



**HUMANE SOCIETY
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B O M E D ²¹

a human pathways approach to disease research

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Existing efforts and roadmaps: EU Perspective

- ✧ Political aspects - 1. H2020 / 2. animal use / 3. economic
- ✧ UK strategy: Delivery Plan / Innovate UK
- ✧ EU 3Rs centers and initiatives
- ✧ Funds and structures
- ✧ Publications - how research is reported; money is obtained/allocated
- ✧ Essential elements for new approaches?



The EU Horizon 2020 Programme

“Horizon 2020 is the financial instrument implementing the Innovation Union, a Europe 2020 flagship initiative aimed at securing Europe’s global competitiveness.”

- ✧ 3 main sections: Excellent Science, Industrial Leadership, Societal Challenges, “nearly 80 billion over seven years”.
 - ✧ “Health, Demographic Change and Wellbeing”
 - Personalising health and care
 - improve our understanding of the causes and mechanisms underlying health, healthy ageing and disease;
 - improve our ability to monitor health and to prevent, detect, treat and manage disease;
 - support older persons to remain active and healthy;
 - and test and demonstrate new models and tools for health and care delivery



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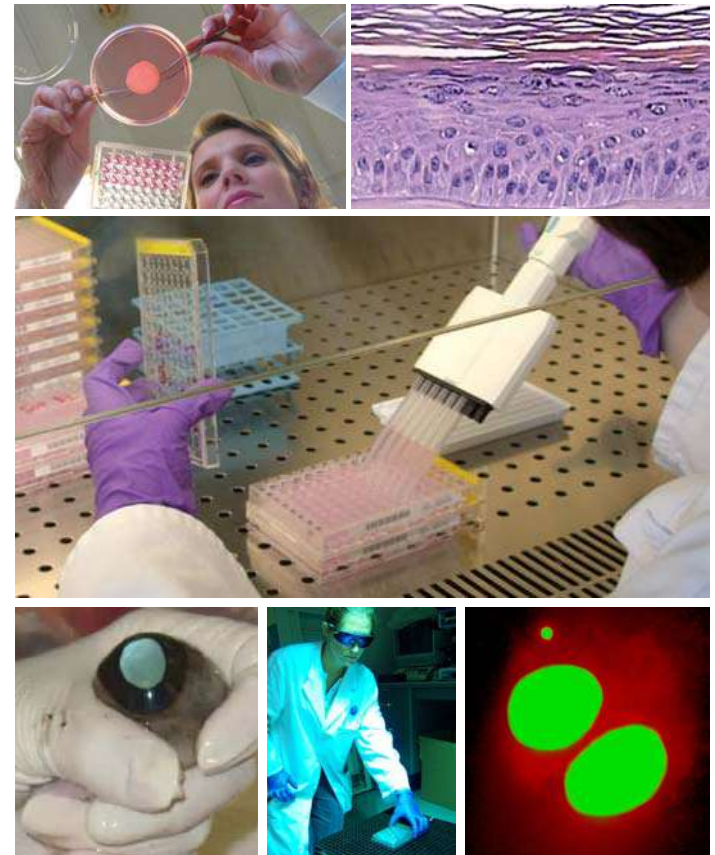
Directive 2010/63/EU

1. 3Rs implementation

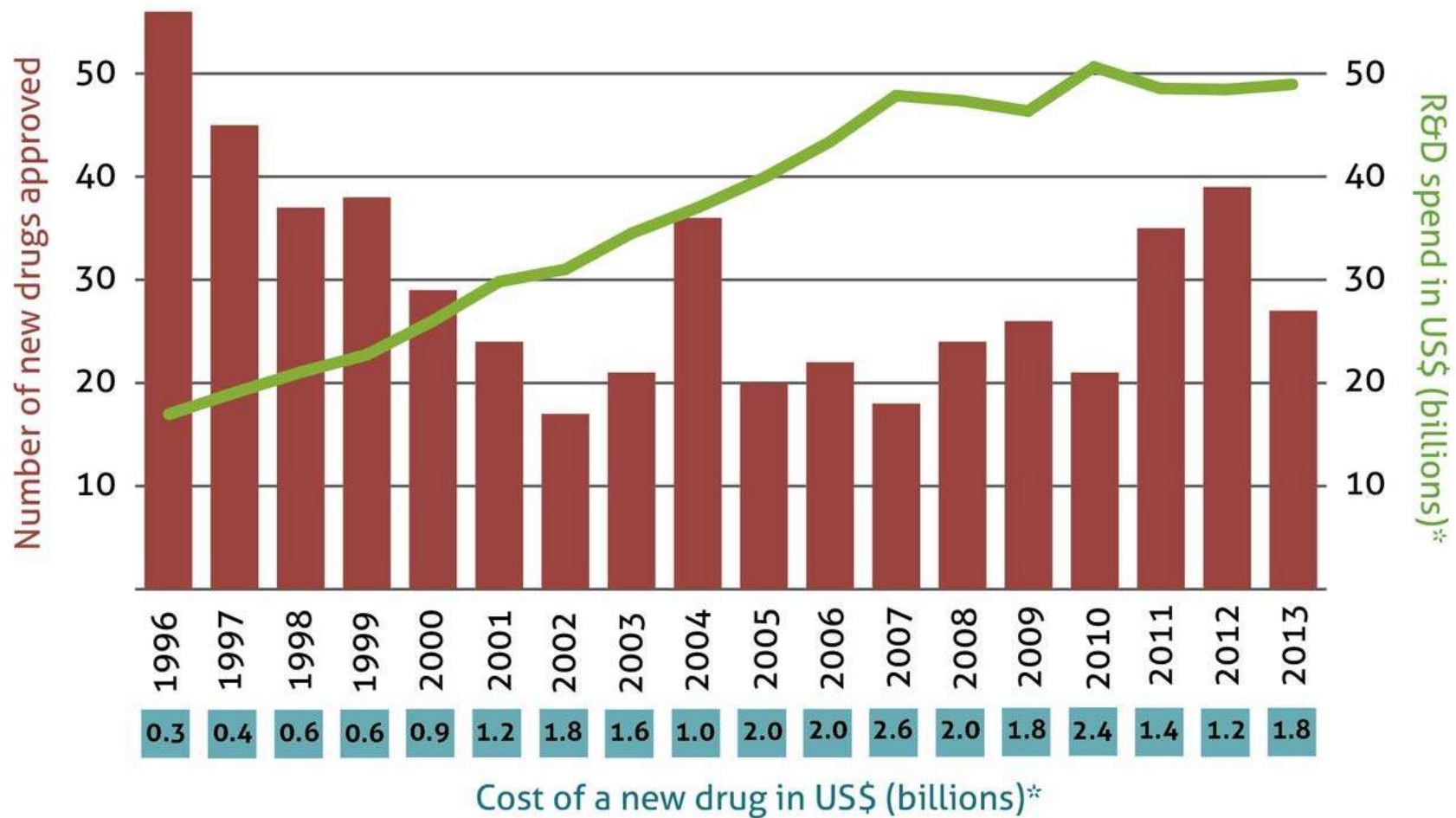
- ✦ Required by law
- ✦ Includes breeders, suppliers and users
- ✦ Project evaluation, retrospective assessment

2. 3Rs innovation

- ✦ **European Union Reference Laboratory (EURL includes ECVAM)**
 - Extended remit from reg. tox to biomedical
 - Network of contact points
- ✦ **Member State contributions**
 - Strategy setting, national and EU
 - Promote development and uptake



Drug Discovery in Crisis



UK “Delivery Plan”

- ✧ Intended to meet government commitment to reduce the number of animals used:
 - ✧ Advance the use of the 3Rs within the UK
 - ✧ Use international leadership to influence the uptake and adoption of 3Rs approaches globally
 - ✧ Promote an understanding and awareness of animals where no alternatives exist.
- ✧ Sets series of targets, actions and milestones. Identifies problem areas, calls for wide collaboration.



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DP: Working across departments & agencies

- ✧ **Government departments and non-ministerial departments** including the Home Office, BIS, Defra, the Department of Health, the Foreign Office and the Food Standards Agency;
- ✧ National Centre for the 3Rs (NC3Rs); and its main funders, the Medical Research Council (MRC) and the Biotechnology and Biological Sciences Research Council (BBSRC);
- ✧ **Agencies:** Public Health England (PHE), the Medicines and Healthcare Products Regulation Agency (MHRA), the Health and Safety Executive (HSE), the Food and Environment Research Agency (Fera), the Animal & Plant Health Association (APHA), the Centre for Environment, Fisheries and Aquaculture Science (Cefas), the Veterinary Medicines Directorate (VMD) and Innovate UK (formerly the Technology Strategy Board).



UK NC3Rs

- ✧ NC3Rs funding (core: Department for Business, Innovation and Skills (BIS) via the Medical Research Council (MRC) and the Biotechnology and Biological Sciences Research Council (BBSRC), and the Home Office.
- ✧ Annual budget of around £7 million
- ✧ £45 million committed to fund projects since 2004
- ✧ Funding for specific programmes from the charitable and commercial sectors
- ✧ Co-funding from other research funders



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Non-Animal Technologies Special Interest Group

- ✦ The NAT SIG is a partnership between the NC3Rs and Innovate UK, supported by the Knowledge Transfer Network
 - ✦ development and application of novel technologies
 - ✦ improve product development across a range of industries, and reduce reliance on animal models
 - ✦ build a research community harnessing recent technological advances and the latest knowledge in human safety, health and disease
 - ✦ generate new technologies with predictive capacity, extend existing technologies to new application areas



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EU: 3R developments

✧ Member state progress

- ✧ Commission survey MS structures and contributions (11 published)
- ✧ PARERE contact points (Preliminary Assessment of Regulatory Relevance Network)
- ✧ NETVAL (EU Network of Laboratories for the Validation of Alternative Methods)

✧ National Centres and Strategies

- ✧ Germany, UK, Sweden, Denmark, Finland have centres
- ✧ NL and Sweden are developing specific strategies
- ✧ Broader scientific agenda = improving models

✧ Commission Communication on the Citizens' Initiative "Stop Vivisection"



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Publication 1: Bias and misreporting

“Every week around 3500 new pieces of research involving animals are published. It is almost impossible for anyone to stay up to date with current knowledge. We have also shown that much of that work is at substantial risk of bias - and the effects observed in animals may be substantially overstated as a consequence.” Professor Malcolm Mcleod, Edinburgh

Post-publication scrutiny?

Retraction Watch (<http://retractionwatch.com>)

RW identifies: failure to declare interests; cherry picking results, authorship etc.

COMpare (<http://compare-trials.org>) top five journals: comparing the clinical trials registry and trial protocol with the trial report, reporting mistakes.



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Publication 2: Conservatism and Money

- ✧ Academic publication and funding: rewarding the best practices or corner cutting?
- ✧ Peer review: strengths when overseen by skilled editors, but can't pick up all instances of fraud or sloppy scientific practices?
- ✧ “Negative” studies not published – duplication, loss of useful knowledge/cumulative science?
- ✧ Bias favouring existing paradigm/animal studies? Examples?

What changes are needed?

M. Mcleod: “If scientists could be confident that their work would be judged on its own merits, then the case for expeditious publication in well-indexed online journals with open access, unlimited space, and the lowest publication costs would become unassailable.”



Essential elements to promote new approaches

Regulation of animal use

- ✧ Rigorous application of project evaluation and retrospective assessment opportunities (Directive 2010/63 EU)
- ✧ Knowledge sharing among evaluators and researchers (new structures/databases?), departments and agencies
- ✧ New focus on drug development / replacement to meet 3Rs obligation

Funding

- ✧ Join funding panels, charity engagement
- ✧ Publication – open access, ethical, comprehensive, fair

Economic and health research benefits

- ✧ Recognise and articulate benefits and need more clearly



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To be continued . . . !

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