



\*HPPMCS & 3Cs4kids  
\*Cohort collaborations  
of treated children



# Trials and Cohorts in Paediatric HIV Infection

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# Types of studies

- Natural History:
  - Birth Cohorts
  - Prevalent cohorts
  - Trials with 'no treatment' or placebo arms
  - Inform about when to start ART
- Effect of ART
  - Trials address specific questions:
    - Drugs and regimens
    - ART management strategies
  - Cohorts:
    - Population effectiveness of ART
      - VL, CD4
      - Clinical
    - Longterm toxicities
    - Need large numbers



# Paediatric European Network for Treatment of AIDS (PENTA)

Penta is an European Union concerted action

Supported since 1992 by:

- *European Commission*: Biomed 1 and 2, Fifth FP, NAS extension.
- *MRC, INSERM/ANRS, Italian Institute of Health, other national AIDS programs*
- *Pharmaceutical companies*: some trial support / educational grants

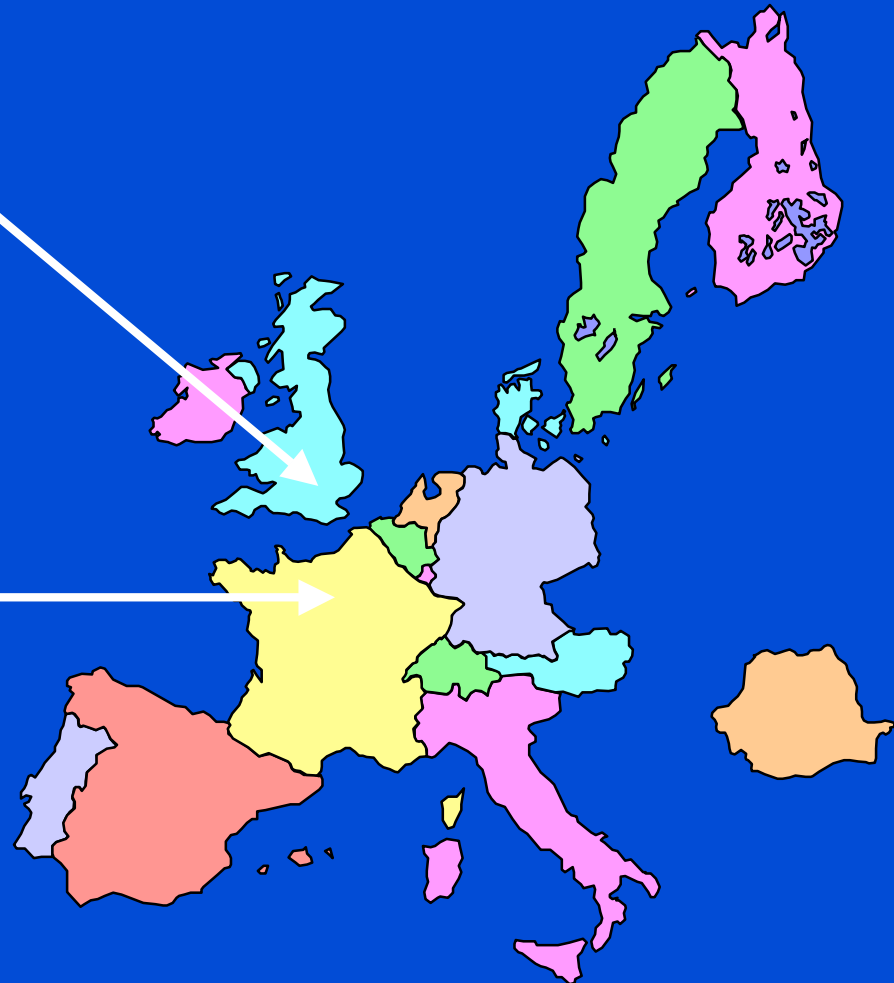
# PENTA countries

MRC CTU, London:  
Austria, Finland,  
Germany, Ireland,  
Italy, Netherlands,  
Sweden, UK

Brazil, Thailand

INSERM SC10,  
Paris: Belgium,  
Denmark, France,  
Portugal, Romania,  
Spain, Switzerland

Argentina



US and Bahamas in PP1



- Trials
- Treatment Guidelines
- PENTA Network
- Publications
- Other activities
- Contacts

## Penta

was established in 1991 as a collaboration between paediatric HIV centres in Europe. Trials are principally funded by the European Union through BIOMED II, by governmental bodies in a number of European countries and by support from the pharmaceutical industry.

Many questions about treatment for HIV can be answered in adult trials and it is unnecessary to repeat all trials in children. However, the natural history of vertical HIV infection differs from that in adults in some important ways and the tolerance of drugs in children may also be different.

## What's new?

The first children have now been recruited to **PENPACT 1** a collaboration between PENTA and the US PACTG (Paediatric AIDS Clinical Trials Group). Please contact a [Trials Centre](#) for help with ethics approvals.

**PENTA 10/PENPACT 2.** Plans for a further collaborative trial between PENTA and the PACTG are pressing ahead with a randomised trial to evaluate IL-2 with HAART in children.

**PENTA Guidelines for the use of antiretroviral therapy in paediatric HIV infection (.pdf file)** were published in HIV Medicine July 2002 (Volume 3, Issue 3). The Guidelines were written by members of the PENTA Steering Committee: Guido Castelli-Gattinara from Rome, José Ramos Amador from Madrid, Stephane Blanche from Paris and Mike Sharland and Diana Gibb from London. Revisions will be made annually.

Recruitment continues to **PERA** (PENTA 8), the first trial assessing the value of resistance testing in the treatment of children. To date 149 children have been recruited in Italy, UK, Spain, Germany, Brazil and Portugal.

48-week results of the **PENTA 5 trial** were published in full in The Lancet on 2nd March 2002 (.pdf file).

**PENTA 5 two year follow-up(.pdf file)** and **adherence data (.pdf file)** were presented as posters at the XIV World AIDS Conference in Barcelona. A three year follow-up of children enrolled in PENTA 5 is currently being undertaken.

[www.pentatrials.org](http://www.pentatrials.org)

# Epidemiology Studies and Cohort Collaborations

- Complement trials by:
  - Addressing questions at a population level
    - Effect of HAART
    - Short and long-term side-effects including lipodystrophy
  - Assist with long-term follow-up of trials
  - Provide data to:
    - explore questions to be addressed by trials
    - inform trial design

# CHIPS



## Collaborative HIV Paediatric Study

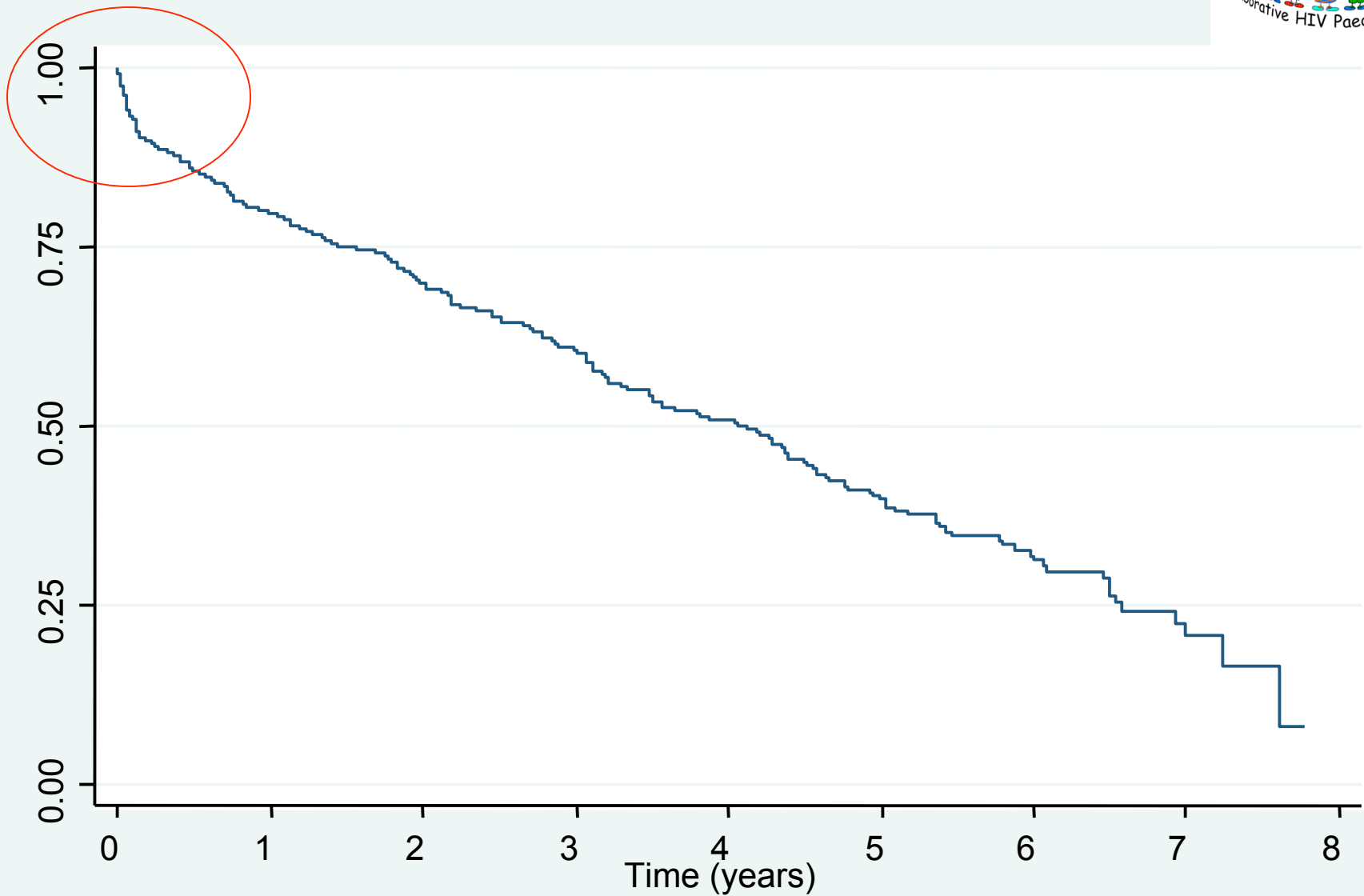
Collaborative **HIV** Paediatric **S**tudy (**CHIPS**) established in April 2000, is a multi-centre cohort study of HIV-1 infected children in the UK and Ireland. CHIPS initially included 16 UK and Irish centres enrolling children into **PENTA** trials (the **P**aediatric **E**uropean **N**etwork for the **T**reatment of **A**ids).

CHIPS is a collaboration between the now 23 centres, the **N**ational **S**tudy of **HIV** in **P**regnancy and **C**hildhood (**NSHPC**), and the **M**edical **R**esearch **C**ouncil, **C**linical **T**rials **U**nit (**MRC CTU**). CHIPS collects detailed follow up, including clinical, laboratory and treatment information.

- Centres and Collaborations
- More about CHIPS
- Annual CHIPS Data
- Publications & Presentations
- Contacts
- Links to other websites

# Time to change from initial regimen

## 595 children starting ART in CHIPS





# PENTA and Cohorts

- In last funding round, joined by ECS
- Charged with also setting up cohort collaborations in Europe
  - European Collaborative Study
  - First cohort collaboration on infants
- National Cohorts to join COHERE

# Adolescents in CHIPS: child to adult cohorts

- 46% of 1065 children in CHIPS are >10 years
- Transfer to adult care
- Important to continue follow-up through adult cohorts:
  - Time of diagnosis known
  - Less confounding with other risk factors
  - ART accurately documented

# COHERE

Collaboration of Observational HIV  
Epidemiological Research in Europe

246,600 Adults  
6,410 Children