

«PV ZOOM»

Introduction

- GK PV Zoom understands that Medical Information is the frontline between our clients and their customers. Our strategy is flexible to your needs and, with input, we are able to tailor our service delivery to mirror your culture — safeguarding your company's values and your customers' expectations.
- Here is an overview of our Medical Information implementation process, explaining our steps from understanding your requirements through to launch and review.

Location

- Smart technology can be used on computer or smart mobile by using any browser App.

Functionality

- Combination, detection, evaluation, monitoring, and prevention of adverse effects with pharmaceutical products then ICSRS recording system according to ICH-E2B R3 international guidelines.

General Approach to the operation of pharmacovigilance

- The company PV Zoom team is only responsible to operate PV Zoom during the contract period as Entering data & Generating XML file to be sent to National Health Authority

- PV Zoom can track different types of reports to be sent to regulatory Authorities
 - Individual Case Safety Reports (ICSRs) in XML format divided into
 - Initial ICSR
 - Follow up ICSR
 - Literature review report with different search options
- You can use as an internal reporting tool inside the company to receive PV reports.
- PV Zoom provides Different ways to detect Duplicate cases.
- Signal Detection
- PSUR Tracking and alert before DLP
- RMP Tracking (under development)
- MedDRA coding Integration (under development)
- Overview on all products of the M.A.H and its related activities & documents
- EPVC Letters tracking (under development)

Their fitness for purpose:

- PV Zoom provides tool to record unlimited ICSRs received either spontaneously or non- spontaneously & allows company Zoom team to
 - Case seriousness
 - Patient details
 - Reporter,
 - ADR detected
 - Company suspected product
- Allow PV Personnel to generate more than version to the same case in case of follow up or new data regarding the same case collected.

- PV Zoom generate XML file according to ICH-E2B R3 guidelines that can be received by national authority & imported to their database directly.

Validation

❖ Installation:

- It is PV Zoom technical team is responsible of illustrating how to use the program & ensure user ability to use it.

❖ Validation during data entering by Users:

- PV Zoom provides guiding messages for PV team (software users) to validate the type of data entered & avoid moving to the next screen unless main data in the screen is entered.
- Dates will be selected from calendar.
- There four types of views to view data
 - View Kanban
 - View pivot
 - View graph
 - View list
- Most fields are dropdown lists.
- Texts boxes are fields that the user will write freely.
- Each user can choose the language.
- The system can add follower to follow up with users.

- Users can make chats with each other.
- There is a log file that can display all changes made to ICSR and you can also write a message or notes as guide for yourself.

Validation testing in the National Health Authority database used

Change control:

○ **Software change control:**

- It is the responsibility of PV Zoom team & it is not allowed for the user.
- PV Zoom will release new version in case there is change that affect user.

○ **ICSR Change Control:**

- version will be created by sending the case to EPVC.
- The user can create more than one version for the same case ID in case there is new data entered & finalized by sending it again.
- Case nullification will be an option for the user.

Nature of testing:

- The user will enter test case & generate XML file that will be sent to national authority to check successful receival by National authority database.

Back up procedure:

- It will be arranged with the company IT department however back up can be done automatically & customized according to company desires.

Security:

- PV Zoom Flow will be accessed by QPPV/Pv personal through user name & password & we can make restriction access for other users.
- In case there are more than one company related to the same owners or that is related somehow in business, PV Zoom can provide specific access to each company.

Duplicate Checking:

Duplicate alert will be raised if the following items are matched more than once:

- Drug name
- Event “MedDRA”
- Any info about the patients

Reports Generations:

- Reports from patients or their representatives remain an important element in pharmacovigilance.
- Regulatory requirements, set forth safety monitoring and reporting responsibilities of sponsors and investigators to ensure the safety and protection of human subjects participating in clinical trials.

- PV Zoom can make tracking as the user needs that can be used also in KPI measurements.