CALL GUIDE

The Health Technology Assessment (HTA) Philippines invites interested Filipino researchers to submit <u>capsule proposals</u> under the HTA Research Agenda 2024 - Batch 2 (Cycle 2 Topics)

- The **HTA Research Agenda 2024: Batch 2 (Cycle 2 Clinical Assessments)** consists of prioritized health technology topics per disease area under the HTA general track.
    - Chronic obstructive pulmonary disease (COPD)
    - Breast cancer
    - Lung cancer
    - Ovarian cancer
    - Diabetes mellitus (DM)
    - Stroke
    - Patients with liver lesions/pathologies
    - Meningococcal infections
    - Diffuse large B Cell Lymphoma

HTA Research Agenda 2024 - Batch 2 topics

The following are the health technology topics for clinical assessments to be funded under this Call for Capsule Proposals:

<u>COPD</u>
- Budesonide/ Glycopyrronium/ Formoterol
- Fluticasone/ Umeclidinium/ Vilanterol

<u>Breast Cancer</u>
- Exemestane
- Pertuzumab
- Pertuzumab/Trastuzumab
- Eribulin for metastatic triple negative breast cancer
- Eribulin for metastatic human epidermal growth factor receptor 2 (HER2)-negative breast cancer

<u>Lung Cancer</u>
- Durvalumab
- Gefitinib
- Lorlatinib
- Alectinib
- Osimertinib

<u>Diabetes mellitus</u>
- Insulin glargine for Type 1 DM
- Insulin glargine for Type 2 DM
- Insulin glargine/Lixisenatide for Type 2 DM

<u>Other Priority topics</u>
- Edoxaban (stroke)
- Gadoxetic (patients with liver lesions/pathologies)
- Meningococcal polysaccharide groups A, C, W-135 and Y conjugate vaccine (infant meningitis)
- Olaparib (ovarian cancer)
- Polatuzumab (diffuse large B cell lymphoma)

Please refer to the attached ***Annex C*** for the details on the project objectives, expected outputs, project duration, and budget estimate.

General Guidelines

1. There shall be two (2) stages in the proposal evaluation. First is the submission of a capsule proposal, and the second is the submission of a full proposal. The full proposal is to be submitted only upon approval of the capsule proposal.
2. Interested and eligible proponents may notify the HTA Philippines through email of their expression of interest to submit a capsule proposal (along with other requirements discussed under *How to Apply* section) within ten (10) working days from the posting of the call. From the date of expression of interest, proponents shall submit capsule proposals within ten (10) working days.
3. The methodologies of the capsule proposal should be guided by the interim second edition of the Philippine HTA Methods Guide.
4. Interested proponents are enjoined to submit proposals based on the clustered health technologies, as shown under *Annex C*.
5. For the estimation of budget proposal, below are our recommended rates depending on the specific clinical assessment methodologies which should be guided by an initial scoping of available evidence:

Clinical Assessment Method	**All-in New Rates** *(inclusive of tax)*	**Tax Exclusive Rates** *(Excluding Tax)*	**Duration**
Pairwise	₱ 400,000.00	₱ 392,000.00	**6 months** 5 months (clinical assessment) + 1 month (payment processing)
Network Meta-Analysis (NMA)	₱ 800,000.00	₱ 696,500.00	

6. The capsule proposal shall be evaluated based on the following criteria:
   a. *Relevance & Sensitivity* - Alignment of the research questions and objectives to the research agenda
   b. *Technical/Scientific* - Sound methodology; alignment to the research questions and HTA Methods Guide
   c. *Data Management* - Technical merit on handling and management of data
   d. *Financial Feasibility* - Alignment of the projected project costs to the allocated budget for the research
   e. *Proponent's/Institutional Capacity* - Good track record or CV with proven competence to implement and complete the project within the approved duration and budget
   f. *Conflict of Interest (COI)* - No significant COI; following the COI declaration in the HTA Process Guide

7. The review process of the HTA Philippines is aimed to be accomplished within five (5) working days from the receipt of the proposal **provided that complete requirements have been submitted**. The proponent may need to revise the capsule proposal on the basis of the recommendations of the reviewers and the deadline for this shall be communicated by the HTA Philippippines to the proponent.
8. Proponents of approved capsule proposals shall be notified to proceed to the submission of the full proposal (*details to be provided*).

Note: These guidelines only refer to the review of capsule proposals. A separate set of guidelines shall be issued for the processing and approval of the full proposals.

Who may apply for the grant?

Filipinos with **at least a Master's Degree** in a relevant field, have proven research competence / track record, and **employed in universities/colleges**, **research agencies/institutions**, **hospitals**, **and other health related agencies** are eligible to apply for the research grant.

How to apply?

Interested researchers shall submit the following requirements via email to **htaresearch@dost.gov.ph**:

- **Capsule proposal** should not be more than two (2) pages (Arial font 11, single spacing) [*Annex A*; Link to downloadable template]
- **Budget Proposal:** [*General Guidelines #5*: Current HTA PH recommended rates for clinical assessment can be adopted and basis of the budget proposal]
- ***Curriculum Vitae* (CV)** or **Personal Data Sheet (PDS)** of the Project Leader and Team Members
- **COI Declaration** of the Project Leader and Team Members [Annex B; Link to downloadable template]
- **Cover letter** to the DOST- HTA Division addressed to:

ANNE JULIENNE G. MARFORI, RPh, MSc
Chief, HTA Division
Department of Science and Technology

1. HTA Philippines will also require the proponent to submit an ethics clearance for studies involving human subjects, if applicable, before the start of project implementation.
2. For submissions from the private sector/non-government organizations, please include the following additional requirements of the Implementing Agency/ Institution:
    - Business/ Mayor's Permit
    - PhilGEPS registration
    - Latest Income Tax Return
    - Certification of completion from previous grants/contracts

Deadline of submission of the abovementioned requirements: *Within 10 days after expression of interest*

Any concerns or questions?

For any questions, comments or concerns, please email us at **htaresearch@dost.gov.ph**.

ANNEX A - Template of Capsule Proposal

Title:
Authors:
Affiliations:

I. **BACKGROUND:**

II. **OBJECTIVES:**

III. **METHODOLOGY:**

IV. **ESTIMATED BUDGET:**

V. **DURATION OF PROJECT IMPLEMENTATION**

VI. **LIST OF REFERENCES:**

Note: The capsule proposal should not be more than two (2) pages (Arial font 11, single spacing).

ANNEX B. Disclosure of Conflict of Interest (COI) Form

DISCLOSURE OF CONFLICT OF INTEREST

PART 1. FINANCIAL INTERESTS ***[Note: Declare all relevant activities for the last 5 years)***
refers to any competing monetary and in-kind benefits interests gained (e.g., salary or other payments for services or equity interests such as stocks, stock options, intellectual property rights, other incentives, among others)

To the best of your knowledge, do you or any of your relatives within the fourth (4th) civil degree have any involvement with any of the following within the last five (5) years:

a. **INVESTMENTS** *(e.g. stocks, bonds, retirement plans, trust, partnerships, sector funds, etc.)* □ **NONE** (If "none", skip to Item b.)

ESTABLISHMENT	TYPE OF INVESTMENT	OWNER (self, spouse, etc.)	NUMBER OF SHARES	CURRENT VALUE	CHECK PERCENTAGE NET WORTH		
					LESS THAN 5%	5-15%	MORE THAN 15%

b. EMPLOYMENT (Full or Part Time) (Last 12 Months, Current or Under Negotiation) □ NONE (If "none", skip to Item c.)

ESTABLISHMENT	RELATIONSHIP	POSITION IN FIRM	DATE EMPLOYMENT OR NEGOTIATIONS BEGAN

c. CONTRACTS/GRANTS □ **NONE** (If "none", skip to Item e.)

TYPE OF AGREEMENT (contract, grant)	PRODUCT UNDER STUDY AND INDICATIONS	AMOUNT OF REMUNERATION TO		TIME PERIOD	SPONSOR*	YOUR ROLE**	AWARDEE	RELATED TO LISTED PRODUCTS/ INDICATIONS/ ISSUES
		INSTITU-TION	YOU					
								□ YES □ NO
								□ YES □ NO
								□ YES □ NO
								□ YES □ NO

* Government, Establishment, Institution, Individual

** Site Investigator, Principal Investigator, Co-Investigator, Employee, Partner, No Involvement, or Other

d. SPEAKING/WRITING □ **NONE** (If "none", skip to Item g.)

FIRM	TOPIC/ISSUE	AMOUNT RECEIVED		DATES	RELATED TO LISTED PRODUCTS/ INDICATIONS/ ISSUES
		HONORARIUM	TRAVEL		
					□ YES □ NO
					□ YES □ NO
					□ YES □ NO

e. INTELLECTUAL PROPERTY (PATENTS/ROYALTIES/TRADEMARKS) □ **NONE** (If "none", skip to Item f.)

FOR	ESTABLISHMENT	RELATED TO LISTED PRODUCTS/ INDICATIONS/ ISSUES	IF "YES", EXPLAIN BELOW AND INDICATE INCOME RECEIVED
		□ YES □ NO	
		□ YES □ NO	
		□ YES □ NO	

OTHER FINANCIAL INVOLVEMENTS (Other Kinds of Relationships) □ **NONE** (If "none", write "N/A'.)
Identify any form of rewards or incentives that would give an "appearance" of a conflict which has not been disclosed above.

_____

_____

_____

_____

PART 2. PERSONAL NON-PECUNIARY INTERESTS
Such interests include, but are not limited to:

- personal views or moral conviction on the importance of a particular area or topic that can influence the scientific opinions of other people;
- a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost- effectiveness of an intervention under review;
- a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence;
- holding office in a professional organization or advocacy group with a direct interest in the matter under consideration;
- other personal relations or reputational risks in relation to an intervention under review

To the best of your knowledge, do you have any *personal non-pecuniary interest* related to the health technology as well as its competing products, including but not limited to the following:
Note: For all past activities, they should be declared regardless of the time/period of involvement.

a. MEMBERSHIP TO A PROFESSIONAL ORGANIZATION OR ADVOCACY GROUP (Full or Part Time) (Last 12 Months, Current or Under Negotiation) □ NONE (If "none", skip to Item c.)

ESTABLISHMENT	RELATIONSHIP	POSITION IN THE ORGANIZATION	DATE INVOLVEMENT BEGAN	SPECIFIC TOPICS/ISSUES ADVOCATED FOR, IF ANY

b. MEMBERSHIP TO SPEAKER'S BUREAU □ NONE (If "none", skip to Item d.)
(Past, Current or Under Negotiation)

ESTABLISHMENT	TOPIC/ISSUE	AMOUNT RECEIVED	DATE FROM	DATE TO	RELATED TO LISTED PRODUCTS/ INDICATIONS/ ISSUES

c. CONSULTANT/ADVISOR □ NONE (If "none", skip to Item d.)
(Past, Current or Under Negotiation)

ESTABLISHMENT	TOPIC/ISSUE	AMOUNT RECEIVED	DATE FROM	DATE TO	RELATED TO LISTED PRODUCTS/ INDICATIONS/ ISSUES

d. EXPERT WITNESS (Past, Current or Under Negotiation) □ NONE (If "none", skip to Item g.)
I appeared for or against the following listed establishment(s) and issue(s)

FIRM AND ISSUE	AMOUNT RECEIVED	RELATED TO LISTED PRODUCTS/ INDICATIONS/ ISSUES	IF "YES", EXPLAIN BELOW
		□ YES □ NO	
		□ YES □ NO	
		□ YES □ NO	

OTHER PERSONAL, NON-PECUNIARY INVOLVEMENTS (Other Kinds of Relationships) **□ NONE (If "none", write "N/A'.)**
Identify any past or ongoing personal relations or reputable risks that would give an "appearance" of a conflict which has not been disclosed above (e.g., involvement in a lawsuit, researcher initiated study, personal views or moral conviction on the importance of a particular area or topic that can influence the scientific opinions of other people, activities of the organization in which you serve as an officer, director, trustee, general partner, or employee).

_____

_____

_____

_____

IF MORE SPACE IS NEEDED, PLEASE ATTACH ADDITIONAL PAGES

PART 3. CERTIFICATION STATEMENT

I, _____ designated as _____ of the _____,
(First Name, MI, Family Name) *(Position/Designation, when applicable)* *(Name of Agency, Office, Bureau, Service, Hospital, or Unit)*

do hereby declare in my honor that the above information is true and complete, to the best of my knowledge. If there are any changes, I will promptly notify you. This includes any change that occurs before or during the meeting or work itself and through the period up to the publication of the final results or completion of the activity concerned.

My response contains ____ pages.

NAME AND SIGNATURE OF DECLARANT	**DATE**

CONFIDENTIALITY STATEMENT

The primary use of this information is for review of the HTA Philippines to determine compliance with its General Procedures in the Disclosure and Management of Conflict of Interest.

This confidential report will not be disclosed to any requesting person, unless authorized by law. Falsification of information or failure to file or report of information required to be reported is subject to disciplinary action by the DOST.	
FOR HTA PHILIPPINES USE ONLY	
NAME AND SIGNATURE OF REVIEWING OFFICIAL	**DATE**
COMMENTS OF REVIEWING OFFICIAL	
IF MORE SPACE IS NEEDED, PLEASE ATTACH ADDITIONAL PAGES	

ANNEX C - KEY DETAILS ON THE RESEARCH TOPICS

No	Topic	Objectives	Expected Outputs	Project Duration	Budget
2024 HTA Research Agenda Batch 2					
1	**Assessment of Health Technologies for Chronic Obstructive Pulmonary Disease (COPD)**	**General objective:** To conduct the clinical assessment (using evidence synthesis methodologies) of the priority topics for COPD that will be used by the HTAC in developing recommendations on coverage and financing decisions for DOH and PhilHealth, specifically: a. Budesonide /Glycopyrronium /Formoterol for patients with COPD who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta agonist (LABA) or combination of a LABA and a long-acting muscarinic antagonist (LAMA) and; b. Fluticasone/Umeclidinium/Vilanterol for moderate to severe COPD **Specific objectives:** ● To conduct literature review and stakeholder consultation in setting the Population, Intervention, Comparator, and Outcome (PICO) per topic ● To conduct an initial scoping of evidence that will determine the clinical evidence synthesis methodology track* per topic	● Inception report per COPD topic, to include: ○ suggested scope of the PICO (Population, Intervention, Comparator, Outcomes) of the research question, after content experts consultation ○ Budget and work plan ● SH-consulted PICO per COPD topic ● Checkpoint meetings, as necessary ● Initial Clinical Assessment Report per COPD topic ● Interim Financial Report ● Final Clinical Assessment Report per COPD topic, including oral presentation to the HTA Council Subcommittee assigned to review the topics ● Final Financial Report	6 months	Rates will depend on the type of assessment to be conducted (NMA or Pairwise)

No	Topic	Objectives	Expected Outputs	Project Duration	Budget
		*Possible *clinical evidence synthesis tracks depending on the existing evidence*: ○ de novo systematic review with meta-analysis or network meta-analysis (*as applicable*) ○ updating of an existing systematic review with meta-analysis or network meta-analysis (*as applicable*) ○ adoption of an updated systematic review with meta-analysis or network meta-analysis (*as applicable*) ● To perform clinical evidence synthesis including GRADE rating of evidence, based on the results of the initial scoping of evidence ● To conduct review of country guidelines relevant to the topics ● To develop a technical report of clinical assessments per topic, including oral presentations to HTA Council Subcommittee			
2	**Assessment of Health Technologies for Breast Cancer**	**General objective:** To conduct the clinical assessment (using evidence synthesis methodologies) of the priority topics for breast cancer that will be used by the HTAC in developing recommendations on coverage and financing decisions for DOH and PhilHealth, specifically: a. Exemestane for hormone-receptor positive advanced breast cancer (ABC) in women with natural or induced postmenopausal status	● Inception report per breast cancer topic, to include: ○ suggested scope of the PICO (Population, Intervention, Comparator, Outcomes) of the research question, after content experts consultation ○ Budget and work plan ● SH-consulted PICO per breast		Rates will depend on the type of assessment to be conducted (NMA or Pairwise)

No	Topic	Objectives	Expected Outputs	Project Duration	Budget
		b. Pertuzumab for human epidermal growth receptor 2 (HER2)-positive metastatic or locally recurrent unresectable breast cancer c. Pertuzumab/Trastuzumab for neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early breast cancer d. Eribulin for metastatic triple negative breast cancer e. Eribulin for metastatic HER2-negative breast cancer **Specific objectives:** ● To conduct literature review and stakeholder consultation in setting the Population, Intervention, Comparator, and Outcome (PICO) per topic ● To conduct an initial scoping of evidence that will determine the clinical evidence synthesis methodology track* per topic *Possible *clinical evidence synthesis tracks depending on the existing evidence*: ○ de novo systematic review with meta-analysis or network meta-analysis (*as applicable*) ○ updating of an existing systematic review with meta-analysis or network meta-analysis (*as applicable*) ○ adoption of an updated systematic review with meta-analysis or network meta-analysis (*as applicable*)	cancer topic ● Checkpoint meetings, as necessary ● Initial Clinical Assessment Report per breast cancer topic ● Interim Financial Report ● Final Clinical Assessment Report per breast cancer topic, including oral presentation to the HTA Council Subcommittee assigned to review the topics ● Final Financial Report		

No	Topic	Objectives	Expected Outputs	Project Duration	Budget
		● To perform clinical evidence synthesis including GRADE rating of evidence, based on the results of the initial scoping of evidence ● To conduct review of country guidelines relevant to the topics ● To develop a technical report of clinical assessments per topic, including oral presentations to HTA Council Subcommittee			
3	**Assessment of Health Technologies for Lung Cancer**	**General objective:** To conduct the clinical assessment (using evidence synthesis methodologies) of the priority topics for lung cancer that will be used by the HTAC in developing recommendations on coverage and financing decisions for DOH and PhilHealth, specifically: a. Alectinib for anaplastic lymphoma kinase-positive locally advanced/metastatic Non-Small Cell Lung Cancer (NSCLC) b. Durvalumab for locally advanced NSCLC c. Gefitinib for locally advanced/metastatic NSCLC with activating mutations of epidermal growth factor receptor (EGFR) d. Lorlatinib for anaplastic lymphoma kinase-positive advanced NSCLC e. Osimertinib for adjuvant treatment after tumor resection in patients with NSCLC whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations	● Inception report per lung cancer topic, to include: ○ suggested scope of the PICO (Population, Intervention, Comparator, Outcomes) of the research question, after content experts consultation ○ Budget and work plan ● SH-consulted PICO per lung cancer topic ● Checkpoint meetings, as necessary ● Initial Clinical Assessment Report per lung cancer topic ● Interim Financial Report ● Final Clinical Assessment Report per lung cancer topic, including oral presentation to the HTA Council Subcommittee assigned to review the topics ● Final Financial Report	6 months	Rates will depend on the type of assessment to be conducted (NMA or Pairwise)

No	Topic	Objectives	Expected Outputs	Project Duration	Budget
		Specific objectives: ● To conduct literature review and stakeholder consultation in setting the Population, Intervention, Comparator, and Outcome (PICO) per topic ● To conduct an initial scoping of evidence that will determine the clinical evidence synthesis methodology track* per topic *Possible *clinical evidence synthesis tracks depending on the existing evidence*: ○ de novo systematic review with meta-analysis or network meta-analysis (*as applicable*) ○ updating of an existing systematic review with meta-analysis or network meta-analysis (*as applicable*) ○ adoption of an updated systematic review with meta-analysis or network meta-analysis (*as applicable*) ● To perform clinical evidence synthesis including GRADE rating of evidence, based on the results of the initial scoping of evidence ● To conduct review of country guidelines relevant to the topics ● To develop a technical report of clinical assessments per topic, including oral presentations to HTA Council Subcommittee			

No	Topic	Objectives	Expected Outputs	Project Duration	Budget
4	**Assessment of Health Technologies for Diabetes mellitus (DM)**	**General objective:** To conduct the clinical assessment (using evidence synthesis methodologies) of the priority topics for DM that will be used by the HTAC in developing recommendations on coverage and financing decisions for DOH and PhilHealth, specifically: a. Insulin glargine for Type 1 DM (T1DM) b. Insulin glargine for Type 2 DM (T2DM) c. Insulin glargine/Lixisenatide for T2DM **Specific objectives:** ● To conduct literature review and stakeholder consultation in setting the Population, Intervention, Comparator, and Outcome (PICO) per topic ● To conduct an initial scoping of evidence that will determine the clinical evidence synthesis methodology track* per topic *Possible *clinical evidence synthesis tracks depending on the existing evidence*: ○ de novo systematic review with meta-analysis or network meta-analysis (*as applicable*) ○ updating of an existing systematic review with meta-analysis or network meta-analysis (*as applicable*) ○ adoption of an updated systematic review with meta-analysis or network meta-analysis (*as applicable*) ● To perform clinical evidence synthesis including GRADE rating of evidence,	● Inception report per DM topic, to include: ○ suggested scope of the PICO (Population, Intervention, Comparator, Outcomes) of the research question, after content experts consultation ○ Budget and work plan ● SH-consulted PICO per DM topic ● Checkpoint meetings, as necessary ● Initial Clinical Assessment Report per DM topic ● Interim Financial Report ● Final Clinical Assessment Report per DM topic, including oral presentation to the HTA Council Subcommittee assigned to review the topics ● Final Financial Report	6 months	Rates will depend on the type of assessment to be conducted (NMA or Pairwise)

No	Topic	Objectives	Expected Outputs	Project Duration	Budget
		based on the results of the initial scoping of evidence ● To conduct review of country guidelines relevant to the topics ● To develop a technical report of clinical assessments per topic, including oral presentations to HTA Council Subcommittee			
5	**Assessment of Health Technologies for other health priority topics**	**General Objective** To conduct the clinical assessment (using evidence synthesis methodologies) of the priority topics that will be used by the HTAC in developing recommendations on coverage and financing decisions for DOH and PhilHealth, specifically: a. Edoxaban for acute ischemic stroke in adults with nonvalvular atrial fibrillation b. Gadoxetic acid (Disodium) for T1-weighted magnetic resonance imaging of the liver c. Meningococcal polysaccharide groups A, C, W-135 and Y conjugate vaccine for the active immunization of individuals from the age of 6 week against invasive meningococcal diseases caused by Neisseria meningitidis group A, C, W-135 and Y d. Olaparib for newly diagnosed advanced BRCA-mutated, high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response to first-line platinum-based chemotherapy e. Polatuzumab for treatment of adult patients with diffuse large B-cell	● Inception report per priority topic, to include: ○ suggested scope of the PICO (Population, Intervention, Comparator, Outcomes) of the research question, after content experts consultation ○ Budget and work plan ● SH-consulted PICO per priority topic ● Checkpoint meetings, as necessary ● Initial Clinical Assessment Report per priority topic ● Interim Financial Report ● Final Clinical Assessment Report per priority topic, including oral presentation to the HTA Council Subcommittee assigned to review the topics ● Final Financial Report	6 months	Rates will depend on the type of assessment to be conducted (NMA or Pairwise)

No	Topic	Objectives	Expected Outputs	Project Duration	Budget
		lymphoma who have received at least one prior therapy **Specific objectives:** ● To conduct literature review and stakeholder consultation in setting the Population, Intervention, Comparator, and Outcome (PICO) per topic ● To conduct an initial scoping of evidence that will determine the clinical evidence synthesis methodology track* per topic *Possible *clinical evidence synthesis tracks depending on the existing evidence*: ○ de novo systematic review with meta-analysis or network meta-analysis (*as applicable*) ○ updating of an existing systematic review with meta-analysis or network meta-analysis (*as applicable*) ○ adoption of an updated systematic review with meta-analysis or network meta-analysis (*as applicable*) ● To perform clinical evidence synthesis including GRADE rating of evidence, based on the results of the initial scoping of evidence ● To conduct review of country guidelines relevant to the topics ● To develop a technical report of clinical assessments per topic, including oral presentations to HTA Council Subcommittee			