

Italian post-marketing registries

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Public Declaration of transparency/interests*

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Interests in pharmaceutical industry	NO	Currently	Last 2 years	More than 2 years but less than 5 years ago	More than 5 years ago (optional)
Direct interests:					
Employment with a company	x				
Consultancy for a company	x				
Strategic advisory role for a company	x				
Financial interests	x				
Ownership of a patent	x				
Indirect interests:					
Principal investigator	x				
Investigator	x				
Individual's Institution/Organisation receives a grant or other funding	x				

*Entela Xoxi, in accordance with the Conflict of Interest Regulations approved by AIFA Board of Directors (26.01.2012) and published on the Official Journal of 20.03.2012 according to 0044 EMA/513078/2010 on the handling of the conflicts of interest for scientific committee members and experts

N.B. I am not receiving any compensation

Outlines of this talk

- ① e-Prescription
- ② Collecting data
- ③ Registers' factory
- ④ Regional dashboard
- ⑤ The benefits of all the actors involved

Electronic drug prescriptions



Change of mentality is essential in life



Collecting data: more info from the real world

A necessity for:

- Academy;
- Regulatory;
- Pharma industry.

Required for:

- Health economic data;
- Experiences data;
- Patient-reported outcomes;
- Reimbursement data;
- Safety surveillance data.

- Registries;
- Drug & Pathology analysis;
- National context;
- Appropriateness & Managed Entry Agreements.



AIFA Drugs Registries

monitoraggio-farmaci.agenziafarmaco.it

Programmi generali:

- Farmaci antineoplastici
- Farmaci orfani
- Farmaci per la psoriasi
- Farmaci antidiabetici
- Farmaci cardiovascolari
- Farmaci oftalmici
- Farmaci antireumatici
- Farmaci dermatologici
- Farmaci per malattie respiratorie
- Farmaci per la cura dell'osteoporosi
- Farmaci neurologici

Progetti specifici:

- ADHD

Eligibles

450,780

MEAs

25

Updated 28/09/2012



Agenzia Italiana del Farmaco

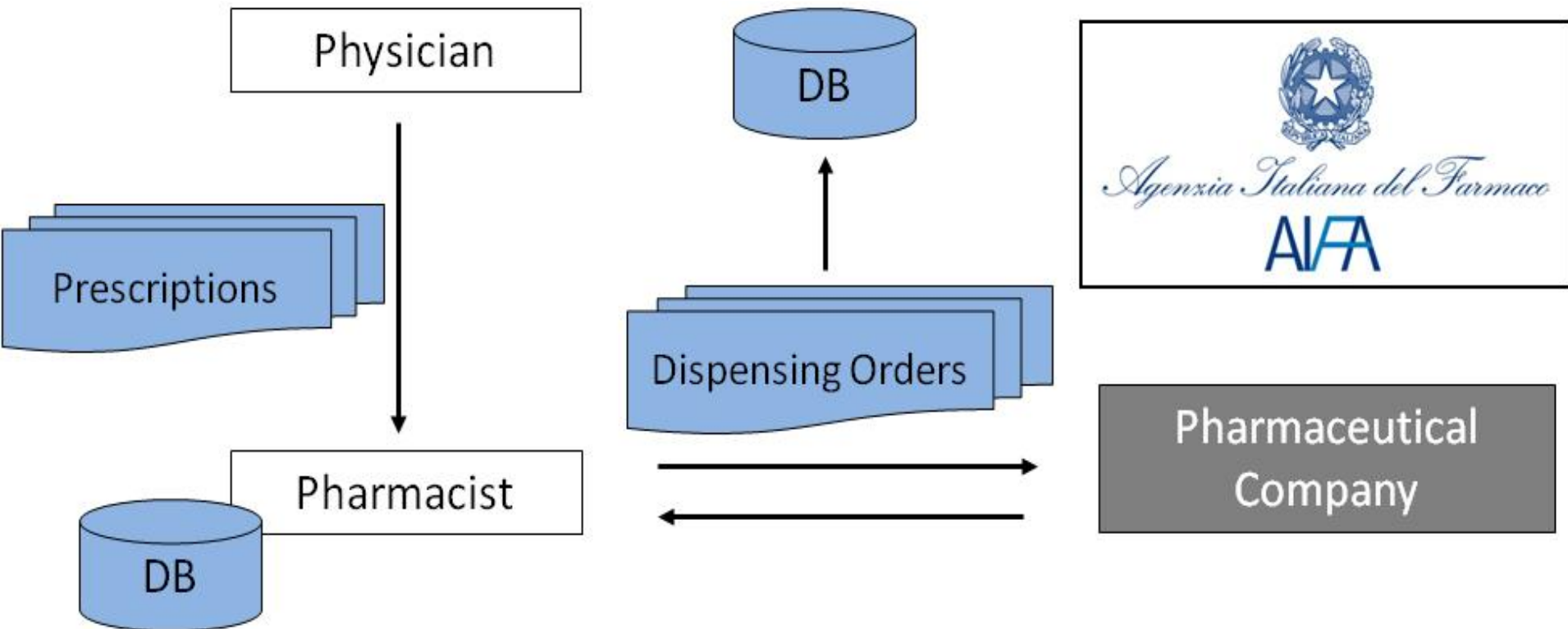
AIFA

Figures

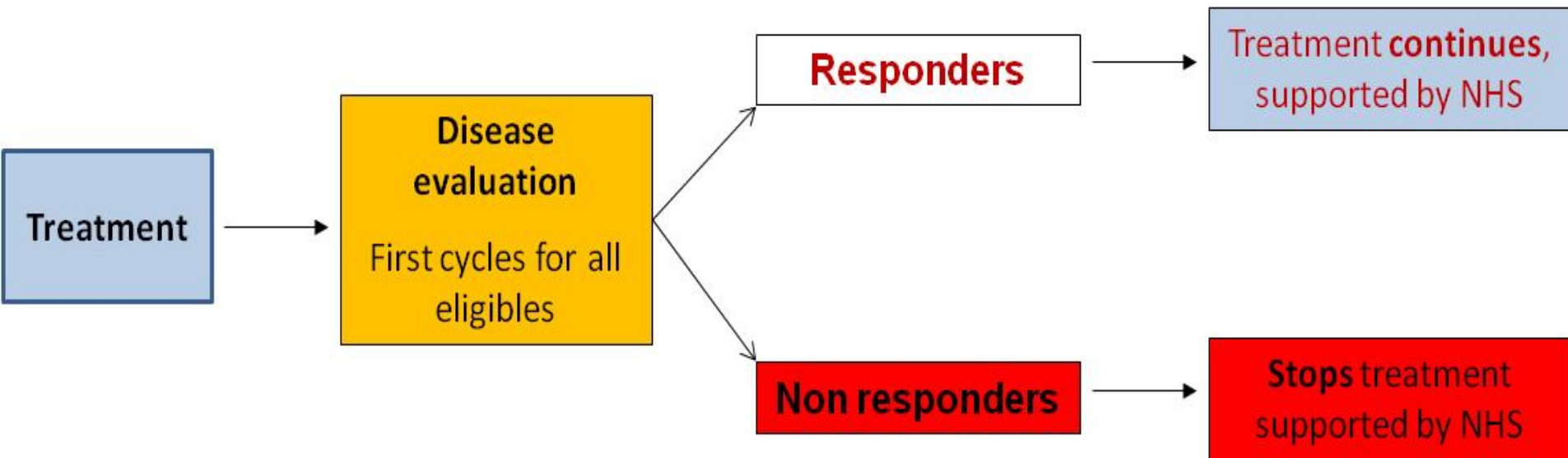
Hospital structures enabled	901
Drugs (total monitoring)	76
Drugs (active monitoring)	51
Therapeutic indications	92
Eligible patients	450,780
Pharma companies	44
MEAs	25

Updated 28/09/2012

Data entry



Algorithm



MEAs: Performance - based risk-sharing arrangements

PBRsAs are payment schemes – they involve a plan by which the performance of the product is tracked in a defined patient population over a specified period of time and the level of reimbursement is based on the health and costs outcomes achieved.

ISPOR performance based Risk sharing arrangements TF Report

AIFA's MEAs rules

Eligible:

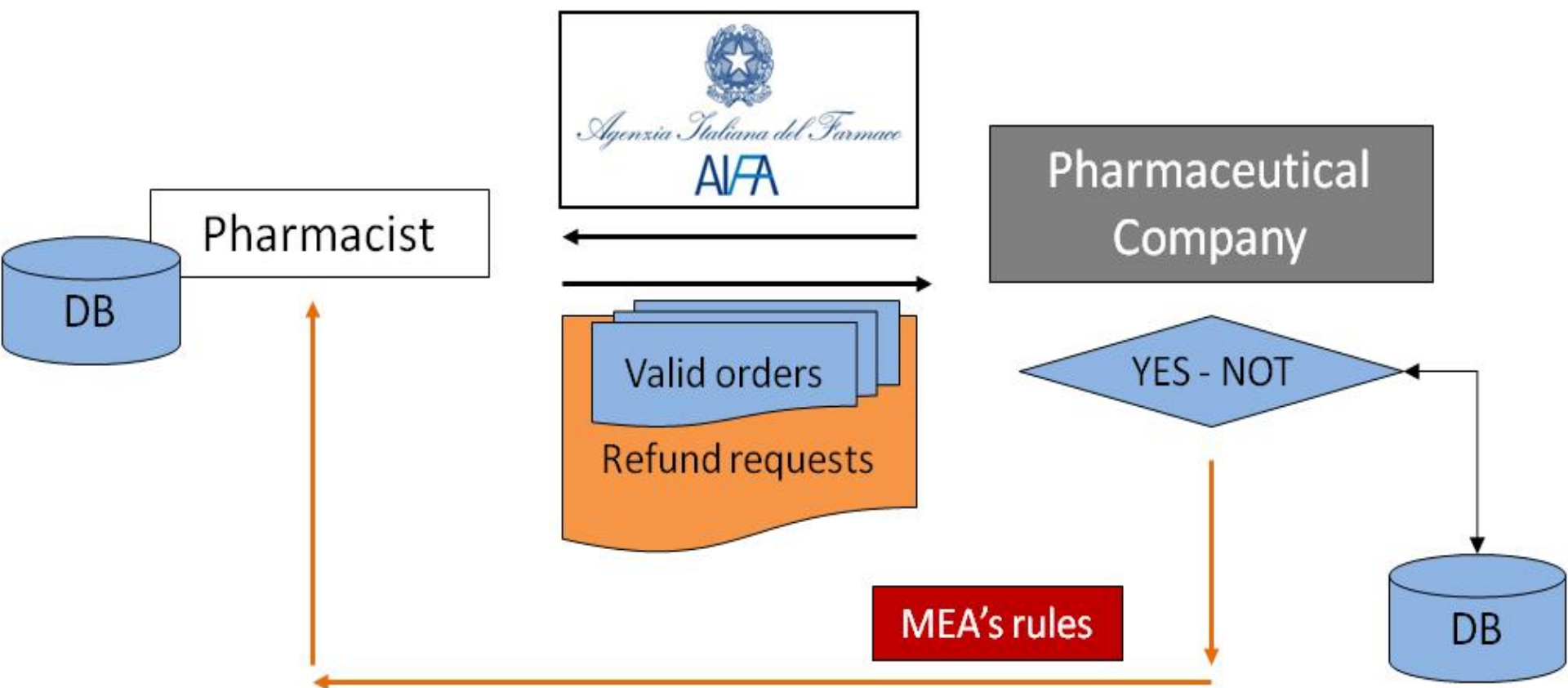
- Cost sharing (CR, special discount)

Non responder:

- Payment by results (PbR, total refund);
- Risk sharing (discount).



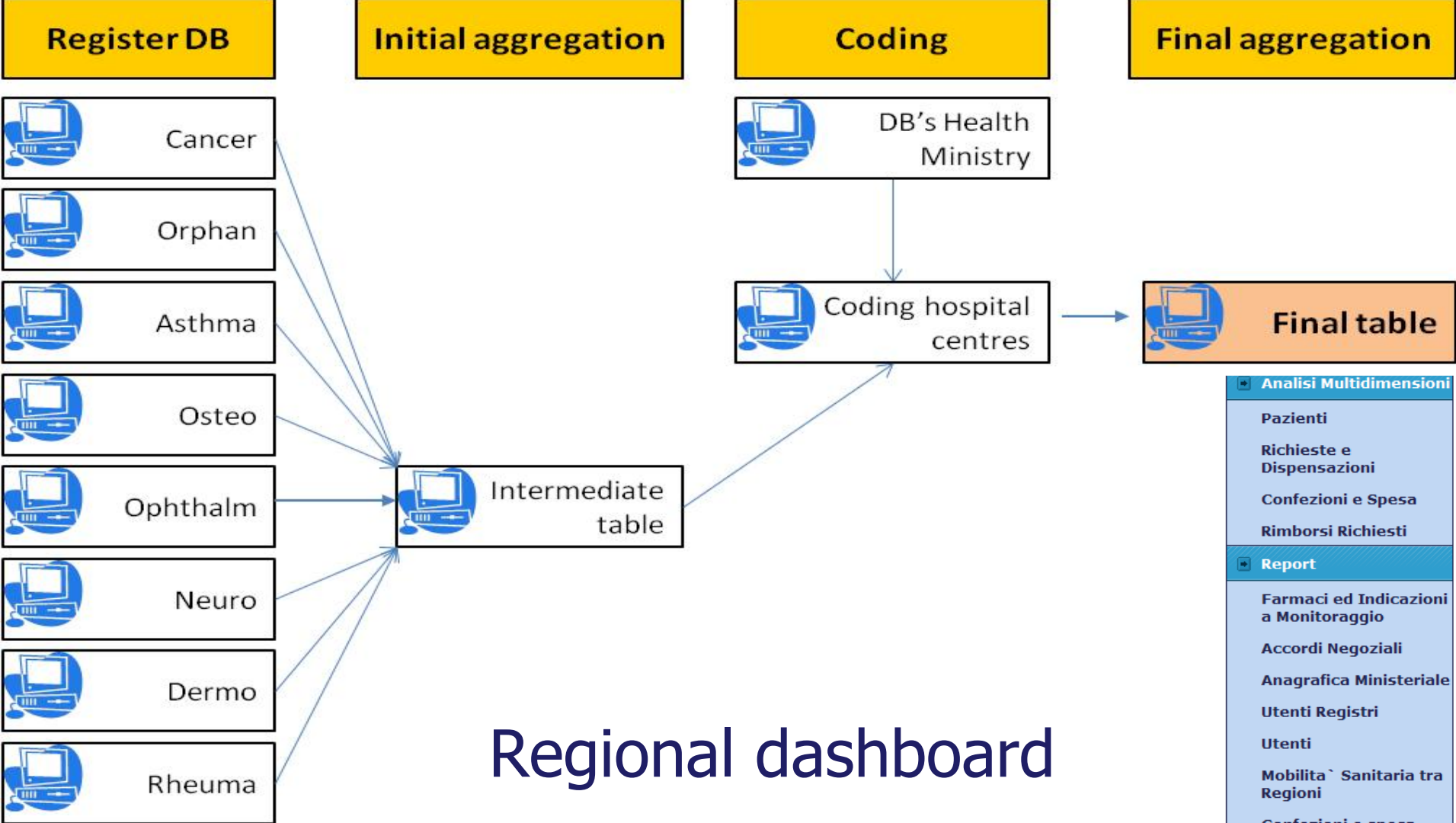
MEA's application



Highlights of an eMEAs application

- i. The system provides an indication of a '*credit*' in favor of the pharmacy based on the count of packs dispensed registered in the system;
- ii. Communicating all the requests, dispensing, revaluation and end treatment records is a mandatory condition;
- iii. Pharma company analyze the requests received and check the real situation and has the right to verify each request and accept or decline the payment of refund (or discount) specially in situations of particular problems. In these cases controls will be activated, with the support of AIFA, to verify the correctness of the requests and the actual enforceability of repayments.





Cruscotto Informativo Regionale Registri CIRR

Analisi Multidimensioni
Pazienti
Richieste e Dispensazioni
Confezioni e Spesa
Rimborsi Richiesti
Report
Farmaci ed Indicazioni a Monitoraggio
Accordi Negoziali
Anagrafica Ministeriale
Utenti Registri
Utenti
Mobilita` Sanitaria tra Regioni
Confezioni e spesa stimata
Rimborsi
Enterprice: Analisi Mult
Pazienti
Richieste e Dispensazioni
Confezioni e Spesa
Rimborsi Richiesti

Business intelligence software: Enterprise

Is an analysis tool which creates
interactive reports & charts
to dynamically examine the data
at different levels of aggregation

Analysis outcomes

Clinical: eligible patients, treated patients, duration of treatment, end of therapy, ADR, per drug or therapeutic indication;

Economic: dispensed drugs per marketing authorisation, expenditure (per treated patient, pathology, difference among prescription sites), expenditure reimbursed by MEAs.

Multi-tier review

Space: region, local health unit, clinical site;

Time: year, semester, month;

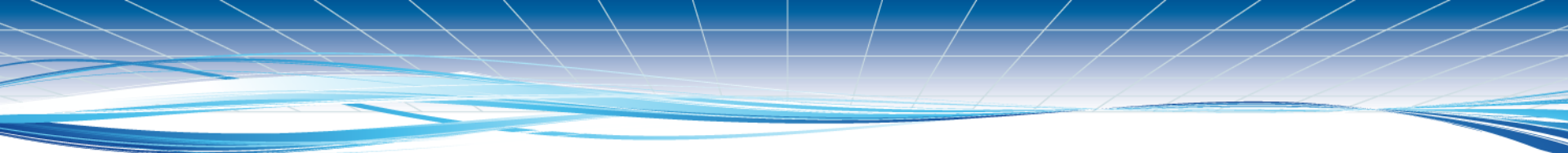
Clinical: therapeutic indication;

Treatment: register, drug.

Exchange of data between:

- Clinicians;
- Pharmacists;
- Local healthcare units & Regions;
- Pharma companies;
- **Regulatory: AIFA**





Properly managed registries can produce a
wealth of valuable data about

a. Patients;

b. Institutions of health care, communities and payers;

c. Pharma Industry.

Patients' benefits

- Rapid access to new drugs, supported by NHS;
- Monitoring of prescriptions and tolerability.



Institutions of health care, communities and payers benefits

- Balance between:
 - rapid access to market and appropriateness;
 - costs and efficacy;
- New sources of relevant clinical data.



Pharmaceutical companies' benefits

- Access to market for a drug, supported by NHS;
- New sources of relevant data.



Nationwide experiment in drug monitoring

Is a complex approach combining
regulatory, clinical & IT aspects



Main objective: effective growth of patient protection

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