CALL GUIDE

The Health Technology Assessment (HTA) Philippines invites interested researchers to submit <u>capsule proposals</u> under the 2024 HTA Topics - Batch 3 Call *[FEC topics and Cycle 1 topics for Economic Assessments and Ethical, Legal, Social, and Health Systems Implication (ELSHI) Assessments]*

- This call consists of prioritized health technology topics that underwent clinical assessment under the HTA general track and are proceeding to the following assessments:
    - **Economic assessment**: Economic evaluation (EE), Budget Impact Analysis (BIA) and Household Financial Impact (HFI) Analysis
    - **ELSHI assessment**: Scoping review of ELSHI evidence *(and systematic review and primary data collection, if deemed necessary)*

2024 HTA topics - Batch 3

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

<u>HTA Topics for Economic Assessment</u>

For Cost-Effectiveness/Utility Analysis (CEA/CUA)

1. Ranibizumab, Aflibercept and Dexamethasone as first-line treatment for Diabetic Macular Edema (DME)
2. Ranibizumab compared to Dexamethasone as first-line treatment for Macular Edema secondary to Retinal Vein Occlusion (ME-RVO)
3. Nilotinib compared with Imatinib for adult patients with Philadelphia-positive, chronic myeloid leukemia in chronic phase
4. Rapid-acting Insulin Analogs (insulin aspart, insulin lispro, insulin glulisine) compared with regular insulin among Type 1 Diabetes Mellitus (T1DM) patients on basal insulins (i.e., neutral protamine Hagedorn (NPH) or long-acting insulins (LAIs))
5. Rapid-acting Insulin Analogs (insulin aspart, insulin lispro, insulin glulisine) compared with regular insulin among Type 2 Diabetes Mellitus (T2DM) patients on non-insulin medications or basal insulins with or without other medications
6. Brentuximab Vedotin versus placebo or standard of care among adult patients with relapsed or refractory CD30+ Hodgkin lymphoma following autologous stem cell transplant (ASCT) or following at least 2 prior therapies when ASCT or multi-agent chemotherapy are not suitable
7. Ivabradine in addition to standard of care (SOC) (i.e., beta blockers) in comparison to SOC alone for adult patients aged 19 years old and above with chronic heart failure and with chronic stable angina or, with resting heart rate (HR) > 70 beats per minute (bpm) who are in sinus rhythm, despite being on optimized guideline-directed medical therapy (GDMT), or when GDMT is contraindicated
8. Ticagrelor 60 mg (alone or in combination with aspirin) compared with aspirin alone or clopidogrel (alone or in combination with aspirin) for adult patients with a history of myocardial infarction at least one year ago and high risk of developing a thrombotic event

For Cost-Minimization Analysis (CMA)

9. Ranibizumab compared to Aflibercept as first-line treatment for Wet Age-related Macular Degeneration (wAMD)

For Model-based CMA

10. Dipeptidyl peptidase-4 (DPP-4) inhibitors compared to sulfonylureas or SGLT2 inhibitors for adult type 2 diabetes mellitus (DM) patients inadequately controlled on metformin monotherapy

HTA topics for ELSHI Assessment

1. Ranibizumab, Aflibercept and Dexamethasone as first-line treatment for Diabetic Macular Edema (DME)
2. Ranibizumab compared to Dexamethasone as first-line treatment for Macular Edema secondary to Retinal Vein Occlusion (ME-RVO)
3. Ranibizumab compared to Aflibercept as first-line treatment for Wet Age-related Macular Degeneration (wAMD)
4. Nilotinib compared with Imatinib for adult patients with Philadelphia-positive, chronic myeloid leukemia in chronic phase
5. Erdosteine compared to acetylcysteine or carbocisteine among adult patients with chronic obstructive pulmonary disease (COPD) GOLD GRADE 1 and above
6. Dipeptidyl peptidase-4 (DPP-4) inhibitors compared to sulfonylureas or SGLT2 inhibitors for adult type 2 diabetes mellitus (DM) patients inadequately controlled on metformin monotherapy
7. Rapid-acting Insulin Analogs (insulin aspart, insulin lispro, insulin glulisine) compared with regular insulin among Type 1 Diabetes Mellitus (T1DM) patients on basal insulins (i.e., neutral protamine Hagedorn (NPH) or long-acting insulins (LAIs))
8. Rapid-acting Insulin Analogs (insulin aspart, insulin lispro, insulin glulisine) compared with regular insulin among Type 2 Diabetes Mellitus (T2DM) patients on non-insulin medications or basal insulins with or without other medications
9. Brentuximab Vedotin versus placebo or standard of care among adult patients with relapsed or refractory CD30+ Hodgkin lymphoma following autologous stem cell transplant (ASCT) or following at least 2 prior therapies when ASCT or multi-agent chemotherapy are not suitable
10. Ivabradine in addition to standard of care (SOC) (i.e., beta blockers) in comparison to SOC alone for adult patients aged 19 years old and above with chronic heart failure and with chronic stable angina or, with resting heart rate (HR) > 70 beats per minute (bpm) who are in sinus rhythm, despite being on optimized guideline-directed medical therapy (GDMT), or when GDMT is contraindicated
11. Ticagrelor 60 mg (alone or in combination with aspirin) compared with aspirin alone or clopidogrel (alone or in combination with aspirin) for adult patients with a history of myocardial infarction at least one year ago and high risk of developing a thrombotic event

Based on the HTA Methods Guide, there are various methodologies for ELSHI assessment. The standard methodology is a scoping review, and additional methodologies, as deemed necessary, may include Qualitative Systematic Review (QSR) or primary data collection methods such as Focus Group Discussions (FGDs) or Key Informant Interviews (KIIs). The determination of whether additional methodologies are needed shall be guided by a review of existing evidence by the proponent.

Please refer to the attached ***Annex C*** for the specific Terms of Reference (TOR) per topic assessment.

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 of the listed health technologies, as shown under *Annex C*.
5. For the estimation of budget proposal, below are our recommended rates depending on the specific economic and ELSHI assessment methodologies which should be guided by an initial scoping of available evidence:

Economic Assessment Method	**Estimated All-in New Rates**	**Duration**
Cost Minimization Analysis (CMA)	₱ 550,000.00	**7 months** 6 months (economic assessment) + 1 month (payment processing)
Model-based CMA	₱ 750,000.00	**9 months** 8 months (economic assessment) + 1 month (payment processing)
Cost-Effectiveness Analysis (CEA)	₱ 850,000.00	**10 months** 9 months (economic assessment) + 1 month (payment processing)
ELSHI Assessment Method	**Estimated All-in New Rates**	**Duration**
Scoping review only	₱ 300,000.00	**3 months** 2 months (ELSHI assessment) + 1 month (payment processing)
Scoping review + adopting Qualitative Systematic Review (QSR)	₱ 400,000.00	**5 months** 4 months (ELSHI assessment) + 1 month (payment processing)
Scoping review + de novo SR/updating QSR	₱ 550,000.00	**7 months** 6 months (ELSHI assessment) + 1 month (payment processing)
Scoping review + primary data collection	₱ 550,000.00	**7 months** 6 months (ELSHI assessment) + 1 month (payment processing)

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 Philippines 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?

Researchers 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.

_____

_____

_____

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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

2024 HTA Research Agenda Batch 3 [FEC and Cycle 1 EE and ELSHI]	
Topic Assessment	**Link to TOR**
Economic Assessment	
1. Ranibizumab compared to Aflibercept as first-line treatment for Wet Age-related Macular Degeneration (wAMD) [CMA]	https://tinyurl.com/CMA-WAMD
2. Ranibizumab, Aflibercept and Dexamethasone as first-line treatment for Diabetic Macular Edema (DME) [CEA/CUA]	https://tinyurl.com/Economic-DME
3. Ranibizumab compared to Dexamethasone as first-line treatment for Macular Edema secondary to Retinal Vein Occlusion (ME-RVO) [CEA/CUA]	https://tinyurl.com/Economic-MERVO
4. Nilotinib compared with Imatinib for adult patients with Philadelphia-positive, chronic myeloid leukemia in chronic phase [CEA/CUA]	https://tinyurl.com/Economic-Nilotinib
5. Dipeptidyl peptidase-4 (DPP-4) inhibitors compared to sulfonylureas or SGLT2 inhibitors for adult type 2 diabetes mellitus (DM) patients inadequately controlled on metformin monotherapy [model-based CMA]	https://tinyurl.com/CMA-DPP4i
6. Rapid-acting Insulin Analogs (insulin aspart, insulin lispro, insulin glulisine) compared with regular insulin among Type 1 Diabetes Mellitus (T1DM) patients on basal insulins (i.e., neutral protamine Hagedorn (NPH) or long-acting insulins (LAIs)) [CEA/CUA]	https://tinyurl.com/Economic-T1DM
7. Rapid-acting Insulin Analogs (insulin aspart, insulin lispro, insulin glulisine) compared with regular insulin among Type 2 Diabetes Mellitus (T2DM) patients on non-insulin medications or basal insulins with or without other medications [CEA/CUA]	https://tinyurl.com/Economic-T2DM
8. Brentuximab Vedotin versus placebo or standard of care among adult patients with relapsed or refractory CD30+ Hodgkin lymphoma following autologous stem cell transplant (ASCT) or following at least 2 prior therapies when ASCT or multi-agent chemotherapy are not suitable [CEA/CUA]	https://tinyurl.com/Economic-Brentuximab
9. Ivabradine in addition to standard of care (SOC) (i.e., beta blockers) in comparison to SOC alone for adult patients aged 19 years old and above with chronic heart failure and with chronic stable angina or, with resting heart rate (HR) > 70 beats per minute (bpm) who are in sinus rhythm, despite being on optimized guideline-directed medical therapy (GDMT), or when GDMT is contraindicated [CEA/CUA]	https://tinyurl.com/Economic-Ivabradine
10. Ticagrelor 60 mg (alone or in combination with aspirin) compared with aspirin alone or clopidogrel (alone or in combination with aspirin) for adult patients with a history of myocardial infarction at least one year ago and high risk of developing a thrombotic event [CEA/CUA]	https://tinyurl.com/Economic-TicagrelorTE

Topic Assessment	Link to TOR
ELSHI Assessment	
1. Ranibizumab, Aflibercept and Dexamethasone as first-line treatment for Diabetic Macular Edema (DME)	**https://tinyurl.com/ELSHI-TOR** *Note: The final TOR to be developed is based on the type of ELSHI assessment to be conducted (after approval of full proposal)*
2. Ranibizumab compared to Dexamethasone as first-line treatment for Macular Edema secondary to Retinal Vein Occlusion (ME-RVO)	
3. Ranibizumab compared to Aflibercept as first-line treatment for Wet Age-related Macular Degeneration (wAMD)	
4. Nilotinib compared with Imatinib for adult patients with Philadelphia-positive, chronic myeloid leukemia in chronic phase	
5. Erdosteine compared to acetylcysteine or carbocisteine among adult patients with chronic obstructive pulmonary disease (COPD) GOLD GRADE 1 and above	
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