

## 5<sup>th</sup> DCVMN/PATH Pharmacovigilance e-Workshop

July 14-15, 2021 via WebEx

**Themes:**

- Collation of AEFIs in validated PV databases
- Knowledge of safety database systems

| Wednesday July 14 <sup>th</sup> 2021 |  |                                    |
|--------------------------------------|--|------------------------------------|
| Time                                 | Topic  | Speaker                            |
| 11:00-12:00 CET                      | ICSR receipt and handling including follow up and reconciliation | Katharina Hartmann<br><i>DCVMN</i> |
| 12:00-12:05 CET                      | Break  |                                    |
| 12:05-12:30 CET                      | Q&A  | Katharina Hartmann<br><i>DCVMN</i> |

| Thursday July 15 <sup>th</sup> 2021 |  |                             |
|-------------------------------------|--|-----------------------------|
| Time                                | Topic  | Speaker                     |
| 11:00-11:40 CET                     | 1. Safety database operation, validation, back-up, disaster recovery<br>2. Expedited reporting to Regulatory Authorities | Varun Sharma<br><i>PATH</i> |
| 11:40-11:45 CET                     | Break  |                             |
| 11:45-12:00 CET                     | Q&A  | Varun Sharma<br><i>PATH</i> |