Multicentre **P**reclinical **A**nimal **R**esearch **T**eam

WP4: Regulation and Ethics

Aim

To identify current practice in participants counties and liaise with relevant local, national and international bodies to establish whether single level ethical and/or regulatory approval is attainable

Deliverables

1. Identify relevant regulatory authorities and approval processes across participating countries (month 6)

2. Establish prototype ethical review roadmap for Multi-PART studies (month 12)

3. Seek approval from regulatory authorities for ethical review roadmap

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

Doomed to fail…

There are two major risks associated with this project:

- Firstly, the work stream for WP4 includes (Task 4.5) engagement with national regulatory bodies in an attempt to establish a single ethical approval system for multicentre animal studies operating within the EU. This will require the engagement of national regulatory bodies in the process, and this engagement may not be forthcoming.
- Secondly, the project coordinator and UEDIN lead is, on paper at least, a relatively junior researcher

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

Consensus documents

- EU directive 2010/63/EU
- NCPs and Commission agreed to discuss a number of articles contained in Directive with a view to finding a common approach throughout the EU
- NCPs and Commission referred some elements of Directive to Expert Working Group (EWG) meetings
- Outcome of EWG meetings, reflecting the collective and invaluable input from Member States' and main stakeholder organisations' experts, submitted to the NCP for endorsement and publication

Single point contact - EWG

- Provide guidance documents
  - Evaluation
  - Severity assessment
  - Education and training
  - Inspections and enforcement
- MultiPART project presented to group
- Subsequently invited example application

Single point approval

- Single common application
- Completed with input from all partners
- Member State Specific Requirements
- Illustrative example for application/evaluation process

Deliverables

1. Identify relevant regulatory authorities and approval processes across participating countries (month 6) ✓

2. Establish prototype ethical review roadmap for Multi-PART studies (month 12) ✓

3. Seek approval from regulatory authorities for ethical review roadmap ?

Acknowledgements

- David Anderson

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