

## **EMERGING INFECTIOUS DISEASE R&D SCOPE**

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This document sets out the priority emerging infectious diseases (EIDs) research and development (R&D) activities that are included within the scope of the G-FINDER survey, as well as the R&D activities that are excluded or partially excluded (restricted).

The survey scope is based on the World Health Organization’s *R&D Blueprint for action to prevent Epidemics* (R&D Blueprint), and includes all of the R&D Blueprint ‘priority pathogens’, grouped by pathogen family for data collection purposes. The survey also includes diseases not included in the priority list, but that have been recognised by the R&D Blueprint as posing major public health risks.

Compared to the G-FINDER survey of global investment in neglected disease R&D, the EID survey has very few scope restrictions: R&D for almost all product development categories (drugs, vaccines, biologics, and diagnostics) is considered in scope for all priority EID pathogens, as is basic research; R&D for vector control products is included where relevant. Broadly-relevant R&D (e.g. development of platform technologies) is included provided it is specific to, or primarily targeted at, EIDs. Funding that is not related to the development of new health technologies is excluded from the survey scope. As with the G-FINDER survey, the EID survey scope will be subject to ongoing review by an expert advisory group.

A quick overview of the EIDs, products and technologies included in the G-FINDER survey scope is presented in the EID R&D matrix.

A description of historical changes to the G-FINDER survey scope for disease and product area inclusions and exclusions, are set out in the Scope changes section.

The R&D activities for each product area included within the scope of the survey are set out in the Scope by product section.

*For the purpose of the G-FINDER survey, the World Bank’s definitions of low- and middle-income countries are used*

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# EID R&D MATRIX

|   |   | Basic research                         | Drugs                                     | Vaccines              | Biologics         | Diagnostics                 | Vector control products          |  |
|---|---|--|---|-----------------------|-------------------|-----------------------------|----------------------------------|--|
| <b>Arenaviral haemorrhagic fevers</b>   | Lassa fever   | ✓                                      | ✓   | ✓                     | ✓                 | ✓                           | -                                |  |
|   | Other arenaviral R&D in combination with Lassa fever            | ✓                                      | ✓   | ✓                     | ✓                 | ✓                           | -                                |  |
|   | Arenaviral haemorrhagic fevers other than Lassa fever           | ✓                                      | ✓   | ✓                     | ✓                 | ✓                           | -                                |  |
| <b>Bunyaviral diseases</b>  | Crimean-Congo Haemorrhagic Fever (CCHF)                         | ✓                                      | ✓   | ✓                     | ✓                 | ✓                           | ✓                                |  |
|   | Rift Valley Fever (RVF)   | ✓                                      | ✓   | ✓                     | ✓                 | ✓                           | ✓                                |  |
|   | Severe Fever with Thrombocytopenia Syndrome (SFTS)              | ✓                                      | ✓   | ✓                     | ✓                 | ✓                           | ✓                                |  |
|   | Other bunyaviral R&D in combination with CCHF and/or RVF        | ✓                                      | ✓   | ✓                     | ✓                 | ✓                           | ✓                                |  |
|   | Bunyaviral diseases other than CCHF, RVF and SFTS               | ✓                                      | ✓   | ✓                     | ✓                 | ✓                           | ✓                                |  |
| <b>Chikungunya</b>  |   | ✓                                      | ✓   | ✓                     | ✓                 | ✓                           | ✓                                |  |
| <b>Coronaviral diseases</b>   | Middle East Respiratory Syndrome coronavirus (MERS)             | ✓                                      | ✓   | ✓                     | ✓                 | ✓                           | ✓                                |  |
|   | Severe Acute Respiratory Syndrome (SARS)                        | ✓                                      | ✓   | ✓                     | ✓                 | ✓                           | ✓                                |  |
|   | Other coronaviral R&D in combination with MERS and/or SARS      | ✓                                      | ✓   | ✓                     | ✓                 | ✓                           | -                                |  |
|   | Highly pathogenic coronaviral diseases other than MERS and SARS | ✓                                      | ✓   | ✓                     | ✓                 | ✓                           | -                                |  |
| <b>Emergent non-polio enteroviruses (including EV71, D68)</b>   |   | ✓                                      | ✓   | ✓                     | ✓                 | ✓                           | -                                |  |
| <b>Filoviral diseases</b>   | Ebola   | ✓                                      | ✓   | ✓                     | ✓                 | ✓                           | ✓                                |  |
|   | Marburg   | ✓                                      | ✓   | ✓                     | ✓                 | ✓                           | ✓                                |  |
|   | Other filoviral R&D in combination with Ebola and/or Marburg    | ✓                                      | ✓   | ✓                     | ✓                 | ✓                           | -                                |  |
|   | Filoviral diseases other than Ebola and Marburg                 | ✓                                      | ✓   | ✓                     | ✓                 | ✓                           | ✓                                |  |
| <b>Henipaviral diseases</b>   | Nipah   | ✓                                      | ✓   | ✓                     | ✓                 | ✓                           | ✓                                |  |
|   | Other henipaviral R&D including in combination with Nipah       | ✓                                      | ✓   | ✓                     | ✓                 | ✓                           | -                                |  |
|   | Henipaviral diseases other than Nipah                           | ✓                                      | ✓   | ✓                     | ✓                 | ✓                           | ✓                                |  |
| <b>Zika</b>   |   | ✓                                      | ✓   | ✓                     | ✓                 | ✓                           | ✓                                |  |
| <b>Other investment applicable to more than one emerging infectious diseases or both neglected and emerging infectious diseases</b> |   |  |   |                       |                   |                             |                                  |  |
| <b>Platform Technologies</b>  |   |  |   |                       |                   | <b>Fundamental research</b> | <b>Broad-spectrum antivirals</b> | <b>Core funding of a multidisease R&amp;D organisation</b> |
| General diagnostic platforms  | Adjuvants and immunomodulators                                  | Drug delivery technologies and devices | Vaccine delivery technologies and devices | Therapeutic platforms | Vaccine platforms |                             |                                  |  |
| ✓   | ✓   | ✓                                      | ✓   | ✓                     | ✓                 | ✓                           | ✓                                |  |

✓ denotes a category where a disease or product is included in the survey

## SCOPE CHANGES

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Although maintaining a consistent scope is important in order to allow analysis of multi-year funding trends, the scope of the G-FINDER EID survey has evolved since the project's inception in 2015 and will continue to change in response to changes in the WHO priority Blueprint and expert consensus.

The G-FINDER survey first included questions about EID expenditure in 2015 (collection of FY2014 data). This first year of the EID survey only included R&D spending on Ebola virus, which also captured grants targeting multiple filoviral diseases including Ebola.

The 2016 survey (the second year in which EID funding was included, collection of FY2015 data), was expanded to include five additional diseases, mostly African viral haemorrhagic fevers (VHFs): Marburg, Crimean Congo haemorrhagic fever (CCHF), Rift Valley fever (RVF) and Lassa fever, as well as Zika. The expanded scope also captured R&D targeting multiple filoviruses, bunyaviruses, or arenaviruses as well as R&D focused on filoviruses other than Ebola and Marburg and bunyaviruses other than CCHF and RVF.

2017 (collection of FY2016 data) marked the third year of EIDs' inclusion in the G-FINDER survey, adding R&D spending on Severe Fever with Thrombocytopenia Syndrome (SFTS), coronaviral diseases (including Middle East respiratory syndrome (MERS) and severe acute respiratory syndrome (SARS)), and henipaviral diseases (including Nipah). 2017 also saw the inclusion of non-disease-specific disease X funding and core funding for multi-EID organisations.

In 2018 (the fourth EID survey year, collection of FY2018 data), the scope of disease X and core funding expenditure was expanded to include the full value of funding intended to support research applicable to *both* neglected diseases and EIDs, including core funding, platform technologies and other R&D, which would previously have been prorated between neglected disease and EID funding totals.

As part of the inclusion of combined EID and neglected disease funding, a new category, multi-disease vector control products, was created to capture funding for R&D not targeted at one specific vector-borne disease. The new category captures funding for VCP R&D where the targeted vector transmits both neglected diseases *and* EIDs. For example, the *Aedes aegypti* mosquito transmits both the dengue virus (a neglected disease) and Zika (an EID). For funding reported for FY2017, the full value of this kind of funding is included under the category of multi-disease vector control products, while pre-2017 funding is pro-rated across the target diseases.

## SCOPE BY PRODUCT

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### I. BASIC RESEARCH

*Studies that increase scientific knowledge and understanding about the disease, disease processes, pathogen or vector, but which is not yet directed towards a specific product.*

#### 1. NATURAL HISTORY AND EPIDEMIOLOGY

- 1.1 Basic mechanisms of disease transmission
- 1.2 Disease prevalence in relation to human genotype, strain variation, and inoculation rates
- 1.3 Genetic diversity and phylogeny
- 1.4 Epidemiological research on the roles of human behaviour and effects of specific host genotypes on disease transmission
- 1.5 Epidemiological research on host genetic factors influencing the prevalence of disease (e.g., sickle cell, HLA type, Rh factor) or the impact of disease in select host genotypes
- 1.6 Epidemiological research on the distribution of pathogen, vectors and the prevalence of morbidity and mortality due to the disease that is not related to specific product development
- 1.7 Epidemiological research on antigenic variability; population studies of human immunity to the disease
- 1.8 Epidemiology of drug resistance or evolutionary studies on resistance development for established, existing drugs
- 1.9 Epidemiological research related to vector behaviour and ecology, and vector control

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#### 2. IMMUNOLOGY OF DISEASE

- 2.1 Defining signalling pathways of immune function (mechanisms of systemic and/or mucosal immunity)
- 2.2 Interaction and impact of the signalling pathways with the pathogen
- 2.3 Development of assays or tools potentially useful for drug, vaccine, diagnostics or biologic research and development
- 2.4 Identification of immune correlates of protection, including *in vivo* and *in vitro* studies on the protective immune response (cellular, humoral, and/or mucosal)
- 2.5 Investigating the immune response to particular antigens; studies of specific antigens or immunogens proposed as vaccine or biologic candidates
- 2.6 Development of animal models to determine immune correlates of protection
- 2.7 Genetics of the immune response to the disease and effects of antigen polymorphism or genetic diversity on specific vaccine or biologic candidates (as recognised from field studies)

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#### 3. BIOLOGY OF DISEASE

- 3.1 Structure and morphology of different developmental stages
- 3.2 Host-parasite interactions and biology of pathogen interaction with vector host
- 3.3 Biology of invasion of host cells (entry mechanisms)
- 3.4 Localisation of pathogen proteins or antigens
- 3.5 Development of culture and purification tools to assist in study of the pathogen

**3.6** Descriptions of pathogenic species and characterisation of strains or subtypes in animal models (course of infection, susceptibility of different hosts)

**3.7** *In vitro* studies of interactions between the pathogen and other infectious agents

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#### **4. BIOCHEMISTRY OF THE PATHOGEN**

**4.1** Metabolism and nutrition

**4.2** Protein sequencing, enzymology, and protein and enzyme characterisation (including antigen analysis)

**4.3** Signal transduction; translation, processing and export of proteins

**4.4** Glycosylation, GPI anchors, transporters, ion channels, mitochondrial metabolism, and electrophysiology studies

**4.5** Influence of pathogen on host-cell biochemistry

**4.6** Characterisation of antigen/protein diversity of pathogenic strains and subtypes

**4.7** Characterisation of proteins and molecular basis for host-cell invasion

**4.8** Analysis and characterisation of drug-resistant strains and studies probing drug resistance mechanism/s or pathways

**4.9** Non-specific research on pathogen or host targets to identify potential drug, vaccine, diagnostic or biologic targets (i.e. target identification)

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#### **5. GENETICS OF THE PATHOGEN**

**5.1** Studies on chromosomes; genomic maps; genetic crosses

**5.2** Cloning and sequencing of genes; cDNAs for functional proteins (including drug targets and vaccine candidates)

**5.3** Expression of proteins from cloned genes; RNA analyses

**5.4** Control and timing of gene expression; post-transcriptional processing

**5.5** Analysis and characterisation of genes involved in drug resistance

**5.6** Genetics of antigenic variability

**5.7** Techniques for the genetic transformation of the pathogen

**5.8** Tests for genotyping the pathogen for laboratory use

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#### **6. BIOINFORMATICS AND PROTEOMICS**

**6.1** Microarray analysis

**6.2** Genome annotation - gene predictions

**6.3** Comparative genomics, sequence alignment, genome assembly

**6.4** Variation, single nucleotide polymorphisms (SNPs)

**6.5** Database applications, data mining tools

**6.6** Structural and functional genomics

**6.7** Structural and functional proteomics

**6.8** Proteome analysis, protein structure alignment

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#### **7. PATHOPHYSIOLOGY AND DISEASE SYMPTOMS**

**7.1** Clinical diagnosis and clinical observations of the disease presentation and pathophysiology in humans and in animals

- 7.2 The role of nutritional status in determining disease severity and treatment effectiveness
- 7.3 Histopathology of the disease in humans and in animals
- 7.4 The mechanisms of pathology of the disease; including, the role of the host immune system, and expression of adhesion molecules
- 7.5 Development of improved animal models to study disease pathophysiology, to evaluate the biological properties of drugs
- 7.6 Identification of biomarkers for diagnostics or therapeutic monitoring
- 7.7 Studies of the mechanisms by which particular susceptible/resistant mammalian host genotypes exert their effect
- 7.8 Research on effects of host co-morbidities and secondary effects of pathogen invasion
- 7.9 Interactions between the disease and other relevant concurrent infections, including determining timing and establishment of infection

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## 8. VECTOR BIOLOGY, BIOCHEMISTRY, AND GENETICS

- 8.1 Characterisation of vector behaviour and ecology
- 8.2 Studies of vector susceptibility to infection; studies of parasites and pathogens of vectors (including potential biological control agents)
- 8.3 Identification of genes responsible for disruption of parasite/virus growth, genetic transformation of vectors, and insect transposable elements
- 8.4 Target identification of vector sites that may become the subject of *in vitro* screening or molecular design
- 8.5 Development of tests for vector identification, taxonomy and systematics, and for the identification of infected vectors
- 8.6 Studies evaluating resistance development, including the genetics and transmission of pesticide resistance

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## II. DRUGS

*Research activities and processes necessary to develop and improve new compounds specifically designed to prevent, cure or treat emerging infectious diseases; including drug discovery or design, preclinical and clinical development and other activities essential for successful drug development and uptake.*

### 9. DISCOVERY AND PRECLINICAL

*Research activities targeted at discovering and optimising investigational compounds and including the processes needed to allow new chemical entities to proceed to human trials; including:*

- 9.1 Target validation, characterisation, and selection
- 9.2 High throughput screening, lead optimisation
- 9.3 Development of analytical tests for assaying drugs, including the development of animal models
- 9.4 Research on drugs from natural products; identification and characterisation of active ingredient
- 9.5 Research on the effects of drug treatment on immune status
- 9.6 Measurement of the activity of potential drugs *in vitro* and in animal models; including safety and efficacy studies necessary to satisfy Investigational New Drug (IND) requirements
- 9.7 Studies evaluating the activity of new drugs on drug-resistant strains, their effect on genes involved in drug resistance, or their effect on resistance pathways

- 9.8 Development of tests for drug susceptibility of the pathogen for research purposes
- 9.9 Drug pharmacokinetic, toxicity and metabolism studies *in vitro* and in animal models, including bioavailability, adsorption, metabolism, and excretion (ADME) studies
- 9.10 Chemistry and synthesis of drugs, including process and scale-up manufacture, production of Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) batch for toxicology studies; and other Chemistry and Manufacture Control (CMC) activities required to allow new chemical entities to proceed to human trials
- 9.11 Preparation of Investigational New Drug (IND) application for regulatory submission
- 9.12 Optimisation and manufacturing of new formulations to support label-expansion<sup>†</sup> for new patient sub-populations (e.g. infants, pregnant women)

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## 10. CLINICAL DEVELOPMENT - PHASE I

*First-in-human clinical trials to determine safety and tolerability of investigational new drugs in a small group of patients or healthy volunteers, including:*

- 10.1 Phase Ia single ascending dose studies to determine pharmacokinetics, pharmacodynamics, and maximum tolerated dose
- 10.2 Phase Ib multiple ascending dose studies to determine the pharmacokinetics, pharmacodynamics, safety and tolerability of multiple doses
- 10.3 Trials of food effect or drug-drug interactions

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## 11. CLINICAL DEVELOPMENT - PHASE II

*Clinical trials to determine the efficacy, safety and therapeutic dose of investigational new drugs in a small set of human subjects (up to several hundred), including:*

- 11.1 Phase IIa proof of concept studies to demonstrate clinical efficacy or biological activity
- 11.2 Phase IIb dose-finding studies to determine dose with optimum biological activity with minimal adverse effects

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## 12. CLINICAL DEVELOPMENT - PHASE III

*Clinical trials to support the registration of investigational new drugs or label-expansion of already registered drugs in a trial population large enough to provide statistical significance (from several hundred to several thousand)*

- 12.1 Regulatory standard clinical trials to assess effectiveness of a new drug against current 'gold standard'
- 12.2 Regulatory standard clinical trials that support a formal registration for label-expansion\* of an existing drug to a new disease or patient group (e.g. paediatric patients, pregnant women or HIV-positive patients)
- 12.3 Regulatory standard clinical trials that support formal registration for label-expansion\* of an existing drug to a new use, such as intermittent preventative therapy and pre-exposure prophylaxis

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<sup>†</sup> Label-expansions refer to changes to drugs or their labels after they have been approved. This includes changes in manufacturing, recommended patient population and/or formulation. To change a label, market a new dosage or strength of a drug, or change the way a drug is manufactured, the company must submit a supplemental new drug application (sNDA) to regulatory authorities to obtain marketing approval

### 13. CLINICAL DEVELOPMENT - BASELINE EPIDEMIOLOGY

*Studies evaluating potential trial site populations to confirm disease incidence, prevalence or exposure risk, and which serve as the foundation for determining the optimal collection, analysis, interpretation and presentation of clinical trial data; including:*

- 13.1** Epidemiological studies directly linked to the conduct or support of clinical trials of products in development, in order to assess or validate the epidemiology of disease, disease incidence, or health of target populations at trial sites
- 13.2** Preliminary studies of morbidity and mortality at potential clinical trial sites, where these studies are directly linked to planned product trials
- 13.3** Pre-trial activities designed to understand trial site conditions before the commencement of trials and to facilitate engagement

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### 14. CLINICAL DEVELOPMENT - UNSPECIFIED

*Other costs required to support clinical testing of investigational new drugs as needed for regulatory approval; including:*

- 14.1** Infrastructure and site development costs directly associated with the conduct of clinical trials for drug development in LMICs (e.g. refurbishment of hospital wing, vehicle purchase, generators, training and community relationship building)
- 14.2** Further pharmaceutical development to generate the final clinical formulation, dosage form and other Chemistry and Manufacture Control (CMC) activities required for regulatory submission
- 14.3** Compiling of all non-clinical and clinical data for submission of a New Drug Application (NDA) to regulatory authorities
- 14.4** Behavioural research prior to registration relating to risk assessment, factors affecting adherence to protocol, and product acceptability
- 14.5** Protocol development, investigator meetings, Good Clinical Practice (GCP)-monitoring, quality control, data management, analysis and reporting, establishing a Data Safety Monitoring Board (DSMB), and trial audits

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### 15. POST-REGISTRATION STUDIES

*Studies relating to the detection, monitoring, evaluation, and prevention of adverse events associated with newly approved drugs so as to bridge the gap between highly controlled clinical trials intended for regulatory approval and the largely uncontrolled use of new drugs by patients. Also includes studies conducted after regulatory approval that assess drug effectiveness in the wider population or which are necessary to support product use in LMICs.*

- 15.1** Pharmacovigilance and post-registration studies of newly registered drugs to assess adverse events, toxicology and safety
- 15.2** Effectiveness studies and head-to-head comparator studies of newly registered drugs (versus other therapies or interventions)
- 15.3** Cost-effectiveness studies of newly registered drugs
- 15.4** Treatment interactions and population level studies of newly registered drugs
- 15.5** Behavioural research post-registration of new drugs relating to risk assessment, factors affecting adherence to protocol, provider compliance, and product acceptability
- 15.6** Case history reports and assessment of long-term prophylaxis using newly registered drugs in communities in LMICs

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### III. VACCINES

*Research activities and processes necessary to develop and improve investigational vaccines specifically intended to prevent infection; including vaccine design, preclinical and clinical development and other activities essential for successful vaccine development and uptake. In 2019 (collection of FY2018 data), the 'vaccines (preventive)' category was renamed 'vaccines' to reflect the distinction between traditional vaccine technologies and biologics.*

#### 16. DISCOVERY AND PRECLINICAL

*Research activities targeted at discovering and optimising investigational vaccines and including the processes necessary to allow a candidate vaccine to proceed to human trials; including:*

- 16.1** Studies supporting novel vaccine design, including target validation and candidate optimisation
- 16.2** Development of animal models to assist in vaccine design and testing
- 16.3** Evaluation of vaccine technologies (e.g. adjuvants, delivery systems) to improve the immunogenicity of an identified candidate
- 16.4** Preclinical safety and immunogenicity studies with candidate vaccines, including use or development of functional assays
- 16.5** Preclinical animal studies, challenge models and addressing the correlation between *in vitro* models, animal models and field results
- 16.6** Studies on the genetics of the immune response to selected antigens as vaccine candidates, optimisation of animal models and correlates to clinical results
- 16.7** Manufacturing scale-up and consistency of manufacture, including production of Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) batches for regulatory toxicology studies and other Chemistry and Manufacture Control (CMC) activities required to allow a candidate vaccine to proceed to human trials
- 16.8** Research on safety and regulatory considerations (e.g. validation of preclinical assays to permit registration)
- 16.9** Preparation of an Investigational New Drug (IND) application for regulatory submission
- 16.10** Optimisation of vaccine candidates for global use (cheaper, more stable, ease of administration)

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#### 17. CLINICAL DEVELOPMENT - PHASE I

*First-in-human clinical trials to determine the safety of investigational new vaccines for the first time in human subjects (up to one hundred) including:*

- 17.1** Phase Ia studies assessing safety, dosing, and immunogenicity in human volunteers
- 17.2** Phase Ib studies assessing safety, dosing, and immunogenicity in clinically exposed or high-risk populations

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#### 18. CLINICAL DEVELOPMENT - PHASE II

*Clinical trials to continue to determine the efficacy and safety of investigational new vaccines in a small set of human subjects (typically several hundred), including:*

- 18.1** Phase IIa challenge studies
- 18.2** Phase IIb safety and preliminary efficacy studies in exposed populations or those at high-risk of infection

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## 19. CLINICAL DEVELOPMENT - PHASE III

*Clinical trials to demonstrate the safety and efficacy in a larger human subject population (from several hundred to several thousand) and support the registration of investigational new vaccines, including:*

- 19.1** Phase III expanded efficacy, effectiveness and safety studies required for registration purposes, including implementation, retention and follow-up of volunteers

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## 20. CLINICAL DEVELOPMENT - BASELINE EPIDEMIOLOGY

*Studies evaluating potential trial site populations to confirm disease incidence, prevalence or exposure risk, and which serve as the foundation for determining the optimal collection, analysis, interpretation and presentation of clinical trial data; including:*

- 20.1** Epidemiological studies directly linked to the conduct or support of clinical trials of preventive vaccines in development, in order to assess or validate the epidemiology of disease, disease incidence, or health of target populations at trial sites
- 20.2** Preliminary studies of morbidity and mortality at potential clinical trial sites, where these studies are directly linked to planned preventive vaccines trials
- 20.3** Pre-trial activities designed to understand trial site conditions before the commencement of trials and to facilitate engagement

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## 21. CLINICAL DEVELOPMENT - UNSPECIFIED

*Other costs required to support clinical testing of investigational new vaccines as needed for regulatory approval; including:*

- 21.1** Infrastructure and site development costs associated with the conduct of clinical trials for vaccine development in LMICs (e.g. refurbishment of hospital wing, vehicle purchase, generators, training and community relationship building)
- 21.2** Further biological/product development to generate the optimal clinical formulation and dosage form, and other Chemistry and Manufacture Control (CMC) activities required for regulatory submission
- 21.3** Compiling all non-clinical and clinical data to obtain a Biologics License from regulatory authorities
- 21.4** Behavioural research prior to registration relating to risk assessment, factors affecting adherence to protocol, and product acceptability
- 21.5** Protocol development, investigator meetings, Good Clinical Practice (GCP) monitoring, quality control, data management, analysis and reporting, establishing a Data Safety Monitoring Board (DSMB) and trial audits

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## 22. POST-REGISTRATION STUDIES

*Studies relating to the detection, monitoring, evaluation, and prevention of adverse events associated with newly approved vaccines so as to bridge the gap between highly controlled clinical trials intended for regulatory approval and the largely uncontrolled delivery of new vaccines. Also includes studies conducted after regulatory approval that assess vaccine effectiveness in the wider population or which are necessary to support product use in LMICs.*

- 22.1** Pharmacovigilance and post-registration studies of newly registered preventive vaccines to assess adverse reactions, toxicology and safety

- 22.2 Effectiveness studies and head-to-head comparator studies of newly registered preventive vaccines (with other therapies or interventions)
- 22.3 Cost-effectiveness studies of newly registered preventive vaccines
- 22.4 Treatment interactions and population level studies (of newly registered preventive vaccines e.g., pharmaco-epidemiological and resistance studies)
- 22.5 Behavioural research post-registration of new preventive vaccines relating to risk assessment, factors affecting adherence to protocol, provider compliance, and product acceptability
- 22.6 Case history reports and assessment of long-term prophylaxis using newly registered preventive vaccines in communities in LMICs

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## IV. BIOLOGICS

*Research activities and processes necessary to develop and improve investigational biological agents specifically intended to prevent or treat infection; including design, preclinical and clinical development, and other activities essential for successful development and uptake. This includes broadly neutralising monoclonal antibodies (bNAbs); polyclonal antibodies; and other bio-therapeutics such as peptide-, DNA- and RNA-based synthetic molecules. In 2019 (collection of FY2018 data), the 'vaccines (therapeutic)' category was renamed 'biologics' to reflect the distinction between traditional vaccine technologies and biologics.*

### 23. DISCOVERY AND PRECLINICAL

*Research activities targeted at discovering and optimising investigational biologics and including the processes necessary to allow a candidate biologic to proceed to human trials; including:*

- 23.1 Studies supporting novel biologic design including target validation, characterisation and selection
- 23.2 Candidate screening and lead optimisation
- 23.3 Development of analytical tests for assaying biologics, including the development of animal models
- 23.4 Evaluation of biologic technologies (e.g. adjuvants, delivery systems) to improve the immunogenicity or delivery of an identified candidate
- 23.5 Biologic pharmacokinetic, toxicity and metabolism studies *in vitro* and in animal models, including bioavailability, adsorption, metabolism, and excretion (ADME) studies
- 23.6 Preclinical safety and immunogenicity studies with candidate biologics, including use or development of functional assays
- 23.7 Preclinical animal studies, challenge models, and studies addressing the correlation between *in vitro* models, animal models and field results necessary to satisfy Investigational New Drug (IND) requirements
- 23.8 Process development and scale-up manufacture, including production of Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) batches for regulatory toxicology studies and other Chemistry and Manufacture Control (CMC) activities required to allow a candidate biologic to proceed to human trials
- 23.9 Research on safety and regulatory considerations (e.g. validation of preclinical assays to permit registration)
- 23.10 Preparation of an Investigational New Drug (IND) application for regulatory submission
- 23.11 Optimisation of biologic candidates for global use (cheaper, more stable, ease of administration, addition of LMIC-specific targets)

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## 24. CLINICAL DEVELOPMENT - PHASE I

*First-in-human clinical trials to determine the safety and tolerability of investigational new biologics in a small group of patients or healthy volunteers, including:*

- 24.1** Phase Ia studies assessing safety, dosing and immunogenicity in human volunteers; including, pharmacokinetic dynamics and tolerance in healthy volunteers.
- 24.2** Phase Ib studies assessing safety, dosing and immunogenicity in clinically exposed or high-risk populations

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## 25. CLINICAL DEVELOPMENT - PHASE II

*Clinical trials to determine the efficacy, safety and therapeutic dose of investigational new biologics in a small set of human subjects (up to several hundred), including:*

- 25.1** Phase IIa challenge studies
- 25.2** Phase IIb safety and preliminary efficacy studies in exposed populations or those at high-risk of infection

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## 26. CLINICAL DEVELOPMENT - PHASE III

*Clinical trials to support the registration of investigational new drugs or label-expansion of already registered drugs in a trial population large enough to provide statistical (typically several hundred), including:*

- 26.1** Phase III expanded efficacy, effectiveness and safety studies required for registration purposes, including implementation, retention and follow-up of volunteers

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## 27. CLINICAL DEVELOPMENT - BASELINE EPIDEMIOLOGY

*Studies evaluating potential trial site populations to confirm disease incidence, prevalence or exposure risk, and which serve as the foundation for determining the optimal collection, analysis, interpretation and presentation of clinical trial data; including:*

- 27.1** Epidemiological studies directly linked to the conduct or support of clinical trials of biologics in development, in order to assess or validate the epidemiology of disease, disease incidence, or health of target populations at trial sites
- 27.2** Preliminary studies of morbidity and mortality at potential clinical trial sites, where these studies are directly linked to planned product trials
- 27.3** Pre-trial activities designed to understand trial site conditions before the commencement of trials and to facilitate engagement

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## 28. CLINICAL DEVELOPMENT - UNSPECIFIED

*Other costs required to support clinical testing of investigational new biologics as needed for regulatory approval; including:*

- 28.1** Infrastructure and site development costs directly associated with the conduct of clinical trials for biologic development in LMICs (e.g. refurbishment of hospital wing, vehicle purchase, generators, training and community relationship building)

- 28.2** Further product development to generate the final clinical formulation, dosage form and other Chemistry and Manufacture Control (CMC) activities required for regulatory submission
- 28.3** Compiling of all non-clinical and clinical data to obtain a Biologics License from regulatory authorities
- 28.4** Behavioural research prior to registration relating to risk assessment, factors affecting adherence to protocol, and product acceptability
- 28.5** Protocol development, investigator meetings, Good Clinical Practice (GCP)-monitoring, quality control, data management, analysis and reporting, establishing a Data Safety Monitoring Board (DSMB), and trial audits

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## **29. POST-REGISTRATION STUDIES**

*Studies relating to the detection, monitoring, evaluation, and prevention of adverse events associated with newly approved biologics so as to bridge the gap between highly controlled clinical trials intended for regulatory approval and the largely uncontrolled use of new biologics by patients. Also includes studies conducted after regulatory approval that assess biologic effectiveness in the wider population or which are necessary to support product use in LMICs.*

- 29.1** Studies conducted after regulatory approval that assess biologic effectiveness in the wider population or which are necessary to support product use in LMICs
- 29.2** Pharmacovigilance and post-registration studies of newly registered biologics to assess adverse reactions, toxicology and safety
- 29.3** Effectiveness studies and head-to-head comparator studies of newly registered biologics (with other therapies or interventions)
- 29.4** Cost-effectiveness studies of newly registered biologics
- 29.5** Treatment interactions and population level studies (of newly registered biologics e.g., pharmaco-epidemiological and resistance studies)
- 29.6** Behavioural research post-registration of new biologics relating to risk assessment, factors affecting adherence to protocol, provider compliance, and product acceptability
- 29.7** Case history reports and assessment of long-term prophylaxis using newly registered biologics in communities in LMICs

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## **V. DIAGNOSTICS**

*Research activities and processes necessary to develop, optimise, and validate diagnostic tests (cheaper, faster, more reliable, ease of use in the field); including discovery and design, preclinical and clinical evaluation, and other activities essential for successful deployment for public health use.*

### **30. DISCOVERY AND PRECLINICAL**

Research activities targeted at discovering and optimising low-cost, stable, easy-to-use diagnostics for emerging infectious diseases and including the processes necessary to allow a potential product to proceed to clinical evaluation including:

- 30.1** Validation, characterisation, and selection of targets suitable for diagnostic use
- 30.2** Validation of new diagnostic markers or biomarkers
- 30.3** Development and testing of low-cost, stable, easy-to-use diagnostic tests (e.g. simpler microscopy, improved sample collection/preparation, cheaper ELISA assays), including manufacturing design

- 30.4** New or improved diagnostics for disease staging and therapy decisions
- 30.5** New or improved diagnostic tools to identify resistant pathogens
- 30.6** New or improved diagnostics to identify specific target populations
- 30.7** Tailoring diagnostic tools for global use, including improved point-of-care tests (rapid test), local laboratory tests, reference laboratory tests and central laboratory tests
- 30.8** Creation of reference material banks

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## **31. CLINICAL EVALUATION**

*Activities and processes associated with clinical evaluation of investigational diagnostic tools so as to demonstrate sensitivity and specificity in human subjects, together with other costs required to support such clinical trials; including:*

- 31.1** Clinical efficacy trials
- 31.2** Small-scale testing in humans to establish sensitivity and specificity and utility
- 31.3** Technical evaluation of tests and studies evaluating product performance
- 31.4** Establishment of product specifications, kit development and quality assurance
- 31.5** Submission of relevant data to regulatory authorities for approval
- 31.6** Assessment and validation of trial sites to carry out product trials
- 31.7** Infrastructure and site development costs directly associated with the conduct of clinical trials for diagnostic development (e.g. refurbishment of hospital wing, vehicle purchase, generators, training and community relationship building)

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## **32. OPERATIONAL RESEARCH FOR DIAGNOSTICS**

*Operational procedures and implementation activities associated with novel diagnostic tools, which are necessary to support World Health Organization (WHO) recommendation for global public health use including:*

- 32.1** Larger-scale demonstration studies (assessing specificity, sensitivity and utility of the diagnostic test in LMICs)
- 32.2** Cost-effectiveness studies assessing the diagnostic test
- 32.3** Identification of pitfalls of the technology and studies of safety measures needed to support the technology
- 32.4** Studies to determine at what level of the health care system the technology is applicable (e.g. reference labs, regional labs)
- 32.5** Identification of training needs
- 32.6** Collecting evidence for expanding the use of a diagnostic tool in different countries
- 32.7** Development of equipment and customer support documents
- 32.8** Head-to-head comparator studies (with current gold standard) and in the context of existing diagnostic algorithms
- 32.9** Behavioural research relating to risk assessment, factors affecting diagnostics use, and user acceptability (patient and provider)
- 32.10** Epidemiological studies to assess or validate the epidemiology of disease, disease incidence or health of target populations at potential trial sites, and which are directly linked to clinical trials of a new diagnostic

## VI. VECTOR CONTROL PRODUCTS

*Research and development activities and processes necessary to develop and improve vector control approaches intended to prevent infection and block transmission of emerging infectious disease from vector and/or animal reservoirs to human; including novel chemical vector control products, biological vector control products and reservoir-targeted vaccines.*

### 33. CHEMICAL VECTOR CONTROL PRODUCTS

*This product category only includes chemical active ingredients and formulations intended for global public health use and which specifically aim to inhibit, kill and/or repel indoor and outdoor vectors associated with emerging infectious disease transmission. This includes new insecticides and formulations in LLINs/IRS; insecticide-based bait and traps; spatial repellents; and chemical larvicides*

*Predation measures, habitat control and infrastructure measures are excluded from the G-FINDER scope.*

#### 33.1 Primary and secondary screening and optimisation

*Laboratory-based design, synthesis and testing of potential insecticides, chemical larvicides, etc., and generation of data sufficient to allow developers to proceed field testing, including:*

- 33.1.1 Primary and secondary screens (e.g. *in vitro* & *in vivo* screens, chemical screens, whole insect screens)
- 33.1.2 Target validation and characterisation
- 33.1.3 Lead optimisation, synthesis optimisation
- 33.1.4 Early toxicology screens (e.g. acute oral toxicity, eye and skin irritation studies, AMES/mutagenicity studies)
- 33.1.5 Applied laboratory research and small-scale field trials, including *in vitro* and glass house efficacy testing
- 33.1.6 Acute toxicology and ecotoxicology studies (e.g. animal studies, exposure studies, fish and wildlife studies)
- 33.1.7 Metabolism and stability studies in plants and animals including mode of action, residue analysis and cross-resistance studies
- 33.1.8 Environmental effect and decomposition studies in soil, water and air

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#### 33.2 Development

*Pre-registration activities and processes associated with clinical testing of investigational chemical vector control products so as to generate data sufficient to allow developers to proceed to product roll-out & dissemination and including other costs required to support such clinical trials.*

- 33.2.1 Small-scale efficacy studies, residue plots and field studies necessary for product optimisation and registration
- 33.2.2 Acute and long-term toxicology and ecotoxicology studies
- 33.2.3 Metabolic and residual fate studies, crop residue and exposure data
- 33.2.4 Environmental assessment and environmental chemistry data
- 33.2.5 Generation of hazard data in humans, domestic animals and non-target plants and animals
- 33.2.6 Compiling of all laboratory and field data necessary for submission to regulatory authorities
- 33.2.7 Behavioural research conducted **pre-registration** relating to risk assessment, factors affecting adherence to protocol, and product acceptability
- 33.2.8 Manufacturing process development, formulation and scale-up

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### 33.3 PQ listing and regulatory approval

*PQ assessment processes and post-registration research activities that comprise entomological, quality, safety and epidemiological evaluation (where appropriate) and development of specifications required for application of insecticide products for use in international public health programmes, including:*

- 33.3.1 PQ assessment of laboratory studies (e.g. determining intrinsic insecticidal activity, diagnostic concentration, irritant or excito-repellent properties, cross-resistance to other insecticides, efficacy and residual activity on relevant substrates)
- 33.3.2 PQ assessment of small-scale field trials (e.g. efficacy and persistence under different ecological settings, dosage of application, handling and application, perceived side-effects)
- 33.3.3 PQ assessment of large-scale field trials (e.g. community level efficacy and residual activity, operational and community acceptance)
- 33.3.4 Assessment & validation of trial sites directly linked to product trials
- 33.3.5 Infrastructure and site development costs associated with the conduct of field trials for pesticide development in LMICs (e.g. refurbishment of hospital wing, vehicle purchase, generators, training and community relationship building)
- 33.3.6 Behavioural research conducted post-registration relating to risk assessment, factors affecting adherence to protocol, provider compliance and product acceptability
- 33.3.7 Studies that confirm efficacy, improve product uptake or confirm safety (e.g. studies to measure impact, usage levels, contamination potential or storage and disposal needs)
- 33.3.8 Surveillance studies **directly** linked to the conduct of field trials for vector control products; including studies that determine prevalence, track distribution, abundance, or significant habits of target vectors or the vector-borne pathogen

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## 34. BIOLOGICAL VECTOR CONTROL PRODUCTS‡

*This product category only includes research and development of innovative biological vector control interventions that specifically aim to kill or control vectors associated with transmitting priority emerging infectious diseases (e.g. microbial/bacteriological larvicides, sterilisation techniques, and genetic modification measures).*

*Biological vector control interventions comprise the use of natural enemies or "engineered" products to manage vector populations either through the introduction of natural parasites, pathogens or predators of the target, or via the introduction of modified vector species to compete with natural sources.*

*Predation measures, habitat control, and infrastructure measures are excluded from the G-FINDER scope.*

### 34.1 Phase I

*Laboratory studies of novel biological vector control techniques*

- 34.1.1 Development of intervention concept and target product profile (TPP) that also specifies the intended product claim (e.g. target vector, entomological effect etc.)

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‡ Unlike the universally accepted definitions for the drug, vaccine and diagnostic R&D pathways, definitions for the biological control product R&D pathway are not firmly established. It is possible that the terminology may change over time as the scientific field develops and as new biological control products undergo regulatory approval. Please note that the activities listed under each stage are not exhaustive but are intended to illustrate the most critical R&D activities within each stage

- 34.1.2 Molecular, genotypic, physiological and behavioural characteristics research in genetically modified vectors
- 34.1.3 Activities related to generating transgenic vector lines, checking stability of the transgene and its phenotype and studies related to the rate of spread of a transgene in laboratory cage populations
- 34.1.4 Ecological modelling to assess environmental risk
- 34.1.5 Quality control to ensure new biological materials are well characterised, stable and detectable
- 34.1.6 Phenotypic evaluation research of transgenic endemic strains, including testing for adverse effects on target or non-target species
- 34.1.7 Laboratory assays to establish mechanism of action
- 34.1.8 Small-scale laboratory studies for efficacy and safety
- 34.1.9 Laboratory-based studies on efficacy and safety in larger population cages
- 34.1.10 Establishment of standard operating procedures for genetically modified vector production and release
- 34.1.11 Activities related to site preparation and hazard containment (risk analysis and risk management)
- 34.1.12 Activities related to data analysis as required by regulators
- 34.1.13 Modelling of expected cost of protection per person

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### **34.2 Phase II**

*Semi-field tests or small-scale field trials (in physical or ecological confinement) to assess the entomological efficacy of the approach<sup>§</sup>*

- 34.2.1 Physically confined (large cage, greenhouse or screen-house type facility that simulates the disease-endemic setting) field trials or semi-field tests to assess entomological efficacy (biological and functional)
- 34.2.2 Ecologically confined (geographic/spatial and/or climatic isolation) small-scale field trials to assess entomological efficacy (biological and functional)
- 34.2.3 Ecological modelling to assess environmental risk
- 34.2.4 Compiling all entomological and epidemiological efficacy data as required by regulators
- 34.2.5 Activities related to site preparation and hazard containment (risk analysis and risk management)
- 34.2.6 Initial cost analysis of prototype or approach
- 34.2.7 Continued monitoring of molecular quality control

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### **34.3 Phase III**

*Large-scale staged field trials to assess the epidemiological efficacy of the approach<sup>\*\*</sup>*

- 34.3.1 Staged, open, large-scale randomised control trials to determine epidemiological efficacy (e.g., reduced disease prevalence, population suppression of target vector)
- 34.3.2 Ecological modelling to assess environmental risk
- 34.3.3 Trial site selection and preparation
- 34.3.4 Baseline studies such as ovitrap surveillance
- 34.3.5 Rearing and sorting of genetically modified vectors
- 34.3.6 Continued monitoring of molecular quality control

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<sup>§</sup> Reduction in the likelihood of disease transmission due to vector population characteristics

<sup>\*\*</sup> Reduction in the incidence of infection or disease in human populations

- 34.3.7 Activities related to data management and statistical analysis
- 34.3.8 Projection of cost per person protected and cost-efficacy of prototype or approach

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#### **34.4 Phase IV**

*Studies, in real-world conditions, that validate the effectiveness of a newly-developed biological vector control product, or post-implementation surveillance of safety and quality*

- 34.4.1 Pilot implementation studies
- 34.4.2 Post-implementation studies to validate feasibility, acceptability and cost-effectiveness
- 34.4.3 Post-implementation surveillance studies to measure mechanism of distribution, molecular quality control, efficacy and safety (including ecological safety) that are not part of routine disease or demographic surveillance activities

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### **35. RESERVOIR TARGETED VACCINES**

*This product category only includes research and development of veterinary vaccines specifically designed to prevent animal to human transmission of relevant priority emerging infectious diseases.*

*Vaccines developed and used solely for veterinary purposes are excluded from this product category.*

#### **35.1 Discovery and preclinical**

*Research activities targeted at discovering and optimising investigational vaccines and including the processes necessary to allow a candidate vaccine to proceed to animal trials; including:*

- 35.1.1 Studies supporting novel vaccine design, including target validation and candidate optimisation
- 35.1.2 Development of animal models to assist in vaccine design and testing
- 35.1.3 Evaluation of vaccine technologies (e.g. adjuvants, delivery systems) to improve the immunogenicity of an identified candidate
- 35.1.4 Preclinical safety and immunogenicity studies with candidate vaccines, including use or development of functional assays
- 35.1.5 Preclinical animal studies, challenge models and addressing the correlation between *in vitro* models, animal models and field results
- 35.1.6 Studies on the genetics of the immune response to selected antigens as vaccine candidates, optimisation of animal models and correlates to clinical results
- 35.1.7 Manufacturing scale-up and consistency of manufacture, including production of Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) batches for regulatory toxicology studies and other Chemistry and Manufacture Control (CMC) activities required to allow a candidate vaccine to proceed to human trials
- 35.1.8 Research on safety and regulatory considerations (e.g. validation of preclinical assays to permit registration)
- 35.1.9 Preparation of a Veterinary Biological Product License application for regulatory submission
- 35.1.10 Optimisation of vaccine candidates for global use (cheaper, more stable, ease of administration, addition of LMIC-specific strains)

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### **35.2 Clinical development**

*Activities and processes associated with clinical testing of investigational vaccines so as to demonstrate safety, immunogenicity and efficacy in animals including animal to human transmission (as needed for regulatory approval), together with other costs required to support such clinical trials, including:*

- 35.2.1 Phase Ia studies assessing safety, dosing, and immunogenicity in animals; Phase Ib studies assessing safety, dosing, and immunogenicity in clinically exposed or high-risk animal populations
- 35.2.2 Phase IIa challenge studies
- 35.2.3 Phase II safety and preliminary efficacy studies in exposed animal populations or those at high-risk of infection
- 35.2.4 Phase III expanded efficacy, effectiveness and safety studies required for registration purposes
- 35.2.5 Infrastructure and site development costs associated with the conduct of clinical trials for vaccine development in LMICs (e.g. vehicle purchase, generators, training and community relationship building)
- 35.2.6 Further biological/product development to generate the optimal clinical formulation and dosage form, and other Chemistry and Manufacture Control (CMC) activities required for regulatory submission
- 35.2.7 Compiling all non-clinical and clinical data to obtain a Biologics License from regulatory authorities
- 35.2.8 Behavioural research during clinical trials relating to risk assessment, factors affecting adherence to protocol, and product acceptability
- 35.2.9 Protocol development, investigator meetings, Good Clinical Practice (GCP) monitoring, quality control, data management, analysis and reporting, establishing a Data Safety Monitoring Board (DSMB) and trial audits

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### **35.3 Phase IV/pharmacovigilance**

*Studies relating to the detection, monitoring, evaluation, and prevention of adverse events associated with newly approved vaccines so as to bridge the gap between highly controlled clinical trials intended for regulatory approval and the largely uncontrolled delivery of new vaccines. Also includes studies conducted after regulatory approval that assess vaccine effectiveness in real world settings or which are necessary to support product use in LMICs.*

- 35.3.1 Pharmacovigilance and post-registration studies of newly registered preventive vaccines to assess adverse reactions, toxicology and safety
- 35.3.2 Effectiveness studies and head-to-head comparator studies of newly registered preventive vaccines (with other therapies or interventions)
- 35.3.3 Cost-effectiveness studies of newly registered preventive vaccines
- 35.3.4 Treatment interactions and population level studies (of newly registered preventive vaccines, e.g. pharmaco-epidemiological and resistance studies)
- 35.3.5 Behavioural research post-registration of new preventive vaccines relating to risk assessment, factors affecting adherence to protocol, provider compliance, and product acceptability
- 35.3.6 Case history reports and assessment of long-term prophylaxis using newly registered preventive vaccines in LMICs

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### **35.4 Baseline epidemiology**

*Studies evaluating potential trial site animal populations to confirm disease incidence, prevalence or exposure risk, and which serve as the foundation for determining the optimal collection, analysis, interpretation and presentation of clinical trial data, including*

- 35.4.1 Epidemiological studies directly linked to the conduct or support of clinical trials of vaccines in development, in order to assess or validate the epidemiological

impact on disease, disease incidence, or health of target animal populations at trial sites

- 35.4.2 Preliminary studies of morbidity and mortality at potential clinical trial sites, where these studies are directly linked to planned vaccines trials
- 35.4.3 Pre-trial activities designed to understand trial site conditions before the commencement of trials and to facilitate engagement

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## VII. CANNOT BE ALLOCATED TO ONE EID

*This category includes all research and development funding that cannot be allocated to a single emerging infectious disease pathogen family (e.g. platform technologies, multiplexed diagnostic assays, core funding). Funding for R&D activities targeting multiple pathogens within the same pathogen family should be included under that pathogen family (e.g. development of a preventive filoviral vaccine targeting both Ebola and Marburg should be included under 'Multiple / Other filoviral diseases' > 'Vaccines (Preventive)').*

### 36. CORE FUNDING OF A MULTI-EMERGING INFECTIOUS DISEASE R&D ORGANISATION

*Disbursements of core or non-earmarked funding to an organisation that researches and develops products for multiple priority emerging infectious disease pathogen families, where it is unclear how the funding has been allocated within that organisation.*

*Example:*

- Core funding has been allocated to an organisation that researches Ebola, Nipah and Zika, but the donor does not know how much has been allocated to each pathogen

### 37. FUNDAMENTAL RESEARCH

*This category includes cross-cutting fundamental research that increase scientific knowledge and understanding that can impact multiple EID families but which is not yet directed towards a specific product.*

*Example:*

- Understanding One Health approaches and animal-human disease epidemiology
- The evolutionary and mechanistic basis of virus host shifts
- Viral genomics, including evolution, spread and host interactions

### 38. BROAD-SPECTRUM ANTI-VIRALS

*Research activities and processes necessary to develop and improve new broad-spectrum therapeutics specifically designed to prevent, cure or treat multiple emerging infectious disease virus families.*

*Example:*

- Development of small molecule therapeutics against RNA viruses
- Development of host-directed inhibitors, such as proteasome inhibitors

### 39. PLATFORM TECHNOLOGIES FOR EMERGING INFECTIOUS DISEASES

#### 39.1 Adjuvants and immunomodulators for emerging infectious diseases

*Research and development of compounds or structures that aim to improve, modulate or potentiate the immune response (e.g. CpG oligonucleotides, lipopolysaccharide derivatives, Toll-like receptor agonists, chemokines and cytokines) to priority emerging*

*infectious disease pathogens, where this research is not associated with an individual pathogen family or product.*

Examples of R&D for adjuvants and immunomodulators included in the survey scope:

- Understanding the innate or adaptive immune response, e.g. studies of Toll-like receptors for the purpose of adjuvant discovery
- Strategies for targeting the cellular immune response to improve the quality of known adjuvants
- Developing a systematic approach to adjuvant discovery (e.g. predictive in vitro assays)
- High throughput screening to identify potential adjuvants

### **39.2 Diagnostic platforms**

*Research activities and processes necessary to develop, optimise, and validate general diagnostic platforms, including multiplexed diagnostic assays allowing detection and identification of multiple emerging infectious disease pathogens from different pathogen families.*

Examples of R&D for diagnostic platforms included in the survey scope:

- Developing a multiplex fever diagnostics
- Development of a highly sensitive multi-pathogen laboratory tests for the simultaneous and differential detection of arthropod-borne viruses
- Amplified detection of viral RNA using catalytic DNA logic circuits

### **39.3 Delivery technologies and devices platforms**

*Delivery technologies and devices comprise mucosal delivery tools, vaccine carrier systems, and alternative delivery technologies that facilitate the successful delivery of pharmaceutical or biological products (e.g. dendritic cell systems, emulsions, sprays, patches and needle-free devices).*

Examples of R&D for delivery technologies and devices included in the survey scope:

- DNA delivery technologies such as CELLECTRA
- Development of a novel mucosal vaccine delivery system phage nanoparticles

### **39.4 Therapeutic platforms**

*Therapeutic platforms includes research and development of biological products to prevent, cure or treat multiple emerging infectious disease virus families.*

Examples of R&D for therapeutic platforms included in the survey scope:

- Heavy Chain Only Antibodies (HCAbs) and H2L2 mAb platforms
- Expression of monoclonal antibodies through injection of a DNA plasmid

### **39.5 Vaccine platforms**

*Vaccine platforms includes research and development of vaccine 'plug and play' platforms, including DNA plasmid vaccine platform, viral vector-based vaccine platform, mRNA vaccine platform, being developed specifically for priority emerging infectious disease pathogens.*

Examples of R&D for vaccine platforms included in the survey scope:

- Virus-like particles (VLP) vaccine technology for irreversibly decorating VLPs by mixing with antigen in a "plug-and-display" manner
- Development of a novel synthetic vaccine platform technology, which can be used to generate a vaccine against Zika or all strains of Ebola and Marburg

#### 40. UNSPECIFIED EMERGING INFECTIOUS DISEASE R&D

*Funding for any other research and development efforts targeting two or more priority emerging infectious disease pathogen families that does not fall under the categories above*

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### VIII. OUT OF SCOPE (EXCLUDED FROM THE SURVEY)

#### 41. GENERAL EXCLUSIONS

*This survey of R&D funding for emerging infectious diseases is designed to capture investments that support pharmaceutical R&D of new products aimed at the prevention, diagnosis, treatment or cure of priority emerging infectious diseases for all patients globally.*

##### 41.1 Non-pharmaceutical tools

41.1.1 Traps, water sanitation tools

##### 41.2 General supportive, nutritional and symptomatic therapies

41.2.1 Oral rehydration therapy

41.2.2 Micronutrient supplementation, vitamins

41.2.3 Anti-pyretics, painkillers

##### 41.3 Products developed and used for veterinary purposes

##### 41.4 In-kind contributions

41.4.1 In-kind R&D contributions are excluded from the survey due to the difficulty in quantifying their value, but will be acknowledged in any analysis of the survey data. Typical in-kind contributions would include training of scientists, sharing of expertise or access to compounds

##### 41.5 Selected categories of private sector investment

41.5.1 Industry overhead costs, capital costs and opportunity costs are excluded, due to the difficulty of quantifying these and allocating them to the emerging infectious disease investment

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#### 42. NON-PRODUCT R&D

*The focus of the survey is on R&D investments related to developing new health technologies for emerging infectious diseases. The following R&D activities are therefore excluded from the survey:*

##### 42.1 Clinical studies that are not linked to development of a new product

42.1.1 Protocol studies and clinical trials using established, available products (not linked to formal label-expansion trials of new products).

42.1.2 Epidemiological surveillance and monitoring studies that are not directly linked to product development. For example, routine DSS (Demographic Surveillance System) activities.

##### 42.2 Health services and access research

42.2.1 Any clinical study not linked to development of a product - disease management, studies of community attitudes, knowledge and practice in relation to emerging infectious disease treatment and control programs.

42.2.2 Health care service studies in relation to delivery of emerging infectious disease treatment and control measures.

42.2.3 Design of treatment and control programs appropriate to local prevailing conditions

42.2.4 Implementation and evaluation of large-scale emerging infectious disease treatment and control programs operated through health care services, government ministries, nongovernmental organizations (NGOs) etc.

- 42.2.5 Roll-out of proven vector control products (e.g. traps and nets, DDT).
- 42.2.6 Advocacy, community education and policy activities related to use, access, or roll-out of new products.

#### **42.3 Operational programme assessment**

- 42.3.1 Reviews on the status of emerging infectious disease product development
- 42.3.2 Studies on the economic impact of emerging infectious disease morbidity and mortality on communities
- 42.3.3 Studies on the economics of emerging infectious disease prevention and control measures
- 42.3.4 Mathematical modelling of the disease (e.g. transmission, immune response)
- 42.3.5 Fostering collaboration between academia, industry, government agencies, and NGOs.

#### **42.4 General capacity building (human and infrastructure)**

Capacity building activities are excluded where they are not directly linked to development of a new emerging infectious disease product. The following activities are therefore excluded:

- 42.4.1 Building academic research capacity; improving existing academic capacity (except where directly linked to development of a specific product).
- 42.4.2 Providing training opportunities; strengthening R&D institutional capacity; developing and maintaining personnel (except where directly linked to development of a specific product).
- 42.4.3 Major infrastructure development (e.g. design, construction and validation of large-scale manufacturing facilities).

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