Getting know the agencies:

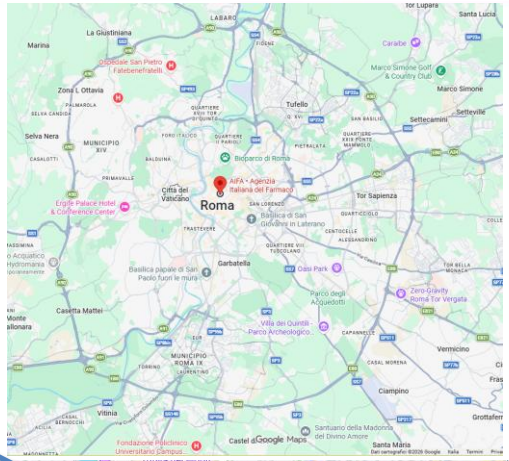
Clinical pharmacology at AIFA

Andrea Logreco

Clinical pharmacology SIA meeting
24/11/2026

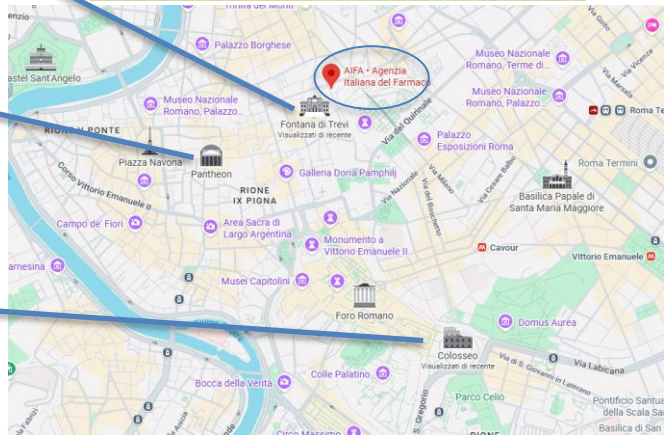
Location of AIFA





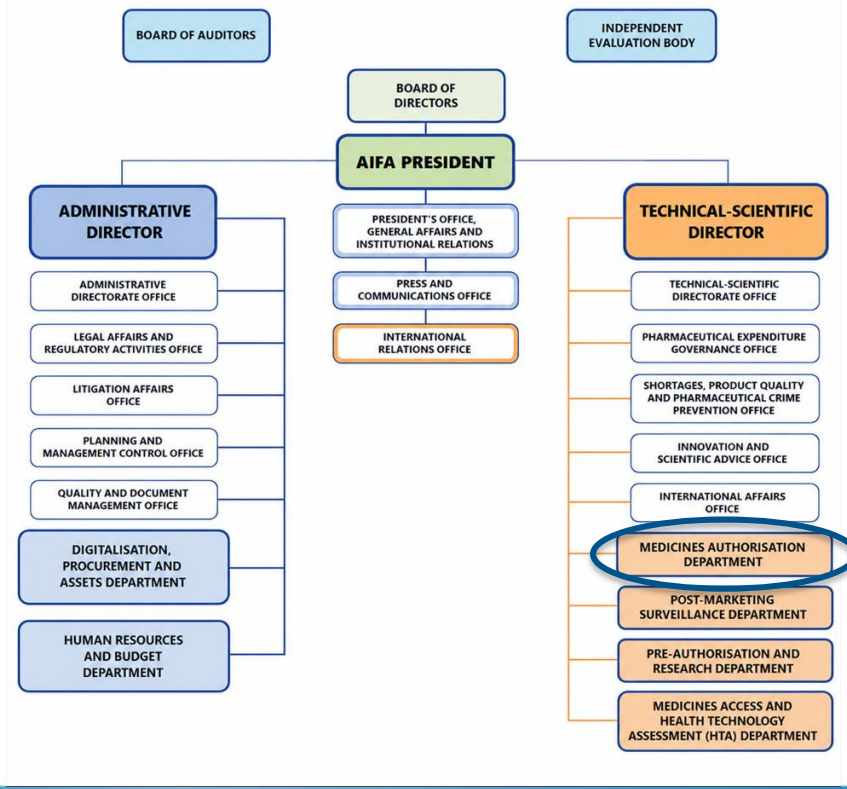






Italian Medicines Agency

Organisational chart



Medicines Authorisation Department

6 Offices

- **Centralised Procedures Office**
- **European and National Procedures Office**
- **Post-Authorisation Procedures Office**
- Certification and Parallel Importation Office
- Medicinal Products GMP Inspections and Authorisations Office
- Active Substances GMP Inspections and Authorisations Office

Clinical Pharmacology

Medicines Authorisation Department

European and National Procedures Office

- 2 non-clinical assessors
- 5 PK-assessors
- 2 clinical assessors

PK assessors provide support to the Post-Authorisation Procedures Office

Post-Authorisation Procedures Office

- 5 clinical assessors

Centralised Procedures Office

- 3 non-clinical assessors
- 4 PK assessors
- 6 clinical assessors

Innovation and Scientific advice Office

1 non-clinical assessor
2 clinical assessors

Representation in the following EMA Working parties and Working groups:

Oncology Working Party
Haematology Working Party
Scientific Advice Working Party
Non-clinical Working Party
Immune and Inflammatory Diseases Working Party

Clinical Pharmacology-OEG
New approach methodologies-OEG
Methodology ESEC
Non-clinical and new approach methodologies ESEC

PK Assessors

Various educational backgrounds:

- Biology
- Biotechnology
- Chemistry
- Pharmacy
- Toxicology

Keep up to date with PK-related topics:

- Weekley or monthly meetings
- PK-Assessors mailing list
- PK-Assessors Microsoft Teams chat

We can work from home 2 days a week

PK Assessors activity

different Offices, specific expertise but…in principle same job

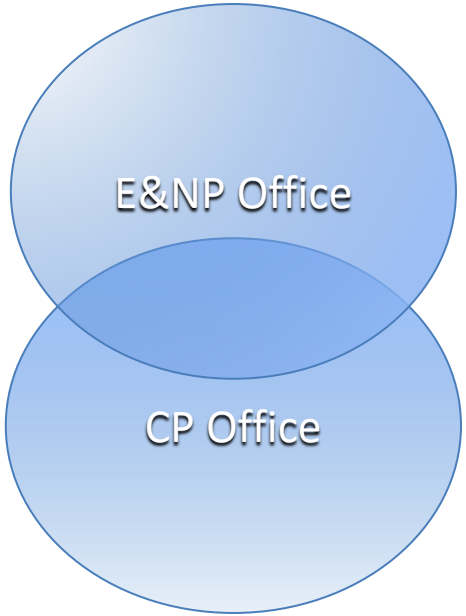
BIOANALYTICAL METHOD
- PK bioanalytics
- Immunogenicity assays

ADME
- Food-effect studies
- Bioequivalence studies
- Mass-balance studies
- Dose-proportionality studies

In-vitro dissolution studies
- BCS-based biowaiver
- Biowaiver for additonal strenghts

DRUG–DRUG INTERACTIONS
- In vitro DDI studies
- Victim DDI studies
- Perpetrator DDI studies

MODELLING AND SIMULATION
- Pop-PK
- PKPD
- PBPK





Thank you!

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