**PDVAC Vaccine Value Profile for Priority Pathogens**

**DRAFT Version 1.1**

*This ‘Vaccine Value Profile’  (VVP) is intended to provide a high-level, holistic assessment of the elements that are currently available to inform the Full Value of Vaccines Assessment (FVVA) (*[*Hutubessy et al, 2021*](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3841999)*), for pipeline vaccines and vaccine-like products against priority pathogens.  A full value of vaccine assessment (FVVA) uses multiple different analyses to describe the health, economic, and societal value of a vaccine to a broad range of global stakeholders, including from a low- and middle-income country (LMIC) perspective, and aims to articulate the full direct (individual) and indirect (population) impact of a vaccine.  For some pathogens, VVPs will be developed for both vaccines and monoclonal antibodies that have  that have vaccine-like properties in terms of delivery, i.e. a long half-life and a programmatically compatible delivery schedule and route of administration.*

*This VVP**template has been developed in collaboration with WHO’s Product Development for Vaccines Advisory Committee (*[*PDVAC*](https://www.who.int/immunization/research/committees/pdvac/en/)*), with input from the policy team at Gavi. The intent is to develop these VVPs for approximately 15 priority pathogens, with a view to generating an assessment of pipelines for vaccines that are approaching pivotal licensure studies within the next 3 years, and may be considered for investment decision-making .*

*The framework herein is a combination of tables and text; the tables are intended to consolidate and compress information, and the italic blue text is intended to guide the summarization or key ‘take-aways’ from the table in brief text. Authors are requested to develop a reference list as part of this assessment.*

*These Vaccine Value Profiles will provide a (early 2022) snapshot view of the perceived public health need, the vaccine development and funding status, investment strategy and research gaps for each pathogen, and will be published collectively as a journal supplement.  They will be updated periodically as new information becomes available.  Each iteration of the pipeline assessment will include 1) an approval date; 2) a last review date, 3) a note of a timeframe when the assessment is considered out-of-date, e.g., the intent is to review the assessment at least every five years and will be considered out-of-date if the last review date is more than five years prior.  Future iterations will include a document change log. In addition to the Vaccine supplement, VVPs will be published on the PDVAC website .*

Contents

[1. The global public health need for a vaccine 3](#_Toc74587217)

[2. Potential target populations and delivery strategies 4](#_Toc74587218)

[3. Pathogen X and its consideration as a global or regional public health priority 5](#_Toc74587219)

[4. Existing guidance on preferences/preferred product attributes for vaccines against pathogen X 6](#_Toc74587220)

[5. Vaccine development 7](#_Toc74587221)

[6. Health Impact of a vaccine on burden of disease and transmission 8](#_Toc74587222)

[7. Social and/or economic Impact of a vaccine 9](#_Toc74587223)

[8. Policy considerations and Financing 10](#_Toc74587224)

[9. Access and Implementation Feasibility 11](#_Toc74587225)

[10. Conclusion 11](#_Toc74587226)

**Appendices:**

Appendix A: Framework to inform section 5 - Vaccine development

Appendix B: Framework to inform section 8 - Access and Implementation Feasibility

Appendix C: Potential list of priority pathogens for FVVA-Lite assessments

**Abbreviations:**

AMR Antimicrobial resistance

CFR Case fatality rate

CSO Civil Society Organization

FVVA Full Value of Vaccines Assessment for Vaccines

HIC High-income countries

LMICs Low- and middle-income countries

PAHO RF Pan American Health Organization Revolving Fund

PPC Preferred Product Characteristics

PTRS Probability of Technical and Regulatory Success

TPP Target Product Profile

VIS Gavi Vaccine Investment Strategy

# 1. The global public health need for a vaccine

*Briefly describe the unmet public health need (i.e., burden of disease), and epidemiology in the context of available interventions.* *What is the relative burden in LMICs? What is the problem statement that a vaccine is seeking to address?*

*Table 1: Summary of epidemiology and potential indirect public health impact*

Use the template below as a framework for this analysis, where data are available:

| Feature | Summary and evidence | References |
| --- | --- | --- |
| 1.1 Epidemiology | | |
| Reservoir | *Describe significant animal +/- vector sources of transmission to humans; if human only, describe transmission reservoir(s)* |  |
| At-risk populations | *Identified at-risk sub-populations, or indicate general population* |  |
| Mortality | *Include case fatality ratio (CFR) by age and/or at-risk sub-populations* |  |
| Morbidity | *Include severity and sequelae by age and/or at-risk sub-populations* |  |
| Geographical and seasonal distribution | *Of burden, by region/country/season (mortality and morbidity); data limitations?* |  |
| Gender distribution | *Comment on heterogeneity, including in transmission; comment on additional risk(s) during pregnancy or breast-feeding to mother and foetus/neonate; data limitations?* |  |
| Socio-economic status vulnerability(ies) (equity/wealth quintile) | *Comment on heterogeneity, including in transmission* |  |
| Natural immunity | *Include age of onset and duration of protection* |  |
| Pathogenic types, strains, and serotypes | *Heterogeneity of serotypes/pathotypes* |  |
| 1.2 Potential indirect impact | | |
| Anti-microbial resistance (AMR) threat | *Include associated infections, % of resistant strains, or level of pathogen-associated antibiotic use, if known, which is a proxy for development of AMR. Note: this will cross reference assessments for WHO AMR value attribution framework where relevant.* |  |
| Epidemic and outbreak potential |  |  |
| Transmission route/potential |  |  |
| Acquired/herd immunity |  |  |
| Co-associated mortality | *Does infection/disease by pathogen of interest contribute to other morbidity/mortality* |  |
| 1.3 Economic burden | | |
| Health facility costs/out of pocket costs/productivity costs |  |  |

*1.4 Current methods of surveillance, diagnosis, prevention, and treatment*

*Brief introduction to the current standard of care, including in LMICs if one exists, that is currently linked to the infection or associated conditions, and standard of care effectiveness in idealized and real-world use. This can include surveillance; vaccine use or other prevention (e.g., preventive anti-microbial use, or non-pharmaceutical personal or public health interventions); access to health services for care; availability of diagnostics and their real-world use; treatment and care (of all kinds including chemotherapeutic prevention, palliative); behaviour change that requires healthcare input, etc.*

*1.5 Summary of knowledge and research gaps in epidemiology, potential indirect public health impact and economic burden*

*Please summarise, in the form of brief bullets, the priority knowledge and research gaps that if addressed, could inform the value assessment of this vaccine.*

# 2. Potential target populations and delivery strategies

How would a vaccine be delivered (fit within the immunization schedule or other intervention delivery mechanism including vaccines for other pathogens, what is the anticipated/optimal schedule)?

*Given the at-risk populations, burden, and potential impact, what are the priority target populations in different sectors (please differentiate by HICs, MICs, LICs if relevant), and is there existing setting/mechanism(s) for delivery in those contexts?*

*Table 2: Overview of potential target and key population(s) and associated delivery strategy(ies)*

Use the template below as a framework for this analysis, where data are available:

| Target and key population(s) *(including vulnerable populations)* | Delivery strategy(ies) *(potential setting and fit within the immunization schedule or other intervention delivery mechanism)*  *What assumptions underlie the anticipated/optimal schedule?* | References |
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# 3. Pathogen X and its consideration as a public health priority by global, regional or country stakeholders

List the types of stakeholders likely to have significant or prioritized interests in a vaccine, and if known, evidence of stakeholder engagements (reports, papers, press releases, advocacy materials). Stakeholders can be sub-divided into global, WHO regional, individual countries, and can include: public and private funders and donors; global, regional, and national policymakers including WHO; global / regional / national advocacy groups.

*What is known about the demand in various market segments, i.e., HIC vs LMICs; private vs public? Is this considered a ‘dual market’ vaccine (with potential demand and uptake in both HICs and LMICs, and/or public and private markets) or a vaccine with potential demand and uptake predominantly in LMIC public +/- private markets?*

*Have value propositions and/or investment cases been generated by global or public health agencies or funders?*

*Table 3: Overview of non-commercial stakeholders engaged, their interest and potential demand*

Use the template below as a framework for this analysis, where data is available:

| Stakeholders engaged  *(global, WHO regional, Individual countries, funders, policy makers, CSOs)* | Summary of position/interest | Potential demand and uptake *(is there any documented assessment of interest/demand/preferences/proxies from country level stakeholders in the vaccine, in HICs and/or LMICs, in public vs private markets)* | References |
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# 4. Existing guidance on preferences/preferred product attributes for vaccines against pathogen X

For priority pathogens with an LMIC burden, candidate vaccine agnostic guidance on preferred product attributes may have been developed by WHO, a funder, or other immunization stakeholder. This section should not include candidate specific-target product profiles that are typically developed by vaccine manufacturers.

*Has a PPC or TPP been developed by WHO or other global priority setting body, for this vaccine to be used in LMIC contexts? If so, please summarise the priority attributes that have been communicated.*

*Table 4: Summary of existing guidance on preferences for product attributes of vaccines intended for use in LMICs*

Use the template below as a framework for this analysis, where data are available. Please expand if a PPC or TPP has been developed and published by more than one (non-commercial) entity. For a PPC, there will not be a ‘minimal characteristic’, only a preferential characteristic. Differentiating attributes have been proposed below.

| Product attribute | Minimal characteristic, if described | Preferential  characteristic | Publishing entity | References |
| --- | --- | --- | --- | --- |
| Indication |  |  |  |  |
| Target population(s) |  |  |  |  |
| Outcome measure(s) and target efficacy |  |  |  |  |
| Safety profile |  |  |  |  |
| Number of doses and schedule |  |  |  |  |
| Route of administration |  |  |  |  |
| Duration of protection |  |  |  |  |
| Co-administration with other vaccine |  |  |  |  |
| Product  stability and  storage |  |  |  |  |
| Vaccine presentation |  |  |  |  |

# 5. Vaccine development

*5.1 Probability of technical and regulatory success (PTRS):*

This section should review **briefly** the evidence for scientific feasibility of developing an effective vaccine of public health value.

*Please briefly describe the natural history, known target antigens, preclinical or clinical proof of concept, sero-epidemiological data and any potential correlate of protection if known – or reference to any benchmark vaccines if appropriate.* ***Please refer to the framework on Biological Feasibility and Product Development Feasibility (in the appendix) to help frame this section.***

*Table 5: Overview of parameters that inform scientific feasibility of developing an effective vaccine for LMIC public market use*

Use the template below as a framework for this analysis, where data are available:

| Parameter | Issues and evidence | Refs |
| --- | --- | --- |
| Diagnosis/case ascertainment | How are cases determined, what methodology is used in LMICs? Is it considered robust? |  |
| Biomarkers/ Correlates of risk and/or protection | Is there an established correlate or biomarker? Are the assays to measure these well-established/standardised?  Or new assays to be developed? |  |
| Sero-epidemiological data | What data are available to support identification of correlates of risk and/or protection, and design of clinical efficacy studies? |  |
| Clinical endpoints | Is there consensus on the primary clinical endpoint(s)? What evidence is available to link the endpoint to clinical outcome, is it feasible to measure and how does it impact feasibility of efficacy study design? |  |
| Controlled Human infection model (CHIM) | Does one exist? What is it being used to inform? |  |
| Opportunity for innovative clinical trial designs | Have non-conventional trial designs been considered? What are the expectations of pivotal efficacy design in terms of size, geography, duration? Are adaptive trial designs for integrated/hybrid phase II/III or III/IV strategies feasible? |  |
| Regulatory approach(es), including potential accelerated approval strategies | What would be the ultimate goal for this vaccine? Licensure in countries with NRAs, stringent NRA review, followed by WHO PQ for Gavi market? What are the target countries for early registration?  Could alternative regulatory pathway be feasible? For example, licensing on immunogenicity and safety (e.g., using serological correlates of protection, CHIM) post-licensure effectiveness studies; integrated/hybrid phase III/IV strategies. |  |
| Potential for combination with other vaccines | Given the route of administration, schedule, number of doses and delivery strategy, is a combination vaccine strategy a possibility? |  |
| Feasibility of meeting presentation and stability requirements | Can the vaccine achieve the presentation, storage and stability requirements, considering the intended delivery setting and strategy |  |
| Vaccine platform | Is the vaccine platform easy to implement for large scale manufacturing, for tech transfer, and for adaptability to alternative strains if needed? |  |
| Large scale Manufacturer capacity / interest | Is there interest from a multi-national pharmaceutical or developing country vaccine manufacturer or other party to scale and commercialise the vaccine? |  |

*5.2 Overview of the vaccine candidates in the clinical pipeline:*

This section is intended to indicate the number of candidates in development at each stage and diversity of antigen presentation platforms and number of developers (robustness)

*If feasible, please briefly describe the anticipated generic steps and timeline to licensure, based on the stage of development for the leading candidate/s.*

*Table 6: Overview of vaccine candidate in clinical trials (may be better to put in landscape format)*

Use the template below as a framework for this analysis, where data are available:

| Candidate | Antigen platform | Developer/manufacturer | Phase of development, population, and location | Route of administration, no. of doses, schedule | Presentation and stability | Clinical trial refs |
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# 6. Health Impact of a vaccine on burden of disease and transmission

*Where available, summarise the conclusions of modelling the incremental impact of use of a vaccine on vaccine-preventable burden of disease and other factors. Also, if other interventions exist and are in use, then summarise modelling of if and when to introduce a vaccine relative to other existing interventions (both pharmaceutical and non-pharmaceutical). Where no formal modelling has been performed, a list of factors (and possible ranges) could be included that influence incremental vaccine impact, from the perspective of both adding a vaccine to standard of care and replacing current intervention(s) with a vaccine.*

*Table 7: Overview of modelling studies that measure health impact on disease burden and transmission*

Use the template below as a framework for this analysis, where data are available:

| Policy question  (what was the model seeking to address?) | Assessment method/  measure  (effectiveness/ vaccine impact modelling etc) | Additional information specific to models *(e.g., type of model, transparency of documentation and models, calibration, uncertainty, sensitivity)* | Assumptions  *incidence rate, CFR, direct vaccine efficacy rate, herd effects, coverage rate, vaccine duration and frequency, target populations (age, location, gender, etc), time period, granularity (country/region)* | Outcomes/interpretation | Refs |
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6.2 Summary of knowledge and research gaps in modelling health impact on disease burden and transmission

*Please summarise, in the form of brief bullets, the priority knowledge and research gaps that if addressed, could inform the value assessment of this vaccine.*

# 7. Social and/or economic Impact of a vaccine

*Please summarise the evidence, if available, on the potential socio-economic impact of a vaccine. This could include any of the parameters in the table below*:

*Table 8: Overview of modelling studies that measure anticipated socio-economic impact of the vaccine*

Use the template below as a framework for this analysis, where data is available:

| Policy question  *(what was the model seeking to address?)* | Assessment method/measure  *(costing study, cost of illness study, cost effectiveness analysis, impact on AMR/ antibiotic use, qualitative/quantitative)* | Additional information specific to models *(e.g., type of model, transparency of documentation and models, calibration, uncertainty, sensitivity)* | Assumptions | Outcomes/ interpretation | Reference |
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7.2 Summary of knowledge and research gaps in modelling studies that measure anticipated socio-economic impact of the vaccine

*Please summarise, in the form of brief bullets, the priority knowledge and research gaps that if addressed, could inform the value assessment of this vaccine.*

# 8. Policy considerations and Financing

*Please describe any* *assumptions / discussions / guidance related to expectations for evidence that are expected to be required to support a global policy recommendation, or financing from Gavi. Also include any additional assumptions / discussions / guidance related to expectations for evidence that are expected to be required to support regional / national policy recommendation, or financing.*

*Table 9: Overview of expectations of evidence that are likely to be required to support a global / regional / national policy recommendation, or financing. Highlight those required for global policy recommendations, and/or financing by Gavi.*

Use the template below as a framework for this analysis, where data are available:

| Parameter for policy/financing consideration | Assumptions | Guidance/reports available | Reference |
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9. Access and Implementation Feasibility

*This section should* ***briefly*** *review the evidence/expectation for access to and implementation feasibility of an effective vaccine of public health value, in LMICs. It aims to consolidate some of the information included in other sections of the document, related to feasibility of deployment, commercial attractiveness, clarity on the licensure, policy, and financing pathway and expected to inform demand and enable uptake.*

***Please refer to the framework on Biological Feasibility and Product Development Feasibility (in the appendix) to help frame this section.***

# 10. Conclusion

*Please summarise the currently available evidence to assess the potential vaccine value for this priority pathogen, including global public health need in the context of other interventions and potential impact. Provide a brief description of the* *PTRS and status of the pipeline, as well as the status of discussions with a view to first licensure approval, potential accelerated approval, global regulatory strategy, policy review, and financing (expected to be Gavi supported or other).*

**Appendix A: Framework to inform section 5 - Vaccine development**

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| **Themes Considered** | **Indicators** | **Very Low** | **Low** | **Moderate** | **High** | **Very High** |
| **Biological Feasibility** | Most advanced vaccine candidate(s) | • Ph1, or preclinical, or no candidates in the pipeline | • Ph2 candidate | • Ph3 candidate | • Ph3 candidate with high likelihood of licensure by a WHO-listed national regulatory authority | • Licensed vaccine by a WHO-listed national regulatory authority |
| **Biological Feasibility** | Existence of immunity from natural exposure | • No evidence that natural exposure confers immunity | • Conflicting or minimum evidence | • Some evidence and/or immunity of limited duration | • Good evidence of relatively long-lasting immunity | • Well established that  natural exposure confers protects against severe disease  (or indicated vaccine outcome) with  durable immunity |
| **Biological Feasibility** | Understanding mechanisms of immunity | • Mechanisms of pathogen induced immunity unknown | • Very limited or conflicted understanding of pathogen-induced immunity and/or immune-enhanced disease | • Some understanding of pathogen- induced immunity and whether immune-enhanced disease exists | • Good understanding of pathogen- induced immunity, however some mechanisms remain unclear; evidence that immune-enhanced disease is unlikely | • All mechanisms of  pathogen-induced  immunity are well  understood; robust evidence that immune-enhanced disease is rare |
| **Biological Feasibility** | Likelihood of vaccine protection against the majority of pathogenic strains | • Evidence that a vaccine would not protect against majority of pathogenic strains, or gap in evidence of that a vaccine would protect against majority of pathogenic strains | • Limited evidence that a vaccine would protect against majority of pathogenic strains | • Some evidence that a vaccine would protect against majority of pathogenic strains | • Strong evidence that a vaccine would protect against majority of pathogenic strains | • No known strain  variation that is relevant  to a vaccine OR  evidence that a vaccine will protect against  all known strains OR new strain can be rapidly developed |
| **Product Development Feasibility** | Existence of animal models to facilitate vaccine development | • Animal models do not exist and no progress has been made to identify them. | • Animal models do not exist but some progress has been made to identify them. | • Animal models are identified but their utility have not been confirmed | • Animal models are identified and used but the mechanisms of immunity are unclear | • Animal models are well -defined and used and m  mechanisms of immunity are  well understood OR  animal models are not  required for vaccine  development |
| **Product Development Feasibility** | Existence of in vitro assays to facilitate vaccine development | • In vitro assays do not exist and no progress has been made to develop them. | • In vitro assays do not exist but some progress has been made to develop them. | • In vitro assays are developed but their utility has not been established or the assays have not been analytically qualified | • In vitro assays are analytically qualified and used but their fit for purpose as a relevant biomarker for decision-making or licensure has not been established | • In vitro assays are  qualified/validate  and are fit-for-purpose for decision-making or licensure |
| **Product Development Feasibility** | Ease of Clinical Development | • A complex trial design (no correlate) and a significant investment in clinical sites/infrastructure needed for testing a vaccine OR low disease incidence a significant impediment to efficacy trial feasibility | • A complex trial design needed (no correlate) that may require investment in clinical sites/infrastructure OR low disease incidence requires a large and/or long efficacy trial | • A standard trial design that may require investment in clinical sites/infrastructure | • Common trial design, potential correlate and a possibility to  leverage existing trial  infrastructure. | • Common trial design, established correlate  and a possibility to  leverage existing trial  infrastructure AND high disease  incidence allows for an  efficacy trial. |
| **Product Development Feasibility** | Availability or need for human challenge models | • Human challenge models OR diagnostic tools are important for vaccine development but are not developed. | • Human challenge models OR diagnostic tools are important for vaccine development and some progress has been made to develop them. | • Human challenge models OR diagnostic tools are important for vaccine development, are developed but not used or their use is unclear. | • Human challenge models OR diagnostic tools would facilitate vaccine development and are developed but their use is limited. | • Human challenge models  OR diagnostic tools are  important for vaccine  development, are developed  and widely used and accepted, OR no  human challenge model is  required |

**Appendix B:** **Framework to inform section 8 - Access and Implementation Feasibility**

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| **Themes Considered** | **Indicators** | **Very Low** | **Low** | **Moderate** | **High** | **Very High** |  |
| **Access and Implementation Feasibility** | Possibility of implementation within existing delivery systems | • No possibility to leverage existing delivery systems due to a complex vaccine immunisation schedule. | • Some evidence that existing delivery systems could be leveraged to deliver a vaccine | • Limited use of existing delivery systems to deliver a vaccine | • Vaccine can be delivered within existing delivery systems with amendments | • Vaccine can be delivered within existing delivery systems as is |  |
| **Access and Implementation Feasibility** | Commercial attractiveness | • Poorly defined target population • Disease burden mainly in LMICs but vaccine unlikely to be supported by Gavi | • Small target population predominantly in LMIC public markets • Difficulty defining target population in LMICs | • Large target population distributed predominantly in LMICs with potential Gavi support | • Well-defined target population in LMIC public markets • Large target populations distributed across HIC and LMIC markets | • Large target population in HIC and LMIC, both private and public markets |  |
| **Access and Implementation Feasibility** | Clarity of licensure and policy decision pathway | • A need for novel licensure and/or policy pathway, which is currently unclear | • A need for novel licensure and/or policy pathway | • A possibility to leverage an existing licensure and policy pathway with major amendments | • A clear licensure and policy pathway with minor amendments | • A clear, highly precedented, fit for purpose licensure and policy pathway currently exists |  |
| **Access and Implementation Feasibility** | Expected financing mechanism | No interest from global funders or national procurement agencies, potential for private market | Unlikely to be of interest to global funders, requiring commitment from national procurement | Potential interest from global funders, depending on public health impact data, interest from national procurement agencies | High level of interest expressed from public financing agencies such as Gavi, PAHO RF, and from national procurement agencies | Advanced purchasing commitment from, for example Gavi, PAHO RF, or other pull mechanism(s) in place |  |
| **Access and Implementation Feasibility** | Ease of uptake | • Extensive challenges with a new vaccination touchpoint required • High level of clinician judgement and clinical engagement • Additional extensive barriers to uptake including lack of national commitment | • Evidence of low uptake for marketed vaccines • Cultural barriers, negative patient perceptions | • New vaccination touchpoint required | •Well-defined target population with likelihood of high acceptability, but possible difficulties in infrastructure for vaccination | •Well-defined target population with likelihood of high acceptability • Evidence of high uptake for marketed vaccine • Lack of other significant barriers to introduce a vaccine • Strong national commitment to introduce a vaccine |  |

**Appendix C:** **Potential list of priority pathogens for Vaccine Value Profiles (VVPs)**

Proposed pathogens for the VVPs (currently approaching or in phase II clinical studies, or potential CHIM pathway), where there is an *anticipated* LMIC need. Ideally would like to limit this to 15 pathogen assessments:

1. Enterotoxigenic *Escherichia coli* (ETEC)
2. *Gonococcus*
3. Group A *Streptococcus* (GAS)
4. Group B *Streptococcus* (GBS)
5. Herpes simplex virus (HSV)
6. HIV vaccine
7. HIV monoclonal
8. *Klebsiella pneumoniae*
9. Leishmaniasis
10. Norovirus
11. Respiratory Syncytial Virus (RSV) vaccine for maternal immunization
12. Respiratory Syncytial Virus (RSV) monoclonal for maternal immunization
13. *Salmonella* paratyphi
14. Invasive non-typhoidal salmonella (iNTS)
15. Schistosomiasis
16. *Shigella*
17. Tuberculosis (adolescent and adult indication)
18. Next gen TB vaccine for infants
19. Next generation Malaria
20. Improved influenza vaccines