

# Cliniminds – Your Life Sciences Training & Skilling Partner



## Career in Pharmacovigilance



# Vision & Mission

**Vision** - To establish a world-class education & training institution that offers the widest range of high-quality life & health sciences skilling & professional training programs and business solutions.

**Mission** - Cliniminds is committed to provide highest quality training, education and management solutions and develop superior human resources for the global life sciences and healthcare industry.



# About Cliniminds

- Established in 2004, trained over 8,500 health & life sciences professionals in India, US, Europe, Middle East and Africa using classrooms, online & eLearning platforms.
- Offers post graduate upskilling, corporate & executive development programs in pharmaceutical business analytics, clinical research, pharmacovigilance, data management, pharma regulatory, medical & scientific writing, biostatistics and other specialized areas.
- Robust placement support program.
- Consulting solutions for pharma and life sciences clients

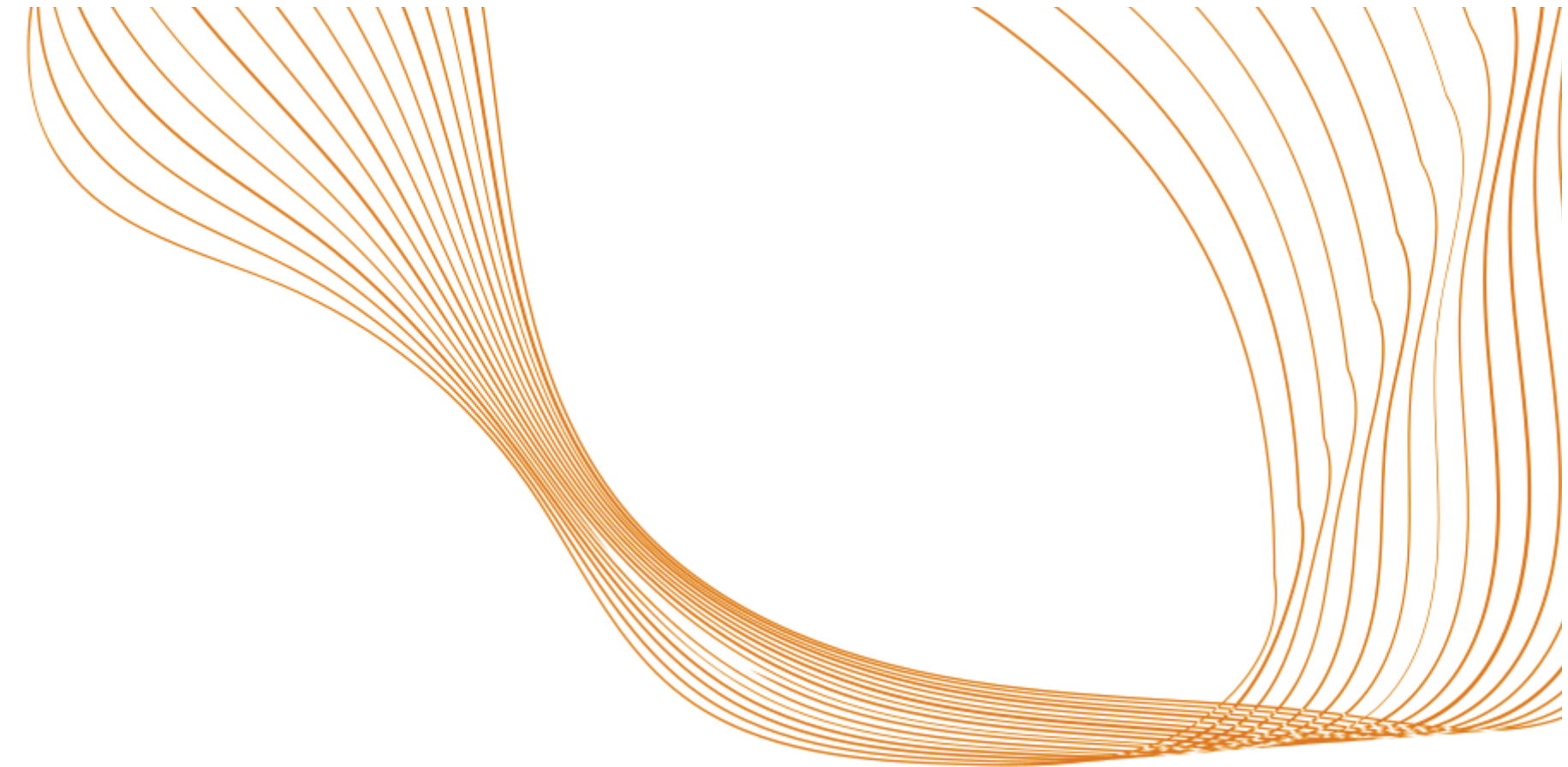






# Awards, Accolades & Accreditations





# Cliniminds Programs Certified by LSSSDC





## Key Awards Accolades & Accreditations

- ASSOCHAM
- Brands Academy & Economic Times
- Best Clinical Research & Health Sciences Business Management Institute in India
- 2011 to 2020 by various agencies

Accreditation by Accreditation Council for Clinical Research Education, United States since 2013



International Student Chapter of Drug Information Association





# **An Introduction to Pharmacovigilance**

## **Global Scenario & Career Path**



# Pharmacovigilance

Pharmaco (Greek) = drug or medicine

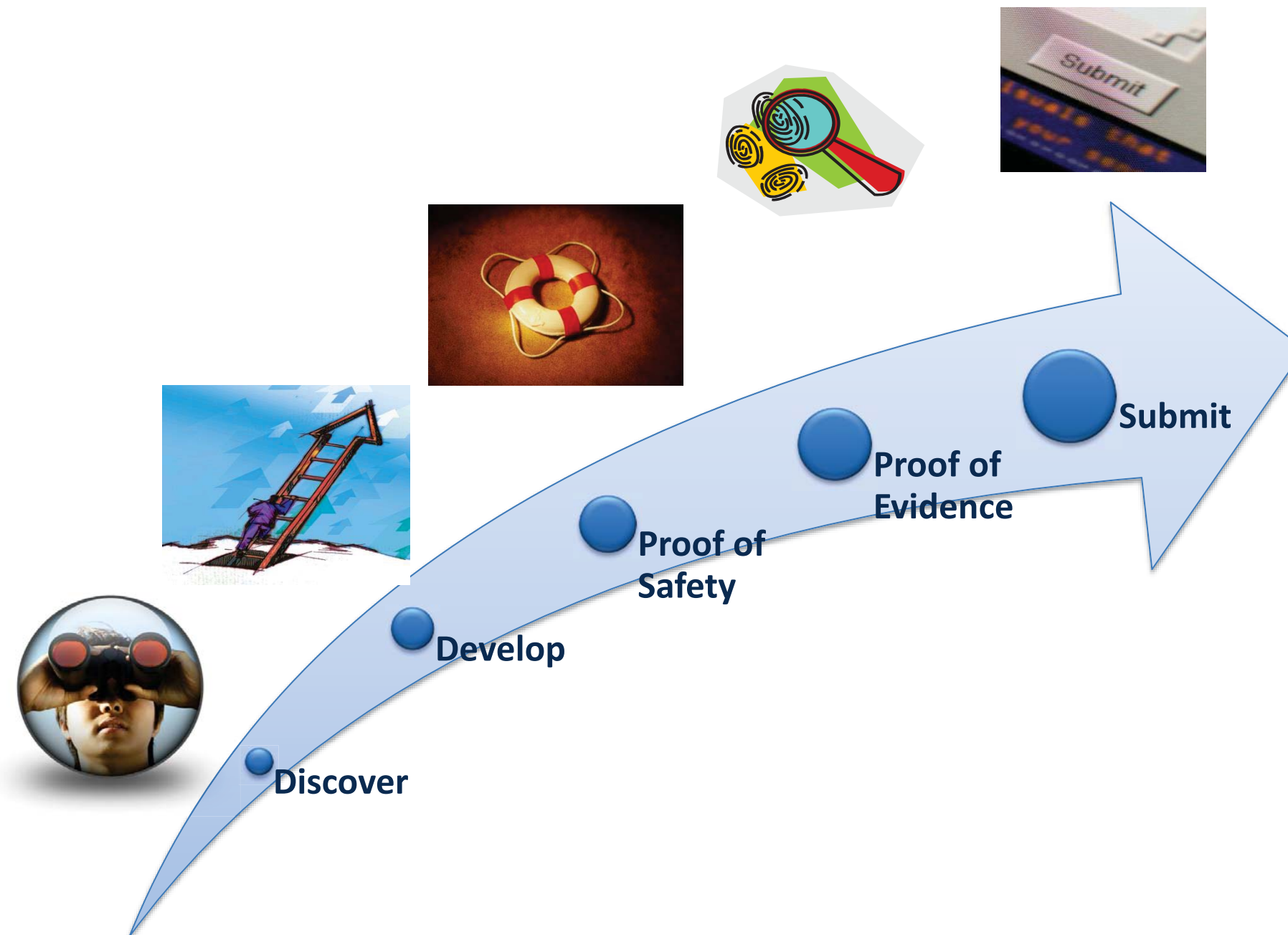
Vigilare (Latin) = To watch, keep awake or alert

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems.

(As per WHO guidelines)



# Pharmacovigilance Overall Process

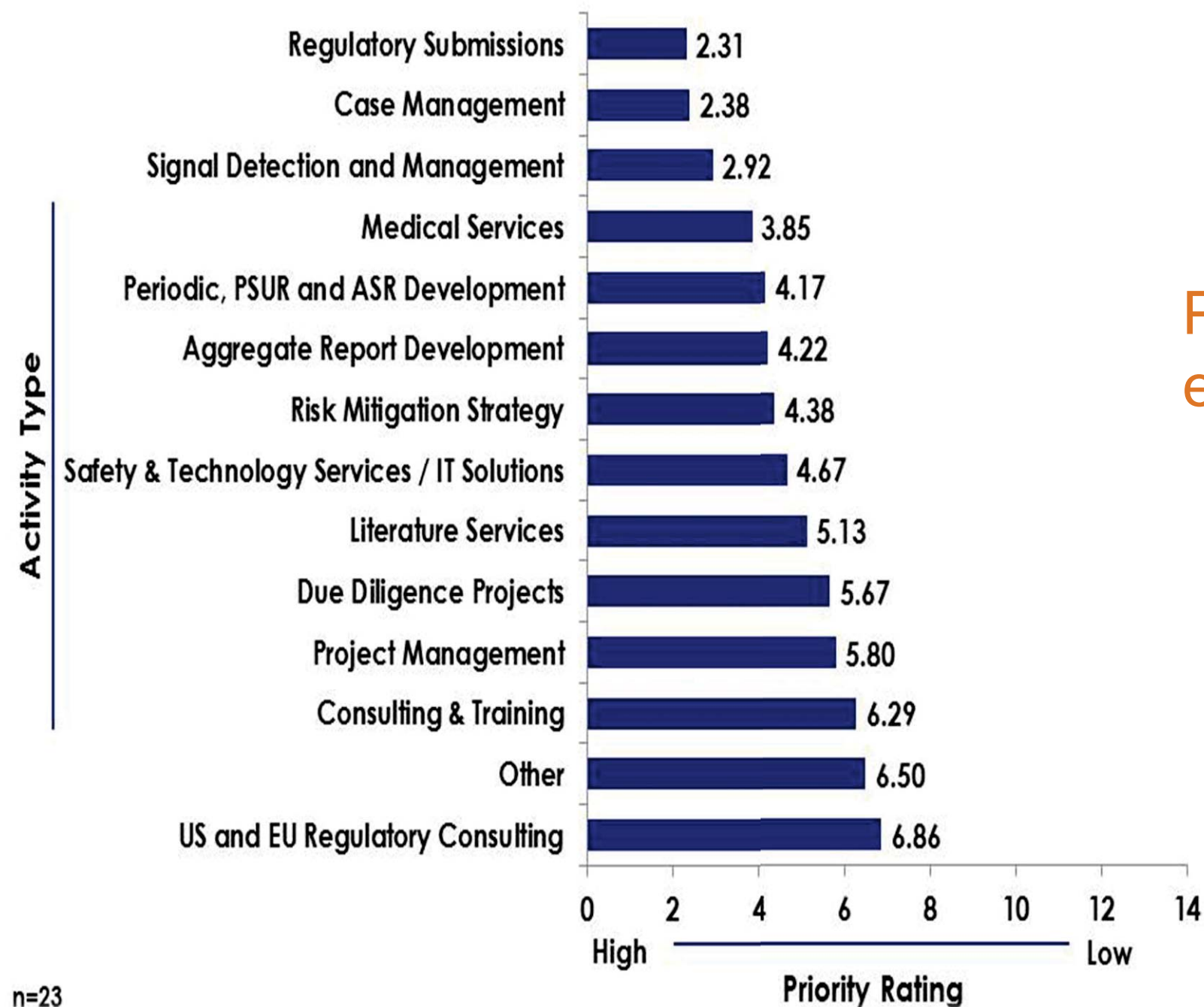


# India – The Global Centre for Pharmacovigilance

- Increasing global regulations for pharmacovigilance reporting driven by EMA, USFDA, DCGI and other international regulators.
- Most global pharmacovigilance companies are outsourcing their pharmacovigilance operations to India.
- India has pool of highly trained and skilled pharmacovigilance professionals and access to global technology.



## Companies' Perceived Importance of Pharmacovigilance Activities



## Pharmacovigilance Market to grow exponentially crossing 8 Bn \$ by 2021

- Pharmacovigilance is booming with its market size expected to expand at a CAGR of 14.2% through 2021. In 2014 the market was at 2,75 Mn \$ which is now expected to reach \$10 billion by 2022.
- It is believed that the growth is attributed to CAGR of 16.5% in Phase III clinical trials, further needless to say that 57% of global pharmaceutical companies outsource their projects to contract research organization.



# Career Path for Drug Safety Physician

- Drug Safety Physician - Entry Level
- Senior Drug Safety Physician - 2 – 3 years
- Team lead - 3 – 5 years
- Associate Director - 6 – 8 years
- Director - 7 – 9 years
- General Manager - 10+
- Vice President - 15+
- President - 20+

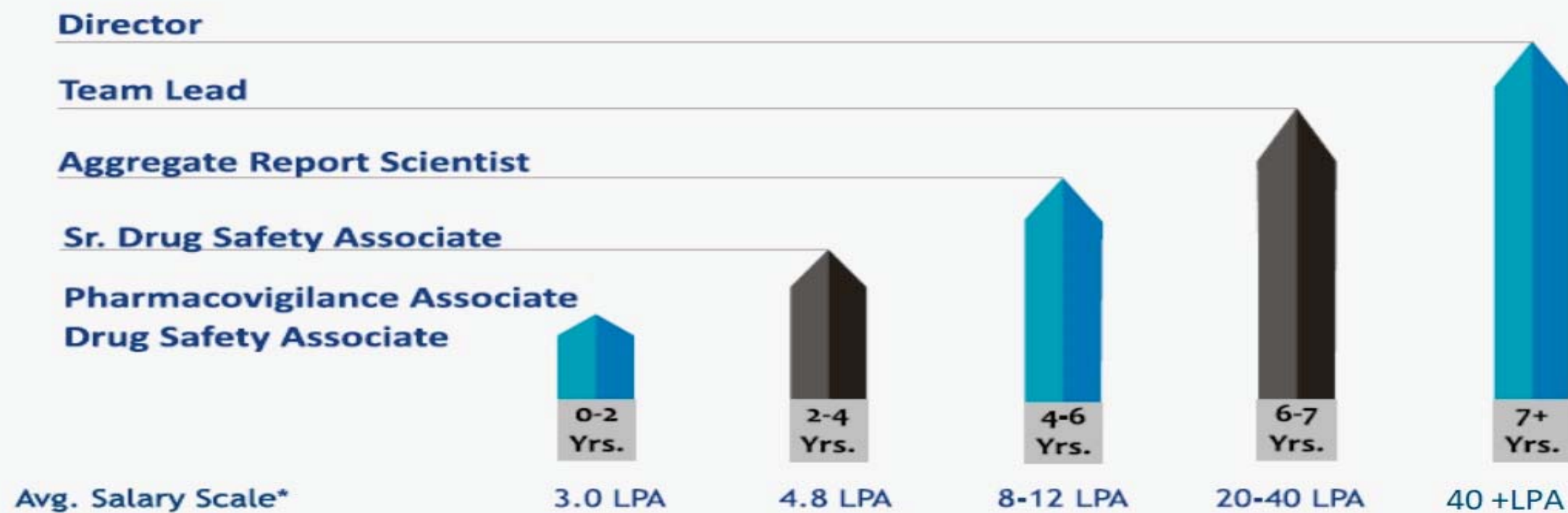
Starting Annual Salary - MBBS : Rs.7 lakh; MD/MS : Rs.12 lakhs, plus other benefits.

Annual Growth : 15 – 20%



# Career Path for Drug Safety Associate

## How Will I Grow In This Industry?



\*The actual salary depends upon many factors such as: candidates knowledge, company and city.

# Am I eligible to start my career in Pharmacovigilance ?

Pharmacovigilance is Career of choice for the following professionals :

Pharmacy (B Pharm, M Pharm & PharmD )

Medical (MBBS, MD,MS )

Dental( BDS, MDS )

Alternative Medicine  
(BAMS,BHMS,BUMS,BSMS)

Nursing (BSc, MSc)

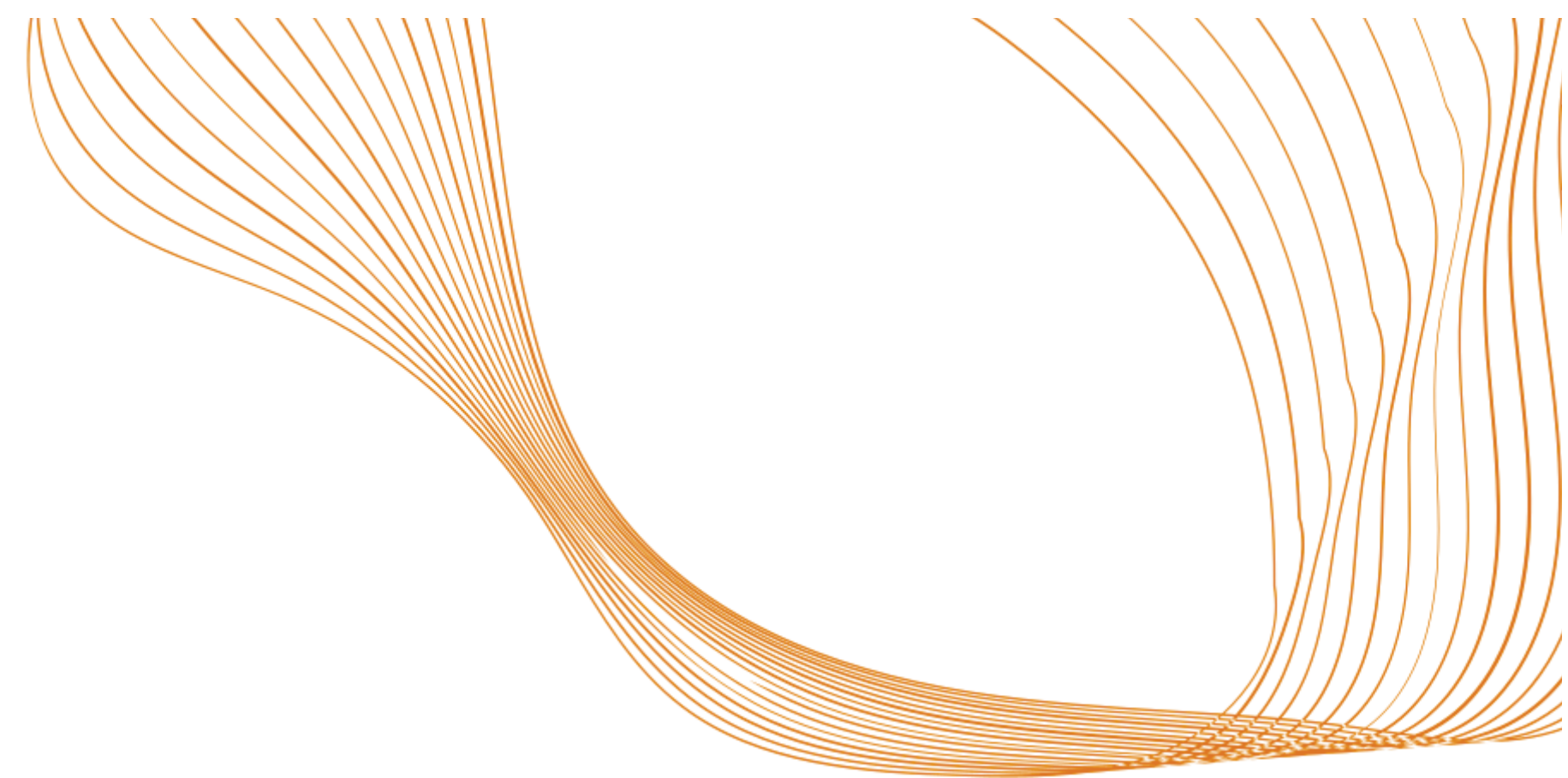
Physiotherapist (BPT, MPT)



# Why Choose Cliniminds

- 15+ Years of experience in providing job oriented skill training & deliver 100% placements.
- 100% Placement track record since 2011
- Full time mode: 5 days regular live sessions on Zoom / GoToMeeting
- Weekend mode: Saturday/Sunday live sessions on Zoom / GoToMeeting
- Live training provide by industry experts
- Online access to full study material
- Hands on training on pharmacovigilance software using safety database.
- Dual certification LSSSDC Govt. of India & ACCRE USA
- Cliniminds LMS – 24x7 access (PPT, Notes, Study Material & Pre recorded sessions)
- Well organized placement structure Organize Interviews | Group Discussions | Poster Presentations | Mock Interviews | Technical & HR Rounds Preparation | Online Tests Preparation | Presentation Skills

# Key Pharmacovigilance Team Members



**Mr. Kamal Shahani**

Managing Director

**Dr. Anu Dambalkar**

Senior Drug Safety Physician –  
Medical Review & Signal

**Dr. Shiva**

Aggregate Report Writing &  
Signal Expert

**Mr. Amit Nakhe**

Senior Manager  
Pharmacovigilance & Data  
Management - Mumbai

**Dr. Gaurav Grover**

Senior Manager  
Pharmacovigilance - Noida

**Joseph Mathew**

Senior Manager –  
Pharmacovigilance - Canada





# Programs for Fresh Pharmacy Graduates & Post Graduates

- Advanced Post Graduate Diploma in Clinical Research & Pharmacovigilance
- Post Graduate Certificate Program in Drug Safety & Medical Review for Physicians
- Advanced Post Graduate Diploma in Pharmacovigilance
- Advanced Post Graduate Diploma in Clinical Research, Data Management & Pharmacovigilance

# Programs For Pharmacovigilance Working Professionals

- Certificate Program in Aggregate Report Writing
- Certificate Program in Signal Detection & Risk Management
- Post Graduate Certificate Program in Drug Safety & Medical Review for Physicians
- Post Graduate Diploma in Pharmacovigilance Audits & Inspections



# Program Delivery

## eLearning

- Live Sessions on Zoom
- Cliniminds LMS – 24x7 access
- Software Training for Pharmacovigilance, Clinical Trials
- Online Exams
- Access to Recorded Sessions
- Job Placement Support

## Online / Distance

Cliniminds LMS – 24x7 access  
Online Study Materials  
Online Exams

## Placement Support

Organize Interviews | Group Discussions | Poster Presentations | Mock Interviews | Technical & HR Rounds Preparation | Online Tests Preparation | Presentation Skills

# Placements

Syneos	Syntel
IQVIA	Parexel
Bioclinica	DDreg
Apcer	PVPI – Government of India
Wipro	JSS Medical Research
Awinsa	Lambda
WNS	Think-i
Cognizant	Novartis
Innovate Research	ICON
Soterius	Accenture
TCS	Kinapse
Sun Pharma	I 3 Global Drug Safety
SIRO	



# Job Description

## Drug Safety Associate /Pharmacovigilance Associate

- Process Safety data according to applicable regulations, guidelines, Standard Operating procedures (SOPs).
- To perform Pharmacovigilance activities per project requirement including but not limited to, collecting and tracking incoming Adverse Events(AE)/endpoint information
- Determining initial/update status of incoming events
- Database entry
- Coding AE and Products, writing narratives, Literature related activities as per internal/ regulatory timelines.
- Quality Reviewer can perform post closure quality and process control on closed cases if the task is assigned to him/her.
- Ensure to meet quality standards per requirements.
- Creating, maintaining and tracking cases as applicable to the plan.
- Identify quality problems, if any, and bring them to the attention of a senior team member.
- To demonstrate problem solving capabilities.
- To mentor new teams members, if assigned by the Manager.
- Feedback errors found in expeditable and non-expeditable cases to team leaders
- To Prioritize and complete the assigned trainings on time and mention manager on any challenges/issues or successes.
- 100% compliance towards all people practices and processes .
- Perform all activities within the required time frames to ensure regulatory compliance.

# Job Description

## Drug Safety Physician

- Report preparation [e.g. Periodic Safety Update Reports (PSURs), ICSR, Addendum PSURs, Bridging Reports, PSUR Line Listings, US PADERs] from aggregate data for products, in accordance with client conventions and requirements;
- Quality checks of aggregate reports; Signal detection-related analyses and reports including cumulative analyses, issue event analyses, Drug Safety Reports , review of published literature and case listings; Vigilance over important/designated medical events;
- Interaction with client personnel to discuss potential signals and issues detected with products; Support preparation and maintenance of Risk Management Plans;
- Follow-up and interaction with clients to obtain incomplete/missing information, with a view to resolving and clarifying issues;
- Performing medical review of individual case safety reports (ICSRs); performing medical review of narratives for Clinical Study Reports (CSRs);
- Providing medical advice to drug safety scientists to assist them with processing of ICSR and CSR narratives;
- Maintaining an excellent knowledge of the adverse event safety profile of assigned drugs, labelling documents, and client guidelines and Standard Operating Procedures (SOPs);
- Maintaining an awareness of global regulatory reporting obligations and organizing workload to ensure compliance with internal and regulatory timelines for report submissions;
- Maintaining records in compliance with guidelines and SOPs



# Our Technology & Knowledge Partners

Cliniminds has tie ups with wide range of healthcare and life sciences companies which provides access to technology and knowledge for our faculties and students. Some of our partners are :



# Cliniminds Footprint

India	Africa
USA	U.K.
Canada	Switzerland
France	Brazil
Argentina	Peru
UAE	Kuwait
Saudi Arabia	Russia
Pakistan	South Africa
Malaysia	Japan
Philippines	Germany



# Contact us



## WEB & EMAIL ADDRESS

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