



# Regulation for Innovation

*Conceptualising a Development Research Agenda for Inclusive and Sustainable Economies in Lower-Income Countries*

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Scoping Study Report  
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## Executive Summary

This study, commissioned by the International Development Research Centre (IDRC), scopes and builds towards a new research agenda on the regulation of innovation. It supports the development of a collaborative research programme to improve the regulation of innovations in priority areas including health, the digital economy, and clean technology. It is motivated by a growing recognition that improved regulatory systems will underpin solutions to seemingly diverse challenges, including global inequities in access to vaccines and medicines, in use and exchange of data and inclusive digital services, in development and deployment of clean, sustainable technologies, and more.

In its treatment of regulation, the study primarily considers marketplace framework laws and policies, including those pertaining to intellectual property, competition, communications, investment, trade, and related fields affecting innovation. These frameworks include not only formal national legal rules, but also multi-level regulatory regimes bridging the global and the local, as well as informal norms, self-regulatory mechanisms, and other forms of knowledge governance.

The goals of this scoping study are to:

- summarise and disseminate the state of knowledge about the important roles played by regulation in innovation ecosystems in lower-income countries;
- provide a synthesis of past IDRC and other work on regulation, drawing out key findings and strategic opportunities for gap-filling in the context of IDRC's Strategy 2030; and
- facilitate development of a research agenda, including a proposal for programming to support partners in low-income countries to address barriers and harness regulatory regimes for critical Sustainable Development Goals.

The study addresses the following questions:

- What are the main (emerging) conclusions from the current debates on intellectual property and related regulatory fields, for an international development research community (including but transcending IDRC-supported researchers) that supports innovation and scaling?
- What is the role of research on innovation and scaling, particularly in low-income contexts, and what are the gaps in current research?
- Which priority areas could IDRC contribute to, and how should these priorities be refined and developed?

Chapter 1 of this study report introduces the challenges of regulating innovation, starting with the current and timely example of access to vaccines. The chapter expands from that foundation to explore other regulatory issues impacting SDGs in other focus areas. Chapter 1 also describes this report's objectives, methods, contributing team, and structure.

This report then explores the regulation of innovation across three IDRC focus areas, presented in three chapters.

In the focus area of global health (chapter 2), this report explores innovations in the delivery of universal care to achieve SDG 3 (Ensure healthy lives and promote well-being for all at all ages). In this exploration, issues related to governance and ownership of global vs. local innovation, including but not limited to the WTO TRIPS Agreement, are considered. In addition, the chapter covers the roles of intellectual property, licensing, and regulatory bodies in shaping access and influencing distribution of health benefits and outcomes. A core insight emerging from this exploration is that successfully achieving the goal of health and well-being is inseparable from other dimensions of sustainability, especially climate action but also access to clean water, education, and social welfare support. Moreover, the chapter points out that COVID-19 was and is not about vaccines only—it is also about ancillary medical innovations. Future pandemics are

anticipated to each have their own unique character, requiring technological and regulatory response agility and adaptation beyond medicines or therapeutics. Data will drive future pandemic and public health responses, making appropriate data governance and regulation a priority issue.

The chapter focussing on democratic and inclusive governance (chapter 3) addresses regulatory challenges emerging around data and technology. This aspect of the study explores regulatory issues related to increasing digitalisation, including matters of competition, intellectual property, platform work, and inclusion. This exploration includes consideration of how countries in developing regions should engage with national, regional and global governance pertaining to the behavior of data-driven firms, including regulation of cross-border data flows, digital services, and digital transactions.

From a sustainable inclusive economies perspective, the study (as reported in chapter 4) explores the regulatory role of competition and trade agencies/institutions, including in the context of the new African Continental Free Trade Area (AfCFTA). It explores the interactions among different types of trade agreements (global, regional, bilateral) and assesses the mechanisms and capacities essential for ensuring that global economic governance supports SDGs. In this exploration, two key areas of interest are identified, both driven by emerging issues in international trade. First, inclusion in the 21<sup>st</sup> century economy requires inclusion in the digital economy. This chapter, therefore, scopes out research questions related to international digital trade, global e-commerce, and the regulation of cross-border data flows (a topic also covered in chapter 3). Second, sustainable economies require widespread diffusion of clean, i.e., low greenhouse gas-emitting, technologies. Thus, this chapter also addresses questions around regulatory regimes that promote or hinder innovations towards greener economies and low-carbon production and consumption.

Chapter 5 offers an integrated analysis of cross-cutting insights. This final chapter identifies important dimensions of innovation regulation, specifically: regulatory systems as market frameworks; global, local, and multi-level governance; and industry and community self-regulatory norms. It reconceptualises the relationships amongst the scoping study's designated focus areas, the SDGs, and regulatory themes. It offers a framework around which a coherent and feasible programme of research could be structured, identifying opportunities for research interventions that could generate policy impact, for on-the-ground field-building, and for catalysing momentum throughout a community of practice.

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## Acronyms and Abbreviations

A2K	access to knowledge
A2K4D	Access to Knowledge for Development Centre, The American University in Cairo
ABS	access and benefit-sharing
ACET	African Centre for Economic Transformation
AERC	African Economic Research Consortium
AfCFTA	African Continental Free Trade Area
AfricaLics	African Network for Economics of Learning
AiAs	Algorithmic Impact Assessments
AI4D	AI for Development
AI HLEG	High-level Expert Group on AI
AMU	Arab Maghreb Union
ARIPO	African Regional Intellectual Property Organisation
ART	antiretroviral therapy
ATPC	African Trade Policy Centre
ACET	African Center for Economic Transformation
AI	artificial intelligence
AU	African Union
AUC	The American University in Cairo
BKC	Berkman Klein Center for Internet and Society
BITs	bilateral investment treaties
BTAs	bilateral trade agreements
CBD	UN Convention on Biological Diversity
CDIP	WIPO Committee on Development and Intellectual Property
CIGI	Centre for International Governance Innovation
CIPIT	Centre for Intellectual Property and Information Technology Law, Strathmore University, Nairobi
CLTS	Centre for Law, Technology and Society, uOttawa Faculty of Law
COMESA	Common Market for Eastern and Southern Africa
COP	Conference of the Parties, i.e., UN Climate Change Conference
COVAX	COVID-19 Vaccines Global Access
CCRED	Centre for Competition, Regulation and Economic Development, University of Johannesburg
CPTTP	Comprehensive and Progressive Agreement for Trans-Pacific Partnership
CSEA	Centre for the Study of the Economies of Africa
C-TAP	COVID-19 Technology Access Pool
CUSMA	Canada-United States-Mexico Agreement
D4D	Data for Development
DSI	digital sequence information
EAC	East African Community
EC	European Commission
ECA	UN Economic Commission for Africa
ECCAS	Economic Community of Central African States
ECOWAS	Economic Community of West African States
EU	European Union



FAIR Principles	findability, accessibility, interoperability, and reusability
FAO	Food and Agriculture Organisation of the United Nations
FDI	foreign direct investment
FOI	freedom of information
FOSS	free and open source software
FTAs	free trade agreements
Gavi, the Vaccine Alliance	previously the Global Alliance for Vaccines and Immunisation
GCIP	Global Congress on Intellectual Property and the Public Interest
GDPR	General Data Protection Regulation
GII	Global Innovation Index
GISRS	Global Influenza Surveillance and Response System
GPAI	Global Partnership on AI
GRs	genetic resources
HMIS	health management information systems
ICT4D	Information and communication technology for development
IGF	Internet Governance Forum
IDRC	International Development Research Centre
IGC	WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
IGF	Internet Governance Forum
IoT	internet of things
IP	intellectual property
IPR	intellectual property rights
IT	information technology
ITU	International Telecommunication Union
JOSA	Jordan Open Source Association
KEI	Knowledge Ecology International
LDCs	least developed countries
LED	Law Enforcement Directive
LMICs	low- and middle-income countries
MCIT	Ministry of Communications and Information Technology, Egypt
MENA	Middle East and North Africa
mRNA	messenger ribonucleic acid
MSMEs	micro, small and medium enterprises
NIS	national innovation system
OA	open access
OAPI	Organisation Africaine de la Propriété Intellectuelle
OD4D	Open Data for Development
ODI	Open Data Institute
OECD	Organisation for Economic Co-operation and Development
OGP	Open Government Partnership
Open AIR	Open African Innovation Research network
PIP Framework	Pandemic Influenza Preparedness Framework
PII	personal identifiable information

PIPEDA	Personal Information Protection and Electronic Documents Act
PIJIP	Program on Information Justice and Intellectual Property
PRIDA	Policy and Regulation Initiative for Digital Africa
PVRs	plant variety rights
RCEP	Regional Comprehensive Economic Partnership
R&D	research and development
RIA	Research ICT Africa
RTAs	regional trade agreements
SADC	Southern African Development Community
SCCR	WIPO Standing Committee on Copyright and Related Rights
SDA	Sustainability in the Digital Age
SDGs	Sustainable Development Goals
SDOH	social determinants of health
STI	science, technology and innovation
TCEs	traditional cultural expressions
TDM	text and data mining
TK	traditional knowledge
tralac	Trade Law Centre
TRIPS	WTO Agreement on Trade-Related Aspects of Intellectual Property Rights
UPOV	International Union for the Protection of New Varieties of Plants
UCT	University of Cape Town
TTIP	US-EU Transatlantic Trade and Investment Partnership
UN	United Nations
UNCTAD	UN Conference on Trade and Development
UNEP	UN Environment Programme
UNESCO	UN Educational, Scientific and Cultural Organisation
UNFCCC	UN Framework Convention on Climate Change
WCT	WIPO Copyright Treaty
WEF	World Economic Forum
WHO	UN World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

# 1. Introduction

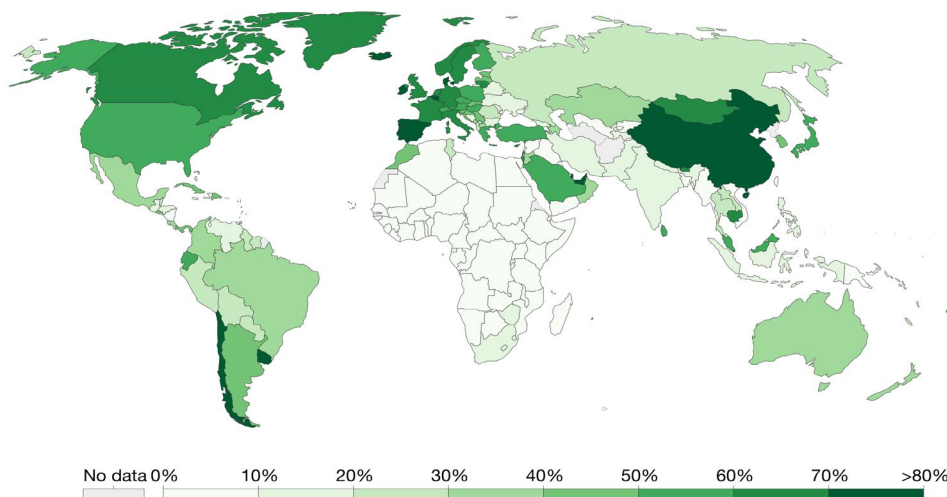
## 1.1 Vaccination Inequity as a Case Study of Symptoms of Regulatory Problems

The global COVID-19 pandemic, caused by the SARS-CoV-2 virus, is amongst the most disruptive forces humanity has faced in modern times. It ranks alongside some of the world's greatest challenges, due to its ubiquity and the immediacy of its transformative impacts. And massive disruption invites rapid innovation. Case in point: the research, development, and deployment of vaccines against COVID-19 at unprecedented pace and scale.

However, despite our human ingenuity in developing technology to fight this virus, we have failed to ensure equitable access to the pandemic's most plausible solution. Vast swathes of humanity have been excluded (see Figure 1) from accessing the vaccines, including boosters, necessary not only for economic recovery and a return to normalcy, but to literally save lives.

### Share of the population fully vaccinated against COVID-19

Total number of people who received all doses prescribed by the vaccination protocol, divided by the total population of the country.



Source: Official data collated by Our World in Data – Last updated 22 September 2021, 08:40 (London time)  
Note: Alternative definitions of a full vaccination, e.g. having been infected with SARS-CoV-2 and having 1 dose of a 2-dose protocol, are ignored to maximize comparability between countries.  
OurWorldInData.org/coronavirus • CC BY

Figure 1: Vaccine exclusion

Regulatory norms and institutions share both credit and blame for this situation. On the one hand, global and national marketplace framework policies on intellectual property, competition, finance and investment, international trade, and related areas have created the conditions that facilitated scientific breakthroughs such as mRNA vaccines. On the other hand, the same policies have hyper-concentrated access to vaccines in the hands of the world's wealthiest nations.

Even if benevolence eventually leads to greater vaccine access globally, the economic rewards of vaccine sales are disproportionately reaped by wealthy shareholders of certain multinational pharmaceutical companies. And meanwhile rich countries benefit from a massive head start on economic recovery, exacerbating already severe global inequalities. The global inequalities are also replicated at national level in low-income countries, where the well-off are more likely than their poor compatriots to be vaccinated and are more able to adapt to, and prosper within, COVID constraints.

To experts in regulatory fields such as intellectual property, little of this is surprising. Research during the last few decades—including much IDRC-supported research—has revealed the paradox: Temporary monopolies enabled by intellectual property rights finance incentives for investment, but at the same time

limit competition, raise prices, impede access to technology, and concentrate wealth. This same body of research has, fortunately, also pointed to solutions.

Open science is one example. Research shows how open science and related models of open innovation do not eschew intellectual property, but rather leverage global regulatory regimes creatively and exploit highly sophisticated acquisition and/or enforcement strategies (de Beer, 2015; de Beer & Gold, 2020; Gold, 2021). Strategies to support open science solutions to COVID-19 include nudging rights owners to voluntarily pool, or pledge to not enforce, intellectual property rights (Contreras et al., 2020; WHO, n.d.-d). Especially in emergency situations, where speedy innovation is imperative, openness helps (Chesbrough, 2020; Mortara et al., 2022). Participatory research, citizen science, and crowdsourcing all offer new solutions to complex public health problems (Masselot et al., 2022).

Oxford University and AstraZeneca openly collaborated to deploy the world's most affordable and widely accessible vaccine, with the ChAdOx vaccine technology 97% financed by public and charitable funding (Cross et al., 2021; Safi, 2021). And the inclusion of a for-profit, global pharmaceutical company, AstraZeneca, in this open science model shows why stereotypes about openness as mere altruism are oversimplifications. A nuanced analysis recognises that market mechanisms can be harnessed for development outcomes. Vaccines against other viruses—rVSV-ZEBOV Ebola, for instance (Herder et al., 2020)—have similar origin stories as public goods.

Inspiringly, the African continent is home to the latest cutting-edge model to combat SARS-CoV-2, with the Africa-based hub, Afrigen in Cape Town, pioneering open science solutions for mRNA vaccines and therapeutics (Maxmen, 2022; Medicines Patent Pool, n.d.). A recent *Nature* editorial explains why this open science model “must succeed” in overcoming “challenges presented by the global vaccine market, world trade rules and an intellectual-property (IP) system that often benefits established corporations, universities and governments in high-income countries” (*Nature*, 2022).

A 10-year IDRC work programme on “open development” helped show how such open science models can be designed, implemented, and scaled for impact (Smith & Reilly, 2013; Smith & Seward, 2020). That work programme contributed to a decade's worth of empirical and normative research on scaling-up of open collaborative innovation in Africa (de Beer et al., 2014, 2020; Open AIR, 2020). And that body of research links to the work that African researchers are undertaking, in the context of COVID-19 specifically, on legal, economic, and policy solutions (dos Santos et al., 2022; Oguamanam, 2020a; Omino, 2016).

The rules regulating international trade can also be calibrated to mitigate side effects of maximalist intellectual property tendencies. This lesson was learned during the HIV/AIDS crisis at the end of the 20<sup>th</sup> century. Then, members of the World Trade Organisation declared that the predominant global framework governing intellectual property, the TRIPS Agreement, does not and should not prevent members from taking measures to protect public health. In pushing for practical reforms to global economic regulatory systems, developing countries were bolstered by evidence and ideas from research communities and civil society groups that the IDRC and like-minded funders have nurtured.

Work on access to medicines continued throughout the first decades of the 21<sup>st</sup> century, again with funding support by the IDRC (Bolo et al., 2016; PIJIP, 2011; The Scinnovent Centre, 2020). Today, many of the same thought leaders from the advocacy work on access to HIV/AIDS treatments are participating in contemporary geopolitical debates, spurred by the COVID context, about a “waiver” of global regulatory rules on intellectual property licensing (Alexander et al., 2021; Gathi et al., 2021; InfoJustice, 2022; Nelson Mandela School of Public Governance, 2021; Oguamanam & O'Flaherty, 2021; Open AIR, 2020).

South Africa and India submitted in October 2020 a proposal to the WTO for a “TRIPS waiver” for COVID vaccines and treatments. The proposal—to suspend international trade law on intellectual property—faced strong opposition from the European Union, the United Kingdom and Switzerland; flip-flopping from the United States; and foot-dragging from Canada and many other countries (WTO, 2022b). After a year-

and-a-half delay, during which millions of people died, the compromise adopted by the WTO in June 2022 looks little different from the flawed law already on the books (WTO, 2022a).

This policy result is especially disappointing because it demonstrates that during the two decades since a similar impasse arose over access to antiretroviral medicines to fight HIV/AIDS (t’Hoen, 2016), the world has failed to make the global intellectual property governance system more inclusive or sustainable, particularly in relation to public health. “It is hard to imagine anything with fewer benefits”, writes Love (2022c) in response to the WTO’s June 2022 agreement. Yu (2023, p. 15) reflects: “At some point, one has to wonder what capabilities the WTO still has to facilitate the development of effective responses to future global and regional crises.”

A difference between previous global public health crises and this one is the crucial role that digital technologies and data governance now play. And ownership of, and access to, data about technologies’ usage is often as valuable as control over the technologies themselves. To illustrate, Pfizer’s profit-maximising vaccine deployment strategy prioritised distribution in Israel over other countries because the Israelis promised, in return for access, something more precious than money—data on safety and efficacy, i.e. “big medical data” from Israel acting as a “*de facto* laboratory” (Birnhack, 2021, p. 821). Meanwhile and more encouragingly, open data was deployed to study dimensions such as mobility (Scotti et al., 2022) and regulatory responses (Peleg et al., 2021) during the pandemic.

A key lesson provided by COVID-19 echoes the mantra intellectual property experts have espoused for years: One size does not fit all (Oguamanam, 2020a). Yet geopolitical and economic pressure to harmonise and ratchet up minimum IP standards persists, led especially by private-sector industry groups and the governments of the countries in which these industries are centred. How, then, can the countries of the world work cooperatively towards global regulatory solutions on public interest matters? The core regulatory tensions in global knowledge governance—between harmonisation and flexibility; between homogeneity and diversity—are not easily resolved and are therefore a natural focal point for future research.

## **1.2 Interconnections between SDGs and IDRC Focus Areas**

While confronting the COVID-19 global health crisis justifiably occupies much of the world’s attention at present, strikingly similar regulatory challenges impact other pressing issues. Unequal access to COVID-19 vaccines has revealed some of the ways in which global, regional, and national regulatory systems are faulty. But regulatory dysfunction in respect of vaccine access equity is merely one symptom of underlying regulatory shortcomings (and thus also opportunities) in respect of pursuit of more sustainable and inclusive innovation. In addition to exposing vulnerabilities, inequalities, and the implications of faulty policies, COVID-19 has fast-tracked numerous transformations (including digital transformations) and, in the process, has also offered signposts and opportunities for intervention via sound policies grounded in the public interest principle of inclusion.

The United Nation’s Sustainable Development Goals (UN General Assembly, 2015) cannot be achieved without addressing regulatory systems. And improved regulatory systems governing innovation must include not only solutions to the COVID-19 crisis but also solutions in other crucial areas prioritised by the SDGs. There are numerous developmental areas where countries of the Global South have lagged in both policy and practice, and where research, innovation and scaling, supported by fit-for-purpose regulation, are needed for inclusion of the marginalised, including cohorts of those becoming the “new poor” as a direct outcome of the pandemic.

There is, for example, a clear need to confront the realities of global and local inequality in access to, and use of, knowledge and innovation in respect of digital technologies and digitally enabled AI, quantum computing, and IoT deployment. Inequalities in access to such core components of the digital economy have been magnified with COVID-19.

Consider further examples: Marketplace framework regulations influence the digital and biotechnological agricultural innovations necessary to achieve food security. Access to technologies necessary to mitigate and adapt to climate change depends on appropriate regulatory systems. Regulation at multiple levels is shaping the way scientific breakthroughs in AI and other digital tools of the fourth industrial revolution are deployed in developing countries. And these regulatory challenges often transcend a single area of focus, having cross-cutting systemic impacts.

Questions of innovation regulation are, therefore, potentially relevant for all areas of IDRC’s *Strategy 2030* (IDRC, 2021a)—around which the conceptualisation of this scoping study on regulating innovation was initially structured. The IDRC *Strategy 2030* envisions work shaped by five areas of focus that contribute to achieving the SDGs, as quoted in Table 1 (IDRC, 2021b).

*Table 1: Areas of focus in IDRC’s Strategy 2030*

- **Climate-Resilient Food Systems** – building inclusive and sustainable food systems to help develop resilience among communities severely affected by climate change and addressing emerging health threats that arise from food systems.
- **Global Health** – strengthening health systems and policies so they can deliver better maternal and child health, improved sexual and reproductive health and rights for women and girls, and more effective and equitable preparedness and responses to epidemics.
- **Education and Science** – ensuring children and youth from vulnerable populations are in school and benefit from high-quality education, while supporting women’s leadership in strong science systems.
- **Democratic and Inclusive Governance** – investing in research and innovation so that people can claim their rights, shape the policies and practices that affect them, and enjoy the benefits that democracy and inclusive governance bring to everyday life.
- **Sustainable Inclusive Economies** – building the evidence base to support sustainable development that reduces greenhouse gas emissions while enhancing climate resiliency, fostering shared prosperity, and expanding economic opportunities for women and youth.

Although all or most SDGs depend on improved regulatory systems, Table 2 lists the SDGs that are most clearly interconnected with regulatory impacts and provides cross-references between these goals and IDRC areas of focus.

*Table 2: Regulatory impacts associated with SDGs and IDRC focus areas*

SDGs, regulatory impacts		IDRC focus areas
2	Zero hunger	Climate-Resilient Food Systems; Democratic and Inclusive Governance
3	Good health and well-being	Global Health; Democratic and Inclusive Governance; Education and Science
4	Quality education	Education and Science; Democratic and Inclusive Governance
5	Gender equality	Cross-cutting all
7, 13	Clean energy; Climate action	Climate-Resilient Food Systems; Education and Science; Democratic and Inclusive Governance

8	Decent work and economic growth	Education and Science; Democratic and Inclusive Governance; Sustainable Inclusive Economies
9	Industry, innovation and infrastructure	Cross-cutting all
10	Reduced inequalities	Cross-cutting all

Because the regulatory challenges revealed or heightened by the global pandemic are interconnected with, and underpin, numerous SDGs, strategies to achieve the SDGs must be able to cut across topics and areas to solve common underlying problems.

### 1.3 Scoping Out a Treatment for Regulatory Challenges

This report’s identification of a research agenda to treat not just the symptoms but also the underlying causes of unhealthy regulatory systems required a clearer scoping of known problems and solutions, building on the preliminary diagnoses above. And that necessitated a review of research done and evidence gathered so far. Synthesising existing knowledge was, therefore, the primary goal of the scoping work that generated this report.

To begin the process of scoping and defining a research agenda around the role of regulation in innovation systems, particularly the importance of regulation to scaling of innovations in the Global South, IDRC hosted an expert roundtable in July 2021. Experts were asked to comment on the questions shown in Table 3.

*Table 3: Questions posed at expert roundtable in June 2021*

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| <ul style="list-style-type: none"> <li>• What are main (emerging) conclusions from the current IPR debate, for an international development research community (including but transcending IDRC-supported researchers) that supports innovation and scaling?</li> <li>• What is the role of research on innovation and scaling, particularly in low-income contexts? What are the gaps in current research?</li> <li>• What priority areas could IDRC contribute to, and how to refine and develop those?</li> </ul> |
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The points of apparent consensus amongst the expert roundtable participants have been reflected in the discussion thus far in this introductory chapter. The next step was to flesh out participants’ ideas and instincts in a more methodical scoping exercise. In January 2022, researchers affiliated with the Open African Innovation Research (Open AIR) network were awarded a nine-month grant to complete a scoping study on the topic of “regulating innovation in lower-income economies”.

#### 1.3.1 Objectives

The overall objective of the study was to scope out and conceptualise a development research agenda on regulating innovation for inclusion and sustainability in lower-income economies. More specifically, this scoping work sought to:

- summarise and disseminate the state of knowledge about the importance of regulation of/for innovation in lower-income countries (building on current evidence about COVID-19 vaccine roll-out);
- provide a synthesis of past IDRC and other work on regulation, drawing out key findings and strategic opportunities for gap-filling; and
- facilitate development of a research agenda, including proposed programming modalities, and policy entry points, for support of partners in low-income countries seeking to address barriers and harness regulatory regimes in support of critical SDGs.

### 1.3.2 Parameters

The study parameters called for scoping of innovation regulation falling under three of the above-listed (Table 1) IDRC focus areas: Global Health, Democratic and Inclusive Governance, and Sustainable Inclusive Economies. Because of the potential breadth of the three IDRC focus areas, the study narrows in on key intersections among the focus areas, SDGs, and regulatory themes. Accordingly, we arrived at three narrower foci for the scoping exercise—(1) health/vaccines, (2) data and technology governance, and (3) trade/environment—as shown in the middle column of Table 4 below.

*Table 4: IDRC focus areas, narrowed scoping foci, elements to be included in scoping*

IDRC focus area	Scoping focus	Elements to be included in scoping
Global Health	Health/vaccines	<ul style="list-style-type: none"> <li>relationships between IPR and innovation ecosystems, specifically in delivery of universal care to achieve SDG 3</li> <li>governance and ownership of global vs. local innovation, including but not limited to TRIPS</li> <li>roles of IPR, licensing, and regulatory bodies in shaping access and influencing distribution of health and economic benefits/outcomes</li> </ul>
Democratic and Inclusive Governance	Data and technology governance	<ul style="list-style-type: none"> <li>digitalisation, intellectual property, and human rights</li> <li>national, regional and global governance, policies and norms related to the behaviour of data-driven firms</li> <li>data justice, algorithmic fairness</li> <li>data flows across borders, cross-border digital services and transactions</li> </ul>
Sustainable Inclusive Economies	Trade/environment	<ul style="list-style-type: none"> <li>roles of competition and trade agencies/institutions, including in the context of AfCFTA</li> <li>interactions between different types of (government) agencies in respect to innovation, trade agreements (global, regional, bilateral), competition</li> <li>mechanisms and capacities for global economic governance in support of SDGs, e.g., fostering environmental sustainability, “clean” innovation, technology transfer</li> </ul>

### 1.3.3 Methods

The study developed using a mixed-methods approach. These methods included:

- a semi-structured literature review (e.g. Boolean searches of databases of scholarly research, supplemented by citation-tracing/trailing and referrals to use-oriented reports, briefs, multimedia);
- institutional, regulatory, and stakeholder mapping: a scan of potentially relevant policy/legal/regulatory instruments, and of the institutions/entities interacting with these instruments, in applicable fields at regional and global levels, for the purposes of hypothesising, investigation and assessment, and for the purposes of eventual identification of entry points (see chapter 5) for regulatory research and engagement as part of a new research agenda;
- conversations with paradigm-defining experts to solicit insights on known problems and solutions, and to explore opportunities for partnership and collaboration; and
- collation, summary, and reporting of results, including gap identification and development of forward-focussed research topics.



The literature was explored via a scoping review rather than a formal systemic review. A scoping review was determined to be the most appropriate method (Arksey & O'Malley, 2005) because the research topic and questions were not yet precisely defined. That is, scoping is an exploratory exercise rather than a meta-analysis of easily comparable existing research. Furthermore, a scoping review is best where a significant portion of the source material is likely to be “use-based” (sometimes pejoratively referred to as “grey” literature), rather than published in refereed scholarly articles and books.

We created a shared library using the open source reference management software Zotero. The library is currently non-public—shared only amongst the project team, research assistants, and IDRC representatives—but will be made public and open, at the appropriate time, as a resource upon which all future collaborators can build.

The conversations conducted as part of the scoping exercise aimed to include appropriately diverse personal, geographic, and disciplinary perspectives. We leveraged, to a large extent, existing networks like the Global Congress on Intellectual Property and the Public Interest, but also explored, and began to forge, new relationships through this scoping study.

#### **1.3.4 Study Team**

The study team worked in close consultation with designated IDRC staff, and formed sub-groups so as to implement the study in each of the three designated scoping focus areas (as shown in Table 4 above). Each working group had a designated leader to steer the team, to spearhead drafting of report content, and to provide the IDRC with a convenient point of contact. Chidi Oguamanam led the health/vaccines working group, supported by Caroline Ncube and Jeremy de Beer. Nagla Rizk led the data and technology governance working group, working closely with Tobias Schonwetter and with support from de Beer. Ncube led the trade/environment working group, with support from de Beer.

The study team recruited a group of five research assistants, based at three of Open AIR's institutional hubs—at UCT, uOttawa and The American University in Cairo (AUC)—to help with review and organisation of the literature (including populating and managing the Zotero library), and a senior research associate who supported the report-writing process and helped link the study with some of IDRC's previously supported research conclusions.

The creation of working groups did not detract from the collective nature of the work. Each study team member has experience and expertise with regulatory issues across the spectrum of IDRC focus areas, and brought those to bear on the study. Each working group followed a similar, though not identical, template for executing the study. That included a generally comparable outline and methodological approach to the research and the writing.

#### **1.3.5 Structure of the Report**

This report is structured into 5 chapters. This chapter 1 has provided an introduction, based on themes derived from the 2021 expert roundtable meeting and subsequent development of a concept note for the study.

Chapters 2, 3, and 4 scope out existing research, synthesise current knowledge, and flag emerging issues in each of three scoping focus areas: health/vaccines (chapter 2), data and technology governance (chapter 3), and trade/environment (chapter 4).

Chapter 5 offers an integrated analysis of cross-cutting insights. Based on a synthesis of knowledge across the other chapters, this final chapter reconceptualises the relationships amongst IDRC focus areas, SDGs and regulatory themes, and offers a framework around which a coherent and feasible programme of

research could be structured. This chapter concludes with recommendations for research interventions that could: rapidly respond to timely opportunities for policy impact; continue on-the-ground field-building; and catalyse momentum throughout a community of practice. The report concludes with a Bibliography.

## 2. Climate, Health and Well-Being in the Shadow of COVID-19

By Chidi Oguamanam

### 2.1 Introduction

One of the direct and most disturbing outcomes of current climate change is the anticipated frequencies of zoonoses-related pandemics and consequential global public health crisis (Carlson et al., 2022). The toxic combination of climate crisis and public health emergencies, in turn, has direst consequences for the world's most vulnerable peoples in the lower- and middle-income countries (LMICs). This era of climate and public health instability is accompanied by unprecedented innovations aimed at tackling the cojoined problem. However, since LMICs contribute less to the climate crisis while bearing most of its brunt, including the effects of the resulting public health catastrophe (Bernstein et al., 2022), it is imperative that the benefits of the innovations around climate and public health be deliberately and sustainably extended to LMICs.

The combination of climate and public health crises imperils sustainability of life on earth, even human life, irrespective of geo-political and other boundaries. Regulation of innovation, or regulation for innovation, requires open-ended interventions (Butenko & Larouche, 2015). The scope of regulation as a concept at the intersection of law, science, technology, economics, politics, etc. is incapable of being mapped fully in one conceptual framework (Butenko & Larouche, 2015). Nonetheless, however framed, regulation is a critical and under-addressed (albeit ever-present), multi-pronged tool for undermining or enhancing inclusivity and equity. Regulation intersects the socio-economic and cultural contexts necessary for extending or obstructing access to innovation to those in direst need at a time of unprecedented crisis.

### 2.2 COVID-19 in Context

In March 2020, the WHO declared COVID-19 a global pandemic (WHO, 2020). Since then, there have been concerted efforts at global, regional, national and local levels across complex strata of policymaking, regulatory intervention and implementation aimed at containing the virus. Cumulatively, those efforts constitute opportune (even if inadvertent) experimentation on the role, potential, and failure of regulation in a pandemic context. Responses to COVID-19 involve interplays among an intricate universe of regulatory tools with a focus on access to medicines, specifically vaccines and other COVID-19-associated medical technology innovations<sup>2</sup> (and services along these innovations' value chains).

Regulatory interventions in response to COVID-19 have emerged against the backdrop of the 1990s international experience of access to medicines within the closed and proprietary framework of intellectual property vis-à-vis the open access and public goods approach (Maskus & Reichman, 2005; Reichman, 2009). Global responses to COVID-19 have revisited those tensions. More importantly, they have mapped fresh innovative pathways to regulatory intervention in a direction that favours active public de-risking of vaccine R&D (Fisher et al., 2022) with consequential attenuation and decentring of intellectual property.

Also, there is a perceptible shift in the positioning of LMICs from being passive export markets for pharmaceuticals to being domestic manufacturing hubs of vaccines and essential medicines. Finally, COVID-19 has put the spotlight on the ascendancy of biopharmaceuticals, and the inevitability of collaborative digital data generation and sharing, in vaccine R&D. The latter is a boost to open science and to open innovation logic. It enhances equitable benefit-sharing and the global public goods approach to innovation

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<sup>2</sup> For example: ventilators, intubation devices, medical masks of varying grades, innovative diagnostic tools, diverse sanitary and public health supplies.

in medicines and in life sciences, while raising a different kind of regulatory dynamic with implications for the attainment of the UN Sustainable Development Goals.

### **2.3 SDG 3 (Health and Well-Being) and the SDGs Dimension**

Not only have the disruptive effects of COVID-19 rolled back progress on SDGs (UNDESA, 2021), notably SDG 3 (health and well-being), they demonstrate the interconnected and organic nature of the SDGs (Fenner & Cernev, 2021). The pandemic's impacts on public health triggered a chain of inequitable outcomes on a range of other SDGs beyond SDG 3, including widening of gender gaps. Women bear the greater pathological burden of the disease and greater effects from the resulting socio-cultural and economic disruptions (SDG 5). Such disruptions not only generally escalate poverty, hunger, education, sanitation, and disincentives for decent work and economic growth (SDGs 1, 2, 4, 6, 8, 10); they also impose these escalations along familiar gendered lines of inequality.<sup>3</sup>

Expectedly, the effects of the pandemic on SDGs are uneven between developed and lower-income countries. A combination of institutional resilience, technological and industrial advancement, fiscal strength, infrastructural endowment, sophisticated public administration fundamentals and educated populaces, among others, positioned developed countries better for pandemic containment.

The asymmetry between developed countries and LMICs in their responses to COVID-19 is symbolised by vaccine nationalism (Oguamanam, 2020b). That lopsided response and outcome is a practical manifestation of the 10/90 global health inequity (Luchetti, 2014). More than two years into the pandemic, developed countries are luxuriating in vaccine glut, with citizens choosing and discriminating across vaccine brands. Some are on their fourth dose. But many LMICs have yet to attain 20% of vaccination with the first dose, notwithstanding prevalent vaccine skepticism.

A compelling takeaway from the COVID-19 experience is the need to re-think SDG 3, and indeed the entire SDG framework for inclusive and sustainable development (UNDESA, 2021). Such an exercise could give priority to emergency preparedness and addressing the lopsided factors that undermine inclusive and equitable outcomes for LMICs.

### **2.4 COVID-19 and TRIPS: From Old to New Access to Medicines Template**

Since the mid-1990s, the TRIPS Agreement has heralded the global harmonisation of intellectual property protection (Reichman, 2009). Such harmonisation has incorporated specific policy spaces for accommodating the particular needs of LMICs in respect of access to essential medicines. The TRIPS concessionary policy spaces, provided to developing countries to mitigate the impact of tightened patents, include: graduated or delayed implementation timelines for least developed countries (LDCs); compulsory licensing of patented medicines for countries lacking domestic pharmaceutical manufacturing capacity; parallel importation of patented medicines; principles pursuant to patent jurisprudence, such as the patent exhaustion doctrine, and other market rules such as market segmentation. Other spaces include national emergency response discretion and circumstances of extreme urgency (Correa et al., 2021).

At the same time, TRIPS Article 27 strengthened protection of innovation, extending it to all fields of technology without discrimination. TRIPS also opened the doors for the rise of what analysts came to call “regulatory property” as a “new form of intellectual property” (R. Feldman, 2016). This refers to categories of supplementary protections for pharmaceutical patent holders based either on market data or a range of undisclosed test data, e.g. clinical trial data submitted for drug approval. Articles 39.3 and 70.9 of TRIPS

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<sup>3</sup> Only roughly five SDGs—11 (sustainable cities and communities); 12 (responsible consumption and production); 14 (life below water); 15 (life on land), and parts of SDG 16 (peace, justice)—may arguably not be *directly* engaged. That is arguable, because they do have immediate relevance to health in the context of COVID-19. It does not, however, mean that these SDGs are not relevant to health. Indeed, the quality of life below water and life on land as well as consumption and production patterns are critical to overall health of the people, cities, and communities and for social and ecological peace and justice.

entrench data and market exclusivities. Data exclusivity rights confer additional and overlaid proprietary rights to patent holders (Gervais, 2019) with deleterious effects on competition from generic drug makers. In effect, TRIPS has escalated the transaction costs of intellectual property, which has translated into unaffordable costs of essential medicines for the world's poor and skewed pharmaceutical R&D priorities and design.

Soon after TRIPS was signed, the HIV/AIDS pandemic tested the instrument's efficacy as an (in)flexible regulatory framework for access to essential medicines, especially for developing countries (Gathii, 2002). While many in developed countries were able to afford expensive blockbuster cocktail medicines for antiretroviral therapy (ART), HIV/AIDS patients in the developing world bore the brunt of the pandemic because of poverty. This state of affairs starkly reinforced the 10/90 global health gap. Consequently, the 2001 Doha Declaration on the TRIPS Agreement and Public Health (Declaration on the TRIPS Agreement and Public Health, 2001) was framed to rid TRIPS of any real and perceived obstacles it posed to the ability of developing countries to mitigate public health crises—by optimising TRIPS flexibilities through purposeful interpretational approach to that effect.

The Doha Declaration resulted in the first-ever amendment of the TRIPS Agreement by adding Article 31*bis*. That Article allows countries without pharmaceutical manufacturing capacity to import a patented drug produced under a compulsory license. To date, Rwanda is the only country to have leveraged Article 31*bis* of Doha, through its agreement with Canada's Apotex Inc. for generic anti-viral AIDS drugs in 2007 (Vincent, 2020).

Overall, developing countries have dismally underexploited TRIPS flexibilities (See Deere, 2009) arguably to some extent due to the latter's fundamental flaws in design and conception. For example, many such countries could do more than they presently do in respect of compulsory licensing and experimental use (and other research exceptions). It was largely in the context of HIV/AIDS that the paradox of intellectual property—as incentive to innovation and disincentive to equitable access to essential medicines for the most vulnerable—was fully drawn into multisectoral policy debate at national and international levels.

Here in this discussion we see evidence of what was referred to earlier, in Table 4 (in chapter 1) of this report: the “relationships between IPR and innovation ecosystems, specifically in delivery of universal care to achieve SDG 3”.

With the outbreak of the COVID-19 global pandemic 20 after Doha, the existing intellectual property regulatory mediation for access to medicines under TRIPS has been revealed to be an abysmal failure. Not only has that system failed to address global health inequity in respect to access to essential medicines, but it has also proven to be of little help in navigating global health emergencies. COVID-19 has tested in practical ways—and exposed the gains, gaps, and failures of—more than 26 years of TRIPS-inspired regulatory engineering as it relates to public health and access to medicines. Consequently, there has been an active search for a more pragmatic and public goods approach, now framed around the calls for a special TRIPS waiver (Ruse-Khan & Paddeu, 2022; Thambisetty et al., 2022).

## **2.5 TRIPS Waiver**

In 2020, South Africa and India presented before the TRIPS Council a proposal for a “Waiver from certain provisions of the TRIPS agreement for the prevention, containment and treatment of COVID-19”. A revised version of the proposal was presented in 2021. However, the 12<sup>th</sup> WTO Ministerial Conference of June 2022, focused on WTO response to COVID-19 and future pandemics, mostly reaffirmed the core of the Doha Declaration (WTO, 2022b). It also highlighted core regulatory imperatives for better pandemic management, including a stable trading environment for goods and services, diversification of production of pandemic-containment goods and services, regulatory cooperation, sharing of regulatory information, recognition of vaccine certificates, and interoperability and harmonisation of digital health applications and technologies. The WTO framed these interventions as voluntary.

The more things change, the more they look the same. In essence, the lack of traction around the TRIPS waiver, and the futile rehash of Doha Declaration by the June 2022 WTO Ministerial Conference, is a clear vote of no confidence in LMICs' aspirations and an affirmation of the failure of the Doha Declaration and operationalisation of Article 31*bis* of the TRIPS Agreement. When the debate over the TRIPS waiver proposal got underway, thought leaders queried the credibility of the presumptive focus on TRIPS, and by extension intellectual property, as the major obstacle to access to COVID-19 vaccines (Thambisetty et al., 2022). Writing in a CNN op-ed, Harvard Law Professor Ruth Okediji maintains that “access to patents alone does not translate into optimal short or long-term ease of access to medicines” (Okediji, 2021).

Like TRIPS Article 31*bis*, the TRIPS waiver debate on the heels of COVID-19 proved intractable as it was bogged down by constraining and counterproductive details. Leading access to medicines campaigner James Love has observed that the June 2022 compromise text of the TRIPS waiver risks entrenchment of TRIPS-plus standards (Love, 2022b) in requiring waiver authorisation to list all patents covered. According to Love, patent profiling is not pragmatic in the context of biologics (Love, 2022a).

COVID-19 heralds a monumental change in vaccine R&D innovation, through the introduction of the new mRNA vaccines (Rutschman, 2021). This DNA-based vaccine pathway is dependent on mapping the structure of the genes of a virus and engineering its mRNA sequence so that it can literally teach the body's immune system to identify and attack the virus (Sheets et al., 2020). mRNA technology is a result of over 30 years of collaborative research by scientific communities, which have developed platforms for making vaccines for conceivably any infectious pathogen by developing and inserting the appropriate mRNA sequence (Brothers, 2020). As biologics, these vaccines are intensely data-driven and interdependent on a network of multiparty information or data assets, such as trade secrets, which are not easily amenable to patent landscaping.

## **2.6 Public/Private, Industry, and Multiple-Actor Partnership Dynamics**

Regulatory tightening of medical innovation through intellectual property is symbolised by TRIPS. That strict market model is blamed for the escalation of perennial global health inequity. It also fuels the appetite for a parallel approach to bridge that inequity through open innovation, which does not mutually exclude the application of intellectual property. The open approach acknowledges medicines and medical innovation as global public goods (Maskus & Reichman, 2005). The latter are goods that the intellectual property and market system cannot efficiently make accessible to those in direst need. Those vulnerable populations are mostly in LMICs.

Supply of global public goods requires non-market mediations by state and non-state actors. Analysts have mapped some of these mediations as happening under the agency of non-state actors in complex forms of partnerships with public, private, non-profit and various uncategorised others (P. K. Yu, 2021). This trend underscores the increased prominence of partnership-building—an important and under-engaged aspect of the SDGs, captured under SDG 17 (Oguamanam & de Beer, 2018). Among the tools that these state and non-state actors have developed are advance market commitments, priority review vouchers, and various orphan drug programmes.

Intellectual property is a market-driven reward and incentive mechanism for fostering innovation and creativity. The underlying, but disputed, assumption in this logic is that without intellectual property, the wheels of innovation and inventiveness may grind to a halt or spin at a lower and unhelpful pace. This conventional justification enjoys perhaps greatest empirical credibility with the patent regime in respect of pharmaceuticals. Despite the inconclusive role of patent grants as stimulants for R&D (see, for example, R. C. Feldman et al., 2021), a special exception is typically proffered to patents' presumed positive impact on innovation and inventiveness in the pharmaceutical sector.

Focusing on the health sector, as this chapter does, requires cognisance of the palpable disconnect between the current pharmaceutical R&D agenda and global public health crises, especially in respect of

access to drugs for needy populations, i.e. cognisance of the health sector's exposure of the clear flaw in the reward-and-incentive theory central to the patent system. What is needed is a creative model for access to the benefits of pharmaceutical research—potentially even a global treaty to empower and institutionalise public–private partnerships in health care provisioning. Such a regime would restore balance in the global IP system that presently undermines its public interest considerations (Oguamanam & O'Flaherty, 2021; Oriola, 2019; Oxfam, 2008; Pogge, 2005). To date, the public–private arrangements have tended to focus on drug- and disease-specific interventions, with nothing on the scale of what is required in the context of the global COVID-19 pandemic. And in the first two decades of TRIPS, the orientation of creative public–private partnerships has tended to conceive of LMICs as essentially lacking in pharmaceutical manufacturing capacity, and as thus representing merely export markets for essential drugs.

With the advent of COVID-19, there has been a noticeable shift in the regulatory interventions for access to medicines and medical technology innovations on many fronts. First, there has been proactive and unprecedented de-risking of R&D in vaccines, as evident in the US Operation Warp Speed initiative (Fisher et al., 2022; Okediji, 2021). Second, there has been intense establishment of new ad hoc global partnerships, and funding mechanisms, directed at COVID-19 vaccine R&D and the delivery of various associated medical technology innovations to LMICs. The partnerships include the Medicines Patent Pool, the COVID-19 Technology Access Pool (C-TAP), the COVID-19 Pledge initiative for mobilisation and sharing of proprietary and other relevant knowledge resources for containing COVID-19, and the COVAX initiative—a WHO partnership with non-state actors, most notably Gavi, the Vaccine Alliance, for global supply of COVID-19 vaccines to LMICs.

Third, there has been traction towards infrastructural, regulatory and other relevant capacity development in LMICs in support of domestic vaccine and essential medicine manufacturing, championed by the WHO and a small number of private-sector entities. Fourth, there has been increasing recognition of the importance of data both as a tool of R&D and as a collaboratively generated asset. This understanding of the centrality of data provides traction for open science and open access, both of which resonate with biologics as the new gamechanger in vaccine development and, beyond that, in myriad other applications of digital sequence information or digital sequence data in the life sciences.

Here in this discussion we see evidence of what Table 2 (in chapter 1) referred to as “roles of IPR, licensing, and regulatory bodies in shaping access and influencing distribution of health and economic benefits/outcomes”. We also see evidence, here, of what Table 2 foregrounded as “governance and ownership of global vs. local innovation”.

## **2.7 Decentering IP and Spotlighting Data**

As a prophylactic strategy, vaccinology and vaccines remain the foremost, time-tested public health intervention tools (Rutschman, 2022). However, vaccines are rarely candidates for the blockbuster drug market (Rutschman, 2021). They tend not to be attractive for private-sector investment, a situation that makes non-market interventions a significant imperative in vaccine R&D. For example, except for the bold political will of the Trump administration in directly de-risking COVID-19 mRNA vaccine R&D—through infrastructural support, a subsidised global market, and an unequivocal advance market commitment—it would have been impossible to develop so rapidly the viable candidate vaccines, especially Moderna's (Brothers, 2020). The US government partnership with Moderna in Operation Warp Speed was instrumental in delivering an historic result.

The success of COVID-19 vaccines is still being scaled globally by WHO, through its push towards global mRNA technology transfer hubs, beginning with South Africa and South Korea, via building infrastructural, skills training and regulatory capacity for vaccine and essential drugs manufacture in LMICs (Arthur, 2022). The initiative is opportune as it leverages the efficacious benefit of biologics manufacture and at the same time aims to boost the (often elusive) LMIC pharmaceutical manufacturing capacity. The WHO mRNA Tech

Transfer Hub programme draws on WHO's 2011 Pandemic Influenza Preparedness (PIP) Framework (WHO, n.d.-a). Through the PIP, WHO Member States collaborate with industry partners and various stakeholders in sharing of influenza viruses with human pathogenic and pandemic prospects, so as to enhance access to resulting or associated innovation, including vaccines and diagnostics to developing countries.

The PIP virus pool includes the WHO Global Influenza Surveillance and Response System (GISRS). This critical data-driven resource is availed, under an access and benefit-sharing (ABS) scheme, to entities, including in the private sector, involved in influenza vaccine research, manufacture, diagnostics and accessories. Similarly, the PIP scheme has inspired another recent initiative of the WHO: the Bio-Hub established in November 2020 in response to COVID-19 and other recent epidemic outbreaks (WHO, n.d.-c-b). The Bio-Hub is mandated to ensure "rapid and broad sharing of pathogens for effective surveillance and the timely development of medical response products such as diagnostics, therapeutics or vaccines" (WHO, n.d.-c-b). This globally instituted permanent Bio-Hub is providing a counterpoint to the current inefficient bilateral, and emergency-driven, practice of sharing of pathogens between individual countries.

From the foregoing, the pertinent and intertwined trends associated with the COVID-19 experience can be summarised as follows: (1) the direct public de-risking of vaccine R&D, symbolised by Operation Warp Speed in US; (2) the escalation of non-state interventions for access to vaccines targeting LMICs, signified by the COVAX initiative; (3) the collaborative R&D and data-sharing inherent in the manufacture of mRNA vaccines and biologics in general; and (4) the WHO's determination to globally scale data-sharing in public health R&D, and the related inclination towards open access and equitable benefit-sharing models in that space.

The cumulative effect of these trends is the decentring (and consequential attenuating) of the patent system and its too-powerful role as an instrument of proprietary regulatory control over access to medicines and to health innovation. De-risked vaccine R&D opens up opportunities for attenuated intellectual property claims, providing impetus for boosting local vaccine and pharmaceutical manufacturing capacity in LMICs. It focuses regulatory attention on standardisation, safety, quality control, use of data, ABS, viability of local patronage, and the design of partnership models to ensure sustainability of manufacturing capacity both during and outside of emergency periods.

## **2.8 Significance of New Research Methods and Non-Patent IPRs**

Notwithstanding the plausible moderating of patents amidst the expanding prominence of data in the new R&D landscape for biologics, leading-edge research methods and tools, as well as non-patent intellectual property, will continue to pose new and additional regulatory challenges. In biologics-driven medicines/vaccines R&D and innovation, efficient and timely conduct of trailblazing research requires new research methodologies and tools. Some of those include expedited access, processing and analyses of scientific literature and data through, for example, text and data mining (TDM) (Flynn et al., 2021). Other tools of advanced research in this new environment involve software-enabled devices and applications, 3- and 4-D printing, repair manuals, and artificial intelligence and machine-learning operations, etc. At one level or another, TDM and the other above-enumerated tools are crucial for advancing biologics R&D and production. Of concern is the fact that these applications' deployment and repair could be undermined by copyright (Flynn et al., 2022), and also that in many LMICs there are at present low levels of capacity to use the applications.

As a related matter, trade secrets constitute sensitive business information—often more valuable than the information disclosed in patents, and fully confidential—that is isolated from the information required for disclosure in patent applications. For example, the recipe for making COVID-19 re-agents can be withheld as a trade secret (or as part of the commercial embodiment of the innovation). Without such recipe, second-comers, including COVID-19 patent licensees, are not able to carry out diagnostics necessary for the



containment of the pathogen. In the words of Flynn et al. (2021, p. 12), “[u]ndisclosed knowledge can be a significant barrier to entry for new firms, even where authorizations to use patented technology [exist]”.

Trade secrets are likely to assume an increased (and troubling) significance a tool of choice for firms—a tool that could potentially undermine the coalescing of interests by multiple R&D stakeholders in the biomedical, agricultural, data and related fields towards open science and shared/collaborative innovation models. Consequently, several non-patent and less-mentioned but increasingly relevant regimes of intellectual property require purposeful regulatory attention if they are not to undermine R&D in, and access to, medicines, medical technologies and diagnostics.

## **2.9 Opportunities for Regulatory Research and Engagement**

The knowledge synthesised in this chapter points towards four opportunities for a developmental research agenda focussing on innovation regulation for health and well-being:

1. Global-level emphasis on access to medicines and vaccines blurs opportunities for digital health innovation and innovation in ancillary medical health technologies in LMICs. This is why the recently brokered TRIPS waiver is inadequate, and why it is necessary to engage in the iterative process of expanding and updating this regulatory instrument. COVID-19 was and is not about vaccines only. It also is about ancillary medical innovations in therapeutics, diagnostics, and miscellaneous accessories. Future pandemics are anticipated to have their own character, requiring technological and regulatory response agility and adaptation beyond medicines or therapeutics. Purposeful regulation could support institutional malleability. For example, LMIC innovators not focused on health innovation could be supported, via funding incentives and other regulatory measures, to pivot their services towards the exigencies of health and other emergencies.
2. There is an opportunity to re-think pursuit of, and more holistically pursue, SDGs in order to render LMICs more pandemic- and public health emergency-ready. In addition to emphasis on delivery of essential health care, it is necessary to integrate regulatory efforts to address essential social determinants of health (SDOH) (WHO, n.d.-b)—for example, housing, public transportation, basic hygiene, access to clean water, public health education, social welfare support for the vulnerable population—in order to render a population more resilient during public health emergencies. In the case of COVID-19, for example, stronger delivery on SDOH would have enhanced adherence to social distancing and other COVID-19 precautionary regulatory measures in LMICs.
3. DNA-based mRNA vaccines represent the entrenchment of biologics as a largely data-driven enterprise. Data is collaboratively produced in this space under a networked model, providing a boost for open innovation across life sciences, including innovation in agriculture, climate mitigation and adaptation, surveillance of zoonoses spill overs, etc. Development research focused on regulating biologics innovation for equity and inclusiveness would require exploration of all models of data governance that can enhance equitable and affordable access to medicinal innovation for LMICs. With increased interest in digital or genetic sequencing of data across agriculture, health and other life sciences, options for data regulation, control or management could be inspired by liberal data access concepts—through, for example, compensatory liability models and benefit-sharing, as opposed to data ownership.
4. There are disparate partnerships, involving a diverse range of public, private, non-profit and other actors, mediating access to medicines and medical technologies for LMICs. Aside from calling attention on how best to regulate partnerships for sustainable development (SGD 17) in this space, the trend reflects the feasibility of political will to de-risk R&D related to public goods. With consequential potential attenuation of intellectual property, this opens opportunities for local vaccine manufacture in LMICs, and this new dynamic raises new regulatory challenges. These challenges include: sustainability of new

vaccine manufacturing infrastructure beyond pandemic emergencies to address other endemic disease burdens in LMICs; standardisation and quality control; regulatory capacity; and sustainable markets and marketing models for LMIC-made medicines and medical technologies.

# 3. Data and Technology Governance

By Nagla Rizk and Tobias Schonwetter

## 3.1 Introduction

This chapter summarises and disseminates the state of knowledge on regulation of data and data-driven innovation, and on the impacts of this regulation on development outcomes. The chapter explores data-related policy and regulatory environments with a view to proposing an agenda for innovative and evidence-based research that promotes regulation of innovation to overcome inequality and promote sustainable and inclusive development. It outlines key issues and points of departure to help facilitate the research agenda, drawing on past IDRC and other work in the area of data and technology governance.

It is important to note at the outset that the governance of data and technology is relevant to multiple development themes. It spans across almost *all* of the SDGs, as data can contribute to, and help achieve, specific SDGs via well-informed policymaking that leads to better livelihoods. For example, better data on the lives of the poor, and on poverty dynamics, will inform policy frameworks addressing poverty alleviation and achievement of the goal of no poverty (SDG 1). As well, proper collection and management of patient-generated health data improves disease prediction, disease reduction, and health services (SDG 3). Additionally, gender-disaggregated data—measuring gaps in education, political environment, health, and economic participation—supports achievement of gender equality (SDG 5). Similarly, accurate data on education, skills and work helps achieve decent work and economic skills (SDG 8). The Global Partnership for Sustainable Development Data highlights how different data initiatives can support different SDGs (GPSDD, n.d.). The World Bank’s explanations of these relationships are summarised in Table 5.

Table 5: Connecting data to the SDGs (World Bank, 2021)

Data and SDGs	
1. No poverty	<i>Better data on who and where the poor are, and on their needs.</i>
2. Zero hunger	<i>Data on crops, weather, prices.</i>
3. Good health and wellbeing	<i>Health data, prediction of disease, better health services.</i>
4. Quality education	<i>Disaggregated data on school enrolment and teachers, the quality of education and attainment levels.</i>
5. Gender equality	<i>Gender-disaggregated data to measure gaps in education, political empowerment, health, and economic participation.</i>
6. Clean water and sanitation	<i>Data on water resources, using resources more efficiently, better access to clean water.</i>
7. Affordable and clean energy	<i>Data on how people who have access to reliable energy and electricity, prediction of better education and income levels</i>
8. Decent work and economic growth	<i>Data on skills and levels of education, prediction of future economic growth</i>
9. Industry, innovation, and infrastructure	<i>Population data, citizen data, investing in better infrastructure; water, energy, housing, transportation, and sanitation.</i>
10. Reduced inequalities	<i>Data-driven approach to inclusion—mapping communities and working with household surveys and other citizen data collection mechanisms.</i>

11. Sustainable cities and communities	<i>Data that captures water and air quality, transportation, and infrastructure</i>
12. Responsible consumption and production	<i>Working towards sustainable consumption by data analysis of consumption patterns and identifying wasteful gaps.</i>
13. Climate action	<i>Data-led decision-making for climate action, climate changes predictions.</i>
14. Life below water	<i>Better data on life below water; monitoring oceans, preventing overfishing and tackling pollution, monitoring climate change, working towards a more sustainable fishing industry</i>
15. Life on land	<i>Data that captures land use and impact, preventing overuse of land to tackle the destruction of fragile ecosystems.</i>
16. Peace, justice, and strong institutions	<i>Civil registration data, population information for government planning</i>
17. Partnerships for the goals	<i>Data to hold and produce partnerships between governments, companies, and people to meet the SDGs.</i>

More broadly, data is key for monitoring progress made towards all SDGs, and hence partnerships must be leveraged to capitalise on the use and management of data to assess SDG fulfillment. Consequently, the regulation of innovation in data and technology is a cross-cutting theme that is overarching and relevant to all components of IDRC’s Strategy 2030, hence calling for collaboration between and across IDRC focus areas. This said, the focus area most closely linked to the study reported on in this chapter is the IDRC’s Democratic and Inclusive Governance programme—with its focus on SDGs 5, 10 and 16.

The governance of data is a key aspect of the overall governance of technology—with data being the “input” for new technologies including artificial intelligence (AI), quantum computing, and the internet of things (IoT). Yet while closely integrated, data and technology each embody a set of unique issues that may warrant separate analysis.

It is important to acknowledge from the outset that data and technology represent potential tools for promoting inclusive development, as demonstrated by the large amount of work carried out under programmes such as “ICT4D”, “Data for Development”, “Data for Good”, “AI4D”, and “AI for Good”. At the same time, data and technology can exacerbate divides. It is therefore imperative to both harness the power of data and technology to promote inclusion, and, at the same time, to mitigate the threats of deepening existing (or creating new) divides. The governance of data and technology then becomes key to the success of such balancing efforts, especially in LMICs where threats are likely to be aggravated.

The topic of data governance and regulation spans a range of issues on the global, regional and domestic levels. In its recent *World Development Report 2021: Data for Better Lives*, the World Bank defines four building blocks for a data governance regime that balances benefits and harms. These are: data infrastructure policies (the World Bank report’s chapter 5); policies, laws, and regulations around data (chapter 6); related economic policies (chapter 7); and data governance institutions (chapter 8). According to the report, these building blocks are meant to establish and enforce “a new social contract [...] that enables the use and reuse of data to create economic and social *value*, promotes *equitable* opportunities to benefit from data, and fosters citizens’ *trust* that they will not be harmed by misuse of the data they provide” (World Bank, 2021, p. xi, italics in original).

Access Now has developed a listing of 10 policy recommendations to be followed when a data protection law is being developed (Access Now, 2018, pp. 4-13): (1) “[e]nsure transparent, inclusive

negotiations” when building the data protection framework;<sup>4</sup> (2) “[d]efine and include a list of binding data protection principles in the law”, including the principles of fairness, lawfulness, purpose limitation, data minimisation, accuracy, retention limitation, users’ rights, integrity and confidentiality, and adequacy; (3) define “a legal basis authorising data to be processed”; (4) “[i]nclude a list of binding users’ rights in the law”, including the rights to access, objection, erasure, rectification, information, explanation, and portability; (5) “[d]efine a clear scope of application”; (6) “[c]reate binding and transparent mechanisms for secure data transfer to third countries”; (7) protect data security and integrity; (8) “[d]evelop data breach prevention and notification mechanisms”; (9) establish an independent authority “and robust mechanisms for enforcement”; and (10) “continue protecting data protection and privacy”.

In its recent report on the data economy, the World Economic Forum (WEF) focuses on data exchange, and its barriers, principles, capabilities, and enablers (specifically availability, usability, and building trust). The WEF report sets out functional architecture, and a governance framework, for data exchange and incentivisation of data-sharing, concluding with a call for a multi-stakeholder approach so as to fulfill the promise of the data economy (WEF, 2021).

On another front, the focus of a recent UNCTAD report (UNCTAD, 2021) is on cross-border data flows and the transformation of the global data value chain, highlighting the severe imbalances in the global data economy and the tensions between national and global regulation.

In reviewing the literature reported on in this chapter, we surveyed both formal and gray literature, including reports by key institutions engaged in this thematic area. We also surveyed selected IDRC selected reports and outputs. In addition, we conducted a mapping exercise in order to identify the institutional and regulatory stakeholders, and instruments and issues/gaps, relevant to our thematic focus. The results of that mapping inform the content of this chapter and are also reported in chapter 5 along with the findings from the mappings conducted by the other two working groups for this study.

For this chapter, we have chosen to highlight six issues that illustrate challenges pertaining to regulation of data, and governance of data-driven innovation, with relevance to development for LMICs. These are (1) the layered digital/data divide; (2) the data divide, market concentration, and government control; (3) data and algorithm biases/inaccuracies; (4) cross-border data flows; (5) data and platform work; and (6) intellectual property, including data ownership. Crucial to this discussion is regulation governing enabling environments, particularly market structures and competition as pertaining to data-driven innovation. An important question is how stakeholders in developing countries should engage with national, regional, and global governance norms related to the behavior of data-driven firms. This question links to one of the three regulatory themes set out in chapter 5 of this report: the theme of multi-level regulation.

The next section (section 3.2) synthesises and unpacks the six issues listed above and reflects on the relevant opportunities and challenges.

## **3.2 Regulatory Issues Related to Data and Technology Governance and Innovation**

### **3.2.1 The Layered Digital/Data Divide**

The governance of innovation in data and technology should be seen against the background of a persisting digital divide between and within countries. Divides exist in terms of income, age, gender, ethnic origin and geographic location, among other variables. Bridging/mitigating these divides is crucial to the discussion of data and technology governance.

The digital divide extends beyond differences in *access* to data and technology to encompass inequality in the *use* and *contribution* to digital content. This is part of the divide in digital infrastructure, but

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<sup>4</sup> This is recommended based on the experience of GDPR negotiations, where even though done transparently, could be improved upon with more accountability in early drafting stages and engagement of external stakeholders should be more transparent and accountable

also in the human capabilities that develop and contribute such content. Indeed, in many ways the digital divides mirror analogue divides encountered by disadvantaged groups, with the poor, the uneducated, the marginalised, women, youth, and members of rural communities experiencing digital inequality (see Gillwald, 2017). The governance of data and technology should be cognisant of the complexities of such inequalities and the socio-economic implications of the digital, data and technology divides reflecting and exacerbating inequalities on the ground.

Moreover, the global digital divide shows signs of deepening in the data economy. With data becoming an economic resource, LMICs stand to be confined to limited roles as raw data providers to “global digital platforms”, with the LMICs then having to pay for the “digital intelligence” acquired by global corporations based on their own data (UNCTAD, 2021). This vicious circle in the “data value chain” adds another layer to the global digital divide, placing LMICs at a severe disadvantage reminiscent of colonial inequities. LMICs also experience a global data governance divide, with the need for a stronger voice in the global arena and institutional architecture of data and technology governance.

While the next sections focus in on governance/regulation of data and technology, it is important to remain cognisant of matters of regulation for bridging the digital divide. These include regulating the ownership of internet infrastructure and internet pricing (encouraging competition), as well as focusing on initiatives that target the marginalised—such as Data for Development (D4D), AI for Development (AI4D), and more generally ICT4D.

### **3.2.2 The Data Divide, Market Concentration, and Government Control**

In line with the discussion above, the data divide exists along another binary, namely: asymmetries between large corporations and small businesses, especially in LMICs, in respect of data ownership, access and use. With data being an economic resource, it becomes a key differentiating factor, typically most available to corporations that can afford to buy, gather and analyse massive amounts of it. The asymmetry in data ownership is likely to feed into market concentration and gets reflected in power dynamics that disfavor local small businesses, homegrown start-ups, and data-driven innovators who are trying to carve out space for themselves in domestic markets. Lack of access to data can inhibit access to the market, thus limiting competition, lessening innovation, and serving to “stifle the energy and fresh ideas that startups and SMEs contribute” (ODI, 2018, p. 19). Allowing access to “essential sources of market data” can, for example, be crucial for advancing competition among platform businesses (World Bank, 2021, p. 14).

The minimal cost of data reproduction and distribution in the digital sphere gives rise to network effects and economies of scale, favoring first-movers, who typically end up being the large corporations. The aforementioned World Bank *World Development Report 2021*, for example, emphasises this challenge and calls for “a paradigm shift”, highlighting the need to address “the tendency of data-driven businesses to tip toward concentrated market structures and entrenched market power”. In terms of relevant regulatory measures, that report cites:

[...] *enforcement of antitrust laws*, with adaptations to the context of data-driven businesses. Enforcement involves detecting and punishing anticompetitive practices (in which a firm abuses its dominant position or a group of firms enters into an anticompetitive agreement) or preventing anticompetitive mergers. (World Bank, 2021, p. 230, italics in original)

Such regulation is especially needed given the tax optimisation practices of large corporations—an indication of the critical role competition and tax policies have to play in mitigating imbalances generated by data ownership concentration (UNCTAD, 2019).

The World Bank recommends enforcing antitrust laws in parallel with designing regulations that allow data-driven businesses fair market entry and competition on a level playing field, along with protecting users.

These regulations would be designed especially for data-driven innovators, while maintaining mainstream regulation of traditional firms (World Bank, 2021).

The above challenges to data-driven innovations are global, and need to be regulated nationally, regionally and globally. On the domestic level, it becomes additionally challenging for innovators in LMICs—as they already face a host of challenges in their respective contexts, including but not limited to nascent legislative infrastructures and convoluted business environments. Regulation of data-driven innovations must be aligned with addressing the analogue challenges in these countries’ respective legislative environments. Proactive measures such as tax breaks and financing incentives may be needed to incentivise data-driven innovation for small business in LMICs.

Over the past two years, due to new forms of market power in the era of big data, competition enforcement has gained momentum in Africa. According to the Baker McKenzie *Competition in Africa Report 2022*, in the last year several African countries have strengthened their competition and antitrust laws and regulations. The report indicates that there have been significant competition law developments in Algeria, Angola, Botswana, Cameroon, Cape Verde, Egypt, Eswatini, Ethiopia, Gambia, Ghana, Kenya, Malawi, Mauritius, Morocco, Mozambique, Namibia, Nigeria, South Africa and Zimbabwe (Naidu & Tzarevski, 2022). South Africa is attempting to regulate digital platforms via competition law enforcement and policy. Expert and policy reviews sourced from various jurisdictions have generated a range of recommendations that include: merger evaluations that encompass the potential harms of market competition; consideration of network effects and placement of obligations on dominant firms; setting up “data units” that have power to obtain information and enforce orders; and addressing anonymisation and privacy issues by regulating data access (Roberts & Vilakazi, 2019).

On the global and regional fronts, there must be cooperation to ensure interoperability across domestic legislations. UNCTAD notes, for example, that “[n]o single country’s authority in competition or taxation alone can tackle the challenges posed by big digital corporations. Even developed countries and groups of countries, such as the United States and the European Union, are struggling in these areas” (UNCTAD, 2021, p. 181).

Market concentration may be amplified by cross-border data flows, as trade in data-enabled goods and services may work for the benefit of large corporations and intensify pressures on domestic competition. The ease of global firms’ access to new markets and data intensifies their dominant position. Meanwhile, competition between local and foreign firms, as well as between digital and analogue businesses, may be undermined due to the inability to tax platform businesses effectively. This affects both competition in domestic markets and competitiveness in global markets (World Bank, 2021).

Some global digital corporations retain the power to extract raw data from developing countries and appropriate most of the value created, which increases the power imbalance and inequalities—and this is because of the current absence of an international system regulating cross-border data flows (UNCTAD, 2021).

In parallel to the data divide in markets, there exist large concentrations of data owned by government national statistical offices, and these are typically “locked” by political and/or technological barriers. “Data lock” exists when the data is not accessible, not updated, and/or its collection methodologies not disclosed. Data may also be “politicized, filtered, incomplete or censored” (Rizk, 2020). The data lock can be manifested in the lack of accessible high quality machine-readable data, “and the cumbersome regulations and need for licenses to allow for reuse” (Rizk, 2020). Locking of data by governments has severe repercussions on freedom of expression and human rights (Fatafta, 2021). “Often data that exists in national HMIS [health management information systems] remains locked away in countries where they are deployed, and few portals host statistical datasets on health that contain full details” (Davies et al., 2019, p. 171).

Data can also be locked by businesses, presenting economic barriers. When combined with the aforementioned data asymmetries between large and small firms, data lock by governments and/or by big business presents a market barrier that hinders innovation, especially for small business and start-ups in LMICs. Regulation is needed to “open up” this data and enable citizens’ and innovators’ rights—in ways that do not breach privacy and security.

An example of an initiative to ease data concentration is the Open Government Partnership (OGP), which requires governments to make their information available in transparent and open data formats for increased access, use, and interoperability (OGP, n.d.). Legal rights to individuals and organisations to access government data are inherent in freedom of information acts, which are prevalent in high-income countries but much less present (and when present typically weakly enforced) in LMICs. (US Office of Information Policy, n.d.) In MENA, four (Tunisia, Lebanon, Jordan and Palestine) out of 22 countries have freedom of information legislation.

Tools monitoring the availability and use of open data serve to guide the governance of data and advocate for open data, which eases the data locks imposed by governments and businesses. One such metric is the Global Data Barometer (GDB), which assesses performance and impact of open data initiatives globally (GDB, n.d.). The GDB maps the availability and use of open data, ranking governments on the readiness, implementation, and impact of open data. The GDB is a useful tool for monitoring progress and supporting policymaking and civil society activities.

As well, the Open Data Inventory (ODIN) compiled by Open Data Watch (n.d.) is another tool to monitor and evaluate the coverage and openness of data. The ODIN provides a score that indicates how complete and open national statistical systems are, in order to inform government entities, the private sector, and the public.

In addition to the above, the OECD has developed legal instruments to address data access and sharing, as adopted in October 2021 (OECD, 2021). It proposes adopting a whole-of-government approach to data access and sharing, so as to ensure alignment with societal, policy and legal public objectives. The OECD posits that for advanced, responsible access and sharing of data, regulatory environments should be agile, technology neutral and innovative, and should engage all different stakeholders (OECD, 2021). The OECD also highlights the importance of a sustainable, scalable and secure foundational infrastructure along the data value cycle. This can be achieved by promoting digital security risk management practices throughout the data value cycle, while encouraging investments across the data ecosystem (OECD, 2021).

### **3.2.3 Data and Algorithm Biases/Inaccuracies**

Another set of issues are those raised by the biases and other inaccuracies inherent in data and technology, which result in exclusion and other forms of harm to communities. In the data landscape, communities suffer from invisibilities and misrepresentations. Invisibility on the data radar is reflected in absence from decision- and/or policymaking. Examples of groups likely to be rendered invisible in data collection processes—e.g. pertaining to credit ratings, social protection policies, and inclusion policies—are informal workers, women, and migrants. Such inaccuracies have implications for exclusion from policymaking and widening of development divides.

Data inaccuracies can also be caused by a lack of detail, providing a “data blur” as “aggregates cloud out granulations which can only be captured by the disaggregation of the data” (Rizk, 2020). Data inaccuracy can also stem from methodological shortcomings, e.g. using a single-dimensional lens that assesses variables top-down and misses significant complex realities that are simply not visible from above (Rizk, 2020). The work of Nobel Laureate Angus Deaton speaks to the importance of data collected ground-up, e.g. household surveys using methodologies that reflect realities on the ground (Deaton, 2019).



Inaccuracies in data are amplified by biases in algorithms typically used in AI models. These occur when algorithms are developed and implemented by so-called “experts” who have control over the ethics and the decision-making, instead of by the main beneficiaries or the “subjects” of the technology—possibly including marginalised groups (Crawford et al., 2019). In this regard, regulation that ensures humanising the algorithm—through inclusion in the process of both domain experts and representatives of the subjects—is crucial to ensure relevance and accountability.

Given that algorithms are part of wider contexts, they may also be used for incurring harms. Most notable are facial recognition algorithms, which incur harms when used for discrimination and/or political surveillance. Regulation is crucial to ensure inclusive and democratic governance of such algorithms, including ensuring robustness and explainability, in order to prevent any intended or unintended harms, especially those to the privacy and security of citizens.

Regulation of data and algorithm biases/inaccuracies is on the agenda of international organisations and think tanks, regional regulatory bodies, and domestic regulatory bodies. Efforts are ongoing, by the Data for Development Network (D4D.net), to establish the first Global Index on Responsible AI, representing the perspective and needs of the Global South (D4D.net, n.d.). The OECD has laid out a set of five value-based AI principles—“Inclusive growth, sustainable development and well-being; [...] Human-centered values and fairness; [...] Transparency and explainability; [...] Robustness, Security and Safety; [...] Accountability”—with the following policy recommendations: invest in responsible AI R&D; foster an accessible digital ecosystem for AI, including data-sharing; avail an enabling policy environment for trustworthy AI; build human skills in preparation for transformation to new work practices; and promote global cooperation, i.e. “share information, develop standards and work towards responsible stewardship of AI” (OECD, n.d.)

Another regulatory/governance example is the UNESCO Recommendation on the Ethics of Artificial Intelligence, which states that UNESCO Member States should provide “effective remedy” for algorithmic biases and discrimination; ensure that AI systems do not replicate any discriminatory biases (e.g. gender stereotyping); and be proactive in identifying and rectifying discriminatory biases. This is especially important to prevent the potential repercussions for gender equality, including violence against women online and offline (UNESCO, 2021).

In the area of AI solutions for healthcare, the UNESCO Recommendation calls for Member States to pay special attention to the regulation of detection, prediction and treatment solutions; to ensure minimisation/mitigation of bias via oversight; to include domain experts in algorithm development; and to ensure mechanisms for personal data privacy (UNESCO, 2021).

The Global Partnership on AI (GPAI) Data Governance Working Group is one of four GPAI working groups.<sup>5</sup> At the core of the work of the Data Governance Working Group are issues related to data justice and data trust, with focus on enhancing data fairness, security, trust, accuracy and relevance. Among the governance tools the group is developing are “trusted mechanisms (e.g., certification badges) for displaying that datasets have undergone processes” to test their responsibility and trustworthiness (GPAI, 2020, p. 12).

Examples of legal and policy tools to address the regulation of data and AI inaccuracies are set out in the *AI Now 2019 Report*, which focuses on the accountability of algorithms and safeguards for biometric and facial recognition (Crawford et al., 2019). The report highlights data protection as “the foundation of the majority of AI regulatory frameworks”, and points to the need for regulating biometric recognition; ensuring accountability of algorithms; and assessing impact (Crawford et al., 2019, p. 31). According to the *AI Now 2019 Report*, one activity recommended to address bias and ensure accountability of algorithms towards achievement of the desired development objectives is the use of “Algorithmic Impact Assessments (AIAs)”, which can “help governments, communities and other entities assess the social implications of AI, and

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<sup>5</sup> These are the working groups on Responsible AI, Data Governance, Future of Work, Innovation and commercialization.

determine whether and how to use AI systems”. Such AIAs must, according to the report, give consideration “to issues of bias, discrimination, and due process” and “account for AI’s impact on climate, health, and geographical displacement” (Crawford et al., 2019, p. 8). The report also calls on machine-learning researchers to “account for potential risks and harms and better document the origins of their models and data” (Crawford et al., 2019, p. 8).

In addition to the above, the utilisation of context-specific data is crucial for ensuring data accuracy. The World Economic Forum highlights local context as a key issue for data governance, explaining that “how data are used and what is legitimate, fair or ethical vary greatly among different geographic and social groups” (WEF, 2015, p. 13). The WEF report acknowledges the difficulty of incorporating context-specific nuances in regulation, yet warns that having “universal data use policies that treat all data equally will face significant challenges to remaining relevant in all contexts and over time” (WEF, 2015, p. 13).

Europe has taken a leadership role in governance to foster trustworthy data and AI through a number of tools, including the EU’s General Data Protection Regulation (GDPR), Law Enforcement Directive (LED), AI strategy, and proposed Artificial Intelligence Act, and the European Commission’s High-level Expert Group on AI (AI HLEG).

The GDPR and the LED both regulate data matters. The GDPR is the EU data protection law that lays out rules and obligations “relating to the free movement of personal data” (EU, 2016b) to ensure the protection of personal data and expansion of privacy rights. In parallel to the GDPR, the LED deals with the processing of personal data controllers that comply with law enforcement purposes (EU, 2016a). The EU’s proposed Artificial Intelligence Act is critical to the European regulatory framework (Kuśmierczyk, 2022). The law as currently proposed stipulates that appropriate governance and management of data should guide the training, validation and testing of data sets, including relevant choices of design, collection and preparation of data, testing biases, identification and addressing data gaps and shortfalls. Article 10 of the proposed Act covers data governance and defines “the quality criteria that data should meet for training models” (Kuśmierczyk, 2022).

The European approach to ensuring trustworthy AI has been translated into a number of concrete steps, including the EU AI strategy of 2018, entitled Artificial Intelligence for Europe, which sets out principles to establish human-centric and trustworthy AI (EC, 2018). The EU also had an active role in the development of the OECD AI Principles, as endorsed by the G20 in 2019. The EU also collaborates with multilateral organisations such the Council of Europe, UNESCO, the WTO, and the International Telecommunication Union (ITU).

The aforementioned AI HLEG produced the *On Artificial Intelligence White Paper* (EC, 2020) identifying the challenges to the current legislative framework and proposes an AI ecosystem that brings the benefits of technology to citizens, businesses and public interests. In the White Paper, the AI HLEG sets out seven requirements for the guidelines on trustworthy AI, as follows:

- Human agency and oversight,
- Technical robustness and safety,
- Privacy and data governance,
- Transparency,
- Diversity, non-discrimination and fairness,
- Societal and environmental wellbeing, and
- Accountability. (EC, 2020, p. 9)

The White Paper points to tensions in the European regulatory framework. First, given the pace of evolution of AI, the AI HLEG recommends that the framework must “leave room to cater for further

developments” and that “[a]ny changes should be limited to clearly identified problems for which feasible solutions exist” (EC, 2020, p. 10). Related to this is the “[c]hanging functionality of AI systems”, especially as AI programs and other software get integrated into products in a way that modifies the functioning of products, with the possibility of giving rise to new unanticipated risks that are not properly addressed in the current legislation (EC, 2020, p. 14). Such flexibility is needed in the governance of technology in order to adapt to and keep up with developments in the technology.

Despite the European efforts to establish a common agenda, the White Paper points to a “current absence of a common European framework” and the lack of “an EU-wide approach” (EC, 2020, p. 10). The paper calls for “[a] solid European regulatory framework for trustworthy AI” that “will protect all European citizens and help create a frictionless internal market for the further development and uptake of AI as well as strengthening Europe’s industrial basis in AI” (EC, 2020, p. 10). This raises a second tension between EU and national legislations, and the need to seamlessly harmonise the two sets of legislations.

Third, the White Paper highlights the plethora of legislative tools governing various aspects of data and AI, directly or indirectly. Examples are legislation covering the protection of fundamental rights and consumer rights (e.g. EU directives on racial equity, equal treatment in employment, consumer protection, and personal data protection and privacy, e.g. the GDPR and LED). Moreover, related legislation includes laws covering financial services, migration, and responsibility of online intermediaries (EC, 2020). There is a need to assess and harmonise the array of tools in a way that ensures ethical governance of data and AI technology. In many ways, the above tensions are universal and can offer lessons for exploration of AI governance frameworks elsewhere.

In the Middle East and North Africa (MENA) region, some governments have been implementing technologies that heavily rely on data—e.g. national digital ID programmes, biometrics passports, e-health services—while data protection legislation is nascent (fewer than half of Arab countries have data protection laws in place, not to mention implementation and enforcement). This presents a clear threat to the privacy of citizens, especially as personal data is held by national security agencies and also may be exploited by private corporations for commercial purposes (Fatafta, 2021).

MENA countries have also taken steps towards open approaches to data regulation. For example, Morocco, Tunisia, Egypt, Lebanon, Jordan and Palestine have all launched open data initiatives and national open data portals (Rizk, 2020). Several countries in the region have made efforts to promote free and open source software (FOSS) at a national level. Egypt’s Ministry of Communications and Information Technology (MCIT) adopted a National Free and Open Source Software (FOSS) Strategy for the country’s ICT sector (MCIT, 2014), and the Jordan Open Source Association (JOSA) is promoting FOSS as integral to that country’s digital transformation that promoted open source solutions (JOSA, 2021).

Egypt passed its first data protection law in 2020, which aims to establish a Center for Personal Data Protection (a regulatory mechanism) to develop policies and regulations for Egyptians’ data. However, the Central Bank of Egypt was left outside the scope of the law and the civil society was not consulted in its drafting and reviewing (Sayadi, 2020). Tunisia, Lebanon, and Morocco have weak and outdated national data protection laws and struggle to implement them (Fatafta, 2021).

Whether in MENA or elsewhere, having the necessary legislation is important but may not be sufficient. Enforcement, implementation, and monitoring, and interoperability with the larger legislative environment, are essential for achieving the desired benefits from data governance. Access Now reminds us that governments should not stop at having comprehensive law to protect personal data and privacy (Access Now, 2018). The correct mindset is to understand a data protection law as a floor and not a ceiling for protection of user rights protection.

The African Economic Research Consortium (AERC) aims to establish a research programme around data governance in Africa (Internet & Jurisdiction Policy Network, 2022) The AERC brings together a group

of experts that includes economists, lawyers, technologists and policy-makers to create an interdisciplinary reference group that produces research and capacity building on data governance in Africa. In early 2022, the AERC released a policy brief on a data governance framework for Africa. In another initiative, the Internet & Jurisdiction Policy Network has recently convened, in collaboration with Research ICT Africa (RIA), two Knowledge Dialogue Workshops as part of a Cross-border Digital Policies for Africa Project (Internet & Jurisdiction Policy Network, 2022).

### 3.2.4 Cross-Border Data Flows

Cross-border data flows cover a range of concepts that are summarised by UNCTAD as follows:

- *Data localization* refers to the requirement to store data in and/or process data using local servers. Data localization is also often referred to as data residency.
- *Cybersovereignty* broadly refers to the control exercised by States over various aspects of Internet and Internet-related activities – including digital content, digital infrastructure and digital services – inside their borders. Unlike multistakeholder models of Internet governance, cybersovereignty places the State at the heart of Internet governance.
- *Data or information sovereignty* refers to States controlling all data flows through the Internet (i.e. within and to and from their territory) to ensure, inter alia, that all data generated and processed within the State are subject to national laws and can be appropriated in any manner that the State deems fit.
- *Data protectionism* refers to the regulation of data flows by Governments to create competitive benefits for the domestic sector, including by adversely affecting level playing competitive conditions for foreign players.
- *Data nationalism* refers to policies that aim to ensure that domestic data are used primarily to benefit national interests. (UNCTAD, 2021, p. 120, italics in original)

The governance of cross-border data flows cuts across a number of axes, most notably the tension between local (domestic) and transnational regulations. On a domestic level, countries need to consider their economic, political and socio-cultural preferences and situation; their domestic regulatory capacities; and their state of technological development (UNCTAD, 2021). From a more transnational/global perspective, countries should consider their foreign policy, including international trade commitments and degree of integration with the global digital economy; the distributed architecture of the internet; and the global nature of many challenges related to internet policy. To this end, the appropriate model for regulating data flows in each country remains a holistically complex policy choice. This balancing exercise is especially important for developing economies to maximise the potential benefits of the digital economy and ensure greater welfare of their citizens (UNCTAD, 2021).

It is notable that most global digital platforms are based in the United States and China, while digital platforms based in the European Union remaining relatively marginal (UNCTAD, 2021). The global digital platforms play host to growing micro, small and medium enterprises (MSMEs) in smaller developing countries (UNCTAD, 2021). Governments, therefore, need to avoid restricting data flows, so as to preserve the quality and functionality of digital products and services available locally; to allow foreign investment and entry in the local market; and to avoid regulatory risks and costs (UNCTAD, 2021).

UNCTAD calls for an integrated approach to regulate cross-border data flows, grounded in legal instruments and regulations that govern data protection, cybersecurity, hardware and software, government procurement, trade agreements, state secrets, taxation and accounting (UNCTAD, 2021). The OECD developed, in 1980, a set of principles known as the Guidelines on the Protection of Privacy and Transborder Flows of Personal Data (OECD, 1980). EU regulation of cross-border data flows includes the privacy protections set out in the European Data Privacy Directive (Directive 95/46/EC) (LeSieur, 2012). This

directive sets up a regulatory framework that governs the transfer of personal data to third countries via a “closed border” approach, which only allows EU Member States to transfer personal data to a third country that ensures an adequate level of protection (LeSieur, 2012). Regulating cross-border data flows on the internet in the US follows a market-based regulatory approach that is grounded in a history of “open skies” internet privacy regulation related to international communication and information flows (LeSieur, 2012).

Emerging digital economies, such as India, can either take a restrictive approach to data regulation and face the risk of chasing investments, or if they do not have adequate capacity to build high-quality local digital platforms, they may better achieve economic development by adopting regulations that facilitate secure and privacy-compliant cross-border data transfers, such that local companies can access services provided by foreign digital platforms. The regulations’ design will depend, among other things, on culture and resources (and potentially also on levels of protectionism) within the country (UNCTAD, 2021).

### **3.2.5 Data and Platform Work**

The pervasive infiltration of technology into work practices globally has nuances for human development and clearly impacts SDGs—pertaining directly to SDG 8 (decent work and economic growth) and indirectly to SDGs 5 (gender equality) and 10 (reduced inequalities). What has been typically referred to as the “future of work” is becoming a present reality that is impacted by new technologies, with the future increasingly impacted by the demographics and skills composition of human capital in LMICs.

With data and technology embedded in work arrangements, the threat of job loss for cohorts of workers in LMICs becomes highly pronounced, especially in the middle skill groups who lose their jobs to automation. As well, women, who often occupy the lower end of the supply chain, stand to lose their livelihoods in a highly divided world because of the impact of technology. A key challenge comes from the threat of job loss to automation, and the impact on medium-skilled workers and women at the low end of the global supply chain. Proper governance of accurate and timely data on work will help mitigate this threat and promote social protection, safety nets, and inclusion of the groups inflicted by the negative impacts of technology.

At the same time, the platformisation of the global economy, especially in the context of the COVID-19 pandemic, has also meant the emergence of new types of work that provide promise for highly skilled workers in LMICs. Examples include online work in architecture, finance, editing, translation and design, all of which offer work opportunities for educated youth and women. Governing data on this work, including its cross-border data flows, is relevant to this scoping study. Also relevant are: regulating online innovations in this field, including data-driven innovation initiatives and start-ups; and the tension, when it comes to taxation, between local and extraterritorial work.

The IDRC has supported pathbreaking projects on data policies and legal frameworks applicable to data-driven platforms in the UK and EU. One study interrogates policy changes and emerging regulatory frameworks in the UK and EU for platform-based user data collection, analysis and sharing, with focus on the EU’s GDPR and the UK’s Investigatory Powers Act and Digital Economy Act (Hintz, 2019). Another study investigates the relationship between digital platforms and users while offering a policy framework for inclusion and protection of users in the platform economy (Delronge et al., 2019). There are also two ongoing IDRC projects on platformised home-based work for women in Asia, with one project focused on Cambodia, Myanmar and Thailand and the other covering Sri Lanka and India. Findings from these two projects will inform evidence-based recommendations for policymakers and for platform firms, with the goal of fostering equitable and sustainable inclusion of women in the platform economy (IDRC, n.d.-d, n.d.-a)

Meanwhile, low-skill gig work has also expanded, with increasing precarity for labor in LMICs. Data governance is part of regulation to ensure fair gig work in LMICs, as gig workers— and consumers—need, in addition to labor and taxation laws, proper regulation of their data, privacy, and security. And proper data

on gig work itself is necessary to inform social protection policies, which are integral to the fair work paradigm.

One example of global research and advocacy for fair work practices in the gig economy is the Fairwork network (n.d.-b). The project's methodology accords a score to gig work platforms based on an assessment of five principles of fairness—fair pay, fair conditions, fair contracts, fair management, and fair representation—and gives each platform a fairness rating out of 10. In order to score a point for the principle of “fair conditions”, platforms should have policies in place to protect workers, including responsible and ethical data protection and management measures laid out in a documented policy. Through this approach, platforms are pushed to implement a data management policy that protects platform/gig workers.

One finding from the Fairwork research on the gig economy in Egypt and South Africa (Fairwork, 2021-a) is the relatively positive performance of homegrown start-ups, in sharp contrast with large multinational companies, when it comes to provision of fair work practices for gig workers. There is, thus, an argument to be made for incentivising local start-ups and working with them to ensure fair work conditions, so that they can serve as model businesses for the rest of the economy (Rizk et al., 2022-b). This would also serve to encourage innovation in these businesses, which are typically youth-led.

The Fairwork research in Egypt, by the Access to Knowledge for Development Center (A2K4D) at the AUC School of Business, generated a notable success story through its interactions with one of the local start-ups being studied—a start-up providing services via the FilKhedma home services platform (a gig work platform). After discussions with the Fairwork Egypt team at A2K4D, the FilKhedma platform agreed to implement a data management policy that satisfies the requirements for the “fair conditions” principle—a policy that will follow the guidelines set out in the EU's GDPR (Rizk et al., 2022).

### **3.2.6 Intellectual Property, Including Data Ownership**

The final set of core issues revolves around intellectual property as a critical element of data governance. Frequently, data governance debates focus on data privacy concerning personal identifiable information (PII) and data security. Yet a comprehensive data governance framework also needs to tackle questions of property or property-like protection in relation to data and data ownership, including data that does not qualify as PII. Much more work is needed in this area. According to the World Intellectual Property Organisation's (WIPO's) then-Director General, Francis Gurry:

[i]t's a question of where you want to locate in the economic system the incentives with respect to these crucial resource data, which are an integral component of economic and cultural production and distribution, but also social and political discourse. [...] Do you want to locate them with the origin of the data? The data subject? With the collector of the data? [...] [T]hat is a question for the future. (WIPO, 2020)

In a research paper co-funded by the IDRC, de Beer focused on legal and non-legal data ownership mechanisms and highlighted the degree to which current IP frameworks (including trade secrets) generally provide (or not) for legal ownership of data and the extent to which such protection—usually through national copyright, patent and/or *sui generis* laws—is extended to compilations of data and databases (de Beer, 2016b). Of particular interest in this context is the EU's Database Directive (EC, 1996). The de Beer paper emphasises the importance of domestic laws for determining ownership in data, as well as (current and future) international instruments shaping such laws.

Some domestic legal frameworks conflict with one another and are, at times, inconsistent with international law. Perhaps even more problematic, existing international and domestic IP frameworks seem to lack contextual grounding and struggle to provide (adequate) answers to the nuanced questions brought about by transformative and disruptive digital technologies, in particular with regard to artificial intelligence.

For instance, based on almost 100 responses received to an initial call for views on AI and IP in 2020 (UK IP Office, 2021), the UK's Intellectual Property Office identified the following three specific copyright and patent issues requiring deeper analysis:

- copyright protection for works that are computer-generated and do not have human authors;
- text and data mining (TDM) licensing and/or copyright exceptions; and
- patenting of inventions developed by AI.

More specifically, some countries—including countries in the Global South such as South Africa—already provide copyright protection for computer-generated works (see, for instance, Republic of South Africa, 1978). However, providing such protection raises several conceptual, legal, economic and philosophical concerns, including questions concerning the ability of AI systems to be “original” and a potential devaluation of human creativity. TDM, on the other hand, can greatly support AI development and training, but it may involve copying of copyright-protected materials. Existing copyright laws may thus hamper AI development and training, especially when statutory copyright exceptions (e.g., for TDM) do not exist, or if they are too narrow. Also, with regard to awarding patent protection for AI-devised inventions, profound concerns have been raised about patent proliferation and the creation of patent thickets as a result of granting such patents, with detrimental effects on innovation and entrepreneurship.

Context-appropriate policy responses for these and other issues (such as the potential lack of algorithm accountability and transparency as a result of overzealous IP protection, including trade secrets) need to be developed for and with strong input from LMICs—with the overarching objective of countering inequality and providing fertile ground for sustainable and inclusive development. These policy and regulatory responses are required to provide adequate protection for those involved in data collection and data creation. However, they also need to speak to questions such as data sovereignty and, crucially, they must facilitate equitable data accessibility, sharing, re-use, and collaboration. This will arguably include contemplating alternative IP models that promote openness (e.g. through open data), inclusion, innovation and entrepreneurship. There is some urgency to this, as certain LMICs have already begun to respond to some of these issues—typically in a somewhat haphazard way without the benefit of being able to build on contextualised and pro-development research evidence in this area.

Current work on an IP Protocol for the AfCFTA (for a reflection in the current status of these negotiations, see Ncube, 2022), as well as domestic developments such as South Africa's ongoing IP law reform processes (and the country's recent patent grant for an invention created by the DABUS AI system) showcase the fact that regulatory guidance in this area is needed timeously, and that this is indeed an opportune juncture for shaping of governance frameworks in this area.

Ideally, efforts in this area need to be realised in collaboration with relevant international and regional law- and policymaking bodies such as the AU (especially in connection with the ongoing conversations linked to the AfCFTA), WIPO, and the WTO. This is because these organisations have not only already heavily invested in identifying pertinent IP (and other) issues with regards to frontier technologies such as AI and distributed ledger technology,<sup>66</sup> but also because they are bound by their respective commitments to make development considerations an integral part of their work.

### 3.3 Conclusions

As noted earlier, probing matters of innovation regulation in the context of data and technology governance opens a wide array of issues, particularly as they pertain to achieving the SDGs. Accordingly, all six of the issues discussed above are, as demonstrated, integral to matters of innovation regulation.

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<sup>66</sup> See, for example, [https://www.wipo.int/about-ip/en/artificial\\_intelligence/topics.html](https://www.wipo.int/about-ip/en/artificial_intelligence/topics.html)

However, at the same time, it is our finding that three of the issues, in particular, demand somewhat urgent regulatory research and engagement. These are: data concentration; platform work; and intellectual property. All three reflect asymmetries that translate into market concentration and data and technology gaps, which in turn aggravate development gaps and thus require rapid response.

First, with respect to data concentration, there are clear trends, at national, regional and global levels, towards concentration of data ownership, which in turn translates to market concentration. As a result, innovative and robust competition regulation is needed to address the myriad implications of this concentration, including both commercial and human rights dimensions, particularly in instances where data ownership asymmetries serve as potential barriers to entry and as tools for aggravating monopolies. A core priority is, thus, devising regulatory tools that can create favorable investment, employment and taxation conditions for data-driven start-ups and other innovative MSMEs that are typically homegrown and that serve to provide work opportunities for youth and the educated in LMICs.

In line with this, it is also imperative to engage, via nuanced and creative regulation, with the powerful forces at play in platform work: the globalised data-driven firms. Governance of the concentration of power (and data) in this sector must be a priority for forward-looking research. The regulatory research and engagement need to take place on two levels: (1) at the platform level, where market asymmetry holds between multinational corporations and small homegrown platforms; and (2) at the service level where the platforms interact with MSMEs and workers.

As mentioned above, A2K4D's Fairwork research on the gig economy in Egypt has illustrated tensions between large multinational companies and the competing homegrown platforms that are trying to find a place for themselves in a highly concentrated market (Rizk et al., 2022). Regulation of these market dynamics needs to be nuanced, and sensitive to the needs of local start-ups. The worst-case scenario can be seen in an example from Egypt, where a 2019 attempt to regulate the platform economy—via Resolution No. 2180 of 2019, popularly known as “the Uber Act”—was focused on (1) ride hailing, and (2) the large platforms. The Resolution required payments that were beyond the financial abilities of small firms and their respective drivers. Small local businesses criticised the Resolution as being tailored only to the large ride-hailing carriers (Rizk, 2021).

Perhaps the starkest reality requiring regulatory attention in the context of the platformisation of work by data-driven platforms is the power asymmetry between platforms and their workers. When assessed against the criteria of “fairness” set out by the aforementioned Fairwork project (Fairwork, n.d.-a), gig work platforms typically demonstrate unfavorable scores, e.g. in terms of fair pay, fair representation, fair contracts. Integral to the power asymmetry is the platform's control over workers' data, which adds to the precarity of the work. Regulation protecting the data rights of workers, along with the larger pool of economic rights (benefits, safety, organisation), is essential to achieving better governance of this radical transformation in service provision mediated by globalised data-driven firms. And, at the same time, data protections for users of these platforms must also not be overlooked.

With respect to intellectual property, it is clear from the discussion above that computer-generated works, TDM and AI are three IP matters generated by the digital economy that, among others, demand nuanced and somewhat urgent regulatory engagement.

In all three of the priority regulatory areas just discussed (and also in the other three areas that made up our group of six issues discussed in this chapter), regulation of innovation to achieve democratic and inclusive governance should be guided by principles of fairness, responsibility, transparency, justice, diversity, democracy, equality and inclusion. Broadly, regulation of democratic and inclusive governance of technologies should happen along two axes: one axis dealing with top-down regulation and ground-up initiatives; and another axis dealing with harmonisation across local, regional and global jurisdictions. And,



based on our research for this chapter, we feel that the following five realities hold true for regulation of innovation.

First, given that data and technology are intertwined with multiple SDGs, governance of innovation in these areas should adopt a holistic approach. The work needs to happen across disciplines and in multiple fields, not in silos. And while tackling the digital, one must not forget about the analogue dimensions of the issues we address.

Second, there is a clear need for interoperability in technologies and jurisdictions— “interoperability in cyberspace” (Internet & Jurisdiction Policy Network, n.d.)—in order to ease tensions between domestic, regional and global frameworks, especially as data, technology and work have already extended beyond territorial borders.

Third, governance of innovation must be a two-way process. In addition to adopting top-down approaches, it is crucial to also incorporate ground-up governance of data and technology, driven by communities and animated by the engagement of citizens and civil society. Moving forward, research should focus on regulatory action(s) to incentivise small data-driven innovation businesses, e.g., via competition law measures and measures fostering enablement of start-ups and ground-up innovation ventures that engage youth, women and the marginalised (particularly relevant post the pandemic and in the current global economic crisis). In that vein, regulations towards open data, open government, and FOI are to be on the priority list for easing the data concentration and lock by governments and opening the door for the engagement of citizens and small private sector firms.

Fourth, there must be innovation in regulation, with careful consideration of when it is appropriate for regulation to try to fit evolving new models and definitions of innovation in data and technology into the old/conventional governance paradigm, and when it is appropriate to devise novel regulatory tools.

Fifth, the following quote from the World Bank’s *World Development Report 2021* (World Bank, 2021) underscores the need for collaboration and adopting a multistakeholder approach:

Although much of data governance is domestic in focus, an efficient and equitable resolution of many data governance challenges is possible only with international collaboration. Bilateral efforts are needed to manage cross-border spillovers of antitrust decisions and to join forces to combat cybercrime. Multilateral cooperation is essential to address global free-rider problems (such as data protectionism or tax evasion in data-enabled services) and to reduce transaction costs through harmonization of legal and technical standards for data protection and interoperability. At the same time, regional collaboration can help amplify the voice of low- and middle-income countries in global data governance negotiations and help realize scale economies in the development of data infrastructure (World Bank, 2021, p. 10).

The multistakeholder approach also needs to include strong national capacity in LMICs. In their CIGI paper focused on African data governance, Ademuyiwa and Adeniran (2020, p. 15) call for each African country to have “autonomous regulatory institutions to coordinate data governance strategies” and to enable development of “appropriate laws for data protection, anti-competition and antitrust, taxation and other aspects of the digital economy”. And Ademuyiwa and Adeniran (2020) make clear that this national capacity cannot follow a one-size-fits-all model, pointing out that

[...] optimal institutional frameworks will vary across countries according to the existing political and economic realities and the level of development of the domestic digital industry. This is why flexibility and peer learning are required to create the right institutional frameworks. (Ademuyiwa & Adeniran, 2020, p. 15)

At the same time, similar to the above-cited emphasis by the World Bank (2021) on the need for regional collaboration, Ademuyiwa and Adeniran (2020, p. 15) posit that “an individual country cannot effectively regulate the digital sector. Building broad partnerships internally and externally, at the continental level, will be important for African countries to annex the digital economy for economic transformation”.

# 4. Trade Rules as Regulatory Tools for Inclusive, Sustainable Innovation

By Caroline B. Ncube and Jeremy de Beer

## 4.1 Introduction

Trade is, by its nature, a cross-cutting theme which applies to all the focus areas of this scoping study—because each focus area has a trade aspect, which is typically addressed in trade agreements. This chapter tackles two emerging dimensions of trade rules as regulatory tools for innovation: inclusion and sustainability.

Creating *inclusive* economies in the 21<sup>st</sup> century requires recognition of the centrality of data, the digital economy, and e-commerce to innovation. Creating *sustainable* economies can only be done with widespread diffusion of “clean” technologies throughout low- and middle-income countries. While those topics may, at first glance, seem unrelated, a closer look shows they are connected by interwoven regulatory threads. Trade law and policy—as key sets regulatory mechanisms in networked global knowledge governance—impact both *inclusive* digital innovation and *sustainable* clean innovation.

Accordingly, in the context of more sustainable, equitable, and inclusive economies with expanded, lasting, and high-quality economic opportunities for women and youth (IDRC, 2021a), this chapter’s enquiry is best summarised as: How does trade interact with and impact the regulation of innovation and, ultimately, achievement of SDGs? While a case can be made for the relevance of all 17 SDGs to this question and the chapter’s focus area, the following SDGs are the most relevant: 1 (no poverty), 2 (food security), 3 (health and well-being), 5 (gender equality), 8 (decent work and economic growth), 10 (reduced inequalities) 13 (climate action), 14 (life below water), and 15 (life on land). health and well-being (SDG 3). Accordingly, the regulatory issues set out in this chapter will pertain mainly to these SDGs.

Regulating an *inclusive* digital economy via trade lies at the intersection of innovation, intellectual property and data governance, and it is a priority in global contexts (Lippoldt, 2022)—as evidenced by ongoing WTO adaptation to the digital (Smeets, 2021) and the e-commerce negotiations that are underway (WTO, 2019). Digital economy regulation is also a priority within regional trading blocs such as the African Continental Free Trade Area (AfCFTA) (Stuart, 2022). This chapter teases out the main aspects of such regulation as they pertain to the creation and facilitation of sustainable, inclusive economies at national, regional and international levels. Based on the global commitment to the SDGs, it should be a common objective of most states to attain inclusive digital innovation via appropriate regulation. Section 4.3 elaborates on these issues.

Regulating a *sustainable* clean economy via trade lies at the intersection of innovation, intellectual property and climate action. International negotiations and agreements to reduce greenhouse gas emissions are deeply affected by IP issues (Consilvio, 2011; Rimmer, 2011, 2018; Sarnoff, 2016). While IP offers incentives to invent clean technologies, appropriate IP rules embedded in international economic and trade law are essential for adoption and diffusion (Menell & Tran, 2014; Suzuki, 2015). After seeing policy debates around IP and access to COVID-19 vaccines play out, clean technology transfer issues are now being discussed in a different light than they were previously (Sarnoff, 2020). Section 4.4 elaborates on these issues.

Trade rules for inclusive digital innovation and sustainable clean innovation also trigger SDG-related outcomes in the fields of health, agriculture, and more. Our concluding chapter, chapter 5, discusses these topics and the implications for research going forward.

## 4.2 Literature Review and Institutional, Regulatory and Stakeholder Mapping

The literature and state of knowledge on IP, trade and innovation are considered here with a view to identifying the key issues and research directions relevant to sketching a research agenda to inform ongoing and future IDRC work. Much of the literature referred to in this chapter has sought to assess the formal positions, arrangements, and undertakings encapsulated in trade agreements which regulate digital trade. There is a wide range of such agreements, including regional trade agreements (RTAs, including the so-called “mega-RTAs”), free trade agreements (FTAs), and bilateral trade agreements (BTAs). Several of them include chapters on digital trade, as will be highlighted in sub-section 4.3.2. We consider trade agreements across the globe, but concentrate analysis “substantially in Sub-Saharan Africa”, in keeping with IDRC’s Strategy 2030 (IDRC, 2021a, p. 10), so as to “focus where needs are greatest around the world”. The African Union’s AfCFTA, as an evolving agreement with phase II negotiations currently underway, serves as a key example for several points made in the chapter (UNCTAD, 2022).

The literature we surveyed is listed in the preliminary bibliography below and curated in this scoping study’s shared Zotero library. The literature survey, which aimed to be illustrative and not exhaustive, was a collaborative keyword-driven search on academic and general online platforms. Conventional academic platforms included published databases of scholarly works, peer-reviewed articles, books, etc. We also paid specific attention to grey or use-based literature generated by the key institutions working in this focus area. Supplementary review methods included footnote-trailing and citation-chasing. Additionally, some literature was sourced via referrals during our consultations.

The keywords and phrases for the literature searching this focus area, in line with the identified key areas outlined above, were combinations of the following words and terms: trade, trade agreement, regulation, data, innovation, intellectual property (IP), climate change, health, agriculture, food security, secrecy, artificial intelligence (AI), regulation, data localisation. The items identified can be classified as follows:

- *Analyses of regulatory approaches for agreements under development:* This literature presents arguments for certain principles to underpin the substantive provisions of trade agreements. Such literature is aimed at agreements that are being formulated—such as the Transatlantic Trade and Investment Partnership (Krajewski & Hoffmann, 2016) and the AfCFTA (Ncube et al., 2019)—so its purpose is to inform and guide norm-setting as well as the processes used in the norm-setting exercise. Therefore, the literature posits legal positions and process/procedural aspects.
- *Analyses of provisions of existing trade agreements:* This literature undertakes ex-post facto reviews of agreements to identify opportunities and challenges. Where shortcomings and gaps are identified, the literature presents possible solutions (Adinolfi, 2020). Works also reflect on the strategic significance and opportunity costs of such agreements (Amadichukwu, 2021; Narayanan & Khorana, 2017).
- *Analyses of the impact of the agreements on lives and livelihoods.* Such literature probes, for example, the extent to which an agreement supports attainment of SDGs.
- *Issue-specific analysis:* Examples include literature critiquing trade approaches to data localisation, or examining the impact of trade agreement provisions on access to medicines and health (Manu, 2015).
- *Comparative analysis of several agreements to identify commonalities and divergences.*
- *Infrastructure- and capabilities-focused literature:* This literature assesses the mechanisms and capacities essential for ensuring global economic governance that supports the SDGs, especially in respect of environmental sustainability, “clean” innovation, and technology transfer.

The literature also varies in terms of its target audience. For example, some items are aimed at a technical audience, some for researchers and the scholarly community, and some for policymakers and trade negotiators.

A high-level review of this broad, yet non-exhaustive, range of literature found that the knowledge and research on the issues surveyed is in a state of flux, and constantly growing in response to both technological developments and evolving trade relations between states. For example, as states continue to enter into mega-RTAs seeking to account for the latest issues, the literature follows. And where the issues are contested, the literature evidences divergent views. For example, scholars' and commentators' understandings of what constitutes regulation are not universal. Meanwhile, there is much that remains unknown, and even where at first glance it appears that there is convergence, closer analysis often uncovers divergence. The core learnings from the literature surveyed are summarised in sections 4.3 and 4.4 below.

We also conducted an institutional, regulatory and stakeholder mapping. The findings from this mapping inform this chapter and are also reported on in chapter 5 (combined with findings from the mappings by this study's other two working groups). The elements identified in the mapping included: relevant legal/regulatory/policy instruments; relevant regulatory agencies, departments, intergovernmental organisations; and relevant non-governmental organisations, think tanks, other entities. The identified entities interact regularly in norm-setting fora, be they at national level between different branches of (government) agencies on innovation and trade, or international level between states in the context of trade agreements (of whatever scale, be they international/global, regional or bilateral).

Presently, a leading LMIC forum for the intersection between trade and innovation is AfCFTA. This is because through the AfCFTA Agreement and ongoing negotiations on its protocols, AU Member States are creating "the largest free trade area in the world measured by the number of countries participating [and encompassing] 1.3 billion people across 55 countries with a combined gross domestic product (GDP) valued at US\$3.4 trillion" (World Bank, 2020). This is the outcome of decades of policy positioning and planning by the AU within its successive developmental blueprints, the latest iteration of which is Agenda 2063 (AU, 2015). The AfCFTA is a special project of Agenda 2063. It is a massive norm-setting exercise grounded and founded in the AfCFTA Agreement, which came into force on 30 May 2019 and has been signed by 54 AU Member States (as of June 2022), with 43 ratifications (as of July 2022) (AU, 2018). The AfCFTA Agreement currently has the following protocols, which form, along with their annexes and appendices, an integral part of the Agreement:

- Protocol on Trade in Goods;
- Protocol on Trade in Services; and
- Protocol on Rules and Procedures of the Settlement of Disputes.

In the AfCFTA Phase II negotiations, which are ongoing and due to close on 30 September 2022, the following protocols are being negotiated:

- Protocol on Intellectual Property Rights;
- Protocol on Investment;
- Protocol on Competition Policy;
- Protocol on Digital Trade (formerly E-Commerce); and
- Protocol on Women and Youth in Trade.

The outcomes of the Phase II negotiations will be critically important because they will complete the regulatory framework for enablement of trade in the AfCFTA. The original deadline for the completion of these negotiations was December 2020 (AU Assembly, 2020a), but this was pushed forward to 31 December 2021 due to restrictions on meetings during the period 2019–2021. When that latter deadline was not met, the current deadline of 30 September 2022 was set (AU Assembly, 2020b). Another important development was the creation of the AfCFTA Secretariat, which began its work in August 2020 and rapidly had to consolidate, and in some cases reconceptualise, previous work done on the negotiations by other organs and sectors of the AU. The Secretariat is on course to meet the 30 September 2022 deadline for the end of Phase II negotiations, and thereafter the above-listed protocols will be subjected to the necessary legal

processes within the AU, following which the protocols will form part of the AfCFTA Agreement “single undertaking” and be binding on signatory AU Member States (Art. 8 of AfCFTA Agreement).

Once these protocols acquire binding force, the next hurdle will be their implementation by AU Member States.

### 4.3 Inclusion: Trade Regulation for Inclusive Digital Economies

The IDRC Strategy 2030 (2021a, p. 18) emphasises that the desired general outcome is that “people in developing countries benefit from more sustainable, equitable, and inclusive economies with expanded, lasting, and high-quality economic opportunities for women and youth”. This outcome is articulated in mega-RTAs, for instance the AfCFTA Agreement has a particular emphasis on the informal sector, women and youth (Ncube, 2022). The IDRC is already supporting a project on Driving a Gender-inclusive African Continental Free Trade Agreement (IDRC, n.d.-b), and there are numerous additional issues that can be considered under the umbrella of IDRC’s Sustainable, Inclusive Economies programme. As stated above, we have identified the intersections between trade, data, intellectual property and both *inclusive digital innovation* and *sustainable clean innovation* as the sources of cutting-edge regulatory issues that will need to be the focus of research for a considerable period of time.

#### 4.3.1 Data as a Resource/Opportunity and Constraint/Challenge

The digital economy and its regulation are inextricably linked to data because, as rightly noted by the Secretary-General of the United Nations, António Guterres, in the foreword to the UNCTAD *Digital Economy Report 2021*:

A key challenge is how to govern and harness the surge in digital data for the global good [...]. Data have become a key strategic asset for the creation of both private and social value. How these data are handled will greatly affect our ability to achieve the Sustainable Development Goals. Determining what is the best way forward will be difficult but necessary. Data are multidimensional, and their use has implications not just for trade and economic development but also for human rights, peace and security. (UNCTAD, 2021, p. iv)

The fundamental challenge here is who has access to, and the ability to regulate, data. States with limited resources have constrained access to data, which means their regulatory ambit is similarly limited and, by extension, so is their capacity to harness data and the digital economy for the public good. Recognition of these constraints has, correctly, motivated national, regional and global digital transformation efforts, and spurred significant research and literature on the topic (Ciuriak & Ptashkina, 2018). These efforts’ key goal is to leverage the opportunities that data presents by transforming the status quo.

An example of such initiatives at regional level is the African Union’s Digital Transformation Strategy for Africa (2020-2030), which expressly states that “Digital Transformation is a driving force for innovative, inclusive and sustainable growth. Innovations and digitalization are stimulating job creation and contributing to addressing poverty, reducing inequality, facilitating the delivery of goods and services, and contributing to the achievement of Agenda 2063 and the Sustainable Development Goals”(AU, 2020, p. 1). Consequently, the strategy’s main objective is “to harness digital technologies and innovation to transform African societies and economies to promote Africa's integration, generate inclusive economic growth, stimulate job creation, break the digital divide, and eradicate poverty for the continent’s socio-economic development and ensure Africa’s ownership of modern tools of digital management”(AU, 2020, p. 2).

The European Commission also has a digital strategy, which aims for a “climate neutral Europe by 2050” (EC, n.d.). Being set in a more resourced environment, the EC strategy largely assumes the existence of digital transformation (to overcome significant challenges) and focuses on leveraging opportunities with emphasis on climate change. Its approach has been considered in some of the literature. Looking at these

African and European approaches together support makes clear that data and the digital economy are critical issues regardless of socio-economic context.

### **4.3.2 Digital Trade, Data and Innovation**

Another key question is how the regulation of trade in data within the digital economy impacts innovation, and by extension development and the achievement of the SDGs. For example, the regulation of digital trade, typically included in trade agreement provisions, invokes issues of:

- regulation of big data;
- privacy/protection of personal data flows and developmental aspects of cross-border data flows (UNCTAD, 2016); and
- regulation of AI, including IP protection of AI's outputs and access-related IP tools such as exceptions and limitations.

A fundamental gateway issue is access to data and the uses that can then be made of the data for innovation and follow-on trade (Burri, 2021). For instance, AI's reliance on data raises questions about the regulation of data (Gervais, 2021; Seuba, 2021; Yakovleva & van Hoboken, 2021) and the treatment of the topic in trade agreements (Goldfarb & Trefler, 2019).

A significant aspect of data governance relates to "the free flow of data, the adoption of open data regimes, and cyber security" (Hlomani & Ncube, 2022, p. 2). Hence the growing body of research on cross-border data flows, data localisation laws, open data, data privacy, and data security (UNCTAD, 2016). The IDRC is already supporting work in some of these areas through its Open Data for Development (OD4D) programme, which in its third phase is focused on improving gender equality and inclusion; good governance; and economic growth (Davies et al., 2019; IDRC, n.d.-c).

Leveraging data for development brings to the fore contemporary IP regulatory puzzles on facilitating access through text and data mining. Much work is being done, and will continue to be done, on exceptions and limitations that enable TDM. An instance of such research is the consideration of TDM exceptions for scientific research and other purposes (Geiger et al., 2018; Margoni & Kretschmer, 2022).

Several trade agreements include efforts to facilitate and enhance digital trade integration (Mitchell & Mishra, 2020). E-commerce chapters in agreements such as the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTTP), the EU-Japan Economic Partnership Agreement, and the Canada-United States-Mexico Agreement (CUSMA) have assessed in terms of their practical implications on issues from labor (McCann, n.d.) to IP (de Beer, 2020a). AfCFTA Phase II negotiations have been engaging some of these aspects in the context of the aforementioned Protocol on Digital Trade, which needs to be informed by lessons learnt from other trade agreements (Banga et al., 2021) and, based on recent work at the UN Economic Commission for Africa (ECA) needs to factor in a human rights perspective (UN ECA, 2019).

There is evidence in the literature that effective regulation can enhance the benefits reaped from digital trade, by rendering more sustainable and inclusive outcomes (Joubert, 2021). This entails a focus on marginalised constituents such as women, youth, the informal sector, and small-scale farmers, and consideration of the full range of digital trade modalities, including, for example, fintech (Musewe & Hiebert, 2022).

## **4.4 Sustainability: Trade Regulation for Sustainable Clean Economies**

### **4.4.1 Trade, Climate Change and Innovation**

Trade agreements typically include climate change actions (Dent, 2021) or environment-related provisions (Berger et al., 2020). The AfCFTA Agreement, for example, includes biodiversity provisions (Benson & Judd, 2021). Climate action is major, topical issue that has been the focus of research for several

years and will continue to occupy a pole position on the research agenda as climate change adaptation and mitigation remain critical priorities. The IP dimension is a strong and fundamental one in development of clean technology innovations, due to the IP protection that is extended to related technologies (Kansal, 2021). The impact of such protection on further innovation is a core consideration addressed in the literature, which posits that it can be both an incentive and a hinderance/impediment, and that the existence of IP rights over climate technologies serves as an indicator/measure (albeit imperfect) of innovation (de Beer, 2020b). Knowledge synthesis work on intersections between IP and clean tech innovation is ongoing (de Beer et al., 2022).

Illustrative topics canvassed by the peer-reviewed and use-oriented literature surveyed so far include work on: trade, climate change and innovation (e.g. Rimmer, 2020); clean technology innovation (e.g. Lane, 2009); IP, cooperation and clean technology (e.g. Xiang, 2019); and IP, renewable energy and climate change (e.g. Jones, 2022).

Whilst this is a broad range of scholarship, there are some gaps and/or shortcomings. Based on preliminary assessments, the literature, written mostly by experts and technicians, does not adequately represent the views of persons whose lives are directly impacted by the technologies and climate action, raising the concern that policies, regulations and trade agreements may not adequately factor in their circumstances. More research is, thus, needed on the intersection between human rights, clean technology and IP, and more research is needed on the intersection between IP rights, gender and clean technologies.

There is also a clear data dimension to the trade issues intersecting IP and clean tech transfer. Increasingly, control over and access to data are driving clean innovation. The links are most obvious in respect of environmental data, including meteorological, hydrological, soil microbial, crop yield, and similar data.

Understanding these data dimensions segues into discussion of two development goals impacted by trade: food security (SDG 2) and health and well-being (SDG 3). Our scoping review suggests that these two “sustainability” topics are, in turn, closely connected with another cluster of SDGs related to climate action and biodiversity (SDGs 13, 14 and 15). The common denominator is the digitisation of genetic resources—from food crops to viruses—that increasingly drives science, technology, and innovation for development.

#### **4.4.2 Digital Genetic Resources Driving Environment, Food, and Health Science**

##### *4.4.2.1 Trade, Data, and IP: Impacts on Agriculture*

Trade agreements serve as powerful tools to enhance trade in agricultural commodities (Falsetti et al., 2022), and the manner in which these agreements regulate agriculture is receiving increasing scholarly scrutiny (Tripp et al., 2006) and policy attention (FAO, 2017). At the same time, development outcomes related to the environment and agriculture are nearly inseparable. Network governance of innovation in agriculture is, in many ways, deeply intertwined with environmental policy, rural economic development, and energy supply (de Beer, 2016a). International trade law around biofuels has been one of the major regulatory and policy issues of the past decade (de Beer & Smyth, 2012), following on from international trade-related regulatory challenges around genetically modified organisms that dominated policy discourse in the last part of the 20<sup>th</sup> century (Cordonier Segger et al., 2013; Kakooza, 2018; Zarrilli, 2005).

The emerging major trade-related regulatory challenges for sustainable agriculture, our scoping suggests, relate to digital and data-driven agriculture. Technological innovation has led to the widespread uptake of what is variously called “precision agriculture” or “smart farming” driven by big data (Bronson & Knezevic, 2016). Published reviews of literature in this field are begin to emerge, identifying research gaps and priorities (Foster et al., 2021; Navarro et al., 2020; Wolfert et al., 2017).

It is not, however, only the “downstream” or “on farm” use of data that is triggering regulatory challenges. At least as important for science, technology, and innovation are the upstream



“dematerialisation” and digitisation of plant genetic resources for food and agriculture. The generation of, and control over, data on-farm, and the dematerialisation of genetic resources for upstream R&D and plant breeding, are two sides of the same coin—because without appropriate regulation, big data in both domains will likely lead to increased marginalisation of farmers and exacerbate inequity (de Beer et al., forthcoming). In the context of plant genetic resources for food and agriculture, the international regulatory conversation around “digital sequence information” (DSI) is coalescing around multilateral or hybrid governance approaches (Hartman Scholz et al., 2022).

More generally, the impact of big data on agriculture, trade and food security is a critically important subject with a clear linkage to SDG 2 (zero hunger). The IP linkage is also very evident and important in respect of agricultural big data, and trade secrets, patents and plant variety rights (PVRs) are all highly relevant to agricultural value chains (Adebanjo, 2020). Ownership of “open” data is a major issue with many unresolved implications (de Beer, 2016b). Preserving a role for, and facilitating full engagement, in trade by small-scale farmers is a key concern. For example, at the Food and Agriculture Organisation (FAO), work on access and benefit-sharing and digital sequencing clearly implicates plant breeders’ rights (FAO, 2021). Consequently, there is a growing body of literature on this dimension (Aubry, 2019; Wynberg et al., 2021), including work directed at policymakers (Karger et al., 2020).

#### *4.4.2.2 Trade, Data, and IP: Impacts on Health*

The intersection between health and intellectual property is (as seen in chapter 2 of this report) an entrenched area of study that considers many dimensions, including human rights and the impact of including health-related IP provisions in trade agreements (Akonumbo, 2022; Barlow et al., 2017; Ruxin, 2010; Westerhaus & Castro, 2006). Technological advances and big data are making their mark on health technologies in a variety of ways. Examples include data-driven systems that trace infections and remote delivery of medical advice through apps, and critical assessment and monitoring functions are now increasingly reliant on data-intensive technologies. For example, monitoring viral loads in wastewater has proven to be a powerful tool for monitoring and evaluating the spread of COVID-19 through populations.

Furthermore, vaccine, therapeutic and diagnostic innovations can be enhanced by access to data. Hence the South Africa–India TRIPS waiver proposal (see chapter 2 of this report) included trade secrets and test data exclusivity. The resultant WTO declaration of June 2022 excludes these elements (WTO, 2022b), but their inclusion in the proposal is instructive as to the extent of their importance to innovation. Test data access remains a critical issue, particularly given that the policy space that states have to work with remains subject to narrowing through trade agreements. A significant body of literature addresses this link between trade, data, IP, and health (Cottier et al., 2017; Fukuda-Parr & Treanor, 2018; WHO, 2017a, 2017b; P. Yu, 2019; P. K. Yu, 2018). Much of the scholarship on health and IP is written from a human rights perspective that centers on the rights to life and health, as shown by another literature review of the topic (Velásquez et al., 2020).

IDRC’s Global South AI4COVID Program is already supporting some work on data-driven health responses, such as an Africa-Canada Artificial Intelligence and Data Innovation Consortium (ACADIC) project that has provided data for policymakers (IDRC, 2021c). As the health landscape evolves and more pandemic and endemic diseases emerge, such research will continue to be relevant and timely.

## **4.5 Conclusions and Agenda for Future Research and Engagement**

The literature surveyed in this chapter has afforded insights into two broad themes that can be expected to remain topical for the next 5-10 years and thus are worthy of inclusion in a forward-looking agenda for research and engagement on regulation of innovation. These are:

- digital trade, data, and IP for inclusive innovation; and
- clean tech trade, data, and IP for sustainable innovation.

The case for the inclusion of each of these has been made above and will not be repeated here, save for one illustration, using the first issue. As shown above, digital trade remains under negotiation at both the WTO and AfCFTA levels. Access to and use of data are critical to successful, inclusive and sustainable trade, and thus regulatory initiatives that support open data, free flows of data—and exceptions that permit uses of data such as TDM—are required. Therefore, research of the various kinds described above continues to be essential to give both normative and procedural guidance to regulatory developments and to critique existing regulatory instruments. This points to the need for an agile and responsive research agenda that feeds directly into engagement with trade negotiations and regulatory developments—for example, research that informs engagement with the outcomes of the Phase II AfCFTA negotiations and the digital trade negotiations at the WTO.

In addition to such responsive and agile, just-in-time research efforts, the research agenda should include more static research projects that pertain to each of the key issues, taking care to emphasize the human rights and gender perspectives that have been identified as needing strengthening. The target of each of these efforts, and of the research agenda as a whole, ought to be to support and facilitate an enabling regulatory and trade environment for states and role players to harness trade for sustainable development—with specific attention paid to marginalised constituencies such as women, youth, the informal sector, and small-scale farmers.

# 5. Integrated Discussion, Analysis, and Recommendations

## 5.1 Introduction

This final chapter discusses and analyses the findings of the scoping study. It identifies and prioritises gaps that might be addressed with a regulatory research and engagement programme (with both short-term and medium-term elements) based on the study findings. The chapter briefly summarises the state of knowledge thus far distilled from the review of existing literature; explains a conceptual reorganisation of the project's core focus areas to facilitate a coherent, integrated research agenda; and, building on the new conceptual matrices, points to:

- key role-players in innovation regulation;
- entry points and gaps for regulatory research and engagement;
- entities and initiatives that can be expected to participate in a community of practice focused on the identified entry points and gaps; and
- a three-pronged agenda for regulatory research and engagement.

## 5.2 Summarising the State of Knowledge

Recall from chapter 1 that a scoping review of literature, rather than a formal systemic review, was chosen as the suitable method, because the research topic and questions still lacked precise definition. Separate but complementary scoping reviews were conducted in each of the three identified focus areas: health/vaccines (findings reported in chapter 2), data and technology governance (chapter 3), and trade/environment (chapter 4).

As these three complementary scoping reviews unfolded, it became apparent that the topic, even broken down into thematic focus areas, is massive and overwhelming. While our review was limited to English-language publications, it was not limited geographically or by academic discipline. We included both peer-reviewed and use-based (grey) literature. As such, we proceeded to gather and analyse an illustrative range of relevant materials instead of trying to compile a comprehensive database.

Insights that cut across all three of the focus areas examined include the following:

“Innovation” is an infeasibly broad topic to research. It includes product innovation, process innovation, business model innovation, governance innovation, and much more. Past IDRC-supported research has successfully managed the broad scope with thematic foci, such as high-tech innovation, informal-sector innovation, and indigenous-community innovation. Our review here has identified an emerging area and opportunities in respect of digital and data-driven innovation. What we discovered was that even where a product or process may not initially seem to be driven by or based on digital technologies, increasingly there are digital or data-driven dimensions to most innovations.

For example, the development and deployment of vaccines depends heavily on data concerning safety and efficacy. Indeed, safety and efficacy data are a non-negotiable prerequisite for vaccine regulatory approval, even in emergency situations as we have seen. Likewise, appropriate data governance rules around privacy, for example, were crucial for the effective roll-out of vaccine passports. While vaccine passports were key to early economic re-opening in high-income countries, countries and regions that lack robust data governance rules and digital infrastructure simply had no hope of safely kickstarting their own economic recoveries, thus exacerbating already-severe inequalities.

“Regulation” is an often used, but also inconsistently used term, with different connotations in different fields and disciplines. In political economic terminology, regulation can be understood as an

institution (not in the organisational sense but in the social or economic structural sense) characterised by power. In a more strictly legal framework, regulation can be understood as rules that govern behavior. Reconciling these understandings from trans-disciplinary perspectives is not easy. Given that effective regulation must be integral to any strategy to achieve the SDGs, the question becomes: Which regulations are most relevant for sustainable and inclusive outcomes?

In exploring that question, we identified three clusters of regulatory themes, presented in Table 6. These themes are present, albeit in different ways, across both low- and high-income countries, and they feature—sometimes explicitly, sometimes implicitly—in the reporting of the scoping findings in chapters 2, 3, and 4.

Table 6: Thematic clusters of regulatory issues

Three themes help to summarize and cluster the key regulatory issues.

1. Marketplace framework laws and policies cannot be isolated from one another but must rather be understood as organic systems. Changes in one area, such as intellectual property, inevitably impact other areas, such as competition. Such systems should, therefore, be examined holistically.
2. Regulatory systems operate on multiple levels, from local to global and on various planes between. Multi-level regulation must, however, be seen as networked not hierarchical, with normative feedback circulating throughout. Regulatory norms cannot flow only top-down, centre-out, or in any other single direction.
3. Regulation for truly sustainable and inclusive innovation must transcend the stereotypes and assumptions underpinning frameworks designed by the most-developed countries. Legal and economic effectiveness depends on community-driven norms—whether informal, traditional, or otherwise socio-culturally complex—including industry/community self-regulation.

Each of these three clusters of issues is elaborated on in the sections that follow. Section 5.2.1 discusses regulation via marketplace frameworks; section 5.2.2 explains the multiple, networked levels at which regulation operates; and section 5.2.3 adds consideration of industry- and community-driven regulatory norms to the analysis.

In identifying these regulatory themes, we are cognisant that we have fused numerous elements from the highly diverse literature on regulation. In their influential volume *Understanding Regulation: Theory, Strategy, and Practice*, Baldwin et al. (2011, p. 40) argue that “[i]n looking at explanations of regulation, one can distinguish between those approaches that emphasize exogenous (external) factors that shape the evolution of regulation (such as the force of interest groups, dominant ideas, or the underlying nature of the economy) and those emphasizing endogenous factors such as institutional cultures”. In our approach, we seek to give due consideration to both exogenous and endogenous factors.

### 5.2.1 Regulatory Systems as Marketplace Frameworks

No single regulatory regime can, in isolation, solve the challenges of sustainable and inclusive innovation. Multiple fields and forms of regulation operate together to form an organic system, where legal or policy changes to one impact many others. These systems provide the operating marketplace frameworks for the sectors in which innovation occurs.

As the example of vaccine inequality shows, intellectual property rights are among the most crucial forms of marketplace regulation, impacting the allocation of benefits. Effective intellectual property laws

and policies incentivise R&D, technological progress, and scientific breakthroughs while, at the same time, intellectual property can pose barriers to access, complicate collaboration, raise prices, and exacerbate inequality. But intellectual property regulation is only one—albeit crucial, and often prominent—part of a broader set of regulatory norms, institutions, and practices. Relevant areas of regulation beyond intellectual property include competition, finance, investment, technology designs, and more.

Competition law and policy, for instance, is integral for governance of global, regional and national digital economies. Acting as a check and balance on the increasing powers of the world’s largest technology firms, competition regulation seeks to ensure fair access to, and fair participation in, the numerous sectors and sub-sectors of digital markets. It also acts indirectly as a form of consumer protection. Competition law and policy is important not only to regulate “big tech”, but also to limit concentrations of market power in other industries, such as biomedical research.

Neither intellectual property nor competition issues can be regulated effectively without considering the rules governing finance and investment, including matters of bankruptcy, insolvency, and taxation. A major challenge is to understand all marketplace regulatory mechanisms in juxtaposition with one another, in order to create the most effective regulatory *systems*.

Furthermore, development outcomes are fundamentally intertwined. Health and environment are a good example. With climate change, human-animal interactions are going to increase, migration of displaced populations will become more common, and one of many consequences is likely to be a spike in future pandemics like the one the world has just experienced. It is not hard to understand how other topics, like food security, are equally inseparable. That is why “regulating innovation” needs to be understood not in sector-specific focus areas but rather as a meso-level issue where the same rules will have diverse impacts across a range of sectors and development outcomes.

Across topical areas and fields of regulation, recent experience indicates that institutions and incentives are not delivering on the promise of marketplace inclusion and are poorly aligned with the aims of social justice. Global inequity persists in respect of access to innovation. Evidence of persistent inequity and failures of existing systems to address innovation access and scale are immediately demonstrable in the context of the COVID-19 vaccine crisis—which is directly linked to SDG 3 (Good health and well-being) and reflects a disheartening replication of the experience with HIV/AIDS treatments.

### **5.2.2 Global, Local, and Multi-Level Governance**

Because regulatory systems in support of innovation cannot be one-size-fits-all, reform strategies need locally and/or regionally specific solutions and capacities. Diversity within the innovation sphere around the world and across the Global South needs to be better understood and evaluated. Better understanding and evaluation need to include clearer pictures of the roles of large emerging economies—especially China, but also India, South Africa and Brazil—and other nations occupying distinct positions with respect to technology development, engagement with global institutions, and development of (state and private-sector) regulatory frameworks and institutions.

Top-down global regulatory models remain a source of pressure on national institutions; pressure to harmonise remains strong. While the necessity for sensitivity to context is recognised, global regulatory institutions’ influences on national institutions tend to flow in a unidirectional channel, without any meaningful attempt to functionally accommodate context. And existing flexibilities tend not to be sufficiently exploited in lower- and middle-income countries (LMICs). Despite evidence of regulatory heterogeneity, the countries in the Global South have, for a complex mix of reasons, generally failed to leverage wiggle room, accommodations, exceptions, staggered implementation of provisions, and other accommodations.

The COVID-19 crisis has renewed scrutiny of the TRIPS Agreement and persisting inequity between the Global North and South on intellectual property matters—with a specific focus, in the COVID context, on a temporary waiver of international legal obligations. Yet deeper analysis shows that a sustainable, inclusive solution cannot lie solely in a waiver, or in another potential accommodation written into TRIPS, because many other regulatory, technical, and economic barriers are not incorporated into such legal “concessions”. Rather, as the pandemic has demonstrated, there is a need to address the numerous barriers present in value chains present, for example, in vaccine production—from sourcing of raw materials to distribution capacity, R&D capacity, and infrastructure capacity—through a collaborative institutional regulation framework aimed at fostering innovation access in support of SDG 3. Such a framework may also be scalable to other contexts, such as climate change, food security, digital inclusion, and more.

There is a need to address regulatory norms and activities at national, regional and global levels, and to consider interactions among and between norms/activities at these levels. Growing global interconnectedness has provided enormous gains and opportunities for development progress, but realising these potentials for equitable progress still depends to a great extent on national institutions and capabilities (interacting to some extent with regional frameworks such as, in the African context, the AfCFTA). There is both the need and opportunity to strengthen national institutions’ capacity to negotiate their countries’ global and regional inter-connections on regulatory matters, such as in global administrative law. Solutions must not come one-way from North to South. Development of regulatory frameworks must be collaborative and inclusive, encouraging ground-up innovation, local and global enabling environments, and intensive capacity-building.

One key question concerning multi-level governance in the Global South is the role that regional trade agreements (for example, the aforementioned AfCFTA) and regional economic frameworks can play in marshalling capacity and cooperation to meet innovation regulation objectives. This is immediately relevant in the context of COVID-19 diagnostics, vaccines, treatment, and medical devices.

### **5.2.3 Industry and Community Self-Regulatory Norms**

As well as interactions across multiple levels of governance, it is crucial to address interactions between public agencies and the private sector. Industry self-regulation (via, for example, technical standard-setting around interoperability, sharing of samples of genetic material, and codes of conduct around privacy) is becoming the norm in fields where governments are unable to coordinate or slow to act. When the private sector sees that external regulation is becoming inevitable, its best option is often to proactively institute self-regulatory measures. This can be a key aspect of (mis)alignment between innovation and inclusion.

Furthermore, alternative forms of knowledge governance are perceptible in regions of the Global South (e.g. Africa)—forms that produce community-serving innovations, and employment of members of vulnerable groups. With appropriate governance, these innovations could be utilised in other regions. One example is traditional knowledge in the area of medicines, which can be harnessed for purposes of healthier communities, locally and globally.

This also implies an expanding view of incentives for innovation that includes, but goes beyond, the private for-profit model. Accordingly, new and better mechanisms to measure innovation are needed, so as to improve or supplement existing tools such as the Global Innovation Index (GII) and help us better understand states of innovation, including in the pandemic context (WIPO, 2021).

It is ironic that while lower-income countries in regions such as Africa, South and Southeast Asia, Latin America and the Caribbean are being pressured to conform their regulatory regimes to long-standing US- and Euro-centric knowledge governance norms, countries of the Global North are pursuing innovative new models of public–private financing and R&D collaboration—e.g. the US Operation Warp Speed

initiative—with potential to scale globally towards harnessing the benefits of innovation in equitable ways to sustainably impact the most vulnerable. Such innovative knowledge governance approaches also reflect a shift from the market-driven concession model to a (human) rights-driven model, specifically the right to health.

There is now greater traction for a global or centralised R&D financing and collaboration that is inspired less by market forces than the imperative to channel innovation to the benefit of all, including the most vulnerable, and to channel innovation, where necessary towards creation of public goods. This trend requires a re-thinking and re-envisioning of global, regional, and national institutions in support of complementary partnerships and creative attention to value chain models that leverage and optimise the contributions of all regions.

Among the questions that arise: What (new) regulatory action(s) need to be taken (e.g. in the competition sphere), to ensure greater enablement of start-ups and ground-up innovation ventures that engage youth, women, and the marginalised in general, including informal workers who lost their livelihood because of the pandemic and the new poor whom the pandemic has squeezed out of the middle class? The private sector is not homogeneous. Small businesses risk being crushed by the market power and anti-competitive behaviours of larger companies. During the emergence from COVID, it is more important than ever to ensure regulatory measures in support of innovative micro, small and medium enterprises (MSMEs). Regulatory norms must also be fit for purpose in the context of the present (no longer the future) of work. Major disruptions have occurred, globally, around work. From rising pockets of unemployment are emerging new work models, and entrenchment of the platformisation of work—driven by the so-called “sharing economy” and the gig economy—at both local and global levels.

#### **5.2.4 Summary of Regulatory Themes**

Sectoral issues, and especially development outcomes, are not easily segregated from one another. While there are discrete bodies of research and groups of researchers especially interested in “health” or “environment” issues for example, innovation regulation rarely discriminates between or specifically targets individual sectors. Indeed, current international law on intellectual property, for example, expressly prohibits states from applying rules differentially to certain technologies or fields of application. That means that the general marketplace regulatory frameworks governing innovation in one sector, food and agriculture for instance, are also going to have major impacts in ostensibly unrelated areas, such as science and education. That is why framework laws and policies must be understood as organic systems.

The concepts of multi-level or networked regulation can be helpful. Regulation within this framework is not merely about formal rules, but also about interactions between public and private entities. And these interactions play out in complex, non-linear ways at global, regional, and local levels. We have identified at least two key kinds of “nodes” of networked regulation especially relevant to digital and data-driven innovation. These are conventional multi-lateral institutions, such as a web of specialised United Nations agencies as well as adjacent organisations like the World Trade Organisation. Another kind of node is the proliferating regional or mega-regional trade agreements taking root around the world, starting in North America and Europe but recently expanding to Asia, Latin America, and now Africa.

Self-regulation can also be conducted by communities that straddle the public, private and academic/research sectors. Open science is an excellent example of this kind of self-regulation. In open science systems, industry and research community partners coordinate to work with or around government regulations pertaining to intellectual property, competition, finance, etc. in order to solve practical, often unanticipated, problems. The interactions amongst models of finance, and the practices of public–private partnerships, in the context of COVID-19 offer one (but by no means the only) example. Other fields where such interactions are influential are agriculture/agri-food innovation, and artificial intelligence/data

governance. This highlights the need for continuous development and reform of the institutions and rules to facilitate the market, again particularly to create level playing fields.

### 5.3 Conceptual Reorganisation

Figure 2 provides a reminder of the three themes that the team scoped, with these three areas distilled (as explained in chapter 1) from three broader focus areas in IDRC’s *Strategy 2030*.

During the research, it became apparent that the three focus areas we were studying in silos were in some ways overlapping, in some ways incomplete, and in some ways incommensurable. That is, the core issues associated with regulating innovation in these three focus areas are not

suitable for “apples-to-apples” comparisons. We invested considerable time discussing, brainstorming, and experimenting with structural conceptualisations of the issues in these areas that could support a coherent, integrated programme of research.

We realised that the issue of inequitable access to vaccines is merely an example of, or manifestation of, regulatory problems in the field of health. This concrete example was necessary to ground discussion of governance and ownership of global vs local innovation, and the roles of intellectual property, licensing, and regulatory bodies in shaping access, and influencing distribution of health benefits and outcomes.

Health, however, as a focus area or development outcome (SDG 3) is not a challenge that can be understood or solved alongside data governance or trade. Health, rather, is a challenge affected by data governance and trade. Health is a focus area more commensurable with other development outcomes such as food security (SDG 2), a sustainable environment (SDGs 7, 11, 13), and quality education (SDG 4).

Similarly, data governance and trade were not topics that we could easily scope out separately. Fundamentally, that is because trade deals are key mechanisms through which data is governed. Data, we realised, is really a raw material that drives innovation. Akin to the transition to a knowledge economy that occurred in the late 20th century, when new rules were locked in through regulations like TRIPS, we are now at the cusp of a data-driven economy. And the patterns of power and influence over regulation-making are repeating. Those countries (and private companies, some as large and powerful as countries) that are best positioned to “harvest” data as a raw material are the ones disproportionately shaping the new regulatory environment.

Trade, meanwhile, is itself not appropriately conceptualised as a separate focus area, but rather as a form (or forum) of regulation. Regulation via trade is changing dramatically from the days of bilateral investment treaties (BITs) and simple free trade agreements (FTAs).

The new phenomenon is mega-regional economic partnerships. We saw this first emerge in Europe (with the European Union being the pioneering and perhaps most ambitious model), and then in North America through NAFTA, now CUSMA. Examples have popped up elsewhere, like Mercosur in Latin America and, more recently, RCEP in Asia, and CPTPP across the Asia-Pacific region. The latest and potentially most pathbreaking new mega-regional is the African Continental Free Trade Area (AfCFTA), Phase I of which is now in place and Phase II of which (regulating intellectual property, competition, and other complex matters) is in the works literally right now.

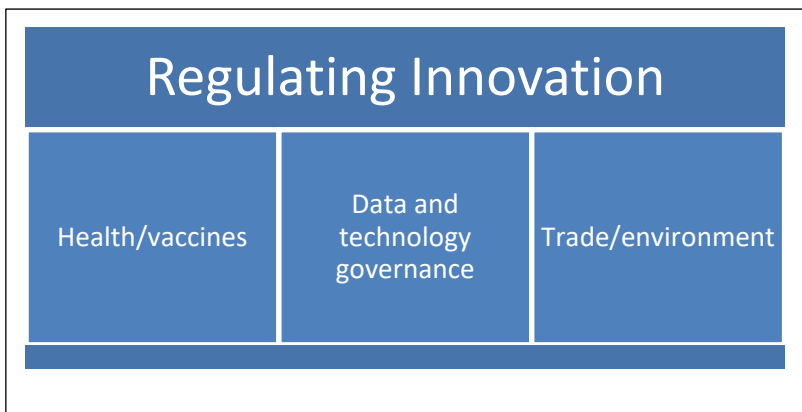


Figure 2: Initial focus areas



Meanwhile, conventional multi-lateral institutions like the United Nations’ World Intellectual Property Organisation, World Health Organisation, Food and Agriculture Organisation, and others are still highly active and relevant. Alongside those are bodies like the WTO, as well as framework-setting treaties like the UN Framework Convention on Climate Change (UNFCCC), probably the world’s most important global forum for setting rules around the regulation of clean innovation through mechanisms like carbon pricing, technology transfer, and more. And, of course, not to be forgotten are the self-regulatory mechanisms, including industry standard-setting bodies as well as Indigenous and local community governance models.

The new conceptualisation we arrived at for the focus areas, grounded in the scoping findings as reported in chapters 2, 3, and 4, is depicted in Figure 3. This reconceptualisation depicts SDG-related development outcomes (health and well-being, food security, a sustainable environment, quality education, as examples) as nested within, and dependent upon, an environment of multi-level, networked regulation. This complex base layer of regulation is being formulated at global, regional, and local levels. Between base-layer regulations and development outcomes are drivers of innovation. Knowledge-sharing and collaboration, and data and digital technologies, are not the only drivers of innovation. But these are among the most impactful, newly emerging drivers. These are the innovation drivers in respect of which the regulatory landscape is still forming. Here is where immediate opportunities exist to shape the governance frameworks that will determine development outcomes for decades into the future.

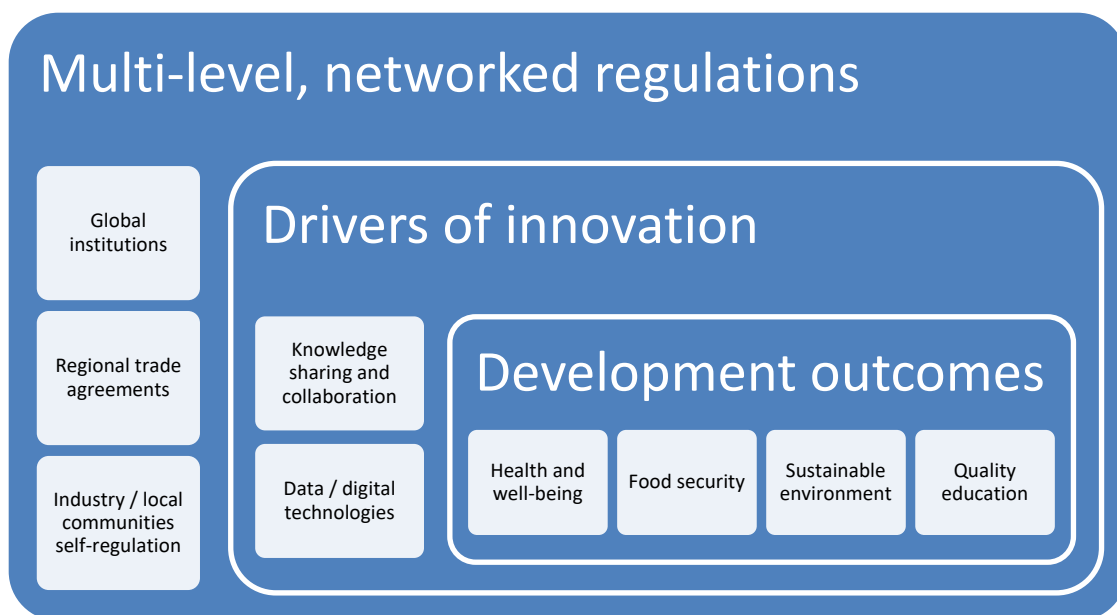


Figure 3: Reconceptualised relationships amongst regulation, innovation, and development

We also identified and articulated a matrix of relevant forms of innovation regulation. As depicted in Figure 4, amongst the relevant regulatory frameworks are: intellectual property; competition policy; taxation and fiscal incentives; and finance and investment. These are, of course, not the only relevant regulatory mechanisms governing innovation, but they are each, in different ways, crucial elements of the overall innovation regulation landscape.

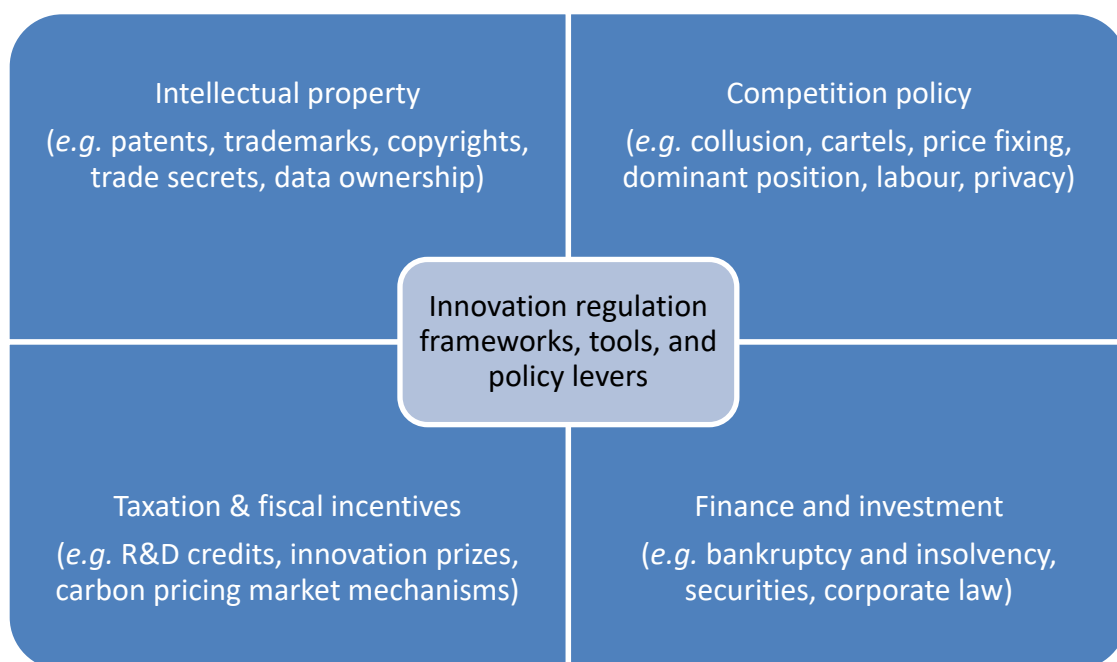


Figure 4: Innovation regulation frameworks, tools, and policy levers

#### 5.4 Entry Points and Gaps for Regulatory Research and Engagement

The findings of the institutional, regulatory and stakeholder mapping exercises carried out by each of the three working groups informed the content of chapters 2, 3 and 4. The findings from these mappings also provide important guidance as to the most likely entry points and gaps for regulatory research and engagement as part of the research programme set out in this report. Table 7 below sets out key role-players identified by the mapping exercise, and the relevance of the role-players to regulation of innovation. Below that, Table 8 (also based on the mapping) sets out entry points and gaps for regulatory research and engagement, and the regulatory instruments/issues at play. A final set of findings from the mapping work is provided in Table 9, which lists entities and initiatives that could be expected to participate in an expanded community of practice focused on some or all of entry points and gaps listed in Table 8.

Table 7: Role-players in innovation regulation

Role-player	Link(s) to innovation regulation
<b>Global/international</b>	
UNFCCC Secretariat (UN Climate Change), UN General Assembly, UNDP, WHO, UNEP, CDB Secretariat, FAO, UNCTAD, UNESCO, IGF	<ul style="list-style-type: none"> <li>• Global norm-setting on sustainable development (SDGs), climate change technology transfer, health, agriculture, trade, science, culture, internet governance</li> <li>• UNFCCC Secretariat (UN Climate Change) leads convening of annual Conference of the Parties (COP), i.e., annual UN Climate Change Conference</li> </ul>
UPOV	<ul style="list-style-type: none"> <li>• Global norm-setting on plant varieties protection</li> </ul>
WTO	<ul style="list-style-type: none"> <li>• Global trade rule-setting and enforcement</li> <li>• Collaborates with UNFCCC (UN Climate Change) on development and transfer of clean energy technology innovation</li> <li>• WTO TRIPS Council engages with global intellectual property matters</li> <li>• WTO Ministerial Conference of 2022 decided on modalities of COVID “TRIPS waiver”</li> </ul>
WIPO	<ul style="list-style-type: none"> <li>• Global rulemaking and norm-setting on intellectual property matters</li> </ul>

	<ul style="list-style-type: none"> <li>• WIPO SCCR engages with access to knowledge matters, e.g., access for the visually impaired</li> <li>• WIPO CDIP engages with technology transfer matters</li> <li>• WIPO IGC engages with knowledge governance in respect of Indigenous and traditional knowledge</li> </ul>
OECD	<ul style="list-style-type: none"> <li>• Rich-world guidance and norm-setting on sustainable development matters</li> <li>• OECD AI Policy Observatory sets standards for human-centric regulation of AI</li> </ul>
ITU	<ul style="list-style-type: none"> <li>• Global norm-setting and regulation on technology matters</li> </ul>
World Bank	<ul style="list-style-type: none"> <li>• Global guidance and finance on sustainable development matters</li> <li>• Guides data governance frameworks, identifies problem areas, monitors impact</li> </ul>
Global public-sector projects, e.g., OGP	<ul style="list-style-type: none"> <li>• Global norm-setting on open government, government open data, freedom of information</li> </ul>
Industry associations	<ul style="list-style-type: none"> <li>• Research and regulatory engagement in support of private-sector interests</li> <li>• Development of codes of conduct for industry self-regulation</li> </ul>
Civil society entities, including research/academic community: e.g. CIGI, KEI etc. (see Table 9)	<ul style="list-style-type: none"> <li>• Research and communities of practice in support of evidence-based regulatory norms and rules</li> <li>• Engagement with norm/rule-setting fora</li> <li>• Development of codes of conduct for self-regulation, e.g., FAIR principles for data management</li> </ul>
Multisector projects: e.g., Datasphere Initiative etc. (see Table 9)	<ul style="list-style-type: none"> <li>• Research and regulatory engagement in support of mix of civil society, government and private-sector interests</li> </ul>
<b>Regional</b>	
EU	<ul style="list-style-type: none"> <li>• European norm-setting on sustainable development matters</li> <li>• EU a global reference point on data governance, e.g. via GDPR</li> </ul>
AU	<ul style="list-style-type: none"> <li>• continental norm-setting on sustainable development matters, led by AU Commission</li> <li>• driver of AfCFTA as part of Agenda 2063: The Africa We Want</li> <li>• AfCFTA Council of Ministers of Trade driving AfCFTA implementation, development of AfCFTA Protocols</li> </ul>
ECA	<ul style="list-style-type: none"> <li>• continental norm-setting on economic matters</li> <li>• ECA's ATPC supports African trade policy development</li> </ul>
African regional commissions/communities: ECOWAS, COMESA, ECA, SADC, AMU, ECCAS	<ul style="list-style-type: none"> <li>• African regional norm-setting on trade and other sustainable development matters</li> </ul>
African regional IP bodies: ARIPO, OAPI	<ul style="list-style-type: none"> <li>• African regional norm-setting and rulemaking on intellectual property matters</li> </ul>
Industry associations	<ul style="list-style-type: none"> <li>• research and regulatory engagement in support of private-sector interests</li> <li>• development of codes of conduct for industry self-regulation</li> </ul>
Civil society, including research/academic community: e.g. tralac, AfricaLics, Open AIR, RIA etc. (see Table 9)	<ul style="list-style-type: none"> <li>• research and communities of practice in support of evidence-based regulatory norms and rules</li> <li>• engagement with norm/rule-setting fora</li> </ul>
Multisector projects: e.g., OD4D, ACET etc. (see Table 9)	<ul style="list-style-type: none"> <li>• research and regulatory engagement in support of mix of civil society, government and private-sector interests</li> </ul>
<b>African national</b>	
Ministries/departments responsible for trade, ICT,	<ul style="list-style-type: none"> <li>• inputs on global/international and regional norm-setting and rule-setting processes</li> <li>• guidance for national implementation of international commitments</li> </ul>

science, technology, innovation	
State entities for research, research funding, innovation support, IP registration	<ul style="list-style-type: none"> <li>• support for R&amp;D, innovation</li> <li>• support for open science, open access scholarly publishing</li> </ul>
Regulators of competition, communications, personal data, privacy, information access	<ul style="list-style-type: none"> <li>• regulation of market behavior of data-driven firms, of management of personal data, of information access</li> </ul>
Industry associations	<ul style="list-style-type: none"> <li>• research and regulatory engagement in support of private-sector interests</li> <li>• development of codes of conduct for industry self-regulation</li> </ul>
Civil society, including research/academic communities	<ul style="list-style-type: none"> <li>• research and communities of practice in support of evidence-based regulatory norms and rules</li> <li>• engagement with norm/rule-setting fora</li> <li>• development of codes of conduct for self-regulation</li> </ul>

Table 8: Entry points and issues/gaps for regulatory research and engagement

Entry point	Regulatory instrument(s) and issues/gaps
AfCFTA	<p>Instruments:</p> <ul style="list-style-type: none"> <li>• Protocol on Intellectual Property Rights</li> <li>• Protocol on Investment</li> <li>• Protocol on Competition Policy</li> <li>• Protocol on Digital Trade</li> <li>• Protocol on Women and Youth in Trade</li> </ul> <p>Issues/gaps:</p> <ul style="list-style-type: none"> <li>• IP, investment, competition, digital trade, women and youth in trade</li> </ul>
African national policy, legal and regulatory processes	<p>Instruments:</p> <ul style="list-style-type: none"> <li>• national competition enquiries</li> <li>• NIS strategies</li> <li>• national STI policies and strategies</li> <li>• national science funding policies, laws, regulations</li> <li>• national data/e-commerce policies, laws, regulations</li> <li>• national copyright bills and acts</li> <li>• national IP policies</li> <li>• BTAs, e.g., US-Kenya FTA</li> </ul> <p>Issues/gaps:</p> <ul style="list-style-type: none"> <li>• market power of big data firms</li> <li>• informal-sector innovation, measuring informal innovation</li> <li>• open science, OA publishing</li> <li>• personal data protections, cross-border data</li> <li>• copyright exceptions and limitations for educational and research activities</li> </ul>
WTO TRIPS Council WTO Ministerial Conferences	<p>Instrument:</p> <ul style="list-style-type: none"> <li>• TRIPS Agreement</li> </ul> <p>Issues/gaps:</p> <ul style="list-style-type: none"> <li>• intellectual property exceptions for live-saving medical vaccines, treatments, diagnostics, e.g., TRIPS waiver</li> <li>• flexibilities for public goods (e.g., essential medicines)</li> </ul>
UNFCCC Secretariat (UN Climate Change) and WTO  (UNFCCC African Group of Negotiators (African Group))	<p>Instruments:</p> <ul style="list-style-type: none"> <li>• UNFCCC</li> <li>• Kyoto Protocol to the UNFCCC</li> <li>• Paris Agreement</li> <li>• Marrakech Partnership for Global Climate Action</li> </ul> <p>Issues/gaps:</p>

UNFCCC Technology Transfer Network)	<ul style="list-style-type: none"> <li>• development and transfer of clean energy technology innovations</li> <li>• clean energy technologies as public goods</li> </ul>
FAO, WHO, CBD Secretariat (UNEP), and WIPO IGC	<p>Instruments:</p> <ul style="list-style-type: none"> <li>• CBD</li> <li>• Nagoya Protocol on Access and Benefit-sharing</li> </ul> <p>Issues/gaps:</p> <ul style="list-style-type: none"> <li>• regulation of digital genetic sequence information</li> <li>• equitable approaches to protection of TK, TCEs, GRs</li> <li>• ABS</li> </ul>
UPOV	<p>Instrument:</p> <ul style="list-style-type: none"> <li>• International Convention for the Protection of New Varieties of Plants</li> </ul> <p>Issues/gaps:</p> <ul style="list-style-type: none"> <li>• equitable and sustainable allocation of PVRs</li> </ul>
UNCTAD	<p>Instrument:</p> <ul style="list-style-type: none"> <li>• Investment Policy Framework for Sustainable Development</li> </ul> <p>Issues/gaps:</p> <ul style="list-style-type: none"> <li>• reform of investment treaty regime in support of climate action</li> <li>• FDI for sustainable development</li> </ul>
WIPO Composite Indicator Research Section	<p>Instrument:</p> <ul style="list-style-type: none"> <li>• GII</li> </ul> <p>Issues/gaps:</p> <ul style="list-style-type: none"> <li>• nuanced treatment of innovation as it occurs in Global South</li> <li>• enhanced data collection in Global South</li> </ul>
WIPO SCCR	<p>Instruments:</p> <ul style="list-style-type: none"> <li>• Berne Convention</li> <li>• WCT</li> </ul> <p>Issues/gaps:</p> <ul style="list-style-type: none"> <li>• copyright limitations and exceptions for educational and research activities, including TDM</li> </ul>
OECD AI Policy Observatory	<p>Instrument:</p> <ul style="list-style-type: none"> <li>• OECD AI Principles</li> </ul> <p>Issues/gaps:</p> <ul style="list-style-type: none"> <li>• trust, innovation and respect for human rights in AI use</li> </ul>
WHO	<p>Instrument:</p> <ul style="list-style-type: none"> <li>• Ethics and Governance of Artificial Intelligence for Health</li> </ul> <p>Issues/gaps:</p> <ul style="list-style-type: none"> <li>• ethical health AI</li> </ul>
UNESCO	<p>Instrument:</p> <ul style="list-style-type: none"> <li>• Recommendation on the Ethics of Artificial Intelligence</li> </ul> <p>Issues/gaps:</p> <ul style="list-style-type: none"> <li>• ethical AI</li> </ul>

Table 9: Potential entities/initiatives for an expanded community of practice

Entity/initiative (in alphabetical order)	Focus of activities
<a href="#">A+ Alliance</a>	AI algorithms that are inclusive of gender, race, class and regional diversity
<a href="#">Access to Knowledge for Development Center (A2K4D)</a> , The American University in Cairo	<b>A2K and inclusive development in MENA</b>
<a href="#">African Centre for Technology Studies (ACTS)</a>	African STI for sustainable development
<a href="#">Access Now</a>	Policy on digital security and privacy
<a href="#">African Centre for Economic Transformation (ACET)</a>	African economic transformation
<a href="#">Africa Digital Rights Hub</a>	Digital rights in Africa
<a href="#">African Economic Research Consortium (AERC)</a>	Economic policy in support of SDG 8
<a href="#">African Network for Economics of Learning, Innovation, and Competence Building System (AfricaLics)</a>	African innovation and development in support of inclusive, sustainable development
<a href="#">AI for Good</a>	AI in support of the SDGs
<a href="#">AI Now Institute</a>	Legal and policy resources on AI development and use
<a href="#">Berkman Klein Center for Internet and Society (BKC)</a>	Cyberspace development, dynamics and legal dimensions
<a href="#">Centre for International Governance Innovation (CIGI)</a>	Intersections between technology and international governance
<a href="#">Centre for Intellectual Property and Information Technology Law (CIPIT)</a> , Strathmore University, Nairobi	Policy, legal and practical dimension of IP and IT
<a href="#">Centre for Law, Technology and Society (CLTS)</a> , uOttawa Faculty of Law	Intersections of technology law, ethics and policy
<a href="#">Centre for Competition, Regulation and Economic Development (CCRED)</a> , University of Johannesburg	Competition, regional value chains, and local industrial development
<a href="#">Centre for the Study of the Economies of Africa (CSEA)</a>	Evidence-based economic policymaking
<a href="#">Datasphere Initiative</a>	Data governance
<a href="#">Data Trusts Initiative</a>	Data trusts in support of data use for empowerment and social benefit
<a href="#">Data for Development Network (D4D.net)</a>	Ethical data use in support of sustainable development in the Global South
<a href="#">Digital Asia Hub</a>	Ethical digitalisation
<a href="#">DSI/NRF/Newton Fund Trilateral Chair in Transformative Innovation, the Fourth Industrial Revolution and Sustainable Development</a> , College of Business and Economics, University of Johannesburg	Innovation and sustainable economic growth
<a href="#">DST/NRF SARChI Research Chair in Intellectual Property, Innovation and Development</a> , Department of Commercial Law, University of Cape Town	IP, innovation and development

<a href="#">Fairwork</a>	Labour practices in the platform economy
<a href="#">Feminist AI Research Network (A+) (FAIR Network)</a>	Technology needs of vulnerable women and girls
<a href="#">Future Earth</a>	Scientific solutions for sustainable development
<a href="#">Global Congress on Intellectual Property and the Public Interest (GCIP)</a>	Intersections between IP law and promotion of the public interest
<a href="#">Global Data Barometer</a>	Benchmarking on data for public good
<a href="#">Global Open Data for Agriculture and Nutrition (GODAN)</a>	Food security enabled by technology and open data
<a href="#">Global Institute for Food Security (GIFS)</a>	Innovation for food security
<a href="#">Globelics</a>	Innovation for development
<a href="#">Global Partnership on AI (GPAI)</a>	AI in support of human rights, innovation, economic growth, SDGs
<a href="#">Global Partnership for Sustainable Development Data</a>	Leveraging data in support of SDGs
<a href="#">International Lawyers and Economists for Development (IlaED)</a>	Empowerment of women and girls via trade, intellectual property, technology, e-commerce and regional integration
<a href="#">IT for Change</a>	Digital inclusion and governance
<a href="#">Knowledge Ecology International (KEI)</a>	Management of knowledge resources for social justice
<a href="#">LIRNEasia</a>	Development of knowledge, information, technology and infrastructures in Asia
<a href="#">LINK Centre</a> , University of the Witwatersrand (Wits)	African digital transformation and the African digital knowledge economy
<a href="#">Nigerian Institute of Advanced Legal Studies (NIALS)</a>	Research and training on Nigerian legal matters
<a href="#">Open African Innovation Research (Open AIR)</a>	Research and engagement on African collaborative innovation and collaborative knowledge governance
<a href="#">Open Data for Development (OD4D)</a>	Use of data in support of gender equality/inclusion, good governance, economic growth
<a href="#">Open Data Institute</a>	Equity in data access and use
<a href="#">Open for Good Alliance</a>	Access to unbiased, localised training data
<a href="#">Open Knowledge Foundation</a>	Freedom to use, build upon, and share non-personal information
<a href="#">Paris Peace Forum</a>	Democratic AI governance for equitable outcomes
<a href="#">Program on Information Justice and Intellectual Property (PIJIP)</a> , American University Washington College of Law	Research and debate on public interest dimensions of global IP policy
<a href="#">Public Citizen</a>	Public-interest consumer advocacy
<a href="#">Research ICT Africa (RIA)</a>	African research on data policy frameworks, open source digital infrastructures, responsible AI
<a href="#">South Centre</a>	Achievement of SDGs
<a href="#">Sustainability in the Digital Age (SDA)</a>	Digital transformation in support of climate-safe, sustainable development
<a href="#">Science Policy Research Unit (SPRU)</a> , University of Sussex	Research and engagement on STI policy and management
<a href="#">Trade Law 4.0: Trade Law for the Data-Driven Economy</a>	Global trade law on matters of data governance
<a href="#">Trade Law Centre (tralac)</a>	Improved African trade governance and policy processes to ensure sustainable development outcomes

<a href="#">UCT Intellectual Property Unit (UCT IP Unit)</a> , University of Cape Town	Research, training and engagement on IP, innovation and public policy
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### 5.5 An Agenda for Regulatory Research and Engagement

As this scoping study report has shown, there is a rich body of research documenting some of the fundamental problems around innovation regulation. It is clear from numerous examples, such as inequities in access to vaccines and other essential medicines, that the global innovation governance system is not adequately inclusive or sustainable. The newest generation of 21st century mega-regional trade deals is failing to address, and potentially exacerbates, problems caused by the multilateral regulatory rules established in the late 20th century (e.g. TRIPS). Some of the root causes are well known, and include:

- inequities in expertise about the appropriate design of innovation regulations;
- capacity shortfalls to participate in increasingly proliferating regulatory fora; and
- imbalances in bargaining power and coercibility to accept short-term trade-offs.

Given that the problems associated with regulating innovation are reasonably well understood, the priorities now need to be (1) deepening the research into core problems and, drawing on that research, (2) identifying solutions and (3) making those solutions known in relevant legal, policy and regulatory fora. This process of identification and proposing of solutions must be grounded in rigorous research, and must avoid the trap of being doctrinaire. Because as Baldwin et al. (2011) correctly point out, “we should be highly sceptical of regulatory solutions or designs that are couched in terms of single values— notions, for instance, that certain strategies will be efficient and therefore are justifiable and should be pursued without further debate” (Baldwin et al., 2011, p. 505).

This is difficult, because the regulatory environment that will determine how inclusive and sustainable innovation is going to be for decades to come is being set literally right now. And opportunities for real-time interventions arise quickly, sometimes with little or no warning.

For example, during the years when the HIV/AIDS crisis was attracting global headlines access to medicines was a hot topic. During some of the start of this century, there were numerous research funders, think tanks, and other non-governmental organisations active in this field. We have witnessed, however, significant ebbs and flows in interest. While funding for research and advocacy waned, academic interest did not. Funders’ interest was piqued again during the COVID-19 pandemic, but a lack of long-term investment in the organisations doing the research and policy groundwork, especially in lower-income countries, made it difficult to impact real-time developments. We think we can learn from this experience by being more ready for the next regulatory flashpoint, which means anticipating the regulatory issues right now “in the pipeline” so to speak.

As seen in Table 7 above, there are numerous entities and initiatives working to influence regulatory norms and rules impacting innovation in LMICs. And as seen in Table 8 above, there are numerous potential entry points and gaps—at global, regional, and national levels—for engagement with regulatory instruments and issues impacting innovation in LMICs. What is needed, however, is a more systematic and strategic approach to engagement with the entry points—so as not to miss out on opportunities to shape the emerging innovation regulation landscape. This systematic and strategic approach would ideally comprise three streams of activities: (1) a rapid-response programme; (2) a momentum catalyst; and (3) on-the-ground field-building.



### **5.5.1 Rapid-Response Programme**

A rapid-response programme could support the engagement of independent experts in real-time innovation-related law- and policymaking, working through the entry points, and focusing on the issues/gaps, outlined in Table 8 above. This would include hosting high-profile side events at meetings of key agenda-setting fora, embedding experts into negotiations to support teams from lower-income countries, and taking a seat at the table where new rules are now being set. Among the most notable entry points and issues/gaps that have the potential to yield dividends through rapid-response interventions are:

- AfCFTA development of regulations around investment, intellectual property, and competition;
- WTO work on the TRIPS waiver agenda;
- WIPO work on intellectual property limitations and exceptions, especially vis-à-vis digital and online learning materials;
- UNFCCC Secretariat (UN Climate Change) and WTO work on the development and transfer of clean technology innovation; and
- FAO, WHO, CBD Secretariat (UNEP) and WIPO IGC work on the regulation of digital genetic sequence information, i.e. dematerialised genetic data that drives R&D across all life sciences.

While some of these topics may seem disparate, they are all affected by the same or similar meso-level regulatory frameworks that govern core drivers of innovation, especially knowledge and data.

### **5.5.2 Momentum Catalyst**

A momentum catalyst would gather, reinvigorate, and deepen the network-of-networks concerned with regulation of innovation. A movement of academic researchers and policy activists was active in these fields during the 2000s and 2010s, but the community of practice has sputtered somewhat due to the withdrawal of support for key organisations and activities and the global pandemic that put a hiatus on idea-sharing and momentum-building events. Fortunately, the pandemic also put a hiatus on the negotiation of new regulatory norms, but we have witnessed in recent months that these regulatory processes are coming alive again. It is imperative that researchers and policy activists catch up, re-energise, and develop new strategies to put the ideas we have all been working on into immediate practice in norm-setting fora. Fortunately, as seen above in Table 9, there are numerous entities and initiatives that can potentially be drawn into the reinvigorated community of practice.

### **5.5.3 On-the-Ground Field-Building**

On-the-ground field-building could occur through feedback and new exploratory research. One of the reasons certain researchers and research networks have been impactful in various fora in the past is that they are trusted as objective brokers of evidence-based research and expertise. Moreover, these researchers and networks are known to have their finger on the pulse, so to speak, of the newest issues, including those coming quickly down the pipeline. In order to maintain these strategic positionings in and around norm-setting fora on matters of regulation of innovation, ongoing field-building is necessary.

There are two important elements here. One is continuing to do boots-on-ground research with grassroots stakeholders affected by, and needing to be enabled by, innovation policy—so that insights brought “up” to policymakers are not merely theoretical but are also relevant and practical. The other is continuing to invest in the next generation of research leaders working on matters of regulation of innovation, mentoring and empowering them to carry out their activities long into the future, thus addressing the capacity deficits that are among the root causes of unequal and unsustainable innovation regulatory frameworks.

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