

**Day 1: 15:50 – 16:05**

## **Barriers in conducting clinical trials and addressing the shortage of physician-scientists and clinical trial professionals in Indonesia**



**Wawaimuli Arozal, MD. PhD.**

(Department of Pharmacology, Faculty of Medicine, Universitas Indonesia, Indonesia )

### **Short CV**

**Dr. Wawaimuli Arozal** is currently Associate Professor of Pharmacology at the Faculty of Medicine, Universitas Indonesia (FMUI) Jakarta, Indonesia. She earned her Bachelor of Medicine at FMUI in 1993, her Master of Biomedicine in FMUI in 1999 and got her PhD in Pharmaceutical Science from Niigata University of Pharmacy and Applied Life Sciences, in Niigata Japan in 2011.

In 1998, Wawaimuli Arozal started a position as a Faculty member in the Department of Pharmacology and Therapeutic in FMUI, as a lecture assistant. After completing her PhD degree she continued her work as a lecturer in FMUI and supervised bachelor, master and PhD students in FMUI. She also got many grants from Government to do research in an area of cardiovascular drugs and collaborate with pharmacy company to do the clinical trial in area of herbal medicine.

Wawaimuli has over 50 refereed publications, with the h-index 17.

### **Abstract**

Indonesia is a middle-income country and one of the developing countries in Asia. The population of Indonesia is about 264.6 million people, consider as the 4th most populated country in the world., Indonesia health data shows maternal and neonatal mortality rates are higher than the World Health Organisation (WHO) target in the context of the Sustainable Development Goals. Beside that Indonesia has also a high infectious disease burden, including malaria, tuberculosis and dengue. On the other hands the recent data from Ministry of Health showed that non-communicable disease such as cancer, stroke, hypertension and diabetes mellitus are now the major health burden in this country.

However, despite its enormous potential, Indonesia has relatively few numbers of clinical trials compared with other ASEAN counterparts. Based on the registries covering over 20 years, only around 500 clinical studies (either observational or interventional) were initiated in Indonesia. Most of the studies were researcher-initiated regional clinical studies and sponsored by the academia/hospital sector from national/local sponsor.

Having ratio of doctors per population 1:2294 nationally, with 92 medical faculties in Indonesia but only about 12 medical schools and a few teaching hospitals are actively involved in clinical research. Most of the physician in Indonesia work as a community physician rather than a clinical researcher. Clinical researchers who get their research ideas through the clinical trial process face many small obstacles that seem insurmountable. These obstacles include locating funding, responding to multiple review cycles, obtaining Institutional Review Board approvals, establishing clinical trial and material transfer agreements with sponsors and medical centers, recruiting patients, administering complicated informed consent agreements, securing protected research time from medical school departments, and completing large amounts of associated paperwork.

As a result of these challenges, many who try their hand at clinical investigation drop out after their first trial. A further barrier is the lack of a supportive clinical research infrastructure, especially in the form of administrative and financial support. For practitioners who become engaged in running a clinical trial and recruiting patients, their financial reimbursement per patient can, in some cases, be less than they would receive from regular practice.

In addition, there is a financial disincentive for physicians to refer their patients to clinical trials. Physicians who do so must often refer those patients away from their care; thus each patient referred represents a lost revenue stream. The solution of those above issues must be sought, by involving various parties, to increase the quality and quantity of clinical research in Indonesia.

**Key words:** Indonesia, Clinical research, Clinical Investigators, Barriers