REGISTRY PRINCIPLES

ABHI is committed to the principles of evidence-based medicine and view well-designed and executed registries as an important component of the evidence base for medical devices, providing useful information about the safety (and efficacy) of medical interventions. The creation and long-term management of registries enables both industry and the clinical community to collaborate positively via an agreed framework.

Below are outlined the guiding principles that we believe registries should adhere to:

1. There should be a clear purpose, objective and analysis plan defined before data collection begins.
2. Data should only be asked for once, therefore consolidation is needed where there are multiple registries in the same field. Alignment with international registries should also be considered where appropriate.
3. Governance policies and written procedures for data ownership, data access, and data use must be established before initiation. All stakeholders views should be represented.
4. A system should be implemented to manage data requests prior to approving the release of any data to qualified scientific and medical researchers for purposes benefiting public health or patient care.
5. Only the minimum data necessary for meeting the stated objectives of the registry should be collected, with a clear, evidence based, rationale in place determining whether additional data is needed. When defining this requirement, all stakeholders views should be represented.
6. A registry must comply with all applicable laws and regulatory requirements.
7. Policies should be established for the use and publication of registry data to protect against unauthorised use and ensure transparency.
8. The sustainable funding of the registry should come from all stakeholders, with clear guidance in place as to how the data can then be accessed.
9. Industry should be involved in the registry governance process, and therefore be an active member in stakeholder steering groups.
10. Registries should be utilised after regulatory approval for the product and as part of an overall plan of post market clinical follow up. Through this, they can play an important role in ensuring the long-term safety of products.
11. A high level of compliance by all stakeholders is fundamental, with the appropriate level of commitment and resource allocated at clinical level to ensure the effective implementation of a registry.

Note: A register of all registries is recommended, which includes clear criteria as to how a registry can become formally accredited or validated by the system.