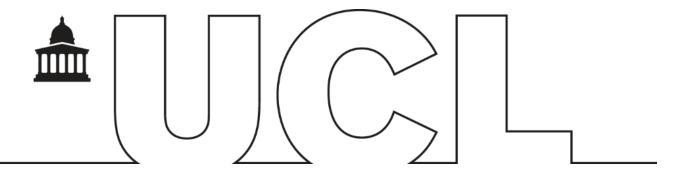




Responsible Personalised Medicine: It all starts here

Saheli Datta Burton Lecturer (Teaching) In Science Policy



Responsible Research & Innovation (RRI)



"A transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society)."

von Schomberg, 2011

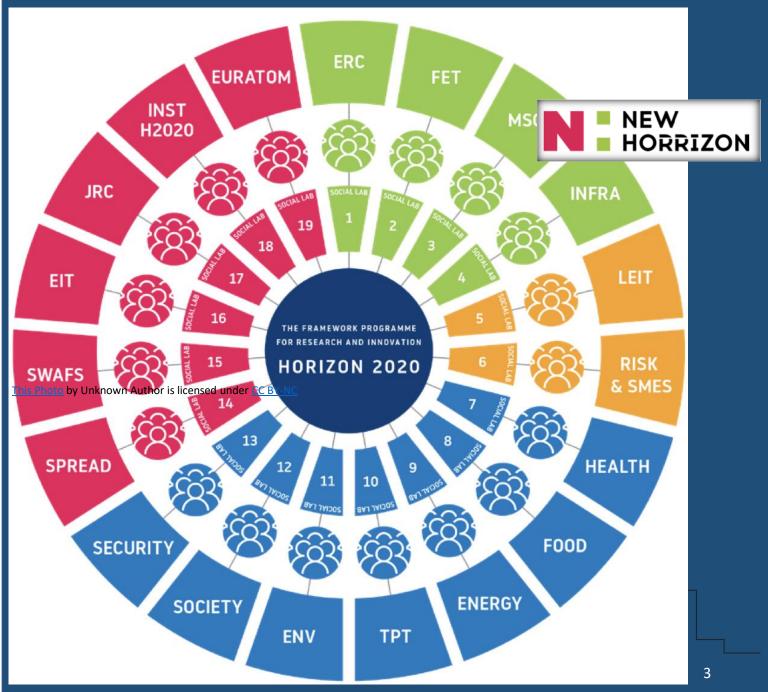




Responsible Research and Innovation (RRI) in Europe









Responsible Innovation (RI) in the UK





Area of investment and support

EPSRC impact acceleration accounts

Impact acceleration accounts (IAAs) are strategic awards providing funding to research organisations to use creatively for a wide range of impact activities.

Budget: EPSRC has invested over £150 million in this programme since 2012.

Duration: This is an ongoing initiative with 36 institutions being invited to submit an IAA application for funding between 2022 and 2025.

Partners involved: EPSRC

Funding opportunity

2

EPSRC equality, diversity and inclusion (EDI) sharing hub

Opportunity status:	Open
Funders:	Engineering and Physical Sciences Research Council (EPSRC)
Funding type:	Grant
Total fund:	£2,500,000
Maximum award:	£2,500,000
Publication date:	4 September 2023
Opening date:	4 September 2023 9:00am UK time
Closing date:	5 December 2023 4:00pm UK time

Timeline

Q June 2023

Pre-announcement

) 4 September 2023 9:00am
Outlines opening date

5 December 2023 4:00pm
Outlines closing date

Week commencing 15 January 2024



Responsible Research & Innovation (RRI)

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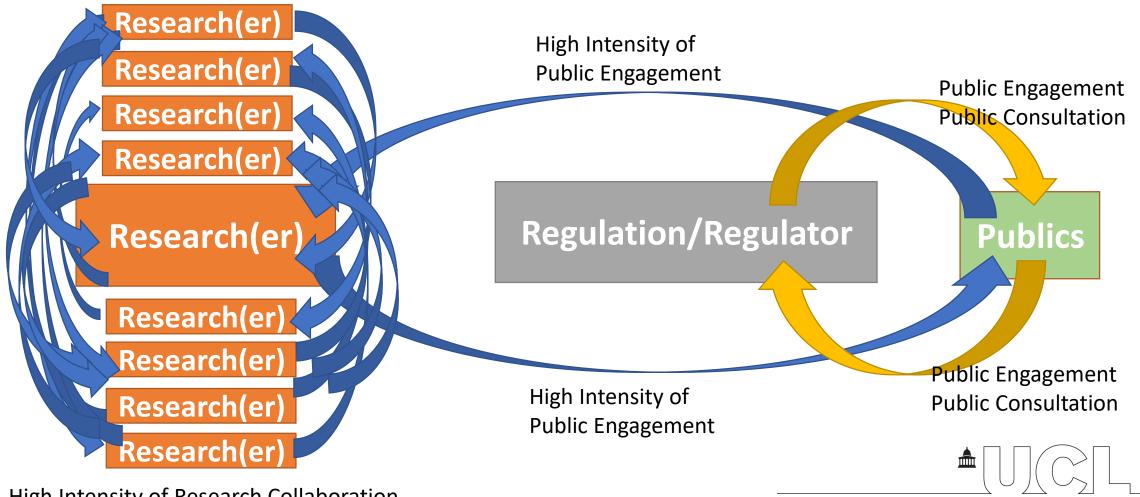
...the meaning of such terms remains contested. Rather than representing a clear novel governance paradigm, we might instead see responsible innovation as a location for making sense of the move from the **governance of risk to** the governance of innovation itself. [bold added for emphasis]

Felt et al., 2007 ²





Current trends of Risk-based Governance...



High Intensity of Research Collaboration

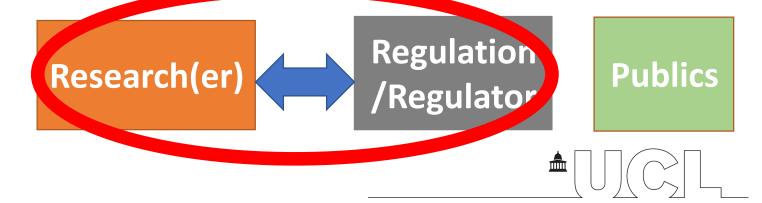


Extending Governance of Risk...

...to



Governance of Innovation



Competence Centre on Technology Transfer



The CC TT provides technology transfer policy related expertise and services to the European Commission and other institutions of the Union and operational support services to a broader range of stakeholders.

"It is well known that the EU is a leader in the production of science. Unfortunately, most research results do not get transferred to the market and wider society.

This is because of several factors, including the lack of professionalised technology transfer project managers at universities, research centres, and related organisations. The CCTT provides training and knowledge to create a support system for the commercialisation of research results."









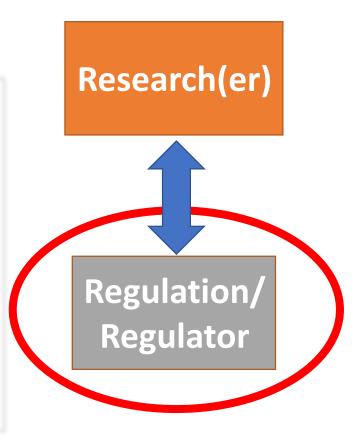
KNOWLEDGE FOR POLICY

Competence Centre on Technology Transfer

"Our support entails the provision of knowledge, methods and tools for identification, evaluation and protection of technologies, management of intellectual property rights, business development, and negotiation of commercial deals.

Upskilling prepares practitioners to actively engage with different players of the innovation ecosystem and to support successful technology transfer."

[highlight added for emphasis]



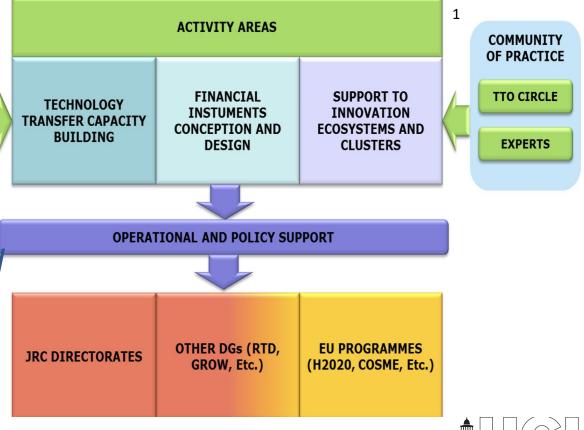


Adapting RRI to Personalised Medicine



 Provision regulatory knowledge exchange specific to health & medicine (beyond current focus on IP).

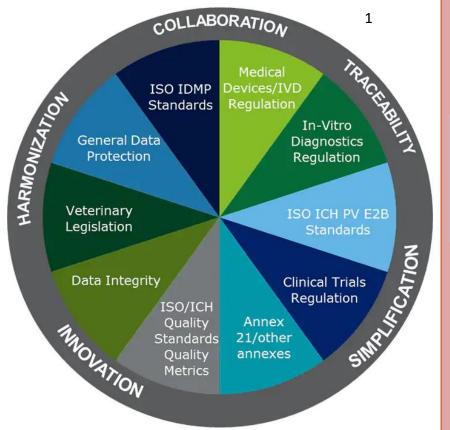
EU Science Hub²:
....Based on several
indicators (patent analysis,
scientific publications, etc.),
JRC builds the technological
profiles of the patent
portfolios of both regions
and companies...

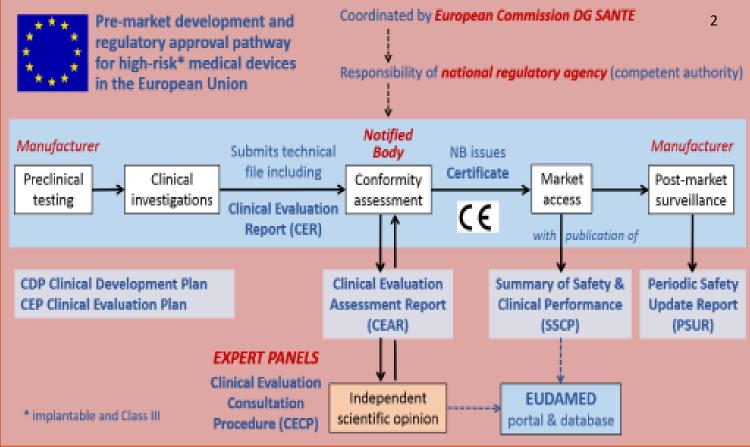






1. Provision for regulatory knowledge exchange specific to health & medicine (beyond current focus on IP).







INTERDISCIPLINARY SCIENCE REVIEWS https://doi.org/10.1080/03080188.2020.1840223







Clinical translation of computational brain models: understanding the salience of trust in clinician-researcher relationships

S. Datta Burton • a, T. Mahfoudb, C. Aicardi • and N. Rosec

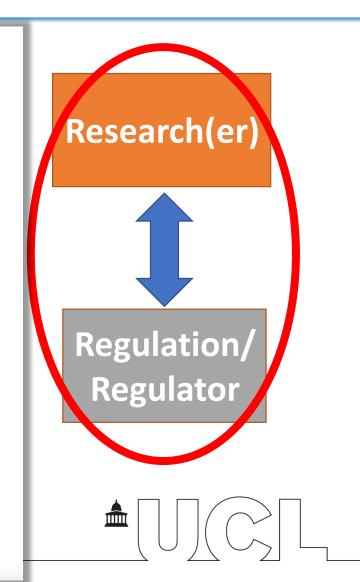
^aDepartment of Science, Technology, Engineering and Public Policy (Steapp), University College London, London, UK; ^bDepartment of Sociology, University of Essex, Colchester, UK; ^cDepartment of Global Health and Social Medicine, King's College London, London, UK

ABSTRACT

Computational brain models use machine learning, algorithms and statistical models to harness big data for delivering disease-specific diagnosis or prognosis for individuals. While intended to support clinical decision-making, their translation into clinical practice remains challenging despite efforts to improve implementation through training clinicians and

KEYWORDS

Human Brain Project; Artificial Intelligence; machine learning; neurology; neuroscience; clinical prediction models; big data; data driven health





"Our interviews with researchers reiterate ...that the successful clinical translation of computational models developed by small and medium developers or public research institutions ... need to build robust investor or public funder's confidence in the commercial viability (end-user uptake) of their innovation to attract the substantial capital resources and regulatory expertise necessary to fund and drive the clinical evidence generation, evaluation, verification, and validation processes needed to reach the market." [highlight added for emphasis].

Datta Burton et al, 2020



Adapting to Personalised Medicine



2. Using existing regulatory knowledge capacity to expand strengthen, (and democratise) capacity e.g., collaboration with established TTOs at large research universities. Hub:

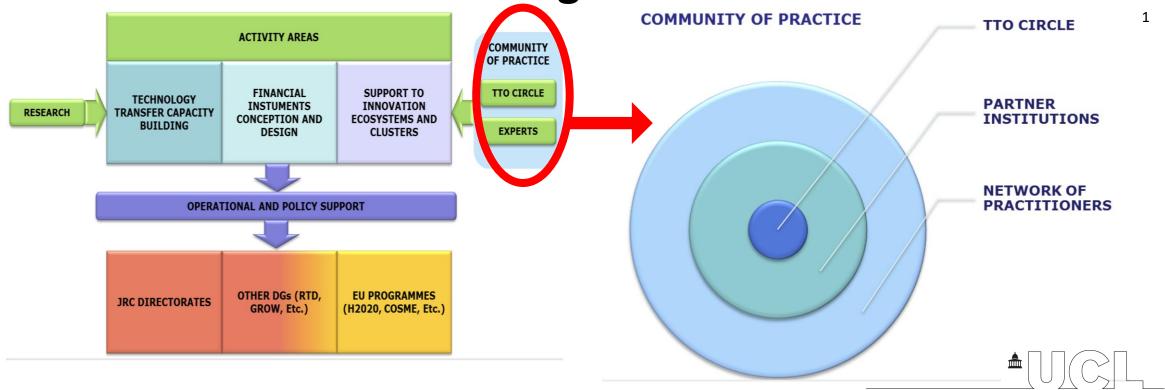
...One of the main components – and main challenges – of technology transfer is its financing. From the viewpoint of traditional risk finance, the technology transfer segment is in a very early stage and its associated potential investment targets are considered to be very risky.

Savvy public sector intervention is required to counter this market failure and to enable the development of adequate policy, which relies on profound understanding of the intricacies of technology transfer.

Adapting to Personalised Medicine



2. Using existing regulatory knowledge capacity to expand strengthen, (and democratise) capacity e.g., collaboration with established TTOs at large research universities.



Adapting to Personalised Medicine



2. Using existing regulatory knowledge capacity to expand strengthen, (and democratise) capacity e.g., collaboration with established TTOs at large research universities.



Congratulations to <u>@odin_vision</u>, a UCL spin out company that develops Al-driven endoscopy technology to help better detect early stage <u>#cancer</u>, has been acquired by <u>@Olympus_Corp</u> for up to £66m.

<u>@UCL_Business @UCLTF @UCLEnterprise</u> <u>ucl.ac.uk/news/2023/jun/...</u>

07/06/2023, 12:45



EDUCATION

RESEARCH

Knowledge transfer

The results of research conducted in Sorbonne Université laboratories lead to numerous innovations with applications in various fields. Whether for direct transfer to companies or the creation of start-ups, Sorbonne Université is industrial stakeholders.



Adapting RRI to Personalised Medicine



Suggested policy pathway 1:

Support for regulatory knowledge exchange could be provisioned as part of the ongoing Responsible Research and Innovation (RRI) Awareness initiatives for research(ers) in health and medicine generally, and PM particularly.



1

FREE ONLINE COURSE: ENACTING RRI IN EUROPE





Adapting RRI to Personalised Medicine



Suggested policy pathway 2:

Support for regulatory knowledge exchange could be integrated in research funding calls for applied (downstream) Personalised Medicine technologies (e.g., as part of *policy impact* or research exploitation).

Exploitation

The utilisation of results in further research activities other than those covered by the action concerned, or in developing, creating and marketing a product or process, or in creating and providing a service, or in standardisation activities.*

- Make use of the results; recognising exploitable results and their stakeholders
- Concretise the value and impact of the R&I activity for societal challenges
- Can be commercial, societal, political, or for improving public knowledge and action
- Project partners can exploit results themselves, or facilitate exploitation by others (e.g. through making results available under open licenses)
- * http://ec.europa.eu/research/participants/portal/desktop/en/support/reference_terms.html



1





Rather, technology "nonadoption and abandonment" is the typical result:

"...when 'the value proposition of the technology [is] unclear, in terms of a viable business venture for its developer [e.g., historical low CPM adoption rates] or in terms of a clear benefit for patients and an affordable real-world service model' [highlight added for emphasis].

Research(er) Regulation **Regulator**

Greenhalgh et al, 2017



Responsible Development of Personalised Medicine



- 1. Provision for regulatory knowledge exchange specific to health & medicine (beyond current focus on IP).
- 2. Using existing regulatory knowledge capacity to expand, strengthen, (and democratise) capacity e.g., collaboration with established TTOs at large research universities.





To continue the conversation: saheli.burton@ucl.ac.uk

Thank You!

https://profiles.ucl.ac.uk/77672-saheli-datta-burton/teaching



Slide 2

von Schomberg, R., (2011). Prospects for technology assessment in a framework of responsible research and innovation. In: Dusseldorp, M., Beecroft, R. (Eds.), *Technikfolgen Abschätzen Lehren: Bildungspotenziale Transdisziplinärer*. Vs Verlag, Methoden, Wiesbaden.

Slide 3

New Horrizon. (2021). Changing the research and innovation system through democratic experimentation. A guide to good practices for Responsible Research and Innovation. https://newhorrizon.wpenginepowered.com/ pp 7

Slide 4, 1

UKRI. https://www.ukri.org/what-we-do/our-main-funds-and-areas-of- support/browse-our-areas-of-investment-and-support/epsrc-impact-acceleration-accounts/

4, 2

https://www.ukri.org/opportunity/epsrc-equality-diversity-and-inclusion-edisharing-hub/

Slide 5

Please see reference for Slide 2





- Slide 6, 1 Kjølberg, K. (2010). The Notion of 'Responsible Development' in New Approaches to Governance of Nanosciences and Nanotechnologies. University of Bergen, Norway (PhD dissertation).
 - 6, 2 Felt, U., Wynne, B., et al. (2007). Taking European Knowledge Seriously.Report of the Expert Group on Science and Governance to the Science, Economy and Society Directorate. Directorate-General for Research European Commission, Brussels, In Owen, R., Macnaghten, P., Stilgoe, J., 2012. Responsible research and innovation: from science in society to science for society, with society. Science and Public Policy 39, 751–760.
- Slide 9 https://knowledge4policy.ec.europa.eu/sites/default/files/leaflet_capacity_ building.pdf
- Slide 10 See Slide 9





- Slide 11, 1 https://joint-research-centre.ec.europa.eu/practical-handbook-regional -authorities/ii-research-and-innovation/supporting-technology-transfer_en
 - 11, 2 https://joint-research-centre.ec.europa.eu/practical-handbook-regional
 -authorities/ii-research-and-innovation_en
- Slide 12, 1 https://www2.deloitte.com/uk/en/pages/life-sciences-and-healthcare/ articles/eu-regulatory-changes-impact-global-life-sciences-industry.html
 - 12, 2 https://www.escardio.org/The-ESC/Advocacy/medical-device-regulation
- Slide 13 Datta Burton, S., Mahfoud, T., Aicardi, C., & Rose, N. (2021). Clinical translation of computational brain models: Understanding the salience of trust in clinician—researcher relationships. *Interdisciplinary Science Reviews*, 46(1-2), 138-157.

Slide 14	See Slide 13
Slide 15	See Slide 11, 1
Slide 16	See Slide 11, 1

Slide 20



Slide 17, 1 https://www.sorbonne-universite.fr/en/research-and-innovation/innovation
-and-exploitation/knowledge-transfer

Slide 18 https://rri-tools.eu/-/free-online-course-enacting-rri-in-europe

Slide 19 https://ec.europa.eu/research/participants/data/ref/h2020/other/events/ 2017-03-01/8_result-dissemination-exploitation.pdf

Greenhalgh, T., Wherton, J., Papoutsi, C., Lynch, J., Hughes, G., Hinder, S., Fahy, N., Procter, R., and Shaw, S. (2017). "Beyond Adoption: A New Framework for Theorizing and Evaluating Nonadoption, Abandonment, and Challenges to the Scale-up, Spread, and Sustainability of Health and Care Technologies." Journal of Medical Internet Research 19 (11): e367.

