EMA
EUROPEAN MEDICINES AGENCY

HMA
Heads of Medicines Agencies

The inspection process

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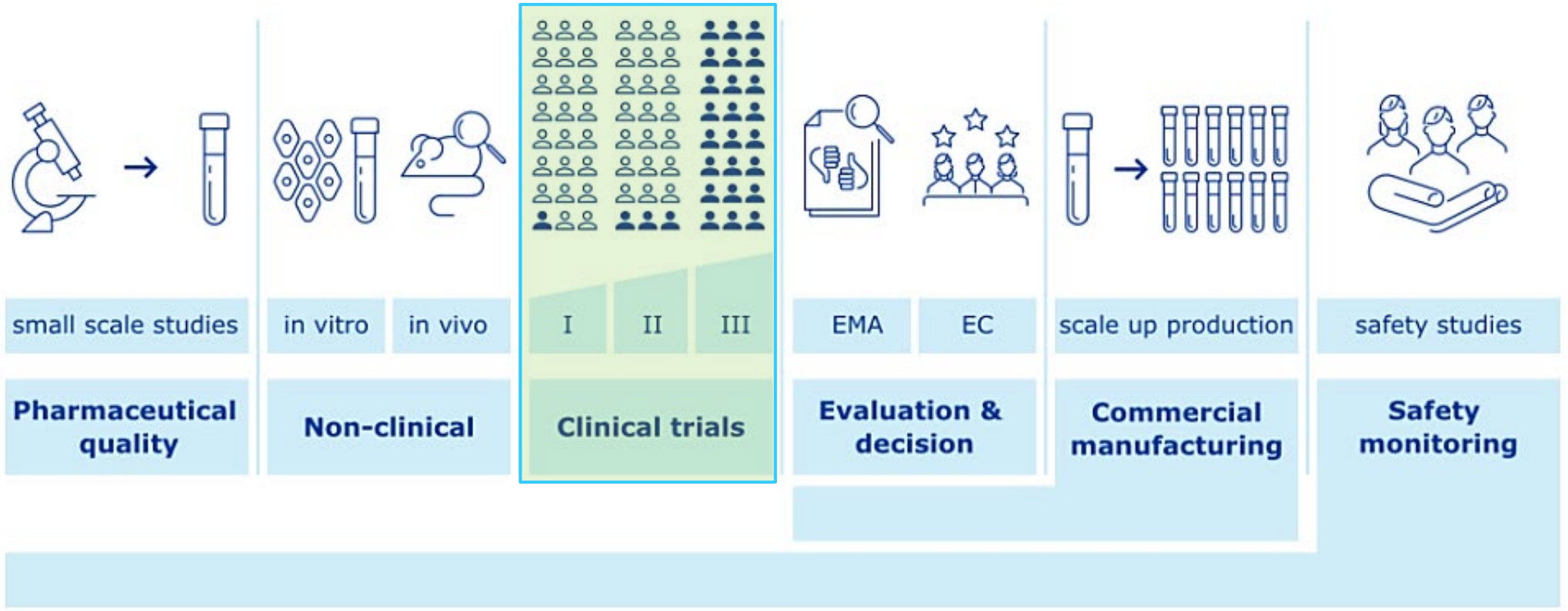
My background

- M.Sc. Pharmacy (pharmacology), University of Helsinki
- Joined the Finnish Medicines Agency FIMEA 21 years ago
- Different areas of medicines regulatory work (pharmacovigilance, quality assessment, clinical trials, inspections)
- Pricing and reimbursement related assessment at Social Insurance Institution and Ministry of Health
- GCP inspector since 2007
- Currently seconded from FIMEA to the EMA Inspections Office

Overview of a medicine lifecycle

Good Practice GxP

GLP **GCP** GMP GVP



Good Clinical Practice (GCP)

- Guideline for good clinical practice ICH E6(R3) – coming into effect on 23 July 2025
- International, ethical, scientific and quality standard for the conduct of clinical trials
- Purpose is to ensure the protection of rights, safety and well-being of trial participants
- Builds on ICH E8 guideline on general considerations for clinical studies
- Applies to trial conduct, i.e. processes from planning to reporting

"Clinical trials vary widely in scale, complexity and cost. Careful evaluation of critical to quality factors involved in each trial and the risks associated with these factors will help ensure efficiency by focusing on activities critical to achieving the trial objectives."

Types of GCP inspections

Routine

- Routine surveillance of GCP compliance
- No specific trigger or concern
- General scope
- No clock-stop

For cause (also referred to as triggered inspections)

- Requested by assessors due to triggers identified during evaluation of application
- Focused scope
- Clock-stop

GCP inspections are performed by the national competent authorities (NCAs) of the EU member states (MSs), for the purposes of:

- Supervision of clinical trials in the MS
- Verification of the reliability and ethical conduct of trials used in marketing authorisation applications (MAAs)

GCP inspections coordinated by EMA

- **Who** inspects?

  GCP inspectors of the NCA of the EU MSs are responsible for carrying out the inspections

  Inspectors from two MSs (Rapp and Co-Rapp or other MSs available)

- **What** is inspected?

  Any clinical trial included in an application for a centrally authorised product

  New applications, variations, extensions or as part of post marketing obligations

- **What** is the purpose of the inspection?

  To evaluate compliance with GCP and provide assurance to the CHMP about the reliability and the quality of the data submitted in the MAA, as well as ethical conduct of the trial used to support the MAA

- **Where** is the inspection taking place?

  Countries within or outside EU/EEA

  Any site relevant for the trial conduct (sponsor, investigator, service provider)

Scope of a GCP inspection

Investigator

- Informed consents of participants
- Compliance to protocol
- Collection and reporting of safety and efficacy data
- Source data
- Investigator Site File (ISF)

Sponsor

- Trial planning & management
- Oversight
- Quality management
- IMP management
- Data management & governance
- Statistical analysis & reporting
- Safety management
- Trial master file (TMF)

Analytical facility

- Sample handling
- Bioanalytical methods
- Pharmacokinetic and statistical analysis

Reporting of inspections

- What was inspected, where and when
- Documents, data and processes reviewed during inspection
- References: applicable legislation, ICH GCP and other relevant guidelines
- Compliance/non-compliance with applicable legislation and GCP
  - Deviations classified as critical, major and minor based on the effect on the rights, safety and well-being of the participants and data reliability
- Opportunity given to respond to findings
- Assessment of the validity and reliability of the data and ethical conduct of the trial

Potential consequences of an inspection

- **In case of critical findings affecting the safety of trial participants and/or reliability of the trial**

In context of a marketing authorisation application

- Non-acceptance of the data to be used in support of a marketing authorisation application

In context of an ongoing trial in the EU / NCA

- Revoking the authorisation of a clinical trial
- Suspending a clinical trial
- Requiring sponsor to modify an aspect of the clinical trial

- **In case of most inspections**

- Knowledge is shared with investigators and sponsors on GCP compliance in trial conduct
- Inspectors gain useful knowledge about the conduct of clinical trials and challenges ”on the field”

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Thank you