Pharmacovigilance

Coach P. Hrytsenko

Pharmacovigilance Training
Understanding Drug Safety and Regulatory Compliance

Pharmasco®

What is Pharmacovigilance?

- Pharmacovigilance is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.
- Goal: Ensure patient safety and improve public health.

Why is Pharmacovigilance Important?

- - Protects patients from harm
- - Identifies unknown adverse reactions
- - Improves drug safety profiles
- - Supports regulatory decisions

Types of Adverse Drug Reactions (ADRs)

- Type A (Augmented): Predictable, dose-dependent

- Type B (Bizarre): Unpredictable, not dose-dependent

- Type C (Chronic): Long-term effects

- Type D (Delayed): Occurs after long latency

How to Detect ADRs

- Patient interviews

- Electronic health records

- Clinical trials

- Post-marketing surveillance

Reporting Systems

Key Systems:

- - WHO Vigibase
- - EudraVigilance (EU)
- - FDA MedWatch (USA)

Reports should include:

- - Patient details
- - Drug information
- - Description of the reaction

Signal Detection & Risk Management

Signal Detection:

- - Identifying patterns in ADR reports

Risk Management:

- - Benefit-risk assessment
- - Risk minimization strategies

Regulatory Framework

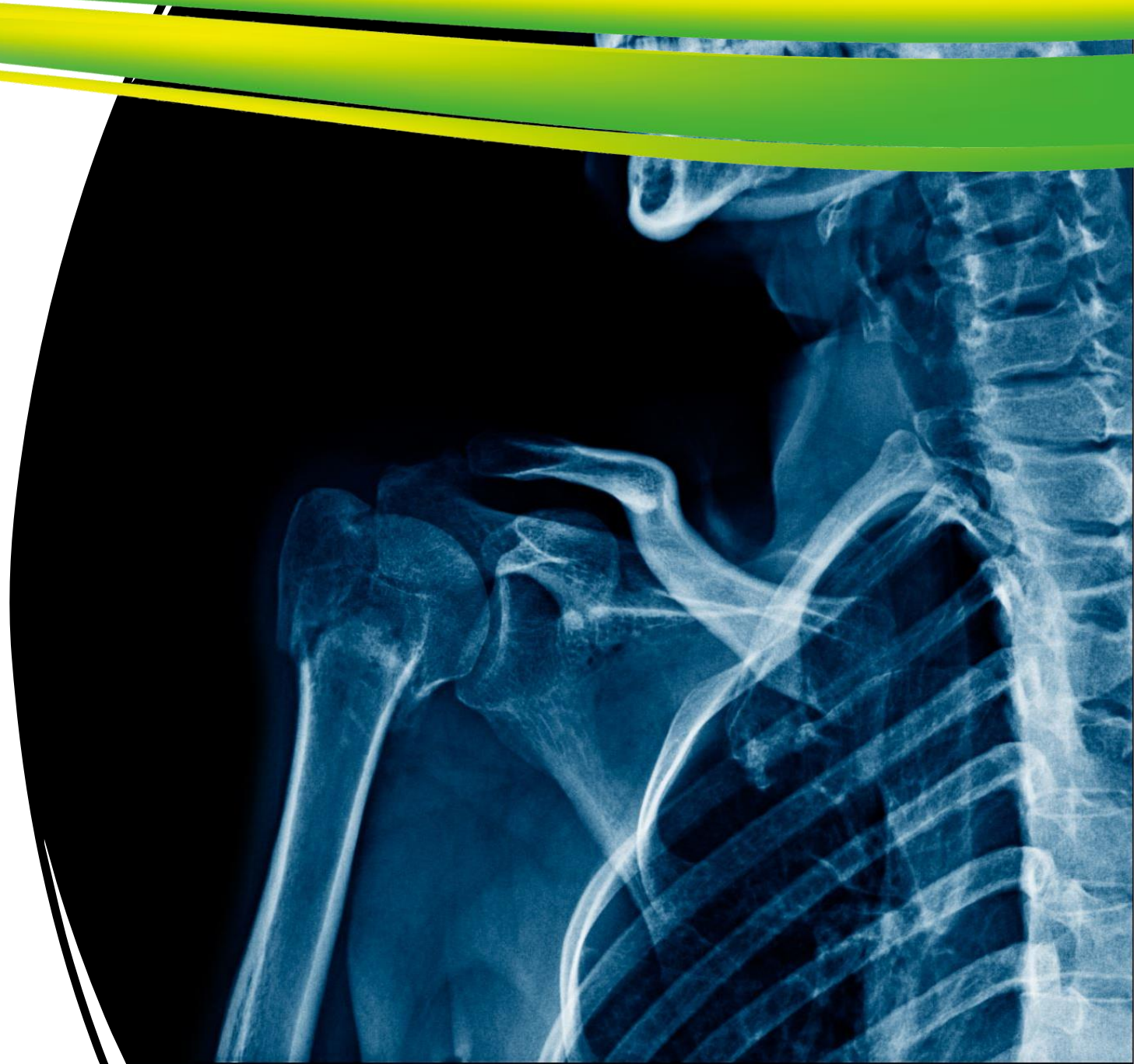
- Global Guidelines:
- - ICH E2E: Pharmacovigilance Planning
- - ICH E2B: Data standards for reporting
- National Regulations:
- - Vary by country, but aligned with ICH

Case Study

Case: A patient reports severe rash after taking Drug X.

Discussion:

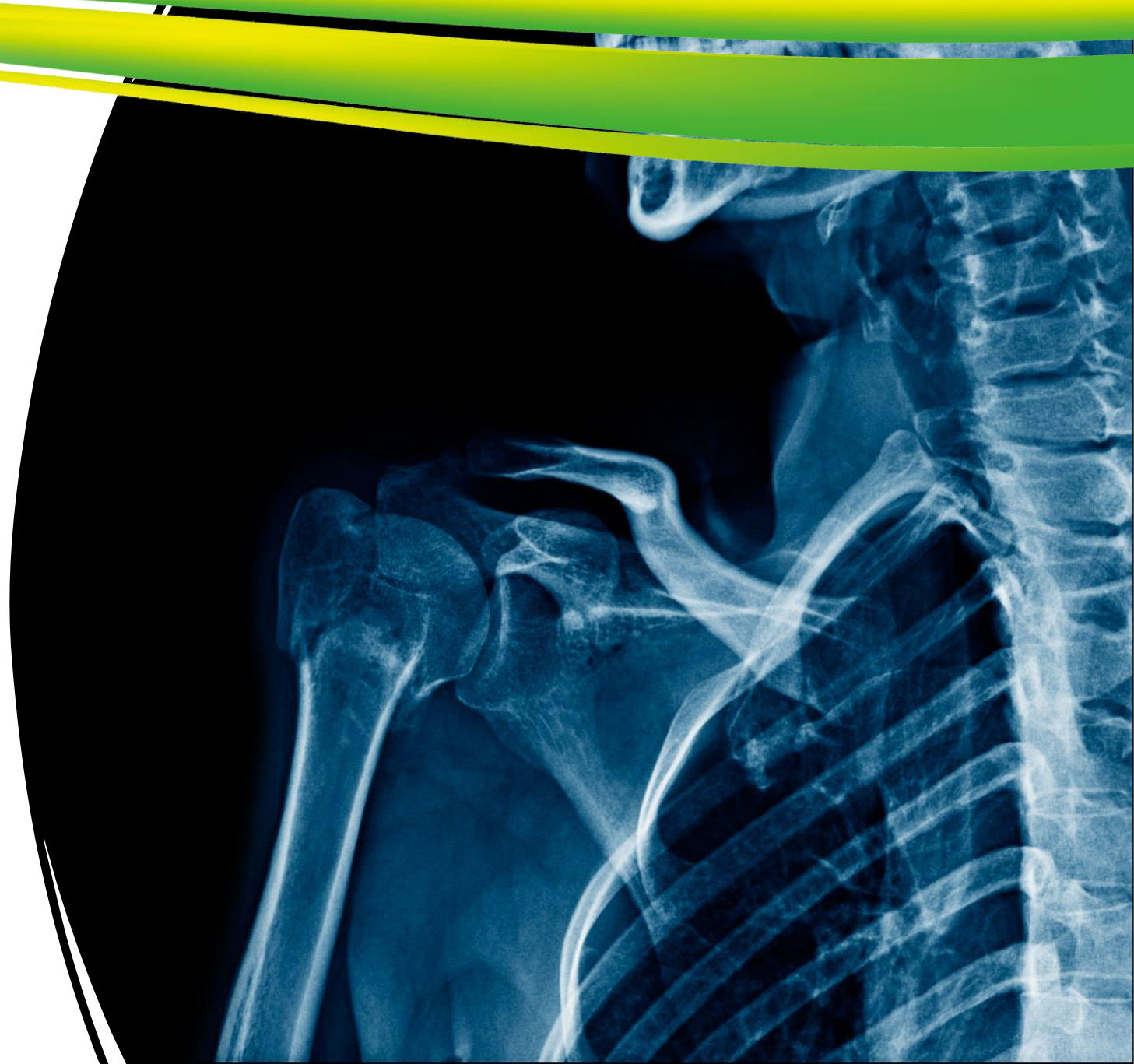
- - What type of ADR is this?
- - How should it be reported?
- - What actions should be taken?



Case Study

A patient reports severe abdominal pain after taking a prescribed medication. Upon investigation, it is found that the pain is dose-dependent and related to the drug's pharmacological action. What type of adverse drug reaction (ADR) is this?

- Type B (Bizarre)
- Type C (Chronic)
- Type A (Augmented)
- Type D (Delayed)



Case Study

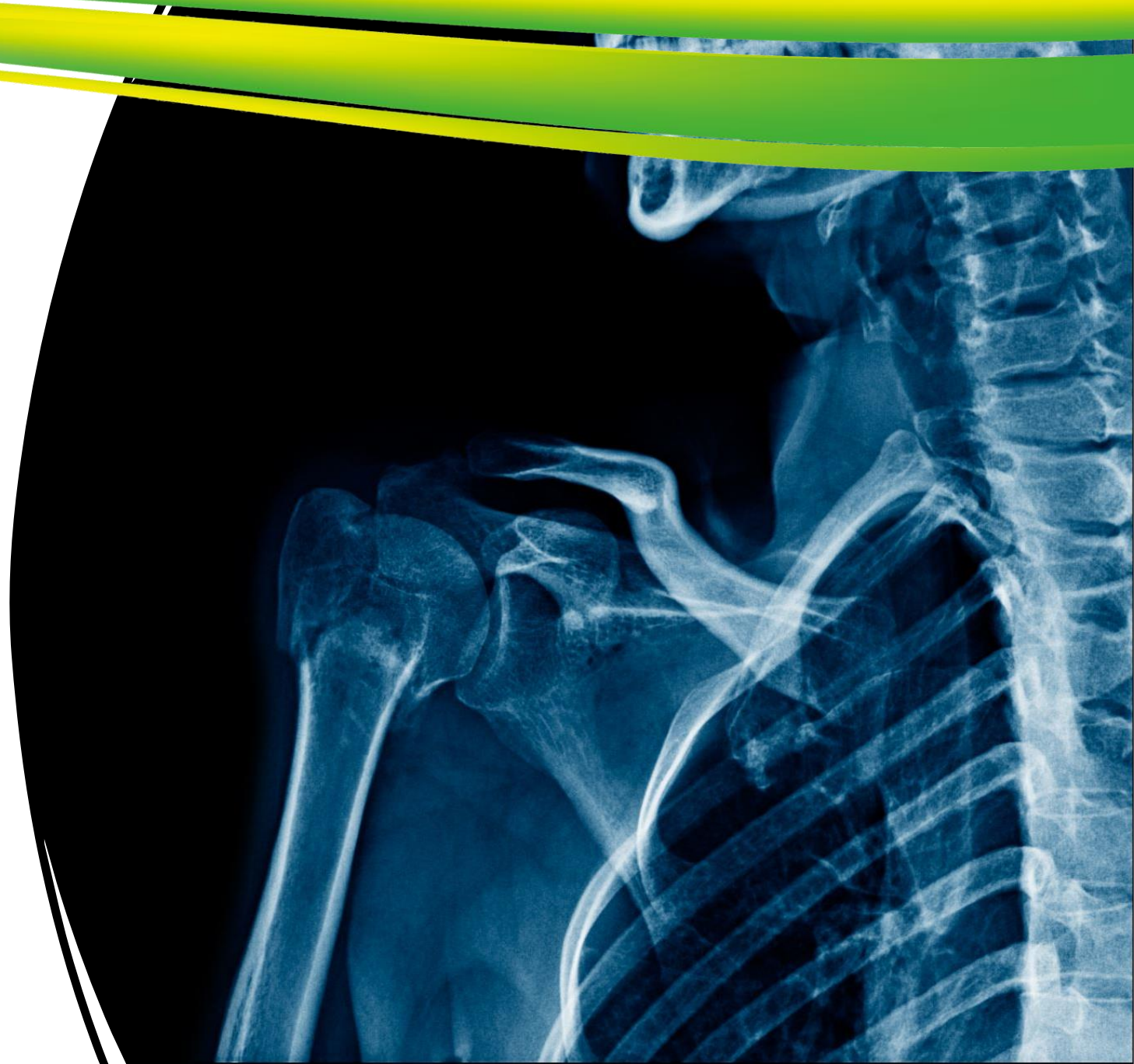
A patient develops a severe rash and difficulty breathing after taking a new antibiotic. The reaction is unpredictable and not related to the drug's dose. What type of ADR is this?

- Type A (Augmente
- Type B (Bizarre)
- Type C (Chronic)
- Type D (Delayed)

Case Study

After prolonged use of a medication for hypertension, a patient develops kidney damage. This adverse reaction is linked to the long-term effects of the drug. What type of ADR is this?

- Type A (Augmented)
- Type B (Bizarre)
- Type C (Chronic)
- Type D (Delayed)



Final Quiz

- Let’s test your knowledge!

- 1. What is the goal of pharmacovigilance?
- 2. Name two types of ADRs.
- 3. What does signal detection mean?

QUIZ

Final Quiz

Thank you for participating!

Stay vigilant. Stay safe.