Emerging Infectious Disease R&D Scope

G-FINDER

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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 EID survey, as well as the R&D activities that are excluded or partially excluded (restricted).

The G-FINDER EID survey scope is based on the World Health Organization's scientific framework for epidemic & pandemic preparedness (R&D Blueprint) as updated in 2024, which shifts focus from individual high-risk pathogens to broader viral families. In line with this approach, the survey includes all WHO-designated 'priority' and 'prototype' pathogens, grouped by their respective viral families for data collection purposes. The survey also includes diseases recognized by other agencies as priority pathogens posing significant public health risks.

Compared to the G-FINDER survey of global investment in neglected disease (ND) R&D, the G-FINDER 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. The G-FINDER EID survey scope will be updated to include any further changes to the R&D Blueprint's scientific framework of high-priority families.

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

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

The G-FINDER project also tracks R&D for neglected diseases (NDs), and women's health (WH) issues. Some of the emerging infectious diseases, issues, products and technologies may overlap with the scope of these other global health areas.

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

EID R&D Matrix

WHO scientific framework: viral families with priority/prototype pathogens[i]		Basic research	Drugs	Vaccines	Biologics	Diagnostics	Vector control products
Arenaviridae (including Lassa fever)	*Mammarenavirus lassaense* - *Lassa fever*	✓	✓	✓	✓	✓	✓‡
	Multiple arenaviral haemorrhagic fevers	✓	✓	✓	✓	✓	✓‡
Bunyaviridae (including ANDV, CCHF, HTNV, RVF, SFTS, SNV)	*Orthohantavirus andesense* - Andes virus (ANDV)	✓	✓	✓	✓	✓	✓‡
	Orthonairovirus haemorrhagiae - Crimean-Congo Haemorrhagic Fever (CCHF)	✓	✓	✓	✓	✓	✓
	Orthohantavirus hantanense - Hantaan virus (HTNV)	✓	✓	✓	✓	✓	✓‡
	Phlebovirus riftense - Rift Valley Fever (RVF)	✓	✓	✓	✓	✓	✓
	Bandavirus dabieense - Severe Fever with Thrombocytopenia Syndrome (SFTS)	✓	✓	✓	✓	✓	✓
	Orthohantavirus sinnombreense - Sin Nombre virus (SNV)	✓	✓	✓	✓	✓	✓‡
	Multiple bunyaviral diseases	✓	✓	✓	✓	✓	✓
Coronaviridae (including COVID-19, MERS)	*Subgenus Merbecoviruses* - Middle East Respiratory Syndrome (MERS)	✓	✓	✓	✓	✓	✓‡
	Subgenus Sarbecoviruses - Coronavirus disease 2019 (COVID-19)	✓	✓	✓	✓	✓	✓‡
	Multiple coronaviral diseases[1]	✓	✓	✓	✓	✓	✓‡
Filoviridae (including Ebola, Marburg)	*Orthoebolavirus zairense and Orthoebolavirus sudanens* - Ebola	✓	✓	✓	✓	✓	✓‡
	Orthomarburgvirus marburgense - Marburg	✓	✓	✓	✓	✓	✓‡
	Multiple filoviral diseases	✓	✓	✓	✓	✓	✓‡
Flaviviridae (including Dengue, Zika)	*Orthoflavivirus denguei* - Dengue^	✓	✓	✓#	✓	✓	✓
	Orthoflavivirus zikaense - Zika	✓	✓	✓	✓	✓	✓
Orthomyxoviridae (including Influenza A)	*Alphainfluenzavirus Influenzae* - Highly pathogenic avian influenza A(H5N1)	✓	✓	✓	✓	✓	✓‡
Paramyxoviridae (Henipaviruses - including Nipah)	*Henipavirus nipahense* - Nipah	✓	✓	✓	✓	✓	✓‡
	Multiple henipaviral diseases	✓	✓	✓	✓	✓	✓‡
Poxviridae (including Mpox)	*Orthopoxvirus monkeypox* - Mpox	✓	✓	✓	✓	✓	✓‡
Togaviridae (including Alphaviruses e.g. CHIKV)	*Alphavirus chikungunya* - Chikungunya (CHIKV)	✓	✓	✓	✓	✓	✓
	Multiple alphaviral diseases	✓	✓	✓	✓	✓	✓

Investment applicable to more than one emerging infectious disease, or to more than one global health area*							
Platform technologies					**Fundamental research**	**Multi-disease vector control**	**Core funding of a multi-disease R&D**
Adjuvants & immunomodulators	Biologics-related platform technologies	Drug-related platform technologies	General diagnostic platforms & multi-	Vaccine-related platform			

			disease diagnostics	technologies			**organisation**
✓	✓	✓	✓	✓	✓	✓	✓

i The G-FINDER EID survey scope aligns with the World Health Organization's Scientific Framework for Epidemic and Pandemic Research Preparedness., incorporating priority/prototype pathogens from the framework as italicized subcategories within the EID scope matrix. The 'multiple disease categories' capture R&D for two or more pathogens within a viral family

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

[1] R&D that involves multiple coronaviruses, including SARS-CoV-1, should be captured under multiple coronaviral diseases.

* The G-FINDER project covers three global health areas: neglected diseases, emerging infectious diseases, and sexual & reproductive health issues.

^ Dengue is captured through the G-FINDER neglected disease survey. R&D involving both zika and dengue fall under R&D for both NDs and EIDs.

Dengue vaccine is restricted to LMIC-specific R&D, including clinical trials, registration and Phase IV studies in the target LMICs

‡ The vector control product (VCP) category consists of three sub-categories: chemical VCPs, biological VCPs, and reservoir-targeted vaccines. Their inclusion depends on whether the pathogen is vector-borne and if an animal reservoir is present. In these non-vector borne diseases, vector control product category includes only veterinary vaccines specifically developed to prevent animal to human transmission

Scope Changes Over Time

The scope of the G-FINDER EID survey has evolved since the inclusion of Ebola in the 2015 G-FINDER survey, and will continue to evolve in response to changes in the WHO R&D Blueprint and expert consensus.

The first priority EID pathogen to be tracked by the G-FINDER project was the Ebola virus, which was included in 2015 G-FINDER survey (collecting FY2014 data) in response to the 2014-15 West African Ebola outbreak. This first year of EID data collection also captured grants targeting multiple filoviral diseases including Ebola.

The 2016 G-FINDER survey (collecting FY2015 data), was expanded to include four additional viral haemorrhagic fevers – 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. R&D funding for these EIDs was analysed separately from the traditional G-FINDER neglected diseases.

In 2017 (collecting FY2016 data) the G-FINDER project formally began separately tracking R&D investment in priority EID pathogens, based on the newly developed WHO R&D Blueprint. Diseases added in this year were 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 (collecting FY2017 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 pro-rated 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 vector control product 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.

In 2019 (collecting FY2018 data), the survey scope was further expanded to include chikungunya and emergent non-polio enteroviruses (including EV71, D68). While these pathogens are not formally included in the WHO R&D Blueprint, both were considered for inclusion in 2018 and may be granted priority status in the future.

In 2020 (collecting FY2019 data), the survey scope was expanded to explicitly include coronavirus disease 2019 (COVID-19), following its inclusion in the WHO R&D Blueprint. EID-specific multi-disease vector control research was also introduced to reflect the applicability of one vector control product to multiple diseases carried by the same vector. This also included the addition of ‘fundamental vector control research’, to capture basic research on vectors that have the potential to carry more than one emerging infectious disease, or both emerging infectious diseases and neglected diseases.

In 2022 (collecting FY2021 data), platform technology categories were merged in line with other G-FINDER global health areas.

In 2023 (collecting FY2022 data), the survey scope was further expanded to include mpox (monkeypox), following the ongoing multi-country outbreak which began in 2022. At this time, mpox is an active area for the WHO R&D Blueprint team and may be granted priority status in the future.

In 2023 (collecting FY2022 data), a specification pointing out that the scope of the vector control product category in all non-vector borne EIDs included the disease matrix is limited to veterinary vaccines specifically developed to prevent animal to human transmission, has been added.

In 2023 (collecting FY2022 data), language describing modelling and related activities where they are designed to inform knowledge about the disease or development of products for the disease was added to the G-FINDER survey scope.

In 2024 (collecting FY2023 data), the diagnostics R&D stages, ‘diagnostics & preclinical’ and ‘clinical evaluation’ were renamed ‘early development and ‘late development’, respectively, to align our categorization with terminology commonly used across the diagnostics landscape.

Aligning with WHO’s scientific framework for epidemic & pandemic preparedness, in 2025 (collecting FY2024 data), we adopted the taxonomical names of priority and prototype pathogens, listed in italicised forms as sub-categories, with common disease/pathogen name equivalents attached for easy identification. The survey was expanded to include Hantaan virus (*Orthohantavirus hantanense*), Highly pathogenic Avian Influenza A(H5N1) virus (*Alphainfluenzavirus Influenzae*) and Dengue virus (*Orthoflavivirus denguei*). However, dengue is included in the neglected disease (ND) scope since 2008.

In 2025 (collecting FY2024 data), the ‘in combination with’ and ‘other than’ categories were replaced with the ‘multiple diseases’ category, capturing R&D funding for multiple pathogens within a single viral family. This approach aligned with previous methods of data analysis and reporting but also the PPR community's shift towards focusing on R&D for viral families rather than individual pathogens. Flaviviridae, Orthomyxoviridae, and Poxviridae do not have a multiple disease category. R&D funding for both Zika and Dengue are captured under R&D for both ND and EID.

In 2025 (collecting FY2024 data), Emergent non-polio enteroviruses (including EV71, D68) and Severe Acute Respiratory Syndrome (SARS-CoV-1) were excluded from the survey. The latter being a result of minimal R&D activity in this area since the emergence of COVID-19. Funding for R&D that involves multiple coronaviruses, including SARS-CoV-1, should be included and captured under multiple coronaviral diseases. Funding targeted at R&D for COVID-19 devices and ventilators was excluded from the survey.

In response to outbreaks in 2026, we began capturing R&D funding (collecting FY2025 data) for Andes virus (*Orthohantavirus andesense*) and Sin Nombre virus (*Orthohantavirus sinnombreense*).

Scope By Product

1.1 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
- 1.10 Epidemiological research examining the human-animal-environmental interface, such as studies investigating animal reservoirs and ecological drivers of disease transmission
- 1.11 Epidemiological research on genetic evolution of a disease (e.g. variants and drug resistance) with the assistance of mathematical modelling where it is NOT linked to routine surveillance activities

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)

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

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)

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

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

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

1.2 DRUGS

Research activities and processes necessary to develop and improve new compounds or repurposed drugs 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 or repurposed drugs, including the processes needed to allow new chemical entities to proceed to human trials; including:

9.1 Target validation, characterisation, and selection

9.2 In silico discovery and development activities for drugs, including the use of pharmacometrics and mechanistic models

9.3 High throughput screening, lead optimisation

9.4 Development of analytical tests for assaying drugs, including the development of animal models

9.5 Research on drugs from natural products; identification and characterisation of active ingredient

9.6 Research on the effects of drug treatment on immune status

9.7 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

9.8 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

9.9 Development of tests for drug susceptibility of the pathogen for research purposes

9.10 Drug pharmacokinetic, toxicity and metabolism studies in vitro and in animal models, including bioavailability, adsorption, metabolism, and excretion (ADME) studies

9.11 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

9.12 Preparation of Investigational New Drug (IND) application for regulatory submission

9.13 Optimisation and manufacturing of new formulations to support label-expansion* for new patient sub-populations (e.g. infants, pregnant women)

10. CLINICAL DEVELOPMENT - PHASE I

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

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

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

13. CLINICAL DEVELOPMENT - BASELINE EPIDEMIOLOGY

* 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.

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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

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

14.6 Transmission modelling to inform clinical trial design and therapeutic administration strategies for drugs in clinical development

14.7 In silico clinical trials designed to assess safety and/or efficacy of drugs in clinical development

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

1.3 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 In silico discovery and development activities for vaccines, including the use of pharmacometrics and mechanistic models

16.3 Development of animal models to assist in vaccine design and testing

16.4 Evaluation of vaccine technologies (e.g. adjuvants, delivery systems) to improve the immunogenicity of an identified candidate

16.5 Preclinical safety and immunogenicity studies with candidate vaccines, including use or development of functional assays

16.6 Preclinical animal studies, challenge models and addressing the correlation between in vitro models, animal models and field results

16.7 Studies on the genetics of the immune response to selected antigens as vaccine candidates, optimisation of animal models and correlates to clinical results

16.8 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

16.9 Research on safety and regulatory considerations (e.g. validation of preclinical assays to permit registration)

16.10 Preparation of an Investigational New Drug (IND) application for regulatory submission

16.11 Optimisation of vaccine candidates for global use (cheaper, more stable, ease of administration)

17. CLINICAL DEVELOPMENT - PHASE I

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

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

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

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

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

21.6 Transmission modelling to inform clinical trial design and therapeutic administration strategies for vaccines in clinical development

21.7 In silico clinical trials designed to assess safety and/or efficacy of vaccines in development

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

1.4 BIOLOGICS

Research activities and processes necessary to develop and improve investigational biological agents and therapeutic vaccines 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 preventive vaccine technologies, and biologics and therapeutic vaccines.

23. DISCOVERY AND PRECLINICAL

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

23.1 Studies supporting novel biologic or therapeutic vaccine design including target validation, characterisation and selection

23.2 In silico discovery and development activities for biologics, including the use of pharmacometrics and mechanistic models

23.3 Antibody screening and optimisation

23.4 Development of analytical tests for assaying biologics or therapeutic vaccines, including the development of animal models

23.5 Evaluation of biologic technologies (e.g. delivery systems) to improve the delivery of an identified candidate

23.6 Biologic pharmacokinetic, toxicity and metabolism studies in vitro and in animal models, including bioavailability, adsorption, metabolism, and excretion (ADME) studies

23.7 Preclinical safety and tolerability studies with candidate biologics or therapeutic vaccine, including use or development of functional assays

23.8 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

23.9 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 or therapeutic vaccine to proceed to human trials

23.10 Research on safety and regulatory considerations (e.g. validation of preclinical assays to permit registration)

23.11 Preparation of an Investigational New Drug (IND) application for regulatory submission

23.12 Optimisation of biologic or therapeutic vaccine candidates for global use (cheaper, more stable, ease of administration, addition of LMIC-specific targets)

24. CLINICAL DEVELOPMENT - PHASE I

Clinical trials to determine the safety and tolerability of investigational new biologics and therapeutic vaccines in a small group of patients or healthy volunteers, including:

24.1 Phase I studies assessing safety and tolerability of biological drugs such as a monoclonal antibody or a fully human polyclonal immunoglobulin in human volunteers; including, pharmacokinetic and pharmacodynamics.

25. CLINICAL DEVELOPMENT - PHASE II

Clinical trials to determine the efficacy, safety and therapeutic dose of investigational new biologics or therapeutic vaccines 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

26. CLINICAL DEVELOPMENT - PHASE III

Clinical trials to support the registration of investigational new drugs or label-expansion of already registered drugs or therapeutic vaccines 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

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 or therapeutic vaccines 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

28. CLINICAL DEVELOPMENT - UNSPECIFIED

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

28.1 Infrastructure and site development costs directly associated with the conduct of clinical trials for biologic or therapeutic vaccine 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

28.6 Transmission modelling to inform clinical trial design and therapeutic administration strategies for biologics in clinical development

28.7 In silico clinical trials designed to assess safety and/or efficacy of biologics in clinical development

29. POST-REGISTRATION STUDIES

Studies relating to the detection, monitoring, evaluation, and prevention of adverse events associated with newly approved biologics or therapeutic vaccines 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 or therapeutic vaccine 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 or therapeutic vaccine 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 or therapeutic vaccine to assess adverse reactions, toxicology and safety

29.3 Effectiveness studies and head-to-head comparator studies of newly registered biologics or therapeutic vaccines (with other therapies or interventions)

29.4 Cost-effectiveness studies of newly registered biologics or therapeutic vaccines

29.5 Treatment interactions and population level studies (of newly registered biologics or therapeutic vaccines e.g., pharmaco-epidemiological and resistance studies)

29.6 Behavioural research post-registration of new biologics or therapeutic vaccines 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 or therapeutic vaccines in communities in LMICs

1.5 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. EARLY DEVELOPMENT

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 In silico biomarker and antigen discovery and development activities, including immune system interaction models

30.3 Validation of new diagnostic markers or biomarkers

30.4 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

30.5 New or improved diagnostics for disease staging and therapy decisions

30.6 New or improved diagnostic tools to identify resistant pathogens

30.7 New or improved diagnostics to identify specific target populations

30.8 Tailoring diagnostic tools for global use, including improved point-of-care tests (rapid test), local laboratory tests, reference laboratory tests and central laboratory tests

30.9 Creation of reference material banks

31. LATE DEVELOPMENT

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)

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

1.6 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 In silico discovery and development activities for chemically active ingredients, including the use of pharmacometrics and mechanistic models
- 33.1.3 Target validation and characterisation
- 33.1.4 Lead optimisation, synthesis optimisation
- 33.1.5 Early toxicology screens (e.g. acute oral toxicity, eye and skin irritation studies, AMES/mutagenicity studies)
- 33.1.6 Applied laboratory research and small-scale field trials, including in vitro and glass house efficacy testing
- 33.1.7 Acute toxicology and ecotoxicology studies (e.g. animal studies, exposure studies, fish and wildlife studies)
- 33.1.8 Metabolism and stability studies in plants and animals including mode of action, residue analysis and cross-resistance studies
- 33.1.9 Environmental effect and decomposition studies in soil, water and air
- 33.1.10 Ecological modelling to assess environmental risk

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
- 33.2.9 Ecological modelling to assess environmental risk

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

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.)
- 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

* 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.

34.1.6 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

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[*]

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

34.3 Phase III

Large-scale staged field trials to assess the epidemiological efficacy of the approach[†]

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

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

34.4 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

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

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 early-phase development

Phase of vaccine development covering from antigen discovery to lead identification and optimisation to field trial application including:

35.1.1 Development of Target Product Profile (TPP), including considerations on the indication for use, the disease prevention claims, the target species as well as the vaccine delivery (route of administration, co-administration with other vaccines)

35.1.2 Research on the livestock or companion animal host immunology

35.1.3 Research on pathogen biology and identification of an appropriate challenge model

35.1.4 Performance of challenge studies with the pathogen and analysis of immune response in the selected challenge model

35.1.5 Studies aiming at the antigen discovery and optimization of the immunogen design (antigen selection and purification, selection of vaccine type/delivery system, e.g. vector-based, subunit, etc.)

35.1.6 In silico antigen and biomarker discovery and development activities, including immune system interaction models

35.1.7 Performance of in vitro and early in vivo studies. Execution of challenge studies with developed antigen and analysis of the immune response in the selected challenge model

35.1.8 Studies with respect to lead identification and optimisation

35.1.9 Lead development studies including quality control, stability testing, vaccine characterization

35.1.10 Process development and non-Good Manufacturing Practice (GMP) activities including production of pilot lots

35.1.11 Assay development including diagnostic tests that can differentiate between infected and vaccinated animals (DIVA)

35.1.12 Performance of in vivo safety and efficacy studies

35.1.13 Assessment of environmental, consumer and user safety

35.1.14 Process validation and scale-up including GMP activities such as bulk and fill and finish

35.1.15 Preparation of a Veterinary Biological Product License application for regulatory submission

35.1.16 Field trial application

35.2 Field trials

Phase of vaccine development covering from safety and immunogenicity trials to efficacy studies to regulatory filling including:

35.2.1 TPP review
35.2.2 Field trial study design and study site selection
35.2.3 In silico field trials designed to assess safety and/or efficacy of vaccines in development
35.2.4 Infrastructure and site development costs associated with the conduct of field trials in LMICs (e.g. vehicle purchase, generators, training and community relationship building)
35.2.5 Regulatory and ethics engagement
35.2.6 Vaccine safety and immunogenicity studies
35.2.7 Vaccine efficacy studies with epidemiological efficacy in humans as the primary end point
35.2.8 Further biological/product development to generate the optimal clinical formulation and dosage form, and other activities required for regulatory submission
35.2.9 Regulatory dossier preparation and submission

35.3 Post-registration studies

Post-marketing authorization phase covering from monitoring of real-world safety and adverse events to intended efficacy in humans:

35.3.1 Post marketing surveillance including adverse events and DIVA compliance
35.3.2 Real-world epidemiological efficacy studies

35.4 Baseline epidemiology

Phase of vaccine development evaluating potential trial site populations to confirm incidence, prevalence or exposure to risk and serving as the foundation for determining the optimal collection, analysis and interpretation of clinical 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

1.7 R&D FOR MORE THAN ONE EMERGING INFECTIOUS DISEASE

This category includes all research and development funding that is applicable to more than 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 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:

i. 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 (basic) research that increase scientific knowledge and understanding that can impact multiple EID families, but which is not yet directed towards a specific product.

Example:

i. Understanding One Health approaches and animal-human disease epidemiology

ii. The evolutionary and mechanistic basis of virus host shifts

iii. Viral genomics, including evolution, spread and host interactions

See sections 1-7 for examples of R&D activities that may fall under this category (to the extent that such activities are not disease-specific or are targeting multiple EID families).

38. MULTI-DISEASE VECTOR CONTROL

This category only includes vector control R&D that is not yet targeted at a specific emerging infectious disease, or that is explicitly targeted at multiple vector-borne emerging infectious diseases. Disease-specific investment associated with R&D of vector control products with multi-disease potential (e.g. assessment of the epidemiological efficacy of Wolbachia carrying mosquitoes in reducing Zika incidence) does not fall under this category.

Example:

i. Design and synthesis of new mode-of-action chemicals for controlling mosquitoes of various species (Aedes and/or Culex)

ii. Development of a sterile-insect technique for controlling mosquito-borne diseases

38.1 Multi-disease chemical vector control products

38.1.1 See section 33 for the full outline of R&D activities included under this category

38.2 Multi-disease biological vector control products

38.2.1 See section 34 for the full outline of R&D activities included under this category

38.3 Multi-disease reservoir targeted vaccines

38.3.1 See section 35 for the full outline of R&D activities included under this category

38.4 Multi-disease fundamental vector control research

This category includes fundamental (basic) research activities on vectors that have the potential to carry more than one emerging infectious disease, or both neglected and emerging infectious diseases, including vector biology, biochemistry, and genetics related to vector control.

38.4.1 See section 8 for the full outline of R&D activities included under this category

39. PLATFORM TECHNOLOGIES FOR EMERGING INFECTIOUS DISEASES

39.1 ADJUVANTS AND IMMUNOMODULATORS

Adjuvants and immunomodulators are substances formulated as part of a vaccine to improve, modulate or potentiate the immune response. These include compounds such as potassium aluminium sulfate, oil in water emulsion composed of squalene (MF59), MatrixM and Cytosine phosphoguanin (CpG 1018).

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

i. Research linked to discovering novel adjuvants, including screening (medium to high-throughput screening, in silico screening) and structure-activity-relationship (SAR) studies

ii. Mechanistic research elucidating mechanism-of-action, including novel receptors

iii. Preclinical development of novel adjuvants, including formulation and stability studies, optimisation of immunisation regimens and delivery routes, toxicology testing and pharmacokinetics/absorption, distribution, metabolism, and excretion studies

39.2 BIOLOGICS-RELATED PLATFORM TECHNOLOGIES

Biologics-related platform technologies include research on developing biotechnology processes, including identification, optimisation and manufacturing of biopharmaceuticals such as monoclonal antibodies, nucleic acid-based therapeutics (siRNA and oligonucleotides) and viral vector-based therapeutics which can be adapted for more than one pathogen.

Examples of R&D for biologics-related platform technologies included in the survey scope:

i. Development of transgenic animals for production of humanised monoclonal antibodies

ii. Development of T cell or innate immunity platforms with the capability of producing therapeutics for multiple infectious diseases

iii. Development of neutralisation assay for testing of monoclonal antibodies

iv. Nucleic acid chemistry research for improving stability and duration of effect of oligonucleotides-based therapies

39.3 DRUG-RELATED PLATFORM TECHNOLOGIES

Drug-related platform technologies include research focusing on developing broad-spectrum therapeutics, including small molecule and host-directed agents, and drug delivery technologies and devices such as long-acting and subcutaneous drug delivery systems.

Examples of R&D for drug-related platform technologies included in the survey scope:

i. Discovery and optimisation of mechanisms for controlled release

ii. Development of methods to enhance oral bioavailability of poorly water-soluble drugs

iii. Development of peptide drug delivery systems

iv. Development of taste-neutral oral formulations to enable high compliance drug delivery to paediatric populations

v. Development of broad-spectrum therapeutics such as antivirals and host-directed agents

39.4 GENERAL DIAGNOSTIC PLATFORMS & MULTI-DISEASE DIAGNOSTICS

General diagnostic platforms & multi-disease diagnostics include research focusing on developing either a multiplex diagnostic technology capable of detecting multiple pathogens or biomarkers simultaneously or a standalone plug-n-play platform that can work with disease-specific assays.

Examples of R&D for general diagnostic platforms & multi-disease diagnostics included in the survey scope:

i. Development of a fully automated nucleic acid amplification testing platform with multiplexing capability designed for use in resource limited settings

ii. Development of paper strip test for detection of multiple haemorrhagic fever pathogens at the point of care level

39.5 VACCINE-RELATED PLATFORM TECHNOLOGIES

Vaccine-related platform technologies include research on developing platforms, such as viral vectors (replicating and non-replicating) and nucleic acid-based platforms (DNA and mRNA) or vaccine development process innovation, such as thermostabilisation processes which can be employed for multiple target vaccines. It also includes research purely focusing on the delivery of a finished product, such as vaccine microarray patches.

Examples of R&D for vaccine-related platform technologies included in the survey scope:

i. Development of novel delivery technologies applicable to multiple vaccines, such as needle-free high-density microarray patches and mucosal vaccine delivery system

ii. Development of a plant-based sub-unit vaccine delivery system

iii. Development of replication-competent or replication-incompetent viral vectored system, such as vesicular stomatitis virus vaccine platform

iv. Development or process innovation linked to nucleic acid-based vaccines platforms

40. OTHER 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

1.8 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

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 including mathematical modelling of economic impact

42.3.4 Mathematical modelling of the disease (e.g. transmission, immune response) where it is linked to routine surveillance

42.3.5 Fostering collaboration between academia, industry, government agencies, and NGOs.

42.4 General capacity building (human and infrastructure)

42.4.1 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:

42.4.2 Building academic research capacity; improving existing academic capacity (except where directly linked to development of a specific product).

42.4.3 Providing training opportunities; strengthening R&D institutional capacity; developing and maintaining personnel (except where directly linked to development of a specific product).

42.4.4 Major infrastructure development (e.g. design, construction and validation of large-scale manufacturing facilities).