

**Meeting Report for the Roundtable on Licensing Terms for
Affordable & Sustainable Access to Diagnostics
Friday, 19 November 2021**

The goal of the Roundtable was to generate recommendations for licensing terms for diagnostics. We hope the record of these discussions and the recommendations that resulted will help guide the work and strategy of various actors, including the Medicines Patent Pool (MPP) to support diagnostics access (including beyond COVID-19) through sharing of technical know-how and pooling of intellectual property.

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This Roundtable was organized by the Fulcrum Project: a partnership of the O'Neill Institute for National and Global Health Law, the University of Pennsylvania School of Medicine, and the

A Fulcrum Project Report

Prepared by Juliette McHardy

SUMMARY OF RECOMMENDATIONS

Re: Licensing models and approaches

Consensus: licensing agreements for diagnostics need a distinct approach and similar instruments for medicines cannot be the model for the terms and obligations needed.

Consensus: a true pooling model for diagnostics is needed with comprehensive coverage of the intellectual property, including know-how, needed for specific end products.

Consensus: policy coherence is needed whereby other tools, such as TRIPS flexibilities, support and complement voluntary licensing and intellectual property pools for diagnostics and, at the same time, the terms of licensing agreements need to be compatible with TRIPS flexibilities as well as existing and future national strategies.

Consideration: competition will not necessarily be enough to get us to affordability—this is different from small molecules—because you may not end up with the economies of scale in production and the market power in distribution needed to reduce prices.

Re: Terms and obligations in licensing agreements

Consensus: the terms and obligations of licensing agreements need to be shaped by the purposes being prioritised in voluntary licensing—i.e., affordability, access, independence.

Consensus: licenses should be non-exclusive and sub-licensable.

Consensus: “intellectual property” needs to be defined broadly to encompass patents, regulatory data, copyright, and know-how.

Consensus: “diagnostics” needs to be defined broadly with a technology agnostic and disease agnostic focus to encompass fundamental technologies, facilitate interoperability, and permit licensees an unrestricted field of use.

Consensus: where practicable, licensors should be obliged to provide support for technology transfer.

SUMMARY OF RECOMMENDATIONS

Consensus: to make licenses dynamic, oblige licensors to include future improvements to diagnostics under already granted licenses, permit licensees to make adaptations and improvement, and require licensees who make sure improvements back-license them.

Consensus: agreements need to be disclosed and provide for transparency, validated with auditing where appropriate, on public and private investment received, costs of production, pricing, servicing and maintenance, and COGs and volumes sold.

Consensus: agreements need to include adequate quality management through warranties and quality assurance.

Consensus: out-licenses should include obligation to seek regulatory approval in line with need and disease burden.

Consensus: there needs to a long duration of time in which to apply for licenses.

Consensus: agreements need to include effective liability clauses for ensuring adherence relevant terms and obligations with specific clauses supported by broader compliance and mitigation plans.

Consensus: out-licenses should include obligations to meet the needs of LMICs including, for example, commitments to supply the public sector, scale-up production to meet need, supply minimum volumes, and register and commercialise in priority countries.

Consensus: although the terms and obligations licensing agreements should, to a lesser or greater extent, promote low royalties and prices to ensure affordability in LMICs, we currently lack information needed to fully address this question (see more below).

Consideration: to determine a reasonable margin, we need to be able to define COGS+ and support COGS+ provisions with transparency requirements and annual audits.

Consensus: “affordability” needs to be defined.

SUMMARY OF RECOMMENDATIONS

Consideration: licensees should commit to negotiate reasonable and capped mark-ups with distributors (for example, a max 10%)

Consideration: include commitment for profits to be recycled to support R&D and ensure access conditions instead of flowing to shareholders.

Re: Criteria for assessing licensees

Consideration: stringent criteria and assessment for licensees may conflict with the objective of supporting LMIC manufacturers.

Consensus: licensees need adequate quality management including capacity to meet SRA criteria, ISO certification, and GMPi.

Consensus: needed capacity and experience criteria include solvency, production and distribution capacity, capacity or experience in developing given technology, plan for the technology's commercialisation or its inclusion as a part of core business, regulatory experience, and HR competencies.

Consensus: desirable capacity and experience criteria include relationships with public procurers, political and financial from government or other parties.

Consensus: key criteria include sufficient commitment to meeting terms of license and supplying for public health needs, including commercialising in LMICs under access terms, and, for HIC manufacturers, sufficient commitment and demonstrable ability to support global south partners.

Re: Preferring local LMIC manufacturers

Consensus: preferring local LMIC manufacturers is appropriate and needed to (1) support development of industrial capacities, (2) benefit from unique knowledge supply and import problems, and (3) ensure global equity, support supply chain resilience and lower costs.

Consensus: preference to select local LMIC manufacturers is dependent on specific technology, target market, and urgency as well as the state of infrastructure and regulatory systems.

SUMMARY OF RECOMMENDATIONS

Consideration: preference for local LMIC manufacturers may entail greater risk, require more technical assistance to be provided, and result in products that are less affordable.

Consideration: in using voluntary licensing for diagnostics, it may be desirable to consider a two-phase approach to achieve early affordability and longer-term local production.

Consideration: broader ecosystem barriers and disincentives to local production of diagnostics will need to be addressed, including through collaboration with other actors and partners.

Re: Preferring governments and parastatals

Consensus: when possible, preferring national governments and parastatals is appropriate and needed to (1) mitigate risk of private sector manufacturers and (2) facilitate market entry and product adoption at national level.

Consensus: viability of government and parastatal licensees depends on the (1) model, governance and strategy of the manufacturer, (2) state of the quality system that can be maintained, and (3) on the manufacturer's commitment to public health and its government support

Consideration: as the line between parastatal entities and government support recipients is blurry, a preference policy may be hard to apply.

Re: Identifying, engaging and attracting manufacturers

Consensus: manufacturers can be engaged with trade shows, invitations to submit EOIs, active efforts to reach out, and selective relationship building with key stakeholders.

Consensus: manufacturers should be mapped through a database of potential suppliers developed in collaboration with WHO, FIND, CHAI, MSF, etc.

Consensus: there is a need to determine and demonstrate market potential by emphasising the wide field of use for diagnostic technologies (going beyond COVID-19) and document through proofs of concept the market's robustness and the potential for reasonable profit

SUMMARY OF RECOMMENDATIONS

Consensus: manufacturers can be attracted with funding to cover the cost of tech transfer, facilitated market access, technological flexibility to cover many diseases, support for user-centred design, tax incentives, support for pooled volumes such as through regional pooled procurement systems, and advance purchase commitments.

Consideration: support from development banks may be contingent on the diagnostics market being mapped out and on there being greater certainty as to its future.

Consideration: need to accept failure as not all diagnostics manufacturers that claim an ability to perform will be able to deliver.

Consideration: efforts to support local production in LMICs may result in geographically clustered manufacturers and regional inequity unless support is provided to ensure production is well distributed across regions.

Re: Affordability

Consensus: We need a lot of information to thread the needle between fair pricing and fair compensation.

Consensus: We need more than competition, we need specific guardrails, we need to think about sustainable decentralised production.

Consensus: COGS+ based pricing must be based on transparency and consider the effect of economies of scale.

Consensus: the key is transparency—not only COGS but also what the costs of R&D, the trials, regulatory dossiers, etc set against the amount of public funding received.

Consensus: there is a need for a flexible framework to negotiate for neglected diseases for which there may not be economies of scale.

Consideration: if COGS+ pricing is too expensive for LMICs, we may need an equitable approach toward differential pricing or external subsidies.

RECORD OF DISCUSSIONS

The key terms and obligations that should be contained in licensing agreements for diagnostics as well as related recommendations

Specific terms and obligations recommended

- 1.1. Defining “intellectual property”: definitions need to be broad including regulatory data, copyright, know how, methods (with the caveat that such methods are not patentable in many countries)
 - There is a need to be clear about what is off and on patent
- 1.2. Defining “diagnostics”: definitions need to be broad to allow licensees to perform necessary activities
- 1.3. Define “interoperability”
- 1.4. Defining the subject of the license: including licenses for the technologies that undergirds the diagnostics and the platforms underneath these technologies is crucial for local production and local innovation
- 1.5. Field of use: we need dynamic licenses that treat diagnostics as a platform rather than a tool, this is important for both public health application and market viability—licenses should not be disease specific, there should be mechanisms to require or facilitate interoperability,
 - Licensing upstream
 - Allowing interoperability will support pooling effect
 - Open source model is a possibility
- 1.6. Although a technology agnostic approach is needed this is particularly the case with CRISPR where licenses should not restrict diagnostics amplification method, detection method, and mechanism
- 1.7. License type: non exclusive and sub-licensable
- 1.8. Royalties: low royalties in line with MPP model
 - Need more information
- 1.9. Include anti-stacking provisions where possible
- 1.10. Pricing: consensus in favour of the desirability limitations on pricing with cost plus a fair markup on 10-20% -- voluntary licensing works well for reducing price in small molecules but will not necessarily be the case for diagnostics and there may need to be other mechanisms to support affordability in LMICs
 - Caution around price fixing

RECORD OF DISCUSSIONS

- 1.11. Commitments to supply LMICs: minimum volumes, focuses on specific markets or countries, commitments to register and commercialise in priority countries, commitment to scale up production to meet need, a duty to supply the public sector
- 1.12. Technology transfer: beyond licensing broadly defined IP (including know-how) there is need for obligations to support technology transfer and ensure manufacturers can, for example, scale-up production
- 1.13. Improvements: licensors should be required to include future improvements in their already granted licenses; licensees should be free to adapt and improve crucial in diagnostics; licensees should be required to back-licenses these improvements
 - Pace of innovation in diagnostics is relatively fast and sustainability will be an issue if the static license model is applied in this rapidly shifting field—we need dynamic licenses that encouraging technology sharing and discourage exclusivities
- 1.14. Transparency: on public and private investments; on costs of production, pricing, service and maintenance; on COGs and volumes with auditing; of the licenses themselves
- 1.15. Adequate quality management: warranties and quality assurance
- 1.16. Regulatory: obligation to seek regulatory approval
- 1.17. Timeliness: a long duration of time in which to apply for licenses
- 1.18. Compliance: liability clauses for ensuring compliance with relevant terms and obligations need to be included in these licenses—these need to be supported with compliance and mitigation plans

Related recommendations

- 1.19. Purpose: terms and obligations need to be shaped by the purposes being pursued in licensing
 - Traditional patent pools for patent thickets and their licenses will look different from local manufacture or access licenses.
- 1.20. Determine pooling approach
- 1.21. Consultations: we need to consult with C-TAP in terms of exploring, PATH in terms of seeking in-licenses and providing out-licenses, and the experience of Mark Radford in terms of business practices, the lessons of MPP in small molecules that can be brought o bear
- 1.22. Distinguish between the licensor and the sub-licensor: different terms apply for each—with the originator licensor you will want broad terms with bundling but with the sub-licensor you want maximal flexibility

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- 1.23. Facilitate scaled up and sustainable production: intellectual property is only part of the problem so license templates should include technology transfer and other supportive provisions needed for manufacturers to scale up production.
- 1.24. Longevity: future updates of a technology should be included
- 1.25. Tailoring: boilerplate language should not be used and the terms from similar instruments for medicines should not be copied over—we need to think of diagnostics and licensing agreements for diagnostics as sui generis.
 - Pace of innovation and also the scope for workarounds in diagnostics is so much higher than in medicines as well
- 1.26. Pooling model: we need to adopt a true pooling model for diagnostics with comprehensive coverage of the intellectual property needed for diagnostic end products.
- 1.27. Pricing: competition is not enough to get us to affordability—this is different from small molecules and medicines more generally—because you may not end up with the economies of scale in production and the market power in distribution needed to reduce prices
- 1.28. Business models: how much of a premium will countries be willing to pay for well-distributed local production particularly when this premium will have to be paid for the local production of other countries, too
- 1.29. Model: a truly pooling model will be needed, a pooling of all the IP required for one specific end product, it will need to be a broad intellectual property pool including know-how
- 1.30. Technology transfer: not all licensor will be able to provide support for technology transfer, each license will need to be tailored to capacity and there needs to be back-ups for when particular licensors cannot support licensees
- 1.31. Policy coherence: voluntary licensing and intellectual property pools need to be supported by other tools such as TRIPS flexibilities
 - There is a need for policy coherence, voluntary licensing terms need to be compatible with TRIPS flexibilities and existing/future national strategies -- we do not want agreements to contradict existing legal tools and frameworks

Considerations and Assessment Criteria for Licensees

RECORD OF DISCUSSIONS

Recommendations on criteria and assessment

Overriding point: Some of these more stringent criteria may be in conflict to supporting LMIC manufacturers—what is the balance and how do different orgs coordinate to get there?

2.1. Quality: adequate quality management; capacity to meet SRA criteria, ISO certification, GMPi

Capacity and experience—being able to meet the needs in the market and being able to ensure affordability

2.2. Production and distribution capacity should be core for HIC manufacturers with the attitude and ability to support global south partners

2.3. Experience or capacity develop given technology

2.4. Commercialisation plan or product part of core business

2.5. Regulatory experience

2.6. HR competencies

2.7. Relationships with public procurers preferable

2.8. Political and financial support from government or other partners desirable

Openness to IP and tech transfer

2.9. Commitment to meet terms of license and supply for public health needs

2.10. Commitment to commercialise in LMICs under access terms

2.11. Prioritisation of diagnostic manufacturers in LMICs

2.12. Solvency

2.13. Publicly traded firms and closely held firms

Recommendations on selection preference

Local diagnostic manufacturers in LMICs

2.14. Is appropriate and needed to (1) support development of industrial capacities, (2) benefit from unique knowledge supply and import problems, and (3) ensure global equity, support supply chain resilience and lower costs

2.15. First there is a need to establish what is needed to support the manufacturers in terms of the ecosystem and to support the quality of production (per ISO 1345, et a)

- For goal of building up LMICs - can't just be MPP alone - need additional expertise of a larger ecosystem. And likely will limit number of licensees.

RECORD OF DISCUSSIONS

- 2.16. Depends on the specific technology, target market, and urgency as well as the state of infrastructure and regulatory systems
 - 2.17. But there must be provision for output to be sold on fair terms to local rather than foreign
 - 2.18. Requires the acceptance of greater risk and the potential need to provide more technical assistance
 - 2.19. Purpose considerations are important: is it access, affordability, independence—consider two phase approach or one strategy for early affordability and one for longer term local access
- National governments and parastatals
- 2.20. Is appropriate needed to (1) mitigate risk of private sector manufacturers and (2) facilitate market entry and product adoption at national level
 - 2.21. But there is a blurry line between parastatal entities and government support recipients
 - 2.22. Viability depends on the (1) model, governance and strategy of the manufacturer, (2) state of the quality system that can be maintained, and (3) on the manufacturer's commitment to public health and its government support

Identifying, Engaging and Attracting Manufacturers

Finding and mapping manufacturers

- 3.1. Use trade shows and EOIs
- 3.2. Develop a database of potential suppliers (e.g. collaboration with WHO, FIND, CHAI, MSF, etc)
- 3.3. Active reach-out and selectively building relationships with key stakeholders
- 3.4. Regional pooled procurement systems

Market potential

- 3.5. Document robust market and potential for reasonable profit (proof of concept)
- 3.6. Wide field of use (diseases beyond COVID-19)

Incentives and market shaping

- 3.7. Funding support to cover cost of tech transfer by a third party as an incentive
- 3.8. Facilitate market access, including in LMICs
- 3.9. Providing technological flexibility for many diseases

RECORD OF DISCUSSIONS

3.10. Providing user-centred design support

3.11. Tax incentives, advance purchase commitments

Good news

- 4.1. Effort being undertaken to match-make between development banks interested in supporting the manufacture of technologies in LMICs and interested countries
- 4.2. Engagement would be more successful when manufacturers are well known, the market is clear, there is more certainty in the market's future

Bad news

- 4.3. Not all diagnostics manufacturers that claim their ability to perform are actually able to deliver
- 4.4. The landscaping has not been done in such a way that it is clear where the diagnostics manufacturers we would want to work with and how to engage them
- 4.5. We are looking at two sides of a question: being able to produce at scale and therefore being able to produce affordable diagnostics
- 4.6. Being able to support local production that is well distributed enough that we are able to respond to need in a whole area when local manufacturers in LMICs are often clustered
- 4.7. Choosing an entity is difficult: are we creating a landscape for real competitive diagnostic manufacturer that serves a public health need or are we choosing winners arbitrarily

Defining Affordability in Licenses

- 5.1. Define COGs: use COGS+ pricing with transparency and annual audits
 - Reasonable margin may be 10-20% with max 20-40% and may decrease with increased volumes
 - FIND is in the process of defining a methodology to determine a reasonable margin
- 5.2. Consider an equitable approach to differential pricing if COGS+ pricing is too expensive for LMICs or external subsidies may be applied
- 5.3. Consider amortization
- 5.4. Service and maintenance should be included (consider using a bundled price estimate or fully-loaded price per test) and potentially consider distribution costs

RECORD OF DISCUSSIONS

- 5.5. Licensees should commit to negotiate reasonable and capped mark-ups with distributors (max 10%)
- 5.6. May allow for increased margins or mark-ups for efficiencies and improvements
- 5.7. Commitment for profits to circle back into R&D and ensuring access conditions instead of flowing to shareholders

Considerations

- 5.8. Need a clear definition of affordability: need to know what it is, who it refers to (end user, manufacturer, both?) with a mind to distribution costs
- 5.9. Compared to medicines there is a lack of information to define what is affordability, what is a fair price
- 5.10. It is all about transparency: not only about COGS but also about what into the R&D, the trials, regulatory dossiers, etc set against the public funding received
- 5.11. COGS+ based pricing needs to be based on transparency and needs to consider the “+” as well as economies of scale
- 5.12. Tiered pricing model (as in CEPI): is this still a valid and sustainable model, whether this should be promoted alongside other models
- 5.13. Need a flexible framework for MPP to negotiate for neglected diseases for which there may not be economies of scale
- 5.14. Bottomline: we need a lot of information to thread the needle between fair pricing and fair compensation
- 5.15. Bottomline: we need more than competition, we need specific guardrails, we need to think about sustainable or decentralised production

Open Questions

- 6.1. A clear call that we are operating in the dark: we need to define the key pieces of information, determine where we can gather information already being collected, and then how to disseminate it—given our low resources we can combine what we have to make the most of it
- 6.2. Need additional specifics for the very particular out-licensing provisions MPP is considering for COVID diagnostics
- 6.3. Question of what the ecosystem for diagnostics needs and how the MPP can respond to those needs: consensus that IP for diagnostics

RECORD OF DISCUSSIONS

requires a broad IP pool—but more than just the MPP needs to be involved and there needs to be mandate for MPP

- 6.4. Question of whether access is just affordability or is it something broader including enriching LMICs production capacity to ensure sustainable access over the long term

ANNEX I

ANNEX I – ROUNDTABLE AGENDA

- 13:00 CET **WELCOME**
- **Introduction**, Sharonann Lynch, O’Neill Institute
 - **Goals**, Jen Cohn, University of Pennsylvania
 - **Agenda**, Vuyiseka Dubula, University of KwaZulu-Natal
- 13:10 CET **Session 1: OVERVIEW** (Ngozi Erundu, Moderator)
- **MPP’s current and future work on diagnostics**, Esteban Burrone, MPP
 - **Diagnostics technology pipeline**, Angelique Corthals, MSF/CUNY
 - **Key issues for COVID-19 diagnostics**, Emma Hannay, FIND
 - **Development and marketing diagnostics**, Teri Roberts, EGPAF
- Q&A
- 13:55 CET Break
- 14:00 CET **Session 2: LICENSING TERMS** (Spring Gombe, Moderator)
- **Survey responses**, Jen Cohn (5 mins)
 - **Break out groups** (3 groups, 30 mins)
 - **Summaries**, rapporteurs (5 mins)
 - Spring Gombe, UNDP
 - Stijn Deborggraeve, MSF
 - Teri Roberts, EGPAF
 - **Discussion** (10 mins)
- 15:00 CET **Session 3: LICENSEES & AFFORDABILITY** (Vuyiseka Dubula, Moderator)
- **Survey responses**, Sharonann Lynch (5 min)
 - **Breakout 3 groups** (30 mins)
 - **Summaries from rapporteurs** (5 mins)
 - Spring Gombe, UNDP
 - Stijn Deborggraeve, MSF
 - Teri Roberts, EGPAF
 - Clarification questions
- 15:55 CET **Summary, next steps, and close** (Sharonann, Jen, Vuyiseka)

ANNEX 2

ANNEX 2 – LIST OF PARTICIPANTS

Emily Adams, Mologic
Brook Baker, Northeastern University
Pascale Boulet, Drugs for Neglected Disease initiative (DNDi)
Emanuele Buratti, International Centre for Genetic Engineering and Biotechnology (ICGEB)
Esteban Burrone, MPP
Jennifer Cohn, University of Pennsylvania
Carlos Correa, South Centre
Angelique Corthals, MSF & City University of New York
Elliot Cowan, Partners in Diagnostics
Smiljka de Lussigny, Unitaïd
Stijn Deborggraeve, MSF
Vuyiseka Dubula, University of KwaZulu-Natal
Ngozi Erundu, Georgetown, O'Neill Institute
Marta Fernandez Suarez, FIND
Joe Fitchett, Institut Pasteur de Dakar (IPD)
Luis Gil Abinader, Knowledge Ecology International (KEI)
Andrew Goldman, MPP
Spring Gombe, UNDP
Sam Halabi, Center for Transformational Health Law, O'Neill Institute, Georgetown
Emma Hannay, FIND
Yuanqiong Hu, MSF
Sharonann Lynch, O'Neill Institute, Georgetown University
Jenny Molloy, University of Cambridge
Sébastien Morin, MPP
Abha Patil, PATH
Rosanna Peeling, London School of Hygiene and Tropical Medicine (LSHTM)
Trevor Peter, Clinton Health Access Initiative (CHAI)
Mark Radford, Global Access Diagnostics (GAD)
Reshma Ramachandran, Yale University
Judit Rius Sanjuan, UNDP
Teri Roberts, Elizabeth Glaser Pediatric AIDS Foundation (EGPAF)
Cheikh Tidiane Diagne, DiaTropix
Marcela Vieira, Graduate Institute
Elena Villanueva Olivo, WHO COVID-19 Technology Access Pool (C-TAP)

ANNEX 3 – QUESTIONNAIRE RESPONSES

1a. What are the key terms and obligations that should be contained in an IN-LICENSE agreement for diagnostics? Please also see corresponding question below.

- The full definition on IP should be used (beyond patents, so including know-how etc.). Licensing and royalties should be in line with public health recommendations and facilitate capacity building and longer term support.
- Set royalty rate in exchange for broad authority to structure transfer of specified diagnostic technologies.
- Broad geographic scope, freedom to adapt/improve, low royalties collectible only where there is relevant IP in the country of use, covers all relevant IP including regulatory data protection, patents, copyright, and know-how if relevant
- Field of use; retained rights; agreement on the Commons (ie shared pre-existing/published knowledge overlap with IP licensed)
- Exclusivity vs not (plus associated time period), geographic terms (countries/regions where license is valid, including list of priority countries for commercialization), allowable and associated terms for further modifications to the licensed IP, access terms (ceiling COGS / ceiling margin / ceiling end-user price and minimum volume commitments to LMICs, with associated definition of eligible purchasers), terms to ensure maintenance of adequate quality management systems, obligations with respect to seeking regulatory approvals/authorization as well as in-country registration for priority countries), terms for what happens to IP (and associated modifications) in the case that there is a breach in the licensing agreement
- Something around a proportion of publicly funded vaccines being free for heavily reduced price point for the country who developed it. Also something about tech transfer to Imics.
- Transfer of know-how, territory, warranties, post-termination use of technology
- Stating up front that I am not familiar with the concepts of in-license and out-license agreements, it should be understood that individuals in all parts of the agreement should agree to maintain the manufacturer's quality system and not interfere or "cut corners" as part of the investment conditions.

ANNEX 3 QUESTIONNAIRE RESPONSES

- Non-exclusive sub-licensable license rights to all IPRs (defined broadly), know-how and data necessary to manufacture, register and sell the relevant diagnostics in the Territory, eg. all LMICs if possible
- It is critical that in-licensing agreements include access conditions on public and philanthropic funding, including:
 - - transparency of cost of goods sold (COGS) and volumes with annual external audits
 - - COGS+ pricing: COGS plus a reasonable/rational profit markup (e.g., 10-20%) – or lowest sustainable pricing
 - - regular volume-based price reductions based on COGs (with a lower margin of profit as volumes increase)
 - - commitment to scale up manufacturing to meet supply needs
 - - obligation to transfer technology (1) in general, or (2) if any of the above conditions are not met
 - - transparency of all public and private R&D and other investments
 - - transparency of all pricing and service and maintenance contracts
- The FIND Global Access Policy and recent RFP provides some language to draw from:
 - https://www.finddx.org/wp-content/uploads/2021/07/FIND-Global-Access-Policy_PL-02-08-07_V1.1_JUL2021.pdf
 - <https://www.finddx.org/wp-content/uploads/2021/07/Request-for-Proposals-POC-MDx.pdf>
- While specific terms and obligations may differ depending on the type of technology, it may be useful to specify whether the innovation/development is limited to human or veterinary use only, if necessary, how to deal with bringing in existing IPs of either partners and perhaps specify agreement termination dates so that it is not open ended
- Geographical scope: For diagnostics, the licensed territory should be worldwide. To sell at low prices, diagnostic manufacturers will likely have to adopt a model with large volumes and small margins. For many diseases, restricting the geographical scope could severely limit the ability to implement a volume-based model and discourage the entrance of new manufacturers to address unmet needs. If patent holders insist on restricting the geographical scope, then the license should allow the manufacture anywhere in the world in order to supply the licensed territory. The license should also recognize the flexibility for manufacturers to supply outside the licensed territory where no

ANNEX 3 QUESTIONNAIRE RESPONSES

patents are infringed or if a compulsory license has been issued.

Field of use: One of the key advantages of CRISPR diagnostics is the possibility of being used as multiplex platforms, with the possibility of detecting multiple pathogens and possibly multiple genetic diseases at once. Because of this, a key issue in the licensing of CRISPR diagnostic platforms will be the field of use limitation. Restricting the field of use in CRISPR diagnostics licenses to specific diseases would undermine the use of this technology as a multiplex platform. Therefore, it is advisable to keep a broad field of use to include diagnosis of multiple diseases. This recommendation applies specifically to patents with broad claims. To the extent that it is applicable, a license should also allow both in-house and point-of-care uses.

Field of use: One of the key advantages of CRISPR diagnostics is the possibility of being used as multiplex platforms, with the possibility of detecting multiple pathogens and possibly multiple genetic diseases at once. Because of this, a key issue in the licensing of CRISPR diagnostic platforms will be the field of use limitation. Restricting the field of use in CRISPR diagnostics licenses to specific diseases would undermine the use of this technology as a multiplex platform. Therefore, it is advisable to keep a broad field of use to include diagnosis of multiple diseases. This recommendation applies specifically to patents with broad claims. To the extent that it is applicable, a license should also allow both in-house and point-of-care uses.

Interoperability: Another issue related to the field of the license is the type of amplification methods, detection methods, and mechanisms used. As a survey by Srivastava et al. (2020) shows, CRISPR diagnostics can be based on a variety of amplification methods, detection methods, and mechanisms. Patent holders should not use their legal rights to favor the use of one specific standard. Therefore, the license should not restrict or bind licensee to one specific type of CRISPR diagnostics amplification method, detection method, and mechanism.

Anti-stacking provision: In the case of CRISPR diagnostics, end products will likely incorporate several layers of inventions that might have to be licensed from different right holders. There are CRISPR diagnostics patents covering, for instance, the specific enzymes used to split nucleic acid sequences, methods of amplifying or analysing samples, and devices useful for amplifying or analysing samples. Many of those patents are held by several different entities. Additional improvements in this field

ANNEX 3 QUESTIONNAIRE RESPONSES

can potentially include, for example, new amplification methods to use CRISPR diagnostics without the need for electricity or the development of wearable devices. Those additional improvements may also be subject to patents. This means that a manufacturer may have to in-license multiple inventions from several patent holders and potentially pay stacked royalties to each one of them in order to obtain freedom to operate. As with other health products, stacking multiple royalties could be economically unsustainable for diagnostics manufacturers. This calls for the inclusion of an anti-stacking provision to reduce the royalty burden if several licenses are needed. Ideally, the net payments collected from manufacturers should be distributed among all of the patent holders with a transparent and predictable method.

Non-exclusivity: Diagnostic licenses should be non-exclusive. The investment required to develop diagnostics products tends to be modest compared to therapeutics or vaccines. In the case of diagnostics, exclusive rights are unlikely to be a necessary incentive to induce investment in the development of new products. There are several examples in the field of diagnostics where a non-exclusive model was adopted successfully. For instance, the decision to license certain patents related to the cystic fibrosis gene non-exclusively led to widespread adoption of diagnostic testing and carrier screening for this condition.

Financial provisions: In general, patent licenses can provide different types of payment, including up-front fees, cash payments triggered when certain developmental milestones have been met, cash payments triggered when certain commercial milestones have been met, and royalties on net sales. To promote the uptake of diagnostics licenses, the financial provisions should be based on a low royalty and avoid high upfront fees or milestone payments. When designing the payment structure it is also important to consider how a specific type of payment may encourage or decenterize the adoption of the preferred volume-based business model.

Standard-essential patents: Some patents related to CRISPR may become essential to implement specific diagnostics standards. Since those patents could be asserted against anyone trying to adopt that standard, the need to openly license them is particularly important.

Defining “diagnostics.” The term “diagnostics” should be defined broadly in order to allow licensees to perform activities related to the

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diagnosis, prognosis, monitoring, screening, and predicting of diseases, or selecting a therapeutic or prophylactic regime, among others.

Open and non-discriminatory. Diagnostics licenses should be open to anyone that applies to it, and the ability to apply for a license should not be limited in time. Some prospective licensees may currently lack CRISPR diagnostics manufacturing capacity, but could develop it in the medium term or long term. If there are real or perceived intellectual property barriers, an open licensing commitment would encourage long term investments in manufacturing capacity. If the ability to apply for a license closes after a certain deadline, or discriminates against prospective licensees, it will fail to create the legal certainty needed to make such long term investments.

Technology transfer: Diagnostic licenses should provide for transfer or know-how.

Transparency: All licenses should be published immediately and available for public scrutiny.

- as broad geographical scope as possible; non or very low royalties in LMICS; should include transfer of technology and know how as well as details on how the support will be provided; should facilitate and allow additional research; should allow use or additional research for more than one disease;
 - Transparency, non-exclusiveness, other public health oriented (compatibility with TRIPs flex, etc)
 - Pricing specific to LMIC affordability, time bound regulatory registration in LMICs wrt registration in HICs/other target markets, agreement to engage with distribution channels, manufacturing capacity/volume agreements, post-market support (customer service, replacement models, maintenance and turnaround times for orders), focus on specific markets or countries (not just LMICs), sub-licensing agreements to ensure licensed products can be handed off for manufacturing to other parties, and reporting and evaluation criteria to ensure enforcement
 - Transparency of the final contract and licensing agreement, including information of all the background IP License the full technology system and dataset, not only the end product
- Support all licensees to get registration under national and regional regulatory bodies, and to support licensees for WHO PQ when applicable

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No restriction on geographic coverage of the licensed IP for development, production and supply, at least covering all LMICs No fragmentation between production and supply in geographic coverage Commit to unconditional and complete transfer of the technology – including know-how, access to raw materials and regulatory assistance where needed

No clauses restricting the right to challenge relevant IP by licensees, and no restriction on using TRIPS flexibilities

Royalty free for LMICs

No terms and conditions to restrict follow-on development and improvement of the concerned technologies, and no unilateral grant-back clause

- Full freedom to operate (including manufacture, purchase/sell and follow on innovation) as it relates to patent and other IP rights (e.g. trade secrets/ regulatory exclusivities...) plus option technology/know-how transfer (if needed), and regulatory support (if needed). Global Scope (all countries, including HIC and MICs). Consistent with TRIPS flexibilities. Terms should be transparent/publically available. Allow for interoperability and use across diseases/health priorities. Consideration to ensure sustainable access strategies to raw materials, reagents and tests components.

1a. What are the key terms and obligations that should be contained in an IN-LICENSE agreement for diagnostics? Please also see corresponding question below.

- No, but key technologies (currently lateral flow, PCR etc.) are most critical for tech transfer.
- Yes.
- No.
- Yes. Different technologies will have different workarounds as well as different applications once it is developed for field use. CRISPR, for example, can easily be performed with the current published protocols. However, CAS, the protein, is less easily produced, and CRISPR-CAS is just the base component of a diagnostic test. The enclosure and catalytic reaction necessary for CRISPR-CAS to be performed in the field can be a secondary, already patented, technology such as LAMP.
- Potentially - it may depend, for example, on the patent landscape of the specific technology.

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- Idk
- No.
- Please see response to 1a above.
- The only term that may vary by type of technology would be that of technology transfer. All other terms would remain the same across technologies.
The only instances where technology transfer may not apply are for complex instrument-based molecular technologies for which generic production may not be feasible or cost effective, given the potentially significant specialized manufacturing infrastructure required. That said, if feasible and cost effective, the obligation for technology transfer would still apply.
For more simple molecular technologies (such as CRISPR-based diagnostics) and lateral flow antigen tests, obligations of technology transfer should always apply because these are relatively simple and inexpensive to manufacture, which would make generic production across LMICs feasible and cost effective.
- yes, specific terms and conditions by type of technology would be important as they may differ depending on how long the technology has been around, how versatile it is and whether it has been well used or not
- Generally, the terms and conditions mentioned above are applicable to any type of technology. However, the need to include some of those terms may be less or more relevant, depending on the type of technology. For example, some patents cover a scope of rights limited to specific diseases. For instance, a patent may cover "methods of using CRISPR techniques to diagnose COVID-19." In those cases, it makes less sense to ask for a field of use that includes a broad set of diseases because licensed patent itself will not limit the manufacture of multiplex platforms (however, if there is a transfer of know-how that has possible multiplex applications, then the need to secure a broad field of use remains important). In any case, however, a license negotiation should start with the terms mentioned above as the starting point.
- Allowing additional research use is crucial in new technologies such as CRISPR. It might be less relevant in others.
- Yes but they can be adapted to the different technologies (C-TAP will have soon example to show you)

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- Consider the downstream enhancement or development of the product for example a biological may need right to sequencing or derivatives. Similarly for software should build in flexible use of the software for other disease areas or platforms where possible.
- No the above terms apply to all types of technologies
- Not sure, I have not thought about this. Let's discuss

2a. What are the key terms and obligations in an agreement for diagnostics? Please also see corresponding question below.

- As for in-licensing.
- possibility of adapting technology for local conditions especially in LMIC countries
- Priority and financial terms for diagnostic access to populations and facilities essential for public health emergency response.
- Quality/GMP, sharing of improvements/adaptations with other licensees, duty to register and market broadly (depending in part on size/region of licensee), duty to price affordably, duty to distribute equitably to all relevant markets
- Field of use; retained rights; agreement on the Commons (ie shared pre-existing/published knowledge overlap with IP licensed)
- Exclusivity vs not (plus associated time period), geographic terms, royalties (which may vary based on target market and sector - LMIC vs HIC, private vs public), conditions and commitment to support the technology transfer process
- I don't know the difference
- Indemnity, warranties, field of use, royalty payments
- As I understand the concept of out-license, there should be provisions for understanding where the product is most needed from a public health perspective. My apologies if I am not interpreting the concepts properly.
- Non-exclusive sub-licensable license rights to all IPRs (defined broadly), know-how and data necessary to manufacture, register and sell the relevant diagnostics in the Territory, eg. all LMICs if possible, based on tiered royalties if needed
- Out-licensing agreements to MPP or a similar body should include:
 - full technology transfer to selected manufacturers
 - no constraints on the countries in which the diagnostics may be

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manufactured and sold

- no royalty payments from the sales of manufactured diagnostics

- It is critical that out-licensing agreements from MPP or a similar body include the following access conditions:
 - transparency of cost of goods sold (COGS) and volumes with annual external audits
 - COGS+ pricing: COGS plus a reasonable/rational profit markup (e.g., 10-20%) – or lowest sustainable pricing
 - regular volume-based price reductions based on COGs (with a lower margin of profit as volumes increase)
 - commitment to scale up manufacturing to meet supply needs
 - transparency of all public and private investments
 - transparency of all pricing and service and maintenance contracts
- assurance of quality of manufacturing, conditions for termination
- Sublicenses should include, mutatis mutandis, the terms mentioned in question 1.
- it should ensure quality to the standards of SRA, it could include a cost-plus clause if competition is not expected,
- Commitment for implementation of the agreement, willingness to share further development or improvements, other access provisions (on a case by case basis may be also related to pricing and affordability)
- Similar to in-licensing terms but usually have more leverage in this scenario so can really push mission-oriented goals.
- To make the product available in all countries at accessible prices and adequate volume, or sublicense to local manufactures under reasonable terms and provide technology transfer and support for obtaining local regulatory approval when needed (and make the license terms fully available).

To license any improvement in the technology under the same terms of the original license.
- Full transparency of the final contract and licensing agreement
Commit to submit timely for regulatory approval (e.g. WHO PQ) and supply public health systems in countries
Commit to affordable prices; disclose cost of production and pricing structures
- Non-exclusivity. Commitments to ensure affordability/registration in countries + quality safeguards. Grant-back of any follow on innovation/discovery.

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2b. Should the terms and conditions above vary by type of technology? Please provide examples, if possible.

- As for in-licensing.
- No
- Yes.
- No
- Yes. As defined for in-licensing.
- Similar as above.
- I don't know the difference.
- No
- Please see above
- Terms and conditions will likely vary depending on the investments made by the originator company, the scope of tech. transfer needed and the market forecast
- All of these conditions apply across types of technologies.
- same as for 1b
- Sublicenses should include, mutatis mutandis, the terms mentioned in question 1.
- Yes but importance of flexibility to be adapted
- Really consider the ultimate use of the product as research vs. commercialization. For research you will want to focus on owning or co-owning the IP so that at some point we may be able to commercialize. But if commercialization is the goal from the beginning, ensure that there is a co-ownership agreement with clear commercialization goals built in.
- No the above terms apply to all types of technologies
To be added for device-based testing systems: (i) commit to providing adequate and affordable service and maintenance packages to LMICs, (ii) commit to providing open-system platforms as much as possible, including the opportunity for 3rd manufacturers to develop and supply cartridges that can run on the device developed on the licensed IP
- Not sure, I have not thought about this. Let's discuss

3a. What are the relevant considerations or assessment criteria that should be used for selecting a diagnostic manufacturer licensee?

- (1) Technology is essential / critical for Dx development and use in LMICs. (2) Manufacturer is open to IP tech transfer and capacity

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building in the global south (e.g. Mologic / GAD). I would actually also strongly suggest moving upstream of this i.e. identifying the key technologies and licensing them at that stage under an umbrella license rather than going downstream test by test and disease by disease (whether this is possible through for the MPP remains debatable as they usually have to wait for a test to be recommended by the WHO first).

- previous experience in the field or a closely related one
- For publicly traded firms, evidence of board independence when weighing shareholder return versus public need, especially in emergencies. For closely held firms, those willing to enter agreements that establish licensor control over threshold level of final output.
- Size, location in underserved regions, ability to produce timeously and at scale, quality control/GMP, regulatory experience desirable, relationships with suppliers desirable, relationship with public procurers desirable, political/financial support from government desirable, capable regulatory authority for inspections, performance record, if any, in meeting delivery/quantity terms
- Basic laboratory safety and QA/QC capacity depending on the technology licensed, capacity to increase production based on demand, flexibility to adapt to changes in the technology if necessary as prescribed by the original IP holder, open-system for catalytic reaction (test 'enclosure')
- Technical: licensee's current or planned manufacturing capacity and QMS; if applicable, licensee's product development capabilities. Business: commitment and demonstrated (or planned) capacity to meet the terms as described in 1a (e.g., commitment to commercialisation in LMICs under access terms, distribution and sales network in target markets...) Depending on strategic fit, licensee's capacity may only need to be relevant to a narrower geographic region, not all LMICs.
- I am not sure as this isn't my field
- Technical capacity, solvency, quality and compliance
- It is essential that an adequate quality management system be in place and that the claims made for performance be supported by well-controlled studies.
- Ability to manufacture in accordance with internationally agreed standards (necessary to benefit from donor funding)
- Diagnostics manufacturers in low- and middle-income countries should be prioritized for selection as licensees, as an effort to increase access

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to diagnostics in these countries. The MSF brief on “Local diagnostics to meet local health needs” provides specific recommendations in the area of “Promoting open IP, technology transfer and access-oriented research and development for local manufacturers” that should be considered: <https://msfaccess.org/improve-local-production-diagnostics>

- ISO certification, track record, human resources and competencies, system capacity
- capacity to absorb the technology, capacity to develop the diagnostic according to SRA criteria, Manufacturing Experience and QMS, production capacity,
- C-TAP has recently created an assessment model of technologies for IVDs and scoring for potential manufacturers that will be shared publicly soon
- Most importantly you need to ensure that the manufacturer holds the commercialization plan or product at the core of their business model, it should not just be an extra social responsibility or unimportant to the business itself. It must be important to the current or future state of the manufacturer to have buy-in and a supportive partner. Other considerations include capacity of regulatory, physical infrastructure/manufacturing, and distribution as well as potential for supply security,
- All manufacturers should have access
Geographical coverage for supply, priority to countries that have limited local manufacturing of diagnostics
Manufacturers and developers that commit to the above terms
- Quality and commitment to supply security/affordability, and follow up innovation. Important to have broad geographical scope and not limit to one of two LMICs.

3b. What are the strategies to find/attract/engage diagnostics manufacturers?

- Those manufacturers interested in public health and LMICs usually reach out to main players e.g. MSF, but there are other platforms e.g. IDEA (JHI), RADx, FIND and other PDPs, C-TAP.
- providing technological flexibility for many diseases, many of our LMIC member countries are still more concerned by diseases other than Covid-19
- N/A

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- MPP should collaborate with others, including WHO, FIND, CHAI, etc., to develop database of potential suppliers; EOIs
- Versatility/flexibility of the technology, ease of use and well-defined protocols, open-access reagents, open-system and low-cost enclosure and technology
- Continuous engagement. Detailed and trusted assessment of the technology and market potential.
- I am not sure as this isn't my field
- Show benefits of possible association (e.g. expanded market, knowledge of local conditions/regulations)
- Manufacturers selling to LMICs are often deterred by the necessarily low price point. A robust market and expectations for reasonable profit are considerations.
- Facilitate market access in LMICs, reasonable margins on top of production costs
- No comment
- use trade shows
- very good question. Interested to hear more about this as it is crucial and both MPP and C-TAp do not have experience on how to do it; would be important to discuss if funding support to cover the cost of the technology transfer by a third partner would be consider crucial. FIND has interesting experiences about this.
- C-TAP is promoting EOI model and mapping of potential manufacturers
- It is often easier to lean on existing manufacturer partnerships but it is critical to showcase your value and attract manufacturers through offering proof of concept testing in own labs, providing user-/human-centered design support, selectively building relationships with key stakeholder such as MOH, using in-country presence to support local implementations, and could offer dossier submission support though it it increases legal responsibility.
- Commitments from the out-licensing party and regional/global actors to support the tech transfer (including regulatory processes)
Active reach-outs to possible licensors and licensees taking into account the nature of diagnostics technology development which require access to multiple types of technologies, materials and data; should look for partners who are open for different business model and approaches
Tax incentives, advances purchase commitments

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Regional pooled procurement systems
Many, key issue for discussion.

3c. Should MPP give preference to entering into license agreements with local diagnostic manufacturers in LMICs? Please explain why and how?

- Yes if they are prepared to share IP (and this should include Universities and other public research organisations who probably own most of the patents), but at this stage most technology will still come from the global North.
- yes, the reason is that very often diagnostic manufacturers in LMICs might have unique knowledge about solving supply/import problems
- Yes. This is an essential aspect of technology transfer, although provision must be made for output to be sold on fair terms to local rather than foreign, especially OECD, markets.
- Some degree of preference is desirable especially for underserved regions. There could be a limited % allowance for the increased costs of start-up and local production, with potential fade-out period, though for smaller manufacturers some ongoing price subsidization may be appropriate.
- Yes, by licensing the non-Commons part of the technology and defining what is and what is NOT part of the Commons (library of open-access knowledge). A hub should provide sub-licenses to designated competent diagnostic manufacturer which will allow: ramping up production where needed; QA/QC; possible centralized/decentralized mechanism of distribution of both technology and up-to-date knowledge
- In general, yes, but it may depend on the specific technology and target market, and the urgency of the implementation. For example, local manufacturers, with smaller production and commercialization capacities, may be better suited for smaller markets that are relevant to their regions. As local manufacturers scale-up, they may then benefit for larger, global markets.
- If those manufacturers have a strong infrastructure and functional regulatory systems then perhaps. I think the epidemiology of the disease matters as well. If the Burden is higher in an Imic then it should get preference.
- Yes, to support development of industrial capacities in LMICs

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- As long as the local manufacturers meet quality system requirements and claims are supported appropriately. This can be done through WHO pre qualification.
- Yes to support diversified and sustainable manufacture, through negotiation of tech transfer provisions from IP owner if required
- Yes, because it is strategic to invest in the capacity of local diagnostic manufacturers in LMICs to manufacture the diagnostics used in their countries and regions. This not only furthers global equity, but it also supports supply chain resilience and may lower costs.
- yes, this will address some of the issues around inequities of access to life-saving commodities including diagnostics and will hopefully create economic benefit for LMICs
- Diagnostics licenses should be open to anyone that applies to it, and the ability to apply for a license should not be limited in time. Some prospective licensees may currently lack CRISPR diagnostics manufacturing capacity, but could develop it in the medium term or long term. If there are real or perceived intellectual property barriers, an open licensing commitment would encourage long term investments in manufacturing capacity. If the ability to apply for a license closes after a certain deadline, or discriminates against prospective licensees, it will fail to create the legal certainty needed to make such long term investments.
- C-TAP and MPP should facilitate diagnostic manufacturers in LMICs to access their licenses. For that, probably support for regulatory approval should be provide by those or other partner entities.
- Not only MPP, Local production should be promoted the problem are quality requirements and standards that need to be defined or reviewed for IVDs
- In an ideal world, yes! But in reality this requires you to take on much more risk and potentially provide more technical assistance. As long as you can build a strong relationship to ensure sustainability this should be the first choice.
- Yes, fostering technology transfer and local capacity of diagnostic is crucial for increasing local availability and access. This has been recommended in a number of UN/WHO documents and requires and active policy to become a reality.
- There should be no restriction in licensing agreements. However, if prioritization is needed by MPP the current inequity in diagnostics

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manufacturing capacity between HICs and LMICs requires prioritization of local diagnostics manufacturers in LMICs.

- yes

3d. Should MPP give preference to entering into license agreements with national government or parastatal diagnostic manufacturers? Please explain why and how.

- Yes as most IP comes out of Universities or public research institutes and you want to license it before it gets stuck in an exclusive licensing contract with a spin-out company.
- possibly yes, but keeping in mind that many LMICs national governments do not have a capillary reach
- Not necessarily. The line between parastatal entities and those that just received government support, even indirectly, is blurry. It is the conditions of licensure that matter more, especially long-term technology transfer and product access terms.
- Yes. This would create a closer nexus because production/procurement/use, mitigating some of the risk of private sector manufacturers worrying about future market conditions.
- A centralized/decentralized model can be adapted thus: a centralized national hub, handling IP licensing, and distributing technology knowledge and sub-licensing to local manufacturers, ensure more open R&D and access to key tools
- To be discussed, as it may depend on the model, governance, and strategy for the particular manufacturer.
- I am not sure as this isn't my field
- Will depend on circumstances
- Again, it depends upon the state of the quality system that can be maintained. Monitoring this state on a regular basis will be essential.
- if possible yes, to facilitate market entry and product adoption at national level
- No comment
- The advantage of parastatal diagnostic manufacturers may be more nimble than govts in rolling out a programme and achieve milestones and deliverables. The downside is that unless laws in the country can be brought to bear on issues such as governance, corruption and consequences of non-compliance of the terms set out in the agreement, there is no recourse to address such issues.

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- See answer to question 3c.
- Not sure I understand the question.
- MPP as an implementing partner of C-TAP has the possibility to increase interaction with WHO Member States including for licensing negotiations with public sector
- In an ideal world, yes! As long as these manufacturers are in fact committed to public health and have a source of sustained support from the government. This should be the second choice.
- Preference could be given to non-profit manufacturers.
- Yes – prioritization should be given to diagnostic manufacturers that are publicly owned entities and/or with a non-profit model.
- Yes

#4 How should affordability be defined in licenses for diagnostics? Are models like cost-plus pricing applicable in diagnostics.

- Yes, cost-plus (max 40% overall) is ideal, but since calculations can vary it would be great to standardise this. Preferably also with conditions around service and maintenance of instruments and in-country prices post shipping and with the distributor mark-up (otherwise all your 'ex-works' low price work will be ruined with high in-country pricing and terrible customer service). Competition law may have to change to facilitate this.
- Cost-plus is justified, though there are some disincentives in terms of achieving manufacturing efficiencies. This could be offset by increasing mark-ups for efficiencies and product improvements.
- Cost-plus pricing are not sustainable in diagnostic, if we want to distribute widely to populations in LMICs. Transparency and sharing the burden of potential rising costs and services amongs hubs and local manufacturers ensures the end user is not burdened with cost plus pricing.
- Standard models are mostly applicable, with some caveats. It is important to define COGS, as different manufacturers include different components into COGS. Distribution mark-ups may also be significant for IVD products and need to be carefully considered during negotiations. Amortization also needs to be carefully considered. Shipment costs also vary significantly by regions, and they fluctuate widely in times of emergencies, like COVID; so other incoterms like CIF/CIP may be best, if applicable.

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- I am not sure as this isn't my field
- Such models may be applied to diagnostics
- This is outside of my expertise - apologies!
- Cost-plus pricing models supports affordability. Why would they not be applicable in diagnostics?
- Affordability for diagnostics should be defined as COGS+ pricing, with public transparency of COGS, annual external COGS audits, and regular volume-based price reductions based on COGS.

COGS+ pricing, however, requires a determination of what is a reasonable/rational profit mark up for the company. An example is 10-20%, but this will necessarily be test-, company-, and volume-specific. A standardized methodology for determining COGS and fair/sustainable profit for the company is needed (FIND is currently in the process of developing such a methodology). Profit margins should decrease as higher volumes are reached.

If COGS+ pricing results in pricing that is not affordable in LMICs (which should be avoided by fully vetting initial investments), external subsidies can lower prices or, if tests will be marketed in high- and low- and middle-income countries, an equitable approach to differential pricing can be applied, as detailed in this article by Suerie Moon:

<https://www.bmj.com/content/368/bmj.l4726>

If external subsidies are applied, these should simultaneously be applied to other manufacturers of similar diagnostics to not favor one technology over another and to support competition.

TAG's policy brief "Advancing Access through Market Interventions: Lessons Learned from the GeneXpert Tuberculosis Test Buy-Down" provides recommendations and conditions on funding agreements to ensure that market interventions result in improved access in the short and long terms:

<https://www.treatmentactiongroup.org/publication/advancing-access-through-market-interventions-lessons-learned-from-the-genexpert-tuberculosis-test-buy-down/>

In any case, all pricing should be transparent and evidence based. The FIND Global Access Policy and recent RFP provides some language on affordable pricing to draw from:

https://www.finddx.org/wp-content/uploads/2021/07/FIND-Global-Access-Policy_PL-02-08-07_V1.1_JUL2021.pdf

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<https://www.finddx.org/wp-content/uploads/2021/07/Request-for-Proposals-POC-MDx.pdf>

- cost-plus pricing should be an important model for ensuring affordability while making it attractive to industry
- affordability is not defined in licenses for drugs. Affordability is expected to be reached via competition. Not sure will be the case for diagnostics. Will be good to discuss.
- Promoting competition among manufacturers is always the best way to reduce prices, however on a case by case basis pricing and other affordability provisions should be explored
- It would be great to have COGS+pricing in diagnostics but really need to consider all other factors that make a market sustainable to assess feasibility. For example if a dual market exists this model can be profitable to the manufacturer while providing global access. However, if only selling in LMIC you really need to consider what the minimal pricing is for manufacturers to stay in the market long-term and not pull out due to a risky environment. Having a transparent and strong relationship with manufacturers allows for discussions and negotiations to ensure affordability.
- Transparency is key and there should be full transparency by the licensee in the cost of production, sales prices, and sales volumes. Pricing should be based on the cost of production (COGS) plus a reasonable profit margin (max 20%).
There should be commitment that profit is circled back into R&D and ensuring access conditions rather than flowing to shareholders
Licensees should commit to negotiate reasonable and capped mark-ups with distributors (max 10%).
- To be discussed, include full cost of delivery, e.g. not only test but reagents and test materials.