

EMERGING INFECTIOUS DISEASE R&D SCOPE DOCUMENT

This document sets out the research and development (R&D) activities that are **included** within the scope of the Policy Cures Research/G-FINDER survey of global investment in R&D for priority emerging infectious diseases (EIDs), as well as the R&D activities that are **excluded** or **partially excluded**.

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).

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, preventive and therapeutic vaccines, 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. Research (and other) 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 list of the emerging infectious diseases, products and technologies included in the survey scope is presented in the emerging infectious disease R&D matrix (see section IX).

Although data on R&D investment in emerging infectious diseases is being collected in conjunction with the G-FINDER survey of R&D investment in neglected diseases, this data will be analysed and reported on separately.

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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, or diagnostics 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 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 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, or diagnostic 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

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-extension^{*} for new patient sub-populations (e.g. infants, pregnant women)

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10. CLINICAL DEVELOPMENT

Research activities and processes associated with clinical testing of investigational new drugs so as to demonstrate safety and efficacy in human subjects (as needed for regulatory approval), together with other costs required to support such clinical trials; including:

- 10.1 Phase I pharmacokinetic, toxicity and metabolism studies in healthy human subjects
- 10.2 Phase II testing of drugs and drug combinations in human patients to establish safety and efficacy including dose-finding, and proof of principle studies
- 10.3 Phase III clinical trials for registration purposes
- 10.4 Regulatory standard clinical trials that support a formal registration for label-extension[†] of an existing drug to a new disease or patient group (e.g. paediatric patients, pregnant women or HIV-positive patients)
- 10.5 Regulatory standard clinical trials that support formal registration for label-extension[†] of an existing drug to a new use, such as intermittent preventative therapy and pre-exposure prophylaxis
- 10.6 Infrastructure and site development costs **directly** associated with the conduct of clinical trials for drug development (e.g. refurbishment of hospital wing, vehicle purchase, generators, training and community relationship building)
- 10.7 Further pharmaceutical development to generate the final clinical formulation, dosage form and other Chemistry and Manufacture Control (CMC) activities required for regulatory submission
- 10.8 Compiling of all non-clinical and clinical data for submission of a New Drug Application (NDA) to regulatory authorities
- 10.9 Behavioural research **during clinical trials** relating to risk assessment, factors affecting adherence to protocol, and product acceptability
- 10.10 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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11. PHASE IV/ PHARMACOVIGILANCE

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 developing countries.

- 11.1 Pharmacovigilance and post-registration studies of newly registered drugs to assess adverse reactions, toxicology and safety
- 11.2 Effectiveness studies and head-to-head comparator studies of newly registered drugs (with other therapies or interventions)
- 11.3 Cost-effectiveness studies of newly registered drugs
- 11.4 Treatment interactions and population level studies (of newly registered products e.g., pharmaco-epidemiological and resistance studies)

^{*} Label-extensions 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

[†] Label-extensions 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.

- 11.5 Behavioural research **post-registration** of new drugs relating to risk assessment, factors affecting adherence to protocol, provider compliance, and product acceptability
- 11.6 Case history reports and assessment of long-term prophylaxis using newly registered drugs

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12. 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:

- 12.1 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
- 12.2 Preliminary studies of morbidity and mortality at potential clinical trial sites, where these studies are directly linked to planned product trials
- 12.3 Pre-trial activities designed to understand trial site conditions before the commencement of trials and to facilitate engagement

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III. VACCINES (PREVENTIVE)

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.

13. 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:

- 13.1 Studies supporting novel vaccine design, including target validation and candidate optimisation
- 13.2 Development of animal models to assist in vaccine design and testing
- 13.3 Evaluation of vaccine technologies (e.g. adjuvants, delivery systems) to improve the immunogenicity of an identified candidate
- 13.4 Preclinical safety and immunogenicity studies with candidate vaccines, including use or development of functional assays
- 13.5 Preclinical animal studies, challenge models and addressing the correlation between *in vitro* models, animal models and field results
- 13.6 Studies on the genetics of the immune response to selected antigens as vaccine candidates, optimisation of animal models and correlates to clinical results
- 13.7 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
- 13.8 Research on safety and regulatory considerations (e.g. validation of preclinical assays to permit registration)
- 13.9 Preparation of an Investigational New Drug (IND) application for regulatory submission
- 13.10 Optimisation of vaccine candidates for global use (cheaper, more stable, ease of administration)

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14. CLINICAL DEVELOPMENT

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

- 14.1 Phase Ia studies assessing safety, dosing, and immunogenicity in human volunteers; Phase Ib studies assessing safety, dosing, and immunogenicity in clinically exposed or high-risk populations
- 14.2 Phase IIa challenge studies; Phase II safety and preliminary efficacy studies in exposed populations or those at high-risk of infection
- 14.3 Phase III expanded efficacy, effectiveness and safety studies required for registration purposes, including implementation, retention and follow-up of volunteers
- 14.4 Infrastructure and site development costs associated with the conduct of clinical trials for vaccine development (e.g. refurbishment of hospital wing, vehicle purchase, generators, training and community relationship building)
- 14.5 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
- 14.6 Compiling all non-clinical and clinical data to obtain a Biologics License from regulatory authorities
- 14.7 Behavioural research **during clinical trials** relating to risk assessment, factors affecting adherence to protocol, and product acceptability
- 14.8 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

15. 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 the wider population.

- 15.1 Pharmacovigilance and post-registration studies of newly registered preventive vaccines to assess adverse reactions, toxicology and safety
- 15.2 Effectiveness studies and head-to-head comparator studies of newly registered preventive vaccines (with other therapies or interventions)
- 15.3 Cost-effectiveness studies of newly registered preventive vaccines
- 15.4 Treatment interactions and population level studies (of newly registered preventive vaccines e.g., pharmaco-epidemiological and resistance studies)
- 15.5 Behavioural research **post-registration** of new preventive vaccines 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 preventive vaccines

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16. 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:

- 16.1 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
- 16.2 Preliminary studies of morbidity and mortality at potential clinical trial sites, where these studies are directly linked to planned preventive vaccines trials
- 16.3 Pre-trial activities designed to understand trial site conditions before the commencement of trials and to facilitate engagement

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IV. VACCINES (THERAPEUTIC)

Research activities and processes necessary to develop and improve investigational vaccines specifically intended to treat infection; including vaccine design, preclinical and clinical development, and other activities essential for successful vaccine development and uptake.

17. DISCOVERY AND PRECLINICAL

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

- 17.1 Studies supporting novel vaccine design including target validation and candidate optimisation
- 17.2 Evaluation of vaccine technologies (e.g. adjuvants, delivery systems) to improve the immunogenicity of an identified candidate
- 17.3 Preclinical safety and immunogenicity studies with candidate vaccines, including use or development of functional assays
- 17.4 Preclinical animal studies, challenge models, and studies addressing the correlation between *in vitro* models, animal models and field results
- 17.5 Studies on the genetics of the immune response to selected antigens as vaccine candidates, optimisation of animal models and correlates to clinical results
- 17.6 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
- 17.7 Research on safety and regulatory considerations (e.g. validation of preclinical assays to permit registration)
- 17.8 Preparation of an Investigational New Drug (IND) application for regulatory submission
- 17.9 Optimisation of vaccine candidates for global use (cheaper, more stable, ease of administration)

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18. CLINICAL DEVELOPMENT

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

- 18.1 Phase Ia studies assessing safety, dosing and immunogenicity in human volunteers; Phase Ib studies assessing safety, dosing and immunogenicity in clinically exposed or high-risk populations
- 18.2 Phase IIa challenge studies; Phase II safety and preliminary efficacy studies in exposed populations or those at high-risk of infection
- 18.3 Phase III expanded efficacy, effectiveness and safety studies required for registration purposes, including implementation, retention and follow-up of volunteers
- 18.4 Infrastructure and site development costs associated with the conduct of clinical trials for vaccine development in endemic countries (e.g. refurbishment of hospital wing, vehicle purchase, generators)
- 18.5 Further biological/product development to generate the optimal clinical formulation, dosage form and other Chemistry and Manufacture Control (CMC) activities required for regulatory submission
- 18.6 Behavioural research **during clinical trials** relating to risk assessment, factors affecting adherence to protocol and product acceptability
- 18.7 Compiling of all non-clinical and clinical data to obtain a Biologics License from regulatory authorities

- 18.8** 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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19. PHASE IV / PHARMACOVIGILANCE

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

- 19.1** Pharmacovigilance and post-registration studies of newly registered therapeutic vaccines to assess adverse reactions, toxicology and safety
- 19.2** Effectiveness studies and head-to-head comparator studies of newly registered therapeutic vaccines (with other therapies or interventions)
- 19.3** Cost-effectiveness studies of newly registered therapeutic vaccines
- 19.4** Treatment interactions and population level studies (of newly registered therapeutic vaccines e.g., pharmaco-epidemiological and resistance studies)
- 19.5** Behavioural research **post-registration** of new therapeutic vaccines relating to risk assessment, factors affecting adherence to protocol, provider compliance, and product acceptability
- 19.6** Case history reports and assessment of long-term prophylaxis using newly registered therapeutic vaccines in communities in endemic areas

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20. 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 to assess or validate the epidemiology of disease, disease incidence or health of target populations at potential trial sites
- 20.2** Preliminary studies of morbidity and mortality at potential clinical trial sites necessary for product development
- 20.3** Pre-trial activities designed to understand trial site conditions before the commencement of trials and to facilitate engagement

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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.

21. 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:*

- 21.1 Validation, characterisation, and selection of targets suitable for diagnostic use
- 21.2 Validation of new diagnostic markers or biomarkers
- 21.3 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
- 21.4 New or improved diagnostics for disease staging and therapy decisions
- 21.5 New or improved diagnostic tools to identify resistant pathogens
- 21.6 New or improved diagnostics to identify specific target populations
- 21.7 Tailoring diagnostic tools for global use, including improved point-of-care tests (rapid test), local laboratory tests, reference laboratory tests and central laboratory tests
- 21.8 Creation of reference material banks

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22. 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:

- 22.1 Clinical efficacy trials
- 22.2 Small-scale testing in humans to establish sensitivity and specificity and utility
- 22.3 Technical evaluation of tests and studies evaluating product performance
- 22.4 Establishment of product specifications, kit development and quality assurance
- 22.5 Submission of relevant data to regulatory authorities for approval
- 22.6 Assessment and validation of trial sites to carry out product trials
- 22.7 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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23. 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:

- 23.1 Larger-scale demonstration studies (assessing specificity, sensitivity and utility of the diagnostic test in endemic countries)
- 23.2 Cost-effectiveness studies assessing the diagnostic test
- 23.3 Identification of pitfalls of the technology and studies of safety measures needed to support the technology
- 23.4 Studies to determine at what level of the health care system the technology is applicable (e.g. reference labs, regional labs)
- 23.5 Identification of training needs
- 23.6 Collecting evidence for expanding the use of a diagnostic tool in different countries
- 23.7 Development of equipment and customer support documents
- 23.8 Head-to-head comparator studies (with current gold standard) and in the context of existing diagnostic algorithms
- 23.9 Behavioural research relating to risk assessment, factors affecting diagnostics use, and user acceptability (patient and provider)
- 23.10 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.

24. 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.*

24.1 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:

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

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24.2 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.

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

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24.3 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:

- 24.3.1 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)
- 24.3.2 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)
- 24.3.3 PQ assessment of large-scale field trials (e.g. community level efficacy and residual activity, operational and community acceptance)
- 24.3.4 Assessment & validation of trial sites **directly** linked to product trials
- 24.3.5 Infrastructure and site development costs associated with the conduct of field trials for pesticide development in endemic countries (e.g. refurbishment of hospital wing, vehicle purchase, generators, training and community relationship building)
- 24.3.6 Behavioural research conducted **post-registration** relating to risk assessment, factors affecting adherence to protocol, provider compliance and product acceptability
- 24.3.7 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)
- 24.3.8 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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25. 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.*

25.1 Phase I

Laboratory studies of novel biological vector control techniques

- 25.1.1 Development of intervention concept and target product profile (TPP) that also specifies the intended product claim (e.g. target vector, entomological effect etc.)
- 25.1.2 Molecular, genotypic, physiological and behavioural characteristics research in genetically modified vectors
- 25.1.3 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

‡ 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

- 25.1.4 Ecological modelling to assess environmental risk
- 25.1.5 Quality control to ensure new biological materials are well characterised, stable and detectable
- 25.1.6 Phenotypic evaluation research of transgenic endemic strains, including testing for adverse effects on target or non-target species
- 25.1.7 Laboratory assays to establish mechanism of action
- 25.1.8 Small-scale laboratory studies for efficacy and safety
- 25.1.9 Laboratory-based studies on efficacy and safety in larger population cages
- 25.1.10 Establishment of standard operating procedures for genetically modified vector production and release
- 25.1.11 Activities related to site preparation and hazard containment (risk analysis and risk management)
- 25.1.12 Activities related to data analysis as required by regulators
- 25.1.13 Modelling of expected cost of protection per person

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25.2 Phase II

Semi-field tests or small-scale field trials (in physical or ecological confinement) to assess the entomological efficacy of the approach[§]

- 25.2.1 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)
- 25.2.2 Ecologically confined (geographic/spatial and/or climatic isolation) small-scale field trials to assess entomological efficacy (biological and functional)
- 25.2.3 Ecological modelling to assess environmental risk
- 25.2.4 Compiling all entomological and epidemiological efficacy data as required by regulators
- 25.2.5 Activities related to site preparation and hazard containment (risk analysis and risk management)
- 25.2.6 Initial cost analysis of prototype or approach
- 25.2.7 Continued monitoring of molecular quality control

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25.3 Phase III

*Large-scale staged field trials to assess the epidemiological efficacy of the approach^{**}*

- 25.3.1 Staged, open, large-scale randomised control trials to determine epidemiological efficacy (e.g., reduced disease prevalence, population suppression of target vector)
- 25.3.2 Ecological modelling to assess environmental risk
- 25.3.3 Trial site selection and preparation
- 25.3.4 Baseline studies such as ovitrap surveillance
- 25.3.5 Rearing and sorting of genetically modified vectors
- 25.3.6 Continued monitoring of molecular quality control
- 25.3.7 Activities related to data management and statistical analysis
- 25.3.8 Projection of cost per person protected and cost-efficacy of prototype or approach

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25.4 Phase IV

[§] Reduction in the likelihood of disease transmission due to vector population characteristics

^{**} Reduction in the incidence of infection or disease in human populations

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

- 25.4.1 Pilot implementation studies
- 25.4.2 Post-implementation studies to validate feasibility, acceptability and cost-effectiveness
- 25.4.3 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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26. 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.*

26.1 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:

- 26.1.1 Studies supporting novel vaccine design, including target validation and candidate optimisation
- 26.1.2 Development of animal models to assist in vaccine design and testing
- 26.1.3 Evaluation of vaccine technologies (e.g. adjuvants, delivery systems) to improve the immunogenicity of an identified candidate
- 26.1.4 Preclinical safety and immunogenicity studies with candidate vaccines, including use or development of functional assays
- 26.1.5 Preclinical animal studies, challenge models and addressing the correlation between *in vitro* models, animal models and field results
- 26.1.6 Studies on the genetics of the immune response to selected antigens as vaccine candidates, optimisation of animal models and correlates to clinical results
- 26.1.7 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
- 26.1.8 Research on safety and regulatory considerations (e.g. validation of preclinical assays to permit registration)
- 26.1.9 Preparation of a Veterinary Biological Product License application for regulatory submission
- 26.1.10 Optimisation of vaccine candidates for global use (cheaper, more stable, ease of administration, addition of developing country-specific strains)

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26.2 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:

- 26.2.1 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
- 26.2.2 Phase IIa challenge studies; Phase II safety and preliminary efficacy studies in exposed animal populations or those at high-risk of infection
- 26.2.3 Phase III expanded efficacy, effectiveness and safety studies required for registration purposes
- 26.2.4 Infrastructure and site development costs associated with the conduct of clinical trials for vaccine development in endemic countries (e.g. vehicle purchase, generators, training and community relationship building)
- 26.2.5 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
- 26.2.6 Compiling all non-clinical and clinical data to obtain a Biologics License from regulatory authorities
- 26.2.7 Behavioural research during clinical trials relating to risk assessment, factors affecting adherence to protocol, and product acceptability
- 26.2.8 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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26.3 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 developing countries.

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

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26.4 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

- 26.4.1 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
- 26.4.2 Preliminary studies of morbidity and mortality at potential clinical trial sites, where these studies are directly linked to planned vaccines trials

- 26.4.3 Pre-trial activities designed to understand trial site conditions before the commencement of trials and to facilitate engagement

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VII. MULTIPLE EMERGING INFECTIOUS DISEASES

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).

27. MULTIPLE EMERGING INFECTIOUS DISEASES

*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)').*

Examples of R&D funding that may be included under the 'multiple emerging infectious diseases' category include:

27.1 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

27.2 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

27.3 Platform technologies for emerging infectious diseases

Research and development of vaccine 'plug and play' platforms, monoclonal antibody platforms, diagnostic platforms, or delivery technologies and devices (e.g. mucosal delivery tools, vaccine carrier systems, and alternative delivery technologies that facilitate the successful delivery of pharmaceutical or biological products) being developed specifically for priority emerging infectious disease pathogens, where this research is not associated with an individual pathogen family or product

27.4 Multiplexed emerging infectious disease diagnostic assays

Research and development of multiplexed diagnostic assays allowing detection and identification of multiple emerging infectious disease pathogens from different pathogen families

27.5 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)

28. 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.

- 28.1 Non-pharmaceutical tools**
 - 28.1.1 Traps, water sanitation tools
- 28.2 General supportive, nutritional and symptomatic therapies**
 - 28.2.1 Oral rehydration therapy
 - 28.2.2 Micronutrient supplementation, vitamins
 - 28.2.3 Anti-pyretics, painkillers
- 28.3 Products developed and used for veterinary purposes**
- 28.4 In-kind contributions**
 - 28.4.1 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
- 28.5 Selected categories of private sector investment**
 - 28.5.1 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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29. 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:*

- 29.1 Clinical studies that are not linked to development of a NEW product**
 - 29.1.1 Protocol studies and clinical trials using established, available products (not linked to formal label-extension trials of new products).
 - 29.1.2 Epidemiological surveillance and monitoring studies that are not directly linked to product development. For example, routine DSS (Demographic Surveillance System) activities.
- 29.2 Health services and access research**
 - 29.2.1 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.
 - 29.2.2 Health care service studies in relation to delivery of emerging infectious disease treatment and control measures.
 - 29.2.3 Design of treatment and control programs appropriate to local prevailing conditions
 - 29.2.4 Implementation and evaluation of large-scale emerging infectious disease treatment and control programs operated through health care services, government ministries, nongovernmental organizations (NGOs) etc.
 - 29.2.5 Roll-out of proven vector control products (e.g. traps and nets, DDT).
 - 29.2.6 Advocacy, community education and policy activities related to use, access, or roll-out of new products.
- 29.3 Operational programme assessment**
 - 29.3.1 Reviews on the status of emerging infectious disease product development
 - 29.3.2 Studies on the economic impact of emerging infectious disease morbidity and mortality on communities
 - 29.3.3 Studies on the economics of emerging infectious disease prevention and control measures
 - 29.3.4 Mathematical modelling of the disease (e.g. transmission, immune response)
 - 29.3.5 Fostering collaboration between academia, industry, government agencies, and NGOs.

29.4 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**:

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

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30. SELECTED DISEASE AND PRODUCT RESTRICTIONS

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'. R&D for emerging infectious diseases not on the 2017 R&D Blueprint priority pathogen list are **EXCLUDED** from the survey.

Research and development of vector control products is subject to a number of scope restrictions and exclusions, and is included only where relevant to the emerging infectious disease pathogen.

30.1 Vector control products

EXCLUDED R&D for vector control products:

- 30.1.1 Predation measures, habitat control and infrastructure measures
- 30.1.2 Chemical vector control products

RESTRICTED R&D for chemical vector control products:

30.1.2.1 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

EXCLUDED R&D for chemical vector control products:

30.1.2.2 Predation measures, habitat control and infrastructure measures

R&D for chemical vector control products is also **EXCLUDED** for the following diseases:

- 30.1.2.3 Ebola, Marburg and multiple/other filoviral diseases
- 30.1.2.4 Lassa fever and multiple/other arenaviral haemorrhagic fevers
- 30.1.2.5 Middle East Respiratory Syndrome coronavirus (MERS-CoV), Severe Acute Respiratory Syndrome (SARS) and multiple/other highly pathogenic coronaviral diseases
- 30.1.2.6 Nipah and multiple/other henipaviral diseases

30.1.3 Biological vector control products

RESTRICTED R&D for biological control products:

30.1.3.1 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 emerging infectious diseases (e.g. microbial/bacteriological larvicides, sterilisation techniques, and genetic modification measures)

- 30.1.3.2 Predation measures, habitat control, chemical pesticides and infrastructure measures

R&D for biological vector control products is also **EXCLUDED** for the following diseases:

- 30.1.3.3 Ebola, Marburg and multiple/other filoviral diseases
- 30.1.3.4 Lassa fever and multiple/other arenaviral haemorrhagic fevers
- 30.1.3.5 Severe Acute Respiratory Syndrome (SARS), Middle East Respiratory Syndrome coronavirus (MERS-CoV) and multiple/other highly pathogenic coronaviral diseases
- 30.1.3.6 Nipah and multiple/other henipaviral diseases

30.1.4 Reservoir targeted vaccines

*All vaccines developed and used solely for veterinary purposes are **EXCLUDED** from the survey.*

RESTRICTED Reservoir targeted vaccines

30.1.3.1 **Reservoir targeted vaccines**

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

*R&D for vaccines targeting animal reservoirs is also **EXCLUDED** for the following diseases:*

- 30.1.4.1 Lassa fever and multiple/other arenaviral haemorrhagic fevers
- 30.1.4.2 Zika
- 30.1.4.3 Multiple highly pathogenic coronaviral diseases (Other than Middle East Respiratory Syndrome coronavirus [MERS-CoV] or Severe Acute Respiratory Syndrome [SARS])

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IX. EMERGING INFECTIOUS DISEASE R&D MATRIX*

		Basic research	Drugs	Vaccines (preventive)	Vaccines (therapeutic)	Diagnostics	Vector control products
Filoviral diseases	Ebola	✓	✓	✓	✓	✓	✓
	Marburg	✓	✓	✓	✓	✓	✓
	Multiple / other filoviral diseases	✓	✓	✓	✓	✓	✓
Bunyaviral diseases	Crimean Congo Haemorrhagic Fever (CCHF)	✓	✓	✓	✓	✓	✓
	Rift Valley Fever (RVF)	✓	✓	✓	✓	✓	✓
	Multiple / other bunyaviral diseases (including Severe Fever with Thrombocytopenia Syndrome (SFTS))	✓	✓	✓	✓	✓	✓
Arenaviral haemorrhagic fevers	Lassa fever	✓	✓	✓	✓	✓	-
	Multiple / other arenaviral haemorrhagic fevers	✓	✓	✓	✓	✓	-
Coronaviral diseases	Middle East Respiratory Syndrome coronavirus (MERS-CoV)	✓	✓	✓	✓	✓	✓
	Severe Acute Respiratory Syndrome (SARS)	✓	✓	✓	✓	✓	✓
	Multiple / other highly pathogenic coronaviral diseases	✓	✓	✓	✓	✓	-
Henipaviral diseases	Nipah	✓	✓	✓	✓	✓	✓
	Multiple / other henipaviral diseases	✓	✓	✓	✓	✓	✓
Zika		✓	✓	✓	✓	✓	✓
Multiple Emerging Infectious Diseases (EIDs)		R&D targeting multiple EID virus families (e.g. platform technologies for EIDs, multiplexed EID diagnostic assays, core funding)					

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

* The survey scope for emerging infectious diseases has not been defined using the same three-step filter used to determine the G-FINDER neglected disease survey scope. All relevant R&D activities for priority pathogens identified in the WHO R&D Blueprint review are considered in scope. The pathogens have been grouped by disease family for data collection purposes.