COVAX Developer Workshop Results

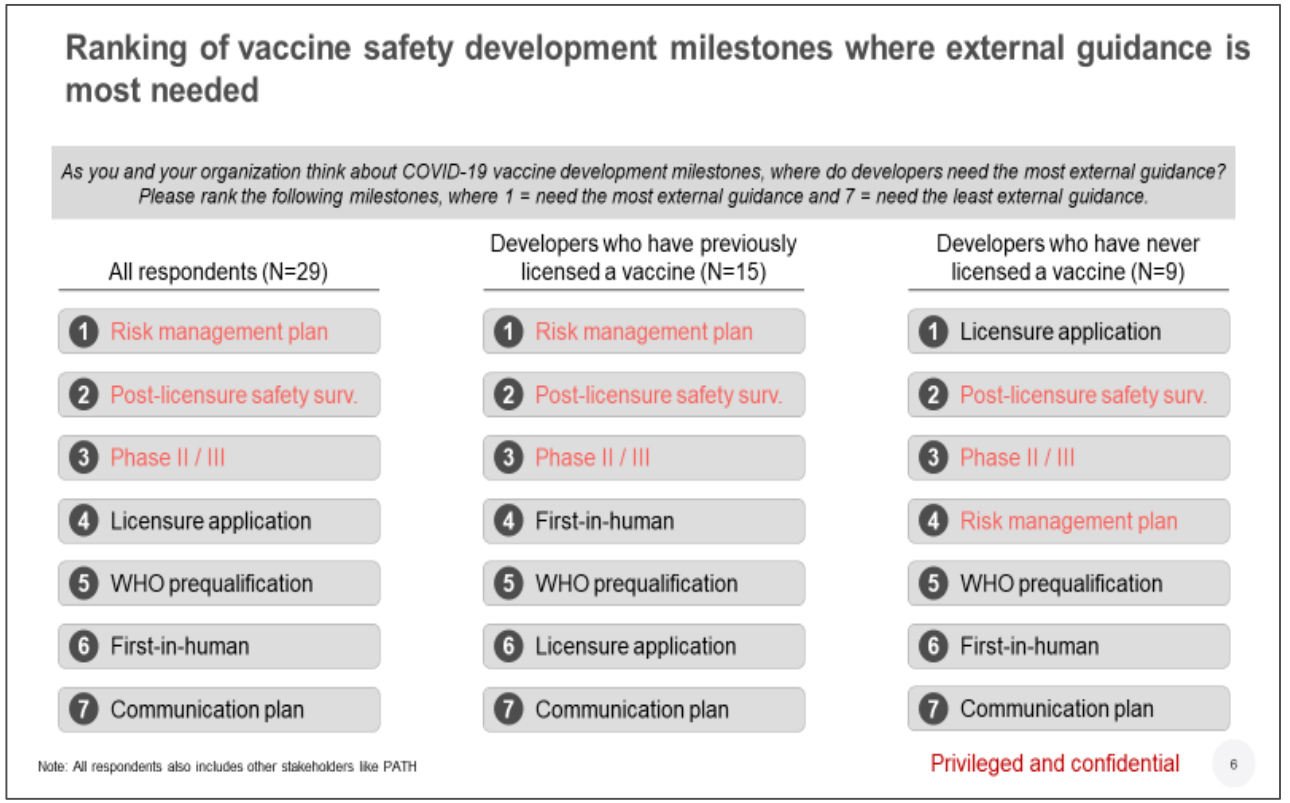
September 9, 2020

Overview of the developer pre-workshop survey

Objectives	• Collect information on developer needs that can inform priorities for Vaccine Safety working group and other organizations
High-level topics covered	• Experience with vaccine safety topics in the development of novel vaccines • Regulatory authorities that developers plan to submit licensure for • COVID-19 vaccines in development – development stage, vaccine constructs, adjuvants • Vaccine development milestones where external guidance is most needed
Who we heard from in the survey	• Developers (N=24): Those in advanced COVID-19 vaccine development • Other stakeholders (N=5): Product Development Partners (PDPs; e.g., PATH)

Key takeaways

- Developer needs differ depending on their **prior (licensing) experience**
- The **top three areas** ranked across all developers are:
  - Risk management plan development
  - Post-licensure safety surveillance
  - Phase II/III
- Vaccine safety guidance and support should be **tailored** to:
  - Specific resource setting
  - Prior licensing experience
  - Vaccine platform/adjuvant
- Several potential **cross-cutting safety issues** identified
- Need to establish an **information sharing platform** across HIC and DCVM developers

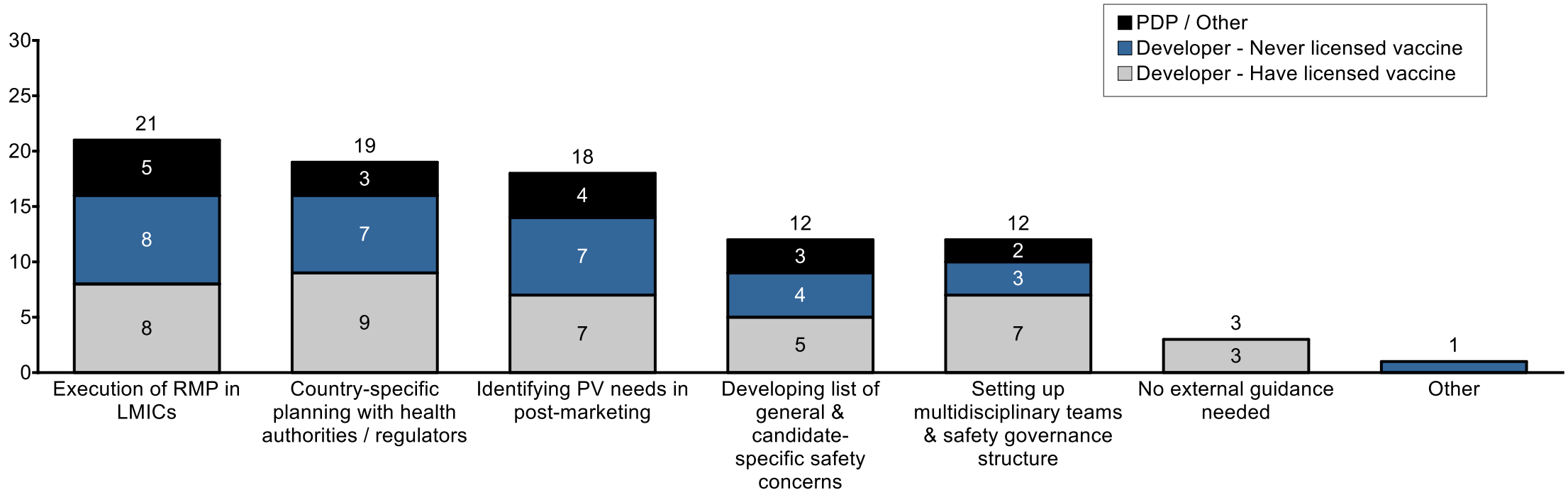


1 Risk Management Plan: Survey results

Developer needs identified

*Within the **Risk Management Plan** milestone, which specific topics do developers need external guidance on? Please select all that apply and feel free to submit topics that are not listed below.*

Respondents who indicated external guidance needed by sub-topic (N=29)



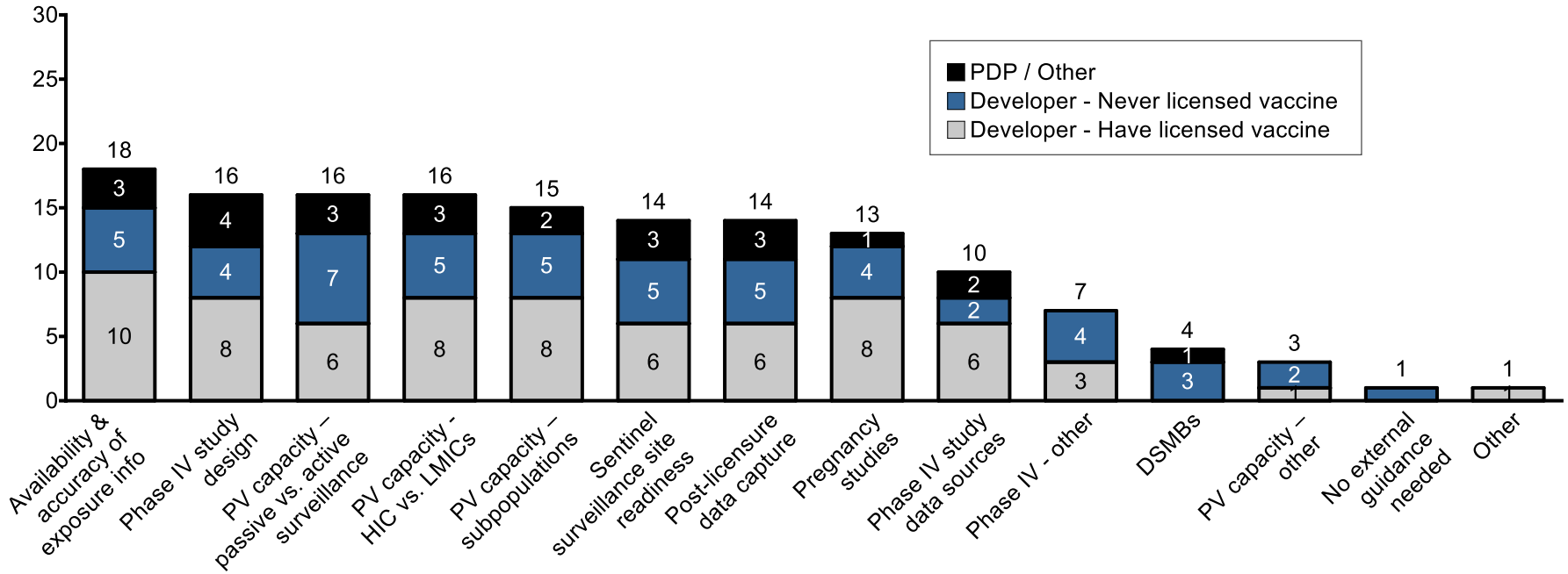
2 Post-Licensure Safety Surveillance: Survey results

Developer needs identified

Other submitted needs

*Within the **Post-Licensure Safety Surveillance** milestone, which specific topics do developers need external guidance on? Please select all that apply and feel free to submit topics that are not listed below.*

Respondents who indicated external guidance needed by sub-topic (N=29)



"Interaction / collaboration between public and private sectors"

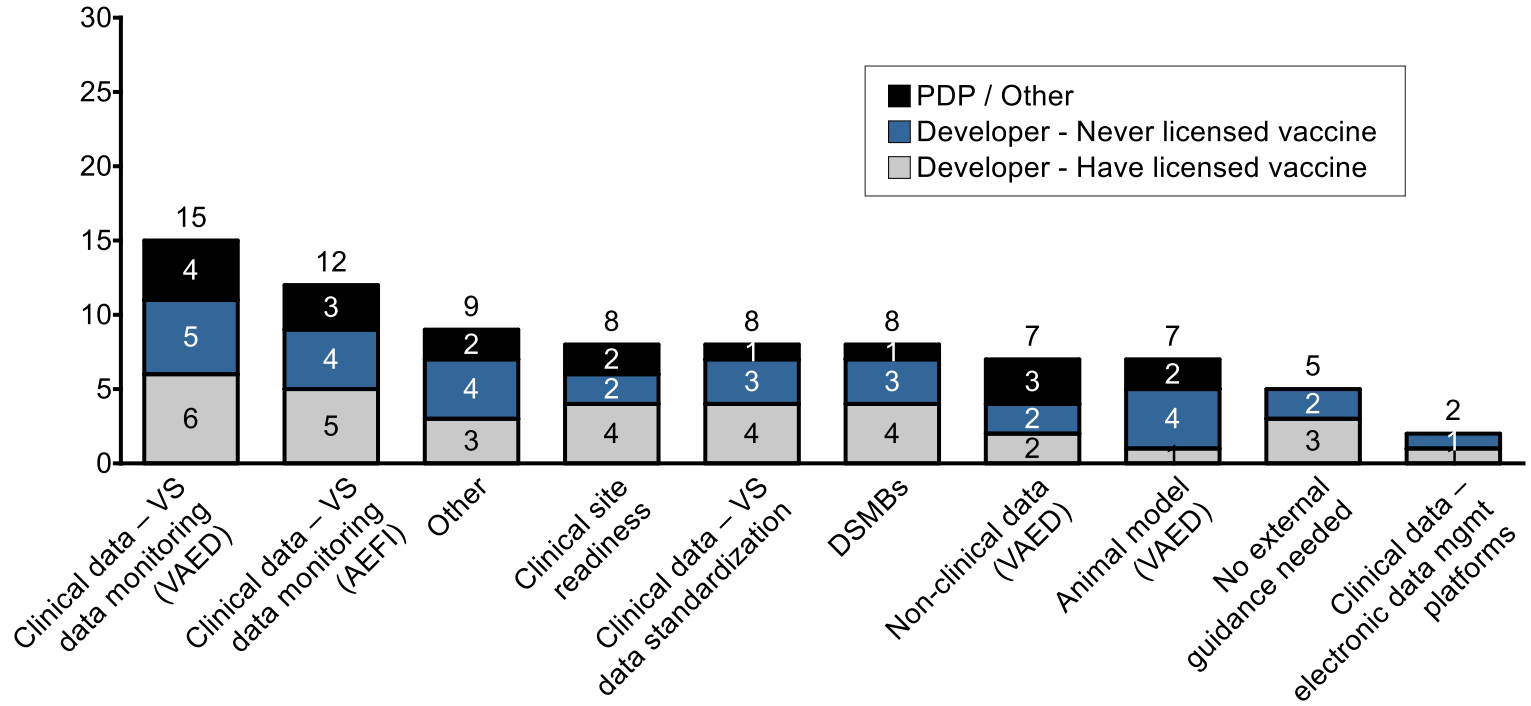
❸ Phase II/III: Survey results

Developer needs identified

Other submitted needs

*Within the **Phase II/III** milestone, which specific topics do developers need external guidance on?*
Please select all that apply and feel free to submit topics that are not listed below.

Respondents who indicated external guidance needed by sub-topic (N=29)



"Signal detection methodology for clinical trials"

"AESI determination and case definitions"

"Sample size to meet statistical threshold"

"Clinical data – specific safety assessment regarding theoretical risk of disease enhancement"

"Primary, secondary, and exploratory endpoints"

"Validation of laboratory assays and grading COVID-19 disease in a robust way across many different healthcare settings"

"Primary efficacy and immunogenicity endpoints"

"Efficacy trial design; correlates of protection"

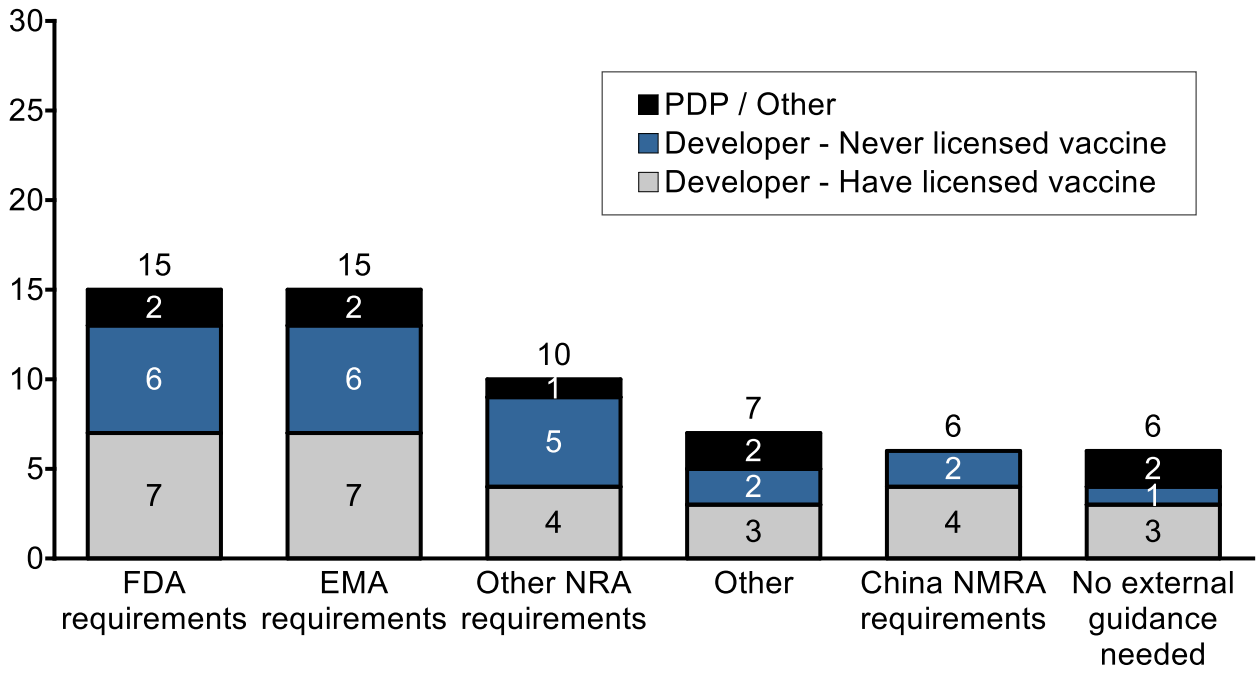
4 Licensure Application: Survey results

Developer needs identified

Other submitted needs

*Within the **Licensure Application** milestone, which specific topics do developers need external guidance on? Please select all that apply and feel free to submit topics that are not listed below.*

Respondents who indicated external guidance needed by sub-topic (N=29)



"Clarity on regulatory pathway(s) for emergency use"

"Needs of NRAs in LMICs (in contrast to FDA and EMA)"

"Guidance on submission in LMICs"

"India, Australia"

"1) Non-live filling lines shall be allowed for filling of live products if adequate risk assessment is performed to make the rapid availability of the Covid19 vaccine 2) Vaccine Vial Monitor (VVM) shall not be applied for commercialization through UNICEF considering the extensive studies required for categorization of VVM 3) Any other new requirements as per country specific NRA"

We also shared a list of cross-cutting issues that need to be addressed relatively soon

Category	Specific issues to be addressed
Data collection, sharing, and comparison	• Comparison of safety data in the absence of a head-to-head trial • Comparison of safety data on similar new technology platforms across different candidates • Comparison of safety data across countries • Willingness to contribute data to harmonized follow-up studies of VAED • Feasibility of registry for COVID-19 trial placebo recipients who remain unvaccinated
Post-licensure safety surveillance	• Collection and utilization of background rates of AEFI and AESI • Tracking of vaccine exposure information so AEFI's provide useful information • Process for formally declaring a "safety signal" and information sharing plan • Access to limited post-introduction active surveillance pharmacovigilance (PIASP) capacity for regulator-mandated studies

Given the feedback from the workshop, below is a list of developer needs to be addressed

- Develop core pandemic COVID-19 **risk management plan**
- Support developers as they **strengthen internal capacity** for RMP development and adoption
- Continue to support **NRA capacity building** activities
- Create forum(s) for **regular engagement** between (1) developers and WHO and (2) IFPMA and DCVMN networks
- **Strengthen and harmonize post-licensure** safety monitoring systems and processes
- Continue to share vaccine safety monitoring **tools** (e.g., SPEAC tools, PATH prototype protocol)
- Contribute to resolution of **cross-cutting issues** as needed

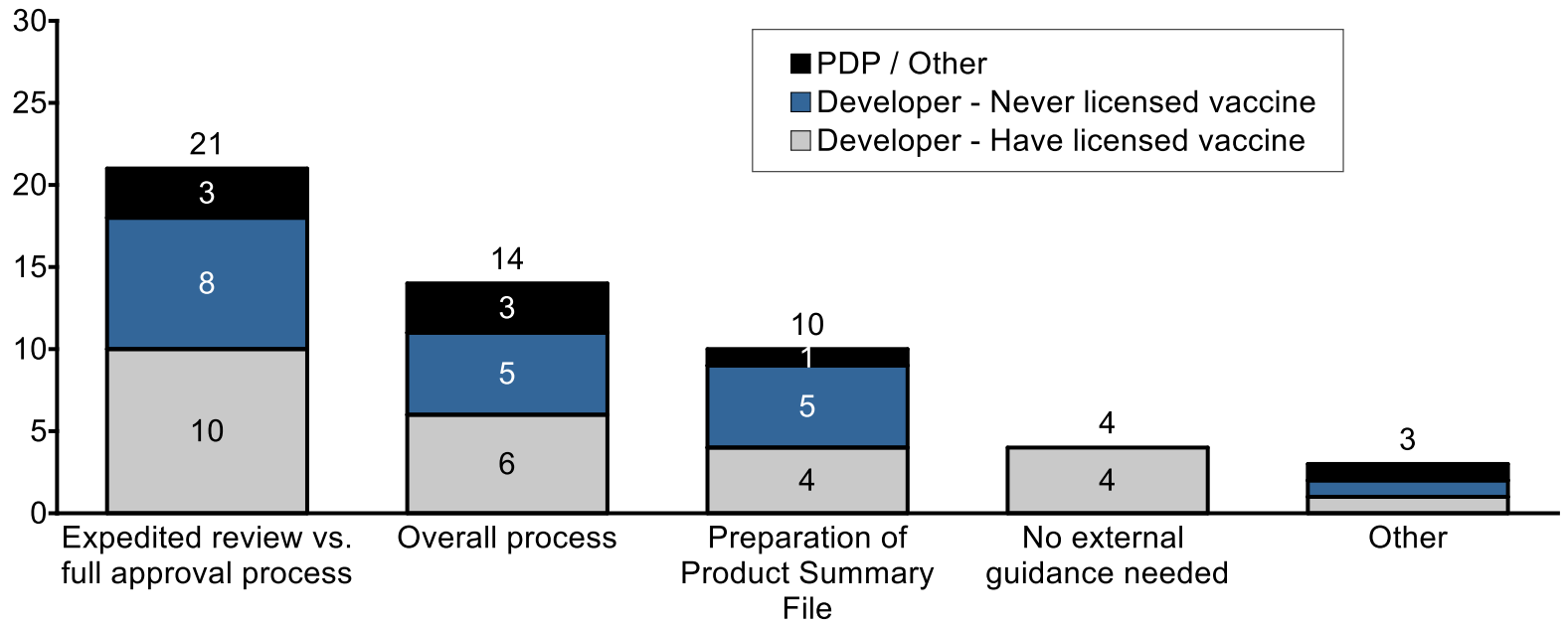
Appendix

5 WHO Prequalification: Survey results

Developer needs identified | Other submitted needs

*Within the **WHO Prequalification** milestone, which specific topics do developers need external guidance on? Please select all that apply and feel free to submit topics that are not listed below.*

Respondents who indicated external guidance needed by sub-topic (N=29)



"Response to WHO questions / concerns"

"No effectiveness trial shall be mandated for emergency use license if the safety was proven as this will significantly delay the vaccine availability"

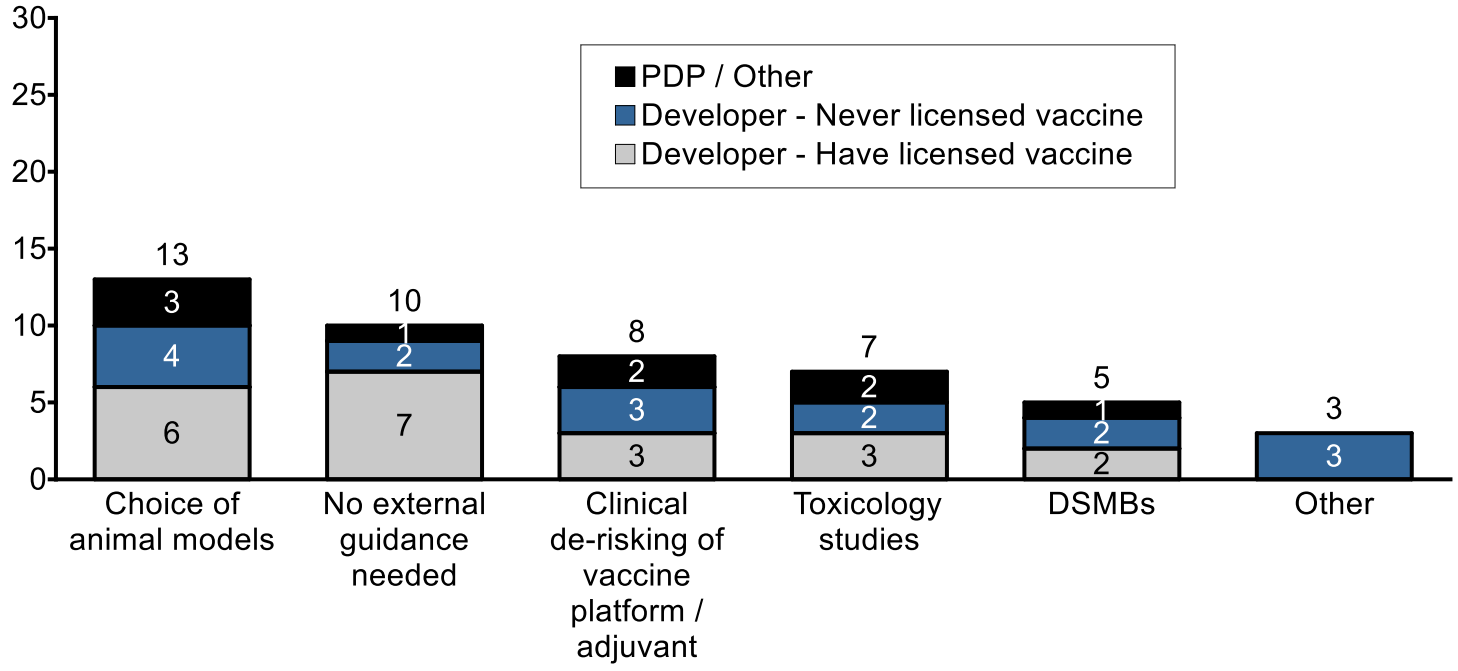
6 First-in-human: Survey results

Developer needs identified

Other submitted needs

*Within the **first-in-human** milestone, which specific topics do developers need external guidance on? Please select all that apply and feel free to submit topics that are not listed below.*

Respondents who indicated external guidance needed by sub-topic (N=29)



"NPH and human challenge"

"How to identify safety concerns in pre-clinical data"

"Clinical trial design"

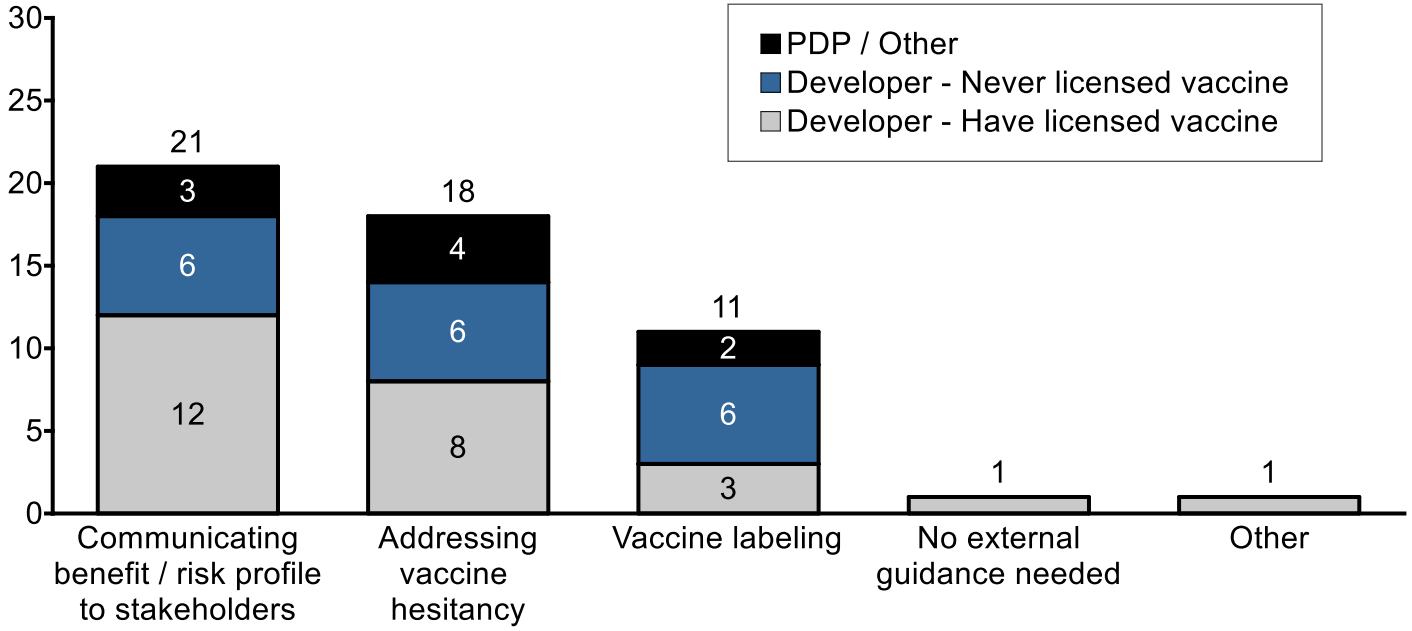
7 Communication Plan: Survey results

Developer needs identified

Other submitted needs

*Within the **Communication Plan** milestone, which specific topics do developers need external guidance on? Please select all that apply and feel free to submit topics that are not listed below.*

Respondents who indicated external guidance needed by sub-topic (N=29)



"Crisis Management"