printing or organs, cloning Stem cell harvesting
Applicable Regulations	Equipment standardization Industry regulations Biomedical Ethics Data Privacy Data Sharing Data Storage Biomedical Ethics		

Source: Authors

4.2 Governance

As can be seen in Exhibit 3, various types of regulatory sandboxes exist. The group that monitors the sandbox is critical to its success. In some cases, the teams are small, but in those cases, they will restrict the number of participants. In some cases, governments may use private parties to fund and manage the sandbox. Because of the dual purpose of the sandbox - regulatory and socio-economic potential, ideally, a monitoring committee should have a core group that can advise on regulations and an expert group which can look at market economic impact but also, more importantly, assess the impact on the consumer and extrapolate its long-term effects. This joint committee will formulate a report that will not only decide the fate of the participant for market deployment, but future regulations, and it may be used to improve the sandbox process.

While the sandbox regulators must answer the questions in Exhibit 7, a reoccurring theme in healthcare is data and the long-term impact. Most sandboxes are only operational for 6 to a maximum of 12 months.

4.2.1 Data

Not only must they have data to ensure that the environment is safe, but that the data is sufficient for feedback. The safe environment is for the (1) customers, (2) publics (3) organization (4) market (5) country.

The key reason a sandbox is being created is to test to see if the new innovation can create value, within the regulatory framework and to do so the sandbox regulators must know what data needs to be collected for appropriate decisions. The information being collected must aid decision making for policymakers. The meta-responsibility is to ensure that the outcomes are beyond "marketable goods" and information collected is shared with all concerned stakeholders. The data must also help participants improve their product innovation and business model.

4.2.2. Ethics & Long-term Implications

Technology is often a dual-edged sword, and hence any healthcare sandbox must address issues of ethics. The Hippocratic injunction primum non nocere (first do no harm or beneficence) applies to practitioners, developers, and other players in this space. There are many concerns like negligence, non-maleficence, health maximisation, efficiency, respect for autonomy, justice, proportionality, data security, privacy and confidentiality, informed consent, fairness and justice, trust, data ownership (Schröder-Bäck et al., 2014; Ienca et al., 2018; Summers, nd). A study of 223 health Technology Assessment reports between 2003 to 2006 in Canada, UK, Denmark, and the USA, found that ethical, social, organizational clinical and economic evaluations, were only considered in 5 % of the reports (Assasi et al., 2014). As the health interventions become more complex, so does the perception of ethics, and this would require a multi-stakeholder approach (Lysdahl et al., 2016). MOH has a clear policy and the Code of Ethics and Professional Conduct for Health Professionals, but no ethics and code of conduct related to technology, AI, and elements of fourth industry revulsion. For example, If malpractice happens in assessed robotic surgery, whom to blame the manufacturer, the doctor monitoring the robotic or the ministry of health.

Another important aspect of the sandbox is IP. Companies are trusting the regulators with data and, in some cases sharing IP to ensure the product is acceptable and functions well. The sandbox regulators must have safeguards for IP, especially as frontier innovations are sources of competitive advantage. Where the government is sharing sensitive data, again, the transparency about ownership of IP is required.

4.3 Operations

Here there are several stages that can be clubbed into (1) eligibility of participants, (2) communication of boundary conditions and process, (3) Exit procedures, and (4) risk management.

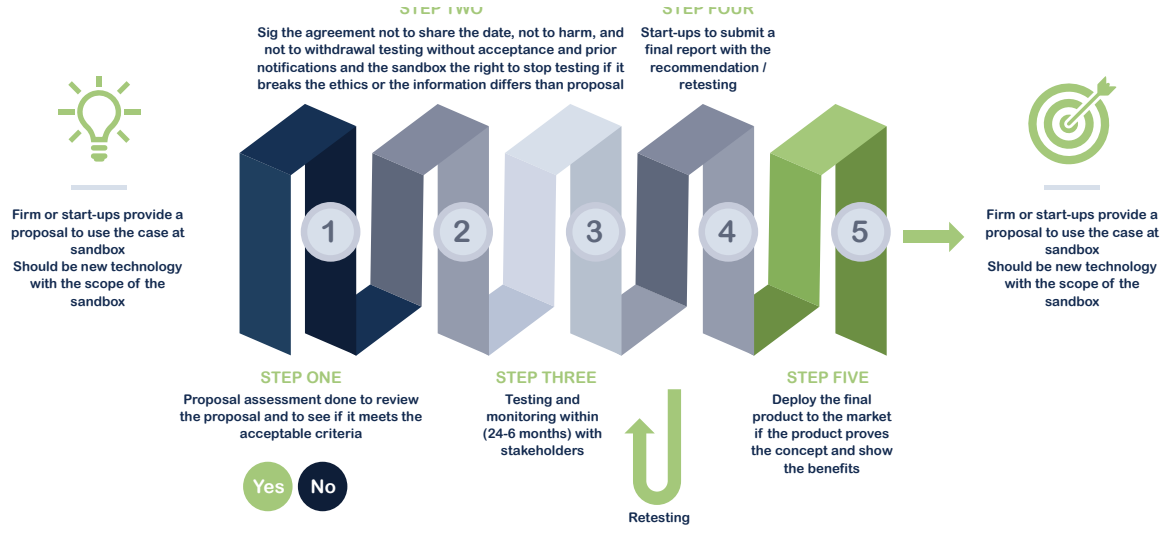
4.3.1 Eligibility Requirements

The eligibility criteria to enter a healthcare sandbox should be clearly communicated wherever possible to ensure fairness and transparency for both the sandbox participant and its customer. The reason is simple, governments are responsible for procedural justice and this then becomes their hallmark. For example, the Singapore MoH has a logo attached to the participants offering products under a sandbox that states "In a regulatory sandbox with Ministry of Health Singapore".

4.3.2: Process

While a health sandbox can borrow from existing frameworks, here is an example suggested in Exhibit 9. The period for trail may depend on the type of innovation as listed in Exhibit 8. Category 3 innovations may require a test time of 24 months or more to ensure there are no unintended side effects. Category 1 may require a shorter time. Application and admission to the sandbox may occur on a rolling basis (at any time), between set dates (with a group of applicants, known as a 'cohort') or both. Many sandboxes are free, others include application fees, some of which may be modifiable depending on circumstances and the jurisdiction.

Exhibit 9: An example of a sandbox process



Sources: Authors

4.3.3 Exit Procedure

Participants who exit the sandbox successfully may need to meet current regulatory obligations, such as applying for and obtaining a full license for deployment. Ideally the participant will receive regulator assistance and authorization to launch outside the sandbox with regulatory incompatibilities addressed. Unsuccessful candidates are typically required to cease operations or in some cases can reapply to join the sandbox again.

4.3.4 Risk Management, Safeguards, Records and Reporting

Sandbox frameworks generally require the applicant to present a plan which adequately protects its consumers. This may include marketplace disclosures, a risk management plan, safeguarding procedures, incident reporting and dispute resolution, redress mechanisms, or insurance (such as a fund for victim compensation). In addition, the applicant should have a plan with key milestones identifying key performance indicators to plot the trajectory on whether key objectives were met and associated learnings.

5.0: The Way Forward

Health is the new innovation frontier but ethically it is subject to a lot of grey areas. The regulatory sandbox is one method that will help nations ensure the best healthcare for their citizens. As discussed above, there are many areas that need to be addressed to develop a robust regulatory sandbox.

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