

EU INNOVATION NETWORK: 16<sup>th</sup> November 2018

# Academia and Training in Regulatory Science



L-Università ta' Malta  
Faculty of  
Medicine & Surgery

Department  
of Pharmacy

# Department of Pharmacy



L-Università ta' Malta  
Faculty of  
Medicine & Surgery

Department  
of Pharmacy



**Malta Medicines Authority**



**University of Malta**

# Collaboration between Department of Pharmacy, University of Malta and Medicines Authority



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of Pharmacy

- **Experiential placements** in Licensing, Pharmacovigilance, Drug Intelligence and Access, Science and Innovation Directorates
  - Experience gained in dossier evaluation, signal detection, clinical and quality assessments and GMP compliance
- **Joint research:** PhD and Doctorate in Pharmacy
  - Pharmacogenetics, pharmacovigilance, advanced therapies

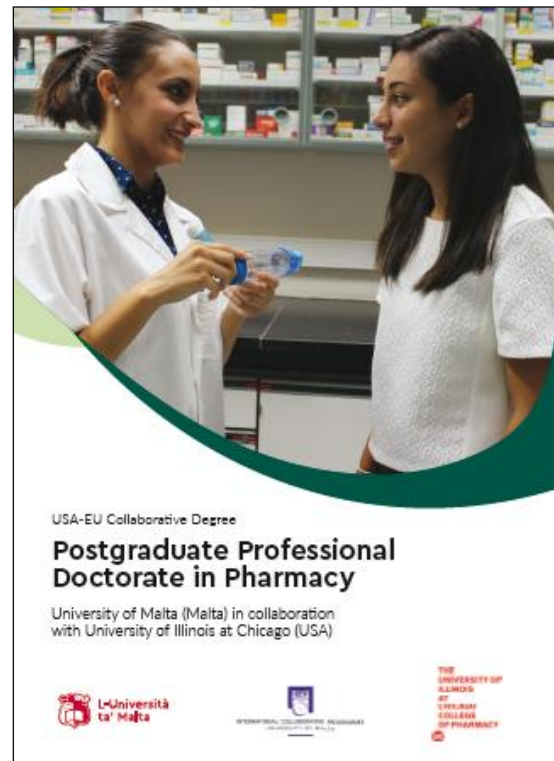
# Postgraduate Doctorate in Pharmacy



L-Università ta' Malta  
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of Pharmacy

- **Research and Innovation**
- **Focus on patient safety in developing and use of innovative drugs**
- **Leadership and advocacy**
- **Drive policies and developments**
- **Regulatory sciences perspectives**



- **Paid Fellowships** offered by the Malta Medicines Authority for pharmacists with interests in regulatory sciences
- **Empowerment** to apply experience gained in clinical environment supported by laboratory practice to the robust requirements in the presentation of an application for marketing authorisation

**Documentation**

**Ethics and Data Protection**

**Study design**

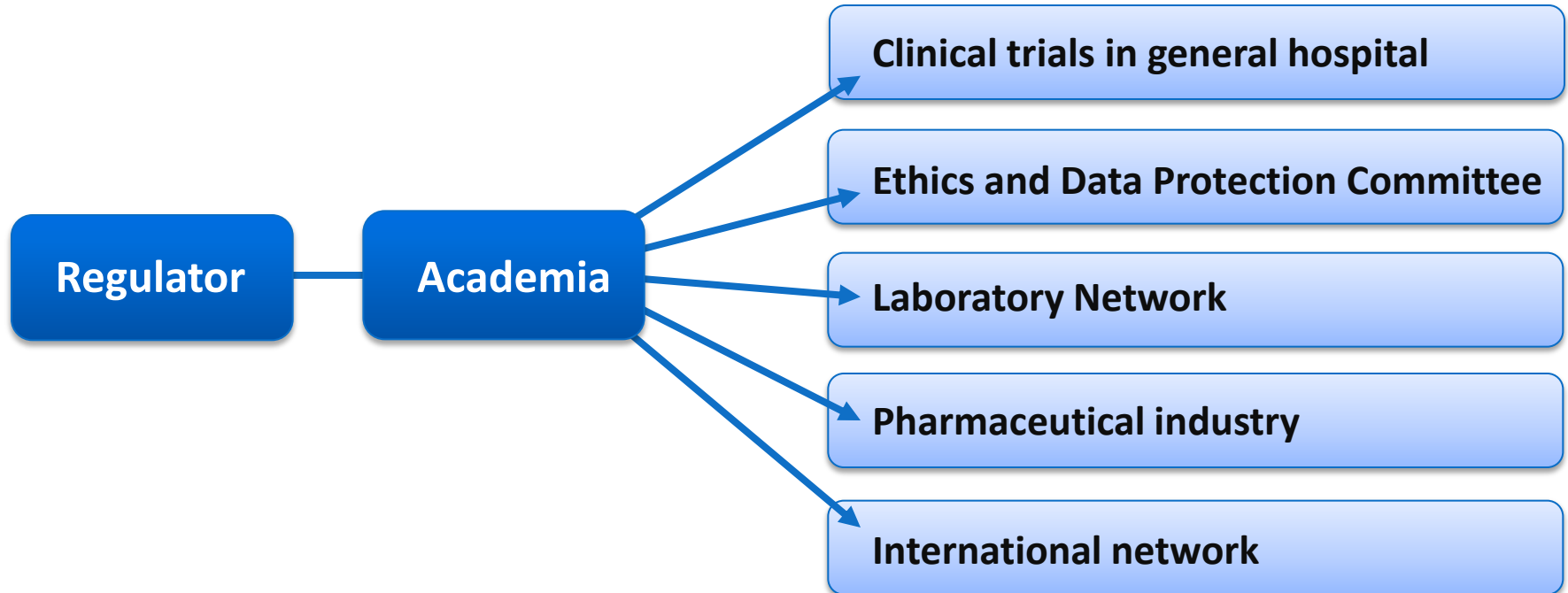
**Data analysis and statistics**

**Critical analysis**

**Analytical sensitivity, specificity, accuracy and precision**

- Merging **different perspectives**: Clinicians, researchers with regulators
- Ascertaining study design: robustness, reproducibility, sensitivity and specificity and regulatory norms from the **start**





DEPARTMENT OF PHARMACY  
UNIVERSITY OF MALTA



- **Patient safety**
- **Regulatory sciences**
- **Drug analysis**
- **Green pharmaceutical principles**
- **Risk management**