Performing a landscape analysis: understanding health product research and development

A quick guide
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What is a landscape analysis?

A landscape analysis related to health products aims to identify and characterize all the products that exist or are being developed in a specific topic area. The topic may be focused or broad, investigating the area by product class or by stage of development – such as all vaccines against malaria in phase III clinical trials, or all antimicrobial therapeutics in preclinical and clinical development, or all rapid diagnostic test (RDT) readers with regulatory approvals in at least one country.

Various sources and tracking processes can be used to monitor developments. These include clinical trial registries, proprietary databases, company/university websites and industry-specific third-party sources. This document is a starting guide for WHO technical teams intending to perform a landscape analysis.
Why do a landscape analysis?

There can be different reasons for performing a landscape analysis, including the following.

Preparing for other processes

🌈 For prioritization – A landscape analysis can be used as a preparatory step for other documents. The landscape analysis can identify the elements of the current situation, as well as gaps, and can determine if and when to develop research priorities or target product profiles. The analysis can be used to inform foresight approaches for long-term strategic planning.

🌈 To prepare for a policy decision or review – A landscape analysis can be used to prepare for early product adoption. It may be used by WHO technical departments and the prequalification team to give advance information of the need to prepare for new products by developing guidelines and new implementation strategies. The landscape may also be used by, for instance, external stakeholders to enable regulatory bodies to understand new products prior to submission, by procurement funders to inform advanced market commitments and by Member States to prepare for the implementation of new interventions.

Driving research directions

🌈 A landscape analysis may indicate knowledge gaps that can become a basis for further research. For instance, scientific challenges or a lack of information on the demand or the market may disincentivize commercial partners from translating preclinical discoveries into clinical benefits, or from investing in late-stage research. These barriers can become visible in a landscape analysis by looking at the numbers of products throughout the value chain. A landscape analysis can generate alignment across stakeholders on key knowledge and information gaps.

🌈 WHO may respond to a landscape analysis in several ways, including: 1) by developing a research agenda, specifically indicating the priority research needed for the greatest public health gains; 2) by producing Target Product Profiles (TPPs) or similar guidance specifying the product characteristics and evidence required for inclusion of the product in policies; and 3) by supporting or implementing studies that demonstrate the potential social, economic and health impact of products to support and incentivize investment and decision-making.

Comparing products

🌈 Standardized product comparisons can be used by decision-makers to prioritize and direct investments for research funding, to make procurement choices, and for the design of health programmes. WHO does not recommend specific branded products but can provide a comparison of all available products.
Advocacy

Communicating the state of the pipeline can support global efforts to develop or improve interventions that address unmet public health needs and to redress the R&D imbalance across different fields. For example, the Global Scientific Strategy Towards an HIV Cure\(^1\) developed by the International AIDS Society in 2016 informed the CIHR Canadian HIV Trials Network to bring Canadian researcher expertise towards the search for a cure\(^2\).

Measuring progress

Pipeline reviews can track investments in products compared to global public health need and can help to identify and track key players (and their portfolios) involved in health product development.

Analyses performed over time may help to determine the health of the pipeline and attrition rates, and can help to optimize – or in some contexts forecast – future product approvals.

Landscape analyses may over time identify factors contributing to the success or failure of product development.

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How does one do a landscape analysis?

There are many ways to do it! It depends on the question(s) you want to answer. The analysis can be as focused or as broad as your resources allow. A systematic approach to defining the question, method, data collection and analysis will help you to make the highest-quality analysis for your purpose.
**Know your question**

Clarity on the purpose and scope of the review will help you to stay on topic so you can target your data collection to what really matters. Being clear on the reason for the analysis will help you to ask the right questions and collect the right data. To define the question(s) consider how the information may be used, by whom, what decisions it might affect and the change you would like to see.

**Common questions to ask**

- What do you want to know? For example, do you want to know what is in the preclinical or clinical pipeline? Do you want to know what is commercially available?
- What is already known? Does existing work need to be complemented by WHO?
- Who is your audience?
- Do you want this to be a snapshot in time, updated regularly, or a living document? How quickly does the subject matter change?
- Do you want to focus on a number of products, dynamism in the research field (e.g. number of trials, regulatory considerations) or market factors?
- Will you monitor the uptake of products when they come into use?
- What resources do you have to monitor the uptake, and does that affect your scope?

**Example 1**

The AMR team started by prioritizing the research questions. The landscape analyses began with medicines in clinical development, where the data are available and can be retrieved through clinical trial registries. These data were then validated against available published peer-reviewed evidence and grey literature. The final interpretation and reporting of findings was done in close consultation with a WHO expert advisory group established for this purpose.

Over the years the scope was expanded to medicines and products in preclinical development, and recently to diagnostics. This was made possible by building on the knowledge gained each year and by supplementing it with information from networks.

**Example 2**

The WHO End TB Strategy recognizes the need for new tools and strategies. To monitor progress, the Global TB Programme publishes annually the clinical development pipeline of new TB vaccines, diagnostics, drugs and treatment regimens through its Global TB Report (WHO). The pipeline provides visualization by stage of clinical development, age group and relevant product-specific features – such as new drug entity or vaccine technology platform. Clinical trial registration links are hyperlinked to allow access for more information.

The pipelines are updated annually through coordination with expert groups – such as the secretariats of the Stop TB Partnership working groups on new TB vaccines, diagnostics and treatment – and through direct communication with developers, complemented by searches of clinical trial registries. Currently, the information provided in the pipelines is basic. The Global TB Programme is preparing to launch an interactive and searchable knowledge-sharing platform called a “TB research tracker” to provide more comprehensive information on the clinical development pipeline of health products on TB, complete with analysis by stage of development, mechanism of action, route of administration, type of technology/platform, target population and product type. The platform will also feature pertinent operational research projects which are primed to facilitate the optimization and scale-up of interventions recommended by WHO.
Develop the method

Developing a protocol with a clear scope will help you to keep on track. It will help you to plan how you want to analyse and report the information in order to answer your primary question. For instance, the information could be organized by criteria such as stage of development, target group, mechanism of action, type of product or expected regulatory filing date. Consider how you could expand the scope of the protocol in future years based on the same datasheet.

Method considerations

- Find out who has the information – databases, Internet searches, reports, literature searches, patient groups, key institutional actors, private and nonprofit sectors or other groups.
- Find out which data are most accurate and recent – e.g. look at the update schedule on the database and the inclusion and exclusion criteria for the dataset. Pay close attention to the limitations of each dataset in order to understand what information may be missing; for instance, trials of diagnostics are not generally registered in clinical trials databases.
- If considering pricing, ensure that the price provided is well described: consider inclusions, Incoterms (for historical procurement data), hidden costs such as maintenance and specimen processing, and whether the price is a manufacturer-supplied reference point or a negotiated price that people can expect to pay.
- Define parameters as to how you will obtain the information – e.g. using only publicly available knowledge, using key informant interviews, using references to confidential information.
- Use your networks or committees for more data sources. Use in-house data sources, expert groups, WHO collaborating centres, or a general call for information.
- Will you incorporate predictions – e.g. on the time to introduction? How will you assess those predictions?
- Broad and varied perspectives help to reduce blind spots. Consider whether you will use an expert group with wide disciplinary representation to review and agree on the method, and later to check that the data are complete.
- A period of public and/or targeted comment may be advisable to ensure buy-in and to avoid missing significant elements of the landscape.
- Develop a protocol for how and where you will search for data. Develop a data sheet (e.g. Excel) to collect the information.
- Keep on scope.
How does one do a landscape analysis?

Common data sources

- International Clinical Trials Registry Platform (WHO).
- Global Observatory on Health R&D (WHO).
- Compendiums of WHO data – e.g. on innovative products.
- Peer-reviewed manuscripts and searches for authors’ other publications.
- Grey literature searches – e.g. of conference proceedings.
- Multiple language searches – e.g. LILACs (LILACS, 2022) and SciELO (Scientific Electronic Library Online, 2022) for Spanish and Portuguese.
- Networks – e.g. expert groups, regional offices, Product Development Partnerships (PDPs), WHO collaborating centres, FIND (FIND, 2022) for diagnostics information.
- Other pipelines that have been published – e.g. market analyses by Unitaid (Unitaid, 2022). Pay close attention to the dates and inclusion criteria used.
- Direct contact by telephone or email with journal article authors, conference presenters and companies involved in the research and sale of products.
- Historical procurement data – e.g. GFATM (The Global Fund, 2022), WHO data (directly from GSM) supplemented with data from other UN agencies. For country procurement information, contact country offices and request assistance with the best way to obtain it. Also consider if you can access private-sector data through sources such as IQVIA (IQVIA, 2022).

Example

The number of HIV innovators is relatively small so direct contact with known entities can reveal the majority of therapeutics. However, this carries a risk of missing new players. A scoping review was designed for a broad search strategy focusing on efficacy and safety, repeated over time. Data were sourced from WHO’s International Clinical Trials Registry Platform (ICTRP), from known developers, and from networks in the research community for unpublished works or works not registered in a clinical trials registry.
Collect the data

Using your file with all the variables of interest (e.g. Excel sheet) search for information and record the data. If you are searching and reviewing files, make a repository containing those files for future updates. Supplement this with information from persons in your networks, from collaborators on journal articles and from companies (by calling them directly). For individuals, discuss attribution preferences. Allocate enough time for collecting the data and keep to the same question and protocol.

Warning

- Be mindful of restrictions on the use of the information you gather – such as confidentiality and non-disclosure agreements. If in doubt, contact WHO’s Legal Office (LEG) to verify any potential legal implication related to publishing the data. LEG may assist in deciding whether or not data can be published and/or can suggest appropriate disclaimers to include in the documents.

Example 1

Vaccine pipelines – vaccines entering clinical trials will almost certainly be found in clinical trials registries. WHO’s Immunization, Vaccines and Biologicals (IVB) department searches both clinicaltrials.gov and ICTRP using the general search term “pathogen name”* AND vaccine, and specified limits (time, recruitment status etc.). This is supplemented by a PubMed search (“pathogen name” AND “clinical trial registry number” OR “manufacturer”) and a review of the websites of vaccine manufacturers to look at their pipeline/press releases etc. to identify whether there are published results.

Example 2

Unitaid’s multipurpose prevention technologies landscape (Unitaid, 2021) is a broad landscape of several technologies with diverse data sources. The protocol included: a) product developer surveys of 18 questions on each technology; and b) a desk review of the products, end-user research, technical and regulatory considerations, and market introduction considerations. The search included a review of databases with peer-reviewed publications, publicly-funded research on ongoing registered clinical trials, and recent conference abstracts from key conferences and annual meetings. Key informant interviews were held with multiple stakeholders – including product developers, regulatory experts, programme implementers, civil society leaders, policy-makers and donors/supporting agencies. Input was sought on missing/outdated information and other additional details on new or ongoing R&D, as well as insights into priority approaches and indications, key gaps and challenges, and recommendations for the field.

* The “Pathogen name” should be replaced by the name of the disease of interest – e.g. a search on malaria vaccine pipelines would include the term Malaria AND vaccine. Further information on how to search ICTRP most effectively can be found at ICTRP search portal - search tips [https://www.who.int/clinical-trials-registry-platform/the-ictrp-search-portal/search-tips](https://www.who.int/clinical-trials-registry-platform/the-ictrp-search-portal/search-tips)
How does one do a landscape analysis?

Analyze and visualize the results
Analyze the data to answer your question and target the output to your audience (see communication steps for target audience tips).

Analysis considerations

- Know the limitations of the data sources and consider how these affect the analyses you can do.
- Make sure to state any caveats and/or limitations of your dataset.
- Consider how the products in the pipeline affect equity, disability, gender and human rights, and whether there are issues of acceptability, sustainability, feasibility, cost or affordability that should be highlighted to guide R&D.
- Consider graphics for quick explanations of key questions and for key populations – e.g. by age or vulnerable groups.
- Consider interactive graphics if they help understanding (examples are hosted on the Global Observatory on Health R&D).

Example

Interactive analyses of landscapes on the WHO’s Global Observatory on Health R&D analyses and syntheses are provided alongside written reports highlighting the key findings. The interactive analyses allow interested parties to explore the data further.
Dissemination of findings

Communicating the findings to the right audience is the last but most critical step. It is necessary to identify the platform and the format that best suit your target audience. In what format does the target audience need the information? Publishing contents on WHO webpages may be best for WHO staff, some researchers and the press; commentaries and journal articles are most read by researchers and funders; interactive visuals may best target policy-makers and analysts; and newsletter articles could target specific stakeholders.

Who needs to see the landscape analysis?
- Who can effect change?
- Who could be an advocate?
- Who influences the use of the health products in question?

What does the target audience want to see?
- Develop infographics and analyses to target the right people.
- A disclaimer may be appropriate depending on the content.

Where should you publish?
- Consider accessibility.
- Diversify your communications: consider written reports (news, journal articles), oral presentations (scientific conferences, webinars), press releases, industry-specific publications, and piggy-back on topic-specific organizations’ reach through their newsletters and reports.

When should you launch?
- Link the launch to a specific event – e.g. a funding call or a world disease day.

How will you measure uptake and impact?

Example

“A blueprint for dementia research” (WHO, 2022) indicates the current state of dementia research across six broad research themes. The blueprint identifies existing gaps and outlines strategic goals, with actions and timebound milestones, to address those gaps. The primary audience that can effect change was identified as funders, research agencies and researchers.

To reach the target audience, a launch event was organized with the presence of some 100 people, including representatives from Member States, WHO’s Chief Scientist and the Assistant Director-General. The launch of the blueprint was reported by several news outlets, and further dissemination was done through internal channels such as departmental news items. The technical unit also presented the blueprint at conferences and seminars and published an article in an essay series of the Ministry of Health, Welfare and Sport of the Netherlands. Further, to facilitate dissemination among academics and researchers, the development process and outcomes of the blueprint were published in leading journals such as The Lancet Neurology and Nature Aging. These activities resulted in the blueprint being downloaded 2500 times in the first month after publication.
Plan for updates

Landscape analyses can easily become obsolete, especially in areas where the pace of innovation is fast. If possible, plan to maintain the relevance of the landscape analysis by using the most up-to-date sources and ensuring an agile way to make amendments, if needed, during the publication process and beyond. In addition, plan for longer-term updates, especially if the publication proves useful to your audience. Updating the document can also enable you to understand the health of the pipeline over time – for instance, where products are failing to progress through the development cycle.

Tips and tricks

- **Stay on topic** – a landscape analysis can quickly become unwieldly so keep to your question(s) and the variables you want to collect. Collecting too much information can make it impossible to synthesize.

- **Avoid an echo chamber** – use a robust systematic process to ensure that you do not miss anything. Use call-outs or consultations to expand your reach, especially if the topic has a fragmented community. Ensure that networks or panels have broad expertise, geography and background in order to make the final product robust and useful.

- **Scrutinize the method** – have experts review the methodology to ensure that the analysis is robust prior to starting. For a full picture, consider research and data searches that include multiple languages and regions. Understand the limitations of each of the data sources you use (e.g. ICTRP contains information from 18 registries worldwide but all these have records in English).

- **Capitalise on specialist knowledge** – engage WHO regional offices and collaborating centres early to obtain valuable advice about research that is ongoing in the regions. If you opt for external support, a specialist may be best able to source the information. Bring in an organization or an individual with contacts and expertise in the area – e.g. product-specific knowledge or regional research knowledge.

- **Interact with industry** – interactions with developers are valuable. You can engage with industry without giving competitive advantage. Incorporation in a WHO landscape analysis does not mean that a product is recommended, but beware of the risk that some companies may make false claims. Follow WHO guidance, speak to the Legal Office and incorporate disclaimers.
Annex 1: Useful links

Links for research data sources


Links for procurement analyses


Links for examples of analyses


## Annex 2: Checklist for WHO staff

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<thead>
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<th>Question</th>
<th>Notes</th>
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<tr>
<td>What do you want to know, and why?</td>
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<tr>
<td>What analyses already exist in the area?</td>
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<tr>
<td>What is missing?</td>
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<tr>
<td>What is your targeted question?</td>
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<tr>
<td>Who is/are your audience/s?</td>
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<tr>
<td>What are the data sources for the question?</td>
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<td>What expertise is required?</td>
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<td>Where will you find it?</td>
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<td>Have you planned:</td>
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<td>• the method</td>
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<td>• the analysis</td>
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<td>• the communication strategy</td>
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<td>• the evaluation</td>
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<td>Have you submitted planning clearance?</td>
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<td>Have you had the method plan checked by a range of experts?</td>
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<td>Have you recorded:</td>
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<td>• the data sources</td>
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<td>• the attributions required</td>
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<td>• the method and any deviations</td>
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<td>• the analysis methods?</td>
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<td>Have you submitted the plan for</td>
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<td>• approvals from experts</td>
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