The five safes framework

1	2	3	4	5
Safe people	Safe projects	Safe settings	Safe data	Safe outputs
• Can the researchers be trusted to use the de-personalised data in an appropriate way? (i.e. with a view to generating benefits that serve the 'public good' and improving health and / or health care) • Grey areas might exist when there are also other benefits that might be realised (e.g profit from the development of a new drug)	• Is the use of de-personalised data appropriate? (e.g. its use is intended to improve health and / or health care?) • Grey areas might exist when 'exploitation of data' may be acceptable if an overall 'public good' is realised (e.g. commercial profit)	• Does the authorised facility (e.g. an NHS trust, or a health data research hub) limit unauthorised use? • In some cases researchers are restricted to using the data in a supervised location. In other cases information is shared via secure transfer if the accessor passes certain criteria.	• Is there a risk of identification? Whilst direct identifiers such as names and addresses have been removed, and the data is depersonalised, it is not completely anonymous. • However, if other standards described here are met, does this provide assurances that this data is safe to use for these purposes?	• Are the results from analysis of the data 'non-disclosive' when published? (i.e. can the accessor ensure there is no risk of identification?)

Case study 4 – Reviewing eye scans

A doctor from a London-based NHS specialist eye hospital is facing an urgent clinical problem: *"The number of eye scans we're performing is growing at a pace much faster than human experts are able to interpret them. There's a risk that this may cause delays in the diagnosis and treatment of sight-threatening diseases, which can be devastating for patients."*

The NHS hospital partners with a globally recognised technology company to explore whether machine learning technology can be trained to identify signs of eye disease and recommend how patients should be referred for care. The researchers employed by the tech firm work alongside clinicians to review thousands of historic de-personalised scans within the hospital setting. No data is downloaded or leaves the hospital.

The researchers discover technology that can recommend the correct referral decision for over 50 eye diseases with 94% accuracy, matching world-leading eye experts. It is hoped that the technology could revolutionise the way health professionals carry out eye tests. Although clinicians would still have to review scans, the technology would allow them to spot conditions earlier and prioritise patients with the most serious eye diseases before irreversible damage sets in.

Case study 5 – A&E attendances

A UK-based University wants to conduct research to understand the circumstances around cases where patients visit A&E for problems that could have been managed by a GP, in order to identify potential solutions that might reduce unnecessary A&E visits, ensuring patients are able to receive the right care, in the right place.

To undertake this research, the University requires access to depersonalised data for all patients who had one or more A&E visit over a 12-month period, including clinical information (e.g. the reason for the visit to the A&E department, reason for discharge) and patient information (e.g. age group, gender and ethnicity).

The University submits an application to the NHS explaining how the study will benefit health and social care. This is reviewed by an independent body that includes patient representation. The University must also show how it will keep the data safe, for example providing evidence that the data will be hosted in a secure environment. Once approved, the University is sent the depersonalised data it needs for the study.

Case study 6 – New drug for diabetes

A clinical researcher (a researcher who designs and runs clinical trials) based in the NHS is working with a pharmaceutical company (companies that make medicines, such as GlaxoSmithKline, Pfizer, AstraZeneca) to trial a new innovative drug that is designed to manage diabetes when a patient also has cardiovascular disease (CVD), e.g. heart disease or stroke.

To see if it is possible to run a trial, the clinical researcher and pharmaceutical company need to undertake a feasibility study to understand how many people might benefit from this type of new treatment and further understand the group of patients that could be invited to participate in the trial.

They are granted access to depersonalised data in a secure NHS setting so they can look at how many people are living with diabetes who also have CVD, and who meet certain criteria (e.g. age, what current medications they are on) relevant for the trial. From this information they are able to see that it is worth progressing with the trial.