



The Orphan Pharmaceutical Company

# Governance of registers: industry perspective

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19th March, 2009, Brussels

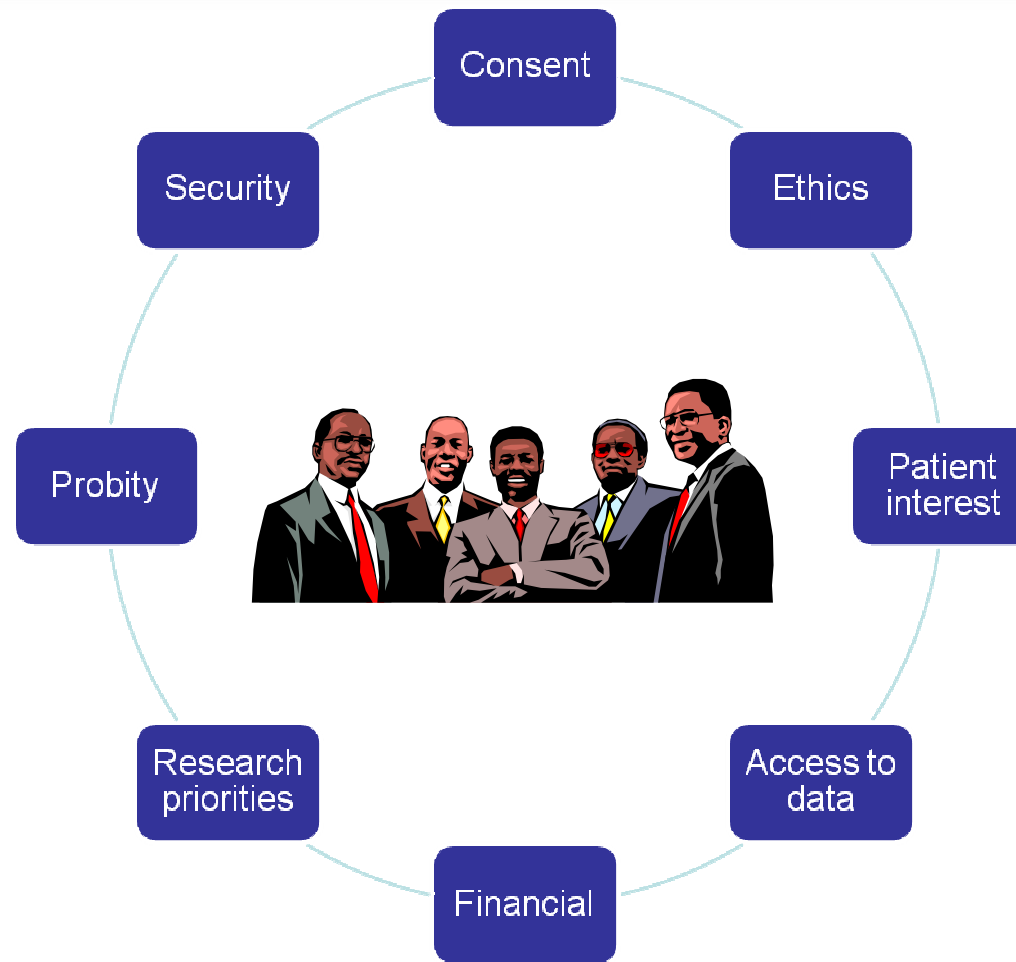
# Presentation objectives

- Evaluate experience of industry involved in academically governed registers
- Develop models of governance for consideration

# Personal background

- Industry background
- Project manager EuroWilson database
- Project manager EPNET
- Advisory board CF database
- Collaborating partner UCD database project
- Advisory board cystinosis registry

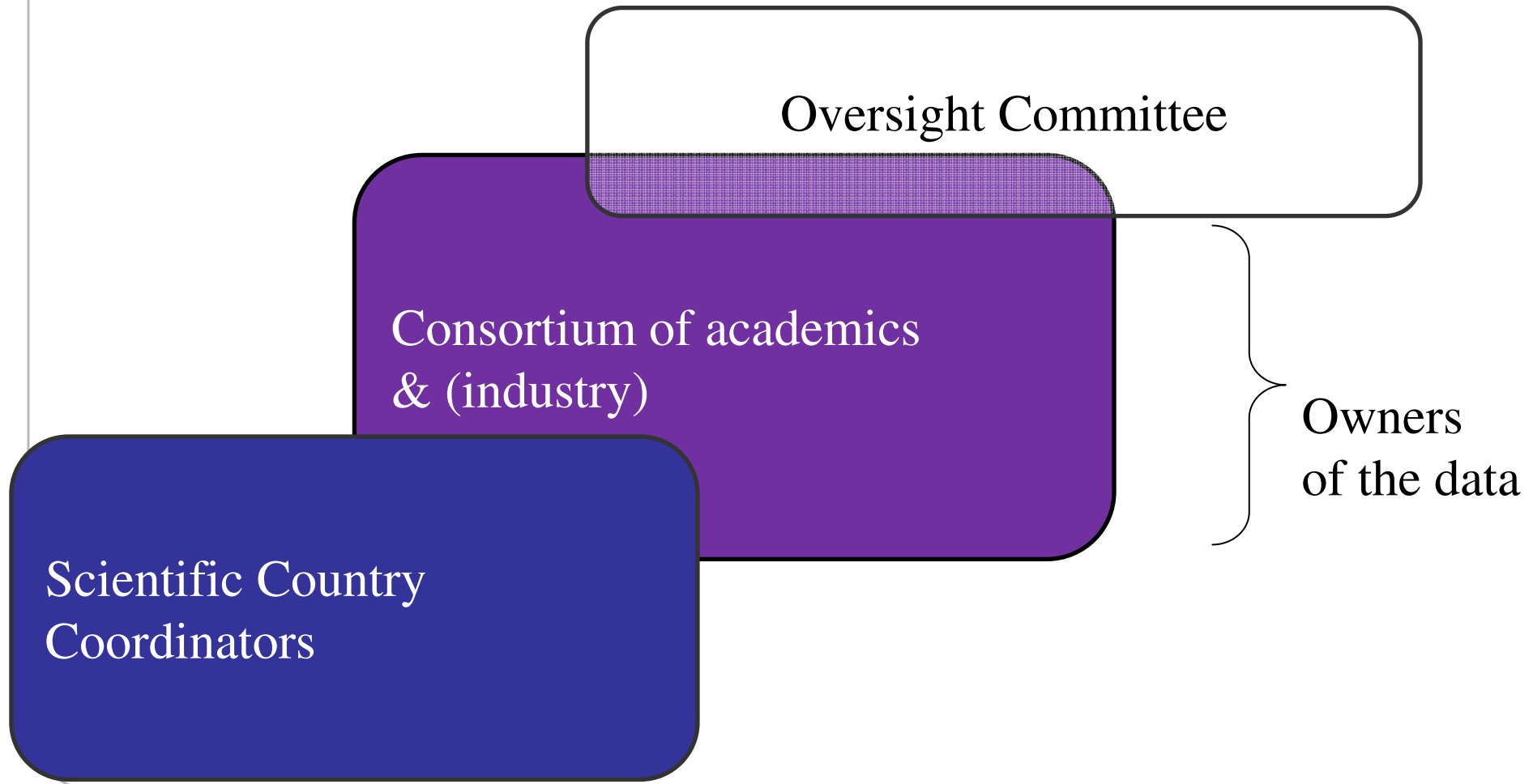
# Governance



# Governance

- Parallel between a gift of tissue and a gift of data
- Need to be aware of issues related to donation of tissue
- Patients give data as a conditional gift
- Ability to withdraw that data
- Whilst in the data base it may be incorporated into a publication or report
- Sensitive to data ownership, but recognise a problem

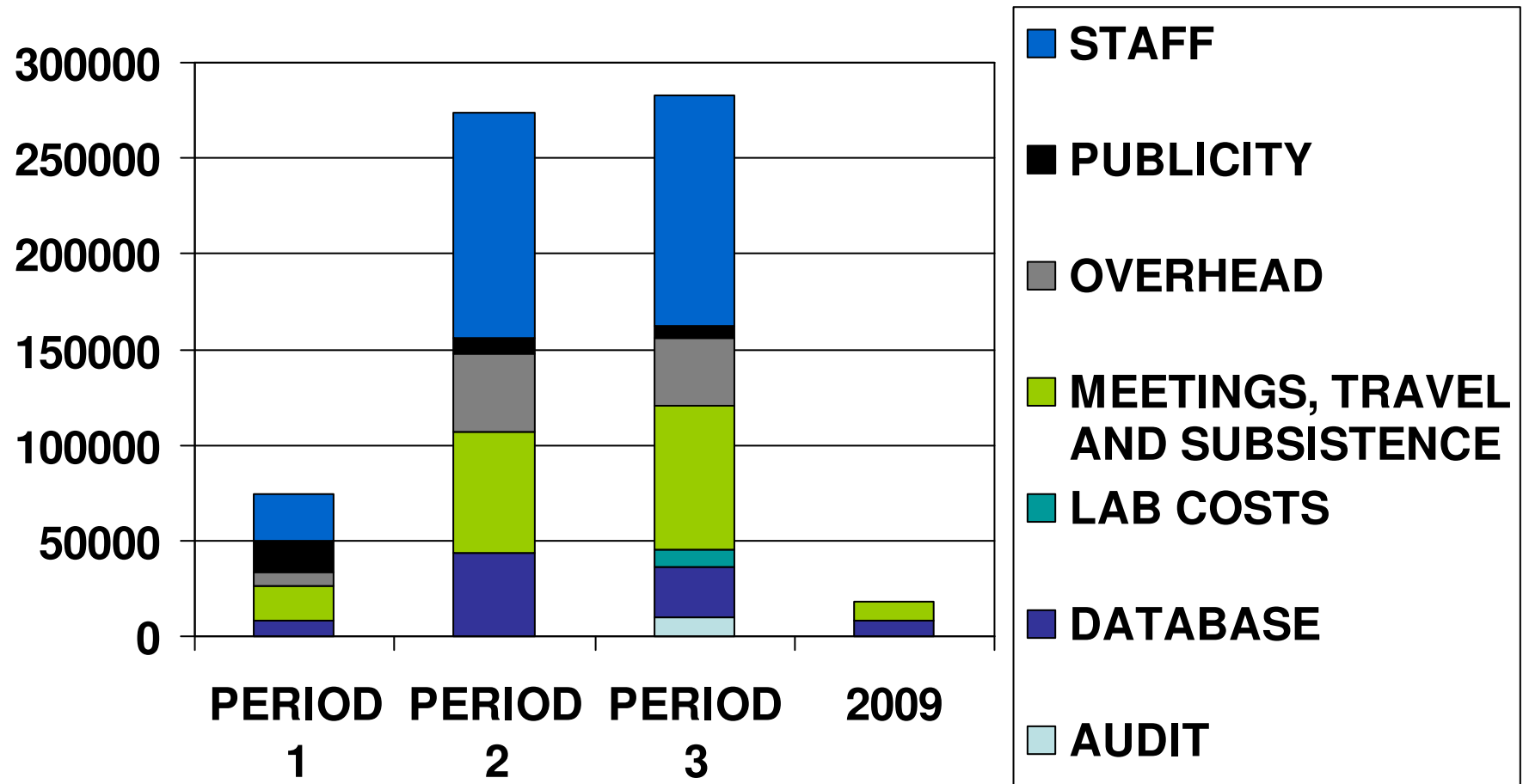
# EUROWILSON: governance



## EUROWILSON: governance

1. The data is owned by the Consortium
2. Applications for use, whether academic or commercial, are made to the Consortium
3. Permission for use should not be unreasonably with-held

# EUROWILSON: sustainability

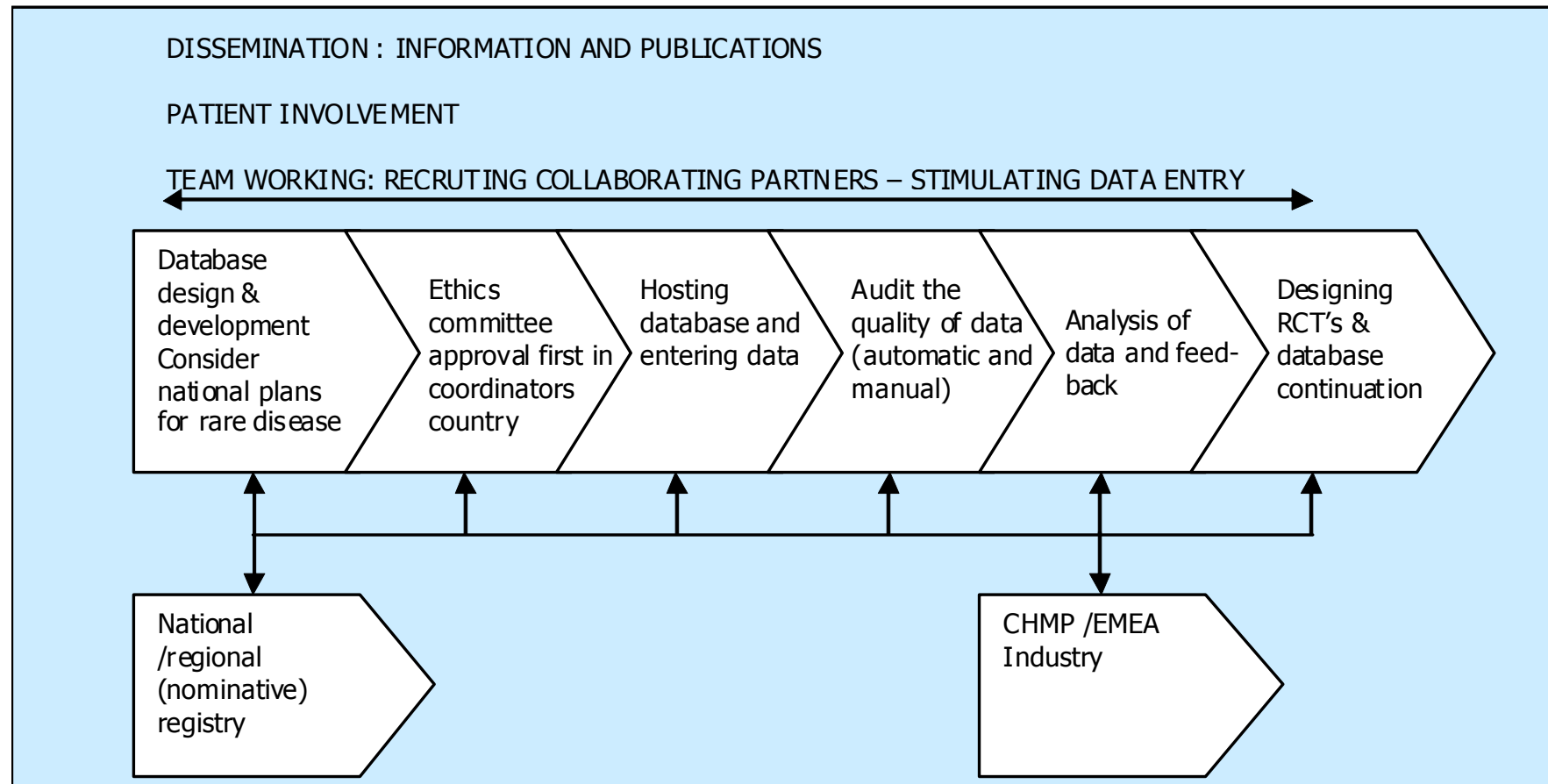


Sustainability is dependant on achieving EU funding

## EPNET: potential database duplication

- European authorities require long-term follow-up data in certain cohorts of patients
- Potential duplication of data collection
- Partnership naturally presumes an interchange of data

# EPNET: A model of interlinking databases



# Conclusion

- Legitimate for four stakeholders of this meeting to press for their interests
- Implications on governance within the database
- Should consider a structure to audit the auditors
- Sustainability should improve with a multi-stakeholder approach and reduction in duplication of registers