

## Capabilities Statement

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### What We Do

*Lücerent enables small and large organizations to conduct high quality, data-driven clinical studies in Cambodia.*

We combine *locally based staff* with an American management team providing the optimal combination of **market expertise** and **customer service**.

### Areas of Expertise

We are your “eyes and ears” when interacting with sites, alerting you of any risks, and developing solid solutions to keep the study on track. Our local staff provides sites with training, support and oversight, ensuring studies consistent with Good Clinical Practices.

- ✓ Feasibility studies
- ✓ Protocol/study design
- ✓ Regulatory submissions
- ✓ Database set-up and installation
- ✓ Phase II-IV clinical study management
  - Site selection, contracting;
  - Site training & support services;
  - Rigorous patient recruitment and retention strategies;
  - Site monitoring
  - Data management
  - Statistical support

### Reaching Your Goals

Our local presence and expert market knowledge are your leading advantages to ensuring a successful clinical study.

While Cambodia may not possess the breadth of clinical bench experience comparable to its neighbors, with Lücerent as your local partner, Sponsor goals can be achieved, and barriers overcome.

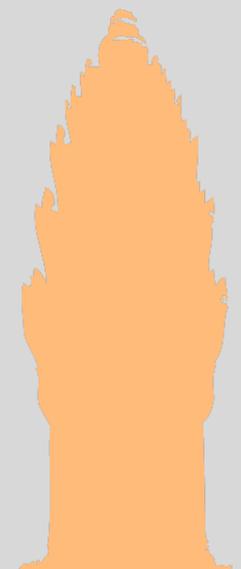
We bridge regulatory and cultural barriers, providing unparalleled access to Key Opinion Leaders and local networks.

### Why Lücerent?

- ✓ Quality data.
- ✓ Regulatory expertise.
- ✓ Access to Key Opinion Leaders.
- ✓ All Clinical Research Associates are ICH GCP- certified.
- ✓ Senior management with 15+ years conducting international clinical trials compliant with ICH GCP standards.

### Contact Us

email: [hello@lucерent.com](mailto:hello@lucерent.com)  
[www.lucерent.com](http://www.lucерent.com)  
+855-92-625-469  
Phnom Penh, Cambodia



## Cambodia: A Kingdom Ripe for Clinical Trials

With a population of 15 million and average GDP growth rate of 7%<sup>i</sup>, Cambodia is undergoing **rapid economic development**. Private sector development, foreign investment and Western influence continue to bring improvements to the country's infrastructure. In spite of economic growth, **many patients are still "treatment naïve,"** thus allowing for efficacy tests not possible elsewhere.

Furthermore, the country is experiencing an epidemiological transition resulting in a **"double-burden" of disease**. While infectious diseases are a leading cause of morbidity, there are an increasing number of patients who have illnesses of interest to developing countries such as cancer, diabetes and cardiovascular diseases.

On December 31, 2015, the ASEAN Economic Community (AEC) will take effect, transforming Southeast Asia into a region with free movement of goods, services, investment, skilled labor and freer flow of capital. **Cambodia's health care sector is well-poised to benefit from this integration.** Private and foreign sector investment is already taking place in anticipation of the AEC resulting in the creation of new specialty hospitals with the required equipment and infrastructure to meet ICH GCP guidelines.



## Sponsor Benefits

- ✓ **Rapid Patient Recruitment:** Access to treatment naïve patients with fewer trials competing for subjects and Investigators;
- ✓ **Patient Retention:** Subjects may depend on the trial for regular medical treatment. Close networks with communities where patients reside increase follow-up rates;
- ✓ **Efficient regulatory process** with the National Ethics Committee; study approval can sometimes be as quick as 3 months from time of submission
- ✓ **Established laboratories** in select hospitals, including diagnostic microbiology laboratories;
- ✓ **Growing pool of qualified and motivated Investigators** who have published research in notable medical journals and understand Good Clinical Practices.

## Selected Work

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In the past year Lücerent has proudly supported our clients in conducting oncology and infectious disease surveillance studies within Cambodia. Below is a snapshot of work performed in 2014-2015.



### [Sihanouk Hospital](#) [Center of Hope](#) [\(SHCH\)](#)

In 2014 SHCH launched its first **cervical cancer screening program**. Cervical cancer is the leading female cancer with 1,515 new cases diagnosed each year and 795 deaths (Globocan, 2012). Cervical cancer rates are specifically high in Cambodia due to lack of widespread prevention. Cervical abnormalities will impact approximately 24% of Cambodian women throughout their lifetime.

The study's objective is to compare cervical cancer screening outcomes of 500 HIV-positive and 500 HIV-negative Cambodian women with subsequent treatment. Patients are screened using the visual inspection with acetic acid (VIA) technique. If VIA is positive for cervical abnormalities, patients are triaged and offered treatment (cryotherapy for eligible patients; colposcopy and cervical biopsy or referred for further evaluation and treatment if advanced disease). Data collection will continue through 2015 and entered by trained study personnel into a secure database.

## Project activities performed by Lücerent:

### **Study Start-Up (Completed)**

- ✓ Review of Case Report Forms by Epidemiologist
- ✓ Design, set-up and implementation of secure electronic database
- ✓ Study protocol and data entry training
- ✓ Drafting of Statistical Analysis Plan

### **Study Operations (In Progress)**

- ✓ On-site monitoring by local CRA to ensure rigorous data collection and study adherence according to Good Clinical Practice standards
- ✓ Data management review (manual review and query resolution); regular meetings with Principal Investigator to discuss data quality

### **Study Close (Upcoming)**

- ✓ Preparation of database lock
- ✓ Statistical analyses for Clinical Study Report by Sr. Biostatistician

## Selected Work

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### [U.S. Naval Medical Research Unit-2 Detachment Phnom Penh Detachment Phnom Penh \(NAMRU-2\)](#)

The U.S. Naval Medical Research Unit-2 Detachment Phnom Penh's mission is to identify infectious disease threats of mutual interest to the United States, the Cambodian Ministry of Health, and the international public health community and to develop and evaluate interventions and products to mitigate those threats.



#### ***Project #1: Surveillance and Etiology of Acute Undifferentiated Febrile Illnesses in Cambodia***

This is a hospital-based febrile surveillance study to evaluate and elucidate the causes of febrile illness in Cambodia.

Subjects are recruited at enrolled health care facilities by study coordinators in collaboration with health care workers.

In collaboration with the Cambodian Ministry of National Defense (MoND) data are collected consisting of an SMS-based disease surveillance program and reporting of human disease to a central database to monitor health trends for potential disease outbreaks.

#### ***Project #2: Acute Disease among Village Cohorts in Kampong Cham Province***

This is a prospective cohort study to monitor the burden of disease of acute respiratory and diarrheal disease among rural and peri-rural Cambodian villages located near the Vietnamese border and near a provincial capital with high commercial activity.

The purpose of this study is to determine the differences in the types of pathogens and the burden of diseases among residents from these two distinct geographical areas.

#### ***Project #3: Austere Environments Consortium for Enhanced Sepsis Outcomes***

This is a prospective observational cohort study of adult patients with suspected sepsis in Cambodia.

The study is being conducted at Takeo provincial hospital with the aim to improve early recognition, diagnosis and effective treatment of severe sepsis from all causes in austere environments.

### **Project activities performed by Lücerent:**

- ✓ Facilitate visits to remote SMS-based surveillance sites to ensure collection of data in compliance with study protocol
- ✓ Facilitate 7 month advanced diagnostic laboratory training for MoND staff
- ✓ Support provision of compensation kits at time of subject enrollment
- ✓ Technical collaboration with the Ministry of Health Communicable Disease Control Department

## Management

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**CHRISTINA HONG**  
Founder and CEO

Christina founded Lücerent Clinical Solutions in November 2012 as the first private, legally registered CRO in Cambodia.

Prior to founding Lücerent, she spent her career in Boston, Massachusetts providing pharmaceutical and biotech clients with expert guidance on the design and execution of international clinical trials in cardiovascular, oncology, pediatric vaccines, rheumatology and endocrinology. These studies often involved working in resource-challenged countries under tight deadlines and local constraints.

Christina is passionate about seeing positive transformation in Cambodia's healthcare sector that will result in quality care and improved patient outcomes. She views customers as partners in creating value and is dedicated to contributing to their success.

## Our Mission

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To be the market leader in providing clinical trial services in Cambodia

## Our Values

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- ❖ **Integrity** – we are honest, fair and trustworthy in all of our company's activities and relationships; the way we deliver results is just as important as the results themselves
- ❖ **Commitment to Excellence** – we do not settle for mediocrity but pursue excellence in all we do and in developing the talent we hire
- ❖ **Passion for our Customers** – our customers are our partners in creating value and we are dedicated to contributing to their success

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<sup>i</sup> Real growth rate (2013 est.) 2014 CIA World FactBook