

## Structure of medConfidential's response to the ASH consultation

This response from medconfidential is in several parts. Published for debate and discussion a few weeks ago, and minimally updated, is a document entitled "A substantive proposal based on a designed process incorporating safe settings.", which builds on our proposal for safe settings for research ( "Towards a Health Research Remote Data Laboratory (HRRDL) some implementation details" ).

From discussion around that document, it is clear that there is a highly varied understanding of both what safe settings/havens can be, and the governance that is required for them to be considered safe and transparent.

As such, this consultation includes two additional parts. One is a detailed response to the consultation, and the issues it raises ("medConfidential response to the DH consultation on Protecting Personal Health and Care Data"), and the second part is a wider look at the data, processes and perspectives that will lead to the potential failure of a bad ASH implementation, and how that can be avoided -- beginning to look at how to deliver the substantive proposal from the current state - "*Getting to safe settings from the status quo*".

All of these are based on a paper originally drafted for HSCIC and care.data, looking at how HSCIC could implement a research remote data laboratory for individual level medical records. We continue to believe, and have seen no evidence to disprove, that this is possible. HSCIC work is continuing on the practicalities, and we look forward to continuing to engage with that work to ensure it meets the requirements of all stakeholders, including the public whose medical records will be contained within.

Less positively, it is also possible to design a "safe haven" following the model of the 1990 Argos catalogue for operation in 2014's amazon world. That can not be safe, and can not be transparent. While an appropriate model and separation of functions can be done both well and safely, decisions and incentives need to be addressed starting at the top. That is not always the case<sup>1</sup>.

To be clear, **if the "Accredited Safe Havens" being proposed are not properly constructed and governed, that will potentially bring the idea of a "safe setting" for health data into disrepute in the eyes of the public.** That will be potentially catastrophic for public trust in both the health research envisaged by care.data, the genomics work envisaged by Genomics England, and other research using properly constituted data laboratories.

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<sup>1</sup> e.g. <http://www.bmj.com/content/349/bmj.g4353>