

# European Network for Hyperkinetic Disorders EUNETHYDIS

What can networks offer?

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# EUNETHYDIS

- Founded 22 years ago to facilitate collaborative research into the causes and consequences of ADHD / Hyperkinetic Disorders
- Focuses both on basic science and clinical research
- Core membership of around 50 senior European academics from psychiatry, psychology and neuroscience
- 40 Associate members from North America, Australia, Asia and Africa
- Strong focus on collaborative interdisciplinary research including;
  - Genetics
  - Behavioural neuroscience
  - Neuroimaging
  - Neuropsychology
  - Neuropsychopharmacology
  - Phase I – IV Clinical Trials (Pharmacological and non-pharmacological)
  - Pharmacovigilance
  - Pharmacogenetics

# Challenges in Paediatric Psychopharmacology in Europe

- Practice outstrips evidence
- Research has been US dominated but there are very significant differences in clinical practice between Europe and US
- Under recognition and under treatment of disorders
- Against a background of a media driven picture of over diagnosis and over treatment
- Controversial treatments
  - Psychostimulants – “abuse” “turn children into zombies”
  - Antidepressants – “suicidality”
  - Antipsychotics – “chemical cosh”

- Need to focus on three areas
  - Poorly studied core treatments for core patients with core disorders
    - SSRIs in depression
    - Atypical antipsychotics in schizophrenia and bipolar disorders
  - Well studied treatments in new populations
    - Psychostimulants in intellectual disability and autism
  - New drugs/formulations

# PERS (Paediatric European Risperidone Studies)

- A programme of research developed in response to a specific call of the FP7 Cooperation Work Programme **“HEALTH- 2009-4.2-1: Adapting off-patent medicines to the specific needs of paediatric populations”**.
- The overarching goal is to perform a series of clinical studies that will lead to a Paediatric Use Marketing Authorisation (PUMA) for risperidone in children and adolescents with CD.
- EUNETHYDIS was involved in:
  - The development of the original application
  - The design of the 3 component studies that make up the Paediatric Investigation Plan (PIP)
    - Short term RCT
    - Long term open label and randomised discontinuation trial
    - Long term observational safety study
  - Troubleshooting implementation of these protocols
  - Implementing the trials
  - Analysing and interpreting results

# European Registration Trials for Lisdexamfetamine (Shire)

- Lisdexamfetamine a new amphetamine prodrug for treating ADHD owned by Shire.
- Licensed for use in North America and Brazil.
- Currently under development for licensing in Europe.
- EUNETHYDIS members have;
  - Provided scientific and clinical advice and support to Shire in the development and design of clinical trials
    - Including mid trial modifications required as a consequence of EMA policy changes
  - Acted as Principal Coordinating investigator for the 4 trials
  - Provided and identified trial sites across Europe
  - Assisted in training of sites
  - Assisted in the interpretation and presentation of results

- Similar to the LDX studies EUNETHYDIS has played a significant role in European studies for Atomoxetine (Lilly), and Medikinet XL (Medice)
- Development and implementation of studies in areas that industry funding is not generally available e.g.
  - Psychostimulants in children with intellectual disability
  - Atomoxetine in children with 22q11.2 deletion syndrome
  - Methylphenidate in prison populations
- Advice for industry with respect early and mid stage development of potential new compounds or new uses for existing compounds
  - Novel ADHD treatments
  - Treatments for child and adolescent anxiety and depression
- Developing understanding of MOA and predictors of response for licensed and unlicensed drugs using a range of techniques including
  - Behavioural neuroscience
  - Neuroimaging
  - Neuropsychopharmacology
  - Pharmacogenetics
- Large scale pharmacovigilance studies of ADHD medication
- Development of evidence based clinical guidelines

# Network Challenges

- Further develop and broaden the network to provide better coverage of child and adolescent mental health
- Address funding issues
  - Internal
  - External
    - Particualrly funding for studies of off patent medications, new indications and clinical sub groups.