

# US NIH Partnership with EU in clinical research

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# NIH-sponsored clinical research

- NIH institutes sponsor clinical research to:
  - Understand how best to keep people healthy
  - Understand risk factors for disease
  - Find new ways to prevent, screen for, diagnose, and treat disease
- NIH clinical research takes place at the NIH, at individual hospitals, clinics, and research sites inside and outside the US, and in networks of hospitals, clinics, and research sites.

# Partners in NIH clinical research

- General public
- Patients and their families
- Doctors, nurses, and other health care professionals
- Patient advocacy groups and NGOs
- Universities and medical centers
- Pharmaceutical and biotechnology industry

# Why we collaborate with EU

- To leverage public investment in clinical research infrastructure and expertise
- Working together we can get answers to our research questions faster; we can study rare diseases; we can evaluate interventions to improve health and treat disease in different settings and among different populations

# Essential elements: local

- Support for clinical research from leadership
- Protected time for doctors and nurses to conduct research
- Data managers, informatics, biobanks
- Educational programs for patients and their families about clinical research
- Clinical trials offices to handle regulatory, scientific, and ethical reviews & monitoring
- Involvement of patient advocates in research

# Essential elements: national

- Scientific prioritization of clinical research
- Timely regulatory, scientific, and ethical review
- Involvement of patient advocates
- Links between health systems and clinical research
- Coverage of routine patient care costs associated with research (& indemnity)

# Essential elements: national

- Education of health professionals, public, and patients about clinical trials
- Payment of research costs
  - Government, charity, institution, & pharma (as appropriate)
- Links between public clinical research networks and regulatory authorities

# Essential international elements

- Forum for exchange of best practices and identification/resolution of barriers
  - EU: ECRIN
  - NIH: Trans-NIH International Research Working Group
- NIH consultation re EU Clinical Trials Directive
- OECD Global Science Forum working group to overcome barriers to international collaboration in academic clinical trials



# Contact information

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