



Early **CANcer Detection in the **LivEr** of Filipinos with Chronic Hepatitis B using
AI-driven Integration of Clinical and Genomic Biomarkers
(CANDLE Study)**

Background

The Philippine Council of Health Research and Development under the Department of Science and Technology has approved the program entitled **Early **CAN**cer Detection in the **LivEr** of Filipinos with Chronic Hepatitis B Using AI-Driven Integration of Clinical and Genomic Biomarkers (CANDLE Study)**.

The CANDLE Study consists of two projects. Project 1 aims to establish a clinical and genomic profile of Filipino population for early detection of liver cancer. This will be implemented by the University of the Philippines Manila. Meanwhile, the general objective of Project 2 is to utilize the recent progress in omics research and leverage on AI capabilities to develop the Computational Omic Analysis Tool (COAT), an AI-driven computational tool that can ingest massive genomic data, ultrasound images, serum biomarkers and other clinical information. This will be conducted in the University of the Philippines Los Baños. The duration of the program is 5 years.

TERMS OF REFERENCE

Laboratory tests and services for the Project 1 entitled 'Establishing a Clinical and Genomic Profile of Filipinos for Early Detection of Liver Cancer':

- I. **Scope of work:** Blood extraction, DNA extraction, ultrasound imaging, transport of DNA to the Philippine Genome Center, and laboratory services - baseline liver function test, viral load testing, serum testing (single contract).
- II. **Tests to be performed per participant:**

YELLOW CARD: HBsAg Positive (Exposed)

<u>VISIT 1</u>	<u>VISIT 2</u>
<ul style="list-style-type: none">• CBCPLT• PT INR• CREATININE• ALBUMIN• ALKALINE PHOSPHATASE• HBSAG• HBEAG• ANTIHBC• ANTIHBS• ANTIHCV• ANTIHAV IGG• LIPOPROTEIN	<ul style="list-style-type: none">• CBCPLT• PT INR• CREATININE• AST• ALT• TOTAL BILIRUBIN• LIVER AND SPLEEN UTZ• AFP + AFPL3 + PIVKAI• ALBUMIN• ALKALINE PHOSPHATASE

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Candle Study

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<ul style="list-style-type: none">• HBV DNA• HBV GENOTYPING• HUMAN DNA EXTRACTION• LIVER AND SPLEEN UTZ• AFP + AFPL3+ PIVKAI• LIVERFAST	
<p><u>VISIT 3</u></p> <ul style="list-style-type: none">• CBCPLT• PT INR• CREATININE• AST• ALT• TOTAL BILIRUBIN• LIVER AND SPLEEN UTZ• AFP + AFPL3 + PIVKAI• ALBUMIN• ALKALINE PHOSPHATASE• HBSAG• ANTIHBS• HBV DNA	<p><u>VISIT 4</u></p> <ul style="list-style-type: none">• CBCPLT• PT INR• CREATININE• AST• ALT• TOTAL BILIRUBIN• LIVER AND SPLEEN UTZ• AFP + AFPL3 + PIVKAI• ALBUMIN• ALKALINE PHOSPHATASE

WHITE CARD: HBsAg Negative (Unexposed)

<p><u>VISIT 1</u></p> <ul style="list-style-type: none">• CBCPLT• PT INR• CREATININE• ALBUMIN• ALKALINE PHOSPHATASE• HBSAG WITH TITER• HBEAG• ANTIHBC• ANTIHBS• ANTIHCV• LIPOPROTEIN• HUMAN DNA EXTRACTION• LIVER AND SPLEEN UTZ• AFP + AFPL3 + PIVKAI• LIVERFAST	<p><u>VISIT 2</u></p> <ul style="list-style-type: none">• CBCPLT• PT INR• CREATININE• AST• ALT• TOTAL BILIRUBIN• ALBUMIN• ALKALINE PHOSPHATASE• LIVER AND SPLEEN UTZ• AFP + AFPL3 + PIVKAI
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<u>VISIT 3</u>	<u>VISIT 4</u>
<ul style="list-style-type: none"> • CBCPLT • PT INR • CREATININE • AST • ALT • TOTAL BILIRUBIN • ALBUMIN, ALKALINE PHOSPHATASE • LIVER AND SPLEEN UTZ • AFP + AFPL3 + PIVKAI 	<ul style="list-style-type: none"> • CBCPLT • PT INR • CREATININE • AST • ALT • TOTAL BILIRUBIN • ALBUMIN, ALKALINE PHOSPHATASE • LIVER AND SPLEEN UTZ • AFP + AFPL3 + PIVKAI

III. **Service:** Willing to do blood extraction, perform the laboratory services and ultrasound imaging on endorsed participants by the study; Willing to do DNA Extraction from whole blood; Willing to transport the extracted DNA to the Philippine Genome Center.

IV. **Criteria for evaluation of proposal:**

- A. Duly registered and DOH licensed medical laboratory
- B. With standardization of laboratory tests across multiple branches in the Philippines wherein tests are performed using the same method and instruments
- C. Has a centralized server for all the branches and will be able to upload the results to the web application of CANDLE Study weekly

Format of Data:

1. Laboratory results: Excel file, and online access will be provided to Authorized Coordinators
2. Genotyping results: PDF
3. Serum Biomarkers: PDF
4. Ultrasound image: JPEG file
5. Ultrasound results : Excel file
6. Naming convention for Ultrasound: <patient id>_<date>.jpeg

V. **Contract duration:** 1 Year — 500 individuals (baseline and follow-up)

VI. **Price:** For Year 2, the total price for the tests of the 500 participants must be within Php 30,888,275.00.

VII. **Basis for the approved budget:** The approved budget is based on the quotation of a laboratory that can provide ALL the tests listed above.

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- VIII. **Payment terms:** Issuance of statement of account every 15 days (15th and 30th of the month) payable through check within 60 days. Start of the 60-day billing count will only be upon complete release of laboratory results (except HBV Genotyping).


APPROVED:

Recommending Approval:


BEATRICE J. TIANGCO, MD, MSCE
Project Leader
CANDLE Study


Eva Maria Cutiongco-de la Paz, MD, FPPS
NIH Executive Director


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