

# Current Status on Oncology Clinical Trials in the Philippines and Expectations from the ATLAS project



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University of the Philippines College of PharmacyにてIndustrial Pharmacy(1991)の理  
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アダムソン大学薬学部学部長(2004~2006)  
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St. Luke's Medical Centerの腫瘍内科特別研究員(2014)、Human Cancer Biobank Project  
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Bachelor of Science in Industrial Pharmacy (1991) and Doctor of Medicine (1997), University of the Philippines  
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Dean, College of Pharmacy, Adamson University (2004-2006).  
Lecturer in Pharmacology, Ateneo School of Medicine and Public Health (2009-2011).  
Chair, Department of Pharmacy Trinity University of Asia (2014-2019).  
Fellowship in Medical Oncology (2014), Proponent and Past Co-Chair of Human Cancer Biobank Project (2015-),  
Vice Chair of Institutional Ethics Review Committee (2018-), and Head, Research Committee, Section of Medical  
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フィリピンにおけるがん臨床試験は完全に製薬会社主導で行われている。現在実施中のがんを対象とした介入的臨床試験のうち、地  
域の学術機関又は研究医師によって開始された試験はない。がん臨床試験の大半は第2相又は第3相試験であり、乳がん、肺がん及  
び頭頸部がんなどの最も多くみられる悪性腫瘍を対象としている。希少がんを対象とした臨床試験は、通常は特定の標的遺伝子変異  
の存在に基づく「バスケット試験」の一部であるか、免疫チェックポイント阻害薬に関係した試験である。治験依頼者又は医薬品開発  
業務受託機関は、施設での治験実施を可能にするために研究医師を求めており、一般的に1施設で必要とされる被験者登録数は1~  
3例である。

フィリピンのATLASプロジェクトへの参加が予定される中、フィリピンで実施される早期臨床試験数が増加し地域の研究医師及び学  
術機関による臨床試験の立ち上げが促進される可能性がある。人材開発及び試験設備の整備により、ATLASプロジェクトを通じて  
我々の研究機関における早期臨床試験の実施体制が向上することが期待される。ATLASプロジェクトにより、希少がんを対象とした  
革新的で命を救うことができる医薬品を提供できる可能性がある。

Oncology clinical trials in the Philippines are entirely pharmaceutical initiatives. None of the current interventional  
clinical trials for cancer are initiated by local academic institutions or local investigators. Majority of oncology  
trials are Phase II or Phase III studies, and cover the most common malignancies such as breast cancer, lung  
cancer, and head and neck cancers. Clinical trials that may include rare cancers are usually part of "basket trials"  
based on the presence of certain target genetic alterations or involve immune checkpoint inhibitors. Sponsors or  
clinical research organizations seek out investigators for site feasibility, and generally the required subject enroll-  
ment for a site range from one to three.

The anticipated participation of the Philippines in the ATLAS project may increase the number early phase clinical  
trials being implemented in the Philippines, and may encourage local investigators and academic institutions to  
initiate clinical studies. By developing manpower and equipment resources, the ATLAS project is expected to  
improve readiness of our institution to initiate and implement early phase clinical trials. The project may allow  
access to innovative and possibly life-saving medicines for rare cancers.

**CURRENT STATUS OF ONCOLOGY CLINICAL TRIALS IN THE PHILIPPINES**

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**CLINICAL TRIAL OVERVIEW**

Philippine FDA Data

- Number of clinical trial applications:
  - 2019: 51
  - 2020: 54

**CLINICAL TRIAL OVERVIEW**

St. Luke's Medical Center Data:

- Total ongoing clinical trials as of December 2020: 105
  - Oncology clinical trials as of December 2020: 25
  - New oncology clinical trials: 9 (2019), 8 (2020)
  - Number of Phase 1 clinical trials: 1

**CLINICAL TRIAL OVERVIEW**

Other Key Information:

- All of the ongoing clinical trials are sponsored by pharmaceutical industries
  - (Investigator-initiated: NONE)
  - (Academia: NONE)

**CLINICAL TRIAL OVERVIEW**

Other Key Information:

- Investigators are approached by sponsor for feasibility studies
- Each chosen site usually contributes 1-3 subjects

**EXPECTATIONS FROM THE ATLAS PROJECT**

- Capacity-building
  - A critical pool of investigators and research associates that are trained to implement and manage early phase oncology trials
  - Infrastructure and equipment available for early phase trials
- Experiential
  - Implement early phase oncology trials
- Early access to novel drugs