UCL/UCLH Sponsored Studies: Protocol Template for Data Studies
UCLH/UCL Research Office
(*Version 1.0, 06/01/2021)*

Guidance

Please check the Joint Research Office website https://www.ucl.ac.uk/joint-research-office/sops-and-templates to ensure you have the most up to date version of this template.

This protocol template is for use by **UCL/UCLH Chief Investigators to submit data-only studies for UCL or UCLH Sponsorship** via the UCLH/UCL Joint Research Office (JRO).

Data studies:
Studies limited to working with anonymised/pseudonymised/anonymised data, for research purposes (i.e. not service evaluations or clinical audits).

Further information on which studies UCL or UCLH will sponsor can be found on its website.

This template is **not applicable** for all studies:

- deemed to be Clinical Studies of Investigational Medicinal Products (CTIMP)
- involving new Devices or Devices being used for a new purpose
- managed via a UCL Clinical Trials Unit (CTU)
- observational and interventional studies

This template has been developed to include all relevant regulatory, ethics and local policy requirements. The template contains all sections recommended by the Health Research Authority (HRA) for regulatory review by the HRA and the Research Ethics Committees.

Investigators may use other templates but must ensure there is sufficient level of detail is presented. Investigators wishing to do so are encouraged to read through this template. Text marked in **black** must be inserted into these protocols.

The JRO will review each protocol submitted to ensure key sections and details are included before Sponsorship is formally agreed.

Instructions for use

Please ensure the protocol is written in third person.

Not all sections will be relevant for all studies. Each section can be modified or deleted as applicable to your type of study.

Instructions and explanatory text are indicated in red and blue and should be removed or replaced in your protocol with the appropriate text.

Post sponsorship approval: any modification to the protocol should be written in the protocol version history table, or in an appendix. The annotation should note exact words that are changed, the location in the protocol, the date the modification was approved by the relevant CI/committee/parties, and the date it became effective.

The protocol must be consistent with the participant information sheet, consent form, IRAS form, and any other relevant study documentation, and should be cross checked prior to finalisation. The JRO will carry out a review of the draft protocol and provide advice and guidance prior to approval.

Guidance notes on Style and Formatting:

1. Abbreviations should be written in full on first appearance and a list of abbreviations should be included in the protocol.
2. Ensure consistency: refer to study 'participants' throughout the protocol (not patients, subjects or volunteers unless explanatory), refer to 'study' throughout the protocol, refer to study 'sites', not 'centres', for a participating institution.
3. Use bullet point lists or tables where appropriate rather than long passages of prose.
4. Logos: ensure all appropriate and relevant logos are added to the front page, and that bodies represented have agreed to the use of their logo.

This covering page and JRO template header should be deleted once the protocol has been drafted

Include other logos as appropriate – study specific logo, funders, collaborators, research networks etc.

Study Protocol Front Page

Full/long title of study If this is a student project, ensure it is clearly identified as such here, and which UCL academic qualification it relates to.	VIVALDI SOCIAL CARE – CARE HOME RESEARCH DATABASE
Short title The full and short title must be the same on the IRAS form and all study documents e.g. participant information sheet. A study acronym is a useful short title.	VIVALDI Social Care Database
Version and date of protocol The protocol should be labelled **draft** until approved for submission to the REC when draft should be deleted, and it should become Version 1	Version [1], [16/08/2023]
Lead Institution:	University College London (UCL)
Lead Institution reference number:	[160619]
Funder (s):	UK Health Security Agency (UKHSA), National Institute for Health and Care Research (NIHR)
IRAS Number:	330194
ISRCTN / Clinicaltrials.gov no: delete as applicable]	[Insert ISRCTN or Clinicaltrials.gov reference no]
UCL Data Protection Number:	Z6364106/2023/07/155

Chief investigator/Academic Supervisor:

Professor Laura Shallcross, UCL Institute of Health Informatics, 222 Euston Road, London NW1 2DA.
Email: l.shallcross@ucl.ac.uk

Lead Institution Representative:

Pushpsen Joshi; pushpsen.joshi1@nhs.net
UCLH/UCL Joint Research Office,
4th Floor, West
250 Euston Road
London
NW1 2PG

PROTOCOL VERSION HISTORY

Version Stage	**Versions No**	**Version Date**	**Protocol updated & finalised by;**	**Appendix No detail the reason(s) for the protocol update**
Current	V1.0	16/08/2023	Prof Laura Shallcross	NB: Appendix is to be attached to current version of the protocol Appendix 1-5
Previous				

DECLARATIONS

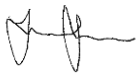
The undersigned confirm that the following protocol has been agreed and accepted and that the investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the U.K Policy Framework for Health and Social Care Research (2017) (as amended thereafter), General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018), Lead Institution and other relevant SOPs and applicable Trust policies and legal frameworks.

I (investigator) agree to ensure that the confidential information contained in this document will not be used for any other purposes other than the evaluation or conduct of the research investigation without the prior written consent of the Lead Institution.

I (investigator) agree to ensure that no research activity or recruitment will commence at participating research sites until the appropriate regulatory approvals and NHS confirmations of Capacity and Capability have been issued, and Lead Institution green light confirmed.

I (investigator) also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest, accurate and transparent account of the study will be given. Any deviations from the study as planned in this protocol will be explained and reported accordingly.

Chief Investigator:



Date...16/.07/2023

Print Name (in full): Laura Shallcross.....

Position: Professor of Public Health & Translational Data Science.....

On behalf of the Lead Institution:

Signature: .....  **.....**
Date..16..../..08..../...2023....

Print Name (in full): .....Pushpsen Joshi.....

Position: .....Research Governance Manager.....

STUDY SUMMARY

IDENTIFIERS	
IRAS Number	330194
REC Reference No.	
Lead Institution Reference No.	160619
Other research reference number(s) (if applicable)	Z6364106/2023/07/155
Full (Scientific) title	VIVALDI SOCIAL CARE DATABASE
Health condition(s) or problem(s) studied	
Study Type i.e. Cohort etc	Open Cohort
Target sample size/data sets	500-1000 care homes (estimated 15,000 – 30,000 residents)
STUDY TIMELINES	
Study Duration/length	18 months
Expected Start Date	October 1st 2023
End of Study definition and anticipated date	Data collection completed and database locked March 31st 2025
Key Study milestones	IRAS and CAG approval Data sharing agreements in place with participating care homes Data pipelines established Creation of research database Extraction of finalised, de-personalised dataset to UCL Data Safe Haven
FUNDING & OTHER	
Funding	UK Health Security Agency (UKHSA) National Institute for Health & Care Research (NIHR)
Other support	NHS England (NHSE)
STORAGE OF DATA (if applicable)	
Data collected / Storage	UCL Data Safe Haven
KEY STUDY CONTACTS Full contact details including phone, email and fax numbers	
Chief Investigator	Professor Laura Shallcross, 0203 549 5540, l.shallcross@ucl.ac.uk
Study Co-ordinator	Borscha Azmi; borscha.azmi@ucl.ac.uk
Lead Institution	UCL UCLH/UCL Joint Research Office, 4th Floor, West 250 Euston Road London NW1 2PG uclh.randd@nhs.net
Funder(s)	UKHSA – Gareth Patefield, Email: gareth.patefield@ukhsa.gov.uk NIHR – Tom Pratt, Email: personal.awards@nihr.ac.uk
Committees	VIVALDI Social Care Steering Committee – administrator contact: gareth.patefield@ukhsa.gov.uk. Role: programme oversight

	VIVALDI Social Care Data Access Committee – administrator TBC. Role: agree which projects are permitted to use the research database.
Sub-contractors	NHSE – Data processor UKHSA – Data processor The Outstanding Society – oversee recruitment and engagement with care homes that are participating in the study
Other relevant study personnel	Data Custodian: Professor Mark Emberton, Dean of the Faculty of Medical Science, UCL

KEY ROLES AND RESPONSIBILITIES

LEAD INSTITUTION: The Lead Institution is responsible for ensuring before a study begins that arrangements are in place for the research team to access resources and support to deliver the research as proposed and allocate responsibilities for the management, monitoring and reporting of the research. The Lead Institution also must be satisfied there is agreement on appropriate arrangements to record, report and review significant developments as the research proceeds, and approve any modifications to the design.

FUNDER: The funder is the entity that will provide the funds (financial support) for the conduction of the study. Funders are expected to provide assistance to any enquiry, audit or investigation related to the funded work. If further arrangements have been agreed with the funder, please refer to the funding agreement and insert.

CHIEF INVESTIGATOR (CI): The person who takes overall responsibility for the design, conduct and reporting of a study. If the study involves researchers at more than once site, the CI takes on the primary responsibility whether he/she is an investigator at any particular site.

The CI role is to complete and to ensure that all relevant regulatory approvals and confirmations of NHS Capacity and Capability are in place before the study begins. Ensure arrangements are in place for good study conduct, robust monitoring and reporting, including prompt reporting of incidents, this includes putting in place adequate training for study staff to conduct the study as per the protocol and relevant standards.

The Chief Investigator is responsible for submission of annual reports as required. The Chief Investigator will notify the REC and JRO of the end of the study (including the reasons for the premature termination, where applicable). Within one year after the end of study, the Chief Investigator will submit a final report with the results, including any publications/abstracts to the REC and JRO.

PRINCIPLE INVESTIGATOR (PI): Individually or as leader of the researchers at a site; ensuring that the study is conducted as per the approved study protocol, and report/notify the relevant parties – this includes the CI of any breaches or incidents related to the study.

OTHER:
Dr Maria Krutikov, Clinical Lecturer, UCL*: project set-up and data analysis*
Dr Oliver Stirrup, Statistician, UCL*: study statistician*
Borscha Azmi, Project Manager, UCL: *project management and engagement with care sector and policymakers*
Zoe Fry, Director of the Outstanding Society*: care home provider recruitment and engagement lead*
Charlotte Lezard, Policy officer for Care England*: engagement with the care sector and policymakers*
Dr Nuno Almeida, CEO Nourish Care*: Access to electronic care provider records from participating care homes*
Gareth Patefield, Project lead at UKHSA*: Collaboration with UKHSA, NHSE and DHSC*
Aileen Schissler, Data Management & Integration Service, NHSE *– information governance*
Wendy Harrison, Senior Lead for Data Governance, NHSE *– information governance*

KEY WORDS

Care homes; public health; Older adults; database; electronic health records; infectious diseases; antimicrobial resistance; health policy

LIST OF ABBREVIATIONS

AE	Adverse Event
AMR	Antimicrobial Resistance
AR	Adverse Reaction
CAG	Confidentiality Advisory Group
CI	Chief Investigator
CRF	Case Report Form
CRO	Contract Research Organisation
CRN	Clinical Research Network
DAC	Data Access Committee
DMC	Data Monitoring Committee
GAfREC	Governance Arrangement for NHS Research Ethics
DHSC	Department of Health & Social Care
HRA	Health Research Authority
HTA	Human Tissue Authority
IB	Investigator Brochure
ICF	Informed Consent Form
MD	Medical Device
NIHR	National Institute for Health & Care Research
NHSE	NHS England
ISRCTN	International Standard Randomised Controlled Studies Number
PI	Principle Investigator
PIS	Participant Information Sheet
QA	Quality Assurance
QC	Quality Control
RCT	Randomised Controlled Trial
REC	Research Ethics committee
SAR	Serious Adverse Reaction
SARS-COV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SAE	Serious Adverse Event
SDV	Source Data Verification
SOP	Standard Operating Procedure
SSI	Site Specific Information
TMF	Trial Master File
UCL	University College London
UKHSA	UK Health Security Agency

CONTENTS

1. INTRODUCTION

Every year care home residents experience infections and disease outbreaks, which reduce their well-being and cause avoidable hospital admissions and mortality. Yet many of these infections could be avoided with better evidence on 'what works in care homes' and systems to monitor and therefore control infection. The urgent need to address this gap in care home specific data and surveillance, which severely undermined the initial response to the COVID-19 in care homes, was recently highlighted by the Chief Medical Officer in his Technical report on the COVID-19 pandemic in the UK.(1)

The pilot study described in this protocol aims to establish a research database that can be used for research on infectious diseases, outbreaks, and Antimicrobial Resistance (AMR) in c. 15-30,000 care home residents in England to inform policy and practice. The database is part of a wider project which is being delivered by UCL in collaboration with the UK Health Security Agency (UKHSA) as part of their service delivery. It aims to explore if it is 1) feasible to establish a network of care homes, underpinned by linked data and 2) if these data add value to existing surveillance and research infrastructure for infection and outbreaks in care homes. This wider project, which will generate reports/dashboards on the burden of infection and outbreaks in care home residents for care providers and policymakers, does not require REC review as it is being delivered as part of UKHSA service delivery, but it does require approval from Health Research Authority Confidentiality Advisory Group. A separate 'service' CAG application is being submitted by UCL for this purpose.

The research database described in this protocol capitalises on the data infrastructure that will be established through the 'wider project' and requires approval from both REC and CAG. Although this protocol is focused on the research database part of this project, from time to time we refer to the 'wider project' i.e., the service delivery component of the study in the protocol to aid understanding of the proposed research.

The research database and wider project build on learning from the highly successful Government funded national VIVALDI (COVID-19 in care homes study), which was led by UCL and delivered in partnership with care providers and the UK Health Security Agency.

A key feature of the research database and the wider study is its goal to be inclusive, so every resident has the opportunity to take part, and our findings are relevant for *all* older adults in care homes. We also want our database to be accurate, up to date, and complete. This is particularly important for research studies which aim to measure the burden of infection and related outcomes because infections spread between people, and short stay residents (who often get excluded) are more likely to bring infections into care homes having recently been in hospital.

Our proposal is informed by extensive engagement with care home residents, relatives, staff and providers (outlined in the PPI section), which has confirmed the need for more research to reduce the impact of common infections (e.g., influenza) and outbreaks in care homes. This engagement has been enabled by a new partnership between the UCL research team, Care England, the largest care sector representative organisation and the Outstanding Society, a community interest company who promote quality in social care. The project plan that is outlined in our application has been developed in partnership with the care sector, and this engagement has informed our decision to seek section 251 approval from the Health Research Authority (HRA) Confidentiality Advisory Group (CAG) to use

individual-level, personal data from all residents in participating care homes, without consent. The engagement work has also informed the decision to prioritise inclusion of care homes that have digital social care records because this makes it feasible to extract (minimal) data from care homes electronically, recognising the rapid digitisation of the social care sector. This will substantially reduce any workload for providers associated with research participation which is extremely important. A further advantage of this approach is that it substantially reduces the risk of a data breach because digital care record suppliers are experts in data security and information governance, whereas care providers may be less familiar with secure data transfer procedures.

Digital care record suppliers will be asked to submit identifiers (NHS numbers) for residents in participating care homes to NHSE at regular intervals (e.g., daily). This will generate an accurate, up to date registry of every resident in each participating care home. Records will be sent securely to NHS England where they will be pseudonymised and then linked in a secure data environment (NHS Foundry[1]) to other NHS datasets, such as records of hospital admission, death, vaccination status, microbiology, and antimicrobial prescriptions. We aim to collect data for a 12-month period. At the end of this period, the pseudo-identifiers will be removed, and the de-personalised dataset will be transferred to the UCL data safe haven for analysis. This de-personalised dataset will be made available for researchers to analyse, subject to approval of their project by the VIVALDI Social Care Data Access Committee (DAC).

The project will be overseen by a stakeholder oversight group including relatives, residents, care home staff, providers, academics, and policymakers. They will review the pilot study processes and outputs and consider whether there is merit in extending the study and embedding it as part of permanent surveillance infrastructure. It is also worth noting that although this pilot project focuses on infectious diseases and AMR, if it is successful and there is strong support from residents, their relatives, care home staff and providers for continued data sharing, the database could be repurposed to host a broader portfolio of studies addressing other care sector priorities e.g., falls, dementia.

BACKGROUND AND RATIONALE

In England, approximately 380,000 people (4% of > 65 year olds) live in 11,000 care homes for older adults(2). The majority of care home residents (hereafter 'residents') are aged > 85 years, at least two-thirds live with dementia, and over half die within 12 months of admission to a care home(3,4) The COVID-19 pandemic has highlighted the extreme vulnerability of residents to severe outcomes following infection (5). However, every year Antimicrobial Resistance (AMR), respiratory (e.g., influenza, pneumonia), gastrointestinal e.g., norovirus, urinary tract and skin infections cause substantial morbidity and mortality and cause outbreaks which close care homes and drive avoidable hospital admissions (6,7). Many of these infections and outbreaks could be prevented by implementing interventions which are known to be effective e.g., vaccination, and generating new evidence on how to prevent or reduce infection where none currently exists. However, efforts to

[1] The linked dataset will be created in the NHS Foundry, which is overseen by NHSE. However, NHSE are currently going through a procurement process to transition NHS Foundry to a 'Federated Data Platform' (FDP). The project will therefore begin in Foundry, and transition across to the FDP during the study period.

reduce the impact of infection are hampered by multiple, complex barriers including an inadequate research and data infrastructure, the fragmentation of social care, multiplicity of providers, poor integration of health and social care and other services that impact on health and wellbeing e.g., housing, and under-developed engagement by researchers with the care sector. The sector has also failed to benefit from advances in care driven by NIHR research which is primarily focused on hospitals and primary care.

Prior to the pandemic, many academics and care sector leaders had highlighted the need for better individual-level data from care homes to enable comparison of care quality and outcomes across the sector, however progress towards this goal had been extremely limited. The NIHR funded "Developing research resources and minimum dataset for care homes adoption and use" (DACHA) study was established in 2018 to synthesise existing evidence and data sources with care home generated resident data to deliver an agreed minimum data set that is usable and authoritative for different user groups(8). However the urgent need to respond to the SARS-CoV2 pandemic catalysed new, complementary initiatives to improve the availability of data from care homes, including the UCL led and DHSC funded (9) VIVALDI observational study [VIVALDI Study | UCL Institute of Health Informatics - UCL – University College London] which ran from May 2020 until 31 March 23.

VIVALDI measured infections, immunity and vaccine effectiveness in care home staff and residents over successive waves of the pandemic. The study findings have enabled policymakers to make difficult but evidence-based decisions to protect the sector and demonstrated how timely surveillance and research on COVID-19 can both inform policy and reduce the impact of infections. It also showed that it is feasible to deliver research and surveillance on infection at scale and pace in care homes. Key to VIVALDI's success was the establishment of strong partnerships with providers, use and linkage of routinely collected data, and close collaboration between academics and policymakers. Importantly, the care sector has been fully engaged in this process and have seen how research can directly benefit them.

In December 2022, Chief Medical Officer's Technical Report(1) on the COVID-19 pandemic in the UK noted that "The value of reliable and comprehensive routine population and health data describing the population living and working in residential care to inform policy decisions and evaluate the impact of interventions cannot be overstated" [Technical report on the COVID-19 pandemic in the UK - GOV.UK (www.gov.uk)]. Similarly, our extensive engagement with care home providers, residents, relatives, and staff has made it clear that there is a strong desire to learn lessons from the pandemic and for continued research (in partnership with academics) to reduce the burden of other infections in care homes such as influenza and norovirus.

The first step in being able to deliver research on infection, outbreaks and AMR in care homes is to quantify the burden and outcomes of different infections in residents at scale. It is not feasible for care homes to collect this information manually due to lack of staff and research infrastructure, so the optimal approach is to use data that are already being collected by the NHS. Whilst this will not provide the depth of information that is desirable, for example on symptoms of infection, it is a valuable first step to quantify the burden of infection, which if successful could be enriched over time through linkage to other data sources e.g., primary care, and integration with mixed methods research. Routinely collected data were used in the VIVALDI study to measure COVID-19 infections in residents, however this was only possible because residents were being tested at regular intervals,

which effectively created a regularly updated cohort of residents that could be linked to other datasets via NHS numbers. Now testing for COVID-19 has stopped this is no longer a viable approach. An alternative would be to use address-based matching to identify care home residents in routinely collected data, an approach that has been used in some research studies. However, the sensitivity and specificity of different approaches to address-based matching varies (5,10), and findings based on these data may not be generalisable because the resident population in care homes for older adults changes rapidly. The average length of stay in a care home is 2.5 years, and many homes provide respite care to temporary residents(3). This limits the use of routine data to measure infection in residents because addresses that are recorded in NHS medical records are time lagged, incomplete and do not include temporary residents, while local authorities which commission some beds do not hold data on other residents who are self-funded. Temporary residents are also more likely to have recently been in hospital and are thus more likely to import infection into the care home(11) – a risk highlighted in the pandemic – so it is essential to include them in surveillance and research studies. A further reason for requiring access to complete, accurate, regularly updated data on care home residents is that if the pilot project is successful, our future ambition (beyond this proposal) is to test whether this same data infrastructure could enable pandemic preparedness by providing near real-time surveillance for infection in care homes.

If there is a desire to undertake inclusive observational research studies to reduce the impact of infection in care homes using routine data, it is critical that the research database we create is unbiased (as far as possible) and that every care home resident has the opportunity to contribute their data (10). As care providers are the only reliable source of accurate information on which residents are in a care home at any point in time, this requires a new mechanism to extract data directly from care providers and/or digital care records, underpinned by robust information governance processes and extensive engagement with the care sector regarding the use of residents' data in research(12).

The de-personalised database that will be developed in this pilot study will be made available to researchers following approval of their proposal by the study's Data Access Committee (DAC). We anticipate that the database will make a major contribution to our understanding of the burden and outcomes of a range of infections in care home residents, enabling estimates of vaccine effectiveness, rates of infection / AMR / hospitalisation / mortality by clinical infection syndrome and pathogen, and rates of antimicrobial prescribing, as well as for example, observational and modelling studies that aim to investigate the relationship between AMR, age, antibiotic exposure and contact with healthcare settings. The database could also be used to inform and enable qualitative studies and quality improvement projects, by identifying care homes that exemplify best practice (to share learning) and those in greatest need of targeted support.

The first research proposal that will be submitted to the DAC will investigate the burden, outcomes, and risk factors for AMR in residents because this AMR project has already been funded by the NIHR Research Professorship which partly funds this proposal, and reducing AMR is a national public health

priority. [2] All other proposals to use the linked dataset will be assessed on a case-by-case basis by the study Data Access Committee.

2. AIM(S) AND OBJECTIVES

Aim: To facilitate large-scale observational research studies on infection, outbreaks, and antimicrobial resistance in care homes for older adults in England, by piloting the establishment of an accurate, regularly updated, research database.

3.1 Primary Objective

To establish a research database comprising information on the burden and outcomes of infection in older adult residents of 500-1500 care homes in England. This will be achieved by establishing an accurate, regularly updated registry of care home residents with linkage to individual level, routinely collected data on infection, hospital admissions, vaccinations, microbiological outcomes and antimicrobial prescribing.

3.2 Secondary Objectives

- To engage effectively with care home stakeholders to support effective design and delivery of the study.
- To recruit 500-1500 care homes to take part in the study.
- To establish information governance approvals and templates to enable sharing of data on residents.
- To establish data pipelines to extract individual-level data on care home residents and transfer this data securely to NHS England.
- To pseudonymise and link individual-level data on care home residents to routinely collected datasets held in NHS Foundry to create the research database.
- To establish a Data Access Committee to oversee future use of the research database and enable its use by researchers.
- To deliver an exemplar study on antimicrobial prescribing and resistance in care home residents using the database.

3. STUDY METHODOLOGY AND STATISTICAL METHODS

Study design
Open cohort

Study population
Individuals who live in residential and/or nursing homes that provide care to older adults in England, including temporary residents.

Care home engagement and recruitment
Since October 2022, researchers from UCL have been working with Care England and the Outstanding Society to raise awareness of the VIVALDI Social Care Project through presentations at Care conferences and events held by the Care Quality Commission, press releases, magazine articles,

[2] Community-onset urinary tract infections are extremely common in care home residents and a major cause of drug resistant gram-negative blood stream infections. There is a national target to halve these types of infections by 2024/5

newsletters, webinars, our organisations' websites and podcasts (https://theoutstandingsociety.co.uk/case-study/vivaldi-care-home-study/).

One of the Directors of the Outstanding Society (ZF) has met individually with many of the care providers to explain the study, its importance, and our proposed use of data from residents without consent. As of May 2023, >800 care providers in England have expressed an interest in taking part in the study and sharing data on their residents to support research on infection.

When the study begins, we will distribute multi-modal study materials to care homes that provide information at three levels: 1) basic information about the study including how to opt out (poster, video – in preparation), 2) detailed information about the study (leaflet), and 3) very detailed information about the study including its design, explanation of the data flows and data controllership etc. (online). All these materials will provide clear instructions for how residents can opt out of sharing their data. These materials have been co-developed with the study's 'engagement working group' which includes relatives, care home staff, and providers, and piloted with a subset of care homes prior to study start, see section 8 below.

Establishing the data platform, data flows and data collection

Following extensive discussions with care providers and their representative organisation Digital Social Care (https://www.digitalsocialcare.co.uk/), it has been agreed to start by working with providers that use Digital Social Care Records that have been assured by the NHS Transformation Directorate in NHS England (because this provides the option to extract NHS numbers directly from the digital record suppliers rather than from care homes). There will also be the opportunity to work with a small number of large, medium, and small providers that have the technical capability to automate data extraction from their electronic record systems. A workstream will be established, with input from Digital Social Care, digital record suppliers (e.g., Nourish, Person Centred Software), Care England, participating providers (e.g., HC-One) and NHS England's data management team. We will extract NHS numbers, the date of data collection and the CQC ID for their care home for each resident at regular intervals e.g., daily to maintain an accurate record of which residents are in a care home at any point in time. Wherever possible NHS numbers for residents will be extracted directly from digital record suppliers. This will be achieved by establishing a permanent data feed from the digital record supplier to NHS Foundry[3] (allowing the dataset to be updated in near real-time). Although this may impact on the generalisability of the sample for the pilot study, the Government has strongly signalled its expectation that all care providers will move to electronic care records (80% of Care Quality Commission registered providers to have digital social care records by March 2024)(13), suggesting it will become increasingly feasible to recruit a diverse set of care homes that use digital care records over time, if the study is continued beyond the pilot. Most importantly, our engagement work with the care sector has made it clear that it is not feasible to extract data from paper-based systems.

To reduce the administrative burden associated with participating, we will partner with Digital Social Care to develop a set of template agreements (data sharing agreements, Data privacy impact assessment, privacy notice) will be developed for use by participating providers. Our goal is to

[3] NHS Foundry will transition to the NHSE Federated Platform (FDP) during the project.

establish data pipelines / data transfer mechanisms by October 2023, however it is likely that providers will continue to onboard throughout the project.

Based on discussions in stakeholder engagement events and working groups, there is strong support for bringing data from residents into an NHS environment because:

1) the NHS is trusted to hold personal data;

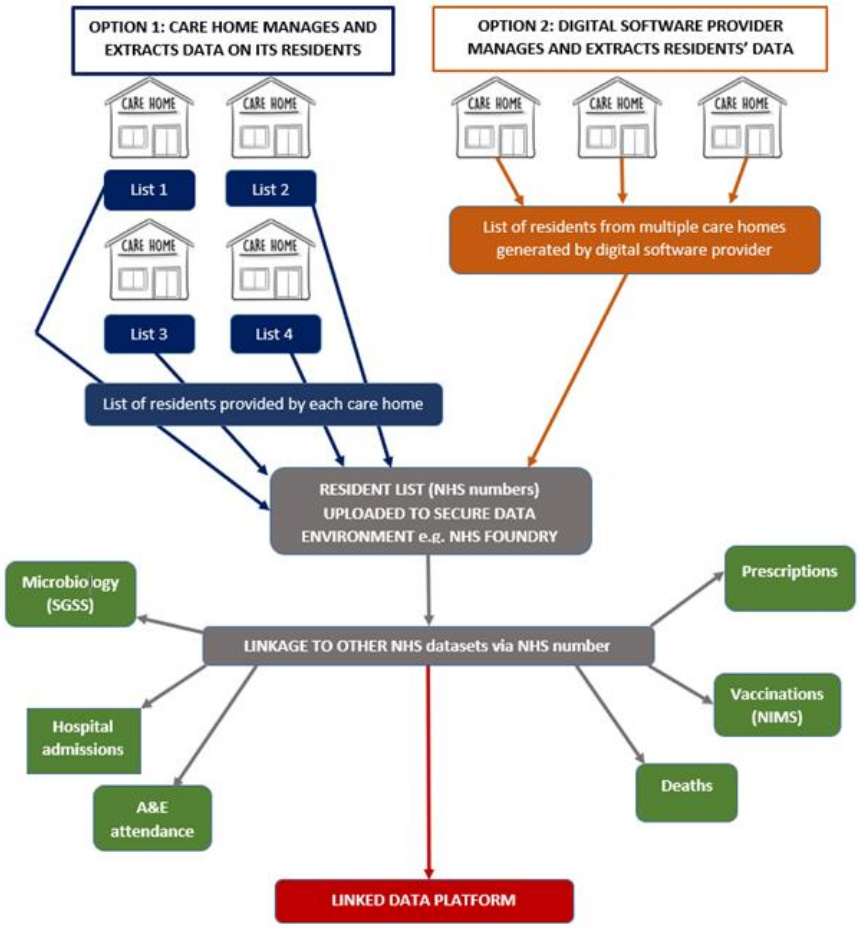
2) the other datasets we want to link to are already held by the NHS; and

3) we have experience of linking datasets in the NHS Foundry through VIVALDI.

It is therefore proposed to establish the linked data platform in NHS Foundry, with NHSE acting as data processors on behalf of the project. NHSE will first pseudonymise data from residents using an automated algorithm and then allocate each record a common pseudo-identifier that is based on NHS number, which can be use to link records from residents to routine collected datasets that are already held in this secure data environment. This will include linkage to the:

- Admitted Patient Care Dataset
- Emergency Admissions Dataset
- Mortality data
- National Immunisations Management System (NIMS)
- Second-Generation Surveillance System (SGSS - laboratory test results)
- Antimicrobial prescriptions via the NHS Business Services Authority (NHS BSA)
- HPZone (data on outbreaks)

Set-up and curation of the linked data platform in NHS Foundry will be led by a software engineer who oversees the VIVALDI data platform. The proposed data structure is outlined in the diagram below. Option 2 is the preferred model for ingesting data on residents.



UKHSA will also act as data processors as they will use the linked dataset held in Foundry to generate aggregate infection metrics / dashboards for policymakers (subject to a separate CAG application as this is part of their service delivery).

Statistical analysis and sample size

Our sample size reflects our desire to generate findings that are generalisable across the care sector and the fact that there are considerable technical, logistical and governance challenges associated with setting up this study (collection of individual-level data from care homes at scale has not previously been attempted in England).

As there are approximately 11,000 care homes for older adults in England (2), if we achieve our target sample size (500-1500 care homes) our sample would represent approximately 5-14% of all care homes. However, there is considerable diversity across the care sector, so our sample is very unlikely to be representative of all the different types of care homes. If the pilot is successful, and there is a desire to establish a long-term data linkage project, our intention would be to work with the Care Quality Commission to understand which types of care homes are not included in our sample, and to try and address these gaps by targeted recruitment. Given the complexity of the data flows and governance, the relatively short timescales, and the absence of a care home registry from which to sample, it is not feasible to develop a sampling frame and attempt to recruit a representative group of care homes in this pilot study.

As the goal of this project is to establish the research database, we have not developed a statistical analysis plan (SAP). All projects using the research database will be expected to develop a SAP before data analysis commences.

Exemplar projects using the research database

The aim of this pilot project is to develop a research database to facilitate observational studies in care homes that address priority, infection-related public health questions in care homes. Given the short study timelines it is not feasible to establish a portfolio of studies that could be delivered using the research database. Instead we will capitalise on existing funding secured through Prof Shallcross's NIHR-funded Research Professorship (https://www.nihr.ac.uk/news/six-research-leaders-awarded-flagship-nihr-career-development-awards/32589) "Care Home Evidence based Research studies that are Sustainable and Holistic (CHERISH)" to deliver an exemplar study estimating the burden of antimicrobial prescribing and resistance in care homes, and how these outcomes vary by care home and resident characteristics. Tackling AMR is a major public health priority(14), and it is well recognised that there is an urgent need for better data on prescribing and resistance in the care home population. For example, care home residents have more than double the rate of microbiologically-confirmed UTI and at least four-fold higher rates of drug-resistant UTI compared to community-dwelling adults aged >70 years(15). Through collaboration with the London School of Hygiene and Tropical Medicine we also propose to model the relationship between AMR and age, considering the relative importance of different exposures (e.g. antimicrobial treatment, contact with healthcare environments) and how this varies by pathogen. Statistical analysis plans will be developed for these studies before data analysis begins, however the first stage for the epidemiological study will be to calculate incidence rates of prescribing and resistance for key drug-bug combinations, and to investigate the association between individual-level characteristics (e.g. age, sex, co-morbidity if available), care home level characteristics (e.g. care home size, care home type, region) and these outcomes. Subsequent analyses will consider the relationship between prescribing and resistance (e.g. patterns and extent of antimicrobial exposure, exposure to specific classes of antimicrobials) and the modelling analyses outlined above.

Data analyses will be undertaken in the UCL Data Safe Haven using R and/or STATA.

The *research database* will also be made available for use by the wider research community, subject to approval of individual projects by the Data Access Committee.

5. ELIGIBILITY CRITERIA

5.1 Inclusion Criteria

Individuals who live in care homes in England that provide residential or nursing care to older adults, including temporary residents.

5.2 Exclusion Criteria

Residents of care homes that primarily provide care to adults < 65 years. For the avoidance of doubt, residents aged < 65 years who reside in care homes that primarily provide care to older

adults are eligible for inclusion. Residents in care homes in Scotland, Wales and Northern Ireland are not eligible for inclusion.

6. CONSENT

Consent to use of data from residents

An estimated 70% of care home residents have cognitive impairment (16) and are unable to provide informed consent to study participation. Whilst it is possible to identify consultees to support the consent process in those who lack capacity, this is time-consuming and requires dedicated staff. Severe staff shortages across the care sector and lack of embedded research infrastructure mean it is not feasible for staff to seek consent from every care home resident. Consequently, if we wish to develop an inclusive study that affords every resident the opportunity to take part, and for our data to be generalisable, the only viable option is to seek Section 251 approval from HRA CAG to collect data from *all* residents without consent, with the option for residents to opt out of data sharing. This is the approach that we intend to adopt in this study. We anticipate that the decision to take part will be taken by care provider organisations e.g. BUPA, HC-One, however at enrolment we will ask providers to confirm that the managers in participating homes are willing for their home to take part. Our experience in the VIVALDI studies has shown that this is essential to ensure there is 'buy-in' at care home level, and that materials such as posters and leaflets are displayed/disseminated.

7. DATA COLLECTION

Digital care record suppliers will be asked to supply 1) NHS numbers for every resident in participating care homes linked to their 2) care home identifier (Care Quality Commission identifying number) and 3) the date of data submission. Every time they upload a new dataset they will also be required to upload a separate list of NHS numbers for individuals who have opted out of data sharing. This will ensure that the list of opt outs remains current. Digital care record suppliers will be asked to securely transfer this information to NHS England. The frequency of data transfer is to be determined but we anticipate this will take place once per day.

NHS numbers will be replaced with the National Commissioning Data Repository (NCDR) pseudo-identifier using an automated process within the secure AGEM DSCRO environment owned by NHS England. The individual NCDR pseudo-identifer will be used to link to the following routine collected datasets:

- Admitted Patient Care Dataset (dates and reasons for hospital admission, other medical conditions)
- Emergency Admissions Dataset (dates and reason for attendance at the ED)
- Mortality data (dates and causes of death)
- National Immunisations Management System (NIMS) (vaccination type, dose, and dates)
- Second-Generation Surveillance System (SGSS) (Microbiology and virology test results, test dates)
- Antimicrobial prescriptions via the NHS Business Services Authority (NHS BSA)

Care home level data on outbreaks derived from HPZone (recorded by UKHSA) will be linked to specific homes using the CQC-ID.

Opting out of data collection

Residents in participating care homes can choose to opt out of data sharing at any point during data collection by informing a member of care home staff. The resident can do this themselves or a relative/friend can act on their behalf. We will also establish a provider-level mailbox that residents and relatives can email to opt out of data sharing. The care home manager will be required to regularly submit lists of residents who have opted out to their provider organisations' data manager who will also monitor the 'opt out mailbox'. The data manager will collate lists from all care participating care homes and send them at regular intervals to the digital record supplier (who already holds NHS numbers for these individuals). This process ensures the opt out process is simple for residents, and that the list is updated regularly. To ensure residents have sufficient time to opt-out before the study start, data transfers will only commence one month after the information materials have been distributed to them.

The list of NHS numbers for residents who wish to opt out will be sent to NHSE. They will apply their standard algorithm to pseudonymise the list of NHS numbers for residents who have opted out and the list will be sent to NHS Foundry. The research database will be filtered against this list to remove records for any residents who have opted out. This filtering process will be re-run every time a new dataset is uploaded.

In the pilot study data will be collected on residents for a maximum of 12 months from the study start date.

8. PATIENT AND PUBLIC INVOLVEMENT (PPI)

This proposal has been informed by extensive engagement with care home residents, their relatives, care home staff, and providers. Full details of our activities to date and those that will take place during the study are provided in Appendix 1. Video recordings from our engagement events are available to watch online: https://theoutstandingsociety.co.uk/case-study/vivaldi-care-home-study/. We have also raised awareness of the VIVALDI Social Care Project through presentations at Care conferences and events held by the Care Quality Commission, press releases, magazine articles, newsletters, webinars, our organisations websites, and podcasts.

Since October 2022, UCL, Care England and the Outstanding Society have established two working groups with representation from care providers, care home staff, and relatives of people who live in care homes to consider how to engage and communicate with care homes, and issues related to data sharing and information governance. The project team have visited 5 care homes in different English regions since November 2021 to talk about the project and the problem of infections in care homes. In addition, the study team have partnered with researchers from the DACHA study to develop VIVALDI Social care 'activity packs', which are delivered by activity providers in participating care homes and provide a non-onerous mechanism to engage residents in the study and seek their views. We have also established a new collaboration with the charity 'Care Rights UK' (https://www.carerightsuk.org/) who represent the views of residents and relatives. We have discussed the study with 8 members of this organisation and they have also inputted into the design of our information leaflets and posters. We will also hold a webinar for members of this organisation

in August 2023 to explain the study and get their views, specifically regarding our use of data from residents without consent. These interactions have strongly informed the design of our study and specifically our decisions to 1) seek section 251 approval to access data without consent from residents and 2) focus the pilot study on care providers that use digital social care records (due to the prohibitive workload associated with extracting information from paper-based systems).

Our two care home working groups (engagement & communications; data sharing and information governance), and Care Rights UK will play a key role in the delivery of this project. Specifically, they will continue to work with us to coproduce multi-modal materials to explain the study to care home residents, relatives and staff and to design templates to support data sharing (e.g. DPIAs, Data sharing agreements), with support from Digital Social Care. Care home residents, relatives, staff and providers will also be part of the stakeholder oversight group and data access committee and will directly oversee decisions about how the research database can be used. Care home stakeholders will also work with the research team to interpret our findings and will advise on how to disseminate findings from our research to people who live and work in care homes.

9. FUNDING AND SUPPLY OF EQUIPMENT

The study funding has been reviewed by the UCLH/UCL Research Office and deemed sufficient to cover the requirements of the study. There are no NHS costs associated with this application.

The research costs for the study have been supported by the UK Health Security Agency (£880,000) and the NIHR (£1,999,968; 1/11/2022 – 30/10/2027).

Research costs have been awarded to the following sub-contractors to enable deliver of this research study:
The Outstanding Society – responsible for overseeing care home recruitment and engagement
NHS England – responsible for establishing the data platform and data linkages.

The Chief Investigator holds an honorary Consultant contract with the UK Health Security Agency but does not have any direct personal involvement in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest.

10. DATA HANDLING AND MANAGEMENT

The study is compliant with the requirements of General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018). All investigators and study site staff will comply with the requirements of the General Data Protection Regulation (2016/679) with regards to the collection, storage, processing, and disclosure of personal information, and will uphold the Act's core principles. UCL, The Outstanding Society and Care England will be joint data controllers for this project; the UCL Data Protection Officer is [data-protection@ucl.ac.uk]. The data processors are NHSE and the UKHSA.

Identifiable data (NHS numbers) from care home residents in homes that are participating in the study will be supplied by digital care software providers to NHSE (data processor) using a regular automated data feed to the Arden & GEM DSCRO (see data flow diagram). These data will be pseudonymised and

cleansed of personal identifiers through automated pipelines. The pseudonymised data will then be transferred into the UDAL environment within NHSE before it is transferred to NHS Foundry. Here the pseudonymised list of residents will be linked to routinely collected, pseudonymised healthcare datasets (hospital admissions, vaccinations, emergency admissions, microbiology and virology results, antimicrobial prescribing, mortality) that are held by NHSE. NCDR pseudo-IDs will be removed before the de-personalised data are transferred securely to UCL and stored in the UCL Data Safe Haven. During the project, NHS Foundry will transition to an updated data platform called the Federated Data Platform (FDP). The data flows in this project (DSCRO>UDAL>Foundry/FDP) will be unaffected by this change.

A multi-disciplinary *stakeholder oversight group* will oversee set up of the research database and the wider study. This group will include representation from residents, relatives, staff, and providers and experts in information governance from care providers, UCL, UKHSA and NHSE. The *stakeholder oversight group* will meet two to three times per year. It will provide reassurance to care providers, residents, relatives, and staff that they maintain control of how their data will be used in the project and is a critical part of building trust between care home stakeholders and UKHSA to enable future studies and continued data sharing.

In parallel we will establish a *Data Access Committee* specifically to oversee the use of the de-personalised, pseudonymised research database. This group will include representation from residents, relatives, staff, academics, UKHSA, and providers and will be responsible for reviewing and approving proposals from researchers who wish to use the linked dataset.

We will submit an application to the Health Research Authority Confidentiality Advisory Group (HRA CAG) for Section 251 approval under the NHS Act 2006 approval to access confidential information from residents without consent, drawing on our recent experience of successful CAG applications in VIVALDI study. The legal basis for processing with regard to GDPR is:

- Article 6 (1)(e) 'processing is necessary for the performance of a task that is in the public interest'
- Article 9 (2)(i) 'processing is necessary for reasons of public interest in the area of public health'
- Article 9 (2)(j) ' processing is necessary for archiving purposes, scientific or historical research purposes or statistical purposes'.

We aim is to submit the CAG and REC applications by August/September 2023. CAG have advised that we are required to submit 2 applications to enable set up of 1) the research database (outlined in this proposal) and 2) surveillance outputs which will be delivered in collaboration with the UKHSA (subject to a separate CAG application).

For the duration of the pilot, to ensure maximum care home engagement, UCL, the Outstanding Society and Care England will act as joint data controllers for research database, with UKHSA and NHSE acting as data processors. This arrangement will be reviewed if the pilot is successful and there is interest in establishing a longer-term study.

Once the pseudonymised linked dataset is established in NHS Foundry (or the FDP), a de-personalised copy of it will be created by removing the NHS number based pseudo-identifier. The

risks of deductive disclosure will be further minimised by converting potentially identifiable fields such as date of death to month and year of death. This de-personalised version of the dataset (.csv file) will be transferred securely to the UCL Data Safe Haven (https://www.ucl.ac.uk/isd/services/file-storage-sharing/data-safe-haven-dsh) for use by researchers, subject to approval of their projects by the study Data Access Committee.

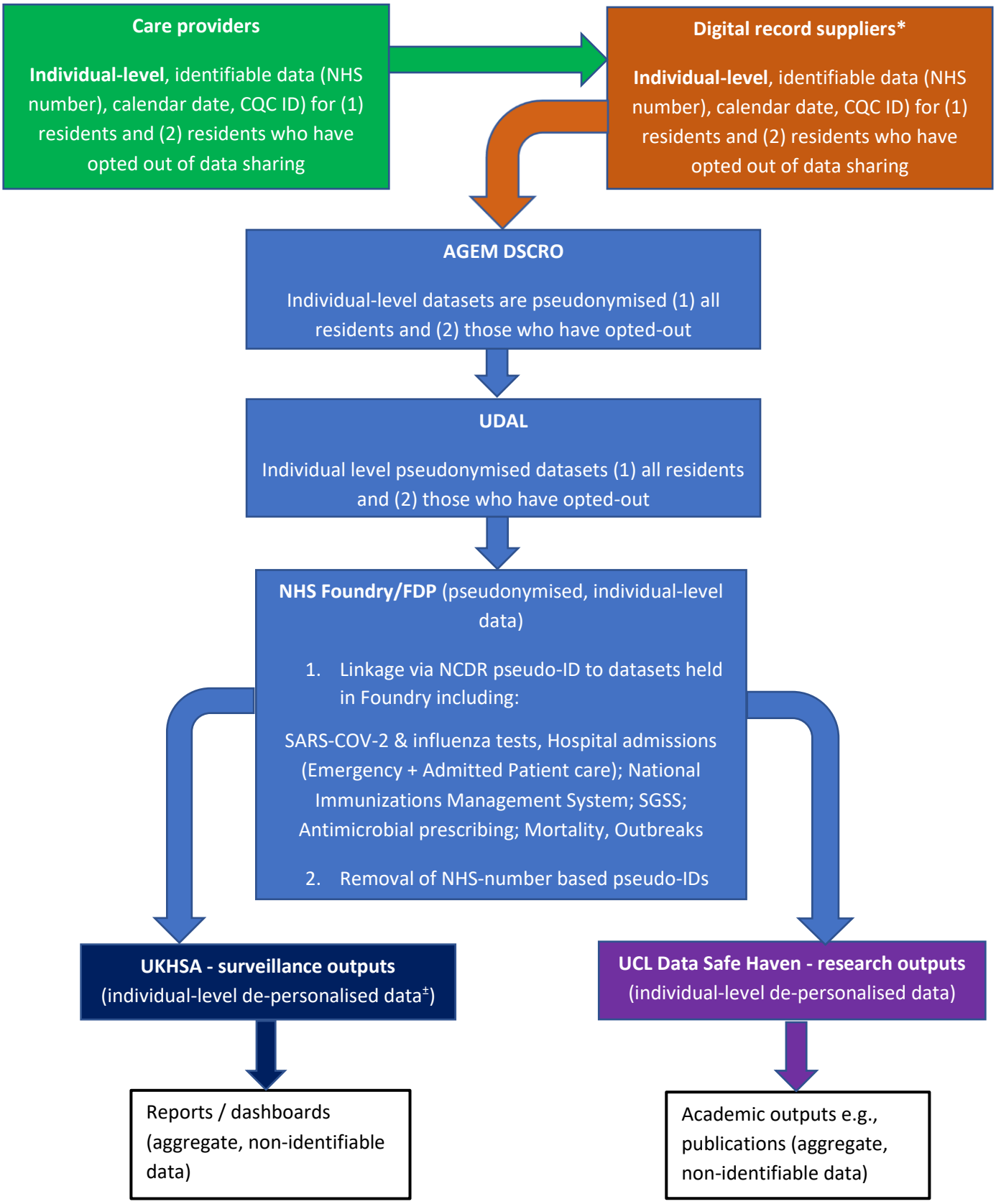
We will establish two drives within the UCL DSH to store the data. The first drive will include the CQC-ID's for participating care homes. This is because there may be some projects e.g. qualitative studies where it would be extremely valuable to use the research database as a sampling frame. Approval to access CQC-IDs by the Data Access Committee would only be granted on a case-by-case basis and no publications or reports will be permitted to reveal to identity of specific care homes. Access to this first data share will be restricted to the study CI and the clinical lecturer only.

We will establish a second data share in which CQC-IDs have been replaced with data on the location of the care home (less identifiable). This second share will be available for researchers following approval of their projects by the Data Access Committee.

The Data Safe Haven where the research database will be held has been certified to the ISO27001 information security standard and conforms to NHS Digital's Information Governance Toolkit. Built using a walled garden approach, where the data is stored, processed, and managed within the security of the system, avoiding the complexity of assured end point encryption. A file transfer mechanism enables information to be transferred into the walled garden simply and securely. Only named researchers who are part of the research team will have access to the research database within the DSH. All researchers seeking to use the DSH are required to complete regular training in information governance.

Professor Mark Emberton, Dean of the Faculty of Medical Sciences at UCL will be the data custodian. The dataset will be stored for 10 years. It will be destroyed securely in the data safe haven using a software-based data erasure method, which overwrites free space on a hard disk or another storage media with a 3-pass overwrite.

VIVALDI SOCIAL CARE – DATA FLOWS



AGEM Arden & GEM; UDAL Unified Data Access Layer; SGSS Second Generation Surveillance System

UKHSA UK Health Security Agency; CQC Care Quality Commission; NHS National Health Service

UCL University College London; NHSE FDP Federated Data Platform

±May be feasible for UKHSA outputs to be created in Foundry.

*Data sharing following approval from the relevant care provider.

11. PEER AND REGULATORY REVIEW

The study has been peer reviewed in accordance with the requirements outlined by UCL.

The Lead Institution considers the procedure for obtaining funding from UKHSA and NIHR to be of sufficient rigour and independence to be considered an adequate peer review.

The study was deemed to require regulatory approval from the following bodies: NHS REC Favourable Opinion and CAG Approval before any site can collect research data. The Chief Investigator or designee will ensure that the appropriate regulatory approvals have been issued.

For any amendments to the study, the Chief Investigator or designee, in agreement with the Lead Institution, will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments as well as the study delivery team) to confirm ongoing Capacity and Capability for the study.

All correspondence with the Lead Institution, REC and HRA will be retained. The Chief Investigator will notify the Lead Institution and REC of the end of the study.

It is the Chief Investigator's responsibility to produce the annual progress reports when required; an annual progress report (APR) will be submitted to the Lead Institution and REC within 30 days of the anniversary date on which the favourable opinion was issued, and annually until the study is declared ended.

If the study is ended prematurely, the Chief Investigator will notify the Lead Institution and REC, including the reasons for the premature termination.

Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the Lead Institution and to the REC and HRA.

12. ASSESSMENT AND MANAGEMENT OF RISK

The main risk is that there is a breach of residents' personal data and consequent reputational risk for the research team and loss of trust from care home stakeholders. This could happen in the following ways:

1. When digital care record vendors upload identifiable data on care home residents to NHSE (this risk is low as care record suppliers are extremely experienced in handling personal data securely and will use an automated data feed).
2. When care providers send a list of residents who are opting out of study participation to the software vendor (this is a potential risk, but likely to involve small numbers of residents. This will use an automated data feed in line with the main data transfer approach to minimise the risk of data breach). We will develop standardised operating procedures to further de-risk this process.
3. Cyber-attack on NHSE or unauthorised data access: NHSE will pseudonymise the dataset minimising this risk if there was a data breach. NHSE are highly experienced in data security.
4. When pseudonymised data are transferred from NHSE to UCL: Data will be downloaded by the CI on to an encrypted memory stick and then uploaded securely to the UCL DSH using a secure file transfer protocol.
5. Cyber-attack on UCL DSH / unauthorised data access: Dataset will be de-personalised. Only named, trained members of the UCL research team will have access to the research database within the DSH. The DSH has been certified to ISO27001 information security standards and uses a walled garden approach to minimise risk of unauthorised data access. This includes preventing customers from accessing external network resources while using the DSH, prevention of accidental or deliberate data transfer to endpoint device by disabling copy & paste and connected storage. The security boundary is also protected by a commercial threat management product.

Mitigations

A DPIA has been completed by NHS England and UCL in relation to this project. The CI has also liaised extensively with NHSE's and UCL's Information Governance and data management team about this project to design the data flows. A DPA will be put in place between UCL/Care England / The Outstanding Society and NHSE before the study starts.
The following measures will be put in place to minimise risk in relation to participants personal data:

1. Identifiable data will be uploaded to NHSE by digital care suppliers rather than care providers themselves. Suppliers are extremely well versed in data security and information governance whereas as many care providers have less expertise in this domain. This approach minimises the risk that of a data breach when personal data is transferred into NHSE.
2. Data pseudonymisation will be undertaken by NHSE who have extensive experience in information governance and data security. No identifiable data will be received by UCL.
3. A copy of the pseudonymised, de-personalised dataset will be transferred to UCL and stored in the UCL Data Safe Haven where it will only be accessed by trained, named researchers. This minimises the risk of data breach.
4. The UCL research team will comply with standard IG procedures in the DSH to reduce the risks of unauthorised data access e.g Joiner, Mover, Leaver reviews, auditing compliance with IG training.
5. We have and will continue to undertake extensive engagement with care homes that are participating in the study to ensure residents and families are aware about the study and that we are using their data without consent. We have developed opt-out pathways with NHSE

and the digital vendors and have engaged with care homes to ensure this process is acceptable and practical. This will help to ensure people have the opportunity to opt out of sharing their data if they would like to.

6. The research team has experience of working in these secure environments and collaborating with care homes and NHSE to share personal data through the VIVALDI study.

12.1 Personal Data Breaches

Personal data breaches will be immediately reported to the UCL Information Security Group (ISG) and the UCL Data Protection Officer [data-protection@ucl.ac.uk], (as per form and guidance: https://www.ucl.ac.uk/legal-services/guidance/reporting-loss-personal-data), and to the Lead Institution via the UCL REDCAP incident reporting form (https://redcap.slms.ucl.ac.uk/surveys/?s=NE5dypTdFo). The following information will be provided: full details as to the nature of the breach, an indication as to the volume of material involved, and the sensitivity of the breach (and any timeframes that apply). Sites will additionally follow their Trust incident reporting mechanisms, and will document this within their TMF/ISFs.

12.2 Protocol deviations and notification of protocol violations

A deviation is usually an unintended departure from the expected conduct of the study protocol/SOPs, which does not need to be reported to the Lead Institution (as per the JRO non-CTIMP Research Incident Reporting SOP). The CI will monitor protocol deviations, and if found to frequently recur, will discuss in the first instance with the Lead Institution to determine re-classification and reporting requirements.

A protocol violation is a breach which is likely to effect to a significant degree –

(a) the safety or physical or mental integrity of the participants of the study; or

(b) the scientific value of the study.

The CI and Lead Institution will be notified immediately of any case where the above definition applies during the study conduct phase via the JRO REDCAP Research Incident Reporting Form (https://redcap.slms.ucl.ac.uk/surveys/?s=NE5dypTdFo) or research-incidents@ucl.ac.uk.

All protocol deviations and violations will also be recorded on the 'Protocol Deviations and Violations Log' which will be filed in the TMF/ISF (the JRO will provide the template for this Log).

12.3 Incidental Findings in Research

Not applicable to this study.

12.4 NHS Serious Incidents and near misses

Serious Incidents and near misses must be reported to the Trust through DATIX as soon as the individual becomes aware of them. A reportable serious incident is any unintended or unexpected

event that could have or did lead to harm, loss or damage that contains one or more of the following components:

a) It is an accident or other incident which results in injury or ill health.
b) It is contrary to specified or expected standard of patient care or service.
c) It places patients, staff members, visitors, contractors or members of the public at unnecessary risk.
d) It constitutes a breach of personal data (i.e. a breach of GDPR).
e) It puts the Trust in an adverse position with potential loss of reputation.
f) It puts Trust property or assets in an adverse position or at risk of loss or damage.

Serious Incidents and near misses will be reported to the Lead Institution and Trust Quality & Safety department as soon as the study team becomes aware of them.

12.5 Complaints from research participants

In the first instance, research participant complaints (patients or healthy volunteers) will be reported to the CI/PI to investigate, as documented in the patient information sheet(s), and to the Lead Institution via research-incidents@ucl.ac.uk, following the *UCL Complaints from Research Subjects about UCL Sponsored Studies and Trials* policy. For participants who are NHS patients, complaints will be reported to the NHS Complaints Manager at the Trust where the recruitment and study procedures was undertaken. Complaints from NHS patients are handled under NHS complaints policies and procedures, with involvement from PALS the Lead Institution where necessary.

13 MONITORING AND AUDITING

The Chief Investigator will ensure there are adequate quality and number of monitoring activities conducted by the study team. This will include adherence to the protocol, procedures for consenting /obtaining and using data as per the CAG application and approval/ and ensure adequate data quality.

The Chief Investigator will inform the Lead Institution should he/she have concerns which have arisen from monitoring activities, and/or if there are problems with oversight/monitoring procedures.

14 TRAINING

The Chief Investigator will review and provide assurances of the training and experience of all staff working on this study. Appropriate training records will be maintained in the TMF/ISF.

15 INTELLECTUAL PROPERTY

All background intellectual property rights (including licences) and know-how used in connection with the study shall remain the property of the party introducing the same and the exercise of such rights for purposes of the study shall not infringe any third party's rights.

All intellectual property rights and know-how in the protocol, the study data and in the results arising directly from the study, but excluding all improvements thereto or clinical procedures developed or used independently of the study by each participating site, shall belong to UCL. All intellectual property rights deriving or arising from the material or any derivations of the material provided to UCL by the participating site shall belong to UCL. Each participating site agrees that by giving approval to conduct the study at its respective site, effectively assigns all such intellectual property rights ("IPR") to UCL and discloses all such know-how to UCL.

Nothing in this section shall be construed so as to prevent or hinder the participating sites from using its own know how or clinical data gained during the performance of the study, at its own risk, in the furtherance of its normal activities of providing clinical care to the extent that such use does not result in the disclosure or misuse of confidential information or the infringement of an intellectual property rights of UCL, or their funder. This section does not permit the disclosure of any of the study data, all of which remain confidential until publication of the results of the study.

A separate agreement that will be drafted with the funder as part of the research contract will also outline intellectual property arrangements.

16 INDEMNITY ARRANGEMENTS

University College London holds insurance against claims from participants for harm caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, as this clinical study is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the clinical study. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of care home employees. This applies whether the care home is an NHS Trust or otherwise.

Participants may also be able to claim compensation for injury caused by participation in this clinical study without the need to prove negligence on the part of University College London or another party. Participants who sustain injury and wish to make a claim for compensation should be advised to do so in writing in the first instance to the Chief Investigator, who will pass the claim to the Lead Institution's Insurers, via the Lead Institution's office.

Care homes selected to participate in this clinical study shall provide clinical negligence insurance cover for harm caused by their employees and a copy of the relevant insurance policy or summary shall be provided to University College London upon request.

Additionally, UCL does not accept liability for sites such as GP surgeries in primary care; investigators/collaborators based in these types of sites must ensure that their activity on the study is covered under their own professional indemnity.

17 ARCHIVING

UCL and each participating site recognise that there is an obligation to archive study-related documents at the end of the study (as such end is defined within this protocol). The Chief Investigator confirms that he/she will archive the study master file at the UCL Institute of Health Informatics for the period stipulated in the protocol and in line with all relevant legal and statutory requirements. The Principal Investigator at each participating site agrees to archive his/her respective site's study documents in line with all relevant legal and statutory requirements. Study documents will be archived for a minimum of 5 years from the study end, and no longer than 20 years from the study end.

The Trial Master File will be archived at UCL, in accordance with the UCL Retentions Schedule and Policy. It will be archived for a minimum of 5 years from the study end, and no longer than 20 years from study end.

NB: UCL data Protection office do not archive student projects and therefore, the length of storage is not subject to the standard Lead Institution requirement.

18 PUBLICATION AND DISSEMINATION

Dissemination of outputs to key stakeholders will use the engagement workstreams outlined earlier in the protocol. Results of analyses conducted using the VIVALDI Database will be published in peer-reviewed academic journals in a timely manner and posted on pre-print sites in cases where results are required to rapidly inform policy decisions. Results will also be presented to policy-makers, academics, clinicians, and providers at national care conferences, academic infection conferences, and regular meetings with policy-makers within UKHSA, DHSC & NHSE. Dashboards and surveillance reports will be accessible to key stakeholders including care providers and public health officials within UKHSA and policy-makers in DHSC. Student projects conducted using this dataset e.g., PhD theses, MSc dissertations, will be reviewed by the CI before submission for publication or further dissemination, to ensure results are accurate. These will be published in line with the university's academic guidelines and in peer-reviewed journals, if they are of sufficient quality and impact. Authorship will be determined based on individual contributions, with the aim of recognising academic inputs across collaborators.

Data arising from the study will be owned by UCL, Care England, and the Outstanding Society. There are no terms or conditions relating to funding which may impact upon publication and dissemination. NIHR and UKHSA funding will be acknowledged in any publications reporting from the database however neither body will review outputs prior to publication. On study completion, a Final Study Report will be generated consisting of analyses of final dataset and data tabulations, and a list of studies that have used the dataset. This report and the study protocol will be published on the UCL VIVALDI website and will be made publicly available. The duration will be determined by the Data Access Committee however maximal duration will be five years.

We will notify participants of study outcomes by disseminating a report at the end of the study which summarises the main outcomes. We will develop this in collaboration with the engagement workstream, and the VIVALDI PPI group to ensure that the results are clear and easy to understand

for the care home population, and to determine the best format for this e.g. video. This will also be published on the Vivaldi website and this link will be widely disseminated so that family members and the wider care population are able to access it. We will also send out thank you cards, participation certificates, and small gifts like biscuits or chocolates to participating care homes as a token of appreciation and to emphasise the value of participation. We have experience of doing this in VIVALDI however we will be guided by the care homes themselves on the exact format that these mementos take e.g., PDF that can be printed locally or emailed as appropriate, posters that are posted to care homes, etc.

19 REFERENCES

1. GOV.UK. Technical report on the COVID-19 pandemic in the UK [Internet]. 2022 [cited 2023 Jul 6]. Available from: https://www.gov.uk/government/publications/technical-report-on-the-covid-19-pandemic-in-the-uk

2. Bell D, Comas-Herrera A, Henderson D, Jones S, Lemmon E, Moro M, et al. COVID-19 mortality and long-term care: a UK comparison [Internet]. 2020 [cited 2023 May 10]. Available from: https://ltccovid.org/wp-content/uploads/2020/08/COVID-19-mortality-in-long-term-care-final-Sat-29-v1.pdf

3. Kinley J, Hockley J, Stone L, Dewey M, Hansford P, Stewart R, et al. The provision of care for residents dying in U.K. nursing care homes. Age Ageing [Internet]. 2014 [cited 2023 Jul 13];43(3):375–9. Available from: https://pubmed.ncbi.nlm.nih.gov/24132855/

4. Alzheimer's Society. Dementia UK Update [Internet]. 2017 [cited 2023 Jul 13]. Available from: https://www.alzheimers.org.uk/sites/default/files/migrate/downloads/dementia_uk_update.pdf

5. Schultze A, Nightingale E, Evans D, Hulme W, Rosello A, Bates C, et al. Mortality among Care Home Residents in England during the first and second waves of the COVID-19 pandemic: an observational study of 4.3 million adults over the age of 65. The Lancet regional health Europe [Internet]. 2022;14:100295. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=pmnm&NEWS=N&AN=35036983

6. Utsumi M, Makimoto K, Quroshi N, Ashida N. Types of infectious outbreaks and their impact in elderly care facilities: a review of the literature. Age Ageing [Internet]. 2010 Mar 23 [cited 2023 Jul 6];39(3):299–305. Available from: https://pubmed.ncbi.nlm.nih.gov/20332371/

7. Strausbaugh LJ, Sukumar SR, Joseph CL. Infectious disease outbreaks in nursing homes: An unappreciated hazard for frail elderly persons. Clinical Infectious Diseases [Internet]. 2003 Apr 1 [cited 2023 Jul 6];36(7):870–6. Available from: https://dx.doi.org/10.1086/368197

8. DACHA. DACHA Study [Internet]. 2023 [cited 2023 Jul 6]. Available from: http://dachastudy.com/

9. Stirrup O, Shrotri M, Adams NL, Krutikov M, Azmi B, Monakhov I, et al. Effectiveness of successive booster vaccine doses against SARS-CoV-2 related mortality in residents of Long-Term Care Facilities in the VIVALDI study. medRxiv [Internet]. 2023 Mar 3 [cited 2023 Jul 6];2023.03.01.23286627. Available from: https://www.medrxiv.org/content/10.1101/2023.03.01.23286627v1

10. Burton JK, Marwick CA, Galloway J, Hall C, Nind T, Reynish EL, et al. Identifying care-home residents in routine healthcare datasets: a diagnostic test accuracy study of five methods. Age Ageing [Internet]. 2019 Jan 1 [cited 2023 Feb 8];48(1):114. Available from: /pmc/articles/PMC6322499/

11. GOV.UK. Consensus statement on the association between the discharge of patients from hospitals and COVID in care homes [Internet]. 2022 [cited 2023 May 12]. Available from: https://www.gov.uk/government/publications/the-association-between-the-discharge-of-patients-from-hospitals-and-covid-in-care-homes/consensus-statement-on-the-association-between-the-discharge-of-patients-from-hospitals-and-covid-in-care-homes

12. Burton JK, Wolters AT, Towers AM, Jones L, Meyer J, Gordon AL, et al. Developing a minimum data set for older adult care homes in the UK: exploring the concept and defining early core principles. Lancet Healthy Longev [Internet]. 2022 Mar 1 [cited 2023 Feb 8];3(3):e186–93. Available from: http://www.thelancet.com/article/S2666756822000101/fulltext

13. GOV.UK. A plan for digital health and social care [Internet]. 2022 [cited 2023 Jul 6]. Available from: https://www.gov.uk/government/publications/a-plan-for-digital-health-and-social-care/a-plan-for-digital-health-and-social-care

14. GOV.UK. UK 5-year action plan for antimicrobial resistance 2019 to 2024 [Internet]. 2019 [cited 2023 Jul 6]. Available from: https://www.gov.uk/government/publications/uk-5-year-action-plan-for-antimicrobial-resistance-2019-to-2024

15. Rosello A, Hayward AC, Hopkins S, Horner C, Ironmonger D, Hawkey PM, et al. Impact of long-term care facility residence on the antibiotic resistance of urinary tract Escherichia coli and Klebsiella. J Antimicrob Chemother [Internet]. 2017 [cited 2023 Jul 6];72(4):1184–92. Available from: https://pubmed.ncbi.nlm.nih.gov/28077671/

16. Wittenberg R, Hu B, Barraza-Araiza L, Funder AR. CPEC Working Paper 5: Projections of older people with dementia and costs of dementia care in the United Kingdom, 2019–2040 [Internet]. 2019 [cited 2023 Jul 6]. Available from: www.modem-dementia.org.uk

20 APPENDICES

Include here **a list** of the supplementary information and documents that will support the protocol and information contained therein, e.g. PIS, ICF, schedule visit, assessment tools, delegation log, case report forms, questionnaires, scales, tables, charts, diagrams, manufacturer's brochures.

It is not advisable to insert copies of documents such as the PIS and ICF due to version control and document management issues. You may wish to list the document titles here or delete if unnecessary.

21 ASSOCIATED DOCUMENTS

Include here supplementary information and documents that will support the protocol and information contained therein.

E.g. data dictionary

Document Name	Document Version	Document Date
VIVALDI Glossary	1	18/07/2023
CAG leaflet residents	1	18/07/2023
CAG leaflet relatives	1	18/07/2023
CAG poster	1	15/08/2023
Vivaldi Social Care Detailed Information Sheet	1	18/07/2023
Data Flow Diagram	1	18/07/2023
Appendix 1: Inventory of engagement activities	1	18/07/2023
Appendix 2: Letter of support Care Rights UK	1	17/07/2023
Appendix 3: DACHA NAPA Toolkit for APs	1	
Appendix 4: Working Group Sept-Dec 2022, membership and ToR	1	
Appendix 5: Engagement Workstream, ToR	1	
Appendix 6: Governance and Oversight workstream, ToR	1	