



Local diagnostics to meet local health needs

Online Supplement 2: Global health organisations and initiatives working on local production and technology transfer of COVID-19 diagnostics in low- and middle-income countries

In addition to the WHO Local Production and Assistance unit,¹ at least three global health organisations and initiatives are contributing to local production of COVID-19 diagnostics in low- and middle-income countries (LMICs): The World Health Organization (WHO)'s COVID-19 Technology Access Pool (C-TAP); FIND, the global alliance for diagnostics; and the Working Group on Local Production and Diagnostics.

COVID-19 Technology Access Pool

In May 2020, WHO launched the COVID-19 Technology Access Pool (C-TAP) in partnership with the Government of Costa Rica and 44 Member State co-sponsors.² Through their Solidarity Call to Action,³ C-TAP has called on the global community to voluntarily share intellectual property (IP), including know-how and data necessary for manufacture of COVID-19 health products such as diagnostics. C-TAP intends 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.⁴ MSF welcomed the launch of the C-TAP and its call for open sharing of technologies in the pandemic.⁵

WHO is coordinating C-TAP, but the actual negotiation, pooling and signing of license agreements concerning medical products is carried out by its implementing partners, including the Open COVID Pledge and the Medicines Patent Pool (MPP).⁶ WHO hosts the C-TAP website and a repository of implementing partners' information, develops documents, and holds consultations with different stakeholders.

The Open COVID Pledge is an implementing partner of C-TAP as an independent initiative managed by Creative Commons and not governed by WHO.⁷ It acts as a repository and relies on voluntary pledging to share IP related to COVID-19 technologies, including health technologies. The Pledge is implemented through a license that details the terms and conditions under which the IP of a given health technology is made available.

The MPP is another C-TAP implementing partner,⁸ managing and coordinating licensee and licensor. The MPP expanded its mandate to include COVID-19 health-related technologies,

including diagnostics – in which they did not have previous experience – in March 2020.⁹ Licensing of diagnostics can involve complex technology transfer and regulatory landscaping across different regions and contexts. Establishing this expertise for diagnostics in MPP may require collaboration with other organisations like FIND. MPP could ultimately also explore where more upstream licensing of diagnostics innovations could be useful, including beyond the COVID-19 pandemic.

The C-TAP initiative has the potential to foster a global platform of open sharing and represents a better approach than bilateral agreements between manufacturers as it promotes transparent and non-exclusive agreement with public health provisions. However, its current operations face challenges. C-TAP initially relied on WHO's Emergency Use Listing (EUL) to determine which products to pursue licensing for, but this can be a lengthy process, slowing down deals during the pandemic. Therefore C-TAP has also released a standardised pre-assessment questionnaire to overcome this limitation and pre-assess technologies in the pipeline, before these technologies are ready to seek WHO's EUL.¹⁰

C-TAP's management of IP and technology sharing relies on the expertise and activities of its implementing partners. In addition, C-TAP relies on voluntary mechanisms for licensing IP from companies. To date, WHO member states who support C-TAP have not maximised their leverage to address the lack of participation of IP and technology holders. As of May 2021, four innovators have approached C-TAP seeking to license their diagnostics technology for manufacture by others. These negotiations are still ongoing, and no transfers are fully executed as of June 2021.

C-TAP does offer the potential to complement an important proposal at the World Trade Organization that aims to alleviate production concerns by suspending certain IP obligations in international trade rules for COVID-19 health technologies, including diagnostics, for the duration of the pandemic (the so-called TRIPS waiver).¹¹ If the waiver is adopted, it can remove key legal barriers and facilitate faster production and supply by local manufacturers. A mechanism like C-TAP could facilitate licensing and transferring of know-how, depositing and sharing key technologies and data through a global platform. If successful, it could be maintained and expanded beyond COVID-19.

FIND

Founded in 2003, FIND, the global alliance for diagnostics, “seeks to ensure equitable access to reliable diagnosis around the world.”¹² FIND focuses on spurring “diagnostic innovation and making testing an integral part of sustainable, resilient health systems,”¹² with an emphasis on diagnostics for poverty-related diseases. FIND's work on technology transfer and local production of raw materials and end products significantly ramped up during the COVID-19 pandemic.

In partnership with Unitaid, FIND launched an expression of interest (EOI) in 2020 to scale up manufacturing capacity for COVID-19 antigen RDTs, including through technology transfer and local production in LMICs. The EOI has an initial budget envelope of \$40 million to accomplish two objectives: 1. accelerate the development and optimisation of quality-assured, low-cost

COVID-19 antigen RDTs and scale up global production capacity, and 2. accelerate and strengthen local production capacity of COVID-19 antigen RDTs.

The intention is not to fund new product innovations but to accelerate market entrance of late stage research and development (R&D) and scaling up COVID-19 antigen RDT production through decentralised manufacturing. This includes technology transfer through royalty-free transfers to two sites in LMICs, with one site in Africa and one in South America.

FIND and Unitaid envision that the infrastructure put in place for COVID-19 RDTs can also be used for production of tests for other diseases once the immediate high COVID-19 testing need subsides, ensuring relevance and sustainability in the longer term. Indeed, this is also part of FIND's new strategy.¹³

In general, as a global product development partnership, FIND can play a key role in supporting local manufacturers in the road from R&D to market entry of diagnostics, as it has done for many years with established large manufacturers, such as Cepheid for TB rapid molecular tests and Abbott (SD Bioline) for human African trypanosomiasis RDTs. FIND's support since 2013 to India's local manufacturer Molbio in the development and evaluation of the TB Truenat tests exemplifies FIND's potential in improving market diversification and access to diagnostics.

Working Group on Local Production and Diagnostics

The Working Group on Local Production and Diagnostics originated from the Diagnostics Subgroup of the UN's TAP. It is now an independent initiative comprised of expert members from the UN Technology Bank, United Nations Development Programme (UNDP), WHO, Georgetown University and the International Centre for Genetic Engineering and Biotechnology (ICGEB), among others. It is chaired by Dr Jenny Molloy from the University of Cambridge.

The Working Group addresses gaps in technical support, policy guidance and regulatory information to support local manufacturing of diagnostics in LMICs and convenes stakeholders. The group, is writing a handbook on technical setup, regulatory processes and quality assurance (supported by the UN Technology Bank), aimed at current and future local manufacturers. They are also developing a roadmap (supported by the University of Cambridge and the UK Engineering and Physical Sciences Research Council), aimed at funders and policy makers. Given the numerous questions on regulatory requirements and pathways by both originators and recipients of diagnostics technology transfer, the Working Group is also producing a complementary mapping of regulatory requirements and strategies (supported by WHO and UNDP) to support local production of antigen RDTs in Africa. The Working Group is also providing technical assistance to C-TAP.

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