MINIMAL REGISTRY DATASET– 21/07/15

The preferred option would be for industry to have access to surgical procedure level raw data for all data-points. The following represents the minimal data-points required.

For each implantation of a given manufacturer's product (product codes and descriptions can be provided) we would require the following raw data-points. This will allow the manufacturers to conduct Kaplan-Meier survivorship analysis and other statistical analyses required for vigilance, PMS and ODEP submissions.

	Required Data-points
Patient	Registry Identifier number [a] Gender Age at index operation Date of birth Primary diagnosis ASA Grade
Operation	Date of surgery Hospital identifier [b] Surgeon identifier number [a]
Products	For all implanted devices [c] Product Code Lot/Batch Number [d]
Outcome	Latest status, select from: Revised/Unrevised/Death If revised: Date of revision Reason for revision [e] Actual components removed Actual components used in revision. If death: Date of death
Overall	Date and details of the data extract [f]

a Anonymous to industry, but ability for registry to identify in case of clinical safety issue

b Reference list supplied to industry

c To include cement, taper adapter, liner as appropriate.

d The product barcode supplies all of this information and reduces the risk of data entry error.

e If possible we would recommend use of ICD10 coding for revision reasons

f This is essential in order to calculate time in-vivo for unrevised implants. For audit purposes, the system should be able to provide the date and credentials of who did the extract as standard.