



HUMAN TISSUE SHARING and EXPERIMENTAL MEDICINE

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Experimental Medicine (EM)

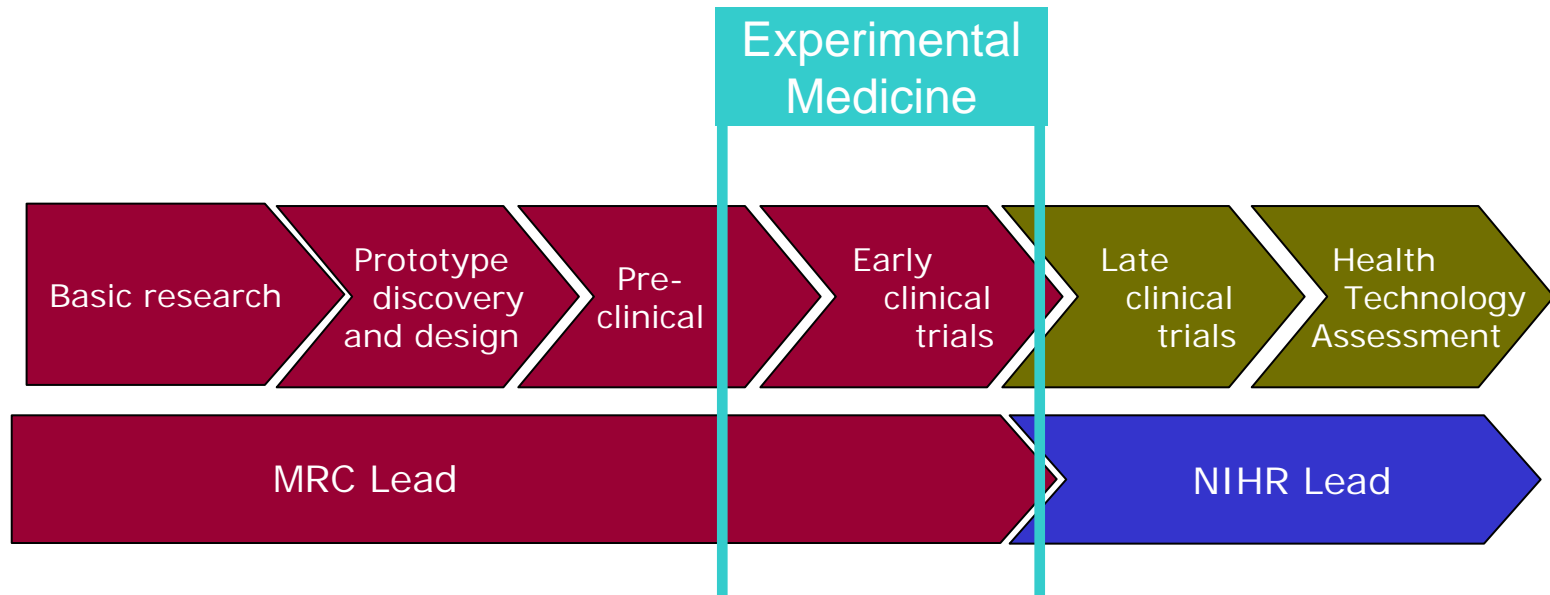
“Investigation undertaken in humans, relating where appropriate to model systems, to identify mechanisms of pathophysiology or disease, or to demonstrate proof-of-concept evidence of the validity and importance of new discoveries or treatments.”

EM can encompass non-clinical studies where these are directly relevant to human clinical disease, but excludes Phase III clinical trials



Experimental Medicine

at the core of MRC translational research



Experimental medicine precedes and informs the development of late phase clinical trials

Experimental medicine can have bi-directional outcomes

Experimental Medicine

MRC ongoing activities

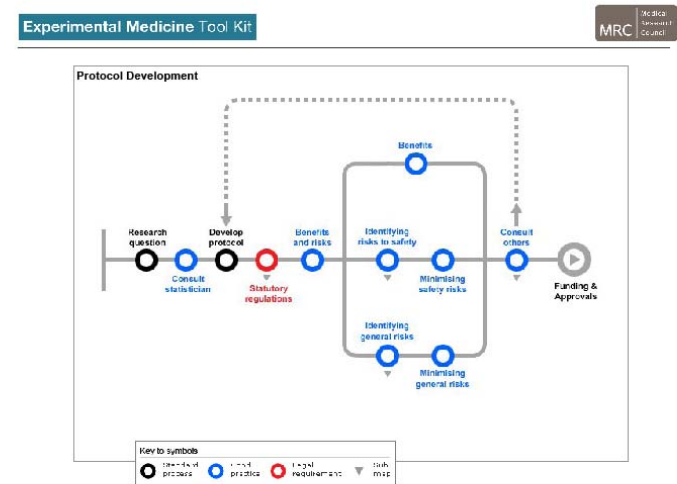
- **2 key calls in Experimental Medicine**
 - focussed on first in man 'proof of concept' studies to continue to strengthen experimental medicine research in the UK
- **2 calls in Biomarker development and evaluation.**
 - to evaluate potential biomarkers (surrogate indicators of a biologic state or process) in diagnosis of disease, disease heterogeneity and underlying mechanisms, susceptibility, exposure or response to interventions.
- **Strategic Awards Models of Disease**
 - for research on the evaluation and validation of human and animal models of disease, *in vivo*, *in vitro* and *in silico*.
- **Patient Cohort awards**
 - An unprecedented initiative to create small, extensively-defined groups of patients to help detect, treat or prevent disease.
- **Stem cell research awards**
 - Stem cell research has the potential to result in life-saving treatments and is an important part of the MRC's portfolio and translational strategy – we continue to support research on both adult and embryonic stem cells.
- **Inflammation and Immunity initiative (I and I)**
 - New approach establishing consortia to address, with industry, key needs in stratified medicine research in COPD and RA research
- **Developmental Clinical Studies**
 - Managed funding scheme for exploratory clinical studies

<http://www.mrc.ac.uk/Ourresearch/ResearchInitiatives/ExperimentalMedicine/index.htm>

Experimental Medicine

MRC resources underpinning EM

- The **Regulatory Support Centre** (RSC) provides support and guidance for those conducting research with human participants, their tissues or data.
- The **EM Toolkit** Developed by the Regulatory Support Centre
 - is designed to offer practical guidance
 - to researchers, research managers and Research Ethics Committees
 - Support risk proportionate management and monitoring of studies
 - Provide the EM community with a means to share best practice;



Experimental Medicine

MRC Co-ordination of

UKCRC Experimental Medicine Funders Group

EMFG brings together the major stakeholders within the UKCRC and more broadly, that influence experimental medicine research in the UK, including governmental, public sector, charitable and commercial funding bodies.

- Association of British Pharmaceutical Industries (ABPI)
- Bioindustry Association (BIA)
- British Heart Foundation (BHF)
- Cancer Research UK (CRUK)
- Chief Scientist Office Scotland (CSO)
- Health and Social Care Northern Ireland (HSC R&D)
- Health Department Wales (WORD)
- MRC
- National Institute of Health Research (NIHR)
- NIHR Clinical Research Network Co-ordinating Centre (CRN CC)
- Wellcome Trust

Experimental Medicine

MRC Co-ordination of

Experimental Medicine Funders Group

EMFG Terms of Reference

- Strategy development /awareness
- Promotion
- Communication and co-operation
- Foster academic-NHS-industry links

Experimental Medicine

MRC Co-ordination of

Experimental Medicine Funders Group

EMFG - Key areas

- Infrastructure and resources
- Regulatory issues
- Comprehensive communication strategy
- Industry-Academia-NHS
- Capacity and skills requirements

Human Tissue Funding

Types of collections funded

- Secondary to clinical trial / research projects
- Large population cohorts – eg birth cohorts, UK Biobank
- Tissue or disease specific banks or cohorts – eg brain banks; cancer banks

Human Tissue Funding

Benefits of funding tissue collections

- Optimal value from donated tissue
- High **quality** tissue available for future research
- Avoidance of **duplication** of funding
- Avoidance of **delay** while tissue collected
- Linkage or **alignment** of subsequent research projects
- Maximising research benefits of donated tissue – respecting **donor** wishes
- Potential for industry and academic **collaboration**

Human Tissue Funding

Risks of funding collections

- Long-term infrastructure funding – may not be competitive in response-mode review
- Expensive resources requiring long-term commitment
- Issues re quality and actual use
- Issues re availability, access and 'ownership' – tension between PI investment and wider sharing
- Difficulties with retirement /moves of PIs

Human Tissue Funding

Potential vicious circle

- Collections not adequately resourced or lacking appropriate access:
 - Insufficient funding for long-term curation
 - Lack of confidence in quality
 - Poor visibility for other researchers
 - Limited access and long-term use
 - Seen as poor investment

New environment and opportunities

Research priorities

- Investment in Experimental Medicine
- Increased focus on disease and patient stratification
- Models of large scale investment – UK Biobank; MRC Brain Bank network

New environment and opportunities

Research regulatory framework

- Models for Research Tissue Banks – HTA and NRES
- Standards for quality and governance – HTA
- Principles for access and sharing – models developed by funders and researchers (UKCRC; NCRI; cohorts; UKB)
- Potential single research regulator
- Changes to UK/EU data and other legislation

New environment and opportunities

Research collaboration

- Collaboration with NHS
 - BMRCs and BMRUs
 - AHSCs
 - NHS Constitution and QF
 - 'Liberating the NHS';
- Collaboration between academics
 - OLS clusters
 - MRC I and I
 - MRC Brain bank network
- Collaboration with industry
 - Need for well phenotyped collections
 - EMFG collaborative agreement templates

Summary

Sharing Human Tissue and Experimental Medicine

- UK environment becoming more facilitatory in regulation; funding and approaches
- Need for more information on what researchers in academia and industry need and will use

Where next?

- Policy, priorities and harmonisation from funders
- Development and use from researchers