

Global AMR R&D Hub approach for presenting the pipeline of antibacterials in clinical development

This representation of antibacterial products in different phases of clinical development and those that have recently been approved by regulators brings together information that is being gathered and analysed by the World Health Organization (WHO) in the reports published since 2017¹ as well as the corresponding data collection and analysis by The Pew Charitable Trusts² (Pew) since 2014.

The Access to Medicines Foundation in its bi-annual Antimicrobial Resistance Benchmark³ also gives information about products in clinical development (reports issued since 2018).

The purpose of this representation is to complement the information shown on the Dynamic Dashboard regarding global investments in AMR R&D as well as the summary of incentives for antibiotic R&D. For detailed analysis, users should access the original sources which provide a large amount of additional information. In this representation the intention was to show a high-level summary, bringing together the information from the WHO and Pew Charitable Trusts analyses.

Approach

The most up-to-date versions of WHO *Antibacterial products in clinical development for priority pathogens* and Pew Charitable Trusts *Antibiotics Currently in Global Clinical Development* were used as the source of information. This representation does not yet fully integrate the information from the Pew Charitable Trusts analysis of *Nontraditional Products for Bacterial Infections in Clinical Development*. Some information was extracted from the Antimicrobial Resistance Benchmark of the Access to Medicines Foundation, especially as regards clinical indications.

The data was downloaded through the Excel spreadsheets available on the WHO and Pew websites and combined into one table. Out of the xxx products currently represented in the Dynamic Dashboard, 34 and 12 were contained only in the WHO and PEW Trusts analyses, respectively. Thirty three products were found in both and information from the two

¹ Most recent edition: 2019 ANTIBACTERIAL AGENTS IN CLINICAL DEVELOPMENT an analysis of the antibacterial clinical development pipeline (available at:

<https://apps.who.int/iris/bitstream/handle/10665/330420/9789240000193-eng.pdf?sequence=1&isAllowed=y>) and https://www.who.int/research-observatory/monitoring/processes/antibacterial_products/en/

² Most recent edition: antibiotics currently in development April 2020, available from

<https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2014/antibiotics-currently-in-clinical-development> and the analysis of non-traditional products for bacterial infections in clinical development, most recent edition March 2020 available from <https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2017/nontraditional-products-for-bacterial-infections-in-clinical-development>

³ <https://accesstomedicinefoundation.org/amr-benchmark>

analyses was manually combined into one data set. In case of divergence, for the phase of clinical investigation in which a product currently is, the value from the newer analysis (Pew) was chosen. Clinical indications and information on the targeted bacteria were combined. In a few cases the assessment of innovation (new target and/or new chemical class) diverges. In such cases the divergent assessments are both shown with their respective source. The methodologies of the two analyses differ, explaining the occasional divergence in assessment.

The available information for each product was combined. Since the data come from different sources and not every source provides the same information, the summaries may not have information for every element.

The products are presented in three large categories, analogous to the manner that products are presented in the WHO analysis:

1. Products addressing priority pathogens
2. Products addressing tuberculosis
3. Products addressing *Clostridioides*

The following criteria can be used for filtering products:

- Phase of clinical testing, product in the approval process or having recently been approved (products that are in more than one phase of clinical development are listed in each of the applicable phases; thus the numbers of products listed for the different phases may not add up to the total number of products)
- New target: yes/no/inconclusive
- New chemical class: yes/no/inconclusive
- Product type: small molecule/biological product
- Expected activity against priority pathogens:
 - Addressing a pathogen that is considered critical by the WHO and that is considered urgent by the US CDC
 - Addressing a pathogen that is considered critical by the WHO
 - Addressing a pathogen that is considered urgent by the US CDC
 - Possibly addressing a pathogen that is considered critical by the WHO and that is considered urgent by the US CDC

This last set of filtering is not relevant for products addressing tuberculosis.

Data was imported into the database running under the Azure environment that is used by the Global AMR R&D Hub for its Dynamic Dashboard and a visualisation was prepared using PowerBI, as for all the Dynamic Dashboard visualisations.

Data will be updated when new analyses are published by either WHO or The Pew Charitable Trusts.