Preclinical Evaluation and Clinical Trial Preparation

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Dartrix

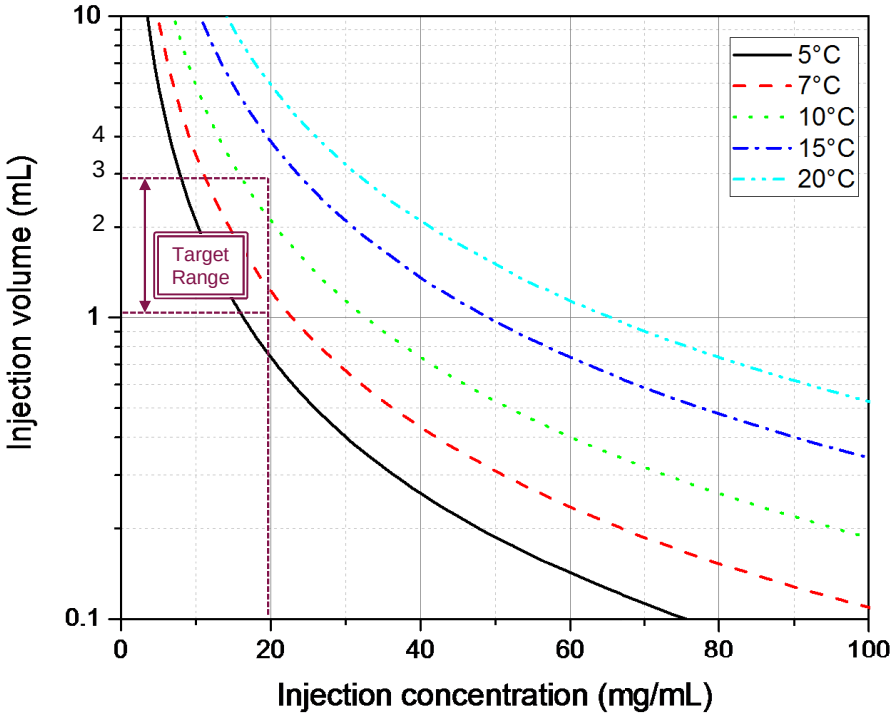
SEVENTH FRAMEWORK PROGRAMME

Grant Agreement n° 278580

Preclinical Evaluation: Progress to Date

- ✓ In-vivo models established
- ✓ Lead DARTRIX particle identified
- ✓ DARTRIX particles injected & retained within subcutaneous tumours and successfully heated following exposure to AMF
- ✓ DARTRIX particles injected into orthotopic tumours and imaged by MRI with no obvious immediate toxicity
- ✓ Tools established to characterise tumour microenvironment responses using immunohistochemistry

Trial Preparation: GLP Toxicity Testing



- BioHeat Equation utilised to predict clinical dose range (20mgFe-60mgFe)
- Toxicity testing protocol produced to test DARTRIX particles based upon this predicted dose
- UCL & TOPASS working closely with Sequani to finalise protocol

E69 GMP Production: Progress to Date

- ✓ Method validation for QC testing completed
- ✓ All GMP documentation ready (e.g. Batch Manufacturing Record and SOPs)
- ✓ all chemicals/disposables available
- ✓ GMP Facility & Equipment production ready
- ✓ E69 production during end January, to generate an Active Pharmaceutical Ingredient (API)
- ✓ G3 Control protein successfully generated as API

Future Directions

- GLP toxicity testing will shortly begin
- Invitation to the final round of applications for The Brain Tumour Charity's 'Quest for Cures' funding call
- UCL CCTU have approved the DARTRIX trial for development and will work with the study team to develop the clinical trial protocol