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# Health Research Strategic Needs in Europe

## Pan European Clinical Trials. EU Clinical Trials Regulation

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# Challenges for clinical research (CT)

- **High attrition rate (1/100)**
- **High regulatory burden for multi-national trials/different international legislative requirements**
- **High costs ( +60% 2000-2005)***
- **Lengthy process (+70%) ****
- **Funding**
- **Decreasing participant enrolment rate (-21% 1999-2005)****
- **Decreasing participants retention rate (- 30% 1999-2005)****
- **Decreasing interest in conducting clinical trials**
- **Shift towards personalised Medicine**
- **Lack of transparency (redundancy)**

➡ Does the new EU CTR improve CT performance?

*DiMasio and Grabowski

** Tufts center for the study of drug development

# EU CT Regulation
# A positive move for clinical trials

- **Harmonise clinical trials with medicines in Europe: 1 dossier-single EU portal (EMA)-coordinated assessment procedure**
- **Increase transparency (all trials registered, outcomes published)**
- **Low-risk clinical trials: less stringent rules**
- **Assessment report for rare and ultra-rare diseases CT: rely on expertise the EMA Scientific Advice Working**

➡ Streamline application process for multi-national CT across EU

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# EU CT Regulation Challenges

- **Does not cover all medical research**
- **The assessment is done by two bodies (CA/ Ethics committees)**
- **No regulation for ethical reviews**
- **No oversight of the whole approval process**
- **Data protection Regulation**
- **No regulation for insurance coverage for academic CT**
- **Education, training, competencies**
- **EMA portal:**
  - **Lack of a data-knowledge database regarding national regulations (radiation,…)**
  - **Avaibility of data?: results, access to raw data?**
  - **Processing/definition of commercially confidential information?**

# Discussion

**Does the new EU CTR improve CT performance?**

# Challenges for clinical research (CT)

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# EU CT Regulation
# Recommendations to overcome challenges

- **Improving patient enrolment and retention: increase education, communication awareness (citizens, patients, healthcare providers**
- **Insurance coverage: adopt a unique insurance system for academic clinical trials in Europe (national indemnification scheme)**
- **Funding mechanism for academic multi-national CT**
- **Explore CT data access and optimal use involving all stakeholders (integration of real-world data, CT data, clinical data from registries, medical records…) Broad consent**
- **PM: Evaluation of new CT designs/usefulness to answer the questions**
- **Post-evaluation of risks categories implemented in the EU CTR**

**Improving coordination**

**Quality of CT**

- **Harmonisation of assessment of investigators and sites**
- **Core competencies (link to OECD project)**
- **Data quality**
- **Professionalisation and LT support of research centers and all stakeholders (identification of best practices at national level, network)**
- **Foster clinical-scientist careers and multi-disciplinarity**