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Post COVID-19 Implications for Genetic Diversity and Genomics Research & Innovation: A Call for Governance and Research Capacity

White paper

June 2021

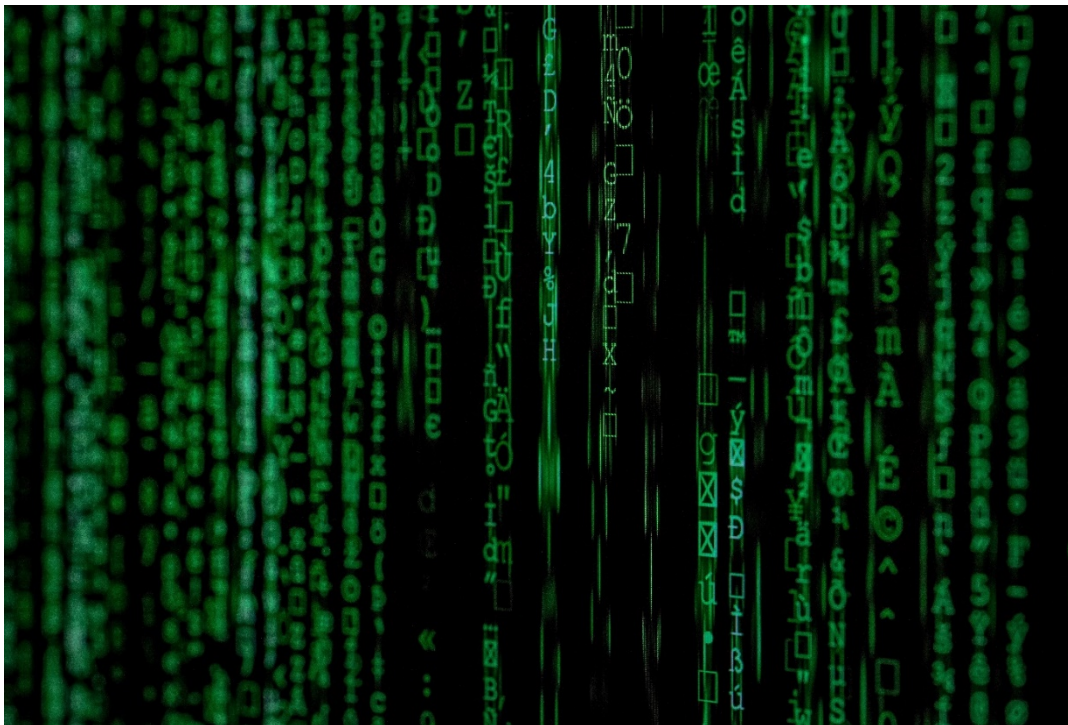


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About this Report

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This white paper emerged from an independent expert consultation commissioned by the Secretariat of International Treaty on Plant Genetic Resources for Food and Agriculture at the Food and Agriculture Organization (FAO) of the United Nations, with support from the Government of Italy. The purpose of the consultation was to identify the lasting impacts and the institutional and policy implications of COVID-19 for genetic diversity and genomic research and innovation, with a special focus on open access, global equity and science capacity.

The Center for Science, Technology and Environmental Policy Studies at Arizona State University, the French Agricultural Research Centre for International Development (CIRAD) and Keystone Policy Center convened, led and facilitated the consultation.

Participants in the expert consultation, as well as additional invited experts and acknowledgements, are listed in Appendix D.

TABLE OF CONTENTS

Executive summary.....	1
1. Context: COVID-19 and governance challenges	2
2. Macro-, meso- and micro-levels of governance of genetic diversity and genomics research and innovation.....	6
3. Limitations of current macro-level and micro-level governance frameworks	9
4. Meso-level collaborative governance: exploring opportunities in global research initiatives..	12
5. Aims and recommendations.....	17
6. Implementation steps.....	24
Appendix A: Selected takeaways from the case studies.....	25
Appendix B: Intellectual foundations	27
Appendix C: References	29
Appendix D: Acknowledgments and Participating Experts.....	32

Executive summary

At a time of significant technological change and digitization in the biological sciences, the COVID-19 pandemic has highlighted again the inequities in the research and innovation ecosystem. Based on a consultation with an internationally diverse group of stakeholders from multiple fields and professions, and on a broadly representative set of case studies, this report offers a new approach to the global governance of genetic diversity and genomic research and innovation.

We recommend that in addition to the many valuable efforts at the macro-policy level and at the micro-level of projects, teams and organizations, **the global community concerned with genetic diversity and genomic research and innovation should devise and implement a meso-level initiative that includes three main components:**

1. First, it should establish a new professional capacity to govern research and innovation at the meso-level.

Governance capacity, built through a networked community of practice, has the benefit of connecting and integrating macro-level policy intentions with micro-level actions. It facilitates a consistent professional basis from which local and regional level flexibilities can generate new norms of reflection that better integrate multiple synergies, reconcile tensions, recognize inequities, and redress persistent inequalities.

2. Second, the global community should redouble efforts to build research capacity in genomic research and innovation in the Global South and for Indigenous Peoples.

Such an effort should be focused on

broader programmatic objectives that facilitate cross-national and cross-regional collaboration, as well as enhancing research communities in the Global South and in Indigenous communities. Together, the twin capacities of governance and research can reduce power differentials among diverse actors and support crisis-based imperatives for data openness.

3. Third, we recommend that existing global policy frameworks interface with research governance and capacity investment. This meso-level approach should gain the commitment and support from national and international policy bodies, embedded within existing specific issue-areas (health, agriculture, environment).

A new approach, one that can better respond to global crises through more open, inclusive and equitable participation in research and innovation, is necessary to resolve the tensions among openness, innovation and equity that the current discourse on genetic diversity reiterates. Failure to systematically address the social and technical governance challenges will result in further fragmentation, inequity and vulnerability for decades to come. Conversely, investing in the current historical moment of the pandemic to build twin capacities for meso-level governance and research is poised to prevent and/or reduce the impact of future ecological crises, while contributing to planetary sustainability and prosperity in the 21st century for current and future generations.

1. Context: COVID-19 and governance challenges



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The acceleration of global research in response to the COVID-19 pandemic has contributed to unprecedented and rapid development and dissemination of data, scientific knowledge, technologies and products for human health. It has leveraged the revolution of genomic science and engineering. Yet, the crisis has also uncovered that stark differences in human, technical and governance capacity across countries that have limited inclusivity and diversity of research teams and research priorities (Johnson, 2020). Acceleration of open data sharing has raised concerns about disparities in who will benefit from the knowledge and products accruing from research, data weaponization and misuse, and consistency of benefits with the self-identified needs of historically marginalized communities, including communities in the Global South and Indigenous communities (Aryeetey *et al.*, 2021; Peeling *et al.*, 2020). While international collaboration has played an important role in understanding the virus, competition in vaccine development and procurement have also reinforced concerns regarding benefit distribution.

These COVID-19 tensions echo those that have been detected in the global governance

of plant genetic diversity, in the age of big data, digitalization and 'dematerialization' of genetic resources exchange and improved genome editing (Welch *et al.*, 2017) (see Box 1 for more information about plant genetic resources).

Convergent governance tensions of openness, competition and equity in human health and agriculture highlight the need for effective governance of genomic data, research and innovation to address global challenges. Such a governance system must navigate among: free and unrestricted access to information for science; the control of information in order to extract and capture economic and reputational value; and the integration of considerations of inclusion, capacity, sustainability and other societal objectives to inform prioritization of needs and distribution of benefits to diverse beneficiaries.

The Secretariat of International Treaty on Plant Genetic Resources for Food and Agriculture (International Treaty) at the FAO, with support from the Government of Italy, commissioned an independent research project to identify the lasting impacts and the institutional and policy implications of COVID-19 for genetic diversity and genomic research and innovation, with a special focus on open access, global equity and science capacity. This White Paper is the result of the independent research project. The recommendations of the White Paper offer an approach to better navigate the tensions of openness, innovation and equity.^{1,2,3}

¹ The independent expert consultation did not address specific issues that are currently under consideration in access and benefit-sharing negotiations, within the International Treaty and in other genetic resources fora, such as terminology and whether genetic sequence data should be included in the scope and operational mechanisms of access and benefit-sharing, in the current or enhanced forms.

² The scope of this White Paper is genetic diversity and genomics research and innovation, as a continuum of collaborative activities where resources are generated, share and used. Given the selection of case studies and the focus on governance that participating experts have opted for, this white paper addresses neither the impact of intellectual property on, nor the role of private sector in, research and innovation. Along the same lines, the recommendations of the white paper do not discuss actual or potential forms of benefit-sharing linked to the commercialization of services and products.

³ Additional information about the consultation and a list of participating experts is in Appendix D to this White Paper.

Box 1: Plant genetic resources

The policy and regulatory framework of plant genetic resources exemplifies some of the current governance challenges of genetic diversity and genomic research and innovation as related to widening scientific research and capacity gaps.



It was designed to pursue global goals such as biodiversity conservation and sustainable use, in a context in which informational components were always considered in relation to biological materials. It is therefore based on the regulation of access to physical samples of genetic material and the allocation of benefit-sharing arising from the use of such material (access and benefit-sharing, or ABS).

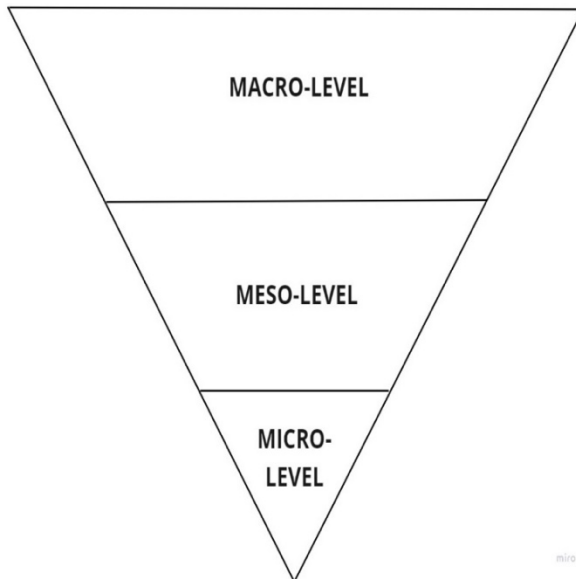
The increasing use of genetic information and DNA sequences as standalone components, along with more accessible and improved genome editing and assembly tools, are making crop research and innovation increasingly dependent on digitalized information, with a reduced interest in access physical samples. Global policy discussions on plant genetic resources are largely polarized around two principles: free and unrestricted access to data and information for the benefit of open science, and the expansion of ABS requirements to include genetic information. In the governance framework of the International Treaty (www.fao.org/plant-treaty/en), negotiations to improve the ABS system among participating countries have not yet produced an agreement on inclusion of genetic information, mostly due to lack of shared values and divergent views between research and industry vis-à-vis developing country stakeholders.

In parallel, other global governance forums are debating the status of genetic sequence data, while developing countries are adding national ABS legislation for research using genetic information extracted from genetic resources under domestic jurisdictions.

Following the COVID-19 outbreak, plant science stakeholders and private sector have taken the example of human health research to reiterate openness as an essential prerequisite for genomics research and innovation. Civil society and developing countries are amplifying concerns related to benefit-sharing as an essential condition for global public goals associated with the management of plant genetic diversity. Because science, technology and governance systems do not operate in isolation, governance tensions are increasingly apparent among multiple stakeholders, across sectors and countries, and at all levels of genomics research and innovation, including teams, networks, and local, national and international organizations.



2. Macro-, meso- and micro-levels of governance of genetic diversity and genomics research and innovation



The consultation recognized that three scales of governance – macro, meso and micro – are relevant for understanding global governance of genetic diversity and genomics (GDG) research and innovation.

In short, macro-level level includes global, regional and national level agreements, legislation, policy and rules. Micro-level refers to the norms, expectations, rules, and behaviors that operate at the research and innovation level carried out by individuals and teams. The meso-level includes the organizations, initiatives or networks and the actors within them that work together to accomplish tasks that further the collective goals. The meso-level mediates and interrogates the space between macro- and micro-levels in two directions: downwards to

flexibly activate macro-level guidelines at the micro-level and upwards from the micro-level to inform broader approaches about local context including capacities, inequities, values and needs.

Box 2 defines governance and provides further discussion that includes distinctions and trade-offs.



Box 2: Defining macro-, micro-, and meso-levels of governance

Governance implies the processes and institutions, both formal and informal, that guide and restrain the collective activities of a group. Government is the subset that acts with authority and creates formal obligations. Governance does not necessarily need to be conducted exclusively by governments. Private firms, associations of firms, universities and other research institutions, nongovernmental organizations (NGOs), and associations of NGOs all engage in it, often in association with governmental bodies, to create governance, sometimes without governmental authority (Keohane and Nye, 2000). Within this conception of governance, distinctions among macro-, micro-, and meso-scale governance are idealized.

Macro-level governance comprises legally-based frameworks that operate at the national, multi-national or global scale. These include frameworks, agreements and policies designed to provide broad guidance and generate benefits across multiple actors. Macro-governance offers scale and coordination of authority, including through formal bilateral or multilateral agreements such as the International Treaty or the Convention on Biological Diversity. The benefits of these broad governance frameworks are often challenged by structural limitations that limit flexibility and adaptability for responding to technological change, social complexities or crises. Similarly, the macro-level frameworks are often far removed from actors and teams at the micro-level, making them less responsive to realities of science collaboration, for example, and less able to address complex social and resource inequities.

Micro-level governance comprises individual, bilateral or small-scale groups of multilateral actors. Micro-level governance often occurs at the collaboration level. While it offers flexibility for learning and innovation and may have its own authorities and legally binding structures, it lacks scale, consistency, and the ability to connect to macro level governance.

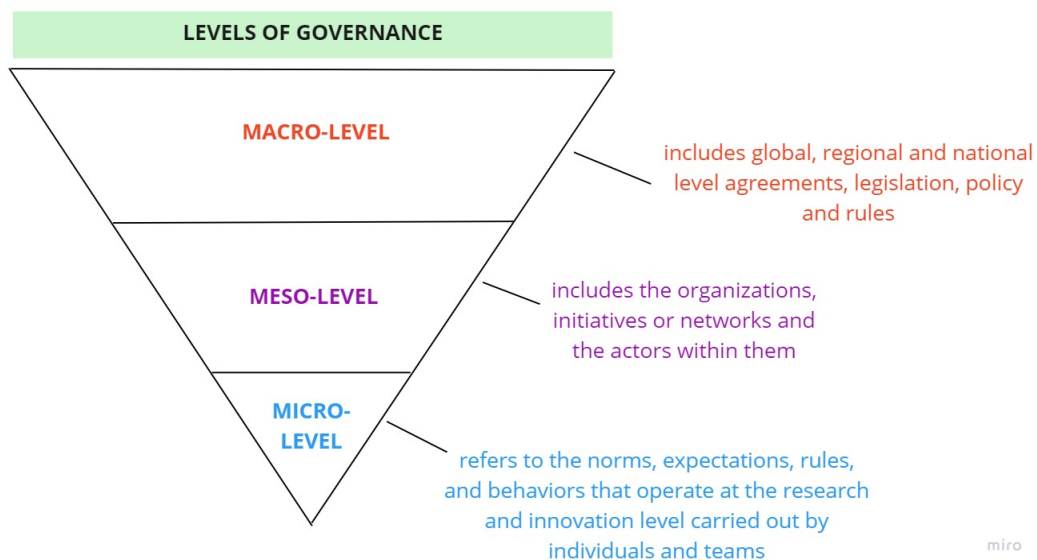
Meso-level governance occupies the middle ground between macro- and micro-levels. It operates through formal and informal means to navigate and bridge the constraints and limitations of the other two levels. Actors may include scientists, governance experts or other stakeholders who are employed in any sector. These actors come together in a particular domain – such as regional collaboration on genomic research – to propose, decide on, implement and assess the rules, procedures and acceptable practices that all participants at the micro-level shall follow. Meso-level governance works within the macro-level guidance, accepting its aims and principles, but seeks practical solutions to addressing multiple, often conflicting values and perspectives, at a local or regional level. The meso-level also values micro-level diversity and variability and acts to reconcile tensions and complexities that arise from technological changes (e.g., the big data revolution in the life sciences), power imbalances, inequities and capacity gaps (e.g., genomics research ability, financial resources, etc.). Meso-level governance:

- Operates through networks, associations, and regional initiatives or groupings and is

generally inclusive of actors from multiple backgrounds who represent different interests, values, identities and legal regimes or contexts.

- Functions within a particular domain, based on substantial knowledge and experience, to instill knowledge and establish guidelines for collaboration. Actors at the meso-level often collectively create goals and norms that are socially, rather than legally, binding. The meso-scale does not reject national legal regimes, but rather seeks to integrate and reconcile multiple legal, ethical, technical and administrative objectives for feasible implementation.

Requires various resources beyond financial resources including: knowledge and skills, infrastructure, venues for discussion, interdisciplinary knowledge, and capacity for collaboration and governance of collaboration in a digital age. Most often, these resources are financed by multiple funders, which enhances collaboration but also adds fragility to the system in the longer term.



The initial postulation of the expert group was that emerging 'meso-level' collaborative governance approaches might serve as potential pathways to address limitations of global frameworks. In collaboration contexts that involve heterogeneous actors (in terms of interest, status and capacities), who have limited knowledge about rights and obligations set out in macro-level frameworks, solutions at the meso-level must go beyond existing or accepted governance arrangements to collectively explore alternative governance solutions that better resolve the tensions between openness, equity and capacity. In essence, the meso-level must proactively address the limitations of the macro and micro-levels.

3. Limitations of current macro-level and micro-level governance frameworks

The expert group discussed and identified limitations of current macro- and micro-level frameworks that new governance approach should overcome.

3.1 Limitations of the macro level

Existing macro-level governance frameworks of GDG research and innovation are important yet insufficient mechanisms for addressing tensions of openness, innovation and equity. Macro-level governance frameworks impact GDG research and innovation at the micro-level of scientific and collaboration practices through different mechanisms (access to research inputs, data access and sharing, intellectual property rights, capacity building) and respond to different challenges (e.g., sustainability and equity). With evolving science and technology and the multiplication of innovation pathways, this structure becomes unrealistic and burdensome as it fails to account for existing normative and organizational resources that are essential in order to mediate between macro and micro levels.

The consultation identified five limitations of macro-level frameworks:

- a. **Power imbalances:** The uneven distribution of capacity, infrastructure and financial resources creates power imbalances at the macro-level resulting in conflictive representation of the norms and needs of wealthier groups and countries vis-à-vis less resource-endowed groups and countries.
- b. **Exclusionary logic:** Current macro-level frameworks usually rely on a narrowly defined set of monetary and regulatory incentives and disincentives to promote research and innovation and manage structural inequities and behaviors. Market-based policy tools (i.e., taxes, subsidies) often correct for negative externalities at the expense of other values –public or common goods, societal impact, ethics, and social responsibility – that are yet essential for the success of meso-level initiatives. As a result, framing of problems and solutions can oversimplify complex social, political, economic, environmental, technological and scientific contexts.
- c. **Policy-science disconnect:** GDG research and innovation is best represented as a complex system in which heterogeneous actors from a variety of disciplines and sectors produce new knowledge, resources and innovations through a non-linear, feedback-rich process over time in which it is increasingly difficult to distinguish resource inputs from outputs. Nevertheless, current macro-level frameworks tend to treat research as a linear process in which different policy frameworks regulate research and innovation inputs and outputs.
- d. **Incomplete approach to capacity:** Capacity is best understood as the ability to not only access and use genomic data but also to contribute and use metadata and other types of relevant data, participate in building the standards and ontologies that underlie the digital commons, and participate in their governance. Current policy approaches often fail to account for complex differences in capacity. Consequently, demands for reciprocity for knowledge and

resource sharing can create barriers to collaboration and exchange.

- e. **Static design:** Even as current macro-level policy frameworks slowly reorient to respond to changes, technological change evolves even

more rapidly. As a result, macro-level frameworks cannot keep up with technological change and may not be able to accommodate innovative collaboration governance approaches that balance tensions of openness, innovation and equity.



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3.2. Limitations of micro-level

At the micro-level, researchers are generally working in small collaborative teams, some of which extend across national boundaries, cultures, disciplines, ways of knowing and interests. They often do not understand or recognize macro-level governance initiatives that are intended to guide decisions and behaviors at a micro-level. Moreover, while generally collegial, team members often vary in reputation and authority, and are not aware of collaboration governance tools that can fairly and effectively reconcile possible conflicts in values.

The consultation identified four possible areas of limitation at the micro-level that could be addressed by meso-level approaches to governance:

- 1. **Power imbalances.** The uneven distribution of research capacity, resources and infrastructure creates

power imbalances among researchers and teams at the micro-level, favoring those with more resources and capacities.

2. **Lack of inclusive knowledge.** In the current research and innovation context organizations prioritize categories of scientific expertise (natural sciences, engineering and technology, medical and health sciences, agricultural sciences) and often exclude the expertise and perspectives of social science as well as practitioners and traditional knowledge systems. As a result, the science-policy interface does not effectively represent diverse sets of knowledge and ways of knowing.

3. **Lack of connection with macro-level objectives.** Macro-level policy guidance or codes of conduct can have variable applicability to specific research projects that are not mutually reinforcing, and that do not build persistent and sustained capacity in the long run. Additionally, multiple and changing macro-level initiatives can lead to confusion at the micro-level.

4. **Lack of research governance expertise.** Scientists and teams are often unaware of relevant governance practices, lack experience or training, and do not know where to obtain governance expertise.



@FAO/Ferenc Isza

4. Meso-level collaborative governance: exploring opportunities in global research initiatives

To understand how the meso-level is currently operating, the expert consultation identified the following nine case studies as potential examples of meso-level collaborative research and innovation:

- 1) African Orphan Crops Consortium
- 2) Bioleft
- 3) CARE Principles for Indigenous Data and Governance
- 4) The Global Indigenous Data Alliance
- 5) CGIAR Big Data Platform
- 6) Council for Health Research for Development (COHRED)
- 7) Just One Gian Lab (JOGL)
- 8) ERACoBiotech
- 9) Global Alliance for Genomics and Health (GA4GH)

The description of the case studies is provided in Appendix A.

The expert consultation did not undertake in-depth analysis of each initiative, but rather engaged through a series of one- to two-

hour webinars, each featuring one to three case studies. Through presentation and discussion, we sought to understand how these organizations and networks organize and govern themselves through both instrumental and normative dimensions of governance; incorporate various institutional logics; balance tensions of openness, equity, and capacity in genetic diversity and genomics research and innovation; create adaptive learning/responsiveness to new context; connect with macro-level frameworks and global UN development goals.

The preliminary findings reflect evidence presented and initial impressions and themes across these case studies, rather than the conclusions of exhaustive investigation. We articulate the findings in three areas, namely: a) tensions; b) COVID-19 implications and limitations; c) governance.

a) Tensions

Across all case studies, common tensions among openness, equity, and capacity are apparent and a number of gaps in addressing those tensions emerge.

- Requirements for transparency and openness with the goal of increasing access to data may drive opposite outcomes by excluding organizations with limited capacity and unable to comply with heavy infrastructure requirements.
- None of the case studies follows a comprehensive approach to capacity, which was reflected by a division of technically-focused initiatives vs. equity-focused initiatives, with only few addressing both design and practice.
- Some requirements or guidelines aimed at advancing equity are so stringent that they require extensive legal advice and compliance monitoring, which only well-funded research institutes can afford.
- Voluntary commitment creates a disadvantage for those entities with limited capacity or limited resources.

- There is limited transparency about (agri)business interests in collaborative research initiatives.
- Sustainability issues for collaborative research, such as a mismatch with funder goals, or lack of long-term donors, are apparent.
- All case studies are weakly connected to global policy, showing a

stronger connection with micro- rather than macro-level actors. While this bottom-up approach has advantages to promote trust, equity and access, there may be tradeoff in how effectively these solutions can scale.

b) COVID-19 implications and limitations

The experts found that the COVID-19 pandemic provided opportunities for innovation but also exacerbated inequities and power imbalances. In many of the case studies, existing gaps and tensions were amplified due to COVID response. Common experiences include:

- Increased time pressure to address the pandemic, leading to quick decision making that may or may not consider equity and openness issues that would be addressed under normal circumstances.
 - Due to emergency and short timeline, genomics research and innovation may not move towards inclusion, and instead generate exclusion due to structural default. As meso-level solutions rely on voluntary participation, this can exclude actors with limited capacity.
- With the creation of new ways to collaborate due to social distancing, a majority of organizations are now

even more reliant on virtual collaboration, which has benefits and drawbacks:

- Virtual collaboration allows for many more diverse stakeholders to have access to resources and be involved in large meetings by removing barriers (funding, travel capacity, etc.).
- However, it is extremely difficult to build the trust and deep lasting partnerships that are needed for sustainability with digital collaboration.
- Also evident on a global scale is a general lack of trust in data, especially related to COVID-19.

c) Governance

The findings from all the case studies indicated that systems to govern research collaboration are either absent or organization-specific. For example, some cases focus entirely on providing technical solutions to providing secure repositories and offering options for facilitating openness and sharing genomic data (CGIAR Big Data Platform; African Orphan Crops Initiative). Others produce statements and guidelines to increase awareness and advocate appropriate practice for the use of genomic data in research (CARE), or act as brokers of services and tools for health research collaboration (COHRED). Some large networked international research collaboration organizations have relatively nascent research governance systems in place (JOGL) while others have more advanced designs that integrate multiple governance considerations in all aspects of research (GA4GH).

Three major observations from all case studies point towards inconsistent connections between macro-level policy and micro-level collaborative research and innovation.

- While some research organizations articulated well the need for and the responsibility to act on collaborative governance that addresses data challenges, inequities and the conflicts associated with international research collaboration, some were less clear. There is a patchwork of approaches to governance of research and innovation, with some much more deliberate and explicit than others. This demonstrates the inconsistencies of international research governance and the absence of organized collective learning processes on the conditions of success of governance arrangements, despite the existence of global institutions.
- One organization, GA4GH, had developed complex governance system that recognizes the social, legal, technical, economic and ethical complexities that are embedded in genomic research. GA4GH has undertaken an effort to build its own capacity to understand and address these complexities through a flexible but highly skilled, experienced and project-specific governance approach. This demonstrates not only the need for meso-level governance action, but also provides an example of a successful effort.
- Important initiatives such as COHRED and CARE, which propose principles, norms and procedures on research governance, are not recognized and integrated into macro-level governance systems at scale. As a result, despite some isolated examples such as GA4GH, there is no systematic uptake and integration of important governance knowledge and stakeholder perspectives in international collaborative research. While there are many reasons for the inconsistencies, this demonstrates the limited integration of global norms for the effective and equitable conduct of research.



After further review and discussion, and informed by the cases, the consultation of experts developed the Table 1 to articulate the potential for a meso-level approach to address the limitations of the macro-level.

Table 1: Meso-level potential to address the limitations of the macro-level

Limits of macro-level	Potential meso-level benefits
<i>Power imbalance</i>	<ul style="list-style-type: none"> • Offset governance and normative tensions by reconciling at the meso-level. • Benefit from more effective contributions of developing countries to global policy frameworks. • Foster adequate operationalization, implementation, and harmonization of existent standards such as the Research Fairness Initiative and similar guidelines. These frameworks promise to assure more procedural fairness and offer more opportunities to developing country researchers to participate in the agenda-setting.
<i>Narrow incentive structure</i>	<ul style="list-style-type: none"> • Contribute to designing and adjusting complementary governance tools based on wider incentives.
<i>Policy-science disconnect</i>	<ul style="list-style-type: none"> • Recognize science -- especially in an era of big data -- as a non-linear, dynamic social process with interrelated inputs and outputs • Learn from meso-level governance experiences and build more evidence-based assessment of governance outcomes (nexus of policy, governance and practice).
<i>Incomplete approach to capacity</i>	<ul style="list-style-type: none"> • Build the capacity of collaborative actors to embed responsible governance approaches into the development and oversight of science, integrating equity concerns and managing heterogeneity (e.g., of resources, actors, geographies, etc.) directly within the process of science and innovation. • Take a holistic approach towards science environments and strengthen overall research capacities in targeted countries, and at the same time harmonize policies with aid donors and research funding-organizations in multilateral activities.
<i>Static design</i>	<ul style="list-style-type: none"> • Create the basis for constructive contestation of existing frameworks and policy reorientation. • Responsive to dynamic developments in science and innovation and informing global institutions of those developments in order to design adequate global policy responses.

A meso-level approach to the governance of genomics research and innovation also generates significant potential benefits for the micro-level (Table 2).

Table 2: Meso-level potential to address the limitations of the micro-level

Limits of micro-level	Potential meso-level benefits
<i>Power imbalance</i>	<ul style="list-style-type: none"> • Address differences in power among actors that limit participation either in collaboration or the governance of research and innovation; minimize expectations of reciprocal capacity and contribution as a basis for participation. • Integrate equity into project goals and methodologies.
<i>Lack of inclusive knowledge</i>	<ul style="list-style-type: none"> • Harmonize donor-policies with regard to the use of expertise, giving preference to local knowledge bases and experts from local universities through open agenda-setting processes and the formulation of research questions. • Benefit from diverse expertise and research engagement in project implementation. • Harness and reconcile competing institutional logics – academic, market, commons, societal impact, ethics/responsibility – in ways that enable inclusive, interdisciplinary research and innovation while building communities and trust.
<i>Limited research governance expertise</i>	<ul style="list-style-type: none"> • Improve project implementation by adding specific governance expertise (e.g., to reduce tensions among openness, capacity and equity issues, and amplify research engagement and uptake).
<i>Limited connection to macro-level</i>	<ul style="list-style-type: none"> • Connect projects to macro policy objectives. • Contribute to feedback to, and monitoring and evaluation of global policy frameworks.

5. Aims and recommendations

Given the observations from the meso-level case studies, it is clear that a novel, more systematic approach for governing research and innovation collaboration is needed to better resolve the multiple tensions that have arisen and/or been underscored during the COVID-19 pandemic. The approach should not only proactively address inequities that arise during future crises, but also provide a stable basis for coordinating and reconciling diverse logics, rules, norms, capacities and perceptions. It also calls for broader recognition of the responsibilities of all actors to better reflect on and engage and invest in collaborative governance of research and innovation. As human-natural systems continue to generate immense global challenges, it is increasingly important to build diverse international research alliances that produce new knowledge and science and engineering solutions that increase resiliency.

Systematically addressing social and technical governance challenges can reduce fragmentation, inequity and vulnerability for decades to come. The confluence of dynamic changes in technology from material to data, the limitations of many macro-level multilateral agreements, and the COVID-19 pandemic provide a critical historical juncture and momentum to recommend implementation of a new meso-level governance system for GDG.

Our recommendations are based on specific aims that build from case studies and the expertise of participants in the consultation. All four aims support our overall goal to devise a feasible, systematic meso-level collaborative governance system for genetic diversity and genomics research and innovation that will proactively address multiple issues (openness, efficiency, and equity) to better respond to global crises.

Aims

Aim 1:

Create both research and governance capacities at the meso-level that balance conflicting tensions, address power differentials, and minimize inequities of access to scientific, engineering and social science research collaboration;

Aim 2:

Create a platform to integrate knowledge, experience and insights from existing global collaboration efforts, networks, teams and individuals that have begun to address meso-level governance at the project level;

Aim 3:

Build norms and mechanisms that reflect diverse capacities, worldviews, expertise and ways of knowing within international collaborative teams, projects and programs to help create an inclusive governance process;

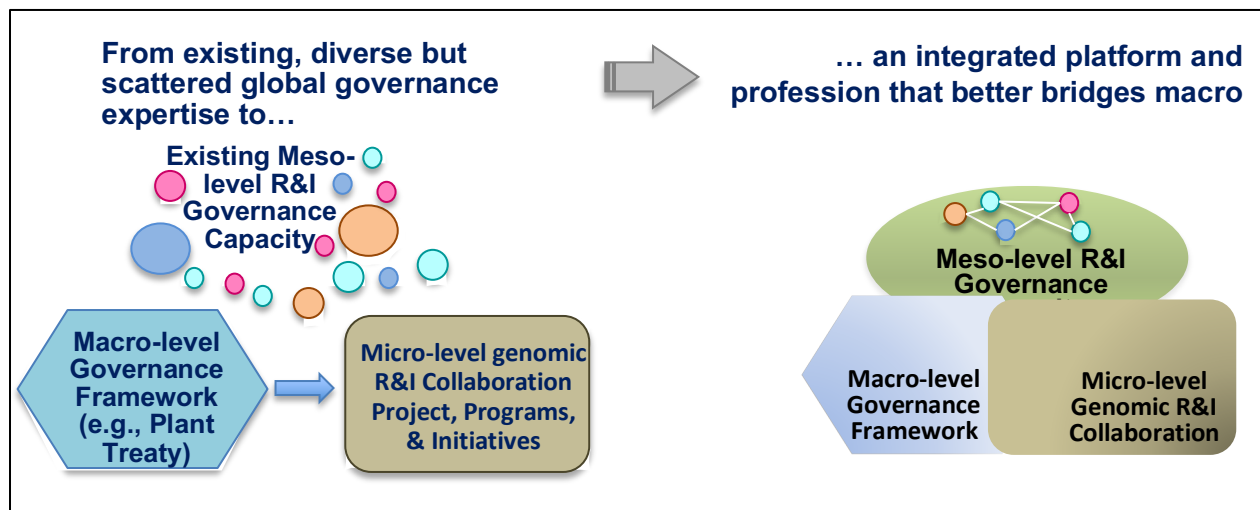
Aim 4:

Identify key international actors (e.g., agencies and organizations) to validate and support an integrated meso-level governance approach.

Recommendations

To address these aims, the consultation recommends the development of meso-level collaborative governance capacity that bridges and complements existing macro-level global frameworks while at the same time facilitating international research and innovation at the micro-level. Development of meso-level governance capacity occurs through the explicit integration of existing governance resources, actors and initiatives into a new expert-led platform, and the design and implementation of a roadmap that activates macro-informed, meso-level governance tools at the micro-level. The meso-level governance capacity will simultaneously address the tensions related to global research and innovation, but also build a community of professionals who apply specific tools and principles for guiding international research collaboration. The meso-level effort is enhanced and strengthened by further refinement at the macro- and micro-levels. Our vision addresses the macro-micro governance gap, which is visualized in figure 1.

Figure 1



Specifically, we propose undertaking a broad-based effort to build and sustain a global research and innovation governance system that includes three main recommendations:

- 1) establishment of new professional capacity to govern research and innovation at the meso level;
- 2) redouble efforts to enhance foundational research capacity in genomic research and innovation in the Global South and for Indigenous Peoples; and
- 3) garner commitment from international policy bodies that recognize and enable meso-level designs both at the issue area specific and multinational contexts.

Recommendation 1: Establish and organize a new globally networked meso-level profession - supported by a community of practice - for the governance of research and innovation, including the development of complementary governance tools.

We recommend establishing a new global meso-level governance profession that takes up the challenge of navigating the space between macro- and micro-levels for the governance of international collaborative research. The new profession would establish forums for meeting to review, plan and coordinate activities. Actors would include individuals from all sectors and regions, all of whom would have different backgrounds, skills, interests and perspectives. All actors would obtain the skills and knowledge necessary to understand and interrogate complexities of a particular research project, program, network or initiative. Initially, diverse actors with diverse skills would participate in founding the profession and establishing the coordination platform. Over time, curricula and experiential training would build skills and knowledge base of broader membership of research and innovation governance experts.

Additionally, we propose a set of allied policy tools that can be used by the profession, refined in ways that build governance capacity, facilitate development effective governance solutions in local contexts, and begin to establish critical norms. This approach mobilizes and synthesizes existing expertise as the basis of the new meso-level profession, increasing the international capacity of research and innovation governance that is responsive to macro-level policy on genetic diversity and genomic research and innovation, new technological changes such as dematerialization and the digital revolution and the realities of research and innovation.

1.1 Establishment and Planning:

Establishment of the profession would be built with support from the global macro-level

on a consciously designed organizational and self-governed structure that would be acceptable to the diverse community, identify principles for collaborative and reflexive governance, and develop training and knowledge base for the profession. The profession would form an association that would provide a central coordinating structure, set goals, create necessary programs and develop evaluative mechanisms to assess effectiveness and progress. The profession would operate as a moderately centralized global network, in which members are connected to the core group of stakeholders, as well as to each other in local or regional communities of governance practitioners. The meso-level organization would facilitate network-wide communication and coordination, but also facilitate flexible local or regional governance discretion.

As a global meso-level initiative, the governance profession would connect to the macro-level through support and input from United Nations agencies and other international organizations. It would also acknowledge and integrate existing initiatives as important components of and sources of input to the profession. At the micro-level, it would connect to individual researchers and collaborative teams by providing contextually relevant expertise and input on governance. Because such a profession risks becoming a new area of power and knowledge inequities, it should be confined to create the conditions for reflection and learning that can support and enhance international collaborative research toward goals integrating openness, equity, interconnectedness and capacity.

1.2 Developing the Practice: As a second step, the profession would develop a

research and innovation governance training program. Training would be built on: 1) a consolidated curriculum drawing existing and emerging knowledge bases in governance and decision-making, global policy regimes, collaboration and team science, ethics and inclusive learning; 2) governance case studies to build knowledge; 3) conflict resolution, evaluation and monitoring; and 4) experiential learning such as through temporary placement in major government research programs, companies, national labs, science-policy interface bodies or public agencies. Core competencies could include: data management/digital skills; science policy; innovation and intellectual property law; Indigenous and traditional rights and knowledge; research governance and administration; research ethics; team science and collaboration, conflict negotiation, and evaluation. We recommend the establishment and curation of an online resource library of global governance materials to provide a knowledge repository and reference valuable to both training and practice. The resource library would include the stock of guidelines and codes of conduct (e.g., FAIR (<https://www.go-fair.org/fair-principles/>), CARE (<https://www.gida-global.org/care>), industry codes of conduct, etc.), case studies and other assessments, grey literature, open-source academic literature, among other items.

Research and innovation governance training would be designed in modules and offered online. Specific training modules would be developed by sub-community governance experts in collaboration with key stakeholders. For example, a module on data governance could be developed by practitioners or academics in collaboration with stakeholder experts on FAIR or CARE principles. Finally, as with most professional groups, it would include a learning component such that would collect and disseminate best practices, exemplary case studies and relevant literature. It would also

organize decentralized interactions of actors through engagement in collective inquiry processes. It would finally undertake evaluative efforts on both formative and summative bases as a means of continued improvement.

1.3 Researcher Training: As a third step, the governance profession would develop a researcher-level certification program designed to inform researchers in genomics and data about the ethical, power and value complexities of global research and innovation. We envision this researcher-level training to be offered through a system such as CITI, which operates world-wide for investigator-level training on research with human subjects and animals (<https://about.citiprogram.org/en/series/human-subjects-research-hsr/>). Training would integrate understanding of existing codes of conduct and best practices related to navigating the tension between, for example, openness, intellectual property rights and ethical use of data and resources. The training would be informed by existing codes of conduct and the relevant grey and academic literatures. Individuals who successfully complete the governance training would receive global research and innovation governance certification recognized by key external bodies (see recommendation 3). For individuals involved in international research, particularly those involved with research with the individuals, teams and organizations in the Global South or Indigenous communities, certification would be required prior to the commencement of research funding and commencement of research activities. The ultimate goals of such training are to 1) develop norms of acceptable behavior related to genomics and genetic diversity, research and innovation globally and 2) complement the meso-level governance profession with micro-level researcher-level training.

Recommendation 2: Revise investment strategy for research capacity in the Global South and for Indigenous Peoples to integrate diverse capacities for genetic diversity and genomics research and innovation.

Diverse individuals, communities, organizations, institutions, networks, countries, and regions each may offer certain kinds of capacity in GDG research and innovation while lacking other kinds of capacity. Integration of these capacities—and an emphasis on the value of human capital development over a narrower focus on the development of any one product or technology—is necessary to effectively reconcile different logics and tensions and to overcome structural inequities that appear in the process of science and innovation, and requires an awareness and willingness of scientists, stakeholders and other experts to work together to identify needs, govern data collection and use, and distribute benefits.

Increasing research capacities in the Global South and Indigenous communities is critical for enhancing participation of low-income countries and marginalized groups in GDG research and innovation. Yet investment is often targeted at the micro-level, in middle-income countries, to specific projects that are often isolated from each other. Moreover, current macro-level approaches in GDG that decouple resource access from benefit sharing tend to avoid the need to build capacity to use data. Viable access to data for research depends on infrastructure and human capital development, being part of the research process, and determining permissions and protocols for sharing data, not solely on making the data available or 'open.' Failure to revise the current grant-based approach to building research capacity in the Global South and Indigenous communities will continue to perpetuate knowledge divides, rather than reduce them.

A meso-level approach would help in developing a more programmatic approach

to investment in research capacity that emphasizes building flexible research infrastructure and matching it with diverse, core competencies depending on research needs as defined by those in the communities. A coordinated investment program would identify research topics and areas for investment and fund a portfolio of projects that target distinct needs across countries and regions in the Global South and for Indigenous Peoples. We believe the revised investment portfolio should support the development of fundamental research capacity through a programmatic approach in which individual projects contribute to and draw on ever-increasing blocks of knowledge and skills. We believe that the WHO Pandemic Influenza Preparedness framework

(<https://www.who.int/influenza/pip/en/>) to invest in clinical capacity provides an early example of this approach. The SING Consortium

(<https://www.singconsortium.org/>), which enhances capacity of Indigenous peoples in genomic research and leadership, provides another example, and has led to efforts such as the Native BioData Consortium (<https://nativebio.org/>), the first nonprofit research institute led by Indigenous scientists and tribal members in the United States.

While acknowledging structural inequity and divide that hamper equal participation in research efforts across countries and actors, the meso-level approach would help point to the importance of the ability to engage collaboratively in a collective inquiry process. This dimension transcends the North-South, well-endowed/marginalized group. The meso-level approach would help implement

capacity building efforts in a more integrated way with the overall aim to increase cooperative capacities of actors to engaging in joint action by setting common objectives that better reflect the diversity of normative expectations of the group and collectively explore a diversity of solutions to their collective action problems.

Funds would encourage and incentivize program-based collaboration among partners with different research capacities, and enhance human capital and

infrastructure necessary to be an effective collaborative partner. In sum, the meso-level approach would increase the research ability of the individual, team, country such that it is in a more authoritative position to: 1) prioritize research that meets the needs of their communities; 2) effectively develop and contribute to research; 3) negotiate the terms of collaboration and resource use, plan processes and develop policy; and 4) steering deliberative governance of convergence and divergence within the collaborative activity.

Recommendation 3: Interface existing global policy frameworks with research governance and capacity investment.

In this section, we explore how existing macro-level governance can understand and implement our recommendations for developing meso-level governance capacity. As our case studies show, efforts to connect meso- with macro-governance are rare. This gap also hints, however, to a productive context where much potential resides to innovate the global governance for science, technology and innovation. Whereas Recommendation 2 is focused on research capacity, we focus here in Recommendation 3 on the need for investment in research governance capacity.

Historically, efforts to innovate global governance have been limited to specific issue-areas related to emerging technology (e.g., the Global Observatory for Genome Editing (and link); see Appendix B, 'Intellectual foundations'). To the best of our knowledge, no mechanism is in place that specifically embeds meso-level governance at the global level and explicitly recognizes the importance of research governance as the nexus of policy, knowledge and practice. As a consequence, current experiences may be of limited value to incubate, test and scale up our recommendations, and by extension,

implementation may need innovative solutions.

Going forward, we envision the support of governance capacity for research and innovation within existing global frameworks on issues-specific areas. The rationale is to build upon existing policy experience about how different governance arrangements shape relevant outcomes in specific contexts, and rely on existing frameworks to obtain political, material and financial support to governance capacity at the meso-level for research and innovation (e.g., by funding a governance capacity training program or coordinating in-kind support).

However, the initiative would have to go beyond the current conception of capacity to implement obligations of international treaties. Deliberations of international fora on capacity often result in generic lists of areas (e.g., legal-administrative, technical) where capacity of developing countries should be built. Even when accompanied by time-bound mechanisms of coordination and implementation, such deliberations rarely, if ever, produce an actual assessment of needs and outcomes, with the result of perpetuating a disjointed and donor-

dependent approach to capacity. These deficiencies may be the result of a narrow conception of capacity as merely functional to implementation of treaty macro-objectives, and of the artificial distinction between capacity providers (e.g., skillful individuals or resource-endowed institutions in OECD countries) and recipients (e.g., individuals and organizations in developing countries).

Under this option, governance is addressed as a stand-alone objective, detached from existing, issue-specific global frameworks and thus less dependent on issue-specific variables. We consider that a commitment to meso-level governance capacity, as an objective and a process on its own standing geared towards collaboration, would change the current framing and dynamics of the policy discussion at the global level— e.g., within the genetic diversity policy frameworks. It would create the necessary space for governance to be a legitimate objective to be integrated into existing, issue-specific, macro-level objectives (e.g., conservation, equity) and delegated to meso-level for implementation through increased learning capacity of actors engaged in collaborative actions.

State and non-State actors would engage in apprehending governance capacity as a goal and governance capacity would become the actual object of multilateral commitment. In our views, this new approach to capacity

would also create an opportunity for constructive contestation of current outcomes by actors and regime shifting towards realignment of existing institutions or creation of new institutions to support cooperation. A multilateral commitment to capacity could gradually prompt policy reorientation at all levels. Such reorientation would produce significant adjustment of behavior, institutional rules and standards, national and international policies, and ultimately build new coherence between research, innovation, and equity. Currently, COHRED has developed an early version of a global learning system for institutional and global research governance through its Research Fairness Initiative (rfi.cohred.org).

Once the support to governance and research capacity is nested in existing frameworks, a new, cross-cutting and stand-alone multilateral commitment to collaborative governance supported by capacity building and meso-level approaches may also be explored. The commitment may be formalized through, by way of example, a joint declaration or a collaborative platform among the different conventions and fora, where research governance is addressed as a stand-alone objective, still connected to existing, issue-specific global frameworks but less dependent on issue-specific variables and tensions.

6. Implementation steps

The expert consultation did not reflect on the implementation plan. Initial ideas are provided as a basis for further discussion.

1. Globally networked meso-level profession

As a first step, and with support from the global macro-level, a diverse *core group of stakeholders* from representative countries would convene to establish the mission, vision and structure of the profession. These founding individuals would come from multiple countries and multiple disciplines, experiences, backgrounds, and positions, with the purpose of building and sustaining a research governance platform and research governance profession that can interpret and adapt to change, address complexity, reconcile conflict and generate opportunity.

The platform would sponsor meetings (virtual and face-to-face) to develop a roadmap for establishing the multiple components of the meso-level profession. The roadmap would set out plans for the gradual development of governance capacities to inform, review and guide international collaborative research projects, programs, and initiatives. The roadmap would articulate the mechanisms by which governance could stimulate collaborative management of genetic diversity, genomics research and innovation, including in times of crisis, while also addressing the tensions inherent within and between existing macro-level policies, codes of conduct, and research community and non-research stakeholder beliefs, values and needs.

2. Investment strategy for research capacity

Under the initiative of a group of leading donors, a *network* of donors and qualified, diverse representatives of research stakeholders in developing countries, would be established. The network would establish permanent dialogue and share experiences and concerns related to the funding of integrated capacities. It would gradually elaborate principles, goals and criteria for investment strategy in research capacity. This body of guidelines should integrate existing standards on research fairness but specifically follow a meso-level approach.

Such body of guidelines would gradually be imported into donor strategies and then used as the basis for continuous feedback, adjustment and specification by the network, and for promoting meso-level coalitions.

3. Interface with existing global policy frameworks

A commitment for developing meso-level governance capacity for genetic diversity, research and innovation could be built in international frameworks (e.g., the Plant Treaty), initially by creating regular opportunities for dialogue between the decision-making bodies of such frameworks, and the core group of stakeholders under #1 and the network under #2.

The benefits of such dialogue would be reciprocal. By way of example, the roadmap for the development of governance capacity could be responsive to developments occurring at the macro-level and macro-level policy making would be informed by the multiple components of the meso-level profession. Coordination of investment strategies with the funding strategies of international frameworks (e.g., the Plant Treaty) would gradually be established.

Appendix A: Selected takeaways from the case studies

<i>Initiative and aims</i>	<i>Actors involved</i>
<u>African Orphan Crops Consortium</u> works to ensure the availability of nutritious orphan crops to consumers in Africa by promoting their production, through the adoption of modern breeding methods for crop improvement purposes and training of farmers.	Research institutions, corporations/industry, individual researchers and breeders
<u>Bioleft</u> is a community for research, co-design and implementation of tools for conservation, dissemination and open and collaborative improvement of seeds.	Network of breeders -small farmers, organic growers, academics and researchers, public institutions
<u>CARE Principles for Indigenous and Data Governance</u>	Indigenous researchers, data practitioners, and; policy activists advocating for Indigenous Data Sovereignty
The <u>Global Indigenous Data Alliance (GIDA)</u> are a set of people and purpose-oriented guidelines and community, reflecting the crucial role of data in advancing Indigenous innovation and self-determination.	Indigenous researchers, data practitioners, and; policy activists advocating for Indigenous Data Sovereignty
<u>CGIAR Big Data Platform</u> uses big data to solve agricultural development problems faster, better and at greater scale through tools, best practices, and consultation.	Agricultural research centers, universities, private industry, core group is 15 existing CGIAR centers and programs and over 70 external partners
<u>Council on Health Research for Development (COHRED)</u> goal is to maximize the potential of research and innovation to deliver sustainable solutions to the health and development problems of people living in low and middle-income countries.	Governments, research institutions and councils, civil society and the media, NGOs and for-profit corporations working in research and innovation for health.
<u>Just One Giant Lab (JOGL)</u> digital social platform that helps people, organizations, and industry, to sync onto fixing urgent and important societal problems using open science, responsible innovation and continuous learning.	Academic labs, corporations/industry, schools/ universities, startups, philanthropic foundations, NGOs, individuals; and public institutions
<u>ERA CoBiotech</u> 's goal is to strengthen the field of Biotechnology through encouraging cooperation and coordination of different national and regional research programs, promoting systems biology and	Researchers, industry representatives, research / innovation funders, representative of the publics

synthetic biology as technology drivers to speed up research and innovation in industrial biotechnology.

Global Alliance for Genomics and Health (GA4GH) aims to accelerate progress in genomic research and human health by cultivating a common framework of standards and harmonized approaches for effective and responsible genomic and health-related data sharing.

Corporations, NGOs

Appendix B: Intellectual foundations

The initiatives set forth in this White Paper are informed and inspired by several literatures: meso-level network governance, institutional theory, responsible research and innovation, and policy design.

We are interested in linking the macro-level global institutions establishing principles and mechanisms for the governance of access and use of digital sequence data and genomics research in general, with micro-level behavior of researchers. Our decision to focus on meso-level governance comes both from the apparent implementation gap and from the literature on meso-level institutions that cuts across numerous social science disciplines including economics, institutional theory, network theory, management science and public administration (Banjade *et al.*, 2007; Faist, 2010 ; Grimmelikhuijsen *et al.*, 2017; Kim and Croidieu, 2016; Orbals *et al.*, 2012; Rasmussen *et al.*, 2019; Schenk & Uiterkamp, 2007; Tummers, 2020). Network structure, composition and relationships play an important role in meso-level governance because they integrate actors horizontally, but also connect them vertically (Klijn *et al.*, 2013; Newig & Pahl-Wostl, 2010; Torfing, 2005). According to Torfing, governance networks are:

“(1) relatively stable horizontal articulations of interdependent, but operationally autonomous actors who (2) interact with one another ... (3) within a regulative, normative, [and cognitive] ... framework that is (4) self-regulating within limits set by external forces and which (5) contributes to the production of public purpose.” (2005:307)

Networks are recognized as important forms of multi-level governance (Provan and Kenis, 2007; Bodin and Crona, 2009). They can facilitate collective action and innovation (Powell and Grodal, 2005; Lejano and de Castro, 2014) through four functions (Berthet and Hickey, 2018): Connecting; Framing; Knowledge brokering; and Exploring. This latter function points to the importance of learning for the success of collective action. Focus on governance cannot simply consist in selecting the best known organizational model for a specific problem (De Schutter, Lenoble, 2010). It should also help generate alternatives beyond an existing set of solutions by stimulating production and analysis of information about an ongoing intervention by the actors involved themselves (Ansell, Bartenberger, 2016).

Institutional theory has increasingly been applied to understand and explain how individuals, organizations and fields combine and integrate multiple, often conflicting, institutional logics (Battilana *et al.*, 2009; Lawrence *et al.*, 2011), which are frameworks that orient actors to interpret reality and act in social situations (Thornton, 2004; Greenwood, 2011). As the number of institutional logics embedded in a social context increases, individuals are subject to greater institutional complexity and need to address conflicts and tensions that stem from diversity of values, beliefs, and approaches. Scientific research, including GRG research and innovation, is institutionally complex because it is embedded in a variety of institutional logics stemming from different regulatory regimes, disciplinary norms, systems of ethics, and field cultures (Dunn & Jones, 2010; Kraatz & Block, 2008). Concrete efforts to proactively reconcile conflicting logics can improve the effectiveness of social processes.

Building on the International Relations literature on ‘transnational communities’, for our purposes global collaboration research and innovation initiatives are governance ‘communities’ with transnational scope (Stone, 2008; Djelic and Quack, 2010). These communities execute and implement global public policies and resource-related policies with diverse actors across different

jurisdictions. The responsible research and innovation (RRI) literature focuses on the inclusion of broader economic, ethical and social considerations in the decision-making process in science not only downstream at the innovation level but also ex ante, by shaping and steering the innovation process. RRI is often referred to, broadly, as an activity that takes into account the societal dimensions of emerging technology, science and innovation. This overarching definition serves as a starting point to enhance reflexivity and bring together diverse actors who share the motivation and values to build bridges between the content and context (be it social, political, material) of knowledge-making in 21st century contemporary science. In doing so, RRI helps redress the long-standing deficits of modernity, of several centuries long, that have falsely treated science as apolitical and devoid of social and cultural context. RRI and related global governance frameworks thus strive for sociotechnical integration, and democratization of science and innovation. They usually take the form of deliberations and enhanced learning process to better anticipate and reflect the diversity of values, needs and concerns in society related to this or that technology (Istratii and Hasan, 2019; Fransmen *et al.*, 2018). One example at the international level is the call for an international network of scholars and organizations (a global observatory) to support a new kind of conversation on genome editing and seek “broad societal consensus” on the norms that should guide research (Jasanoff and Hurlburt, *Nature*, March 2018). The CARE principles respond to the same kind of logic of providing normative guidance to research practices. RRI enables meso-level governance of collective arrangements and practices of science by moving towards more collaborative, reflexive and co-productive practices of research and innovation (Calvert and Martin, 2009) that embed governance aims in ongoing internal decision-making processes of research (Landeweerd *et al.*, 2015). The challenge is to increase the collective capacities of the different actors within global initiatives to cooperate in the pursuit of the wider general interest.

Just as meso-level network governance frames the context of our initiatives, the policy-design literature provides a foundation for components of our recommended way forward. In particular, we focus on the policy-tools approach. Policy tools are specific instruments that convey or require information, authority, resources or organizations for accomplishing specific policy aims (Howlett, 2009; IPBES, n.d.; Schneider & Ingram, 1990). Because governance systems are complex, this approach recognizes that to achieve desired outcomes, it is necessary for policy designers to select coherent mixtures of policy tools, techniques and methods (Huttunen *et al.*, 2014; Rogge and Reichard, 2016). The policy tools approach to policy design draws on different sources of authority and legitimacy in a nested structure of instruments that reinforce and support each other.

Appendix C: References

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Appendix D: Acknowledgments and Participating Experts

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