

A large, semi-transparent graphic in the background featuring a white 'V' on a grey square and a green play button icon on a grey square.

# Chap 1. Intro to PE

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A large, semi-transparent graphic at the bottom of the slide featuring the word 'Vizle' in white on a green background.

# Vizle



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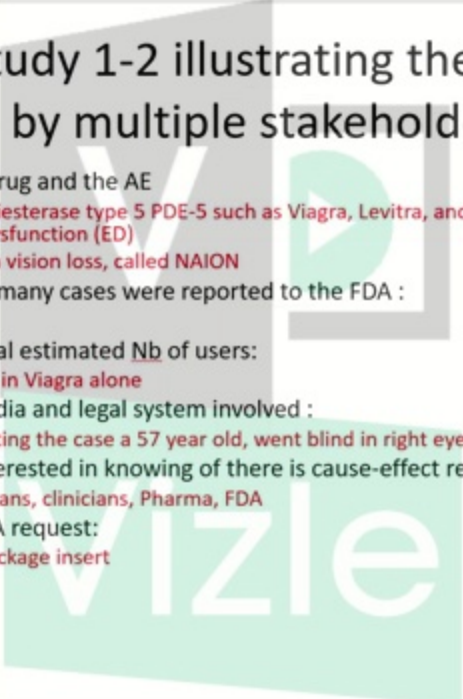
## 3.3 Adverse Event Reporting

- Adverse events reporting system to collect spontaneous report of drug issues have been developed by different parties:
- Name that by FDA:
  - **Medwatch**
- Vaccine Adverse Event Reporting System VAERS was it which 2 governmental organizations ?
  - **FDA and CDC**
- Who else has some form of systems :
  - **pharma comp, and health care organizations worldwide**
- Academician usually report using what form?
  - **Case report**



# Case study 1-2 illustrating the use of PE by multiple stakeholders

- What's the Drug and the AE
  - Phosphodiesterase type 5 PDE-5 such as Viagra, Levitra, and Cialis to treat erectile dysfunction (ED)
  - AE sudden vision loss, called NAION
- In 2005 how many cases were reported to the FDA :
  - 43
- What the total estimated Nb of users:
  - 23 Million in Viagra alone
- How was media and legal system involved :
  - CBS reporting the case a 57 year old, went blind in right eye, he sued Pfizer
- So who is interested in knowing of there is cause-effect relation:
  - Academicians, clinicians, Pharma, FDA
- What did FDA request:
  - update package insert





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