Aim

The aim of this workshop is to provide organisations and groups information on ‘Ethics and regulatory affairs requirements’ for new medical devices and diagnostic tools.

Specifically, working knowledge and case study examples from an EC funded project ‘Healthy Aims’ will be presented to attendees. The procedures developed and processes followed within the project to enable the medical products to enter pilot animal and clinical trials will be described. This will be through examples which have been successfully concluded within Healthy Aims. It will cover a range of products, ranging from ‘on the body’ sensors to the highest medical classification, ‘active medical implants’.

The reasons for regulatory requirements will be discussed and then the process flow that projects are likely to have to follow will be presented. This topic is extremely broad and it will not be possible to describe all the possible combinations. However, reasons why regulatory approval is required in some cases and not others will be presented referring to Medical Classifications of different products.

The classification for each type of product will be described and the reasons given as to why some require animal trials and others don’t will be explained.

The process of applying for trials to the relevant regulatory body and obtaining Ethics Approval will be discussed using the case studies as examples.

Human Trials

- Activity Monitor - On the body sensor in human clinical trials
- Glaucoma Sensor - On the body sensor in human clinical trials
- Retina Implant - In the body actuator system in human clinical trials
- 2 Channel Upper Arm FES - In the body actuator system in human clinical trials

Animal Trials

- FES for bowel control - In the body actuator – acute and chronic animal trials
- Intra-cranial pressure sensor (ICP) system - In the body sensor system in acute and chronic trials
- Modiolus electrode for cochlear - In the body actuator in acute animal trials

Attendees will be provided with a pack, which identifies the overall processes followed, key directives and other relevant material.
At the end of the workshop attendees should have an understanding of the process they need to follow for them to be able to enter clinical trials. They should know the relevant regulatory body that they need to approach and the likely timescales.

It must however be recognised that this is a dissemination activity and the ‘Healthy Aims’ project team will not accept any responsibility regarding providing specific advise to other projects on their regulatory requirements.

**Target Audience**

Attendees should be from FP6 projects where medical devices and/or diagnostic equipment is being developed and planned for trials. They should be involved in the approvals process, either as the clinical partner or the designers or manufacturer.

**Date and time**

The workshop will run from 10.30-16.00 on Thursday, 27\(^{th}\) September 2007 and will be held at the Holiday Inn Hotel London-Heathrow Airport

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**REPLY SLIP**

I/We will be attending the event being held at the Holiday Inn London-Heathrow Airport, on Thursday 27\(^{th}\) September 2007 (This hotel is close to the main airport Terminals 1, 2 and 3, with easy access to and a short ride from Terminal 4 by cab or train and ‘Hoppabus' shuttle (Line H4)).

1. Name:...............................................................................
   Company: ..........................................................................

2. Name:...............................................................................
   Company: ..........................................................................

Please register by email to: doreen.mascall@etb.co.uk
Or return this form to: Fax No: 01438 822811