

# eCourse on Clinical Validation of Products for Entrepreneurs and Start Ups

This course is offered by PHFI Centre for eLearning



An eLearning Programme for Aspiring Innovators / Entrepreneurs, Start-ups, Quality Managers, and Engineers



Indian Institute of Public Health Gandhinagar NIDHI - Technology Business Incubator

# Background

eCourse on Clinical Validation of Products for Entrepreneurs and Start Ups is a three-month eLearning program designed to cover basics of epidemiology and various epidemiological studies for product validation. The course has been developed by Indian Institute of Public Health Gandhinagar (IIPHG). It will be deliveredby a multidisciplinary team from IIPHG and experts from the Industries.

During the past two decades, India has witnessed major changes in technology development, heralding an information age. As a result of the information and communication boom, a combination technologies is being used to obtain, disseminate, and share information as never before. moreover, social media has become a powerful tool to share ideas and solutions in almost all spheres of daily life. This offers great opportunities to incorporate technology for bringing better health to populations at large. With information and communication devices available even in remote villages, there is a potential that technology could revolutionize health service delivery too and can assist in developing an efficient and people-centered health care system

A key gap amongst the start-ups is their ability to move their products after reaching proof-of-concept stages especially through the clinical validation, adoption, and market entry besides raising capital.

## Aim and purpose

Indian Institute of Public Health Gandhinagar with its expertise in multi-disciplinary science is best positioned to offer a program on clinical validation of medical products. It will help participants to:

- Understand the basics of epidemiology and various epidemiological studies for product validation.
- Basics of Statistics and Interpret and undertake analysis of clinical studies.
- Plan and implement the clinical studies for the validation of products
- Understand the ethical issues of clinical studies
- Learn from the experts from the industries.
- Economic analysis of products or innovation.

# Target Audience/Eligible Candidates

Entrepreneurs, Start-ups & Innovators, Quality Managers & Engineers. This executive friendly in-depth and comprehensive program is best suited for professionals creating cutting-edge technology solutions in eHealth, Personalized Healthcare, Biotech, Medical Devices, Wearables, Digital Therapeutics, and validation of the product.

# Mode of Delivery

This is a three-month eCourse offered in eLearning mode. The program will be based on a combination of online lectures (asyncronous), electronically submitted assignments, Interactive Sessions, Case Study Discussions, Exercises and Self-learning.

## List of modules

Module-1: Preclinical Validation- 1) Introduction & overview of the course. 2) Basics of need assessment and gap analysis. 3) Process of registration of Idea/clinical trials 4) Introduction to study designs for preclinical validation & Epidemiology.

Module-2: Clinical Validation- 1) Introduction to clinical study designs & sample size calculation. 2) Overview of data collection & data management. 3) Analysis and interpretation of clinical studies. 4) Case-studies on clinical validation.

Module-3: Post Clinical Validation (Case studies from successful start-ups- 1) Overview of market launch and marketing. 2) Operational Research 3) Economic Analysis 4) Commercialization.

#### Evaluation/Assessment

Evaluation and assessment of the course will be online based: multiple-choice questions, short online module-based tests.

# Number of Seats

50 per batch.

## Course Fee

Indian Candidates: INR 9,000 South Asian Candidates: US \$140 International Candidates: US \$330

(\*Provision of partial scholarship will be available for entrepreneurs, post graduate students / doctoral students)

## Registration

Interested candidates may apply online using following url: https://cdl.phfi.org/portal/node/329

#### Course coordinator

Dr. Poonam Trivedi, (Epidemiologist, IIPHG NIDHI TBI)

## Course Instructors

Dr. Somen Saha, (Associate Professor, IIPHG)

Dr. Komal Shah, (Assistant Professor, IIPHG)

Dr. Kamlesh Patel, (C.E.O, IIPHG NIDHI TBI)

Dr. Deepak Saxena, (Professor, IIPHG & P.I – IIPHG NIDHI TBI)

For online application visit: <a href="https://cdl.phfi.org/portal/node/329">https://cdl.phfi.org/portal/node/329</a> or visit: <a href="https://www.iiphg.edu.in/elearning-programs">https://cdl.phfi.org/portal/node/329</a> or visit: <a href="https://www.iiphg.edu.in/elearning-programs">https://www.iiphg.edu.in/elearning-programs</a> or <a href="https://www.iiphg.edu.in/elearning-programs">www.phfi.org</a>.

Program Associate (eLearning Education) Indian Institute of Public Health Gandhinagar Opp. Airforce Head Quarters, Nr. Lekawada Bus Stop, Lekawada CRPF P.O Gandhinagar - 382042, Phone: 9998905263, / 079-66740700

E-mail: cvp\_tbi@iiphg.org , hhimani@iiphg.org Last Date of application: 15 August, 2021