School of Pharmacy
University College Cork

EU Innovation Network Academia and Training in Regulatory Science Workshop

Presentation at EMA Workshop
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Supporting Innovation – a key strategic objective in Ireland

HRB Health Research Board

sfi Fondúireacht Eolaíochta Éireann
Science Foundation Ireland

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Ireland ranked 11th on a global basis in terms of its R&D and innovation sectors

My Background and Interest in Regulatory Science

- Research interests in ATMPs
  - Nano Technology –new BioMaterials
  - Gene therapy, Non-viral delivery of RNAi
  - Design, formulation, manufacture and assessment of RNA therapeutics
- Funding sources
  - EU Framework 7, COST & MedTrain Fellowship
  - SFI Centers: Curam, SSPC and AMBER

  all focused on novel materials and advanced therapeutics

- Board member of HPRA
- Board member of Critical-Path Institute Ltd., Arizona, USA
- Chair and co-founder of Regulatory Science Ireland

The Definition and Role of Regulatory Science?

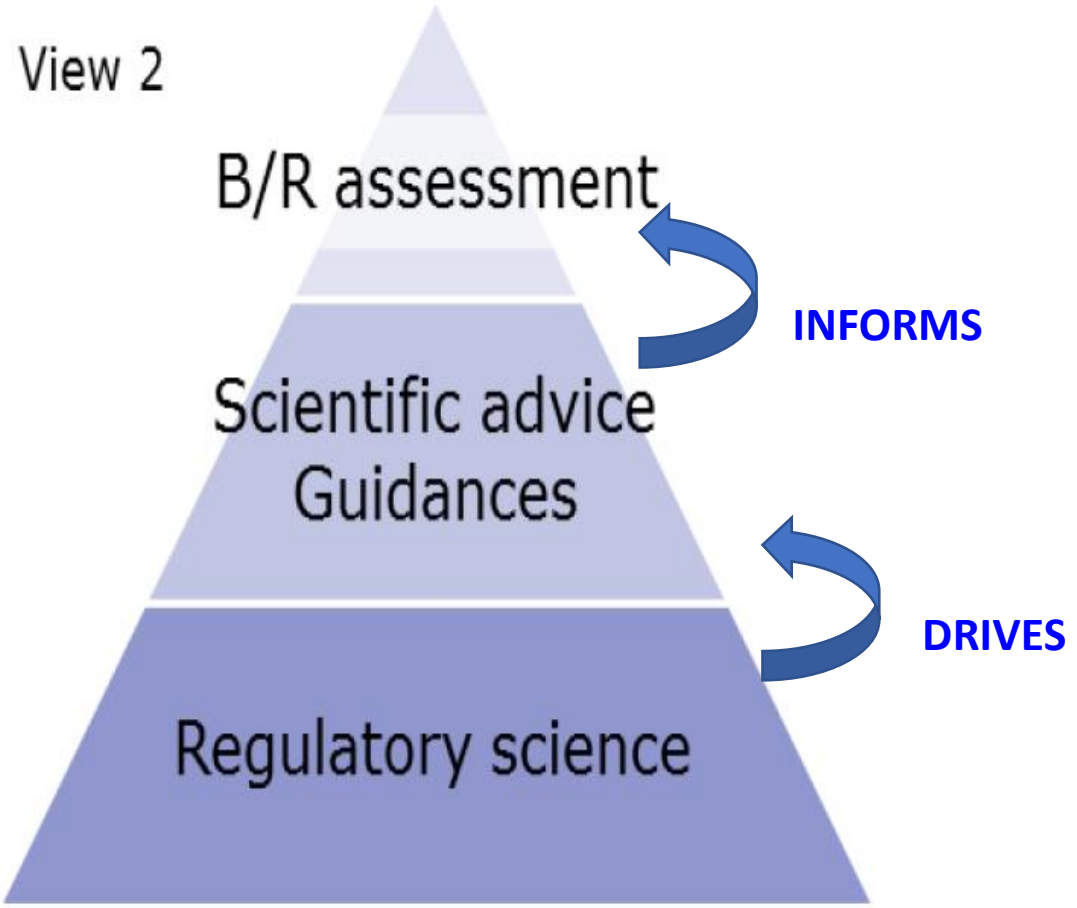
ATMPs

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 October 2018
EMA/723198/2018
Scientific Committees Regulatory Science Strategy

EMA Regulatory Science to 2025

Reference material



Challenges for Academic Clinical Studies

General Issues

- Cost
- Patenting & Patent life
- Legal issues Academic Institutions
- GDPR
- Lack of training in Regulatory requirements
- Unaware of supports available from HPRA Innovation Office

Pre-Clinical

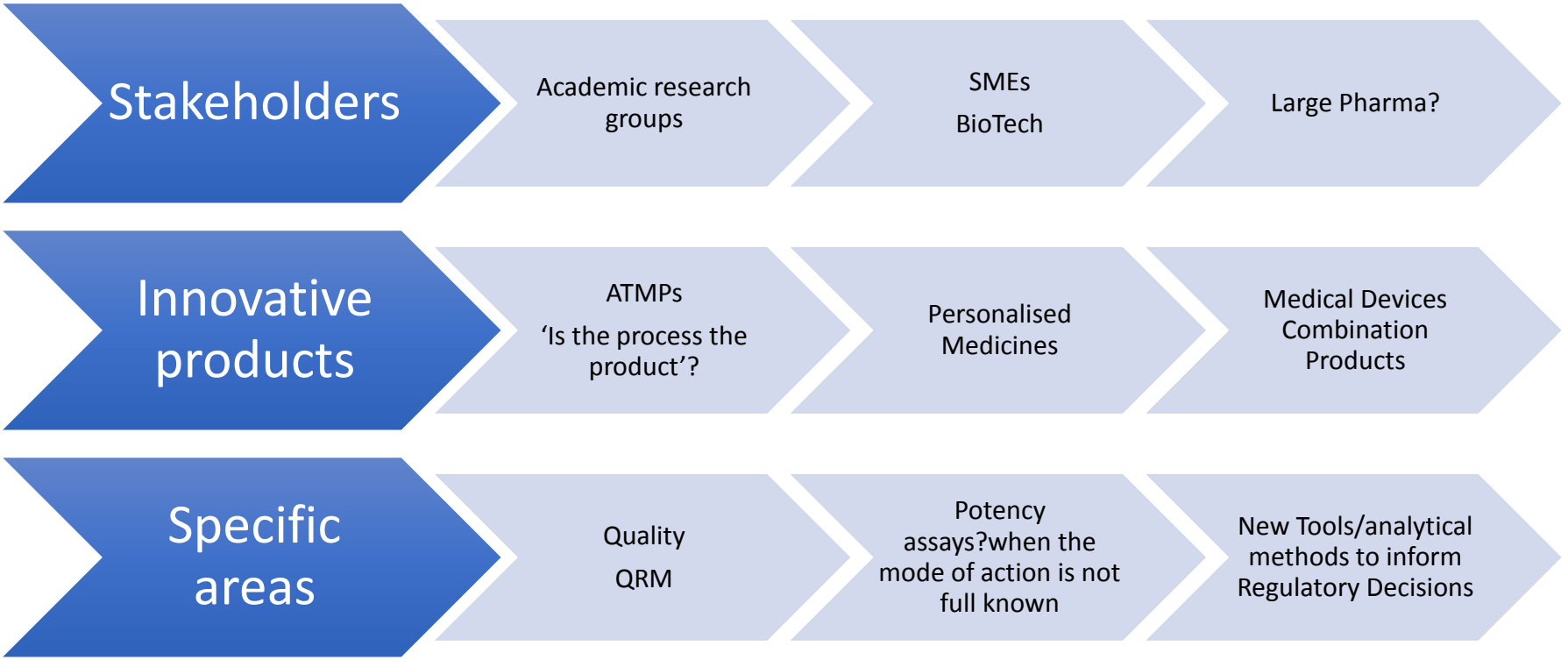
- Complex dosage form design -new bioactive materials
- Starting materials
- Manufacturing Scale-up
- Variation in global regulatory standards
- Classification?
- Access to GMP facilities

Clinical

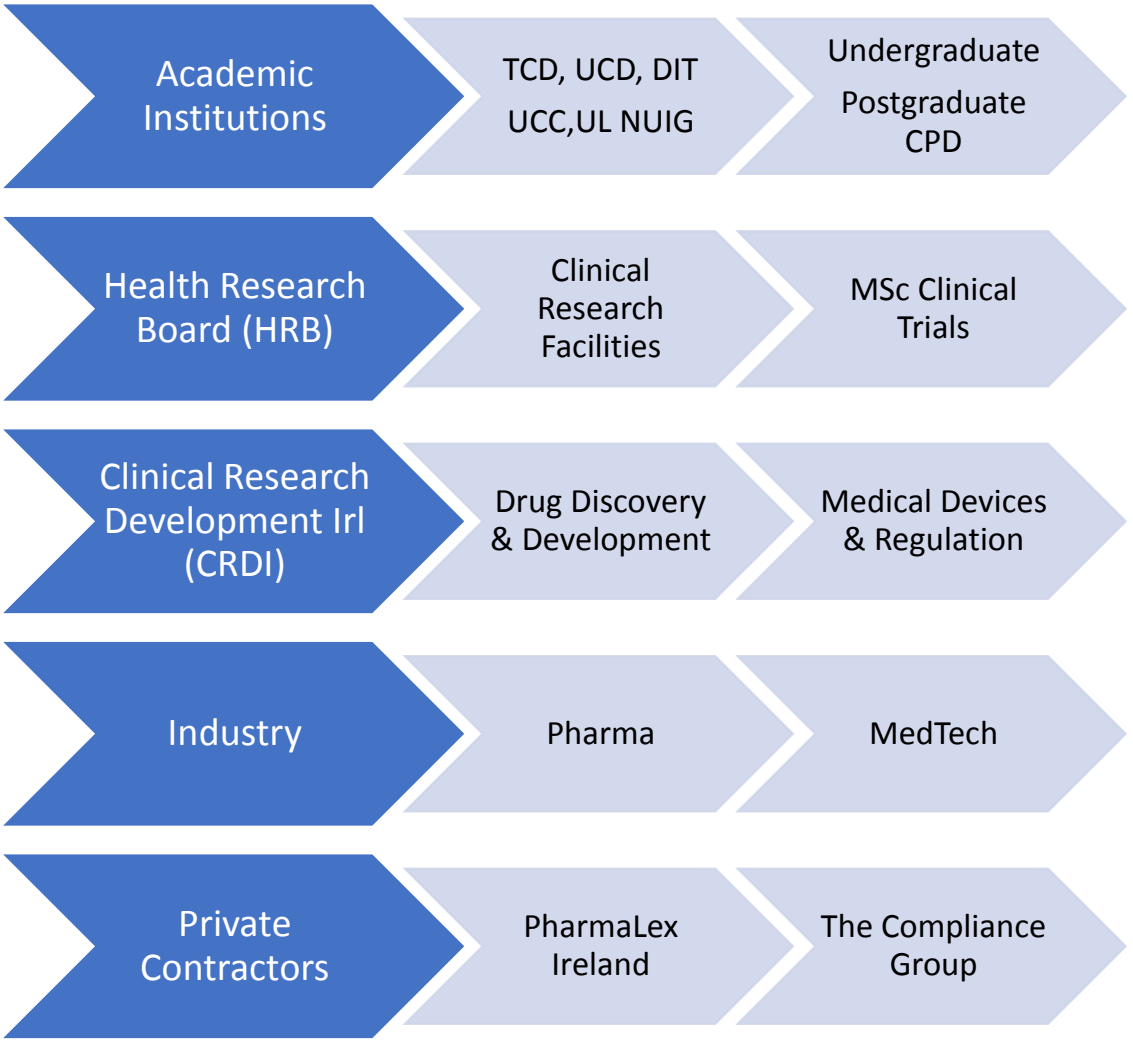
- Clinical trial design
- Adaptive CTs?
- Cost/benefit analysis – patient access
- Access to clinical research facilities
- Protected time for clinicians
- Research support staff-nurses

Need for a European-wide ecosystem to support and promote innovation and translational research

Need for Training-
Regulatory Guidelines & Processes



Training available in Regulatory Affairs vs Regulatory Science in Ireland



Fragmented, need for a Directory listing different types and levels (accreditation) of training available

H2020 Research and Innovation Programme

Marie Sklodowska-Curie actions

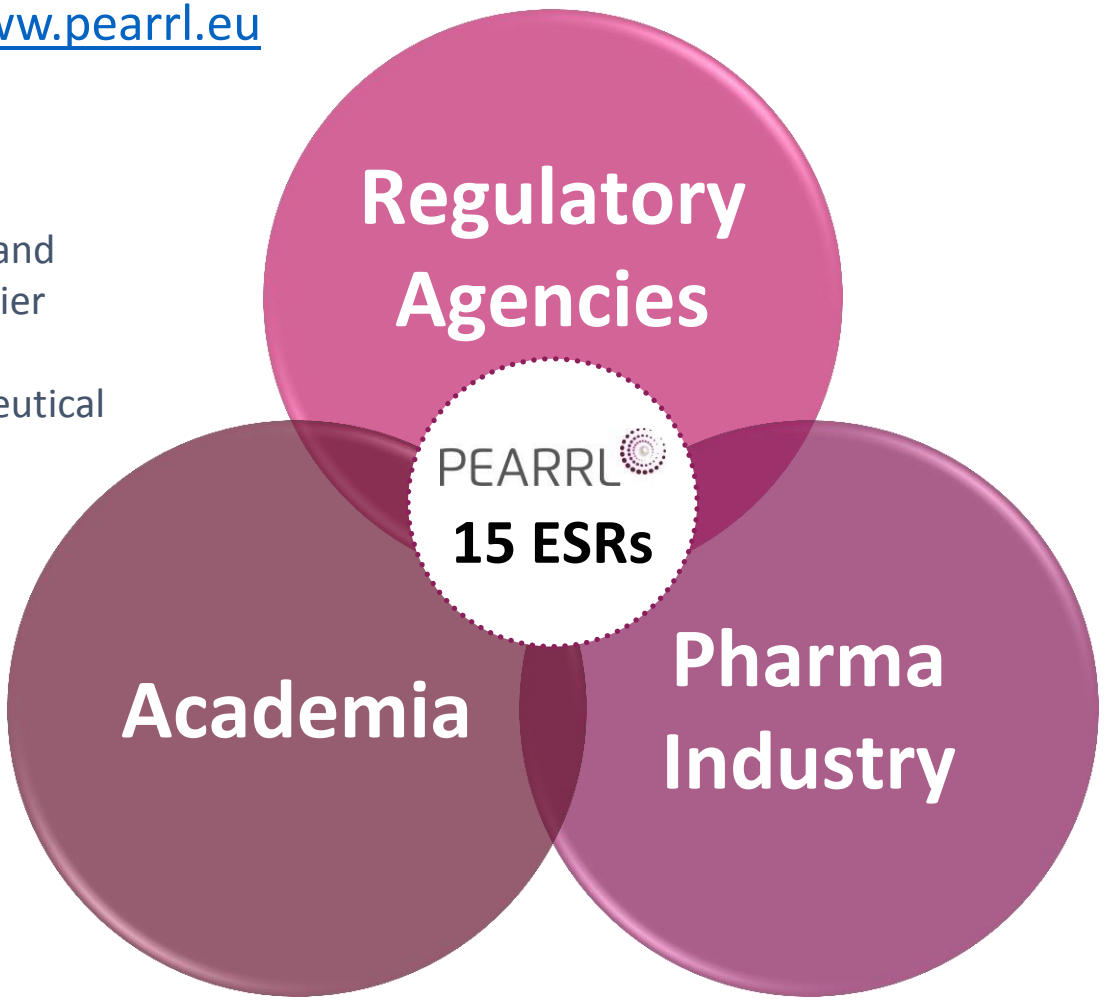
European Training Network (ETN) 2016-2020- coordinated by UCC

Pharmaceutical **E**ducation **A**nd **R**esearch with **R**egulatory **L**inks (PEARRL) www.pearrl.eu

8 EU Countries

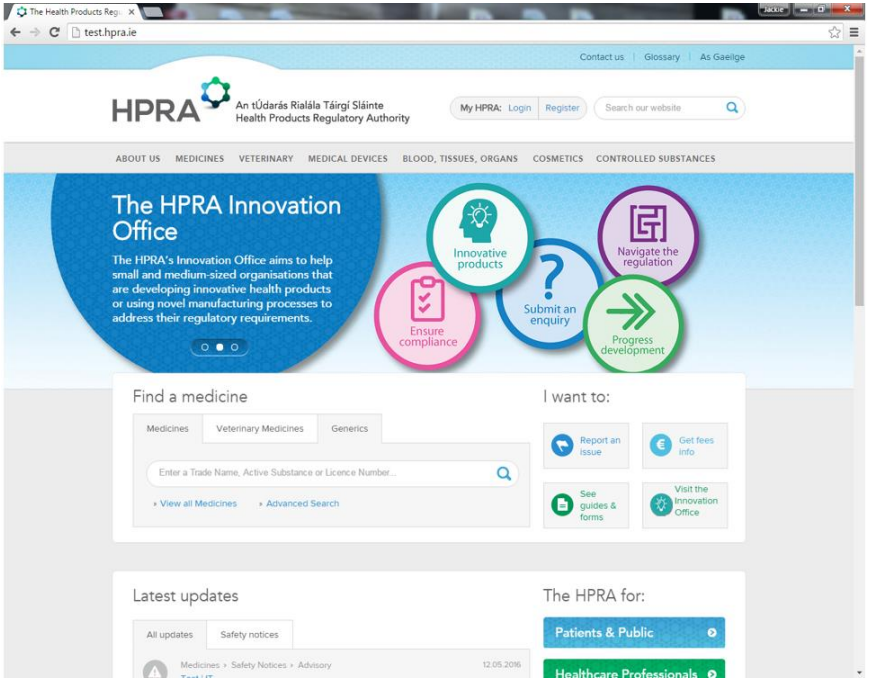
Overall Aims:

- Innovative drug development strategies and regulatory tools tailored to facilitate earlier access to medicines
- Educate the next generation of pharmaceutical scientist with a regulatory background

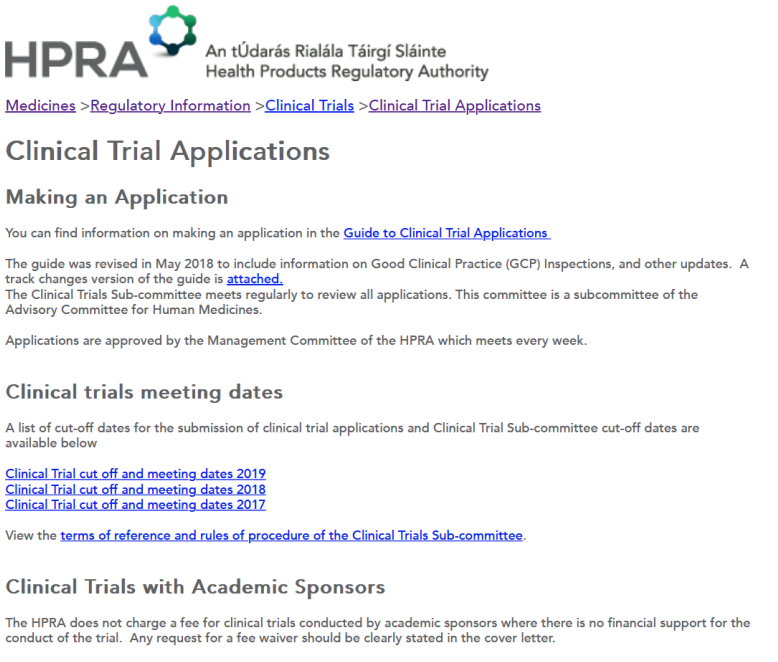


Experiences in dealing with National Regulatory Authority

- HPRA Mechanisms to Support Innovation



Experiences in dealing with National Regulatory Authority



HPRA An tÚdarás Rialála Táirgí Sláinte Health Products Regulatory Authority

Medicines >Regulatory Information >Clinical Trials >Clinical Trial Applications

Clinical Trial Applications

Making an Application

You can find information on making an application in the Guide to Clinical Trial Applications

The guide was revised in May 2018 to include information on Good Clinical Practice (GCP) Inspections, and other updates. A track changes version of the guide is attached.
The Clinical Trials Sub-committee meets regularly to review all applications. This committee is a subcommittee of the Advisory Committee for Human Medicines.

Applications are approved by the Management Committee of the HPRA which meets every week.

Clinical trials meeting dates

A list of cut-off dates for the submission of clinical trial applications and Clinical Trial Sub-committee cut-off dates are available below

Clinical Trial cut off and meeting dates 2019
Clinical Trial cut off and meeting dates 2018
Clinical Trial cut off and meeting dates 2017

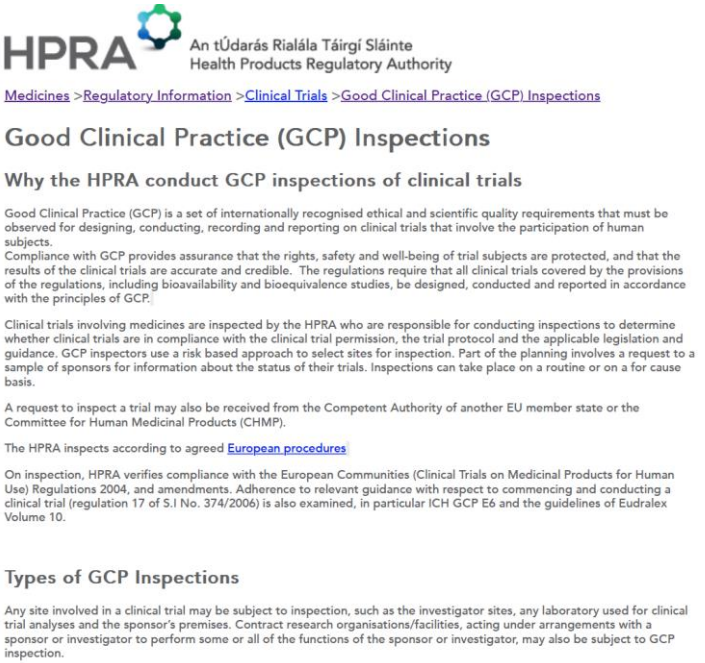
View the terms of reference and rules of procedure of the Clinical Trials Sub-committee.

Clinical Trials with Academic Sponsors

The HPRA does not charge a fee for clinical trials conducted by academic sponsors where there is no financial support for the conduct of the trial. Any request for a fee waiver should be clearly stated in the cover letter.

Feedback from Academic Groups:

- Clinical Trial applications very welcome
- Staff very proactive,
- Efficient turn around time
- No fees for academic sponsors



HPRA An tÚdarás Rialála Táirgí Sláinte Health Products Regulatory Authority

Medicines >Regulatory Information >Clinical Trials >Good Clinical Practice (GCP) Inspections

Good Clinical Practice (GCP) Inspections

Why the HPRA conduct GCP inspections of clinical trials

Good Clinical Practice (GCP) is a set of internationally recognised ethical and scientific quality requirements that must be observed for designing, conducting, recording and reporting on clinical trials that involve the participation of human subjects.
Compliance with GCP provides assurance that the rights, safety and well-being of trial subjects are protected, and that the results of the clinical trials are accurate and credible. The regulations require that all clinical trials covered by the provisions of the regulations, including bioavailability and bioequivalence studies, be designed, conducted and reported in accordance with the principles of GCP.

Clinical trials involving medicines are inspected by the HPRA who are responsible for conducting inspections to determine whether clinical trials are in compliance with the clinical trial permission, the trial protocol and the applicable legislation and guidance. GCP inspectors use a risk based approach to select sites for inspection. Part of the planning involves a request to a sample of sponsors for information about the status of their trials. Inspections can take place on a routine or on a for cause basis.

A request to inspect a trial may also be received from the Competent Authority of another EU member state or the Committee for Human Medicinal Products (CHMP).

The HPRA inspects according to agreed European procedures

On inspection, HPRA verifies compliance with the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, and amendments. Adherence to relevant guidance with respect to commencing and conducting a clinical trial (regulation 17 of S.I No. 374/2006) is also examined, in particular ICH GCP E6 and the guidelines of Eudralex Volume 10.

Types of GCP Inspections

Any site involved in a clinical trial may be subject to inspection, such as the investigator sites, any laboratory used for clinical trial analyses and the sponsor's premises. Contract research organisations/facilities, acting under arrangements with a sponsor or investigator to perform some or all of the functions of the sponsor or investigator, may also be subject to GCP inspection.

Feedback from Academic Groups:

- GCP Inspections- HPRA strong reputation
- Constructive feedback to stakeholders on inspections

- GCP training- helpful in understanding how a clinical trial should be conducted, along with the responsibilities of the relevant bodies and investigating team

?QUESTIONS?