Methotrexate and Prednisolone study in Erythema Nodosum Leprosum

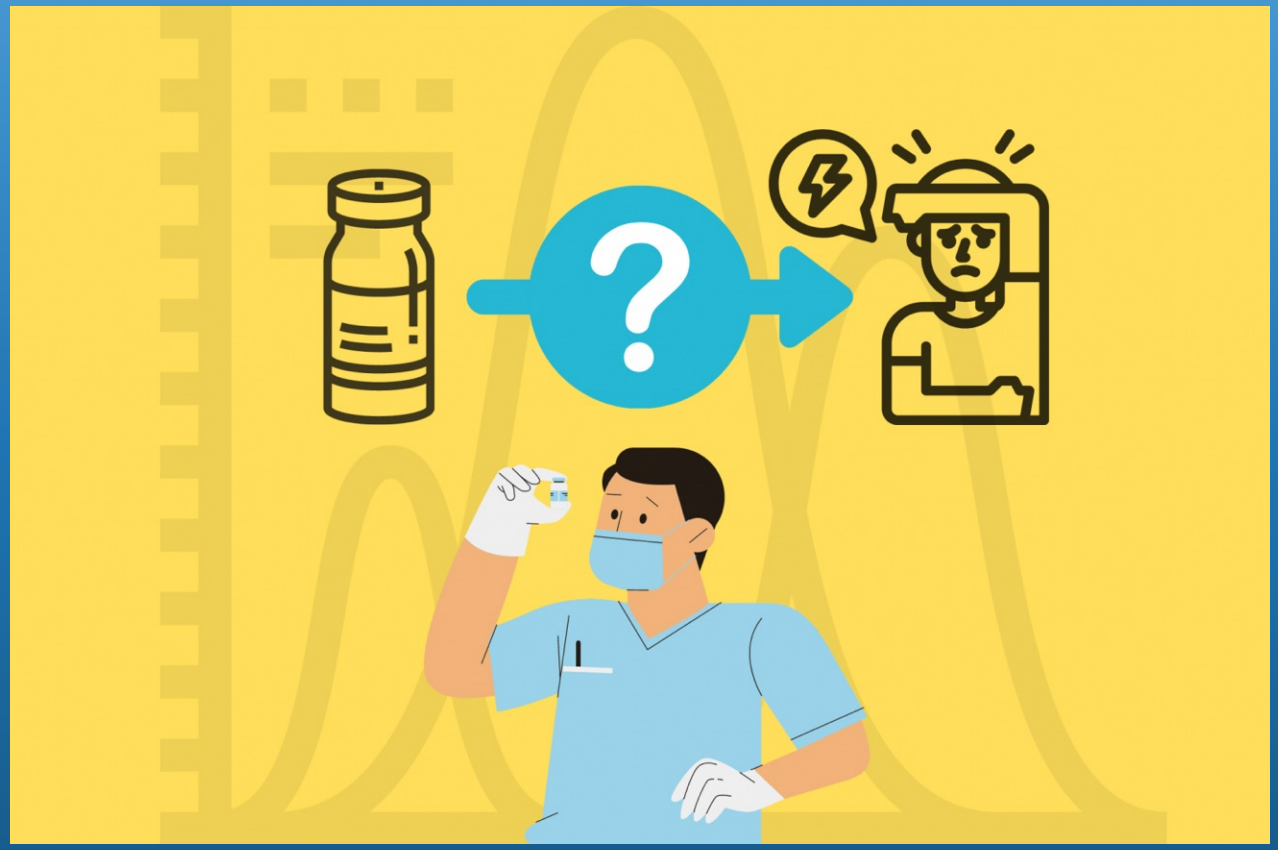
MaPs in ENL

Training session 13 – Adverse Events

Dr. Barbara de Barros – MaPs study manager

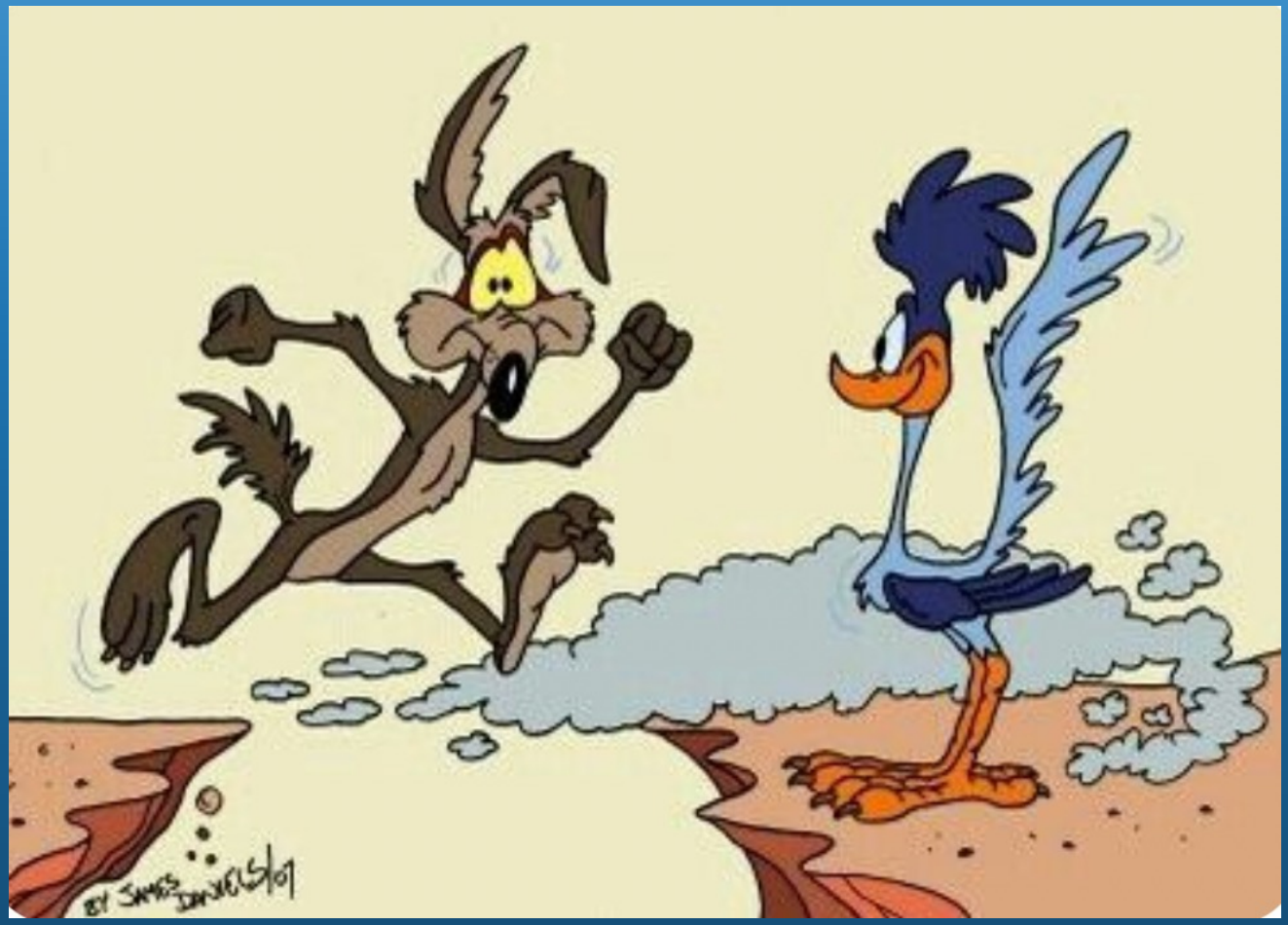
Adverse Events

- **Definitions**
  - **Adverse event**
  - **Adverse reaction**
  - **Serious adverse event**
- **What to do**



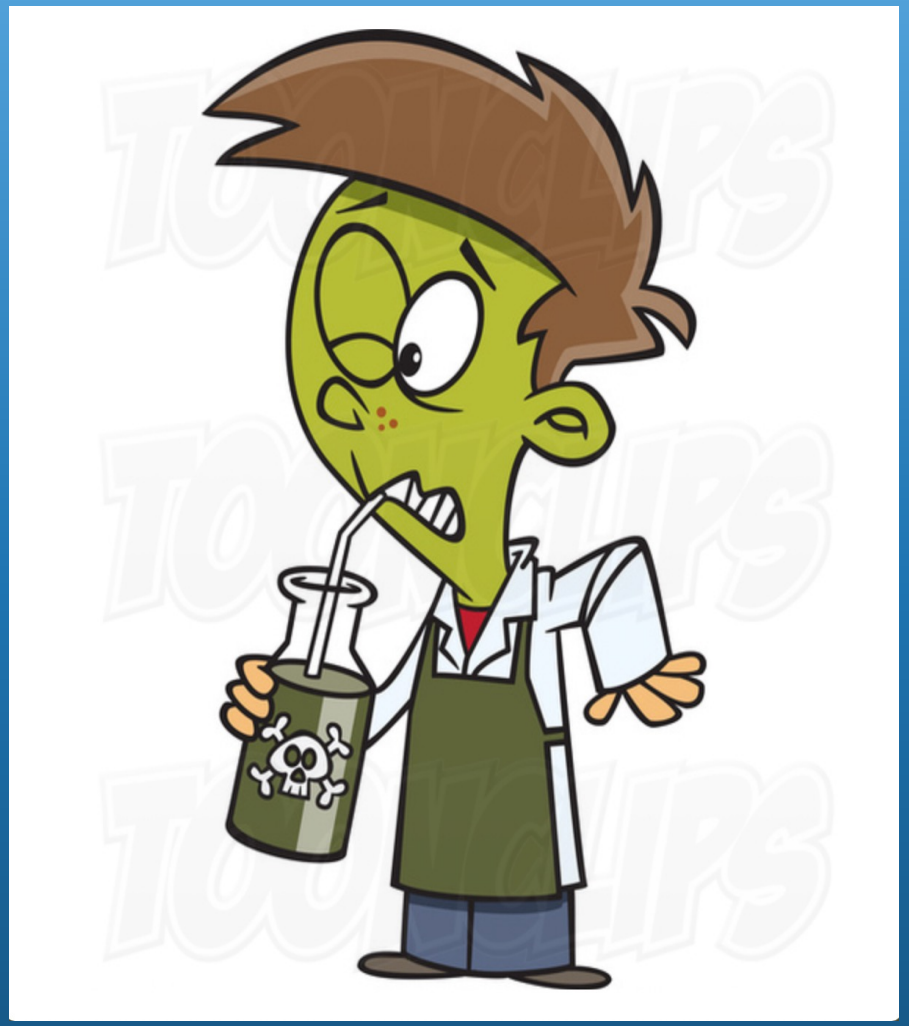
Adverse Event (AE)

- ANY unexpected medical occurrence in a participant to whom a medication or medical procedure has been administrated.
- It doesn’t need to be necessarily caused by or related to the medication



Adverse Reaction (AR)

- Adverse reaction is a type of adverse event
- ANY unexpected and unintended response in a participant to an investigational medicinal product which is related to any dose administrated to that participant.
- Casual relationship between the trial medication and the event is at least a reasonable possible
- In trial all unexpected medical occurrence are classified as an adverse event.



Serious Adverse Event (SAE)

- **Results in death**
- **Is life-threatening**
- **Requires patient hospitalisation or prolongation of existing hospitalisation**
- **Results in persistent or significant disability/incapacity**
- **Consists of a congenital anomaly or birth defect**

Adverse Event Report Flowchart

Adverse Event

Not serious

Do not need management

Need management:

- **Monitoring**
- **Medication**

Serious

Discuss with local Principal Investigator

Do not need to break randomisation code

Break the randomisation code

Management:

- **Medication**
- **Hospitalisation**

Report to study manager and Principal Investigator within 24 hours

Complete Adverse Event form

Summary

- **Adverse event is any medical occurrence in a participant having a medical treatment**
- **All adverse events will be recorded**
- **The adverse event form must be completed for all adverse events**
- **Serious adverse events must be reported as soon as possible**
- **Management will depend on the adverse event**