

Models of EU-US Collaborations at the NICHD

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Three Models for Cooperation

- Agency to Agency: HHS/EC Pediatric Pharmacology
- Network to network: US EU HIV AIDS collaborations
- Project to project: International Childhood Cancer Cohort Consortium (I4C)

Advantages

- Expand populations under study for clinical trials on longitudinal surveys
- Leverage resources
- Reduce time to outcomes
- Ability to address cultural and health systems differences that may lead to health disparities

US-EU Collaboration in Pediatric Pharmacology

- EU US Joint Research Initiative
 - Goal is to coordinate and leverage the experience, science and funding of pediatric therapeutic research in the US and the EU.
 - Compare research priorities and regulatory activities for pediatric therapeutics
 - Explore joint funding of research proposals for jointly prioritized medications

US-EU Collaboration in Pediatric Pharmacology

- Passage of US Best Pharmaceuticals for Children Act and EU Pediatric Medicines Regulation
- 2007 NIH and DG Research explored cooperation based on:
 - Similar EU and US legislation
 - Established teams and networks with expertise in pediatric drug studies
 - Developed populations with similar pediatric disease

Pediatric Pharmacology

- Jan 2008 meeting to discuss opportunities (DG Research, EMEA, FDA, NIH)
- July 2008 regulatory and scientific prioritization processes and opportunities for collaborations through

Pediatric 2008 meeting

- Shared prioritization information
- Updated current studies
- Shared written requests- to FDA and EMEA
- Share study designs
- Develop working groups for specific drugs, age groups and formulations
- Discuss framework for MOU and discussed future joint funding initiatives

Clinical Trials Networks

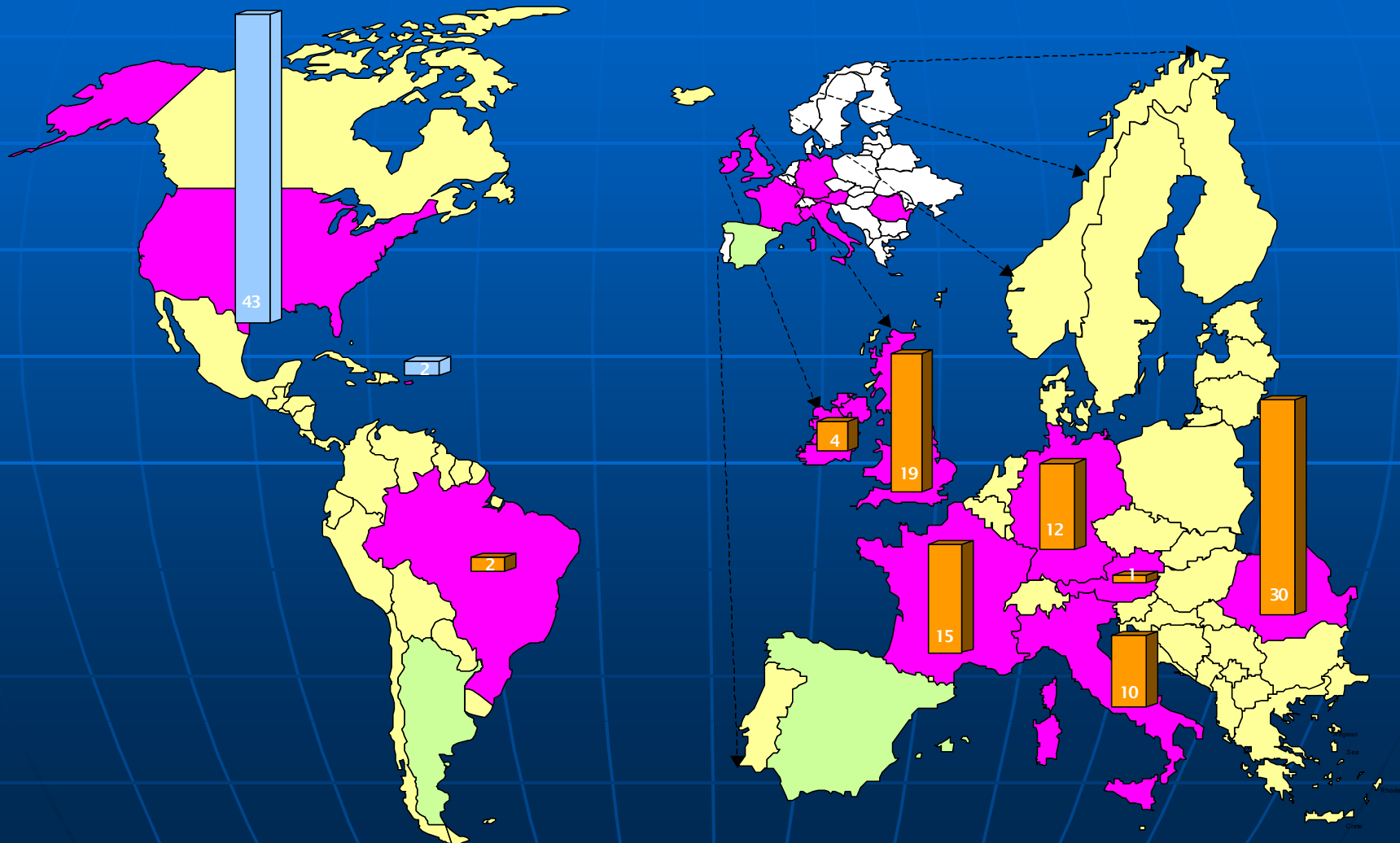
- NIH: NICHD, NIAID; EU: Pediatric European Network for Treatment of AIDS
- Collaboration in international and domestic studies on pediatric , maternal and adolescent trials AIDS networks
- Attend each others steering committee meetings, identify areas of collaboration and cooperate on common protocols or meta-analyses

Network Collaborations

- Three Collaborations
 - When to start and when to switch in children
 - Can therapy be interrupted in children
 - Meta-analysis of US and European data on association of surrogate markers and morality/progression to AIDS
- Two potential new projects
 - Adolescent studies
 - Pediatric HIV/AIDS Cohort study addressing in utero antiretroviral exposure and perinatally infected children.

PACTG 390/PENPACT 1: What to Start and When to Switch

Recruitment started in late 2002. Children enrolled from 50 centres in the PENTA and NICHD/NIAID networks. Countries include Austria, Brazil, France, Germany, Italy, Ireland, Puerto Rico, Romania, UK and USA.



Multinational Project Cooperation I4C

- Consortium of longitudinal birth cohorts in Europe, North America Australia, and Asia
- Need to test hypotheses for causes of rare conditions requiring N's larger than any single cohort
- Majority of cohorts are in Europe funded nationally and EC funding provided to strengthen comparability across cohorts (New Generis)