CALL GUIDE

The Health Technology Assessment (HTA) Philippines invites interested researchers to submit <u>capsule proposals</u> under the 2024 HTA Topics - Batch 3 & Batch 4 Call [REPOST of FEC topics and Cycle 1 topics for Economic Assessments]

This call consists of prioritized health technology topics that underwent clinical assessment under the
HTA general track and are proceeding to economic assessment which includes economic
evaluation (EE), budget impact analysis (BIA) and household financial impact (HFI) analysis to
assess both the value for money of a health technology and its affordability or the feasibility of publicly
funding the health technology relative to the Philippine context.

2024 HTA topics - Batch 3 & Batch 4

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

HTA Topics for Economic Assessment

For Cost-Effectiveness/Utility Analysis (CEA/CUA) + Budget Impact Analysis (BIA) + Household Financial Impact (HFI) Analysis

- 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. 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))
- 4. 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
- 5. 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
- 6. 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
- Tirofiban in combination with heparin compared to usual care [e.g., unfractionated or low-molecular weight heparin (alone), aspirin, clopidogrel] among patients aged > 19 years old with coronary ischemic syndromes (CIS) undergoing coronary angioplasty or atherectomy
- Tirofiban in combination with heparin compared to usual care [e.g., unfractionated or low-molecular weight heparin (alone), aspirin, clopidogrel] among patients aged > 19 years old with Non-ST Elevation Acute Coronary Syndrome (NSTE-ACS) including Non-ST Elevation Myocardial Infarction (NSTEMI) or Unstable Angina (UA)

For Cost-Minimization Analysis (CMA) + BIA + HFI Analysis

- 9. Ranibizumab compared to Aflibercept as first-line treatment for Wet Age-related Macular Degeneration (wAMD)
- 10. Paliperidone palmitate 3-months (PP3M) compared to Paliperidone palmitate 1-month (PP1M) among adult patients with schizophrenia who have been adequately treated with PP1M for at least four months

For Model-based CMA + BIA + HFI Analysis

11. 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

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.
- 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 <u>interim second edition of the</u> <u>Philippine HTA Methods Guide</u>.
- 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 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) + BIA + HFI Analysis	₱ 550,000.00	7 months 6 months (economic assessment) + 1 month (payment processing)
Model-based CMA + BIA + HFI Analysis	₱ 750,000.00	9 months 8 months (economic assessment) + 1 month (payment processing)
Cost-Effectiveness Analysis (CEA) + BIA + HFI Analysis	₱ 850,000.00	10 months 9 months (economic 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 working 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

			DISCLOSU	RE OF CONFLICT	OF INTEREST			
PART 1. FINANCIAL IN refers to any competin other incentives, amon	ig monetary and in-k			years) lary or other payments fo	r services or equity i	interests such as st	cocks, stock options, inte	ellectual property rights,
To the best of your kno	wledge, do you or any	y of your relatives wi	thin the fourth (4t	h) civil degree have any ir	volvement with any	of the following w	vithin the last five (5) ye	ars:
a. INVESTMENTS (e.g. sector funds, etc.)	g. stocks, bonds, retir	rement plans, trust,	partnerships,		f "none", skip to Iten	n b.)		
		TYPE OF	OWNER (self,		CURRENT	СН	IECK PERCENTAGE NET \	WORTH
ESTABLI	ISHMENT	INVESTME NT	spouse, etc.)	NUMBER OF SHARES	VALUE	LESS THAN 5%	5-15%	MORE THAN 15%
	II or Part Time) (Last 1					E (If "none", skip to	o Item c.) DATE EMPLOYMENT (OR NEGOTIATIONS
ESTABLI	SHMENT	RELATIONSHI	P	POSITION			BEGA	N
c. CONTRACTS/GRAM	NTS						□ NONE (If "none", sk	ip to Item e.)
TYPE OF	PRODUCT UNDER STUDY		UNT OF RATION TO					RELATED TO LISTED
AGREEMENT (contract, grant)	AND INDICATIONS	INSTITU-TION	YOU	TIME PERIOD	SPONSOR*	YOUR ROLE**	AWARDEE	PRODUCTS/ INDICATIONS/ ISSUES
								□ YES □ NO
								□ YES □ NO
								□ YES □ NO
								□ YES □ NO
* Government, Establ	lishment, Institution, I	ndividual		1		1		

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

d. SPEAKING/WRITING				□ NONE (If "n	one", skip to Item g.)
FIRM	TOPIC/ISSUE	AMOUNT RECEIVED HONORARIUM TRAVEL		DATES	RELATED TO LISTED PRODUCTS/ INDICATIONS/ ISSUES
					□ YES □ NO

							□ YES □ NO	
							□ YES □ NO	
e. INTELLECTUAL PROPERTY (PATENTS	/ROYALTIES/TRADEMARKS)					□ NONE (If "no	one", skip to Item f.)	
FOR	ESTABLISHMENT		RELATED TO INDICATIONS/ ISSUES	RELATED TO LISTED PRODUCTS/ INDICATIONS/ ISSUES			IF "YES", EXPLAIN BELOW AND INDICATE INCOME RCEIVED	
			□ YES □ NO	□ YES □ NO				
			□ YES □ NO					
			□ YES □ NO	∃ NO				
HER FINANCIAL INVOLVEMENTS (Oth entify any form of rewards or incentive	• •	NONE (If "none nce" of a conflict v		d above.				
	be declared regardless of the t	o an intervention un ry interest related t time/period of invo	nder review to the health technology as v Ivement.			-	not limited to the following:	
	RELATIONSHIP	POSITION IN	I THE ORGANIZATION	DATE INVOLVEMENT BEGAN			CIFIC TOPICS/ISSUES	
							OCATED FOR, IT ANT	
b. MEMBERSHIP TO SPEAKER'S BURE				one", skip to Ite	am d)			
(Past, Current or Under Negotiation) ESTABLISHMENT		TOPIC/ISSUE		DATE FROM		DATE PI	RELATED TO LISTED RODUCTS/ INDICATIONS/ ISSUES	
:. CONSULTANT/ADVISOR Past, Current or Under Negotiation)			□ NONE (If "n	one", skip to Ite	m d.)			
ESTABLISHMENT	TOPIC/ISSUE	TOPIC/ISSUE		DATE FROM	1	DATE PR TO	RELATED TO LISTED ODUCTS/ INDICATIONS/ ISSUES	

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d. EXPERT WITNESS (Past, Current or I appeared for or against the following					□ NONE (If "none", skip to Item g.)	
FIRM AND ISSUE	AMOUNT RECEIVED RELATED INDICATION			TED PRODUCT	S/ E	IF "YES", EXPLAIN BELOW	
			□ YES □ NO				
			□ YES □ NO	NO			
			□ YES □ NO				
Identify any past or ongoing personal initiated study, personal views or more	OTHER PERSONAL, NON-PECUNIARY INVOLVEMENTS (Other Kinds of Relationships) INONE (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 ATT	ACH ADDITIONAL PAGES						
PART 3. CERTIFICATION STATEMENT							
occurs before or during the meeting or w	I, of the,						that
My response contains pages.			l				
NAME AND SIGNATURE OF DECLARANT	ME 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.							
	le or report of information required to be i	reported is	subject to disciplinary acti	on by the DOST.			
FOR HTA PHILIPPINES USE ONLY NAME AND SIGNATURE OF REVIEWING (OFFICIAL		DATE				
COMMENTS OF REVIEWING OFFICIAL							
COMMENTS OF REVIEWING OFFICIAL							
IF MORE SPACE IS NEEDED, PLEASE ATTA	CH ADDITIONAL PAGES						

ANNEX C - KEY DETAILS ON THE RESEARCH TOPICS

202	24 HTA Research Agenda Batch 3 & Batch 4 [FEC	C 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/WAMD-Economic					
2.	Ranibizumab, Aflibercept and Dexamethasone as first-line treatment for Diabetic Macular Edema (DME) [CEA/CUA]	https://tinyurl.com/DME-Economic					
3.	Ranibizumab compared to Dexamethasone as first-line treatment for Macular Edema secondary to Retinal Vein Occlusion (ME-RVO) [CEA/CUA]	https://tinyurl.com/MERVO-Economic					
4.	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/DPP4i-Economic					
5.	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/T1DM-Economic					
6.	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/T2DM-Economic					
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 [CEA/CUA]	https://tinyurl.com/lvabradine-Economic					
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 [CEA/CUA]	https://tinyurl.com/TicagrelorTE-Economi					
9.	Tirofiban in combination with heparin compared to usual care [e.g., unfractionated or low-molecular weight heparin (alone), aspirin, clopidogrel]among patients aged > 19 years old with coronary ischemic syndromes (CIS) undergoing coronary angioplasty or atherectomy	https://tinyurl.com/TirofibanCIS-Economi					
10.	Tirofiban in combination with heparin compared to usual care [e.g., unfractionated or low-molecular weight heparin (alone), aspirin, clopidogrel] among patients aged > 19 years old with Non-ST Elevation Acute Coronary Syndrome (NSTE-ACS) including Non-ST Elevation Myocardial Infarction (NSTEMI) or Unstable Angina (UA)	https://tinyurl.com/TirofibanNSTE-Economi					
11.	Paliperidone palmitate 3-months (PP3M) compared to Paliperidone palmitate 1-month (PP1M) among adult patients with schizophrenia who have been adequately treated with PP1M for at least four months	https://tinyurl.com/PP3M-Economic					