



EBMT AUDIT PROGRAMME 2008

I. **Background**

Data transmission from individual centres to EBMT registries has been based on mutual trust right from the start. This continues to be the basis for data transfer. However, verification of data is required today in many instances for scientific publications. Accreditation also depends on some control mechanisms. At the Annual Meeting in Vienna in 1996, the EBMT general assembly approved introducing an audit programme, which was successfully initiated in 1997. In 2003 the requirement to check for informed patient consent was added, to ensure compliance with EU directive (95/46/EC) regulating personal data.

II. **Objectives**

To ascertain the presence of an institutional unique patient number list (UPN list), verify consecutive case reporting and control accuracy of reported data, as compared to institutional medical records. To ensure compliance with EU directive (95/46/EC) regulating personal data.

III. **Audit operations**

EBMT members are subject to be audited once every three years. Ten institutions are first selected randomly. For each of these centres, a board or working party member near the institution is identified. The Principal Investigator is contacted and asked whether they accept the proposed Auditor. If the Principal Investigator perceives that there may be bias on the part of the selected auditor, they are given one week to request another auditor. Auditors are asked to sign a waiver stating that they have no political, financial, or other conflict of interest with the team to be audited and are then asked to contact the Principal Investigator directly to arrange a mutually convenient date for the audit to take place. This date should be immediately communicated to the Secretariat. Three weeks prior to the date of audit, the institution is notified of the 10 MED-A cases selected at random from among its contributions during the preceding five years. The audited institution in question is expected to have medical records, its UPN list, and all necessary supporting information gathered and available at the time of the audit for each of these ten cases.

a. **Verification of consecutive reporting**

Cases reported to the EBMT registries by the audited team for 2 previous years will be compared by the auditor with institutional records of all transplants performed in the last 5 years to verify that all eligible cases were reported. The auditor will verify that records of the transplant programme confirm reporting of all cases and will confirm the conduct of a UPN list. The UPN list will be compared with the EBMT Activity Survey submitted by the team for the two previous years.

b. **Verification of accurate reporting and consistent data**

At the time of the audit, the auditor selects five of the ten available cases for detailed review. For these five cases, all MED-A items reported will be compared with data in the institutional medical record. Deficits and discrepancies are documented by question number and discrepancy, using a form-specific check list prepared by the EBMT audit committee and data office. The total number of allogeneic and autologous transplants performed in the 2 years indicated on the centre's accreditation form will be specifically noted and compared with the accreditation submission form.

c. **Conformity with EU directive (95/46/EC) regulating personal data**

As of 1 September 2002 all new patients and patients attending for follow-up