



EUROPEAN
COMMISSION

Community research

EDCTP

Past, Present and Future



Networking
the European
Research Area

Dr. Manuel ROMARÍS
Directorate for Health Research
European Commission



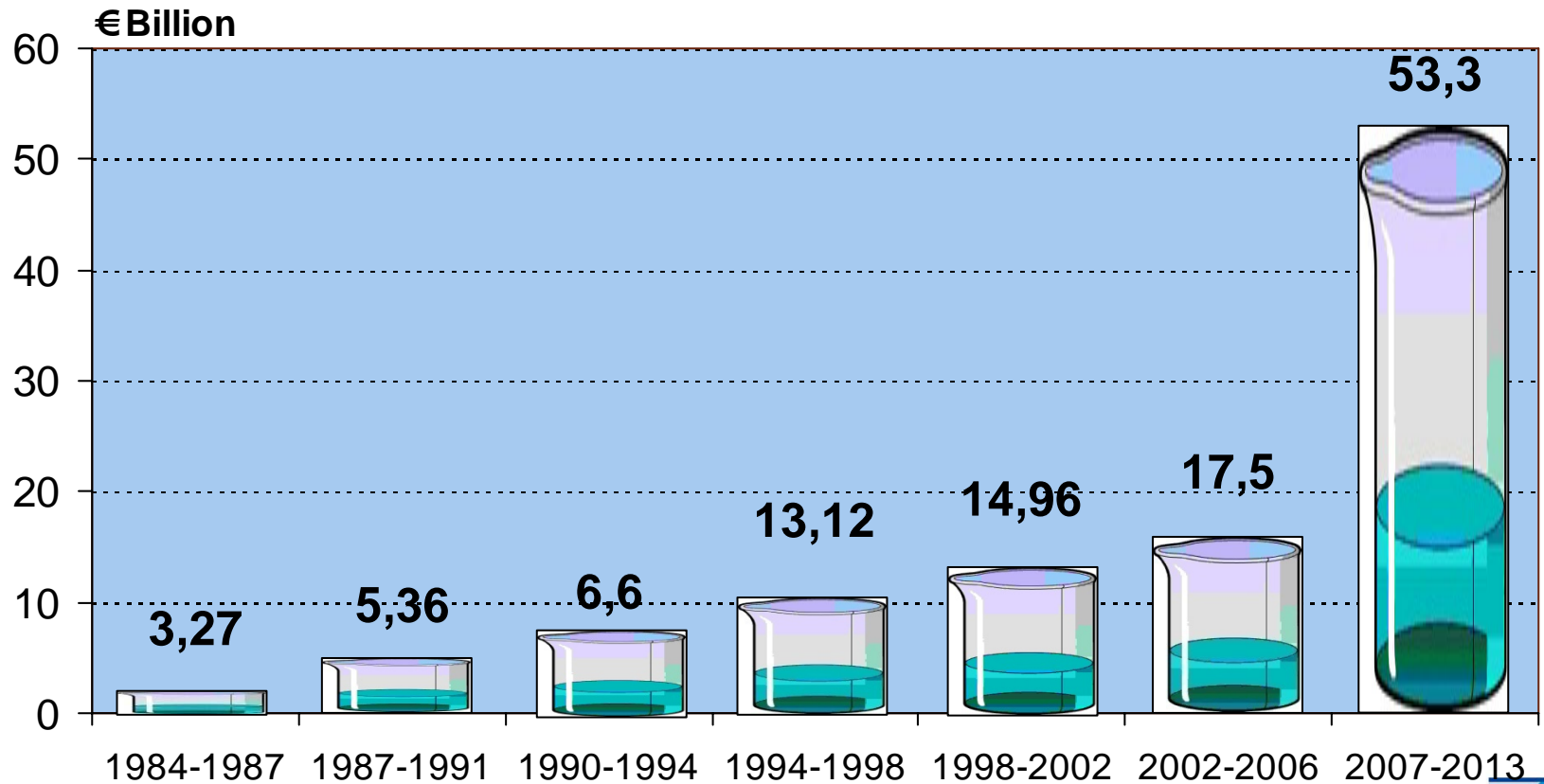
Putting together
the pieces of the puzzle



SEVENTH FRAMEWORK
PROGRAMME



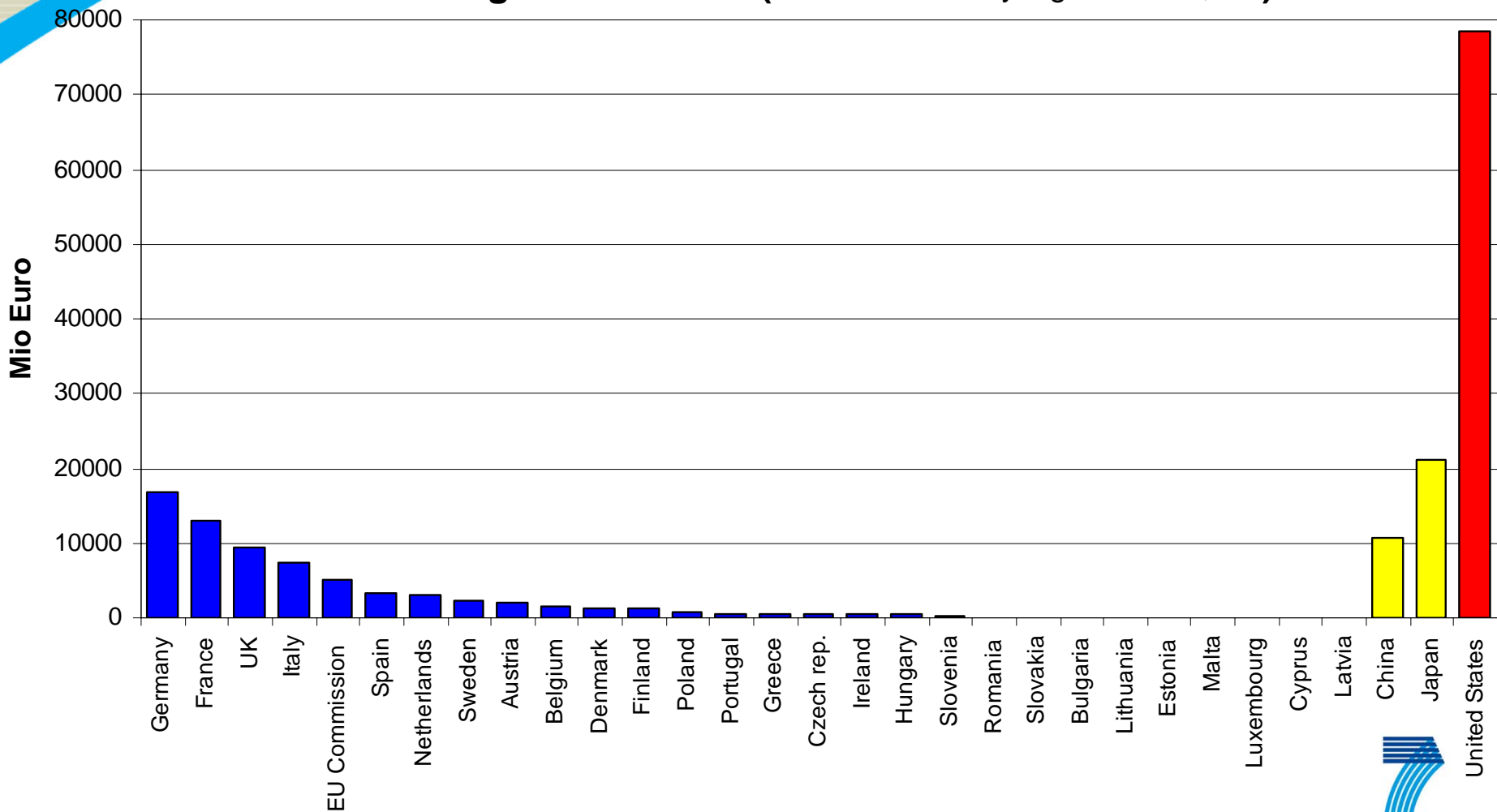
Budgets of the EU Framework Programmes





Restructuring a fragmented ERA

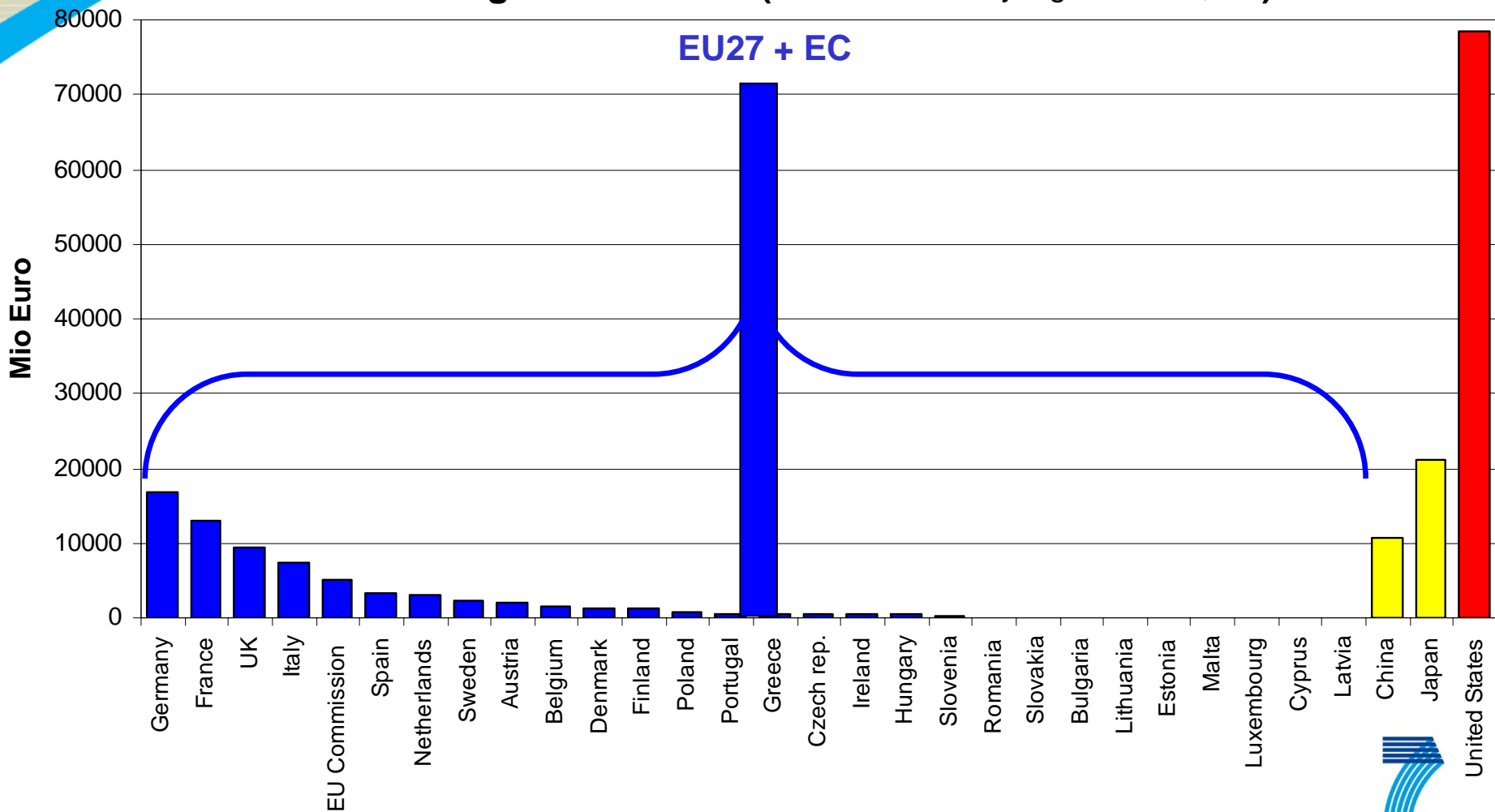
Public Funding for Research (Source : ERA Key Figures 2005, EC)





Restructuring a fragmented ERA

Public Funding for Research (Source : ERA Key Figures 2005, EC)



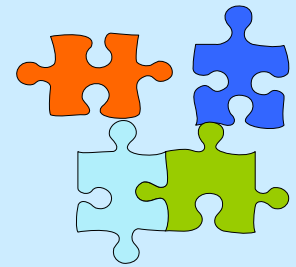


Coordination of national programmes FP6

ERA-NET

Coordination of national programmes

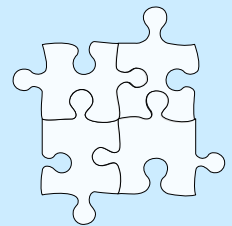
- ✓ MS agree and fund joint calls/programmes
- ✓ EU funding only for coordination



ERA-NET *Plus*

New in FP7: Top up of a single joint call

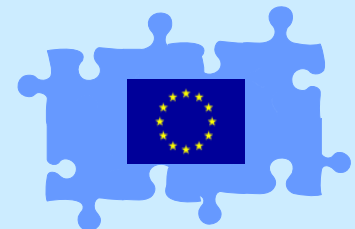
- ✓ MS contribute to a joint trans-national call 2/3
- ✓ EU funding for research: 1/3 of the joint call



Art. 169

Full integration of national programmes

- ✓ Scientific and financial: strong EU funding
- ✓ Single implementing structure



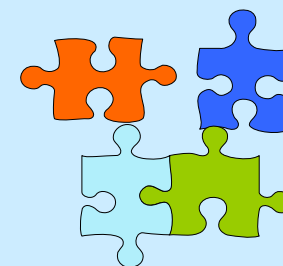


Coordination of national programmes FP7

ERA-NET

Like in FP6: Coordination of programmes

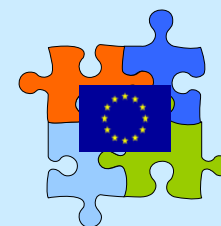
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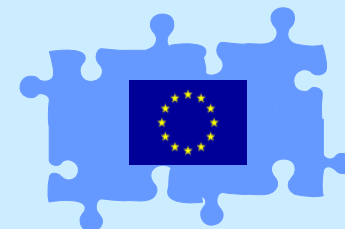
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Art. 169

Full integration of national programmes

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Co-ordination of national research programmes - Article 169 of the Treaty



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EUROPEAN AND DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP



PRD Research at the EU

From FP6 to FP7

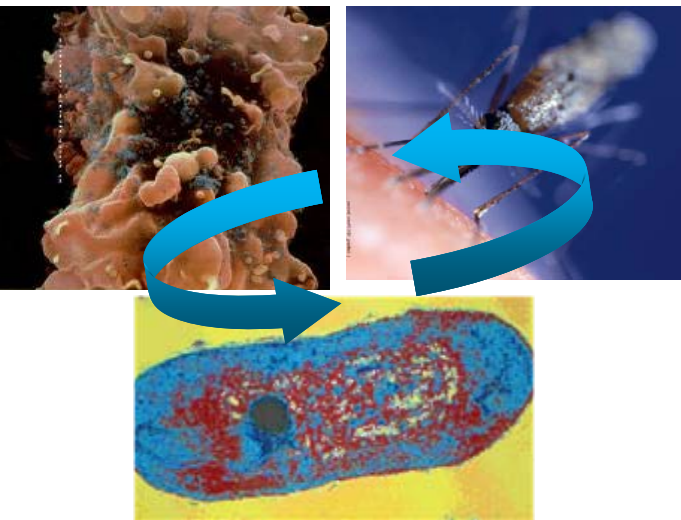
Why clinical trials for PRDs?



PRDs Political Context

Programme for Action (2001) (updated 2006)

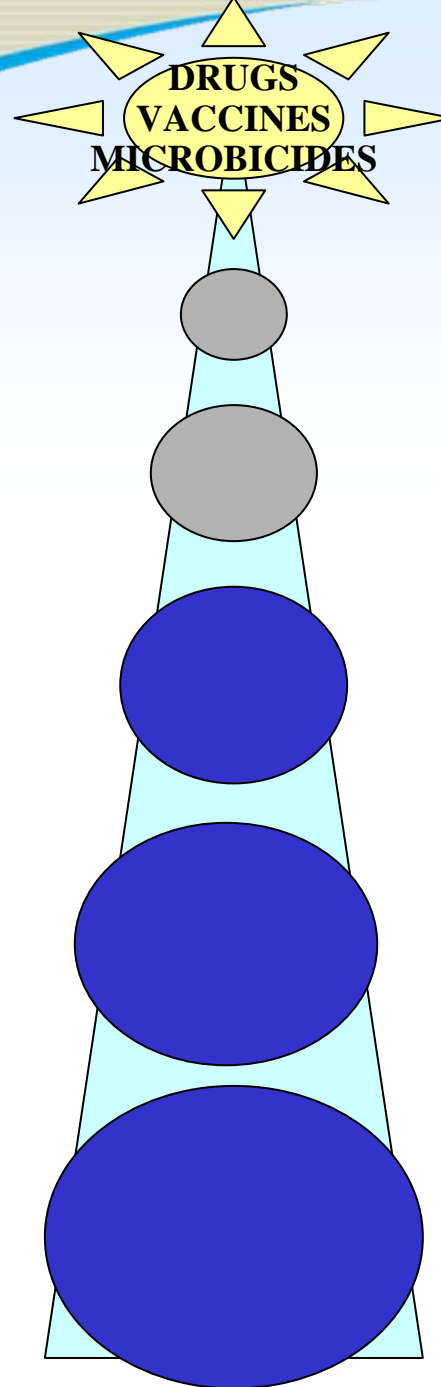
- **Trade:**
Make pharmaceuticals more affordable for Developing Countries (TRIPS, Doha, etc.)
- **Development:**
Health-related interventions (Global Fund ATM, etc.)
- **Health:**
Europe + Neighbouring Countries Policy
- **Research:**
New interventions against HIV/AIDS, malaria and tuberculosis





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• Phase IV Trials

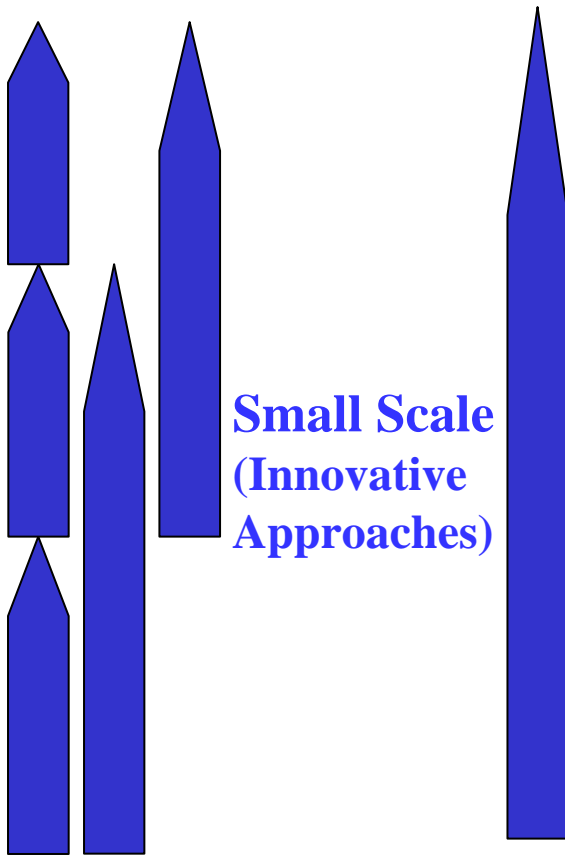
• Phase III Trials

• Phase II Trials

• Phase I Trials

• Pre-Clinical Research

• Basic Research



**Small Scale
(Innovative
Approaches)**

**Large Scale
(IP and NoE)**



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Clinical Trials in
and for Africa

Small Scale
(Innovative
Approaches)

Large Scale
(IP and NoE)

DRUGS
VACCINES
MICROBICIDES

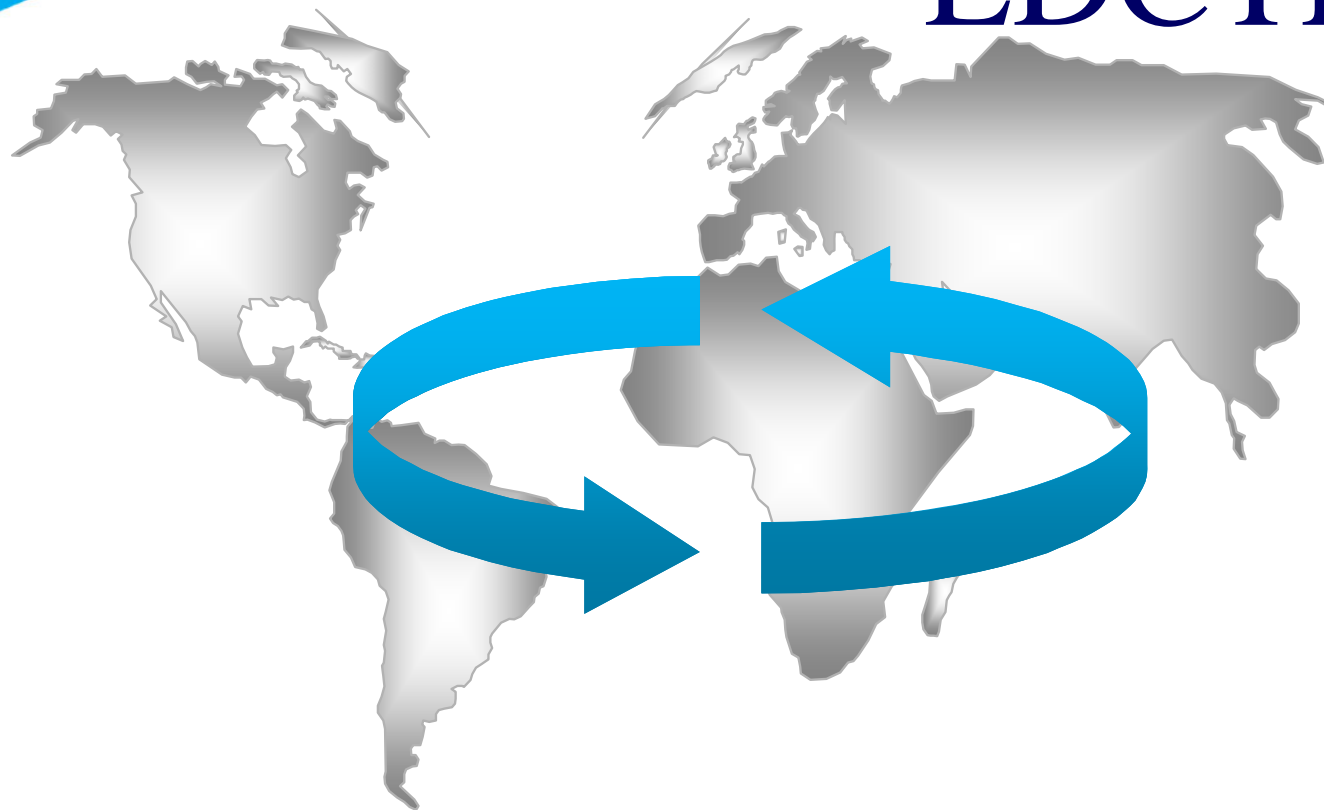
- Phase IV Trials
- Phase III Trials
- Phase II Trials
- Phase I Trials
- Pre-Clinical Research
- Basic Research



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EUROPEAN AND DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP



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E D C T P

European and Developing Countries Clinical Trials Partnership





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EDCTP INDEPENDENT EXTERNAL REVIEW

IER / 12 July 2007

Independent External Review Report

European and Developing Countries

Clinical Trials Partnership

(EDCTP Programme)

Review conducted by the IER / EDCTP Panel:

Wim Van Velzen (Chair),
Adetokunbo O. Lucas, Allyson Pollock, Jean Stéphane
and Fernand Sauer (Rapporteur).



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IER Experts

Adetokunbo O. Lucas

Former director the WHO Tropical Diseases Research Programme

Allyson Pollock

Director, Centre for International Public Health Policy, Univ. of Edinburgh

Fernand Sauer (Rapporteur)

Former Executive Director of the European Medicines Agency, EMEA

Jean Stéphenne

President and General Manager Glaxo-SmithKline Biologicals

Wim Van Velzen (Chair)

Former Member of the European Parliament





IER KEY RECOMMENDATIONS

1. To the EDCTP:

- 1.1. Define a clear, convincing and realistic EDCTP strategy
- 1.2. Make the GA more political with an Executive Steering Committee
- 1.3. Expand association with major PDPPPs
- 1.4. Renew calls for appropriate projects
- 1.5. Simplify and streamline co-funding, from a virtual to an actual common pot



IER KEY RECOMMENDATIONS

2. To the EDCTP Member States:

- 2.1. Renew “EDCTP vows”, reform EEIG and finance a “common pot”
- 2.2. GA decisions restricted to MS with financial contributions
- 2.3. African presence in GA should be reinforced, with decision-making status
- 2.4. MS to accept evaluation conducted by EDCTP
- 2.5. MS to enforce Art. 169 concepts in their own countries

3. To the European Commission, in relation to future EDCTP activities:

3.1. Report to Council and Parliament about current status

3.2. Create DG Research / DG Development platform with EDCTP

3.3. Reformulate health research strategy before refinancing EDCTP

3.4. Consult African Governments on EDCTP future and international health research

3.5. Involve African Governments to link capacity strengthening to national Strategies

3.6. Submit a new funding proposal to the Council and Parliament provided that:

- Interested Members States political/budgetary/administrative commitments are clear
- EDCTP programme integrates relevant national ones, with a common funding pot
- EDCTP governance is properly adjusted and more open to African partners
- EDCTP performance complies with targets from the EDCTP Roadmap



IER KEY RECOMMENDATIONS

4. To the European Commission, in relation to new Article 169 initiatives:

- 4.1. Set out future Article 169 pre-conditions
- 4.2. There must be pre-existing national programmes, strong commitment by Member States to provide funding and irreversible national support
- 4.3. There must be: common work-plan; sound governance structure; fixed national financial contributions; clear evaluation criteria and procedures; clear deliverables; solutions for the liability issue



MAIN RECOMMENDATIONS

1. The EDCTP must strictly comply with its mandate
2. For the EDCTP Programme to continue, Member States should provide the promised levels of financial support and improve the EDCTP governance and performance
3. If by end of 2008, the EDCTP did not improve significantly, the IER panel does not recommend the renewal of the EDCTP



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EDCTP Latest Developments

Are we in the right track?

New Executive Director

Roadmap to 2010 + Scientific Strategy

Stakeholder meetings

11 Calls for proposals + BMGF call on HIV vaccines

MS starting to commit to EDCTP

**In July 2007 the EC gave EDCTP a 2-years extension to 2010
approved ca. 40 Million Euros payment to EDCTP**





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What will happen in 2008?

Deadline for deciding on renewal beyond 2010

Project contracts to be negotiated, signed and financed
Huge task for the EDCTP Secretariat
Big financial commitment from Member States

Commission to start procedure for EDCTP 2010-2014





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EDCTP 2010-2014

Broader scope of EDCTP?

Public Health Research for Africa (beyond products)

Other continents?

Neglected Infectious Diseases?

EDCTP to make a recommendation

Member States to decide (Budget!!)



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EDCTP 2010-2014

EU national research programmes for PRD in place
Full integration of national programmes: Article 169 Fulfilled

Full coordination with African countries
Real Public-Private Partnership

Full ownership of Member States by EDCTP 2014-2019





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Additional Information

- **DG Research:**
europa.eu.int/comm/research
- **EDCTP:**
edctp.org

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