OPERATIONALISING THE COVID-19 TECHNOLOGY ACCESS POOL (C-TAP)

A CONCEPT PAPER

INTRODUCTION

On 23 March 2020 the President of Costa Rica, Carlos Alvarado Quesada, asked the Director-General of the World Health Organization (WHO), Dr Tedros Adhanom Ghebreyesus, to “undertake an effort to pool rights to technologies that are useful for the detection, prevention, control and treatment of the COVID-19 pandemic.”¹

The letter envisaged a voluntary arrangement whereby owners of intellectual property (IP) and other forms of knowledge, clinical data and know-how relevant to the development and manufacture of diagnostic tests, devices, medicines, or vaccines would contribute these to a pool. The details of the arrangements would need to be determined through consultation with the holders of the relevant knowledge and technologies.

The resolution on the COVID-19 response passed at the World Health Assembly in May 2020 called on international organizations and other stakeholders to work together to develop, test, and scale-up production of diagnostics, medicines and vaccines for the COVID-19 response, including existing mechanisms for voluntary pooling and licensing of patents in order to facilitate timely, equitable and affordable access.²

On 29 May 2020, the Pool was formally launched by President Carlos Alvarado Quesada and Dr Tedros Adhanom Ghebreyesus with the Solidarity Call to Action.³ The initiative has to date been endorsed by 40 countries along with Office of the United Nations High Commissioner for Human Rights (OHCHR), the Joint United Nations Programme on HIV/AIDS (UNAIDS), the United Nations Development Programme (UNDP), the United Nations Educational, Scientific and Cultural Organization (UNESCO), Unitaid, the UN Technology Bank and several non-governmental organizations and individuals.⁴

Dr Tedros Adhanom Ghebreyesus noted that based on strong science and open collaboration, this information-sharing platform would help provide equitable access to life-saving technologies around the world. The aim was to accelerate the development of all kinds of technologies needed for the prevention, detection, and treatment of COVID-19 through open-science research and to fast-track product development and availability by mobilizing additional manufacturing capacity.⁵

The COVID-19 Technology Access Pool (C-TAP) is intended to provide a means to accelerate the development of products needed to fight COVID-19 as well as to accelerate the scale-up of manufacturing and the removal of barriers to access in order to make products available globally. Sharing information, knowledge, data and other resources is a powerful way to accelerate product development and avoid unnecessary duplication of efforts arising from the absence of such sharing.

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Key Points in the Solidarity Call to Action

**RESEARCH FUNDERS SHOULD:**

- Take action to promote innovation, remove barriers, and facilitate open sharing of knowledge, IP and data necessary for COVID-19 detection, prevention, treatment and response through measures to ensure availability, affordability and assured-quality of the concerned products.
- Make appropriate provisions in funding agreements regarding accessibility and affordability of resulting health products globally including through non-exclusive voluntary licensing and other means to expand access by sharing know-how and other data.
- Ensure that all research outcomes are published under open licenses that allow access free of charge with appropriate provisions for their use, adaptation and redistribution by others, including through initiatives such as the FAIR Guiding Principles for scientific data management and stewardship.\(^6\)
- Encourage open and collaborative approaches in pre-competitive drug discovery and work together with international organizations towards equitable distribution and access to products needed for COVID-19.
- Ensure that research results are registered and published in line with WHO’s Joint statement on public disclosure of results from clinical trials.\(^7\)

**RESEARCH ORGANIZATIONS SHOULD:**

- Voluntarily license technologies developed to the Medicines Patent Pool (MPP) or through other public health research and development mechanisms that facilitate global access, for example voluntary non-enforcement of IP rights, in order to facilitate equitable, affordable and timely access for all countries.
- Share relevant knowledge, IP and data to enable widespread and worldwide production, distribution and use of such technologies and necessary raw materials through mechanisms such as the Technology Access Partnership (TAP) hosted by the UN Technology Bank or the Open COVID Pledge Initiative hosted by Creative Commons.
- Share viral genome sequences and associated metadata in a timely manner through transparent mechanisms, such as the one provided by the Global Initiative on Sharing All Influenza Data (GISAID) initiative, to contribute essential knowledge to the response efforts, recognizing the need for fair and equitable access to health products that are developed using genetic sequence information.
- Place in the WHO Global Observatory on Health Research and Development, relevant information and analyses on COVID-19 research and development activities.

This paper seeks to clarify how C-TAP might work in practice, how its constituent parts fit together and its governance. It covers the following:

- Why C-TAP?
- The respective roles and objectives of the COVID-19 Tools Accelerator (ACT-A) and C-TAP
- How C-TAP will be structured
- How C-TAP will operate
- C-TAP Governance
- C-TAP Consultative Arrangements

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WHY C-TAP?

In order to achieve its objectives C-TAP needs to be able to make a coherent case to the holders of knowledge and technologies for the benefits to be achieved by pooling their data, regulatory dossiers, and manufacturing processes and other kinds of ‘know-how’ as well as making IP available for public health-driven non-exclusive licensing through the Medicines Patent Pool, the UN-backed Technology Access Partnership, the Open COVID Pledge and other initiatives.

The International Monetary Fund (IMF) estimated in June 2020 that COVID-19 could cost the world economy $12 trillion up to the end of 2021, equivalent to a daily cost of over $15 billion with further large losses projected even if the pandemic is controlled in 2021. This number conceals the sheer scale of the devastation it is wreaking on livelihoods and indeed health outcomes throughout the world which could persist for years to come. But it also indicates the urgency of bringing the pandemic to an end as soon as possible in order to stem the damage to health and the global economy by whatever means possible. C-TAP, along with other initiatives, offers one way to do this.

Commitments by partners to promote development, access and affordability by any means, including non-exclusive licensing of new technologies, will be particularly important in achieving this objective. Limiting the scale of this devastation as much as possible depends on developing vaccines, therapeutics, medical devices and diagnostics and making them widely available globally as soon as possible. Every day counts and every part of the world needs to be covered if the pandemic is finally to be ended.

Sharing data and information which is normally kept secret or protected by IP could materially advance the speed at which technologies are developed and avoid, for example, the repetition and duplication of research carried out by others and reducing transaction costs in negotiations. Making the know-how associated with new technologies available and widely licensing it around the world would shorten the time needed to make them available as soon as possible to all who need them.

Success for C-TAP objectives will depend on the active participation of key partners including funders and innovators in the private, public, philanthropic and academic sectors. Private sector companies need to consider where their best interests lie. No company in the world will benefit by the prolongation of the pandemic. Their collective interest must be in restoring the world economy to health as quickly as possible, which will be facilitated by much greater openness in sharing their data, knowhow and IP. Several companies have already demonstrated their readiness to do that by making relevant IP available for licensing during the pandemic. Similarly, other research organizations in the public, academic and philanthropic sectors possess valuable knowledge products whose value could be increased by wider sharing in order to promote development and accelerate global access.

Governments, in their role as policymakers, regulators and funders have an important role to play in stimulating collective action to facilitate sharing. Some decisions have already being taken in respect of product development, licensing and allocation that may be at odds with the collective approach.

It is a challenge in the face of intense pressures on governments to look after their own populations to convey the message that collaboration and knowledge sharing are preferable to competitive nationalism. There are powerful arguments for collective action. For example, in respect of vaccines, some governments are contracting bilaterally to secure potential vaccines which in the end may prove ineffective or unsafe. In that case they will need access to ones they have not backed.

Funders, whether in the public, private or philanthropic sectors, also have a very important role to play in encouraging or obliging funding recipients to practise open sharing of knowledge and data and the licensing of products to maximize global access.

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ACT-A AND C-TAP ROLES AND OBJECTIVES

ACT-A is a partnership between WHO and a number of global health actors including the Bill & Melinda Gates Foundation, the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, the Vaccine Alliance, the Global Fund, Unitaid and Wellcome Trust as well as participants from industry, civil society and other organizations. Its mission is the accelerated development, equitable allocation and scaled-up delivery of vaccines, therapeutics and diagnostics. Underpinning these three pillars are two cross-cutting programmes, the Health Systems Connector, to strengthen local capacities to deliver new tools, and an Access and Allocation Programme, which is developing the principles, frameworks and mechanisms needed to ensure the fair and equitable allocation of these tools. The current estimate of funding requirements is $38 billion with the objective of providing two billion vaccine doses by the end of 2021, 245 million therapeutic courses by mid-2021 and 500 million tests for low- and middle-income countries (LMICs).

Thus ACT-A is principally about funding the development of the new tools necessary to fight COVID-19 with associated activities seeking to promote equitable access to these new tools.

C-TAP has the overall objective of promoting open science in order to accelerate product development and to facilitate access to the resulting health technologies by pooling IP, data, regulatory dossiers, and manufacturing processes and other kinds of 'know-how'. Sharing knowledge of all kinds which is normally only available to funders, originators or technology holders, or confidentially held by regulators will facilitate accelerated innovation and the scale-up of manufacturing globally. It will facilitate more affordable access to new tools, through non-exclusive and public-health driven licensing accompanied by enhanced arrangements for technology transfer. In particular, it will support technology transfer to boost local production of relevant products in LMICs through the Medicines Patent Pool and the Technology Access Partnership.

Thus ACT-A and C-TAP are complementary initiatives. ACT-A is principally about mobilizing funds to develop new tools for COVID-19, prioritizing technologies needed, coordinating international action, and ensuring that new products that are safe and effective become available at country level through scaling up production.

C-TAP provides additional and complementary advantages including concrete interventions to increase access to data, IP and knowledge that are key for accelerating product development and manufacturing by promoting through voluntary means open innovation models, knowledge sharing and technology transfer as well as promoting equitable global access through non-exclusive and access-oriented licensing or other voluntary strategies that facilitate technology transfer and access. These include, for example, free licenses and pledges offered by the Open COVID Pledge and other initiatives and the waiving of patent rights by some companies on products that may prove effective against COVID-19.

As complementary initiatives, the linkages and mutual benefits between the two should be made more explicit and further promoted, for example, the data, know-how and IP associated with technologies prioritized for development and subsequent manufacture under ACT-A could be made available for sharing within C-TAP mechanisms.

HOW C-TAP WILL BE STRUCTURED

It is envisaged that the operational parts of C-TAP will be built around existing institutions which will constitute the engine room of C-TAP. These are:

- The Technology Access Partnership (Tech Access Partnership)\(^\text{11}\) launched by the UN Technology Bank in partnership with UNDP, WHO and United Nations Conference on Trade and Development (UNCTAD), focuses particularly on promoting technology transfer to, and local production of, personal protective equipment (PPE), medical devices such as ventilators and other oxygen-related technologies and diagnostics and testing materials/components in LMICs. The Tech Access Partnership draws on the respective expertise and mandates of partner agencies to comprehensively vet and make recommendations for effective technology transfer transactions between technology seekers in LMICs and technology holders from anywhere in the world. The partners make these assessments, and provide procedural guidance, in close consultation with organizations and institutions expert in particular aspects of the focal technologies, including the regulatory, political, legal issues.
and financial contexts in which the transactions will be completed. The Tech Access Partnership currently focuses on supporting technology transfer and local production for the production of COVID-19 technologies, to mitigate the immediate impact of the crisis and resultant supply chain shortages, disproportionately impacting LMICs. In its first five months to date, the Tech Access Partnership has received requests for assistance from 10 countries, the majority in Africa.

- The Medicines Patent Pool (MPP)\(^\text{12}\) expanded its mandate in March this year to include any health technology that could contribute to the global response to COVID-19. **MPP’s experience in facilitating access to medicines through its voluntary licensing mechanism means that it could play a central role in applying its IP and licensing expertise to patented products and technologies identified in the fight against COVID-19 to facilitate availability to those who need them most.** The MPP is also, through its MedsPaL database of patents and licenses in LMICS, including medicines candidates that may have relevance for treating COVID-19 infections. The database provides transparency on the patent status and licensing of these products.

- **The Open COVID Pledge (OCP)\(^\text{13}\)** currently operates as a repository for mainly soft and hard technologies relevant to COVID-19 but is open to offers from vaccine or therapeutic manufacturers. The OCP is a mechanism whereby companies make available a non-exclusive, royalty-free, world-wide license for a time-limited period - until one year after WHO declares the COVID-19 pandemic over, or 1 January 2023, whichever is earlier, unless further extended by the pledgor. So far about 30 companies have made pledges - these include large technology companies such as Microsoft and IBM. In Japan, a similar initiative has been launched – the Open COVID-19 Declaration – supported by 90 companies and covering nearly a million patents.\(^\text{14}\)

- **Global Initiative on Sharing All Influenza Data (GISAID)** enables the unprecedented sharing of genomic and associated data from cases of COVID-19, thereby enabling genomic epidemiology and real-time progress in the understanding of the new disease and in the R&D of candidate medical countermeasures. Since 2008, GISAID provides Member States with a choice on how to make their genomic sequences and associated virus data publicly accessible, providing transparency on its use and an effective mechanism to safeguard contributors’ interests in their data.\(^\text{15}\) GISAID’s data access and usage license agreement (DAA) was developed with Member States’ participation. While all data are publicly accessible, those sharing data through GISAID do not forfeit their inherent rights to the data.\(^\text{16}\) Data in GISAID is open to everyone, provided they identify themselves, to foster collaboration and to permit an effective oversight to uphold the sharing principles enshrined. A guiding principle for those using data in particular in publications is the requirement to acknowledge the contribution of data providers. By contrast, traditional public-domain archives (e.g., Genbank) offer only anonymous access and use of data without consideration of data providers’ interests.

- **The WHO Global Observatory on Health R&D\(^\text{17}\)** is a comprehensive and authoritative ‘one-stop-shop’ for up to date information and analysis on health R&D, including resources, processes, outputs and capacity. It supports evidence-informed decisions related to health R&D gaps and funding based on public health needs. It does so by consolidating, monitoring and analyzing relevant information on health R&D, building on existing data collection mechanisms, and supporting coordinated actions on health R&D. The ‘Observatory’ covers all health-related fields and all types of research. It includes data and analyses on health products in the pipeline, clinical trials, R&D investments and research capacity, among others. In response to the COVID-19 pandemic, the Observatory is pulling together and continuously updating a comprehensive list of data tracking and synthesis systems on R&D for COVID-19 and will be developing relevant analyses and interactive data visualizations of these resources, which will include C-TAP repositories.

- **The WHO C-TAP database** will be at the core of C-TAP operations, being the repository for data and know-how on key Covid-19 health technologies to be part of C-TAP and for the submission of Member States pledges to support C-TAP. The WHO C-TAP database will act as a coordination platform and be connected to other data-sharing platforms and databases where Covid-19 related health technology information is already available.

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12 Medicines Patent Pool. [https://medicinespatentpool.org/](https://medicinespatentpool.org/)
13 Open COVID Pledge. [https://opencovidpledge.org/](https://opencovidpledge.org/)
15 Shu, Y. et al (2017) GISAID: Global initiative on sharing all influenza data
16 Elbe, S. et al (2017) GISAID’s innovative contribution to global health
17 Global Observatory on Health R&D. [https://www.who.int/research-observatory/en/](https://www.who.int/research-observatory/en/)
HOW C-TAP WILL OPERATE

C-TAP would operate on the basis that there is mutual advantage in a crisis in sharing data and know-how in ways that accelerate product development, widespread manufacturing and reduce barriers to access. The need is to identify an operating model that is attractive to the funders and holders of IP, knowledge, data and technology recognizing the exceptional circumstances the world currently faces.

Some of the incentives for participation by funders and owners of knowledge may be commercial. The holders of knowledge and technology will also wish to make their own contribution to the defeat of COVID-19 for non-commercial reasons.

In respect of accelerating product development of healthcare products, there are a number of relevant examples which have often drawn on the experience of open source software development such as the Linux model. Examples include the Medicines for Malaria’s Open Source Drug Discovery programme which already has a COVID Box which has made available 80 compounds with potential for treating COVID-19 in return for which researchers are expected to share data resulting from research on the molecules from the box in the public domain within two years of its generation. Other initiatives include the Open Source Pharma Foundation, Open Source Malaria, and the Structural Genomics Consortium.

In respect of promoting access and affordability, the experience and expertise of the Medicines Patent Pool is very relevant particularly in relation to non-exclusive public-health oriented licensing of medicines in LMICs. MPP estimates that its generic licensees have been responsible in 2012-19 for 31.4 million patient years of treatment saving $1.44 billion in treatment costs.

In devising the operating model, there are a number of issues that need to be addressed, including through consultation with different groups of potential C-TAP partners. An important aspect will be for WHO to establish a prioritization process (with clear criteria and a rationale) to identify which products/technologies and “pooled assets” C-TAP should initially focus on for near term impact, while recognizing C-TAP’s more ambitious longer term objective of covering a broad range of products and types of “assets” necessary to tackle COVID-19.

C-TAP has immense potential to deliver as an emergency operation in the short term by supporting faster development of, and equitable global access to, vaccines, therapeutics and diagnostics and necessary medical equipment for this phase of the COVID-19 pandemic. The experience to date is that the great majority of countries in the world, both LMICs and high-income countries (HICs), were drastically underprepared to address the pandemic. Notably, most countries were woefully short of PPE, testing capacity and tools needed in intensive care. Thus, there is a medium- to long-term role for C-TAP in being one element in helping build country capacities to produce and/or secure the range of products which will be needed to address future epidemics. Indeed, success of C-TAP could lay a foundation to address the looming pressure on healthcare systems everywhere from increasing longevity, expansion of non-communicable disease, and resistance of established infectious diseases to conventional antivirals and antibiotics.

C-TAP GOVERNANCE

WHO has an important leadership role in mobilizing and interacting with key actors, such as Member States, funders and strategic partners such as industry, research institutes and academia and civil society, to participate actively in making commitments or pledging support and in sharing their information, know-how and IP. This will require the strategic engagement of senior WHO officials such as Assistant Director-Generals (ADGs), Regional Directors and up to the Director-General. It should also seek to involve other UN agencies with relevant expertise.

There is an important role for WHO in the governance of C-TAP at a strategic level in setting standards and providing guidance for information, know-how and IP to be shared/“pooled” (through the Technical Advisory Group) prioritizing products to be considered by C-TAP and its implementing partners, carrying out coordination of implementing partners, monitoring C-TAP outcomes and communicating about it in an open and transparent manner with C-TAP Steering Committee and C-TAP partners and stakeholders.

18 About the Linux Foundation. https://www.linuxfoundation.org/about/
19 COVID Box. https://www.mmv.org/mmv-open/covid-box
20 Open Source Pharma Foundation. https://www.ospfound.org/
22 Pioneering Science to Inspire Pioneering Medicines. https://www.thesgc.org/about/what_is_the_sgc
**Steering Committee**

The C-TAP Steering Committee is a group of international partners involved in C-TAP implementation and advising on the overall direction of C-TAP. It is chaired by the WHO Assistant Director-General for Access to Medicines and Health Products and composed of C-TAP key partner organizations such as Unitaid, the UN Technology Bank, MPP, GISAID and the Open COVID Pledge, UNDP, and UNAIDS. The Chairs of the Member States Working Group and the Technical Advisory Group have observer status in the Steering Committee. The Committee will:

- Provide strategic guidance to the WHO Secretariat on the operationalization of C-TAP
- Serve as a platform to update partner organizations members of the Steering Committee on C-TAP implementation and to exchange information on ongoing and planned activities of C-TAP partners
- Support development of the physical structure and governance of C-TAP, for example, by advising in the process of defining interoperability standards and/or standard operating procedures
- Monitor and assess implementation and outcomes thereof, including taking stock of key challenges and level of achievement of results
- Promote policy dialogue and advocacy on C-TAP objectives
- Advise on and facilitate collaboration and coordination with other relevant initiatives, such as ACT-A

**Technical Advisory Group**

A Technical Advisory Group (TAG) will be composed of experts in fields relevant to C-TAP operations. They may include experts from key stakeholder groups including funders, civil society, academics, researchers and the private sector, providing that these experts act in their personal capacity, as independent experts, and be clear of conflicts of interest. The role of the TAG would be to provide guidance on tools and methods for sharing of information, know-how and IP needed for C-TAP, advise on priority products to be considered by C-TAP and inform the Steering Committee and the WHO C-TAP Secretariat accordingly. It should be established paying due regard to diversity and equitable geographic representation. Its chair should also be an observer on the Steering Committee.

The exact terms of reference of the TAG need to be determined but could include:

- Providing independent advice on the scientific, technical and strategic matters related to the COVID-19 Technology Access Pool (C-TAP)
- Advising on relevant information and know-how packages on C-TAP candidate health products to be made available in the C-TAP database and disseminated
- Making recommendations to the WHO C-TAP Secretariat regarding license negotiations and other technology transfer agreements taking account of C-TAP partners’ existing mechanisms for negotiations.
- Advising on best practices to facilitate technology transfer and local production for needed COVID-19 technologies and how to work with the implementing partners and other stakeholders to implement them.

**C-TAP Secretariat**

The WHO C-TAP Secretariat will be located in the WHO Access to Medicines and Health Products Division, will work in collaboration with the Science Division in charge of the Global R&D Observatory and coordinate with other relevant WHO departments. C-TAP Secretariat will compile, in one place, the C-TAP Database, pledges of commitment made under the Solidarity Call to Action as well as the voluntarily shared COVID-19 health technology-related knowledge, IP and data. The secretariat will draw on relevant data from existing mechanisms like the MPP or the Technology Access Partnership (TAP) and will need to manage and maintain the website and database platform for C-TAP. The WHO C-TAP Secretariat will:

- Plan and monitor C-TAP related work carried out by WHO and other C-TAP partners
- Carry out day to day coordination of C-TAP related work including from implementing partners, on strategic and technical issues
- Support organization of meetings of the C-TAP Steering Committee and of the Technical Advisory Group
- Prepare C-TAP related activity progress reports
- Develop C-TAP advocacy and communication materials
- Share information on C-TAP progress and implementation plans with the Co-sponsors Working Group, Member States and other partners’ groups involving key stakeholders.
C-TAP Member States Working Group

In addition to the core governance bodies, the Steering Committee, the Technical Advisory Group and the C-TAP Secretariat, it will be important to have strong mechanisms for consultation with Member States and the key stakeholders involved in C-TAP.

The Member States Working Group will be the interface between the Steering Committee and the global Member States community. Its Chair should participate in the meetings of the Steering Committee as an observer, and act as a liaison and ensure information sharing on C-TAP related issues between the Steering Committee, co-sponsors and Member States. Its role will be to carry out advocacy on behalf of C-TAP and to encourage more Member States and other stakeholders to join the Solidarity Call to Action. C-TAP Secretariat should meet regularly with the Working Group to share information and seek feedback on progress of C-TAP implementation.