

# **Europa Uomo & The European Medicines Agency**

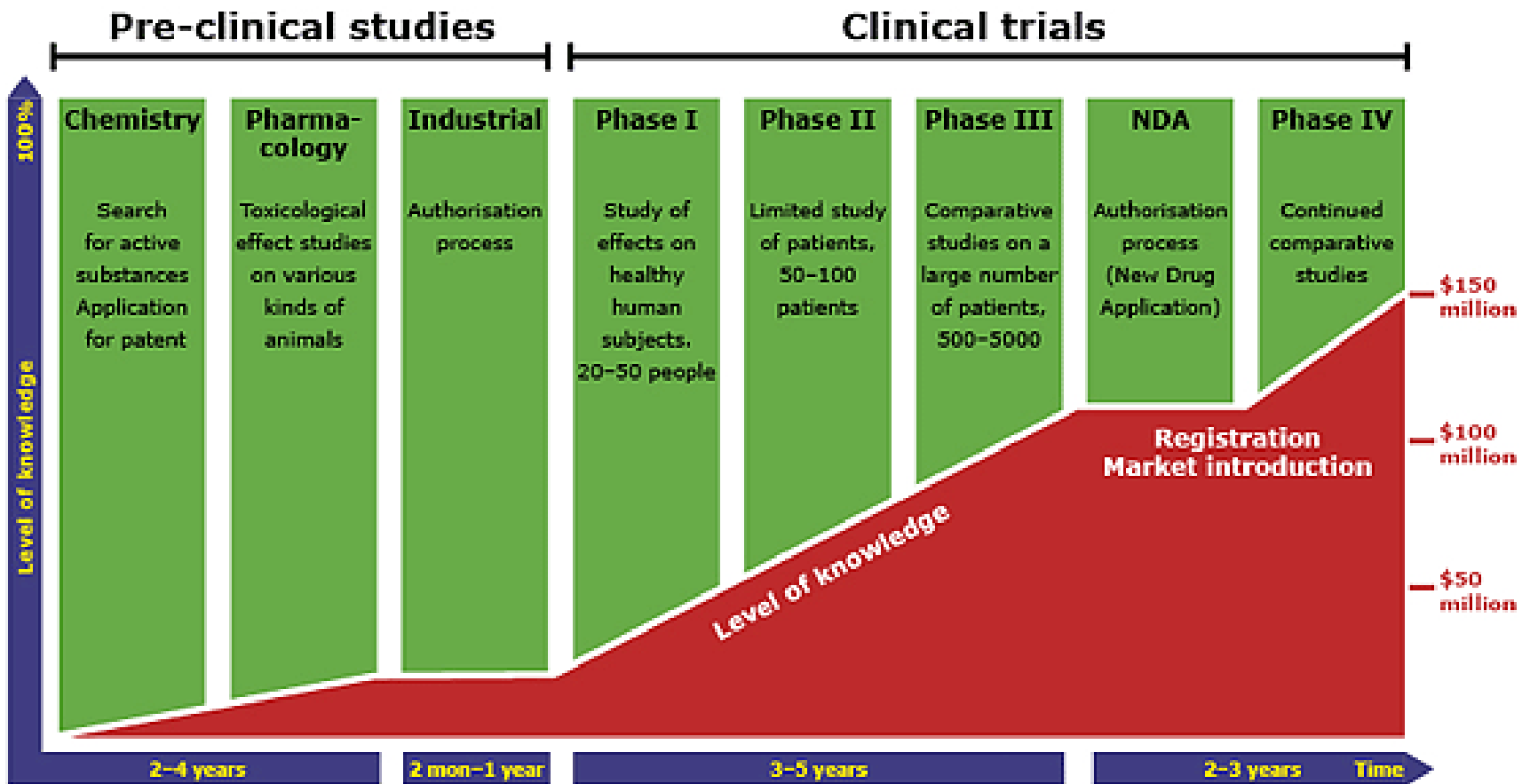
# Outline of the presentation

**Drug development**

**European Medicines Agency (EMA)**

**EUomo & EMA**

# Drug development

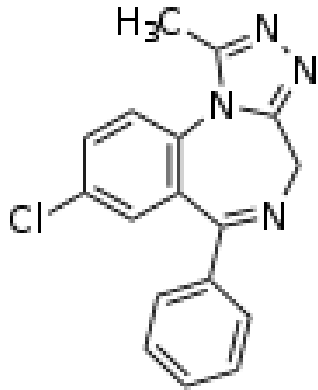


# Where do new drugs come from?

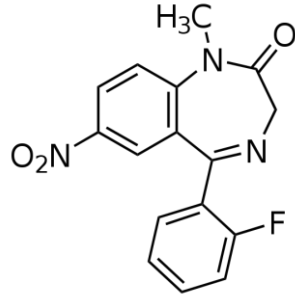
## Research

- **Chemical modification of known drugs**
- **Translational research**
- **Fundamental research**

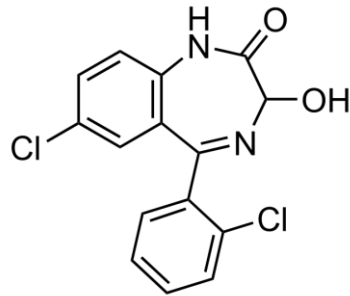
# Chemical modifications



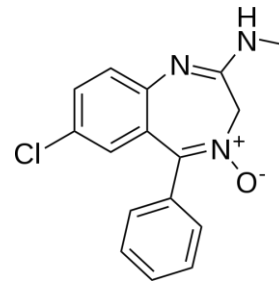
Xanax



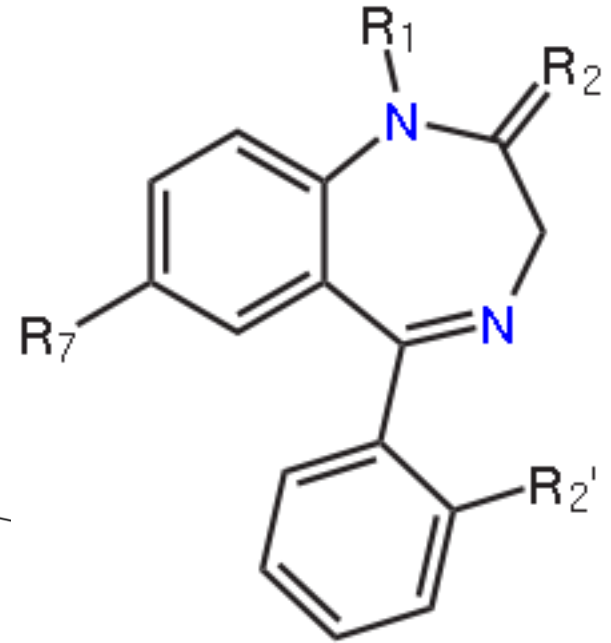
Funitrazepan  
Rohypnol



Lorazepam  
Temesta



Chlordiazepoxide  
Librium



Benzodiazepines

# T & Fundamental research

Translational: real medical research close to the bedside of patients, objective to move new findings quickly to applications in patients

Pure/Fundamental research: no application in sight, the objective is to understand processes in nature on a basic chemical level. Sometimes these findings lead to applications in the clinic.



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# European Medicines Agency

Medicinal products for human use

Medicinal products for veterinary use

Orphan medicinal products

Herbal medicinal products

Paediatric

Advanced therapies

Pharmacovigilance

# European Medicines Agency

The Agency is responsible for the scientific evaluation of applications for European marketing authorisations for both human and veterinary medicines (**centralised procedure**).

Under the centralised procedure, companies submit a **single** marketing-authorisation application to the Agency. Once granted by the European Commission, a centralised (or 'Community') marketing authorisation is valid in all European Union (**EU**) and **EEA-EFTA** states (Iceland, Liechtenstein and Norway).

# European Medicines Agency

All medicines for human and animal use derived from biotechnology and other high-tech processes must be approved via the centralised procedure.

The same applies to all advanced-therapy medicines and human medicines intended for the treatment of HIV/AIDS, cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions, and viral diseases, as well as to all designated orphan medicines intended for the treatment of rare diseases.

# European Medicines Agency

For medicines that do not fall under any of the above-mentioned categories, companies **can submit** an application for a centralised marketing authorisation to the Agency, provided the medicine constitutes a significant therapeutic, scientific or technical innovation, or is in any other respect in the interest of patient or animal health.

# European Medicines Agency

The Agency constantly monitors the safety of medicines through a **pharmacovigilance** network, and **takes appropriate actions** if adverse drug reaction reports suggest that the **benefit-risk balance** of a medicine has changed since it was authorised. For veterinary medicines, the Agency has the responsibility to establish safe limits for medicinal residues in food of animal origin.

# European Medicines Agency

Six scientific committees, composed of members of all EU and EEA-EFTA states, **some including patients' and doctors' representatives**, conduct the main scientific work of the Agency:

the Committee for Medicinal Products for Human Use (**CHMP**), the Committee for Medicinal Products for Veterinary Use (CVMP), the Committee for Orphan Medicinal Products (**COMP**), the Committee on Herbal Medicinal Products (HMPC), the Paediatric Committee (PDCO) and the Committee for Advanced Therapies (CAT)

# European Medicines Agency

The Agency can be considered as the 'hub' of a European medicines network comprising over **40 national competent** authorities in 30 EU and EEA-EFTA countries, the European Commission, the European Parliament and a number of other decentralised EU agencies.

The Agency works closely with its European partners to build the best possible **regulatory system for medicines** for Europe and protect the health of its citizens.

# European Medicines Agency **does not:**

Evaluate all medicines in use in the European Union

**The Agency only becomes involved in the assessment of such medicines when they have been referred to the Agency due to a disagreement between two or more Member States about the authorisation or use of the medicine, or due to some other issue that requires resolution in the interest of protecting public health.**

# European Medicines Agency **does not:**

Evaluate all medicines in use in the European Union

**Research or develop medicines**

**Evaluate pricing or availability of medicines in individual countries**

**National competent authorities (human – veterinary)**

**Establish ethical codes in relation to the development of medicines or  
evaluate applications based on ethical considerations**

# European Medicines Agency

Centralised authorisation procedure

**derived from biotechnology processes, such as genetic engineering;**

**advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines;**

**intended for the treatment of HIV/Aids, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions;**

**officially designated 'orphan medicines' (medicines used for rare diseases).**

# European Medicines Agency

Centralised authorisation procedure

**National authorisation procedures**

**Decentralised procedure**

**Mutual-recognition procedure**

# European Medicines Agency

Pre-authorisation

**For full applications according to Article 8(3) of Directive 2001/83/EC, the results of pharmaceutical tests (physico-chemical, biological or microbiological), pre-clinical tests (pharmacological and toxicological), and clinical trials need to be submitted.**

# European Medicines Agency

Public assessment reports

**The European Medicines Agency publishes a full scientific assessment report called a European public assessment report (EPAR) for every medicine granted a central marketing authorisation by the European Commission.**

**Use this search to find key information on medicines authorised for human use, including a public-friendly summary in question-and-answer format and the **Package Leaflet**. You can also find information on medicines that have been refused a marketing authorisation or that have been suspended or withdrawn after being approved.**

# European Medicines Agency

Contents of “product information”

Annex I - Summary of product Characteristics

Annex IIA - Manufacturing Authorisation Holder responsible for Batch Release

Annex IIB - Conditions of the Marketing Authorisation

Annex IIIA - Labelling

Annex IIIB - Package Leaflet

# European Medicines Agency

European Medicines Agency completes its review of Avastin used in breast cancer

**Q&A** | **Press release** | **Key facts** | **All documents**

▶ Expand all items in this list

- ⊕ **About**
- ⊕ **What is Avastin?**
- ⊕ **Why was the use of Avastin in metastatic breast cancer reviewed?**
- ⊕ **Which data has the CHMP reviewed?**
- ⊕ **What are the conclusions of the CHMP?**
- ⊕ **What are the recommendations for patients and prescribers?**

Name	Language	First published	Last updated
 <a href="#">Questions and answers on the review of Avastin (bevacizumab) in the treatment of metastatic breast cancer</a>	(English only)	16/12/2010	

# European Medicines Agency

Patients and consumers

**being members of its scientific committees and Management Board;**

**responding to specific requests from the Agency's scientific committees, working parties and scientific advisory groups;**

**reviewing information on medicines prepared by the Agency;**

**being involved in the preparation of guidelines;**

**regularly taking part in Agency conferences and workshops.**

# European Medicines Agency

## Patients and consumers

► Expand all items in this list

- ✚ Alzheimer Europe (AE)
- ✚ DEBRA International
- ✚ European AIDS Treatment Group (EATG)
- ✚ European Cancer Patient Coalition (ECPC)
- ✚ European Consumers' Organisation (BEUC)
- ✚ European Federation of Allergy and Airways Diseases Patients' Associations (EFA)
- ✚ European Federation of Neurological Associations (EFNA)
- ✚ European Genetic Alliances' Network (EGAN)
- ✚ European Headache Alliance (EHA)
- ✚ European Heart Network (EHN)
- ✚ European Institute of Women's Health (EIWH)
- ✚ European Multiple Sclerosis Platform (EMSP)
- ✚ European Myeloma Platform (EMP)
- ✚ European Older People's Platform (AGE)
- ✚ European Organisation for Rare Diseases (EURORDIS)
- ✚ European Parkinson's Disease Association (EPDA)
- ✚ European Patients' Forum (EPF)
- ✚ European Public Health Alliance (EPHA)
- ✚ European Prostate Cancer Coalition (EUomo)
- ✚ Global Alliance for Mental Illness Advocacy Networks (GAMIAN-Europe)
- ✚ Health Action International (HAI)
- ✚ Insulin Dependent Diabetes Trust (IDDT)
- ✚ International Alliance of Patients' Organizations (IAPO)
- ✚ International Confederation of Childhood Cancer Parents Organisations (ICCCPO)
- ✚ International Diabetes Federation (IDF)
- ✚ International Patient Organisation for Primary Immunodeficiencies (IPOPI)
- ✚ Myeloma Euronet (ME)
- ✚ Rett Syndrome Europe (RSE)
- ✚ Thalassaemia International Federation (TIF)



# European Medicines Agency

## ■ European Prostate Cancer Coalition (EUomo)

The [European Prostate Cancer Coalition \(EUomo\)](#) is the umbrella organisation of prostate patient organisations in Europe. As an umbrella organisation Europa Uomo has no "patients" as members. Europa Uomo serves all European patients on an international level to further the case of prostate health.

### **Representativity**

Only patient led organisations can be members. In the general assembly each country has one vote only and each country decides on the person to be the voting member. Today Europa Uomo's membership is from more than 25 countries.

### **Vision**

Europa Uomo stands for evidence based and optimal medical treatment of prostate diseases in a multi professional team. This care should be patient centred and holistic based on maintaining optimal quality of life.

### **Mission and objectives**

Europa Uomo aims to make:

- ▶ Governments to be aware of prostate diseases, to support research on prostate biomarkers, educate on the risk of prostate cancer, provide tailored treatment of the individual patient through the appropriate use of PSA testing and to build partnerships to reduce the burden of the disease to overcome inequalities in medical treatment and holistic care.

*Last updated: 22/11/2010*

# European Medicines Agency

Patients and consumers

**In general, patients are expected to bring real-life experience of the disease and its current therapeutic environment; as a consequence:**

- It would enrich regulatory outcome by complementing it with the views of those directly affected by regulatory decisions;**
- It would increase confidence and trust in the regulatory process;**
- It would lead to a higher level of transparency;**
- It would allow to prepare for any future integration of patients as CHMP members when foreseen in new Community legislation.**

# European Medicines Agency

Patients and consumers

- feasibility of **Risk Management Plan** in real life environment (and feedback on its implementation);
- specific information to be put in the **Package Leaflet and its wording**;
- communication related issues (the decision on when to communicate, the content, etc);
- explore their views on the potential impact of a possible **withdrawal or suspension**;
- feasibility of **CT design** (e.g. availability of patients to enrol, acceptability of comparator);
- open dialogue with PCOs in certain situations (e.g. negative opinion). Explaining the reasons for such opinion, despite not being a consultation itself, can build transparency and trust in regulatory decisions, as it can lead to higher level of acceptability and understanding of regulatory decisions by medicine users.

# EUROPA UOMO

**Present at EMA**

**Members of EUomo to take action in their own country**

- **ethical com.**
  - **national level?**
  - **local level, every institution that does clinical trials has to have a ethical com.**

**Partner with the local national authority, they allow the medicinal products to the market and decide on the price.**