

Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 23rd March 2023

09:30 – 16:20

(Remote meeting via videoconference)

INDEPENDENT ADVISERS IN ATTENDANCE:	
Name:	Role:
Paul Affleck (PA)	Specialist Ethics Adviser
Maria Clark (MC)	Lay Member Adviser
Prof. Nicola Fear (NF)	Specialist Academic Adviser
Kirsty Irvine (KI)	Chair
Dr. Imran Khan (IK)	Specialist GP Adviser
Dr. Geoffrey Schrecker (GS)	Specialist GP Adviser
Jenny Westaway (JW)	Lay Adviser
NHS ENGLAND STAFF IN ATTENDANCE:	
Name:	Role / Area:
Victoria Byrne-Watts (VBW)	Data Access Request Service Senior Approval Team (DARS SAT) (Observer: item 6.2)
Michael Chapman (MCh)	Data and Analytics representative
Garry Coleman (GC)	Senior Information Risk Owner (SIRO) representative (Presenter: item 6.1)
Dave Cronin (DC)	Data Access Request Service Senior Approval Team (DARS SAT) (SAT Observer: item 4.1) (Observer: items 4.2 to 4.3) (Presenter: item 7.1)
Cath Day (CD)	Data Access Request Service Senior Approval Team (DARS SAT) (SAT Observer: item 4.2) (Observer: item 6.2)
Louise Dunn (LD)	Data Access Request Service Senior Approval Team (DARS SAT) (SAT Observer: items 4.3 to 4.4) (Observer: item 6.2)
Duncan Easton (DE)	Data Access Request Service Senior Approval Team (DARS SAT) (Observer: item 6.2)
Dan Goodwin (DG)	Data Access Request Service (DARS) (Presenter: items 4.4 to 4.5)

Liz Gaffney (LG)	Head of Data Access, Data Access Request Service (DARS) (Presenter: item 7.2)
Dickie Langley (DL)	Data Protection Officer (DPO) representative (Delegate for Jon Moore)
Sara Lubbock (SL)	Data Access Request Service (DARS) (Observer: item 4.1)
David Morris (DM)	Data Access Request Service (DARS) (Presenter: item 4.3)
Shaista Majid (SM)	Data Access Request Service (DARS) (Presenter: item 4.2)
Karen Myers (KM)	Secretariat Team
Dr. Jonathan Osborn (JO)	Caldicott Guardian Team representative
Jodie Taylor-Brown (JTB)	Data Access Request Service (DARS) (Observer: item 4.4)
Kimberley Watson (KW)	Data Access Request Service Senior Approval Team (DARS SAT) (SAT Observer: item 4.5) (Observer: items 6.2 and 7.1)
Vicki Williams (VW)	Secretariat Team
Clare Wright (CW)	Data Access Request Service (DARS) (Presenter: item 4.1)
INDEPENDENT ADVISERS NOT IN ATTENDANCE:	
Dr. Robert French (RF)	Specialist Academic / Statistician Adviser
Dr. Maurice Smith (MS)	Specialist GP Adviser
NHS ENGLAND STAFF NOT IN ATTENDANCE:	
Dr Arjun Dhillon (AD)	Caldicott Guardian Team Representative (Delegate for Dr. Jonathan Osborn)
Jon Moore (JM)	Data Protection Officer (interim)

1	<p>Welcome and Introductions</p> <p>The NHS England Senior Information Risk Owner (SIRO) Representative advised attendees that, noting the statutory guidance and the AGD Terms of Reference (ToR) had not yet been agreed, the meeting could not be held under the draft ToR, until they have been approved, and recognised that the draft ToR may change as the statutory guidance evolves. As NHS England would like to seek advice on a number of areas, the NHS England SIRO Representative therefore proposed that:</p> <ul style="list-style-type: none"> • Kirsty Irvine (as an independent adviser) will be asked to Chair the AGD meetings; • The meeting will be minuted, with advice and minutes published; • Attendees will include both independent advisers from outside NHS England and representatives from within NHS England. Attendees from NHS England include representatives covering the
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	<p>offices of the Data Protection Officer (DPO); Privacy, Transparency, Ethics and Legal (PTeL); the Caldicott Guardian; and the SIRO.</p> <ul style="list-style-type: none"> Attendees would not be listed as “members” in minutes during the transitional period; NHS England representatives would not, during the transitional period, be formally part of any consensus that is reached, but would be active participants in the meeting; It was agreed to use the Data Access Request Service (DARS) Standards / Precedents in relation to applications for external data sharing. <p>The attendees present at the meeting considered the proposal put forward by the NHS England SIRO Representative and, as no objections were raised, it was agreed that the meeting would proceed on this basis.</p> <p>Kirsty Irvine noted and accepted the request from the NHS England SIRO Representative to chair; and welcomed attendees to the meeting.</p>
2	<p>Review of previous AGD minutes:</p> <p>The minutes of the 16th March 2023 AGD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting.</p>
3	<p>Declaration of interests:</p> <p>There were no declarations of interest</p>
EXTERNAL DATA DISSEMINATION REQUESTS:	
4.1	<p>Reference Number: NIC-667559-J3L9G-v0.8</p> <p>Applicant: University of Oxford</p> <p>Application Title: Evaluating Clinical Outcomes in Hip, Knee, Foot, and Ankle Surgery</p> <p>Presenter: Clare Wright</p> <p>SAT Observer: Dave Cronin</p> <p>Observers: Sara Lubbock</p> <p>Application: This was a new application.</p> <p>The purpose of the application is for a project, to analyse national Hospital Episode Statistics (HES) data, to determine the rate of adverse events associated with commonly performed orthopaedic procedures of the lower limbs; to investigate the impact of surgeon and unit volume on outcomes; and benchmark proposed thresholds for care outcomes (rate of adverse events or outcomes) that could permit the monitoring of the quality of care and outcomes in the future.</p> <p>Should an application be approved by NHS England, further details would be made available within the Data Uses Register.</p> <p>Outcome of discussion: The group were broadly supportive of the application if the following significant comments were addressed, and wished to draw to the attention of the SIRO the following significant comments:</p>

<p>4.1.1 The independent advisers noted that the datasets requested in this application were “<i>pseudonymised</i>”; however, queried whether this was correct, in light of the consultant code field requested as part of the Hospital Episode Statistics Admitted Patient Care (HES APC) dataset, which is identifiable via the publicly available General Medical Council (GMC) register.</p> <p>4.1.2 The independent advisers therefore queried whether a PConsult_Code could be flowed instead of the consultant code, which would be pseudonymised. If the PConsult_Code was not suitable, then the data would be deemed identifiable, and therefore suggested that the applicant addressed any ethical issues of this potentially identifiable flow of data, and updated the application accordingly.</p> <p>4.1.3 It was also suggested by the independent advisers that as part of the ethical issues addressed, it was explored what would happen in the event that, for example, worrying trends were identified, how would this be addressed and what would happen with this information / knowledge. It was suggested that the Healthcare Quality Improvement Partnership (HQIP) Outlier management for National Clinical Audits guidelines may offer further guidance.</p> <p>In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review:</p> <p>4.1.4 In respect of the internal application assessment form, the independent advisers suggested that NHS England may wish to separate section 2.3 (Benefits Evaluation) to ensure there was a limb for 1) benefits to the health and social care system for all applications; and 2) the proportional balance of benefits for commercial applicants or applications that had a commercial element.</p> <p>4.1.5 In addition, the independent advisers suggested that in respect of section 5.1 (REC Approval) of the internal application assessment form, that NHS England may wish to separate this, to ensure there was a limb for 1) Health Research Authority Research Ethics Committee (HRA REC) support; and 2) local / University ethical support.</p> <p>4.1.6 In respect of the ethical review for this application, the independent advisers noted that the application and supporting documents provided do not necessarily align. The supporting documents stating the processing was not research and not generalisable, whilst the application stated the reverse stated. However, the group was of the view that HRA REC support was not necessary as there was not a flow of confidential health data, and the independent advisers suggested that NHS England liaise with the applicant to clarify whether they had complied with their own local / University ethics committee requirements and sought any necessary support.</p> <p>4.1.7 The independent advisers noted within the internal application assessment form, that there had been ongoing discussions between NHS England and the applicant, in respect of the volume of historical data requested; and suggested that the application was updated to clearly articulate a justification for the extended period of follow-up, for example, the current lack of long-term outcomes data may be a justification for the long-term follow-up.</p> <p>4.1.8 Noting the expected benefits outlined in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and / or Social Care), the independent advisers suggested that this was edited, and further refined to be clear on the expected benefits for the various scenarios and what the applicant hopes to achieve, in line with NHS Digital DARS Standard for Expected Measurable Benefits.</p>	
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<p>4.2 Reference Number: NIC-351722-W7D4N-v14.5</p> <p>Applicant: CRAB Clinical Informatics</p> <p>Application Title: Commercial work by CRAB to support CQC and Trusts</p> <p>Presenter: Shaista Majid</p> <p>SAT Observers: Cath Day</p> <p>Observer: Dave Cronin</p> <p>Previous Reviews: The application and relevant supporting documents were previously presented at the DAAG / IGARD meetings on the 25th August 2015, 5th July 2018, 4th October 2018, 11th October 2018 and the 14th March 2019.</p> <p>Application: This was a renewal and amendment application.</p> <p>The amendments are 1) to update section 5 to improve clarity; and 2) to updates section 5 to reflect that C2-Ai may also start to supply reports for independent sector providers.</p> <p>Should the application be approved by NHS England, further details would be made available within the Data Uses Register.</p> <p>Outcome of discussion: The group were supportive of the application and wished to draw to the attention of the SIRO the following key comments:</p> <p>4.2.1 The independent advisers noted the statement in section 5(a) (Objective for Processing) <i>"Furthermore, analysis is required to be down to the consultant level by general medical council (GMC) code in order to verify speciality of clinical practice within a specific NHS Trust/ Independent Sector Providers offering NHS services as is required by the CQC to provide targeted, key lines of enquiry for their on-site inspection teams."</i>; and queried whether the applicant actually required the GMC codes, or, if the PConsult_Code would suffice.</p> <p>4.2.2 In addition, the independent advisers suggested that if the GMC code was required, then the Healthcare Quality Improvement Partnership (HQIP) Outlier management for National Clinical Audits guidelines may offer further guidance.</p> <p>In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review:</p> <p>4.2.3 The independent advisers noted that the Legitimate Interest Assessment (LIA) document, contained a number of outputs for the Department of Health and Social Care (DHSC), and that these were not referenced within the application; and suggested that the application was updated to reflect / align with the DHSC outputs in the LIA.</p> <p>4.2.4 NHS England noted that one statement in the LIA was incorrect and should be updated with a more accurate / factually correct statement. The Senior Information Risk Owner (SIRO) representative advised that he would be content to have further discussions to ensure the applicant was fully aware of what NHS England's role was in terms of data sharing.</p> <p>4.2.5 The independent advisers queried the statement in section 5(a) <i>"...in order to improve care standards it is a reasonable expectation for a patient receiving care to have their fully anonymised details and treatment prescribed included in an aggregate dataset to be processed..."</i>; and noting that the data will not be fully anonymised, asked that this was updated to correctly reflect the status of the data flowing.</p>

	<p>4.2.6 Noting the statement in section 5(a) and section 5(e) (Is the Purpose of this Application in Anyway Commercial) “C2-Ai is a private company...”, the independent advisers, suggested that this was updated to be clear that C2-Ai is a commercial company generating a profit from the work outlined in this application; in line with NHS Digital DARS Standard for Commercial Purpose.</p> <p>4.2.7 In addition, the independent advisers suggested that section 5(a) was updated to make clear that an assessment had been undertaken that the commercial benefit accruing to the commercial organisation is proportionate to the benefit to health and social care, in line with NHS Digital DARS Standard for Commercial Purpose.</p> <p>4.2.8 The independent advisers queried the statement in section 5(d) (Benefits) (iii) (Yielded Benefits) “Preliminary data has shown a 100% reduction in expected complications...”; and asked that this was reviewed and amended if not correct.</p>	
4.3	<p>Reference Number: NIC-204903-P1J7Q-v5.13</p> <p>Applicant: Imperial College London</p> <p>Application Title: SAHSU annual renewal and extension</p> <p>Presenter: David Morris</p> <p>SAT Observer: Louise Dunn</p> <p>Observer: Dave Cronin</p> <p>Previous Reviews: The application and relevant supporting documents were previously presented at the DAAG / IGARD meetings on the 10th November 2015, 30th August 2018, 20th September 2018, 4th October 2018, 17th November 2020 and the 15th July 2021.</p> <p>It was also previously discussed at the IGARD – NHS Digital COVID-19 response meeting on the 26th May 2020.</p> <p>The application was presented to the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 9th June 2021.</p> <p>Application: This was a renewal and extension application.</p> <p>Should the application be approved by NHS England, further details would be made available within the Data Uses Register.</p> <p>Outcome of discussion: The group were supportive of the application and wished to draw to the attention of the SIRO the following comments:</p> <p>4.3.1 The independent advisers queried if the General Practice Extraction Service (GPES) data for Pandemic Planning and Research (GDPPR) dataset was still required, noting that although no new GDPPR data had been requested, there was nothing in the public domain clarifying how this data had been used to date. If the GDPPR data was still being processed, the independent advisers suggested that the application was updated with further clarification of how and why this data was being processed.</p> <p>4.3.2 The independent advisers suggested that a special condition was inserted in section 6 (Special Conditions), restricting the use of the GDPPR data to COVID-19 purposes as set out in the relevant Direction.</p>	

	<p>4.3.3 In addition, the independent advisers suggested that for the purpose of transparency, section 5(a) (Objective for Processing) was also updated, to make clear that the use of the GDPR data was restricted to COVID-19 purposes as set out in the relevant Direction.</p> <p>4.3.4 The independent advisers noted the 'PAG special conditions' in section 6; and asked the Caldicott Guardian Team representative for a view on this, noting that this has been discussed on a number of occasions at the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) meetings. The Caldicott Guardian Team representative, who was also the Deputy PAG Chair, reiterated information from the 23rd June 2022 IGARD minutes, that PAG provide feedback, as outlined in their published Terms of Reference and that their feedback should not directly populate section 6 of a DSA without the requisite rationale being provided as part of that feedback. PAG feedback on individual applications should be added as an appendix to the appropriate IGARD minutes to show that IGARD had taken account of feedback from BMA and RCGP when making their recommendations. This is consistent with the PAG Terms of Reference.</p> <p>4.3.5 The independent advisers noted that how NHS England managed previous compliance with 'PAG special conditions' in applications, was for them to determine.</p> <p>4.3.6 The independent advisers noted the content of the first paragraph of section 5(a), which provided clarity on the datasets requested; however suggested that this was updated further, to provide further clarity as to why the request for identifiable data was necessary, for example, for the purpose of linkage.</p> <p>4.3.7 The independent advisers noted the volume of information in section 5(d) (Benefits), and suggested that the information was edited, for example, to include two to three examples of specific benefits / yielded benefits, with a link to any relevant websites that provides any additional information, in line with NHS Digital DARS Standard for Expected Measurable Benefits.</p> <p>4.3.8 Separate to the application, the independent advisers advised NHS England that it would be helpful / beneficial to have a consistent approach to programmatic access, for example, what NHS England is looking for / requires applicants have, by way of internal oversight, lay involvement etc.</p>	
4.4	<p>Reference Number: NIC-460711-S8W6S-v1.6</p> <p>Applicant: Liverpool Heart and Chest Hospital FT</p> <p>Application Title: FFRCT In Stable Heart disease & CTA Helps Improve Patient care and Societal costs (FISH & CHIPS)</p> <p>Presenter: Dan Goodwin</p> <p>SAT Observer: Louise Dunn</p> <p>Observer: Jodie Taylor-Brown</p> <p>Previous Reviews: The application and relevant supporting documents were previously presented at the IGARD meeting on the 13th September 2018.</p> <p>Application: This was an amendment application.</p> <p>The amendment is the inclusion of Medicines dispensed in Primary Care (NHS Business Services Authority (BSA) data).</p>	

	<p>Should the application be approved by NHS England, further details would be made available within the Data Uses Register.</p> <p>Outcome of discussion: The group were supportive of the application and wished to draw to the attention of the SIRO the following comments:</p> <p>4.4.1 NHS England advised the group, that the application currently referred to “<i>type 2 opt-out</i>”; and noted that the application would be updated to correctly refer to the “<i>National Data Opt-out</i>”.</p> <p>4.4.2 NHS England also noted that section 5(a) (Objective for Processing) incorrectly referred to “<i>Article 6(1)€</i>” of the UK General Data Protection Regulation (UK GDPR); and advised that this would be amended to correctly refer to Article “<i>6(1)(e)</i>”.</p> <p>4.4.3 The group noted and supported the verbal updates outlined by NHS Digital.</p> <p>4.4.4 The independent advisers noted the information in section 1 (Abstract) of the application, in relation to the data fields for the Medicines dispensed in Primary Care (NHS BSA data), including the item cost; and suggested that further detail was included outlining how these item and actual cost data fields were relevant to measuring the safety and efficacy of the drug / medicine being studied.</p> <p>4.4.5 Separate to this application, the independent advisers advised NHS England, that they would welcome a discussion with the NHS BSA Information Asset Owner (IAO) in respect of the content of the Direction and the onboarding instructions, and any potentially restrictive wording; and be provided with a copy of the onboarding instructions as part of this discussion.</p> <p>ACTION: NHS BSA IAO to attend future AGD meeting to discuss the content of the Direction and the onboarding instructions, and any potentially restrictive wording.</p> <p>ACTION: AGD to receive a copy of the onboarding instructions from DARS prior to the IAO attending a future AGD meeting.</p> <p>4.4.6 The independent advisers suggested that a special condition was inserted in section 6 (Special Conditions), that any use of the NHSBSA data must be within the parameters of the relevant Direction authorising that collection.</p> <p>4.4.7 The independent advisers noted that due to resource issues within NHS England’s Data Production Team, this may be impacting on additional data handling; or more data than necessary flowing to applicants; and that although there may the appropriate legal basis to flow the data, it was suggested that, if possible, NHS England should make additional resources available, to reduce the data handling and / or the data flowing.</p> <p>4.4.8 The independent advisers noted the excellent description in section 5(e) (Is the Purpose of this Application in Anyway Commercial) of the role of HeartFlow Inc; however suggested that section 5(a) was updated to make clear that an assessment had been undertaken that the commercial benefit accruing to the commercial organisation is proportionate to the benefit to health and social care, in line with NHS Digital DARS Standard for Commercial Purpose.</p>	<p>NHSE</p> <p>NHSE</p>
4.5	<p>Reference Number: NIC-148096-PT589-v4.7</p> <p>Applicant: Institute of Cancer Research (ICR)</p> <p>Application Title: MR1069 - BREAKTHROUGH GENERATIONS study</p>	

<p>Presenter: Dan Goodwin</p> <p>SAT Observer: Kimberley Watson</p> <p>Application: This was an application coming for advice.</p> <p>Should the application be approved by NHS England, further details would be made available within the Data Uses Register.</p> <p>NHS England were seeking advice on the following points:</p> <ol style="list-style-type: none"> 1. Whether the transparency that has been provided, including what can be provided – provides a legal basis to address the common law duty of confidentiality through reasonable expectation; and, <ol style="list-style-type: none"> a) Whether a newsletter would be sufficient; and, b) Is the intended wording satisfactory / sufficient to cover the additional cohort being sent to NHS England for linkage; and, c) Whether a newsletter is not sufficient and the participants who ICR are still in contact with will need to reconsent. <p>Outcome of discussion: The group were supportive of the proposed newsletter approach. The group made the following observations/points of advice:</p> <p>In response to point 1</p> <p>4.5.1 The independent advisers advised NHS England, that they were broadly supportive of the newsletter approach, proposed by the applicant, which appeared to be pragmatic and consistent with the NHS Digital DARS Standard for Duty of Confidentiality.</p> <p>4.5.2 In addition, the Caldicott Guardian Team representative also confirmed he was supportive of the proposed approach of a newsletter.</p> <p>4.5.3 The independent advisers noted the content of the proposed newsletter, however suggested that it was amended to be more direct in respect of what they are proposing, and provided some draft wording in-meeting for NHS England colleagues to discuss further with the applicant.</p> <p>4.5.4 The independent advisers noted that whilst recruitment has ceased, and whilst there was no active recruitment, there were 175 individuals, who have joined the cohort since 2015; and suggested that the applicant proactively updated the existing consent materials for the small group of additional cohort members; to ensure that any new cohort members moving forward, would be recruited under the new consent materials.</p> <p>4.5.5 The independent advisers noted a number of conflicting statements relating to data sharing, for example, the newsletter referred to data sharing with other scientists, the website refers to the involvement of other researchers, and the patient information sheets refers to potential commercial involvement. It was also noted that section 5(a) (Objective for Processing) states “<i>The data will be accessed and analysed solely at ICR...</i>”, and suggested that NHS England explore with the applicant further, to 1) ensure compliance with the data sharing agreement (DSA) now, i.e. no sharing of NHS England data; and 2) to ascertain future processing of the NHS England data, and that there is sufficient transparency with the cohort.</p> <p>4.5.6 The independent advisers also suggested that any sharing of data would need to be aligned with the NHS Digital DARS Standard for Commercial Purpose.</p>	
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	4.5.7 The independent advisers suggested that the applicant avoided the term 'opt-out' since cohort members who ask not to be followed up in this way will actually be withdrawing their consent.	
AGD Operations		
5.1	Standard operating procedures The ongoing forward plan of work for creating Standard Operating Procedures was discussed.	To note
6	New Operational Actions & those carried forward from previous meetings of AGD:	
6.1	Inside Scope of IR35 Garry Coleman provided a further verbal update in respect of IR35 and the impact on independent advisers who were previously on IGARD, noting that they would fall inside scope of IR35 from the 1 st April 2023. Garry Coleman reiterated that there was urgent work ongoing within NHS England to clarify the impact on the independent advisers of falling in scope of IR35, and the options available to NHS England to mitigate the impact / risks on independent advisers, AGD and NHS England as a result of this.	
6.2	DARS Standard Expected Measurable Benefits and DARS Standard Commercial Purpose Liz Gaffney attended the meeting, to discuss with the independent advisers, potential updates to the NHS Digital DARS Standard for Expected Measurable Benefits and NHS Digital DARS Standard for Commercial Purpose , to align with the National Data Guardian (NDG) guidance on enabling better public benefit evaluations when data is to be used in planning, research and innovation. The independent advisers made a number of comments and suggestions to NHS England; who advised that an updated version of both Standards would be shared with the group in due course.	
6.3	NHS England Statutory Guidance On Protection of Patient Data and the impact on AGD ToR The independent advisers noted that following receipt of the draft statutory guidance from the Department of Health and Social Care (as noted in the AGD minutes on the 16 th March 2023); a response had been sent on the 21 st March 2023.	
7 Any Other Business		
7.1	Honorary Contracts Dave Cronin attended the meeting to discuss with independent advisers a draft honorary contract policy summary and a draft Data Sharing Standard; both were produced following a meeting with NHS England's Privacy, Transparency, Ethics and Legal on the 30 th January 2023.	

7.2	<p>The independent advisers made a number of comments and suggestions to NHS England; who advised that an updated version of both the draft honorary contract policy summary and a draft Data Sharing Standard, would be shared with the group in due course.</p> <p>USA Patriot Act</p> <p>Liz Gaffney attended the meeting to discuss NHS England's policy position with regard to 1) USA based Data Controllers or Data Processors / Data Controllers or processors with a USA parent company; and / or 2) USA based cloud storage, when handling NHS England data, vis a vis the US Patriot Act.</p> <p>The independent advisers noted that a draft briefing paper had been provided in advance of the meeting; and made a number of comments and suggestions.</p> <p>The independent advisers noted that the impact of the USA Patriot Act and the risks associated with this, should be determined by at NHS England Board level; and that it was not necessarily the responsibility of colleagues within DARS to undertake additional checks.</p> <p>It was noted by the NHS England SIRO representative that an interim policy position would need to be agreed within NHS England, for example, to determine what checks will be undertaken; and that further information would be provided to the group in due course.</p>
	<p>Meeting Closure</p> <p>As there was no further business raised, the Chair thanked attendees for their time and closed the meeting.</p>