

1. Challenges and strategic areas of regulatory science in the UK

Recent years have seen the development of innovative healthcare products including genome- and cell-based therapies, mobile health products, artificial intelligence and implantable devices. This survey seeks to understand how regulatory science in the UK and beyond can remain at the cutting edge of increasingly-complex innovations so that they can be translated safely and swiftly into effective, high-quality therapies (Hines P. et al, 2019).

Prior to completing the survey please read the **participant information sheet** (<https://drive.google.com/file/d/1byBV0II0-JQPhafMqmY8ip4dkVUC6BvF/view?usp=sharing>) sent to you in the invitation email – in summary:

Your participation in this survey is voluntary. We anticipate it will take approximately **15 minutes** to complete. You can **save your progress** and access the survey to complete at a later date if you wish. An email will be sent to you with the relevant link. All information that is collected about you during the course of the research will be **anonymised at individual level**, kept **confidential** and **stored securely**. We aim to publish the results in relevant scientific journals. You **will not be identified** in any report or publication. You may **withdraw** without giving a reason up to **7 working days** after submission of the study. If you wish to withdraw, please contact Samantha Cruz Rivera (s.rivera@bham.ac.uk) quoting the **unique ID** generated on the first page of the survey.

If you have concerns about any aspect of this study, please contact Samantha Cruz Rivera (s.rivera@bham.ac.uk) or the principal investigator Professor Melanie Calvert (+44 121 414 8595 or m.calvert@bham.ac.uk), who will do their best to answer your questions.

By progressing to the next page you confirm that you have read the information sheet and consent to take part of the study.

Thank you for taking the time to participate in this survey.

Yours sincerely,
Melanie Calvert, PhD

Professor of Outcomes Methodology
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2. Demographics

1. In order to keep your answers anonymised please generate your own unique ID. This should be formed by two letters and four numbers of your choice (e.g. SC1909) *

2. Please select the main stakeholder group you belong to: *

- ☐ Healthcare professional
- ☐ Academic
- ☐ Patient representative
- ☐ Health technology assessment agency
- ☐ Regulator
- ☐ Pharmaceutical company
- ☐ Large med-tech
- ☐ Small or Medium Size Enterprise
- ☐ Ethicist
- ☐ Trade association (please state)
- ☐ Other (please specify):

Please specify your disease or methodological area of expertise: ***3. Approximately how many years experience do you have in the development or application of regulation ***

- ☐ 1 year or less
- ☐ 2 - 5 years
- ☐ 6 - 10 years
- ☐ More than 10 years

3. Defining regulatory science in healthcare

4. Below are presented different definitions of regulatory science. Which one do you think provides the most accurate definition based on your understanding of the discipline? *

- ☐ "Regulatory Science is the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products." (FDA, 2010)

☐

Technological and scientific challenges -genomics and increased personalisation/specialisation of products

☐

Developing effective tools to track and evaluate outcomes for reimbursement

☐

Professional development (i.e. workshops or courses to supplement knowledge base)

☐

Workforce retention rates

☐

Other (please specify):

5. Current challenges and opportunities in regulatory science

6. Please rank (drag and drop the question boxes) the most important features of future regulation for UK healthcare innovation, which regulatory sciences needs to more effectively enable: *

Co-development: collaboration across sectors, e.g. patients, manufacturers, regulators and educators working together to develop appropriate training for novel product deployment

Responsiveness: the preparation of frameworks which enable timely innovation required by emerging events

Speed: the rate at which new products can reach the market

Flexibility: the capability of regulations to adapt to novel products and target patient outcomes

Reimbursement: developing effective tools to track and evaluate outcomes for "pay for performance" products

Education and professional development

6. Strategic areas for development

The Medicines and Healthcare Products Regulatory Agency's Corporate Plan 2018-2023 identifies a number of actions, activities and projects related to Regulatory Science.

7. Thinking about your stakeholder group, which of the actions below are most important for the development of UK regulatory science. Select all that apply Patient Centered Drug Development *

☐

Ensure that patients' experiences, perspectives, needs, and priorities are captured and meaningfully incorporated into drug development and evaluation.

8. Thinking about your stakeholder group, which of the actions below are most important for the development of UK regulatory science. Select all that apply Enhancing innovation *

- <https://app.smartsurvey.co.uk/survey/print/id/722319?t=1&dst=false&dsl=true&dpt=true&dpb=false&dpn=true&dqn=true&dqb=false&st=473078> 5/13

☐ Other (please specify):

9. Strategic areas for development

10. Thinking about your stakeholder group, which of the actions below are most important for the development of UK regulatory science. Select all that apply Organisational excellence/efficiency *

- ☐ Identify future capability needs and ensure the right skill mix is available to support innovation and deliver priority programmes and core functions
- ☐ Identify opportunities to recruit, retain and develop staff; including new training opportunities
- ☐ Invest in scientific capabilities to meet emerging needs. Invest in staffs specialist skill sets, and in facilities to deliver state of the art regulation and services.
- ☐ Focus on identifying and developing talent and on the importance of leadership, in the context of organisational development in an environment of scientific advance and environmental change
- ☐ Explore new methodologies for detecting data integrity issues associated with regulatory studies
- ☐ Explore opportunities to develop collaborations and information sharing with key global regulators, international partnerships with WHO and other key players
- ☐ Other (please specify):

10. Current training and future needs

Regulatory science encompasses a wide range of subjects, including not only disciplines associated with regulation, such as statistics, engineering and clinical research, but also disciplines outside the biomedical sciences such as informatics, economics, risk communication, and sociology.

Please state whether you agree with the following statements:

11. Due to its breadth and dynamism, regulatory sciences require life-long learning* and development.

***Life-long learning: Voluntary and self-motivated education or learning, beyond formal education, to improve personal or professional development. ***

☐ Yes

☐ No

12. This learning and development needs to be responsive to the development of innovative technologies and products. *

☐ Yes☐ No

11. Current training and future needs

13. Are you aware of any regulatory science training courses or training schemes (programmes) in: Select all that apply *

☐ United Kingdom

☐ United States

☐ Any of the countries in the European Union

☐ Any other country☐ I'm not aware of any of these training courses

☐ Other (please specify):

12. Current training and future needs

14. Have you attended any of these training courses before? *

☐ Yes☐ No

13. Current training and future needs

15. Please state the reasons why you haven't attended to any of these courses: *

14. Current training and future needs

16. Please state which courses you have attended and why: *

15. Current training and future needs

17. What kind of additional/novel training formats and topics do you think regulatory science would benefit from? *

18. Would these training be useful for current or future regulatory science needs? *

- ☐ For current priorities
- ☐ For future priorities

16. Current training and future needs

19. At what level of education and training do you think regulatory science should be focused? Select all that apply *

- ☐
- Undergraduate

- ☐ Yes
- ☐ No

20. When working in a highly regulated area, do you know how to access expertise? *

21. If you are to search for such expertise, would your starting point be the UK or international market? *

22. Are you aware of the MHRA Innovation Office? *

23. Have you accessed them? *

26. What legal, structural and other barriers have you experienced in creating collaborations? *

27...Do you see the need for academic leadership in the UK in developing cutting-edge technologies to evaluate safety, efficacy, quality, and performance of developed new health products and technologies? *

- ☐ Yes
- ☐ No

28.... Would you consider any of these area as particularly benefiting from academic leadership? Select all that apply *

24. Infrastructure required

☐ Yes

☐ No

25. Additional information

31. Please provide your email if you would like to be receive future publications arising from the data collected:

32. Would you like to be acknowledged in future publications? *

- ☐ Yes
- ☐ No

33. Please provide your name and affiliation in the way we should acknowledge you in the publication: