EMA – HCPWP

Regulatory sciences in fellowships and young researchers

Share practices and experiences

AN ITALIAN EXPERIENCE ON REGULATORY SCIENCE

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EFPC

F.I.M.M.G.

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Patent application

Preclinic

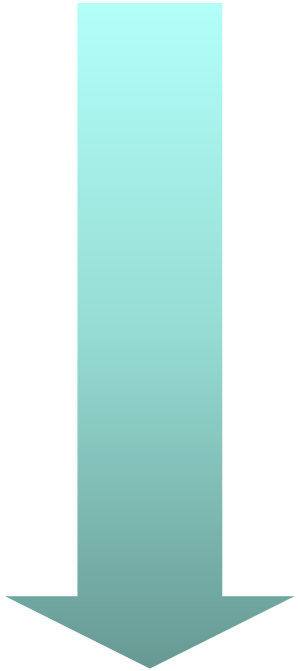
Phase I-II

Phase III

Registration/Autorizzation of Marketing

Reimbursement

Pharmacovigilance



the drugs enter the market and used in real patients

the approach to the drug use is suffering by a lack of structured information and data deriving from PC

prescribing GPs do not know well the authorization path of the drugs and therefore also the authorization conditions

F.I.M.M.G. (Italian Federation of General Practitioners)

has created courses for the School of Research in General Medicine and Drug Management.

This school is aimed at GPs, young and not only, who wish to acquire skills in the management of Drug Research.

The aim was to explain:

1. What it takes to develop a drug and to get it authorised.
2. How to access medicines on the market, both through the European and the national (Italian) path.

E-Learnig Course – Resident Course

Each participant had to attend:

first a E-Learnig Course, *then* a 3-days Resident Course

COURSE	GPs had been attending
E-Learnig	1,000
Resident 3-days Course	500

Among the different topics, great importance has been given to:

1) THE AUTHORIZATION PROCEDURES AND THE PRINCIPLES OF ACCESS TO THE DRUG
2) THE PHARMACOVIGILANCE PRE AND POST MARKETING (this theme was managed by a speaker authorized by AIFA).

- The experience lasted 3 years and we plan to repeat it
- Currently the 2 Relations are also proposed in the Postgraudate General Practice Training

CORSO DI FORMAZIONE A DISTANZA

RICERCA IN MEDICINA GENERALE
E GESTIONE DEL FARMACO - FIMMG

E-LEARNING COURSE

RESIDENT COURSE

Added value for participants

Added value for participants

GPs must:

1. Improve knowledge of the access processes of drugs on the market (the medicine can be marketed accross the EU)
2. Become aware of how important it is to participate in defining better the profiles of efficacy, safety and usefulness needed to define the « place in therapy « of (new) drugs.
3. Apply the best prescriptive and disbursement modalities according to the economic sustainability of the NHS and fairness of access to care

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