

Agenda

- Welcome
- Background
- Key Findings
- Recommendations
- Reflections
- Questions from the audience
- Close

Complex Collaborations

Efficiency, Equity, Quality and Security in International Research

Published March 2023

Prepared by

Sapna Marwaha, Joe Timlin, Linsey Dickson Eva Kagiri-Kalanzi and Jennifer Johnson



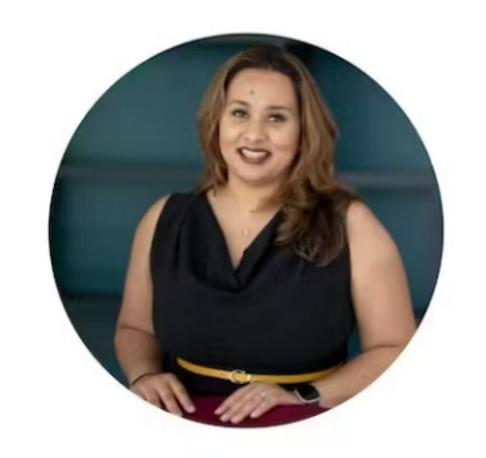
Instructions

Where are you joining us from today?

Waiting for responses ···

Complex Collaborations

Efficiency, Equity, Quality and Security in International Research



Sapna Marwaha, Co-Investigator



Joe Timlin, Project Officer







Some history – Phase One

February 2020 - April 2021

In Phase One, the ARMA-led consortium set out to:

- Develop a core questionnaire for gathering due diligence information from partners (ARMA due diligence questionnaire)
- Scope whether a case existed to establish a clearing house to act as a national repository for due diligence questionnaires
- Scope whether a case existed to establish a national service to complement the clearing house, providing additional services such as advice, training and development





Some history – Phase One

Phase One Recommendations

- Sector agencies should collaborate to establish a Clearing House and National Service in support of Due Diligence for International Research.
- The next stage of work to establish a Due Diligence Clearing House and National Service should be grant funded
- It should consider a funding model for the Due Diligence Clearing House and National Service to support its long-term sustainability.







Efficiency, Equity, Quality and Security in International Research Collaboration

In May 2022, the ARMA-led consortium was awarded funding from Research England to explore how the recommendations made by the ARMA-led 'Due Diligence in International Research' report could be broadened to encompass all international research collaborations and address the Trusted Research agenda and wider security related issues.

Key Deliverables:

- Broadening the focus to all international research collaborations with focus on Trusted Research and security
- Engaging with a diverse range of stakeholders
- Assessing the feasibility of a 'Clearing House' and 'National Service' as a solution
- Developing a technical assessment with project partner, Jisc
- Exploring appropriate ownership and funding models





Trusted Research and Security

The <u>Trusted Research agenda</u> promotes due diligence; understanding conflicts of interest; and data segregation and the use of legal frameworks (including export control, data protection and investment regulation) to protect intellectual property, sensitive research and personal information.





Advisory Group

Ara Tahmassian Chief Research Compliance Officer, Harvard University **Dr Ross McLennan** Australasian Research Management Society | Pro-Vice Chancellor, Research Services, Macquarie University

Pamela Webb Associate Vice President for Research, University of Minnesota | Federal Demonstration Partnership Clearing House

Kelly Pullin Head of Strategic Coordination, Research England, UKRI **Morag Campbell** Assistant Director, Scottish Funding Council

Daniel Wake Policy Manager, Universities UK

Dr Victoria Moody Director of Research and Innovation Sector Strategy, Jisc

Gareth Macdonald Head of Funding Assurance, UKRI

Noleen Morgan Global Compliance Officer, Queen's University Belfast

Anjana Choudhuri Research Integrity Manager, Swansea University

Joe Marshall Chief Executive, The National Centre for Universities and Business

Zareen Saleem Head of Research Contracts and Due Diligence, The Royal Veterinary College, University of London



43

Institutions responded to our survey



Institutions participated in our interviews



Groups and organisations consulted from across the sector

SURVEY

ROUNDTABLES

INTERVIEWS

CASE STUDIES

76

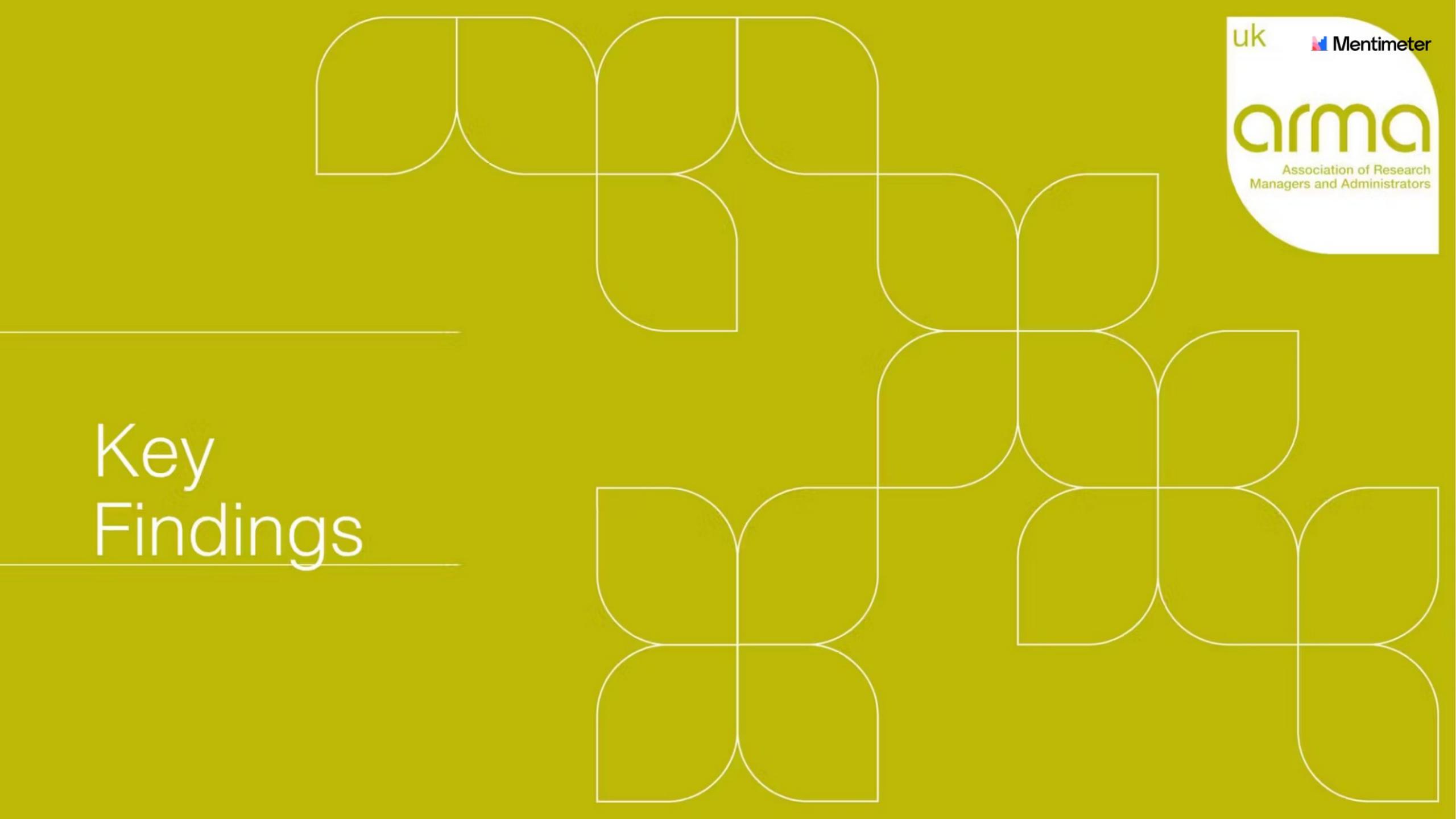
Research organisation representatives

24

Funding and sector body representative

6

Roundtables



Legal Frameworks

The growing burden of research compliance

Primary Legislation

- Patents Act 1977 Animals (Scientific Procedures) Act
- Copyright Designs and Patents Act 1988
- Competition Act 1998

Primary Legislation

- Freedom of information Act 2000
- Anti-terrorism, Crime and Security
- Export Control Act 2002
- Mental Capacity Act 2005
- Terrorism Act 2006

Secondary Legislation

- The Medical Devices Regulations
- The Medicines for Human Use (Clinical Trials) Regulations 2004
- The Export Control Order 2008
- The Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010

Primary Legislation Bribery Act 2010

- Care Act 2014
- Intellectual Property Act 2014
- Modern Slavery Act 2015
- Higher Education and Research Act
- Data Protection Act 2018
- · Sanctions and Money Laundering Act
- Counter-terrorism and Border Security Act 2019

Secondary Legislation

- The Human Medicines Regulations
- The Genetically Modified Organisms (Contained Use) Regulations 2014
- The Public Contracts Regulations 2015

Primary Legislation · Medicines and Medical Devices Act

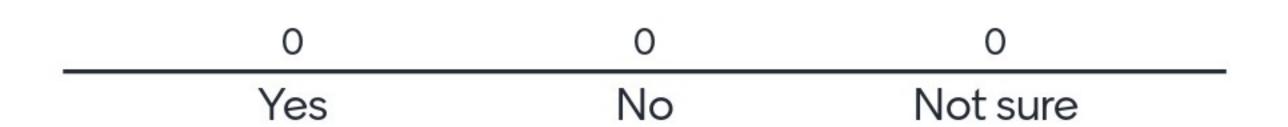
- National Security and Investment Act
- Subsidy Control Act 2022
- · Higher Education (Freedom of Speech) Act 2023
- National Security Act 2023

Secondary Legislation

- The Competition Act 1998 (Research and Development Agreements Block Exemption) Order 2022

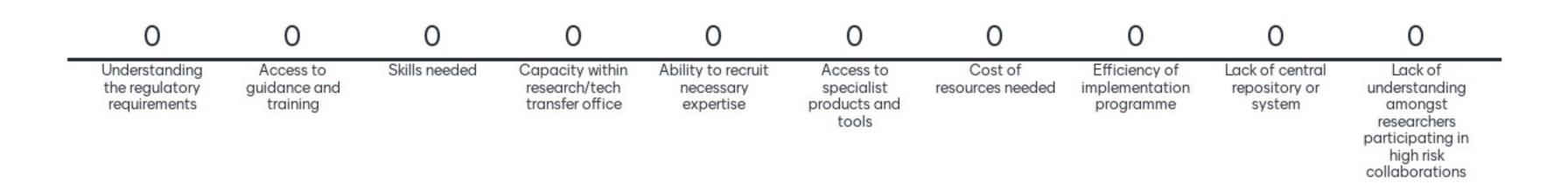


Does this align with your experiences in your own country?





What are your top concerns when it comes to operationaling due diligence and research security protocols?



Menti poll:

Q3 What are your top concerns in operationalising a response to new research security requirements?

What are your primary concerns in operationalising new controls in ^{Mentimeter} relation to Trusted Research and security in international research collaboration?

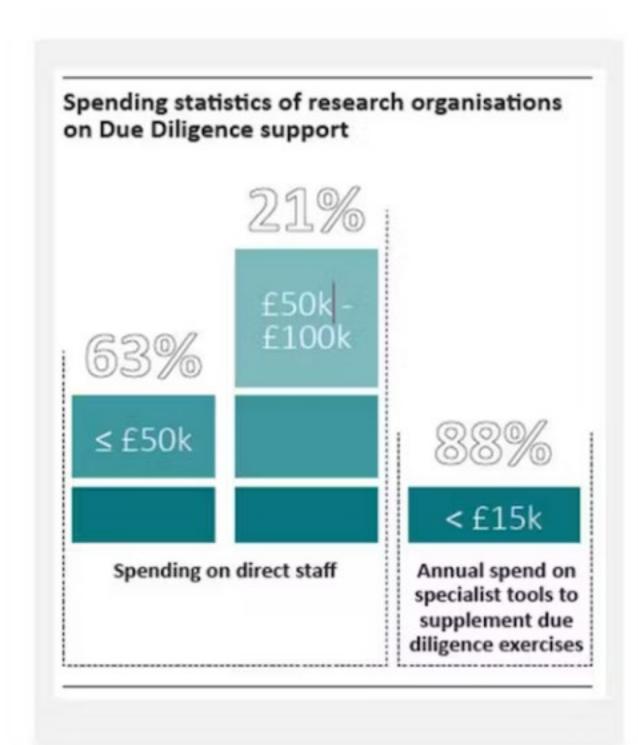
Understanding of the information needed to satisfy Trusted Research and security requirements

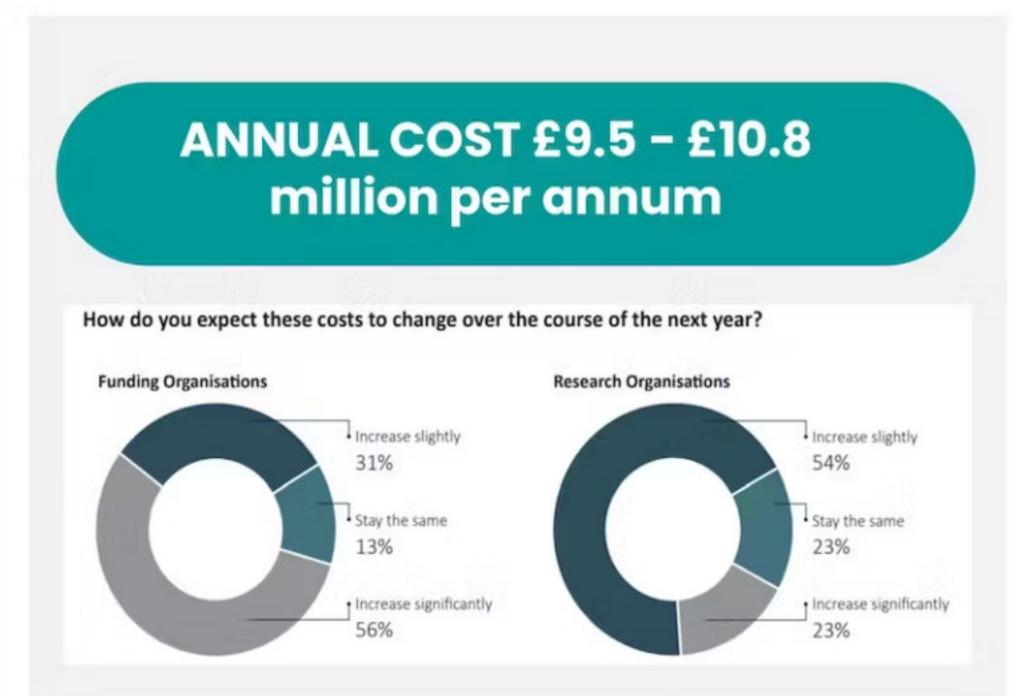
Access to guidance and training relevant to Trusted Research and security decision-making

Specific skills needed to operationalise Trusted Research and security requirements

Capacity of professional services staff to operationalise Trusted Research and security requirements









RESPONSE TO TRUSTED RESEARCH/RESEARCH SECURITY

84%

33%

HAVE BEGUNTHE PROCESS OF ADAPTING 33/0

BELIEVE THEY
HAVE COMPLETED
THE PROCESS

TOP 3 CONCERNS IN OPERATIONALISING TRUSTED RESEARCH

Capacity of professional services staff to operationalise trusted research and security requirements

#1

Lack of a central repository for trusted research and security information

#2

Understanding of the information needed to satisfy trusted research and security requirements

#3

Trusted research maturity curve 2. EMERGING 3. FUNCTIONAL 5. CULTURAL 1. LEARNING 4. INTEGRATED 'Embedded' 'Overwhelmed' 'Inconsistent' 'Consistent' 'Comprehensive' Processes are established, Research organisations have Some dedicated resource Research organisations are and knowledge of how to decision making and aware of trusted research and allocated some resources but implement new processes, escalation happening, resilient security but have yet to start approach is undefined and to change in environment. to adopt their processes. sponsors in executive, greater inconsistent consistency of approach All areas of the research Advocacy yet to Advocacy within organisation have brought in reach all corners Still a single research organisations and understand the value of still needed point of failure trusted research and security and how it is implemented at all levels of collaboration Some resources allocated but not Complexity and enough lack of clear guidance Trusted research and security Agile processes in place and flexible are embedded in culture of 21% completely all services to change or slightly lacking Decision making in confidence processes and Lack of ownership, Research compliance escalation in place is integrated and inconsistent, processes and fit-for-purpose Research compliance decision making robust etc is still a new function No one person with Risk appetite is defined No ownership the skills to respond and understood Processes not yet resilient to change in Lack of environment awareness 'Unconscious Competence' 'Conscious Incompetence' -'Conscious Competence' -



Where would you place your organisation on the maturity curve?



RESEARCH OUTPUTS FEATURING INTERNATIONAL CO-AUTHORSHIP

56%
OF OUTPUTS BY PARTICIPANT RESEARCH ORGANISATIONS

89,146

INDIVIDUAL INSTANCES



ESTIMATED EFFICIENCY SAVINGS

46%

AVERAGE PER INSTITUTION WITH ACCESS TO RESEARCH COLLABORATION DILIGENCE EXCHANGE AND SYSTEM

90%

Believe a research collaboration diligence exchange and system would have a positive impact

APPETITE TO ENGAGE

CONSIDERATIONS

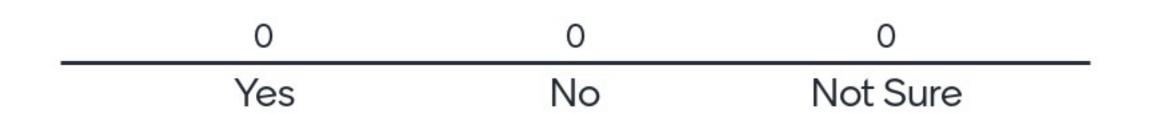


BREAKDOWN BY RESEARCH INCOME

Institution RGCI Banding	Efficiency Saving
£0 ≥ £1,000,000	38%
£1,000,000 ≥ £5,000,000	33%
£5,000,000 ≥ £10,000,000	55%
£10,000,000 ≥ £50,000,000	49%
£50,000,000 ≥ £150,000,000	32%
£150,000,000+	18%



Do you believe that a national system to support due diligence and research security requirements would have a positive impact for your institution?







"There is significant appetite for more collaborative working and significant opportunity to improve practice across the sector with coordinated action"



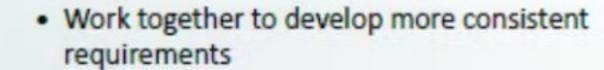
RESEARCH ORGANISATIONS

- Additional / dedicated resource
- Access to software / databases
- Investment in staff development / expertise
- Drive greater cooperation between departments and institutions, while establishing a clear lead department and contact
- Improved guidance on risk appetite / proportionality
- Greater engagement from senior management
- Increased standardisation across institutions
- Greater clarity of roles and responsibilities
- Senior level advocacy

GOVERNMENT/REGULATORY BODIES

- Work together to develop more consistent requirements and guidance
- Share more detailed information on the need for regulation
- Share real examples of risks materialising
- Share real examples of sanctions imposed
- Share statistics relating to compliance
- Provide training and development opportunities
- Make resources more accessible (e.g. dual use lists)

RESEARCH FUNDERS



- Share more detailed case studies (good and bad)
- Communicate consequences of failure (e.g. will there be leniency in learning phase)
- Make costs recoverable or otherwise provide funding to support additional requirements
- More detailed advice and guidance
- More transparency around assurance processes for trusted research
- More detailed training opportunities

ARMA

- Create more opportunities for due diligence managers to convene and discuss operational challenges
- Create more opportunities for leadership to convene and discuss strategic challenges
- Facilitate greater standardisation across institutions
- Facilitate knowledge sharing and development of best practice
- Maintain online library of resources

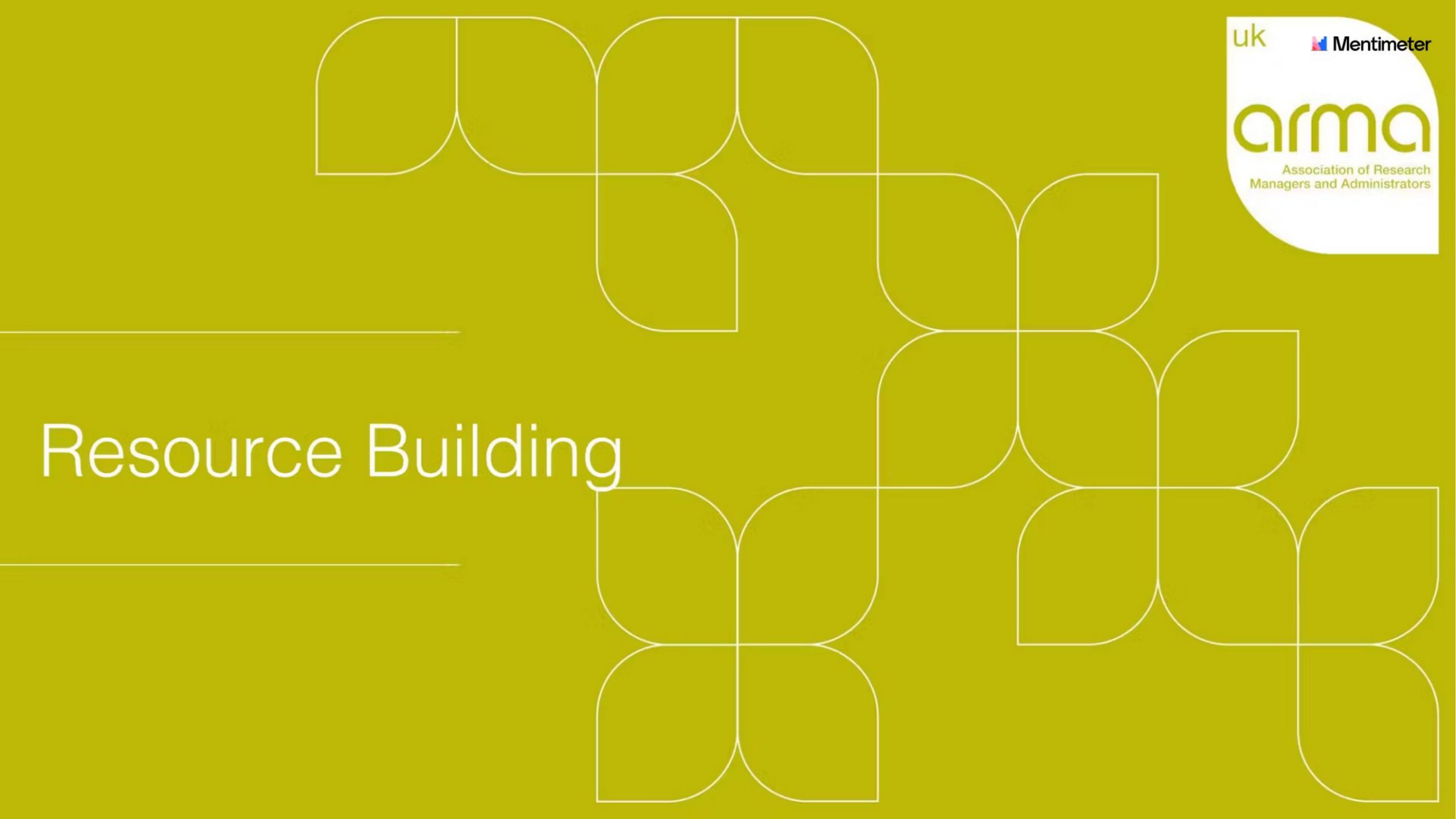


Recommendation One: A series of regular round table events with key sector stakeholders including research managers, academics and policy makers should be established to continue conversations and build on relationships developed during this project, ensuring ongoing coordination and collaboration in the area of trusted research and security.

Recommendation Two: A series of best practice exchange events and training courses should be developed and launched to support research organisations in their implementation of research security policies and procedures.







"Our data has shown that inaction is not an option and that there is both an overwhelming need and support for a sector-led intervention which has the potential to deliver significant benefit across the whole ecosystem"



Recommendation Three: A research compliance unit should be established within an independent sector body to bring together existing tools, guidance, and training and to co-create and maintain further tools and training, with the sector, for use by the sector. It should be tasked to engage with a broad range of stakeholders to ensure that the advice, guidance and support it provides address the needs of a diverse range of institutions.

Recommendation Four: The ARMA due diligence questionnaire should be reviewed and updated to produce a revised version that more comprehensively addresses trusted research and security related issues.





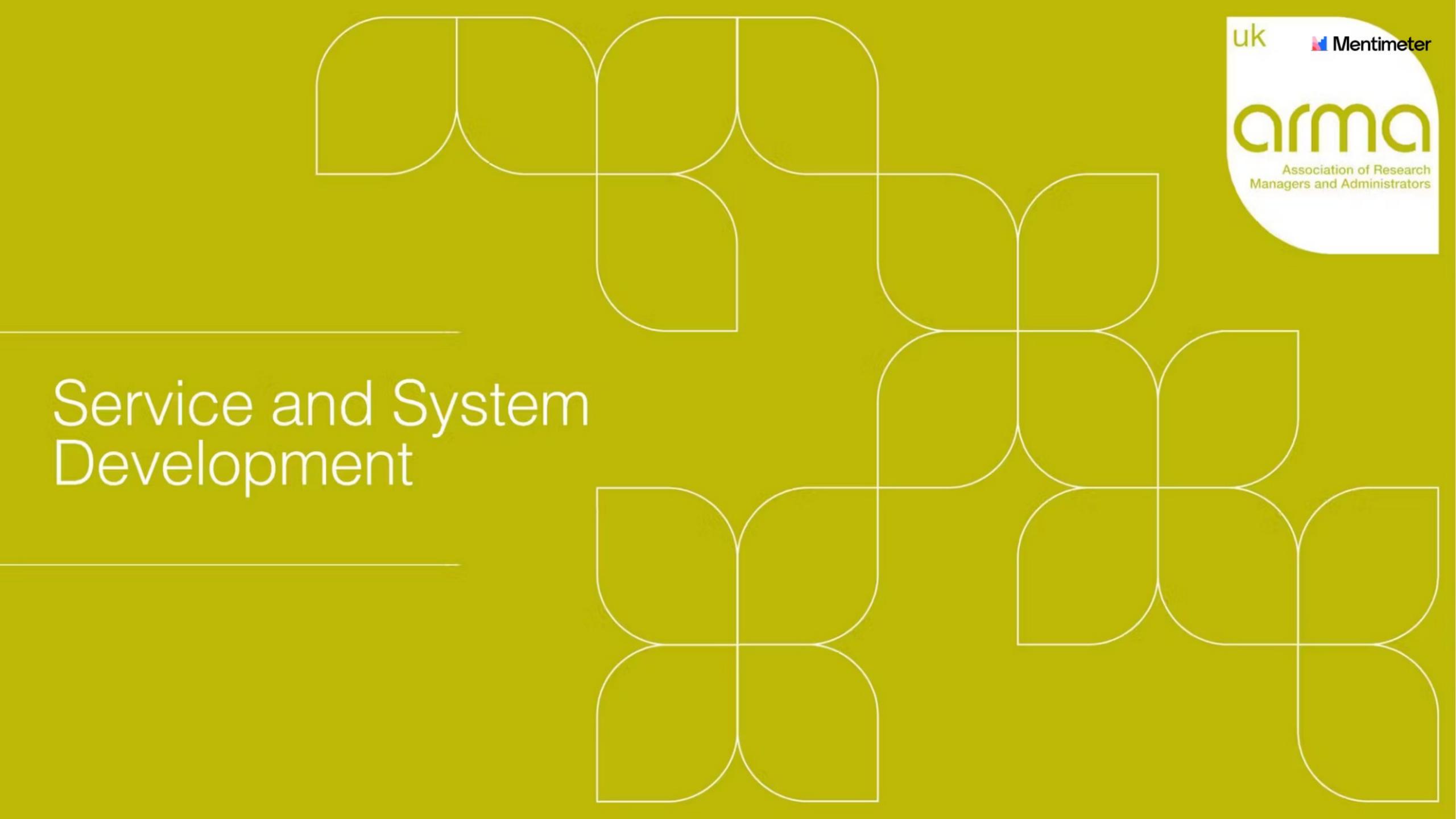
Recommendation Five: A new checklist should be developed that provides for the internal checks and desk-based research that need to be carried out within the institution on both broader due diligence and trusted research and security related issues.

Recommendation Six: A tool kit and resource bank should be developed and maintained to complement the revised questionnaire and new checklist. This should be made freely available, ensuring greater knowledge sharing and support across the sector.

Recommendation Seven: The research compliance unit should establish a new working group of early adopters to trial the published questionnaires and checklists, and the sharing of completed questionnaires and checklists within the parameters of technology currently available to all research organisations. The early learning and insight from this trial should inform the development of future services and a system-based solution.







"Over 90% of respondents felt a sector-led system and service would have a positive impact on efficiency, equity, quality and security for their institution"



Recommendation Eight: As it develops and grows, the research compliance unit should be spun out to establish a national research compliance office, established to address the unmet need within the sector and drive both operational and cultural change around due diligence, trusted research and security.

Recommendation Nine: During the initial incubation period of the research compliance unit, hosted within an appropriate sector body, it should be tasked with developing:

- a) a full business plan for spin out including a governance structure, a stakeholder engagement plan, and a sustainable financial model.
- b) a technical specification and requirements for a research compliance system and to identify a technical partner through a tender process to deliver the solution for the sector.





Recommendation Ten: The teams engaged to form the research compliance office should include rotating fixed term secondments from research organisations, ensuring strong insight into research operations and supporting the development of knowledge and expertise across the sector.

Recommendation Eleven: The research compliance office should provide support services including tools, resources, advice, guidance, and training for sector, acting as a vehicle for culture change through its advocacy and engagement.





Recommendation Twelve: A central function of the research compliance office will be to host a research compliance system. The system should be developed with three pieces of core functionality. The design and build should take a modular approach, enabling each component to be accessed by the sector as it is developed. The core functionality will be:

- a) The ability to host and share core due diligence questionnaire data points that would be completed by partners
- b) The ability to host data relating to internal due diligence and desk-based research and decision making related to individual projects
- c) The ability to draw data from open access and commercial governance, compliance and risk software systems

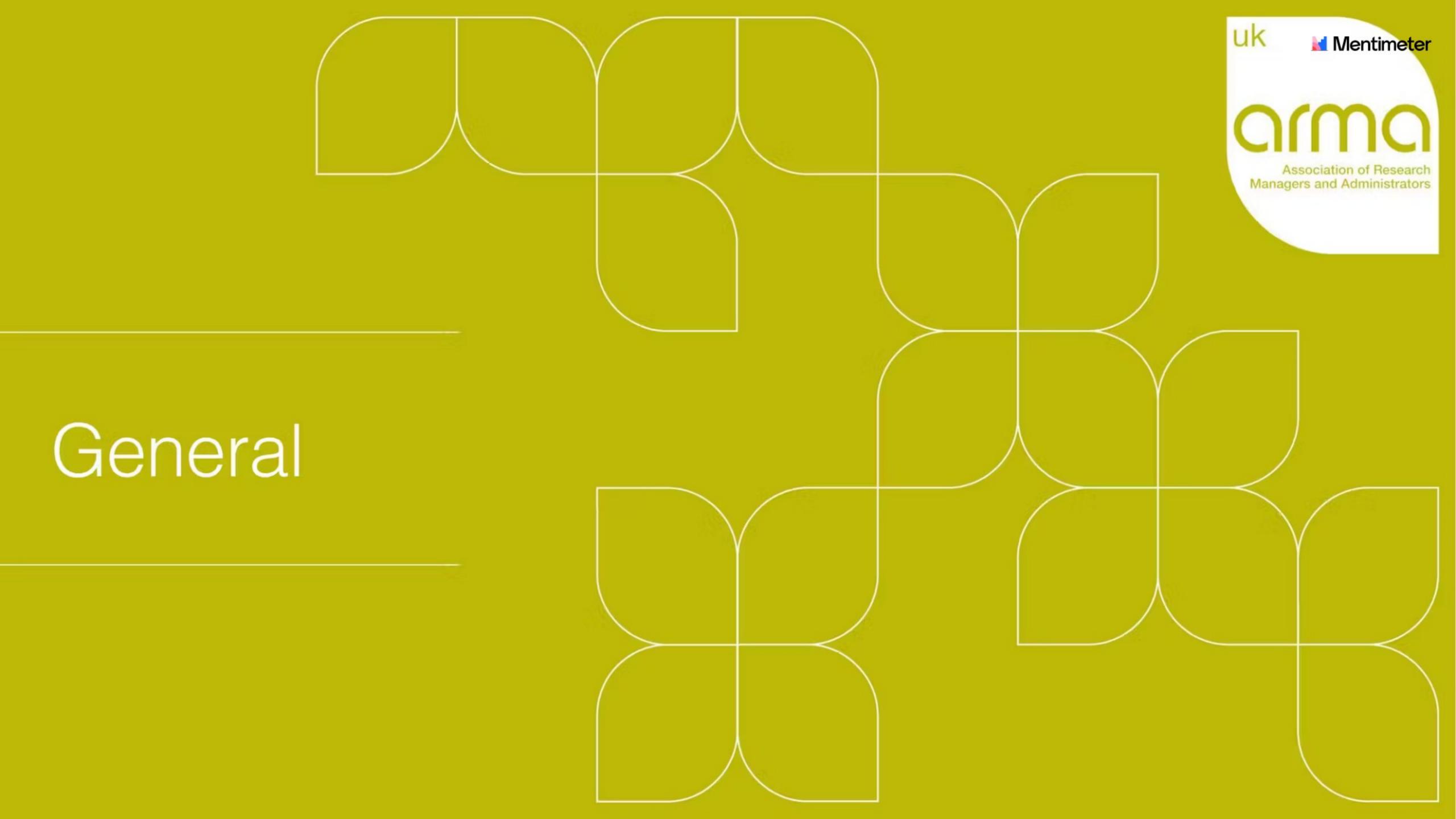
Recommendation Thirteen: The research compliance unit should provide data to test and pre-populate the research compliance system with any due diligence information submitted as part of any interim solution developed with early adopters.





"Accessibility, credibility, quality, efficiency and value were the most important factors in determining whether to engage with a clearing house and national service"





"We propose that a research collaboration diligence exchange should be an authoritative voice regarding due diligence and Trusted Research to drive cultural and operational change"



Recommendation Fourteen: The initial development of the research compliance unit, research compliance office and research compliance system should be grant funded by UKRI, potentially in partnership with a broader consortium of UK research funders and/or government departments.

Recommendation Sixteen: The involvement of international peers has been invaluable to this project and each of the initiatives proposed should continue to encompass international engagement to ensure ongoing knowledge sharing and collaboration.

Recommendation Fifteen: The funding should continue through a tapered mechanism over a five-year period that allows for the entity to become resilient and financially sustainable while delivering demonstrable value before moving to a subscription and service-based funding model.





Discussion

Q5 Do you think that these recommendations have relevance where you are?

Discussion

Q6 Would you like to see more international collaboration in this space?

Complex Collaborations

Efficiency, Equity, Quality and Security in International Research

March 2023

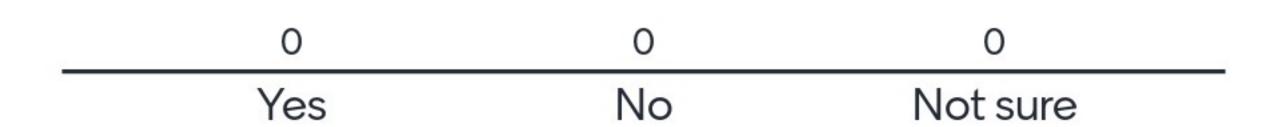
Prepared by

Sapna Marwaha, Joe Timlin, Linsey Dickson Eva Kagiri-Kalanzi and Jennifer Johnson



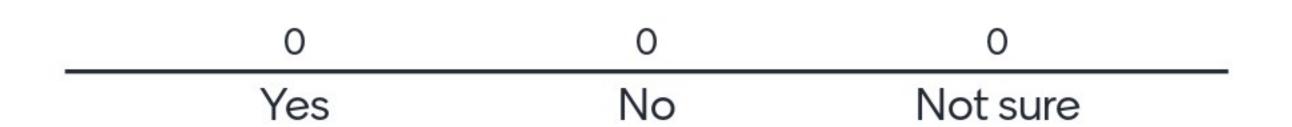


Do you think the recommendations we have made would have relevance where you are?





Would you like to see more international collaboration in this space?





Ask us anything

O questions
O upvotes