



## BioMed Alliance reaction to opt-out model proposed in EHDS negotiations

The Biomedical Alliance in Europe (BioMed Alliance), a unique initiative of 36 medical and research societies, has followed the legislative discussions on the European Health Data Space (EHDS) proposal with great interest. We very much welcome the initiative to facilitate health data sharing for healthcare and research, as we believe both will generate significant added value for patients.

Healthcare professionals and researchers represented within BioMed Alliance believe that we should reduce barriers to health data sharing, while putting in place the appropriate safeguards and maintaining a harmonised approach across the EU. We believe that the proposal from the European Commission on the EHDS already provides the necessary safeguards to ensure the privacy of citizens is protected, by facilitating data sharing for secondary use either in anonymised form or, when deemed absolutely necessary, in pseudo-anonymised form in a secure processing environment.

We welcome the approach of the Commission, as BioMed Alliance considers an opt-in model to be a barrier to life-saving (academic) health research because consent-based procedures are unworkable for both researchers and healthcare professionals, will do much scientific damage (data will be incomplete, thus not representative, and conclusions will often be wrong), and will thus not advance, and can even damage, the health of European citizens.

Following ongoing discussions in the European Parliament and the Council, an opt-out approach has been discussed to provide citizens with the right to be excluded from the EHDS. **While BioMed Alliance believes that the privacy of citizens is already sufficiently protected in the Commission proposal, an opt-out approach could be a way forward to achieve compromise, if this approach is implemented properly.**

### Our views on an opt-out option for citizens under the EHDS:

- We believe the Commission is already putting in place the necessary safeguards to protect the privacy of citizens in the EHDS proposal, and note that a broad inclusion of EU citizens is necessary for the data to have a concrete positive impact on health research performed by healthcare professionals, researchers and e.g. academia and medical societies.
- If an opt-out model is put in place, it needs to be rolled out in a harmonised format across Europe with the necessary detailed governance compliance rules and safeguards, along with guidance to ensure uniform implementation across Europe.
- We note that an opt-out model may not work for all types of data included in the scope of the EHDS, e.g. with the use anonymised data, the privacy of citizens is already almost fully protected and an opt-out clause will not have an added benefit. In addition, we believe that a retroactive opt-out will be extremely challenging to implement particularly in the case of ongoing or completed health research activities.
- Citizens need to be appropriately informed on the benefits and impact of sharing their health data, and on the safeguards that are put in place to protect their privacy so they can make an informed decision about the use of their data.
- An opt-out model must not contribute excessively to the, often heavy, workload that healthcare professionals already face, and they must receive the necessary guidance to assist their patients in making an informed decision.
- Ethical principles may need further elaboration for the specific purposes of secondary use. This ethical oversight could be performed by the Health Data Access Bodies (in collaboration with ethical bodies and the European Data Protection Board) but they will need time to develop that competency and it will not come overnight.