

CONSULTATION QUESTIONS

Are you responding *primarily* as a data custodian, data user or data subject? (We recognise all people are data subjects and many organisations act as data guardians and data users, but please tick only one box)

- Data Custodian
- Data User (e.g. researcher)
- Data Subject (e.g. member of the public or group representing citizens)

The research-based medicines and vaccines sector welcomes the consultation, the proposals and the constructive tenor of the document.

There is nothing in the paper that precludes partnership working with industry. Indeed, the industry is keen to enter into detailed dialogue on working with the public sector information gatherers around data linkage.

1. Are there any benefits of data linkage for statistical and research purposes that are not sufficiently described here?

Yes, there are further benefits No, the benefits are described fully

If you ticked 'yes', please describe the further benefits of data linkage for statistical and research purposes.

- 1) Scotland's unique CHI (Community Health Index) numbering system allows tracking of treatments to prove that they are fit for purpose. This has a significant economic potential for Scotland in terms of attracting longitudinal tracking of the benefits of a medicine or treatment in a way that is not possible in most other European jurisdictions.
- 2) Promising progress is currently being made on an initiative to make medicines usage statistics collected by the ISD of NHS National Services Scotland available in an agreed form to the industry. Already pilots for three medicines are being undertaken to work out the practicalities of gathering the data. Some of the issues resolved in the development of this work around the protection of identity of patients and NHS users will be important to inform the wider work to broaden data linkage.
- 3) For commercial entities the opportunity exists for the costs of the data gathering process to be defrayed through an open and transparent charging mechanism such that carefully anonymised data can be shared with industry researchers. We would therefore suggest that there would be a benefit in terms of income for data gatherers.

2. Are there challenges or barriers preventing more effective and efficient data linkages for statistical and research purposes taking place that are not sufficiently described here?

Yes, there are further challenges No, the challenges have been identified

If you ticked 'yes', please describe the challenges or barriers.

We would commend the CHI system and suggest that it not be undermined in any way when moving to any harmonised system.

There needs to be a mechanism that allows a route to access to data for commercial researchers, for instance those running a long term "real world/post launch" clinical trial. We would welcome an explicit statement from the Scottish Government that there is no expectation that academics only should have access to data as, although medicines and vaccines industry staff operate in academic environments, they can be separate from universities and such a restriction to academics only would limit the speed and reach of the process.

3. Are the guiding principles sufficient and appropriate? Please explain your answer fully and make suggestions for improvement.

Yes, they are sufficient and appropriate No, they are not

Please explain your answer fully and make suggestions for improvement.

ABPI Scotland has no comment to make on this question.

4a. Are the objectives set out for a Privacy Advisory Service in Section 3c the right ones?

Yes, the objectives are right

No, they are not

Please explain your answer fully and make suggestions for improvement.

ABPI Scotland has no comment to make on this question.

4b. Do you wish to be consulted on firmer proposals for a Privacy Advisory service as and when they are developed?

Yes No

5a. Are the functions that will be led by the National Data Linkage Centre set out in section 3d the right ones?

Yes, they are the right functions

No, they are not

Please explain your answer fully and make suggestions for improvement.

The research-based medicines and vaccines industry would be keen that there be consideration of whether there could be a reduced number of bodies to which applications for data need to be made. There may be some merit in the National Data Linkage Centre having a “clearing house” role as a single portal for researchers to approach. We know that other organisations find the NHS difficult to navigate and a single entry point would be attractive and another positive differentiator to set Scotland apart when competing against other jurisdictions for research investment.

5b. Do you wish to be consulted on firmer proposals for a National Data Linkage Centre as and when they are developed?

Yes No