Clinical Trials

Regional Overview:

- CT in Romania

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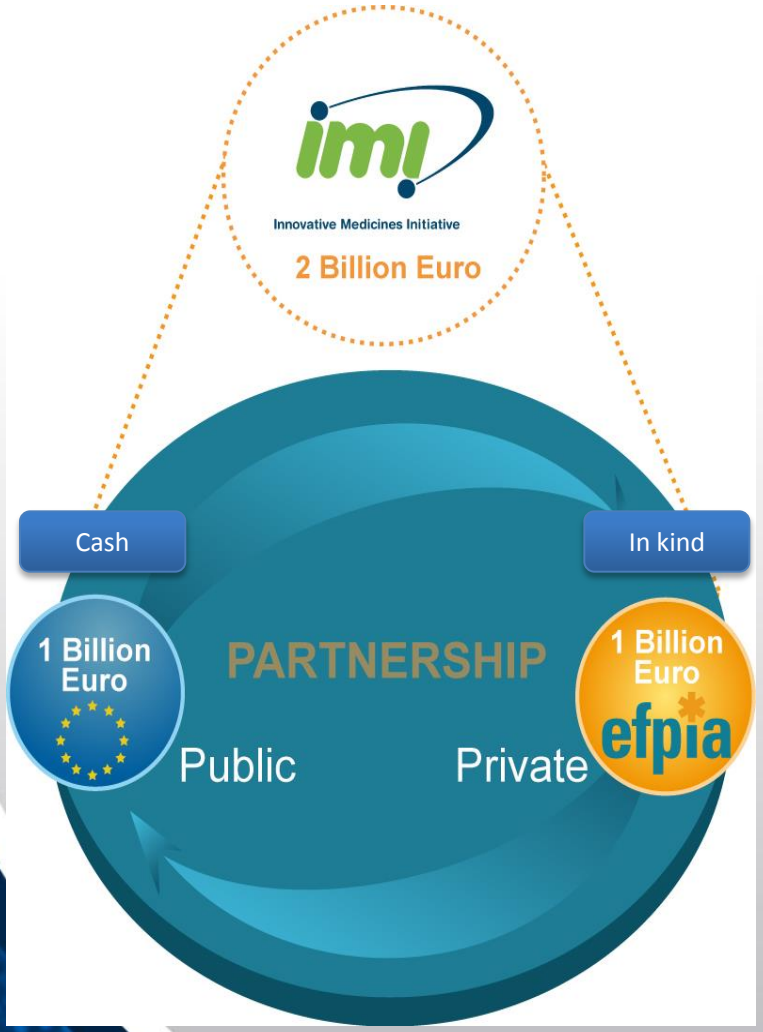
Pharma Law Convention

Bucharest, 3rd of April 2014

EU objective 2014 - 2020

- Increase the EU competitiveness through significant investments in R&D including “Life sciences”
  - Europe has historically enjoyed an enviable position in pharmaceutical innovation.
  - Although it has been on a decline recently, Europe possesses the right capabilities to be a winner once again.
- R&D Pharma industry has a vital role to play in Europe’s growth and future competitiveness

Innovative Medicines Initiative:
The Origin



European Union and EFPIA CEOs

joined forces to make

drug development in the EU more innovative and efficient and to address main societal/healthcare challenges

by

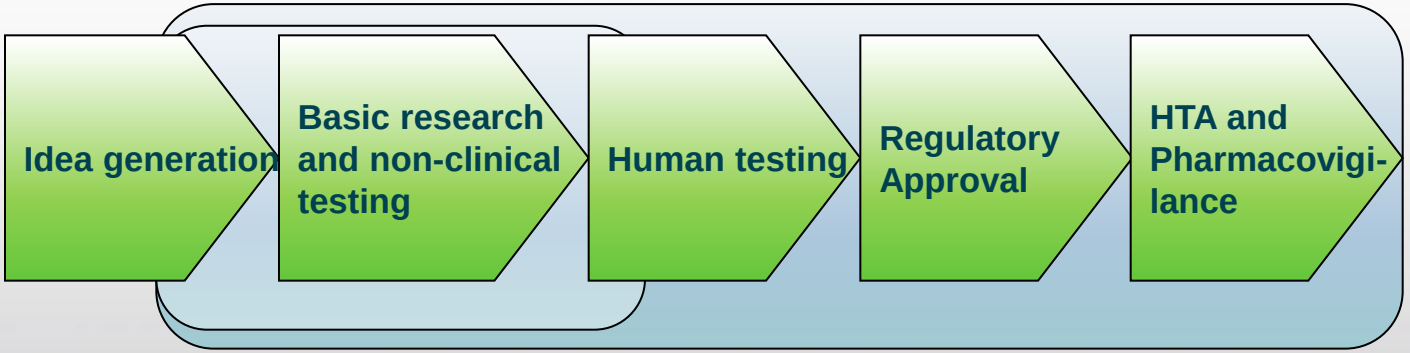
forming the biggest PPP in Life Science

(adopted on December 20, 2007
by the European Council)

Innovative Medicines Initiative:

From bottlenecks in industry – to bottlenecks in Industry and Society

Make Drug R&D processes in Europe more efficient and effective and enhance Europe's competitiveness in the Pharma sector



Primary focus of early IMI calls 2007 SRA

Shift to also addressing challenges in in society and healthcare 2011 SRA

SRA – Strategic Research Agenda

Key influencing factors

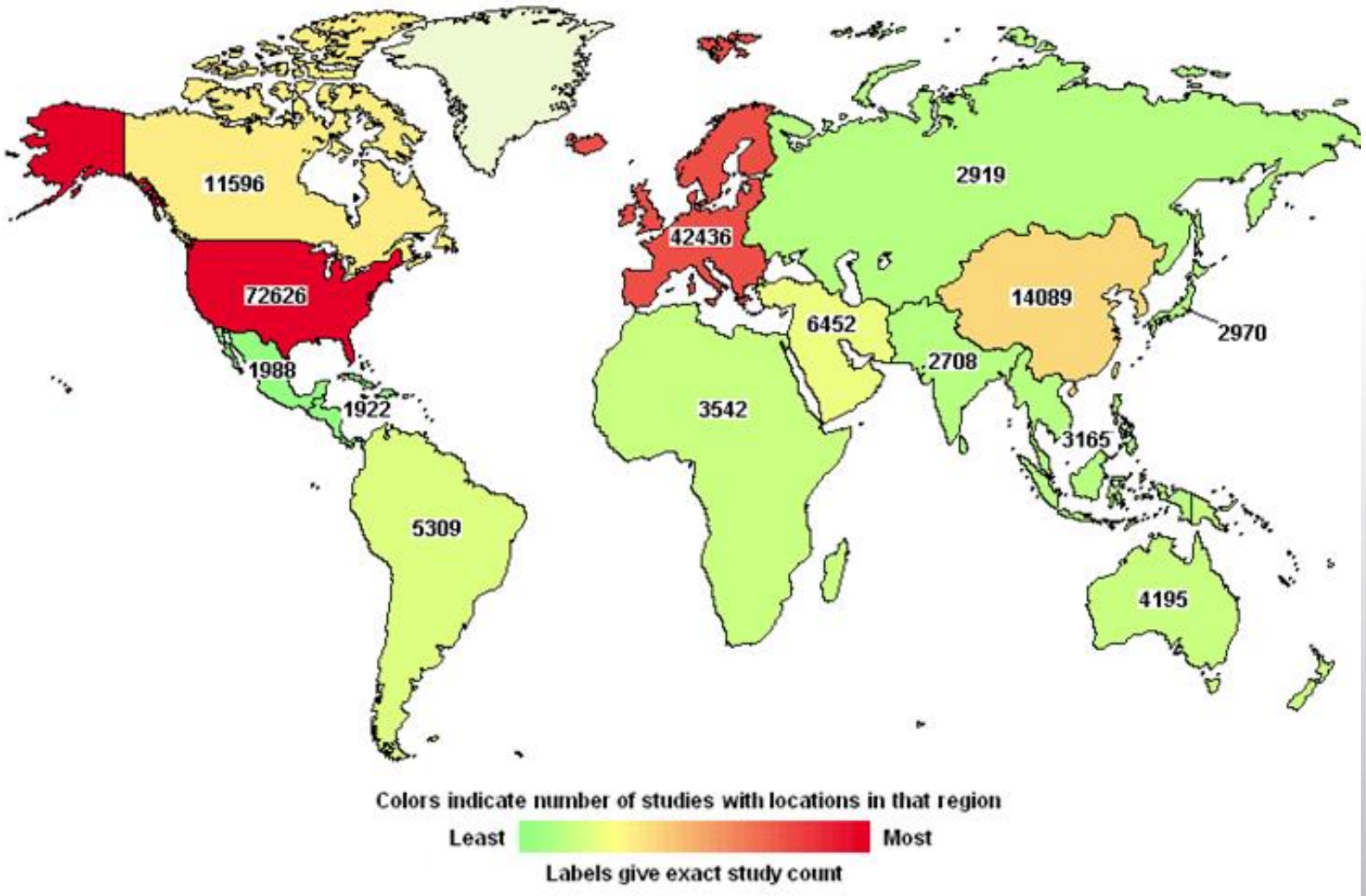
- EU Parliament and Regulatory Authorities can play a major role in accelerating or delaying the R&D evolution:
  - Directive 2001/20/EC – Clinical Trials has generated unpredictable procedures, a significant increase of birocratic burden in the EU member states without bringing additional gains for the safety of the patients;
  - EU Directive for the disclosure of the CT data;
  - CE proposal for the Regulation of the CT aiming to harmonize the European frame for Clinical research.

Clinical Research

- The pharmaceutical industry's investment in R&D within Europe was valued at € 30 billion in 2013.

- ARPIM's estimation of the annual pharmaceutical industry's investment in R&D in Romania, (mainly representing CT), is valued at € 220-250 million representing 0.83% of total EU R&D investment.

Nr. of clinical trials recorded worldwide (www.clinicaltrials.gov)



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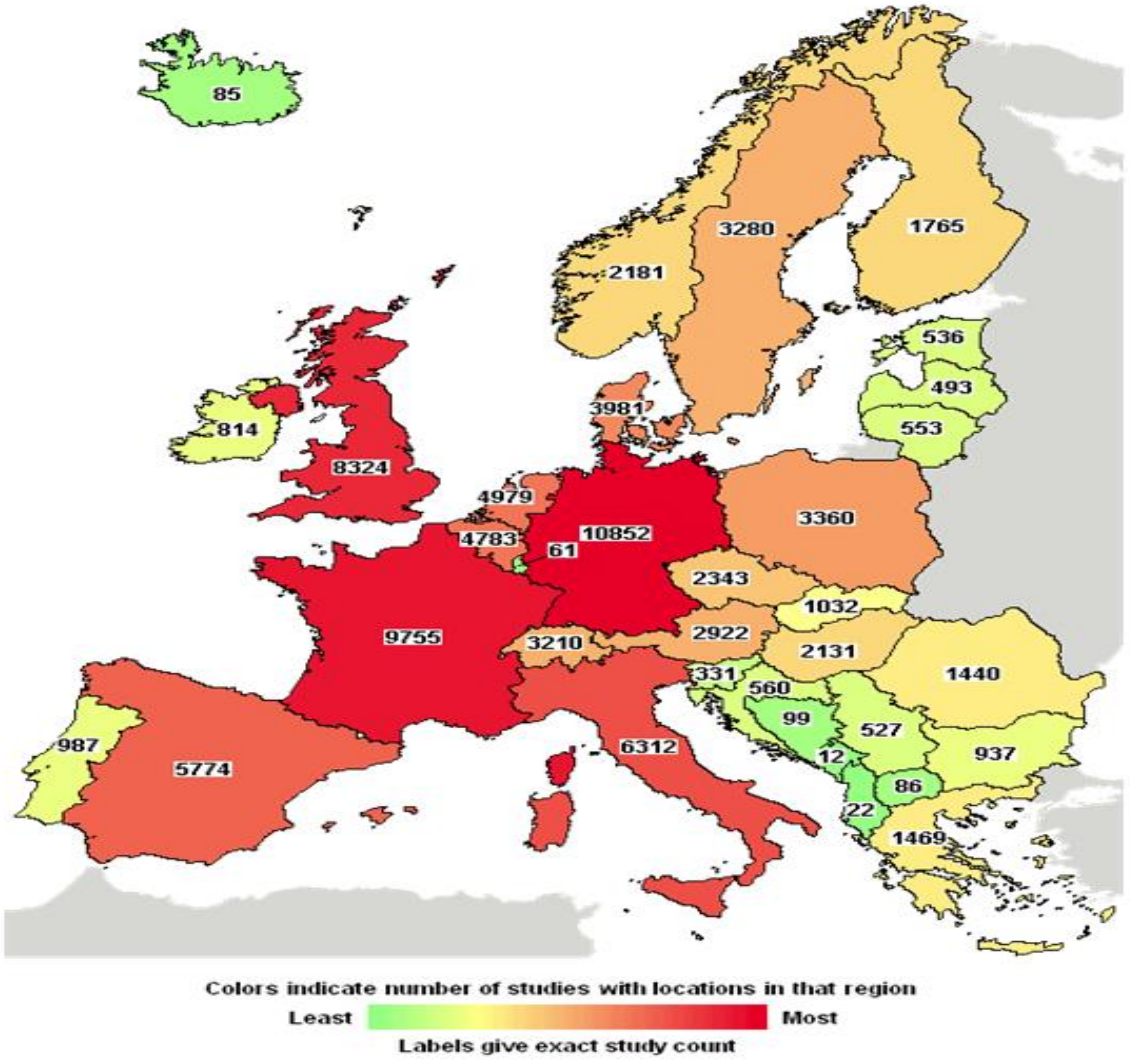
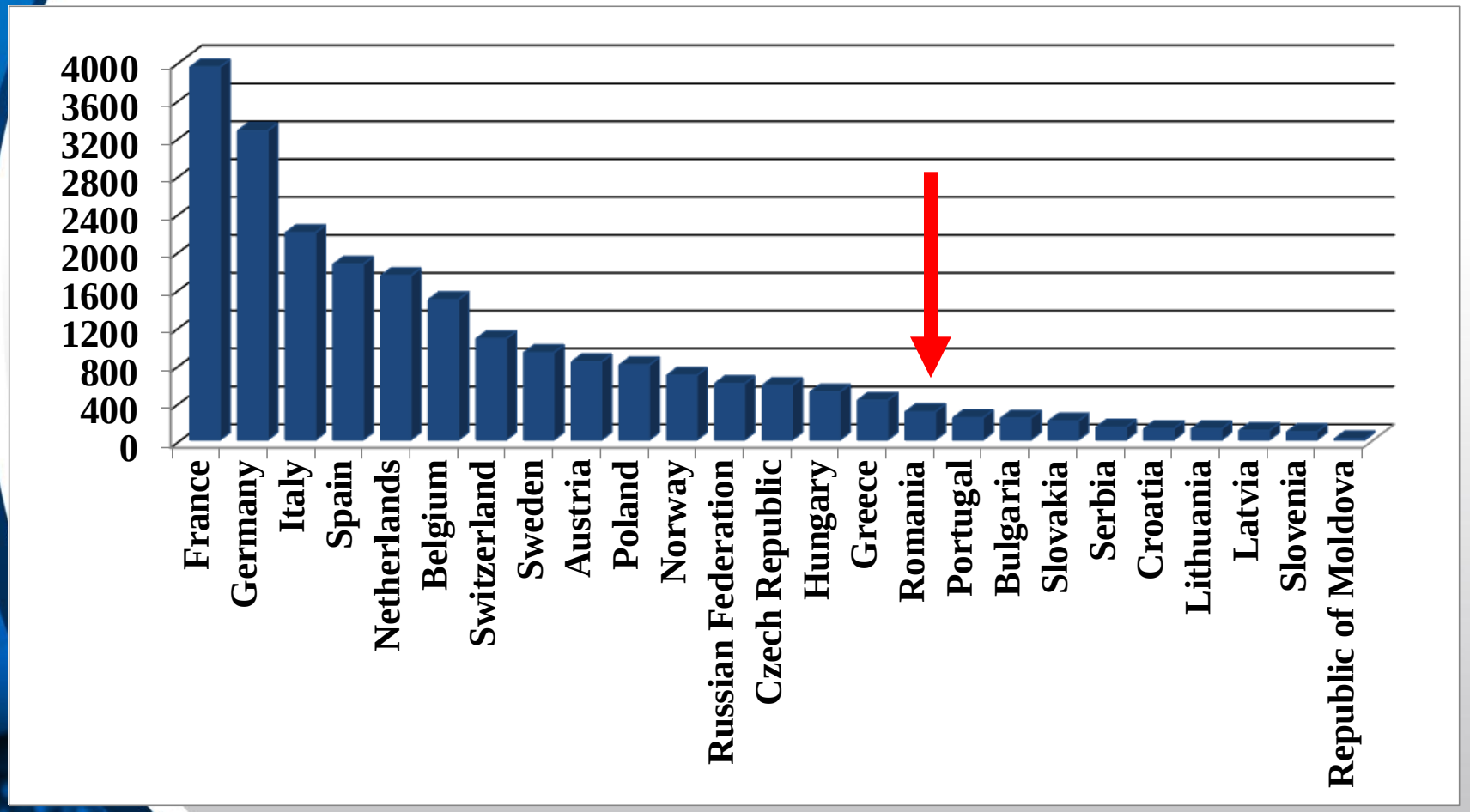
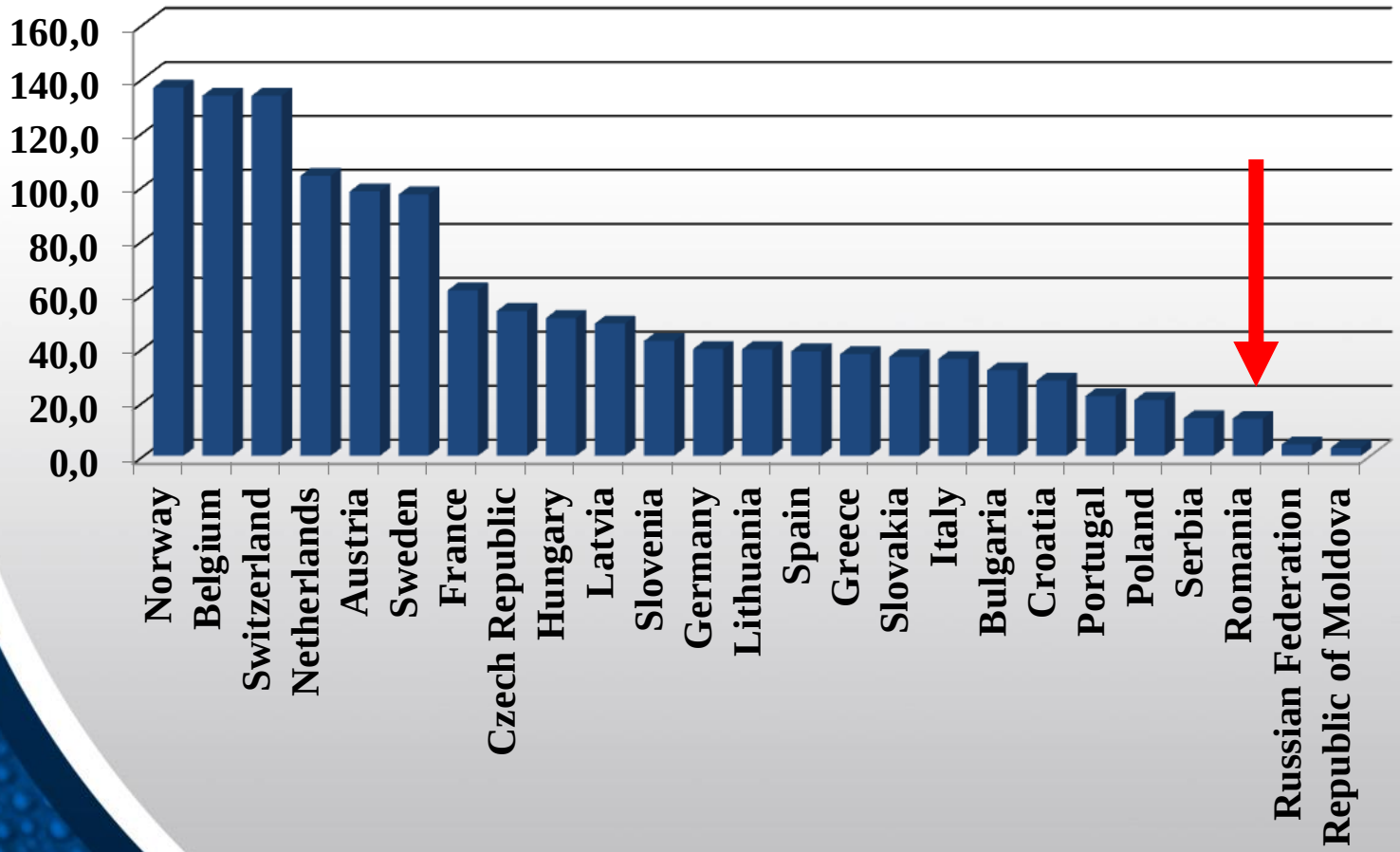


Number of active clinical trials/country April 2014 (Ro=296)



Sursa: www.clinicaltrials.gov
www.worldometers.info

Number of active clinical trials/1 mil. citizens/country – April 2014 (Ro= 13,7)



Sursa: www.clinicaltrials.gov
www.worldometers.info

Number of clinical trials Romania 2008-2013

Year	2008	2009	2010	2011	2012	2013
Clinical Trials	266	288	266	244	270	282

Total 1495 Studies since 2008

www.clinicaltrials.gov

2008 – The last update of the reimbursement list

- **1495 clinical studies have been running in Romania**
  - Approximately 150,000 patients have got access to the latest medicines treatments and to the related required analyzes
  - Direct investments of approximately 1,5 billion EUR
- **2 out of 10 Romanian patients have received free medicines through the industry's contribution at the claw-back tax in the last two years**

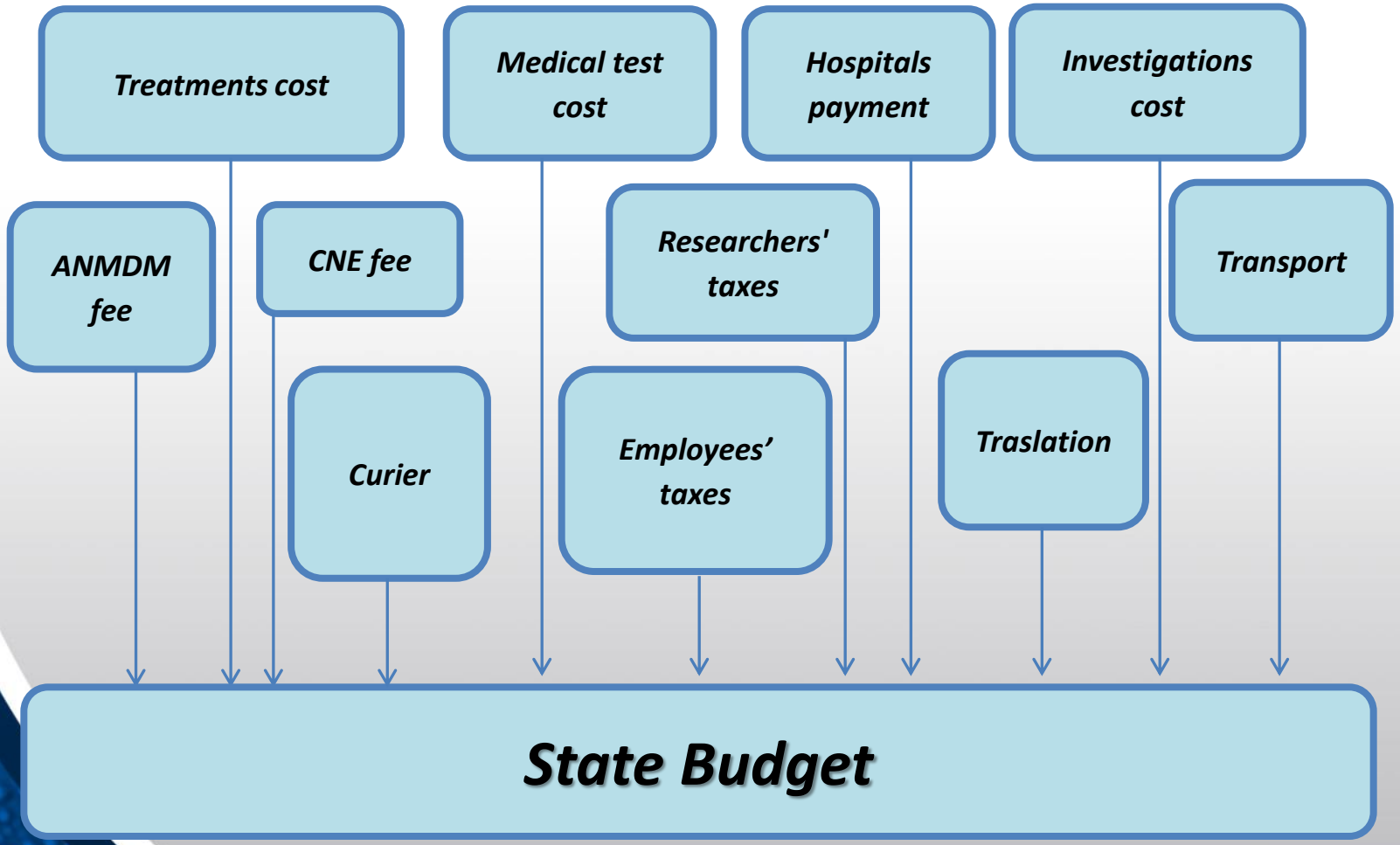
Advantages of the clinical trials for Romanian patients

- **Increase access to :**
  - Innovative medicines (i.e. chemotherapy, clotting factors, anti-viral vaccines, etc.);
  - Concomitant medication and access to the registered medical devices which are provided throughout the study;
  - Approved medication, sometimes very expensive, such as phase IV study cases;
  - Latest diagnostic investigations.

Advantages of the clinical trials for the Romanian state & budget

- Bear the cost of medical tests and laboratory investigation specific to the study;
- Payments to clinical investigation centers;
- Opportunity for young doctors to gain faster experience with modern drugs and realize additional incomes (from extra budgetary sources);
- Taxes and contribution paid to the state budget by doctors working in clinical trials (based on contracts physician / sponsor);
- Taxes and contributions paid by employees of sponsor companies / CRO working in clinical trials;
- Revenues from ANMDM fees / CNE (about 1000 Euro/study for an average of 250 new studies/year);
- Other advantages (i.e. providing free of charge laboratory equipment and IT equipments to investigational centers).

Contribution to the state budget



Conclusion

- We should be optimistic thinking that Europe aims to become more competitive through innovation during the period 2014 – 2020, including the pharma sector:
  - It has been decided to allocate the necessary financial resources and from this point of view the premises are favorable to the growth of clinical research.
  - However, we must observe carefully the measures envisaged by the authorities, (by the way, with the best intentions), to not turn into powerful brakes, which significantly could undermine and delay this process.
- We must be even more optimistic and to imagine that we will be able to improve significantly the patient access to innovation in Romania between 2014 - 2020, so that the hiatus existing between 2008 - 2014 will not repeat and the last hope of a patient will not remain the enrolment in a Clinical Trial.

Vă mulțumesc!