# **Multi**centre **P**reclinical **A**nimal **R**esearch **T**eam

WP4: Regulation and Ethics

# Tasks

✓ 1. Identify relevant regulatory authorities across countries

✓ 2. Examine existing ethical approval processes across participating countries

✗ 3. Establish ethical review process for Multi-PART studies

✓ 4. Co-ordinate with WP2 Task 1 (Stroke models)

✓ 5. Explore the potential to establish a single point of contact and approval for preclinical studies

? 6. Explore the role of other regulatory bodies

# Single common application

- Draft application sent to partners
  - based on UK project licence application for beta test
- Comment from partners in relation to:
  - relevant information
  - what is missing i.e. what additional details they would be required to include to gain approval
- Discussions with UK representative on EU directive

# Differences between countries

UK

- High level information
- Focus on harm/benefit analysis for a whole stream of work (5 years)
- Description of individual protocols but not actual experiment
- Covers a range of models and interventions

Germany, Switzerland, Spain, Netherlands, France

- Approval given for single experimental study
- Detailed experimental design
- Exact description of procedures

***What level of information is appropriate for a multi-centre trial?***

# Level of approval: pros & cons

| | Approval per protocol | Approval for stream of work |
|---|---|---|
| PROs | ▪ Justification for choice of intervention can vary<br>▪ All centres approved for same protocol (extra check)<br>▪ Easy for experimental design<br>▪ External feedback on protocol<br>▪ Link with trial pre-registration<br>▪ Level of standardisation | ▪ Several studies covered by same licence |
| CONs | ▪ New application for each study, may incur delays<br>▪ Level of standardisation | ▪ Difficult to provide justification for interventions to test in advance |

# Information required

- Background
  - Disease area & need
  - Choice of intervention to be tested
- Objectives
- Scientific benefit *versus* cost (to animals)
  - Advantages of multi-centre study
  - Severity assessment
- 3Rs
- Protocols and justifications

# Protocol & Justifications

- Species, strain, sex etc
- Choice of model
  - transient, permanent, mode of induction
- Outcomes
  - time points, clinical relevance
- Number of groups & sample size
  - exclusion criteria
- Pre- and post-op care
  - analgesia, husbandry, welfare monitoring etc
  - humane endpoints

# Next stage

- Finalise common application
- Presented to National Contact Points meeting in Brussels (June 2015)
- Amend based on feedback

# Deliverables

1. Seek approval from regulatory authorities for ethical review roadmap