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| **ABPI data governance principles consultation** |

Your feedback

Each principle is accompanied with some background information to support feedback. We would welcome comments against specific principles, and there is an opportunity to leave more general comments at the end of this survey.

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**Question Title**

**Principle 1:**  
  
**Transparency of purpose:** Industry will be clear and open about what company researchers aim to do with health data; how the data will be analysed, what the expected benefits are and how risk will be managed.  
  
*Background: Considering the complex process of research, discovery, development and deployment of new medicines, analyses of health data can help move the process forward at all stages. For example, analysis of various health datasets can help any of the following:*  
  
*o   Understanding disease processes and progression, identifying which patients respond best to different approaches and interventions, and defining current ‘unmet need’*  
  
*o   Identifying new biological targets, and designing new medicinal interventions*  
  
*o   Stratifying and selecting the right patients for clinical trials to develop new medicines*  
  
*o   Supporting delivery of precision medicines to the right patients*  
  
*o   Assessing the performance and cost effectiveness of medicines in routine clinical practice, and identifying indicators of variable response*  
  
*o   Analysing and refining patient pathways to ensure the best patient outcomes for different patient groups, and to support equality of access to the best pathways for the best patient outcomes*  
  
*All industry data analysis projects will be described in a short abstract covering aims, approach, anticipated benefits and risks that can be posted on a public database or website hosted by the data custodian and/or the researching organisation.*  
  
**Do you have any specific comments on this proposed principle?**

FPM would recommend that an abstract must be provided in plain language and in suitable translations and accessible versions. It is important to highlight the commitment to disseminating findings upon completion of projects. Planned timelines should also be provided.

The ABPI code highlights the need for transparency and was recently extended to registries and retrospective studies. IFPMA provides recommendations for posting details of the studies. FPM would recommend that the abstract *must* be posted publicly. Transparency of this information about projects is important in supporting public confidence. Having information distributed across multiple organisations’ websites, probably of variable quality, may mean it's not easy to find. We would recommend the provision of a single, centralised registry.

**Question Title**

**Principle 2:**  
  
**Clarity of arrangements:** Contractual arrangements with data custodians will be designed to return ‘fair value’ as agreed by both parties, with the goal of contributing to the sustainability of the system (recognising the costs associated with collecting, validating, curating, storing, and analysing the data), regardless of whether the outcomes of individual projects are positive or negative.  
  
*Background: There is a huge potential variety of projects analysing health datasets for different purposes. These can range from a single analysis at a point in time, to a regular follow-up at specified intervals to explore trends, to analysis of linked datasets through to a partnership with a custodian to explore detailed understanding of disease over a period. The costs associated with curating and managing the data vary, depending upon the scale, detail and duration of longitudinal follow-up. It will be important that the custodian(s) and researchers can efficiently reach a common understanding of what any project seeks to achieve, share the legal basis for data use and analysis, the model of commercial arrangements, and the data architecture including whether or not a Trusted Research Environment (TRE) is used. This should be publicly available including:*  
  
*o   The legal basis for data use and analysis*  
  
*o   The commercial model (eg fee for service, license of data, shared benefit/risk) excluding pricing*  
  
*o   The data architecture (eg where the data will be stored, processed and analysed and how access will be controlled)*  
   
  
**Do you have any specific comments on this proposed principle?**

FPM would seek clarity on how ‘fair value’ is defined. The ‘commercial model’ information made public should also include whether the agreement is for a one-off access to data or regular data release updates. Under the ‘data architecture’ information it will be important to clarify that the data will be deidentified and anonymised and that data will be available for the duration of the project only or for ‘n’ months afterwards, with possibilities of extension, and whether the data will be destroyed after project completion.

**Principle 3:**  
  
Patient and Public Involvement and Engagement (PPIE): Industry will support the trend towards efficient involvement of patient/public representatives in the design and approval of health data projects, whether within their organisations or when projects are reviewed by data custodians.     
  
*Background: Data custodians are now more frequently involving patient and public representatives in reviewing applications from data ‘users’ – those who wish to research and analyse their datasets. There is a wide range of types of data analysis project supporting research, discovery, development and evaluation of medicines, and these projects may be undertaken by researchers and analysts in biopharmaceutical companies as well as from academia, the NHS and charities etc.*  
  
*As PPIE becomes increasingly embedded in the overall design of development programmes for new medicines, involvement of patients in design of individual data projects should become increasingly routine; and demonstrating such PPIE should help ensure projects are accepted first-time by data custodians’ review panels.*  
  
**Do you have any specific comments on this proposed principle?**

FPM does not think that the wording of this principle goes far enough - ‘support the trend’ sounds too passive and there needs to be a strong call for all parties to demonstrate they are actively undertaking PPIE for these projects, particularly industry, not just ‘supporting’ it.

We would recommend an emphasis on ‘efficient *and effective* involvement of patient/public representatives’. Being efficient about things could become just a tick box exercise and doesn't necessarily mean that it's *effective* involvement. Further guidance should be provided in terms of expectations of efficient and effective involvement, the level of engagement expected, and methods to best facilitate PPIE when researchers first contact the data custodians.

**Principle 4:**  
  
**Non-exclusivity of arrangements:** Benefits accruing will be applied across the UK health service, for the benefit of all appropriate patients, hence supporting the principle that any dataset should be available for analysis by any bona fide researchers at any time.  
  
*Background: Industry supports the principle that all health data collected in and by organisations within the NHS should be readily and equally available for all bona fide research projects. Given that the anticipated benefits of analysing health data will be improving individual patient outcomes; and/or improving patient pathways and hence the efficiency of the NHS; and/or supporting development of new medicines with improved efficacy/safety profiles, all of these benefits should become available to all relevant patients across the whole NHS. Analyses of Real World Data has the potential to significantly help in addressing health inequalities. To ensure this can be achieved, companies will not ‘buy’ or ‘own’ specific datasets (ie become a data custodian) at the expense of these datasets being readily available to other researchers, or for the purpose of the company being the sole beneficiary (commercial or otherwise) of the insights gained.*  
  
**Do you have any specific comments on this proposed principle?**

The term ‘benefits accruing’ is a bit vague and need further definitions. We believe it to mean benefits in terms of new knowledge arising, and shared with the NHS, from a given dataset. However:

a) some benefit of some analyses will be to the company using the data and some of these will surely remain proprietary

b) some benefit to the NHS may not be knowledge (which should be shared) but instead be financial & might not necessarily be shared - e.g. if one trust goes out of its way to provide good quality data on a topic, it might be legitimate for it to be financially rewarded for that & not share the income.

It is unclear why these principles should be restricted only to data collected within NHS, they should apply to all public resources, including, for instance, the Private Healthcare Information Network.

**Principle 5:**  
  
Compliance with prevailing laws and regulations: All projects and arrangements will adhere to national level legal, regulatory, privacy and security obligations.  
  
***Background:****All researchers will collaborate fully with data custodians to ensure that all analyses of health datasets are conducted within existing national laws and regulations. Each project must be clear as to the legal basis for undertaking the data analysis. While the basis for managing data within traditional clinical trials has always been that of ‘informed consent’, many analyses of health data are now conducted on different legal bases. The way this is covered under the UK GDPR provisions is currently the subject of a DCMS consultation; industry commits to comply with whatever laws and regulations are current at any given time.*  
  
*The NHS offers patients the opportunity to opt out of data re-use. Industry supports the right of patients to opt out and will consult with data controllers to ensure that no datasets analysed include data from patients who have opted out.*  
  
**Do you have any specific comments on this proposed principle?**

No

**Do you have any general comments about these draft principles?**

There are existing principles from the Office for Data Release (ODR) which should be considered here to avoid ambiguity or contradictions.