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METHODOLOGY

This document provides users of the G-FINDER data portal with background information on the data presented in the portal, the scope it encompasses, and the methodology behind the G-FINDER project.

If you have any questions, please contact us at g-finder@policycuresresearch.org.

Table of content

METHODOLOGY	1
Table of content	1
Key methodology notes for the use of the G-FINDER data portal	2
Aggregation of pharmaceutical industry R&D funding	2
Annual changes in survey participation	2
Changes in economic and income country groupings	2
Identifying funding from individual national governments	3
Impact of changes in the G-FINDER scope over time	3
Direct and indirect funding	3
Scope of the G-FINDER project	4
Defining neglected diseases and products	4
Defining emerging infectious diseases and products	4
Defining sexual and reproductive health issues and products	5
General exclusions to the scope	5
General G-FINDER project methodology	7
Survey methodology	7
Data validation and standardisation	8
Data limitations	g

Note: Select a section heading to jump to that page



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Key methodology notes for the use of the G-FINDER data portal

Aggregation of pharmaceutical industry R&D funding

All pharmaceutical industry funding data is aggregated and anonymised to protect respondents' confidentiality. In order to prevent the identification of individual industry funders, funding provided or received by industry is attributed to 'aggregate industry' and multinational pharmaceutical company (MNC) country allocations are anonymised. Because the funder/recipient country for MNC funding is coded as 'Not specified', this is the category label you will see in the Funder Country and/or Recipient Country visualisation modules for this funding.

Annual changes in survey participation

While survey participation from the major funders has stabilised over the history of the G-FINDER survey, there remains significant annual variation in survey participation, as a result of survey dropout, increased response from long-term funders and entry of new players in the global health sector. The net effect of these changes is typically relatively small, other than between 2007 and 2008 (the first and second survey years). However, care should be taken in interpreting apparent changes in funding, which may, in some cases, have been contributed to by the artefactual effects of changes in survey participation. The relevant year's G-FINDER report provides participation-adjusted estimates of the true underlying change in funding which can be used as a supplement to the figures contained in the portal in areas where changes in survey participation are a particular concern.

Our <u>organisation participation overview</u> table (to be found under 'About the data' on the G-FINDER data portal menu) can be used to understand overall changes in participation. Analysis of how these changes influenced individual funding estimates can be found in the G-FINDER reports for the relevant year.

Changes in economic and income country groupings

Membership of country groupings, including high-income status and membership of economic groups such as the EU and the OECD, is current as of 2022. These 2022 membership lists are applied to all historical grants to or from that country, so that pre-2018 funding from Lithuania, which joined the OECD in 2018, is nonetheless captured under the 'OECD' funding filter across all years. Similarly, Argentina, which became a high-income country in 2018 and returned to middle-income status in 2019, sees all its funding captured under the 'middle-income country' grouping, regardless of its income status at the time the funding in question was disbursed.

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Identifying funding from individual national governments

The <u>annual G-FINDER reports</u> aggregate national (country) funding data on the basis that only funding from national government agencies is properly attributable to the national government of the country in which the funder is located, and that funding from other public funders, principally multilateral organisations like the World Bank and academic and other research institutions, might ultimately come from other sources – including other national governments.

In order to replicate the public funder analysis presented in the G-FINDER reports, users of the G-FINDER data portal should filter for 'Public Government' funding only, and exclude funding from 'Multilaterals' and 'Other Public' funders.

Impact of changes in the G-FINDER scope over time

Changes in the G-FINDER scope since the initial 2008 survey – including the addition of new health areas and the inclusion of new health area/product combinations – mean that data may not be available for every health area/product combination over the full time period available from the portal. New additions to the survey scope – such as COVID-19 and scabies in 2020 and yaws and Mpox in 2022 – are only covered by more recent survey years.

Full details of the year in which each health area and product was first included in the G-FINDER survey are available in the G-FINDER health area and product inclusions over time table under 'About the data' on the G-FINDER data portal.

Direct and indirect funding

The majority of global health R&D funding goes straight from funder organisations to product developers. However, a significant portion of investments flows from funder organisations to product developers via product development partnerships (PDPs) and other intermediary organisations. We call funding from funder organisations to intermediary organisations 'inward' funding, and that of intermediary organisations to product developers 'onward' funding.

The default setting in the portal is to display funding going straight to product developers (including self-funding) in addition to inward funding to PDPs and other intermediaries, referred to as DIRECT funding. This is also the default analysis used in the majority of our reports. When selecting direct funding in the portal, funding totals include contributions provided to PDPs and other intermediaries by their funders, but does not include grants where an intermediary organisations is the funder, since all onward funding is excluded to avoid double counting the value of funders' original contributions.

In mid-2022, we have added the option to view the alternative flow of funding: keeping the funding going straight to product developers (including self-funding), but substituting the inward funding to PDPs and other intermediaries for the onward funding they provide to product developers. We call this the INDIRECT funding view. When INDIRECT funding is selected, funding totals include the payments to product developers disbursed by PDPs and other intermediary organisations, but not any funds given to these intermediaries, since including both flows would result in double counting. As a result, direct and indirect funding figures relate to different measures of global funding and differ substantially. Note that some intermediaries report limited or no onward funding to the G-FINDER survey, causing us to underestimate the true levels of indirect funding. We hope to fill those gaps in the coming years.

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Scope of the G-FINDER project

The G-FINDER project started tracking funding data for neglected diseases in 2008 (collecting FY2007 data), emerging infectious diseases in 2015 (collecting FY2014 data), and sexual & reproductive health issues in 2019 (collecting FY2018 data), covering the spectrum from basic research to post-registration studies of new products.

Defining neglected diseases and products

Prior to the commencement of the G-FINDER project, there was no generally accepted definition of 'neglected diseases' and, for many diseases, no agreement on which new products were needed. Before the start of the survey in 2008, in order to reach a consensus position on these questions, a list was created of all diseases classified by major health bodies or publications as a 'neglected disease'. This list was then assessed by an international Advisory Committee of 17 experts in neglected disease and R&D, who filtered candidates against

- the burden of the disease or condition disproportionately affects people in low- and middle-income countries;
- there is no existing product to treat / prevent the disease or condition, OR a product exists but is poorly suited for use in low- and middle-income countries; AND
- there is no commercial market to stimulate R&D by industry.

We maintain ongoing consultation with the Advisory Committee for advice on applying this definition in response to changes in the R&D or pathogenic landscape. Where the Advisory Committee does not reach a consensus, their views are supplemented by advice from further technical and R&D experts.

The result of this consultation is that not all areas of research are judged as meeting our definition of 'neglected' in relation to every disease, and some are included only with restrictions. For example, investments in pneumonia drug R&D are excluded because a sufficient commercial market exists; while pneumonia vaccine R&D investments are only included if they meet specific requirements for strain, vaccine type and target age group.

Defining emerging infectious diseases and products

Policy Cures Research began gathering data on R&D targeting emerging infectious diseases in response to the 2014 West African Ebola epidemic. In our 2015 G-FINDER survey and report (looking at investments made in 2014), this focused exclusively on Ebola R&D. Since then, we have adopted a progressively broader scope in each subsequent year, determined in consultation with the G-FINDER Advisory Committee and a separate emerging infectious diseases Expert Advisory Group.

Our current definition of emerging infectious diseases closely follows the list of priority diseases endorsed by the World Health Organization research and development Blueprint for action to prevent epidemics (the <u>Blueprint</u>). The survey also gathers data on emerging infectious diseases and disease groups not included in the Blueprint priority list, including several pathogens which have been considered for inclusion.

Compared to our neglected disease definition, our definition of emerging infectious diseases has very few restrictions. R&D for almost all product development categories (drugs, vaccines, biologics, and diagnostics) is included without further restrictions for all priority emerging infectious diseases pathogens, as is basic research. R&D for vector control products is included where relevant.

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Defining sexual and reproductive health issues and products

After a one-off report on global funding for reproductive health published by Policy Cures in 2014, Policy Cures Research again began tracking annual funding for R&D for sexual & reproductive health issues in 2019 (when we collected 2018 data), this time with a broader scope. Our updated definition of sexual & reproductive health issues was determined through a multi-stage process, starting with an initial, broad stakeholder consultation with 46 of the world's leading stakeholder organisations. Participants included major donors, NGOs, peak bodies and coalitions, and research and innovation organisations. An Expert Advisory Group comprising 23 global experts in sexual & reproductive health was then convened to refine our definition, which is reviewed annually with their input.

As with neglected diseases, our definition of sexual & reproductive health aims to capture R&D that is relevant to the sexual and reproductive health needs of people in low- and middle-income countries according to the following overarching criteria:

- the area is a significant health issue affecting people in low- and middle-income countries; AND
- there is a need for new products (i.e. there is no existing product, or improved or additional products are needed to meet the needs of people in low- and middle-income countries).

We maintain an ongoing consultation with the Expert Advisory Group for advice on how to apply our definition of sexual & reproductive health issues in particular contexts. Where there is disagreement between experts, their decisions are supplemented by advice from further technical and R&D experts.

Not all basic research and product types are included in our definition of sexual & reproductive health issues, and some are included only with restrictions. For example, chlamydia drugs are excluded because cheap and efficacious treatment with oral azithromycin already exists and is appropriate for use in low- and middle-income settings; while syphilis drugs are included but restricted only to those that target latent, tertiary, maternal or congenital syphilis, since drugs to treat early stage syphilis are effective and readily available.

We also include platform technologies, where the product could feasibly be used for both sexual & reproductive health issues or neglected diseases, such as general drug or vaccine delivery platforms. HIV and hepatitis B are part of both our neglected disease and our sexual & reproductive health definitions, and may therefore appear in our analysis covering either of these disease areas.

General exclusions to the scope

The purpose of the G-FINDER project is to track and analyse global investment in the research and development of new health technologies for global health issues such as neglected diseases, emerging infectious diseases, and sexual & reproductive health issues. G-FINDER does not, and is not intended to, capture investment in the entire spectrum of global health research. Many research activities that are extremely important for global health are excluded from this project because they are not related to the development of new tools for the diseases included in our scope.



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Research activities that are NOT included in the scope of G-FINDER include:

- health systems and operations / implementation research (for example, research into health systems or policy issues, or research into the programmatic delivery of non-product interventions, or existing health technologies), and
- sociological and behavioural research not related to the development of new health technologies.

We also generally exclude investment into non-pharmaceutical tools, for example the development of untreated bed nets. General therapies such as painkillers or nutritional supplements are also excluded, as these investments cannot be ring-fenced to use in low- and middle-income countries only. Investment that is not research-related is similarly excluded: although we recognise the vital importance of activities such as health programme delivery, advocacy, routine disease surveillance programmes, community education and general capacity building to address global health issues, investment in these activities falls outside the scope of G-FINDER.

Investments that do not meet the G-FINDER scope are excluded from the G-FINDER data portal.

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General G-FINDER project methodology

Since 2008, the G-FINDER survey has operated according to two key principles: capturing and analysing data in a manner that is consistent and comparable across all funders and diseases; and presenting funding data that is as close as possible to 'real' investment figures.

Survey methodology

Identification of survey participants

The G-FINDER project aims to survey all key public, private and philanthropic organisations involved in R&D for global health. Although the primary focus is on funders, we also survey key research, intermediary and industry groups to allow us to better track funding flows.

In 2008 (the first year of the project, then focused exclusively on neglected diseases), survey participants were identified through various avenues, including: our own database of contacts; previous surveys covering HIV/AIDS, tuberculosis, and malaria R&D; and research to find previously unknown funding organisations in countries with high R&D expenditure as a percentage of gross domestic product. In the following year we focused on groups and countries that were missing or poorly represented in 2008, developing proactive strategies to both increase the number of survey participants and improve response rates in these areas. Major Indian public agencies involved in funding R&D for neglected diseases were identified and incorporated in our list of participants, and additional diagnostics organisations and small pharmaceutical and biotechnology firms were also included.

Since then we put in place a number of targeted strategies to further increase survey participation of major public funders and product developers in low- and middle-income countries, including those in South America, Africa and Asia. In addition, each time that a new disease or health issue is added to the survey scope, organisations known to be active in these areas are identified and surveyed.

Data collection

G-FINDER was originally designed as an online survey. An online survey platform was developed to capture grant data and is still used by the majority of survey participants. An offline grant-based reporting tool is also available. Industry (pharmaceutical companies and biotechnology firms) investment in R&D is not grant-based, so the reporting tool has been tailored for these participants. Instead of grants, companies enter the number of staff working on global health programmes, their salaries, and direct project costs related to these programmes. Companies are required to exclude 'soft' figures such as in-kind contributions and costs of capital.

For some organisations with very large datasets, the online survey and equivalent offline reporting tool are difficult to use. The G-FINDER team therefore uses publicly available databases to identify the relevant funding.

All participating organisations are asked to only include disbursements (or receipts), rather than commitments made but not yet disbursed. In general, only primary grant data is accepted; the only exception is in the case of data collection collaborations between G-FINDER and other R&D funding surveys, such as the Resource Tracking for HIV Prevention Research & Development Working Group. Data from all sources is subject to verification using the same processes and inclusion criteria.

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The survey

Survey participants – funders, intermediaries and product developers – are asked to enter grant-by-grant expenditures incurred or disbursements received during their financial year with the largest overlap with the previous calendar year (which is different from the financial year in many countries). Survey participants are asked to enter details of every global health investment they disbursed or received, including:

- a specific disease or health issue, from a predefined list
- a product type (e.g. drugs, vaccines, microbicides), from a predefined list
- an R&D stage within the product type (e.g. discovery and pre-clinical, clinical development), from a predefined list
- the name of the funder or recipient of the grant
- a brief description of the grant
- an internal grant identification number
- the grant amount

Where survey participants cannot provide data to this level of detail, they are asked to provide the finest possible level of granularity. Where survey participants are not able to allocate the grant to a single disease, five options are available:

- 1. 'Core funding of a multi-disease / issue organisation' such as funding to an organisation working in multiple diseases or sexual & reproductive health issues, where the expenditure per health issue was not known to the funder
- 2. 'Platform technologies', further allocated as investment into adjuvants and immunomodulators; biologics-related platform technologies; broad-spectrum antivirals; drug-related platform technologies; general diagnostic platforms & multi-disease diagnostics; or vaccine-related platform technologies. These categories capture investments into technologies which were not yet directed towards a specific disease or product
- 'Multi-disease vector control products', which captures funding for vector control product R&D that is not yet targeted at a specific disease, or that is targeted at multiple vectorborne diseases
- 4. 'Multi-purpose prevention technologies' which target more than one sexual & reproductive health issue
- 5. 'Unspecified R&D' for any grants that still cannot be allocated to any of the above categories

Data validation and standardisation

Validation

All grants reported in the G-FINDER survey are verified against the inclusion criteria. Cross-checking of grants reported by funders and recipients is then conducted using automated reconciliation reports – which match investments reported as disbursed by funders with investments reported as received by intermediaries and product developers – followed by manual grant-level review. Any discrepancies are resolved by contacting both groups. For grants from the US NIH, funding data is supplemented and cross-referenced with information received from the Office of AIDS Research (OAR) and the National Institute of Allergy and Infectious Diseases (NIAID).

Industry figures are reviewed against industry portfolio information held by Policy Cures Research and against full-time equivalent (FTE) and direct costs provided by other companies. Costs that fall outside the expected range, for example, above average FTE costs for clinical staff, are queried with the company and corrected.

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Inflation and currency adjustments

All funding data we collect is adjusted for inflation and converted to US dollars for the relevant financial year to eliminate artefactual effects caused by inflation and exchange rate fluctuations, allowing accurate comparison of year-on-year changes. Due to these adjustments, historical USD funding data in tables and figures in the G-FINDER data portal will differ from data published in older reports.

All reported data is adjusted for inflation using consumer price index (CPI) estimates from the <u>International Monetary Fund</u> (IMF) and any data entered by survey participants in their local currency is converted to USD based on the average annual exchange rate of the relevant financial year as reported by the <u>IMF</u>, <u>Bank of England</u>, <u>United Nations Treasury</u> and <u>OANDA</u>.

The G-FINDER data portal allows all data – reported, by default, in 2022 US dollars (USD) – to be converted to 2022 Euros (EUR) or British pounds sterling (GBP) based on the average nominal exchange rate between the USD and the target currency over the 2022 calendar year.

Differences between G-FINDER and other data sources

Other groups also publish annual surveys of global R&D investment into selected global health areas, such as HIV/AIDS and TB. Although we work in close collaboration with some of these groups, both to ease survey fatigue on the part of participants and to clarify any major variance in our findings, each survey nevertheless has slightly different figures. This is chiefly due to differences in scope, in particular inclusion in other surveys of funding for advocacy, capacity building and operational studies – all excluded from G-FINDER. Methodological differences also lead to variations, particularly the adjustment of G-FINDER figures for inflation and exchange rates, which is not always the case for other surveys. As noted above, classification of some funding as 'unspecified' in G-FINDER (e.g. multi-disease/multi-issue programmes) may in some cases also lead to different figures than those published in disease/issue-specific surveys.

Data limitations

While the survey methodology has been refined over the past decade, there are limitations to the data presented, including survey non-completion, time lags in the funding process, an inability to disaggregate some investments, and non-comparable or missing data.

Survey non-completion

Some global health R&D funding may not be captured because organisations are not identified as active in this field and are therefore not invited to participate, or because organisations are invited to participate, but do not respond. Despite this, we are confident that the majority of neglected disease, emerging infectious disease, and sexual & reproductive health R&D funding is captured by G-FINDER, because large funders active in this area and target groups identified by our Advisory Committee are typically responsive and, where they are not, are prioritised during survey follow-up.

Time lags in the funding process

Time lags exist between disbursement and receipt of funding, as well as between receipt of funds and the moment they are actually spent. Thus, grants by funders will not always be recorded as received by recipients in the same financial year, and there may be a delay between R&D investments as reported by G-FINDER and actual expenditure on R&D programmes by product developers and researchers. Nevertheless, as most of our reports analyse trends over an extended period, the impact of time lags is minimal.

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Inability to disaggregate investments

A small proportion of funding is reported to the survey each year as 'unspecified', usually for multidisease/multi-issue programmes where investment cannot easily be apportioned by disease or issue. A proportion of funding for some health issues is also 'unspecified', for instance, when funders report a grant for research into TB basic research and drugs without apportioning funding to each product category. This means that reported funding for some diseases or issues and products will be slightly lower than actual funding, with the difference being included as 'unspecified' funding.

Another small, though increasing, fraction of global funding is given as core funding to R&D organisations that work in multiple health areas, for example, the European and Developing Countries Clinical Trials Partnership (EDCTP) and the Coalition for Epidemic Preparedness Innovations (CEPI). As this funding cannot accurately be allocated by disease or health issue, it is reported as unallocated core funding. In cases where grants to a multi-disease or multi-issue organisation are earmarked for a specific health area or product, they are included under the specific disease/issue-product area.

Non-comparable data

Due to a significant increase in the size of survey participation in 2009 (when we collected FY2008 data), data from 2008 (when we collected FY2007 data) is the least comparable to other years. Furthermore, the current public official databases for the US NIH data, the RCDC and RePORTER, used for data collection from 2009 onwards, uses a different structure than the US NIH database used in 2008, making this data less comparable. As such, apparent shifts in funding between 2007 and 2008 should be interpreted with caution.

Missing and inaccurate data

G-FINDER can only report the data as it is given to us. Although strenuous efforts are made to check the classification, accuracy and completeness of grants, in a survey of this size it is likely that some data will have been incorrectly entered or that funders may have accidentally omitted some grants. We periodically make amendments to historical G-FINDER data after the publication of a report if better data is provided or errors are identified, which take immediate effect on the G-FINDER data portal. We believe that the checks and balances built into the G-FINDER process mean that mistakes, if present, have only a minor overall impact.