

Regulatory and ethics environment: difficulties and challenges

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CONTEXT

- Need of new drugs
Need of good research
Need of adequate environment
- Different initiatives on going for that with different actors
- Some achievements in term of awareness, capacity building, international debate, networking
- Challenges remained to be adressed

ISSUES RAISED

- Duplication of activities and lack of information
- Diversity of systems in the management and regulations of CT
- Scope of ERC versus NRA
- Inadequate and non sustainable funding of ERC activities
- Lack of sufficient expertises for evaluation and monitoring CT
- Inadequate legislation and regulation

Recommendations

- **Improve coordination and information between stakeholders and joint activities**
- **Collect and dissemination of information on on going activities (training, networks, fundings, ...)**
- **Harmonization needed but uniformisation to be avoided**
- **Continuation of support of networking**
- **Developing of harmonized SOP's and regulations for ERC's and NRA's**
- **Clarification of functions and coordination needed between ERC's and NRA's**
- **Provide tools and guidelines in different languages**
- **Advocacy for sustainable fundings for ERC**
- **Strengthening capacities of NRA and ERC to be continued**