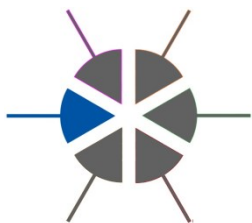
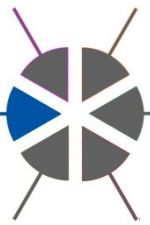




# Multicentre Preclinical Animal Research Team

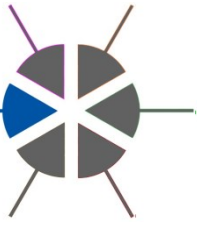


WP4: Regulation and Ethics



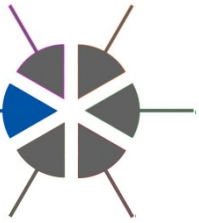
# Tasks

- ✓ 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

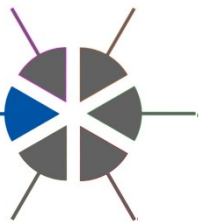
## UK

- 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

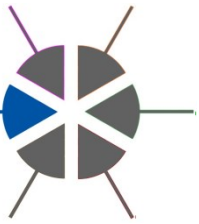
- Approval given for single experimental study
- Detailed experimental design
- Exact description of procedures

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



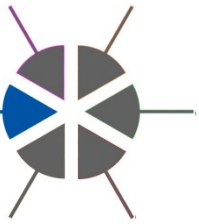
# Level of approval: pros & cons

	Approval per protocol	Approval for stream of work
PROs	<ul style="list-style-type: none"><li>▪ Justification for choice of intervention can vary</li><li>▪ All centres approved for same protocol (extra check)</li><li>▪ Easy for experimental design</li><li>▪ External feedback on protocol</li><li>▪ Link with trial pre-registration</li><li>▪ Level of standardisation</li></ul>	<ul style="list-style-type: none"><li>▪ Several studies covered by same licence</li></ul>
CONs	<ul style="list-style-type: none"><li>▪ New application for each study, may incur delays</li><li>▪ Level of standardisation</li></ul>	<ul style="list-style-type: none"><li>▪ Difficult to provide justification for interventions to test in advance</li></ul>



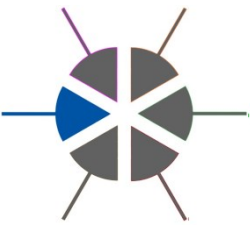
# Information required

- 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

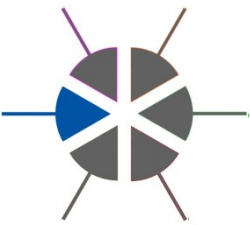
- Species, strain, sex etc
- Choice of model
  - transient, permanent, mode of induction
- Outcomes
  - time points, clinical relevance
- Number of groups & sample size
  - exclusion criteria
- Pre- and post-op care
  - analgesia, husbandry, welfare monitoring etc
  - humane endpoints



# 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