EMA – Regulatory Science to 2025

Session 1: Responding to the needs of the 21st century patient. Addressing challenges and opportunities across the European Regulatory Framework

Olga Solomon

Health and
Food Safety

Horizon Europe

is the Commission proposal for a research and innovation funding programme for seven years (2021-2027)

to strengthen the EU's scientific and technological bases

to boost Europe's innovation capacity, competitiveness and jobs

to deliver on citizens' priorities and sustain our socio-economic model and values

Real world data in health care

Multiple sources of data:

- Clinical databases (prescriptions, EHR, registries)
- Clinical trials
- Imaging data
- 'Omic data'
- Published literature
- Regulatory pharmacovigilance data
- Social media/mHealth data

Commission Communication of 25 April
3 Priority areas on digitising Health and Care

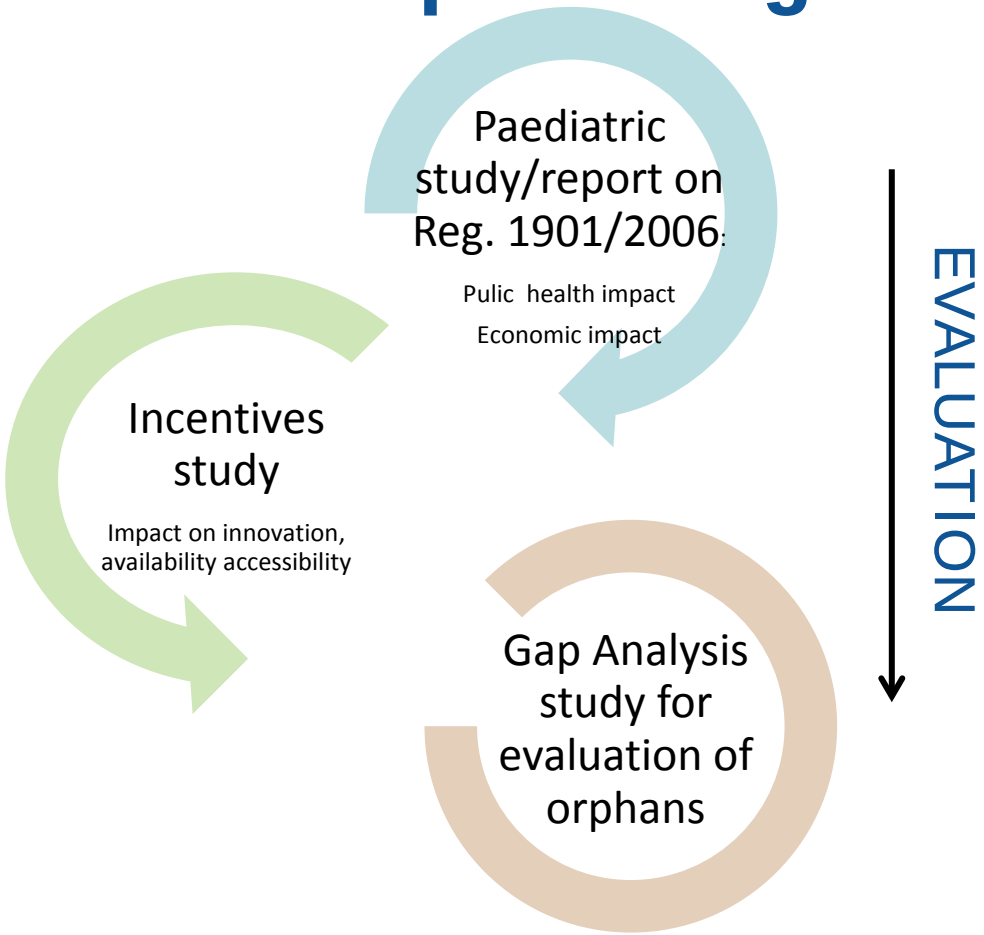
EU Legislation on Clinical Trials

Regulation EU No 536/2014

"It's a big misconception. Everyone thinks hell is all fire. Actually, it's all paperwork."

- Simplified and harmonized administrative provisions
- Closer coordination between MS for international CTs
- Increased transparency

Evaluation of the paediatric and of the orphan regulations



Evaluation

- Identification of the problems;
  - Strengths and weaknesses of paediatric and orphan legislations alone and combined;
  - How incentives have been used;
- Finalisation by the end of 2019;
- Base for the next Commission to decide future policy choices.

From Directives to Regulations

Directive 90/385/EEC on active implantable medical devices

Directive 93/42/EEC on medical devices

→ ***Regulation on MD (2017/745)***

Directive 98/79/EC on in vitro diagnostic medical devices

→ ***Regulation on IVD (2017/746)***

Necessity to harmonise the legislation in Member States

and to adapt to health scandals:

PIP implants; metal on metal hip implants…

Health Technology Assessment (HTA)

Proposal for a
Regulation
31 January 2018

WHAT'S NEW?

- **Common** European **assessment methods**
- **Shared data** and expertise
- **Common procedures** across the EU

WHAT ARE THE BENEFITS

- Higher level of **human health protection**
- Faster market access for **innovative products**
- More **transparency** for patients and producers
- No more **duplication** of work for health authorities and industry

eunethta
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

EU ASSESSMENT (jointly done by the Member States)

NATIONAL ASSESSMENT

National decisions on pricing and reimbursement

NEW MEDICINES

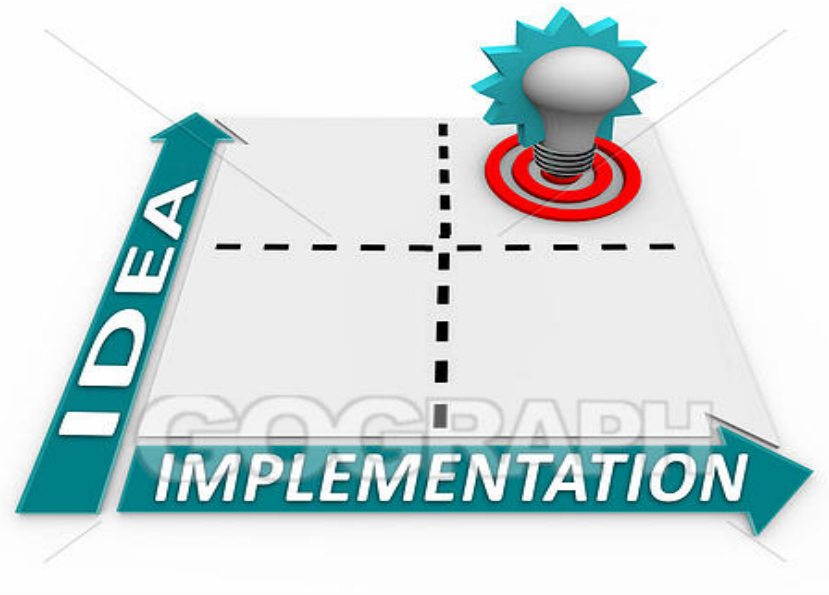
- **CLINICAL ASSESSMENT** (benefits compared to existing treatments)
- **NON-CLINICAL ASSESSMENT** (economic, social and ethical aspects)

NEW MEDICAL DEVICES

High-risk devices with high impact on patients, public health and EU health systems

- **CLINICAL ASSESSMENT** (benefits compared to existing treatments)
- **NON-CLINICAL ASSESSMENT** (economic, social and ethical aspects)

Implementation and Looking to the future



Thank you for your attention !