EFI/ASHI Standards Accreditation

WBMT Workshop-WHO
Hanoi, 11 November 2011
HLA – The Responsibility
History ASHI/EFI

1974 Establishment of the Accreditation Committee ASHI
1976 Start of Laboratory Evaluations
1986 Upon recognition of the increasing diversity of histocompatibility testing and the growing number of laboratories seeking ASHI Accreditation, the ASHI Council charged the Accreditation Committee to revise the program to make it more specific to the activities of the laboratory

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1991 Foundation of EFI

1996 First EFI accredited laboratory in Europe

since Formal annual contacts between chairpersons of the the EFI and ASHI accreditation programme

2006
EFI Constitution - Article 3 (Purposes)

• To support the development of Immunogenetics and promote research and training in this field.

... 

• To develop recommendations for the standardisation of techniques, quality control and criteria for accreditation and to support their implementation.

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# EFI LABORATORY ACCREDITATION

<table>
<thead>
<tr>
<th>REGION</th>
<th>ACCREDITED LABORATORIES</th>
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<tbody>
<tr>
<td>01</td>
<td>Scandinavia</td>
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<tr>
<td>02</td>
<td>Benelux</td>
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<tr>
<td>03</td>
<td>Uk + Ireland</td>
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<tr>
<td>04</td>
<td>Germany</td>
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<tr>
<td>05</td>
<td>Central Europe</td>
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<tr>
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<td>France + Switzerl.</td>
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<td>Italy</td>
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<tr>
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<tr>
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<td>Spain + Portugal</td>
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<tr>
<td>99</td>
<td>South Africa</td>
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EFI Standards

- Proposed by any member
- Discussed and phrased by the Standards Committee
- Commented by the membership
- Re-evaluated by the Standards Committee
- Accepted by the Executive Committee
- Published and obligatory for all accredited laboratories
EFI Standards Outline

• A - GENERAL POLICIES
• B - PERSONNEL QUALIFICATIONS
• C - QUALITY ASSURANCE
• D - HLA ALLELES AND ANTIGENS
• E - SEROLOGICAL HLA CLASS I AND CLASS II TYPING
• F - ANTIBODY SCREENING AND CROSSMATCHING
• G - RENAL and/or PANCREAS TRANSPLANTATION
• H - OTHER ORGAN TRANSPLANTATION
• I - HAEMATOPOIETIC STEM CELL TRANSPLANTATION
• J – HLA AND TRANSFUSION
• K - DISEASE ASSOCIATION
• L – NUCLEIC ACID ANALYSIS
• M - FLOW CYTOMETRY
• N - ENZYME-LINKED IMMUNO SORBENT ASSAY (ELISA)
I - HAEMATOPOIETIC STEM CELL TRANSPLANTATION

- I1.000 Histocompatibility testing for related transplants.
- I2.000 Histocompatibility testing for unrelated transplants.
  - I2.100 Volunteer bone marrow donor registries.
  - I2.200 Typing of Units for Cord Blood Banks
  - I2.300 Histocompatibility testing for transplants from unrelated donors.
  - I2.400 Unrelated Cord Blood Unit Typing at Transplant Centre for Donor Selection
  - I2.500 Unrelated Cord Blood Unit Typing Prior to Transplantation
- I3.000 Crossmatching.
- I4.000 Haemopoietic Chimaerism and Engraftment (HCE) Monitoring
Most Frequent Findings

• I1.110 HLA typing for HLA phenotypically identical siblings must include adequate testing to definitively establish HLA identity by descent (D2.120 applies), or use high resolution Class I and/or Class II typing by DNA methods to determine the degree of HLA matching as documented in the transplant protocol.
Institutions Requiring EFI or ASHI Accreditation

- **WMDA** (WORLD MARROW DONOR ASSOCIATION)
- **NMDP** (NATIONAL MARROW DONOR PROGRAM)
- **JACIE** (JOINT ACCREDITATION COMMITTEE OR ISCT-EUROPE AND EBMT)
- **NETCORD-FACT** (CORD BLOOD SHARING ORGANISATION)
- **BSBMT/UKCCSG** (BRITISH SOCIETY FOR BONE MARROW TRANSPLANTATION)
- **EUROTRANSPLANT** (ORGAN SHARING ORGANISATION)
If theory and reality differ, this is bad for reality

Hegel