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# Emerging opportunities in vaccine innovation

DCVMN Webinar

June 22, 2021

# Vaccine innovation includes both improving current vaccines as well as developing novel vaccines for diseases for which no vaccine exists

## Improved vaccines

*Offer additional value over existing products for the same disease*

- Improvements can take many forms e.g.,
  - **Increasing efficacy** (e.g., increasing PCV, HPV serotype coverage, etc.)
  - **Increasing ease of implementation / delivery** (e.g., MR microarray patch, combination vaccines such as hexa, heat stable rota, etc.)
  - **Decreasing price** (e.g., lower COGS technologies)

## Novel vaccines

*For diseases with no vaccine available*

- Address unmet health needs
- Needs often characterized based on direct mortality but may also be benchmarked to other factors e.g.,
  - Morbidity
  - Epidemic potential
  - Impact on AMR (antimicrobial resistance)
- Novel vaccines for needs related to these alternative factors typically require a unique business case

*Today's webinar will focus on evaluating opportunities within novel vaccine development while recognizing that improved vaccines may also play an important role in DCVM innovation strategies and pipelines*

# Prioritization for novel vaccine development may be evaluated based on detailed analysis of 1) commercial opportunity and 2) developer fit

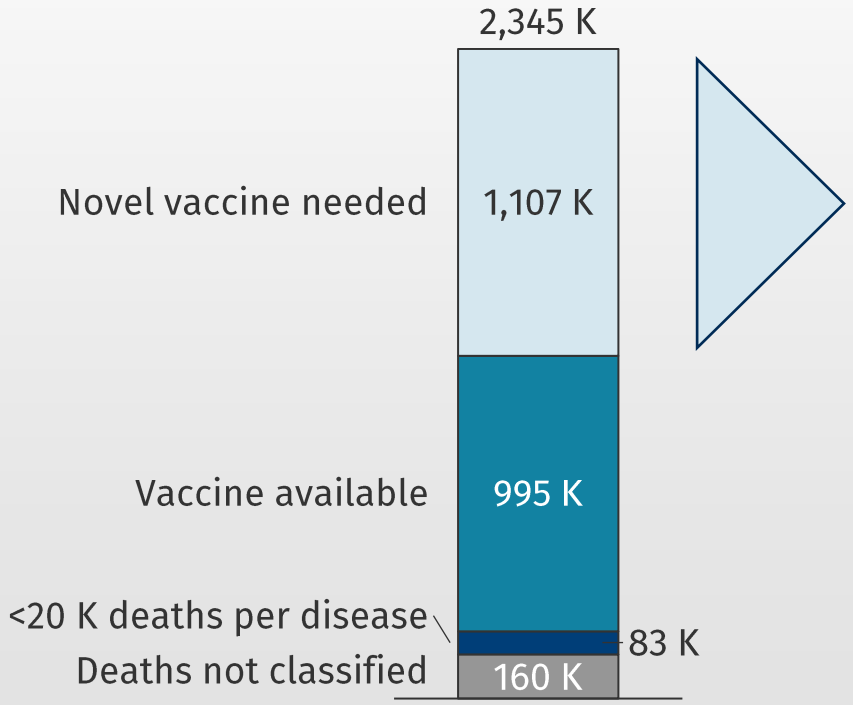
| Commercial Opportunity | |
|---|---|
| **Health burden and need** | • Unaddressed mortality and morbidity of disease |
| **Total market size** | • Total demand (based on expected uptake)<br>• Pricing potential |
| **Competitive landscape** | • Likely share if potential for multiple novel entrants |

| Developer Fit | |
|---|---|
| **Technical expertise** | • Ability to successfully develop / manufacture technology |
| **Go-to market reach** | • Ability to access / compete in relevant markets |
| **Strategic fit** | • Contribution to company objectives / long-term vision |
| **Portfolio balance** | • Complements / offers synergy with broader portfolio |

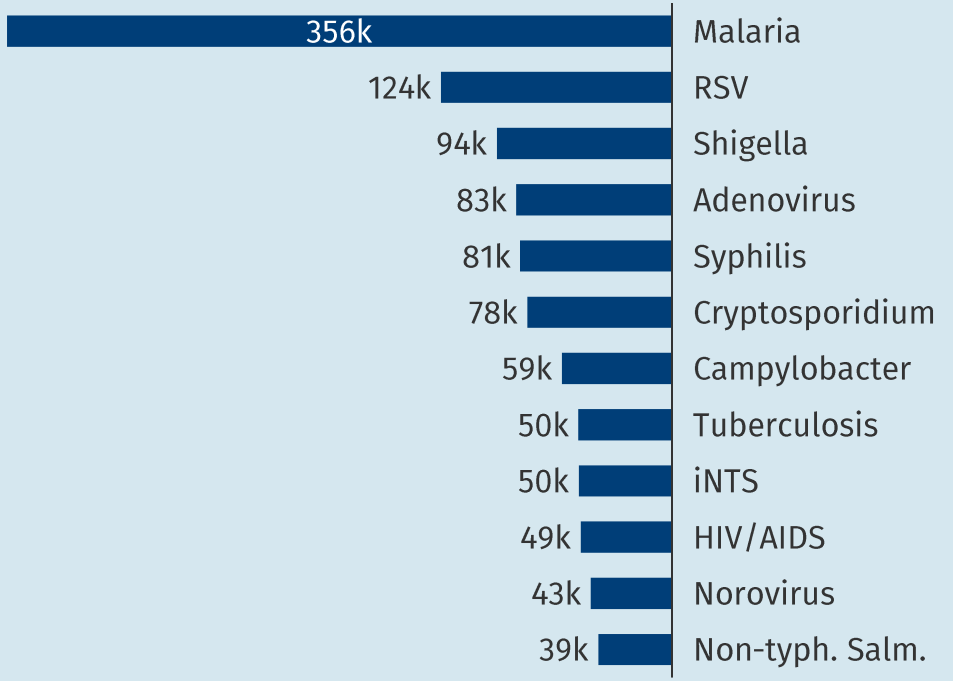
*Please contact CHAI if you would like tailored support in evaluating novel vaccine development opportunities*

# Understanding key drivers of vaccine preventable deaths is one lens through which to identify needs in novel vaccine development

## Global U5 deaths from infectious disease causes (2019)[1]



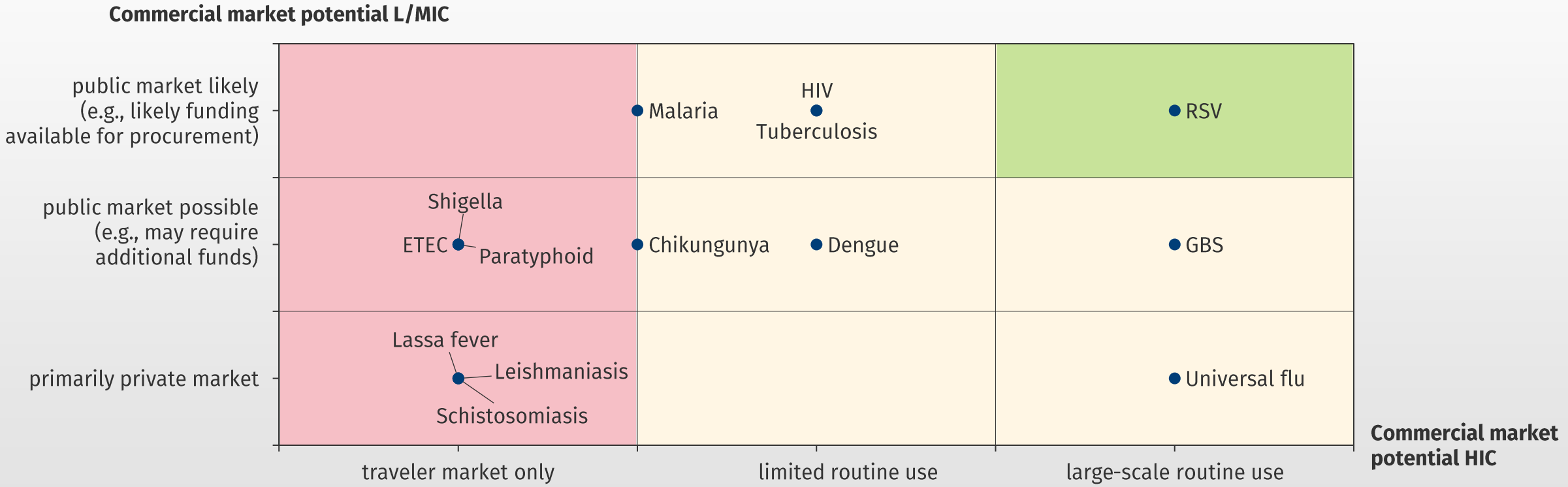

## Global U5 deaths from infectious disease needing novel vaccines[2] (2019)[1]




Source: [1] IHME GBD Data. [2] Note: List of diseases does not consider technical feasibility of development – for several diseases there may be no vaccines currently in development. RSV: Respiratory syncytial virus. iNTS: Invasive non-typhoidal salmonella. NTS: Non-typhoidal salmonella.

# CHAI conducted a high-level assessment of the market potential of several novel vaccines, considering both L/MIC and HIC opportunities

*Non-Exhaustive*




Note: Vaccines assessed included those nearing or in Phase 2/3, which are prioritized by partners and have notable burden – they do not necessarily correspond 1:1 with optimal opportunities for DCVMs

# Within novel vaccine development, there are several novel vaccine archetypes and today we will evaluate case studies across archetypes

*Decreasing burden and clarity of market opportunity*

| | **The "Big Three": High burden, defined opportunity** | **Moderate burden, defined opportunity** | **Moderate burden, uncertain market opportunity** |
|---|---|---|---|
| *Description* | • Infectious diseases with the highest annual deaths<br>• Clear expectation of market opportunity due to high burden | • Diseases with moderate burden (e.g., > 100 K) and an early indication of support (e.g., funding to develop/procure) | • In most cases of diseases with moderate burden, there is not a clear indication of the market opportunity, increasing risk of development |
| *Examples* | • TB, HIV, Malaria | • RSV | • Shigella, iNTS |
| *Today's deep dive* | • **TB** | • **RSV** | • **GBS** |

# TB is the world's biggest infectious killer, and vaccine is a major priority for global partners, donors and some high-burden countries

## Health burden and need

1.4 M deaths (2019)

- Models show adolescent/adult vaccine likely greatest impact
- Most absolute burden is in key MICs (RSA, China, India), but many LICs have significant need

## Total market size

*Focus on adult/adolescent vaccine*

Key factors informing market size:

- **Eligible population** Adults/adolescents in high- and mid-burden countries
- **Uptake:** TB burden well-understood, but funder policy remains open
- **Coverage:** Challenges of adult vaccine delivery

## Competitive landscape

*Focus on adult/adolescent vaccine*

| Phase 1 | Phase 2 | Phase 3 |
|---|---|---|
| 8 | 8 | 2 |

- M72/AS01 candidate expected to enter Ph 3 in 2023
- Opportunity for manufacturing partnerships may emerge
- See tools from TBVI and IAVI: https://www.tbvacpathway.org/

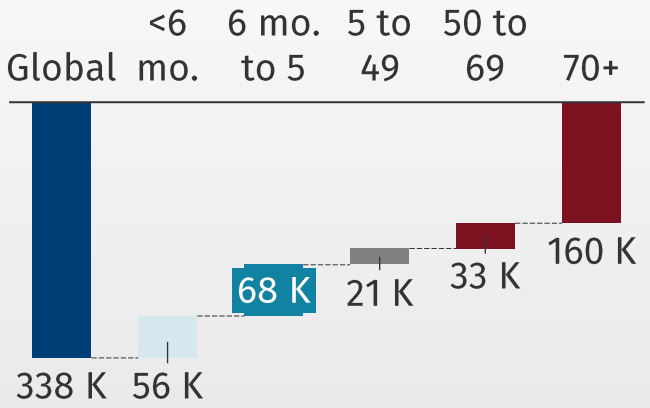
**Key Takeaways**

- High priority for funders and countries
- Developers may require partnerships with manufacturers to achieve LMIC access
- Some DCVMN members already playing key role

# RSV presents a clear health need with likely Gavi funding despite possible uptake challenges: however, to date DCVM RSV development limited

## Health burden and need

**Global RSV Deaths by Age** (2019)




Infant mAb / maternal vaccine

Pediatric vaccine

Elderly vaccine (e.g., 60+)

## Total market size
*Focused on infant mAb and maternal vaccine*

Key factors informing market size:

- **Eligible population:** Live births (mAb) or pregnancies (vx)
- **Uptake:** Limited awareness and surveillance may slow uptake, but have in principle Gavi support
- **Coverage:** Platform challenges

## Competitive landscape
*Focused on infant mAb and maternal vaccine*

| | | |
|---|---|---|
| Ph. 1 | 1 vx | |
| Ph. 2 | - | |
| Ph. 3 | 2 mAbs | 2 vxs |
| | MERCK | Pfizer |
| | SANOFI AstraZeneca | gsk |

**Key Takeaways**

- If market materializes as expected, there might be a potential opportunity for DCVMs to help facilitate L/MIC access, e.g., via a tech transfer

Source: IHME GBD Data 2019; https://www.path.org/resources/rsv-vaccine-and-mab-snapshot/

# GBS poses a moderately high disease burden in infants, but an uncertain commercial opportunity may have limited development to date

## Health burden and need

~147 K stillbirths and infant deaths annually[1]

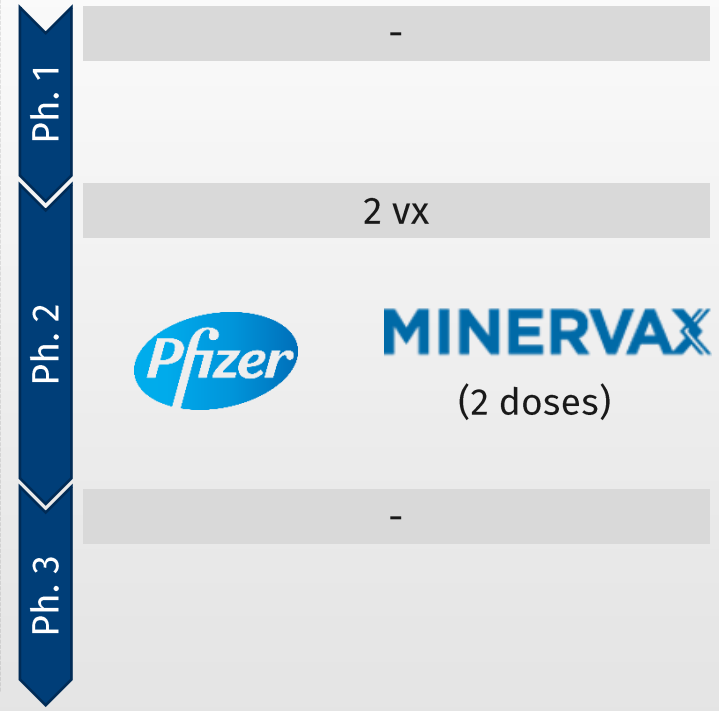
- Conservative estimate – may be greater
- Burden highest in LMICs where screening pregnant women and use of antibiotic prophylaxis limited → ~65% of still births and infant deaths in Africa

## Total market size

Key factors informing market size:

- **Eligible population:** Pregnancies
- **Uptake:** Uncertain funder policy (e.g., Gavi, countries)
- **Coverage:** May be limited by maternal platform challenges, particularly if two dose

## Competitive landscape




**Key Takeaways**

- Need for greater clarity on commercial opportunity, particularly funding, despite moderately high burden
- If commercial opportunity confirmed, potential opportunity for DCVMs to play greater role in GBS given relatively sparse pipeline

Source: [1] https://pubmed.ncbi.nlm.nih.gov/29117332/.

# In addition to determining *which* vaccines, considering the trade-offs of *how* (in-house vs. in-licensing) is also key for engaging on novel vaccines

## How to add novel vaccines to pipeline?

### In-house develop.

- Avoids licensing costs
- Higher scientific and technical expertise needed

### In-licensing

- Early
- Late

- Allows rapid access to expertise and technology

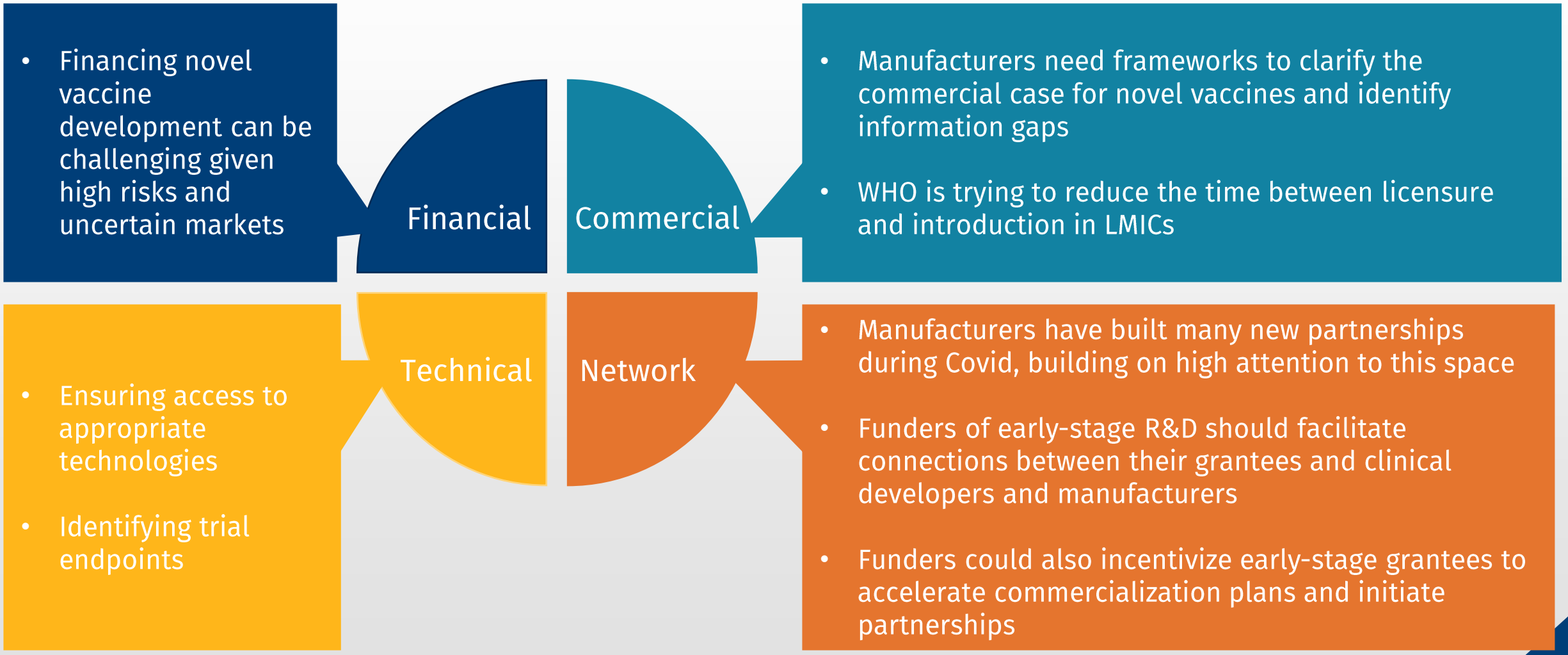
- While in-licensing offers key benefits, 2019 survey of ~20 DCVMs found only ~20% of innovation programs were in-licensed and **> 60% of DCVMs noted limited access to partnerships** as a barrier to novel vaccines
- Increased access to in-licensing opportunities needed

## Key questions for in-house vs. in-licensing

- Capabilities needed (i.e., technical)?
- Cost and resources needed?
- Time-to-market for in-house vs. in-licensing?
- Availability of candidates for in-licensing?
- Specific benefits of in-licensing?
- IP landscape?

Source: [1]Hayman, Bowles, Evans, Eyermann, Nepomnyashchiy, Pagliusi. *Vaccine*. 2021. https://pubmed.ncbi.nlm.nih.gov/33487466/

# Potential challenges for DCVMs innovating can be divided into four categories – each of which will require specific efforts to overcome



# Q&A Session

Thank you for your participation!

Please contact Alex Bowles (abowles@clintonhealthaccess.org) with any questions.

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