

LIST OF PRINCIPLES RELATING TO THE OPERATION OF THE MEDICAL DEVICE INFORMATION SYSTEM

Governance

- To ensure joint four UK nation agreement to and control over the MDIS database, but with each nation retaining control over their own data;
- To have joint four UK nation agreement on the strategy, function, operation and direction to be followed by the proposed MDIS by close engagement in the development of regulations so that all can contribute to ensure the best possible integration of the MDIS with their national data collection arrangements.
- To be involved in agreeing the MDIS' reporting arrangements and procedures for handling disagreements /conflicts and how they would be resolved.
- To ensure that the full costs of setting up and operating the MDIS, including those to be incurred by the four UK nations, are accurately recorded and that full provision is made for them in the appropriate financial settlements.
- To have full involvement in the setting of common information standards such as data collection, quality and retention standards;
- To have full involvement in key decisions such as whether there should be a UK wide medical device registry and its specifications, sales of data to commercial organisations;
- To retain control of whether, when and by whom enforcement action should be taken and penalties imposed within each nation's jurisdiction.

Operational/Data

- To set up a joint agreement between the four UK nations for the identification of the data to be collected, how, by whom, the flow and usage of the data and provide for equal access to it, including the raw data, so that no one nation can do more with the data than another nation/country;
- To ensure early and meaningful engagement with patients, clinicians, the public and industry about the MDIS so that it is understood how their data is collected and used, recognising issues of consent and privacy and to agree how patients, clinicians, the public, industry and others could best access the data.