Data collection process

Five sources of information were used to build the database: the outputs from two research projects, the internal knowledge of the research team, literature reviews and snowball sampling through interviews.

First, the project used as its baseline the report <u>"RE:ROUTE, A map of the alternative biomedical R&D landscape"</u>, (Kiddell-Monroe, Greenberg, and Basey 2016), produced by members of Universities Allied for Essential Medicines (UAEM). This report mapped initiatives that used alternative R&D models, defining alternative as those initiatives that met the following inclusion criteria:

- "the initiative is driven by the needs of patients globally
- the initiative is based on a clear and broad application or planned application of one or more of the following innovative principles:
 - providing a pull mechanism
 - providing a push mechanism
 - providing an IP pooling mechanism¹
 - allowing broad collaboration²
 - adopting open approaches to R&D (open source, open data sharing, open innovation)³"

Our project's conception of alternative business models builds on, adapts and expands on this one, as described <u>here</u>. We included 41 initiatives from this research report in our database. Second, we added the list of initiatives selected for a <u>previous research</u> <u>project</u> focused on non-commercial R&D for neglected diseases. This led to the inclusion of 30 additional initiatives out of the 43 initiatives that this previous project included for analysis, as the other 13 initiatives overlapped with the UAEM report.

Third, we identified 48 more initiatives through various literature reviews and online searches. For example, the development of literature syntheses on <u>Biosecurity R&D</u>,

¹ For a definition of pull, push and pool mechanism see Suleman F, Low M, Moon S, Morgan S G. New business models for research and development with affordability requirements are needed to achieve fair pricing of medicines BMJ 2020; 368:I4408 doi:10.1136/bmj.I4408

² Defined as: "An R&D initiative that involves a network, consortium, or partnership between two or more of any academic or research institutions, non-profit organizations, NGOs, governments, government entities, or members of the private sector including biotech and pharmaceutical companies. Exchange of information and data pooling is often regulated via Material Transfer Agreements and restricted to within the involved entities unless the initiative is also open."

³ R&D initiatives that apply open source, open access, open data, or open knowledge principles. Interested parties are able to contribute knowledge or know-how, data, technology, etc. to be shared in the public domain and, in the case of open source, in coordination with patent-free research.

<u>Small- and Medium Enterprises (SMEs)</u>, <u>Priority Review Vouchers (PRVs)</u> or <u>Public</u> <u>Benefit Corporations (PBCs)</u> led to the inclusion of more organizations. Through nonsystematic online searches, we included initiatives that approached innovation coupled with access-related principles embedded in its business model. This was particularly relevant for COVID-19-related initiatives, as the project aimed to understand how the different initiatives aimed to overcome some of the problems of the R&D system in order to increase global access.

Finally, the research team identified eleven organizations through snowball sampling during interviews with experts throughout the research project.

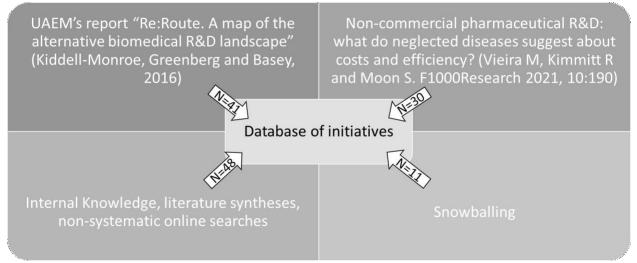


Figure 1. Data collection strategy

Data processing and analysis:

The organizational form was assigned to each initiative reviewing each initiative legal status, bylaws or any other relevant information that could point at the legal status of the initiative.

Given the geographical diversity in the initiative, some fields were used as umbrella terms to capture the variety of legal forms used in different countries: Not-for-profit organization corresponds to all those legal entities whose purpose is not generating profits (e.g., 501(c) organizations in the US, Swiss Fondations or British charities), or that facilitate the inclusion of the non-profit principle in the bylaws of the organization (e.g., Dutch Stichtings or German Stiftungs).

The categories "national government agencies" and "academic and other research institutions" are taken from PolicyCures G-Finder Glossary. Public Benefit Corporations



are those organizations that follow that mechanism of incorporation, and are not the same as B-Corps.

There are four cases where the organizational form was unclear. These are publicprivate partnerships involving at least one academic institution and philanthropic funders. However, it was not possible to find incorporation agreements online.

The field "Disease Area" does not follow a particular disease or technology categorization, it was created by manually reviewing the initiative's websites. The description field relies on previous descriptions made by Kiddell-Monroe, Greenberg and Basey, as well as on the initiatives' websites.

The database does not claim to capture all relevant initiatives, and continues to evolve. Suggestions for additional initiatives to include are welcome at:

The development of this database is the result of the collective effort of the NBM research team members: Suerie Moon, Adrián Alonso Ruiz, Marcela Vieira, Kaitlin Large, Iulia Slovenski, Yiqi Liu, Danielle Navarro, Temmy Sunyoto and Surabhi Agarwal.

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