Neglected Disease R&D Scope

G-FINDER

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

The G-FINDER scope has been defined by an expert advisory group, in line with the following three criteria:

1. The disease disproportionately affects people in low- and middle-income countries (LMICs)*
2. There is a need for new products (i.e. there is no existing product, or improved or additional products are needed)
3. There is market failure (i.e. there is insufficient commercial market to attract R&D by private industry)

Diseases where commercial incentives for R&D already exist (including diseases prevalent in both high-income and low- and middle-income countries, where product R&D already occurs in response to high-income country markets) are excluded from the G-FINDER survey.

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

A description of the G-FINDER survey scope restrictions by disease, including historical changes to survey scope for disease and product area inclusions and exclusions, are set out in the ‘Scope restrictions and 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 emerging infectious diseases (EIDs), and women’s health (WH) issues. Some of the neglected diseases, issues, products and technologies may overlap with the scope of these other global health areas.

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

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ND R&D Matrix

		Basic research	Drugs	Vaccines	Biologics	Diagnostics	Microbicides	Vector control products
Bacterial pneumonia & meningitis	*S. pneumoniae*	Restricted	-	Restricted	-	✓	-	-
	N. meningitidis	Restricted	-	Restricted	-	✓	-	-
	Both *S. pneumoniae* and *N. meningitidis*	Restricted	-	-	-	✓	-	-
Buruli ulcer		✓	✓	✓	-	✓	-	-
Cryptococcal meningitis		-	✓	-	✓	-	-	-
Dengue		✓	✓	Restricted	✓	✓	-	✓
Diarrhoeal diseases	Rotavirus	Restricted	-	Restricted	-	-	-	-
	Cholera	✓	Restricted	✓	Restricted	✓	-	-
	Shigella	✓	Restricted	✓	Restricted	✓	-	-
	Cryptosporidiosis	✓	Restricted	✓	Restricted	✓	-	-
	Enterotoxigenic *E. coli* (ETEC)	Restricted	-	✓	-	✓	-	-
	Enteroaggregative *E. coli* (EAEC)	-	-	✓	-	✓	-	-
	Multiple diarrhoeal diseases	✓	Restricted	✓	Restricted	✓	-	-
Helminth infections (worms & flukes)	Schistosomiasis (bilharziasis)	✓	✓	✓	✓	✓	-	✓
	Onchocerciasis (river blindness)	✓	✓	✓	-	✓	-	✓
	Lymphatic filariasis (elephantiasis)	✓	✓	-	-	✓	-	✓
	Tapeworm (taeniasis / cysticercosis)	✓	✓	-	-	✓	-	✓
	Hookworm (ancylostomiasis & necatoriasis)	✓	✓	✓	-	-	-	-
	Whipworm (trichuriasis)	✓	✓	-	-	-	-	-
	Roundworm (ascariasis)	✓	✓	-	-	-	-	-
	Strongyloidiasis & other intestinal roundworms	✓	✓	✓	-	✓	-	-
	Multiple helminth infections	✓	✓	✓	-	✓	-	✓
Hepatitis B		Restricted	Restricted	-	Restricted	✓	-	-
Hepatitis C		-	Restricted	✓	-	✓	-	-
Histoplasmosis		✓	✓	-	-	✓	-	-
HIV/AIDS		Restricted	Restricted	✓	Restricted	✓	✓	-
Kinetoplastid diseases	Sleeping sickness (HAT)	✓	✓	✓	✓	✓	-	✓
	Leishmaniasis	✓	✓	✓	✓	✓	-	-
	Chagas' disease	✓	✓	✓	✓	✓	-	✓
	Multiple kinetoplastid diseases	✓	✓	✓	✓	✓	-	✓
Leprosy		✓	✓	✓	✓	✓	-	-

		Basic research	Drugs	Vaccines	Biologics	Diagnostics	Microbicides	Vector control products
Leptospirosis		-	-	-	-	Restricted	-	-
Malaria	*P. falciparum*	✓	✓	✓	✓	✓	-	✓
	P. vivax	✓	✓	✓	✓	✓	-	✓
	Multiple / other malaria strains	✓	✓	✓	✓	✓	-	✓
Mycetoma		✓	✓	-	-	✓	-	-
Rheumatic fever		-	-	✓	-	-	-	-
***Salmonella* infections**	Typhoid and paratyphoid fever (*S.* Typhi, *S.* Paratyphi A)	✓	✓	✓	✓	✓	-	-
	Non-typhoidal *S. enterica* (NTS)	✓	✓	✓	✓	✓	-	-
	Multiple *Salmonella* infections	✓	✓	✓	✓	✓	-	-
Scabies		Restricted	✓	-	-	✓	-	-
Snakebite envenoming		Restricted	Restricted	-	Restricted	Restricted	-	-
Trachoma		-	-	✓	-	✓	-	-
Tuberculosis		✓	✓	✓	✓	✓	-	-
Yaws		Restricted	-	-	-	Restricted	-	-

Investment applicable to more than one neglected disease, or to more than one global health area*						
Platform technologies					**Multi-disease vector control**	**Core funding of a multi-disease R&D organisation**
Adjuvants & immunomodulators	Biologics-related platform technologies	Drug-related platform technologies	General diagnostics platforms & multi-disease diagnostics	Vaccine-related platform technologies		
Restricted	Restricted	Restricted	Restricted	Restricted	✓	✓

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

Restricted denotes a category where only some investments are eligible, as defined in the G-FINDER neglected disease R&D scope document

* The G-FINDER project covers three global health areas: neglected diseases, emerging infectious diseases, and women's health

Scope Restrictions and Changes by Disease

Bacterial pneumonia & meningitis

Bacterial pneumonia & meningitis have been included in the scope of the G-FINDER survey since the project's inception. In 2017 (collection of FY2016 data) the bacterial pneumonia & meningitis category was expanded to explicitly include LMIC-focused basic research for *Streptococcus pneumoniae* and *Neisseria meningitides*.

The scope of the inclusion of funding for bacterial pneumonia & meningitis R&D is currently restricted in the following areas:

- **Basic research**: only includes basic research related to the natural history, epidemiology, biochemistry, and genetics of *S. pneumoniae* and/or *N. meningitidis* in LMIC contexts (e.g. epidemiological research on serotype/serogroup distribution in LMICs; impact of age, HIV status, and malnutrition on disease prevention strategies; impact of the nasopharyngeal microbiome on disease transmission dynamics)
- **Vaccines: Bacterial pneumonia caused by *S. pneumoniae***
  - Only includes R&D on vaccines being developed specifically for LMIC needs, or in support of registration of suitable vaccines in LMICs
  - To be considered 'suitable' a vaccine must at a minimum:
    a) Be designed for use in infants less than two years of age;
    b) Provide broad coverage across all *S. pneumoniae* serotypes, or focused protection against strains prevalent in LMICs (at minimum serotypes 1, 5, and 14); and
    c) Be of equivalent or better efficacy than existing approved conjugate vaccines.
  - Vaccines being developed specifically for LMIC needs would be expected to be low-cost, regardless of whether using a whole cell, non-conjugate, combination conjugate-non-conjugate or low-cost conjugate approach
  - For multi-valent vaccines covering both HIC and LMIC strains, only LMIC-specific costs are included; for example, for trials, registration, and Phase IV/pharmacovigilance studies in LMICs
- **Vaccines: Bacterial meningitis caused by *N. meningitides***
  - Only includes R&D on vaccines specifically for LMIC registration, or in support of registration of suitable vaccines in LMICs
  - To be considered 'suitable' a vaccine must at a minimum:
    a) Provide coverage against *N. meningitidis* serotype A;
    b) Be a conjugate vaccine;
    c) Be designed for use in infants less than two years of age; and
    d) Be designed to cost less than one US dollar per dose
  - For multi-valent vaccines covering HIC and LMIC strains, only LMIC-specific costs are included; for example, for trials, registration and Phase IV studies in LMICs.

Cryptococcal meningitis

In 2013 (collection of FY2012 data) cryptococcal meningitis was added to the survey. In 2019 (collection of FY2018 data), with the renaming of the 'vaccines (therapeutic)' category to 'biologics' – to reflect the inclusion of antibody-based products and other complex therapeutics – R&D for biologics for cryptococcal meningitis was added to the survey.

Dengue

Dengue has been included in the scope of the G-FINDER survey since the project's inception. In 2014 (collection of FY2013 data) vaccines for dengue were determined to no longer fulfil the criteria for inclusion in the G-FINDER survey given the emergence of a commercial market, and dengue vaccine R&D funding (including all previously reported investment) was removed from the survey. All other dengue product areas were retained. In 2019 (collection of FY2018 data), with the renaming of the 'vaccines (therapeutic)' category to 'biologics' – to reflect the inclusion of antibody-based products and other complex therapeutics – R&D for biologics for dengue was added to the survey. In 2025 (collection of FY2024 data), dengue scope was expanded to explicitly include LMIC-focused vaccine R&D.

The scope of the inclusion of funding for dengue R&D is currently restricted in the following area:

- **Vaccines**: only includes LMIC-specific R&D, including clinical trials, registration and Phase IV studies in the target LMICs.

Diarrhoeal diseases

Enterotoxigenic *E. coli* (ETEC)

ETEC has been included in the scope of the G-FINDER survey since the project's inception. In 2021 (collection of FY2020 data), the ETEC scope was expanded to explicitly include LMIC-focused basic research.

The scope of the inclusion of funding for rotavirus R&D is currently restricted in the following area:

- **Basic research**: only includes research that is explicitly targeted at LMIC-related disease burden (e.g. aetiology-specific estimates of the global incidence and mortality of ETEC-associated diarrhoeal disease)

Rotavirus

Rotavirus has been included in the scope of the G-FINDER survey since the project's inception. In 2021 (collection of FY2020 data), rotavirus scope was expanded to explicitly include LMIC-focused basic research.

The scope of the inclusion of funding for rotavirus R&D is currently restricted in the following area:

- **Basic research**: only includes research that is explicitly targeted at LMIC-related disease burden (e.g. aetiology-specific estimates of the global incidence and mortality of rotavirus-associated diarrhoeal disease)
- **Vaccines**: only includes LMIC-specific R&D, including clinical trials, registration and Phase IV studies in the target LMICs

Cholera, *Shigella*, cryptosporidiosis, and multiple diarrhoeal diseases

Cholera, *Shigella*, cryptosporidiosis, and multiple diarrhoeal diseases have been included in the scope of the G-FINDER survey since the project's inception. In 2019 (collection of FY2018 data), with the renaming of the 'vaccines (therapeutic)' category to 'biologics'- to reflect the inclusion of antibody-based products and other complex therapeutics – R&D for biologics for these diarrhoeal diseases was added as a restricted category.

The scope of the inclusion of funding for R&D for these diarrhoeal diseases is currently restricted in the following areas:

- **Drugs**: only includes pharmacological interventions that target the pathogen. Supportive therapies (e.g. zinc treatment, oral rehydration therapy, or other fluid and nutritional supplements) are excluded
- **Biologics**: only includes R&D for biologics being developed specifically for LMIC needs, or in support of registration of biologics in LMICs

Giardiasis

Giardiasis has been part of the G-FINDER scope since the project's inception, with diagnostics being the only product area included, based on R&D gaps identified in 2008. On review, in 2023 (collection for FY2022 data), the

disease was determined to no longer fulfil the criteria for inclusion in G-FINDER and was removed from the survey, as multiple diagnostics exist, filling the R&D gap identified in 2008.

Helminth infections (worms & flukes)

Lymphatic filariasis (elephantiasis)

Lymphatic filariasis has been included in the scope of the G-FINDER survey since the project's inception. In 2009 (collection of FY2008 data) diagnostics for lymphatic filariasis were included, reflecting the need for a diagnostic tool for detection, monitoring treatment, and surveillance to support elimination.

Tapeworm (taeniasis/cysticercosis)

Tapeworm has been included in the scope of the G-FINDER survey since the project's inception. In 2018 (collection of FY2017 data) diagnostics for tapeworm were included, recognising that existing tools are sub-optimal for use in LMIC settings.

Hepatitis B

In 2019 (collection of FY2018 data) hepatitis B was added to the survey.

The scope of the inclusion of funding for hepatitis B R&D is currently restricted in the following areas:

- **Basic research**: only includes basic research that is explicitly targeted at LMIC needs, such as that related to HBV epidemiology and genetics in LMIC contexts (e.g. epidemiology of HBV drug resistance or vaccine escape mutants in LMICs)
- **Drugs**: only includes LMIC-specific costs for label-expansion clinical trials of new drugs, reformulations for LMIC use (e.g. curative therapies; drugs for preventing mother-to-child transmission of HBV; long-acting treatment formulations), registration of suitable drugs in LMICs, or preclinical research targeted at developing such products
- **Biologics**: only includes R&D for biologics being developed specifically for LMIC needs, or in support of registration of biologics in LMICs. Such biologics must at a minimum provide coverage across HBV genotypes prevalent in LMICs (A, B, C, D, E, F, H and/or I)

Hepatitis C

In 2014 (collection of FY2013 data) hepatitis C (genotype 4) was added to the survey. In 2015 (collection of FY2014 data), the category was expanded to capture investment in R&D for additional genotypes disproportionately affecting people in developing countries, genotypes 5 and 6. In order to exclude commercially-driven R&D investment targeting HIC markets, only investment in R&D for hepatitis C specifically focused on the genotypes disproportionately affecting developing countries (genotypes 4, 5 & 6), or LMIC-specific R&D investment in multi- or pan-genotypic technologies was included. In 2019 (collection of FY2018 data) the genotype-specific restriction was removed, due to the availability of multiple pan-genotypic technologies and therapies. In 2021 (collection of FY2020 data), all restrictions for HCV vaccines were removed, as the restriction in practice excluded almost all early-stage vaccine research (which represents almost all of the current hepatitis C vaccine pipeline), and we have identified little to no commercially driven activity in this area.

The scope of the inclusion of funding for hepatitis C R&D is currently restricted in the following areas:

- **Drugs**: only includes LMIC-specific costs of label-expansion clinical trials of new drugs, reformulations for LMIC use (e.g. fixed-dose combinations), registration of suitable drugs in LMICs, or preclinical research targeted at developing such products

Histoplasmosis

In 2021 (collection of FY2020 data), histoplasmosis was added to the survey.

HIV/AIDS

HIV/AIDS has been included in the scope of the G-FINDER survey since the project's inception. In 2017 (collection of FY2016 data), LMIC-specific research into therapeutic vaccines for HIV/AIDS was added as a restricted category, reflecting emerging research into broadly neutralising anti-HIV antibodies (bNAbs) and their potential use in developing countries, and the scope of the basic research category was expanded to include basic research relevant to therapeutic vaccines. In 2019 (collection of FY2018 data) this category was renamed 'biologics' to reflect the inclusion of antibody-based products and other complex therapeutics.

The scope of the inclusion of funding for HIV/AIDS R&D is currently restricted in the following areas:

- **Basic research**: only includes basic research that is related to vaccines (e.g. immunological responses to potential antigens), biologics and microbicides (e.g. mechanism of mucosal transmission), or basic research that is explicitly targeted at LMIC needs
- **Drugs**: only includes LMIC-specific costs for label-expansion clinical trials of new drugs and reformulations for LMIC use (e.g. paediatric or slow-release formulations; fixed dose combinations; low dose drug formulations for prophylaxis; long-acting injectables for treatment or prophylaxis), or preclinical research targeted at developing such products
- **Biologics**: only includes R&D for biologics being developed specifically for LMIC needs, or in support of registration of biologics in LMICs.

Kinetoplastid diseases

Kinetoplastid diseases have been included in the scope of the G-FINDER survey since the project's inception. In 2019 (collection of FY2018 data), with the renaming of the 'vaccines (therapeutic)' category to 'biologics'- to reflect the inclusion of antibody-based products and other complex therapeutics – R&D for biologics for the kinetoplastid diseases was added to the survey.

Sleeping sickness (HAT)

Sleeping sickness (HAT) has been included in the scope of the G-FINDER survey since the project's inception. In 2019 (collection of FY2018 data), with the renaming of the 'vaccines (therapeutic)' category to 'biologics' – to reflect the inclusion of antibody-based products and other complex therapeutics – R&D for biologics for sleeping sickness was added to the survey.

Leishmaniasis

Leishmaniasis has been included in the scope of the G-FINDER survey since the project's inception. In 2019 (collection of FY2018 data), with the renaming of the 'vaccines (therapeutic)' category to 'biologics' – to reflect the inclusion of antibody-based products and other complex therapeutics – R&D for biologics for leishmaniasis was added to the survey.

Chagas' disease

Chagas' disease has been included in the scope of the G-FINDER survey since the project's inception. In 2018 (collection of FY2017 data), chemical vector control products for Chagas' disease were added to the survey, due to the need for new products following the rise in pyrethroid resistance in Triatoma in some South American countries.

Leprosy

In 2019 (collection of FY2018 data) vaccines for leprosy were included, in recognition of increased funding and R&D in the field.

Leptospirosis

In 2014 (collection of FY2013 data) diagnostics for leptospirosis were added to the survey.

The scope of the inclusion of funding for hepatitis B R&D is currently restricted in the following areas:

- **Diagnostics**: only includes R&D on diagnostics suited to resource-limited settings. Such a diagnostic must, at a minimum;

  a) Detect the disease during the septicaemic or early acute phase of disease;

  b) Be accurate, easy to interpret, with little or no processing and give the results within 1-2 hours; and

  c) Be cheap, stable, easy to use (i.e. should not require specific equipment and/or laboratory and highly trained staff).

Malaria

Malaria has been included in the scope of the G-FINDER survey since the project's inception. In 2019 (collection of FY2018 data), with the renaming of the 'vaccines (therapeutic)' category to 'biologics' – to reflect the inclusion of antibody-based products and other complex therapeutics – R&D for biologics for malaria was added to the survey.

Mycetoma

In 2019 (collection of FY2018 data) mycetoma was added to the survey.

Salmonella infections

Salmonella infections have been included in the scope of the G-FINDER survey since the project's inception. In 2009 (collection of FY2008 data) the typhoid and paratyphoid fever disease category was expanded to include non-typhoidal *Salmonella* enterica and multiple *Salmonella* infections.

Scabies

In 2021 (collection of FY2020 data), scabies was added to the survey.

The scope of the inclusion of funding for scabies R&D is currently restricted in the following area:

- **Basic research**: only includes research that is explicitly targeted at LMIC-related disease burden (e.g. understanding recrudescence of transmission in settings where ivermectin MDA has been phased out).

Snakebite envenoming

In 2019 (collection of FY2018 data) snakebite envenoming was added to the survey.

The scope of the inclusion of funding for snakebite envenoming R&D is currently restricted in the following areas:

- **Basic research**: only includes basic research that is explicitly targeted at LMIC needs (e.g. proteomic analysis of snake venom from high burden regions)

- **Drugs**: only includes drugs being developed specifically for LMIC needs (e.g. antivenoms incorporating small molecule inhibitors; heat-stable venom-agnostic oral drugs to slow down neurotoxicity), or in support of registration of drugs in LMICs
- **Diagnostics**: only includes R&D for diagnostics capable of identifying envenomation by medically important snake species common to LMICs
- **Biologics**: only includes R&D for biologics being developed specifically for LMIC needs (e.g. antivenom immunoglobulins based on the venom of snakes from LMICs), or in support of registration of biologics in LMICs.

Trachoma

Trachoma has been part of the G-FINDER scope since the project's inception, with diagnostics and vaccines being the only product areas included.

Tuberculosis

Tuberculosis has been included in the scope of the G-FINDER survey since the project's inception. In 2019 (collection of FY2018 data), with the renaming of the 'vaccines (therapeutic)' category to 'biologics' – to reflect the inclusion of antibody-based products and other complex therapeutics – R&D for biologics for tuberculosis was added to the survey.

Yaws

In 2023 (collection of FY2022 data) yaws was added to the survey. The scope of the inclusion of funding for yaws R&D is currently restricted in the following areas:

- **Basic research:** only includes basic research that is focused on understanding the epidemiology of the disease, specifically the geographical distribution of the pathogen and the prevalence of morbidity and mortality of the disease
- **Diagnostics:** only includes R&D for novel Point of Care tests capable of:
  a) Identifying a single active case of yaws infection and/or
  b) Detecting azithromycin-resistance.

Vector control products

Vector control products have been included in the G-FINDER survey since the project's inception. In 2018 (collection of FY2017 data) a new product category – multi-disease vector control products – was introduced to reflect the applicability of one vector control product to multiple diseases carried by the same vector. In 2020 (collection of FY2019 data) a new category – fundamental vector control research – was introduced to capture basic research on vectors that have the potential to carry more than one neglected disease, or both neglected and emerging infectious diseases.

The scope of the inclusion of funding for vector control products is currently restricted in the following areas:

- **Chemical vector control products**

  This 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 neglected disease transmission. This includes new insecticides and formulations in LLINs/IRS; systemic insecticides and endectocides; insecticide-based bait and traps; spatial repellents; and chemical larvicides. Predation measures, biological larvicides, habitat control and infrastructure measures are excluded from the G-FINDER scope
- **Biological vector control products**

This category only includes research and development of innovative biological control interventions that specifically aim to kill or control vectors associated with transmitting poverty-related diseases (e.g. microbial/bacteriological larvicides, sterilisation techniques, and genetic modification measures). Predation measures, habitat control and infrastructure measures are excluded from the G-FINDER scope

- **Reservoir targeted vaccines**

  This category only includes research and development of veterinary vaccines specifically designed to prevent animal to human transmission of neglected diseases. Vaccines developed and used solely for veterinary purposes are excluded from this product category

- **Fundamental vector control research**

  This category includes fundamental (basic) research on vectors that have the potential to carry more than one neglected disease, or both neglected and emerging infectious diseases. This includes vector biology, biochemistry, and genetics related to vector control. See section 8 for the full outline of R&D activities included under this category.

R&D for more than one neglected disease or global health area

R&D that cannot be allocated to one disease has been included in the G-FINDER survey since the project's inception. The scope of the inclusion of funding that is applicable to more than one neglected disease, or to more than one global health area, including emerging infectious diseases, and sexual & reproductive health is restricted in the following areas:

- **Adjuvants and immunomodulators**: only includes funding for R&D which meets the following conditions;

  a) It is conducted by public, philanthropic or not-for-profit entities

  b) It is research that is not directed towards a specific disease or product

  c) It is research aimed at developing safer, cheaper, more immunogenic adjuvants and immunomodulators

  d) The resulting research findings or leads must be accessible to organisations developing pharmaceutical or biological products intended to treat or prevent neglected diseases

- **Biologics-related platform technologies**

  a) It is conducted by public, philanthropic or not-for-profit entities

  b) It is research that is not directed towards a specific disease or products

  c) It is research aimed at developing cheaper, faster, more user-friendly biologics-related platform technologies, intended for use in resource-limited settings

- **Drug-related platform technologies**: only includes funding for R&D which meets the following conditions;

  a) It is conducted by public, philanthropic or not-for-profit entities

  b) It is research that is not directed towards a specific disease or product

  c) It is research aimed at developing cheaper, faster, more user-friendly broad-spectrum therapeutics and drug delivery technologies and devices, intended for use in resource-limited settings

- **General diagnostic platforms & multi-disease diagnostics**

  a) It is conducted by public, philanthropic or not-for-profit entities

  b) It is research that is not directed towards a specific disease or products

  c) It is research aimed at developing cheaper, faster, more user-friendly diagnostic platforms or technologies, intended for use in resource-limited settings

- **Vaccine-related platform technologies**

  a) It is conducted by public, philanthropic or not-for-profit entities

  b) It is research that is not directed towards a specific disease or product

  c) It is research aimed at developing cheaper, faster, more user-friendly vaccine delivery technologies and devices, intended for use in resource-limited settings.

Renaming diagnostic R&D stages

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.

Scope by Product

1.1 BASIC RESEARCH

Studies that increase scientific knowledge and understanding about the disease, disease processes, pathogen or vector, but which are not yet directed towards a specific product. Please see the section on scope restrictions and changes by disease for disease-specific restrictions to research activities in this category.

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 the development of a specific product
- 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, microbicide, or biologic research & 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 the biology of pathogen interaction with the 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 (e.g. Epstein-Barr virus)

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, Glycosylphosphatidylinositol (GPI) anchors, transporters, ion channels, mitochondrial metabolism, and electrophysiology studies

4.5 Influence of the 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 & characterisation of drug-resistant strains and studies probing drug resistance mechanism/s or pathways

4.9 Non-specific research on the pathogen or host targets to identify potential drug, vaccine, biologic, or diagnostic 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 and microbicides

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 the effects of host co-morbidities and secondary effects of pathogen invasion (e.g., research on anaemia /neurological effects of malaria)

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 small molecule compounds or repurposed drugs specifically designed to prevent, cure or treat neglected diseases; including drug discovery or design, preclinical and clinical development and other activities essential for successful drug development and uptake. Please see the section on scope restrictions and changes by disease for disease-specific restrictions to research activities in this category.

9. DISCOVERY AND PRECLINICAL

Research activities targeted at discovering and optimising investigational small molecule 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

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 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 products e.g., pharmaco-epidemiological and resistance studies)
- 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. Please see the section on scope restrictions and changes by disease for disease-specific restrictions to research activities in this category. 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 & 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, addition of LMIC-specific strains)

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. Please see the section on scope restrictions and changes by disease for disease-specific restrictions to research activities in this category. 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 or therapeutic vaccines, 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 vaccines, 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 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 or therapeutic vaccines in clinical development

28.7 In silico clinical trials designed to assess safety and/or efficacy of biologics or therapeutic vaccines in 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 vaccines 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 vaccine in communities in LMICs

1.5 DIAGNOSTICS

Research activities and processes necessary to develop, optimise, and validate diagnostic tests for use in resource-limited settings (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. Please see the section on scope restrictions and changes by disease for disease-specific restrictions to research activities in this category.

30. EARLY DEVELOPMENT

Research activities targeted at discovering and optimising low-cost, heat stable, easy-to-use diagnostics for neglected diseases 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, heat 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 LMIC use, including improved point-of-care tests (rapid test), local laboratory test, 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 & 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 in LMICs (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 recommendations 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 MICROBICIDES

Research activities and processes necessary to develop and improve topical microbicides specifically intended to prevent HIV transmission; including microbicide discovery or design, preclinical and clinical development, and other activities essential for successful microbicide development and uptake.

Applications that may have high-income country (HIC) markets or be useful for other STIs (e.g. mucosal delivery technology, adjuvants) are excluded from the ND G-FINDER scope.

33. DISCOVERY AND PRECLINICAL

Research activities targeted at identifying, optimising, and characterising investigational microbicides and including the processes necessary to allow lead compounds to proceed to human trials; including:

33.1 Specific research aimed at discovery of topical applications for microbicide use (e.g. vaginal defence enhancers, surfactants, entry/fusion inhibitors and replication inhibitors)

33.2 In silico discovery and development activities for microbicides, including the use of pharmacometrics and mechanistic models

33.3 Target validation, characterisation and selection

33.4 Preclinical evaluation of microbicide candidates including determination of acceptable formulation and delivery modes

33.5 Studies supporting safety & tolerability testing in animal models and looking at in vitro correlates of in vivo protective response

33.6 Developing reagents and standardised methods to assess microbicide-induced immune response in animals and humans

33.7 Optimisation of microbicide candidates, bioprocess development, formulation and mode of delivery of novel prevention tools for broad international use (cheap, easy to produce, stable, easy to administer) including production of Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP)-grade product for regulatory toxicology studies

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

34. 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:

34.1 Phase Ia single ascending dose studies to determine pharmacokinetics, pharmacodynamics and maximum tolerated dose

34.2 Phase Ib multiple ascending dose studies to determine the pharmacokinetics, pharmacodynamics, safety and tolerability of multiple doses

35. CLINICAL DEVELOPMENT - PHASE II

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

35.1 Phase IIa proof of concept studies to demonstrate clinical efficacy or biological activity

35.2 Phase IIb dose-finding studies to determine dose with optimum biological activity with minimal adverse effects

36. 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), including:

36.1 Regulatory standard clinical trials to assess effectiveness of novel microbicide products

37. 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:

37.1 Epidemiological studies directly linked to the conduct or support of clinical trials of microbicides in development, in order to assess or validate the epidemiology of disease, disease incidence, or health of target populations at trial sites

37.2 Preliminary studies of morbidity and mortality at potential clinical trial sites, where these studies are directly linked to planned microbicide trials

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

38. CLINICAL DEVELOPMENT - UNSPECIFIED

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

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

38.2 Further microbicide development to generate the final clinical formulation, dosage form and other Chemistry and Manufacture Control (CMC) activities required for regulatory submission

38.3 Compiling of all non-clinical and clinical data for submission of a New Drug Application (NDA) to regulatory authorities

38.4 Behavioural research prior to registration relating to risk assessment, factors affecting adherence to protocol and product acceptability

38.5 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

38.6 Transmission modelling to inform clinical trial design and therapeutic administration strategies for microbicides in clinical development

38.7 In silico clinical trials designed to assess safety and/or efficacy of microbicides in development

39. POST-REGISTRATION STUDIES

Studies relating to the detection, monitoring, evaluation, and prevention of adverse events associated with newly approved microbicides so as to bridge the gap between highly controlled clinical trials intended for regulatory approval and the largely uncontrolled delivery of new microbicides; including:

39.1 Studies conducted after regulatory approval that assess microbicide effectiveness in the wider population or which are necessary to support product use in LMICs

39.2 Pharmacovigilance and post-registration studies of newly registered microbicides to assess adverse reactions, toxicology and safety

39.3 Effectiveness studies and head-to-head comparator studies of newly registered microbicides (with other therapies or interventions)

39.4 Cost-effectiveness studies of newly registered microbicides

39.5 Treatment interactions and population level studies (of newly registered preventive microbicides e.g., pharmaco-epidemiological and resistance studies)

39.6 Behavioural research post-registration of new microbicides relating to risk assessment, factors affecting adherence to protocol, provider compliance, and product acceptability

39.7 Case history reports and assessment of long-term prophylaxis using newly registered microbicides in communities in LMICs

1.7 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 a neglected disease from vector and/or animal reservoirs to human; including novel chemical vector control products, biological vector control products and reservoir targeted vaccines.

40. 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 neglected disease transmission. This includes new insecticides and formulations in LLINs/IRS; insecticide-based bait and traps; spatial repellents; systemic insecticides and endectocides; and chemical larvicides. Predation measures, habitat control and infrastructure measures are excluded from the G-FINDER scope.

40.1 Primary and secondary screening and optimisation

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

40.1.1 Primary and secondary screens (e.g. in vitro and in vivo screens, chemical screens, whole insect screens)

40.1.2 In silico discovery and development activities for chemically active ingredients, including the use of pharmacometrics and mechanistic models

40.1.3 Target validation and characterisation

40.1.4 Lead optimisation, synthesis optimisation

40.1.5 Early toxicology screens (e.g. acute oral toxicity, eye and skin irritation studies, AMES/mutagenicity studies)

40.1.6 Applied laboratory research and small-scale field trials, including in vitro and glass house efficacy testing

40.1.7 Acute toxicology and ecotoxicology studies (e.g. animal studies, exposure studies, fish and wildlife studies)

40.1.8 Metabolism and stability studies in plants and animals including mode of action, residue analysis and cross-resistance studies

40.1.9 Environmental effect and decomposition studies in soil, water and air

40.1.10 Ecological modelling to assess environmental risk

40.2 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.

40.2.1 Small-scale efficacy studies, residue plots and field studies necessary for product optimisation and registration

40.2.2 Acute and long-term toxicology and ecotoxicology studies

40.2.3 Metabolic and residual fate studies, crop residue and exposure data

40.2.4 Environmental assessment and environmental chemistry data

40.2.5 Generation of hazard data in humans, domestic animals and non-target plants and animals

40.2.6 Compiling of all laboratory and field data necessary for submission to regulatory authorities

40.2.7 Behavioural research conducted pre-registration relating to risk assessment, factors affecting adherence to protocol, and product acceptability

40.2.8 Manufacturing process development, formulation and scale-up

40.2.9 Ecological modelling to assess environmental risk

40.3 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:

40.3.1 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)

40.3.2 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)

40.3.3 PQ assessment of large-scale field trials (e.g. community level efficacy and residual activity, operational and community acceptance)

40.3.4 Assessment & validation of trial sites directly linked to product trials

40.3.5 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)

40.3.6 Behavioural research conducted post-registration relating to risk assessment, factors affecting adherence to protocol, provider compliance and product acceptability

40.3.7 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)

40.3.8 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

41. BIOLOGICAL VECTOR CONTROL PRODUCTS

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

Biological 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.

41.1 Phase I

Laboratory studies of novel biological vector control techniques

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

41.1.2 Molecular, genotypic, physiological and behavioural characteristics research in genetically modified vectors

41.1.3 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

41.1.4 Ecological modelling to assess environmental risk

41.1.5 Quality control to ensure new biological materials are well characterised, stable and detectable

41.1.6 Phenotypic evaluation research of transgenic endemic strains, including testing for adverse effects on target or non-target species

41.1.7 Laboratory assays to establish mechanism of action

41.1.8 Small-scale laboratory studies for efficacy and safety

41.1.9 Laboratory-based studies on efficacy and safety in larger population cages

41.1.10 Establishment of standard operating procedures for genetically modified vector production and release

41.1.11 Activities related to site preparation and hazard containment (risk analysis and risk management)

41.1.12 Activities related to data analysis as required by regulators

41.1.13 Modelling of expected cost of protection per person

41.2 Phase II

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

41.2.1 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)

41.2.2 Ecologically confined (geographic/spatial and/or climatic isolation) small-scale field trials to assess entomological efficacy (biological and functional)

41.2.3 Ecological modelling to assess environmental risk

41.2.4 Compiling all entomological and epidemiological efficacy data as required by regulators
41.2.5 Activities related to site preparation and hazard containment (risk analysis and risk management)
41.2.6 Initial cost analysis of prototype or approach
41.2.7 Continued monitoring of molecular quality control

41.3 Phase III

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

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

41.4 Phase IV

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

41.4.1 Pilot implementation studies
41.4.2 Post-implementation studies to validate feasibility, acceptability and cost-effectiveness
41.4.3 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

42. RESERVOIR TARGETED VACCINES

This product category only includes research and development of veterinary vaccines specifically designed to prevent animal to human transmission of neglected diseases. Vaccines developed and used solely for veterinary purposes are excluded from this product category.

42.1 Discovery and early-phase development

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

42.1.1 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)
42.1.2 In silico biomarker and antigen discovery and development activities, including immune system interaction models
42.1.3 Research on the livestock or companion animal host immunology
42.1.4 Research on pathogen biology and identification of an appropriate challenge model
42.1.5 Performance of challenge studies with the pathogen and analysis of immune response in the selected challenge model

42.1.6 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.)

42.1.7 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

42.1.8 Studies with respect to lead identification and optimisation

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

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

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

42.1.12 Performance of in vivo safety and efficacy studies

42.1.13 Assessment of environmental, consumer and user safety

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

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

42.1.16 Field trial application

42.2 Field trials

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

42.2.1 TPP review

42.2.2 Field trial study design and study site selection

42.2.3 In silico field trials designed to assess safety and/or efficacy of vaccines in development

42.2.4 Infrastructure and site development costs associated with the conduct of field trials in LMICs (e.g. vehicle purchase, generators, training and community relationship building)

42.2.5 Regulatory and ethics engagement

42.2.6 Vaccine safety and immunogenicity studies

42.2.7 Vaccine efficacy studies with epidemiological efficacy in humans as the primary end point

42.2.8 Further biological/product development to generate the optimal clinical formulation and dosage form, and other activities required for regulatory submission

42.2.9 Regulatory dossier preparation and submission

42.3 Post-registration studies

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

42.3.1 Post marketing surveillance including adverse events and DIVA compliance

42.3.2 Real-world epidemiological efficacy studies

42.4 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:

42.4.1 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

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

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

1.8 R&D FOR MORE THAN ONE NEGLECTED DISEASE

43. MULTI-DISEASE VECTOR CONTROL

This category only applies to vector control R&D that is not yet targeted at a specific neglected disease or is explicitly targeted at multiple vector-borne neglected 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 dengue incidence) does not fall under this category.

Example:

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

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

43.1 Multi-disease chemical vector control products

43.1.1 See section VII.40 for the full outline of R&D activities included under this category

43.2 Multi-disease biological vector control products

43.2.1 See section 41 for the full outline of R&D activities included under this category

43.3 Multi-disease reservoir targeted vaccines

43.3.1 See section 42 for the full outline of R&D activities included under this category

43.4 Multi-disease fundamental vector control research

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

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

44. CORE FUNDING OF A MULTI-DISEASE R&D ORGANISATION

This category applies to organisations that disburse core funding or non-earmarked funding to an organisation that researches and develops products for multiple neglected diseases, and where it is unknown how the funding has been allocated within the recipient organisation.

Example:

i. Core funding has been allocated to an organisation that researches tuberculosis, Buruli ulcer and leprosy, but the donor does not know how much has been allocated to each disease

45. PLATFORM TECHNOLOGIES

45.1 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).

Only includes funding for R&D which meets the following conditions:

a) It is conducted by public, philanthropic or not-for-profit entities

b) It is research that is not directed towards a specific disease or product

c) It is research aimed at developing cheaper, more immunogenic adjuvants and immunomodulators suitable for use in LMICs

d) The resulting research findings or leads must be accessible to organisations developing pharmaceutical or biological products for neglected diseases

If the adjuvant or immunomodulator is being developed as part of a specific product, this investment is included under the relevant disease and product category (e.g. adjuvant R&D as part of a malaria vaccine construct is included under malaria vaccines).

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

45.2 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.

Only includes funding for R&D which meets the following conditions:

a) It is conducted by public, philanthropic or not-for-profit entities (i.e. private sector investment in delivery technologies and devices is excluded)

b) It is research that is not directed towards a specific disease or product

c) It is research aimed at developing cheaper, faster, more user-friendly biologics-related platform technologies, intended for use in resource-limited settings

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

45.3 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.

Only includes funding for R&D which meets the following conditions:

a) It is conducted by public, philanthropic or not-for-profit entities

b) It is research that is not directed towards a specific disease or product

c) It is research aimed at developing cheaper, faster, more user-friendly broad-spectrum therapeutics and drug delivery technologies and devices, intended for use in resource-limited settings.

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

45.4 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.

Only includes funding for R&D which meets the following conditions:

a) It is conducted by public, philanthropic or not-for-profit entities
b) It is research that is not directed towards a specific disease or product
c) It is research aimed at developing cheaper, faster, more user-friendly diagnostic platforms or multiplex diagnostic tool, intended for use in resource-limited settings

Examples of R&D for general diagnostic platforms 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 Triplex HIV/HCV/HBsAg self-test for simultaneous detection of HIV and hepatitis B and C
iii. Development of paper strip test for detection of multiple gastrointestinal pathogens at the point of care level

45.5 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.

Only includes funding for R&D which meets the following conditions:

a) It is conducted by public, philanthropic or not-for-profit entities
b) It is research that is not directed towards a specific disease or product
c) It is research aimed at developing cheaper, faster, more user-friendly vaccine platform or delivery technologies, intended for use in resource-limited settings

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

46. OTHER R&D

The other R&D category is for funding disbursed or received for research and development efforts that simultaneously focus on two or more neglected diseases, and which therefore cannot be apportioned to the specific disease categories.

Examples of other R&D:

i. Research into the interaction between HIV and tuberculosis:

   If research is part of the normal development path of a product for a specific disease (e.g. testing new TB drugs in special populations such as AIDS patients), it is included under the specific disease and product category where the product will be used (e.g. TB drugs)

ii. Development of a diagnostic to differentiate between different causes of fever (e.g. between malaria and meningitis)

iii. Development of a multi-disease diagnostic (e.g. the test can identify tuberculosis, malaria or sleeping sickness depending on the reagents used)

iv. Development of a multi-disease vaccine (e.g. a combination pneumonia/meningitis vaccine)

1.9 OUT OF SCOPE (EXCLUDED FROM THE SURVEY)

47. GENERAL EXCLUSIONS

The G-FINDER survey only captures investments that support pharmaceutical R&D where products aimed at preventing, treating or curing neglected diseases for patients in LMICs either do not already exist, or are inappropriate for LMIC contexts.

The following categories are therefore excluded from the survey:

47.1 Non-pharmaceutical tools

47.1.1 Adult male circumcision, cervical barriers, HSV-2 prevention, untreated bed nets, traps, water sanitation tools

47.2 General supportive, nutritional and symptomatic therapies

47.2.1 Oral rehydration therapy

47.2.2 Micronutrient supplementation, vitamins

47.2.3 Anti-pyretics, painkillers

47.3 Products developed and used for veterinary purposes

47.4 In-kind contributions

47.4.1 In-kind R&D contributions are excluded from the survey due to the difficulty in quantifying their value; however, a sample of these contributions is highlighted in G-FINDER reporting. Typical in-kind contributions would include training of LMIC scientists, sharing of expertise or access to compounds

47.5 Additional exclusions for private sector investment

47.5.1 Industry overhead costs, capital costs and opportunity costs are excluded, due to the difficulty of quantifying these and allocating them to the neglected disease investment. However, the published report will acknowledge the role of these in contributing to costs

48. NON-PRODUCT R&D EXCLUSIONS

The intention of the G-FINDER survey is to capture investments into neglected disease product development as accurately as possible.

The following R&D activities are therefore excluded from the survey:

48.1 Clinical studies not linked to development of a new product

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

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

48.2 Health services and access research

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

48.2.2 Health care service studies in relation to delivery of neglected disease treatment and control measures

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

48.2.4 Implementation and evaluation of large-scale neglected disease treatment and control programs operated through health care services, government ministries, non-governmental organizations (NGOs), etc.

48.2.5 Roll-out of proven vector control products (e.g. traps and nets, DDT)

48.2.6 Advocacy, community education and policy activities related to use, access, or roll-out of new products

48.3 Operational programme assessment

48.3.1 Reviews on the status of neglected disease product development

48.3.2 Studies on the economic impact of neglected disease morbidity and mortality on communities

48.3.3 Studies on the economics of neglected disease prevention and control measures including mathematical modelling of economic impact

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

48.3.5 Fostering collaboration between academia, industry, government agencies, and NGOs

48.4 General capacity building (human and infrastructure)

Capacity building activities are excluded unless they are directly linked to development of a new neglected disease product.

The following capacity building activities are therefore excluded:

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

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

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