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|  | **CONSULTANCY** |

**Draft Terms of Reference**

To be signed & uploaded as **Contractual** - Terms of reference in GSM/Manage documents

The consultancy is ordered by:

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| Unit: | Impact Initiatives and Research and Coordination (IRC) |
| Department: | Global Coordination and Partnership (GCP) |

1. **Purpose of the Consultancy**

To support the IRC unit in the implementation of the *Global Action Plan* on Antimicrobial Resistance by guiding the data collection and preparation of the advisory group meeting for two subsequent updates of the WHO antibacterial clinical pipeline analysis in 2020 and 2021 respectively.

1. **Consultant’s Name**

TBD

1. **Background**

Antimicrobials resistance is a global public health threat, acknowledged through the endorsement of the Global Action Plan on antimicrobial resistance (AMR)[[1]](#footnote-1) by the World Health Assembly (resolution WHA68.7) on May 2015, the Political Declaration of the high-level meeting of the General Assembly on AMR[[2]](#footnote-2) in September 2017 as well as the report of the UN Interagency Coordination Group (IACG) on Antimicrobial Resistance[[3]](#footnote-3).

Objective five of the Global Action Plan is to develop the economic case for sustainable investment that takes account of the needs of all countries and increases investment in new medicines, diagnostic tools, vaccines, and other interventions. Further political commitments to implement the global action plan and foster R&D of new antibiotics was shown at the United Nations General Assembly at its Seventy-First Session in 2016 at a high-level meeting on antimicrobial resistance and more recently in 2017 at the meeting of the Group of 20. In response, on September 2017, WHO released the priority pathogens list including TB to prioritize R&D efforts for new. Coupled with this report, the WHO undertook the first global analysis of antibacterial agents in clinical development in 2017 and subsequently update this annually. In 2019, for the first time reviewed the preclinical antibacterial pipeline, which will also be updated regularly.

The annual updates of the pipeline analysis aim to assess the robustness of the clinical pipeline overtime against the priority pathogens and TB to facilitate further priority setting for R&D of new therapeutic options. To facilitate two annual updates of the antibacterial clinical pipeline as well as to advise the preclinical pipeline, it is proposed to hire a consultant on a part-time basis to support data collection, analysis and the preparation of two advisory group meetings (2020 and 2021). The data from the updated analysis will feed into the WHO Global Observatory on Health Research and Development (R&D).

1. **Work to be performed**

Objective 1: Review of the existing clinical pipeline and collection of new data to support the update of the WHO global antibacterial clinical development pipeline analysis in 2020 and subsequently in 2021.

Deliverable 1.1: Update the existing WHO clinical pipeline data by collecting new products in phase-1 and reviewing the existing antibacterial products in the clinical pipeline

(<http://www.who.int/medicines/areas/rational_use/antibacterial_agents_clinical_development/en/> ),

including the name, developer, phase, antibiotic class, route of administration, expected activity against the WHO priority pathogens list, *C. difficile* and TB and potential innovativeness of each product as well as the funder/s for each product for validation by the advisory group in 3rd/4th quarter of 2020 and 2021.

Deliverable 1.2: Collect data on non-traditional antibacterial agents in clinical development, including the name, developer, phase, antibiotic class, route of administration, expected activity against the WHO priority pathogens list, and potential innovativeness of each product, as well as the funder/s for each product t for validation by the advisory group in 3rd/4th quarter of 2020 and 2021.

Deliverable 1.3: Support the WHO IRC/GCP unit in developing additional criteria for evaluating the clinical antibacterial pipeline products focusing on their potential clinical utility.

Objective 2: Support two advisory group meetings in 2020 and 2021:

Deliverable 2.1: Support the WHO IRC/GCP unit in the preparation for the advisory group meeting in the 3rd/4th quarter of 2020 and 2021 including preparation of meeting background documents and presentation of the data collected on the antibacterial products in the clinical pipeline. Participate in both meetings.

Deliverable 2.2: Finalize the qualitative analysis of antibacterial agents in clinical pipeline in 2020 and 2021 following the advisory group meetings resulting in two WHO publications.

Delivery 2.3: Review and update the excel document of the pipeline documents for uploading in the WHO Global Observatory on Health R&D

([http://www.who.int/research observatory/monitoring/processes/antibacterial\_products/en/](http://www.who.int/research%20observatory/monitoring/processes/antibacterial_products/en/)) in 2020 and 2021.

Deliverable 2.3: Prepare two WHO reports of the respective expert meetings with input from WHO IRC/GCP unit and one journal publications (2020 or2021) for peer-review based on the above analysis for potential submission to relevant journals/periodicals.

Objective 3: Provide advice to the 2020 and 2021 preclinical pipeline review of the pipeline.

Deliverable 3.1: Provide advisory support to the 2020 and 2021 preclinical review update including the annual open data call and the overall data review.

1. **Technical Supervision**

The selected Consultant will work on the supervision of:

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| Responsible Officer: | Sarah Paulin, Technical Officer, GCP, IRC | Email: | paulins@who.int |
| Manager: | Peter Beyer, Senior Advisor, GCP, IRC | Email: | beyerp@who.int |

1. **Timelines**

Start date: 01/04/2020

End date: 01/12/2021

1. **Specific requirements**

Qualifications required:

* Ph.D. in microbiology, molecular biology, organic chemistry or another field related to antibiotic drug discovery

Experience required:

* At least 15 years of relevant experience in the area of microbiology and antibacterial drug R&D.
* Strong expertise in Pharmacokinetics/Pharmacodynamics in order to evaluate the effect of dosages and formulations on the effectiveness of drugs and the likeliness of resistances to emerge.
* In-depth understanding of clinical needs in bacterial infections and experience with antibacterial clinical trials
* A track record of coordinating international scientific projects, preferably in the field of antibiotic resistance
* Experience in communicating research projects and their results to policymakers and the research community
* Track record of peer-reviewed publications on antibiotic resistance and drug discovery
* Good writing skills, the track record of publications on antibiotic resistance and drug discovery

Language requirements:

* English – proficient (reading, writing, speaking)

1. **Place of assignment**

Most of the work under this consultancy will be home-based and carried out at the consultant’s usual place of residence. One travel to Ho Chi Minh City, Vietnam in 2020 and one travel to Geneva, Switzerland (or another venue) in 2021 for the advisory group meetings.

1. **Medical clearance**

The selected Consultant will be expected to provide a medical certificate of fitness for work.

1. **Travel**

The Consultant is expected to travel according to the itinerary and estimated schedule below:

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| **Travel dates** | | | | **Location:** |
| From | Nov 2020 | To | Nov 2020 | Ho Chi Minh City, Vietnam |
| **Purpose:** | | Advisory Group meeting 2020 | | |

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| **Travel dates** | | | | **Location:** |
| From | Oct/Nov  2021 | To | Oct/Nov  2021 | Geneva, Switzerland |
| **Purpose:** | | Advisory Group meeting 2021 | | |

*All* ***travel arrangements*** *will be made by WHO – WHO will not be responsible for tickets purchased by the Consultant without the express, prior authorization of WHO. While on mission under the terms of this consultancy, the Consultant will receive* ***subsistence allowance****.*

*Visas requirements: it is the consultant’s responsibility to fulfil* ***visa requirements*** *and ask for visa support letter(s) if needed.*

1. Global Action Plan on Antimicrobial Resistance. Geneva: World Health Organization; 2015 [↑](#footnote-ref-1)
2. Political Declaration of the High-Level Meeting of the General Assembly on Antimicrobial Resistance. New York: United Nations; 2016 [↑](#footnote-ref-2)
3. https://www.who.int/antimicrobial-resistance/interagency-coordination-group/en/ [↑](#footnote-ref-3)