SCOPE OF THE INFECTIOUS DISEASE R&D TRACKER

Table of Contents

1 Introduction

The Infectious Disease R&D Tracker includes drugs, vaccines, biologics, diagnostics, and vector control products for neglected and emerging infectious diseases (NDs and EIDs). It includes both products which have been approved on or after 1 January 1999, and candidates in the pipeline.

This document details the specific neglected and emerging infectious diseases that are included in the R&D Tracker, as well as the background behind their inclusion. Not all product types are included for all diseases, and restrictions in specific diseases/product combinations are described. Additionally, the document explains the nuances surrounding the treatment of diagnostics in the R&D tracker.

2 Neglected disease R&D scope

The neglected disease (ND) scope in the Infectious Disease R&D Tracker mirrors the G-FINDER scope for neglected diseases.

The neglected disease scope of G-FINDER has been defined (and refined) over a period of 15 years by an expert international Advisory Committee, in line with the following three criteria:

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

Diseases or product areas 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 scope.

Overall, the scope for neglected diseases includes 43 disease areas. The matrix below provides an overview of the disease scope, and further details on restrictions in specific conditions/product categories are detailed below.

		Drugs	Vaccines	Biologics	Diagnostics	Microbicides	Vector control products
Bacterial pneumonia & meningitis	*S. pneumoniae*	-	Restricted	-	✓	-	-
	N. meningitidis	-	Restricted	-	✓	-	-
	Both *S. pneumoniae* and *N. meningitidis*	-	-	-	✓	-	-
Buruli ulcer		✓	✓	-	✓	-	-
Cryptococcal meningitis		✓	-	✓	-	-	-
Dengue		✓	-	✓	✓	-	✓
Diarrhoeal diseases	Rotavirus	-	*Restricted*	-	-	-	-
	Cholera	*Restricted*	✓	Restricted	✓	-	-
	Shigella	*Restricted*	✓	Restricted	✓	-	-
	Cryptosporidiosis	*Restricted*	✓	Restricted	✓	-	-
	Enterotoxigenic *E. coli* (ETEC)	-	✓	-	✓	-	-
	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	✓	-	-
Hepatitis C		Restricted	✓	-	✓	-	-
Histoplasmosis		✓	-	-	✓	-	-
HIV/AIDS		*Restricted*	✓	*Restricted*	✓	✓	-
Kinetoplastid diseases	Sleeping sickness (HAT)	✓	✓	✓	✓	-	✓
	Leishmaniasis	✓	✓	✓	✓	-	-
	Chagas' disease	✓	✓	✓	✓	-	✓

		Drugs	Vaccines	Biologics	Diagnostics	Microbicides	Vector control products
	Multiple kinetoplastid diseases	✓	✓	✓	✓	-	✓
Leprosy		✓	✓	✓	✓	-	-
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		✓	-	-	✓	-	-
Trachoma		-	✓	-	✓	-	-
Tuberculosis		✓	✓	✓	✓	-	-

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

2.1 Bacterial pneumonia & meningitis

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

- **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:
    - be designed for use in infants less than two years of age;
    - provide broad coverage across all S. pneumoniae serotypes, or focused protection against strains prevalent in LMICs (at minimum serotypes 1, 5, and 14); and
    - 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:
    - provide coverage against *N. meningitidis* serotype A;
    - be a conjugate vaccine;
    - be designed for use in infants less than two years of age; and
    - 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

2.2 Diarrhoeal diseases

Rotavirus

The scope of the inclusion of funding for rotavirus 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

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

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

2.3 Hepatitis B

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

- **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)

2.4 Hepatitis C

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

2.5 HIV/AIDS

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

- **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

2.6 Leptospirosis

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:
  - detect the disease during the septicaemic or early acute phase of disease;
  - be accurate, easy to interpret, with little or no processing and give the results within 1-2 hours; and
  - be cheap, stable, easy-to use (i.e. should not require specific equipment and/or laboratory and highly trained staff)

2.7 Vector control products

The scope of the inclusion of research 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

2.8 Snakebite envenoming

A separate comprehensive database of all snakebite envenoming (SBE) medicines was created by Policy Cures Research in partnership with Wellcome in 2022. Consequently, while SBE is included in the G-FINDER scope for neglected diseases, all SBE candidates and products have been excluded from the Infectious Disease R&D Tracker.

More details on the neglected disease scope of G-FINDER can be found here.

3 Emerging infectious disease scope

3.1 Included diseases

The emerging infectious disease (EID) scope in the Infectious Disease R&D Tracker is based upon the priority diseases identified in the World Health Organization's R&D Blueprint for Action to Prevent Epidemics (R&D Blueprint), and CEPI's priority diseases. Altogether, the list of diseases includes:

- Lassa Fever
- Crimean Congo Haemorrhagic Fever
- Rift Valley Fever
- Chikungunya
- MERS
- SARS
- COVID-19
- Ebola
- Marburg
- Nipah

- Zika

Drugs, vaccines, biologics, and diagnostics are in scope for all emerging infectious diseases except for COVID-19, and vector control products are included where relevant.

3.2 Exclusions for COVID-19

Pre-clinical vaccine candidates and diagnostics for COVID-19 are excluded. The reason for this exclusion is two-fold. Firstly, the number of preclinical vaccine candidates and diagnostics for COVID-19 is high, and filling this data would take a large amount of time and resources. Secondly, there is uncertainty surrounding the utility of this data and whether it would add additional value on top of what is already available. Given the large number of clinical COVID-19 vaccine candidates that already exist, there are questions about how many of these will progress through to clinical development. Similarly, there are large numbers of 'me too' diagnostics which utilise the same technology and don't offer added benefit over existing diagnostics. Consequently, for these two product areas, exhaustive lists of candidates are unlikely to be particularly needed or useful. Additionally, there are other organisations who have tracked COVID-19 products during the pandemic.

4 Special considerations for diagnostics

The diagnostics field has many 'me too' products which utilise the same technology, and therefore large numbers of diagnostic tests for one disease does not necessarily translate to diversity in diagnostic type. Consequently, similar technologies, where applicable, have been represented as one record, so that the diagnostic pipeline is not artificially inflated. For example, all Hepatitis B diagnostics have been grouped (i.e. HBV surface antigen (HBsAg), HBV IgM core antibody (anti-HBc), etc.), whereas diagnostics for helminth infections have been represented as individual records.